Witness Name: Professor Richard Adams
Statement No.: 1
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Dated:

UK COVID-19 PUBLIC INQUIRY

WITNESS STATEMENT OF PROFESSOR RICHARD ADAMS

I, Professor Richard Adams, Consultant in Clinical Oncology at Velindre University NHS Trust (**the Trust**), Unit 2 Charnwood Court, Heol Billingsley, Parc, Nantgarw, Cardiff, CF15 7QZ, will say as follows:

1. I make this statement in response to a Rule 9 request for information by the Covid-19 Public Inquiry Module 3 Team, dated 26 May 2023. This statement provides information regarding the colorectal service provided by the Trust, specifically in relation to how this was affected by and adapted to the impact of the Covid-19 pandemic.

2. I am a consultant clinical oncologist, specialising in colorectal cancer (**CRC**), at the Velindre Cancer Centre (**VCC**) and have worked here prior to and during the relevant period.

3. I make this statement based on my own knowledge and recollection. Where I have no direct knowledge, in order to assist the Inquiry, I have referred to accounts and documentation provided to me by other members of the Trust. Where responses are not from my direct knowledge, this has been made clear in my statement.

General information and situation prior to the relevant period

4. Within the Trust there are separate oncological site specific teams (**SSTs**), depending on the site/location of the cancer. The CRC SST is a large SST and effectively covers two sub-sites as the anal cancer team is incorporated within it. The CRC SST was (and still is) an active participant in the Lower GI Cancer Site Group. The Cancer Site

Groups were established as a single clinical structure providing advice and expertise to the Wales Cancer Network (**WCN**) and the Cancer Implementations Group. VCC is represented on the WCN.

5. Consultants within the CRC SST would attend multi-disciplinary team (**MDT**) meetings within hospitals run by the Health Boards in the south-east of Wales, namely Aneurin Bevan, Cardiff and Vale, and Cwm Taf Morgannwg. Although the Trust covers additional Health Boards, such as Swansea Bay and Hywel Dda, for some additional specialist services, save for requested second opinions these are not within the domain of the CRC SST.

6. At MDT meetings there would be a discussion regarding the reasonable alternative treatment options for CRC patients. If non-surgical oncology treatment was recommended, then the patient would be referred to the Trust for a discussion with the patient about the treatment options, risks and benefits. Non-surgical oncology treatment includes radiotherapy and systemic anticancer treatment (**SACT**), which in turn includes treatments such as chemotherapy and immunotherapy, a significant component of this work is symptom control and, where appropriate, palliative care input.

7. Following referral, patients would not necessarily be treated on location at VCC. The Trust's CRC SST attended oncology outreach clinics and ran chemotherapy suites situated within hospitals managed by the Health Boards. There were outreach clinics within Prince Charles Hospital (Cwm Taf Morgannwg), Princess of Wales (Cwm Taf Morgannwg), Neville Hall Hospital (Aneurin Bevan) and Royal Gwent Hospital (Aneurin Bevan). There were also chemotherapy suites within Prince Charles Hospital, Neville Hall Hospital and Royal Gwent Hospital. Further, the Trust ran a mobile outreach chemotherapy unit with SACT and staff supplied by the Trust, three days a week, to provide treatment to patients closer to their homes. Radiotherapy was only performed at VCC.

8. The number of monthly CRC referrals from the Health Boards fluctuated **[RA/01 INQ000408940]** From the data available, in the years immediately prior to the relevant period, I note the following:
    a. March 2018 – February 2019:
        i. Total number of CRC referrals = 673
        ii. Monthly mean = 56.08

iii. Monthly range = 43 – 74

b. March 2019 – February 2020:

i. Total number of CRC referrals = 726

ii. Monthly mean = 60.5

iii. Monthly range = 54 – 77

9. With regard to treatment, from March 2018 to February 2019, there were 584 referrals for SACT and 216 for radiotherapy. From March 2019 to February 2020, there were 668 referrals for SACT and 230 for radiotherapy. Patients were treated on an outpatient basis. The predominant treatment for CRC patients was chemotherapy and radiotherapy. Only a small number of patients received immunotherapy at this time. The number of CRC referrals and the number of referrals for treatment do not correlate as some patients will receive both SACT and radiotherapy whilst some patients may not be referred for either.

