Public Health England

Minutes

Title of meeting	5th meeting of the National Strategy Group for Viral Hepatitis (NSGVH)
Date	19 November 2018
Time	10.30 to 16:00
Venue **Teleconference details**	LG20/21 Wellington House, 133-155 Waterloo Road, London SE1 8UG +44 208 495 3300 VoIP Ext 53300 (Conference ID: 903183) Join Skype Meeting
Meeting topic	Monitoring and enabling elimination of Hepatitis C virus (HCV) as a significant public health threat
Attendees	Will Irving (Chair) Mary Ramsay (Deputy Chair) Peter Moss (Hull and East Yorkshire Hospitals) Mark Gillyon-Powell (NHS England) Eamonn O'Moore (PHE) Iain Brew (Care UK) Jackie Kemp (NHS England) Gillian Armstrong (DoH NI) Helen Bennett (NHS England) Ginny Belson (DHSC) Stuart Smith (Hepatitis C Trust) Rachel Halford (Hepatitis C Trust) Ahmed Elsharkawy (University Hospitals, Birmingham) Graham Cooke (Imperial College London) Peter Vickerman (Bristol University) Matt Hickman (Bristol University) Giri Shankar (Public Health Wales) Sema Mandal (PHE) Helen Harris (PHE) Dan Bradshaw (PHE) Tamyo Mbisa (PHE) Richard Tedder (PHE) Samreen Ijaz (PHE) Steve Taylor (PHE) Mike Gent (PHE) Ross Harris (PHE) Koye Balogun (PHE) Daniela De Angelis (University of Cambridge) Ray Poll (Royal Hallamshire Hospitals) Graham Foster (Queen Mary University of London) Rachel Roche (PHE)

Dialed in	Noel Craine (Public Health Wales) Lucy Jessop (HSC NI) Sharon Hutchinson (NHS Scotland)
Apologies	Sarah Hart (Haringey) Donna McInnes (DoH) Blake Dark (NHS England) Jane Salmon (Public Health Wales) George Leahy (PHE)

1.0 Chair's welcome and apologies for absence
Conflicts of interest – none raised

2.0 Minutes and actions from the previous meeting

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

2.2 Actions from the previous meeting:

Action 3.1 (for RH/HH): Consider separating ESLD and HCC in elimination model.
ESLD and HCC are modelled separately. HH can provide further update if required. This will be covered in Item 5 of the agenda.

Action 3.2 (for RH/HH): RH to consider potential of HARS data on HCV/HIV coinfection
HIV and AIDS reporting system (HARS) data on HCV/HIV coinfection could be examined, although as a small proportion of total HCV burden this would likely be undertaken as a separate exercise to examine treatment impact in this sub-population.

Acton 3.3 (for RH/HH): Look into source of patient postcode in HES
Allocation of ODN is based on the CCG of patient GP where available (which it is for most), or patient CCG if not. Or, for a very small number, the PCT. If there is any bias due to liver centres, it's differential ascertainment of HCV rather than patients travelling.

Action 4.1 (for SM): Add timescales to table on case finding interventions
This has been superseded by case-finding evidence review being presented by RR and will be covered in Item 11.1 of the agenda.

Action 4.2 (for AES/SM): Pull together action research being undertaken by ODNs
Item 9.5 on agenda.

Action 4.3 (for GC/PV): Pull together overview of NIHR funded projects
Item 11.1 on agenda.

Action 4.4 (for PH /AE/ HH /SM/ CG): Draft letter to DH requesting awareness-raising campaign by PHE
This was taken forwards by Derrick Crook – email has been sent and awaiting Ginny Belson feedback. Item 4 on agenda.

Action 4.5 (for WI): Invite contributions from attendees at Drug Service Providers Roundtable meeting.
Completed and meeting has taken place. Item 7 on agenda.

Action 4.6 (for DG): Liaise so that a representative from NSGVH attends the Scottish group meeting.
Pending.

Action 4.7 (for HB/SM): Share the FAQs, GP letter and templates from lookback exercise with GS (Public Health Wales).
Completed.

Action 5.1 (for HB): Share rules of engagement document for tender with the group.
Sent with papers for this meeting.

Action 6.1 (for all): All to contribute their agenda for research (starting in a year for 2-3 years) needed to meet the elimination agenda, ideally matching this to NIHR streams of funding.
None received yet – will pick up under Item 11.

3.0 Update from PHE (public health lab and epi) on other hepatitis viruses' priority issues

3.1 HAV (SM)

Vaccine supply issues: vaccine supply issues are mostly resolved and issue is now closed.

MSM outbreak: this was closed as an incident in July 2018 following increased availability of vaccine in GUM clinics and kickstarting GUM vaccination programmes that had been suspended. Commissioning of HAV vaccination for MSM is now clearly in the sexual health service specification but ongoing work is needed to ensure that local authorities commission the vaccination programme

Discussion:

- Question of whether the outbreak data be used to evaluate cost-effectiveness. PV is currently costing the outbreak and investigating how it was influenced by vaccination coverage, and stated it would also be useful to look at the downturn of the outbreak to understand what influenced this.

3.2 HBV (MR)

Universal infant vaccination programme: this has been successfully in place since Aug 2017 and no evidence of detrimental impact on selective neonatal immunisation programme.

