Bwrdd Iechyd Prifysgol Bae Abertawe
Swansea Bay University Health Board

Cadeirydd Dros Dro/ Interim Chair: **Emma Woollett**
Prif Weithredwr/Chief Executive: **Tracy Myhill**

gofalu am ein gilydd, cydweithio, gwella bob amser
caring for each other, working together, always improving

Rydym yn croesawu gohebiaeth yn y Gymraeg ac yn y Saesneg. We welcome correspondence in Welsh or English.

Dyddiad/Date: 18th December 2019
Ein Cyf / Our Ref: 19-J-041

01639 648363
FOIA.Requests@wales.nhs.uk

[redacted]

Corporate Services
Headquarters
1 Talbot Gateway
Baglan
Port Talbot, SA12 7BR

[redacted]

I refer to your Freedom of Information Act Request acknowledged by ourselves on 29th October 2019. Your request sought information relating to trocar supply.

Part A – Decision making framework

1. **Has the Health Board considers the standardisation / rationalization of its trocar supplies (or when it comes to do so), please provide:**
   Yes

   a. **Which person(s) or committee within the hospital is responsible for undertaking the analysis of options, making recommendations or ratifying/deciding which brand to choose.**
      The responsible committee is the Clinical Cabinet at Morriston Delivery Unit

   b. **How / on what basis will the decision be made – ie:**

      i. **to what extent will clinical input be taken into account and how (eg will all the suppliers be considered on a sliding scale or will certain brands be ruled into or out of consideration altogether?**
      An initial data analysis exercise will be presented to the Clinical Cabinet. Clinical input is then sought from the Clinical Cabinet and elements such as the complexity of procedures undertaken is factored into the final decision.

      ii. **To what extent will financial considerations be taken into account and how (eg will there be a stand-alone assessment of the costs of**

trocars only or will there be an assessment of the financial impact across a range of products that include both trocars and other items)?
The Health Board are in the process of determining its approach to this. The agreed approach is subject to further engagement with internal and external stakeholders.

c. **The reasons given from the clinical staff as to whether Applied Medical should be considered and, if so, why/why not?**
This information is not held by the Health Board. However clinical staff would make any decision on clinical products.

d. **The reasons given from a financial perspective to pursue the possibility of standardising to Medtronic branded trocars.**
The Health Board holds an analysis document on costings, but disclosing this would prejudice ongoing activity in terms of the Health Board establishing a way forward. Therefore this information has been withheld. Section 43 of the Act sets out an exemption for the right to know if release of the information is likely to prejudice the commercial interests of any person (a person may be an individual, a company, the public authority itself or any other legal entity). Section 43 is a qualified exemption. That is, it is subject to the public interest test.

The procurement of trocars, is currently being reviewed and therefore the tendering process is imminent. Therefore although there is a public interest in the scrutiny of how public money is spent, the timing of the release of this information in a commercial environment is of critical importance. Releasing this information at this present time could be disadvantageous to the Health Board. To disclose the expenditure would give unfair advantage to potential bidders/competitors and could lead to distorted pricing in the market. In addition to the pricing sensitivities, disclosure may compromise the delivery of value for money, when the contract is renewed. In conclusion we feel we feel that the public interest in withholding the information outweighs the public interest in releasing at this time.

Part B – Adverse Event Details

2. **Has there been an adverse event at the Health Board involving Applied Medical's trocars any time in the last 10 years?**
Yes

3. **If yes, please provide a copy of the closing report for the adverse event (ie the document that records the details of what occurred, any assessment of cause and effect and what actions should follow).**

The Health Board reports incidents locally on its incident reporting system – Datix. However the reports are withheld under Section 31 of the FOIA.

Section 31(1)(g) FOIA provides that information is exempt if its disclosure would, or would be likely to, prejudice functions exercised for a number of specified purposes including :

- the purpose of ascertaining the cause of an accident
- the purpose of protecting persons other than persons at work against risk to health or safety arising out of or in connection with the actions of persons at work.

I am satisfied that the disclosure under FOIA of incident reports would be likely to prejudice functions exercised by the Health Board for these purposes.

The reason for my view that disclosure would have such an adverse effect is as follows: The effectiveness of incident reporting depends heavily on the willingness of Health Board staff, when reporting incidents, to provide full and open accounts of events. They do so with a reasonable expectation of confidentiality. Certainly they have an expectation that any information they supply when reporting a serious incident will be used only for the purpose of investigating and managing the incident and ensuring that necessary lessons are learnt.

There is a real concern that the disclosure of serious incident reports under FOIA will deter prompt and candid reporting which is essential for the effectiveness of the Health Board's management of specific incidents and of clinical risks generally. If staff are not confident that information they supply for the purpose of serious incident reports will be managed on a confidential basis and for the sole purpose of ensuring lessons are learnt and appropriate action taken to minimise the likelihood of recurrence, the risk is that staff will become defensive in their reporting and will reduce the level of detail they supply to the bare minimum.

This in turn would have a detrimental effect on the quality of information supplied for the purpose of serious incident reports which in turn would affect the Health Board's ability to identify and address risks and to monitor and improve the quality of its services.

