Annual Report of the

Clinical Ethics Committee

Dr Richard Hain, Chair
STRATEGY

1 Membership and Attendance

1.1 The Clinical Ethics Committee (CEC) has continued to meet monthly. There are currently 20 members who are listed in Appendix 1, and a further four individuals seeking membership who are currently observing meetings. While nursing, medical and legal representation remains strong, the only chaplain has recently stepped down and only two members are formally trained in bioethics. The CEC has formalised a process for membership (Draft Terms of Reference appendix 4 paragraph 2.1.1) that should allow purposive recruitment to fill these skills gaps.

1.2 The CEC has continued to welcome observers. These have included individuals wishing to be considered for membership of the CEC, others who are interested in setting up CECs elsewhere, and one who is involved in research into the work of CEC.

2 Terms of Reference

2.1 The Terms of Reference have been extensively reviewed recently following the change in Board structure, with particular attention to extending and formalising the process of membership in order to accommodate primary as well as secondary and tertiary care. They remain in draft form at this point.

ENGAGEMENT

3 Achievements

3.1 There has been a growing number of referrals of individual cases by clinicians, as well as ongoing support of development of protocols and guidelines, most
notably the Advanced Care Pathway for paediatrics which will be launched in the Board in November. A new development has been the referral to CEC by Dr Sharon Hopkins of public health strategies in relation to smoking and obesity. There have also been referrals of projects relating to audit, research or service evaluation that we have referred on to the appropriate groups.

One important development this year has been the capacity to respond to requests for urgent opinions where necessary. There have been three such requests.

3.2
The 4th annual conference of the CEC was rather different from in previous years. Cardiff was host to the National UK Clinical Ethics Network conference. This was a considerable honour and a subcommittee within the CEC took on its organisation. The theme of the conference was ‘Ethical Narratives on Disability’ and it attracted several of the best known authorities in the UK currently working in the field.

Although the focus of the conference was on the ethics of disability, several of the delegates and even some of the speakers chose also to address the political rights agenda. This added a further dimension to the debate, and both presentations and the discussions that followed were well received by delegates (appendix 3).

3.3
The committee has been invited to act as an editorial board for a specially themed edition of the journal of Clinical Ethics, using speakers’ presentations as the basis for journal articles. Again, this is a great honour as the journal has a national and international readership.

3.4
In April, the Chair presented a semi-fictionalised account of one of the cases discussed by the CEC at Grand Rounds, using it as a starting point for discussion of different ethical frameworks and the origin of the four-principle approach. The Chair has also given talks on the systematic basis of a clinical ethics approach to various
groups in Wales Wales, and has also written an article outlining the purpose of the Clinical Ethics Committee in Signpost magazine. These events are all in accordance with the remit of the CEC to disseminate good practice and understanding of clinical ethics in the Board and elsewhere.

3.5
Two members of the committee have now received training in order to be able to update the committee's web page on the board intranet. This currently provides access to referral forms and terms of reference.

3.6
A number of members of the CEC took part as tutors in undergraduate teaching workshops of ethics and professionalism teaching for year 1 medical students. The teaching was highly rated by students and by the University.

3.7
The new referral form developed last year has been largely successful but minor modifications have been suggested, most significantly inclusion of the legal disclaimer distinguishing ethical from legal advice (see Terms of Reference appendix 4, paragraph 4.2). Although there are plans for auditing this using a tool developed by committee members, this is not yet under way.

ASSURANCE

4.1
There have been two training events which members of the CEC have attended; ‘Train the Trainers’ (22nd June) organised by UKCEN and a workshop on ‘Moral Theory and Healthcare Practice’ (Cardiff, 28th-29th June) and of course several members attended the UKCEN conference for which this year Cardiff was the host CEC. A number of members are planning to attend a further training event later this year, so that we will have reached our target of at least one third of members having
attended a training event each year (See appendix 4 paragraph 3.2).

4.2
Arrangements have also been made with Swansea University Department of Applied Ethics to provide two afternoon workshops for in-house training each year, which will ensure an ongoing programme of structured and cost-effective teaching.

4.3
Dr Wulf Stratling remains the Cardiff CEC representative on the Board of Trustees of the U.K. Clinical Ethics Network (UKCEN).

CONCLUSION

5.1
The CEC is very grateful to the Board for its continued support and especially for continuing the annual allocation from endowments despite the current austere financial climate. This has allowed the provision of secretarial support (subject to availability) and has enabled the CEC to subsidise and commission training for members. Training remains an important priority for members.

5.2
The range of referrals for ethical opinion from the Committee is expanding to include health care policies and urgent clinical requests. Although it has so far been possible to accommodate all the Committee’s business in a single monthly meeting ten times a year, there are indications that this might not continue and more frequent meetings and/or alternative approaches to referrals may become necessary.

5.3
The committee continues to raise the profile of clinical ethical issues and disseminate knowledge about bioethical matters through Grand Rounds and other presentations, journal articles and the annual conference.
5.4
Secretarial support remains a problem, as taking minutes is seen as time-consuming and arduous. There has been valuable support from Ceri Abbott in Child Health, for which the Chair would like to take this opportunity to thank Ceri and her managers who supported her. Ceri has felt unable to continue to take this on and at the moment there is once again no secretarial support for the CEC.

RECOMMENDATION

6.1
The Quality and Safety Committee is asked to NOTE this report, which will also be forwarded to the Cardiff and Vale University Health Board for information and consideration.

6.2
The Quality and Safety Committee is asked to APPROVE a request to continue the present level of funding for training and administrative support for the work of the Clinical Ethics Committee.

Dr. Richard Hain
Chair of Clinical Ethics Committee
September 2010
### SOURCES OF INFORMATION AND EVIDENCE

