Witness Name: Claire Foreman
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INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF CLAIRE FOREMAN
ON BEHALF OF THE NHS COMMISSIONING BOARD
(KNOWN AS NHS ENGLAND)

I, CLAIRE FOREMAN, Head of Acute Programmes (formerly National Programme of Care Senior Manager) within the Specialised Commissioning Directorate of NHS England, will say as follows:-

1. I make this statement to respond to the questions raised by the Infected Blood Inquiry (IBI) via two Rule 9 requests received by NHSE, the first addressed to Professor Stephen Powis[1], National Medical Director of NHSE on 12th August 2019 and the second addressed to me on 16th January 2020 ("the Rule 9 Requests").

2. The first of the Rule 9 Requests sets out 11 questions for NHSE to answer in relation to the history of treatments for the Hepatitis C virus ("HCV"). The second

[1] Professor Stephen Powis is the National Medical Director of NHS England and NHS Improvement. In this role he is the most senior doctor within the National Health Service in England. His medical directorate is also responsible for commissioning the national clinical audit programme, developing professional standards for doctors throughout England and developing clinical policy for the NHS. He is also the Professor of Renal Medicine at University College London. Professor Powis joined the organisation in early 2018.

request sets out further questions in relation to the commissioning of psychological support for those affected by infected blood and the tests and follow-up HCV patients can expect. The second Rule 9 request also requested information about the support arrangements put in place for those affected by Grenfell and any similar arrangements for those affected by infected blood. NHSE's response to the questions in the second Rule 9 request which are not already covered in this statement are dealt with as a supplemental witness statement.

3. I am making this statement on behalf of Professor Powis and NHSE as part of our full support to the Inquiry. NHSE commends the work of the IBI in support of the thousands of patients and their families whose lives have been irrevocably changed as a result of receiving infected blood and/or blood products. This statement sets out the work of NHSE in arranging for the provision of services and treatments for HCV in particular. A list of exhibits to this statement are set out in appendix 1 and a list of key abbreviations used in the statement are set out in appendix 2.

4. NHSE came into being in April 2013. Since its inception, I have been employed by NHSE in a number of management roles related to the commissioning of treatments for a wide range of conditions including HCV, HIV and Haemophilia as part of NHSE's specialised commissioning function ("Specialised Commissioning") which is part of its statutory responsibilities.

5. Specialised Commissioning is responsible for commissioning, planning and purchasing 149 "Prescribed Specialised Services" using an annual budget of over £17 billion (2018/19). To illustrate the extent of these services, I have included a copy of NHSE's annual publication about the work of specialised commissioning [WITN3953002]. For 2019, this document sets out NHSE's work in relation to the elimination of HCV in England as a public health threat ahead of the World Health Organisation's ("WHO") goal of 2030, elimination of new HIV infections by 2030 through increased diagnosis, treatment and reduced stigma, and access to a new drug to treat Haemophilia A to prevent bleeds, as well as a range of other innovations in other clinical areas.

6. NHSE operates at a national level to coordinate the commissioning of Prescribed Specialised Services, with regional teams focused on working with healthcare providers to support delivery. The services commissioned tend to support people with a range of rare and complex conditions and they tend to be those where the number of patients affected is small and the services they need are very specialist. They often involve treatments provided to patients with rare cancers, genetic disorders or complex medical or surgical conditions. High cost drug treatments or services are also part of Prescribed Specialised Services. There are four factors which determine whether NHSE commissions a service as a Prescribed Specialised Service which are:-

   a. The number of individuals who require the service;
   b. The cost of providing the service or facility;
   c. The number of people able to provide the service or facility; and
   d. The financial implications for Clinical Commissioning Groups ("CCGs") if they were required to arrange for provision of the service or facility themselves.

7. Unlike CCGs or Local Authorities who commission goods and services for their local populations, Specialised Commissioning focuses on purchasing services from specific providers, irrespective of the originating population, ensuring equitable, national access to approved services and treatments.

8. After working as a Regional Programme of Care Manager within the clinically focused Cancer & Blood Programme of Care from 2013, I was appointed in February 2015 as the National Programme of Care Senior Manager for the newly established Blood & Infection Programme. The Programme for which I was the Senior Manager included a number of clinical areas including stem cell transplantation, specialised blood disorders, HIV, infectious diseases (including but not limited to hepatitis C), haemoglobinopathies and specialised immunology and allergy services. My role was to lead a programme of work to support the national commissioning of Prescribed Specialised Services and treatments in these areas. This included developing national commissioning tools such as

service specifications, clinical commissioning policies, the creation of operational delivery network ("ODN") models to improve the quality of and access to Prescribed Specialised Services, schemes to financially incentivise the NHS to improve the delivery of care as part of the Commissioning for Quality and Innovation framework known as "CQUINs", service reviews to transform the clinical model of care, and improving value schemes [WITN3953003] aimed at improving value in medicines (such as reducing drug wastage or reducing drug costs), managing demand more appropriately and reducing unwarranted variation in clinical quality and efficiency.

9. In my role as National Programme of Care Senior Manager, I supported and reported to Peter Huskinson[2] in relation to the Blood & Infection Programme of Care Board and HCV, although he was not my line manager. I acted as the Programme Lead for HCV from 2015 and this involved establishing an internal operational group called the Hepatitis C Programme Oversight Group ("HCVPOG") which met every two weeks to drive forward NHSE's work on implementing HCV treatments. I also supported Peter in reporting progress on HCV to the Blood & Infection Programme of Care Board and to NHSE's Board and committees.

10. I stepped back from this role in early 2019 following my appointment as Head of Acute Programmes and the successful conclusion of the most recent procurement for HCV drugs in 2019. I line managed the manager who is currently supporting the HCV programme until December 2019 when responsibility for HCV moved to the specialised commissioning director responsible for implementation.

11. Supporting the introduction of new drugs for HCV was the biggest single investment by the NHS at the time, providing treatments to help treat and eliminate a single disease. James Palmer, the National Medical Director for

[2] Peter Huskinson was the National Commercial Director at NHSE responsible for medicines procurement and subsequently became the Senior Responsible Officer ("SRO") in relation to HCV from December 2015 until he left NHSE at the end of 2018. Peter also chaired the clinically focused Programme of Care Board for Blood & Infection. This Programme oversaw the work relating to HCV from early 2015. A description of the Programme of Care is set out in paragraph 8.

Specialised Services was initially the director level lead for HCV. He led work in relation to early access to new HCV treatments ahead of National institute for Health and Care Excellence (NICE)[3] recommendations for patients with decompensated cirrhosis and cirrhosis. Peter Huskinson, led the work to design and manage the sustainable roll out of NICE recommended HCV treatments from 2016 ensuring that NHSE and the wider NHS could meet the statutory duty to implement NICE guidance without destabilising other statutory responsibilities to commission and provide other health services. The NHSE Board and its committees took decisions in relation to the strategy for implementing access to HCV drugs as well as the approach to the strategic procurement for HCV drugs concluded in 2019.

12. Given my experience and the length of time I've spent working in these roles, I believe that I am best placed to produce the witness statement in response to the Rule 9 Requests. This is supported internally by NHSE and I confirm that the contents of this statement have been authorised by Professor Powis on behalf of NHSE.

13. Except where otherwise indicated, the facts and matters referred to in this Statement are made within my own knowledge and I believe them to be true. Where they are not within my personal knowledge, I confirm they are true to the best of my knowledge, information and belief and the source of that information is set out in this Statement.

Legal framework for the NHS and for NHSE

14. In order to assist the IBI, I have set out below an explanation of the roles and responsibilities of NHSE in the context of HCV. This includes a short account of some of the legal framework for NHSE but is not exhaustive. Although this is technical, it is relevant to fully understand NHSE's role as the commissioner

[3] The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care.

rather than provider of direct patient services, and the purchaser rather than the supplier or quality controller of medicines.

15. NHSE, legally known as the National Health Service Commissioning Board is a statutory body established by the National Health Service Act 2006 (“The NHS Act”) as amended by the Health and Social Care Act 2012 ("HSC Act"). Section 1(H)(2) of the NHS Act imposes upon NHSE the duty (shared with the Secretary of State for Health and Social Care) to continue the promotion in England of a comprehensive health service. NHSE is undergoing a programme of joint working with NHS Improvement (NHSI), to bring greater alignment of goals and objectives. This means whilst they remain legally separate bodies, NHSE and NHSI ("NHSE/I") are now operating as one organisation in respect of many, but not all, functions. One example of where NHSE continues to operate separately is with regards to the direct commissioning function of Specialised Commissioning.

16. For the purpose of discharging its duty pursuant to Section 1H of the NHS Act, NHSE has the function of arranging for the provision of services for the purposes of the health service in England (section 1H (3)). In other words, NHSE does not have a duty to deliver services directly to patients in its own right, but it does have a duty to ensure they are provided. For example, NHSE contracts with primary care providers for the delivery of GP services (in most cases now via a delegation of that role to CCGs) and also funds CCGs to contract for secondary care services.

17. The NHS Constitution ("the Constitution") sets out rights for patients, public and staff. It outlines NHS commitments to patients and staff, and the responsibilities that the public, patients and staff owe to one another to ensure that the NHS operates fairly and effectively. All NHS bodies and private and third sector providers supplying NHS services are required by law to take account of the Constitution in their decisions and actions.
https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england [WITN3953004].

18. The Constitution establishes the principles and values for the NHS in England. It sets out rights to which patients, public and staff are entitled, and pledges which the NHS is committed to achieve, together with responsibilities, which the public, patients and staff owe to one another to ensure that the NHS operates fairly and effectively.

19. The Constitution's principles and values are designed to ensure the NHS as a whole provides a comprehensive service, available to all without discrimination and on the basis of clinical need, not an individual's ability to pay. The NHS strives to maximise resources for the benefit of everyone ensuring nobody is excluded, discriminated against or left behind. It is committed to providing the best value for taxpayers' money and is accountable to the public, communities and the patients that it serves, as well as to Parliament. The NHS must follow NICE recommendations for access to approved medicines and make local decisions about services or treatments in a rational and transparent way.

20. Section 23 of the HSC Act places specific obligations on NHSE with regards to its role in the NHS. These obligations include requiring NHSE, in the exercise of its functions, to *"act with a view to securing"* that health services are provided in a way which promotes the Constitution. NHSE must also work to secure continuous improvement in the quality of services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness or the protection or improvement of public health, as well as work to reduce inequalities between patients with respect to their ability to access health services, including innovation in the arrangements made for their provision.

21. As a purchaser of clinical services, NHSE is under a duty to ensure that spend for the whole population comes within the budget it receives from Parliament. For example, Section 223C (1) of the NHS Act imposes a statutory duty on NHSE to ensure that total health expenditure it receives in respect of each financial year does not exceed the amounts allotted to and received by it. Section 223D (2) requires NHSE to "ensure that total capital resource in a financial year does not exceed the amount specified by the Secretary of State". Section 223D (3)

requires NHSE to “ensure that total revenue resource use in a financial year does not exceed the amount specified by the Secretary of State”.

22. Growth in Prescribed Specialised Services relative to growth in the rest of the NHS has historically been greater due to the increase in the number of patients needing Prescribed Specialised Services as a result of an ageing population and significant advances in medical technology.

23. NHSE is one part of the wider NHS. NHSE buys rather than delivers clinical services having regard to its statutory obligations set out above.

NHSE's role and the role of others in the wider NHS

24. As stated above, NHSE buys clinical services; it does not deliver them.

25. When it comes to buying clinical services as part of its direct commissioning functions, NHSE does this on the basis of specific documents. Service Specifications set out the service standards, outcomes and quality expected. Clinical policy, which includes NICE guidance, defines patient eligibility and patient access to specific treatments or interventions. Agreed volumes of activity to be purchased and the funding allocated are included in contracts with providers, taking into account overall budget availability. These all form part of the Standard NHS Contract (https://www.england.nhs.uk/nhs-standard-contract/19-20/) [WITN3953005]. This way NHSE sets out what it will purchase from NHS hospitals or other providers who then deliver those services and treatments direct to patients.

26. When it comes to treatments, NHSE funds approved drug treatments and therapies (hereafter “treatments”). NHSE does not regulate or licence treatments and does not prescribe treatments that are delivered directly to patients.

27. The treatments that are funded by NHSE go through a specific process. Treatments are recommended for licence by either the Medicines and Healthcare products Regulatory Authority ("MHRA") in the case of generic medicines or the

European Medicines Agency ("EMA") in the case of branded medicines, as was the case with the new HCV treatments. In most cases, the Department of Health and Social Care ("DHSC") then formally requests that NICE undertakes an assessment of the treatments and technologies. The treatment's manufacturer is responsible for providing the data and case on which NICE undertakes its assessment. Where NICE assesses the clinical and cost effectiveness of medicines, this is done within their licenced indication. If NICE issues a recommendation, known as a technology appraisal guidance ("TA") or a highly specialised technology guidance ("HST"), CCGs, NHSE and (with respect to their public health functions), local authorities, are required to comply with the recommendations. This includes making funding and/or services available to enable access generally within 3 months of the publication of recommendations. This is set out in Regulations 7(3) and 7(6) of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 ("the NICE Regulations"). NICE methods can be viewed here https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-technology-appraisal-guidance

28. NICE has also published a process guide to how it conducts technology appraisals https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/technology-appraisal-processes-guide-apr-2018.pdf [WITN3953006].

29. Since April 2017, NICE has undertaken a Budget Impact Test (BIT) to assess the financial impact of each individual technology over the first 3 years of its use in the NHS. If the budget impact exceeds £20million, in any of the first 3 years, NHSE may engage in commercial discussions with the manufacturer of that technology to secure an agreement for its use in the NHS. These discussions are designed to mitigate the impact that funding the technology would have on the rest of the NHS. NICE states that "a commercial discussion may not lead to an agreement between NHS England and the company. In such cases, NHS England may request a change to the usual 90 day implementation period, known as a variation to the statutory funding requirement"

https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/budget-impact-test [WITN3953007].

30. In addition to NICE recommendations, NHSE can make decisions about the funding of treatments which have not been reviewed by NICE. These investments are discretionary spend over and above all the annual baseline commitments NHSE makes which are rolled forward from one year to the next to ensure continuity of access to care. Where such proposals are considered, evidence is reviewed to inform the clinical and cost effectiveness of treatments before a decision is taken. It is worth noting that where such local decisions are taken, then NHSE is required to plan and produce a policy for all eligible patients to be able to access a treatment if it is approved for funding. In other words, all patients who meet the criteria for access should be able to receive a treatment. Eligibility for a treatment is determined based on clinical factors such as diagnosis, disease progression, comorbidities and contraindications. Eligibility is not determined by how or why a patient needs treatment. This is in line with the core principles of the NHS and its Constitution and NHSE's duties to promote equalities and reduce health inequalities.

