WALES CANCER BANK

Annual Report | April 2011 - March 2012
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## Abbreviations

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<th>Abbreviation</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>ABPI</td>
<td>Association of British Pharmaceutical Industries</td>
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<tr>
<td>BMD</td>
<td>Bone Mineral Density</td>
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<tr>
<td>CANSIC</td>
<td>Cancer Network Information System Cymru</td>
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<td>CRW</td>
<td>Cancer Research Wales</td>
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<tr>
<td>DNA</td>
<td>Deoxyribonucleic Acid</td>
</tr>
<tr>
<td>ECMC</td>
<td>Experimental Cancer Medicine Centre</td>
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<tr>
<td>EDTA</td>
<td>Ethylenediamine Tetraacetic Acid</td>
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<tr>
<td>EGFR</td>
<td>Epidermal Growth Factor</td>
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<tr>
<td>ER</td>
<td>(O)estrogen Receptor</td>
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<tr>
<td>FFPE</td>
<td>Formalin Fixed Paraffin Embedded</td>
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<tr>
<td>GCP</td>
<td>Good Clinical Practise</td>
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<tr>
<td>H&amp;E</td>
<td>Haematoxylin and Eosin</td>
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<td>HTA</td>
<td>Human Tissue Authority</td>
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<tr>
<td>IBMS</td>
<td>Institute of Biomedical Science</td>
</tr>
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<td>ISBER</td>
<td>International Society for Biological and Environmental Repositories</td>
</tr>
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<td>IT</td>
<td>Information Technology</td>
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<td>LLEG</td>
<td>Lay Liaison and Ethics group</td>
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<td>MREC/REC</td>
<td>Multi-centre Research Ethics Committee / Research Ethics Committee</td>
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<td>NCRI</td>
<td>National Cancer Research Institute</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>NISCHR</td>
<td>National Institute for Social Care and Health Research</td>
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<td>NHS Wales Informatics Service</td>
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<td>PGR</td>
<td>Progesterone Receptor</td>
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<td>Quality Assurance</td>
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<td>RNA</td>
<td>Ribonucleic acid</td>
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<td>SAIL</td>
<td>Secure Anonymised Information Linkage (system)</td>
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<td>SMP</td>
<td>Stratified Medicine Programme</td>
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<td>WCB</td>
<td>Wales Cancer Bank</td>
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<tr>
<td>XML</td>
<td>Extensible Markup Language</td>
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Figures

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<td>Figure 1</td>
<td>Annual recruitment by centre by year</td>
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<td>Figure 2</td>
<td>Consent by age and gender</td>
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<td>Figure 3</td>
<td>Consent numbers with at least one available sample by tumour type</td>
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<td>Figure 4</td>
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<td>Figure 5</td>
<td>The MAPKinase pathway activated by EGFR, showing the commonly activated oncogenes</td>
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Tables

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<tr>
<td>Table 1</td>
<td>SMP Genetic tests</td>
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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.

The printed version of this year’s Annual Report is an edited version to reduce printing and related costs. A link to the full version of the Annual Report can be found on the WCB website (www.walescancerbank.com) homepage.
The last year has been one of great changes, both inside and outside Wales. In terms of cancer treatment, we have stronger confirmation than ever that the molecular era is here, with the introduction of specific drugs such as Vemurafenib for melanomas that bear a mutation in the BRAF gene, and Crizotinib for patients with lung cancer that bear a mutation in the ALK gene.

These now join existing molecularly targeted treatments, including herceptin for breast cancer, erlotinib for lung cancer, and cetuximab for colon cancer. For the Wales Cancer Bank, too, the molecular era is here, as we have the results of our pilot study to molecularly characterise the tumour samples that we hold, summarised in the Scientific Report in this document. Thanks to the generosity of Cancer Research Wales, we have been able to begin this new phase in our activities, with intriguing results in colorectal cancer. As well as understanding how gene alterations affect the behaviour of cancer, we may gain insights into the nature of cancer in the Welsh population. Are the frequencies of gene mutations the same as in other populations? If the preliminary finding of a higher rate of p53 mutations is true, what does this mean? What if other mutations - targets of drug activity - are present at significantly higher or lower rates in the Welsh population? This has wide implications for healthcare planning in Wales, and I hope that the NHS in Wales will be alert to and responsive to the new challenges that the molecular era poses. This is ‘Stratified Medicine’ - selecting those patients who specifically benefit from a novel treatment, based on the molecular characteristics of their tumour.

In addition to the characterisation of our pre-existing collection, WCB has had immense pride in participating in the Cancer Research UK Stratified Medicine Programme, as one of the Clinical Hubs in the UK, collecting tumour tissue to establish working methods and resilience for the NHS in analysing and reporting molecular abnormalities in a timely fashion. This is of the utmost importance to the future of healthcare delivery in the NHS, not just in cancer, but in time, in other fields of medicine. It is vital that the NHS in Wales does not view Stratified Medicine as living solely in a ‘research’ silo, of no relevance to healthcare delivery. It is here already, and is only going to accelerate in the future. It is the future of medicine and we must prepare for it now.

The core activities of the Wales Cancer Bank have continued, with nearly 6,000 patients consenting in total. This is a real tribute to the faith that our patients have shown in this initiative, to the dedication of our superb staff in supporting them, and in processing and storing their tissue and blood samples, and I would like to thank all of them.

Finally, I would like to thank our Funders, the Welsh Government, Cancer Research Wales, and Velindre NHS Trust for their support for our core activities, and for Cancer Research Wales’ support for our pilot study of molecular characterisation. In addition, I would like to thank Cancer Research UK, for their supporting our contribution to their Stratified Medicine Programme. Each of these areas is quite distinct and, I believe, complimentary. Each is vital as we go forward.

Professor Malcolm Mason
Director, Wales Cancer Bank
Targets & Recruitment

Targets for 2011/12

<table>
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<th>Targets for 2011/12</th>
<th>Achieved</th>
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<tr>
<td>Accrue 5,600 patients in total</td>
<td>January 2012</td>
</tr>
<tr>
<td>Profile sample collection and requests</td>
<td>June 2011</td>
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<tr>
<td>Begin characterising sample sets</td>
<td>January 2012</td>
</tr>
<tr>
<td>Continue development of the web accessible version of database</td>
<td>Ongoing</td>
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<tr>
<td>Supply five new projects with biosamples</td>
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Recruitment

1244 patients were recruited between April 2011 and March 2012 across all collecting sites to take the total number of patients consented since the beginning of the project to 5869. The gender split of patients recruited since inception is 55% female and 45% male, showing a 1% shift towards female donors since last year. The majority of donors (74%) are aged 60 or over with 80% of male donors over 60 but 68% of female donors over the age of 60. 88% of consents are obtained pre-operatively.

Breast, colorectal and prostate remain the three largest collections in the bank and consent rates have increased from last year in three out of the five geographic locations.