10. A single patient would often have to attend multiple times for a course of treatment, for example a neoadjuvant (pre-operative) rectal cancer patient might be given 25 daily fractions of radiotherapy over a 5-week period. The attendances for CRC treatment in the two years prior to the relevant period are as follows: **[RA/01 INQ000408940]**

a. March 2018 – February 2019:

i. Non-oral SACT attendances = 3,591

ii. Oral SACT attendances = 335

iii. Radiotherapy attendances = 3,107

iv. Total = 7,033

v. Monthly mean = 586

b. March 2019 – February 2020:

i. Non-oral SACT attendances = 3,640

ii. Oral SACT attendances = 332

iii. Radiotherapy attendances = 3,162

iv. Total = 7,134

v. Monthly mean = 595

Velindre Cancer Services (VCS) changes made due to Covid-19

11. Prior to the relevant period, in early 2020, there was already concern within the CRC SST regarding Covid-19 and how this might impact upon the treatment of patients. There was concern regarding the risk of infection with Covid-19, given the need for repeated attendance at hospital for consultations and treatment. Further the risk to patients of receiving treatment with toxic side-effects, during the Covid-19 pandemic, were not clearly understood at this time. I recall the following:

a. The Welsh Government issued guidance to healthcare providers in February 2020 [**RA/02 INQ000262070**];

b. In early 2020, there was international concern given the emergence of a novel coronavirus and the acknowledgement that this can be a global challenge for public health, see for example The New England Journal of Medicine article by Na Zhu et al [**RA/03 INQ000409314**];

c. In February 2020, within VCC, there was concern leading to guidance being circulated on travel plans, information for doctors to watch out for patients with possible Covid-19 symptoms, risk assessments and donning and doffing of PPE [**RA/04 INQ000409315**]; [**RA/05 INQ000409316**]; [**RA/06 INQ000409317**]; [**RA/07 INQ000409318**]; and [**RA/08 INQ000409319**].

12. By 2 March 2020, the CRC SST, had compiled an SST Business Continuity Plan **RA/09 INQ000408941]**. This considered where assessments, provision of results and MDTs could be dealt with remotely, rather than face-to-face. Consideration was given to delaying/deferring follow ups. It was also agreed that our risk/benefit approach should integrate the risk posed by Covid-19 and that it may be better for some new patients not to have chemotherapy. For patients with stage II microsatellite instability-High (**MSI-H**) tumours, that had been resected surgically, it was considered that adjuvant chemotherapy could be omitted, given the very small benefit, in these patients.

13. In March 2020, it was considered necessary to close the outreach clinics and the chemotherapy clinics within the District General Hospitals, with the Prince Charles Hospital being the last to pause this service, in early April 2020 **[RA/10 INQ000408942]** and **[RA/11 INQ000408943]**. There was a staggered repatriation of services to VCC, which became a 'green zone'. The intention was to continue to deliver chemotherapy and radiotherapy safely for the region in the knowledge that the other hospitals were likely to become 'red zones'. The mobile outreach chemotherapy unit

was temporarily suspended on 10 April 2020 (with limited service resuming in September 2020). Green zones were used for patients who were tested and Covid-19 negative and had no symptoms of Covid-19. Red zones were used for patients who had tested positive for Covid-19 and were displaying symptoms of Covid-19. Repatriation was considered necessary for patient safety. The Health Boards took back spaces used by VCC for their own purposes, to permit social distancing. By repatriating clinics and suspending the mobile outreach chemotherapy unit (and making some consultations remote) it was also easier to provide cover for clinics especially as junior staff were undertaking enhanced rotas. It was easier to cover staffing gaps caused by short notice absence for sickness or isolation. I am not aware of any specific impact on patients, save for the possibility that, for some patients, they needed to travel further for treatment.

14. MDTs continued but these were undertaken remotely rather than in person to prevent unnecessary contact and risk of infection.

15. Therefore, the referral process remained the same; however, the outreach clinics were closed and the majority of consultations were now performed remotely by telephone or by video call, using the NHS Attend Anywhere service, which went live at the Trust on 27 April 2020. We continued to see some patients face-to-face **[RA/12 INQ000408944]**. In June 2019, for the CRC outpatients practice, there were 604 outpatient department clinic attendances face-to-face with only 139 via telephone call and none by video call, whilst, in June 2020, there were only 118 face-to-face attendances with 463 via video call and 6 via video call. All chemotherapy was centralised and provided directly by VCC.

16. Save that consultations were remote, the review of patients considered appropriate for ongoing therapy remained the same regarding consultations. However, interval scans were considered on an individual basis and often undertaken over a slightly longer period to reduce exposure of patients to the risk of Covid-19 and to reduce the burden on radiology departments. Interval scans are CT scans done at regular intervals, such as every 3 months or every 3 cycles, to evaluate and monitor disease. In most cases this relates to patients with advanced or metastatic cancer. Interval scans are used to assess the response to treatment to ensure this is effective and they will guide changes on treatment. Other approaches, such as monitoring of tumour markers, continued.

17. Initial NHS guidance for the management of cancer patients during the coronavirus pandemic was published on 17 March 2020 [**RA/13 INQ000262193**]. This advised that patients be categorised by priority groups, for radiotherapy and SACT, considering the risk-benefit ratio associated with the treatment. NICE guidelines followed, adopting this approach (**NG161**) [**RA/14 INQ000408946**].

