Public Health England

Title of meeting	National Strategy Group for Viral Hepatitis (NSGVH)
Date	12 December 2017
Time	10.00 to 15.30
Venue	Room LG20, Wellington House
Attendees	Will Irving (Chair) Mary Ramsay (deputy Chair) Charles Gore (speaking to agenda item 3.1) Helen Harris (speaking to agenda item 3.1) Ross Harris (contributor to agenda item 3.1) Claire Foreman (speaking to agenda items 3.2 and 4.1) Ahmed El Sharkawy (speaking to agenda item 4.2) Mike Gent (contributor to agenda item 4.3) Sema Mandal (speaking to agenda items 4.3 and 7.0) Iain Brew (speaking to agenda item 5.2) Peter Moss (speaking to agenda item 5.2) Ray Poll Graham Foster Matthew Hickman Sarah Hart Samreen Ijaz Koye Balogun Giri Shankar [Wales observer] Steve Taylor Ruth Parry (secretariat) Kevin Dunbar (present for agenda item 7.0 only)
Invited speakers	Ceri Townley (Agenda item 3.2) Denise Farmer (Agenda item 5.1) Karen Hinsley (Agenda item 5.2) Peter Vickerman (Agenda item 6.0)
Dialed in	Sharon Hutchinson [Scotland observer] Noel Craine [Wales observer] Lucy Jessop [Northern Ireland observer] Emma Kain Ginny Belson (pm only) [DH observer]
Apologies	Eamonn O'Moore Rosanna O'Connor Richard Tedder Peter Huskinson Peter Kohn

1.0 The deputy Chair welcomed all of those in attendance and online.

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 2.1 (for CT) – Data transfer from NHSE to PHE. Can we receive updates on how ODN nodes are signing up to deliver identifiable data?
CT reported that twenty one of the 22 ODNs have submitted their provider acceptance forms thereby indicating that they are willing to share data and load them onto the system. GF has written to the remaining ODN to prompt them to respond. Within ODNs there are now around 50 separate providers (spread across many ODNs) who had not yet submitted provider acceptance forms confirming their acceptance of the IG information packs. Once all ODNs are represented, the data can be used.

Action 2.2 (for CT/HH) – Can we have clarity on which data fields are mandatory? Can NHSE provide assurance that key public health fields will be retrospectively completed and prospectively become mandatory, using whatever levers/incentives are available in CQUINs? Most of the fields in the database are now optional, with some marked as being required to pass NHS England (NHS E) data quality requirements. CT could not give assurance that the key fields would be populated. PHE highlighted that some key public health fields remained optional (in particular those relating to equity of access to treatment for marginalised groups, and those required to monitor elimination) and that these optional fields are likely to be poorly completed. NHS E representatives were not in favour of making these fields mandatory at this stage, but preferred to endeavour to improve completeness by feedback to ODN's via data quality reports. The interface to HepCare should also help with securing improvements in the quality of data captured. This will be kept under review. CT indicated that there are already a volume of data quality reports available to ODNs within the system and providers are expected to routinely be using those reports.

Post meeting note: on 13 December we were informed by NHS England that "we have this morning received a signed provider acceptance form from representation of the last outstanding ODN. This means that we can now start publishing reports from the Hep C registry and treatment outcome system."

Actions 2.3 & 2.4 (for CT) WI had shared some anonymised outputs from the system which can be de-anonymised once the final ODN has signed up.

3.0 HCV elimination actions from the last meeting

3.1 Agreement of targets for England
HH acknowledged the input from RH and set out proposed UK 5-year targets for HCV, which included a reduction in chronic prevalence of HCV in PWID of just over 40% by 2022 and reduction in the incidence of HCV-related end stage liver disease/hepatocellular carcinoma (ESLD/HCC) of 27% by 2022. The former is monitored via the UAM survey and the latter via HES. The model 'predicts' that England would meet the WHO mortality target before 2030. The 5-year service coverage targets for 2022 include diagnosing 11,500 previously

