

# hiv treatment+ bulletin (e)

*Ukraine support, CROI 2022 (2 May 2022)*

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EDITORIAL

**With global news still dominated by the war in Ukraine we include links to ways you can help. This includes donating unused medicines and medical supplies and the chance to directly support HIV positive organisations in Ukraine.**

This is the third issue of HTB that includes reports from the CROI 2022.

We include a full report on the VISEND and NADIA studies that should change WHO guidelines on second-line therapy. Key results showed that recycling TDF is more effective than switching to AZT, that darunavir should be the preferred PI, and that additional adherence support increases rates of viral suppression.

A second report from the conference reviews the most important studies on COVID-19.

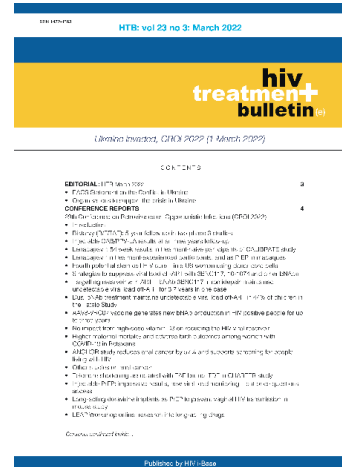
We report good news on a new dispersible formulation of dolutegravir/abacavir/lamivudine for children.

And also worrying news that ibalizumab access might be uncertain in Europe, just as this is being appraised by NHS England. The very low predicted demand for drugs that overcome HIV multidrug resistance in Europe are has led to Theratechnologies returning their EU marketing agreement to TaiMed.

But pricing is also key, with EU countries not prepared to match inflated US prices.

Either way, people currently depending on ibalizumab need to be assured of continued access, which given the low numbers should be simple to ensure.

Aside from reporting the welcome news that HIV testing in A&E will become opt-out in some high prevalent UK cities, the rest of the issue returns to COVID-19, including that two of the longest cases of COVID-19 involved people followed in a UK cohort.



## Sending unused meds to Ukraine: emergency appeal

Simon Collins, HIV i-Base

**The current war against Ukraine will be disrupting treatment for people living with HIV, whether they stayed in Ukraine or left as refugees to other countries.**

This led to urgent requests for unused HIV and other meds, and medical supplies. This is even though International agencies and drug manufacturers are also organising to meet this demand.

The UK-CAB collected more than 100 bottles in the first week of a new campaign led by EACS and BHIVA.

Please send all donations in the UK to:

**FAO: HIV consultants, 5th Floor Mortimer Market Centre, London, WC1E 6JB.**

**People living with HIV often have unused meds from when our last treatment was changed. If these are returned to your clinic they will be destroyed, even if unopened and in date.**

Medicines need to be in original packaging, ideally in unopened packs. All HIV and related meds are acceptable, *even if they are past the use by date.*

All donations will be screened beforehand to make sure they are suitable.



### Donations from other EU countries

This project is linked to the **Young Investigators (YING) network in the European AIDS Clinician Society (EACS)** who are working to support HIV care in the Ukraine and other countries most directly affected.

Their website appeals for medical supplies, HIV treatments and financial support.  
<https://awarehiv.com/en/Dare-to-Share-Care/Ukraine>

### Donations from the US

Donations of unused meds from the US is being co-ordinated by AID for AIDS. This organisation has been recycling HIV meds globally for over 25 years. Other meds can be included that are not ARVs, but the US programme only wants medicines that are still in date.

People in the US should please post to: **AID for AIDS**, 131 Varick Street, Suite 1006 New York, NY 10013.

Tel: (+1) 212.337.8043

Free FedEx or USPS shipping is available via the website:

[aidforaids.org](http://aidforaids.org)

*Note: The current crisis has meant that UK regulations have been relaxed to allow all donations. This is an exceptional situation. People in the UK are advised to not use out-of-date medications.*

## Organisations to help support Ukraine

Simon Collins, HIV i-Base

**The following organisations are collecting donations to help people affected by the crisis in Ukraine. This list has been expanded since the last issue to include two HIV organisations in Ukraine: 100% Life and Alliance for Public Health.**

**100% Life** is Ukraine's largest organisation of people living with HIV.

<https://network.org.ua/donate-en>

**Alliance for Public Health** is a leading non-governmental professional organisation in Ukraine working on HIV, hepatitis and TB in Ukraine.

<https://aph.org.ua/en/donate4ukraine>

**Ukraine's Ministry of Defense** designated bank account to accept donations for its troops.

<https://ukraine.ua/news/donate-to-the-nbu-fund>

**Come Back Alive** is a Ukrainian NGO that raises crypto funds for the Ukrainian army.

<https://savelifeline.in.ua/en/donate>

**Nova Ukraine** is a US-based NGO that works with organisations in Ukraine to support families. It provides citizens with everything from baby food and hygiene products, to clothes and household supplies.

<https://novaukraine.org>

The **Ukrainian Red Cross** covers many areas of support, from aiding refugees to training doctors.

<https://redcross.org.ua/en/donate>

**The Young Investigators (YING)** network in EACS is working to support HIV care in the Ukraine and other countries most directly affected. They have appealed for medical supplies and HIV treatments and financial support.

<https://awarehiv.com/en/Dare-to-Share-Care/Ukraine>

**Frontline AIDS Ukraine Appeal** (previously the International HIV/AIDS Alliance) are appealing for support for their partner HIV organisation in Ukraine, Alliance for Public Health (APH)

<https://frontlineaids.org/donate>

**United Help Ukraine** is another US-based non-profit that receives and distributes donations, food, and medical supplies to displaced Ukrainians, anyone affected by the conflict, and the families of wounded or killed soldiers.

<https://www.facebook.com/donate/337101825010055/>

**Sunflower of Peace** is a charity that helps paramedics and doctors with medical tactical backpacks - they have everything to preserve a person's life and get them to proper medical care alive.

[https://lnkd.in/eea5g-\\_E](https://lnkd.in/eea5g-_E)

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## CONFERENCE REPORTS

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### **29th Conference on Retroviruses and Opportunistic Infections (CROI 2022)**

**13–16 and 22–24 February 2022**

**Simon Collins, HIV i-Base**

#### **Introduction**

**The 29th Conference on Retroviruses and Opportunistic Infections (CROI), was held from 13–16 and 22–24 February 2022.**

The conference programme is now online as open access.

