27 August 2014

To:

NICE Project Manager, Sofosbuvir, Kate Moore
kate.moore@nice.org.uk

NICE Executive Lead, Sofosbuvir, Gillian Leng
gillian.leng@nice.org.uk

NICE Technical Lead, Sofosbuvir, Richard Diaz
richard.diaz@nice.org.uk

NICE Communications Manager, Sofosbuvir, Lyndsey Unwin
lyndsey.unwin@nice.org.uk

and under separate cover, copied to

Hepatitis C Trust

British Liver Trust

NHS England
NHS Commissioning Board,

All Party Parliamentary Group on Haemophilia and Contaminated Blood
and

Other key interested members of Parliament

Tainted Blood

Contaminated Blood UK

The Haemophilia Society

cc:

BY EMAIL ONLY

Dear Sir / Madam,

Draft Guidance on Sofosbuvir Published by NICE on 15 August 2014 (the "Draft Guidance") – further consideration needed by NICE in respect of Haemophiliacs and patients with HCV where the infection was caused by NHS Contaminated Blood Products

I have read, with interest, the Draft Guidance, together with all paperwork published by NICE in relation to the Draft Guidance.

I note that despite accepting Sofosbuvir's clinical efficacy in treating, and in all likelihood curing, HCV where the patient has Genotype 4, 5 or 6, the Draft Guidance suggests that NICE is not currently minded to recommend that Sofosbuvir be prescribed to HCV sufferers with Genotypes 4, 5, or 6. That decision is based purely on QALY assessments for those Genotypes. NICE's current thinking in relation to Genotypes 4, 5 and 6 is out of sync with the advice published by the Scottish Medicines Consortium which has recommended Sofosbuvir be prescribed to all HCV Sufferers, including those with Genotypes 4, 5, or 6. It is also out of sync with the decisions taken by other equivalent bodies across Europe and North America.

I also note that stakeholders from neither the Haemophilia nor the Contaminated Blood Product communities were consulted by NICE as part of NICE's evaluations of Sofosbuvir.

Whatever the background to this lack of consultation (a failure by NICE to consult, or a failure by representative bodies for those communities to participate), such lack of consultation has, I would suggest, led to **Draft Guidance which, at present:**

(a) fails to correctly assess the QALY for HCV sufferers who are Haemophiliacs;

(b) fails to take into account other health related benefits which would flow from recommending that Sofosbuvir be made available to treat HCV sufferers who are Haemophiliacs; and

(c) inadvertently places a significantly greater cost burden, outweighing the cost of Sofosbuvir by a multiple, on limited NHS resources where HCV sufferers who are Haemophiliacs require a consequential procedures or surgery as a result of the HCV going uncured.

From a wider "cost to the NHS perspective", given that the clinical efficacy of Sofosbuvir for Genotypes 4, 5 and 6 is accepted by NICE, the current Draft Guidance also:

(d) potentially opens up the NHS to wide-ranging and expensive litigation from

HCV sufferers where the infection was caused by NHS contaminated blood products (given the higher incidence of Genotypes 4, 5 and 6 sufferers within that community) and they can establish that NHS negligence caused the infection, compounded by the fact that some may now be denied potentially life-saving treatment if the Draft Guidance is followed;

(e) potentially opens up the NHS to the risk of discrimination allegations (on the grounds of race) – given the greater prevalence of HCV sufferers with Genotype 4, 5 or 6 within communities where the HCV patient is a British subject of African (including Egyptian) or Asian descent (compared to Genotypes 1, 2 and 3); and

(f) potentially opens up the NHS to the risk of discrimination allegations (on the grounds of disability) – given the greater incidence of Genotype 4, 5 or 6 within the Haemophilia community (particularly where the HCV infection was caused by NHS contaminated blood products which were imported from abroad), again compared to Genotypes 1, 2 and 3.

