34% of patients have had at least one sample used in a research project.
## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbreviations</td>
<td>i</td>
</tr>
<tr>
<td>Figures and Tables</td>
<td>ii</td>
</tr>
<tr>
<td>Aim</td>
<td>1</td>
</tr>
<tr>
<td>Director’s report</td>
<td>2</td>
</tr>
<tr>
<td>2013/2014 targets</td>
<td>3</td>
</tr>
<tr>
<td>Recruitment</td>
<td>3</td>
</tr>
<tr>
<td>Cancer delivery plan</td>
<td>6</td>
</tr>
<tr>
<td>Governance</td>
<td>7</td>
</tr>
<tr>
<td>Ethics submission</td>
<td>7</td>
</tr>
<tr>
<td>Annual report to REC</td>
<td>8</td>
</tr>
<tr>
<td>Audit précis</td>
<td>9</td>
</tr>
<tr>
<td>Pathology and follow up data reviews</td>
<td>10</td>
</tr>
<tr>
<td>Lay liaison and ethics group</td>
<td>11</td>
</tr>
<tr>
<td>Scientific Report</td>
<td>12</td>
</tr>
<tr>
<td>Applications and Supply of biomaterials</td>
<td>15</td>
</tr>
<tr>
<td>Applications received</td>
<td>15</td>
</tr>
<tr>
<td>Change of review process</td>
<td>16</td>
</tr>
<tr>
<td>Supply of samples</td>
<td>17</td>
</tr>
<tr>
<td>CRUK stratified medicine programme</td>
<td>19</td>
</tr>
<tr>
<td>Information Technology</td>
<td>20</td>
</tr>
<tr>
<td>Clinical Trial hosting</td>
<td>24</td>
</tr>
<tr>
<td>Marketing</td>
<td>26</td>
</tr>
<tr>
<td>Researcher survey</td>
<td>26</td>
</tr>
<tr>
<td>Previous user survey</td>
<td>28</td>
</tr>
<tr>
<td>Conferences</td>
<td>29</td>
</tr>
<tr>
<td>Looking Ahead</td>
<td>30</td>
</tr>
<tr>
<td>2014/15 targets</td>
<td>31</td>
</tr>
<tr>
<td>Financial Statement</td>
<td>32</td>
</tr>
<tr>
<td>Appendices</td>
<td>40</td>
</tr>
<tr>
<td>Appendix A - WCB Personnel list</td>
<td>40</td>
</tr>
<tr>
<td>Appendix B - Courses attended</td>
<td>42</td>
</tr>
<tr>
<td>Appendix C - 2013 Audit Report</td>
<td>44</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
<tr>
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<tr>
<td>BBMRI</td>
<td>Biobanking and Biomolecular Resources Research Infrastructure</td>
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<tr>
<td>CaNISC</td>
<td>Cancer Network Information System Cymru</td>
</tr>
<tr>
<td>CCB</td>
<td>Confederation of Cancer Biobanks</td>
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<tr>
<td>CHC</td>
<td>Community Health Council</td>
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<tr>
<td>CRUK</td>
<td>Cancer Research UK</td>
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<tr>
<td>CRW</td>
<td>Cancer Research Wales</td>
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<tr>
<td>DNA</td>
<td>Deoxyribonucleic acid</td>
</tr>
<tr>
<td>EDTA</td>
<td>Ethylenediamine tetraacetic acid</td>
</tr>
<tr>
<td>ELSI</td>
<td>Ethical, legal and social issues</td>
</tr>
<tr>
<td>FAP</td>
<td>Fibroblast Activation Protein</td>
</tr>
<tr>
<td>FFPE</td>
<td>Formalin fixed paraffin embedded</td>
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<tr>
<td>HGF</td>
<td>Hepatocyte Growth Factor</td>
</tr>
<tr>
<td>ISBER</td>
<td>International Society for Biological and Environmental Repositories</td>
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<tr>
<td>IT</td>
<td>Information Technology</td>
</tr>
<tr>
<td>LHB</td>
<td>Local Health Board</td>
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<tr>
<td>LLEG</td>
<td>Lay Liaison and Ethics group</td>
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<tr>
<td>MAPK</td>
<td>Mitogen Activated Phospho Kinase</td>
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<tr>
<td>NCRI</td>
<td>National Cancer Research Institute</td>
</tr>
<tr>
<td>NGS</td>
<td>Next Generation Sequencing</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>NISCHR</td>
<td>National Institute for Social Care and Health Research</td>
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<tr>
<td>NSCLC</td>
<td>Non-Small Cell Lung cancer</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>RCPath</td>
<td>Royal College of Pathologists</td>
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<td>REC</td>
<td>Research Ethics Committee</td>
</tr>
<tr>
<td>RNA</td>
<td>Ribonucleic acid</td>
</tr>
<tr>
<td>SAIL</td>
<td>The Secure Anonymised Information Linkage databank</td>
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<tr>
<td>SMP</td>
<td>Stratified Medicine Programme</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>TMA</td>
<td>Tissue Microarray</td>
</tr>
<tr>
<td>TNB</td>
<td>Triple Negative breast cancer</td>
</tr>
<tr>
<td>UHW</td>
<td>University Hospital of Wales</td>
</tr>
<tr>
<td>WCB</td>
<td>Wales Cancer Bank</td>
</tr>
<tr>
<td>WCTU</td>
<td>Wales Cancer Trials Unit</td>
</tr>
</tbody>
</table>
FIGURES

Figure 1  Annual recruitment by year  Page 5
Figure 2  Consent by age and gender  Page 5
Figure 3  Prospective v Retrospective consents  Page 5
Figure 4  Number of biosamples sourced by tumour type  Page 5
Figure 5  Consent as percentage of incidence by LHB of residence  Page 6
Figure 6  MAPK signalling pathway  Page 7
Figure 7  Percentage of cases of colon cancer with positive mutations in the key genes  Page 8
Figure 8  Kaplan Meier survival curve by BRAF mutational status  Page 9
Figure 9  Kaplan Meier survival curve by PIK3CA status  Page 9
Figure 10 Applications received by year  Page 10
Figure 11 Sample types supplied  Page 11
Figure 12 SMP transition phase data  Page 12
Figure 13 SMP Phase 2 progress  Page 13
Figure 14 Unified pathology report data entry screenshot  Page 14
Figure 15 Iconsent screenshot  Page 15
Figure 16 Forecast patient recruitment to April 2015  Page 16

TABLES

Table 1  3 year rolling consent averages by Local Health Board  Page 6
Table 2  SMP Phase one data  Page 7
Table 3  Ratings for sample application process and supply by researchers based in Wales  Page 18
Table 4  Ratings for sample application process and supply by researchers based outside of Wales  Page 20
Our Aim

“

To provide a population based resource of tissue and blood samples from all patients in Wales, who are undergoing an operation to remove tissue where cancer is a possible diagnosis, for future research into cancer.

“
Ten years, and ten thousand patients later...

As I write this, we are preparing for the special meeting and the scientific symposium to celebrate the 10th anniversary of the Wales Cancer Bank, and it seems appropriate to reflect on what has been achieved, and on the future. To have consented 10,000 patients is an awesome, and a humbling experience, which reflects the importance that our patients attach to the work we are doing. Around one-third of patients have already had their samples used in research. That does not mean that their contribution is used up - on the contrary, because we ‘aliquot’ our samples, in other words, because one patient’s donation will be divided into many samples (sometimes 20 or 30), we will be able to re-visit that patient’s tumour again in the future. I am confident that, one day, all of our samples will have been used in research.

Our reputation in the UK and internationally has also been very high. The Wales Cancer Bank has been selected as the host organisation to manage samples taken in many clinical trials across the UK. The most notable of recent trials is the ‘Add Aspirin’ trial, for which the Wales Cancer Bank will be one of two centres hosting samples. Our role in the Cancer Research UK Stratified Medicine Programme has been reported on previously, and this continues.

All of this is good, but like all organisations, we face our challenges, especially in the current climate. As the project grows, the task of keeping the data - including the patient data - up to date becomes increasingly challenging. As the number of requests to use our samples increases, so does the challenge of processing them and providing them in a timely manner.

Cancer science is also changing, and so must we. Thanks to the generosity of Cancer Research Wales, we have embarked on a programme of molecular analysis of our samples. This will be a challenging and complex exercise, but as many new drugs appear in clinical trials, it is also becoming important to acquire and use up to date data if a patient’s treatment is to be decided based on their cancer’s molecular characteristics - which can change substantially over the course of an illness. In some instances, especially in breast cancer and colon cancer, it is becoming common practice to biopsy or to remove some areas of recurrent or secondary (metastatic) tumours, and we should be able to store and to supply these types of samples for research. I believe that this will be one of our greatest challenges over the next 5 years, but with the support of our funders, especially the Welsh Government and Cancer Research Wales, I also believe that we can rise to that challenge. We are proud to be regarded as the flagship project for Cancer Research Wales, and we will do all we can to ensure that they continue to regard us in the same vein.

Most of all, and as ever, our thanks to our patients, all 10,000 of them, for whom we are doing this, and without whom none of this would be possible.

Professor Malcolm Mason
Director, Wales Cancer Bank
TARGETS FOR 2013/14

<table>
<thead>
<tr>
<th>TARGETS FOR 2013/14</th>
<th>ACHIEVED</th>
</tr>
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<tr>
<td>Accrue 9,775 patients in total</td>
<td>January 2014</td>
</tr>
<tr>
<td>Survey cancer researchers in Wales</td>
<td>November 2013</td>
</tr>
<tr>
<td>Complete pathology data audit and implement new database pages</td>
<td>September 2013</td>
</tr>
<tr>
<td>Implement online sample search facility</td>
<td>September 2013</td>
</tr>
<tr>
<td>Supply five new projects with biosamples</td>
<td>March 2014</td>
</tr>
</tbody>
</table>

OFFICE MOVE

In February 2014, the central administrative office of the Wales Cancer Bank relocated. The office is now situated in the main building of the University Hospital of Wales on the second floor. Email addresses remain the same but the office address and new phone numbers are below:

Wales Cancer Bank
Cardiff University
Room 273, B-C link corridor
2nd Floor
UHW Main Building
Heath Park
Cardiff, CF14 4XN

Tel: 029 20743243
Fax: 029 20744309

RECRUITMENT

1,836 patients were consented in the last twelve month period, 399 of those were consented retrospectively in oncology clinics in Velindre. Figure 1 shows the annual recruitment figures by geographic collection site from April 2006 to April 2014, giving a total of 10,031 patients consented. The consenting figures are slightly lower than the previous twelve months as there was considerable focus on data cleansing and ensuring all follow up data was current and the integration of the new pathology reporting structure required hundreds of records to be manually updated to reflect the new categories.

The gender and age profile of donors remains constant at 53% female donors and 76% of all donors are aged 61 or above. The percentage of patients consented post operatively has risen from 12% to 20% which reflects the continued consenting in Velindre, whilst staff in the other centres reduced consenting to focus on the data collection and cleansing. The largest number of consents come from breast patients (23%), with colorectal (17%), prostate (14%), kidney (8%) and lung (7%) the next largest. The lung consents have increased over the last year with the emphasis on late stage lung patients for phase 2 of the Stratified medicine project. The profile of samples currently held in the bank for tumour types with more than 75 associated donations (plus the total percentages for all tumour types collected) is shown in figure 4. This shows the percentage of donations,
10,031 patients in Wales have consented to donate samples to the Wales Cancer Bank
by tumour type, for which the bank holds each type of biosample. The total number of donations varies and is shown on the x axis with the tumour type. For example, 781 kidney patients have consented and 80% of those donations have FFPE tumour tissue, 64% have a whole blood sample, 62% have a serum sample and 32% have a frozen tissue block associated with the donation.

Figure 1 Annual recruitment by year

Figure 2 Age and gender of donors

Figure 3 Prospective v retrospective consents
CANCER DELIVERY PLAN

The Welsh Assembly’s Cancer Delivery Plan (2012) included research targets, one of which was to increase consent rates to the WCB. The Local Health Boards were given a target of consenting 20% of cancer patients by 2016. When the initial benchmarking exercise was carried out it showed the all Wales average consent rate was 7% (see table 1).

These figures used the hospital of consent as the numerator with the annual incidence of cancer in each LHB as the denominator. The incidence figures did not include under 18s (as WCB only consents adults) or figures for haematological cancers (as WCB does not approach these patients).

<table>
<thead>
<tr>
<th>2009-2011 ROLLING AVERAGE CONSENT PERCENTAGE</th>
<th>LOCAL HEALTH BOARD</th>
</tr>
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<tbody>
<tr>
<td>14.1</td>
<td>Abertawe Bro Morgannwg</td>
</tr>
<tr>
<td>4.0</td>
<td>Aneurin Bevan</td>
</tr>
<tr>
<td>2.6</td>
<td>Betsi Cadwaladr</td>
</tr>
<tr>
<td>10.4</td>
<td>Cardiff and Vale</td>
</tr>
<tr>
<td>0</td>
<td>Cwn Taf</td>
</tr>
<tr>
<td>5.8</td>
<td>Hywel Dda</td>
</tr>
<tr>
<td>0</td>
<td>Powys</td>
</tr>
<tr>
<td>7.0</td>
<td>ALL WALES</td>
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</table>
Subsequent data has been prepared using the LHB of residence of patients consented as the numerator to more accurately reflect the patient demographic. This shows that patients from LHBs with no WCB funded activity have been consented during visits to hospitals outside their LHB. The all Wales total percentage for 2013 was 14%, with Cardiff and Vale at 38%.

