REGIONAL UPDATES

WELCOME TO NEW REGIONAL REPRESENTATIVES

LIVING WITH MEDICINES

RESEARCH FROM THE UNIVERSITY OF KENT ON MEDICINES USE EXPERIENCES IN PLWH

VIRTUAL EVENTS

STUDY DAYS AND CONFRERENCE EVENTS 2020/21

HIVPA NEWS

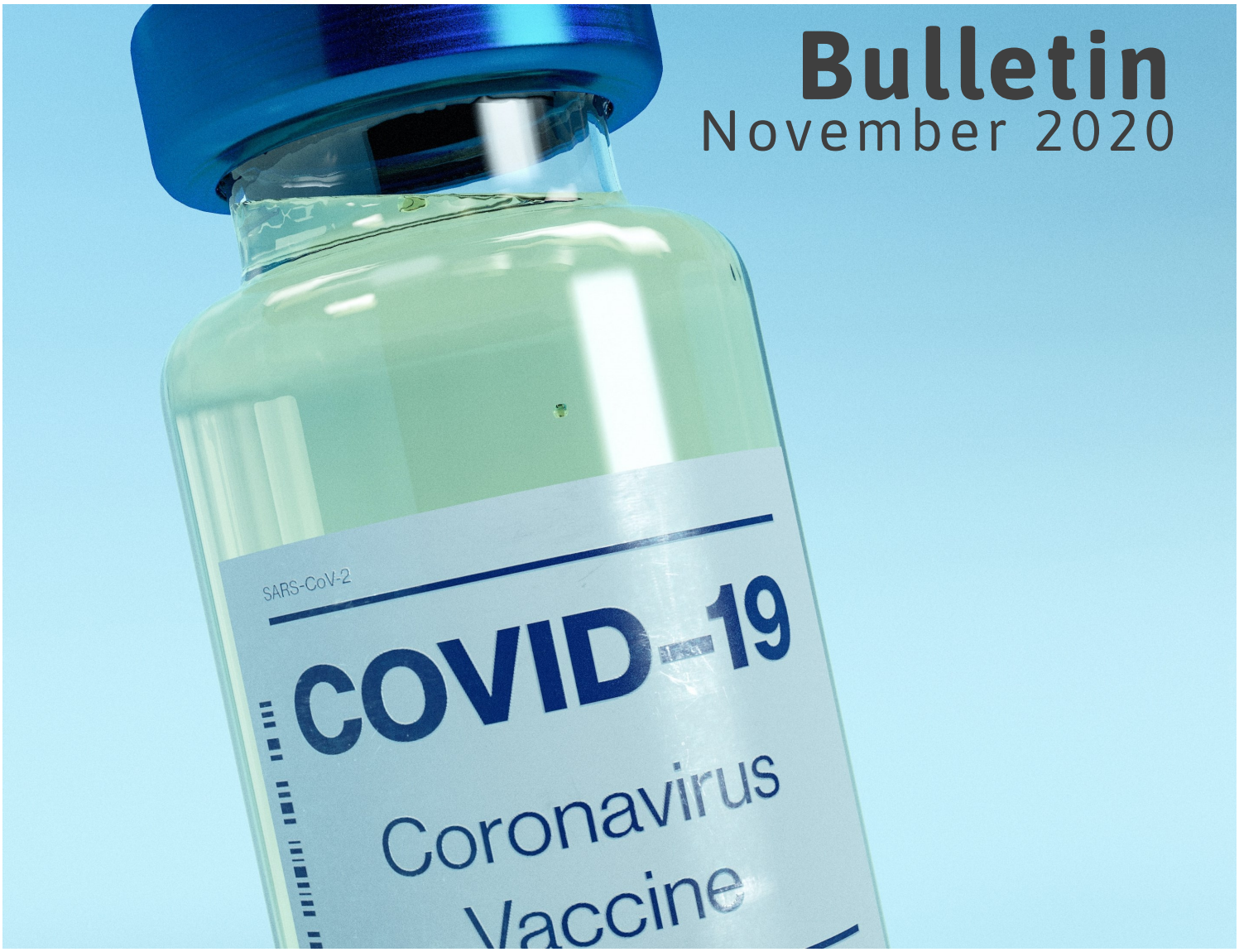
LATEST UPDATES FROM THE COMMITTEE

HIVPA

HIV Pharmacy Association

Bulletin

November 2020



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HIVPA News

Hello and welcome to the HIVPA bulletin! With recent breakthroughs in COVID-19 vaccine candidates, we might now allow ourselves to look cautiously look towards the future for both our services and ourselves. No doubt there has been innovation from HIV pharmacy to meet the challenges this year has brought and the bulletin continues to be a great way to share in the successes, connect with colleagues or even highlight new challenges.
Thanks to all the contributors this year for finding the time to submit pieces with all that's going on. For future editions of the bulletin, 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

REGIONAL UPDATES

I'm delighted to welcome 3 new Regional Representatives to the Team: Amy Harris and Sarah Hulse as the Regional Representatives for Wales and Karen McMullan for Northern Ireland. Karen is currently on maternity leave but is expected to be back in post in November 2021.

The Regional Representative(s) for your region are your local point of contact with HIVPA. To make contact with them, please email: hivpaoffice@gmail.com and we will put you in touch.
Each region also has a thread on the HIVPA Discussion Forum, so please also keep an eye on this as your Regional Representative(s) may post information about any regional events they are co-ordinating or any other relevant information pertaining to local issues here. You can also engage with members in your region on local matters via this thread.

It would be great to hear from you!

Portia Jackson

HIVPA Regional Representative Lead

Update from the Regional Representative for East Anglia

Plans are coming together for a regional virtual educational event scheduled for January 2021. It is proposed that the event, kindly supported by Gilead, will be held via Microsoft Teams. Further details will follow shortly; please check out the regional thread on the Discussion Forum. It would be fantastic to 'see' you there!

Portia Jackson

HIVPA Regional Representative Lead

EVENT UPDATES

West & East Midlands Regional Virtual Event

The West & East Midlands will be hosting their first virtual event endorsed by HIVPA and supported by MSD on Wednesday 18th November 2020 9-11.30am. We will first hear from Dr. Grahame Moyle about the evidence base for doravirine and case studies outlining its clinical use.