undiagnosed infections annually from 2018 to 2022 (monitored by PHE laboratory reports of new infections) and to treat at least 11,100 people in 2018; 13,000 in 2019; 14,800 in 2020; 13,300 in 2021 and 12,100 in 2022 with at least 33% of all treatments being in current PWID (monitored via NHS England treatment monitoring system).
It was noted that the model does not include a dynamic transmission component in which reductions in incidence would occur as a function of falling prevalence in PWID; a 15% year-on-year reduction in incidence in susceptible PWID is assumed.
Challenges with monitoring were highlighted and suggestions made in order to mitigate some of these.
The experience in Scotland was shared and it was noted that Scotland had a target regarding end stage liver disease and morbidity, which England has, and will be met earlier than the WHO target. England also includes a target which aims to reduce prevalence in PWID, which Scotland did not include.
There was discussion about whether the targets were appropriate and it was suggested that of primary importance was seeing mortality/ morbidity reduced but that it was also important to monitor incidence of new chronic infection, even if only via proxy measures. It was agreed that a dynamic model should be considered.

Action 3.1 – RH/HH to review modelling on which targets are based and report back at the next meeting.

Discussion –

- It was noted that the challenge of engaging all patients diagnosed in treatment and re-engaging the lost to follow up should not be underestimated, and our success rate/the challenge of engaging the diagnosed is not considered in the model.
- The question “to what extent setting targets was within the scope of NSGVH?” was raised, with the use of the phraseology “targets” carrying an implicit message that agencies could be held to account for under-achievement. In response, the following points were made:
    - It is appropriate to at least understand the implications of the WHO targets and how that translates into how many patients we need to diagnose and treat to achieve those targets. The model also provides a framework for being able to track progress against the WHO goals.
    - It was noted that the WHO targets are global targets and include countries with very few resources and a large burden and we should at least aspire to England being able to exceed those targets
- It was suggested that rather than use the word ‘target’ an alternative, such as ‘aspiration’ or ‘intention’ was employed as ‘target’ has the implication that funding would need to be provided.
- CG felt that whilst the proposed England targets track to elimination of HCV as a major public health threat as defined by WHO, England should be more ambitious and aim to exceed WHO targets.
- A re-ordering of the document was suggested, setting out the aspirations first, and then itemising what needs to be in place for NSGVH to be able to monitor progress
- It was noted that the treatment “targets” are within the NHS England spending commitments and numbers treated
- Members were invited to send technical questions relating to the presented model directly with Dr H and Mr R Harris

3.2 Arden & Gem database
A simplified version of some of the data that has been downloaded was circulated and discussed earlier in the meeting.

3.3 Hepatitis C data workshop 17 November
Minutes from the workshop have already been circulated to NSGVH members. The 2 main issues were:
1) how to recapture patients already diagnosed who are not accessing treatment
2) prospectively, how to increase the efficiency of movement of newly diagnosed patients from diagnosis to the ODN for treatment

Solutions –
1) PHE has the information (20 years of known diagnoses of HCV) on a named-patient basis and are willing to provide this data to ODNs, having first removed patients who have died or have already been treated. A letter is being approved by PHE (Anthony Kessel) and is to be signed off by the Medical Director (Paul Cosford). There was unanimous support for this. It is hoped the data would be transferred in January. The timeline may slip a little because high level sign up is being sought.
It was noted that Wales have data going back to 1991 and have identified 5,000 patients spread between 7 Health Boards. There were no IG issues when patients were contacted.

KD outlined the remaining issues from the Caldicott point of view, itemising the process of data transfer and the associated risks in some detail. GF agreed to discuss with ODN leads and report back to PHE in advance of the PHE Caldicott panel meeting in January

In relation to the downstream action of contacting patients, the importance of working with GPs and having their 'buy in' was noted.

2) WI carried out an exercise in writing to labs asking if they are/would be willing to report newly diagnosed individuals directly to their ODN node (paper 3.3b) – concerns remain about governance, getting spoke laboratories to report centrally and it was noted that no central list of laboratories to contact is available yet. There is also a need to re-iterate the need for reflex RNA testing in order to generate more meaningful data. In discussion, it was agreed that it would be helpful to ask which labs are doing DBS testing and if so, do they do reflex RNA testing on anti-HCV positive samples.

It was agreed that a further meeting of the HCV data workshop group would be helpful to encourage further action

Action 3.2 – liaise with Sarah Culkin to arrange a further meeting of the HCV data workshop; further planning of communication with diagnostic laboratories is necessary, to reassure re governance issues; encourage reflex RNA testing; get clarity on DBS testing.

3.4 National datasets of unusual subtypes and resistance mutations
WI reported that Tamyo Mbisa (PHE) is setting up a process for doing NGS and setting up a database. TM has established an expert advisory group that has yet to meet

Action – WI to report back when the advisory group has met.