These figures only represent the number of patients consented to the bank. Not all consents will have samples associated with them, especially if the patient is consented retrospectively. This depends upon tissue availability from the originating histology department and the ability to take a blood sample at the time of consent.

Figure 5  Consent rate as % incidence by LHB of residence

GOVERNANCE
ETHICS SUBMISSIONS

Between 1 April 2013 and 31 March 2014, the Wales Cancer Bank submitted two substantial amendments to the Research Ethics Committee for Wales. One of these was to streamline the application process and further information can be found in the Applications Received section. The other was to introduce a xenografting specific supplemental patient information sheet and consent form. A successful amendment to ethics in March 2013 made it possible for the WCB to supply fresh tissue to research groups with the intention of the tissue being used for xenografting projects and to comply with Human Tissue Authority regulations, supplemental information and consent must be in place for patients whose tissue may be used for xenografting.

Xenografting is the transplantation of tissue or organs from one type of animal to another. This approach is already used to treat diseases in humans, such as the use of pig heart valves in patients with heart disease. In cancer research, xenografting involves inserting some
As part of the research tissue bank conditions of approval from the REC for Wales, an annual report detailing the applications made for samples during the previous twelve months and also the projects supplied with samples was submitted in October 2013. The report showed the name and institution of the applicant, the number and type of the samples requested and supplied and the date on which the application was received and fulfilled.

ANNUAL REPORT TO REC

cancer cells from a human tumour into a mouse to grow a replica tumour that behaves in a similar way to the cancer in the patient. Mice have been used for many years to study cancer, but there is often a gap between how a mouse tumour behaves and how a human tumour behaves. To reduce that gap and produce a more accurate model for cancer research, xenografting has been developed as an alternative method. Xenografts have been shown to mimic the human tumours from which they come more closely than other types of models, for example, cells grown in a dish in the lab. Xenograft models have already been used to investigate new cancer drug targets and to work out which drugs are most effective against cancers.

These supplemental information sheets and consent forms will only be used when it is known that fresh tissue may be collected from that patient’s donation for a xenografting project. The patient is able to consent to routine WCB collection and decline the use of their samples in the xenografting project if they wish.
AUDIT PRÉCIS

The 2013 audit of all collection centres took place in October and November 2013. The full audit report can be found in the online version of this annual report on the WCB website (www.walescancerbank.com). Generally, most sites are performing well and adhering to standard operating procedures. There are some issues regarding shipments and logging samples out correctly for movement or QA. Clear workflows must be in place for those sites where paperwork has to move between sites to ensure the exact location of paperwork is known at all times.

ACTIONS

To be implemented centrally:

- Draft action points outstanding from audit and circulate to all sites.
- Create a REC status sheet for file comparison and send it as a document log to all sites.

To be implemented at sites:

- Address action points circulated by Central Office and send a report within 4 weeks of receipt detailing that issues have been addressed and in what way.
- Treatment and outcome data should go onto a WCB standardised follow up sheet and transferred onto the database.
- Database records must be updated following QA and labels reprinted accordingly.
- ALL sample movement must have a document trail as per WCB SOPs in conjunction with the electronic shipment process within the WCB database.

Any outstanding issues identified at audit are to be rectified within one month and a report sent to the central office to show how issues were corrected with related timescales.
PATHOLOGY DATA AUDIT AND REVIEW/ FOLLOW UP DATA

In order to more accurately group and record the histology data collected and input into the WCB database a complete review was undertaken during 2013. This required a lengthy process of consultation to select the most common diagnoses categories for each malignant and non-malignant tumour type. An automated mapping exercise of the old categories to the new resulted in several hundred records that needed manual review to ensure they were correctly categorised and it gave an opportunity to audit the data transcription from the pathology report to the database.

From both of these audits and reviews, several issues were raised that were addressed at the face-to-face staff meeting in December 2013, some of which required changes to be made to the database:

• additional information fields on the database for cause of death to clarify if the cause of death was cancer related, if it was the cancer episode for which WCB held tissue or whether it was another malignancy.
• pathology reports must be checked to ascertain whether there was previous malignancy to which the report is linked.
• the first follow up data gathering exercise must review the clinical data prior to WCB consent to clarify the point of entry on the patient pathway to ensure samples are entered correctly as primary or metastatic.
• biochemical relapses to be recorded separately for prostate, ovarian and thyroid cancers.

In November there were 1,025 records that required follow up review and 398 for pathology review. By the end of March this had reduced to 243 follow up reviews and 157 pathology reviews and a target is in place to complete all reviews by the end of April 2014.
LAY LIAISON AND ETHICS GROUP (LLEG)

The year 2013-2014 has seen significant changes in the group with Mr Bob Hall taking over as chair in 2013 following the death of Neil Formstone. Bob brings a great deal of experience of the health service, especially patient involvement in cancer provision. He has been the vice Chair of the Wales board of Community Health Councils (CHC), Chair of Gwent CHCS, Chair of the Cancer Coordinating Group patient forum and the South Wales patient group, and a member of the Wales Research Ethics Committee 1 ethics panel. There are now 12 patient and carer members on the committee, including three new members this year; Stephen Thomas, Sue Campbell and Dr Sheena Vacheena.

In July 2013 the group had the opportunity to inform guidance being drafted in Holland regarding engaging with patients and public for the Dutch BBMRI biobanking infrastructure. A researcher from Nijmegen, Martin Boeckhout, aimed to explore how various forms of patient and public engagement should be institutionalised into the governance of biobanks and he travelled to Cardiff to conduct interviews with WCB staff and members of the Lay Liaison and Ethics group. He conducted a number of in-depth case studies of best practices in the field and was of the opinion that the Wales Cancer Bank stood out in this respect. He learned about the background and history of patient engagement in the WCB as well as the impact it has had on the operation and governance of the WCB over the last ten years.

A conference hosted by the South Wales patient network at Margam Park in September 2013 was attended by around a hundred people, including members of LLEG, with the Minister for Health and Social Services Mr Mark Drakeford, AM as the keynote speaker. The conference gave the opportunity to raise the profile of the Wales Cancer Bank and Suzanne Dolphin gave a potted history of the Cancer Bank and also opened up a debate about whether it was appropriate for lay, volunteer people to consent for tissue banking. There was a consensus that consenting by research nurses was the preferred way. Two of the other LLEG members gave accounts of their cancer journeys and why they both consented for their blood and tissues to be used by the bank.

Exploring the various ways of taking consent and how they could make the bank more effective has been discussed at length in the LLEG meetings. In November one of the LLEG members, Brian Burt, travelled to Nottingham with the lead WCB nurse, Suzanne Dolphin, and the WCB manager, Dr Alison Parry-Jones to observe an example of volunteer consenting at the Nottingham Health Science Biobank. They were able to observe one of the volunteers taking consent from patients in a breast clinic and were given an overview of the volunteer recruitment process, training package and review process. A positive report was fed back to the LLEG group with the cautionary note that patients consented for WCB may potentially be in a more vulnerable state than the general clinic patients approached in Nottingham and careful consideration should be given to any potential implementation in WCB.

The WCB IT manager, Daniel Naeh, also gave a presentation to the group of how electronic consenting could work using mobile, tablet devices. The consensus of the group was that, although some elderly patients may not be comfortable with the technology, technological advances such as this should be integrated into the working practices to keep pace with advances.

One of the changes to the sample application process has requested that a sub group of the LLEG committee become involved in reviewing the applications. Members will scrutinise the lay summary provided by researchers to ensure it is in plain language that would be understandable to the general public. Researchers will not receive samples until a satisfactory lay summary is appended to the application.

The activity over the last year and the upcoming events have shown how patient representatives can get involved, feel valued and provide valuable guidance to projects, such as WCB. It has been an exciting year and the members of LLEG are looking forward to the 10th anniversary celebrations in June 2014 and are also looking forward to next year with anticipation and hope to see the bank celebrate another ten years of life.
Many patients with cancer are treated satisfactorily with surgery, radiotherapy with sometimes the addition of chemotherapy. The focus of cancer research now concentrates on those patients who need more tailored treatment using drugs that target particular pathways that make cancers more aggressive. However, using these new drugs as single agents has been disappointing, suggesting that we do not fully understand the role that these targets play in cancer development. Cancer is a diverse disease and targeting of treatment in the future is likely to require an understanding of how the various molecular targets we have identified work together or against each other. In a proportion of cancers, none of the common targets are identifiable, suggesting that other changes have occurred, in molecules that might themselves become novel targets in the future. These patients would possibly benefit from drugs aimed at these novel targets, once they have been identified.

One aim of the WCB is to identify the proportions of breast, urological, gynaecological, lung and head and neck tumours in the WCB that have the common targets for the new cancer drugs, and to identify the small, but significant number where new targets are still to be identified. The presence of these drug targets will also be linked with clinical presentation and outcome. This will help to identify, in the future, which patients can be treated appropriately with conventional cancer therapy and which should be selected for tailored treatment, using more expensive diagnostic tests and treatment regimens.

One of the key pathways that controls division in many types of cancer cells is the Mitogen Activated Phospho Kinase (MAPK) Pathway. Normally the activity of the MAPK pathway is controlled by an external factor, called a growth factor which binds to a receptor on the surface of the cell (the blue box in Figure 6) causing activation.
of the MAPK pathway. This means that the cell can be stimulated to divide when more cells are needed, but division can be switched off by turning off the supply of the growth factor. The changes in the DNA sequence (mutation) of key genes which occurs in cancer switches the genes to “on” and results in the MAPK pathway being continually activated in the absence of the external controller of the pathway. This means cell division is no longer under its normal external control that would restrict cell division. Clinical trials have already shown that mutation of BRAF and KRas genes desensitisces colon cancers to the effects of drugs that block the Epidermal Growth Factor Receptor, one of the key external growth factors for colon cells.

In addition, there is some new evidence that suggests that presence of a mutation in PI3KCA can indicate that addition of aspirin to treatment regimes for colon cancer may increase survival. Working with the Wales Gene Park, we have used a technique called polymerase chain reaction to amplify sections of DNA from cancer cells from 407 patients with colon cancer, and then to sequence the amplified DNA to look for base changes in 4 important genes in this pathway; BRAF, two forms of the Ras gene (KRAS and NRAS) and PI3KCA (these are circled in Figure 6). In the majority of cases, we were able to study all 4 genes. In a small minority of cases, there was either insufficient DNA available from the sample for all genes to be studied, and, rarely, the quality of the DNA was too bad for the techniques we used to work.

Pathologists use a system called the Dukes system, based on morphological characteristics and the how far the cancer has invaded the gut wall to divide colon cancer patients into different groups. The groups are called Dukes A, B, C1, C2 and D, with D being the highest stage and therefore the group with the worse prognosis. In our initial analysis we have looked at whether the Dukes stage correlated with the mutation in these key genes and whether the presence of an individual mutation correlated with patient outcome (see Figure 7).

Figure 7 shows that KRAS is most commonly mutated in our samples, and that BRAF mutation showed a strong correlation with Duke’s stage. The presence of BRAF mutation also showed a negative correlation with survival (see Figure 8), suggesting that BRAF mutation may drive factors such as invasion that relate to increasing Duke’s stage.

Mutations in PI3KCA commonly occur in two different parts of the gene, called exon 9 and exon 20. Our results show that mutation in exon 9 are more common in Dukes stage A, whereas no mutation in exon 20 were found in Duke’s stage A.

As expected, there patients with an exon 9 mutation live longer than those with an exon 20 mutation (see Figure 9), as they are likely to have a lower stage tumour. However, the presence of either mutation has a significant negative effect on outcome.

In just under one third of cases (31%) no mutation in any of these key genes could be identified. Further studies using techniques that allow identification of unknown mutations would be needed to identify targets for cancer therapy in these patients.

Key genes in the MAPK pathway are currently being investigated in other cancer types, using a new method, called Next Generation Sequencing, which enables very small amounts of DNA to be used to identify many different mutations in different genes at the same time. Colleagues at the All Wales Genetics Service have already validated the new technique using DNA from the colon cancers in this study. The work carried out here was funded by Cancer Research Wales (CRW) and has helped to develop the capability to identify potential therapeutic targets in cancers from Welsh patients, this offering the potential of stratified medicine for patients in Wales in the near future.
Figure 7: The percentage of cases of colon cancer that are positive for mutation in the key genes PI3KCA, KRAS, NRAS or BRAF.

Figure 8: A graph called a Kaplan Meier plot that shows what proportion of the patients are still alive over time. The top line on the graph shows survival time for patients that do not have a BRAF mutation, and the lower line the survival time for patients who do have a mutation. The presence of the mutation has a significant negative effect on survival. The results are stratified on Dukes stage.