31. NHSE also has a process for considering the treatment needs of individuals – as opposed to populations - in relation to new treatments which are not covered by NICE guidance or specific policies and in the wider context of its discretionary decision making. This is called the 'Commissioning Policy: Individual Funding Requests' which was first published in 2013 and updated in 2017. This states *"Every year, the resources that NHS England receives are allocated to the services and treatments provided for patients. NHS England decides the* [new] *treatments it will invest in on an annual basis* [over and above all the baseline spend which is rolled forward from one year to the next] *through a prioritisation process (twice a year for specialised commissioning treatments and services) so that, as far as possible, funding is shared fairly and appropriately, considering the competing demands on NHS England's budget. When a new service or a change to a service is proposed, it would not be fair for that to bypass the prioritisation process and be funded without comparing it to other possibilities for investment. Because of this, NHS England's default position is that a new service*

will not be routinely commissioned until it has been assessed through the full-service development process. Very occasionally a development is of such importance that there should be no delay in its introduction. If this is the case it is considered under the urgent development process - www.england.nhs.uk/commissioning/spec-services/service-development-policy-and-methods/. On an individual basis, there may be situations where a clinician believes that their patient's clinical situation is so different to other patients with the same condition that they should have their treatment paid for when other patients would not. In such cases, NHS clinicians can ask NHS England, on behalf of a patient, to fund a treatment which would not usually be provided by NHS England for that patient. This request is called an Individual Funding Request (IFR). Funding for additional treatments outside the prioritisation process can only be done by reducing the funding that is available for other established treatments. There is not an allocated separate budget to meet the costs of providing treatments agreed through the IFR process. It is because of this that very careful consideration is required before the decision is taken to fund a treatment for an individual that is not usually available". Copies of the Commissioning Policy and Standard Operating Procedures are attached at [WITN3953008] & [WITN3953009].

32. As Specialised Commissioning tends to be focused on high cost, low volumes services and treatments, it is worth emphasising here that one of the seven core principles of the Constitution is *"providing best value for taxpayers' money and the most effective, fair and sustainable use of finite resources".* As set out above, NHSE is under a statutory duty to ensure that total health expenditure in respect of each financial year does not exceed the amounts allotted to and received by NHSE. As a purchaser of services and treatments, NHSE has an important role in ensuring the principles of universality, best use of public resources and securing the greatest possible health gain for patients for every pound spent. This is also reinforced in the recently published Long Term Plan https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf [WITN3953010].

33. NHSE is the key body responsible for ensuring commercial activities are undertaken to secure the best deal for the NHS as a whole and for taxpayers when it comes to buying medicines.

34. Much of the work undertaken by NHSE through its direct commissioning functions is subject to commercially confidential negotiations generating commercially confidential information. Protection of this confidentiality is of paramount and critical importance. The pharmaceutical industry relies on the NHS being trusted with their commercially confidential information in order to negotiate on price. This is why such information is exempt under Freedom of Information regulations. The whole NHS relies on being able to strike such deals so the best possible value is secured for taxpayers, which in turn ultimately benefits all patients. These principles are also enshrined in the 2019 Voluntary Scheme for Branded Medicines Pricing and Access - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761834/voluntary-scheme-for-branded-medicines-pricing-and-access-chapters-and-glossary.pdf [WITN3953011].

35. The Commercial Medicines Unit ("CMU"), which transferred into NHSE in April 2017 (it was part of DHSC until this time) is the part of the organisation responsible for running tenders to procure hundreds of different treatments from pharmaceutical companies. Its activity includes procuring licenced, regulated and approved blood products for the treatment of haemophilia, and drugs for the treatment of a wide range of conditions including HIV and HCV.

36. NHSE recently consulted on its draft commercial framework[4] [WITN3953012] which sets out how it will continue to develop its commercial activity which plays a pivotal role in ensuring patient access to the most clinically and cost-effective new treatments and technologies, while also maximising health outcomes for the people of England and value for money for taxpayers.

[4] https://www.engage.england.nhs.uk/consultation/nhs-commercial-framework-for-medicines/user_uploads/commercial-framework-001218.pdf

How NHSE commissions services and treatments in relation to HCV

37. When it comes to HCV, Regulation 11 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 sets out NHSE's responsibility for arranging services including *"highly specialist services for adults with infectious diseases"* (paragraph 66 of Schedule 4), "liver transplantation service" (paragraph 70), and *"specialist services for complex liver, biliary and pancreatic diseases in adults"* (paragraph 132). This sets out the scope of NHSE's responsibility in relation to the treatment of HCV.

38. The Prescribed Specialised Services as referred to above and agreed by the Secretary of State as being the commissioning responsibility of NHSE, are set out in a manual ("the Manual") [WITN3953013] which can be viewed on the NHSE website[5].

39. NHSE's approach to arranging services or treatments operates at a national clinical population level. This means NHSE is concerned to understand the total number of people with a condition at different stages of disease, how the number of patients is distributed across the country and what is needed by way of clinical service specifications and organisation to ensure that ***all*** patients in a similar position have equitable access to care. This is how Specialised Commissioning ensures resources are planned and services are universally available on a consistent and equitable basis of clinical need rather than other criteria such as how a patient became unwell. The result of this approach is expressed in commissioning policies for access to treatments (including NICE guidance) and service specifications. The approaches to this are set out on the NHSE website https://www.england.nhs.uk/commissioning/spec-services/key-docs/ and I have exhibited a Service Development Process map [WITN3953014].

40. At this point, it is worth noting that Public Health England ("PHE"), an executive agency of the DHSC, is the public body with responsibility to protect and improve

[5] https://www.england.nhs.uk/publication/manual-for-prescribed-specialised-services/

the nation's health and wellbeing and reduce health inequalities. PHE promotes healthier lifestyles, raises awareness, advises government and supports action by local government, the NHS and the public. PHE also has the responsibility for supporting local authorities and the NHS to plan and provide health and social care services such as immunisation and screening programmes, and to develop the public health system and its specialist workforce. PHE is the body responsible for surveillance of a range of diseases and healthcare, including HIV and HCV. In HCV, PHE produces an annual report [WITN3953015] of the incidence, prevalence and treatment of HCV in both the UK and England, based on laboratory reports and national surveys of behaviours, awareness and diagnosis of at-risk populations. PHE's reports and toolkits have informed NHSE's commissioning approach and planning for access to HCV treatment.

41. It is important to note that NHSE is not responsible for all aspects of care along treatment or service pathways, and the Manual sets out the different commissioning responsibilities between NHSE, CCGs and/or local authorities taking into account the four factors described in paragraph 6. This is true for HCV where no one commissioner or provider is responsible for planning, buying and delivering care. For example, local authorities commission and fund HCV prevention and testing activities in drug and alcohol services. CCGs commission and fund routine primary and secondary care services where patients may be diagnosed through 'opportunistic' testing for HCV (that is, testing where patients show symptoms of the disease), as well as routine hepatology and infectious diseases care which may then treat patients with HCV and other liver problems or co-infections. The table below sets out the different responsibilities of different commissioners relating to HCV. This complexity is relevant because it means that sometimes when the commissioners responsible for one bit of the pathway make an investment, it is other parts of the pathway that benefit most, for example CCGs and local authorities fund prevention and testing activity whilst NHSE funds the cost of the drugs used to treat HCV.

Commissioner	**Commissioned Service**
Local Authority	Drug Addiction Treatment services Sexual Health Services

Clinical Commissioning Group	Diagnostic services Specified GP referrals to hospitals Consultant referrals Hospital attendances Acute inpatient care Associated critical care Diagnostics
NHS England Specialised	Consultant referrals to Liver services HIV Services Some infectious diseases services Liver transplant services Associated critical care HCV treatments
NHS England Health and Justice	Prison health services
NHS England primary care	GP clinical services

42. As set out in paragraphs 37-38, the treatment of HCV is one of the Prescribed Specialised Services for which NHSE is the responsible commissioner. NHSE organises the work it does in relation to planning and purchasing services and treatments for specialised services through 6 clinically focused 'programmes of care' (Cancer, Mental Health, Trauma, Internal Medicine, Women & Children, and Blood & Infection). HCV falls into the Blood & Infection programme of care and liver care falls into the Internal Medicine programme of care. These programmes include expert clinicians who advise and inform the approach to, and specification of, prescribed specialised services and clinical policies for treatment.

43. In addition to some specific HCV services, NHSE also commissions a range of health services which may benefit those with HCV including for children, young people and adults across secure and detained settings, health services for those in the Armed Forces and some primary care services, such as General Practice, Dental, Ophthalmic and Pharmaceutical Services. Services for people with HCV in detained settings - such as prisons and immigration removal centres - are the commissioning responsibility of NHSE's Health & Justice commissioning team.

Question 1 - A timeline detailing the history of HCV treatments available through the NHS

44. I think it is important to explain a little about HCV and the challenges of that illness from a patient perspective to put the work that NHSE undertakes, as a purchaser of some HCV services and all HCV treatments from 2013, into context.

45. HCV is a blood-borne virus meaning it is spread as a result of coming into contact with the virus via blood. This can happen mainly through sharing needles with someone who is infected, receiving infected blood or blood products as part of medical care, or through having unprotected sex with someone who has the infection. People at risk of HCV are a highly heterogeneous group and include some of the most disadvantaged people in society, such as those who inject drugs, who are homeless or who are in prison. There is currently no effective vaccine for HCV.

46. Although it is not fully understood why it happens, in around 25% of people who become infected with acute HCV, the infection will naturally clear within six months without any medical or other intervention. However, the remaining people go on to develop chronic HCV which can be lifelong and have a range of symptoms and complications.

47. As symptoms may not manifest themselves for years in some cases, people infected with HCV may go undiagnosed. When this happens, people can pass on the virus if they don't know they have it or how to protect themselves or others from catching HCV. According to PHE's annual reports, in the UK it is estimated that about half of those people who have HCV are unaware they are infected with HCV. The true prevalence of HCV infection is therefore difficult to establish because of the high levels of undiagnosed infection and the fact that many people do not have symptoms that are directly attributable to HCV. Estimates have therefore ranged from between 91,000 – 210,700 patients infected with HCV in the UK. PHE is responsible for HCV surveillance and their annual reports set out

the basis for calculating these estimates. The latest estimate published by PHE in 2019 is that a total of 113,000 people in England have HCV.

48. HCV causes inflammation of the liver and affects the liver's ability to function. Symptoms of chronic HCV are typically mild and non-specific, including fatigue, flu-like symptoms, anorexia, depression, sleep disturbance, pain, itching and nausea.

49. Until very recently, there were six main genetic types of HCV, known as genotypes 1 to 6, with further subtypes. I now understand from the national HCV Clinical Lead Professor Graham Foster that there are 7 genotypes (the seventh being a variant of G6 and found mainly in the Far East so not much is known about it at this stage although it is expected to respond to the HCV treatments now available). As I understand it, in England and Wales genotypes 1 and 3 account for more than 80% of all diagnosed infections, whilst genotypes 2 and 4 account for about 8% and 4% respectively. Historically, different genotypes responded differently to the antiviral treatments available before direct acting antivirals ("DAAs"), with the response to treatment generally better in people infected with genotypes 2 or 3 than in those infected with other genotypes.

50. There are three primary disease stages which can affect patients. The first is chronic HCV where the infection has not resolved itself and patients will move from having no symptoms to developing symptoms over time. The second is cirrhosis of the liver which is a condition in which the liver does not function properly due to long-term damage. This damage is characterised by the replacement of normal liver tissue by scar tissue. The third is 'end stage' which is where the liver is seriously damaged and cannot function properly. About 30% of people with chronic HCV will develop cirrhosis; the timeframe for progression to cirrhosis varies depending on a range of factors, taking up to 20 years or more to develop. When cirrhosis progresses to be decompensated, the remaining liver can no longer compensate for the loss of function. Decompensated cirrhosis is a medical emergency with a high mortality. Effective early interventions can save lives and reduce hospital stay. Around 5% of patients with cirrhosis may go on to

develop liver cancer over time. Liver transplantation may be needed for people with decompensated cirrhosis or liver cancer. Alcohol can further exacerbate the effect of HCV on the liver. Over time, complications of untreated HCV can lead to related and therefore avoidable hospital admissions, liver transplants and avoidable deaths associated with End Stage Liver Disease ("ESLD").

51. The primary goal of treatment is to reduce the levels of virus in the blood to an undetectable level that remains undetectable once the treatment has ended. This is called achieving a "sustained virological response" (SVR) and this is a clinically accepted proxy measure for cure. Standard practice is to undertake a test of SVR at 12 weeks after the end of treatment (SVR12) to determine whether cure has been achieved. Although individuals can achieve this proxy measure of cure, some patients can relapse. Treatment of HCV does not protect patients from reinfection. Patients who go on to be infected with the virus again will also subsequently need treatment for each time they are newly infected with HCV.

52. I understand from the NICE website, guidance for treatment of HCV goes back to 2004 when interferon alpha and ribavirin were the main treatments for chronic HCV. Below in Table 1, I have set out the publication dates for NICE guidance for the treatment of HCV from 2004 to 2018 as taken from the NICE website. As I understand it, all NICE recommendations were positive, recommending treatment within the licence of the treatments appraised. Treatments which have subsequently been discontinued by the manufacturer and therefore the recommendations revoked are identified in italic text.