Although abstracts are online, webcasts will initially only be available to registered delegates for 30 days after the meeting.

<https://www.croiconference.org/preliminary-agenda>

A PDF file of the full programme is available:

<https://www.croiconference.org/wp-content/uploads/sites/2/resources/2022/croi2022-program-abstract-ebook.pdf> (PDF)

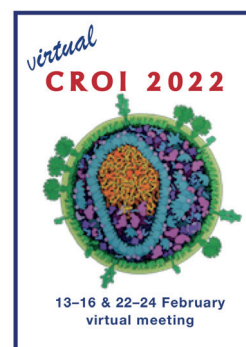
Other conference material including searchable abstracts, webcasts and posters are expected to become open access four weeks after the meeting ends.

<https://croi2022.onlineeventpro.freeman.com>

i-Base will post links to early reports from this holding page.

Further reports from CROI 2022 are listed below.

- CROI 2022: Webcasts now online and open access
- Dolutegravir plus recycled tenofovir rather than switch to AZT: public health approach to second-line ART
- CROI 2022: Other COVID-19 studies



### **Dolutegravir plus recycled tenofovir rather than switch to AZT: public health approach to second-line ART**

**Polly Clayden, HIV i-Base**

**Results from the NADIA and VISEND trials provide further evidence for dolutegravir and recycled tenofovir in second-line adult ART. These findings were presented at CROI 2022.**

Week 48 results from NADIA, presented last year, found both dolutegravir (DTG) and boosted darunavir (DRV/r)-based regimens maintained high levels of viral suppression in second-line – including in combination with NRTIs with no predicted activity. [1, 2]

In the VISEND trial, people failing tenofovir disoproxil fumarate (TDF), lamivudine (3TC) plus NNRTI first-line regimens had better outcomes when switched to DTG with either TDF/3TC or tenofovir alafenamide (TAF)/emtricitabine (FTC) compared to those switched to standard-of-care boosted-PI ART at week 48. [3]

In NADIA, at week 96 DTG remained non-inferior to DRV/r. The results also showed the TDF backbone to be superior to zidovudine (AZT) and this may protect against DTG resistance. DTG resistance did not increase substantially during longer follow-up. [4]



## VISEND

VISEND is an ongoing 144 week, randomised, open-label, phase 3 non-inferiority trial conducted in Zambia.

The study is looking at four second-line regimens in 1201 participants who received TDF/3TC plus efavirenz (EFV) or nevirapine (NVP) first-line.

In Arm A, participants with viral load <1000 copies/mL were randomised to receive TDF/3TC/DTG (TLD, n=209) or TAF/FTC/DTG (TAFED, n=209).

In Arm B, participants with viral load  $\geq$ 1000 copies/mL were randomised to TLD (n=208), TAFED (n=211), or a second-line boosted protease inhibitor (PI/r)-based regimen: lopinavir/ritonavir (LPV/r, n=167) or atazanavir/r (ATV/r, n=197) plus AZT/3TC.

The primary end point is viral load <1,000 copies/mL at week 144 (ITT population). The non-inferiority margin is 10%.

At baseline, participants in arm A were a median age of 44, approximately 60% were women, about 80% had viral loads <50 copies/mL and median CD4 was just over 400 cells/mm<sup>3</sup>.

In arm B, across the four groups, the participants were a median age of 38, 58–67% were women, 20–31% had viral load above 100,000 copies/mL and median CD4 was about 170 cells/mm<sup>3</sup>.

Viral load testing was performed at weeks 12, 24, 48, 72, 96 and 144. Participants with two consecutive viral load results >50 copies/mL received enhanced adherence counselling. Those with viral loads >1000 copies/mL on two consecutive visits had resistance testing.

In Arm A, 74% of participants in the TAFED group and 80% in the TLD group had viral load <50 copies at week 48 (ITT).

In Arm B, 82% in TAFED, 72% in TLD, 71% in ATV/r and 56% of participants in LPV/r group had viral loads <50 copies/mL (ITT).

Differences were similar in the <1000 copies/mL analysis with 86% in the TAFED group achieving viral suppression compared with only 69% in the LPV/r group (ITT).

The non-inferiority analyses found TAFED and TLD to be comparable and superior to the PI-based regimens for viral suppression to both <50 and <1000 copies/mL.

In arm A, participants in the TAFED group gained more weight from baseline to week 48 than those in TLD (2.8 vs 1.1 kg).

In arm B, participants in the TAFED and TLD groups gained 5.4 kg and 5 kg, compared to 2.8 kg and 2 kg in ATV/r and LPV/r, respectively.

Women in the TAFED group experienced greater weight gain (5.7 kg) compared to the other groups. In men, the greatest weight gain was in those in the TLD group (4.6 kg).

## NADIA

NADIA randomised participants receiving EFV or NVP/TDF/3TC first-line with viral load >1000 copies/mL to receive second-line ART of DTG or DRV/r and TDF or AZT, all with 3TC (2 x 2 factorial randomisation).

The primary endpoint was viral load suppression to <400 copies/mL at 96 weeks (non-inferiority margin 12% for each comparison and separate comparisons for each study question).

Open viral load testing was performed at 24, 48 and 96 weeks (and 72 weeks, if not stable at week 48 and 12 weeks after any result >1000 copies/mL). There was also open resistance testing following confirmed viral load test >1000 copies/mL (and stored batched samples from baseline and for participants with viral load rebound >400 copies/mL).

The study enrolled 464 participants at seven sites in Kenya, Uganda and Zimbabwe: 61% women, 51% CD4 <200 cells/mm<sup>3</sup>, and 28% viral load >100,000 copies/mL.

At baseline, 58% had intermediate-high level resistance to TDF, 18% to AZT and 92% to 3TC.

At week 96, 89.8% in the DTG group and 86.9% in the DRV/r group achieved <400 copies/mL (ITT analysis): difference 2.9% (95% CI -3.0 to 8.7%), p=0.332. This showed non-inferiority of DTG, but not superiority.

These results were consistent in sensitivity analyses and at <1000 copies/mL and <50 copies/mL.

Approximately 10% of participants had viral rebound >1000 copies/mL. Of these, seven participants had one or more DTG mutation and none had DRV mutations.