In the second part of the morning we will turn our attentions to the impact of COVID-19 on HIV care hearing both from a local clinic on how pharmaceutical provision has changed and the patient perspective from Jamie Styler who formerly worked for a local sexual health charity and continues to run focus groups for PLWHIV.

HIVPA News

We will round up our morning with an update from NHSE and the HIV IVN to include an update on PrEP provision and a review of our prescribing choices for patients newly initiated on ARVS. To book your place email r.leese@nhs.net

The programme can be found here

Rachael Leese

Liverpool Masterclass in Antiviral Pharmacology

The team at the university of Liverpool responsible for hiv-druginteractions.org held a one day programme on HIV PK & PD. The programme includes sessions on long-acting antiretrovirals, discussed complex DDIs as well as a brilliant panel discussion on difficult pharmacology cases submitted by attendees. Recordings of the sessions are freely available to all.

https://www.livmap.org/program

HIVPA September Education Series — Women's Health

In September we released a series of presentations on women's health replacing the usual (in person) September study day. The talks included:

Transgender women's health – Dr. Tara Suchak

Transgender Women , Hormone Therapy Case Studies – Yemi Daramola

Pregnancy in women living with HIV – Dr. Yvonne Gilleece

Women with perinatal HIV, pragmatic, prescribing, pregnancy and preparations – Dr. Caroline Foster

Menopause and women living with HIV (WLWH) – Dr. Sheema Tariq

Recordings of the talks are available to HIVPA members via the eHIVE website.

https://ehive.hivpa.org/training-modules/

BHIVA COVID-19 GUIDANCE & STATEMENTS

BHIVA COVID-19 interim adult antiretroviral guidance

This interim guidance is intended for use during the COVID-19 pandemic and is temporary. The need to utilise the guidance will depend on local circumstances, which may vary over time. We advise that where any service has the capacity to operate as they would usually, they continue to do so, but where circumstances limit access to investigations or appointments, the appropriate parts of this guidance are followed accordingly...

https://www.bhiva.org/BHIVA-COVID-19-interim-adult-antiretroviral-guidance

BHIVA '2nd COVID peak' guidance for HIV services

In light of the rising number of COVID cases, and NHS organisations reinitiating contingency plans for managing the epidemic, we are updating our guidance for HIV services.