Vaccine supply issues: supply has improved but one manufacturer still has shortages in adult vaccine. GSK believe they can cover the whole supply. Vaccine demand is still lower

than before the shortages, unsure whether this is due to decreased vaccination of low-risk or continued perception of shortages.

Discussion:

- There is evidence of a decrease in prison-based HBV vaccinations, possibly due to perceptions of vaccine access difficulties. National Intelligence Network on Drug Harms is discussing this issue.
- Due to lower demand manufacturers are now concerned that they are not moving stock fast enough and have surplus adult vaccine; risk is that stock is reallocated to other countries.
- Communications with the 9 PHE regional centres asking them to cascade information have only happened recently; need time to bed in before deciding next steps.

NHSE Clinical Reference Group (CRG) (PM): the group terms have been changed to cover all viral hepatitides, from now on HBV and HDV drugs will also be considered through this route.

Vaccine escape (RT): RT asked what the forward-looking view is on vaccine escape. WI stated that this can be discuss in the next meeting which will focus on HBV.

Local Medical Committee (LMC) advice to GPs on public health actions (MG): a recent Pulse article states that LMCs are advising GPs not to take public health actions as they are not funded for it. This would include vaccination of HBV contacts.

Discussion:

- The Welsh Government has issued a national enhanced service specification for GPs to cover these actions as a fee-per-item covering all non-routine vaccination or chemoprophylaxis activity in response to similar pushbacks.
- Commissioning arrangements in England make this more complicated as there is no national clarification of responsibility, but the issue is being discussed.

3.3 HEV (SI)

SI presented an overview of enhanced surveillance of acute HEV, in place since 2003:

- Year on year increase in case numbers since 2011, plateauing in 2016, and decrease in 2017. Same trends seen in Scotland, Ireland and the Netherlands, meeting with ECDC next week to find out if there is a wider European trend.
- Similar trends seen in blood donors; about 1 in 5,000 donations are HEV RNA positive, historically this was about 1 in 2,000 to 1 in 3,000. There have been transmissions from infected organs, all individuals have been treated successfully.
- Cases of persistent/chronic HEV now seen. The majority are treated with ribavirin, but as more are treated more failures are being seen. Some failures are due to incorrect sampling, while others appear to be genuine failures.
- More positive engagement with FSA, Defra and the pig industry in terms of control and transmission, now scoping out and prioritising projects and looking for funding, particularly from pig industry.

Discussion:

- It was asked whether there were explanations for the decrease in incidence. SI stated that these were hard to identify but could be due to changes in the pig industry or food processing.
- British Transplant Society guidelines for liver function tests in transplant recipients are now in use. Recent research shows that it is cost-effective to screen transplant patients for liver abnormalities, test to confirm whether these are due to HEV and treat if they are, due to the rapid progression of HEV to ESLD.
- Bulk of HEV infections from transplants are in solid organ transplant patients, who are unlikely to be screened post transplantation. There is a lack of awareness of HEV in the wider transplant community.

4.0 HCV Elimination agenda: Public awareness campaign (WI/GB)

WI recapped that in April NSGVH agreed its support for a public awareness campaign for HCV elimination and agreed actions to take this forward. However, responsibility for drafting the letter was taken on by Derrick Crook (PHE) and it was uncertain what progress had been made.
GB informed that the awareness raising campaign was discussed at a DH meeting discussing PHE Comms spend for the coming year. Spend was already committed for the year, however getting it on the agenda was an achievement and may pave the way for the future.

Discussion:

- Suggestion that the campaign should be funded by NHSE, or potentially shared between NHSE, DHSC and PHE.
- No awareness campaigns are planned in Northern Ireland, Wales or Scotland.
- Discussion of whether the scope of HIV testing week could be widened to include other BBV. This has been done before, resources are available, and drug services often take advantage of HIV testing week to do HCV testing but an overarching campaign has never been agreed. GUMCAD data from sexual health testing shows an increase in HCV testing during HIV testing week. Sentinel surveillance data do not currently contain all DBS testing results so would underreport this.
- Suggestion that more could be done to push the resources that PHE have already produced, and more use could be made of social media. There are lots of channels available but for some there is a cost.
- Suggestion of approaching industry for funding: need to await the outcome of the procurement contract, which is delayed by the court case with Abbvie .
- Agreement that there is a need to collate activities that are currently underway.

ACTION: RH / SM to begin work on collating resources (SM to discuss with PHE Comms)

5.0 HCV Elimination agenda: Monitoring metrics

5.1 HES data issues – Impact of changes implemented by NHS Digital (NHSD) during 2017 to 2018 resulting in the inappropriate removal of identifiers the HES ESLD dataset (HH)

HH reported on a major data loss incident caused by erroneous changes made to the NHSD legally restricted codes list in 2017 to 2018:

- Hepatitis codes were prematurely introduced to the legally restricted codes list, meaning that PII data for these codes were stripped before being sent to NHSD. This was later retracted.
- This dramatically reduced the identifiable submitted activity data for hepatitis, meaning that new cases of HCV-related end stage liver disease (ESLD) and cancer could not be identified for this year or going forwards, affecting PHE's ability to track patients through the dataset and rendering the 2017 to 2018 HES data unusable for this surveillance activity and future modelling.
- In May 2018, NHSD asked providers to resubmit the data, but the deadline was very short and many providers did not resubmit, so a large chunk of data is still missing.
- The issue was escalated to John Newton in PHE who raised it with Tom Denwood at NHSD. There have been subsequent meetings between senior staff at PHE and NHSD to discuss potential fixes, but these have not been fit for purpose and likely to be expensive in terms of ongoing modelling costs. NHSD have stated they would consider seeking resubmission of the data from providers but felt it was unlikely as not part of routine procedures.
- HH asked whether the group felt they could support a request for resubmission of the data, or any other actions that might be appropriate.