Over 90% of participants in both groups with no predicted active NRTIs achieved viral load <400 copies/mL.

In the second comparison, 91.8% in the TDF group and 84.8% in the AZT group were suppressed <400 copies/mL: difference 7.0% (95% CI 1.2 to 12.8%), p=0.019. This indicated superiority of TDF at week 96 (progressing from non-inferiority at week 48).

Again, the various sensitivity analyses for this comparison were consistent with the main results.

Viral load rebound >1000 copies/mL occurred in 5.6% of participants in the TDF group and 14.3% in the AZT group: difference -8.7% (95% CI -14.1 to -3.3%), p=0.002.

Of the seven cases of DTG resistance, five were in the AZT group. There were a further two participants with resistance among the retrospective samples from those with rebound >400 copies/mL; one each in the TDF and AZT groups.

In the subgroup of participants with the K65R/N at baseline, 95.7% achieved suppression in the TDF group (93.6% in the AZT group).

Presenting author Nick Paton, suggested that: "The best way to avoid dolutegravir resistance is to simply stop combining it with zidovudine in second-line"

#### C O M M E N T

**Current World Health Organization (WHO) guidelines recommend optimised NRTIs, including a switch from TDF to AZT for second-line therapy in the public health approach. [5]**

**These data suggest that this recommendation should be reconsidered and discussions are underway to inform the upcoming guideline revisions.**

**From both an individual and programmatic standpoint, using TLD second-line after NNRTI with TDF and 3TC would have several advantages.**

**NADIA data also support upgrading DRV/r to preferred PI second-line. Since the DRV/r pricing agreement, announced last year by Unitaid and CHAI, this has become more feasible in terms of cost. [6]**

**Remaining questions associated with TDF vs TAF and with weight gain (which may increase risk for non-communicable diseases and/or metabolic complications) still need longer-term follow up.**

**WHO also recommends enhanced adherence counselling before switching to second-line for people with detectable viral loads.**

**A sub study of VISEND – also presented at this conference – looked at data from participants with viral load >1000 copies/mL, who received three counselling sessions over three months, according to existing guidance. [7]**

**This led to viral suppression rates near the WHO target of 70%, although outcomes varied by sex, education, and other factors. The investigators recommended incorporating this counselling into clinical trials and practice before switching to optimise outcomes.**

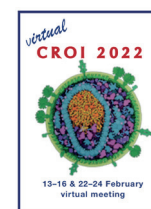
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## CROI 2022: Other COVID-19 studies

Kirk Taylor, HIV i-Base

**CROI 2022 included 214 studies that related to COVID-19 – almost a quarter of the overall programme. These covered all aspect of the new pandemic, including antivirals, transmission, testing and disease management.**



The selected studies reported below also cover a wide range of topics, though some have small sample sizes or are retrospective in nature.

Further research is still needed to develop strategies to mitigate and eliminate COVID-19.

### COVID antivirals

Several studies reported data on antivirals for people with COVID-19. Herein three studies covering COVID-19 pre-exposure prophylaxis, disease severity for people with HIV on effective ART and use of remdesivir in non-hospitalised people. [1-3]

A double-blind phase 3 study reported efficacy and safety data of sub-cutaneous (SC) casirivimab plus imdevimab (CAS+IMD; 1200 mg SC) as COVID-19 pre-exposure prophylaxis. [1]

Household contacts of positive COVID-19 index cases were recruited and randomised to CAS+IMD (n=841) or placebo (n=842).

Primary efficacy at day 28 showed an 81.4% reduction in symptomatic COVID-19 cases and 66.4% reduction in transmission to household contacts. Efficacy was maintained at similar levels at month 7. No new safety concerns were reported.

These data were collected before the emergence of the Omicron variant and further data are required to assess efficacy against this, and future, variants.

A retrospective study evaluated severity of COVID-19 in HIV positive people on effective ART with undetectable viral load. [2]

Participants were recruited from 69 Spanish clinics and were female (21%) and median age was 50 (IQR: 39 to 58). COVID-19 severity was assessed in groups stratified by ART regimen as follows TDF/FTC (n=6,160), TAF/FTC (n=20,432), ABC/3TC (n=13,715) and other (n=11,251).

The relative risk of COVID-19 was similar for each group. However, a modest reduction in COVID-19 severity was reported for HIV positive people on TDF/FTC regimens. This limited benefit might only be in adults > 50 years old.

It should be noted that this is a retrospective study and randomised controlled trials are required.

Finally, a phase three placebo-controlled study evaluated the impact of a 3-day remdesivir regimen upon COVID-19 progression. [3]

Participants were recruited from USA, UK, Spain and Denmark and randomised to remdesivir (n=279) or placebo (n=283). Remdesivir reduced hospitalisation of people at high risk of COVID-19. No serious adverse events were recorded in either group and remdesivir was well-tolerated in non-hospitalised individuals.

However, several studies have reported no benefit from remdesivir on risk or mortality remdesivir in moderate and severe stage infection. [4, 5]

### Transmissibility

A study of COVID-19 cases in Qatar reported a 50% reduction of transmissibility following vaccination. [6]

Cycle thresholds (CT) of RT-PCR COVID-19 tests indicate the level of virus in a sample. The authors used CT as a surrogate marker for transmissibility with higher CT values indicating lower viral load and reduced transmissibility.

CT values from PCR tests conducted between February 2020 to July 2021 were analysed.

Four groups were identified:

- COVID positive and unvaccinated (n=301,424).
- Re-infection and unvaccinated (n=1,695)
- Breakthrough COVID-19 after Pfizer vaccine (n=4,262).
- Breakthrough COVID-19 after Moderna vaccine (n=283).

Average CT values increased for breakthrough cases: Pfizer (1.3 cycles higher, 95% CI: 0.9 to 1.8) < Moderna (3.2, 95% CI: 1.9 to 4.5) < unvaccinated (4.0, 95% CI: 3.5 to 4.5).

### **COVID-19 coagulopathy**

Blood clots are a known complication of COVID-19 and have been associated, in rare cases, with COVID-19 vaccinations. [7]

Dr Mauricio Montano from the Gladstone Institute of Virology presented results from a mechanistic study investigating the composition and properties of these clots. [8]

Clots in COVID-19 disease are abnormal and more resistant to anticoagulation with standard therapy.

