RESEARCH

IMPACT OF DEFERRED VIRAL LOAD MONITORING DURING COVID-19 PANDEMIC

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HIVPA

HIV Pharmacy Association

Bulletin

Winter 2021

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HIVPA NEWS

Hello and welcome to the HIVPA Bulletin! I write this as many of you have recently returned from conferences such as EACS and BHIVA as well as the 40 year World AIDS day celebrations. As always within the speciality, it has been an exciting year for HIV medicine with new developments in treatment modalities and reframing of the conversation towards "zero transmissions". HIV Pharmacy professionals continue to work at the forefront of these developments and the bulletin is a great way to share work with colleagues nationally.

I extend my thanks to all who contributed to this edition and continue to welcome all contributions. If you have been involved in a project, attended a conference, enjoyed recent success or have any suggestions please get in touch directly at yemi.daramola@nhs.net.

Yemi Daramola, HIVPA Bulletin Lead

HIVPA Conference

Following postponement this year due to COVID-19, the HIVPA Annual conference will return in spring of 2022! Further information on pricing and the programme will follow via email and on the HIVPA website with the details of the event

https://hivpa.org/hivpa-annual-conference/

The HIVPA educational programme

will return in 2022 with new content delivered in line with government guidance, including some talks originally planned for 2021.

Keep an eye on HIVPA emails for further information on dates and topics.

Past HIVPA educational content and recordings of past study events can be accessed by members via the eHIVe site.

Leonie Swaden, consultant HIV pharmacist retires, after 30 years of contribution to the field of HIV pharmacy. She has provided leadership and guidance to many, in a career filled with achievements and accolades. To name a few she :

Lead the HIV Pharmacy service at the Royal Free for nearly 30 years.

Played a crucial role in incorporating homecare into the HIV outpatient model, creating value for the NHS.

Is one of the first consultant pharmacists in HIV medicine in the country, paving the way for many more

Has been recently honoured with a fellowship from the Royal Pharmaceutical Society

The HIVPA committee and expert panel would like to thank Leonie for her contributions and wish her a happy retirement.

HIVPA NEWS

Heather Leake-Date appointed Fellow of the Royal Pharmaceutical Society!

Heather, a member of the HIVPA expert panel has continued to share her wealth of knowledge with the HIV & SRH speciality and we are delighted to see her efforts and hard work recognised.

Being appointed a Fellow of the RPS is one of the highest accolades that can be paid to a member and recognises the significant contribution members have made during their careers.

Major changes to end HIV being a barrier to service in the Armed Forces in the UK .

There is no reason, medical or otherwise, why HIV should be a barrier to recruitment or deployment in the UK Armed Forces. Indeed, modern care means people with HIV can lead normal lives. People living with HIV can today perform open heart surgery, police our nation's streets and serve in parliament so they should also be able to protect their country...

https://www.bhiva.org/major-changes-to-end-HIV-being-a-barrier-to-service-in-the-Armed-Forces-in-the-UK

BHIVA HIV at 40

BHIVA was part of a new HIV programme from ITN Productions on World AIDS Day 2021, with the Terrence Higgins Trust and the Elton John AIDS Foundation, looking back at milestones over the last 40 years, and how advances in treatment are steering the UK towards the 2030 zero new HIV transmissions goal.

Watch at: https://www.bhiva.org/HIV-at-40

NICE approves first long-acting injectable HIV-1 treatment

NICE recommends IM Cabotegravir and Rilpivirine as a valuable treatment option for PLWH in recently released draft guidance. The final document is expected in January 2022 with commissioners required to comply within 3 months of publication. This exciting development will increase choice for PLWH.

https://www.nice.org.uk/news/article/nice-approves-first-long-acting-injectable-hiv-1-treatment

BHIVA Autumn Conference Presentations

For those who were unable to attend the BHIVA Autumn conference in November this year, some of the presentations are available online here with video to follow.

https://www.bhiva.org/AutumnConference2021

SPONSORS

HIVPA would like to thank all of our sponsors for their continued support:

