RESEARCH NOTE

Challenges in implementing the 2015 BASHH guidelines for the appropriate use of post-exposure prophylaxis for HIV following sexual exposure [version 1; referees: 1 approved, 2 approved with reservations]

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Abstract

The use of post exposure prophylaxis for human immunodeficiency virus (HIV) following sexual exposure (PEPSE) was retrospectively audited in an inner city genitourinary clinic against the 2015 national guidelines by the British Association for Sexual Health and HIV (BASHH). One-hundred out of a total of 101 patients (99%) had a baseline HIV test done. 82.1% (n=83) of patients were given PEPSE prescriptions fitting within recommended indications lower than the 90% target set by BASHH. 84.2% (n=85) of patients had PEPSE administered within 72 hours lower than the 90%. 61.4% (n=62) of patients were known to have completed four weeks of PEPSE lower than the 75% target. 61.4% (n=62) of patients were screened for sexually transmitted infections (STIs) lower than the 90% target. 59.4% (n=60%) of patients had post-PEPSE HIV bloods slightly lower than the 60% target.

Open Peer Review

Referee Status: ? ✓ ?

	Invited Referees 1	2	3
version 1 published 09 Jun 2016	? report	✓ report	? report

1 **Theresa Marié Rossouw** , University of Pretoria, South Africa

2 **Paul Volberding** , University of California, San Francisco, USA

3 **Rachel Beanland** , Independent Public Health Specialist, France

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Comments (0)

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Competing interests: The authors declare no conflict of interest.

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Introduction

Post-exposure prophylaxis for HIV involves taking antiretrovirals by human immunodeficiency virus (HIV)-negative individuals for four weeks, after a suspected or known exposure to HIV to reduce the risk of transmission[1,2]. In 2015 the British Association for Sexual Health and HIV updated national guidelines on the appropriate use of post exposure prophylaxis after sexual exposure to HIV (PEPSE)[3]. -- The guidelines provide indications for when PEPSE use; is recommended; can be considered; or is not appropriate. It also recommends PEPSE use within 72 hours; baseline HIV testing, appropriate sexually transmitted infection (STI) testing, and completion of four weeks of PEPSE with follow up HIV bloods after completion of PEPSE. BASHH have specified auditable targets for these recommendations, and this retrospective audit compares the use of PEPSE in our genitourinary clinic against these recommendations.

Method

A retrospective case note review was carried out at Walsall Centre of Sexual Health. One-hundred one patients who were coded as having received PEPSE between June 2013 and September 2015 were identified on the computer system. No permission was required to conduct the study and publish these results. Notes of these patients were reviewed and data regarding; the indication of PEPSE administration; time since exposure; investigations carried out; completion of four weeks of PEPSE and whether the patient had follow up investigation were uploaded onto a Microsoft Excel database.

Results

The results of 101 patients who received PEPSE were analysed (Table 1). 48.5% (n=49) of patients were male, 61% (n=30) of the male patients were bi-sexual/homosexual.

Baseline HIV tests were done in 99% of patients (n=100). One patient did not have baseline HIV tests. This patient initially visited a local emergency department where she received PEPSE without HIV testing. This patient subsequently came to our genitourinary medicine clinic one week later and had a HIV test done. Baseline HIV test was done on the first visit to the clinic in all 100 cases.

52.5% (n=53/101) of prescriptions for PEPSE were given under recommended indications by BASHH (Table 2), and 29.7% (n=30/101) of patients were given PEPSE under indications where BASHH state they can be considered. All of the patients in the considered category in this audit were female patients who had been sexually abused. In total, 82.2% of patients were given PEPSE for recommended/considered indications lower than the 90% target. 5% (n=5/101) of patients had no documented reason for starting PEPSE.

84.2% (n=85) of patients received PEPSE within 72 hours of exposure lower than the 90% target. 13.9% (n=14) of PEPSE was prescribed after 72 hours since exposure, while 5% (n=5) of patients had no documentation of when the exposure occurred.

61.4% (n=62) of patients had documentation showing that they had completed four weeks of PEPSE, lower than the 75% target. 13.9% (n=14) of patients did not complete four weeks of PEPSE while 24.8% (n=25) of patients had no documentation regarding whether they had completed four weeks of PEPSE.

59.4% (n=60%) of patients had post-PEPSE HIV bloods slightly lower than the 60% target.

Table 1. Auditable targets for prophylaxis for human immunodeficiency virus (HIV) following sexual exposure.

	Patients		
	Number	**%**	**BASHH recommended target %**
Baselines HIV Test	100	99	100
Indication			
Recommended Consider	53 30	52.5 29.7	90
Not Recommended	13	12.9	
No documentation	5	5.0	
Exposure to PEP Time			
<72 hours	85	84.2	90
>72 hours	11	10.9	
Not documented	5	5	
Completion of 4 weeks of PEPSE			
Yes	62	61.4	75
No	14	13.9	
Unknown	25	24.8	
STI Screening			
Hep B immunity/booster /Syphilis	101	100	
Chlamydia/gonorrhoea	62	61.4	90
Post-PEPSE HIV Test			
	60	59.4	60

Table 2. Patients that fit into recommended indications (n=83).

