Public Health England

National Strategic Group for Viral Hepatitis (NSGVH)

Minutes of meeting held on 1 October 2019
Skipton House, London Road, London

Attendees:

Members:	Chris Lovitt (CL)	**Invited:**	Annette Wood (AW)
	Graham Foster (GF)		Emily Phipps (EP)
	Helen Bennett (HB)		Geoff Dusheiko (GD)
	Iain Brew (IB)		Helen Harris (HH)
	Mary Ramsay (MR)		Koye Balogun (KB)
	Matt Hickman (MH)		Ross Harris (RH)
	Rachel Halford (RH)		Stuart Smith (SS)
	Richard Tedder (RT)		Ellen Heinsbroek (EH)
	Samreen Ijaz (SI)		Ceri Townley (CT)
	Will Irving (WI, Chair)		Patrick Kennedy (PK)
	Sema Mandal (SM)		Ruth Simmons (RS)
	Daniela DeAngelis (DD)		Brian Eastwood (BE)
	Peter Vickerman (PV)		Graham Spearing (GS)
	Kazim Beebeejaun (KBE, Secretariat Scientist)		
Observers:	Tim Ellis (TE)		
	Noel Craine (NC)		

Apologies:

Ahmed ElSharkawy	Tanya Scanlon	Peter Huskinson
Blake Dark	Giri Shankar	Peter Moss
Eamonn O'Moore	Gillian Armstrong	Rosanna O'Connor
George Leahy	Neil McDougall	Sarah Hart
Janette Harper	Annelies McCurley	Steve Taylor
Mike Gent	David Goldberg	
Claire Neill	Sharon Hutchinson	
Pete Burkinshaw	Graham Cooke	

1. Welcome

Chair welcomed all those in attendance and online and requested a round of introductions for new attendees. Agenda was adjusted to first discuss HCV NHSE elimination initiatives.

2. Updates and minutes

2.1 The minutes of the previous meeting were agreed as an accurate record

2.2 Update on items discussed at the last meeting

Action 2.1 – To be discussed at next meeting

Action 2.2 – To be discussed at next meeting

Action 4.1 – Ross Harris leading on HCV data subgroup due to have first meeting in November.

Action 6.1 – Ongoing

Action 6.2 – No feedback

Action 7.1 – Meetings between NHSE and PHE are organised to further discuss data integration.

7. HCV NHS England elimination initiatives

7.1 Update from elimination initiatives – Primary care, pharmacy and drug services

GF presented an overview to the group of the HCV elimination initiatives recently approved by NHS England following a tender process. GF provided a summary to group of current activities and how initiatives are progressing in improving testing and treatment for HCV, including:

- £500 incentive per patient for any service (for example GP or ODN) treating a patient diagnosed with HCV
- NHSE have plan to test and treat in 30 prisons by March 2020 and a further 60 by March 2022.
- Sign off for national community pharmacy point of care testing scheme
- Gilead are funding a number of drug treatment services; including needle exchange and NHS service providers alliance, Care UK prisons and testing in Asian communities.

- Merck Sharp & Dohme (MSD) are providing point of care testing machines for prisons, community liaison and peer support in collaboration with Hepatitis C trust to engage people in care.

  80% of drug service providers now have a contract with Gilead that ensures they can deliver HCV testing and treatment with the target of 90% testing and 90% treated by 2022.

  Discussion

  Testing registry progress:

  Registry is undergoing beta testing and debugging and should be rolled out in the next two to three weeks. PHE (SM and RS) are in talks with GF and are optimistic details of registry data flows will be finalised soon.

  Issues over point of care test sensitivity and specificity:

  There were concerns over the quality of the DBS tests used and the protocols involved. The majority of services have now in response switched to a new supplier with more robust DBS tests.

  Core antigen testing:

  Concerns were raised by group over small proportion of labs using antigen testing. RS explained that some labs have switched to antigen testing – they have been contacted by PHE to query.

  Testing concerns from HCT:

  SS explained that the majority of rapid testing by HCT used an anonymous 5-minute result finger prick test where only positive results were recorded. Concerns discussed by group about picking up such point of care tests in the registry. GF and SM noted that this issue will be taken up by NHS England and PHE during the development of the registry.