Lab studies demonstrated that spike protein increased fibrin polymerisation, leading to more complex and dense clots. Spike protein interacted with multiple sites on fibrinogen, including a site important for driving inflammatory responses.

A mouse model confirmed enhanced coagulopathy induced by spike protein. Infusion of 5B8 antibodies against the inflammatory epitope of fibrinogen reduced fibrinogen deposits and inflammatory responses without altering haemostasis.

This study provides important insights into COVID-19 coagulopathy and highlights a potential therapeutic target.

### **COVID-19 linked to higher rate of false positive HIV tests**

Inflammation and infectious diseases have been associated with false positive (FP) HIV tests.

A retrospective cross-sectional study in Detroit evaluated COVID-19 positivity within two weeks of a positive HIV test using medical records (n=23,278). [9]

Overall, 10.2% (n=2,382) were COVID-19 positive and >99% of all HIV tests were negative.

True positive and FP tests were reported for 167 and 70 people, respectively.

FP accounted for 0.3% of results, but were more common for COVID-19 positive individuals, with an odds ratio of 7.04 (p=0.001).

This study only evaluated FP using the Elecsys HIV Duo 4th generation test (Roche).

### **Management of severe COVID-19: tocilizumab, biosimilars, and increased dosing**

Tocilizumab is a humanised monoclonal antibody against the IL-6 receptor. It is recommended for people with COVID-19 that have CRP >7.5 mg/dL and works by reducing the impact of the inflammation from the COVID-19 cytokine storm.

A multicentre double-blind active-controlled trial was conducted in India to evaluate whether biosimilar tocilizumab reduces the requirement for mechanical ventilation. [10]

The study randomised 172 participants with severe COVID-19 in a 3:1 ratio to either biosimilar (n=131) or reference product (n=41). Biosimilar product performance was comparable to reference product. The results show that biosimilars might provide a more cost-effective alternative for management of severe COVID-19 in resource-limited settings.

An observational cohort study confirmed that administration of tocilizumab in people with severe COVID-19 is only beneficial for those with CRP  $\geq$ 7.5mg/dL. [11]

Just under 1000 people with severe COVID-19 pneumonia were randomised 2:1 to monotherapy (n=597) or intensification with tocilizumab (n=395).

The primary endpoint was mortality at day 28. Intensification with tocilizumab reduced survival benefit in participants with CRP <7.5 mg/dL.

Substantial benefit from intensification was conferred for participants with CRP >15 mg/dL.

However, larger studies are required to determine clinical cut-offs for intensification with tocilizumab.

### **Zinc supplementation**

Zinc has important roles in immune cell function, antioxidant and anti-inflammatory activity.

A mechanistic study evaluated serum zinc levels in people at time of COVID-19 diagnosis (n=159). [12]

Median age was 53 (IQR: 38 to 63), 42% were female and 48% were white. COVID-19 was classified as asymptomatic or mild (50%), moderate (41.5%) or severe (8.5%).

Participants with zinc deficiency (serum zinc < 75  $\mu$ g/dL) had significantly increased COVID-19 severity (AHR 0.24; 95% CI: 0.06 to 0.93, p=0.037), although the confidence intervals were wide..



## C O M M E N T

**Despite a large proportion of presentations on COVID-19, there were relatively few significant findings reported.**

**As countries shift public health focus from pandemic to endemic strategies, it will be important to continue research into the efficacy of antiviral therapies and vaccines.**

**Although potential strategies for prophylactic COVID-19 antivirals were reported, case numbers remain globally high and the lag time between exposure and onset of symptoms may limit the usefulness of such strategies.**

**Studies on long COVID (PASC) at the conference have also been reported in an earlier issue of HTB. [13]**

## References

Unless stated otherwise, references are to the 29th Conference on Retroviruses and Opportunistic Infections, 12–16 and 22–24 February 2022, virtual meeting. Depending on CROI policy, links might require conference registration and might only be active for a limited time on this platform after the meeting.

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- 13 i-Base. COVID-19: long COVID  
<https://i-base.info/htb/section/long-covid>

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## ANTIRETROVIRALS

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### **FDA approves dispersible dolutegravir/abacavir/3TC for children**

**Simon Collins, HIV i-Base**

**On 30 March 2022, the US FDA approved a single tablet regimen of dolutegravir/abacavir/3TC in a dispersible formulation for children weighing 10 kgs to 25 kgs.**

This will provide a simpler and easier to take option for children living with HIV.

#### Reference

ViiV Healthcare. ViiV Healthcare announces US FDA approval of Triumeq PD, the first dispersible single tablet regimen containing dolutegravir, a once-daily treatment for children living with HIV. (30 March 2022).

<https://www.gsk.com/en-gb/media/press-releases/viiv-healthcare-announces-us-fda-approval-of-triumeq-pd-the-first-dispersible-single-tablet-regimen-containing-dolutegravir-a-once-daily-treatment-for-children-living-with-hiv>

### **Access to ibalizumab uncertain in Europe: TaiMed looking for new partner after Theratechnologies quits**

**Simon Collins, HIV i-Base**

**On 27 April 2022, Theratechnologies announced that the company will no longer look to market ibalizumab in the EU, ending their contract with TaiMed Biologics within the next six months. [1]**

This means that future access to ibalizumab, a monoclonal antibody recently approved by the FDA in March 2018 and in the EMA in September 2019, is now uncertain. [2, 3]

However, TaiMed who developed ibalizumab and own the license said they are determined to continue to make ibalizumab to people who need it globally and that they are already looking for a new commercial partner for the European region. Their press release suggests that TaiMed might have had a roll in setting the minimum floor price for ibalizumab, that was not acceptable to countries in the EU. [4]

Ibalizumab is indicated for treatment of people with multiclass HIV drug resistance.

The press release blamed 'pricing and reimbursement conditions in key European countries' where sales have been low, accounting for less than 2% of the company's revenue and less than 10% of global sales.

The annual price for ibalizumab in the US is \$118,000 (WAC/Wholesale Acquisition Cost), which doesn't include costs for providing the two-weekly infusions.

Ibalizumab will continue to be marketed in North America under the tradename Trogarzo.