Paragraphs (d) to (f) above are challenging for me to make, on one level, as somebody who has relied throughout my life on the fantastic care and treatment by so many in the NHS. They are observations that are not intended to be threatening. They are made because in Appendix B of the Draft Scope relating to Sofosbuvir published by NICE in June 2013, NICE specifically requested (at p6):

"In particular, please tell us if the proposed remit and scope:

- ***could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which Sofosbuvir will be licensed;***
- ***could lead to recommendations which have a different impact on people protected by the equality legislation than on the wider population e.g. by making it more difficult in practice for a specific group to access the technology;***
- ***could have an adverse impact on people with a particular disability or disabilities."***

It is my opinion that the Draft Guidance has failed to consider each of these, in the context of Genotypes 4, 5 and 6 in particular.

Background

In the late 1970s and 1980s, over 4800 British Haemophiliacs were infected with Hepatitis C through contaminated blood as part of their NHS treatment. A further 170 British non-Haemophiliacs were also infected with Hepatitis C through contaminated blood received as part of NHS treatment. Many of those were also co-infected with HIV. A significant number of those infected have since passed away.

While bodies such as the Skipton Fund and Caxton Foundation have offered some financial recompense for HCV sufferers who were infected through contaminated blood products received from the NHS, this remains a great tragedy in the history of the National Health Service.

I am a [redacted] male with Severe Haemophilia A, with inhibitors. I acquired HCV through contaminated blood products as a youngster. I was formally diagnosed in 1991 with Genotype 4.

Earlier this year, I was diagnosed with Cirrhosis.

I have previously (in 2011) received 48 weeks' treatment with Interferon & Ribavirin (during which I successfully cleared the virus in 2012, only to find that I had later relapsed).

The QALY, other Health Benefit and wider NHS Cost Argument

In Appendix B of the Draft Scope relating to Sofosbuvir published by NICE in June 2013, NICE specifically requested (at p6):

> ***"Do you consider that the use of the technology can result in any potential significant and substantial health related benefits that are unlikely to be included within the QALY calculation?"***

In the context of Haemophiliacs, the answer is a resounding yes.

[redacted]

For Haemophiliacs who suffer from HCV, regardless of their Genotype, then it is clear that Sofosbuvir has potentially significant and substantial health related benefits that are unlikely to be included within the QALY calculation. And potentially huge future cost savings to the NHS when compared to not curing HCV in a Haemophiliac patient.

This letter is on behalf of all Haemophiliacs and Contaminated Blood Sufferers, who have HCV.

Conclusion

Where the clinical efficacy of Sofosbuvir has been accepted by NICE, for any particular Genotype, I believe that NICE should recommend, within its final guidance, that Sofosbuvir should be prescribed to all HCV sufferers regardless of Genotype, prior treatment experience or cirrhotic condition.

This would mirror the position in Scotland, be equitable from an equalities legislation perspective, though go beyond the current recommendation in the Draft Guidance, for patients with Genotypes 4, 5 or 6.

If NICE feels unable to reach that conclusion, then NICE should – at the very least – recommend the following as an exemption to its proposed general recommendation in relation to Genotypes 4, 5 or 6.

"Where the clinical efficacy of Sofosbuvir has been confirmed by NICE for any particular Genotype (including, for this purpose, Genotypes 4, 5 and 6), and the prescribing of Sofosbuvir would:

- **(a) lead to potential significant and substantial health benefits for patients with a particular disability or disabilities in addition to HCV (such as Haemophilia); or**
- **(b) avoid the potential for a future increased cost burden on the NHS resulting from complications in treating that HCV patient, due to that existing disability (a future cost burden to the NHS with that patient group which could be otherwise reduced by curing HCV),**

then NICE recommends that Sofosbuvir should be prescribed to those HCV patients with that particular disability or disabilities (such as Haemophilia) regardless of Genotype."

I would request that the Draft Guidance is amended to reflect this in the final version, and would hope that the recipients to this letter can support this view in their direct consultations with NICE.

