

<b>Reference:</b>	FOI.2911.20
<b>Subject:</b>	5FU Toxicity
<b>Date of Request:</b>	9 April 2020

**Requested:**

1. What is the protocol or approach used by the Oncology Specialty in your Health Board since 01/01/2016 to prevent serious or fatal toxicity to 5-FU or capecitabine or tegafur when prescribed for a range of malignancies, particularly breast and gastrointestinal cancers?
2. How many fatalities or cases of serious toxicity have occurred in your Health Board due to this specific issue since 01/01/2016?

**Response:**

1. Hywel Dda University Health Board (UHB) confirms it follows the peer-reviewed, validated and audited protocols from the South West Wales Cancer Network on ChemoCare. On 20 April 2020, the European Medicines Agency (EMA) made recommendations on Dihydropyrimidine Dehydrogenase (DPD) testing prior to starting treatment with Fluorouracil, Capecitabine and Tegafur. The UHB will introduce DPD testing if the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK adopts these recommendations.
2. The UHB is unable to provide you with the number of fatalities or serious toxicity cases as it is estimated that the cost of answering your request would exceed the “appropriate level” as stated in the Freedom of Information (Fees and Appropriate Limit) Regulations 2004. The “appropriate level” represents the estimated cost of one person spending 18 hours or (2 ½ working days) in determining whether the UHB holds the information, and locating, retrieving and extracting the information.

In order to provide you with the information requested, the UHB would be required to conduct a manual trawl of all cancer patients’ medical records to establish those that undertook these treatments to identify how many resulted fatalities or cases of serious toxicity. It is estimated that conducting this search would take longer than the 18 hour ‘appropriate limit’ as stated within the Act.

The UHB is therefore applying an exemption under Section 12 of the Freedom of Information Act 2000, which provides an exemption from a public authority’s obligation to comply with a request for information where the cost of compliance is estimated to exceed the *appropriate limit*.

Under section 16 of the Freedom of Information Act, the UHB has an obligation to provide advice and assistance.

All fatalities are discussed in the Swansea Bay University Health Board’s (SBUHB) Mortality and Morbidity (M&M) meetings. We would therefore recommend that you redirect your request to the Freedom of Information Team in SBUHB who may be able to help you with your enquiry:-

[FOIA.Requests@wales.nhs.uk](mailto:FOIA.Requests@wales.nhs.uk) or alternatively, you can contact: FOIA Team, Swansea Bay University Health Board, Health Board Headquarters, 1 Talbot Gateway, Port Talbot, SA12 7BR.