**APPENDIX 1 – Current membership list (as at September 2010)**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position/Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richard Hain (Chair)</td>
<td>Cardiff University (doctor)</td>
</tr>
<tr>
<td>Dewi Holt (Vice chair)</td>
<td>Clinical Scientist (UHB)</td>
</tr>
<tr>
<td>Wulf Stratling</td>
<td>UHB Anaesthetics (doctor)</td>
</tr>
<tr>
<td>Tessa Shellens</td>
<td>Morgan Cole (solicitor)</td>
</tr>
<tr>
<td>Suzanne Thomas</td>
<td>Trauma And Orthopaedics UHB</td>
</tr>
<tr>
<td>Stephen Sims</td>
<td>Cardiff CHC</td>
</tr>
<tr>
<td>Mike McNamee</td>
<td>Swansea University (Ethics)</td>
</tr>
<tr>
<td>Mary Dykes</td>
<td>Senior Social Worker</td>
</tr>
<tr>
<td>Maria Roberts</td>
<td>Clinical Governance Facilitator</td>
</tr>
<tr>
<td>Keithley Wilkinson</td>
<td>Corporate management, UHB</td>
</tr>
<tr>
<td>Julia Barrell</td>
<td>Mental Capacity Act advisor, UHB</td>
</tr>
<tr>
<td>John Viney</td>
<td>Vale of Glamorgan CHC</td>
</tr>
<tr>
<td>Jane Rowlands-mellor</td>
<td>Lead Nurse for Bereavement Services</td>
</tr>
<tr>
<td>Jacinta Tan</td>
<td>Swansea University</td>
</tr>
<tr>
<td>Doug Harrett</td>
<td>Cardiff and Vale UHB - Administration</td>
</tr>
<tr>
<td>Delyth Alldrick</td>
<td>Consultant in Old Age Psychiatry (retd)</td>
</tr>
<tr>
<td>Claire Quinn</td>
<td>Clinical Psychologist</td>
</tr>
<tr>
<td>Catherine Thompson</td>
<td>Ty Hafan Children’s Hospice</td>
</tr>
<tr>
<td>Angus Clarke</td>
<td>Professor of Clinical Genetics</td>
</tr>
<tr>
<td>Angela Hughes</td>
<td>Care Pathways Co-ordinator</td>
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</tbody>
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APPENDIX 2 – CEC 4th Annual Conference Programme

United Kingdom Clinical Ethics Network

Annual Conference 2010

Preliminary Programme

**Disability – Ethical issues**

Julian Hodge Building, Colum Drive, Cardiff, CF10 3EU

Wednesday, 23rd June 2010

*(Pre-Conference Workshop: ‘Clinical Ethics - Train the Trainers’,

  Tuesday, 22nd June)*
Invitation:
On behalf of the organisers we are pleased to invite you to Cardiff, Capital of Wales, for the annual conference of the UK Clinical Ethics Network (UKCEN). The main topic of the conference this year is Disability – Ethical Issues. The Clinical Ethics Committee (CEC) of the Cardiff and Vale University Local Health Board and Cardiff University are the joint hosts. We are sure you will have an enjoyable and stimulating educational time in Cardiff!

Dr. Richard Hain  Dr. M. Wulf Stratling
CVUHB – CEC  Local Organising Committee
(Chair)  (Chair)

Background:
The aim of the conference is to provide a programme of multi-professional interest: Speakers from a variety of backgrounds (Medicine, Ethics, Law, Social Sciences) will thoroughly analyse the topic and facilitate the cross-fertilisation of ideas, views and understanding. We hope the Conference will attract disabled persons and carers who would be willing to very actively participate in the discussions. The theme of the conference reflects a growing recognition of Disability-related challenges, both within our society as a whole and within the NHS. Clinical Ethics Committees and other elements of Clinical Ethics Consultation, as key elements of good clinical governance and practice, can be instrumental in raising awareness of ethical issues in medicine and in providing practical support on teaching and training, general guidance and case-based consultation. Poster-Sessions will facilitate ample opportunity for networking and learning for anyone interested in Disability Issues and Ethics in the Practice of Medicine. This year, for the first time, UKCEN will also offer a pre-conference Train the Trainers Course. This workshop is part of a larger strategy to create a leadership role for members of Clinical Ethics Committees to streamline the education of new CEC members and to enable them to integrate and improve clinical ethics within their organisation.

Practical Information:
The Conference and workshop will be held in and around the Julian Hodge Building of Cardiff University; Colum Drive, Cardiff, Wales, CF10 3EU; in walking-distance of the city centre. Certificates of attendance (CPE / CME) will be issued. Deadline for Booking is 25th May 2010.

All further information concerning most notably registration, booking of accommodation, special needs or dietary requirements, preliminary program, call for abstracts / poster submission, participation in the “Train the Trainers Course” etc. can be obtained from the attached registration form and from the website of the UK Clinical Ethics Network: www.ethics-network.org.uk
UK Clinical Ethics Network (UKCEN)

- Pre-Conference Programme -
  Tuesday, 22nd June 2010

13:00–
17:00  Workshop: Train the Trainers
         (Break 15:00-15:20)

17:00–
19:00  UKCEN Board of Trustees Meeting
         (Break 17:00-17:30)

20:00  Conference Dinner
       Bayside Brasserie, Mermaid Quay, Cardiff Bay CF10 5BZ
       Tel (029) 20 358 444

- Annual Conference Programme -
  Wednesday, 23rd June 2010

8:00 – 9:00  Registration (tea / coffee)
9:00 – 9:30  Welcome
9:30 – 11:00 Session I: Disability – a general introduction
3:00-10:00  Discourses of disability: An introduction  Dr Mikey Dunn, Senior Researcher in Health and Social Care Ethics, Ethox Centre, University of Oxford
10:00-10:30 The legal framework - past, present and future: ‘Disability’ within the context of a Single Equality Act and International Human Rights  Professor Luke Clements, Director of the Centre for Health and Social Care Law, Cardiff University Law School
10:30-11:00 Returning to the debate about Ashley X: What can be learned ?  Professor Steve Edwards, School of Human Sciences, Swansea University
11:00–11:30  Tea / Coffee
11:30–12:30 Session II: Disability issues - the ethical framework

11:30-12:00 Learning from Disability Studies in Medical Ethics: impacts on autonomy, beneficence and non-maleficence  
Ms Heather Bradshaw, Researcher, Centre for Medical Ethics, Bristol University

12:00-12:30 Disability vs. Equality – Managing the Balances  
Professor Julian Savulescu, Chair of the Oxford Uehiro Centre for Practical Ethics, University of Oxford

12:30–13:45 Lunch Break  
UKCEN General Assembly Poster Sessions

13:45–16:00 Session III: Attitudes – learning from one another's experience

13:45 – 14:15 Wellcome funding opportunities for research in and engagement with biomedical and health-related ethics  
Mr. Jacob Leveridge, Medical Humanities Adviser (Biomedical Ethics), Wellcome Trust, London

14:15-14:45 Partnership in Healthcare – delivering a world class service  
Dr Kevin Fitzpatrick, Welsh Institute for Health and Social Care, University of Glamorgan, Former Welsh Disability Rights Commissioner

14:45-15:15 The experiences and perceptions of Family and Carers - You Don't Care...!?  
Mr. John Viney JP, Cardiff UHB Clinical Ethics Committee, (Lay-) Member; Patient Representative - Community Health Council