We outline core service elements that should be maintained whilst recognising that all NHS staff have a role to play in dealing with the unprecedented pandemic and national emergency that is COVID-19. Ensuring patients understand that services will be limited, non-urgent care restricted, and that changes may be implemented at short notice, but that all services will ensure a safe standard of care, is crucial...

https://www.bhiva.org/BHIVA-2nd-COVID-peak-guidance-for-HIV-services

HIVPA News

BHIVA, DAIG, EACS, GESIDA & Polish Scientific AIDS Society Statement on risk of COVID-19 for people living with HIV (PLWH)

Case series of people living with HIV (PLWH) with COVID-19 have been published from China, Spain, Germany, Italy and the United States (1-15) with no clear evidence for a higher COVID-19 infection rate or different disease course in people with and without HIV. Of note, most case series of PLWH report a younger age in their study population than in HIV-negative hospitalised COVID-19 patients, but comparable rates of comorbidities...

https://www.bhiva.org/updated-BHIVA-DAIG-EACS-GESIDA-Polish-Scientific-AIDS-Society-statement-on-risk-of-COVID-19-for-PLWH

COMISSIONING

The NHS England commissioning policy for the reimbursement of drugs for pre exposure prophylaxis of HIV is now available. This is a significant step forward towards ending the HIV epidemic.

https://www.england.nhs.uk/publication/reimbursement-for-the-use-of-generic-drugs-for-pre-exposure-prophylaxis-prep-for-the-prevention-of-hiv/

SPONSORS

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

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Dr Reddy's Laboratories

The support of our sponsors is essential to much of the work carried out by HIVPA including events such as study days and conference.

Thank You!

HIVPA Study Days

Dates and Topics for 2021

An introduction to HIV	**JANUARY**
Cancer, critical care & COVID-19	**APRIL**
HIV and paediatrics	**SEPTEMBER**
HIV & mental health	**NOVEMBER**

Due to the COVID-19 pandemic and government restrictions, the HIVPA study days will be replaced by a series of online pre-recorded sessions from expert speakers. The talks will be released simultaneously on a date in the designated month and members will be notified by email once the presentations are available on the eHIVE site.

Any further changes to the educational format will be communicated nearer the time.

Previous feedback comments from study day attendees:

Very informative and highlights areas that may not be experienced in each clinic.

A very interesting and extremely informative meeting.

Very informative study day, lots of very useful information + some very impressive speakers. Starting later a good idea in terms of travel. Thanks!

Dates for your dairy

BHIVA "*Autumn is the new Spring*" Conference 2020

22–24 November 2020

https://www.bhiva.org/AutumnConference2020

Conference on Retroviruses and Opportunistic Infections (CROI) 2021

6-10 March 2021

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

Annual CHIVA conference 2021

13th March 2021

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

International Workshop on HIV & Women 2021

26-27 April 2021

https://www.virology-education.com/event/upcoming/hiv-women-2021/

Evaluation of Medicines use experiences among people Living with HIV in the UK

Dr Barbra Katusiime,
Lecturer in Pharmacy Clinical and Professional Practice, University of Kent

Lessons learned from the LMQ project - a patient-centred screening tool for identifying medicine burden in HIV care

Barbra Katusiime[1], Rebecca Cassidy[1], Jackie Holland[2], Vanessa Burton[2], Raj Hembrom[2], Jessica Clements,[2] Sarah Corlett[1]

Background

The UK met the 2020 UNAIDS 90:90:90 targets in 2018, with over 98% of people living with HIV (PLWH) on long-term antiretroviral therapy achieving adequate viral load suppression.[1] Although clinically beneficial, self-management of HIV as a complex chronic condition can be challenging.[2] We know that polypharmacy and multimorbidity are prevalent in the UK's increasingly aging HIV+ population.[3,4] Almost a quarter (22%) of PLWH may experience a high pill burden (of ≥ 10 pills per day), mostly from non-HIV medicines.[4] The concept of medicine burden encompasses a wide range of issues.[5] Coping with a new diagnosis, navigating care pathways, and learning about strict antiretroviral therapy (ART) can be difficult for some. PLWH may experience stigma and social pressures,[6] amidst juggling medicine use with day-to-day to life. All this can impact on both wellbeing and adherence outcomes. Multidisciplinary specialty teams play a significant role in supporting medicines use of PLWH (including initiating, switching, or maintaining ART). However, medicine burden from the perspective of PLWH is not well understood and rarely assessed in everyday clinical practice. Patient-reported outcome measures (PROMS) can support PLWH to report their experiences of medicine burden.