The Health Board's conclusion therefore is that there is a real and significant risk that the disclosure of anyse reports in response to FOIA requests will have an adverse impact on the quality of information supplied by staff in the event of a serious incident serious incident reports and that this will prejudice functions relating to the monitoring and improvement of healthcare which are exercised by the Health Board for the purposes set out above and provided for by Section 31(1)(g) FOIA

The public interest test

Section 31 FOIA is a conditional or qualified exemption. This means that, even where it is considered to apply, it may be relied on only if the public interest in applying the exemption outweighs the public interest in disclosure.

The Health Board recognises that there is a significant public interest in knowing about adverse incidents involving patients in its care. We also appreciate that there is a public interest in openness and transparency generally.

However, insofar as the detail of serious incident reports are concerned we consider that the public interest in disclosure does not outweigh the public interest in applying the s31(1)(g) exemption. This is because it is overwhelmingly in the public interest that systems in place within NHS bodies such as this Health Board for the investigation and management of specific incidents and of clinical risk more generally should be as effective as possible. There is an obvious and very considerable public interest in avoiding adverse impact on the quality of serious

incident reporting where this will prejudice the ability of the Health Board to ensure lessons are learnt, to take corrective action to address risks and improve patient outcomes.

4. ***Only if*** **no such document exists (or if it lacks one or more of the following items of information) please provide the following information:**

    a. **The date the event occurred.**

    b. **The procedure being performed.**

    c. **A description of the event including what happened to any devices being used; whether anything adverse occurred for the patient; and what corrective interventions may have been needed.**

    d. **The key patient characteristics (ie ten-year age group 20-30; 30-40 etc; gender; BMI and whether the patient had had any previous procedures).**

    e. **The name of the surgeons and registrars in attendance and what is their surgical specialty.**

    f. **The model number and lot number of the Applied Medical product and its current whereabouts.**

    g. **The brand and model description of another surgical devices involved in the event.**

    h. **Whether the event was reported to the MHPRA and/or SMTL and why/why not.**

    See question 3.

5. **If no such adverse event has occurred involving Applied Medical trocars has occurred at any time in the last 10 years, please confirm whether any clinical staff have made representations that there may have been such an incident in the context of the current trocar standardisation consideration. If representations have been made from the clinical staff:**

    Not applicable – see question 2.

    a. **Who made the representation?**

    b. **Was it by email, orally or otherwise?**

    c. **What was said?**

Part C – Medtronic Proposal

6. **Is the Hospital Board (or within the last year has the Hospital Board) actively considered a "bundled product deal" including trocars from Medtronic. A bundled product deal includes:**

a. an arrangement by which the prices, discounts, rebates or credits paid/received for the purchase of trocars depends in whole or in part on the volume or value of other products purchased by the Hospital Board; or

This information has been withheld. Section 43 of the Act sets out an exemption for the right to know if release of the information is likely to prejudice the commercial interests of any person (a person may be an individual, a company, the public authority itself or any other legal entity). Section 43 is a qualified exemption. That is, it is subject to the public interest test.

The procurement of trocars, is currently being reviewed and therefore the tendering process is imminent. Therefore although there is a public interest in the scrutiny of how public money is spent, the timing of the release of this information in a commercial environment is of critical importance. Releasing this information at this present time could be disadvantageous to the Health Board. To disclose the expenditure would give unfair advantage to potential bidders/competitors and could lead to distorted pricing in the market. In addition to the pricing sensitivities, disclosure may compromise the delivery of value for money, when the contract is renewed. In conclusion we feel we feel that the public interest in withholding the information outweighs the public interest in releasing at this time.

b. an arrangement by which the prices, discounts, rebates or credits paid/received for the purchase of other products depends in whole or in part on the volume or value of trocars purchased by the Hospital Board.

This information has been withheld. Section 43 of the Act sets out an exemption for the right to know if release of the information is likely to prejudice the commercial interests of any person (a person may be an individual, a company, the public authority itself or any other legal entity). Section 43 is a qualified exemption. That is, it is subject to the public interest test.

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7. If the answer to question 6 is yes:

a. what products are included in the bundled deal?
See Question 6.

b. **are the terms of the bundled deal wholly consistent with, and included in, the current framework agreement for NHS Wales (or some other tender process – in which case please advise which tender process)?** Swansea Bay UHB are only considering options for the procurement of Trocar in line with a current NHS Wales framework agreement.

On the 22nd November 2019 you sent a further addition to your request for information:

8. **If an item or items of information held by the Health Board falls within the answer to questions 1 to 7 but an exception applies under the Freedom of Information Act 2000 such that you have decided not to provide that item/ those items of information to us, please provide the following information in relation to those items:**

Description of the item, the date of the item and the quantity of them (eg in answer to question 6, four bundled deals were proposed)	**Which question does the item fall within**	**Which of the Freedom of Information Act exception(s) apply**	**How/ why is that exception applicable**

This information has been answered in our response above.

I hope this information is helpful. If you require anything further please contact us at FOIA.Requests@wales.nhs.uk.

Under the terms of the Health Board's Freedom of Information policy, individuals seeking access to recorded information held by the Health Board are entitled to request internal review of the handling of their requests. If you would like to complain about the Health Board's handling of your request please contact me directly at the address below or register your complaint via FOIA.Requests@wales.nhs.uk.

If after Internal Review you remain dissatisfied you are also entitled to refer the matter to the information commissioner at the Information Commissioner's Office (Wales), 2nd Floor, Churchill House, Churchill Way, Cardiff, CF10 2HH. Telephone Number: 029 2067 8400.

Yours sincerely

P. a. Wenger

Pam Wenger
Director of Corporate Governance