Freedom of Information Request	FOI 22-433	29th September 2022

Please can I request answers relating to the below questions. A national collation of this information will be made available to any trust requesting it in reply.

1. **How many patients in the last 12 months has the trust treated for metastatic Cholangiocarcinoma (CCA) or Acute myeloid leukaemia (AML)?**
   26

   a. **For each of AML and CCA, how many have IDH-1 mutation?**
      <5

      Please note where less than five (5) patients have been identified, Section 40 of the Freedom of Information Act 2000 has been applied as the Health Board cannot provide the exact numbers due to the low numbers of individuals involved (5 or less). The Health Board believes there is a potential risk of individuals being able to be identified, when considered with other information already available within the public domain, if this was disclosed. Therefore, the data is classed as personal data as defined under the General Data Protection Regulation (GDPR) and Data Protection Act 2018 and its disclosure would be contrary to the data protection principles and constitute unfair and unlawful processing in regard to Articles 5, 6, and 9 of GDPR. We are therefore withholding this detail under Section 40(2) of the Freedom of Information Act 2000. This exemption is absolute and therefore there is no requirement to apply the public interest test.

   b. **How many CCA are intrahepatic vs extrahepatic?**
      i. **How many of each of these present at 2nd line? How many of these at 2nd line have IDH-1 mutation?**
         0

   c. **For AML, how many patients were not fit for intensive chemotherapy? How many of these AML patients have IDH-1 mutation?**
      15 patients were not fit for intensive chemotherapy.
      0 had an IDH1 mutation.

2. **How many patients have been treated with pemigatinib (CCA), venetoclax plus azacitadine dual therapy or azacitadine monotherapy (AML)?**
   11 patients were treated with Venetoclax dual therapy (generally we use Venetoclax plus low dose cytarabine).
   <5 patients were treated with Azacitidine monotherapy.

a. **What is the average treatment duration for CCA patients treated with pemigatinib and AML patients treated with azacitadine dual therapy and azacitadine monotherapy? What is the preferred azacitadine product?**
Patients treated with Venetoclax/LDAC vary between 1 and 12 months at present.

3. **What is the real-world dosing for venetoclax (in combination with a CYP3A4)?**
Cycle 1 Venetoclax 100mg D1, 200mg D2, 300mg D3, 100mg D4-D28 orally, once daily.

Cycle 2 onwards Venetoclax 100mg a day 1-28 (unless dose adjustments are needed).

a. **What is the antifungal of choice for patients treated with venetoclax?**
Posaconazole or Voriconazole are used during the treatment.

b. **What is the antifungal average treatment duration when used in combination with venetoclax ?**
Posaconazole or voriconazole are started on day 4 of the first cycle, and then given for 28 days with each cycle.

c. **what proportion of patients are treated with an antifungal in combination with venetoclax? In what proportion of patients is the antifungal treatment stopped? In what proportion of these pts is the venetoclax dosage altered following cessation of the antifungal?**
All patients are started on an antifungal in combination with their venetoclax-based regime. To date no patients have had to stop the antifungal treatment, but if this were to happen the dose of the Venetoclax would be increased.

4. **Do you routinely test CCA and AML patients for IDH-1 mutation?**
AML patients are investigated for IDH-1 mutations.

If so when does the testing take place. E.g. at diagnosis or following
a. **1st line progression? Is this done using NGS panel? Is this done using PCR testing?**
The investigation is performed at diagnosis via an NGS panel. This test can also be repeated at relapse.

b. **What is the average turnaround time for these tests?**
NGS results usually take around 2-4 weeks

5. **Who is responsible for the routine management of patients with CCA and AML?**
Currently patients with AML who need intensive chemotherapy are transferred to Cardiff and Vale University Health Board for this therapy.

Other patients who are not suitable for intensive SACT treatment are treated by the Health Board.

a. Clinical oncologist / medical oncologist / specialist nurse etc? – Patients in the Health Board who need AML therapy are under the care of consultant haematologists with the support of Clinical Nurse Specialist. There are three myeloid consultants who have patients with AML under their care.

b. How many admissions have occurred in the last 12 months for patients with CCA and AML?
The majority of patients were admitted at diagnosis. Subsequently many patients need to be readmitted, with the number of admissions per person varying between 1 and 10 admissions.

c. What is their average length of stay?
This can vary between 1 day and 28 days.

d. How many of these patients were readmissions or readmitted during this time? If readmitted, can you state the main reason?
14 patients were re-admitted. The main reason for readmission was due to a complication of their AML/SACT treatment such as neutropenic sepsis.