This project aimed to test a PROM for use in HIV care (known as the Living with Medicines Questionnaire (LMQ-3). As a patient-centred instrument, the 41-item LMQ-3 has been widely validated for use in the context of multimorbidity and polypharmacy.[7–10] It has acceptable validity and reliability and was developed with considerable patient involvement,[7] but we have not tested its application and relevance to PLWH.

Methods

Locally researchers and clinicians recognised that some PLWH may experience difficulties which impact on engagement with care. This survey aimed to gather views of service users who were 18 years or older and using ART for at least 6-months. Eligible patients were identified by the HIV team in two outpatient clinics (Clover Street in Medway and the Gate in Canterbury), and referred to final-year pharmacy students, who obtained participant consent, and asked participants to complete a paper or online survey after their clinic appointment.

We asked participants about the eight aspects of medicine burden, which are covered in the LMQ-3: side effects, efficacy, practical difficulties, interferences with day-to-day life, patient-provider relationships and communication about medicines, autonomy/flexibility to vary regimes, cost-related burden related to non-HIV medicines, and general concerns.[8]

Evaluation of Medicines use experiences among people Living with HIV in the UK

The survey also asked about the level of comfort they felt sharing their diagnosis, and their experience of stigma (assessed using an 8-item scale).[11] This is the first study that has attempted to assess experiences of medicine burden for PLWH in Kent and we are unaware of similar initiatives in the UK. The study was approved locally by Kent Community Health NHS Foundation Trust and by the NHS Health Research Authority (Ref: 18/NE/0321).
Following completion of the survey, participants were asked to contact their HIV pharmacist if this process had raised concerns about their medicines so as to gain additional support if needed.
We have so far recruited 58 patients in Kent. 168 have also accessed our UK-wide online survey promoted via social media and HIV charities. Our preliminary results show that most PLWH perceive themselves to have a low medicine burden. Researchers outside of the UK have reported perceived lower treatment burden in PLWH, although this is a broader concept than medicine burden.[12] However, despite reporting this some specific aspects of medicine use were reported as challenging within our study.

Results & Conclusions

About 1 in 5 felt that using ART affected their social relationships, sexual life or day-to-day life. Side effects appeared to be bothersome for most PLWH and contribute to prescribing cascades and polypharmacy. As illustrated by a 66-year old male who wrote 'My HIV medicines have left me with lipodystrophy and peripheral neuropathy for which I take painkillers, but this causes erectile dysfunction affecting my sexual life, side effects have caused me problems as I suffer from insomnia, which affects my wellbeing. I have to take statins because HIV medicines raise my cholesterol, but this gives me muscle pain'.

Although most participants were satisfied with the effectiveness of their ART, weighing the risks and benefits of ART was a common occurrence. The following quote from a 25-year old male illustrates this point 'The medication can cause slight light headiness, but considering the benefits, they are definitely worth the hassle'. This may explain why the vast majority of participants self-reported low levels of burden overall, and yet reported challenges with specific aspects of medicines use. To many PLWH, their medicines were seen as a necessity to get through life and further qualitative research is planned to investigate the meanings of 'burden' through the voices of PLWH.

Practical difficulties were reported, particularly with respect to the times PLWH had to use their ART and/or non-HIV medicines. Some reported concerns about forgetting doses. One 54-year-old male participant said 'I do have some difficulty in juggling my medicines with working nights'.

Evaluation of Medicines use experiences among people Living with HIV in the UK

Most participants reported good communication and healthy relationships with their health care providers, but some wanted additional information about their condition and their medicines.