ACTION: WI to draft a letter of support stating that data resubmission is the only acceptable response, asking what is being done to ensure that this does not happen again, highlighting the cost impacts of the incident, and inviting NHSD to attend the next NSGVH meeting to discuss this issue. GF offered to co-sign this letter or write a separate letter.

5.2 Update on surveillance issues which contribute to monitoring metrics (SM)

Update on laboratory diagnosis and detection rate: ongoing work to get PCR data in routine laboratory reporting to PHE, including retrospective data going back to 2014, has now been accelerated and data is starting to come through.

DBS testing in drug services and prisons: samples tested in laboratories outside the NHS/PHE system are not reported to PHE, leading to underreporting of lab diagnoses of HCV. Colindale has been working with the 3 main drug service provider laboratories to get them to submit their data and this is now coming through.

Labs doing antigen testing rather than PCR reflex: PCR testing has decreased, particularly in sentinel surveillance which reports both positive and negative tests. Extracts from sentinel labs suggest this may be due to some labs doing antigen testing rather than PCR.

Discussion:

- (GF) As Cepheid point of care (POC) PCR testing in pharmacies is increasing there is a need to ensure data from this is reported to PHE. A system which transfers Cepheid pharmacy data directly to the national registry is in development, however it may be difficult to match to the existing dataset depending on which identifiers are present. Other organisations are doing POC testing and also need to be brought in.

5.3 Hepatitis C Virus testing – UAM survey in PWIDs (RT)

RT presented results from the UAM survey, looking at combined results from RNA testing and antibody reactivity:

- Around half of the samples were antibody positive, with nearly 50% of antibody positives RNA positive, so around 25% of the whole dataset were RNA positive.
- There was linearity in the level of antibody reactivity, with population distribution of optical density (OD) showing tailing negativity on the left, and people persistently infected with a good antibody response on the right.
- Prevalence of RNA positives was dispersed across quartiles of antibody reactivity; 68% of people with very strong antibody reactivity are RNA positive, down to 2% in the bottom quartile.
- Plotting RNA prevalence on OD shows two extremes; at the left and right are people with RNA, with a scattering of serology in between. Most people with intermediate OD are RNA negative, indicating these are not acute infections.
- A ‘life-cycle’ for HCV infection plots PCR crossing threshold (inverse of viral load) on the y axis and OD on the x axis. People enter at the top left; antibody negative, with low levels of RNA. There is no time axis but one can speculate that as time progresses they drop down to the bottom left quarter of the left quartile, having high levels of RNA and either antibody negative or transiting into the major population on the right-hand side (medium to high levels of RNA and strongly antibody positive). People also exit to the top where RNA negative and various antibody levels.
- A significant proportion of RNA positives report treatment; speculated that these are people currently being treated who in time will lose their RNA.
- Many RNA negatives have remaining high levels of antibody but no current infection. Again, there is a significant amount of treatment going on in this group. Many antibody negatives are also being treated, suggesting that infection has been picked up very early, which is important in terms of affecting onwards transmission.
- Summary: putting RNA and antibody testing together gives a much finer analysis. The positive/negative concept is dangerous as these viruses are under a lot of pressure, both viral and time. The UA survey will continue to generate both antibody and viral quantification which will enable continued analysis of these results.

Discussion:

- Question of how treatment status is known. The patient questionnaire asks about any treatment, past or present. Patients may answer this incorrectly.
- Question of whether we can be certain that treated antibody negatives were previously positive – this could be ambiguity over treatment rather than people losing antibody.
- Comment about pursuing de-anonymised cohort to allow linkage to treatment and lab diagnoses datasets.

6.0 HCV Elimination agenda: HCV Case finding and referral

6.1 Patient re-engagement exercise: PHE lab data release to ODNs (SM)

SM presented a summary of the PHE lab data release for the patient re-engagement exercise:

- Data release aimed to support ODNs to find people previously diagnosed who may still be infected but not treated by using PHE data on laboratory notifications of HCV from 1996 to 2017.
- Dataset matched with the NHS spine, patient demographic service (PDS), to identify where patients were living and their current GP, and this list provided to ODNs to contact GPs and then patients to offer confirmatory testing and treatment if viraemic.
- Extensive work was done to mitigate the Caldicott and information governance risks; NHSE CCO endorsement was obtained in December 2017, PHE Caldicott approval in February 2018 and approval from DH and senior leaders by September 2018.
- Data was released in September 2018, all 22 ODNs have now received the datasets.
- Data flow and drop outs: between 1996 and 2017 there were 176,555 lab reports submitted to PHE, mainly anti-HCV. In the final dataset, after matching and exclusions, there were 55,329 patients.
- Limitations of the data: mainly antibody data so final PCR positive number will be lower; lab underreporting and poor early assays means that not all cases are included and some false positives will be present; can't exclude people treated prior to 2015 or spontaneously cleared; and can't include people with missing or erroneous identifiers who can't be matched
- Patients who had their first diagnosis in GUM, prison or drug services are underrepresented as they may not have an identifier so can't be linked to a GP.
- Outcomes: 1,000 to 5-6,000 patients per ODN identified. Majority of GPs have <10 patients on the list but a few ~100 GPs have >40, these appear to be those with special interests, for example drug services. Very little change in patients' ODNs since time of diagnosis, reassuring in terms of matching.
- Supporting documentation is available on GOV.UK website, including HCV flyer, patient leaflets and information (FAQs) for GPs and ODNs.

Feedback from ODNs:
GF: it is early days, feedback so far is that there is a low hit rate (10 to 20%) from a few ODNs who have reported patient contact with the remainder mostly cleared in interferon era and known to services, but worth doing. There is a proposal to collect data from each ODN to be able to understand this better.

AES: Birmingham have 4,800 patients and have not started contacting people yet because they are cleaning the data. They have asked spoke centres to confirm whether they previously treated patients with interferon but the quality of data returns variable.

PM: around 700 patients have been contacted and problems are in line with those predicted: many don't turn up, several said they were unaware they had been tested, although with some of these it was clearly recorded in the notes that they had been seen and had this discussed, one had never been tested for HCV, some people angry with those who had done original test that they had not been referred at the time but pleased to have been picked up now. There have been no complaints about the process.

Discussion:

- Risk of legal claims due to delayed or failed referral by GPs for HCV were flagged based on reports from Medical Protection Society
- The HepC Trust requested that it would be useful to know when ODNs are sending out letters as their helpline number is given on most letters / FAQ being sent out.

Action: GF/SM to share this information with Hep C Trust when communicating with ODNs

6.2 Direct reporting of lab diagnoses to ODNs – will be brought up under Item 7

6.3 HCV in prisons. Update on opt-out testing and implementation issues (MG-P and EO'M)

MG-P outlined the work being done by the NHSE Health and Justice Team to improve opt-out testing in prisons.
Context:

- Central team manage policy, service specifications and so on, and 9 regional Health and Justice teams directly commission the healthcare providers in prisons.
- Currently in a procurement process, MG-P is one of the evaluators in the process around Health and Justice interventions.

HCV in prisons indicators:

- Section 7a contains 2 metrics relating to HCV; rate of opt-out testing offer within 72 hours of arrival in prison, and uptake of testing within 4 weeks of arrival in prison.
- Current metrics are useful indicators of what happens at reception but don't tell us about the population; NHSE are looking at changing this for next year, with an aim of including monitoring of testing, diagnosis and repeat testing for the standing population in the prison system in addition to current measures.

Joint working:

- NHSE have been working closely with the Hep C Coalition and are supporting them in holding a roundtable event with ministers and interested others in relation to HCV in prisons, taking place on 4 December.
- Work with pharmaceutical committees and companies is on hold during the procurement exercise. Previously they helped by undertaking evaluations such as the effectiveness / cost-effectiveness of different testing options.

Delivery:

- Reception testing performance data for HCV testing is hugely varied. It has improved over the past three years from awful to not good enough.

EO'M discussed recent performance:

- Mean testing uptake at reception now ~28%, varying from ~24% to >40%, a seven-fold increase from 4% before opt-out testing was implemented as a national policy.
- Figures are far below what is wanted and below the performance metrics agreed with DHSC and NHSE, but the impact has been significant and is showing an increasing trajectory over time, which was achieved with no additional funding.
- Data and level of uptake still suggests more of an 'opt-in' approach despite the opt-out approach being advocated.
- Testing in the prison estate occurs at different points of contact, which is not captured in current metrics, so the overall level of testing is probably higher. However, there is still a lot of re-sampling with the wrong test, that is repeated antibody testing.
- Inclusion of prisons is essential for the success of the overall programme to eliminate HCV; prisons are a setting for micro-elimination. The new DAAs provide the opportunity to test, treat and cure people in one period of incarceration.
- Risk if prisoner populations and at or near prison social networks are not included that super-spreader networks will win in this group. As they are often underserved by community-based services, if they are not treated in prison there is a risk that there will not be an opportunity to treat them again.
- There is an opportunity within and near prison networks to get targeted information to people who would not be reached by other more general campaigns. The personal experience of seeing a friend/relative diagnosed and treated to cure is a powerful enabler of further testing and treatment in wider at or near prison populations. The principle of providing programmes in prison populations having an impact beyond the prison gates is established in other areas of public health practice.