91% of all consents have at least one biosample available for use and figures 3 below and figure 4 over show the detail by tumour type and then by sample type.

Figure 1 - Recruitment by centre by year

Figure 2 - Consent by age and gender

Figure 3 - Consent numbers with at least one available sample by tumour type
Since the WCB was established, cancer research has focused more and more on the development of targeted drugs for treatment. However, monotherapy using these agents has been disappointing, suggesting that our understanding of the precise role that these targets play in tumourigenesis is lacking. Cancer is a heterogeneous disease and treatment targeting in the future is likely to require knowledge of inter- and intra-tumour variability with respect to tumour type and individual patients. In addition, there will remain a fraction of tumours within a given tissue type that have developed alternative drivers to the common oncogenes. There is therefore a need to identify the proportion of tumours that lack the involvement of the common oncogene drivers to provide targeted treatment for all patients, not just those whose tumours harbour the common oncogene mutations.

The response of both normal and tumour cells to their environment is mediated via intracellular signaling pathways. Activation of these pathways can be triggered by binding of any of a number of different growth factors to the extracellular domain of a G protein-coupled receptor. An intracellular pathway that involves phosphorylation of a number of different proteins, including members of the Ras family of G proteins, is then activated. Examples of pathways activated by signaling via Ras include the MAPKinase and PI3K/Akt pathways (Figure 5). Activating mutations in key factors in these pathways e.g. mutation in KiRas or Braf, can cause dysregulation of cell growth. Similarly, mutations causing loss of activity of other participants in these pathways, such as PTEN, can lead to release of inhibition of signaling molecules such as PI3K, resulting in changes in the regulation of cell growth and death.
It has been shown that efficacy of some inhibitors of growth factors (e.g. EGFR inhibitors in colorectal cancer or Her2 inhibitors in breast cancer) can be affected by either activating mutations in key drivers of the pathway (KiRas, BRaf) or loss of activity of regulators such as PTEN.

In the era of personalised medicine and with finite NHS resources, it will become increasingly important to target expensive diagnostic tests and treatment, to those patients who will benefit most from them. Many patients may be treated appropriately and effectively by surgery, radiotherapy, and, where appropriate, older, less expensive targeted treatments (for example, tamoxifen in Grade 1 node-negative breast cancer), rather than needing expensive novel targeted treatments.

The extensive tissue collection within the Wales Cancer Bank is of considerable value in the identification of links between common oncogene mutations in the MAPKinase signaling cascade with differing clinical presentation phenotypes (age, pathological subtype, grade, lymph node invasion) and outcome. This would enable selection of groups with higher clinical/oncogene-driven risk of recurrence for further molecular testing/tailored treatment regimes. In addition, categorising the presence of known oncogene mutations enables identification of the smaller number of known oncogene-negative tumours, which will provide researchers with a fertile group for identification of novel oncogenes.

**Results so far**

We have so far characterised a group of 119 cases from a potential 674 colorectal cancer cases for mutations in some of the key oncogenes highlighted in Figure 5. These include mutations in KiRas and NRas, BRaf, PIK3CA, all of which are involved in MAPKinase pathway signaling, and p53, which is involved in cancer progression through its regulation of apoptosis. Our initial results show that the two commonest mutations in this series involved the p53 and KiRas oncogenes.

In all but 13 of 119 cases, all 5 oncogenes were analysed for mutation. In the 111 cases analysed for p53 mutation, all but 7 (93.7%) showed a change in DNA sequence. The majority of these involved the common polymorphism at codon 72 (55 (49.5%), and 42 (37.8%) a more complex profile involving codon 72 and at least one other codon). Eight other mutations were observed involving codons 151, 168, 175, 178, 249, 273, 277, and 282. Twelve other mutations were observed involving codons 151, 168, 175, 178, 249, 273, 277, and 282.

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**Figure 5:** The MAPKinase and PI3K/AKT pathways activated by EGFR, showing the commonly activated oncogenes. Loss of the inhibitory function of PTEN can also activate the pathway. The red arrows indicate the key oncogenes analysed in the current and the proposed study.
175, 238 and 248. The codon 72 polymorphism has been associated with increasing the risk of a variety of cancers and other diseases, but it is unclear whether this polymorphism on its own contributes to risk with respect to sporadic colorectal cancer [1].

Although KiRas mutation could not be assigned in one case, 50/118 cases (42.4%) were mutated. These included tumours that were positive for mutation in codon 12 (36/118: 30.5%), 13 (6/118: 5.1%) and 61 (5/118: 4.2%) of the KiRas gene. The remaining 3 mutation-positive cases harboured a mutation at codon 146 (3/118: 2.5%). 2 additional tumours each harboured two mutations - one with two different mutations at codon 12 and 1 with mutations in codon 60 and 61. These are both predicted to be single complex mutations, but require further investigation to validate this. These figures are strikingly similar to results from a large international study [2] in 773 primary colon cancer cases where the frequencies were 40% overall positivity, with 36.3% with mutations at codon 12 or 13, 2.1% at codon 61 and 2% at codon 146.

BRaf mutation status could not be assigned to 5 cases. 10/114 (8.5%) cases were positive for BRaf mutation; all were the common V600E mutation. This frequency is higher than that reported by de Roock et al [2] (4.7%).

NRas mutation status could not be assigned in 3 cases. Of the remaining 116 cases, 7 were positive for mutation (5.1%); of these 4 at codon 12, 1 at codon 13, and 2 were mutated at codon 61. PIK3CA mutation was identified in 12 (11%) of 108 cases tested. 10 cases harboured mutations in codon 9 and 2 in codon 20.

In only two cases were no changes in DNA sequence detected; a further 21 cases were positive only for the p53 codon 72 polymorphism. 19 of the 50 KiRas positive cases were also positive for the codon p53 polymorphism. 3 of the 10 BRaf positive cases were positive for p53 mutations other than the codon 72 polymorphism. In only 1 case was more than 2 mutations identified in different genes: in NRas, PIK3CA and p53. Two cases were positive for mutations in KiRas and PIK3CA but not p53, and one case was positive for both KiRas and NRas. As has been shown in a number of other studies, BRAF and KiRas mutations were mutually exclusive.

In 4 cases, DNA extracted from two different tissue blocks of the same tumour was examined. In one case the mutational analysis was concordant, and in a further 2 cases, there were additional changes in p53 sequence in one of the two blocks. In one case, which was positive for both KiRas and p53 polymorphism, a PIK3Ca mutation was found in one block but not the other, suggesting a degree of tumour heterogeneity.

References
1 Naccarati A et al., Mutagenesis. 2012, 27: 211-8
2 de Roock et al., Lancet Oncology 2010, 11: 753-762
During the period 1st April 2011 - 31st March 2012, 15 applications for biosamples were received by WCB, taking the total number of research project applications received since 2006, to 65, of which 50 have been approved. 8 applications received during the reporting period were from the UK, 1 from Belgium and 1 from South Korea.