Table 1: Published HCV treatment Technology Appraisals guidance issued by NICE

Code	Name	Published date
TA75	Interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of chronic HCV	28 January 2004

TA106	Peginterferon alfa and ribavirin for the treatment of mild chronic HCV	23 August 2006
TA200	Peginterferon alfa and ribavirin for the treatment of chronic HCV	22 September 2010
TA252	Telaprevir for the treatment of genotype 1 chronic hepatitis C *Telaprevir is no longer available in the UK so this guidance has been withdrawn.*	25 April 2012
TA253	Boceprevir for the treatment of genotype 1 chronic hepatitis C *Boceprevir is no longer available in the UK so this guidance has been withdrawn.*	25 April 2012
TA300	Peginterferon alfa and ribavirin for treating chronic HCV in children and young people	27 November 2013
TA330	Sofosbuvir for treating chronic HCV	25 February 2015
TA331	Simeprevir in combination with peginterferon alfa and ribavirin for treating genotypes 1 and 4 chronic hepatitis C *The guidance was withdrawn because Janssen withdrew their marketing authorisation on 1 May 2018. The availability of direct-acting antiviral combination treatments for hepatitis C has reduced the use of simeprevir, so the company decided to discontinue it.*	25 February 2015
TA361	Simeprevir in combination with sofosbuvir for treating genotype 1 or 4 chronic hepatitis C (terminated appraisal) *The appraisal was withdrawn because Janssen withdrew their marketing authorisation on 1 May 2018. The availability of direct-acting antiviral combination treatments for hepatitis C has reduced the*	28 October 2015

	use of simeprevir, so the company decided to discontinue it.	
TA363	Ledipasvir–sofosbuvir for treating chronic HCV	25 November 2015
TA364	Daclatasvir for treating chronic hepatitis C *This guidance has been withdrawn because Bristol-Myers Squibb has discontinued daclatasvir (Daklinza).*	25 November 2015
TA365	Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for treating chronic HCV	25 November 2015
TA413	Elbasvir–grazoprevir for treating chronic HCV	26 October 2016
TA430	Sofosbuvir–velpatasvir for treating chronic HCV	25 January 2017
TA499	Glecaprevir–pibrentasvir for treating chronic HCV	24 January 2018
TA507	Sofosbuvir–velpatasvir–voxilaprevir for treating chronic HCV	21 February 2018

53. As indicated above, prior to the advent of DAAs in 2013/14, treatment for HCV was with pegylated interferon with or without ribavirin. Interferon was the first type of treatment used. It had to be injected. Later, an antiviral drug called ribavirin was added to improve cure rates. The next development was pegylated interferon which reduced the frequency of the injections required. Other antivirals (boceprevir and telepravir) were later added to the treatment options. Although all these different treatments achieved cure in a proportion of cases, they had limitations, including significant side effects. These treatments were provided by secondary care expert clinicians, experienced in the diagnosis and management of viral hepatitis. These treatments were given as weekly injections for up to 48 weeks. Patients with the most advanced disease were untreatable and even for patients with early disease, cure rates ranged from below 50% for some patient cohorts up to around 70%. These treatments also had side effects, including nausea, diarrhoea and flu-like symptoms which affected whether people could

start, continue and conclude treatment. Based on data about uptake rates in PHE annual reports and from information I learned from clinicians and patients, many patients declined the offer of treatment because from their experience treatment effects were worse than the disease itself. Data on uptake of these treatments just before the new DAAs became available showed that numbers of patients entering treatment were continuing to decline. Consequently, in 2014 Public Health England reported around 3% of the estimated infected UK population was treated by the NHS each year, for England this was fewer than 5,000 patients [WITN3953016]. By comparison, the new HCV treatments - DAAs - are protease inhibitor drugs taken in an oral formulation. The first DAAs still had to be used with interferon and / or ribavirin. Now all-oral, interferon-free options are the standard of care. They have cure rates near 100% and very few side effects.

54. As I understand it and confirmed by the national specialised Clinical Reference Group on hepatobiliary care and from CMU information about the tenders they ran, these older treatments recommended by NICE were available through the NHS and funded by the responsible commissioners at the time. These treatments would have been provided by NHS hospitals and access for individual diagnosed patients depended on clinical factors such as genotype of the HCV, how progressed the disease was, whether the patient had any other infections or comorbidities and whether the patient had received any previous but unsuccessful treatments.

55. NHSE began operating in April 2013 and from that point NHSE's direct commissioning responsibilities included reimbursing the use of NICE approved HCV treatments. When a decision about reimbursement was made (as a result of NICE guidance or an NHSE policy) this was notified to the NHS via a drugs list, the most recent version of which can be viewed here https://www.england.nhs.uk/wp-content/uploads/2019/04/nhs-england-drugs-list-v14.1.pdf [WITN3953017]

56. In January 2014 and May 2014 the first of the new HCV treatments (sofosbuvir and simeprevir) were granted marketing authorisation by the EMA. Following

clinical trials and any early access or compassionate access schemes, all medicines must be authorised before they can be marketed and made available to patients. In Europe, this is done by the EMA. The EMA determines if medicines are safe, effective and of good quality and therefore suitable for use on patients. If approved to be made available by the EMA, then EU countries can make decisions about the pricing and reimbursement of the treatments. This is how *available* treatments become *accessible* to patients.

57. Only when a decision about funding has been completed can treatments become generally accessible to eligible patients.

58. So, from 2014, new treatments for HCV began to be considered by NICE in terms of decisions about access. These treatments were seen as innovations because treatments were easier to take than previous treatments, had higher cure rates and achieved cure quicker. Treatment involved daily medication for a set number of weeks, typically between 8 and 12 weeks (but in some cases as many as 24 weeks) depending on the medicine, genotype and patient's condition. By January 2017 these treatments included interferon-free and all-oral options for patients. This meant that unless there was a clinical need to use such treatments (which remain approved and recommended by NICE today), clinicians could recommend and prescribe alternatives without interferon / ribavirin and their associated side effects.

59. Although NICE is able to undertake Single Technology Appraisals (STAs) or Multiple Technology Appraisals (MTAs), the ten products containing either a single DAA or DAAs in combination assessed between 2015 and 2018 by NICE were all assessed as STAs.

60. So, in summary, the publication dates of NICE recommendations set out in Table 1 above can be seen as the point from which patients in England were notified that they would be able to access available treatments for HCV following EMA's marketing authorisation and NICE recommendations for funding and

reimbursement. Actual access to NICE recommended treatments is typically 90 days after publication.

61. As I set out in Table 2 and subsequent paragraphs below, NHSE actually took the fairly unusual step of funding a number of HCV treatments in advance of NICE recommendation, providing early access to groups of patients with the most severe complications of HCV.

Question 2 - The recommendations made by the National Institute for Health and Care Excellence (NICE) regarding the treatment of HCV over time.

62. NICE has produced a wide range of testing, clinical management and treatment guidance which can be viewed on its website and here https://www.nice.org.uk/guidance/conditions-and-diseases/infections/hepatitis [accessed 28/01/2020].

63. Table 1 above shows the list of recommendations published by NICE for drug treatments for HCV over time. I have also included reference to guidance which has been withdrawn following discontinuation of treatment availability by the manufacturer.

64. In addition to the table above, and for ease of reference and understanding, I have also set out in Table 2 below, a glossary of the brand or marketing names of the HCV medicines and their generic form name as it is usual in the NHS to refer to the generic rather than brand name to avoid any suggestion that the NHS is promoting a particular company. The table also includes the NICE recommendation publication date and the date they became accessible to patients on the NHS. I have also indicated how long before NICE recommendation, NHSE took the decision through its Board or management committees to make the treatments accessible to patients. In some cases, this meant NHSE approved use of the drugs whilst the licence was being finalised or approved 'off label' use where the drug was used outside of its licence. This was so that access could be expedited for those patients with life threatening or severe symptoms.

65. For one drug – sofosbuvir – NHSE requested an extension beyond the 90-day period given to the NHS to implement NICE recommendations. The NICE regulations allow for such requests in certain circumstances and NICE must decide whether such a request should be granted.

66. I explain in more detail in paragraphs 72-110 how NHSE engaged with NICE on these recommendations.

Table 2: Summary of Positive NICE Recommended Direct Acting Antiviral HCV drugs by brand name, generic form and by publication and NHS access start dates

Brand/marketed name and manufacturer plus genotype served	**Generic name**	**NICE recommendation publication date**	**Date on which access for NHS patients began**
Olysio (Janssen) GT1, GT4	Simeprevir	February 2015	• April 2014 for patients with decompensated cirrhosis via NHSE policy • May 2015 as per NICE recommendation • June 2015 for patients with cirrhosis via NHSE policy NHSE made this treatment accessible to certain patient groups based on disease severity 11 months before NICE implementation
Sovaldi (Gilead) GT1 (with Peginterferon alfa & ribavirin) GT2 (with ribavirin) GT3 (mainly for those with cirrhosis in combination with	Sofosbuvir	February 2015	• April 2014 for patients with decompensated cirrhosis via NHSE policy • June 2015 for patients with cirrhosis via NHSE policy • August 2015 as per NICE recommendations following variation in deferral period applied from May to August NHSE made this treatment accessible to certain patient groups

Peginterferon alfa & ribavirin or ribavirin only) GT4-6 (only for those with cirrhosis in combination with Peginterferon alfa & ribavirin)			based on disease severity 15 months before NICE implementation
Daklinza (Bristol-Myers Squibb) GT1 (for those with fibrosis or cirrhosis and in combination with sofosbuvir) GT4 (for those with fibrosis or cirrhosis and in combination with sofosbuvir) GT3 (for those with fibrosis or cirrhosis and in combination with sofosbuvir and ribavirin)	Daclatasvir	November 2015	• April 2014 for patients with decompensated cirrhosis via NHSE policy • June 2015 for patients with cirrhosis via NHSE policy • February 2016 as per NICE recommendations NHSE made this treatment accessible to certain patient groups based on disease severity 22 months before NICE implementation

Viekirax (also with Exviera) (Abbvie) GT1, GT4	Ombitasvir-Paritaprevir-Ritonavir (also with dasabuvir)	November 2015	• April 2014 for patients with decompensated cirrhosis via NHSE policy • June 2015 for patients with cirrhosis via NHSE policy • February 2016 as per NICE recommendations NHSE made this treatment accessible to certain patient groups based on disease severity 22 months before NICE implementation
Harvoni (Gilead) GT1, GT4	Ledipasvir-Sofosbuvir	November 2015	• April 2014 for patients with decompensated cirrhosis via NHSE policy • June 2015 for patients with cirrhosis via NHSE policy • February 2016 for NICE recommendations NHSE made this treatment accessible to certain patient groups based on disease severity 22 months before NICE implementation
Zepatier (Merck Sharp & Dohme) GT1, GT4	Elbasvir-grazoprevir	October 2016	• October 2016 for NICE recommendations and NHSE access NHSE made this treatment accessible 3 months at NICE publication
Epclusa (Gilead) GT 1- 6	Sofosbuvir-Velpatasvir	January 2017	• March 2017 for NHSE access and ahead of the 90-day funding requirement

Decompensated cirrhosis			
Maviret (Abbvie) GT 1 - 6	Glecaprevir–pibrentasvir	January 2018	• May 2017 via the MHRA Early Access to Medicines Scheme for patients with compensated cirrhosis (https://www.gov.uk/apply-for-the-early-access-to-medicines-scheme-eams) • September 2017 via CMU tender • April 2018 for NICE recommendations NHSE made this treatment accessible based on lowest acquisition cost 8 months before NICE implementation
Vosevi (Gilead) GT1-6	sofosbuvir–velpatasvir–voxilaprevir	February 2018	• 11 May 2018 via CMU tender • 22 May 2018 for NICE recommendations

67. As I indicated in the section above, it is worth restating at this point that treatment for HCV is based on a number of clinical factors and these would have been taken into account by NICE when it developed its recommendations for access and were also taken into account by NHSE in the decisions it took about access for patients with different levels of clinical need for different drugs.

68. The first consideration is genotype of the disease. In January 2017 the first pan-genotypic treatments were approved allowing treatment irrespective of genotype. Before then, the different treatments available were able and recommended to treat some but not all the 6 relevant genotypes. Use of the first DAAs was also

based on disease severity. Whether a patient had mild disease, fibrosis, cirrhosis or decompensated cirrhosis could affect whether the treatment NICE approved could be used based on its licence and the evidence available. Whether patients had received previous treatment with pegylated interferon/ribavirin was also a factor in which treatments NICE recommended in terms of clinical and/or cost effectiveness, again based on drug licences and evidence. The early DAAs were not all oral treatments and so relied on the continued use of pegylated interferon and / or ribavirin. Not all patients were able to complete these treatments and so to avoid drug resistance and ensure treatment compliance, clinicians would also need to consider how well patients would take the treatments. As with all medicines, contraindication with other medicines or complications of other conditions was also relevant to prescribing options. All of this meant that whilst the DAAs represented a step change in more highly effective treatments, they were complex to prescribe.

69. When NICE published its guidance relating to ledipasvir–sofosbuvir [WITN3953018], daclatasvir [WITN3953019], and ombitasvir–paritaprevir–ritonavir [WITN3953020] in November 2015, recommendation for access included that

"the decision to treat and prescribing decisions are made by multidisciplinary teams in the operational delivery networks put in place by NHS England, to prioritise treatment for people with the highest unmet clinical need".

70. To the best of my knowledge, this was the first time NICE had issued guidance of this nature, setting out the need to prioritise patients.

71. In the next sections, I set out the engagement NHSE had with NICE and explain how NHSE approached implementation of HCV NICE guidance.

Question 3 - A brief account of any engagement and liaison between NHS England and NICE prior to the issue of any recommendations by NICE in connection with HCV treatment.

The NICE process

72. I want to begin by explaining my understanding of how NICE works with a range of stakeholders, including NHSE, in respect of technology appraisal in general. This is also set out on the NICE website (see [WITN3953006] referred to above).

73. NHSE is generally involved with NICE throughout the development of its guidance as set out below.

74. Based on information on its website, information from colleagues and some personal experience, I understand the NICE process to be an independent process which starts with horizon scanning to identify data on what medicines or interventions are in development and likely to achieve market authorisation / licence. At this stage, NICE pulls together a list of future/emerging medicines and shares it with an independent panel of people to advise on whether items should be allocated to an "A list" or "B list". 'A list' items proceed to the next step in the NICE review process whereas 'B list' items might need further consideration. Based on feedback from NHSE colleagues involved at the time, I understand NHSE commented that from its perspective all HCV treatments should progress to list A. This process is known as Decision Point 1 ("DP1").

75. The next step – Decision Point 2 ("DP2") – involves internal consideration by NICE as part of its independent process. NHSE is not involved in this stage.

76. Decision Point 3 ("DP3") is when the scope of an appraisal is developed. NHSE is formally invited to be part of this process. This involves draft scopes being reviewed by NHSE staff and being shared with relevant Clinical Reference Groups ("CRG") for clinical advice. CRGs consist of clinicians, commissioners, public health experts, patients and carers whose purpose is to improve the

commissioning of the Prescribed Specialised Services and are the main source of clinical advice to NHSE.

77. Depending on that review, NHSE submits feedback. Where a topic is directly relevant to NHSE's commissioning responsibility and it considers it important to do so, an NHSE commissioner and/or nominated clinician attends the scoping meeting organised and facilitated by NICE. NICE consults on the scope of potential appraisal items. NHSE is a standing consultee for all NICE scoping. Again, this comes into NHSE via a single point and is cascaded to relevant staff and CRGs for comment.

78. At Decision Point 4 ("DP4"), NICE manages a process for making any revisions to the scope following the consultation feedback. Changes can be made to the comparator against which the treatment should be appraised, the indication for the treatment, or the population of patients to be considered. This can include scoping workshops or other discussions. Although I did not attend such a meeting for HCV, I understand from a colleague involved at the time that a scoping workshop was organised and held by NICE. As all new DAAs were generally similar in their clinical action and efficacy compared to the existing treatment and therefore posed similar issues from a technology appraisal process perspective for NICE, I understand that a single scoping workshop was held.

