

## National Institute for Health and Clinical Excellence

### 855 – Drainage, irrigation and fibrinolytic therapy (DRIFT) for post-haemorrhagic hydrocephalus in preterm infants Consultation Comments table

**IPAC date: Thursday 8 September 2011**

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 NHS Professional	1	Agree	Please respond to all comments Thank you for your comment.
2	Consultee 2 NHS Professional	1	Work refining and simplifying such a treatment prior to RCT should also be allowed in centres that have experience of this procedure with favourable outcome data.	Thank you for your comment. Section 1 of the guidance states that the procedure should only be used in the context of research – it does not specify RCTs.
3	Consultee 3 NHS Professional	1	The fibrinolytic component of the DRIFT is blamed for the increased risk of secondary haemorrhage and its consequences and the need for shunt insertion. The authors of the paper recommend to use this technique without fibrinolytic component. A trial can be considered with DRIT(Drainage and Irrigation treatment) without fibrinolytic component. Despite an increase in secondary haemorrhage, DRIFT reduced severe cognitive disability which is promising.	Thank you for your comment.
4	Consultee 4 Specialist Adviser	1	The conclusion that the evidence for efficacy is lacking in quantity is justified as the numbers speak for themselves but the conclusion that quality was lacking is not substantiated. Which aspects of the design or conduct of the studies were of poor quality and why?	Thank you for your comment. Section 1.1 of the guidance will be changed.

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5	Consultee 4 Specialist Adviser	<b>1</b>	Given the very serious prognosis for this condition, the biological basis and the limited evidence suggesting benefit but with some risk, research should concentrate on making the procedure simpler, safer and easier to teach so that a larger multicentre randomised trial can be planned and resourced to increase the quantity of evidence.	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
6	Consultee 5 NHS Professional	<b>1</b>	I agree. As well as being reported separately they should be reported jointly since the appropriate primary outcome should be death or disability. Measures of disability need to be pre-defined.	Thank you for your comment. NICE would expect standard disability outcome scales to be used in research. NICE would not wish to imply that death and disability are equivalent outcomes, hence the recommendation for research to report them separately.
7	Consultee 1 NHS Professional	<b>2.1.1</b>	IVH can be of differing severity, 2.1.1 implies post-haemorrhagic hydrocephalus is a common occurrence in babies who have IVH this is not the case.	Thank you for your comment. Section 2.1.1 of the guidance will be changed.
8	Consultee 3 NHS Professional	<b>2.1.2</b>	2.1.2 There is no consensus about the timing of intervention. We need more evidence to recommend early or late intervention.	Thank you for your comment. Section 2.1.2 of the guidance does not specify the timing of intervention.

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9	Consultee 5 NHS Professional	<b>2.1</b>	This seems to be incidence and natural history rather than procedure. Some infants have post-haemorrhagic ventricular dilatation (PHVD) without excessive head growth. this can be due to increased CSF pressure (due to increase production, not relevant here, or obstruction to flow) or to cerebral atrophy or to a combination of both. 2.1.1 and 2.1.2 taken together seem to imply that 50% of infants with post-haemorrhagic hydrocephalus require insertion of a V-P shunt. The correct percentage figure depends on the precise operational definition of hydrocephalus used in this context: if PHH is used to refer to dilatation of the lateral cerebral ventricles above 97th centile after IVH, a lot less than 50% will require insertion of a V-P shunt. Statistics are available from previous treatment trials all of which have inclusion criteria that capture a subset of patients at the more severe end of PHVD. Inclusion of an operational definition of post haemorrhagic hydrocephalus in the statement would reduce the potential for misunderstanding.	Thank you for your comment. Section 2.1.1 of the guidance will be changed.
10	Consultee 3 NHS Professional	<b>2.2</b>	Was the monitoring done by medical or nursing personnel?	Thank you for your comment. It is not clear what the consultee means by 'monitoring'. In one of the papers (Whitelaw et al., 2003) it was noted that developmental assessments were done by a paediatrician and motor assessments were done by a physical therapist.
11	Consultee 5 NHS Professional	<b>2.2</b>	I have no information to lead me to disagree.	Thank you for your comment.
12	Consultee 2 NHS Professional	<b>2.3</b>	DRIFT is the only treatment that has been shown to improve outcome.	Thank you for your comment.
13	Consultee 3 NHS Professional	<b>2.3</b>	It will be very useful how DRIFT group did clinically well rather than giving a score (MDI score) which were better in DRIFT group as compared to standard treatment group.	Thank you for your comment. The scores reported in section 2.3.4 of the guidance were those used in the evidence to represent severe disability.

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14	Consultee 5 NHS Professional	<b>2.3</b>	I have no information to lead me to disagree. Clearly long term outcomes when the children are of primary school age would be very useful. In younger children, parent-reported developmental outcomes are reliable, as predictive as direct assessments of infants and feasible in a multi-centre trial setting and might be recommended for future trials. References could be supplied if this is considered controversial.	Thank you for your comment. Section 1.1 of the guidance states that research should include long-term outcomes.
15	Consultee 2 NHS Professional	<b>2.4</b>	The safety profile, appears as good as repeated tapping and shunting in terms of infection, trauma. The re-bleeding appears to be non-significant clinically	Thank you for your comment.
16	Consultee 3 NHS Professional	<b>2.4</b>	Is safety related to the skill of the person doing the procedure? Patients recruited at Bristol site seems to have had a better safety outcome when compared to other sites.	Thank you for your comment. In one paper (Whitelaw et al., 2007) it was noted that there was no significant difference between centres in the frequency of secondary intraventricular haemorrhage.
17	Consultee 5 NHS Professional	<b>2.4</b>	I have no information to lead me to disagree	Thank you for your comment.
18	Consultee 2 NHS Professional	<b>2.5</b>	Given that there is no other treatment and the favourable results in the trial, experienced centres should be allowed to develop this treatment bundle for further RCT.	Thank you for your comment. Section 1 of the guidance states that the procedure should only be used in the context of research – it does not specify RCTs.
19	Consultee 3 NHS Professional	<b>2.5</b>	The logic behind DRIFT is good	Thank you for your comment.
20	Consultee 5 NHS Professional	<b>2.5</b>	I agree. It would be helpful if the committee could express a view whether further trials are justified and if so whether critical review of inclusion and exclusion criteria of previous studies would be appropriate for use in future studies.	Thank you for your comment. The Committee recommended that the procedure should only be used in the context of research, but does not normally specify details of inclusion and exclusion criteria in such studies..

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21	Consultee 2 NHS Professional	<b>General</b>	In a randomised controlled trial Ventricular Lavage reduced the number of infants with severe disability, especially mental disability, at age 2 years. This is the only treatment that has been shown to be of any benefit for these patients. The cost of looking after a disabled child to society and the family are huge. I urge NICE to consider endorsing the development of this treatment in appropriate (supra?) regional centres with a cohesive medical and neonatal-neurosurgical team. I must declare a degree of bias as i have in the past worked with Professor Whitelaw in the past on other projects.	Please respond to all comments  Thank you for your comment. Recommendations about service configuration are not within the remit of the Interventional Procedures Programme.

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