Of the 9 research project applications received by WCB during the last year, 7 have been approved for supply of tissue, 1 was rejected and 1 is currently out for review.

1116 samples were supplied during this year to 6 different research projects, 1 clinical trial (POETIC), 1 QA project and the CRUK Stratified Medicine programme. 66% of those were sent to applications received in previous years and 34% to applications received during this reporting year. The breakdown of sample type and tumour type is shown in Figure 9, and some of these samples were a continued supply to projects reported in last year's annual report.

Supply of Biomaterials

1116 samples were supplied during this year to 6 different research projects, 1 clinical trial (POETIC), 1 QA project and the CRUK Stratified Medicine programme. 66% of those were sent to applications received in previous years and 34% to applications received during this reporting year. The breakdown of sample type and tumour type is shown in Figure 9, and some of these samples were a continued supply to projects reported in last year's annual report.

**Figure 6: Applications for biomaterials by year**

**Figure 7: Biosamples issued**

The lay summary for the new project supplied during the reporting period follows.

**12/003 - Dr Judy-Anne Chapman**

*Queen’s University, Ontario, Canada*

Breast cancer tumour estrogen receptor (ER) and/or progesterone receptor (PgR) positivity is a prerequisite for responsiveness to endocrine therapy. Benefit from endocrine therapy is likely related to level of ER, PgR, and Her2. Poor international inter-laboratory comparability of ER/PgR/HER2 assay results leads to our proposal of statistical standardization as an adjunct to external laboratory quality assurance measures. The World Health Organisation mandated statistical standardisation of bone mineral density (BMD), and we will utilize the same process here of continuous ER/PgR/HER2 laboratory values being categorised by their number of standard deviations above/below the mean to determine benefit from aromatase inhibitor therapy with tumours of patients accrued to the international NCIC CTG MA.27 trial of exemestane versus anastrazole; Welsh kidney specimens will act as assessment controls for available breast trial tumour specimens to demonstrate statistical standardisation process.
The Cancer Research UK Stratified Medicine pilot programme is being co-ordinated through 7 clinical hubs and 3 technology hubs across the UK. As the Cancer Bank is already well-established within Wales, Cardiff was the ideal location to host both a clinical and technology hub. As a recognised organisation with existing nurses, incorporating this programme into the Cancer Bank has been a smooth and straightforward process with patients being successfully consented in Newport, Swansea and Cardiff.

The study focuses on 6 tumour types - Breast, Colorectal, Lung, Metastatic Melanoma, Ovarian and Prostate - collecting both tissue and blood samples from 9000 patients across the UK over a 2 year period. The Cardiff clinical hub has undertaken to contribute over 400 sample sets (blood and tissue) to this programme in the first year and is working closely with CANISC - the All Wales clinical database - to allow the results to be available to clinicians for research purposes across Wales.

The technology hub is based within the All Wales Molecular Genetics laboratory in Cardiff and Vale University Health Board and is investigating tissue samples for molecular changes using a range of genetic testing as shown below:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Gene</th>
<th>Scope of test</th>
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<tbody>
<tr>
<td>Colorectal</td>
<td>KRAS</td>
<td>Codons 12, 13, 61 and 146</td>
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<tr>
<td></td>
<td>BRAF</td>
<td>Exon 15 / codons 599, 600, 601</td>
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<tr>
<td></td>
<td>NRAS</td>
<td>Codons 12, 13, 61</td>
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<td></td>
<td>PI3KCA</td>
<td>Exons 9 and 20</td>
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<td>TP53</td>
<td>Exons 4-9</td>
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<tr>
<td>Breast</td>
<td>PI3KCA</td>
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<td>Prostate</td>
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<td>EGFR</td>
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<td>KRAS</td>
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<td>EML4-ALK</td>
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<td></td>
<td>BRAF</td>
<td>Exon 15/ codons 599, 600, 601</td>
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<td>Ovary</td>
<td>TP53</td>
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<td>CKIT</td>
<td>Exons 11, 13 and 17</td>
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<td></td>
<td>NRAS</td>
<td>Codons 12, 13, 61</td>
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<tr>
<td></td>
<td>PI3KCA</td>
<td>Exons 9 and 20</td>
</tr>
</tbody>
</table>
The knowledge gained from this study, combined with information on how a patient responds to different treatments, aims to help find the best treatments for tumours with particular molecular changes and minimise the use of potentially ineffective treatments - meaning each patient will receive the best treatment for their particular case.

**Figure 8: Year one SMP progress**
Advisory Board
The Advisory Board has undergone some changes over the last year, due to retirements, relocations and reorganisations. WCB thanks those who have now left the Advisory Board, Dr Stuart Bell, Dr Tony Hazell and Mr Dave Morrey for their valuable contributions to the Wales Cancer Bank. Professor Brian Davidson, Dr Jem Rashbass, Mr Andrew Griffiths and Mrs Debbie Beirne have all agreed to join the Advisory Board and will attend their first meeting in June 2012. The Advisory Board met twice during the year.

Lay Liaison and Ethics Group
The patient group has welcomed two new members this year, Peter Thomas and Emma Jane Woozley. Both have already shown themselves to be proactive and enthusiastic and bring fresh ideas and points of view to the group.

The group has looked at further public promotion and information and a Facebook page has been started to engage with patients and the public across Wales, and the world, which it is hoped will allow the public to learn more about the importance of this type of medical research.

Members regularly attend other organisations meetings and conferences and have promoted the Banks activities to audiences of both public and professional delegates.

We are very proud that the bank has reached its recruitment target of 5,600 patients in January 2012 and know that we must continue to lead the engagement with both professionals and patients so that this figure grows and researchers benefit from the high quality samples collected which will improve cancer services for all Welsh patients.

Ethics Approval
The WCB ethics approval from the (then) Wales MREC expired in June 2011. The renewal process was being developed by NRES over the summer of 2011 and WCB submitted a renewal application at the end of August. The application, reference number 11/WA/0279, was favourably reviewed by the REC for Wales in October and the ethics approval to collect, store and issue samples was renewed until October 2016.
Developments

The WCB database functionality has increased this year in order to support the Stratified Medicine Program (SMP). Efforts have been directed to automate and validate communications between the Clinical hub and the Genetic testing hub. The result is a one button press solution for the creation and transfer of XML data files. SMP management reports have been added and work commenced with the NWIS CANISC system to supply Clinical information required back to the SMP UK database.

The development of the Web enabled sample search for researchers has continued and an online application module is now in its final stages. This solution will allow researchers to build detailed lists of samples, to create online applications, and to monitor the progress of their application. Researchers will also be informed of any necessary actions required to progress their applications.

In the last year the WCB has replaced its old bar-coding printing system at all its sites with Zebra printers and this upgrade has brought improved performance in the reliability and readability of the barcodes. This year a key decision has been taken by the WCB executive group to purchase the PathXL digital slide image viewer. This new software will allow the WCB to store and view its digital images.