79. At this stage in the appraisal process, NICE then refers the list of potential appraisals to be undertaken to the Secretary of State or Minister for approval. Once items are confirmed for NICE appraisal, NICE issues invitations for relevant organisations to be a stakeholder to the appraisal. NHSE is not automatically granted stakeholder status and must submit an application. As some technologies to be appraised are commissioned by CCGs and not NHSE, NHSE does not apply to be a stakeholder in all cases.

80. The next stage in an appraisal is the Technology Appraisal Committee ("TAC"). The TAC is an independent advisory committee made up of people appointed by NICE for a three-year term. NICE has 5 main committees, including one

specifically for Highly Specialised Technologies, and their membership and minutes are made available on their website.

81. In addition to receiving stakeholder feedback, the committee identifies experts. These experts can provide written evidence and attend the Committee meeting to help in the Committee's discussion of the technology being appraised. Where it is relevant to its commissioning responsibility, NHSE acts as the commissioning expert. This is a role I have undertaken twice in the past. Firstly, for one of the later HCV drugs in 2017 and then again for a new gene therapy for cancer. The TAC produces its independent recommendations following technology appraisal.

82. The final determination is shared in advance of formal publication with the stakeholders to the appraisal. In 2015/2016, this was the point at which NHSE would have the opportunity to review the costing templates setting out expected financial impact for the NHS as assessed by NICE.

83. This is the context in which NHSE made its contributions to the assessment of the HCV drugs in 2014/15.

84. It is the role of NHSE to actively participate in the NICE assessment and appraisal process, giving an expert commissioner view of proposed new treatments and interventions within its direct commissioning function. This includes commenting on the clinical, implementation and financial impact of a potential treatment and NHS readiness to deliver it. As NHSE has duties in relation to ensuring the provision of a comprehensive service available to all, NHSE also comments on the potential impact of a treatment on the ability of the wider NHS to meet its wider obligations in relation to all patients and services.

85. In respect of HCV treatments from 2013 (ie. the date that NHSE was established), NHSE was engaged with and liaised with NICE in the following ways:-

a) along with other stakeholders, NHSE commented on the proposed scope of the HCV TAs;

b) along with other stakeholders NHSE responded to consultations throughout the development of the TA appraisals.

c) in its role as the commissioning expert, NHSE gave advice to the NICE committees on the issues for implementation.

86. In these roles, NHSE provided feedback at various stages on all HCV TAs. NHSE also raised particular issues relating to sofosbuvir, ledipasvir-sofosbuvir (known as Harvoni), daclatasvir, and ombitasvir–paritaprevir–ritonavir, and latterly glecaprevir-pibrentasvir.

87. At this time, NHSE's concern around HCV drugs in general was that as the prevalent population was estimated to be around 160,000 people with HCV and therefore eligible for treatments that NICE would recommend, the NHS could be inundated with new patients attending services for the first time to access a drug that would cost between £35,000 and £70,000 per course per person / per infection excluding VAT. NHSE was concerned that services were not prepared for this. Although NHSE thought it was unlikely that all 160,000 people would seek treatment immediately – not least because around 50% were as yet undiagnosed – there was no data or consensus on which to plan a more reliable rate of take up. For example, should even 20,000 individuals per year take up treatment, significant specialist service scale-up for treatment would be needed, together with dedicated resources to achieve this. If the NHS could not negotiate price discounts – another unknown variable – then even taking a mid-price point of the list price would result in a drugs bill of c£1 billion per year. NHSE felt it was important that the undoubted benefits of HCV treatments were secured in a way which did not put the health benefits of other services and treatments at risk for all NHS patients. Given that HCV develops over time, NHSE thought that greater consideration needed to be given to treating those with the highest clinical need first, and then pursuing other strategies such as watchful waiting and use of existing treatments first, where clinically appropriate, before moving on to treat with new and expensive DAA drugs. NHSE believed this would be a manageable way for NHS resources to be used in response, and also believed that the

competition for the HCV treatment market would rapidly develop and this would mean that within months premium priced treatments would begin to reduce in price, reducing the financial risk to the NHS.

Sofosbuvir

88. With regards to sofosbuvir, Table 2 above shows that NHSE had already been making this drug available to patients with decompensated cirrhosis since April 2014, well before NICE concluded its technology appraisal process. This treatment was made available by NHSE to patients likely to suffer serious harm in the period prior to NICE's approval. These patients included those with decompensated cirrhosis and those with life threatening complications, including lymphoma and vasculitis. These patients were extremely fragile and NHSE was committed to providing high quality care to them during this intervening time.

89. When NICE started its consultation on its assessment of sofosbuvir, NHSE requested a variation to the funding period (which would have otherwise elapsed on 27th May 2015, this being 3 months after the TA being issued). In the end, a variation to the funding requirement of 65 days to the end of July 2015 was approved by NICE. The NICE Regulations state that if 'NICE considers it appropriate, NICE must specify a longer period' than the usual 3 months to make a treatment available following recommendation in certain circumstances.[6] NHSE's position was that sofosbuvir could not be appropriately administered until certain health service infrastructure requirements including goods, materials or other facilities, or other appropriate health services resources, including staff were in place[7]. Extracts from NICE's committee papers are attached at [WITN3953021].

90. In requesting an extension, NHSE set out 4 reasons why it considered a variation to the deferred funding period was justified. Firstly, a 'task and finish' service redesign group had been established to fully understand the issues and

[6] Regulation 7(4)
[7] Regulation 7(5)

challenges that delivery of the new innovative treatments for HCV would raise [WITN3953022]. Secondly, NHSE anticipated substantial demand for the new treatment as those with diagnosed HCV decided to come forward for treatment for the first time. Patient advocacy organisations, including the Hepatitis C Trust, were involved in the NICE process and were quite rightly keeping their membership informed on DAA progress through assessment and when they expected access would be available. NHSE also anticipated that approval would lead to a step-up in public health campaigns to encourage improved and accelerated diagnosis and treatment. Thirdly, NHSE considered that HCV Operational Delivery Networks ("ODN") needed to be established across England (ODNs were subsequently established) with the staff, systems and resources necessary to provide a multidisciplinary team ("MDT") approach to care ensuring the best quality of clinical care, clinically and cost-effective prescribing of high cost drug treatments and equitable access for those with the greatest need within coherent regional networks. The role of ODNs is set out in paragraph 128a. Fourthly, NHSE stressed the need for the establishment of a national database and dashboard to monitor and support individual care.

91. Without these supporting measures in place, NHSE was concerned that the NHS would not be able to make the necessary arrangements to ensure the treatments were made available in a planned way and to monitor the outcome of such treatments for all those patients who would want to access the treatment.

92. NHSE recognised that there was a group of patients (mainly but not exclusively those with cirrhosis) for whom a variation in the funding period could run the risk of serious harm if treatment was delayed. As a result, NHSE took decisions, on the back of clinical advice, to provide access to treatments outside of licence, as I have explained above. Later, NHSE also undertook to extend early access to treatment it had already delivered to those with decompensated cirrhosis and 'fast track' an interim policy to provide oral antiviral therapy to all patients with cirrhosis (plus a small number with severe non-hepatic complications of HCV). The policy was subsequently published in June 2015 [WITN3953023].

93. NICE consulted on the implementation period before making its decision at the end of 2014. NHSE's position was published as part of NICE's independent committee papers, together with the consultation responses to NHSE's position. The papers state that NICE considered NHSE had an arguable case in respect of the likely increase in levels of patient expectation for which the NHS needed to make the necessary arrangements. If services were not planned, NICE recognised that there was a risk that sub-optimal treatment decisions could be made and current service provision could be put under undue stress. NICE recognised the work already underway by NHSE with regard to early access to treatment for those with decompensated and compensated cirrhosis and the DHSC supported the proposal on condition that arrangements were put in place to provide access to treatment for the most seriously ill patients. All of the submissions by NHSE and other stakeholders are publicly available at https://www.nice.org.uk/guidance/ta330/documents/committee-papers.

94. NICE accepted NHSE's representations and approved an extension of time for implementation.

95. NICE also published a costing template to prepare the NHS for the impact of the guidance. The new DAAs were significantly more expensive than existing HCV treatment. The list price of sofosbuvir was between £35,000 and £70,000 per course per person excluding VAT, although commercially confidential discounts were negotiated. NICE estimated that for sofosbuvir alone "The estimated cost of implementing the guidance is £106 million for the population of England. This cost includes savings from onward transmissions avoided of £10 million and resources released from reduced treatment periods £10 million. The population eligible for treatment is approximately 28,600 people per year in England". The guidance is attached and can be accessed at: https://www.nice.org.uk/guidance/ta330/resources/sofosbuvir-for-treating-chronic-hepatitisc-pdf-82602540657349 [WITN3953024].

Simeprevir

96. Another treatment, simeprevir, was licenced in May 2014 and appraised by NICE. My understanding from clinical colleagues and treating clinicians is that whilst this treatment was an improvement on existing treatments, it did not represent the same step change as sofosbuvir. The recommendations for access were published in February 2015 and NHSE made arrangements for implementation from 27th May 2015 in accordance with NICE requirements. This guidance was subsequently withdrawn by the manufacturer because availability of other DAAs led to a reduction in the use of simeprevir and the company decided to discontinue it.

Daclatasvir, Ombitasvir-Paritaprevir-Ritonavir (also with dasabuvir) and Ledipasvir Sofosbuvir

97. In February 2015, NICE issued an initial appraisal consultation document for ledipasvir-sofosbuvir (Harvoni) and two other drugs (declatasvir and ombitasvir-paritaprevir-ritonavir also with dasabuvir) and invited comments before its Appraisal Committee met for the second time on 1 April 2015. As had been the case with sofosbuvir, these three treatments had already been made available by NHSE from April 2014 to patients with decompensated cirrhosis.

98. From March 2015, NHSE submitted its responses to the consultations suggesting that commissioning should aim to safeguard and ensure early access to treatment for patients in urgent need of treatment and advised that due to constraints of both finance and capacity, prioritisation of treatment would be required.

99. NHSE's position was that the innovation of the new treatments and the potential for health outcomes improvement was welcome, but in the context of the NHS fixed budget and its statutory duties, NHSE was concerned about affordability of multiple treatments being available for all patients at the same time without any regard to the presenting clinical need of patients. In the submission, NHSE explained in its response to NICE that "if there is access to all patients at all

stages of disease ... with chronic HCV, NHS England estimated this could move patient treatment numbers to range from 7,000 (manageable but not currently affordable within current clinical services) to 20,000 patients per annum which will require significant service transformation along the entire pathway (from diagnosis to treatment) in order to meet expectation generated by the guidance even if this were affordable, which it is currently not."

100. Implementation would also have come part way through a financial year and budgets had already been set. NHSE envisaged that the scale of investment would likely require significant transfer of resources away from existing and committed funding for other treatments and services to cover the forthcoming HCV drugs spend once approved by NICE. NHSE also stressed that whilst it supported new investment in HCV, the potential scale of the investment needed for the expected NICE guidance was such that the NHS would have to make substantial reductions in other areas (without assessment of the impact) to release the required funding.

101. Other consultees and stakeholders did not agree with NHSE's view of the potential uptake figures and fed this back as part of the response to the second consultation in July 2015. In their submissions to NICE as part of the consultation and reproduced on the NICE website, other stakeholders stated the most likely estimate of patient numbers to be treated per year was 7,000-10,000. NICE accepted the expert judgement of their independent clinical experts and patient groups and the figures about the estimated annual uptake of treatment were included in the resources NICE published on its website (such as the costing template) to help the NHS to plan for implementation of the guidance.

102. When issuing further consultation for TA363, TA364 and TA365 in July 2015, NICE recommended that "decisions to treat and prescribing decisions were to be made by multi-disciplinary teams in the ODNs put in place by NHSE, to prioritise treatment for people with the highest unmet clinical needs". This was the first occasion on which NICE had recommended that approved drugs should be subject to clinical prioritisation. The ODNs were a comprehensive national network enabling consistent focus on patients with the highest clinical need to be

targeted first, and then other patients depending on capacity. The ODNs were local and as such there was local decision-making by clinicians with direct contact and care of the patient about assessing highest unmet clinical need.

103. As part of the July consultation, NHSE made a further submission to NICE relating to all 3 of these treatments. NHSE emphasised the innovation represented by these treatments compared to existing treatment options. However, NHSE remained concerned about the capacity of the NHS to implement positive guidance which it believed could see around 20,000 patients a year seeking treatment at a cost of c£1 billion. Put simply, whilst there was a high degree of certainty about the cost effectiveness of the treatments, there was also a high degree of uncertainty about likely levels of uptake and the ability of the NHS to change funding decisions in-year to release cash from other services and/or treatments to make available the funding needed to pay for all people with chronic HCV who could potentially come forward following NICE's recommendations. It is worth re-emphasising that in order not to breach a NICE mandate, NHSE would need to be able to make available funds to treat all patients who were covered by NICE recommendations.

104. NHSE argued that in view of the natural course of the disease and existing clinical practice, that a phased approach to treatment should be given some consideration. As there was a very large cohort of infected people but disease progression was usually slow, a stratified approach could focus resources in such a way as to balance clinical need of individuals and population health outcomes. Any such strategy would have to be clinically led and based around unmet clinical need, contribute to reduced overall prevalence of infection in the population and recognise that for some patients, the disease had a significant impact on their quality of life.

105. According to clinical experts aware of academic research in the field, early data was emerging that suggested in untreated patients without cirrhosis shorter courses of treatment might prove to be just as effective as the longer courses being granted marketing authorisation. If effective, shorter courses could be used first and where they achieved cure this would offer potential benefits to patients

as well as reducing costs to the NHS. However, this was early data in academic research not in the trials conducted by manufacturers to secure licences. As drugs considered by NICE were not licenced for shorter durations, NICE was unable to make recommendations outside of the market authorisation for the new drugs. This was why NHSE raised with NICE the issue of the ongoing research and the merits of a stratified approach to treatment given the rapidly changing treatment landscape.

106. Although clinical experts to the committee felt that NHSE had over-estimated the numbers likely to access treatment (which they considered was more realistically likely to be 7,000 and 10,000 each year), the patient representative on the committee recognised the potential capacity constraints on the NHS as a result of the new treatments.

107. While NICE did not agree with NHSE's proposal for access 'only in research' for untreated patient with genotype 1, NICE did recognise that the new treatments would not be affordable within the existing NHS budget and therefore continued to recommend prioritisation of treatment and prescribing decisions by ODNs. NICE considered that as the existing approach to treatment decisions took account of clinical characteristics including HCV genotype, level of liver damage, comorbidities and treatment history, treatment prioritisation for those with highest unmet clinical need as determined by ODN multidisciplinary teams (MDTs) could be acceptable to patients. Not all consultees agreed with this position.