Figure 9: A graph called a Kaplan Meier plot that shows what proportion of the patients are still alive over time. The top line on the graph shows survival time for patients that do not have a PI3KCA mutation, and the lower two lines the survival time for patients who do have a mutation in exon 9 (middle line) and exon 20 (lowest line). The presence of the mutation has a significant negative effect on survival.
APPLICATIONS AND SUPPLY OF BIOMATERIALS

During the period 1st April 13 - 31st March 14, 10 applications for biosamples were received by the WCB, taking total number of research project applications received since 2006 to 72, of which 62 have been approved. Applications received during this reporting period were 3 from Cardiff University, 1 from Velindre Cancer Centre, 1 from GE Healthcare, Cardiff, 1 from University of Bristol, 2 from Spain, 1 from Merck in Germany and 1 from Switzerland.

Of these 10 applications, 7 were approved and 3 have been asked to supply further information by the review panel before a final decision whether to approve or not can be given.

3 applications were for breast tissue, 2 were for prostate tissue, 1 for metastatic colorectal, 1 for a TMA created from head and neck samples and 3 applications for combined tissue type consisting of 1 for metastatic melanoma and colorectal tissue, 1 for pancreas and lung and 1 for bladder, prostate and breast.
A review of the time from application to the date of supply of samples showed the average time was unacceptably high and an evaluation of all steps of the process was undertaken. As expected the projects that took the longest time to supply were those requiring DNA or RNA or large numbers of samples of specific quality. This highlighted the backlog of samples without quality assurance data at the time of procurement and, as no samples will be issued without known QA data, the need to acquire this data prior to issue extended the time taken to fulfil sample requests. However, the application review process itself was identified as too cumbersome so a streamlined process was successfully submitted to ethics to attempt to reduce the time taken. The review panel is an international group of 8 experts who scrutinise all applications for samples.

The new process now requires a single reviewer (instead of the project being sent to all reviewers) to critique and score the application within 1 week of receipt. The other panel members are then given a further week to record any dissent with the initial reviewers comments, scores or decision. Assuming no further information is requested by the reviewer, this should reduce the average review process time from 8 weeks to 3 weeks. A sub-committee of the Lay Liaison and Ethics group will also start to assess the lay summary provided in the application to ensure that it is suitable as a lay summary and is understandable to the general public. They will also have 1 week to register any dissatisfaction with the text and, if there are issues the principal investigator will be required to amend the lay summary prior to sample issue.
SUPPLY OF SAMPLES

The total number of samples supplied to approved research projects was 2,755 and those were supplied to 11 different research projects, 1 clinical trial (POETIC) and the CRUK Stratified Medicine programme. 91% of those were sent to applications during this reporting year and 9% to applications received in previous years. The breakdown of sample type and tumour type is shown in Figure 8 (NB. different y-axis values), and some of these samples were a continued supply to projects reported in previous years’ annual reports.

Lay summaries of the five new research projects supplied with samples between 1 April 2013 and 31 March 2014 follow:

10/006 - Prof Gwyn Williams - Keele University

Recently, several laboratories, including our own, have made the unexpected discovery that a group of non-protein coding RNAs, the snoRNAs, control key processes within the cell- including the crucial “life or death” decision processes which fail during the development and progression of cancer. 3 related snoRNA-containing genes are found at positions implicated in prostate cancer by genetic studies. Using techniques already established here, we propose to test clinical prostate cancer samples at different stages of the disease to look for abnormalities in these genes which will reveal their involvement in prostate cancer development and progression. In preliminary studies, some changes, both in the concentrations of these molecules within the cell, and in the genes themselves, i.e. mutations, have already been detected in prostate cancers. This investigation will allow us to determine the extent to which abnormalities in these genes are associated with the development and progression of prostate cancer and will open up a completely new avenue for improvements in prostate cancer diagnosis and treatment.

13/004 - Professor Ian Weeks - Cardiff University/EKF Molecular Diagnostics

EKF Molecular Diagnostics wishes to access samples from the Wales Cancer Bank to test the accuracy of new diagnostic kits for three cancer types (melanoma, lung and colorectal cancer). The EKF Molecular Diagnostics tests have significantly greater sensitivity than products sold by other companies and we hope will benefit patients by minimising the need for surgical sampling of cancerous tissue during cancer treatment by the use of
blood samples. Additionally, the EKF Molecular tests have the potential to be used in blood and/or urine tests to aid in earlier diagnosis of cancer and thus allowing earlier treatment increasing patient survival rates.

13/008 - Chad Brokopp - Swiss Centre for Regenerative Medicine

Fibroblast Activation Protein (FAP) is expressed by most human carcinomas and contributes to tumour growth and metastasis. Elevated levels of carcinoma-associated FAP expression and also circulating FAP levels have been associated with shorter patient survival. Therefore, FAP has gained attention as a biomarker for colorectal cancer with potential diagnostic and prognostic value. However, circulating FAP exists in multiple complexes with other proteins and also in truncated forms which are not collectively measurable using a single immunoassay. As a solution to this problem, our group has developed an FAP blood test to quantify all serum FAP forms collectively, with anticipated superior sensitivity and specificity compared to previous generation FAP immunoassays. We would now like to employ this assay to determine its predictive value on overall survival in patients with metastatic colorectal cancer. If predictive value is verified, this FAP blood test will be used as a companion diagnostic in clinical trials for selecting patients with elevated serum FAP levels; who we anticipate are most likely to respond to FAP-blocking medications. After regulatory approval of these FAP-blockers, the FAP companion diagnostic is expected to justify prescriptions of these medications by identifying patients with elevated circulating FAP levels.

13/009 - Dr Friedhelm Bladt - Merck, Germany

c-Met, the high affinity receptor of hepatocyte growth factor HGF, has been implicated in the development and progression of several human malignancies and their metastatic lesions, and thus has become an attractive therapeutic target. Emerging preclinical and clinical data indicate that tumors with clear signs of c-Met activation (c-Met amplification, c-Met overexpression, high levels of phospho c-Met and HGF) are sensitive to c-Met inhibition.

Aim of this study is to determine the degree of aberrant c-Met activation (as measured by c-Met expression, c-Met amplification, phospho c-Met and HGF levels) in TNB, basal like breast cancer, glioblastoma, bladder cancer and prostate cancer. If available biopsies from progressing lesions, later stages (opposed to early stages) and matched normal tissue will be analysed. Available matched plasma samples will be analysed for circulating HGF levels.

13/014 - Dr Richard Martin - University of Bristol

Fascin-1 is an actin-bundling protein with roles in cell migration that has been correlated with an aggressive clinical course in human colorectal and gastric cancers, and with mortality in human breast cancer. Only one small retrospective study has investigated the effect of fascin-1 in prostate carcinoma, but the findings were promising: carcinomas with high fascin-1 expression were associated with increased rate of prostate-specific antigen relapse after radical prostatectomy. Our objective is to conduct a pilot study to compare fascin-1 protein localisation (and related biomarkers) in men with high-grade (Gleason score 8-10) vs. low-grade (Gleason score <7) prostate cancer, using tissue from radical prostatectomy samples, vs. uninvolved control prostate tissue. This pilot will provide initial proof of principle data to inform a proposal for a definitive study to test the hypothesis that fascin-1 protein and its transcriptional activators in human prostate tissue samples predicts the development of aggressive compared to latent prostate carcinoma. This goal addresses the need to identify new predictive biomarkers that distinguish indolent vs aggressive prostate carcinomas.
Phase Two

Stratified Medicine Phase Two focuses on late stage (III/IV) Non Small Cell Lung Cancer (NSCLC) that make up about 78% of all lung cancers diagnosed in England and Wales. Clinical hubs across the UK are targeting patients with a good-fair performance status who may benefit from specific second-line treatment due to be offered as part of the National Lung Matrix trial (scheduled to open later in 2014). "This...is a multi-drug, genetic marker directed, non-comparative multi-arm phase II trial...(which) will give researchers unprecedented access to libraries of drugs developed by (CRUK’s partnered pharmaceutical companies), AstraZeneca and Pfizer - allowing several of these drugs to be tested at the same, within one trial." Cancer Research UK press release, 17th April 2014.

Cardiff is again hosting both a clinical and technical hub with the clinical hub activity being coordinated and managed by WCB, in close liaison with the technical hub, based in the All Wales Genetics Service department in Cardiff and Vale UHB. A 6-month transition period (Jul-Dec 2013) was implemented to adapted existing pathways to allow for new patient eligibility and to introduce and embed the Next Generation Sequencing (NGS) panel in the technology hub. The Cardiff Clinical Hub target for this period was to contribute 80 tissue samples across the three collection sites (University Hospital Wales, Cardiff; Royal Gwent Hospital, Newport; and Morriston Hospital, Swansea). Eligibility of samples was gradually changed throughout the transition phase to ensure hubs were in a position to begin full recruitment from January 2014 onwards. Sample type (resection/biopsy); disease stage; and patient performance status were all factors which were narrowed down to late stage (III/IV) biopsies of NSCLCs. Patients were to be assessed as having a performance status of 0-2 at the time of consent and it was agreed that late stage resections and cytology samples were acceptable for gene testing. Cardiff clinical hub consented a total of 98 patients during this transition phase, with tissue samples for 61 patients being sent to the Technical Hub for testing - falling slightly under the CRUK target, see graph to the right.

### Table 2. SMP Phase 1 data

<table>
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<td>290</td>
<td>268</td>
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<tr>
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<tr>
<td>Prostate</td>
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<td>335</td>
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Cardiff Clinical Hub has been targeted with collecting 110 tissue samples from 1st January 2014 to 31st December 2014 - approximately 9-10 samples per month. Amending consenting pathways to allow contact with patients early in their journey was a huge hurdle which has been successfully overcome; changes to informatics and data transfer have also proved to be obstacles which have been effectively tackled. Data is presented here for the period 1st January 2014 to 31st March 2014. Recruitment is currently on target with 27 eligible patients consented across this 3 month period; 56% (15) of these consents have had tissue sent to the Technical Hub for testing with a small number of molecular results returned, see figure 13.

Cwm Taf Health Board will start to consent patients for SMP in Prince Charles Hospital, Merthyr Tydfil in April 2014. Consent and tissue pathway are currently being developed to allow maximum patient uptake and minimum disruption to existing protocols. Further collaboration with the Cancer Network Information System Cymru (CaNISC) will see live transfer of molecular results directly into the patient record to allow clinicians to view any potential gene mutations (for research purposes only).

A milestone decision has been taken by the WCB Executive Group and the WCB IT Board to host the WCB databases and web applications on Swansea University servers. The change of hosting is expected to improve service and enable linkage to external data sources such as the SAIL database. The WCB patient CaNISC registration will continue, to ensure data from CaNISC will be available to the WCB database.

**INFORMATION TECHNOLOGY (IT)**

**GOVERNANCE**

The IT Board decided to focus on the macro management and stewardship of the service using the highlight reports to determine the service performance. The quarterly highlight reports will replace the reviewing of each development cycle. The WCB User Group has taken an increasing role in the management of the WCB IT requirements and in determining work priorities. A three day workshop has been conducted to determine the new data model for collection of longitudinal patients’ samples. The new model will allow accurate patient profiling and identification of patient cohorts with matching samples.
38% of newly diagnosed adults living in Cardiff and Vale area consented to the WCB last year.
The focus of the first three months of the year was the delivery of a single pathology data entry form (Fig 14). The new form replaced the separate Royal College of Pathology (RCPath) minimum data entry forms. The aim was to simplify the data entry process and to ensure improved data completeness for the most important data fields.

The main effort also included a major database re-coding exercise. The previous WCB 'own diagnosis categories' were replaced with ICD-0-3 standard codes. The tissue types’ category was restructured to include both operation site and tissue type. The new module was delivered for the face to face training meeting in Cardiff on 2 July 2013. The module also included auditing screens to complete the mapping of records where rule-based mapping could not be achieved.

The WCB continued this year with its strong commitment to the development of Apps for mobile
working. The target is to enable WCB staff to work more effectively by utilising the time spent in hospital wards and laboratory also for data input. The additional benefit will be an increase in data accuracy, as the data is entered at source without a delay, rather than entering data at a later time in the office.

As a first step an electronic patient consent App for a mobile device named Iconsent was developed (Fig 15). The new App will allow the consenting nurse to create a paperless consent. There are also advantages in the use of Iconsent for a lay person consenting or even the possibility of self-consent. The Iconsent App is fully functional and allows the configuration and versioning of the consents content. This includes adding additional multimedia help material. The App also includes the facility for a patient to input a digital signature using a stylus pen. The original consent PDF file (digitally signed) is sent and kept by a third party (NHS) server.

The new WCB Mobile App for sample management project began this year, with expected completion next year. The Pilot project for data import of the CaNISC SMP dataset has been successful and was followed with the development of a new generic Canisc data import program. This included screens for record matching, where records cannot be matched automatically.

CHANGE MANAGEMENT

Parallel to the web development undertaken, the WCB continued to support and develop the legacy sample management system. This year there were 234 change management tickets, of which 222 were closed.

The WCB IT section continues to support external project requirements such SMP phase one and two and the Wales Cancer Trials Unit (WCTU) website for the hosted WCB samples.
A Phase I/II single-arm trial to evaluate the combination of cisplatin and gemcitabine with the mTOR inhibitor temsirolimus for treatment of advanced cancers, including first-line treatment of patients with advanced transitional cell carcinoma of the urothelium.