Figure 9: Screenshot of new online application form for researchers
The Wales Cancer Bank is continuing to host sample collections attached to clinical trials. Samples continue to be collected for TOUCAN, SCALOP, SCOPE, RTVIN, SUCCINCT, TFRAG, FOLFERA, and COIN. The Xerxes trial has recommenced collection during the year.

**XERXES**

Examining the role of early neoadjuvant and synchronous Erbituxin preoperative chemoradiotherapy using Xeloda followed by excisional surgery.

Neoadjuvant systemic chemotherapy with either 5FU & mitomycin C, or capecitabine and oxaliplatin.

**Clinical Trial Hosting**

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**IT Governance**

The Executive group, with the support of the Advisory Board, has agreed the terms of contract to supply its IT services with the health informatics research group at Swansea University. This group has over 30 IT professionals and researchers in its team who are engaged in a wide range of research areas related to the use of information and communications technologies in healthcare settings. The aim of the contract is to deliver a better basis for the optimal use of the current WCB IT posts. It will also ensure better capacity to deliver WCB IT services including software and hardware. The agreement will enable the WCB to tap into Swansea’s high performance computing infrastructure. There may be also opportunities to link WCB datasets to the existing massive Welsh public sector datasets resource held under the SAIL project.

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Examining the role of early neoadjuvant and synchronous Erbituxin preoperative chemoradiotherapy using Xeloda followed by excisional surgery.

Neoadjuvant systemic chemotherapy with either 5FU & mitomycin C, or capecitabine and oxaliplatin.

**Conferences And Marketing**

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).
Developments

The trend line on the graph below forecasts the patient recruitment to the end of April 2013, using the accumulated recruitment totals since inception. It predicts that a total of 7,000 patients will be consented by the end of the next reporting period, assuming current staffing levels and patient access are maintained across all current recruiting sites.

Looking Ahead

Developments

Figure 10: Forecast patient recruitment to April 2013

Targets for 2012/13

<table>
<thead>
<tr>
<th>Targets for 2012/13</th>
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<tbody>
<tr>
<td>Accrue 7,000 patients in total</td>
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<td>Complete characterisation of first 950 sample sets</td>
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<td>Supply five new projects with biosamples</td>
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## Financial Statement

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<tr>
<th></th>
<th>Assembly Funding</th>
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<th>Velindre</th>
<th>CRUK*</th>
<th>General Account</th>
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* Cancer Research UK (CRUK) funding is via the Experimental Cancer Medicine Centre in Cardiff University
WALES CANCER BANK AUDIT 2011

The annual audit schedule in 2011 took place between 10th October and 3rd November 2011. All sites were visited by the WCB Project Officer and a WCB BMS from Cardiff. A random selection of donations, spanning all years of collection, was 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. This year saw the introduction of follow up information audit at each site comparing 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.

The new collection site in Velindre starting collecting samples during 2011 and so received their first internal inspection as part of this year’s programme of audits. Four sites have been collecting for nearly seven years and the 2011 audit was the seventh such internal inspection during this time. Royal Gwent has been collecting samples for five years and this was the fifth internal audit at the site. 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 1 November 2011).

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 2012 ahead of the audit and inspections due later in the year. The majority of SOPs are due to be reviewed in January 2012, after which the updated SOP log will be circulated to each site to ensure all site SOP files are up to date at audit 2012.

Audit Schedule

<table>
<thead>
<tr>
<th>Site</th>
<th>Date of Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiff (UHW, Medical Genetics, Llandough)</td>
<td>10th October 2011</td>
</tr>
<tr>
<td>Swansea (Singleton, Morriston)</td>
<td>12th October 2011</td>
</tr>
<tr>
<td>Withybush</td>
<td>18th October 2011</td>
</tr>
<tr>
<td>Royal Gwent</td>
<td>20th October 2011</td>
</tr>
<tr>
<td>Bangor</td>
<td>31st October 2011</td>
</tr>
<tr>
<td>Velindre</td>
<td>3rd November 2011</td>
</tr>
</tbody>
</table>
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.

Similar data queries will be generated every 3 or 4 months and sent to each site as interim data quality/completeness checks.

**General**

Some specialities not on database so pathology reports not able to be completed. Information is held on paper copies but transfer to database not possible. Therefore a number of the missing pathology reports highlighted on the audit paperwork are as a direct consequence of datasets not being available on database, although the dataset for lung has been added to allow the staff to begin entering the backlog of pathology reports for this tissue type. Diagnosis should be entered onto the database to ensure information present for potential applications.

**CONCLUSIONS**

All sites are generally operating well and 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 2012.

Regular reviews of data to be encouraged via the quarterly mini audit scheme and the importance of collecting clinical data reinforced with all staff. It must also be stressed that accurate data entry onto the WCB tracking database is essential.

Sample tracking and shipment procedures are now well established in all sites and need to be continued to ensure the exact location of every sample is known and quarterly internal audits will continue in 2012.

The management teams wishes to express its thanks to all staff, not only for their hospitality during the audit visits, but for their continued enthusiastic support for the project.

**ACTIONS**

**To be implemented centrally:**

- Issue 3 monthly local sample tracking and missing data audit exercise.
- The standardisation of fields on WCB samples paperwork and that of the information going into them.
- Create a REC status sheet for file comparison.
- Move the NPI field on database.
- Prioritise outstanding pathology reports onto database.

**To be implemented at sites:**

- Diagnosis needs to be entered from paper pathology report.
- QA needs to be kept up to date to ensure prompt fulfilment of sample transfer to projects or extraction for projects.
- Incomplete records to be checked regularly to enter new data when available.
- Follow up treatment and outcome data to be collected.
- Scanning of H&E slides to be kept current.
- Ensure all samples are accurately stored.
- Change Management requests to be created for all database issues.
- Ensure REC file is current.
- Ensure data is accurately transcribed onto database.
- Radiotherapy information provided by Swansea should go onto a follow up sheet and transferred to originating site for entry onto the database.
**Notes by centres**

**CARDIFF**
The data queries were run against the live WCB database on 6th October 2011 and the results are outlined below.

1. Donations with missing diagnosis - 8 instances for all Cardiff consented patients.
2. Donations without any blood samples - 5 instances for all Cardiff consented patients.
3. No pathology reports for donations over 30 days old - 1 instance was found at Cardiff.
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 technician to address. In addition, 7 WCB numbers from UHW were randomly chosen to check the data and sample tracking. The numbers were, 372, 608, 713, 769, 817, 844 and 900

All paperwork for the UHW samples is in Llandough so this was collected and brought back to Central Office to audit. In the absence of a Cardiff Research Nurse, the follow up data for Cardiff as a whole was not audited this year.