Other Recipients

As neither a stakeholder, nor a consultee, I have copied in key representatives for the consultees set out below in the hope that should NICE not feel minded to take into account the points raised by this letter, one of more of the other recipients will feel that thy can raise these points they will formally raise the points in this letter, as part of their final feedback on the Draft Guidance (before **5 September 2014 deadline**).

(a) the British Liver Trust;

(b) the Hepatitis C Trust; and

(c) NHS England.

I have also copied in representatives from:

(d) [redacted] The Haemophilia Society;

(e) [redacted] Tainted Blood; and

(f) [redacted] and [redacted] All Party Parliamentary Group on Haemophilia and Contaminated Blood.

I have also copied in my Consultant Haematologist, [redacted]

I have also copied in my Hepatology consultant, [redacted]

While the views expressed in this letter are my own, I would strongly suggest that NICE speak with [redacted] to ascertain his professional view on the "QALY, other Health Benefit and wider NHS Cost Argument", in the context of Haemophiliac HCV patients. I think he and I are in agreement on this point and I know NICE have consulted with [redacted] on similar matters previously.

I look forward to receiving the support of the recipients to this letter and I sincerely hope that NICE will take account of the points I have raised when they publish their final guidance.

Yours faithfully

[redacted]

Positively UK welcomes and endorses the NICE appraisal for Sofosbuvir for treating chronic hepatitis C. Positively UK is a registered charity supporting over 1,000 people living with HIV every year, many of whom are co-infected with Hepatitis C.

We agree with the preliminary recommendations for the use of Sofosbuvir as summarised on pages 3-5 of the appraisal document. We particularly welcome the recommendation for Sofosbuvir in treating patients co-infected with HIV and Hepatitis C. People living with these conditions are met with stigma. We believe the availability of such medications will tackle some of this stigma, encourage people to seek earlier diagnosis and be treated. For people living with HIV, and at risk of additional co-morbidities, it will ensure access to the best quality care and in improved quality of life.

With Sofosbuvir also approved for use in Scotland, the NICE appraisal, will ensure equitable access to care and treatments across the UK.

In declaring interests Positively UK do receive core funding from Gilead Sciences, which account for no more than 2% of our annual turnover.

Thanks

Positively UK

Tel:

Web: www.positivelyuk.org

Twitter

Facebook

Email disclaimer

Registered Charity No. 1007685

Dear Sirs,

Please see below for correspondence I have received from a constituent regarding the consultation on the drug Sofosbuvir (Sovaldi). I have tried to submit this information for consideration through the webpage, but not been able

to do so within its formatting, and therefore would appreciate confirmation you have received this correspondence and it will be included in the submissions for this consultation.

[redacted]- please contact NICE to ensure they have this as part of this consultation.

with kind regards

[redacted]

On Wed, Sep 3, 2014 at 9:29 AM, [redacted] wrote:

Dear [redacted], I hope you are well.

Last year I was diagnosed with Hepatitis C (HCV), Genotype 3.

Hepatitis C is a blood-borne virus that predominantly infects the cells of the liver. This can result in inflammation and significant damage to the liver. It can also affect the liver's ability to perform its essential functions and also affects digestive system, the lymphatic system, the immune system and the brain. Unlike some who have the virus, it is unknown how I contracted the illness.

It has been an interesting year learning about the stigma attached to HCV. I now have even more empathy for those who are already shunned by some sections of society such as intravenous drug users and HIV sufferers who are at a higher risk of HCV or have the virus. The prejudice carries into the healthcare system.

I live in fear that I will pass it on to my family if not treated but her lies the problem. An effective treatment the drug Sofosbuvir (Sovaldi) has not been approved by NICE for use, but a consultation is taking place to decide whether to approve it. The consultation closes on 5thSeptember 2014 and as

my MP I would like to ask if you can please contribute on behalf of the general population of those infected with the disease and myself, to ask for Sofosbuvir to be made available to everyone.