The prognosis for patients with advanced urothelial (predominantly bladder) cancer is poor and approximately 4,700 patients in the UK die each year from the disease. Approximately 50% of patients who are fit enough to undergo (cisplatin-based) chemotherapy will respond to treatment. Median progression-free
survival for such patients is approximately 8 months and median overall survival 14 months. Despite a recent increase in our understanding of the molecular basis of bladder cancer, there have been few clinical studies using molecularly-targeted compounds in advanced urothelial cancer.

Temsirolimus (Torisel®) is a treatment which limits the growth of tumours and has recently been demonstrated to improve survival in advanced renal cancer [4]. Preclinical studies suggest that temsirolimus may be active against urothelial cancer too. This trial aims to assess whether adding temsirolimus to standard gemcitabine/cisplatin (GC) chemotherapy in the treatment of advanced urothelial cancer is a safe and effective treatment for patients with advanced urothelial disease. All participants will be administered a maximum of six 21-day cycles of the 3-drug gemcitabine/temsirolimus/cisplatin (GTC) chemotherapy by drip into the arm.

The optimum dose and schedule for temsirolimus will be determined in the Phase I stage of the trial by dose-escalation in successive cohorts of 3-6 participants, until the MTD is met. Dose escalation will follow strict rules and intra-participant dose escalation will not be permitted. Once the recommended Phase II dose has been identified it will then be given to an expanded group of participants in Phase II.

Up to 42 participants with advanced non-haematological malignancy will be enrolled in Phase I. Patients with advanced TCC of the urothelium may be included, provided they have not had prior chemotherapy for advanced disease. In Phase II, additional participants with advanced TCC of the urothelium will be treated with the three-drug combination, including temsirolimus at the recommended dose determined in the Phase I stage, up to a total of 63 evaluable participants at that dose level. Efficacy data collected in Phase I may contribute to the Phase II data analysis. Therefore, the maximum number of participants that will be treated in the entire trial is 105.

If results confirm that administration of the 3-drug GTC chemotherapy combination is safe, feasible and sufficiently active in advanced TCC of the urothelium, the combination treatment will be taken forward into a future Phase III, randomised trial.

WCB staff have attended a variety of workshops, seminars and conferences over the year to keep their professional skills current, enhance their knowledge in specific areas and exchange ideas and experiences. A full list can be found in Appendix B in the online version of the annual report (www.walescancerbank.com).
MARKETING

Two surveys have been carried out during the last twelve months to inform the future strategy of WCB and to gauge satisfaction of users who have previously received WCB samples. The first survey was sent to all cancer researchers based in Wales to ascertain awareness of WCB. The second survey was sent to researchers around the world who had previously sourced samples from WCB.

Staff from WCB attended the annual Cancer Research Wales open day in January 2014 and hosted a laboratory tour where attendees learned how tissue samples are processed and stored for research. The attendees were given the opportunity to use the microtome to cut tissue sections and saw how the digital images of the stained slides could be magnified and manipulated to aid diagnosis.

Talks have also been given to two Rotary clubs, the Cardiff Breakfast club and the Abertillery and Blaina club to raise awareness of WCB and its activities. Both clubs provided excellent hospitality and were keen to learn more about tissue banking and the progress of the sample collection.

Cancer researchers in Wales survey

The survey was sent to 185 researchers based in Wales (primarily connected to Cardiff, Swansea and Bangor universities or associated health boards) via email for completion between 4th and 25th October 2013. Two reminders were sent to the participants during this period, at weekly intervals.

93 (50%) responses were received, of which 84 completed the survey questions relevant to their previous responses (9 were shown as incomplete responses). 65/93 (70%) of respondents said they were involved in cancer research projects and needed to use tissue/blood from cancer patients in their research activities. Of those 64 respondents completed the survey - 35/64 (55%) did so anonymously, with 29/64 (45%) providing their contact details.

18 respondents had previously obtained samples from WCB - 16 of these went on to answer the relevant questions in the remainder of the survey. The remaining 46 who had not had samples from WCB previously had all heard of WCB, and from various sources; colleague (10), conference (1), email (1), poster/flyer (1), press (1), WCB newsletter/leaflet (2), WCB website (1), word of mouth (7) and workplace (9). Of this group of respondents, asked if they would consider using WCB samples, 52% said they would, 13% said they would not, 33% said maybe and 2% did not know - there were various comments given in response to this question.

As mentioned above, 16 respondents who had previously used the WCB service completed the relevant survey questions. They were asked to rate WCB on a number of areas - please see the table below for the number of ratings given for each category provided (additional comments supported some of these answers).

<table>
<thead>
<tr>
<th>Category</th>
<th>POOR</th>
<th>AVERAGE</th>
<th>GOOD</th>
<th>DON’T KNOW OR N/A</th>
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<td>Application Process</td>
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<td>5</td>
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<tr>
<td>Communication</td>
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<td>5</td>
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<td>Turnaround time of application</td>
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<tr>
<td>Cost of samples</td>
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Table 3 Ratings for sample application process and supply by researchers in Wales
OVER

900

PROSTATE SAMPLES

WERE SUPPLIED TO

RESEARCHERS LAST YEAR
This groups of respondents were then asked whether they would use the service again - 81% said they would and 19% said maybe (none of the respondents said that they would not).

The final question for this group of respondents was whether they would be encouraged to use the service if the cost of samples was reduced - 63% said they would, with the remaining 37% evenly split between no, maybe and don’t know (two respondents for each of these answers). At the end of the survey, respondents had the opportunity to add additional comments - 15 of them did so.

Previous user survey

Following on from the previous survey to Welsh researchers to gauge overall awareness of WCB and feedback on the service, a survey was sent to previous users of the WCB service (not based in Wales). The aim of this survey was to gather feedback and comments on a number of aspects of WCB:

- To understand how they heard about the WCB service initially
- To gather feedback on the application process, turnaround time of samples, quality and availability of samples, and the overall interaction with WCB
- The likelihood that they would use the service again
- To specifically gather feedback on the costs involved in using the service
- Gather information about any published papers as a result of the research work done using WCB samples
- Ask for any improvements that could be made to the service

The survey was initially sent to 33 previous service users using the email addresses held in the WCB records but 5 email delivery failures were received, so 28 researchers were invited to take part in the survey for completion between 20th February and 14th March 2014. One reminder was sent to the participants during this period, after two weeks. The invitees had the option to provide their details or complete the survey anonymously.

8 (29%) responses were received, one of which did not complete the survey. 6 respondents provided their details, the others completed the survey anonymously. 7/8 people said that they had heard about WCB from a colleague or by word of mouth; the remaining person said via the internet. The survey participants were asked to rate WCB on a number of areas - please see the table below for the number of ratings given for each category provided (additional comments supported some of these answers - see below the table):

<table>
<thead>
<tr>
<th>Category</th>
<th>POOR</th>
<th>AVERAGE</th>
<th>GOOD</th>
<th>DON'T KNOW OR N/A</th>
</tr>
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<td>Application Process</td>
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<td>1</td>
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<td>Communication</td>
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<td>Overall service</td>
<td>1</td>
<td>0</td>
<td>7</td>
<td>0</td>
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</table>

Table 4: Ratings for sample application process and supply by researchers outside of Wales.
The next question asked whether they would use the service again - 5/8 said yes (“helpful availability of samples”), 1/8 said no (“no further studies”) and 2/8 said maybe. They were then asked about the cost of accessing WCB samples. Firstly, what did they think about the cost - 5/8 said that they thought that the cost was fair, 1/8 said that it was cheap and 1/8 said that it was expensive. 3/8 said that they be encouraged to use the service if costs were reduced, 2/8 said it would not influence them and 2/8 said maybe. The final question asked whether the researcher had published or presented any findings from the work done using the samples - 4/8 said no and 3/8 said yes (and some provided relevant details).

Although the response rate was less than 30%, so may not be representative of the overall experience of all previous service users, the participants did give some detailed answers and comments in their survey responses. Most of the responses were positive, and although one said that they would not use the service again, the reason was ‘no more research studies to do’ rather than a problem with the service itself. A couple of areas highlighted in the comments and ratings were tissue type, availability and quality, and cost. These could be areas to review in light of this survey.

CONFERENCES

Individuals from the Wales Cancer bank have attended a number of conferences during the year, either as attendees (NCRI - November 2013), exhibitors (BioWales - March 2014) or speakers (ISBER - May 2013 and the Biobanking 2013 Europe - September 2013).

ISBER
Professor Gerry Thomas and Dr Alison Parry-Jones were invited (along with Associate Professor Nik Zeps from the St John of God hospital, Perth, Australia) to run a workshop at the annual conference of the International Society for Biological and Environmental Repositories (ISBER), which was held in Sydney, Australia in May 2013. The workshop was entitled ‘Banking on Success: Are biosamples and clinical data enough?’ The talk focussed on the need for biobanks to evolve to keep pace with the research they strive to support and it queried:

• Is science being compromised because of a lack of available samples?
• Is cross border collaboration the way forward?
• How much annotation is required?
• How to go beyond pathology data and include molecular data?

The workshop was well attended and positive feedback was received.

BioWales
In September 2013, Dr Parry-Jones was invited to speak at the Biobanking 2013 Europe conference on Commercial, Ethical and Scientific Issues with Biobanking. Her talk was called ‘The ethical considerations for biobanking’ and covered a range of ethical, legal and social issues (ELSI) including consent, sample ownership, return of results, social issues and sample use. These were all related back specifically to biobanking and suggestions were made as to what biobanks should consider, how biobanks should approach these areas and what documentation needs to be in place. The talk prompted a lively and stimulating discussion between the attendees, which included biobankers, researchers, pharma representatives and technical industry delegates.

Biobanking 2013 Europe
In September 2013, Dr Parry-Jones was invited to speak at the Biobanking 2013 Europe conference on
LOOKING AHEAD

The trend line on the graph below forecasts the patient recruitment to the end of April 2015, using the accumulated recruitment totals since inception. It predicts that a total of 11,850 patients will be consented by the end of the next reporting period (end March 2015), assuming current staffing levels and patient access are maintained across all current recruiting sites.

Looking forward:
The 10th anniversary of the WCB launch will be on 19th June 2014 in the Masonic Hall in Cardiff and will celebrate the achievements to date, whilst looking forward to the rollout of testing for stratified medicine and the potential impacts. The day before the 10th anniversary event, WCB is also hosting a Confederation of Cancer Biobanks (CCB) workshop to look at how biobanks can raise public awareness of biobanking and engage the public.

The current WCB funding from NISCHR ends on 31st March 2015 and the structure and format of the WCB will be reviewed over the next few months. NISCHR are restructuring all their infrastructure grants and it is likely that WCB will be part of a bid for a Wales wide cancer centre. This gives the opportunity to examine and appraise the methodology of the last 10 years and use the information gathered to focus the future activity on ensuring samples are used, not predominantly collected and stored. Sample collection and recruitment strategies will be evaluated to ascertain whether current policies should be modified to fit with future aims. The outcome of the restructuring and funding levels will be known by October 2014.

Figure 16  Forecast patient recruitment to April 2015
TARGETS FOR 2014/15

- Accrue 11,800 patients in total
- Update user manual
- Complete follow up audit
- Complete database re-write
- Supply five new projects with biosamples
## FINANCIAL STATEMENT

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<td>Newport site</td>
<td>17,987</td>
<td>44,600</td>
<td>6,226</td>
<td></td>
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</tr>
<tr>
<td>Bridgend site</td>
<td>66,510</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SUBTOTAL</strong></td>
<td>538,695</td>
<td>117,125</td>
<td>68,298</td>
<td>46,606</td>
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<tr>
<td><strong>NON STAFF COSTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular characterisation</td>
<td></td>
<td></td>
<td>41,560</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment/maintenance/ consumables</td>
<td>100,585</td>
<td>1,645</td>
<td>24,489</td>
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</tr>
<tr>
<td>Travel/conference/training</td>
<td>16,633</td>
<td></td>
<td>425</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HTC licence</td>
<td>8,600</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Office expenses</td>
<td>16,937</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IT</td>
<td>160,579</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>SUB TOTAL</strong></td>
<td>303,334</td>
<td>43,205</td>
<td>425</td>
<td>24,489</td>
<td></td>
</tr>
<tr>
<td>Cost recovery</td>
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<td></td>
<td></td>
<td></td>
<td>-20,609</td>
</tr>
<tr>
<td>Trial related</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32</td>
</tr>
<tr>
<td>Service delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brought forward 12/13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-159,115</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>842,029</td>
<td>160,330</td>
<td>68,723</td>
<td>71,095</td>
<td>-32</td>
</tr>
</tbody>
</table>

* SMP

**TOTAL GRANT INCOME SPENT 2013/14** £1,142,177
“well run service with proportional review process”

“detailed interaction with helpful staff”
“manageable paperwork and review process”