**UHW**

Donation 372
- All samples in correct place.
- The Control consent form was present in the patient pack but not entered onto the database. The boxes on the Control consent were not initialed.
- Follow up data recorded on database but no follow up form in patient pack. This was picked up in the 2010 audit but not yet rectified in the absence of a research nurse in Cardiff.

Donation 608
- All samples in correct place.
- Serums 1 - 4 barcode labels could not be scanned due to overlap.
- Time place in paraffin unknown for paraffin samples.

Donation 713
- All samples in correct place.
- Time taken had been completed on the blood forms but not entered on the database.
- Number of tumour and normal paraffin blocks had been written in pencil on the form.
- Follow up data recorded on database but no follow up form in patient pack. This was picked up in the 2010 audit but not yet rectified in the absence of a research nurse in Cardiff.

Donation 769
- All samples in correct place.
- Frozen form shows four tumour blocks taken but database shows five.
- Database shows two frozen samples both labelled FT 2A.

Donation 817
- All samples in correct place.
- Time specimen left patient written in pencil on frozen form.
- Two normal paraffin samples recorded on the paraffin form but three normal paraffin samples on the database.
- Co-ordinates of paraffin samples not entered on the form.
- Follow up data recorded on database but no follow up form in patient pack. This was picked up in the 2010 audit but not yet rectified in the absence of a research nurse in Cardiff.

Donation 844
- All samples in correct place.
- Theatre form was present but not completed.
- The number on the Pathology report does not reconcile with the database.

Donation 900
- All samples in correct place.
- Frozen forms initialled only not signed.
- Number of tumour and normal paraffin blocks not noted on the forms but match the information on the QA form.
- Paraffin forms also initialled not signed.
Additional Random Sample Summary

5 H&E Drawers randomly scanned revealed:
- 1 H&E labelled as a paraffin block

6 Paraffin trays randomly scanned revealed:
- No anomalies

1 DNA box randomly scanned revealed:
- No anomalies

3 EDTA racks randomly scanned revealed:
- No anomalies

5 Camlab boxes of Serum randomly scanned revealed:
- 3 cases with no barcode labels
- 2 cases requiring new barcode labels

4 Camlab boxes of Frozen Tissue randomly scanned revealed:
- 1 sample with no barcode label
- 1 sample requiring new barcode label

LLANDOUGH

Donation 444
- All samples in correct place.
- Time sample left patient not recorded or entered onto the database.
- The number on the Pathology report does not reconcile with the database.

Donation 534
- All samples in correct place.
- EDTA and serum barcodes would not scan due to incorrect printing.
- Clotting time completed on blood form but not entered on database.
- Time left patient entered on the theatre form but not entered on database.
- The number on the Pathology report does not reconcile with the database.

Donation 625
- All samples in correct place.
- Serums 1 - 6 would not scan due to incorrect printing.
- Time placed in formalin was unknown.

Donation 634
- All samples in correct place.
- Serums 1 - 6 would not scan due to incorrect printing.
- Time placed in formalin was unknown.

Donation 640
- All samples in correct place.
- Donor blood form was initialled not signed and the year was incorrect.

Serums were not logged in after transfer from Llandough to Velindre. As such some serums were found in alternate coordinates to those on the database. All samples have now been moved to match the database and are therefore in the correct place.

VELINDRE

The data queries were run against the live WCB database on 1st November 2011 and the results are outlined below.

1. Donations with missing diagnosis - 17 instances for Velindre consented patients.
2. Donations without any blood samples - 3 instances for Velindre consented patients.
3. No pathology reports for donations over 30 days old - included in the overall Cardiff instances.
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 technician to address. In addition, 7 WCB numbers from UHW were randomly chosen to check the data and sample tracking. The numbers were 1205, 1213, 1227, 1232, 1235, 1262 and 1263.

Donation 1205
- All samples in correct place.
- Patient details form says control consented but no control consent in patient pack.

Donation 1213
- All samples in correct place.
- Blue copy of consent form was completed as original instead of white.
- No blood forms present but blood on database.

Donation 1227
- All samples in correct place.
- Boxes ticked not initialled on patient consent form.
- Person taking consent is not the same as listed on the database.
- No blood forms present but blood on database.

Donation 1232
- All samples in correct place.
- No blood forms present but blood on database.

Donation 1235
- All samples in correct place.
- Patient pack not available to audit.

Donation 1262
- All samples in correct place.
- Patient name not completed on consent form.
- Date not completed for patient on consent form.
- No blood forms present but blood on database.

Donation 1263
- All samples in correct place.
- No blood forms present but blood on database.

**Additional Random Sample Summary**

1 EDTA rack randomly scanned revealed:
- No anomalies

**Samples moved to velindre from other sites**

6 EDTA racks randomly scanned revealed:
- 4 samples missing
- 8 cases requiring new barcode labels
- 1 case with no barcodes

15 camlab boxes of serum randomly scanned revealed:
- 1 case with no barcode labels
- Anomaly of Llandough storage explained in Llandough summary

2 H&E Drawers randomly scanned revealed:
- 10 cases in the wrong coordinates
- 5 cases missing
- 1 case that doesn’t exist on database

**MEDICAL GENETICS**

14 records showing either EDTA or extracted DNA being present in Medical Genetics were randomly chosen for checking. Donations originated from 2 different collecting sites. Donations: 131 and 784 from Cardiff 1292, 1299, 1332, 1417, 1443, 1511, 1516, 1539, 1557, 1572 and 1619 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.

Donation 131 - Cardiff
- All paperwork present

Donation 784 – Cardiff
- All paperwork present

Donation 1292 - Swansea
- 24 hour difference between bloods and serum - destroy serum?
- Clotting time taken completed on form as 9 hrs 55 minutes but on database 19.55
Paraffin samples on database but no paraffin form in patient pack to compare.

Donation 1299 - Swansea
- Control consent on database but no control consent form in patient pack.

Donation 1332 - Swansea
- All paperwork present.

Donation 1417 - Swansea
- All paperwork present.

Donation 1443 – Swansea
- Clotting time on database does not match time on form.

Donation 1511 – Swansea
- Patient consent form not signed by nurse
- Pathology form present but not on database as dataset not available.

Donation 1516 - Swansea
- Pathology form present but not on database as dataset not available.

Donation 1539 - Swansea
- Time specimen left patient not written on frozen form.
- Time sample left patient not on paraffin form.

Donation 1557 - Swansea
- Pathology form present but not on database as dataset not available.
- Patient is deceased but site unable to tick 'no further treatment' box.

Donation 1572 - Swansea
- Time EDTA taken is not on the form.

Donation 1619 - Swansea
- Pathology form could not be located.

Additional Random Sample Summary

2 camlab boxes randomly scanned revealed:
No anomalies

7 EDTA racks randomly scanned revealed:
No anomalies

ROYAL GWENT

The data queries were run against the live WCB database on 17th October 2011 and the results are outlined below.