108. It is also worth noting in the final recommendations and committee papers issued (screenshots and extracts are attached at [WITN3953025]), NICE acknowledged and recognised the actions being taken by NHSE to try to manage and mitigate the financial impact of using these new drugs such as tendering. NICE also considered the need for further work to explore whether there are "combinations or sequences of treatments (for example, by genotype, treatment experience or cirrhosis status) that could be of particular value to people with chronic HCV, clinicians and the NHS" given the rapid sequential assessment of DAAs. This was in essence the work that was progressed by NHSE via the ODNs and the

commercially confidential drugs pricing shared with them, explained in more detail in paragraph 138.

Later treatments and engagement with NICE

109. In November 2017, NICE was undertaking an appraisal of glecaprevir with pibretasvir for treating chronic hepatitis C (TA499) (see screenshot and extracts attached at [WITN3953026]). At that time, NICE considered whether the recommendation for prioritisation was still required and asked for NHSE's position to be set out. NHSE made an additional submission to NICE setting out why this recommendation remained an important part of the sustainable roll out of HCV treatment. NHSE set out its view that ODNs ensured historical inequities in treatment were addressed and that the right patient was getting the right treatment at the right time. According to both PHE surveillance data and NHSE's own transplant activity data, this had already started to reduce HCV related mortality, morbidity and demand for HCV related transplantation. ODNs continued to enable the NHS to manage access within capacity constraints in a planned way, focussing first on treating those whose health consequences are most likely to escalate before scheduling treatment of others. NHSE also stressed the key role of the ODNs in mitigating the potential financial impact of treatment rollout to the whole NHS by ensuring consistent use of lowest acquisition clinically appropriate treatment options. NHSE also stressed that significant investment had been made into the ODNs and removing their role from the guidance would be disruptive and costly and potentially undermining to the commercial strategy that was underway to drive down drug prices and maximise access. Clinical experts also made a submission in support of the continuation of this recommendation.

110. NHSE continued to engage with NICE as part of the usual process of appraisal in relation to the remaining HCV treatment recommended in 2018 (TA507) set out in Table 2 and the relevant NHSE submissions are included within NICE's published committee papers and provided as exhibits [WITN3953027].

Question 4 - A summary of the implementation by NHS England of the recommendations made by NICE in connection with treatment for HCV, including information regarding the number of patients seeking HCV treatment and any delays and/or restrictions that may have been applied in individual cases.

111. In this section, I set out the implementation by NHSE of new HCV treatments. This includes the decisions taken over time by the NHSE Board, its delegated formal committees and by director level operational committees, as well as the work undertaken by internal NHSE management groups and work undertaken in collaboration with partners. It includes early access provided to patients with decompensated cirrhosis and cirrhosis well ahead of NICE recommendations. It also sets out the request by NHSE to vary the deferred implementation period beyond the usual 3 months in relation to sofosbuvir, which relates to the previous section. I also set out the reasons why NHSE advocated for an approach to prioritisation of treatment for 3 new treatments recommended by NICE at the end of 2015. Finally, in this section I set out the current position with regard to access to treatment.

112. Before I recount the history of implementation there are a few key points to make.

113. The first is that since 2013/14, NHSE has funded the treatment of over 46,000 people with DAAs. If we set aside new infections during this time, this would represent over quarter of the total prevalent population (which includes those who are undiagnosed) based on PHE estimates back in 2015 and over 40% of PHE's revised estimate of 113,000 infected in England published in April 2019 [WITN3953028].

114. Secondly, as set out above, over 6000 patients with the most severe disease had access to the first of the new HCV treatments months in advance of NICE recommendations being published and implemented. In line with its commercial strategy, NHSE was able to take decisions to begin to provide access to some of the later DAAs ahead of NICE recommendation as competition in the market began to drive down the prices charged by the manufacturers.

115. In 2019, PHE's 'Hepatitis C in England' report (see Report at [WITN3953028] above) noted that "an important milestone is that the World Health Organization (WHO) target to reduce HCV-related mortality by 10% by 2020 has already been exceeded in England - 3 years ahead of time". The report contextualises England's progress towards WHO targets to eliminate HCV as a public health threat. This is measured by reducing incident infections and prevalence, reducing mortality, improving diagnosis and treatment, and improving harm reduction services for those at risk of HCV infection.

116. To date, NHSE has spent in the region of £700m on new HCV treatments.

117. Understanding the financial context in which NICE made its recommendations for the first DAA HCV drugs in 2015 is important. A private board paper available on NHSE's website from November 2014 sets this context [WITN3953029].

118. As previously stated, the new DAAs had a list price of up to £70,000 excluding VAT per treatment. Even at a reduced price of, say, £50,000 per patient, treatment of 20,000 would result in a bill of c£1 billion. Making provision for PHE's estimate of an HCV prevalent population of 160,000 would require setting aside £8 billion to cover the bill to drug suppliers for the DAAs alone. This is equivalent to the total annual spend on thousands of other medicines for every single health condition in every hospital in the country and represented just under half the total current annual Specialised Commissioning Budget.

119. Although undoubtedly innovative, the high prices of these medicines was a major barrier to health economies across the world in securing universal access to HCV cure for their populations. Eliminating HCV and achieving WHO targets would require both the eradication of avoidable morbidity and mortality by curing individuals with diagnosed HCV and preventing transmission and new infections by diagnosing and treating all the prevalent population, thereby halting transmission of the infection.

120. Implementing patient access began with the first of the new DAAs - Sofosbuvir – which received its European licence in January 2014. The NICE assessment of the drug was published in February 2015 https://www.nice.org.uk/guidance/ta330/chapter/1-Guidance [WITN3953024].

121. NHSE began preparing for the commissioning of new HCV treatments which were expected to be approved by NICE in advance of those recommendations and as early as 2013/2014. NHSE wanted to follow a strategy that was clinically led focussing first on minimising the impact of established ESLD due to HCV. Late stages of the disease affected patients and their families, led to avoidable deaths and represented a significant burden on NHS resources. Next, NHSE wanted to minimise HCV related cirrhosis, avoiding progression to decompensated cirrhosis and reducing the number of patients developing liver cancer. NHSE also wanted to prevent and minimise cirrhosis due to HCV by planning for the identification and treatment of patients with advanced fibrosis (a precursor of cirrhosis). With this approach, NHSE planned to focus first on those with the greatest clinical need to immediately reduce morbidity and mortality, before focusing on people with lower levels of the disease, thereby improving population outcomes in terms of reduced HCV prevalence and incidence.

122. Returning to HCV treatment implementation from 2014, Professor Graham Foster, who subsequently became the Chair of the CRG for Hepatobiliary and Pancreas in July 2016 and the National Clinical Lead for HCV in 2016, proposed the development of a policy to provide access to treatment for patients with decompensated cirrhosis. This was developed in accordance with the usual policy development process by NHSE at the time involving clinical experts in the assessment of evidence and setting criteria for access.

123. In April 2014, the first early access programme began to provide access to new HCV treatments for the sickest patients – those with decompensated cirrhosis. This access started almost a year before NICE published its recommendations for sofosbuvir and around 18 months before the recommendations were issued for ledipasvir / sofosbuvir (Harvoni) and other DAAs. NHSE approved an investment of over £18 million at that time (see press article at [WITN3953030])

to fund sofosbuvir for patients at risk of death or irreversible harm within 12 months due to decompensated cirrhosis or other life-threatening complications (chiefly vasculitis and lymphoma) and/or awaiting liver transplantation. The policy also allowed for the use of two other drugs - daclatasvir or ledipasvir. Both of these drugs were part of phase 3 clinical trials at the time and so were available initially cost-free, for compassionate use in combination with sofosbuvir. The early access arrangements also included special arrangements for considerations by NHSE's clinical experts of individual cases that were considered to be 'critically urgent'. The published policy has since been archived as it has been superseded by newer drugs but can be viewed here https://webarchive.nationalarchives.gov.uk/20180501160704tf_/https://www.england.nhs.uk/wp-content/uploads/2014/04/sofosbuvir-pol-stat.pdf and at [WITN3953031].

124. This Early Access Programme treated around 1000 patients.

125. Also in 2014, NHSE and PHE jointly chaired an informal group called the 'Hepatitis C Partnership Group'. This group brought together commissioners, clinicians and service users from across the pathway to increase understanding of the topic and different commissioning responsibilities. The group aimed to facilitate system wide collaborative action to improve hepatitis C diagnosis and treatment. Work progressed on a document to scope the ambitions for joint working across organisations. Although NHSE fully supported exploration of the work needed by the whole system to find, diagnose and treat people with HCV, not all organisations were represented on the group. By early 2016, NHSE's work on HCV treatment roll-out was about to begin, setting the implementation approach for increasing HCV treatment and this effectively overtook this earlier work from NHSE's perspective.

126. At the same time, and under the direction of James Palmer, the National Medical Director for Specialised Services, a "Task and Finish" group of clinical experts was established to help advise further on the issues relating to HCV and its treatment in the era of the new emerging DAAs.

127. Across all treatment areas, new innovations raise different challenges of implementation. HCV was no exception with an estimated 160,000 infected (although not all diagnosed) people who could be legally entitled to access treatment all at the same time, irrespective of their presenting clinical need and the readiness of NHSE commissioned services. For planners, this was a huge conundrum given the low uptake and relatively low cost of previous treatments compared with the very expensive but cost-effective new treatments which clearly had patient support.

128. NHSE also established a number of streams of work to optimise its HCV treatment strategy and support uptake of the new DAAs including the following:-

a. the establishment of a comprehensive national network of HCV Operational Delivery Networks (ODNs). The vision was for the HCV pathway to be supported by a formal ODN for a defined population of patients. Each ODN would be made up of multiple hospitals within a defined geographical area seeing patients with HCV, with a host/lead centre managing treatment decisions and prescribing. Dispersed prescribing and delivery models would support partnership working and local access for patients in England. ODN leadership would be provided through specialist lead centres with proven expertise in managing HCV, and with prescribing decisions made through MDT meetings. This, along with quality standards defined in the specification, would ensure rational and cost-effective use of available resources. A service specification was developed with the advice of clinicians and patient representatives [WITN3953032]. Once approved, NHSE embarked on a process of provider selection whereby NHS Trusts could apply to be considered as a host for an ODN. The 22 ODNs became operational in August 2015.
b. development of an advanced fibrosis treatment policy. Work was progressed on this but not completed as the objectives were felt to be covered by the establishment of the ODNs;
c. development of a programme for fibrosis surveillance including a significant capital investment programme to purchase additional fibroscanning equipment for each of the 22 ODNs. This was achieved in 2016/17; and

d. engaging with community groups to debate other clinical sub-groups in need of treatment prioritisation and improvement. This work was supported through engagement with PHE and other analysts including the University of York to better understand the available data with regard to HCV and to model different scenarios with regard to treatment approaches, uptake and impact on disease progression. Whilst PHE was responsible for collecting surveillance data on the incidence, prevalence and outcomes of HCV, NHSE was aware that no nationally consistent dataset existed for collection of data on the outcomes of HCV treatment.

129. With input from clinical experts, NHSE began to further develop the idea of a stratified treatment strategy for access to new HCV drugs. This focused on treating those with the most advanced HCV via early access programmes. The next step was to ensure that people with worsening HCV – those with fibrosis – were identified early so treatment could begin as needed.

130. NHSE's second early access scheme was implemented by June 2015. This extended access to sofosbuvir to patients with cirrhosis ahead of the treatment becoming available to all other patients from August 2015. The scheme also gave early access for all patients with cirrhosis to other new DAAs ledipasvir–sofosbuvir, daclatasvir, and ombitasvir–paritaprevir–ritonavir via an NHSE published interim policy: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/06/hep-c-cirrhosis-polcy-statmnt-0615.pdf (see exhibit [WITN3953023 referred to above). The policy provided more patients with access to treatments that would not otherwise have occurred until February 2016.

131. Whilst these two schemes gave early access for some groups of patients, inevitably there were some patients who did not meet the clinical criteria but who wished to access treatment. NHSE worked with an expert clinical sub group (which became known as the Hep C Advisory Group) to consider individual cases in a way similar to individual funding requests.

132. To support this early access, NHSE announced in June 2015 an increase in funding for the new HCV treatments, taking planned spend from levels of c£40m in 2014/15 to £190m in 2015/16 [WITN3953033]. By December 2015, NHSE's Board was notified that pressure on the specialised commissioning budget was increasing and that the considerable pipeline of NICE treatment recommendations for 2016/17, principally for HCV, posed the single biggest risk to stability of NHSE's finances (see NHSE Board Paper of December 2015 [WITN3953034]).

133. By February 2016, following two years of investment to fund early access to HCV for patients who were most unwell, NHSE prepared to take further specific action to be able to prepare for roll out of the treatments more widely and in a way which could be managed financially.

134. On 24th February 2016, the Specialised Services Commissioning Committee – a committee of the NHSE Board - endorsed a strategy for action to manage sustainable roll-out of increased treatment rates in line with the forthcoming NICE recommendations within the identified budget. It took the decision about the funding it would set aside to fund treatment access in 2016/17. This funding was based on the level of investment in 2015/16 (c.£200m).

135. NHSE saw three main challenges to achieving sustainable roll out within budget:-

    a. How to ensure clinicians would consistently use the lowest cost clinically appropriate HCV treatment option ("Challenge 1").
    b. How to get some certainty about the numbers of patients who would be treated to avoid having to set aside a huge budget to address a major financial risk which would deprive other NHS services of vital funds and jeopardise NHSE's financial balance ("Challenge 2").
    c. How to encourage pharmaceutical suppliers to lower their prices to the NHS as they had done in other countries ("Challenge 3").

136. NHSE focused on an approach to implementation that would comply with the TAs in a planned and managed way, prioritising those with the highest unmet

clinical needs. The approach aimed to manage spend and encourage the whole NHS to be part of the effort to achieve a sustainable roll out.

137. In terms of addressing Challenge 1, NHSE looked to the ODNs. MDTs would consider patients for treatment and prescribe the relevant treatment. To assist in the selection of the lowest cost clinically appropriate treatment, NHSE produced and supplied commercially confidential drug pricing information to clinicians, pharmacists and NHS Trusts on a regular basis following tenders. This information - which was updated after every drug procurement tendering round - set out for clinicians and pharmacists the clinically appropriate treatments available by genotype, disease state and treatment history in order of price. In some cases, a patient could not have the lowest cost option on clinical grounds and so NHSE established a process which buddied up ODN clinical leads so that a process of auditable peer review of decisions could be undertaken. This process was supported by NHSE's Regional Medical Directors for Specialised Commissioning. As with most high cost drugs, clinicians wishing to prescribe one of the new DAAs had to complete an on-line prior approval form known as Blueteq (which is the name of the on-line system). This prior approval system is a standard part of specialised commissioning contracts used in a wide range of high cost drug prescribing and enables compliance with clinical commissioning policy to be demonstrated and clinical decision-making to be audited. The system is automated and clinicians complete a form on-line confirming eligibility and so long as the eligibility is confirmed, they can treat a patient without delay. Examples of Blueteq forms for Sofosbuvir-ledipasvir are exhibited at [WITN3953035].