“efficient and timely service”
## APPENDIX A

### WALES CANCER BANK PERSONNEL LIST AS AT 31ST MARCH 2014

<table>
<thead>
<tr>
<th>STAFF</th>
<th>SITE</th>
<th>TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor Malcolm Mason</td>
<td>Central</td>
<td>Director</td>
</tr>
<tr>
<td>Professor Gerry Thomas</td>
<td>Central</td>
<td>Director of Scientific Services</td>
</tr>
<tr>
<td>Professor John Chester</td>
<td>Central</td>
<td>Deputy Director</td>
</tr>
<tr>
<td>Dr Alison Parry-Jones</td>
<td>Central</td>
<td>Manager</td>
</tr>
<tr>
<td>Sarah Phillips</td>
<td>Central</td>
<td>Project Officer</td>
</tr>
<tr>
<td>Abigail MacArthur</td>
<td>Central</td>
<td>SMP Administrator</td>
</tr>
<tr>
<td>Debbie Way</td>
<td>Central</td>
<td>Clerical officer</td>
</tr>
<tr>
<td>Monica Willis</td>
<td>Central</td>
<td>Clerical officer</td>
</tr>
<tr>
<td>Michaela John</td>
<td>Central</td>
<td>PR/Marketing</td>
</tr>
<tr>
<td>Daniel Naeh</td>
<td>Swansea University</td>
<td>IT Manager</td>
</tr>
<tr>
<td>Robert Wilson</td>
<td>Swansea University</td>
<td>Database</td>
</tr>
<tr>
<td>Charles Keene</td>
<td>Swansea University</td>
<td>Programmer</td>
</tr>
<tr>
<td>Suzanne Williams</td>
<td>Swansea</td>
<td>Lead nurse</td>
</tr>
<tr>
<td>Helen Bevan</td>
<td>Swansea</td>
<td>Nurse</td>
</tr>
<tr>
<td>Pam Hayward</td>
<td>Swansea</td>
<td>Nurse</td>
</tr>
<tr>
<td>Amanda Hewitt</td>
<td>Swansea</td>
<td>Nurse</td>
</tr>
<tr>
<td>Colleen Lloyd</td>
<td>Swansea</td>
<td>Biomedical Scientist</td>
</tr>
<tr>
<td>Emma Miles</td>
<td>Swansea</td>
<td>Biomedical Scientist</td>
</tr>
<tr>
<td>Gary Ash</td>
<td>Swansea</td>
<td>Medical Laboratory Assistant</td>
</tr>
<tr>
<td>Dr Lisa Spary</td>
<td>Cardiff</td>
<td>Post doctoral researcher</td>
</tr>
<tr>
<td>Kevin Pearse</td>
<td>Cardiff</td>
<td>Nurse</td>
</tr>
<tr>
<td>Peita-Lee Ambrose</td>
<td>Cardiff</td>
<td>Nurse</td>
</tr>
<tr>
<td>Heather Hyatt</td>
<td>Cardiff</td>
<td>Nurse</td>
</tr>
<tr>
<td>Zoe Davies</td>
<td>Cardiff</td>
<td>Nurse</td>
</tr>
</tbody>
</table>
### HTA/Local Management Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Site</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor Malcolm Mason</td>
<td>Central</td>
<td>HTA Licence holder</td>
</tr>
<tr>
<td>Professor Gerry Thomas</td>
<td>Central</td>
<td>Director of Scientific Services</td>
</tr>
<tr>
<td>Dr Alison Parry-Jones</td>
<td>Central</td>
<td>HTA Designated Individual</td>
</tr>
<tr>
<td>Professor Nick Stuart</td>
<td>Bangor</td>
<td>HTA Person Designated / Local lead</td>
</tr>
<tr>
<td>Professor Julian Sampson</td>
<td>Cardiff</td>
<td>Local lead</td>
</tr>
<tr>
<td>Mrs Julie Maynard</td>
<td>Cardiff</td>
<td>HTA Person Designated</td>
</tr>
<tr>
<td>Dr Meleri Morgan</td>
<td>Cardiff</td>
<td>HTA Person Designated</td>
</tr>
<tr>
<td>Dr Paul Griffiths</td>
<td>Swansea - Morriston</td>
<td>HTA Person Designated</td>
</tr>
<tr>
<td>Mrs Christine Davies</td>
<td>Swansea</td>
<td>HTA Person Designated / Local lead</td>
</tr>
<tr>
<td>Dr Margaret Cotter</td>
<td>Bridgend</td>
<td>HTA Person Designated / Local lead</td>
</tr>
<tr>
<td>Mr Adam Carter</td>
<td>Royal Gwent</td>
<td>HTA Person Designated</td>
</tr>
</tbody>
</table>

| Fiona Morgan                  | Cardiff                | Biomedical Scientist                                |
| Dr Chi Lee                    | Cardiff                | Biomedical Scientist                                |
| Jane Greenwell               | Cardiff                | Trials Technician                                    |
| Mark O’Brien                 | Cardiff                | Technician                                           |
| Christopher Cockayne         | Cardiff                | Technician                                           |
| Julie Maynard                | Cardiff                | Genetics technician                                  |
| Jennifer Jones               | Bangor                 | Nurse                                               |
| Alex Makanga                 | Bangor                 | Biomedical Scientist                                |
| Rachel Hughes                | Withybush              | Nurse                                               |
| Elizabeth Meech              | Bridgend               | Nurse                                               |
| Jacqueline Jones             | Bridgend               | Medical Laboratory Assistant                        |
| Lisa Gilby                   | Newport                | Nurse                                               |
| Karen Wild                   | Newport                | Nurse                                               |
| Natalie Stacey               | Newport                | Biomedical Scientist                                |
### APPENDIX B

**CONFERENCES, WORKSHOPS AND COURSES ATTENDED**

**APRIL 2013**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd</td>
<td>South Wales Urology nurses group seminar</td>
<td>Cardiff</td>
</tr>
<tr>
<td></td>
<td>Clare Jones chaired</td>
<td></td>
</tr>
<tr>
<td>18th</td>
<td>STRATUM outcome meeting</td>
<td>London</td>
</tr>
<tr>
<td>23rd</td>
<td>Cryogenic Gases, Dry Ice and Carbon Dioxide safety training</td>
<td>Cardiff</td>
</tr>
<tr>
<td>24th</td>
<td>NISCHR conference</td>
<td>Cardiff</td>
</tr>
<tr>
<td></td>
<td>Dr Parry-Jones presented a poster</td>
<td></td>
</tr>
</tbody>
</table>

**MAY 2013**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>4th</td>
<td>Marble Arch Working group of International Biobank Leaders meeting</td>
<td>Sydney, Australia</td>
</tr>
<tr>
<td>5th - 9th</td>
<td>ISBER Annual meeting Prof Thomas and Dr Parry-Jones ran a workshop event entitled 'Banking on Success: Are biosamples and clinical data enough?'</td>
<td>Sydney, Australia</td>
</tr>
<tr>
<td>8th</td>
<td>Information Governance Awareness</td>
<td>Bridgend</td>
</tr>
<tr>
<td>13th</td>
<td>Carriage of Dangerous Goods Training</td>
<td>Cardiff</td>
</tr>
<tr>
<td>28th</td>
<td>Soroptimist International Group</td>
<td>Milford Haven</td>
</tr>
<tr>
<td></td>
<td>Suzanne Dolphin and Pam Hayward gave an oral presentation</td>
<td></td>
</tr>
</tbody>
</table>

**JUNE 2013**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>27th</td>
<td>Aneurin Bevan UHB R&amp;D conference</td>
<td>Newport</td>
</tr>
<tr>
<td></td>
<td>Lisa Gilby and Karen Wild presented a poster entitled 'The growth of the Wales Cancer Bank within the Aneurin Bevan Health Board'</td>
<td></td>
</tr>
</tbody>
</table>

**JULY 2013**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>7th</td>
<td>Breast Cancer support group</td>
<td>St. Clears</td>
</tr>
<tr>
<td></td>
<td>Suzanne Dolphin gave an oral presentation</td>
<td></td>
</tr>
</tbody>
</table>

**AUGUST 2013**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>11th</td>
<td>Biobanking in Europe conference</td>
<td>London</td>
</tr>
<tr>
<td></td>
<td>Dr Parry-Jones gave an oral presentation entitled 'The Ethical Considerations for Biobanking'</td>
<td></td>
</tr>
<tr>
<td>25th</td>
<td>The Patient Voice in Shaping Cancer Services conference</td>
<td>Margam</td>
</tr>
<tr>
<td></td>
<td>Suzanne Dolphin gave an oral presentation</td>
<td></td>
</tr>
<tr>
<td>27th</td>
<td>All Wales Lung Cancer Forum</td>
<td>Swansea</td>
</tr>
<tr>
<td></td>
<td>Heather Hyatt gave an oral presentation</td>
<td></td>
</tr>
</tbody>
</table>

**OCTOBER 2013**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>8th</td>
<td>Stratified Medicine programme (CRUK) workshop</td>
<td>London</td>
</tr>
</tbody>
</table>
### NOVEMBER 2013

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
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</thead>
<tbody>
<tr>
<td>3rd - 6th</td>
<td>NCRI annual conference</td>
<td>Liverpool</td>
</tr>
<tr>
<td>7th</td>
<td>South Wales Urology nurses group seminar</td>
<td>Cardiff</td>
</tr>
<tr>
<td>8th</td>
<td>North Wales Cancer Network Cancer CPG (Lung Clinical Advisory Group)</td>
<td>Bangor</td>
</tr>
<tr>
<td>26th</td>
<td>CRUK Stratified Medicine Phase I presentation workshop</td>
<td>London</td>
</tr>
<tr>
<td>26th - 27th</td>
<td>NISCHR CRC Symposium, WCB exhibited with promotional literature and presented a poster</td>
<td>Llandudno</td>
</tr>
<tr>
<td>29th</td>
<td>South Wales Gynaecological Oncology Group 9th Educational meeting</td>
<td>Swansea</td>
</tr>
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</table>

### DECEMBER 2013

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>12th</td>
<td>NCRI Gynaecological Oncology CSG Trials Meeting</td>
<td>London</td>
</tr>
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</table>

### FEBRUARY 2014

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>7th</td>
<td>Carriage of Dangerous substances and Dry ice by road and air training course</td>
<td>Cardiff</td>
</tr>
<tr>
<td>10th</td>
<td>CaNISC new referrals training</td>
<td>Cardiff</td>
</tr>
<tr>
<td>19th</td>
<td>Cardiff Breakfast Rotary Club, Dr Parry-Jones gave an oral presentation entitled 'The Wales Cancer Bank'</td>
<td>Cardiff</td>
</tr>
<tr>
<td>24th</td>
<td>Abertillery and Blaina Rotary Club, Dr Parry-Jones gave an oral presentation entitled 'The Wales Cancer Bank'</td>
<td>Abertillery</td>
</tr>
</tbody>
</table>

### MARCH 2014

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>6th - 7th</td>
<td>BioWales Conference, WCB exhibited as part of Biobanks in Wales</td>
<td>Cardiff</td>
</tr>
<tr>
<td>11th</td>
<td>NISCHR CRC Collaborators Briefing, 'Collaborating for Success: Research Delivery in Wales'</td>
<td>Cardiff</td>
</tr>
<tr>
<td>13th</td>
<td>GE Healthcare Science and Technology week, Dr Parry-Jones gave an oral presentation entitled 'The Wales Cancer Bank'</td>
<td>Cardiff</td>
</tr>
<tr>
<td>31st</td>
<td>Stratified Medicine programme (CRUK) workshop, Workshop on 'Optimising sample and DNA quality for NGS'</td>
<td>London</td>
</tr>
</tbody>
</table>

Suzanne Dolphin regularly lectures to pre and post-registration nursing students at Swansea University about communication, WCB and clinical Trials.

All staff have attended courses to update GCP, communication and skill sets relevant to their post.
The annual audit schedule in 2013 took place between the 10th October and 14th November 2013. All sites were visited by the WCB Project Officer and a WCB BMS from Cardiff and Swansea. A random selection of donations, spanning all years of collection, were inspected at each site with a sample trail completed for all audited donations. A list of incomplete data was generated to show donations without a donation, blood samples, no diagnosis, questionable ischaemic times or no pathology report after one month. The follow up information audit at each site compared the information on the database against each completed follow up form. Additional samples were audited that were co-located with the sample numbers identified for audit. This resulted in a far larger number of samples being checked for location accuracy.

Four sites have been collecting for nearly nine years and the 2013 audit was the ninth such internal inspection during this time. Royal Gwent has been collecting samples for seven years and this was the seventh internal audit at the site and Velindre has been collecting samples since July 2011 and this was the third internal audit at the site. The Princess of Wales Hospital in Bridgend began consenting in April 2013 and this was its first internal audit. During the last 12 months and due to Pathology restructuring, histology has moved from Withybush General Hospital to Carmarthen so the decision was taken to move the freezer, paraffin and H&E cabinet to UHW, Cardiff along with the centrifuge. A new sample pathway was then tailored to fit the consenting of patients both in Withybush and Carmarthen to facilitate the processing and storage of samples in Singleton Hospital, Swansea. Pathology was also restructured in North Wales with the WCB BMS relocated to the laboratory in Ysbyty Glan Clwyd. The first audit since this move will incorporate both Ysbyty Gwynedd, Bangor and Ysbyty Glan Clwyd to approve the altered work flow and to ensure that the WCB are adhering to the HTA licence requirements. The workflows and role responsibilities of staff at each site have local variation in order to fit in with routine clinical practice. Role responsibilities at each site are documented and included in the Service Level Agreements signed by each participating LHB and NHS Trust. All SLAs were redrafted to cover the new funding period to March 2015 and distributed in 2010. Cardiff and Vale University Health Board is still to respond (as at 14th November 2012).