The Department of Health has asked the National Institute for Health and Care Excellence (NICE) to produce guidance on using sofosbuvir, a treatment for HCV, in the NHS in England. The Appraisal Committee has considered the evidence submitted by the manufacturer and the views of non-manufacturer consultees and commentators, and clinical specialists and patient experts.

The draft recommendations are that Genotype 3 patients will onlyget sofosbuvir if they have failed treatment before or are cirrhotic. I am neither but am already being affected by the virus. Following a biopsy, my liver shows signs of scarring/fibrosis (3 out of 6 as it's measured) and inflammation. I have lichen planus and suffer from affected brain function, tiredness and skin problems. According to [redacted] the liver expert who has been advising me at Royal London these are all caused by the HCV infection.

Unfortunately many patients including myself do not fall into either category NICE are proposing and are condemned to wait until we either develop more serious life threatening illnesses before treatment is given or are forced to take the current treatment which includes pegylated interferon and ribavirin, drugs that have huge debilitating side effects.

Interferon and ribavirin are very strong drugs and both have potential side effects. Not everyone experiences these side effects, but it is rarefor someone to have none at all.

Occasionally, the side effects can be so severe that they could force sufferers to abandon treatment. You could even be left with an illness after you stop treatment, such as thyroid disease or diabetes. Some people have reported

that the side effects have persisted, leaving them feeling constantly unwell. Sounds joyful, nice (pun intended).

The major disadvantage to treatment consists of these side effects. Not everyone necessarily experiences them. It can take a few months after the treatment ends before the drugs are cleared from your system. Ribavirin can take up to 6 months to clear. Treatment could therefore impact on work (might have to take time off), on relationships, and on social life.

There is also the possibility that interferon/ribavirin treatment might not work for me whereas Sofosbuvir quite likely will (90% more affective [redacted] 2014).

I am sure you can understand why interferon is not a course I wish to take.

I have been told I am interferon unsuitable as I have certain symptoms that could be aggravated by it. However, interferon is the only thing available until I develop cirrhosis or liver cancer or need a liver transplant– of course by then it's all too late.

The argument of costs which I believe NICE are using to prevent general use to treat HCV seems a moot point as surely treating the outcomes will be more expensive than the cost of Sofosbuvir?

I hate to make a value judgement on illnesses but there are estimated to be 160,000 with HCV in UK but only around 100,000 with HIV yet the latter have access to more expensive treatments.

The NICE consultation is here.

http://www.nice.org.uk/guidance/indevelopment/GID-TAG445/consultation

About 1 in 3 people infected with the hepatitis C virus will eventually develop liver cirrhosis, where normal liver tissue is replaced by scar tissue.

A percentage of people with chronic hepatitis C and cirrhosis also develop liver cancer.

Professor Carole Longson, Director of the NICE Centre for Health Technology Evaluation, said: "Hepatitis C is a major public health challenge. It is difficult to diagnose and each year there are many new infections.

"The problem is made worse because the potential side-effects of current treatments, such as interferon, which often needs to be given for a long period of time, mean that many people with the disease either don't complete the full course, or are reluctant to seek treatment in the first place.

"New treatments, like sofosbuvir, can shorten the duration of interferon-based therapy and in some cases don't need to be taken with interferon at all. This could potentially encourage more people to seek treatment."

NICE sees the clinical benefits but are recommending that only SOME patients receive treatment. Many of those with the virus fall outside the 'some'.

Please [redacted], ask NICE to approve use for everyone with HCV.

You can contact [redacted] direct or through [redacted].
Tel: [redacted]

[redacted] is a good man and is fighting for approval of a treatment for all with HCV. He is at the forefront of tackling the disease and will be able to give you any supporting information and his perspective of the effectiveness, as a clinical expert.

Charles Gore, CEO of the Hepatis Trust is another advocate for sufferers who will be able to give advice too. [redacted]

I apologise for the short notice, I only heard about this consultation on Monday.

Yours sincerely

[redacted]

[redacted]

[redacted]