18. Dr Andrew Goodall, Director General Health and Social Services, wrote to cancer leads, on 1 April 2020, highlighting the importance that urgent cancer diagnosis, treatment and care continued as well as possible [**RA/15 INQ000227390**]. He advised that the Welsh Government were working with the WCN to produce guidelines to provide a framework within which to make difficult decisions regarding treatment. On 23 April 2020, WCN produced a SACT prioritisation document for solid tumours during Covid-19 [**RA/16 INQ000408948**]. This adopted the priority categorisation definitions from NG161.

19. On 2 March 2020, VCC finalised its own Covid-19 SACT guidance based upon local knowledge and national international discussions, documents, and guidelines (including adoption of the NHS and NICE guidance above regarding the prioritisation of patients for SACT [**RA/17 INQ000408949**]. This guidance was reviewed and updated to reflect experience and further guidance on 24 April 2020 (adopting the WCN guidance above) [**RA/18 INQ000408950**] and 2 December 2020 [**RA/19 INQ000408951**].

20. At national and international level, the consensus was that treatments with low level benefit may need to be avoided, in discussion with the patient. The focus was on reducing the frequency with which patients needed to attend hospital, given the risk of infection and the avoidance of more immunosuppressive treatments. The CRC SST gave specific consideration to the guidance in relation to treatment of CRC patients and formulated a VCC centred document, which was then reviewed and approved by Bronze and Silver command [**RA/20 INQ000408952**]. This internal document provided background information on Covid-19 and recommendations in relation to clinic structure, clinical management and chemotherapy and radiotherapy for CRC, based on our knowledge of Covid-19 risk in this group of patients. The guidance was consistent with the national consensus guidance but was reviewed and approved by members of the Trust's CRC SST.

21. There were some key changes to the treatment pathway made in discussion with colleagues in Wales and the rest of the UK and individually with patients, see SST Business Continuity Plan for Radiotherapy Services during Coronavirus Pandemic **[RA/21 INQ000408953]**, Lower GI Response to the Covid-19 Outbreak guidance paper **[RA/22 INQ000408954]** and SBAR for Locally Advanced Rectal Cancer **[RA/23 INQ000408955]**. **[RA/21 INQ000408953]** was an internal document complied with input from the separate SSTs within VCC. Oncologists from VCC contributed to **[RA/22 INQ000408954]** including Dr Arif, Dr Crosby and myself. The published version, 24 April 2020, was brought together by Oxford Health NHS Foundation Trust colorectal oncologists, led by Dr Muirhead, and had input from a number of oncologists from across the UK, whose names are listed in this document. This document was shared across Wales. **RA/23 INQ000408955]** was a document complied by the CRC SST at VCC.

22. I note the following key changes to the treatment pathway:

a) Long course chemoradiotherapy (**LCCRT**) was changed to short course radiotherapy (**SCRT**) in many but not all patients e.g. for locally advanced rectal cancer the standard of care was for LCCRT followed by imaging at 8 weeks and radical surgery after 8-12 weeks. This was changed to SCRT followed by radical surgery which was delayed for up to 12-15 weeks, in the majority of patients. LCCRT related to 5 weeks of treatment with 25 treatments on 25 different days, whilst SCRT related to 1 week of treatment with 5 treatments on 5 different days;

b) SACT was discussed, in line with NG161, which indicated that; when prioritising patients for treatment we take into account the level of immunosuppression associated with individual treatment and cancer type, and any other patient specific factors. Then, balance the risk of cancer not being treated optimally with the risk of the patient being immunosuppressed and becoming seriously ill from Covid-19;

c) During the relevant period we expedited, led, piloted and commissioned the introduction of DPYD testing for all patients receiving the common chemotherapy drugs containing fluoropyrimidines. DYPD testing evaluates the genes or DNA in an individual that are responsible for metabolising one of the most frequently used classes of chemotherapy drugs (the fluoropyrimidines). There is a natural variation in these genes but 1 in 14 people have a change which indicates a higher risk that the enzyme produced by the gene will metabolise or break down the chemotherapy much more

slowly. Pilot work commenced in April 2020 with the findings later contained within a presentation 'All Wales Medical Genomics Service: DPYD Service' [**RA/24 INQ000409320**]. The blood genetic test enabled us to identify up to 1 in 14 patients about to start chemotherapy who were at significantly increased risk of developing severe toxicities with likely admission to hospital for prolonged periods. Despite the challenges of the Covid-19 period we took this challenging step, to reduce risk to life of patients (predominantly but not exclusively with CRC) and to prevent additional burden on over stretched inpatient services;

d) Depending upon the risk of cancer recurrence after surgery patients are either offered 6 months, 3 months or no adjuvant chemotherapy. Patients who would usually have received 6 months adjuvant chemotherapy were informed about the risk and benefits of reducing to 3 months, stopping or not initiating chemotherapy, after risk benefit analysis on an individual basis. Where appropriate oral therapy was used without the addition of an intravenous drug every three weeks to reduce risk of immunosuppression and exposure of patients to the hospital environment for prolonged intravenous chemotherapy;