Theratechnologies is a Canadian company that is also responsible for marketing tesamorelin (Egrifta) in Canada and the US. This is a treatment for central fat accumulation that is was never approved in the EU.

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#### C O M M E N T

**Similar to Gilead's withdrawal of the EU application for F/TAF for PrEP last year, this is due to corporate financial rather than clinical decisions. This is driven by inflated drug pricing in the US together with a limited EU market.**

**A few days before this announcement, NHS England has recently circulated the draft commissioning report for ibalizumab to stakeholders for comment. [5]**

**Although uncontrolled multiclass resistance is thought to affect very few people in the UK, likely less than 20, in these cases ibalizumab could be a life-saving option.**

**Neither press statement gave an indication that people in Europe will continue to access ibalizumab, other than in the immediate short-term. TaiMed has said that they are committed to making ibalizumab available to those who need it in the EU but it is difficult to see how this will happen.**

**Thera say that the price offered in France of €40,000 would not cover manufacturing costs, but this is linked to the price of fostemsavir which shows similar efficacy data. But if TaiMed were involved in directing the minimal acceptable price, then finding a new marketing partner won't fix the problem that caused Thera to quit.**

**Even if demand across the EU is less than several hundred people (anecdotally, about 20 in Germany, 70 in Italy, less than 20**

in the UK etc) this might suggest the need for a new European approach for very difficult cases. These low numbers should be used for orphan drug designation for similar compounds.

**More recent bNABs should have similar or greater efficacy compared to ibalizumab, assuming baseline sensitivity, but will have easier dosing. Researchers focused on prevention could perhaps be persuaded to also work collaboratively on with an MDR cohort.**

**TaiMed might also be legally obliged to continue to supply treatment to people currently using ibalizumab, as part of the conditions of EU approval, as the drug is still being used in other regions.**

#### References

1. Theratechnologies press statement. Theratechnologies to focus its commercialization activities on the North American territory. (27 April 2022). <https://www.newswire.ca/news-releases/theratechnologies-to-focus-its-commercialization-activities-on-the-north-american-territory-860560170.html>
2. FDA approves ibalizumab in the US to treat multidrug HIV resistance. HTB (March 2018) <https://i-base.info/htb/33659>
3. Ibalizumab approved in the EU. HTB (November 2019). <https://i-base.info/htb/36786>
4. TaiMed press statement. TaiMed receives from Theratechnologies notification of returning commercialization rights for Trogarzo in European territory. (27 April 2022). <http://www.taimedbiologics.com/news/info/104>
5. NHS England, Policy testing: Ibalizumab for multi-drug resistant HIV-1 infection. Draft circulated 22 April 2022.

## COMPLICATIONS: COVID-19

### Asymptomatic COVID-19 is common in people living with HIV

Simon Collins, HIV i-Base

**A sub-study in about one-third of participants in the international REPRIEVE trial reported COVID-19 infections from April 2020 in approximately 13%. Of these, roughly 60% were asymptomatic.**

Overall, median age was 53 years, 35% were women, 47% Black or African American. The median CD4 count 649 cells/mm<sup>3</sup>, and 97% with HIV undetectable viral load (<400 copies/mL).

Of the 2,464 participant included, 318 had either SARS-CoV-2 antibodies (260/318), without previous vaccination and 58/318 had were diagnosed clinically.

In a self-completed questionnaire, only 40% reported symptoms. These rates were lower rates in low and middle income countries, is Black or African American race, older in age, and with higher ASCVD risk score.

Symptoms were more common with obesity, metabolic syndrome, and low HDL levels.

There was no association by CD4 counts and HIV viral load.

#### Reference

Overton ET et al. Asymptomatic SARS-CoV-2 infection is common among ART-treated people with HIV, JAIDS Journal of Acquired Immune Deficiency Syndromes: - Volume - Issue - 10.1097/QAI.0000000000003000 doi: 10.1097/QAI.0000000000003000. (12 April 2022).

[https://journals.lww.com/jaids/Abstract/9900/Asymptomatic\\_SARS\\_CoV\\_2\\_Infection\\_is\\_Common\\_among.27.aspx](https://journals.lww.com/jaids/Abstract/9900/Asymptomatic_SARS_CoV_2_Infection_is_Common_among.27.aspx)

### Longest COVID-19 infection lasted 505 days in an immunocompromised person in London

Simon Collins, HIV i-Base

**A UK study of nine group people with significantly reduced immune protection and extended COVID-19 infections, managed at Guy's and St Thomas's NHS Trust in London, includes the longest active infection reported globally to date.**

This cohort was enrolled between March 2020 and December 2021 were immunocompromised due to organ transplant, HIV, cancer, or due to treatments with chemotherapy or biologic antibodies associated due to other underlying conditions.

This study date was reported by Medscape ahead of presentation at the European Congress of Clinical Microbiology & Infectious Diseases on 25 April 2022. [1, 2]

All participants tested positive for SARS-CoV-2 for at least eight weeks (mean 73 days) with 2/9 having persistent infection for over a year. Although some remained asymptomatic, 4/9 have died, including the case of an infection lasting 505 days. COVID-19 as not always reported as the cause of death.

Phylogenetic analysis confirmed the continuous infection was not due to reinfection, and also tracked the development of multiple mutations associated with variants of concern (including Alpha, Delta, and Omicron variants). One person developed 10 mutations that have arisen separately in these variants.

Of the five patients who are still alive, 2/5 cleared the infection and one has continued for more than 430 days, and will clear 505 days if they are still positive at the next follow up appointment.

This report stressed the importance of finding effective strategies to prevent infection in people who are most vulnerable to infection. Although monoclonal antibodies can be used in people with reduced immunity if vaccines fail to generate protection, those currently licensed in the UK are not active against the latest Omicron BA.2 variants.