138. In terms of Challenge 2 and to monitor and support nationwide equitable access to treatment, NHSE developed an anticipated treatment 'run rate' ("run rate") approach which applied nationally and for each ODN to ensure all ODNs were focussing on finding and treating those patients with the highest unmet clinical. At the national level, NHSE was clear that NICE guidance recommended "decisions to treat and prescribing decisions were to be made by MDTs in the ODNs put in place by NHSE, to prioritise treatment for people with the highest unmet clinical needs". As set out above, NICE had also published "Putting NICE

Guidance into Practice - Costing Template" alongside its guidance for TA363, TA364 and TA365 - https://www.nice.org.uk/guidance/ta363/resources. Whilst the costing template did not prescribe the number of treatments that should be made available in each year, it was the planning tool provided to the NHS to prepare for implementation of NICE guidance. This document therefore provided the basis for NHSE's planning assumptions for the number of patient treatments each year from 2015/16 which it envisaged would more than double within 5 years:

2015/16	2016/17	2017/18	2018/19	2019/20	2020/21
6,500	10,000	12.500	13,000	14,000	15,001

139. With the national treatment figures identified, each ODN's figure was then allocated a proportion of the national total based on PHE's commissioning templates for estimating HCV prevalence at a local level and taking into account treatment flows to hospitals (see Hepatitis C: Operational Delivery Network (ODN) profile tool at [WITN3953036]). This principle ensured that anticipated treatment rates were in line with data about HCV prevalence, not with historical treatment levels, and therefore likely levels of local need going forward. NHSE involved ODNs in the approach about anticipated run rate allocations. ODNs were required to develop local prioritisation plans relevant to their patient populations with the involvement of their patient representatives. These needed to be refreshed annually and NHSE reviewed them as part of the CQUIN reporting and peer review. Providers report on quality indicators annually. As implementation of ODNs progressed some adjustments were made to the methodology for identifying ODN level run rates to keep true to the principle of anticipated treatment rates sensitive to data on estimated prevalence. The approach was also sensitive such that if an area was facing some barriers to treatment – such as staffing issues – and another area was seeing higher levels of referrals than expected, by mutual agreement, treatment slots could be moved from one ODN to another. This required approval by NHSE so any budgetary changes could also be enacted to ensure reimbursement could be made, and to maximise treatment rates.

140. Given the scale of impact to the resources of the wider NHS, it was important to ensure the wider NHS was supporting the action for sustainable roll out. To achieve this, NHSE developed, with clinical advice, a financial incentive scheme for HCV known as CQUIN (Commissioning for Quality and Innovation). The CQUIN framework supports improvements in the quality of services and the creation of new, improved patterns of care. The scheme has been updated annually and is published on the NHSE website [WITN3953037]. The value of the CQUIN overall was significant and represented a multi-million pound incentive for the whole NHS to play its part in ensuring equitable access to the sustainable roll out of treatment based on clinical need and in the context of management of the wider NHS budget.

141. As indicated above, the CQUIN scheme was updated each year. Despite small changes, the main focus remained consistent. This included evidence that the ODNs were fully established, investing in infrastructure to roll out treatment and were linking with partners in a way which would enable locally relevant and clinically appropriate approaches to prioritisation in line with NICE. The ODNs also needed to develop plans for improvement in the future. The CQUIN also incentivised treatment rates to tally with the anticipated run rates provided, consistent use of the lowest acquisition cost treatments based on the commercially confidential pricing provided unless a patient was approved through peer review as a clinical exception, retesting of patients cured to help prevent reinfection, and data submission to a new HCV patient registry.

142. The implementation approach was set out in the Circular issued on 1st March 2016 and distributed to ODNs [WITN3953038]. This set the commitment to almost double treatment rates in 2016/17 to 10,000 in line with the rates anticipated by NICE.

143. I talk more about Challenge 3 in the next section when discussing NHSE's role in the provision of treatments for HCV through the NHS. However, suffice to say here that NHSE also developed its approach to how it structured its procurements for these drugs in order to encourage drug companies to reduce their prices and secure better value for money for these drugs.

144. Not all clinicians, patient groups and patients agreed with NHSE's approach to how it was implementing NICE's guidance. The Hepatitis C Trust sought to challenge NHSE's decision to implement NICE's recommendations by means of a monthly anticipated run rate, arguing that this was unlawful because it amounted to an arbitrary cap on the number of treatments that would be provided each year. Permission to challenge was refused by the Court, which agreed with NHSE's position that the anticipated run rate was not an arbitrary cap but a legitimate way of giving effect to the guidance from NICE to prioritise treatment for patients with the highest unmet clinical need. Copies of the pleadings, the Court's decision and Consent Order are attached at [WITN3953039].

145. Working as part of the team that implemented this phased approach, I regularly listened to the views of clinicians and patients. I knew and understood that they felt frustrated by what they saw as limitations on access to treatment.

146. However, this planned approach supported and resourced a rapid expansion of services and treatments available for HCV patients. Although there were some examples of ODNs who felt they had more patients awaiting treatment than slots available, this was not consistently the case and treatment rates were roughly in line with those set out in the approach that NHSE took.

147. Once the approach was set up, significant amounts of management time were needed to support implementation. Peter Huskinson continued to act as SRO and I supported him. The HCVPOG met every two weeks bringing together representatives from different parts of NHSE including contracting, finance, commissioning, commercial, pharmacy and clinical expertise from Professor Graham Foster. This group monitored the blueteq weekly reports which included numbers of patients to be treated and spend data on treatments by each ODN. HCVPOG also supported work to prepare for procurements. It developed approaches to encourage and support more efficient dispensing. It was also where NHSE worked on policy development ideas (such as the retreatment policy for patients with cirrhosis who were not cured by their first treatment) and prepared for the HCV TAs which came through NICE. It also organised an ongoing programme of communications and engagement with ODNs, patient

groups and others. The group also provided a forum to share information on relevant issues. For example, during 2016, we became aware that some patients were buying their own generic HCV treatments. Although the DAAs were covered by patents, the drug companies authorised generic companies to manufacture generic versions for low-income countries. Whilst the NHS was unable to access these generic medicines for the whole patient population in England due to patent regulations, individuals could choose to source their own DAAs if they so wished. NHSE issued information to clinicians to clarify that the NHS did not advise patients to buy their own generic medicines, but in the event that patients did so, clinicians were able to provide clinical management of such patients if it was in the best interests of patients to do so. NHSE encouraged clinicians to provide testing where such patients sought it through standard outpatient appointments to ensure the effectiveness of the treatment received. NHSE saw that this would optimise the population benefits of ensuring that the infectious disease of an individual had been effectively managed.

148. I also supported the Hep C Advisory Group of clinicians to meet regularly to discuss any issues with implementation and to help develop further tools to support implementation, such as the development of the second sign off process for clinical review of prescribing decisions in the case of clinical exceptions. At the end of 2016, we conducted a programme to secure significant capital investment for additional fibroscanners so that we could allocate a scanner to each ODN to enable them to assess patients and prioritise them based on the progression of their disease.

149. NHSE's health and justice commissioning team were also working with PHE from 2015 to implement a blood borne virus opt out testing programme in prisons. It is widely recognised that people in prisons are at higher risk of having or catching HCV and other blood borne viruses (HIV, hepatitis B). In 2015, uptake of testing was very low for various reasons. Through a range of actions including training, support (such as peer support commissioned from the Hepatitis C Trust), collaboration with the Prison Service and Ministry of Justice and performance monitoring, there has been a twelve-fold increase in uptake of testing with performance currently over 46% nationally in 2019/20, with a range reaching

almost 60% in the London region. In some prisons or other detained settings 'micro-elimination' has been achieved. There is where all people in the prison and tested and all those found to have HCV are treated and achieve cure.

150. For each subsequent financial year to 2019/20, NHSE updated the anticipated treatment run rates, the commercially confidential pricing on lowest cost treatments and the CQUIN arrangements. NHSE also continued to support the ODNs to roll out treatments to their local patient populations under the clinical leadership from Professor Graham Foster.

151. In the following paragraphs I have summarised some of the additional key actions NHSE took to implement access to HCV treatments during this time.

152. During 2017, NHSE implemented NICE recommendations for access to sofosbuvir-velpatasvir, the first DAA that could treat all genotypes of HCV and the first all-oral option. This was an important milestone and NHSE was able to facilitate all-oral treatment, interferon-free as the first-choice treatment for patients. NHSE also published a retreatment policy for those with advanced or decompensated cirrhosis for whom their first DAA treatment was unsuccessful in achieving a cure [WITN3953040].

153. NHSE also worked with AbbVie in 2017 to enable AbbVie's new pan-genotypic treatment, glecaprevir–pibrentasvir, to be included in one of its CMU tenders in advance of receiving NICE guidance recommendation, subject to them achieving market authorisation. As a result, and following conclusion of the EAMS scheme, NHSE made glecaprevir–pibrentasvir available to patients from 1 September 2017, over seven months before NICE published its TA (on 24 January 2018 which would require NHSE to make this treatment available within 90 days).

154. Work on the HCV registry also continued. Ultimately, NHSE funded and developed a bespoke HCV registry for all those with diagnosed HCV. NHSE worked with PHE and through the National Strategic Group for Viral Hepatitis (coordinated by PHE) to identify the barriers to identifying those with

undiagnosed HCV in order that the whole system could work together to find, diagnose and treat those with HCV.

155. During 2017 and 2018, NHSE continued to work with DHSC and PHE informing ministers and parliamentarians about the work to roll out treatments for HCV including work with industry on the strategic procurement design. This included submitting evidence to the All Party Parliamentary Group (APPG) on Liver Health Inquiry [WITN3953041] which published a report in March 2018 http://www.appghep.org.uk/download/reports/Eliminating%20Hep%20C%20APPG.pdf. Regular meetings about HCV were held with the Parliamentary Secretary for Health (Lords) Lord O'Shaughnessy and as part of this work, we also worked closely with the Clinton Health Access Initiative ("CHAI"). CHAI had experience and learning in relation to increasing HCV testing and diagnosis globally[8] and we were able to apply this to our strategic procurement plans. During 2018, joint work plans with health and justice with regard to the roll out of opt out blood borne virus testing in prisons and improving access by ODNs to prison populations for treatment continued. Also underway was work with primary care commissioning on exploring how to make the optimal use of community pharmacies for testing for HCV. In 2018, NHSE supported PHE to share information with ODNs about laboratory diagnoses of HCV reported to PHE and its predecessor organisations since 1996 in order to ensure individuals could be supported to access confirmatory HCV tests and HCV treatments if they hadn't already done so.

156. During 2019, NHSE continued to progress its strategic procurement, its work on the registry, and work with stakeholders on HCV elimination initiatives. In September 2019, NHSE published a policy which permitted the use of DAAs for adults with recent onset (acute) hepatitis C (HCV), including the treatment of acute HCV infection in immunosuppressed adults (e.g. post transplantation

[8] CHAI is a not-for-profit foundation which was working with the UK government contributing to international efforts to achieve the WHO goals to eliminate Hepatitis C as a major public health concern. CHAI has expertise in case finding and negotiating agreements for low cost drugs in lower and middle income countries with an aim of curing 16 -20 million people of hepatitis C over the next seven years in 29 countries.

patients) [WITN3953042]. Despite the fact that about a quarter of people infected with HCV can clear their virus without treatment, during the period they are infectious the virus can be transmitted to others. Focused on its ambition to be one of the first countries in the world to eliminate HCV as a public health threat, NHSE decided, based on a review of evidence and clinical advice, to make these available. As I understand it, DAA manufacturers did not include treatment of acute HCV in their trials and so did not pursue licences for this indication. The mode of action of the drugs on viral replication means they work much the same in acute HCV as they do in chronic HCV. As side effects of these drugs are very low and evidence suggested that this was a safe and effective treatment to use in HCV, NHSE supported commissioning in this indication. In addition, the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) which advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation, advises that organs from HCV infected donors may be used in certain circumstances with patient consent. In such circumstances, post-transplant organ recipients can develop acute HCV and the NHSE policy enables the use of DAAs to cure the infection.

157. In addition to its work on HCV related liver disease, NHSE is working to improve liver care generally. In 2019/20 it published a scheme to incentivise "Networked Delivery of Cirrhosis Care Bundle in specialised Hepato pancreas biliary services" [WITN3953043]. This can also be viewed on the NHSE website https://www.england.nhs.uk/wp-content/uploads/2019/03/PSS14-Cirrhosis-Care-Bundle-flat-final-PSS-CQUIN-Indicator-1920.pdf.

Question 5 - An account of the roles played by Specialised Commissioning and the Commercial Medicines Unit (CMU) in the provision of treatments for Hepatitis C through the NHS.

The CMU

158. The CMU's role has focused on managing the process of purchase of available drugs which it did firstly as part of the DHSC, then latterly as part of NHSE.

159. In April 2017, the CMU - which is responsible for medicines procurement for all hospitals - transferred from the DHSC to NHSE's Commercial Medicines Directorate. In the paragraphs below I have set out a brief explanation of the role of the CMU then and now which has been provided to me by Christopher Theaker, the Head of the CMU.

160. The objective of the directorate is summarised as undertaking commercial activity to support patient access to the latest innovative and most clinically effective new healthcare treatments/solutions and at the same time, securing maximum value for the NHS and taxpayers from spend on medicines and other healthcare solutions.

161. Within these overall objectives, activities of CMU include:-

a. Delivering commercial expertise for the NHS in secondary care, working collaboratively with NHS Chief Pharmacists to deliver commercial arrangements for the supply of medicines and addressing security of supply issues;
b. Developing and implementing category procurement strategies segmented into medicines categories including generic, near patent expiry generics (known as transition tenders) and branded/biosimilar medicines in addition to blood products and homecare medicines services;
c. Where possible ensuring plurality of supply products will be awarded to multiple suppliers.

162. This work is undertaken within the requirements of public procurement law with tenders and invitations to tender issued and suppliers submitting confidential pricing offers for their medicines. Tenders are subject to formal adjudication against a set of pre-determined award criteria via a network of procurement and clinical pharmacists providing expertise to inform procurement decisions.

163. Once adjudication is concluded and decisions ratified, the outcomes of tenders are communicated to suppliers. Details of the products, including commercially confidential offer prices awarded are shared with the NHS via an online catalogue to enable hospitals to place call off orders to meet their requirements.

164. The approach taken to support the supply of branded medicines (which include medicines for HCV) has been to ensure all eligible products offered are made available on the frameworks allowing hospitals the flexibility to order their requirements from any contracted supplier in line with the recommendations of NICE and / or NHSE policy.