15:15-16:15 Plenary / Panel Discussion

16:15-16:45 Closing Remarks, lessons learnt, awards
# Summary of Evaluation Data

**UK Clinical Ethics Network Annual Conference 2010**

*Disability – Ethical Issues*

<table>
<thead>
<tr>
<th>Session</th>
<th>C</th>
<th>P</th>
<th>R</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Discourses of disability: An introduction</strong>&lt;br&gt;Dr Michael Dunn, Oxford</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>Excellent introduction/overview, too fast, needed more time, would benefit from case study, hard to follow but interesting.</td>
</tr>
<tr>
<td><strong>The legal framework – past, present and future: ‘Disability’ within the context of a Single Equality Act and International Human Rights</strong>&lt;br&gt;Professor Luke Clements, Cardiff</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Interesting and thought provoking focus on carers issues, would have benefited from visual aids.</td>
</tr>
<tr>
<td><strong>Returning to the debate about Ashley X: What can be learned?</strong>&lt;br&gt;Professor Steven Edwards, Swansea</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Thought provoking, but too much time on story, not enough discussion.</td>
</tr>
<tr>
<td>Learning from Disability Studies in Medical Ethics: impacts on autonomy, beneficence and non-maleficence</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>Interesting, complex, challenging, difficult to understand, slides too busy.</td>
</tr>
<tr>
<td><strong>A Welfareist Account of Disability</strong>&lt;br&gt;Professor Julian Savulescu, Oxford</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>Interesting, stimulating and engaging, too much content for time available, would benefit from greater integration with other talks.</td>
</tr>
<tr>
<td>Wellcome funding opportunities for research in and engagement with biomedical and health-related ethics&lt;br&gt;Mr. Jacob Leveridge, London</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Clear and informative, nicely presented.</td>
</tr>
<tr>
<td><strong>Partnership in Healthcare - delivering a world class service</strong>&lt;br&gt;Dr Kevin Fitzpatrick, University of Glamorgan</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>Spectrum of comments ranging from ‘very interesting’ and ‘the way forward’ to ‘nothing new’ and ‘out of date’. Many found it unfocussed and rambling.</td>
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**Summary of Evaluation Data (Continued)**

**UK Clinical Ethics Network Annual Conference 2010**

**Disability – Ethical Issues**

<table>
<thead>
<tr>
<th>Session</th>
<th>C</th>
<th>P</th>
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<th>Comments</th>
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<tbody>
<tr>
<td>The experiences and perceptions of Family and Carers - You Don't Care...?</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>A welcome blast of reality, warm and good humoured, nice ending to the day.</td>
</tr>
<tr>
<td>Mr. John Viney JP, Cardiff</td>
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</tbody>
</table>

**Plenary / Panel Discussion**

<table>
<thead>
<tr>
<th>Organisation: Location and Facilities:</th>
</tr>
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<tbody>
<tr>
<td>Suggestions for future meetings or other comments:</td>
</tr>
</tbody>
</table>

**Further Comments:**

Very interesting speakers posing provocative and important ideas, very good day.

Very enjoyable.

The last two talks should have come first as the context for the rest of the talks. Overall an excellent topic and very thought provoking conference.

Would have been good to have some discussion or workshop opportunities.

Excellent summary by Stephen at the end.

Too long to sit and listen, more discussion needed.

Thought provoking day, different views and definitions stimulating discussion.

The majority of speakers tried to do too much in their allotted time. Either give them more time or be more specific with the topic.

Handouts of presentations and list of participants requested.
1. Introduction

The University Health Board recognises that health care providers are sometimes called upon to make decisions with significant ethical implications. These decisions may cut across several departments or disciplines. The Board is aware of the increasing public requirement for accountability in decision-making and expectations that it will provide clear statements on ethical issues that are accessible to the public and subject to review.

The Board believes that those called upon to make difficult ethical decisions would benefit from knowledge of how these issues are approached within this Board and also in others. The Board therefore recognises the benefit of a forum for the support, co-ordination, facilitation and articulation of discussion on ethical issues. The Clinical Ethics Committee (CEC) will aim to address these. It will serve primarily to support staff at all levels in making decisions with significant ethical implications and to communicate the Board’s commitment to maintaining the highest standards of care.

The purposes of the CEC are:

- To consider ethical problems within the University Health Board.
- To provide a forum for discussion of these issues
- To construct an informed, and reasoned position on matters of ethical concern for consideration by Board Staff and the Board Executive.
- To contribute in an integrated way to the evolving process of development of standards, guidelines and policies related to better patient care.
- To develop ways of educating Board staff on fundamental aspects of clinical ethics.

2. Composition of the Clinical Ethics Committee
2.1 Membership

It is not intended that every profession or interest group has automatic representation, but rather that members should have something positive to contribute to the committee’s deliberations. An enthusiasm for the subject of clinical ethics is essential and some existing knowledge of the issues desirable. Membership of the committee should include those from primary, secondary and tertiary care providers in order to reflect the Board’s new structure.

To be effective, the committee will need to represent a broad range of professional background and expertise. Each member will bring core skills (that is, skills needed for effective participation in the work of the committee) and specific expertise (that is, skills arising from the individual’s own training and experience.

The committee will ideally consist of:

- Physicians (consultant and general practitioner)
- Clinical Nurses
- Representatives of professions allied to medicine (e.g. Psychology, Occupational Therapy, Physiotherapy, Dietetics, Pharmacy etc.)
- A representative of the Cardiff University
- Chaplain
- An ethicist
- A Lawyer (From Board Solicitors)
- A Non Executive Director of the Board
- Representatives of the CHCs (Cardiff and Vale)
- A Social Services Representative
- Other lay people
- Students and trainees. These will be encouraged to observe the work on the Committee and, where appropriate, be invited to serve (see below).
- At least 3 members not affiliated with the Board.

This list is clearly indicative and not exhaustive.

The CEC will be quorate if at least one third of the members are present. There should be two doctors and a lawyer at each meeting. If a member is consistently unable to attend then consideration will be given to asking them to relinquish their membership so that another person can take their place.
Total membership will generally not exceed 25 and members will be expected, if possible, to serve for a minimum of 3 years so that experience can be built up.

2.1.1 Becoming a member

- Individuals expressing interest in becoming members of the CEC should make themselves known to the Chair by email. These can be actively solicited by members of the CEC, particularly in order to fill ‘skills’ gaps’.
- The Chair will request from the potential member a ‘personal statement’ outlining his/her skills and interest in the CEC.
- The CEC will consider this in the light of the skills needed by the Committee at that time.
- The Chair will invite selected individuals to attend three meetings as an observer, following which he/she will usually be approved as a member. The CEC reserves the right to withhold invitation to become a member.
- The CEC will carry out an annual ‘skills audit’ to try and identify gaps so that recruitment to the committee can be as effective as possible.

2.1.2 Ending membership:

- Any member can step down by informing the Chair.
- The term of members will usually be three to five years, renewable to a second term. The term as Chair will be the same.
- Members may be asked to leave by the Chair at his/her discretion after discussion with and a quorate vote by the Committee. The Chair will usually discuss this with the member before the process is initiated, and members will be allowed to appeal against the decision in writing.