#### References

1. McCall B. Patient Identified Who Battled COVID for 505 Days. Medscape. (22 April 2022). <https://www.medscape.co.uk/viewarticle/longest-covid-infection-identified-patient-who-battled-virus-2022a1001163>
2. Snell LB et al. A longitudinal study of evolution of SARS-CoV-2 variants in immunocompromised individuals with persistent infection. European Congress of Clinical Microbiology & Infectious Diseases (ECCMID). Lisbon. 253-26 April 2022. Abstract L0535. [https://markterfolg.de/ESCMID/Final\\_Programme\\_2022](https://markterfolg.de/ESCMID/Final_Programme_2022)

## **Herd immunity unlikely to control COVID-19: opinion article from US NIAID**

**Simon Collins, HIV i-Base**

**This opinion piece from the US NIAID reevaluates the relevance of herd immunity for COVID-19 and concludes that this is unlikely to generate long-term protection on a population level.**

The article is optimistic that COVID-19 will still become more controlled, with minimal disruption to everyday life, at least in some settings (with vaccine access).

It also clearly shows that the leadership of NIAID want to move public expectations for future control away from potential of eradication such as smallpox.

Instead the article draws parallels with the Spanish influenza in 1918, whose variants were responsible for later pandemics (H2N2 in 1957, H3N2 in 1968, and H1N1 in 2009).

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#### C O M M E N T

**The failure of herd immunity to prevent transmission should not be a surprise given the high incidence new infections in the UK, despite high levels of vaccination and booster shots for vulnerable populations.**

**The success of current vaccines are clearly shown by the lower rates of hospitalisations and mortality in those with vaccine cover.**

**However, future risks are largely dependent on the pathogenic properties of new variants and whether broader vaccines are developed that will cope with these.**

#### Reference

Morens DM, Folkers GK, Fauci AS. The Concept of Classical Herd Immunity May Not Apply to COVID-19. *JID*, jiac109, doi:10.1093/infdis/jiac109. (31 March 2022).

<https://doi.org/10.1093/infdis/jiac109>

## The challenges of prioritising access to molnupiravir and nirmatrelvir–ritonavir for COVID-19

Simon Collins, HIV i-Base

**An opinion article in Lancet Infectious Diseases stresses the importance of clear guidelines for prioritising access to new antiviral drugs to treat COVID-19 in different countries.**

This includes situations when medical need might be highest in those who have not been vaccinated while still remaining very high in other people who have actively engaged in vaccinations.

Molnupiravir and nirmatrelvir–ritonavir both need to be prescribed within five days of symptoms of confirmed COVID-19. Demand currently exceeds supply in every country.

Prioritisation needs to account for transparency, relevance, appeals, enforcement, and fairness – and on defining clinical need by using evidence-based scoring.

It also needs to overcome the data limitations of the phase 3 registrational studies being carried out in those who were unvaccinated.

Reference

Dal-Ré R et al. Availability of oral antivirals against SARS-CoV-2 infection and the requirement for an ethical prescribing approach. Opinion. Lancet Infectious Diseases. DOI: 10.1016/S1473-3099(22)00119-0. (29 March 2022).

<https://www.sciencedirect.com/science/article/pii/S1473309922001190>

## Increased risk of blood clots after COVID-19: higher with underlying conditions and more severe symptoms

Simon Collins, HIV i-Base

**A study of more than one million confirmed COVID-19 in Swedish national registries between February 2020 and May 2021 reported increased risks of clotting and bleeding.**

- A 5-fold increased risk of deep vein thrombosis up to three months after covid-19 infection.
- A 33-fold increased risk of pulmonary embolism (a blood clot in the lung) up to six months.
- An almost double risk of bleeding events up to two months.

Cases were matched by age, sex, and county of residence to more than four million people who had not had SARS-CoV-2.

Deep vein thrombosis occurred in 401 vs 267 cases vs controls (absolute risk 0.04% vs 0.01%). Pulmonary embolism in 1,761 vs 171 (absolute risk 0.17% vs 0.004%). And first bleeding event in 1,002 vs 1,292 (absolute risk 0.10% vs 0.04%). Rates were higher in people with underlying conditions and who had more severe COVID symptoms.

The researchers said their results supported the benefits of thromboprophylaxis, especially for high risk patients, and showed the importance of vaccine protection.

Reference

Tang ME et al. People with HIV have a higher risk of COVID-19 diagnosis but similar outcomes to the general population. BMJ, doi: 10.1111/hiv.13312. (08 April 2022).

<https://www.bmj.com/content/376/bmj-2021-069590>

## Two new platform vaccines against COVID-19 report phase 3 results

Simon Collins, HIV i-Base

**Results from two large randomised phase 3 international studies of two COVID-19 vaccines developed on new platforms were just published in the NEJM, together with an editorial supporting research for these and additional options.**

Efficacy results from the ZF2001 vaccine, which is based on the receptor-binding domain with aluminum hydroxide as an adjuvant, was studied in Uzbekistan, Indonesia, Pakistan, and Ecuador. This vaccine was given as three doses, 30 days apart. [1]

Compared to placebo, symptomatic COVID-19 was reduced by about 75% and severe infection by 87% (6 vs 43 cases), over 6 months follow-up.

The second study involved a recombinant plant-based adjuvanted vaccine, given as two intramuscular injections, 30 days apart, at 85 sites in Argentina, Brazil, Canada, Mexico, the UK, and the US.

Symptomatic infection was reduced by 70% and moderate-to-severe disease by 79%, with no severe cases in the vaccine arm.

Limitations for both studies are that they were conducted before Omicron became the dominant variant and participants were generally younger adults at low risk of severe COVID-19.

The editorial comment reports that out of almost 350 vaccine candidates in development, 31 are now approved for widespread use, using five different vaccine platforms. It also supports continued research, for compounds with formulation or efficacy benefits over the currently available vaccines.

Although it notes optimistically that by mid 2022 vaccine supply should not be a limiting factor for global coverage, there is still dramatically inequitable access and this will continue for much longer. In many low income countries, less than 10% of the population is fully vaccinated.