e) Capecitabine tablet chemotherapy was dispensed for 2 cycles rather than 1 cycle; with telephone assessment prior to commencement of the second cycle. This reduced the numbers of visits for patients and improved pharmacy dispensing time overall;

f) For patients receiving palliative SACT, risk benefit analysis and discussions with these patients resulted in typical adaptations including:
    i. Third line treatment being stopped or not initiated. Specifically, this related to the use of Lonsurf therapy, which has limited survival benefit and toxicities, including significant neutropenia;
    ii. Chemotherapy was paused. There is good evidence to suggest that patients with metastatic CRC may receive therapy intermittently with treatment breaks without overall detriment in survival. In England some drugs such as panitumumab or cetuximab could not be stopped for longer than 6 weeks without a risk of funding being lost. This was not a problem in Wales where breaks in the use of these drugs had been accepted for many years;
    iii. Non-immunosuppressive therapies were used more frequently where treatment was felt to be required, without delay. This included the use of cetuximab or panitumumab in patients with RAS/RAF wild type

metastatic CRC. Also, approval was given to use of nivolumab immunotherapy for patients with MSI-H tumours and encorafenib and cetuximab for patients with BRAF mutant tumours.

iv. On 3 August 2020, NHS England issued updated guidance relating to interim treatment changes for the Covid-19 pandemic **[RA/25 INQ000408957]**.

1. Allow intermittent treatment with chemotherapy regimens that contain cetuximab or panitumumab to reduce the need for immunosuppressive treatment;
2. Give nivolumab as immunotherapy instead of chemotherapy for the treatment of metastatic colorectal cancer with high levels of micro-satellite instability and/or deficient mis-match repair to reduce the number of admissions and reduce the risk of neutropenia;
3. Option to give encorafenib and cetuximab for BRAF positive metastatic disease instead of chemotherapy to reduce risk of immunosuppression [added 3 August 2020] was administered or immunotherapy was considered, if appropriate.

23. Early on, it was understood that some members of the public and cancer patients were at higher risk from death due to Covid-19 infection, than others. The earliest feature identified was "age". Older patients were more likely to become seriously ill from Covid-19, perhaps because of the comorbidities associated with old age, and, therefore, the age of a patient became a relevant criterion when considering treatment options. Increasingly data indicated that patients with other comorbidities, independent of age, had significant additional risk from Covid-19 such as renal failure, diabetes etc. It also became apparent that not all SACT had the same risk in relation to Covid-19 infection and risk of dying, specifically patients with blood cancers fared worse than those with solid cancers. This was reviewed regularly, and data was shared amongst the clinical team. In the risk benefit discussions with patients the stage of disease and likely curative or palliative outcome were factored into these discussions.

24. In around March/April 2020, we started giving immune-boosting injections (**GCSF**) to selected patients. The recommendation was to give these injections for SACT that has a 10% or higher risk of inducing immune suppression as assessed by "neutropenia" **[RA/26 INQ000408958].** The Trust's clinical management guideline **[RA/26 INQ000408958]** provided specific guidance on systemic therapies in both early and

advanced/metastatic colorectal cancer, based on updated published evidence. Neutrophils are white blood cells that help fight infection. Neutropenia is defined by a reduced level of neutrophils, which is an expected side-effect of many SACTs but also indicates a reduced ability for the patient to fight off infection and therefore a higher risk of sepsis and death. Certain SACT treatments carry a higher risk of immune suppression and treatments such as GCSF (administered by the patient to themselves at home) were used more liberally where these regimens were being used or where a patient had had evidence of immunosuppression in prior cycles of therapy. GCSF injections help speed up recovery of the neutrophil count to permit the next cycle of treatment to proceed. Most SACT regimens used for CRC do not carry a 10% or higher risk of inducing immune suppression.

25. On 11 June 2020, the NHS Wales Health Collaborative in conjunction with WCN and Professor Tom Crosby, produced a framework for the reinstatement of cancer services in Wales during Covid-19 **[RA/27 INQ000353461]**. This document provided a framework from which organisations and services should plan for delivery of cancer services in a safe and effective way acknowledging the further likelihood of services being impacted by Covid-19 surges. The need to minimise harm to patients with cancer, as a result of delayed presentation and reduced access to diagnostic tests, was a particular focus. It was recommended to be used as a service-specific guide and read in conjunction with Covid-19: NHS Principles Framework for Hospitals, published by the Welsh Government, in March 2020.

26. Towards the end of 2020, a revised VCC clinical framework, for defining the clinical model and treatment decision making, was prepared for the second wave of Covid-19 **[RA/28 INQ000408960]**. This document was created to support cancer service delivery at VCC, during the second wave of the pandemic. It took account of lessons learned during the first Covid-19 surge and the subsequent recovery phase. The NICE definitions of patient priority level continued to be used along with the WCN priority matrix for SACT.