1. Donations with missing diagnosis - none
2. Donations with no blood samples - none
3. No pathology reports for donations over 30 days old - 7 instances 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. 9 WCB numbers were randomly chosen to check the data and sample tracking. Numbers generated were 184, 186, 206, 209, 259, 276, 313, 350 and 474.

The WCB theatre form is not used in the Royal Gwent.

Donation 184
- All samples in correct place except paraffin block which was found in incorrect row.
- No date against the nurse’s signature on the patient consent form.
- Clotting time entered as 20 minutes instead of the time on the clock. Unable to amend at time of audit.

Donation 186
- All samples in correct place except paraffin block which was found in incorrect row.
- Clotting time entered as 20 minutes instead of the time on the clock. Actual time not recorded on the blood form.
- Number of tumour and normal blocks not entered on the paraffin form.

Donation 206
- All samples in correct place except paraffin block which was found in incorrect row.
- Clotting time entered as 20 minutes instead of the time on the clock.
- Number of tumour and normal blocks recorded but not on correct part of paraffin form.

Donation 209
- All samples in correct place except paraffin block which was found in incorrect row.
- Clotting time entered as 20 minutes instead of time on clock.

Donation 259
- All samples in correct place.
- Clotting time entered as 20 minutes instead of time on clock.
- One paraffin block taken that contained both tumour and normal. Site had ticked tumour and normal on form which would indicate a block of each.
- The number on the Pathology report does not reconcile with the database.

Donation 276
- All samples in correct place.
- Clotting time entered as 20 minutes instead of time on clock.

Donation 313
- All samples in correct place.
- Clotting time entered as 20 minutes instead of time on clock.

Donation 350
- PT 1AH was listed in the paraffin drawer but was changed to reflect the true co-ordinates within the H&E cabinet.
- Dates on consent form were not the same on the database.
- Clotting time entered as 30 minutes instead of time on clock.
- The number on the Pathology report does not reconcile with the database.

Donation 74
- Follow up sheet completed but not entered on to database.

Donation 101
- Follow up sheet completed and entered accurately on to database.

Donation 117
- Follow up sheet completed and faxed to Swansea for entering. Follow up not on database.

Donation 148
- Follow up sheet completed and faxed to Swansea for entering. Follow up not on database.

Donation 160
- Follow up sheet completed. 1st follow up faxed to Swansea for entering but not on database. 2nd follow up entered on database.

Donation 178

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1 H&E Drawer randomly scanned revealed:
12 cases requiring new barcode labels

10 Paraffin trays randomly scanned revealed:
Numerous cases in the wrong coordinates
14 cases of paraffin blocks labelled as H&E slides
6 cases that don’t exist on database
1 case with duplicate number
1 Paraffin coordinate that would not show on the Stock Control Function of the Database

Entire paraffin and H&E collection audited
Most sample anomalies resolved on the day
Database anomaly resolved within 1 week

3 EDTA racks randomly scanned revealed:
No anomalies

5 Camlab boxes of Serum randomly scanned revealed:
No anomalies

Follow up 2011
10 WCB numbers were randomly chosen to check the follow up data. Numbers generated were 74, 101, 117, 148, 160, 178, 199, 215, 240 and 259.

Donation 74
- Follow up sheet completed but not entered on to database.

Donation 101
- Follow up sheet completed and entered accurately on to database.

Donation 117
- Follow up sheet completed and faxed to Swansea for entering. Follow up not on database.

Donation 148
- Follow up sheet completed and faxed to Swansea for entering. Follow up not on database.

Donation 160
- Follow up sheet completed. 1st follow up faxed to Swansea for entering but not on database. 2nd follow up entered on database.

Donation 178

---

Additional Random Sample Summary

1 H&E Drawer randomly scanned revealed:
12 cases requiring new barcode labels

10 Paraffin trays randomly scanned revealed:
Numerous cases in the wrong coordinates
14 cases of paraffin blocks labelled as H&E slides
6 cases that don’t exist on database
1 case with duplicate number
1 Paraffin coordinate that would not show on the Stock Control Function of the Database

Entire paraffin and H&E collection audited
Most sample anomalies resolved on the day
Database anomaly resolved within 1 week

3 EDTA racks randomly scanned revealed:
No anomalies

5 Camlab boxes of Serum randomly scanned revealed:
No anomalies

Follow up 2011
10 WCB numbers were randomly chosen to check the follow up data. Numbers generated were 74, 101, 117, 148, 160, 178, 199, 215, 240 and 259.

Donation 74
- Follow up sheet completed but not entered on to database.

Donation 101
- Follow up sheet completed and entered accurately on to database.

Donation 117
- Follow up sheet completed and faxed to Swansea for entering. Follow up not on database.

Donation 148
- Follow up sheet completed and faxed to Swansea for entering. Follow up not on database.

Donation 160
- Follow up sheet completed. 1st follow up faxed to Swansea for entering but not on database. 2nd follow up entered on database.

Donation 178
Follow up sheet completed. The initial 6 month follow up was faxed to Swansea for entering but not on database. 1st and 2nd follow up data is entered on database.

Donation 199
- Follow up sheet completed. The initial 6 month follow up was faxed to Swansea for entering but not on database. 1st and 2nd follow up data is entered on database.
- Gleason Score on pathology report differed to that on follow up.

Donation 215
- Follow up sheet completed and entered accurately on to database.

Donation 240
- Follow up sheet completed and entered accurately on to database.

Donation 259
- Follow up sheet completed and entered accurately on to database.

**BANGOR**

The data queries were run against the live WCB database on 17th October 2011 and the results are outlined below.

1. Donations with missing diagnosis - none.
2. Donations without blood samples - 4 instances for Bangor 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 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 WCB staff to address. In addition, 7 WCB numbers were randomly chosen to check the data and sample tracking. Numbers generated were 284, 339, 363, 384, 470, 502 and 536.

Donation 284
- All samples in correct place.
- Theatre form present but not signed.
- The number on the Pathology report does not reconcile with the database.

Donation 339
- All samples in correct place.
- Time placed in formalin on database differed to time on form.
- Theatre form present but not signed.
- The number on the Pathology report does not reconcile with the database.

Donation 363
- All samples in correct place.
- Theatre form present but not signed.
- The number on the Pathology report does not reconcile with the database.

Donation 384
- All samples in correct place.
- Theatre form present but not signed.
- The number on the Pathology report does not reconcile with the database.

Donation 470
- All samples in correct place.
- Time placed in formalin on database differed to time on form.
- Theatre form present but not signed.
- The number on the Pathology report does not reconcile with the database.

Donation 502
- All samples in correct place.
- Patient was consented for two operations by WCB and had two WCB numbers. Theatre forms and cut up forms give conflicting times for sample out of patient for each tissue type. Colorectal and Prostate tissue taken.
- Theatre form present but not signed.
- The number on the Pathology report does not reconcile with the database.

Donation 536
- All samples in correct place.
- Time placed in formalin unknown.
Theatre form present but not signed.