Action: SM (PHE) to liaise with the Hepatitis C Trust on issue of hidden point of care testing not picked up by registry

7.2 Update from elimination initiatives – Prisons

- IB presented an overview to the group of initiatives performed by Care UK funded by Gilead to improve case finding and linkage to care. Funding was approved for 6 regional BBV coordinators and one national coordinator to cover the 43 prisons Care UK are involved with. So far, 3/6 coordinators have been employed as well as one national coordinator.

- The introduction of point of care antibody testing instead of DBS testing has increased uptake over the last 6 months due to quicker results.

- On World Hepatitis Day this year Care UK performed a high intensity test and treat initiative at HMP Leeds. 1200 prisoners were offered point of care testing for HCV, HBV and HIV. Good uptake (74%) was achieved with 7 new HCV diagnoses made and referred by the MDT. No new HBV or HIV diagnoses were made.

- IB noted issue that it was likely not cost effective in Leeds to include HBV and HIV in the point of care test given no new cases were identified.

Discussion

Addition of HBV and HIV to HCV point of care testing schemes:

Considerations were made by group over cost effectiveness of including HBV and HIV alongside HCV elimination point of care testing schemes. Point was raised of potentially writing guidance on when to include triple point of care testing. It was noted that within reception prison testing, HBV and HIV are included but not other settings. NICE and PHE have made strong recommendations for BBV testing, however implementation is poor. Although the efficiency of including HBV was noted it was agreed by group that funding streams were approved specifically for HCV and not other BBVs.

3. Monitoring HEV incidence

A longer slot will be set for the next meeting. However, SI summarised to group that there has been an increase in the number of cases of HEV

Action: WI to invite new head of British Viral Hepatitis Group to next meeting to discuss HEV.

4. Monitoring HCV incidence

Chair proposed a number of questions to group relating to the recent HCV in England report showing that there had been no evidence of a decrease in incidence of HCV. The group wished to explore; (1) is the decrease due to data quality issues, (2) if the data is robust why has there not been a decrease and what are the potential interventions.

4.1 Background and existing monitoring metrics

HH presented an overview to group of how HCV incidence is measured. HH explained that there are a number of data sources that are used to estimate HCV incidence. Although there are a number of limitations to the data, overall there is no evidence to show any decrease in HCV incidence.

Data quality:

HH explained to the group that directly measuring incidence is challenging. Prevention of infection or re-infection via harm reduction is key for any sustainable decrease in HCV. The ideal is to either (a) monitor the actual number of new infections or (b) monitor the number of new infections in PWIDs each year. However, (a) is difficult because most

acute infections are asymptomatic and undiagnosed. (b) is challenging because there are no good estimates of the denominator of the number of PWIDs in England.

Currently there are 3 main methods of estimating HCV incidence; (1) estimate incidence among PWIDs using UAM survey, (2) Monitor prevalence of anti-HCV among recent initiates to IDU using UAM survey, (3) Monitor prevalence of anti-HCV among young adults as a proxy measure. There are also a number of other possibilities including modelling and sentinel methods.

Needle and syringe provision: HH explained that there is currently no national data on the numbers of needles and syringes distributed amongst PWIDs. This can only be estimated using the UAM survey.

PWIDs receiving treatment: The proportion of opioid dependent PWIDs receiving opioid substitution treatment is only available up to 2011 to 2012. The proportion of PWIDs on treatment can however be estimated in the UAM survey but is biased by recruitment from services. Issue will be taken up by HCV data sub-group in November

4.2 Data from UAM

EH presented to the group an update on the UAM survey and metrics estimating HCV incidence. The UAM survey has around 3000 tests per year recruiting from a wide variety of regions and settings and includes 2020 to 2022 ODNs. Around 200 tests are performed per region per year in England.

Chronic prevalence: EH explained to group that there has been a slight decrease in chronic prevalence since 2016 from 56% of PWIDs to 50% in 2018 (Ab+, RNA+).

Incidence: Prevalence of anti-HCV among people who recently began injecting drugs has not decreased over the last 8 years. It is important to note that numbers of recent initiates are small overall and have been getting smaller over time. This suggests that the statistical power to confirm any decrease in incidence from UAM is low and likely to decrease in the future.

Indicators for harm reduction uptake: Around 60% of PWIDs in 2017-2018 reported adequate needle and syringe provision in England. Levels of direct sharing has remained constant (20%) over the last ten years with no signs of decline.