27. On 24 December 2021, the WCN produced a SACT delivery and prioritisation during Covid-19 pandemic (solid tumours) interim update in response to Omicron **[RA/29 INQ000408962]**. This document provided guidance for reducing disruption to SACT delivery and prioritisation of SACT when there were workforce shortages, with the subsequent reduced capacity, resulting from the Covid-19 pandemic. It had been developed as a consensus document following a rapid consultation with cancer clinical

teams and was an update to the previous WCN guidance (version 1c from April 2020) [**RA/16** **INQ000408948**). This update recognised the impact of Covid-19 relating to workforce shortages.

Changes outside VCC remit

28. As noted above, the CRC SST provided non-surgical oncology treatment to patients diagnosed and referred to VCS. Due to the impact of Covid-19 there were changes that occurred which I anticipate will have had an impact on diagnosis and treatment separate to the service provided by VCS.

29. Some population-based screening programmes were temporarily suspended. Bowel Screening Wales was one of the screening programmes affected. VCS played no role in relation to this decision or the running of this programme.

30. I understand that colonoscopies for lower GI complaints were also suspended for a period as these were considered aerosol generating procedures. This is a key investigation leading to the diagnosis of CRC. However, these are not investigations which are performed by or at the VCC. I expect that further information could be obtained from the Health Boards with District General Hospitals providing this service.

31. Further, theatre lists for CRC were also impacted upon with surgery being deferred. Again, I expect that further information could be obtained from the Health Boards with District General Hospitals providing this service.

Impact of changes

Referrals and Attendances

32. From March 2020 to February 2021, there were 673 new CRC referrals [**RA/01** **INQ000408940].** This was the same figure as in March 2018 to February 2019. However, the monthly range was 28 to 77, with May 2020 accounting for the low figure in that range. During this year there were 642 SACT referrals and 261 radiotherapy referrals.

33. It is important to note that the referral figures to a non-surgical cancer centre, providing treatments such as radiotherapy and SACT, are not always reflective of the full CRC diagnostic pathway. Specifically, early CRCs targeted through the Bowel Screening Programme, and affected by colonoscopy service provision, are likely to have a smaller

impact on referrals to a centre such as VCC. I might have expected the referral numbers to decrease due to disruption to the diagnostic and surgical pathways, as noted above. However, the referral figures for March 2020 to February 2021 remained the same as the preceding year. Save for a noticeable dip in May 2020, the remaining months were broadly in line with previous years.

34. Referrals to VCS are a composite of SACT and radiotherapy referrals and of patients being treated palliatively (often being diagnosed based of imaging rather than colonoscopic screening) and those being treated with curative intent (most frequently with radiotherapy prior to surgery or with SACT after surgery has been completed). Each of these pathways and referrals was affected differently. For instance, guidance for the use of radiotherapy for rectal cancer (e.g. change from LCCRT to SCRT and its use as a bridging or tumour holding measure whilst surgery was unavailable) would have led us to believe that we would see an increased in radiotherapy referrals but a reduction in the number of attendances for treatment. In the 2 years prior to the relevant period, we had, on average, 18 referrals per month for radiotherapy and this increased to 21 and 23 referrals per month for the first and second 12-month periods within the relevant period. I would note that in the second 12-month period we had seen also seen new evidence from randomised trials recommending an increase in radiotherapy in some patients [**RA/30** **INQ000409321**]

35. The above data is in keeping with the data presented in the Lancet Oncology paper in which English practice is reviewed [**RA/31 - INQ000236234**]. In this paper, there is no data in relation to the overall referrals for SACT. Our data suggests that our overall referrals went from an average of 58 CRC referrals per month, in the 2 years preceding the relevant period, to 56 per month in the first 12 months and then 71 in the second 12-month period within the relevant period. By way of caution, the figures here are relatively small so we have to be careful not to over interpret the data. If we acknowledge that there was a small increase in referrals of 3 and 5 per month in terms of radiotherapy then there would appear to be a small decrease of up to about 10% of referrals for SACT in the first 12 months and a significant increase in the second 12 months. The 10% drop is in keeping with our risk adaption in reducing the use of SACT where Covid-19 risk was high and chemotherapy benefit small, e.g. such as in stage II resected CRC in the more co-morbid population of patients. The increase in the second 12-month period, which notably stretched the service, relates, in some part, to changing practices with more chemotherapy being used up front prior to surgical resection based upon clinical trial data, (see, for example, the Bahadoer et al and the

Conroy et al articles referenced in paragraph 34 above). It is possible that there is an element of stage migration with those who were delayed by the screening programme now being more likely to have a cancer of a stage that required SACT, i.e. stage II and stage IV cancers, along with the return to relatively normal practice in terms of patients with stage II cancers.