2.1.3 Observers and co-optees
• A maximum of three observers may be invited to attend CEC meetings at the discretion of the Chair. Where an observer is present, CEC members should introduce themselves at the beginning of the meeting. Observers should also introduce themselves, giving any specific reason for their attendance.

• Observers should not usually contribute to the discussion unless specifically invited to do so. The committee should ensure that advice asked from observers is appropriate to their area of interest and expertise. An observer wishing to contribute to the discussion in ways other than this, should discuss this with the Chair beforehand.

• Minutes should record views expressed by observers, but it should be made clear that these are not the views of committee members. This is to protect observers and members in the event of legal involvement.

• Observers will not normally receive agenda or other papers for the meeting or participate in email discussions where they are necessary, but in all other respects should be subject to the same restrictions as substantive members, particularly with respect to confidentiality and declaration of interest.

• It is recognised that the Committee may need expertise that is not found among its members. Under those circumstances, the Chair will invite individuals to attend meetings and advise the committee as co-optees. Most often this will be the referrers of clinical cases themselves. Such co-opted members will function as full members of the committee for the duration of the co-optee but will have no right to vote and will not contribute to the quorum.

2.1.4 Offices of the CEC

Chair

The Chair will be selected from the membership of the committee and will serve for a minimum of 5 years, renewable for a second term. The appointment will be ratified by the Board.
Vice Chair

The Vice-chair will be selected from the membership of the committee and will serve for a minimum of 3 years. It is suggested that the Vice-Chair is of a different profession from the Chair or is one of the non-affiliated members.

Secretarial support

A minute-secretary will be available to take anonymised notes of the meetings, to distribute information to the members, to schedule meetings and to type reports to the Board etc.

3. Practical aspects of CEC

3.1 Frequency of meetings

- Meetings of the full CEC will initially be held monthly.

- If an urgent clinical ethical problem requires consideration, the Chair (or Vice Chair in the absence of the Chair) may take action at short notice involving a few available members of the CEC. These smaller meetings will report to the full CEC at the next meeting.

- Subgroups may also be convened to assist with guidelines or protocols in response to a request from the Board.

3.2 Training

- It is recommended that at least one-third of the CEC members undergo training annually. The Chair will be responsible for arranging in-house training sessions twice a year for CEC members.

- CEC members will be encouraged and, where possible, supported financially to attend training events.

- It is part of the CEC role to disseminate understanding and good practice in clinical ethics across the Board. The CEC will achieve this various ways including holding an annual Clinical Ethics Conference and participating in Board teaching events such as Grand Rounds.
3.3 Confidentiality

- Proceedings within the meetings are confidential to members of the CEC. Members must agree to the same standards of confidentiality as are specified in professional guidelines such as those prescribed by the Nursing and Midwifery Council and the General Medical Council.

- Members of the CEC who do not have a professional affiliation involving standards of confidentiality and/or are not employees of the Board will be required to sign a confidentiality agreement.

- Minute of the meeting will be taken but discussions will be summarised, preserving the anonymity of clinicians, cases and members. Care will be taken to avoid the inclusion of any details, which could be used to identify patients in particular.

3.4 Reporting arrangements

Appendix 1 shows how the CEC is accountable within the new University Health Board administrative structure. The CEC reports to the Quality and Safety committee and through them directly to the executive of the Board itself. An annual report will be made to the Board and will also be posted on the Board Web site and Intranet.

3.5 Access to the CEC

- Referrals will be made to the Chair of the C.E.C. who will consider the best way to deal with the request for help or advice. In most cases, the clinician will be asked to present the issue to the C.E.C. at the next meeting.

- If an urgent response is needed, the Chair will convene an additional meeting or else moderate an electronic discussion as the circumstances demand.

- The Telephone number and e-mail address of the Chair’s secretary will be published on the Board’s intranet and on information leaflets and posters which will be available in all clinical areas.
• In the absence of the Chair and Vice-Chair, a third member of the CEC will be delegated the tasks of dealing with referrals.

• To deal with areas of clinical specialism not included in the expertise of committee members, other staff may be co-opted as necessary (see above). In cases where gender, ethnicity, faith tradition, disability or sexual orientation is a component, the CEC will if necessary and appropriate either co-opt a person or persons who has experience or knowledge of these issues or will consult with an organisation representing people affected by these issues.

• Referrers will usually be required to complete a formal referral form to ensure that they give sufficient detail (using the 4 topics method) of the impact of their patient’s gender, ethnicity, age, faith tradition, disability and sexual orientation on the dilemma they face. These issues will be addressed as part of the CEC’s discussion in all cases so as to comply with the Board’s Equality Policy. (The Equality Policy can be accessed through the Clinical Portal, by clicking on Policy Database and searching for Equality Policy).

4. Legal Issues

4.1 Indemnity for the C.E.C

In the event of any advice or opinion given by the C.E.C. to a clinician on an ethical issue, which leads to subsequent criticism or a potential claim against the Board, the individual clinician and the Board would be liable in the normal way. Members of the CEC who are directly employed by the Board are indemnified for their actions as employees. For those who are not employees, the Board would indemnify them individually using the following form of words:

“In consideration of X member accepting appointment as a member of the Ethic Committee established by the Board, the Board agrees to indemnify X member in relation to an claims costs or proceedings which may arise from the work of the CEC in giving an advice or an opinion to a Clinician on the
management of an ethical issue which the Clinician may take into account in reaching a decision as to the provision of appropriate care. This Indemnity applies provided that the X member is acting in good faith and without malice in the performance of his/her duties as a member of the Ethics Committee and in accordance with its terms of reference.”

The clinician should understand that he/she will be ultimately accountable for any decision made having taken into account the opinion or advice of the C.E.C. (see below).

4.2 Legal disclaimer

In order to clarify the distinction between ethical and legal advice, the following will be added to all CEC recommendations to referrers:

“This response from the Cardiff and Vale ULHB Ethics Committee should not be regarded as a source of legal advice. The role of the Committee is restricted to the provision of guidance on the ethical issues and this response should be considered on that basis.

The Committee in its deliberations will of necessity have taken into account any legal parameters which may apply generally to the situation presented by the referrer. This is done so that its guidance on what may ethically be advised as right or wrong is set within the overall framework of what is considered to be lawful.

However in giving its response the Committee is not providing legal advice to the referrer. Where the response identifies that there are relevant legal issues to take into account, then the referrer is advised to consider whether legal advice should be sought from the UHB’s legal advisers.”

4.3 Terms of Reference

The Terms of Reference will be amended to reflect the experience of ways of working as and when these are required.
AGENDA ITEM 8.2

<table>
<thead>
<tr>
<th>REPORTING COMMITTEE/GROUP</th>
<th>Research Governance Group (RGG)</th>
</tr>
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<tbody>
<tr>
<td>CHAIRED BY</td>
<td>Professor Jonathan I Bisson</td>
</tr>
<tr>
<td>DATE OF LAST MEETING</td>
<td>13th July 2010</td>
</tr>
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**KEY AGENDA ITEMS / RISKS TO NOTE**

**Introductions**
The Group Chair welcomed the group and signed off the minutes off the 27th April 10 meeting as a true record.