4.0 CQUIN incentivisation

4.1 View from NHS England

CQUINs are part of the NHS standard contracts; part of stretch targets. Large scale changes would need to wait until April 2019 as we are in the first year of a 2-year contract cycle. Benefits of the HCV CQUIN – it was intended to use this area of NHS England's discretion to put significant investment into the CQUIN to support the sustainable roll out of strategy with regard to access to treatment.

4.2 View from the ODN leads

CQUINs are published, can be useful leverage and have helped drive down drug prices. The ODNs have helped deliver almost 10,000 treatments in 2016 to 2017.

One of the major issues (in the context of a hub ODN that sits in a large geographical area with 13 NHS trusts, some of which are in rural locations) is that the financial penalty and incentive sits within one Trust; the hub ODN Trust. It is difficult to convince Financial Directors to invest in other secondary care providers who are often competitors. Other issues that were raised included-

- Second buddy sign off leading to delays in patients accessing therapy
- Limited clinical autonomy in individualizing therapy
- Lack of knowledge of the cost of drugs
- The difficulty in bringing back patients for post-therapy testing at between 48 and 96 weeks
- The requirement that Hub sites apply pressure to partner sites without the ability to give anything back
- The large administrative burden associated with collecting data to be able to assess compliance with the CQUINs
- The pressure to treat patients within a narrow window when they may not be ready.

Discussion

The focus is shifting to ensure that the ODNs are doing what they already ought to be doing about local relationships.

There is no control over what happens in the local prison or drug and alcohol clinic.

4.3 How can PHE help ODN sites to achieve targets?

SM detailed the sources of data held by PHE. The legal framework for processing viral hepatitis data was outlined, including the fact that as from 2010 hepatitis as a causative agent was made notifiable to PHE under the Health Protection (notification) Regulations 2010, if found in human samples. This means that the manager/operator of the diagnostic laboratory is obliged to notify PHE and provide specific information including name, date of birth and address of the patient in whom the agent was identified. This data transfer is mostly automatic.

The number of laboratory reports indicating a person's first anti-HCV positive result for the years 1996 to 2015 was shown, but it was noted that there may have been some under-ascertainment in the early years.

There was some breakdown of the data on the number of persons tested for anti-HCV and the proportion positive between 2006 and 2015 in 21 sentinel laboratories in England, with an upward trend in the number tested and a downward trend in the % positive. Between 2010 and 2015 the largest number of positives came from tests requested by GPs, with the highest percentage positives being in those tested in the prison or drugs services.
The NICE recommendation on reflex RNA testing was highlighted.

MG highlighted the data available at a local level, including the 'workbook' of laboratory reports and local authority profiles.

The potential involvement of PHE centre leads in ODNs was described.

Action 3.3 – MG to share list of viral hepatitis leads, who should be linked into the ODNs

Action 3.4 – MG to go back to the hepatitis leads and request that the "workbook" is distributed to their local ODNs

In the East of England (EofE) the CCDC is using Second Generation Surveillance System (SGSS) data, linking to PDS and writing to GPs asking them to refer, awaiting evaluation. In Yorkshire and Humber the same database has been built to provide the same data but not been implemented as yet - awaiting evaluation from EofE and outcome of national system. There is also national work using SGSS to identify previously diagnosed cases to provide ODNs with a line list of patients to contact for assessment for treatment; the IG issues and process details are being worked through.
Risks identified include false positive results not corrected on lab system; inappropriate disclosure to patients; confidentiality breach if wrong patient or address on lab system. Kevin Dunbar (deputy Caldicott Guardian) attended for this agenda item and advised that PHE IG leads are supportive with the checks that are proposed will be put in place.

Questions/comments
There is a major issue with private laboratories not reporting positives to PHE. There is a similar lack of reporting of results of Dried Blood Spot testing.
Do PHE Centres match to ODNs? Not entirely.
Is there anyone in the group who represents DH? The DH observer is Donna McInnes (Ginny Belson is deputy and dialled in for agenda item 7).

Re national exercise: similar approach being piloted in Wales (GS reported).
IB and AES – mentioned importance of informing GPs of proposal and prior to contacting patients.