Although HIV medicines are provided free of charge, the cost of non-HIV prescription charges appeared to be burdensome to some. About a third worried about paying for their other medicines and a minority agreeing that they had to choose between paying for basic essentials or medicines.
The majority expressed limited autonomy over medicines use and had to adhere to stringent dosing regimens to achieve undetectable viral loads, with little or no room to alter the dosing times. We found a positive linear correlation between medicine burden and experiences of stigma, suggesting that PLWH need further support in both areas. Stressing aspects of medicine-related stigma, one participant wrote that 'the tablets are quite large but do not bother me however they may bother others' and some felt the size of pills made them difficult to take in public.

Pharmacy students' involvement in this research was key for the success of this pilot project. As one final-year student said 'HIV is an area which isn't explored much. This project allowed us to gain insight into this topic. I definitely wanted to do a pharmacy practice project because as pharmacists we tend to focus on the clinical [or adherence] aspect, so this project enabled me to gain holistic insight into living with HIV from a patient point of view'. As part of this project, students collaborated with the NHS Trust in promoting the National HIV testing week (16th – 22nd November 2019), and encouraged University students to engage in HIV testing and prevention services provided on the Medway Campus.

This project was a collaborative effort between Medway School of Pharmacy student researchers, the HIV multidisciplinary team at Kent Community Health NHS Foundation Trust, academic pharmacists and researchers at the University of Kent.
The results from this study will be used to inform service improvement and may lead to future integration of person-centred outcome measures in future HIV care models. We do not suggest that everyone will experience medicine burden but we provide insight into the challenges of some PLWH. This study has implications for healthcare providers and policymakers. Assessment of medicine burden could enable identification of those people who need additional support with both their HIV and non-HIV treatments. However, a larger sample size is needed to validate the findings from this pilot study.

Please contact Dr Barbra Katusiime, b.katusiime@kent.ac.uk if you wish to learn more about this project or how you could be involved.

References

1. Progress towards ending the HIV epidemic in the United Kingdom: 2018 report. 2018;68.
2. Martin S, Chinnock P, Perales J, Lee H, Lee CY, Wu Y, et al. Self-management interventions for people living with HIV/AIDS. Cochrane Database of Systematic Reviews [Internet]. 2014 [cited 2020 Apr 7];(9). Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008731.pub2/full
3. Holtzman C, Armon C, Tedaldi E, Chmiel JS, Buchacz K, Wood K, et al. Polypharmacy and risk of antiretroviral drug interactions among the aging HIV-infected population. Journal of general internal medicine. 2013 Oct;28(10):1302–10.
4. Edelman EJ, Gordon KS, Glover J, McNicholl IR, Fiellin DA, Justice AC. The Next Therapeutic Challenge in HIV: Polypharmacy. Drugs Aging. 2013 Aug;30(8):613–28.
5. Mohammed MA, Moles RJ, Chen TF. Medication-related burden and patients' lived experience with medicine: a systematic review and metasynthesis of qualitative studies. BMJ Open. 2016;6(2):1–16.
6. Hibbert M, Crenna-Jennings W, Kirwan P, Benton L, Lut I, Okala S, et al. The people living with HIV stigma survey UK 2015: HIV-related sexual rejection and other experiences of stigma and discrimination among gay and heterosexual men. AIDS Care. 2018;30(9):1189–96.
7. Kotronoulas G, Cooper M, Johnston B. Core Patient-Reported Outcomes (PROs) and PRO Measures (PROMs) for Polypharmacy Medicines Reviews: A Sequential Mixed-Methods Study. Patient Preference and Adherence. 2019;13:2071–2087.
8. Katusiime B, Corlett SA, Krska J. Development and validation of a revised instrument to measure burden of long-term medicines use: the Living with Medicines Questionnaire version 3. Patient Relat Outcome Meas. 2018 May 28;9:155–68.
9. Katusiime B, Corlett S, Reeve JL, Krska J. Measuring medicines related experiences from the patient perspective: a systematic review. Patient Relat Outcome Meas. 2016;7:157–71.
10. Katusiime B. Development and validation of the Living with Medicines Questionnaire a generic measure of patients' experiences of medicine use and associated burden [Internet] [PhD]. University of Kent, The University of Greenwich; 2017. Available from: https://kar.kent.ac.uk/62939/
11. Molina Y, Choi SW, Cella D, Rao D. The stigma scale for chronic illnesses 8-item version (SSCI-8): development, validation and use across neurological conditions. Int J Behav Med. 2013 Sep;20(3):450–60.
12. Schreiner N, Perazzo J, Currie J, Daly B, Webel A. A descriptive, cross-sectional study examining treatment burden in people living with HIV. Appl Nurs Res. 2019;46:31–6.

