Appendix G - professional organisation statement template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Sofosbuvir for treating chronic hepatitis C

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

Your name: [redacted]

Name of your organisation: Royal College of Nursing

- a specialist in the treatment of people with the condition for which NICE is considering this technology **Yes**
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology **(Member: Royal College of Nursing)**

What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

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*Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.*

The use of Sofosbuvir will need to be incorporated into the existing clinical guideline for the treatment of hepatitis c as directed through specialist hepatology clinical networks. The aim is to provide evidence based standardized care whilst allowing the influences of local catchment and resources.

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

It has been a long wait to obtain what should be a successful treatment for hepatitis C that has little in the way of side-effects. Current treatments consist of Pegylated interferon, ribavirin and in some cases a protease inhibitor. These are toxic drugs that approximately 15% of patients will not tolerate and discontinue treatment. The whole aim of HCV therapy is to reduce the number of people progressing to established cirrhosis with the complications of potential cancer or the potential need for liver transplantation. In addition by curing people of HCV this reduces the infection pool.

Sofosbuvir in some cases needs to be used in combination with both Pegylated interferon and ribavirin however in other cases, just Sofosbuvir and ribavirin can be utilised and also if Pegylated interferon

is not tolerated continuation can occur with just the two former drugs. In addition the length of treatment can be significantly reduced.

Whilst Sofosbuvir comes at a cost of £35,000 for a 12 week course, a reduction in outpatient visits would occur due to a lesser side-effect profile and potentially less adjunct therapy medications would be used.

When considering which patient population should have access to Sofosbuvir it should be a decision between clinician and patient as to which treatment course to take and efficacy associated with each regime. In clinical practice the use of protease inhibitors have not been without problems and all patients with chronic hepatitis C should have the option to use Sofosbuvir. The NICE guidance on HCV mild disease allows all patients to have access to therapy and it should be noted that therapy tends to be more efficacious in patients without significant fibrosis.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

We are not aware of additional evidence other than what can be obtained through systematic reviews.

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

Whilst some of the Hepatitis C service specification has leaned towards a hub and spoke model for HCV treatment, all hospitals with a speciality

Hepatologist and specialist Hepatology nurses should be able to make decisions on patient treatment. Many Hepatitis C patients are disadvantaged regarding the ability to attend patient consultations and these should be as close to the patient's home as possible to increase engagement with secondary care. Outreach treatment services for patients should also be considered, particularly in rural circumstances.

Equality
NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;
- could lead to recommendations that 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 lead to recommendations that have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Sofosbuvir will be particularly useful for pre and post liver transplant patients with active HCV. It is also appropriate that the licensing has been changed to include those with Genotype 1 disease who have been previously treated. Like most new drug situations further investigation in real world settings will be required to optimise treatment length efficacy.

It is hoped that Sofosbuvir will change the landscape of HCV therapy, improving treatment adherence for patients as well as increasing sustained virological response rates. The use of the drug in practice will require clinicians to keep up to date with developments and also regularly audit local patient populations however the overall treatment with Sofosbuvir, ribavirin and with or without Pegylated interferon should be easier to manage and less time-consuming than current regimes that include the protease inhibitors.