Action 3.5 – NHSE to seek CCIO and high-level signature for letter to ODNs on proposal
Action 3.6 – SM to submit PHE Caldicott application for approval
Action 3.7 – escalate issue of private laboratories not reporting HCV positives to PHE

5.0 HCV in prisons

5.1 What do we know about prevalence/incidence of HCV infection?
A strategic overview of hepatitis C testing in prisons was presented.

It was noted that there are 110 adult prisons in England with a population of 86,307. NHS England commissions healthcare for the adult prisons (including 12 women's prisons), 9 immigration removal centres (IRCs), 3 secure training colleges (STCs), 4 youth offending institutions (YOIs), 14 secure children's homes (SCHs).
It was noted that the majority of prisoners are on shorter sentences of less than one year; 70% will have gone within 6 months and that there is a high turnover which brings with it a major challenge for the delivery of healthcare.
BBV opt-out testing in prisons was described.
It was noted that according to figures published by PHE in sentinel surveillance data for 2015 the HCV antibody positivity was around 4 times higher in prisons (6.7%) than in community primary care services (1.6%).
There have been a number of prison health performance and quality indicators since 2002, with the BBV opt-out programme implemented since 2014.
Quarter 1 data for 2017/18 were presented which indicated that of 36,079 HCV tests offered 8,797 were carried out. Of these 1590 were antibody positive and of the 532 PCR tests done, 434 were positive and 226 specialist referrals were made. There is a need to test more people pro-actively with the end result that more people are treated.
Dried blood testing in Pathfinder prisons was highlighted. Evaluations were carried out by PHE; waiting times for Hep C specialist access were acceptable and referral rates were found to be good. The BBV testing algorithm will be circulated with the minutes

Action 3.8 – Secretariat to circulate the BBV testing algorithm with the Minutes of the meeting

Challenges:

- Limited third sector engagement for rehabilitation of BBV positive prisoners and to support treatment
- BBV champions available in only one prison

Conclusions:

- Prison populations are now increasingly tested for BBV, including HCV, but there are points in the testing pathway at which people are 'lost' which need to be addressed
- Data collection capability needs to be improved to enable continuity of care
- Treatment support and continuity of care can be further improved

Discussion:

- NHS England described ongoing actions – a) A SystemOne solution flag will be attributed to patients to confirm they have an HCV diagnosis. b) Discharge letters will be improved by inclusion of more details so that as the patient leaves they can be picked up by community GPs or Drug Treatment Services
- A central H&J programme of work is commencing in January 2018 to support the reduction of people 'lost' within the testing pathway

5.2 How good is testing in prisons?
Opt-out testing in HMP Leeds was described and initially there was a high number of refusals, thought to be due to the fact that a large proportion already knew their HCV status. An action plan was developed with CareUK which included updating the reception template and the use

of dried blood spots instead of venous blood for testing. Data for the year to date were shown and the increase in uptake after the relaunch of opt-out was noted.
Future priorities were to appoint a lead BBV link nurse, finesse patient 'refusals' and train staff to 'sell' opt-out.

Discussion points:

- Known positives are referred for treatment
- Results from testing in community drug treatment services are obtained, with consent
- Re-testing is offered if the most recent test was carried out more than six months ago

5.3 How good is the pathway from diagnosis to cure in prisons?
There are no figures on what proportion of people are being treated in prison or what proportion of people being treated are prisoners. 15% of all patients being treated in East Yorkshire are in prisons. The numbers have gone up but the proportion has remained the same.
Issues:

- Referral – do prisons have a timely effective way of referring prisoners? What goes into that referral? The hospital appointments system does not work for prisoners
- If the length of sentence is known the doctor can act accordingly
- Where should the appointment be? – In the prison

Pathways – have moved to rapid pathways with referral to cure within 3 months, although some may not finish the course. It is preferable to complete the course of treatment within the prison system.

Onward movement – medical holds can be effective. Patients need an equivalent service wherever they go. Release into the community can be more of a problem, particularly out of the area of the prison.

Discussion:

- Mapping prisons against ODNs is in progress
- The prescribing of a DAA happens at a Trust so should be on record
- Possible strategies -concentrating on improving those prisons where action is already being taken versus trying to bring all prisons up to a specified level of service in relation to HCV diagnosis and treatment. The meeting agreed the latter was preferable

Action 3.9 – for the next meeting, supply information about which prisons are in which ODNs.
Is it possible to see rates of testing and rates of treatment on a prison-by-prison basis?