UNIVERSITY of GREENWICH

medway school of pharmacy

University of Kent

EVALUATION OF MEDICINES USE EXPERIENCES AMONG PEOPLE LIVING WITH HIV IN THE UK

Mancy Visana,

Supervisor: Dr Barbra Katusiime,

Co-supervisor: Dr Rebecca Cassidy & Dr Sarah Corlett

Cynthia Ragui, Jeninah-Charlotte Bazolana-Hetuba, Linda Ireti Adesina & Tsitsi Blessing Awor-Onono

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BACKGROUND

At present there are over 100,000 people living with HIV (PLWH) in the UK, of which 98% are using antiretroviral treatment (ART). The UK has successfully achieved the United Nations targets for diagnosis, treatment and viral suppression, in advance of 2020[1]. Medicines are essential in the management of HIV, in order to achieve optimal health outcomes. Despite this medicine burden remains a chronic issue. Approximately 1 in 8 PLWH experience stigma[2], and the consequences can be detrimental, resulting in poor health behaviours, thus poor HIV-related health outcomes (i.e. onset of AIDS-related illnesses)[3].

AIM AND OBJECTIVES

AIM

To quantify the burden of using medicines among patients receiving HIV care in the UK

OBJECTIVES

(a) Identify types of medicine-related and socio-demographic factors which impact medicine burden among people receiving HIV care in the UK

(b) To understand the extent to which illness-related stigma affects this population

METHODS

Study setting: Study conducted between October 2019 to January 2020

Eligibility: HIV-positive, living in the UK, at least18 years old, and using ART

Study Instruments:
The Living with Medicines Questionnaire-version 3 **and** Stigma Scale for Chronic Illnesses 8-item

Survey distribution:
Online- Facebook, Instagram **and** Twitter **AND** to organisations providing HIV services in the UK
In-clinic- 2 HIV-clinics in Kent and Medway

Data Analysis: Statistical & thematic analysis
Non-parametric statistical tests:
- Mann-Whitney-U for dichotomous variables
- Kruskal-Wallis for multiple categories,
- Spearman's rank order correlation test- to assess relationship between medicine burden and stigma.

RESULTS

Participant Charactertics

53 PLWH were recruited and majority were male (n=34), white (n=36) and employed (n=28). Age range of participants was between18-67 years (mean=49.1). Participants were using an average of 4 medicines, (range 1-20), 8.5% needed assistance with medicine use and 42.6% paid for their medicines.

Table 1 showing medicine-related and sociodemographic factors contributing to medicine burden

Factors contributing to medicine burden	Significance (p-value)
Employment status	0.032
Number of medicines	0.016
Post-Hoc analysis revealed	
5-9 medicines Vs 1-4 medicines	0.038
≥10 medicines Vs 1-4 medicines	0.019
Frequency of medicine use	0.039
Stigma experiences	<0.001

Relationship between medicine burden and stigma experiences

Figure 1 Scatter plot showing a positive linear relationship between medicine burden and stigma experiences **(Speakman's rho = 0.465, p<0.001)**

DISCUSSION AND CONCLUSION

Overall this sample reported low medicine burden, however statistical analysis identified specific sociodemographic and medicine-related factors contributing to high medicine burden including, employment status, number of medicines and frequency of medicine use. Also, stigma experiences were positively correlated with medicine burden.

This study has implications for employers, healthcare providers and policymakers involved in the care of PLWH, as findings highlight that PLWH find specific aspects of medicine use challenging.

REFERENCES

1. Terrence Higgins Trust 2018- HIV statistics,
2. Vanable et al 2006
3. Claborn et al 2017
4. Koch J. 2017

ACKNOWLEDGMENTS

Dr Barbra Katusiime, Dr Rebecca Cassidy, Dr Sarah Corlett, Dr Raj Hembrom, Vanessa Burton and Jackie Holland.