The Group Chair explained that new Divisional Research and Development Leads had been appointed and become members of the RGG. Their role is to bring R&D to the agenda and raise its profile within the Divisions.

**Progress against the Forward Plan 2009/10**
This was summarised to the group and is to be presented in the Annual Report to the Welsh Assembly Government covering the period April 2009 to April 2010.

**Research Governance Issues raised by Divisions**
Clinical Diagnostics & Therapeutics Division fed back that the main analysers within Medical Biochemistry and Immunology had been changed. It was confirmed that all Principal Investigators of current Clinical Trials were emailed with this updated information.

**Summary of Monitoring Visit Reports Received:**
- **Cardiff and Vale UHB – sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs)**
  Feedback was provided of 1 trial which has now closed, close-down will be complete after a pharmacy meeting. There were no issues of concern.
- **Cardiff University – sponsored CTIMPs**
  Feedback was provided of one ongoing trial that had received a monitoring visit during the reporting period, no issues were detected. A close-down visit had also been carried out.

**Random Research Governance Audit Reports**
The group was informed that there were two routine audits during the past
quarter; the completion of the Corrective and Preventative Action Plans (CAPA) was anticipated for mid July. Both were given a perceived level of Research Governance Compliance of Amber. An audit of Trial Site Agreements in non-Commercial CTIMPs had been completed which showed 100% compliance.

**Sponsor Responsibilities for Investigator’s Brochure (IB)**

It was agreed that in future, CTIMPs will not be approved unless the trial has an IB and there is a management group in place, including a pharmacist to participate in a review of the IB, which is a legal requirement. Kathryn Bethune has produced a set of guidelines for writing an IB. This will also be discussed at the Good Clinical Practice (GCP) R&D Group (formally referred to as the GCP Clinical Trials Group) meeting on 15th Sept.

**MHRA GCP Compliance Report 2010**

The Group Chair informed the group that this report was completed and sent to the MHRA on time.

**Receiving Annual Safety Reports**

It was agreed that as a condition of R&D approval for a study, copies of the Annual Safety Reports and the Final Report at the end of the trial have to be submitted to the R&D Office. There have been difficulties in obtaining these reports. It was agreed that in future, no new studies would be approved for a Principal Investigator until they comply with all terms and conditions for R&D approval regarding their current projects; including providing the Annual Safety Report.

**ONGOING WORK / ACTIONS**

**Development of a Forward Plan 2010/11 and the Work Programme for the forthcoming year**

It was agreed that this will be discussed further as an agenda item at the RGG on 26th October 2010.

**Internal Research Governance Audit Report and Response beginning of 2010**

The group was informed that the audit conclusion provided a rating of ‘Adequate’ with some control weaknesses. The R&D Office response to the audit was discussed with respect to: Monitoring of Hosted Clinical Trials of Investigational Medicinal Products, Accuracy of Database Records and Database Security.

**The MHRA Statutory GCP Inspection at Cardiff and Vale UHB**
The group was informed that the list of MHRA Action Points still to be addressed has now reduced to 8. The Group Chair informed the group that a lot of positive work had taken place and that the end was in sight for addressing all actions.

Summary of Monitoring Visit Reports Received:
Triggered Audit of SAE Reporting
Feedback was given from a recent triggered SAE audit from Cardiff University. Cardiff University is in discussion with the MHRA as to what information is required for SAE/SUSAR reporting in cancer trials.

Exception Reporting
The group was informed that 1 trial was suspended earlier this year. There were outstanding actions from monitoring visits that were slow to be addressed. The Principal Investigator (PI) is unable to act as PI on any further projects until the outstanding issues with the suspended trial have been resolved.

Triggered Research Governance Audit Reports
Feedback was given on a triggered audit carried out due to the death of a patient in a trial. The Coroner’s Report concluded that the trial drug had not contributed to the cause of death. A CAPA is being addressed. The trial is now supported by CRC Cymru staff. The IMP management procedures and delegation of responsibilities in the particular circumstances of this trial have been reviewed and restructured by the Pharmacy Department and the Principal Investigator with support from Research Governance. An audit of the Informed Consent Process is ongoing; this was triggered by an incident in a trial involving two Directorates.

Random Research Governance Reports
An ongoing audit of Version control Logs of Core Trial Documents was discussed.

Research Governance Issues affecting Commercial Trials
The Group Chair reported that there was a Commercial Trial in which the trial medication may have interfered with laboratory test results. This trial is currently on hold pending further information. It was agreed that further discussions would take place between the R&D Office and Clinical Governance once the Commercial Trials Manager had completed an investigation. A review would then be considered. The lab should be involved and a report prepared for the October RGG meeting.
Cardiff and Vale Pharmacy Department: Procedure for the Safe Handling of Clinical Trials Medicines within Cardiff and Vale University Health Board (CT1, Ref No. 363) Version 2.0, February 2010
It was reported that there are a few amendments required to this document.

<table>
<thead>
<tr>
<th>ITEMS TO RECEIVE OR FOR APPROVAL (Where required)</th>
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</thead>
<tbody>
<tr>
<td>Policy for Good Clinical Practice Training for Personnel Undertaking Clinical Research Reference No. UHB 015, Version 1</td>
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<table>
<thead>
<tr>
<th>MINUTES SUBMITTED TO QUALITY &amp; SAFETY COMMITTEE</th>
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<tbody>
<tr>
<td>Yes [  ] No [ x ]</td>
</tr>
<tr>
<td>The minutes will follow with the next summary report, once they have been approved.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DATE OF NEXT MEETING</th>
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<tbody>
<tr>
<td>26th October 2010</td>
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</table>
# POLICY FOR GOOD CLINICAL PRACTICE TRAINING FOR PERSONNEL UNDERTAKING CLINICAL RESEARCH

<table>
<thead>
<tr>
<th>Reference No:</th>
<th>Version No:</th>
<th>Previous Trust / LHB Ref No:</th>
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<tbody>
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<td>UHB015</td>
<td>1.0</td>
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## Documents to read alongside this Policy, Procedure etc (delete as necessary)

### Classification of document:
Research and Development

### Area for Circulation:
UHB Wide

### Authors:
- Professor Jon Bisson (R&D Director)
- Dr Kate Craig
- Mr Chris Shaw

### Executive Lead:
Medical Director

### Group Consulted Via/ Committee:
Research Governance Group

### Ratified by:
Quality and Safety Committee (date)

### Date Published:
Date becomes live

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<th>Version Number</th>
<th>Date of Review</th>
<th>Reviewer Name</th>
<th>Completed Action</th>
<th>Approved By</th>
<th>Date Approved</th>
<th>New Review Date</th>
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<tr>
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</tbody>
</table>

## Disclaimer

When using this document please ensure that the version you are using is the most up to date either by checking on the UHB database for any new versions. If the review date has passed please contact the author.

