

Freedom of Information Request

Ref: 22-037

7 February 2022

By Email

Dear Sir/Madam

Thank you for your request for information under the Freedom of Information Act 2000. The Trust's response is as follows:

- We can confirm that we do hold the information you are requesting

I request that you provide me with the information you hold relating to the length of time of cervical ripening balloons (including the cook balloon) is in place and the information relating to the risk of pyrexia or infection from such balloons. In particular, please could you provide any information relating to the trusts policies for the length of time a balloon is left in place.

1. The Cook Cervical Ripening Balloon (CRB) (double balloon catheter) is licensed for use up to 12 hours.
2. Risks associated with the Cook Cervical Ripening Balloon and labour induction (as stated in the manufacturer's product information) may include, but are not limited to: placental abruption, uterine rupture, spontaneous rupture of membranes, spontaneous onset of labour, device expulsion, device expulsion and/or fragmentation, maternal discomfort during and after insertion, failed cervical dilatation and need for caesarean delivery, cervical laceration, bleeding, risk of preterm labour and birth in a subsequent pregnancy.

Risks relating to maternal pyrexia or infection

A systematic review and meta-analysis (McMaster et al., 2015) designed to evaluate associations between a single balloon catheter (Foley catheter) and infectious morbidity evaluated 26 randomised trials including 5,563 women. Compared with prostaglandin preparations alone, women who had cervical ripening with a Foley catheter versus those induced with prostaglandins had similar rates of chorioamnionitis (56/782 [7.2%] v. 54/754 [7.2%]; endometritis (40/1,042 [3.8%] v. 35/991 [3.5%]) and overall maternal infection (237/2,699 [8.8%] v. 257/2,864 [9%]).

A meta-analysis (Du et al., 2017) comparing use of double-balloon catheter versus prostaglandin E2 for cervical ripening and labour induction demonstrated no significant

difference in presence of maternal fever (20/113 [17.7%] v. 18/107 [16.8%] women) or prescription of antibiotics (19/113 [16.8%] v. 26/107 [24.3%]).

A systematic review evaluating the risk of maternal, fetal and neonatal complications associated with the use of transcervical balloon catheters in induction of labour included 84 articles reporting on 13,791 women (Gommers et al., 2017). Importantly, the review included studies which used both single and double balloon catheters. The overall risk of developing intrapartum maternal infection was 11.3% (912/8079 women), with 3.3% (151/4538 women) developing postpartum infection.

3. We enclose the Trusts clinical guideline 'Management of Induction of Labour' (updated November 2021) for your reference.

This concludes our response. We trust that you find this helpful, but please do not hesitate to contact us directly if we can be of any further assistance.

If, after that, you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to:

Director of Corporate Governance
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
BS1 3NU

Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Publication

Please note that this letter and the information included/attached will be published on our website as part of the Trust's Freedom of Information Publication Log. This is because information disclosed in accordance with the Freedom of Information Act is disclosed to the public, not just to the individual making the request. We will remove any personal information (such as your name, email and so on) from any information we make public to protect your personal information.

To view the Freedom of Information Act in full please click [here](#).

Yours sincerely

Freedom of Information Team
University Hospitals Bristol and Weston NHS Foundation Trust