	Number of patients	%
Patients that fit recommended Indications		
HIV +ve partner VL Unknown or >40	20	24.1
Men who have sex with men (MSM) High prevalence/ unknown	18	21.7
Sexual Assault	31	37.3
Needle stick Injury	15	18.1

All 100 patients that had baseline HIV bloods taken had appropriate investigations into hepatitis B and syphilis. However 61.4% (n=62) of patients were screened for chlamydia and gonorrhoea lower than the 90% target. None of the patients who had come for PEPSE after needle stick injury had testing for gonorrhoea and chlamydia, and not taking into account these patients 73% of patients had screening for chlamydia and gonorrhoea.

Discussion

The majority of patients prescribed PEPSE where given so under indications that were deemed compliant with BASHH guidelines and within 72 hours of the suspected exposure. All but one of these patients had baselines HIV bloods taken, and appropriate testing for syphilis and hepatitis B, with post-PEPSE follow-up testing levels being near the BASHH target.

Documentation regarding whether patients were taking or discontinuing PEPSE was lacking. There was also difficulty determining whether patients who did not attend after their initial visit had completed their PEPSE course.

One particular guideline that we found difficulty in reaching was screening for chlamydia and gonorrhoea, especially in patients coming in after needlestick injuries. Often times it is either not considered suitable or the patient declines the screening as they do not feel they are at risk. Screening should always be encouraged and there should be documentation that the screening tests have been declined if that is case.

Another issue is patients not visiting for follow-ups. Often screening for chlamydia and gonorrhoea is delayed until after the window period for investigations to identify these organisms. Follow-ups are also important for identifying whether the patient is compliant with the antiretrovirals, and for post-PEPSE HIV blood tests.

Carrying out an audit against the BASHH guidelines have highlighted areas in our clinical practice which need improvement. In response to this audit we have created clear proformas for prescribing PEPSE which include; whether the indication the patient is coming in with fits with BASHH guidelines; whether the exposure was less than 72 hours ago, and a list of the relevant investigations that should be considered. Proformas for follow-up have also been made to assess whether the patient is completing the course of PEPSE and having follow-up bloods after completion of therapy. Training has been given to educate all staff on the indications for PEPSE prescribing, the need to identify HIV status and viral load of source, the need to have accurate documentation, to offer rapid-HIV testing, and fourth generation HIV testing for post-PEPSE follow-up. We have also decided to get patients to book their follow-up appointment during their initial visit to the clinic. We will then send SMS reminders the day before the follow-up appointment to remind patients to attend. We plan to carry out a re-audit in one year.

Data availability

All raw data are provided in the tables above.

Competing interests

The authors declare no conflict of interest.

Grant information

The author declared that no grants were involved in supporting this work.

References

1. Pinto LA, Landay AL, Berzofsky JA, *et al.*: **Immune response to human immunodeficiency virus (HIV) in healthcare workers occupationally exposed to HIV-contaminated blood.** *Am J Med.* 1997; **102**(5B): 21–24.
PubMed Abstract | Publisher Full Text
2. Bourry O, Mannioui A, Sellier P, *et al.*: **Effect of a short-term HAART on SIV load in macaque tissues is dependent on time of initiation and antiviral diffusion.** *Retrovirology.* 2010; **7**: 78.
PubMed Abstract | Publisher Full Text | Free Full Text
3. British Association for Sexual Health and HIV: **United Kingdom guideline for the use of post-exposure prophylaxis for HIV following sexual exposure.** 2015; accessed 19 November 2015.
Reference Source

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Current Referee Status: ? ✔ ?

Version 1

Referee Report 07 June 2017

doi:10.5256/f1000research.9631.r23142

? **Rachel Beanland**
Independent Public Health Specialist, Gaillard, France

This is an interesting report of a clinical audit conducted to assess the implementation of UK BASHH guidelines on Post Exposure Prophylaxis following sexual exposure. The paper provides a clear summary of the methods and results compared to national guidelines. The recommendations and subsequent actions taken following the results are of interest to the audience. Further clarification in some sections could enhance the key message of the paper. In places the grammar and language could be improved.

Comments and considerations for the authors:

Method

- Please provide further geographical detail (region, country) to allow the audience to understand the context of the setting.
- Consider rewording the sentence regarding permission. As secondary data has been used no patient consent was needed but how was confidentiality maintained, was the data anonymised? Did you seek any ethical approval or institutional approval?
- Note Excel is not a classic database, please revise to spreadsheet, unless alternative database was used for analysis.

Results

- Consider using 'performed' or 'conducted' in place of 'done'.
- Table 2. The article focuses on prophylaxis from sexual exposure, it is not clear why needle stick injury is included in this data set. If this is the case, please specify why included. Please review the data presented in the table for accuracy.
- Do you have any detail on the ARVs prescribed and how adherent the individuals were?