**OUT OF DATE POLICY DOCUMENTS MUST NOT BE RELIED ON**
1.0 INTRODUCTION

All individuals undertaking clinical research must have knowledge and training to ensure that the rights and safety of participants in research are protected. Participants in clinical research may be NHS patients, volunteers identified as suitable by their previous medical history or healthy volunteers.

In particular, legislation governing the conduct of Clinical Trials of Investigational Medicinal Products (CTIMPs), namely, The Medicines for Human Use (Clinical Trials) Regulations Amendment 2006 (SI2006/1928) states that "each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks".

In addition the Medicines and Healthcare products Regulatory Agency (MHRA) has stated that ‘The frequency of training is not defined in the regulations, however, in accordance with Regulation 12, all staff must conduct the trial in accordance with the conditions and principles of Good Clinical Practice (GCP) defined in the legislation, hence the training should be given at intervals appropriate to ensure staff maintain current awareness of the UK Regulations and applicable European Guidelines. How often this training is repeated is a business decision for the organisation concerned. Appropriate updates should be provided when applicable procedures, guidance or legislation change.’

2.0 STATEMENT

It is the policy of Cardiff and Vale University Health Board that all staff undertaking research undertake appropriate training.

3.0 SCOPE OF THE POLICY

This policy applies to all personnel undertaking clinical research (including Clinical Trials of Investigational Medicinal Products (CTIMPs)) in the UHB or CU, including those individuals:

- holding substantive or honorary contracts/titles with either the UHB or CU;
- holding ‘letters of access’ to UHB or CU;
- undertaking clinical research involving UHB patients;
- undertaking clinical research on UHB or CU premises.

4.0 AIMS

Cardiff and Vale University Health Board (UHB) and Cardiff University (CU) have produced this joint policy document to define the type and frequency of
GCP training that should be undertaken by staff working within the clinical research environment.

5.0 OBJECTIVES

This policy has been developed to ensure that

- All personnel involved in undertaking clinical research within the UHB, CU and others as described above, have undertaken appropriate Good Clinical Practice (GCP) training;
- Appropriate training is defined by the UHB and CU;
- UHB and CU provide GCP training opportunities to support this policy.
- Timescales for renewal of GCP training are identified

6.0 ROLES & RESPONSIBILITIES

Responsibility for the implementation of this policy and the operational management of the provision of topic specific training will be overseen by a group of three individuals: one (1) representative from the Research and Commercial Division (RACD), Cardiff University; one (1) representative from the Research and Development Office, University Health Board and one (1) representative from the Clinical Research Facility (CRF). The strategic direction of the group will be set by the R&D Director, supported by the CRF Operational Director.

6.1 Administrative Support

Administrative support to the group will be provided by a member of the UHB R&D Office administrative team. This will include the maintenance of a record of the training undertaken which will be shared with RACD.

6.2 Frequency of and venue for training sessions

Training will be provided on a monthly basis for ten (10) months of the year (excluding August and January). Training will take place whenever possible, within the Seminar Room of the CRF, Upper Ground Floor C Block, University Hospital of Wales.

7.0 WHO NEEDS TO UNDERTAKE GCP TRAINING?

Category 1: Staff conducting CTIMPs

This category includes all staff conducting CTIMPs sponsored, co-sponsored or hosted by the UHB and/or CU

- Chief Investigators
- Principal Investigators
- All staff with delegated responsibilities (as recorded on the study delegation log)
Level of Training:
Evidence of approved GCP training (usually a certificate of attendance/completion) is a mandatory requirement for all staff in Category 1 who are taking part in studies sponsored, co-sponsored or hosted by the UHB and/or CU. Failure to meet this requirement will result in withdrawal of the sponsorship/co-sponsorship or withdrawal of R&D approval for hosted CTIMPs. There may be circumstances where individuals are only required to undertake topic related modules specific to their role. This should be discussed with CU RACD or UHB R&D Office (depending on the researcher’s substantive employer).

Category 2: Chief/Principal Investigators of non-CTIMPs
This category includes all Chief Investigators and Principal Investigators conducting non-CTIMPS i.e. studies that involve direct contact with participants or their data.

Level of Training:
Evidence of approved GCP training is a mandatory requirement for all Chief/Principal Investigators in Category 2 who are taking part in studies sponsored, co-sponsored or hosted by the UHB and/or CU.

Category 3: Research staff
This includes:
- all staff with delegated responsibilities on the study delegation log conducting non-CTIMPs;
- all staff who have contact with subjects of CTIMPs as part of their routine clinical work and who are responsible for delivery of protocol directed interventions and treatment.

Level of Training:
All staff in Category 3 will be required to undertake topic related training specific to their role although they are eligible to undertake full GCP training and are encouraged to do so in the interests of ensuring continuous quality improvement. It is the responsibility of the CI/PI to ensure that each member of the research team has the appropriate training, and their qualifications are documented and retained in the Investigator/Trial Site File and in the individual’s training record.

Category 4: Staff who are exempt from undertaking GCP training
Whilst all staff involved in research are encouraged to undertake GCP training as part of their own professional development, staff whose sole contribution to a study protocol is limited to routine care (that is, the procedures that they undertake are the same as in standard clinical care and are not specific to the research protocol) need not undertake GCP training or be listed on the study delegation log (eg Radiology staff undertaking standard Chest X rays as part of study screening)
External contractors who provide a service for a study (eg scanning in private hospitals) need not undertake GCP training or be listed on the study delegation log.

8.0 DEFINITION OF GCP TRAINING:

GCP training should be updated and renewed every 2 years for all relevant researchers (as described by Categories 1 to 4).

In the first instance, appropriate GCP training will include either:
   a) Attendance at a GCP training seminar; or
   b) Completion of a recognised online GCP training course.

Staff will be required to provide evidence (usually a certificate) of attendance/completion of GCP training.

All individuals who have undertaken the face-to-face or online GCP training will be able to fulfil the subsequent requirement to renew their GCP training every two years in any of the following ways:
   1. Attendance at a GCP training seminar or
   2. Completion of a recognised online GCP training course or
   3. Attendance at a GCP update/refresher training seminar; or
   4. Attendance at three topic specific training sessions, delivered as part of the joint UHB/CU training plan within a 2 year period. For researchers involved in CTIMPs one of the three sessions must include a mandatory overview seminar, which will be run twice yearly as part of the training plan. This is the equivalent of attending a 3hr GCP update training course every 2 years. Successful completion of three sessions within 2 years will entitle the researcher to a two year certification of GCP training.