36. Over the entirety of the relevant period there were 1,839 CRC referrals. This relates to a monthly mean of 65.68. Again, over this period there were 1,546 SACT referrals and 647 radiotherapy referrals. Therefore, a total of 2,193 with a monthly mean of 78.32.

37. In the first 6 months of the relevant period there was an 8% reduction in SACT referrals compared to the monthly average from the preceding 2 years (289 v 313 per month). This was in line with the SACT guidance document [**RA/19** **INQ000408951**], which indicated avoidance of adjuvant chemotherapy in lower cancer risk and higher Covid-19 risk patients, longer treatment breaks for those receiving palliative SACT and avoidance of later lines of SACT, after first and second line therapies have failed in high Covid-19 risk patients.

38. Therefore, the referral figures for the relevant period showed an increase in referrals. An increase year upon year is to be expected as this would reflect an increase in diagnoses in a growing population and also with the introduction of new treatments options, as new evidence emerges. For example, since the beginning of the relevant period there has been new evidence to suggest an increase in neoadjuvant therapy, prior to surgery, using both SACT and radiotherapy as appropriate, with a resultant increased number of patient referrals and visits.

39. With regard to attendances, I note the following referrals [**RA/01** **INQ000408940**]:

a. March 2020 – February 2021:
    i. Non-oral SACT attendances = 2,943
    ii. Oral SACT attendances = 269
    iii. Radiotherapy attendances = 2,329
    iv. Total = 5,541
    v. Monthly mean = 462

b. March 2021 – February 2022:
    i. Non-oral SACT attendances = 4,211

ii. Oral SACT attendances = 344
iii. Radiotherapy attendances = 3,340
iv. Total = 7,895
v. Monthly mean = 658

c. March 2022 – June 2022 (4-month period only):
i. Non-oral SACT attendances = 1,428
ii. Oral SACT attendances = 118
iii. Radiotherapy attendances = 1,434
iv. Total = 2,980
v. Monthly mean = 745 (pro-rated)

40. Therefore, there was a significant decrease in attendances in the period March 2020 to February 2021. This was a decrease of 22% from the preceding year (monthly mean of 462 whilst it was 595 in the period March 2019 to February 2020). Attendances in relation to all treatments were down in 2020. This data corresponds with my recollection at the time. This was in line with a reduction in the number of radiotherapy fractions from 25 to 5 in most patients (discussed further below) and a switch to oral therapy, or longer treatment breaks. Specifically, colorectal radiotherapy attendance fell by 26% in the first year of the relevant period compared to the 2 preceding years and then recovered in the following year, in keeping with the published English data.

41. Looking at the figures month to month it is evident that there was a dip in radiotherapy attendances in June – August 2020. This is attributed to the fact that there was increased use of hypofractionated radiation therapy as such patients needed to attend far fewer times for their course of treatment, e.g. rather than 25 daily fractions of radiotherapy over a 5-week period, a patient received only 5 fractions over a week. The absolute number of referrals for radiotherapy slightly increased. This increase is likely due to a readjustment of the risk benefit for the use of radiotherapy in patients with rectal cancer, at a time when complex pelvic surgery was considered of significant risk to these patients. Radiotherapy can appropriately be given in some patients, with intermediate and high-risk cancers, with a resultant postponement by 3 months of the time at which surgery then needs to be undertaken.

42. I note that March 2021 to February 2022 saw an approximate increase in attendances of 10% on the 2019/2020 figures (7,895 attendances between March 2021 and February 2022 and 7,134 between March 2019 and February 2020). This again

broadly fits with my recollection that by the beginning of 2021, matters had largely returned to normal, both in terms of SACT and radiotherapy

Remote Access to Healthcare

43. By holding virtual clinics, with telephone and video, we prevented vulnerable patients from attending hospital and being exposed to the risk of Covid-19. For some scenarios and patient circumstances, it was still felt important that patients were reviewed face to face and these continued with appropriate triage occurring as they entered VCC, with optimisation of social distancing, inside and outside the hospital. Clinic rooms in outpatients were cleaned between each patient and PPE was worn as per the most recent national advice.

44. Patients that were referred to VCS would have already received a diagnosis and been informed of the need for treatment, as such it is not expected that patients would be reluctant to engage with the recommended treatment.

45. I recall that patients became scared of attending hospitals, although the level of fear appeared to be lower in relation to visiting VCC as it was seen as a place where we were not focused on treating patients with Covid-19 infection. I understand that symptomatic patients on treatment continued to ring our 24hour hotline with queries and for those that required clinical assessment we were often able to facilitate face to face clinical review in VCC. However, this was not available to all. The alternative location for clinical review remained the District General and University Hospitals and patients appeared to have concerns with attending these sites due to the perceived risk of Covid-19 infection. This, at times, did result in patients delaying or avoiding physical review, there were certainly examples, I recall, of primary care helping in these circumstances with clinical review. Significant use was made of the telephone advice line for patients on treatment at the Trust, although 38.9% of patients who called were not on SACT **RA/32** **INQ000408956]**.