MG-P updated on recent work done:

- Detailed work on the guidance around data collection to address the issue of some prisons reporting testing data on patients not part of their eligible population, so appearing to be failing as eligible denominator incorrect.
- Looking at points of attrition between testing offer, accepting testing, receiving testing, and coming back for results, and how to deal with each one. Working with Hep C Trust around getting peers into every prison across the country to encourage testing uptake and remove stigma, with a national programme rolling out 2019 to 2020

- Prison-specific communications work with the Hep C Trust, providing information to prisons through posters, booklets and looking into other options, for example video and radio.
- Developing methods of rapid workforce development for opt-out testing in response to rapid turnover of prison workforce. Examples include sending out scripts for the wording of opt-out testing and potentially creating a DVD/YouTube video with the Hep C Trust that models a good / bad opt-out offer and shows how to deliver positive/negative results.
- Testing technology has the potential to help manage some attrition problems, for example POC testing may be better than DBS testing in reception prisons as people are only in a reception prison for 5 days and can move on flagged as tested positive and then access treatment.
- Demonstration projects to see what works well in different types of prisons: one local prison getting a high-volume Cepheid POC machine so people can get tested through reception and take their result with them; joint work at HMP Humber developing rapid pathway for testing and treatment, aiming for same day treatment initiation.
- Work with regions that are doing well and not so well with HCV testing offer and uptake. One region working closely around ramping up their activity and improving quality, have put in extra resource.
- Working with Care UK in relation to the services they provide in 42 adult prisons comprising a third of the prison population. Learning from this can be shared with other prisons.
- Considering a ‘hit squad’ approach to prisons who are not testing, working with Hep C Trust, prison healthcare, ODN, and interested others to go into a prison for 3 to 4 days with peers and a range of support and do whole prison testing. Provides an opportunity to know the status of the whole population, and then if catch everyone on reception maintain a ‘clean/treated’ prison status going forward.

Discussion:

- Suggestion of designating Hep C champion prisons where patients with HCV could be sent and clinical services could be clustered. Although there are other instances of clustering of prisoners, the difficulty of this is that it results in prisoners being further from family and support networks. With the reconfiguration, there will be reception and training and resettlement prisons, the latter will have more stable populations and health opportunities can be looked at as part of the reconfiguration agenda.
- The Hep C Trust has been discussing having champion prison governors, and there have been instances of prison GPs being trained to deliver treatment.
- Question about the big jump in testing uptake from last year to this year: this is partly due to improvements in data quality, due to a lot of political pressure on prisons.
- Discussion of the impact of other problems in prisons which are getting worse. Select committee report was published on 1 November which identifies significant challenges within the prison estate that impact on delivery of all services.
- Suggestion of NHSE centrally commissioning testing in prisons, this would give an opportunity to specify how services should be delivered and would address the issue of moving from prison to prison.

AOB – Update on contaminated blood enquiry (GB)
This opened at the end of September, evidence was given and it is now closed while they look at the evidence.

7.0 HCV Elimination agenda: Report from Drug Service Roundtable meeting (WI)

WI fed back on key issues raised at the meeting:

- There are difficulties and complexities around commissioning responsibility for provision of HCV care, which vary in different parts of the country. This makes it difficult to find ways to implement consistent pathways and make improvements. This is a structural problem which is hard to do anything about.
- There was discussion around ensuring that local service commissioning had the right contracts in place to ensure that everything regarding HCV testing and referral was in place. One suggested outcome was that templates for local service commissioning could be provided.
- A clear pathway is needed from testing to result going to ODN so that they can take responsibility for treatment. This partly relates to Item 6.2.
- Discussion about PWID being tested in drug treatment but the data being lost. This is a serious deficit as it means PHE don't have data on diagnosed PWID. This is being taken up by Ruth Simmons with laboratories, some are now providing data but there is still a sticking point with one lab. There may be other labs that are processing tests that we are not aware of.
- A lot of innovative work around case-finding and getting patients into treatment was taking place, but all were pilot studies that were successful but not sustainable. This is a great missed opportunity which requires identifying who can fund these and make them part of routine care.

WI asked for feedback on the NHSE option appraisal about testing and treatment in pharmacies which was noted in the minutes to the roundtable meeting, HB and AES reported back:

- Community pharmacy testing pilots in Manchester, Birmingham and London.
- LJWG was first site, done as a research project funded by MSD and LJWG. Phase 1 was oral swab testing, tested 180 patients and 23 entered treatment over 18 months.
- MSD then approached Birmingham and Manchester as part of bridging tender to ask them to run pilots, commissioning 8 Cepheid machines in 8 sites each.
- In Birmingham 5 pharmacies have been live since end July, have tested 270 people of which 65 have been positive. All were referred, 23 seen and 12 started treatment.
- Patients are incentivised £5 to get tested and get their result. Payment is made by voucher when they collect their result, with a £10 voucher for attending hepatology.
- As this is part of bridging tender if success is shown it may be possible to fund more sustainably longer term.
- NHSE has a task and finish group considering how to roll the model out across the country. Two main issues: legislation requires that the drugs are bought by community pharmacist, so they pay list price which is a lot higher than what NHSE pays. Commissioning is also difficult and could be by NHSE, local authorities or CCGs. Each model has an issue and there are no quick wins.

Discussion:

- Hep C Trust have a commissioning template that has gone out to all commissioners but was not widely read. Work could be done to disseminate this.
- Although there is lots of innovative work going on there has been no definitive large scale or wide trial or implementation. When wider implementation begins, some pathways will fall over and others will be more resilient and there is a need to capture the effect of moving to scale. Academics, PHE and ODNs will need to work together to capture this data.

