Consultation Report

Topic details

Title of Policy:	Vertebral Body Tethering (age 8-18 years)
Programme of Care:	Trauma
Clinical Reference Group:	Spinal Services
URN:	1750

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposition.

2. Background

Idiopathic scoliosis is a curvature of the spine without any obvious cause. When scoliosis continues to worsen in children that are still growing and who have tried bracing and other non-surgical methods of control, surgery may be considered.

Often, a scoliosis just needs to be monitored. If it worsens then a brace will usually be tried. If the brace does not control the scoliosis, surgery may be needed. Currently, surgery consists of inserting metallic rods into the back of the spine that need lengthening at regular intervals to keep growth going (growing rod techniques) or a fusion to correct the spine with rods that are locked and do not move (instrumented scoliosis correction and fusion). Growing rods have to be converted to a fusion at the end of growth.

Spinal Rods work well in controlling the scoliosis and in maintaining some growth. However, they do stiffen the spine rather than leaving it flexible. They may also sacrifice some growth.

Vertebral Body Tethering (VBT) is a new treatment that involves putting screws into the front of the spine (so the scar is on the side of the chest) which are connected by a flexible cord rather than a metal rod. The system works by compressing (squeezing) one side of the curved spine which aims to change the growth of that part of the spine and slowly improve the curve. The system can only be used in children that have enough growth left in their skeleton and are above the age of 8 years. It is not helpful for older children and teenagers or adults.

The aim of VBT is to leave the spine flexible rather than stiff. Currently, it is not known if VBT preserves growth or what the long-term effects of VBT are.

3. Publication of consultation

The policy was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 90 days. The consultation closed on 10th January 2019. Comments were shared with the Policy Working Group (PWG) to ensure full consideration was given to feedback and to support a decision as whether any changes to the service specification might be necessary.

Respondents to consultation were asked the following questions:

- Has all the relevant evidence been taken into account? If not, please provide details
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described
- Are there any changes or additions that need to be made to this document? If so, please describe.

4. Results of consultation

There were 24 responses to the public consultation in total.

- 10 from clinicians (3 of whom responded on behalf of their organisations, the remaining 6 responded as individuals);
- 1 from a service provider;
- 2 from patients;
- 8 from parents of a patient;
- 2 from professional bodies
- 1 from a device manufacturer;

Common themes in the responses related to:

- Several responses highlighted one piece of recently published, new evidence. The new evidence has been reviewed and a conclusion has been made that the policy proposition does not need to be changed.
- Several respondents highlighted the high rates of failure, complications and the need for revision surgery. This included two cases of life threatening complications on patients treated in other countries, paid for privately.
- Many respondents detailed the success of the treatment of their children and believed this grade of evidence was significantly important.

5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity

- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change

- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document

- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility.

All of the issues raised fell into the category of level 2, in that no changes to the draft policy have been made as a result of consultation. However, one piece of new evidence, highlighted by several responses to the consultation, was carefully assessed.

6. Has anything been changed in the policy as a result of the consultation?

There have been no changes made to the wording of the policy.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No.