46. The patients seen by the CRC SST were predominantly not inpatients at VCC. Therefore, there was minimal impact on the length of hospital stays caused by Covid-19 amongst our cohort of patients. I was not aware of any difference regarding the length of recovery time.

47. In November 2020, we performed an audit review regarding virtual/remote assessment clinics within the VCS CRC SST over a 2-month period, April to May 2020, and

compared this data to the 2-month period January to February 2020 **[RA/32 INQ000408956].** In the earlier period, there were 7 virtual/remote consultations and 349 face-to-face consultations for 180 patients. This changed significant in the April/May 2020 period during which there were 231 virtual/remote consultations occurred, with 17 face-to-face consultations, for 150 patients.

48. Towards the end of 2020, approximately 50% of CRC SST clinics remained virtual **[RA/33 INQ000408963]**. A patient questionnaire was undertaken by the Trust with responses from 61 patients (with a number of cancer types) to evaluate their experiences with virtual assessment, during the relevant period **[RA/34 INQ000408964]**. These results indicated that all rated it between 6 and 10 on a scale of 1 being bad and 10 being excellent, with 49% rating as a 10 (excellent). Patients particularly liked a number of features including: less risk of COVID exposure (47%), more flexible (48%), less stressful (28%) and reduced waiting times (31%). Although there was a phased return to more face-to-face consultations, given the feedback from some patients certain features are maintained even now where this enhances patient experience.

49. Oral SACT could be delivered to a patient's home, again avoiding the need for that patient to travel to hospital to collect this.

50. There was still the need for many patients to attend hospital for treatment. The repatriation of services to VCC had a huge impact on staffing given the additional workload. Further, it is accepted that this will have required certain patients to travel further. However, this was considered necessary to secure sustainable services within the District General Hospitals and to ensure patient safety at the time.

51. Once chemotherapy suites reopened, patients were able to obtain treatment nearer to their homes. However, I recall even when the chemotherapy suites did reopen, there was initially limited capacity. Even by January 2021, VCS continued to take a significantly greater number of patients as day cases than prior to the pandemic due to limitations with outreach capacity **[RA/35 INQ000408998]**. For example, the weekly number of chairs for SACT administration, in December 2019, were split 105 VCC / 81 outreach clinics, whilst, in January 2021, the split was 152 VCC / 34 outreach clinics.

52. Shielding was important for immunocompromised patients. Advice was provided by the Welsh Government regarding shielding for vulnerable people. I was not aware of any issues regarding this advice, and this did not impact on our ability to treat CRC patients. Notably, we gained significantly in our discussions by offering all patients Covid-19 vaccination at VCC when these vaccinations became available for priority groups including cancer patients. The relevant vaccination clinics used the Trust triage system and outpatients department staffed by the Trust's staff volunteers at the weekend.

Treatment delays / change in treatment

53. I cannot comment on other tertiary centre or secondary care hospitals regarding cancellation, delay or de-escalation of non-surgical treatment for CRC.

54. I have not seen any data regarding whether there was an increase in CRC patients requiring more complex or advanced treatment at VCC, although I anticipate that this will have been the case, given the need for temporary suspension of the bowel screening programme and the issues with undertaking colonoscopies and surgery. This data would be accessible in evaluation of migration of pathological and MDT staging of cancers and through surgical data from Health Boards. Notably data has been published for Wales demonstrating a reduction of diagnoses during this period, however this is not data collated by the Trust who only have access to patients requiring non-surgical treatment [**RA/36 INQ000328592**]. Regarding the exhibited article, I note the following:

a. The publication indicated a reduction in colorectal cancer diagnoses across Wales, with a reduction across all stages, although it acknowledged that there was a significant increase in the number of diagnoses without a documented stage;

b. The data indicated that the number of patients diagnosed as emergency presentations did not significantly decline (this being a group of patients that ultimately are likely to be referred for additional specialist oncological intervention);

c. There was a 19.9% reduction in urgent colorectal cancers by the urgent suspected cancer pathway, as referrals from GPs, which represents a group that are more likely to need input from the VCC;

d. The article ended indicating that the authors could not conclude from this current study that a shift to a later stage at diagnosis occurred in the true population cancer incidence during 2020, as many cases remained undiagnosed. Instead, they observed a decrease to various extents in all stages of colorectal cancer. It is also notable that those cancer patients at a late stage may have died without being diagnosed, as predicted by modelling studies and it is also suggested that this group of patients are not deemed fit for palliative SACT but are referred directly into palliative care services, so would not be represented in the usual VCS figures.