Gilead Sciences

Mylan

Merck Sharp & Dohme Limited

ViiV Healthcare

Dr Reddy's Laboratories

DATES FOR YOUR DIARY

CROI 2022

Colorado, 12th –16th 2022

https://www.croiconference.org/

BHIVA Spring Conference 2022

Manchester Central, 20th - 22nd April 2022

https://www.bhiva.org/AnnualConference2022

16th Annual CHIVA Conference & CHIVA Family Conference

London & Virtual, 20th—21st May 2022

https://www.chiva.org.uk/ourworkprof/conferences/

HIVPA Annual Conference

Birmingham, 10th—11th June 2022

https://hivpa.org/hivpa-annual-conference/

The 24th International AIDS Conference

Montreal, Canada & Virtual, 29th July - 2nd August 2022

https://www.aids2022.org/

CHIVA NEWS

The 16th Annual CHIVA conference will happen on Friday 20th May 2022 at Friends House, London and online.
It will be an extra special year, with CHIVA celebrating its 20th birthday.
So, do save the date!
The CHIVA family conference is also returning and will be held on Saturday 21st May 2022 at Friends House, London.

The impact of deferred HIV viral load monitoring in people living with HIV during the COVID-19 pandemic

Stephanie Tyler, Daniella Chilton, Peter Richards, Matthew Craven, Ranjababu Kulasegaram
Harrison Wing Department, Guy's and St Thomas' Hospital NHS Foundation Trust, London, UK

Guy's and St Thomas' NHS
NHS Foundation Trust

Background

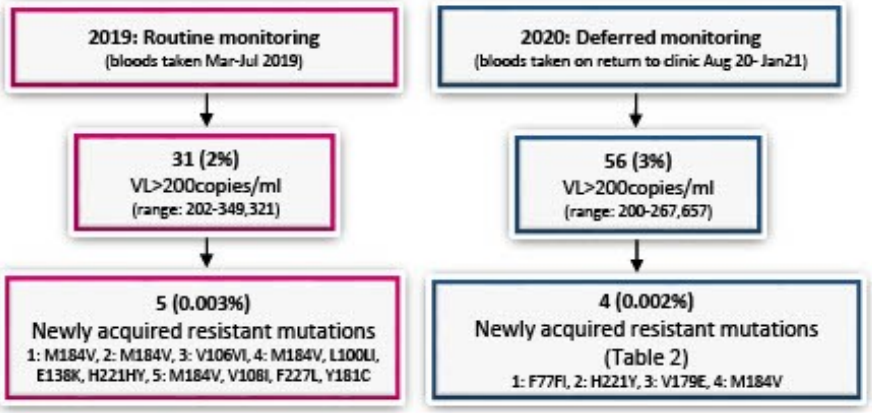
- Deferred routine monitoring during COVID-19 gave us an opportunity to evaluate whether all people living with HIV (PLWH) need to be seen every 6 months for monitoring.
- We aim to determine the number of PLWH with a detectable viral load (defined VL>200copies/ml) and development of resistance before and after the period of deferred monitoring.

Method

- Retrospective observational cohort study was conducted using electronic medical records.
- Target population: All PLWH who had deferred monitoring during UK COVID lockdown (Mar- Jul 20).
- Viral load data was captured on return to clinic after deferred monitoring and compared to the previous year where routine monitoring was done (Mar- Jul 19).

Results

Figure 1: Target population virological outcomes:
1618 PLWH identified had deferred bloods in 2020 due to COVID.



Conclusion

- 3% had detectable viral loads and <1% developed resistant mutations after deferred monitoring compared with 2% that had detectable viral loads and <1% developed resistant mutations during routine monitoring in 2019.
- 6 monthly routine viral load monitoring could be extended to annually as an option in selected groups of PLWH with prior counselling through risk stratification.
- Concerns are virological failure and development of resistance leading to transmission.
- The findings are limited by not including the impact of deferred monitoring of other routine tests such as sexual health screening, liver, renal function and did not assess mental health.