Data on young adults: RH presented to the group an update on data available from 15 sentinel laboratories. Although a slight decrease in % testing positive was observed this is likely due to differences in testing practices rather than a real decrease in incidence. Similarly, national laboratory reports have shown a decrease in reports of HCV but this is highly influenced by testing practices.

4.3 Availability of data on OST and NSP provision in NDTMS

BG presented to group on harm reduction metrics explaining that there has been a steady decline in the proportion of opiate users in treatment since 2009/10. It is not

possible to estimate the proportion of opioid dependent PWIDs receiving treatment because of the lack of denominator data.

There is no good monitoring system available to estimate the proportion of PWIDs receiving targeting information. However, UAM data suggests that 79% of PWIDs reported receiving direct HCV information. This is the first year that UAM has been able to collect this data which covers around 1500 PWIDs.

4.4 Discussion: why is HCV incidence in PWID not decreasing and how can data on incidence be improved

Too early:

Point raised by group that it may be too early to see incidence decrease in response to interventions. It is the first year where a decrease in chronic prevalence has been observed which if sustained may be a signal for a decrease in incidence in the coming years.

UAM is not statistically sensitive enough:

Group discussed point raised that UAM survey may not have enough statistical power to be able to detect any decrease in incidence due to the limited number of providers. The idea for expanding UAM was proposed. Although a challenging option with costs implicated, group agreed that it may be useful to expand the survey to improve power and representativeness.

Action: EH (PHE UAM) to liaise with SS (The Hepatitis C Trust) to discuss expansion of UAM

Agreed by group that it is likely that a decrease in HCV incidence should be seen in one to 2 years' time. Group agreed that there should be the right data collections and funding in place to ensure robust data is available at that point. HCV data sub-committee will discuss this issue as a core objective of group in November.

5. HES hepatitis data issues

GS gave an update to the group on the HES HCV data issue discussed at the last meeting, he explained that 33% of the 11,103 records have now been recovered from 31 providers. The data will be available in HES by the end of November. Chasing an additional 17 providers for resubmission would provide an additional 50% of missing records. The remaining 40 providers cover a small number of records each. GS explained that amongst the 17 providers most would find it very challenging to resubmit data.

GS assured that the issue has been resolved going forward and should not occur again. The historical codes list has now been reinstated.

Group discussed that the low number of resubmissions was a major issue. Gap in HES data has ruled out the ability to be able to measure new cases of HCV related end-stage

liver disease going forward. Group agreed that it was a major barrier to monitoring HCV elimination targets. It was agreed that it was of critical importance to find a solution to the issue with a last resort of writing to each hospital directly requesting the data. However, for those external to PHE using HES HCV data this solution would not be ideal. Group agreed that writing a joint letter to senior colleagues may encourage more providers to resubmit data. Group discussed a number of options to attempt to resolve the issue including option of providing a monetary incentive to providers and writing a joint letter from senior colleagues at PHE/ NHSE or a government minister. TE offered his support in escalating in DHSC if needed.

It was agreed by group that:

Action: GS to chase trusts further for resubmission.

Action: SM / HH to liaise with GS to get more detail on what data is missing and the challenges across providers in resubmitting data.

Action: GS to lead on drafting an options appraisal with PHE (SM) and NHSE outlining; (1) Size of remaining problem (2) Progress on resubmissions (3) Potential costs (4) Potential solutions

6. National HCV treatment database and data reporting group

Ceri Townley gave an update to the group; NHSE has the intention to create a HCV user group including; frontline users, ODNs, community pharmacists, PHE and other stakeholders. CT plans for group to meet in November. Group aims to act as a forum for users to talk about data issues related to HCV and testing registry.

7. HCV re-engagement exercise

SM updated group that while at varied implementation stages, many ODNs are now contacting patients directly as part of the reengagement. Seventy-six patients have been identified and registered on the treatment registry in response to the re-engagement exercise.

Three FOIs have been received from patients in response to asking what data is held on them.

8. Monitoring HBV elimination

Chair introduced topic of HBV elimination proposing to discuss issue of existing population within the UK who have chronic hepatitis B (CHB) and what information is available; how many patients are being managed in secondary care and amongst those attending care who is being treated with what and with what outcomes.

8.1 Epidemiology of HBV in secondary care

PK presented to the group an overview of the changing landscape of CHB in secondary care, including; current treatment regimens for CHB, risk factors for HCC and new treatments.