References
Please review the references and provide uptodate citations. WHO PEP guidelines http://apps.who.int/iris/bitstream/10665/145719/1/9789241508193_eng.pdf the supporting evidence Clinical Infectious Disease supplement https://academic.oup.com/cid/issue/60/suppl_3 be helpful.

Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Referee Report 26 May 2017

doi:10.5256/f1000research.9631.r22154

Paul Volberding
UCSF-GIVI Center for AIDS Research, University of California, San Francisco, San Francisco, CA, 94121, USA

This is an interesting report of the use of post-exposure prophylaxis following possible sexual exposure to HIV in a UK retrospective cohort. While it shows that British guidelines were generally followed well, it of course leaves open the question of what effect the prophylaxis had in terms of eventual HIV seroconversion. Another question raised is how many of those receiving PEP in this study may have also been appropriate candidates for PeEP given our current knowledge of the effectiveness of that prevention approach.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Referee Report 20 April 2017

doi:10.5256/f1000research.9631.r22009

Theresa Marié Rossouw
Department of Immunology, Institute for Cellular and Molecular Medicine, University of Pretoria, Pretoria, South Africa

There are some language and grammatical errors that need attention.

The link provided to the BASHH guidelines is for the draft document and not the final version.

More detail about the context is need e.g. where is the Walsall Centre of Sexual Health located?

Reference 1: I could unfortunately not access the full article, but the reference to this 1997 article in support of post-exposure prophylaxis does not seem to be the best choice since it deals with "Immune response to human immunodeficiency virus (HIV) in health care workers occupationally exposed to HIV-contaminated blood" and does not seem to deal with post-exposure prophylaxis.

The second reference in support of PEP is also not the most relevant reference since it is an animal study and the final conclusion of this article is that “limited antiviral drug diffusion in secondary lymphoid tissues may allow persistent viral replication in these tissues and could represent an obstacle to HIV prevention and eradication”.

It would be interesting to know how many of the patients were repeat users of PEPSE. A possible recommendation could be monitoring for repeat users of PEPSE and referring them for PrEP.

It would also be interesting to know what antiretroviral medication had been prescribed for PEPSE and whether this complied with the guidelines.

It is preferable not to refer to "bi-sexual/homosexual" but rather to men who have sex with men and/or women.

Table 1:
Under “Baselines HIV Test” and “Post-PEPSE HIV Test”, grammar and placing of results should receive attention.

Table 2 needs more explanation since the numbers do not add up. For instance, the text shows that 53/101 had a recommendation for PEPSE, whereas the table shows only 20 HIV+ with unknown or high

VL and 18 MSM. The text shows that 30/101 had circumstances under which PEPSE could be considered but the table shows 31 cases of sexual assault. There were 15 cases of needle stick injury. This seems to be very high and since the guideline only covers needle stick injuries in the community, the circumstances surrounding the injuries should be explained. I recommend that all exposure categories be listed in order to improve understanding. It seems that Tables 1 and 2 could be merged.

Table 2: The recommended VL above which PEPSE should be given is 200 copies/ml and not 40 copies/ml – the unit of measure is not given in the table. In addition, the meaning of the category “Men who have sex with men (MSM) High prevalence/unknown” is unclear.

The proportion of PEPSE prescriptions administered within 24 hours (and not 72 hours) of risk exposure is the auditable outcome and should also be shown.

The author states that “There was also difficulty determining whether patients who did not attend after their initial visit had completed their PEPSE course”. What measures were taken to determine this?

What steps had been taken to assess the VL of HIV-infected partners?

“No permission was required to conduct the study and publish these results.” I presume the author means that informed consent was not considered relevant since the data used were anonymous, but surely institutional permission was needed?

Article should make reference to other related work, e.g.
Ladipo Z, Chauhan M, Foster K. Survey of PEPSE provision: lessons to be learnt. *Sex Transm Infect* 2015;**91:**164[1].

Currie S, Shafiq V, Mellor J*, et al*. P73 The source of the problem – re-audit of pepse provision at an inner city sexual health clinic. *Sex Transm Infect* 2015;**91:**A39-A40[2]

Raha D; Gilson R. An audit of PEPSE in an integrated sexual and reproductive health centre resulting in change of local protocol in accordance to national guidelines: room for improvement. HIV Medicine. 17():33–34, Apr 2016[3]

References

1. Ladipo Z, Chauhan M, Foster K: Survey of PEPSE provision: lessons to be learnt. *Sexually Transmitted Infections*. 2015; **91** (3). Publisher Full Text
2. Currie S, Shafiq V, Mellor J, McCord J, Houston J, Babu C: P73The source of the problem – re-audit of pepse provision at an inner city sexual health clinic. *Sexually Transmitted Infections*. 2015; **91** (Suppl 1): A39.3-A40 Publisher Full Text
3. Raha, D Gilson, R: An audit of PEPSE in an integrated sexual and reproductive health centre resulting in change of local protocol in accordance to national guidelines: room for improvement.*HIV Medicine*. 2016; **17**: 33-34

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Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
No

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.