Table 2: Target population that acquired new resistant mutations after the period of deferred monitoring

PLWH	Baseline +/- pre-lockdown mutations	Post-lockdown mutations	Pre-lockdown viral load	Post-lockdown viral loads	Re-suppressed to VL<200	Pre-lockdown ART	Post-lockdown ART
1	Wild type	F77FL	51	199, 343, 298, 109, 93	Y	TAF/ FTC/ RPV →	TAF/ FTC/ DRV/ CCS
2	M184V, D67N	H221Y	108	366, 505, 780, <20, <20	Y	TAF/ FTC/ DRV /CCS + DTG →	TAF/ FTC/ BIC + DRV/CCS
3	Not known	V179E	<20	88863, 238838, 267657	N	ABC/ 3TC/ DTG	Stopped ART
4	Wild type	M184V	45	733, 55, <20, <20	Y	ABC/3TC + DRV/r →	ABC/ 3TC/ DTG

West / East Midlands Virtual Event—Feedback

The West/East Midlands HIVPA Region ran our second virtual event on Wednesday 22nd September 2021 in partnership with Gilead. The event was well attended and extended to delegates from outside the West/East Midlands HIVPA Region.

Experiences working through the pandemic

During the first session professional facilitator Judy Willits expertly guided delegates to openly share their experiences of working as HIV pharmacy specialists throughout the pandemic. Common themes were identified in the way we initially adapted our working practices e.g. increased use of telephone/virtual clinics, taking on new professional roles as colleagues were redeployed and finding innovative ways to ensure medication reached our patients. Some pre-pandemic challenges to delivering HIV pharmacy such as lack of clinic space have continued and even been exacerbated by the pandemic in some settings. As we learn to live with COVID-19 HIV pharmacy services have adapted further still embracing the best of those changes in practice e.g. developing pathways to review selected stable patients on an annual basis and gathering formal patient/clinician feedback.

Headlines from Midlands HIV Pharmacy Network

Rachael Leese then shared a round-up headlines from recent Midlands HIV Pharmacy Network meetings, provided an update on product discontinuations/pending product approvals and discussed the then topical logistics of identifying patients within our cohorts eligible for their third primary COVID-19 vaccination. We were also fortunate enough to have several delegates whom were able to share their experiences of using compassionate use IM cabotegravir/rilpivirine during this session.

Case Studies—Dr Mas Chaponda

We finished the meeting with an interactive session on the use of Biktarvy with Dr Mas Chaponda. Delegates opted to hear two case studies: the first about switching to Biktarvy from TDF in renal impairment and the second a switch from Triumeq in a patient experiencing nausea/ headache/sleep disturbance. We were provided with informative data on the thresholds for TAF in renal impairment and the CNS adverse effect profile of Biktarvy. This was followed by a more general question/answer session with delegates about Biktarvy. Approval is pending to release a recording of this session with Dr Mas Chaponda to those unable to attend.

Feedback from those who attended demonstrated that the event was successful. Delegates expressed that it was an informative event, relevant to their practice and despite the challenges of a virtual platform provided a great opportunity to engage with other HIV pharmacy specialists.

So thank you (!!!) again to those who attended and actively participated on the day; it wouldn't have been a success without your support. For those who weren't able to make it this time; the next event is being planned for Spring/Summer 2022 (further details to follow). Please do get in touch with West Midlands HIVPA Representative Rachael Leese r.leese@nhs.net if you have anything you'd particularly like to see at the next event or are able to support the event by sharing your local practice/audit/research.

Rachael Leese,
West Midlands HIVPA Representative

MSD

Delstrigo▼ doravirine/lamivudine/tenofovir disoproxil fumarate

Pifeltro▼ doravirine

An option in HIV-1

Advertisement

Make Doravirine▼ a Part of Every Day

Flexible and Convenient Dosing[1,2]

DELSTRIGO

Tablets are not to scale

Complete regimen

Can be taken once daily, any time of day

Free of food restrictions

Doravirine does not contain a booster

PIFELTRO

Tablets are not to scale

Single agent to be used as part of a regimen with other ARVs

The most frequently reported adverse reactions considered possibly or probably related to doravirine were nausea (4%) and headache (3%). Please refer to the SPC for the full list of adverse events.