Redressing Health Inequalities in HIV Care

Samm Kabagambe, Medical Scientist
Gilead Sciences LTD

Because of ART, the life expectancy of people living with HIV has approached that of the general population.[1] This is excellent progress, but the resulting ageing HIV population presents new challenges that require a step change in HIV care.

Foremost among these is the need to ensure that every person living with HIV (PLWHIV) has access to the same quality of services and care regardless of age, gender or ethnicity. Given the diverse HIV population in the UK, which includes demographic groups particularly vulnerable to health inequalities, this is a priority issue.

The health inequalities that have been highlighted by COVID-19 existed long before this pandemic in many areas of health. Outcomes in hospitalised patients have shown that people from Black, Asian and Minority Ethnic (BAME) backgrounds experience higher mortality from COVID-19 and are more likely to require invasive ventilation in intensive care.[2]

Within HIV care, inequality in care is a matter of serious concern. It is vital that a national strategy for HIV is created which includes measures to address health inequalities specifically in HIV.

Gilead Sciences, in partnership with The African Advocacy Foundation and Sophia Forum has commissioned a report **"Striving towards health equalities in HIV"** which examines the issues of demographic inequalities in HIV diagnosis and care.

The report investigates the way women and BAME communities experience HIV care in the UK from the point of diagnosis through to treatment and support for broader mental and physical well-being.

It brings to light trends such as:

- BME people living with HIV feel less informed about their condition
- BME people living with HIV are less engaged with their clinician when their treatment is altered
- Two-fifths of women living with HIV are diagnosed with a mental health condition
- Women are less likely than men to feel comfortable asking their GP questions about HIV

While probing these findings in greater depth, the report also sets out a series of recommendations as to how these problematic gaps in different groups' experiences can be addressed:

- All healthcare professionals involved in HIV care should be supported to encourage BME and female PLWHIV to engage in shared decision-making and reporting patient outcomes
- A quality of life indicator, including measures to monitor ageing with HIV, should be established and routinely measured for all people living with HIV, to ensure that they age well with the condition
- The NHS, HIV charities and educational organisations should ensure that BME and female PLWHIV are signposted to accessible and relevant information through an appropriate range of HIV support services, for example support through the menopause for women
- Public Health England should investigate the causes of late diagnosis in BME and female PLWHIV, and agree actions to address these
- A public health campaign should be developed seeking to reduce late diagnosis amongst BME and female PLWHIV, including through addressing stigma, in partnership with these groups
- BME PLWHIV should be encouraged to take part in decisions about changes to their treatment

If you would like to find out more information on this report and obtain a copy, please contact Dan Murphy at dan.murphy@gilead.com

October 2020. UK-HIV-2020-10-0071

References

Katz, I.T. and Maughan-Brown, B., 2017. Improved life expectancy of people living with HIV: who is left behind?. The Lancet HIV, 4(8), pp.e324-e326.

ONS: Coronavirus (COVID-19) related deaths by ethnic group, England and Wales: 2 March 2020 to 15 May 2020 available at https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/articles/coronaviruscovid19relateddeathsbyethnicgroupenglandandwales/2march2020to15may2020 (Accessed 14/10/2020)

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Dovato prescription is recommended in line with SmPC requirements and inclusion, which should be evaulated by a healthcare professional

DHHS

NOW A RECOMMENDED INITIAL REGIMEN[1]

Recommended as an initial regimen for most PLHIV (A1)* and as a good option for virologically suppressed patients who have no evidence of resistance to either drug

Exclusions for treatment-naive patients:†
- HIV viral load >500,000 copies/mL
- HBV co-infection
- Where ART is to be started before the results of HIV genotype resistance testing for reverse transcriptase or HBV testing are available

EACS

NOW A RECOMMENDED INITIAL REGIMEN[2]

Recommended as an initial regimen for treatment-naïve patients and as a switch strategy for virologically suppressed patients

Requirements for treatment-naive patients:†
- HBsAg negative
- HIV viral load <500,000 copies/mL

***Rating of recommendation:** A=strong; **Rating of evidence:** I=data from randomised controlled trials;
†The requirements and exclusions listed here are not the full list as shown in the Dovato SmPC

DOVATO is indicated for the treatment of HIV-1 in adults and adolescents above 12 years weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