#### References

1. Dai L et al. Efficacy and Safety of the RBD-Dimer-Based Covid-19 Vaccine ZF2001 in Adults. NEJM. DOI: 10.1056/NEJMoa2202261. (4 May 20-22).  
<https://www.nejm.org/doi/full/10.1056/NEJMoa2202261>
2. Hager KJ et al. Efficacy and Safety of a Recombinant Plant-Based Adjuvanted Covid-19 Vaccine. NEJM. DOI: 10.1056/NEJMoa2201300. (4 May 20-22).  
<https://www.nejm.org/doi/full/10.1056/NEJMoa2201300>
3. Nohnek H and Wilder-Smith A. Does the World Still Need New Covid-19 Vaccines? NEJM. DOI: 10.1056/NEJMe2204695. (4 May 20-22).  
<https://www.nejm.org/doi/full/10.1056/NEJMe2204695>
4. Reuters COVID-19 vaccination tracker.  
<https://graphics.reuters.com/world-coronavirus-tracker-and-maps/vaccination-rollout-and-access>

## HIV PREVENTION

### **A&E adopts opt-out HIV testing in London, Manchester, Salford and Brighton**

**Simon Collins, HIV i-Base**

**From April 2022, A&E departments in hospitals in key areas of high HIV prevalence will move to opt-out HIV testing.**

This means that when blood is drawn, HIV will be included for all adults age 16 and over, unless the person opts-out.

This policy has been discussed for many years and was outlined in a policy paper in December. [1]

This was one of the recommendations from joint UK testing guidelines (including by BHIVA) published in 2020. It is also recommended by the HIV Commission last year as part of the target to end new infections by 2030, and as part of the fast-track cities initiative. [2. 3. 4]

Testing for hepatitis B and C are due to be added later this year, together with hopefully wider roll-out to other cities.

#### References

1. Gov.uk. Towards Zero: the HIV Action Plan for England - 2022 to 2025 (21 December 2021).  
<https://www.gov.uk/government/publications/towards-zero-the-hiv-action-plan-for-england-2022-to-2025>
2. BHIVA/BASHH/BIA Adult HIV Testing Guidelines (2000)  
<https://www.bhiva.org/file/5f68c0dd7aefb/HIV-testing-guidelines-2020.pdf> (PDF)
3. HIV Commission. How we expanded opt-out HIV testing. (19 April 2022).  
<https://www.hivcommission.org.uk/2022/04/19/how-we-expanded-opt-out-hiv-testing>
4. Fast Track Cities. Blood testing in all London emergency departments. (23 March 2020).  
<https://fasttrackcities.london/testinginae>

## Zimbabwe decriminalises HIV transmission

Simon Collins, HIV i-Base

**In March 2022, the Zimbabwean government announced that criminalisation of HIV transmission will be repealed as part of a new Marriage Act about to be signed into law. [1. 2]**

This recognises that such laws actively reduce the willingness to test, and block access to effective treatment.

This is a very progressive move and positive signal to the 130 countries that still criminalise HIV non-disclosure, exposure and transmission.

Approximately 15 million people live in Zimbabwe and nearly every family is expected to have had personal experience of HIV. Generally, social change is only ever legislated after popular opinion has already changed.

Access to ART is also >90%, with approximately 1.3 million estimated to be HIV positive, with 1.2 million on ART.

### Reference

1. UNAIDS. UNAIDS welcomes parliament's decision to repeal the law that criminalizes HIV transmission in Zimbabwe. (18 March 2022). [https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2022/march/20220318\\_law-hiv-transmission-zimbabwe](https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2022/march/20220318_law-hiv-transmission-zimbabwe)
2. All Afrika. Zimbabwe: Decriminalisation of HIV Transmission a Milestone Development <https://allafrica.com/stories/202203210214.html>

## CURE-RELATED RESEARCH

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### Community webinar series on HIV cure-related cell and gene therapy

Simon Collins, HIV i-Base

**A new series of community monthly webinars on HIV cure research will focus on cell and gene therapy research and will include discussions with leading researchers.**

The use of cell and gene therapy against HIV is a promising new cure-related strategy with the potential to target the virus with a limited number of doses.

The series begins in June 2022 and ends in February 2023. Each monthly session will last an hour with Q&A discussions that include community members.

The programme includes many leading researchers.

- **21 June 2022: The basics:** Jennifer Adair, Global Gene Therapy Initiative; Michael Louella, DARE CAB Co-Chair
- **19 July 2022: Designing T cells for HIV cure studies:** James Riley.
- **16 August 2022: Cutting out HIV with CRISPR:** Kamel Khalili, Tricia Burdo.
- **20 September 2022: Silencing HIV:** Priti Kumar, Yale University, HOPE
- **18 October 2022: Gene therapy in Germany:** Prof. Dr. Joachim Hauber.
- **15 November 2022: Duo CAR T cells:** Kim Anthony-Gonda.
- **17 January 2023: Engineering B Cells:** Paula Cannon.
- **28 February 2023: Gene Therapy in Africa:** Boro Dropulic.

Registration is required:

<https://bit.ly/3kapavg>.

Each webinar will last an hour.

This project is being coordinated by the Delaney AIDS Research Enterprise (DARE) with the DARE Community Advisory Board (CAB).

For more information, contact Lynda Dee at [LyndaDee@aidsactionbaltimore.org](mailto:LyndaDee@aidsactionbaltimore.org)

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## OTHER NEWS

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### **Family of Greek activist Zak Kostopoulos decry minimal sentence given to his killers**

**Simon Collins, HIV i-Base**

**On 3 May 2022, the two men who killed 33-year-old LGBTQ activist Zak (Zacharias) Kostopoulos were given ten year sentences in the Athens lower court. However, Greek penal code is likely to mean that the eldest of these men might only serve 2.5 years that will be served at home. [1, 2, 3]**

Zak was an HIV positive, sex positive, queer, human rights activist and defender, also raising awareness performing as drag queen Zackie Oh. He was brutally assaulted in September 2018 and died as a consequence of brutal beatings. [4]

The four police officers, who were charged with deadly bodily harm because they handcuffed Zak face down even though he was already unconscious, were acquitted.

Numerous LGBTQ and human rights protests have been held demanding justice for Zak.

His family, friends and the wider community have decried the verdict.