Visit MSD Connect for more information

https://www.msdconnect.co.uk/products/doravirine/about-doravirine.xhtml

This link will take you to a promotional page where MSD products will be discussed. This information is for UK licensed products.

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DELSTRIGO®▼ Doravirine/Lamivudine/Tenofovir disoproxil fumarate

PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics before prescribing

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (Tel: 0208 154 8000). By clicking the above link you will leave the MSD website and be taken to the MHRA website.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to MSD (Tel: 01-299 8700).

PRESENTATION

Pifeltro: film-coated tablet containing 100 mg doravirine.

Delstrigo: film-coated tablet containing 100 mg doravirine, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate, equivalent to 245 mg of tenofovir disoproxil.

USES

Pifeltro: For use in combination with other antiretrovirals, for the treatment of HIV-1 without past or present evidence of resistance to non-nucleoside reverse transcriptase inhibitors (NNRTI).

Delstrigo: For the treatment of HIV-1 without past or present evidence of resistance to NNRTIs, lamivudine or tenofovir.

DOSAGE AND ADMINISTRATION

Therapy should be initiated by a physician experienced in HIV infection management. **Pifeltro:** One 100 mg tablet once daily. **Delstrigo:** One 100/300/245 mg tablet once daily. **Pifeltro and Delstrigo:** If co-administered with rifabutin or other moderate CYP3A inducers, increase doravirine dose to 100 mg twice daily (12 hours apart). **Pifeltro:** *Elderly:* No dose adjustment necessary. *Renal impairment:* No dose adjustment necessary. *Hepatic impairment:* mild to moderate: no dosage adjustment required; severe: use with caution. **Delstrigo:** *Elderly:* Special care advised. *Renal impairment:* estimated creatinine clearance (CrCl) ≥ 50 mL/min: no dose adjustment necessary; estimated CrCl <50 mL/min: not recommended. *Hepatic impairment:* mild to moderate: no adjustment required; severe hepatic: use with caution.

CONTRA-INDICATIONS

Hypersensitivity to the active substance or excipients. Co-administration with strong CYP3A inducers.

PRECAUTIONS

A residual risk of sexual transmission of HIV-1 cannot be excluded and precautions should be taken in accordance with national guidelines. Use with CYP3A inducers may reduce the exposure of doravirine. Autoimmune disorders and immune reactivation syndrome have been reported in patients treated with combination antiretroviral therapy which may require investigation and treatment. Contains lactose monohydrate.

Delstrigo: Post-treatment exacerbation of HBV (including hepatic decompensation and liver failure) have been reported in patients co-infected with HIV-1 and HBV following discontinuation of lamivudine or tenofovir disoproxil. Monitor patients co-infected with HIV-1 and HBV after discontinuation of Delstrigo and if appropriate initiate anti-HBV therapy. Renal impairment, including acute renal failure and Fanconi syndrome have been reported with tenofovir disoproxil. Assess estimated CrCl prior to initiation and during therapy. In patients at risk of renal dysfunction, serum phosphorus, urine glucose, and urine protein should also be assessed. Discontinue therapy if estimated CrCl declines below 50 mL/min. Avoid with concurrent or recent use of nephrotoxic medicinal products (e.g. high-dose or multiple NSAIDs). Evaluation of renal function is recommended for persistent or worsening bone pain, pain in extremities, fractures, and/or muscular pain or weakness. Assessment of bone mineral density should be considered for patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss. Hypophosphatemia and osteomalacia secondary to proximal renal tubulopathy should be considered in patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms. Doravirine/lamivudine/tenofovir disoproxil must not be co-administered with other medicinal products containing lamivudine, tenofovir disoproxil, or tenofovir alafenamide or with adefovir dipivoxil.

Doravirine/lamivudine/tenofovir disoproxil should not be administered with doravirine unless needed for dose adjustment (e.g. co-administered with rifabutin).