Each site is covered by a HTA licence to store tissue for research purposes. No major issues were highlighted that could potentially jeopardise the licence at any site. All sites are working within local and WCB guidelines on Health and Safety and adhere to WCB Standard Operating Procedures, although staff are reminded to ensure that they are fully conversant with all SOPs. SOP files and site files were not inspected on this occasion but a list of REC and R&D approvals will be circulated by March 2014 ahead of the audit and inspections due later in the year. The majority of SOPs were reviewed in February 2013, after which the updated SOP log was circulated to each site to ensure all site SOP files are up to date at audit 2013.
A number of data queries were run to check integrity of data at each site:
1. Donations with missing diagnosis.
2. Donations without blood samples.
3. No pathology reports for donations over 30 days old.
4. Samples without a donation.
5. Query ischaemic time.

General

All specialities are on the database so pathology reports can now be completed. Information is still held on paper copies but then transferred on to the database. However, there remains a backlog of pathology reports not yet entered on to the database which has been highlighted with all sites who have been asked to routinely visit to complete the backlog.

ACTIONS

To be implemented centrally:

• Draft action points outstanding from audit and circulate to all sites.

• Create a REC status sheet for file comparison and send it as a document log to all sites.

To be implemented at sites:

• Address action points circulated by Central Office and send a report within 4 weeks of receipt detailing that issues have been addressed and in what way.

• Treatment and outcome data should go onto a WCB standardised follow up sheet and transferred onto the database.

• Database records must be updated following QA and labels reprinted accordingly.

• ALL sample movement must have a document trail as per WCB SOPs in conjunction with the electronic shipment process within the WCB database.

Ongoing:

• QA needs to be kept up to date to ensure prompt fulfilment of sample transfer to projects or extraction for projects.

• Follow up treatment and outcome data to be routinely collected.

• Scanning of H&E slides to be kept current.

• Ensure REC file is current.

• Ensure data is accurately transcribed onto database.

• Strict adherence to WCB SOPs should be observed.

Conclusions

The audit gave a good opportunity for the exchange of views and discussions about local practice and the project in general. The action points identified involve both central and local activity. It is hoped that all points can be actioned by the end of March 2014.
NOTES BY CENTRES

Cardiff

The data queries were run against the live WCB database on the 15th October 2013:

1. Donations with missing diagnosis - 307 instances for all Cardiff consented patients.
2. Donations without any blood samples - 106 instances for all Cardiff consented patients.
3. No pathology reports for donations over 30 days old - 35 instances for all Cardiff consented patients.
4. Samples without a donation - 31 instances found for all Cardiff consented patients.
5. The ischaemic time query returns results for those donations that have either a negative ischaemic time or the ischaemic time is greater than 3 hours - 3 instances found for all Cardiff consented patients.

A list of the missing data was sent to the WCB nurses and lab staff to address. In addition, 10 WCB numbers from UHW were randomly chosen on the 12th November 2013 to check the data and sample tracking. The numbers were 713, 832, 917, 1035, 1507, 1672, 2564, 2644, 3108 And 3514.

The follow up data for UHW and Velindre was not audited this year.

UHW

Donation 713
• All samples in correct place.
• Follow up sheet not in patient pack.
• Some information in treatment and outcome but no paperwork to check for accuracy.

Donation 832
• All samples in correct place.
• Nurse has not signed the consent form.
• Follow up outstanding.

Donation 917
• All samples in correct place.
• Control consent not entered on the database.
• Follow up sheet not in patient pack.
• Some information in treatment and outcome but no paperwork to check for accuracy.

Donation 1035
• All samples in correct place.
• Time sample left patient entered on paraffin form but not on database.
• QA form completed in patient pack but information not entered on to database.
• Follow up sheet not in patient pack.
• Some information in treatment and outcome but no paperwork to check for accuracy.

Donation 1507
• All samples in correct place.
• Version of Patient Information Sheet not entered on consent form.
• Blood samples on database but no blood form created/present in patient pack.
• Paraffin samples taken from cores. Data form does not show how many cores taken for WCB but database shows 2 tumour and 2 normal blocks.
• Follow up sheet not in patient pack.
• Some information in treatment and outcome but no paperwork to check for accuracy.

Donation 1672
• All samples in correct place.
• No signature against serum samples on data form.
• QA form completed in patient pack but information not entered on to database.
• Follow up sheet not in patient pack.
• Some information in treatment and outcome but no paperwork to check for accuracy.

Donation 2564
• All samples in correct place.
• Pathology number entered on database but no paper copy to check for accuracy.
Follow up sheet not yet created as newly consented patient.

Donation 2644
• All samples in correct place.
• Follow up sheet not yet created as newly consented patient.

Donation 3108
• All samples in correct place.
• Coordinates for blood tubes on database do not match blood forms and samples have not moved.
• Follow up sheet not yet created as newly consented patient.

Donation 3514
• All samples in correct place.
• Follow up sheet not yet created as newly consented patient.

Additional Random Sample Summary
5 H&E Drawers randomly scanned revealed:
1 Case not registered on database

6 Paraffin trays randomly scanned revealed:
4 Cases would not scan
1 Case not registered on database
1 Case missing from file

9 EDTA racks randomly scanned revealed:
3 Cases not registered on database

8 Camlab boxes of Serum randomly scanned revealed:
No yellow cryocaps in one cambox

3 Camlab boxes of Frozen Tissue randomly scanned revealed:
2 Cases not labelled
Cryocaps missing from majority of one cambox

Laboratory Report
1. Freezer Alarm/Power Fail Test - Circuit breaker switched to 'off', freezer audibly alarmed. No call from switchboard after 5 minutes. Called switchboard, no alarms activated there. Rear of freezer was checked and a lead was in place connecting freezer to a phone port.

Noted: Alarm for low battery sounded continuously when the circuit breaker was switched off.

2. Maintenance Records - No freezer maintenance log. No centrifuge maintenance log.

3. Temperature Logs - Freezer temperature log up to date and located correctly on freezer door.

4. SOP File - Located in lab office. All recent new versions SOPs present. Reviewed SOPs require updated cover sheet.

5. HTA License - Displayed correctly on freezer.

Llandough
9 WCB numbers from Llandough were randomly chosen on the 7th October 2013 to check data and sample tracking. The numbers were 524, 1958, 1984, 2137, 2149, 2450, 2678, 3203 and 3083.

Donation 524
• All samples in correct place.
• Patient date on consent form not clear.
• Blood forms dated but not signed.
• Follow up sheet not in patient pack.
• No date of follow up entered on database but some information on treatment and follow up.

Donation 1958
• H&E Slides missing from file.
• Version of Patient Information Sheet not entered on consent form.
• Follow up not started yet as newly consented patient.

Donation 1984
• H&E Slides missing from file.
• Version of Patient Information Sheet not entered on consent form.
• Co-ordinates for EDTA on form did not correspond to form and samples had not moved.
• Blood data form for serum was not signed.
• Frozen data form was not signed.
• Paraffin data form was not signed.
• Time left patient on form but not entered on to the database.
Donation 2137
• All samples in correct place.
• Follow up not started as newly consented patient.

Donation 2149
• All samples in correct place.
• Follow up not started yet as newly consented patient.

Donation 2450
• All samples in correct place.
• Pathology form present in pack but database would not allow it to be saved due to new re-write format requirements.
• Follow up not started as newly consented patients.

Donation 2678
• All samples in correct place.
• Follow up not started yet as newly consented patient.

Donation 3203
• All samples in correct place.
• Patient gave verbal consent so boxes were not initialled on the consent form.
• Patient had placed a cross in the ‘control’ box highlighting control was not to be approached.
• Follow up not started yet as newly consented patient.

Donation 3083
• All samples in correct place.
• Patient added extra digit to date but very clear as to what date was and matches the nurse’s date.
• Follow up not started yet as newly consented patient.

Additional Random Sample Summary
2 H&E Drawers randomly scanned revealed:
1 Slide would not scan.
2 Drawers missing slides - one missing 97, the other missing 16. Slides had been shipped to another site but shipment had not been accepted.

3 Paraffin trays randomly scanned revealed:
2 Blocks labelled as slides

5 EDTA racks randomly scanned revealed:
No anomalies

4 Camlab boxes of Serum randomly scanned revealed:
No anomalies

Laboratory Report
1. Freezer Alarm/Power Fail Test - Circuit breaker switched to ‘off’, freezer audibly alarmed. No call from switchboard after 5 minutes. Autodialler present but not connected to freezer or power.

Noted: Freezer very noisy. Filter cleaned.

2. Maintenance Records - No freezer maintenance log. No centrifuge maintenance log.

3. Temperature Logs - No freezer temperature log.

4. SOP File - Located in nurses office. All recent new versions of SOPs present. Reviewed SOPs all present and up to date.

5. HTA License - Displayed correctly on freezer.

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Velindre

The data queries were run against the live WCB database on 12th November 2013 and the results are outlined below.

1. Donations with missing diagnosis - 296 instances for Velindre consented patients.

2. Donations without any blood samples - 9 instances for Velindre consented patients.

3. No pathology reports for donations over 30 days old - 1 instance.

4. Samples without a donation - none

5. The ischaemic time query returns results for those donations that have either a negative ischaemic time or the ischaemic time is greater than 3 hours - none

A list of the missing data was sent to the WCB Research Associate to address. In addition, 9 WCB numbers from Velindre were randomly chosen on the 12th November 2013 to check the data and sample tracking. The numbers were RQFHS000161, 279, 302 and 404 and RWMBV2302, 2331, 2347, 2365 and 2397.

Donation 161
• All samples in correct place.
• Follow up not started yet as newly consented patient.

Donation 279
• All samples in correct place.
• Follow up not started yet as newly consented patient.
Donation 302
• All samples in correct place.
• Retrospective box was not ticked on consent tab.
• Pathology number entered on database but no form in patient pack to compare accuracy.
• Follow up not started yet as newly consented patient.

Donation 404
• All samples in correct place.
• Follow up not started yet as newly consented patient.

Donation 2302
• All samples in correct place.
• No consent form present in patient pack.
• No blood form present in patient pack but samples created on database.
• Paperwork from lab to show intention to create FFPE blocks from cores.

Donation 2331
• All samples in correct place.
• Follow up outstanding - 2012 consent.

Donation 2347
• All samples in correct place.
• Nurse had signed patient consent but not printed name.
• Follow up outstanding - 2012 consent.

Donation 2365
• All samples in correct place.
• Blue copy of patient consent completed in error but completed correctly.
• Pathology number entered incorrectly on to database.
• Follow up outstanding - 2012 consent.

Donation 2397
• All samples in correct place.
• Patient consent form had not been signed by consenting nurse.
• Pathology number entered on database but no pathology report in patient pack to compare.
• Follow up outstanding - 2012 consent.

Additional Random Sample Summary
7 EDTA rack randomly scanned revealed:
1 case not registered on database

Laboratory Report
1. Freezer Alarm/Power Fail Test - Circuit breaker switched to ‘off’, freezer audibly alarmed. Autodialler called pre set phone numbers.
3. Temperature Logs - Freezer temperature log up to date and located correctly on freezer door.
4. SOP File - Located in lab office. All recent new
versions of SOPs present. Reviewed SOPs require updated cover sheet.

5. HTA License - Displayed correctly on freezer.

Medical Genetics

13 records showing EDTA being present in Medical Genetics were randomly chosen for checking. Donations originated from 3 different collecting sites.
Donations: 362 from Withybush
317 from Royal Gwent
271, 812, 916, 1211, 1973, 2391, 2817, 2844, 2846, 2850 and 3012 from Swansea

All samples were present and in the correct place. Internal shipment requests are filed in the site file. Extraction worksheets and lists are filed.

Withybush

Donation 362
• All samples in correct place.
• Date on paraffin form differed from date on database for ‘time sample left patient’.
• No follow up form in patient pack but date entered on the database.

Royal Gwent

Donation 317
• All samples in correct place.
• Clotting time entered as minutes instead of time on clock.
• Paraffin form showed a normal block being taken but not showing on database. 1 x tumour and 1 x H&E only.
• Follow up sheet created and entered.

Donation 1211
• All samples in correct place.
• Pathology report not present in patient pack against which to check the entered pathology number.
• Follow up sheet created and entered. When checked at audit, patient had since died so amended at audit.

Donation 1973
• All samples in correct place.
• Follow up sheet created and entered.

Donation 2391
• All samples in correct place.
• Follow up outstanding.

Donation 2817
• All samples in correct place.
• Blood forms not signed by lab.
• Follow up not started yet as newly consented patient.

Donation 2844
• All samples in correct place.
• Follow up not started yet as newly consented patient.

Donation 2846
• All samples in correct place.
• Follow up not started yet as newly consented patient.

Donation 2850
• All samples in correct place.
• Follow up not started as newly consented patient.