Between 70% to 80% of patients across the majority of clinics across England are in the e-antigen negative phase of CHB. PK explained to group:

- Broadening treatment candidacy means there are now a greater number of patients on treatment without being discharged.
- There needs to be better stratification of CHB to inform management decisions
- Key research questions around CHB need to be addressed in a more cohesive way. There have been a number of pursuits of consortia across the UK to address the lack of information on CHB patients but with no success.
- Greater use of technology may transform the current 'out-patient' clinic

Discussion

Functional cure:

There are very small numbers of patients each year that are able to achieve functional cure (surface antigen loss). The levels of surface antigen loss are about 1% a year. New therapies on the horizon however are more likely to lead to more patients functionally cured.

What proportion of newly diagnosed patients have advanced disease?

There is only anecdotal evidence. Some patients will present with liver disease and that will be the first CHB diagnosis. However, in London PK explained his experience that patients are generally younger (referred through antenatal screening) and less likely to have advanced disease.

8.2 HBV treatment monitoring

SM presented to group on the challenges, potential ways forward to monitor HBV treatment and clinical collaboration. How can we monitor CHB? Who is eligible for treatment? Can we monitor this through routine surveillance? Do we need more clinical collaboration?

SM explained to group that one of the key issues in reaching the WHO targets first lies in estimating the prevalence of CHB in England. Current figures are estimates based on models with a number of data quality caveats. There are currently no robust data on CHB prevalence in England and this should be a key objective of elimination activities.

There are also no data on the proportion of people with CHB who have been diagnosed nor the number that are linked to care nor the number that achieve viral suppression.

- What is the prevalence of CHB in England?
- Amongst those with CHB, how many have been diagnosed?
- How many cases of CHB have been linked to care?

- How many cases of CHB have been treated and achieved viral suppression?

  Population eligible for treatment:

  The last large collaborative study looking at those with suspected CHB and their treatment outcomes was the CUSHI-B study back in 2008. There have been a number of attempts to do similar large national studies to expand on this work but this has not been achieved.

  Estimating number of people tested, number eligible for treatment and number on treatment

  SM outlined a number of options to the group including:

  An option would be to use the existing sentinel BBV testing surveillance programme, which includes PII to link to clinical treatment databases. However, some of the downsides are that; (1) it is sentinel, (2) would require access to be granted to clinical databases such as HepCare.

  A second option would be to start a bespoke national treatment monitoring system. This could be done through a collaborative research network, but it seems that there isn't much appetite from potential funders, given recent grant rejections.

  A third option would be to establish a collaborative multicentre cohort study across England.

  Linking lab sentinel surveillance to clinical databases:

  SM explained to group that the BBV sentinel surveillance programme currently covers around 40% of the population and includes testing in both primary and secondary care.

  HBV DNA test within one month of diagnosis can be used a proxy for referral as the vast majority of HBV DNA tests are only done in secondary care.

  The key issue is in linking the sentinel surveillance to other clinical databases to get fibro-scanning results, eligibility for treatment and evidence of treatment.

  Discussion

  Linkage to HES:

  HES data can be used to show the number of people referred for HBV related liver disease or a liver transplant but does not show the cascade of care from testing.

  Funding:

  Group agreed that getting funders involved in HBV elimination is a key issue. Being able to show the current and future burden of HBV in England using a number of key metrics may be a good way of getting funding for HBV elimination initiatives.

Getting large secondary care hepatology clinics involved in a collaborative research network is an option that could be pursued. PK explained that this is an avenue that has been pursued in the past. The issue from a clinicians perspective is that they do not have the necessary resources to be able to extract the correct data efficiently to be able to contribute.

Medical Research Foundation (MRF) funding – there is currently an MRF funding call for viral hepatitis and autoimmune hepatitis but may not be suitable for a treatment outcomes project.

NIHR Programme grants – group discussed option of applying for an NIHR programme grant, potentially focussing on setting up systems to assess new HBV treatments in the future.

Using existing lab records of CHB:

SM proposed option of using existing lab records of CHB patients and writing to GPs to find out whether they had been referred and if they have to then write to commissioners (analogous to HCV re-engagement exercise). The obvious challenge is scale of exercise, cost and getting GPs to respond but may be a way of creating a register that could be followed up.

RS proposed that sentinel surveillance could be a starting point. Clinics from sentinel sites could be followed up to extract data of CHB patients. RS explained that there are a number of barriers that have been met with this approach; including ethics and Caldicot restrictions.