8.0 HCV Elimination agenda: HCV treatment monitoring (HH)

HH shared preliminary findings from the Hepatitis C patient registry and treatment outcome system in England:

- New data collection system developed by PHE/NHSE and produced by Arden and Gem CSU which contains all identifiers needed to comprehensively link to other datasets.
- ODNs have been entering data on the system since the treatment roll out in 2017.
- Report circulated with today's agenda summarises the content and completeness of data within the patient registry at the end of April 2018, which gives a preliminary assessment of the database and status of treatment in England.

Key statistics 30 April 2018:

- >33,000 records on the database, after duplicates >32,000
- 7,800 on register have not been treated
- >24,000 have one episode of treatment in the database
- Nearly 200 have 2 treatment episodes in the database
- For each patient sociodemographic, infection, clinical characteristics are described, along with information about treatment outcome and completeness of data in the register

Data completeness:

- Age and sex nearly 100% complete; ethnicity ~ 90% complete; Country of birth ~ 70% complete; only about 20% of postcodes complete, and not all are valid
- HCV genotype nearly 100% complete; first year of diagnosis ~ 65% complete
- Injecting route of transmission (current/recent or past PWID or never injector) ~60%; how infection acquired ~ 50% complete

Equity measures:

- Current/recent PWID are treated in significant proportions in some ODNs but this varies across the country
- 16% of referrals come from drug services and prisons
- About a third of patients had cirrhosis prior to commencing treatment, and about 58% had no cirrhosis or mild disease, which suggests that most of the ODNs have got through individuals with severe disease that they know about
- Nearly all treatment is in secondary care

Conclusions:

- Data completion exceeded 90% for many key variables. Where data completion lower, still better than what we had previously. Need to look at dichotomous variables

going forward – for some variables (for example HCC) it's not possible to distinguish absence of condition from missing data.

- 95% of treated individuals are achieving SVR. Of those having a subsequent course of treatment 87% are getting SVR.
- Treatment is reaching key risk groups although there is still more to do. 11% of those treated come from South Asian population, just under a third were born outside the UK. 70% report injecting drug use as their likely risk for acquiring HCV. 16% of those treated were current / recent PWID. Only 13% of treatment taking place in outreach settings.

Discussion:

- Question of whether ODN numbers could be put in context of their denominators as this would be useful to benchmark the data. Although denominator estimates are available from the commissioning template, the way ODNs put patients on to the treatment registry varies so comparisons between ODNs may not be valid.
- Question of whether definitions were clear. GF stated that they were not, initially the aim was to keep requirements as simple as possible to encourage compliance, guidance is now planned and will start increasing the pressure to improve quality.

9.0 HCV Elimination agenda: Guidance on resistance testing (DB)

DB gave an update on the recently published guidance document:

- Produced by PHE HCV resistance group comprising 15 experts, mainly clinicians
- Not intended as a treatment guideline but to summarise the evidence and provide guidance to support clinicians as there is a lot of conflicting advice currently in circulation
- There are five groups of patients where resistance testing may be useful:
    - NS5A RAS in GT1a prior to Elbasvir / Grazoprevir
    - NS5A RAS in GT3 with compensated cirrhosis prior to Sofosbuvir / Velpatasvir
    - NS5A RAS in all patients with decompensated cirrhosis prior to DAA therapy
    - NS5A RAS in subtypes not commonly found in high income countries, including genotypes 4, 5 and 6
    - NS3 and NS5A RAS in all patients with prior exposure to NS3 and/or NS5A inhibitors, prior to re-treatment
- Data tables summarise resistance testing regimes for different patient groups
- Field is very dynamic, lots of new data coming through which led to revisions while the document was being produced
- Document also gives background on mechanisms of resistance, types of resistance testing, what happens when resistance mutations are found; information on each of the individual regimens, looking at in vitro, clinical trials and real world data; and summarises the evidence relating to NS5A inhibitor experienced patients who are the most difficult to treat

Discussion:

- Question of how the report will be disseminated. The target audience are prescribing clinicians, it will be sent to NHSE and hope it gets to ODNs through that route. PHE

Comms have said it is not suitable to go on GOV.UK. It was agreed that the group should support dissemination, either by sharing on other websites or by pushing for its publication on GOV.UK.

- It was noted that the guidance does not align with the current rate card, which may make it difficult for clinicians to make prescribing decisions. The response was that the intention of the report is to provide evidence, which may influence what happens with the rate card rather than being driven by what is currently on the rate card.
- A question about the timeliness of getting results from resistance testing back from Colindale was raised. A new assay based on whole genome sequencing is currently being validated, from early next year this will be run weekly and turnaround times will improve.

Action: DB to share email from PHE comms about why this has not been published on PHE website so that group can support with getting it published.