An immediate community response included a protest against the verdict and a procession in memory of Zak was attended by over 1000 people in central Athens. [5]

#### References

1. Tanea report. Ten-year prison sentence for two men who lynched LGBTQ activist Zak Kostopoulos. (3 May 2022). <https://www.tanea.gr/2022/05/03/english-edition/ten-year-prison-sentence-for-two-men-who-lynched-lgbtq-activist-zak-kostopoulos/>
2. Greek Reporter. Greek Court Convicts Killers of Gay Rights Activist Zak Kostopoulos. (3 May 2022). <https://greekreporter.com/2022/05/03/greek-court-convicts-killers-zak-kostopoulos/>
3. Liberation. A Athènes, le verdict des meurtriers d'un jeune gay, icône du mouvement LGBT, provoque l'indignation. (3 May 2022). [https://www.liberation.fr/international/europe/a-athenes-le-verdict-des-meurtriers-dun-jeune-gay-icone-du-mouvement-lgbt-provoque-lindignation-20220504\\_IKQ6IEAJFHDLGVGHNJUS5FZMI/](https://www.liberation.fr/international/europe/a-athenes-le-verdict-des-meurtriers-dun-jeune-gay-icone-du-mouvement-lgbt-provoque-lindignation-20220504_IKQ6IEAJFHDLGVGHNJUS5FZMI/)
4. LGBTQ HIV activist Zak Kostopoulos murdered in Athens: campaign calls for justice. HTB (19 October 2018). <https://i-base.info/htb/35047>
5. Zak Kostopoulos: A march in his memory in the center of Athens. (3 May 2022). <https://www-news247-gr.translate.google.com/koinonia/zak-kostopoulos-se-exelixa-poreia-sti-mnimi-toy-sto-kentro-tis-athinas.9618006.html>



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## Future meetings and webinars 2022/23

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**The following listing covers selected upcoming HIV-related meetings and workshops. Registration details, including for community and community press are included on the relevant websites.**

Due to the new coronavirus health crisis, most meetings will now be virtual, including those that were rescheduled in the hope that COVID-19 restrictions would be relaxed.

**Academic Medical Education (AME)** meetings and workshops

Several AME workshops (previously Virology Education) are highlighted below but 35 meetings are planned each year. Many virtual meetings include free registrations for health workers, researchers and community.

<https://academicmedicaleducation.com> (meetings listings)

Webcasts from meetings (YouTube listing)

2022

### **24th International AIDS Conference (AIDS 2022)**

29 July – 2 August 2022, Montreal, Canada, and virtually

<https://www.aids2022.org>

### **13 International Workshop on HIV & Aging**

13 – 14 October 2022, USA (tbc)

<https://academicmedicaleducation.com>

2023

### **19th European AIDS Conference (EACS 2023)**

18-21 October 2023, Warsaw, Poland

<https://www.eacsociety.org>

## PUBLICATIONS & SERVICES FROM i-BASE

### i-Base website

All i-Base publications are available online, including editions of the treatment guides.

<http://www.i-base.info>

The site gives details about services including the UK Community Advisory Board (UK-CAB), our phone service and Q&A service, access to our archives and an extensive range of translated resources and links.

Publications and regular subscriptions can be ordered online.

The Q&A web pages enable people to ask questions about their own treatment:

<http://www.i-base.info/qa>

### i-Base treatment guides

i-Base produces six booklets that comprehensively cover important aspects of treatment. Each guide is written in clear non-technical language. All guides are free to order individually or in bulk for use in clinics and are available online in web-page and PDF format.

<http://www.i-base.info/guides>

- Introduction to ART (May 2022)
- HIV & quality of life: side effects & long-term health (Sept 2016)
- Guide to PrEP in the UK (February 2022)
- HIV testing and risks of sexual transmission (June 2021)
- Guide to changing treatment and drug resistance (August 2021)
- Guide to HIV, pregnancy & women's health (April 2019)

### Pocket guides

A series of pocket-size concertina folding leaflets that is designed to be a very simple and direct introduction to HIV treatment.

The five pocket leaflets are: Introduction to ART, HIV and pregnancy, ART and quality of life, UK guide to PrEP and HCV/HIV coinfection.

The leaflets use simple statements and quotes about ART, with short URL links to web pages for more information in a similar easy format.

### U=U resources for UK clinics: free posters, postcards and factsheets

i-Base have produced a new series of posters, postcards and leaflets to help raise awareness about U=U in clinics.

This project was developed with the Kobler Centre in London.

As with all i-Base material, these resources are all free to UK clinics.

Until our online order form is updated to include the U=U resources, more copies can be ordered by email or fax.

email: [subscriptions@i-base.org.uk](mailto:subscriptions@i-base.org.uk)

### Customise U=U posters for your clinic

i-Base can customise U=U posters to include pictures of doctors, nurses, pharmacists, peer advocates or any other staff that would like to help publicise U=U.

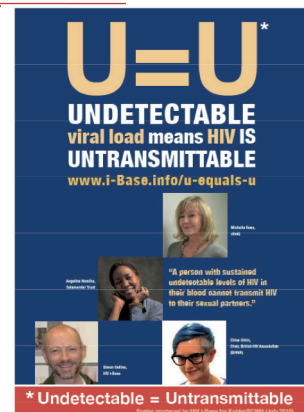
Personalising these for your clinic is cheap and easy and might be an especially nice way to highlight the good news.

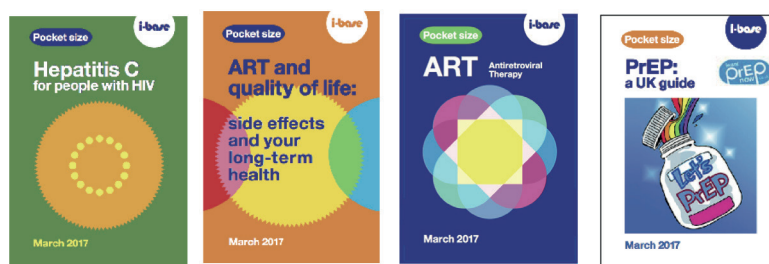
For further information please contact Roy Trelvelion at i-Base:

[roy.trelvelion@i-base.org.uk](mailto:roy.trelvelion@i-base.org.uk)

### Order publications and subscribe online

All publications can be ordered online for individual or bulk copies. All publications are free. Unfortunately bulk orders are only available free in the UK. <http://i-base.info/order>





## ***h-tb***

### HIV TREATMENT BULLETIN

HTB is published in electronic format by HIV i-Base. As with all i-Base publications, subscriptions are free and can be ordered using the form on the back page or directly from the i-Base website:

<http://www.i-Base.info>

by sending an email to: [subscriptions@i-Base.org.uk](mailto:subscriptions@i-Base.org.uk)

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Dr Edmund Wilkins, Manchester General Hospital, Manchester.

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