The number on the Pathology report does not reconcile with the database.

Brady barcode printer is still not functional. The barcode labels are being printed and sent to Bangor from Cardiff until such time the newly acquired Zebra printer can be installed by IT Manager with local IT support.

**Additional Random Sample Summary**

2 H&E Drawers randomly scanned revealed:
- 7 cases in the wrong coordinates
- 1 case of H&Es labelled as paraffin blocks
- 4 cases missing (‘OLD’ Bangor numbers that should have been shipped to Cardiff)
- 1 case that doesn’t exist on database (incorrect barcode format requiring re-printing)
- 2 cases that doesn’t exist on database
- 3 cases requiring new barcode labels
- 1 case missing (out of storage for QA)
- 1 case missing

6 Paraffin trays randomly scanned revealed:
- 2 cases in wrong coordinates
- 1 case missing (‘OLD’ Bangor numbers that should have been shipped to Cardiff)

5 EDTA racks randomly scanned revealed:
No anomalies

6 Camlab boxes of Serum randomly scanned revealed:
No anomalies

**Follow up 2011**

10 WCB numbers were randomly chosen to check the follow up data. Numbers generated were 52, 81, 86, 209, 279, 293, 306, 339, 378 and 448.

Donation 52
- Follow up sheet completed.
- Finish date on Adjuvant Therapy was incorrect.
- Tumour grade on follow up but no grade on Pathology Report.
- Older numbers not as complete. JJ will source further follow up data.

Donation 81
- Follow up sheet completed and entered accurately on to database.

Donation 86
- Follow up sheet completed.
- Oncologist/surgeon not entered.

Donation 209
- Follow up sheet completed.
- No clear grade on ovary samples. Pathology fields are confusing.
- Chemo care required but was flagged by site on form.

Donation 279
- Follow up sheet completed.
- Date of operation incorrect.

Donation 293
- Site unsure what to put in ‘duration’ - should this be relapse free time.
- Tumour grade needs clarifying.

Donation 306
- Follow up sheet completed and entered accurately on to database.

Donation 339
- Follow up sheet completed and entered accurately on to database.

Donation 378
- Follow up sheet completed and entered accurately on to database.

Donation 448
- Follow up sheet completed and entered accurately on to database.

**SWANSEA**

The data queries were run against the live WCB database on 6th October 2011 and the results are outlined below.

1. Donations with missing diagnosis - 67 instances for Swansea consented patients.
2. Donations without blood samples - 88 instances for Swansea consented patients.
3. No pathology reports for donations over 30 days old - 36 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 - 4 instances.

A list of the missing data was left with the WCB staff to address. In addition, 7 WCB numbers from Singleton and 7 WCB numbers from Morriston were randomly chosen to check the data and sample tracking. Numbers generated for Singleton were 1257, 1372, 1504, 1563, 1696, 1795 and 2043. Numbers generated for Morriston were 1245, 1349, 1401, 1613, 1727, 1891 and 2054.

Random samples of DNA and RNA were also audited and the majority of samples were found to be in the correct co-ordinates except for RR6BL0000606 FT 1ARS 1 - 7, which were found in stock aliquot co-ordinates.

The WCB Theatre form is not used in Swansea.

**Singleton**

Donation 1257
- All samples in correct place.
- Number of normal skin blocks are recorded on the database but not on the paraffin form.

Donation 1372
- All samples in correct place.

Donation 1504
- All samples in correct place.

Donation 1563
- All samples in correct place.

Donation 1696
- All samples in correct place.

Donation 1795
- All samples in correct place.

Donation 2043
- All samples in correct place.
- Time sample left patient on database but not noted on the paraffin form.

**Additional Random Sample Audit**

9 H&E Drawers randomly scanned revealed:
- 2 cases requiring new barcode labels
- 1 sample that doesn’t exist on database (incorrect barcode format requiring re-printing)

9 Paraffin trays randomly scanned revealed:
- 2 sample requiring new barcode label
- 3 cases in wrong coordinates

2 EDTA racks randomly scanned revealed:
- 1 sample requiring new barcode label

5 Camlab boxes of Serum randomly scanned revealed:
- No anomalies

5 Camlab boxes of Frozen Tissue randomly scanned revealed:
- 1 case with no barcode label

23 boxes of DNA / RNA randomly scanned revealed:
- 1 case missing

**Morriston**

Donation 1245
- All samples in correct place.

Donation 1349
- All samples in correct place.
- Pathology form present but not on database as dataset not inputted yet.

Donation 1401
- All samples in correct place.
- Pathology form present but not on database as dataset not inputted yet.

Donation 1613
- All samples in correct place.
- Pathology form present but not on database as dataset not inputted yet.
Donation 1727
- All samples in correct place.

Donation 1891
- All samples in correct place.
- Pathology form present but not entered as dataset 
  not inputted on database yet.

Donation 2054
- All samples in correct place.
- Storage co-ordinates of EDTA not entered on 
  blood form

Additional Random Sample Audit

3 Camlab boxes of Serum randomly scanned revealed:
No anomalies

1 Camlab box of Frozen Tissue randomly scanned revealed:
No anomalies

Swansea Follow up 2011
10 WCB numbers were randomly chosen to check 
the follow up data. Numbers generated were 16, 66, 
74, 90, 129, 210, 536, 1060, 1402 and 1413.

Donation 16
- Follow up sheet completed and entered accurately 
  onto the database.

Donation 66
- Follow up sheet completed and entered accurately 
  onto the database.

Donation 74
- Alive box not ticked on database.
- Boost in comments.

Donation 90
- Follow up sheet completed and entered accurately 
  onto the database.

Donation 129
- Therapy was switched.

Donation 210
- Grade on follow up did not match the grade on 
  the Pathology report.

Donation 536
- Follow up completed and entered accurately onto 
  the database.

Donation 1060
- Chemotherapy start and finish dates were 
  incorrect.
- Most recent follow up date on entered onto to 
  the database.

Donation 1402
- Follow up completed and entered accurately onto 
  the database.

Donation 1413
- Follow up completed and entered accurately onto 
  the database.

WITHYBUSH
The data queries were run against the live WCB 
database on 17th October 2011 and the results are 
outlined below.

1. Donations with missing diagnosis - 2 instances.
2. Donations without blood samples - 3 instances.
3. No pathology reports for donations over 30 days 
  old - 21 instances.
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 found.

A list of the missing data was left with the WCB 
staff to address. In addition, 7 WCB numbers from 
Withybush were randomly chosen to check the data 
and sample tracking. Numbers generated were 494, 
576, 604, 643, 705, 687 and 802.

Donation 494
- All samples in correct place.
- All paperwork present.
Donation 576  
- All samples in correct place.
- Time sample left patient not included on paraffin form.

Donation 604  
- All samples in correct place.
- Theatre form not completed.

Donation 643  
- All samples in correct place.
- All paperwork present.