10.0 HCV Elimination agenda: Drug Procurement (GF)

GF fed back from NHSE on how the drug procurement exercise has gone to date:

- Very good bids were received from all three providers
- Abbvie have taken NHSE to court, if they win the procurement process will be invalid and will have to start over
- Procurement announcement planned for November has been postponed until mid-January assuming court case ruling is out before Christmas, in which case procurement could hopefully begin in April

11.0 HCV elimination agenda: research updates

11.1 Case-finding interventions: evidence report (RR)

RR reported a summary of the evidence for interventions to increase testing uptake and linkage to care for people with HCV:

Methodology:

- Non-systematic rapid evidence review methodology used.
- Inclusion criteria: high risk groups for HCV, interventions to increase uptake of testing and diagnosis for HCV; improve linkage to care and/or (re)engagement in treatment for those diagnosed with HCV; increase retention in treatment and treatment completion for those diagnosed with HCV; studies with a comparator group, including before and after studies.
- Focus on UK studies, also include Western Europe, Australia, Canada and US.
- Grouped by risk group, focus first on PWID interventions, separated by setting and then by setting for non-PWID populations.

Results summary:

- PWID testing in drug treatment: 2 randomised and 4 non-randomised studies. A UK randomised study of DBS testing showed increased testing but did not achieve high testing rates. HepCATT initial results show a nurse-led complex intervention in drug treatment substantially increased testing. Studies on educational interventions did not show a strong effect. No economic evaluations but HepCATT CEA pending.

- PWID linkage to care in drug treatment: 3 international randomised studies and 4 non-randomised, 2 UK and 2 international. Good quality studies on complex interventions such as multidisciplinary teams involving motivational interviewing and psychological support showed increased treatment uptake. A US RCT of onsite treatment showed improved treatment outcomes, but had small numbers and was pre-DAAs. Limited evidence on educational interventions. No published economic evaluations but HepCATT CEA pending. May be more onsite treatment taking place but no published studies.
- PWID testing and linkage to care in pharmacies: 3 UK studies, one randomised, 2 non-randomised. RCT of testing and treatment in pharmacies showed treatment was successful and testing increased. Limited evidence that providing testing in needle exchange pharmacies was more successful in accessing patients that were not in drug treatment and less likely to have been recently tested. More intervention studies are ongoing through the LJWG.
- PWID testing in primary care: 2 studies. One identified former PWID from medical records and had a small increase in testing through opportunistic testing, the other was a complex intervention in methadone prescribing pharmacies in Ireland that was more successful in increasing testing.
- PWID linkage to care in primary care: same 2 studies. Only the Irish study reported with a comparator and showed some evidence of increased referrals, but no significant evidence of increased treatment initiation.
- Testing in prisons: few studies in prisons due to difficulties in study access, 2 randomised and 2 non-randomised. Studies showed low rates of testing overall with mixed evidence on DBS testing. Qualitative evidence on barriers in prisons, difficult to get access to prisoners, staff capacity, and prisoner trust the setting, wording of opt-out offer is important.
- Linkage to care in prisons: one non-randomised study which was thought to be at high risk of confounding; a pathway intervention with non-medical referrals and outreach clinics, which showed some evidence of increased referrals.
- Primary care testing (non-PWID): 2 randomised studies, one UK and one US and 9 non-randomised studies, 2 UK and 7 international. Most international are from US. Body of evidence on birth cohort testing, most of these use electronic medical records, flagging patients for testing and all increased testing. HepFREE is due to be published: study of incentivised testing for migrants in GPs in the UK, successful in increasing testing. A non-randomised pilot study in Leeds of opt-out testing in GP practices shows how variable implementation is across different GPs.
- Linkage to care in primary care: few studies, despite the number of testing in primary care studies, and where reported, rates were low. HepFREE migrant GP study trialled community care as an alternative to secondary care for diagnosed patients, this made no difference to linkage to care. Several US studies use patient navigator concept, but none report on linkage to care outcomes. One study showed that telehealth could support primary care in delivering HCV care in areas where this had not been previously provided.
- Emergency departments: few studies with a comparator group. Two randomised studies looked at whether brief interventions increased testing uptake, both found that it did not. A UK study implemented opt-out testing and then looked at whether

quality improvement interventions increased testing rates, temporary improvements were made but not sustained.

- Homeless populations, street outreach interventions are taking place but there are no published interventions with a comparator group. Seroprevalence estimates vary in homeless populations and this is an undefined population. It is useful to understand injecting status of homeless populations and whether they may be picked up elsewhere in PWID interventions.
- MSM: although there are several prevalence studies, no study designs with a comparator group. Testing for HCV is low compared to HIV testing in this group, evidence on HIV interventions may be transferrable.
- Cost-effectiveness: used evidence from a systematic review which had 30 studies of screening interventions, plus 6 other UK studies. Robust body of evidence for screening, much less on linkage to care or complex interventions. Good evidence that screening drug users is cost-effective. Mixed evidence on screening in prisons, sensitive to treatment uptake. US studies on birth cohort screening show that it is cost-effective, but a UK study suggests that it isn't in the UK. Important to consider timing of studies, more recent studies which have correct assumptions on treatment efficacy and uptake since DAAs are more likely to have accurate results. For more recent studies there are cost-comparisons but few cost-effectiveness studies.

Conclusions:

- Few randomised studies due to the nature of the populations considered.
- Further research needed: pharmacy studies are promising but need more research, linkage to care is a big gap overall. Evidence for multi-faceted interventions is there but difficult to disentangle.
- Even within studies that did the same intervention at multiple sites there was a lot of variability; a lot is down to individual staff buy-in, individual populations and settings; implementation is key.