Swansea

Donation 217
• All samples in correct place.
• Follow up sheet created and entered.

Donation 812
• All samples in correct place.
• Follow up sheet created and entered

Donation 916
Donation 3012
• All samples in correct place.
• Follow up not started as newly consented patient.

Additional Random Sample Summary
8 camlab boxes of DNA randomly scanned revealed:
No anomalies

2 EDTA racks randomly scanned revealed:
No anomalies

Laboratory Report
1. Freezer Alarm/Power Fail Test - Circuit breaker switched to ‘off’, freezer audibly alarmed. No call from switchboard after 5 minutes. Called switchboard, no alarms activated there. Checked rear of freezer, lead attached but could not see further connection to autodialler.
2. Maintenance Records - No freezer maintenance log.
3. Temperature Logs - Freezer temperature log up to date and located correctly on freezer door.
4. SOP File - Located in lab. All recent new versions SOPs present. Reviewed SOPs require updated cover sheet.
5. HTA License - Displayed correctly on freezer.

Royal Gwent
The data queries were run against the live WCB database on 15th October 2013 and the results are outlined below.

1. Donations with missing diagnosis - 7 instances found
2. Donations with no blood samples - 2 instances found
3. No pathology reports for donations over 30 days old - 1 instance found
4. Samples without a donation - none
5. The Ischaemic time query returns results for those donations that has either a negative ischaemic time or the ischaemic time is greater than 3 hours - none

A list of the missing data was left with the nurse to address. 11 WCB numbers were randomly chosen to check the data and sample tracking. Numbers generated were 25, 134, 240, 322, 488, 572, 630, 345, 824, 930 and 944. One further WCB number (317) had the paperwork checked as a result of samples audited in Medical Genetics. The WCB theatre form is not used in the Royal Gwent.

Donation 25
• All samples in correct place.
• Dates on consent form did not match date entered on the database.
• Early patient and no formal paraffin form created.
• No barcode on form recording paraffin samples taken.
• Follow up sheet completed but date of death was incorrect on database.

Donation 134
• All samples in correct place.
• Paraffin form does not state how many blocks taken for WCB. One block created on the database and staff confirmed this is correct.
• Follow up sheet created and entered.

Donation 240
• All samples in correct place.
• Clotting time entered as minutes instead of the time on the clock e.g. 30 mins not 11am.
• Follow up sheet created and entered.

Donation 322
• All samples in correct place.
• Patient signature on line for name and vice versa.
• Control signature on line for name and vice versa.
• Clotting time entered as minutes instead of the time on the clock.
• Paraffin sample shows as tumour but should be showing as normal.
• Follow up sheet has not been created as only sample for WCB is normal.

Donation 488
• All samples in correct place.
• Clotting time entered on database as minutes instead of time on clock.
• Time sample left patient not known and box not ticked on database.
• Follow up sheet created and entered.

Donation 572
• All samples in correct place.
• Clotting time entered as minutes instead of time on
clock. Noted that nurse cannot overwrite correct time but has noted correct time on sample paperwork.

- Time sample left patient not known and box not ticked on database.
- Follow up sheet created but noted that no information available at that time.

**Donation 630**
- All samples in correct place.
- Time sample left patient on form but incorrect on database.
- Follow up sheet created and entered.

**Donation 645**
- All samples in correct place.
- Control present in patient pack but not entered on database.
- Clotting time entered as minutes instead of time on clock.
- Follow up sheet created and entered.

**Donation 824**
- All samples in correct place.
- Follow up sheet not yet created as new patient.

**Donation 930**
- All samples in correct place.
- Follow up sheet not yet created as new patient.

**Donation 944**
- Paraffin tumour block showed in H&E cabinet on database.
- Follow up sheet not yet created as new patient.

**Additional Random Sample Summary**

**2 H&E Drawer randomly scanned revealed:**
RVFAR 240 selected audit case - 1 missing slide previously shipped to Cardiff but still in transit at time of audit. Later accepted at Cardiff.

RVFAR 944 selected audit case - paraffin block PT1A incorrectly recorded on database as being in a slide drawer location. Actual block location found and database correctly amended.

**6 Paraffin rows randomly scanned revealed:**
RVFAR 240 selected audit case - corresponding block to previous slide also in transit to Cardiff. Later accepted at Cardiff.

**3 EDTA racks randomly scanned revealed:**
RVFAR 630 and RVFAR 645 selected audit cases - samples shipped to Cardiff but not accepted there at time of audit, therefore samples showing as in transit on database. Samples later accepted at Cardiff.

**4 Camlab boxes of Serum randomly scanned revealed:**
RVFAR 645 selected audit case - serum samples 3 & 4 previously shipped to Cardiff but not accepted there at time of audit, therefore samples showing as in transit on database. Samples later accepted at Cardiff.

8 samples without barcode labels (written in pen)

**Laboratory Report**

1. Freezer Alarm/Power Fail Test - Circuit breaker switched to ‘off’, freezer audibly alarmed. Freezer is located in a Blood Science Laboratory that is staffed 24 hours. The procedure here for all equipment failures / alarms is therefore comprehensive as all will be attended to first hand and immediately. WCB Staff would only be contacted if there was no way of recovering the temperature and disaster recovery procedure was executed. Contact details for WCB are to be placed on the freezer in case Disaster Recovery is initiated during Bank Holiday or extended Annual / Sickness Leave by Gwent WCB staff.

2. Maintenance Records - Freezer maintenance not present but Blood Science staff regularly maintain freezer. Centrifuge maintenance log not present but Tristol Fusion wipes are present.

3. Temperature Logs - Freezer temperature log is electronic and constant on a central laboratory system.

4. SOP File - Located in lab office. All recent new versions of SOPs present. Reviewed SOPs require updated cover sheet.

5. HTA License - Displayed correctly above the freezer (under bench unit).

**Follow up 2013**

10 WCB numbers were randomly chosen to check the follow up data. Numbers generated were 5, 40, 177, 252, 322, 372, 488, 556, 563 and 761

**Donation 1**
- All follow up sheets completed and entered accurately on to the database but name of oncologist was omitted.

**Donation 40**
- Follow up sheet completed and entered accurately on to database.
Donation 177
• Follow up sheet completed and entered accurately on database.

Donation 252
• Query chemotherapy and radiotherapy on 1st relapse. Dates not entered for neo adjuvant treatment and date of death was 1 day out on database compared with follow up sheet.

Donation 322
• Follow up sheet completed but noted that tissue for WCB is normal only.

Donation 372
• This patient also consented against 227. Nurse to clarify which follow relates to which donation as at the moment it seems all follow relates to 227 and has been entered under the 372 episode.

Donation 488
• Follow up sheet completed but date not entered onto database.

Donation 556
• Follow up sheet completed and entered accurately onto database.

Donation 563
• Follow up sheet completed and entered accurately onto database.

Donation 761
• Follow up sheet not yet created as newly consented patient.

Donations that have either a negative ischaemic time or the ischaemic time is greater than 3 hours - 9 instances found.

A list of the missing data was left with the WCB staff to address. In addition, 10 WCB numbers were randomly chosen to check the data and sample tracking. Numbers generated were 309, 319, 422, 428, 526, 560, 649, 683, 736 and 761.

Donation 309
• All samples in correct place.
• Time left patient was entered in time sample placed in formalin.
• Used date of death as date of follow up instead of actual date patient was followed up.

Donation 319
• All samples in correct place.
• No tissue for this patient but pathology report number written on paraffin form and matched database.
• Follow up outstanding.

Donation 422
• All samples in correct place.
• Follow up sheet created and entered.

Donation 428
• All samples in correct place.
• Patient consent form was not barcoded.
• Follow up sheet created and entered. Radiotherapy field did not match form and dose of letrozole was 0.1mg out on database compared to form.

Donation 526
• All samples in correct place.
• Patient consent form was not barcoded.
• Theatre form completed but time placed in formalin 1 min out on database.
• Follow up sheet created and entered. 2 out of 3 dates on form entered on database. Data entered into the comments field on the database but not recorded on follow up sheet so unable to compare for accuracy.

Donation 560
• All samples in correct place.
• Follow up sheet created and entered. Comments
entered on the database were not recorded on follow up sheet to compare for accuracy.

Donation 649
• All samples in correct place.
• Follow up sheet created and entered. Oncologist entered on database does not correspond to data on sheet.

Donation 683
• All samples in correct place.
• Follow up sheet created and entered. Oncologist entered on database does not correspond to data on sheet.

Donation 736
• All samples in correct place.
• Pathology number entered on database was one year out compared to pathology report in patient pack.
• Follow up sheet created and entered. The follow up sheet and database had not recorded dates of follow up. Therapy information on sheet had not been entered on to the database.

Donation 761
• All samples in correct place.
• Follow up sheet not yet created as newly consented patient.

Additional Random Sample Summary
3 H&E Drawers randomly scanned revealed:
4 slides exist in duplicate.
1 slide needed a new barcode label as current barcode would not scan. Label needs to be requested from Ysbyty Gwynedd label printer.
1 slide did not exist on the database and needed to be created.
Multiple slides had been 'signed out' on the database for QA purposes and not signed back in but were present in the slide drawer.
3 slides found in the drawer which did not exist on the database initially found to not have corresponding blocks. Investigations revealed tumour blocks had been found to be normal during QA process but corrective procedure was not complete to convert tumour to normal for all blocks, slides, paperwork and scanned images.
Other anomalies noted and WCB BMS left a list to resolve.

9 Paraffin trays randomly scanned revealed:
16 blocks (4 cases) found in alternate locations
4 further cases with blocks that didn’t exist on the database. Investigations revealed QA required the blocks to be changed from tumour to normal and vice versa but this process was not complete for all blocks, slides, paperwork and scanned images.
One case where paraffin blocks had been recut in addition to existing paraffin blocks but had been labelled incorrectly. Labelled PT1, PT2 and PT3 in duplicate rather than PT4, PT5 and PT6 as it should be in sequential order.

5 EDTA racks randomly scanned revealed:
No anomalies

8 Camlab boxes of Serum randomly scanned revealed:
No anomalies

Laboratory Report
1. Freezer Alarm/Power Fail Test - Circuit breaker switched to ‘off’, freezer audibly alarmed. Freezer known not to be connected to autodialler or external monitoring system since move from Ysbyty Gwynedd.

3. Temperature Logs - Freezer temperature log up to date and located correctly on freezer door.

4. SOP File - Located in lab. All recent new versions of SOPs present. Reviewed SOPs require updated cover sheet.

5. HTA License - Displayed correctly on freezer.

Follow up 2013
11 WCB numbers were randomly chosen to check the follow up data. Numbers generated were 1, 74, 217, 283, 359, 431, 507, 525, 584, 638 and 682

Donation 1
• Follow up sheet completed but 6th date of follow up was entered incorrectly.

Donation 74
• Follow up sheet completed and entered accurately on database.

Donation 217
• Follow up sheet completed and entered accurately on database.

Donation 283
• Follow up sheet completed and entered accurately on database.

Donation 359
• Follow up sheet completed and entered accurately on database.

Donation 431
• Follow up sheet completed and entered accurately on database.

Donation 507
• Follow up sheet completed and entered accurately on database.

Donation 525
• Follow up sheet completed and entered accurately on database.

Donation 584
• Follow up sheet could not be completed as patient consented in Ysbyty Glan Clwyd (YGC). YGC use different system to Ysbyty Gwynedd (YG) and WCB nurse does not have access.

Donation 638
• Follow up sheet completed but field not completed on database for radiotherapy. Total ‘gy’ field seems incorrect but database will not acknowledge the decimal point.

• All data for patients entering clinical trials has not been entered to date. WCB nurse will do all at once with clinical trials nurses.

Donation 682
• Follow up sheet completed and entered accurately on database.

Bridgend
All patients currently consented in the Princess of Wales Hospital; Bridgend will be within the colorectal speciality and under the same prefix as Swansea as Bridgend are part of the newly merged Abertawe Bro Morgannwg Local Health Board. The data queries for Bridgend were included in the Swansea run on the live WCB database on 22nd October 2013 and the results are outlined under Swansea. To date, the WCB nurse in Bridgend has consented 50 patients between April 13 - November 13, and they confirmed that none of these consents were included in the 5 main criteria for data queries.

A copy of the Swansea list of missing data was left on site for information. In addition, 9 WCB numbers for those allocated to Bridgend were randomly chosen to check the data and sample tracking. Numbers generated were 3053, 3059, 3062, 3068, 3070, 3075, 3078, 3080 and 3083.

Donation 3053
• All samples in correct place
• Transposed times on database for separating and clotting in relation to serum.
• Follow up sheet not yet created as newly consented patient.

Donation 3059
• All samples in correct place.
• Follow up sheet not yet created as newly consented patient.

Donation 3062
• All samples in correct place.
• Time sample left patient on paraffin form not entered but a time has been entered on the database. Unable to check to accuracy.
• Follow up sheet not yet created as newly consented patient.

Donation 3068
• All samples in correct place
Follow up sheet not yet created as newly consented patient.

Donation 3070
• All samples in correct place.
• Patient had not completed the date on the consent form.
• Follow up sheet not yet created as newly consented patient.