Use of HepCare – group agreed that a viable option would be to explore whether HepCare, a system funded by Gilead for HCV could be used to extract data on patients with HBV. However, it would only be useful for sentinel sites that use HepCare.

8.3 HBV prevalence estimates

SM and RS presented to group on the current methods for estimating HBV prevalence in England.

No formal studies have robustly estimated the prevalence of HBV, with most current estimates ranging from 180,000 to 400,000. Prevalence data from universal antenatal screening shows around 0.4% of those giving birth each year are living with CHB.

There are currently no surveillance programmes or studies that are representative of the general population including migrants. Ethnicity and country of birth are not routinely collected and completion rates are generally poor.

There are a number of opportunities to improve estimates including options of using multiple parameter evidence synthesis models, with the starting point being antennal CHB prevalence estimation and using sentinel surveillance to allow for sub-national estimates.

Update on using antenatal CHB prevalence and extrapolating to general population:

Universal screening as part of the IDPS programme is around 99%, hence the starting point; however country of birth and/or ethnicity are often missing. Ethnicity can be estimated using software algorithms but there are clear limitations to the method.

- RS presented to group on 2 methods for estimating HBV prevalence in antenatal population by country of birth. RS explained to group that country of birth could either be extrapolated using data from DBS test of baby at 12 months which records mother's country of birth or using matching to ONS birth registry data each year. Validate against local antenatal screening data
- Potential for more complete data with surveillance enhancements to antenatal and neonatal programmes
- Different methods with data linkage and indirect estimations to estimate CHB prevalence in non-antenatal women and men based on distribution of ethnicity and/or CoB in antenatal population and adjusted risk ratios for HBV test positivity in other groups
- Move from distribution of regions to country of birth; and England regions to national
- Apply ethnicity software to ONS Births dataset CoB to see how they 'match'

Action: Matt Hickman and Patrick Kennedy to take forward potential application for an NIHR Programme grant for HBV treatment outcomes funding.

Action: Ruth Simmons to liaise with Gilead to explore options for extracting HBV treatment outcomes from HepCare systems.

Action: In order to improve data access and collaborations between hepatology clinics, WI to write to new president of BASL and new chair of BVHG explaining the barriers to reaching HBV elimination from NSGVH perspective.

8. Research updates

Group agreed that it is proving difficult to meet criteria for NIHR call on liver disease, a further meeting organised by SM and GD to discuss issue and possible angles.

PV (Bristol university) has recently received provisional acceptance for a grant to improve case findings for HCV elimination targets.

HPRU contracts are coming to an end with interviews for new HPRUs currently ongoing.

9. Any other business

GD and SM updated group on recent ECDC meeting on Hepatitis elimination. Meeting focussed on strengthening surveillance, with challenge of combining epidemiological with clinical data on treatment outcomes.

KBE to look into potential of developing a webpage for NSGVH with details of aims of group, members and terms of reference.

Actions from 1 October 2019 meeting:

Action number	Action	Who
1	SM (PHE) to liaise with Hepatitis C trust on issue of hidden point of care testing not picked up by registry	Sema Mandal
2	WI to invite new head of British Viral Hepatitis Group to next meeting to discuss HEV.	Will Irving
3	EH (PHE UAM) to liaise with SS (HepC trust) to discuss expansion.	Ellen Heinsbroek Stuart Smith
4	GS to chase trusts further for resubmission.	Graham Spearing
5	SM/ HH to liaise with GS to get more detail on what data is missing and the challenges across providers in resubmitting data.	Sema Mandal Helen Harris Graham Spearing
6	GS to lead on drafting an options appraisal with PHE (SM) and NHSE outlining; (1) Size of remaining problem (2) Progress on resubmissions (3) Potential costs (4) Potential solutions	Graham Spearing
7	Matt Hickman and Patrick Kennedy to take forward potential application for an NIHR Programme grant for HBV treatment outcomes funding	Matt Hickman Patrick Kennedy
8	Ruth Simmons to liaise with Gilead to explore options for extracting HBV treatment outcomes from HepCare systems.	Ruth Simmons
9	In order to improve data access and collaborations between hepatology clinics, WI to write to new president of BASL and new chair of BVHG explaining the barriers to reaching HBV elimination from NSGVH perspective.	Will Irving