Drug interactions: Refer to SmPC for full information on drug interactions. **Pifeltro and Delstrigo:** Doravirine is metabolized primarily by CYP3A. Do not co-administer with strong CYP3A enzyme inducers. If co-administration with rifabutin or other moderate CYP3A inducers cannot be avoided, increase doravirine dose to 100 mg twice daily (taken 12 hours apart). Use with caution when co-administering doravirine with medicinal products that are sensitive CYP3A substrates that have a narrow therapeutic window (e.g., midazolam, tacrolimus and sirolimus). **Delstrigo:** Do not administer with other antiretroviral medicinal products. Co-administration of doravirine/lamivudine/tenofovir disoproxil with medicinal products that reduce renal function or compete for active tubular secretion may increase serum concentrations of lamivudine. Co-administration of doravirine/lamivudine/tenofovir disoproxil with medicinal products that reduce renal function or compete for active tubular secretion via OAT1, OAT3 or MRP4 may increase serum concentrations of tenofovir. Avoid with concurrent or recent use of nephrotoxic medicinal products.

Pregnancy and Lactation: Pifeltro and Delstrigo: Avoid use during pregnancy. An Antiretroviral Pregnancy Registry has been established. Breastfeeding is not recommended.

SIDE EFFECTS

Refer to SmPC for complete information on side-effects.

Pifeltro and Delstrigo: ***Common:*** abnormal dreams, insomnia, headache, dizziness, somnolence, nausea, diarrhoea, abdominal pain, vomiting, rash, fatigue, flatulence, increased alanine aminotransferase. ***Uncommon:*** depression, hypophosphataemia, suicidal ideation, paraesthesia, asthenia. ***Rare:*** rash pustular, hypomagnesaemia, aggression, hallucination, dyspnoea, acute kidney injury, renal disorder, calculus urinary, nephrolithiasis, chest pain. **Delstrigo:** ***Common:*** cough, nasal symptoms, alopecia, muscle disorders, fever. ***Uncommon:*** neutropenia, anaemia, thrombocytopenia, pancreatitis, rhabdomyolysis, proximal renal tubulopathy (including Fanconi syndrome). ***Rare:*** lactic acidosis, hepatitis, angioedema, myopathy, acute renal failure, renal failure, acute tubular necrosis, nephritis (including acute interstitial) and nephrogenic diabetes insipidus. ***Very Rare:*** pure red cell aplasia, peripheral neuropathy (or paraesthesia).

Delstrigo: Lactic acidosis has been reported with tenofovir disoproxil alone or in combination with other antiretrovirals. Predisposing factors such as decompensated liver disease, or patients receiving concomitant medications known to induce lactic acidosis are at increased risk of experiencing severe lactic acidosis during tenofovir disoproxil treatment, including fatal outcomes.

PACKAGE QUANTITIES AND BASIC NHS COST

Pifeltro: Bottle of 30 tablets £471.41

Delstrigo: Bottle of 30 tablets £578.55

Marketing Authorisation number Great Britain:
Pifeltro: PLGB 53095 0045
Delstrigo: PLGB 53095 0015

Marketing Authorisation holder Great Britain:
Merck Sharp & Dohme (UK) Limited 120 Moorgate London EC2M 6UR UK

UK (Northern Ireland):
Pifeltro: EU/1/18/1332/001
Delstrigo: EU/1/18/1333/001

UK (Northern Ireland):
Merck Sharp & Dohme B.V. Waarderweg 39 2031 BN Haarlem The Netherlands

Legal Category: POM

Date of review of prescribing information: February 2021

PI.PIF-DEL.20.GB-NI.7390.CoO.RCN019429.RCN019439

Merck Sharp & Dohme (UK) Limited,
120 Moorgate, London, United Kingdom EC2M 6UR
Telephone: +44(0) 208 154 8000
Email: medicalinformationuk@msd.com
www.msd-uk.com

References:
1. DELSTRIGO Summary of Product Characteristics.
2. PIFELTRO Summary of Product Characteristics.

GB-DOR-00226. Date of preparation: November 2021.

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