165. Procurement strategies are developed and agreed with two stakeholder groups. The National Pharmaceutical Supply Group provides input to procurement strategy and the Pharmaceutical Market Support Group provides operational input to the procurement process.

166. In the case of HCV medicines, during 2014 NHSE led an Expressions of Interest process for an Early Access Programme for patients who were classified as "critically urgent" in line with the policy published in April 2014

167. The CMU put in place agreements for supply as part of the delivery of branded medicines tenders. A spreadsheet setting out the tender workplan and medicines included on frameworks, including the dates at which agreements for specific products commenced, is provided [WITN3953044]. CMU has maintained a programme of tenders ensuring HCV medicines are available to all regions in England and undertaking tenders on a regional basis provides six monthly opportunities to refresh prices. In 2015 a procurement was undertaken to include newly available HCV medicines on framework agreements. This was delivered

as part of an interim tender to encourage all suppliers of newly available medicines to participate in a tender exercise and as a result ensuring the framework was a preferred route to purchase for the NHS going forward. Volume related offers were encouraged and offers assessed and adjudicated by the appropriate regional pharmacy groups. All suppliers were invited to pre-offer discussions in advance of submitting tenders and these meetings included representation from NHSE Specialised Commissioning and NHSE's Medical Director in addition to DH, officials from CMU and representation from NHS Regional Procurement Pharmacists. Companies were encouraged to offer their best prices. The new framework went live in August 2015.

168. Following the transfer of CMU to NHSE in 2017 CMU maintained these frameworks to ensure continued availability up to the point at which these procurements were succeeded by the strategic agreements reached following a tender undertaken by the Commercial Directorate in Specialised Commissioning. Ordering details continue to be shared in the CMU online catalogue.

169. During the period CMU was located in DHSC, CMU also worked to support the work of policy colleagues and where appropriate NICE. CMU also liaised with NHSE Specialised Commissioning sharing outputs of tenders to support implementation.

170. An example was the considerations by DH policy colleagues regarding a scheme to provide access to HCV treatment for individuals infected via infected blood/products which, if progressed, would have required tendering or procurement actions.

Specialised Commissioning

171. Turning now to the role of NHSE Specialised Commissioning in relation to HCV, this can broadly be described as enabling access to treatments for HCV and to ensure the arrangements are in place to make this happen. This includes making provision from within the budget voted by Parliament; allocating resources to healthcare providers, negotiating deals with drugs companies, setting the quality

standards for the delivery of services, setting the contract terms for delivery and working with providers on implementation.

172. As set out above, the legal framework requires that NHSE must, in the exercise of its functions, *"act with a view to securing"* that health services are provided in a way which promotes the Constitution. NHSE must also work to secure continuous improvement in the quality of services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness or the protection or improvement of public health, as well as work to reduce inequalities between patients with respect to their ability to access health services, including innovation in the arrangements made for their provision. NHSE must ensure that patients have access to drugs and treatments recommended by NICE through its TA guidance.

173. The role of Specialised Commissioning therefore covered enabling procurement of drugs as well as strategically planning to meet the needs of patients most effectively. Historically drug supply had been done through the CMU procurements through cost and volume contracts whereby reduced prices are achieved in return for allocating greater market shares as set out above. However, in HCV this strategy alone was not sufficient to procure HCV treatments most effectively. With the introduction to the market of new branded DAA drugs at high list prices, NHSE had to address the issue of high prices (Challenge 3) by using its commercial buying power differently to leverage better value and competition in a small market with a small number of manufacturers in order to continue its sustainable roll out of these drugs. Whilst the traditional approach to tenders allowed for a standardised approach, it was not designed to respond to particular challenges in particular therapeutic areas. So for example, although price reductions were achieved in HCV through these tenders, prices went up as well as down.

174. As NHSE's strategic commercial focus changed due to the new DAAs on the market and NICE's recommendations, it became clear that the nature of procurements that were run had to change too. In addition to the usual approach to drugs procurement, NHSE wanted to undertake a more strategic procurement

of treatments in HCV with a view to securing a long-term deal that would be a significant step on the road to elimination of HCV in England and so a Procurement Lead for the Strategic Procurement was appointed in May 2016. The remit of this role was to develop and implement an innovative procurement process that would maximise competition between drug suppliers to get the best deals and reduce the price per treatment to enable greater numbers of patients to be cured whilst limiting the financial exposure to the NHS. By treating patients sooner, NHSE wanted to reduce the impact on those with HCV, reduce the cost of HCV ill health and reduce the number of people becoming infected.

175. NHSE took responsibility for running new innovative procurements to drive better value and competition in the market and the most recent procurements carried out in 2018/19 focused on working with the pharmaceutical companies to develop elimination initiatives designed to push forward NHSE's ambition to be the first country in the world to eliminate HCV.

176. For example, in 2018 a 'bridging tender' was in operation which began to focus on the role drug companies could play in helping increase the identification of so-far undiagnosed people to accelerate HCV elimination efforts. NHSE undertook to make available 50% of any savings on drug prices to increase the number of patients overall who could be treated in that financial year. NHSE honoured this commitment although in the end actual treatment rates did not increase further as ODNs continued their efforts to case find additional patients.

177. In February 2018, NHSE launched its strategic procurement to accelerate elimination by encouraging suppliers to assist with efforts to find, engage and treat individuals with HCV who so far were not connected with services. In the meeting with suppliers organised by NHSE and attended by Lord O'Shaughnessy, companies were encouraged to support the procurement through improved pricing and diagnosis and treatment efforts. Companies were asked to submit a range of elimination initiatives to improve testing and treating, taking account of all the key groups affected by HCV. The Public Health Minister at the time had sought assurances on this point and NHSE has provided these stating equity was a central principle in the procurement. Suppliers had to submit

bids addressing all groups and the multidisciplinary adjudication panel marked all bids in accordingly.

178. This new commercial approach to HCV procurements has been implemented with some supplier resistance. The 2018/19 procurement was challenged in the courts by one of the suppliers of pan-GT drugs but the claim ultimately failed [WITN3953045]. In short, NHSE pushed ahead with both the procurement and its defence of the challenge in order to drive forward its ambition to deliver elimination of HCV in England within the WHO timescales. Any delay to that procurement could have jeopardised those timescales to the detriment of patients and population health.

Question 6 - An account of the information provided to healthcare professionals by NHS England surrounding funding for and availability of HCV treatments over time.

179. When it comes to funding and contracting arrangements, primarily this information is shared by NHSE contract managers with contract managers in NHS hospitals or other contracted providers. HCV services are included in baseline contracts using the NHS Standard contract and communication follows to notify of changes. This is done by letter which acts as a notice or variation to contract arrangements. NHSE uses 'specialised services circulars' and letters to notify the NHS of HCV treatment updates.

180. An example is the circular issued on 1st March 2016 (SSC 1615 – "the circular"), which on this occasion was sent directly to NHS providers. This circular is exhibited at [WITN3953038] referred to above. This set out the aim of implementing NICE guidance with equality of access across the country for those with similar levels of need and capacity to benefit. Based on advice of clinical experts, NHSE expected that clinicians would focus on treating those with cirrhosis, significant fibrosis and severe symptoms before scheduling treatment of patients who were asymptomatic, in line with NICE guidance. Nationally, and for each ODN, the circular also set out the idea of the run rates or the anticipated treatment levels based on expert clinical advice about national uptake and taking into account local prevalence. The circular also set out the operational arrangements for reporting patient treatments and invoicing for drugs via Blueteq, Minimum Dataset Returns and outcomes data submissions.

181. In addition to ongoing contracting communications between specialised commissioning regional teams and local contracted providers, NHSE's national specialised commissioning team uses circulars to notify providers via their regional commissioning teams of any national changes to HCV service delivery arrangements.

182. During the sustainable roll out of HCV DAAs, NHSE also organised several events to bring together the ODN clinical leads to share information and to seek

advice as the roll out and commercial strategy progressed. For example, in September 2015 the first ODN summit was organised to share information about the newly established ODNs. In January 2016 another ODN summit was organised involving all ODN clinical leads, PHE and the Hepatitis C Trust to prepare for the implementation of the NICE guidance, update the ODN clinical leads about the NHSE approach and to seek feedback and engagement. Copies of agendas are exhibited [WITN3953046].

183. In addition, NHSE provides regular updates to ODN clinical leads. In terms of content these would include information about NICE recommendations, changes to the drug prices and therefore the preferred lowest cost treatments to use, assessment of the CQUIN, any changes to ODN anticipated run rates and any new policy or other developments, such as guidance about how NHS services should support any patients who bought their own generic DAAs. Through these information sharing routes ODNs were supported to implement the sustainable roll out in all aspects.

184. During 2018/2019, NHSE, PHE and other partners came together to prepare for a campaign to contact individuals who, according to PHE laboratory reports, had a positive HCV diagnosis but there was no evidence they had been in contact with health services since. This was widely communicated via NHSE CCG bulletins to ensure those contacted would be appropriately signposted by GPs or other healthcare professionals. Later this was followed up by a further communication from NHSE to GPs making them aware of the IBI in order that they could fully support any patients who came forward concerned that they may have been infected. A bundle of communications provided by NHSE is exhibited [WITN3953047].

185. NHSE also produced a number of blogs and news stories regarding HCV. These would be issued at key milestones or in celebration of World Hepatitis Day. I have included some links by way of example. This blog written jointly by Professor Graham Foster and Peter Huskinson describes the sustainable roll out approach in March 2016 https://www.england.nhs.uk/2018/01/hepatitis-c-2/. This news item announces the launch of the strategic procurement in 2018

https://www.england.nhs.uk/2019/01/nhs-englands-plan-to-eliminate-hepatitis-c-decisively-backed-by-high-court/. This news item announces the outcome of the procurement litigation https://www.england.nhs.uk/2019/01/nhs-englands-plan-to-eliminate-hepatitis-c-decisively-backed-by-high-court/

186. The NHS also make information available to clinicians, patients and the public on a range of conditions and treatments. Information concerning HCV can be seen here https://www.nhs.uk/conditions/hepatitis-c/treatment/ [WITN3953048].

Question 7 - A summary of the current treatments available for HCV, their effectiveness and availability, including any restrictions and/or delays on obtaining treatment.

187. To the best of my knowledge the range of treatments currently recommended by NICE and available for clinicians to prescribe as clinically relevant to do so are those that are set out in Table 2. This information and table also show that there are treatments which were recommended and previously available but which have since been withdrawn from the market by their manufacturer.

188. NHSE does not generally undertake its own assessment of the effectiveness of HCV treatments as this is undertaken by NICE, although exceptionally NHSE can and did do that in the case of early access and off label use of HCV drugs. I commend the NICE website to the Inquiry for information about the individual treatments and the published evidence of their effectiveness.

189. NHSE concluded its strategic procurement in April 2019. This procurement signals a key change in HCV treatment strategy. This change occurred because of significantly lower confidential prices achieved in the procurement and as a result of additional offers from drug companies to assist with patient finding. The Overview document and examples of the submission requirements to bidders included in the Invitation to Tender ("ITT") for the strategic procurement are exhibited [WITN3953049]. As usual, company bids as part of the procurement are considered strictly commercially confidential.

190. The NHSE strategy is to accelerate treatment to eliminate HCV as a public health threat ahead of the WHO goal of 2030. As such, and with identified patients with the most severe HCV having been treated, ODNs are now treating all patients with HCV who present for treatment.

191. In terms of the commissioning of available treatments, it remains the case that all NICE recommended treatments made available by the manufacturer are accessible for prescribing where clinically appropriate.

192. In terms of the selection of treatments by clinicians, there continues to be guidance on which treatments represent the lowest acquisition cost treatments as established by the strategic procurement. This is provided by NHSE to ODNs / providers. It remains the case that where there is a clinical need to do so, clinicians can use treatments which are not the lowest acquisition cost.

193. The market for provision of DAAs to treat the various types of HCV has matured significantly since their emergence in 2014 and now the main treatments are elbasvir-grazoprevir (Zepatier) supplied by Merck Sharp & Dohme, ledipasvir-sofosbuvir (Harvoni) supplied by Gilead, sofosbuvir-velpatasvir (Epclusa) supplied by Gilead and ombitasvir-paritaprevir-ritonavir with dasabuvir (Viekirax + Exviera ("V&E")) (until the end of 2019 – see below) and glecaprevir-pibrentasvir (Maviret), both supplied by Abbvie. Gilead also has another licenced and recommended product called sofosbuvir–velpatasvir–voxilaprevir (Vosevi) which is also a pan-genotypic drug. It is also the only drug licenced as an effective drug treatment where a patient has already been treated with a DAA that did not work. Although the treatment is licenced and NICE recommended as an option for treatment of naïve patients, the company has marketed and priced this treatment differently to other first line DAAs and therefore this treatment is not a lowest acquisition cost option and is reserved for clinical exceptions and retreatment. Whilst NHSE would not prevent access to NICE recommended treatments, as we saw in Table 1, manufacturers sometimes withdraw a product from market. For example, NHSE was notified at the end of 2019 by the manufacturer that they will no longer actively market ombitasvir-paritaprevir-ritonavir with dasabuvir and there is now just one pegylated interferon available (pegasys which is peginterferon alfa 2a).

194. As pan genotypic drugs sometimes carry a price premium, their use is guided by clinical circumstances where waiting for a genotype test may delay an individual's treatment. It is worth noting that in themselves, the newer pan-genotypic drugs as listed in the tables above are not necessarily better drugs - they do not achieve a quicker or better cure. They offer a potential benefit of not having to undertake a genotype test before selecting the clinically appropriate treatment and this might speed up the point at which treatment can start. For

patients such as those in a prison setting or attending drugs services as an active drug user, pan-genotypics offer a way to quickly get people on treatment who might otherwise be lost to follow-up. However, patients would still achieve the same cure outcome from non-pan-genotypic DAA drugs and in some cases depending on their clinical circumstances, patients would need to avoid using the pan-genotypic drug to meet their treatment needs based on clinical grounds.

195. The conclusion of the strategic procurement has put a framework in place to build on the hard work that NHSE has so far undertaken to maximise access for patients and support the NHS elimination goals and at prices fair and responsible for patients and the taxpayer. Whilst UK list prices for drugs have remained unchanged, and whilst there remains a multi-million pound cost to the NHS of these medicines, the significant reduction in price has been critical to balancing the overall specialised commissioning financial position. The new type of procurement – which encouraged drug companies to submit commercially confidential elimination plans as well as their best drug prices for NHSE's assessment – now means that in addition to full choice of HCV drugs, the NHS has access to increased testing initiatives and peer support programmes aimed at increasing diagnosis and treatment rates.