55. Waiting times for radiotherapy were not affected by Covid-19. In part this may have been due to the adoption of SCRT, which required fewer attendances and therefore permitted greater capacity. There remains uncertainty in the clinical community globally about the optimum strategy of SCRT or LCCRT and both remain reasonable options, however, many clinicians, including in VCC, have subsequently returned to use of the LCCRT approach. There remains an increase in SCRT use based upon new clinical data that was reported and published during the pandemic period. Spencer et al 2021 concluded "Radiotherapy activity fell significantly, but use of hypofractionated (SCRT) regimens rapidly increased in the English NHS during the first peak of the COVID-19 pandemic. An increase in treatments for some cancers suggests that radiotherapy compensated for reduced surgical activity" **[RA/37 INQ000408967]**.

56. I am aware of the research conducted and published in The Lancet on the 'Impact of the Covid-19 pandemic on the detection and management of colorectal cancer in England: a population based study', March 2021 [**RA/38 INQ000236234**]. This paper considered a reduction in the number of patients referred with suspected cancer, diagnosis of CRC and surgery. Although the conclusions largely correlate from my understanding of issues at the time, these are all matters outside the remit of VCS as a tertiary unit providing non-surgical oncology treatment to known CRC patients. The only aspect, which we had control over, that is relevant to this study, relates to radiotherapy. We made use of shorter fractionation, in line with the ESMO guidance. All other aspects were within the remit of external partners for which we do not hold data. As noted above, there is Wales specific data which suggested a lower number

of diagnoses, but this was not highly borne out by the referrals to VCS [**RA/37 INQ000408967**].

57. There was a time, towards the end of the relevant period, in 2022, when there was a delay regarding commencement of treatment with SACT of approximately 6-8 weeks. This did not indicate that all patients waited 6-8 weeks but instead related to a higher proportion of patients experiencing delays of 6-8 weeks. Rather than relating to concerns regarding Covid-19 and patient safety, which had been the key focus at the beginning of the pandemic, this was due to staff shortages and also the impact of increased referrals, across the VCS. Although not directly involved in mitigating this delay myself, I am informed that a number of options were considered at this time to try and address this issue, including the use of private services, as discussed further below. I understand that this issue was successfully addressed by way of a combination of:

a. The establishment of a task and finish group to support the establishment of a Saturday Daycase Service for the delivery of immunotherapy agents from August to October 2022;

b. The full reopening of the Macmillan Unit at Prince Charles Hospital, which enabled up to a maximum of 13 additional patients per day to be treated.

58. VCS and the CRC SST were aware, regarding concerns of inequalities, of the difficulties of providing tailored, optimal treatment strategies during the Covid-19 pandemic. Actions were taken in the best interests of the individual patient, considering the guidance and the emerging evidence on Covid-19 and its impact, especially on patients receiving treatment with toxic side-effects. It is appreciated that age and certain comorbidities such as renal failure and diabetes were criterion which we considered relevant when discussing the risk/benefit ratio with patients and recommending treatment, which had not previously been given such weight.

Utilisation of Resources from Private Healthcare

59. On 27 May 2022, approval was received to utilise Rutherford Cancer Centre (**RCC**), which was part of the Rutherford Group, private healthcare provider.

60. The service was due to start on 9 July 2022. This was an interim solution to increase SACT daycase capacity whilst VCS secured additional staffing recourses [**RA/39** **INQ000408968**].

61. It was intended that some patients, including colorectal cancer patients, would be moved from VCS daycase to RCC for SACT to free up capacity at VCC and enable more new patients to be treated at VCC. VCS would still maintain clinical responsibility for all patients.

62. However, this service never commenced. The plans were put on hold on 2 June 2022, and I understand that the RCC went into liquidation [**RA/40** **INQ000408969**].

63. Other than the foregoing, which proved to be unsuccessful, I am not aware of any other attempt to utilise private healthcare resources for treatment of VCS's CRC patients during the relevant period. As far as I am aware, the private healthcare sector did not impact on the provision of care and treatment by the Trust of CRC patients during the relevant period.

Concluding Remarks

64. Despite the considerable challenges imposed by Covid-19, I consider that we continued to provide a compassionate and caring service to our patients. By repatriating clinics to VCC we sought to create a safe environment for patients to attend whilst reducing pressure on other hospitals which we anticipated would be seeing a surge of infected patients. The prompt shift to virtual/remote clinics was to protect our patients and our workforce. However, from auditing (which continued despite the pandemic) we noted other advantages relating to the use of technology. We learned from this experience and this has led to the adoption of changes in the service we provide to this day.

65. We have always benefitted from a collaborative approach with other cancer services, both within Wales and further afield, and this was invaluable during the relevant period. We all gained from shared experiences, especially at a time of significant change. We sought to provide leadership and continued to innovate with programmes, such as the DPYD testing and the administration of Covid-19 vaccinations to patients registered under our care, using the outpatients department at VCC at weekends.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: .....Personal Data.....

Dated: 7th February 2024