Discussion:

- Discussion about how work will be disseminated
- Discussion of whether this could be shared with NIHR / MRC to inform them about the lack of evidence.

Action: (RR) – Final report to be shared with NSGVH, plan to publish report on gov.uk and alert stakeholders, for example NIHR /MRC

11.2 Update on NIHR funded projects and future opportunities (GC)

GC provided an update on the discussion about finding more strategic ways to approach funding bodies and identifying the gaps in the research:

- GC has asked NIHR to scope out what is currently being funded; overall NIHR have spent £13 million on hepatitis, difficult to be clear on where that money is going. There are clear gaps, one example is research in prisons as also identified in evidence review; no recent evidence of spend on prison topic which would support building a case.

Discussion:

- It was agreed that this group needs to agree priorities for research; no replies were received to the request for individuals' research agendas so we again invite emails of suggested research which would support elimination of HCV.
- It was agreed that there was a gap in research in prisons which could be addressed through this call. The idea that research in prisons is difficult was challenged; support is available from the Worldwide Prison Health Research Network which provides a 'how to' guide on prison research and has 1,000 collaborators registered worldwide. The select committee report on prisons also highlighted research needs, including improving knowledge of the prevalence of infectious diseases in prisons, interventions that are prison specific and how these differ from interventions in the community, and continuity of care.
- It was suggested that research needs to address the question of how things work at scale, and that this should be an underlying context to any suggested research; often small-scale pilot studies are done which may work in the right context, but don't take us as far as we need to go.
- It was asked whether drug trials in prisons could be funded, as shortening treatment duration could improve treatment completion in prisons. Response was that this was less likely to be funded and would raise issues, and that the key issue in prisons was the numbers still not being tested.
- Timeliness of research was highlighted, and the need for research projects to deliver in 2 years for utility to NHSE for elimination strategy.

Action: All – to email Rachel.roche@phe.gov.uk with any suggestions for research, a list will then be circulated to agree priorities.

Action: EO'M – to share suggested research questions in prisons.

11.3 NIHR PRP: HepCATT / HepFree

HepCATT (WI/MH):

- HepCATT has 2 arms, one in a drug treatment service setting and one in primary care. The study in drug treatment setting finished a year ago. A manuscript for the quantitative data has been submitted to Addiction and is awaiting final outcome, qualitative data has been published in Journal of Viral Hepatitis and a cost-effectiveness paper led by PV is in draft form. The report for the primary care study with CEA has been submitted to NIHR.

HepFREE (GF):

- HepFREE was a study of migrant testing in primary care which incentivised GPs with £25 per patient tested and gave them support from a clinical fellow. Testing increased from 1% to 20%. There was high completion of treatment ~90%, outreach clinics did not make a difference to this. The intervention was highly cost-effective at £7,000 per QALY. The report is due to be published in Lancet Gastro Hep next week.

11.4 HPRU workstreams (PV):

Ongoing / submitted paper topics in the evaluation of interventions HPRU include:

- Homeless outreach linked to find and treat in London.
- Needle and syringe programme testing linked with Eradicate in Dundee.
- HepCATT in drug and alcohol clinics.
- Birth cohorts screening in the UK.
- GP drug treatment testing.
- A&E testing.
- MSM and linking to PrEP.

11.5 EPIToPe (PV)

- RNA testing in UAM.
- Planned similar RNA testing in NESI (Scottish UAM).
- Find and treat trial ongoing with UCL.

11.6 Research in the ODNs (AES)

- Nottingham: community MDT led by substance misuse service GPs, funded by Gilead, ED screening bid has gone into NIHR, joint bids with Barts (awaited)
- Steve Ryder, Nottingham: Gilead CHIME application around microelimination in prisons (post meeting feedback – bid was successful)
- North East: single site study looking at quality of life, cardiovascular risk and developing lifestyle interventions in HCV patients with 100 recruits; assessing the impact of HCV testing in community pharmacies; ongoing work around testing in prisons
- Brighton: ITTreat – providing treatment in drug and alcohol services; Project 5 – homeless screening project funded by Gilead and Dunhill Medical Trust; just received a Gilead CHIME fund for intervention in community pharmacies, homeless drop ins and drug and alcohol services in Brighton and homeless hostels in Worthing
- Birmingham: small Abbvie grant to do community pharmacy testing in ethnic minority populations; Gilead fellowship to look at peer testing in ethnic minorities and attitudinal work in ethnic minorities about attitudes to HCV; working with LJWG and Manchester on community pharmacy testing, looking to pool data and publish

12.0 Any other business

12.1 Updates on other key meetings and reports:

Upcoming meetings:

- HBV endpoint meeting in March
- Hep C Coalition roundtable meeting on prisons in December

Action: All to send in any updates on key meetings

12.2 Update on BHIVA micro-elimination initiative (GC):

- Pushing the microelimination agenda among the HIV/HCV co-infected population
- There are good data on this cohort and can monitor progress
- Targets were put out in a press release in October: aiming to cure 80% of people by April 2019, 90% the year after and 100% the year after that, with baseline April 2016