Questions 8 – 10

Harvoni (sofosbuvir with ledipasvir)

- **An account of Harvoni's commissioning and funding history.**
- **A summary of the differences and benefits of Harvoni treatment compared to other treatments previously available for HCV including, but not limited to, Interferon and Ribavirin.**
- **The position regarding availability of Harvoni in early 2015.**

196. I have described the commissioning and funding history of all the DAAs, including Harvoni in Tables 1 and 2 and in paragraphs 97 to 110.

197. Harvoni is a drug which combines 2 drugs (sofosbuvir with ledipasvir) in a single tablet and is used to treat genotypes 1 and 4 of the HCV virus. It can cure the virus in some people who have never had treatment or who had treatment before but were not cured.

198. Based on its licence and the trial conducted, NICE recommended access to Harvoni for patients based on their genotype, their treatment history and their disease progression. The duration of treatment was affected by these factors meaning courses could be between 8 and 24 weeks and in some cases ribavirin was also needed for the treatment to be effective.

199. The appraisal of Harvoni was conducted by NICE and ran from September 2014 to publication date in November 2015.

200. NHSE provided access to Harvoni for people with decompensated cirrhosis from April 2014 and for people with compensated cirrhosis from June 2015. NICE recommendations were then implemented from the end of February 2016.

201. The table below (Table 3) has been taken directly from NICE's publication TA363 and sets out when Harvoni can be recommended for treating adults with chronic HCV.

Table 3 Ledipasvir–sofosbuvir for treating adults with chronic hepatitis C

HCV genotype, liver disease stage	Duration (weeks)	Recommendation according to treatment history	
		Untreated	**Treated**
Ledipasvir–sofosbuvir			
1, without cirrhosis	8	Recommended	Not the licensed regimen for this population
	12	Not recommended	Recommended
	24	Not the licensed regimen for this population	Not recommended
1, with compensated cirrhosis	12	Recommended	Recommended only if all the following criteria are met: • Child–Pugh class A • platelet count of 75,000/mm^3 or more • no features of portal hypertension • no history of an HCV-associated decompensation episode • not previously treated with an NS5A inhibitor.
	24	Not recommended	Not recommended
4, without cirrhosis	12	Not recommended	Recommended

	24	Not the licensed regimen for this population	Not recommended
4, with compensated cirrhosis	12	Recommended	Recommended only if all the following criteria are met: • Child–Pugh class A • platelet count of 75,000/mm^3 or more • no features of portal hypertension • no history of an HCV-associated decompensation episode • not previously treated with an NS5A inhibitor.
	24	Not recommended	Not recommended
Ledipasvir–sofosbuvir plus ribavirin			
1	Not the licensed regimen for this population		
3	24	Not recommended	
4	Not the licensed regimen for this population		
Abbreviation: HCV, hepatitis C virus. Treated – the person's hepatitis C has not adequately responded to interferon-based treatment.			

Question 11 - Please comment on the suggestion that if and when new treatment becomes available for HCV, that those persons infected through infected blood or blood products should be given priority access.

202. In 2013, NHSE published on its website 'Commissioning Policy: Ethical framework for priority setting and resource allocation' [WITN3953050]. This document states that "a commissioner should not give preferential treatment to an individual patient who is one of a group of patients with the same clinical needs. Either a treatment or service is funded in order to create the opportunity for all patients with equal need to be treated or, if this cannot be afforded, it should not be commissioned as part of NHS treatment for any patients. NHSE considers that if funding for a treatment cannot be justified as an investment for all patients in a particular cohort, the treatment should not be offered to only some of the patients unless it is possible to differentiate between groups of patients on clinical grounds. A decision to treat some patients but not others has the potential to be unfair, arbitrary and possibly discriminatory". This can be viewed here - https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-01.pdf

203. In compliance with this policy, access to treatment for all patients - including those who contracted their HCV infection through infected blood / products - has been based on clinical need in the same way that it has for patients who contracted their disease via other routes.

204. As I understand it, in 2014 the DHSC was exploring whether it could provide priority access to new HCV treatments for those infected by infected blood. The proposal by the DHSC was to offer priority access to treatment to individuals who were in receipt of financial assistance through one of its infected blood financial assistance schemes, including the Skipton Fund. The DHSC proposed to focus on those who had received Stage 1 payment (confirmed HCV infection). Those who had received Stage 2 payment (confirmed HCV infection & liver disease) were not included. DHSC tested its ideas with NHSE and NHSE advised that a DHSC funded scheme for priority access could be administered by NHSE on behalf of DHSC. For example, NHSE could support

implementation via its commissioned hepatology services within a relatively short timescale. NHSE offered some advice when considering such a scheme. The first was that, based on experience, any such scheme would need to be for a well-defined patient cohort, like the scopes NICE produced for its guidance. NHSE also raised two ethical/equality considerations which it suggested DHSC would need to address before approving the scheme. The first related to prioritising patients infected via blood product transmission in advance of other patient cohorts infected by HCV through other routes. The second related to the proposal to provide access to those infected in advance of those with complications of their infection. Further discussions about approaches to priority access were raised again in 2015. Again, NHSE advised the DHSC that it could provide assistance to the DHSC in the implementation of a DHSC funded programme but noted that there were significant clinical concerns about prioritising patients based on how they became infected.

205. In January 2016, the DHSC launched a consultation on "Infected blood: reform of financial and other support" [WITN3953051]. This included a proposal to offer some access to new HCV treatments for those considered clinically appropriate on the basis of a treatment assessment. I have reproduced excerpts of the consultation document here: "We would like to fund a separate scheme to enhance access to treatment for those infected as a result of treatment with blood products. Specifically, we would like to focus on those who fall just outside of the current NHS roll out plans. However, depending on the level of interest expressed in response to this consultation, we will work to include as many people as is possible. At this stage, we are interested in understanding how many Skipton Fund beneficiaries who have not yet started treatment would be interested in being considered for such a scheme. Depending on the level of response we will need to understand what could be feasible in each of the next few years. It is unlikely that we would be able to treat everyone at the same time, so patients within the scheme would also be prioritised on the basis of clinical need".

206. The DHSC published the response to the consultation in July 2016 [WITN3953052] and again I have reproduced excerpts. The conclusions stated

"the consultation sought views on whether the scheme should provide enhanced access to the new hepatitis C drug treatment being rolled out by the NHS. Over 70% of respondents felt that access to hepatitis C treatment should be part of the reformed scheme; however, of those who commented, 38% said that treatment should be provided by the NHS and not this scheme, and some argued that providing treatment through the scheme would amount to beneficiaries paying for their treatment. Since launching the consultation.., the NHS expects to increase the number of patients treated with new therapies to 10,000 in 2016/17, with numbers increasing to up to 15,000 per year in the following years. In line with the consultation responses, and on account of the need for fairness towards all those in need of this NHS treatment, access to hepatitis C treatment for scheme beneficiaries will be provided by the NHS on the basis of clinical need in line with NICE guidelines. We have decided not to use funding available for the scheme to provide enhanced access to the new treatments. However, we will ensure the new scheme administrator works with the NHS to ensure that beneficiaries are signposted to, and made aware of, treatment services and the treatments available. We will also review how many beneficiaries are being treated and/or have already completed their treatment".

207. In 2018/19, work was undertaken again with DHSC to facilitate awareness of all patients infected through infected blood on government financial assistance schemes of the new HCV treatments and to support treatment where they wished to receive this. As I understand it, ODN clinical leads advised that, in their opinion, all diagnosed patients in contact with services who acquired the disease through infected blood and want treatment have now accessed it. Therefore no further work specifically to make contact with individuals from this group is being actively progressed at this time and based on this clinical advice.

208. We are not aware of any new drugs in development for the treatment of HCV.

209. The NHS continues to operate on the principles of universality and of care provided free at the point of use, based on clinical need, reducing inequalities, and ensuring best value for the taxpayer. For those with infected blood, this means that they can be assured that where they have a clinical need they will

receive treatment, irrespective of the stage that their HCV infection has reached.

210. As a commissioner, NHSE could be in breach of its equality and other statutory duties if it took a decision with the funding it receives to prioritise access to treatment based on how a patient became ill rather than on criteria about their clinical need for treatment. In the event of a Government led initiative where a specific project or remit with specific additional funding was provided to NHSE for this purpose, NHSE would be able to facilitate and support such a scheme.

211. NHSE is proud of the work that it has led on HCV elimination since its inception and how it has been able to work with manufacturers and stakeholders to drive its plans forward. NHSE's sustainable roll out programme has focused on providing early access to HCV treatments for patients based on highest unmet clinical need and also in line with NICE recommendations.

212. NHSE is focused on an elimination programme that ensures all people with HCV can access treatments that can cure in order to achieve elimination at an individual and population level.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed: GRO-C

Dated: 14th February 2020

APPENDIX 1 – LIST OF EXHIBITS

Notes/Description of Documents (dated where applicable)	Exhibit Number
NHS Publication: Spotlight on Specialised Services	002
NHS Publication: Improving Value in Specialised Services – Menu of Opportunities	003
The NHS Constitution for England	004
NHS Standard Contract 2019/2020	005
NICE Guide to the Processes of Technology Appraisal (April 2018)	006
NICE Budget Impact Test Guidance	007
NHS England Commissioning Policy: Individual Funding Requests (November 2017)	008
NHS England Standard Operating Procedures: Individual Funding Requests (May 2018)	009
The NHS Long Term Plan (January 2019)	010
Department of Health and Social Care Publication: The 2019 Voluntary Scheme for Branded Medicines Pricing and Access – Chapters and Glossary (December 2018)	011
Draft NHS Commercial Framework for Medicines (November 2019)	012
NHS England Manual for Prescribed Specialised Services 2018/2019 (September 2018)	013
Specialised Commissioning: Service Development Process	014
PHE Publication: Hepatitis C in England 2019 (April 2019)	015
PHE Publication: Hepatitis C in the UK 2014 Report (July 2014)	016
NHS England Drugs List (April 2019)	017
NICE Guidance Ledipasvir-Sofosbuvir for treating chronic Hepatitis C – TA363 (November 2015)	018

NICE Guidance Declatasvir for treating chronic Hepatitis C – TA364 (November 2015)	019
NICE Guidance Ombitasvir-paritaprevir-ritonavir with or without dasabuvir for treating chronic Hepatitis C – TA365 (November 2015)	020
Extracts from: NICE Technology Appraisal for Sofosbuvir	021
NHS England Collaborative Task & Finish Group Report - Hepatitis C: Examination of the Issues Report (September 2015)	022
NHS England Clinical Commissioning Policy Statement: Treatment of Chronic Hepatitis C in patients with cirrhosis (June 2015)	023
NICE Guidance for Sofosbuvir for treating chronic Hepatitis C – TA 330 (February 2015)	024
Screenshots and Extracts from NICE Committee Papers	025
Screenshots and Extracts from NICE regarding TA 499	026
NHS England submissions provided in NICE's published Committee Papers for TA507	027
PHE Publication: Hepatitis C in England 2019 (April 2019)	028
NHS England Private Board Paper (November 2014)	029
NHS Press Release 'NHS England agrees funding for life-saving hepatitis c drug' (April 2014)	030
Interim Clinical Commissioning Policy Statement: Sofosbuvir + Declatasvir/Ledipasvir +/- Ribivirin for defined patients with Hepatitis C (April 2014)	031
NHS England Service Specification for Operational Delivery Networks for Hepatitis C Care in Adults	032
NHS England Press Release 'Thousands more patients to be cured of hepatitis c' (June 2015)	033
NHS England Board Paper (December 2015)	034
Examples of Blueteq forms for Sofosbuvir -Ledipasvir	035
Hepatitis C: Operational Delivery Network (ODN) profile tool	036
BI1: Improving HCV Treatment Pathways through ODNs for blood and infection programme of care schemes which forms	037

part of the 2016-17 prescribed specialised services Commissioning for Quality and Innovation (CQUIN) Schemes (June 2018)	
NHS England Specialised Services Circular (March 2016)	038
Copies of the Pleadings, Court Decision and consent order in proceedings CO/2950/2016	039
NHS England Urgent Clinical Commissioning Policy Statement: Retreatment of Chronic Hepatitis C Infection in Adults with Advanced Decompensated Cirrhosis (September 2017)	040
APPG on Liver Health inquiry into hepatitis C elimination – NHS England Evidence Submission	041
Clinical Commissioning Urgent Policy Statement Antivirals for adults with recent onset (acute) hepatitis C (URN:170135P)	042
NHS England 2019/20 PSS CQUIN Scheme Indicator Template	043
List of Frameworks covering Hepatitis C products in England from March 2002 delivered by the Commercial Medicines Unit located in DH up to 31/03/2017 and NHS England from 01/04/2017	044
Judgment – Abbvie Limited v NHS Commissioning Board (January 2019)	045
Hepatitis C Operational Delivery Networks (HCV ODNs) Clinical Summit Agendas (January 2016)	046
Bundle of communications provided by NHS England	047
NHS Choices information concerning HCV	048
ITT overview and examples of submission requirements	049
Commissioning Policy: Ethical framework for priority setting and resource allocation (April 2013)	050
Department of Health publication: Infected blood: reform of financial and other support (January 2016)	051
Department of Health publication: Infected blood: Government Response to Consultation on Reform of Financial and Other Support (July 2016)	052

APPENDIX 2

Key abbreviations:

Abbreviation/short form	Full term
APPG	All Party Parliamentary Group
BBV	Blood Borne Virus
CCGs	Clinical Commissioning Groups
CHAI	Clinton Health Access Initiative
CMU	Commercial Medicines Unit
CQUIN	Commissioning for Quality and Innovation
CRG	Clinical Reference Group
DAA	Direct acting antiviral drugs
DHSC/DH	Department of Health and Social Care (prior to 2018 Department of Health)
DP	Decision point
EMA	European Medicines Agency
ESLD	End Stage Liver Disease
GT	Genotype
HCV	Hepatitis C / Hepatitis C virus
HCVPOG	Hepatitis C Programme Oversight Group
HIV	Human Immunodeficiency Virus
HST	Highly Specialised Technology
IBI	Infected Blood Inquiry
IFR	Individual Funding Request
LAs	Local Authorities
MDT	Multi-Disciplinary Team
MHRA	Medicines and Healthcare products Regulatory Authority
MTA	Multiple Technology Appraisal
NICE	National Institute for Health and Care Excellence
NHSE	NHS England
NHSI	NHS Improvement
ODN	Operational Delivery Network

Pan-GT	Pan-genotypic / applying to all genotypes
PHE	Public Health England
SaBTO	Scientific Advisory Committee on Safety of Blood, Tissues and Organs
SSC	Specialised Services Circular
SSCC	Specialised Services Commissioning Committee
SRO	Senior Responsible Officer
STA	Single Technology Appraisal
SVR	Sustained Virological Response
TA / TAG	Technology Appraisal / Technology Appraisal Guidance
TAC	Technology Appraisal Committee
WHO	World Health Organization