6.0 Health economics – what can we learn?
It was noted economic evaluations are crucial in enabling understanding of how best to use limited resources.
Cost-effectiveness analyses include the incremental costs of both testing and treatment for a case-finding intervention, and the costs saved from HCV disease care averted in the future so that the incremental costs for any incremental benefits achieved in terms of quality adjusted life years saved (QALYs) can be calculated. Costs and health benefits are discounted at a rate of 3% per year, which

is the NICE standard. NICE consider that an intervention is cost-effective if it costs less than £20,000 per QALY saved.

Some existing analyses based on previously published papers (and prior NICE guidance on HCV case finding) and some new on-going analyses on the cost-effectiveness of HCV case-finding were presented.

Existing cost-effectiveness analyses of case finding interventions in England have considered: (1) screening of ex injectors in a GP setting; (2) introducing dried blood spot (DBS) testing in drug treatment services; and (3) opt-out DBS testing in prisons. It was found that the GP intervention and the drug services intervention were both cost-effective according to the NICE threshold. The interventions in prisons could be highly cost-effective if the level of linkage to treatment is sufficient (>2.5%); also it was important that the treatment was short enough to be completed during the prison sentence. Although these analyses mainly considered IFN based treatments, sensitivity analyses suggest these results will hold for the new DAA treatments at current costs (<£15,000 per treatment course).

Currently the HEPCATT intervention, based in drug services is being evaluated. Preliminary results suggest it is highly cost-effective compared to the NICE threshold, whether the treatment costs are £20,000 per person or £10,000 per person.
Another intervention that is being evaluated is birth cohort screening in a GP setting; this analysis is based on a hypothetical intervention that has not been piloted in the UK, so a number of assumptions have been made resulting in uncertainties about costs and uptake. Preliminary analyses suggest that the intervention may be cost-effective in later birth cohorts (1970 onwards) but not earlier ones, although these results were dependent on the HCV disease progression parameters used in the model.

Discussion of birth cohort screening:
Could it be “bolted onto” other interventions (40+ health check) to improve cost effectiveness?
Most of the cost is for the screening, so targeted screening could be used.

Action 3.10 –
(i) NSGVH members to communicate to PV scenarios which might improve CE for future analysis
(ii) Could an approach be made to NIHR to create a call for funding cost-effectiveness research into screening for HCV infection in primary care?

Other ongoing economic analyses were highlighted.

7.0 Case finding
SM presented a paper describing possible approaches to case-finding. There are already a number of interventions in place, some of them being pilots; others which have been evaluated, for example DBS testing in drug services. Some other interventions are being evaluated as part of large scale research studies with cost-effectiveness analysis that are not yet complete. It was noted that the main case finding and engagement in treatment intervention types are summarised in table 2.
The existing, evidence based guidance was detailed, as well as research and service evaluations on case finding.

A spreadsheet has been set up to gather together the evidence from studies of HCV case finding interventions; this is intended to be a live document in order to capture ongoing work.
Table 3 within this paper details some of the potential system levers that could be enacted by stakeholders who are members of the NSGVH.

Action 3.11 – SM to share the spreadsheet on case finding interventions with the group

Discussion:
It was noted that private providers of drug services play a crucial role in the HCV care pathway (CGL being the largest of these and have hundreds of needle exchange services).
If NSGVH could engage with the people who are providing 60% of drug services and link them to ODNs it would be a large step forward.
It was suggested that a meeting with the three largest companies to discuss issues around HCV diagnosis, reporting of DBS results, and linkage to care might be useful.

Action 3.12 – Chair to organise a meeting with senior people in drug service providers, for example medical directors, from the main providers (or Collective Voice) and commissioners.

It was noted that paying for the testing was part of the commissioned service and therefore there is a risk that this may be dropped in order to reduce costs.

In relation to Table 3 in the paper from SM, all NSGVH members were asked to review the tasks allocated to their particular organisation, and assess feasibility and priority. Feedback before the next meeting should allow reconstruction of the table according to priority and if any items were missing.

Action 3.13 – Members to go through table 3 with a view to fielding a consensus view on what is already being done, what is doable, what are the priorities and what is missing.

The role of primary care providers was also discussed briefly. It was suggested that the RCGP liver diseases champion should be invited to the next NSGVH meeting in order to discuss what actions may be helpful in this setting.

Action 3.14 – Chair to invite RCGP liver disease champion to next meeting

Date of next meeting – March or April 2018