There may be circumstances where individuals are only required to undertake topic related modules specific to their role. This should be discussed with CU RACD or UHB R&D Office (depending on the researcher’s substantive employer).

From time to time, the Sponsor and/or researcher’s substantive employer may identify further specific training that an individual researcher should undertake. Should this occur, the requirements and reasons behind shall be discussed with the researcher.

9.0 RESOURCES

The personnel required to implement this policy have been identified within the workload of existing members of the UHB and CU research staff. In the longer term, investment will be required in a database to track researcher compliance with this policy. As part of the development of the all Wales Academic Health Sciences Collaboration, it is planned that an All Training for personnel undertaking:

Good Clinical Practice  Page 6 of 7  Reference No: Version No. 1.0
undertaking clinical research
Wales R&D management system will be procured which will hopefully provide a facility for this aspect of the policy.

10.0 IMPLEMENTATION AND REVIEW

The operational team will meet monthly to set up and monitor the programme which has been running from April 2010.

11.0 EQUALITY

An equality impact assessment has been carried out and is appended. No adverse impact has been identified.

12.0 DISTRIBUTION

This policy will be made available on the UHB intranet and internet site.

13.0 AUDIT AND REVIEW

This policy will be reviewed every three years or sooner if appropriate.

The training programme will be reviewed by the R&D Director and the CRF Operational Director following consultation with the operational management team. In addition, feedback will be sought via consultation with the users of the programme to elicit areas that require improvement and to identify areas that might usefully be included in future programmes. A report and recommendations for any required alteration to the programme will be provided to the Research Governance Group at the end of the first year of operation, namely March 2011.

Acknowledgement:

This document was based upon a policy document produced by Lynda McSorley of the Glasgow Clinical Trials Unit and we are very grateful for her permission to use her work as a basis for our document.
Part A: Preparation and Assessment of Relevance and Priority

Part A is a three step process which will help you to prioritise work and prepare for EqIA.

**Step 1 - Preparation:**
identify the title of the Policy/function/strategy, the main aims and the key contributors (see Form 1)

**Step 2 - Gather Evidence:**
collect, but do not analyse information at this stage - just see what evidence is available (see Form 2)

**Step 3 - Assessment of Relevance and Priority:**
determine whether or not the evidence demonstrates high, medium, low, or no relevance and priority across the core dimensions of the equality duties, by each of the equality strands (see Form 3)
Form 1: Preparation

Part A must be completed at the beginning of a Policy/function/strategy development or review, and for every such occurrence. (Refer to the Step-by-Step Guide for additional information).

<table>
<thead>
<tr>
<th>Step 1 – Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Title of Policy</strong> - what are you equality impact assessing?</td>
</tr>
<tr>
<td>2. <strong>Policy Aims and Brief Description</strong> - what are its aims? Give a brief description of the Policy (The What, Why and How?)</td>
</tr>
<tr>
<td>3. <strong>Who Owns/Defines the Policy?</strong> - who is responsible for the Policy/work?</td>
</tr>
<tr>
<td>4. <strong>Who is Involved in undertaking this EqIA?</strong> - who are the key contributors to the EqIA and what are their roles in the process?</td>
</tr>
<tr>
<td>5. <strong>Other Policies</strong> - Describe where this Policy/work fits in a wider context. Is it related to any other policies/activities that could be included in this EqIA?</td>
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<td>6.</td>
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<tr>
<td>7.</td>
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</table>
Form 2: Evidence Gathering

<table>
<thead>
<tr>
<th>Equality Strand</th>
<th>Evidence Gathered</th>
<th>Does the evidence apply to the following with regard to this Policy/work? Tick as appropriate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race</td>
<td>No evidence</td>
<td>X Eliminating Discrimination and Eliminating Harassment</td>
</tr>
<tr>
<td>Disability</td>
<td>No evidence</td>
<td>X Eliminating Discrimination and Eliminating Harassment</td>
</tr>
<tr>
<td>Gender</td>
<td>No evidence</td>
<td>X Eliminating Discrimination and Eliminating Harassment</td>
</tr>
<tr>
<td>Sexual Orientation</td>
<td>No evidence</td>
<td>X Eliminating Discrimination and Eliminating Harassment</td>
</tr>
<tr>
<td>Age</td>
<td>No evidence</td>
<td>X Eliminating Discrimination and Eliminating Harassment</td>
</tr>
<tr>
<td>Religion or Belief</td>
<td>No evidence</td>
<td>X Eliminating Discrimination and Eliminating Harassment</td>
</tr>
<tr>
<td>Welsh Language</td>
<td>No evidence</td>
<td>X Eliminating Discrimination and Eliminating Harassment</td>
</tr>
</tbody>
</table>

People have a human right to: life; not to be tortured or treated in a degrading way; to be free from slavery or forced labour; to liberty; to a fair trial; not to be punished without legal authority; to respect for private and family life, home and correspondence; to freedom of thought, conscience and religion; to freedom of expression and of assembly; to marry and found a family and to not be discriminated against in relation to any of the rights contained in the European Convention.

| Human Rights | N/A |

* This column relates only to Disability due to the specific requirement in the DDA 2005 to treat disabled people more favourably to achieve equal outcomes. This is not applicable to the other equality strands.
Form 3: Assessment of Relevance and Priority

<table>
<thead>
<tr>
<th>Equality Strand</th>
<th>Evidence: Existing evidence to suggest some groups affected. Gathered from Step 2. (See Scoring Chart A)</th>
<th>Potential Impact: Nature, profile, scale, cost, numbers affected, significance. Insert one overall score (See Scoring Chart B)</th>
<th>Decision: Multiply ‘evidence’ score by ‘potential impact’ score. (See Scoring Chart C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Disability</td>
<td>1</td>
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<tr>
<td>Gender</td>
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<tr>
<td>Human Rights</td>
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</tr>
</tbody>
</table>

Scoring Chart A: Evidence Available

3  Existing data/research
2  Anecdotal/awareness data only
1  No evidence or suggestion

Scoring Chart B: Potential Impact

-3  High negative
-2  Medium negative
-1  Low negative
0   No impact
+1  Low positive
+2  Medium positive
+3  High positive

Scoring Chart C: Impact Decision

-6 to -9  High Impact (H)
-3 to -5  Medium Impact (M)
-1 to -2  Low Impact (L)
0   No Impact (N)
1 to 9   Positive Impact (P)
### FORM 4: (Part A) Outcome Report