Donation 3075
• All samples in correct place.
• Time sample left patient was incorrect on database but completed by BMS in Swansea.
• Follow up sheet not yet created as newly consented patient.

Donation 3078
• All samples in correct place.
• Dates did not match on form as patient entered 12th August but nurse corrected hers to 13th August which was the correct date of consent.
• Follow up sheet not yet created as newly consented patient.

Donation 3080
• All samples in correct place.
• Follow up sheet not yet created as newly consented patient.

Donation 3083
• All samples in correct place.
• Follow up sheet not yet created as newly consented patient.

Additional Random Sample Summary
1 H&E Drawer randomly scanned revealed: No anomalies
5 Rows in paraffin trays randomly scanned revealed: No anomalies
2 EDTA racks randomly scanned revealed: No anomalies
2 Camlab boxes of Serum randomly scanned revealed: No anomalies

Laboratory Report
1. Freezer Alarm/Power Fail Test - Circuit breaker switched to ‘off’, freezer audibly alarmed. Autodialler called pre set phone numbers.
2. Maintenance Records - Freezer maintenance log completed, displayed correctly on freezer door. Centrifuge maintenance log completed, located correctly in close proximity to the centrifuge.
3. Temperature Logs - Freezer temperature log up to date and displayed correctly on freezer door.
4. SOP File - Located in nurses office. All recent new versions of SOPs present. Reviewed SOPs all present and up to date.
5. HTA License - Displayed correctly on freezer.

Swansea
The data queries were run against the live WCB database on 22nd October 2013 and the results are outlined below.

1. Donations with missing diagnosis - 74 instances for Swansea consented patients.
2. Donations without blood samples - 44 instances for Swansea consented patients.
3. No pathology reports for donations over 30 days old - 12 instances in Swansea.
4. Samples without a donation - none.
5. The Ischaemic time query returns results for those donations that has either a negative ischaemic time or the ischaemic time is greater than 3 hours – 8 instances.

A list of the missing data was left with the WCB staff to address. In addition, 10 WCB numbers from Singleton and 10 WCB numbers from Morriston were randomly chosen to check the data and sample tracking. Numbers generated for Singleton were 726, 1043, 1371, 1542, 1795, 2043, 2120, 2330, 2605 and 2683. Numbers generated for Morriston were 617, 1158, 1248, 1577, 1814, 1956, 2266, 2470, 2726 and 2838.

The WCB Theatre form is not used in Swansea.
The control consent form not routinely barcoded.

Singleton

Donation 726
• All samples in correct place.
• Follow up sheet created and entered.
• pTNM entered but not written on follow up form to cross check.

Donation 1043  
• All samples in correct place.  
• Follow up sheet created and entered.

Donation 1371  
• All samples in correct place.  
• Follow up sheet created and entered.

Donation 1542  
• All samples in correct place.  
• Follow us sheet created and entered.  
• Date of neo adjuvant chemotherapy on database did not match date on follow up form.

Donation 1795  
• All samples in correct place.  
• Follow up sheet created and entered.

Donation 2043  
• All samples in correct place.  
• Follow up sheet created and entered.

Donation 2120  
• All samples in correct place.  
• Follow up sheet created and entered.

Donation 2330  
• All samples in correct place.  
• Follow up sheet not yet created and follow up outstanding.

Donation 2605  
• All samples in correct place except slides were missing from file (see below).  
• Follow up sheet not yet created and outstanding.

Donation 2683  
• All samples in correct place.  
• Follow up sheet not yet created as new patient.

Additional Random Sample Audit
17 H&E Drawers randomly scanned revealed:  
3 cases where slides had been labelled as the corresponding block labels not slides  
RVCC4 2605 selected audit case - slides not found in file

17 Paraffin trays randomly scanned revealed:  
No anomalies

6 EDTA racks randomly scanned revealed:  
RVCC4 2648 BD1 labelled as BC1

8 Camlab boxes of Serum randomly scanned revealed:  
No anomalies

5 Camlab boxes of Frozen Tissue randomly scanned revealed:  
3 samples needed a new barcode label printed as current labels would not scan.  
1 sample found in an alternate location

0 boxes of DNA / RNA randomly scanned this year

Laboratory Report
1. Freezer Alarm/Power Fail Test - Circuit breaker switched to ‘off’, freezer did not audibly alarm first time but did on second attempt.  Freezer connected to central laboratory monitoring system that detects temperature fluctuations but is not affected by circuit breaker test as temperature remains constant during this time.  Battery Low and power fail light on digital display was noted.

3. Temperature Logs - Freezer temperature log up to date and located correctly on freezer door.

4. SOP File - Located in lab office. All recent new versions of SOPs present. Reviewed SOPs updated cover sheet present.

5. HTA License - Displayed correctly on freezer.

Donation 617
- All samples in correct place.
- Follow up sheet created and entered.

Donation 1158
- All samples in correct place.
- Date on consent form is incorrect.
- Follow up sheet created and entered.

Donation 1248
- All samples in correct place.
- Follow up sheet created and entered.

Donation 1577
- All samples in correct place.
- Follow up sheet created and entered.

Donation 1814
- All samples in correct place.
- Follow up sheet created and entered.

Donation 1956
- All samples in correct place.
- Follow up sheet created and entered.

Donation 2266
- All samples in correct place.
- Follow up sheet created and entered.
- Relapse information on follow up sheet but not entered on the database.

Donation 2470
- All samples in correct place.
- Follow up sheet created and entered.
- Date of follow up not entered on database but recorded on follow up sheet.

Donation 2726
- All samples in correct place.
- Follow up sheet not yet created as new patient.

Donation 2838
- All samples in correct place.
- Follow up sheet not yet created as new patient.

Additional Random Sample Audit
4 Camlab boxes of Serum randomly scanned revealed:
No anomalies

Laboratory Report
1. Freezer Alarm/Power Fail Test - Circuit breaker switched to ‘off’, freezer audibly alarmed. No call from switchboard after 5 minutes. Called switchboard, no alarms activated there. Checked rear of freezer, lead attached freezer to autodialler but autodialler did not call any contacts.


3. Temperature Logs - Freezer temperature log up to date and located correctly on freezer door.

4. SOP File - Located in lab. All recent new versions of SOPs present. Reviewed SOPs require updated cover sheet.

5. HTA License - Displayed correctly on freezer.

Swansea Follow up 2013
12 WCB numbers were randomly chosen to check the follow up data. Numbers generated were 46, 429, 531, 728, 1105, 1404, 1533, 1910, 2478 and 2708. Patients 361 and 1123 were compared using the follow up sheet, database and Myrddin.

Donation 46
- Follow up sheet completed and entered accurately onto the database.

Donation 429
- Follow up sheet completed but dates of follow up on database did not reflect dates on sheets.

Donation 531
- Follow up sheet completed but of the 2 dates entered on the form, 1 was not clear and in wrong field.
Donation 728
• Follow up sheet completed but 1 date of follow up on the database but not recorded on the sheet.
• Clinical trial recorded in regimen but no clinical trial at that time.

Donation 1105
• Follow up sheet completed but 1st date of follow up entered on database incorrectly.

Donation 1404
• Follow up sheet completed and entered accurately onto the database.

Donation 1533
• Follow up sheet completed and entered accurately onto the database.

Donation 1910
• Follow up sheet completed but is outstanding from 2011.

Donation 2478
• Follow up sheet completed but is outstanding from 2011. Patient consented 2012.

Donation 2708
• Follow up sheet completed but is outstanding from 2011. Patient consented 2012.

Donation 361
• Follow up sheet completed but dates of follow up on form did not match dates on database.

Donation 1123
• Follow up sheet completed but sheet showed adjuvant therapy dated 2 years after operation.
• Further investigated using Myrddin and conclusion using data and oncologists letter was that it was not adjuvant but in fact a relapse.
• Site asked to destroy current follow up sheet and create a new sheet using the accurate data gleaned from audit.
• Database was updated at time of audit and a copy of letter will be held in patient pack.

Withybush
This year’s audit was conducted in the absence of the WCB nurse due to serious illness. All available paperwork was audited at the time but based on past performance, where paperwork was not available on the day of audit, it is likely the WCB nurse would have it filed securely in a locked cabinet that the Project Officer could not access on the day.

The data queries were run against the live WCB database on 16th October 2013 and the results are outlined below.

1. Donations with missing diagnosis - 12 instances.
2. Donations without blood samples - 2 instance.
3. No pathology reports for donations over 30 days old - None.
4. Samples without a donation - 1 instance.
5. The Ischaemic time query returns results for those donations that has either a negative ischaemic time or the ischaemic time is greater than 3 hours - 5 instances found.

A list of the missing data was left with the WCB staff to address. In addition, 10 WCB numbers from Withybush and 3 from Carmarthen were randomly chosen to check the data and sample tracking. Withybush numbers generated were 230, 327, 401, 531, 630, 777, 896, 952, 1113 and 1234. Carmarthen numbers generated were 1024, 1106 and 1247.

Donation 230
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet created and entered. Last date of follow up on database is 28/03/13 but no form in patient pack.

Donation 327
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• 6 blocks recorded on paraffin paperwork but 7 blocks on database. PT 2A entered twice.
• Follow up sheet created and entered. Last date of follow up on database is 28/03/13 but no form in patient pack.
Donation 401
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• QA carried out on FT1 was not entered on to the database.
• Follow up sheet created and entered.
• Date of 2nd follow up date was 3 days out on database compared to follow up form. Last date of follow up on database is 30/3/14 but no form in patient pack.

Donation 531
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet created and entered.

Donation 630
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• 4 blocks recorded on paraffin form but 5 blocks on database. PT 1A created twice.
• Follow up sheet created and entered. Last date of follow up on database is 25/01/13 but no form in patient pack.

Donation 777
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• 3 pathology reports in patient pack. 2 relate to patient 777 and the other to another patient.
• Follow up sheet created and entered. Last date of follow up on database is 31/05/13 but no form in patient pack.
• Date of death recorded but no paperwork to check the date against.

Donation 896
• All samples showing in Withybush Freezer which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet created and entered.

Donation 952
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet created and entered.

Donation 1113
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet not yet created as new patient.

Donation 1234
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet not yet created as new patient.

Donation 1024
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet created and entered.

Donation 1106
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet not yet created as new patient.

Donation 1247
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet not yet created as new patient.

Carmarthen

Donation 1024
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet created and entered.

Donation 1106
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet not yet created as new patient.

Donation 1247
• All samples showing in Withybush storage which is now situated in UHW, Cardiff.
• All samples in correct co-ordinates.
• Follow up sheet not yet created as new patient.

Additional Random Sample Audit
Problem identified at previous years audit remains for all samples numbered approx 770 - 830, due to misalignment on printer. Labels are being reprinted for samples as required.

7 H&E Drawers randomly scanned revealed:
29 Cases would not scan - Due to aforementioned printer misalignment

8 Paraffin trays randomly scanned revealed:
11 blocks missing - Paraffin cabinet recently moved from Withybush to UHW, some disruption to paraffin block filing during the move. A full audit of this paraffin cabinet should be carried out.
1 case would not scan - Due to aforementioned printer misalignment

9 EDTA racks randomly scanned revealed:
1 Case labelled incorrectly, extra zero added to patient number.
7 cases would not scan - Due to aforementioned printer misalignment

3 Camlab boxes of Serum randomly scanned revealed:
No anomalies

3 Camlab boxes of Frozen Tissue randomly scanned revealed:
1 Case would not scan - Due to aforementioned printer misalignment

Laboratory Report - Withybush Freezer now housed in UHW, Cardiff

1. Freezer Alarm/Power Fail Test - Circuit breaker switched to ‘off’, freezer did not audibly alarm. Call from switchboard regarding a fridge alarming. Assume port needs to be renamed with switchboard.
2. Maintenance Records - No freezer maintenance log.
3. Temperature Logs - Freezer temperature log up to date and located correctly on freezer door.
4. SOP File - Located in Withybush office. All recent new versions of SOPs present. Reviewed SOPs require updated cover sheet.
5. HTA License - No licence displayed on freezer but would be covered under the Cardiff HTA licence for UHW. A copy will be made and displayed as required.

Follow up 2013
10 WCB numbers were randomly chosen to check the follow up data. Numbers generated were 81, 163, 300, 371, 531, 633, 762, 836, 912 and 1011

Donation 81
• Addressograph covered 1st follow up date so couldn’t check it. Last date of follow up on database was 27/12/12 but no form in patient pack.

Donation 163
• Last date of follow up on database was 28/02/13 but no form in patient pack.

Donation 300
• Follow date on database one day out compared to follow up form. Last date of follow up on database was 28/02/13 but no form in patient pack.

Donation 371
• Follow up sheet completed and entered accurately onto the database.

Donation 513
• Last date of follow up on database was 30/04/13 but no form in patient pack.

Donation 633
• Last date of follow up on database was 28/02/13 but not form in patient pack.

Donation 762
• Follow up sheet completed and entered accurately onto the database.

Donation 836
• Follow up sheet completed and entered accurately onto the database.

Donation 912
• Follow up form completed and entered accurately onto the database.

Donation 1011
• Follow up sheet completed and entered accurately onto the database.
For general information please contact:

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