Donation 687  
- All samples in correct place.
- All paperwork present.

Donation 705  
- All samples in correct place.
- Theatre form completed but not signed.

Donation 802  
- All samples in correct place.
- All barcode labels need reprinting.
- All paperwork present.

**Additional Random Sample Audit**

All cases numbered 800 onwards require complete barcodes re-printing for all samples. Misalignment on printer discovered and rectified.

**6 H&E Drawers randomly scanned revealed:**
7 cases requiring new barcode labels
Random scanning of 1 drawer not possible due to:
All cases numbered 800+ also requiring new barcode labels

**6 Paraffin trays randomly scanned revealed:**
1 sample requiring new barcode label
Random scanning of 1 tray not possible due to:
All cases numbered 800+ also requiring new barcode labels

**5 EDTA racks randomly scanned revealed:**
2 samples requiring new barcode label
Random scanning of 1 rack not possible due to:
All cases numbered 800+ also requiring new barcode labels

**2 Camlab boxes of Serum randomly scanned revealed:**
No anomalies

**Random scanning of 1 camlab box not possible due to:**
All cases numbered 800+ also requiring new barcode labels

**2 Camlab boxes of Frozen Tissue randomly scanned revealed:**
1 case requiring new barcode label (numbered 800+)

**Follow up 2011**

10 WCB numbers were randomly chosen to check the follow up data. Numbers generated were 2, 98, 170, 206, 233, 291, 396, 449, 512 and 602.
Follow up sheet completed and entered accurately onto the database.

Donation 2  
- Start date on chemotherapy incorrect

Donation 98  
- Radiotherapy data provided by Swansea did not include a start date.

Donation 170  
- Radiotherapy start and finish dates need to be checked with Swansea. Form and database do not match.

Donation 206  
- Follow up sheet completed and entered accurately onto the database.

Donation 233  
- Follow up sheet completed and entered accurately onto the database.

Donation 291  
- Colorectal grade was incorrect. Dukes B not Dukes C1 as shown.

Donation 396  
- Follow up sheet completed and entered accurately onto the database.
Donation 449
- Follow up form and database do not agree on field I for radiotherapy.

Donation 512
- Follow up form completed and entered accurately onto the database.

Donation 602
- Query regarding reporting of endometrial grading as follow up grade does not image pathology report grade.
# CONFERENCES, WORKSHOPS AND COURSES ATTENDED

## April 2011
- 5th: South Wales Urology Nurses Group, Cardiff
- 20th: Manual Handling Update, Cardiff

## May 2011
- 14th: RadSoc Clinical Oncology Conference, Cardiff
  - Fiona Morgan gave a talk on WCB
- 15th - 18th: ISBER Annual meeting, Arlington, USA
  - Dr Parry-Jones is a member of the ISBER marketing committee
- 19th: Good Clinical Practice, Swansea
- 25th: Cellular Pathology Specialist Portfolio Seminar Series, Cardiff
  - Fiona Morgan gave a talk on WCB

## June 2011
- 15th: ‘Talking about randomised controlled trials’, Cardiff
- 16th: ‘Improving patient outcomes through research’, Newport

## July 2011
- 5th: Breakthrough Breast Care conference, Birmingham
- 21st: ABPI Cancer group, London
  - Prof Leonard, Prof Thomas and Dr Parry-Jones presented
- 26th: Human Tissue Authority review, London

## August 2011

## September 2011
- 14th: Kidney Cancer Study Day, Rhyl
- 20th: NHS Engagement in Research, Wrexham
  - Jennifer Jones took WCB promotional items and a stand to both the above
- 21st: South Wales Urology Nurses Group, Haematuria, Bladder and Renal Cancer study day, Cardiff
- 22nd: Refresher Training in Good Clinical Practice, Rhyl
- 23rd: Confederation of Cancer Biobanks workshop, London
- 27th: Welsh Portal Access Training, Bangor

## October 2011
- 11th: Good Clinical Practice, Cardiff
- 14th: Prostate Cancer Charity Conference, London
- 19th: Infection Control update workshop, Newport
November 2011
6th - 9th  NCRI Annual Conference  Liverpool
15th - 19th  ESBB conference  Marseille, France
23rd  2nd National Conference on Rural Cancer Care  Bangor
  Jennifer Jones took WCB promotional items and a stand
24th – 25th  NISCHR symposium  Swansea

December 2011
9th  Stratified Medicine programme workshop  London

January 2012
31st  ‘Chemocare’  Bangor

February 2012
1st  Welsh Clinical Portal training  Bangor
9th  ‘Molecular techniques for diagnosis of healthcare
  associated infections-can we justify them?’  IBMS online lecture
14th  Personal Safety/Awareness  Newport
14th  Good Clinical Practice refresher  Cardiff
29th  IT training  Cardiff

March 2012
21st  Good Clinical Practice  Abergele
27th  Dry Ice and specimen transportation course  Cardiff
27th  Blood taking theory  Bangor
28th  The Applications of molecular techniques in
  cellular pathology  IBMS online lecture
28th  Pathology QIPP and the need for service redesign  IBMS online lecture

Suzanne Williams 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.
# WALES CANCER BANK PERSONNEL LIST AS AT 31ST MARCH 2012

## STAFF

<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>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>Mr Daniel Naeh</td>
<td>Central</td>
<td>IT Manager</td>
</tr>
<tr>
<td>Sarah Phillips</td>
<td>Central</td>
<td>Project Officer</td>
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<tr>
<td>Debbie Way</td>
<td>Central</td>
<td>Clerical officer</td>
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<tr>
<td>Suzanne Williams</td>
<td>Swansea</td>
<td>Lead nurse</td>
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<tr>
<td>Helen Bevan</td>
<td>Swansea</td>
<td>Nurse</td>
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<tr>
<td>Pam Hayward</td>
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<td>Colleen Lloyd</td>
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<tr>
<td>Craig Baker</td>
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<td>Medical Laboratory Assistant</td>
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<tr>
<td>Kevin Pearse</td>
<td>Cardiff</td>
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<td>Peita-Lee Ambrose</td>
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<tr>
<td>Jane Greenwell</td>
<td>Cardiff</td>
<td>Trials Technician</td>
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<tr>
<td>Jennifer Jones</td>
<td>Bangor</td>
<td>Nurse</td>
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<tr>
<td>Dawn Whalley</td>
<td>Bangor</td>
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<td>Alex Makanga</td>
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<tr>
<td>Linda Kirk</td>
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<td>Lisa Gilby</td>
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<td>Karen Wild</td>
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<tr>
<td>Natalie Stacey</td>
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### HTA/Local Management Committee

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</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>Professor Bharat Jasani</td>
<td>Cardiff</td>
<td>HTA Person Designated</td>
</tr>
<tr>
<td>Mrs Vicky Humphreys</td>
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<td>Dr Paul Griffiths</td>
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<td>Mr Adam Carter</td>
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