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Attachments	No

Freedom of Information Act Disclosure log - Reply Extract

- 1) **Please state the number of people diagnosed with Hepatitis C in your ODN area in FY 2015/2016**

The Trust does not hold the information. The Trust is not aware of all cases and you would need to approach Public Health England for any data they may hold. Please find the attached link to their FoI contact page details.

<https://www.gov.uk/government/organisations/public-health-england>.

- 2) **Please state the number of people who are clinically appropriate for any of the following treatments under the relevant NICE guidance within your ODN area, and who are currently on your waiting list for treatment with them. Please provide numbers for each individual drug, if available.**

a) **Harvoni (Ledipasvir-sofosbuvir) - manufactured by Gilead.**

b) **Daklinza (Daclatasvir) manufactured by Bristol-Myers Squibb.**

c) **Viekirax (Ombitasvir-paritaprevir-ritonavir) and Exviera manufactured by Abbvie.**

d) **Zepatier (elbasvir/grazoprevir).**

Patients on a waiting list for treatment are not allocated specific drugs until the month of treatment to respond to changes in drug allocation determined by NHS E run rates.

- 3) **Please state the number of people within your ODN area who are clinically appropriate for any of the following treatments under the relevant NICE guidance who are currently receiving the treatment. Please provide numbers for each individual drug, if available.**

a) **Harvoni (Ledipasvir-sofosbuvir) - manufactured by Gilead.**

- b) Daklinza (Daclatasvir) - manufactured by Bristol-Myers Squibb.**
- c) Viekirax (Ombitasvir-paritaprevir-ritonavir) and Exviera - manufactured by Abbvie.**
- d) Zepatier (elbasvir/grazoprevir).**

As of Monday 7th March 17 there have been 97 patients registered for HCV treatment by the SW Peninsula ODN since 1st January 2017. These patients will be on treatment or about to commence. The number on specific drug regimens remains confidential, but now includes EPCLUSA in addition to the drugs listed.

4) Please state the run rates for each of the following treatments issued by NHS England to your ODN for the number of Hepatitis C patients that may be treated per calendar month in

a) 2016/17

- i) Harvoni (Ledipasvir-sofosbuvir) - manufactured by Gilead.**
- ii) Daklinza (Daclatasvir)-manufactured by Bristol-Myers Squibb.**
- iii) Viekirax (Ombitasvir-paritaprevir-ritonavir) and Exviera manufactured by Abbvie.**
- iv) Zepatier (elbasvir/grazoprevir).**

b) 2017/18.

- i) Harvoni (Ledipasvir-sofosbuvir) - manufactured by Gilead.**
- ii) Daklinza (Daclatasvir) -manufactured by Bristol-Myers Squibb.**
- iv) Viekirax (Ombitasvir-paritaprevir-ritonavir) and Exviera manufactured by Abbvie.**
- iv) Zepatier (elbasvir/grazoprevir).**

The run rate is not based upon individual drug treatments. The SW Peninsula ODN run rate for 2016/17 is 328.

- 5) Please state the financial penalties your ODN could incur should your treatment rate for persons with hepatitis breach the criteria stipulated in CQUIN guidance for FY2016-18.**

Please state the penalties that could be incurred for treatment overruns in each of the following financial years.

i) 2015-16 = We did not have a Hep C CQUIN in 15/16

ii) 2016-17 Please state how these penalties would be calculated, i.e. what the penalty would be for each treatment given by your ODN that is over the limit set.

The CQUIN states on run rates:

One fifth of the stewardship incentive available through trigger A is payable provided the ODN delivers MDT treatment initiations in line with the published run rate for the half year. To qualify for payment the ODN treatment rate must be not less than 90% and not more than 100% of the published half year rate. There is no payment for partial achievement of this element.

One fifth of the stewardship payment is worth approx. £300k (annual figure). As we cannot be over 100% then even one case over the run rate for the half year would trigger none payment.

- 6) Please provide current guidance set by your ODN for providing the following new treatments.**

- a) Harvoni (Ledipasvir-sofosbuvir) - manufactured by Gilead.**
- b) Daklinza (Daclatasvir) (manufactured by Bristol-Myers Squibb.**
- c) Viekirax (Ombitasvir-paritaprevir-ritonavir) and Exviera manufactured by Abbvie.**
- d) Zepatier (elbasvir/grazoprevir).**

The ODN follows the NHS E rate card according to lowest acquisition cost options and applies for second line therapy whenever clinically indicated.

Please provide guidance as to how guidelines are to be applied with your ODN, not more general NICE guidance.

The peninsula ODN prescribes NICE approved treatments for HCV according to the NHS E run rate card which is determined by lowest acquisition cost. The specific drug regimen has varied over time according to the contracts negotiated by NHS E north and south. Regarding the prioritisation of who to treat, the ODN agreed at a meeting in May 20-16 the following:



South West Liver Unit

Level 7

Derriford Hospital

Plymouth

PL6 8DH

SW Liver unit, Derriford Hospitals Hepatitis C local prioritisation for treatment statement of practice

At the SW Peninsula ODN review meeting on the 12th May, it was agreed that by the end of June 2016 the ODN would have treated the majority of the cirrhotic and F3 patients that treatment centres aware of or engaging with their service.

Each centre to be allocated a number of patients per month, allocated by the ODN lead, to treat their own patients according to the local prioritisation and ensuring those with the greatest unmet clinical need get treated first. It was agreed by all present that cirrhotic and F3 patients would continue to take priority if they come to clinical attention.

Local Prioritisation guidelines for Derriford Hospital Hepatology department (SW Liver unit) Plymouth

It was accepted that local factors would be taken into account, but priority should be based upon a combination of factors including, but not limited to:

- transplant recipients
- presence of HIV co-infection
- anticipated / planned pregnancy
- hospital/healthcare acquired HCV infection

- duration of engagement with clinical services
- co-morbidity and extra hepatic manifestations of Hepatitis C
- optimum timing with regard to rehabilitation or sentencing, etc.

Patients will be identified on the non-cirrhotic waiting list that fulfil these conditions and allocated a place each month. Patients will then be informed of when they can expect to start their treatment regimen.