Prescribing Information
Dovato dolutegravir 50mg/lamivudine 300mg tablets
See Summary of Product Characteristics (SmPC) before prescribing
Indication: HIV-1 in adults & adolescents above 12 years of age weighing ≥40kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine. **Dosing:** One tablet once daily with or without food. Use an additional 50mg tablet of dolutegravir approximately 12 hours after the dose of Dovato when co-administered with efavirenz, nevirapine, tipranavir/ritonavir, etravirine (without boosted PI), carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St John's Wort or rifampicin. *Elderly:* Limited data in 65+ yrs. Not recommended in patients with creatinine clearance < 50 mL/min. Caution in severe hepatic impairment. **Contraindications:** Hypersensitivity to any ingredient. Co-administration with substrates of OCT-2 with narrow therapeutic windows, such as fampridine. **Special warnings/precautions:** Risk of hypersensitivity reactions. Discontinue dolutegravir and other suspect agents immediately. Risks of osteonecrosis, immune reactivation syndrome. Monitor LFTs in Hepatitis B/C co-infection and ensure effective Hepatitis B therapy. Caution with metformin: monitor renal function and consider metformin dose adjustment. Use with etravirine requires boosted PI or increased dose of dolutegravir. Use with Mg/Al-containing antacids requires dosage separation. Use with calcium, multivitamins or iron also requires dosage separation if not taken at the same time with food. Use with cladribine or emtricitabine not recommended. When possible, avoid chronic co-administration of sorbitol or other osmotic acting alcohols (see SmPC section 4.5). If unavoidable, consider more frequent viral load monitoring. **Pregnancy/ lactation:** The safety and efficacy have not been studied in pregnancy. Women of childbearing potential should be counselled about the potential risk of neural tube defects with dolutegravir (a component of Dovato), including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and the risks of continuing treatment with Dovato should be discussed with the patient. If a pregnancy is confirmed in the first trimester while on Dovato, the benefits and risks of continuing Dovato versus switching to another antiretroviral regimen should be discussed with the patient taking the gestational age and the critical time period of neural tube defect development into account. Most neural tube defects occur within the first 4 weeks of embryonic development after conception (approximately 6 weeks after the last menstrual period). Dovato may be used during the second and third trimester of pregnancy when the expected benefit justifies the potential risk to the foetus. Do not breast-feed. **Side effects:** See SmPC for full details. Headache, GI disturbance, insomnia, abnormal dreams, depression, anxiety, dizziness, somnolence, rash, pruritus, alopecia, fatigue, arthralgia, myalgia, hypersensitivity, suicidal ideation or suicide attempt, hepatitis, blood dyscrasias, acute hepatic failure, pancreatitis, angioedema, rhabdomyolysis, lactic acidosis, peripheral neuropathy. Elevations of ALT, AST and CPK. **Basic NHS costs:** £656.26 for 30 tablets. **MA number:** EU/1/19/1370/001. **MA holder:** ViiV Healthcare BV, Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands. Further information available from: customercontactuk@gsk.com Freephone 0800 221 441.

POM

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Date of approval: July 2020 PI-2451v4

Adverse events should be reported. For the UK, reporting forms and information can be found at *www.mhra.gov.uk/yellowcard* or search for **MHRA Yellowcard** in the **Google Play** or **Apple App store**. Adverse events should also be reported to GlaxoSmithKline on 0800 221441.

References: 1. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Dec 18, 2019. http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed 6th October 2020. **2.** European AIDS Clinical Society Guidelines. Version 10.1. October 2020. https://www.eacsociety.org/files/guidelines-10.1.finalsept2020.pdf Accessed 6th October 2020. **3.** NHS England Clinical Commissioning Policy http://www.england.nhs.uk/publication/dolutegravir-lamivudine-for-the-treatment-of-human-immunodeficiency-virus-hiv-1-infected-adults-and-adolescents-over-12-years-of-age/ Accessed 6th October 2020. **4.** http://www.scottishmedicines.org.uk/media/4708/dolutegravir-plus-lamivudine-dovato-abbreviated-final-august-2019-for-website.pdf Accessed 6th October 2020. **5.** All Wales Medicines Strategy Group Advice on Dovato http://www.awmsg.org/awmsgonline/app/appraisalinfo/3659 Accessed 6th October 2020.

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