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<th>GCP Training Policy</th>
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<tr>
<td>Organisation:</td>
<td>Cardiff and Vale University Health Board</td>
</tr>
<tr>
<td>Name:</td>
<td>Dr Helen Bass</td>
</tr>
<tr>
<td>Title:</td>
<td>Research Governance Coordinator</td>
</tr>
<tr>
<td>Department:</td>
<td>R&amp;D Office</td>
</tr>
<tr>
<td><strong>Summary of Assessment:</strong></td>
<td>No evidence of any impact since the policy is consistent and applies to everyone involved in research within Cardiff and Vale University Health Board</td>
</tr>
<tr>
<td><strong>Decision to Proceed to Part B Equality Impact Assessment:</strong></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Decision taken based on the fact that policy is consistent and applies to everyone involved in research within Cardiff and Vale UHB</td>
</tr>
<tr>
<td>Report of</td>
<td>Medical Director</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Paper prepared by</td>
<td>Director of Research and Development, Research and Development Manager</td>
</tr>
<tr>
<td>Purpose of Paper</td>
<td>To provide the Committee with a summary of the UHB Annual Report on Research and Development (2009-2010).</td>
</tr>
<tr>
<td>Action/Decision required</td>
<td>For information</td>
</tr>
<tr>
<td>Link to Health Board’s Strategic Direction and Corporate Objectives / Legislative and Regulatory Framework</td>
<td>High quality research helps deliver improved health services. Research governance aspects of the report are linked to legislative requirements under the Medicines for Human Use (Clinical Trials) Regulations 2004 and to compliance with the Research Governance Framework for Health and Social Care in Wales (WAG, 2\textsuperscript{nd} edition 2009)</td>
</tr>
</tbody>
</table>
Executive Summary
This report has been developed utilising the UHB R&D Office Annual Report to the Welsh Assembly Government which was submitted in September 2010 and reports on the research performance of the UHB and its compliance with the legislative infrastructure surrounding research and development.

1.0 Research Performance

Research Activity
During 2009-10, the UHB has continued to host a substantial and diverse research portfolio, supported by £12.5m from the National Institute for Social Care and Health Research (NISCHR) via the R&D Support Funding for NHS Providers funding stream. The positive impact on patient care of the R&D from several well established research groups has resulted in international recognition.

For the purpose of capturing information for the full report, 705 proformas were sent to Principal Investigators to gather up to date information on research impacts and outputs of projects currently ongoing or completed since April 2008. The response rate was 73%. The report highlights 250 projects with an output in the last financial year (one or more publications and/or one or more presentations and/or the award of a higher degree to a researcher involved in the project). 113 projects reported an impact on patient management, service delivery or patient outcome in the same period.
572 non-commercial projects and 135 commercial projects were ongoing at some point during this financial year. 283 new projects, including 73 commercial and 15 primary care projects were registered with the R&D Office between 1st April 2009 and 31st March 2010. 31 of the new studies registered were non-commercial clinical trials of investigational medicinal products (CTIMPs), requiring a high level of governance in order to meet the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2004.

**Partnership working with Cardiff University**
The vision and purpose to develop a new partnership between the UHB and Cardiff University built upon world-leading research, teaching and patient care that is designed to have a positive impact on the improvement of the health of the people of Cardiff, Wales and beyond has been significantly progressed during this reporting period.

In January 2010, the UHB and Cardiff University School of Medicine underlined their commitment to joint working by the appointment of a Joint Chair of Research and Development. The successful candidate, Professor Jonathan Bisson, brings clinical and academic expertise from his previous roles as a Consultant Psychiatrist with an international reputation in research in the area of Traumatic Stress.

The appointment of the Joint R&D Director has facilitated the ongoing integration of R&D work between the UHB (R&D Office and Clinical Research Facility (CRF)) and Cardiff University Research and Commercial Division and the health related Schools. The advent of joint monthly senior manager meetings has led to closer working and has laid the ground work for common approval processes, governance and oversight of all R&D within both organisations. The relocation of the UHB R&D Offices to the second floor of the Main Building UHW, alongside the School of Medicine Research Office in January 2010 has also facilitated joined up working. This integration will be supported in future by the better alignment of the new UHB’s and University’s research strategies, particularly those principally concerned with clinical and translational research.

**Clinical Research Facility**
The CRF has hosted a variety of studies over the past 12 months and has continued with the aspiration of the Wellcome Trust in ensuring that the mix of commercial to non commercial projects ensures that all researchers in Wales have access to state of the art facilities required
to carry out high quality research that meets all the regulatory requirements.

The CRF continues to be included on the Experimental Medicine Resource database [http://www.ukrcexpmed.org.uk/Pages/default.aspx](http://www.ukrcexpmed.org.uk/Pages/default.aspx) and this coupled with its proven ability to undertake First in Human studies has increased the type of funded studies hosted.

The prestigious Medical Research Council 1946 Cohort study is now nearing completion with the last participant due to be seen in the CRF in October 2010. This nurse-led study and data collection led in Cardiff by the CRF Operational Director has studied ageing and its lifetime precursors in over 300 individuals from throughout Wales and South West England.

National Institute for Social Care and Health Research – All-Wales Academic Health Science Collaboration (NISCHR AHSC)

The NISCHR AHSC is a collaboration between the Welsh Assembly Government, Health Boards, NHS Trusts and Universities, building on the links and partnerships that exist between the individual universities and their linked Health Boards/Trusts. The UHB expects to play a full and important role in this new All-Wales collaboration. The development of the proposed NISCHR AHSC strategy has been led, from an NHS and academic capacity, by Professor Jonathan Bisson. The aim of the strategy is for the NISCHR AHSC to be recognised for its international distinction and impact, for the excellence and innovation of its clinical research and for the promotion and support of the distinctive research agenda needed to impact on the health and wealth of the people of Wales. Because of the perceived importance of this strategy and the major role that Professor Jonathan Bisson has played in its development, it was agreed that the new Joint UHB/Cardiff University R&D strategy should not be finalised until the NISCHR AHSC strategy has been finalised and accepted on a Wales wide basis.

2.0 Financial Performance

For the Financial Year 2009/10 the former Cardiff and Vale NHS Trust received £12.6m R&D funding from NISCHR. The allocation for the period did not include any growth funding although an inflation uplift of 1.7% was included. The lack of growth funding in the years since 2004/05 continues to have an impact on the development of R&D within the UHB. This continues to be the case where there are increasing
requirements to satisfy regulatory frameworks, new monitoring regimes, increased training to comply with R&D practices etc. Notwithstanding this, the non commercial R&D activity continues to be maintained at a consistent level and supported within the organisation.

The Procurement department continues to have responsibility for the management of Intellectual Property (IP) relating to research and works closely with the UHB’s legal representatives in these matters. The R&D Office aids in identifying research projects with IP potential and liaises with the Procurement department on the development of business cases and IP agreements with funding bodies where appropriate. One potentially valuable IP item has been identified in 2009/10. There are 12 items in total still being evaluated including those from previous years. Seven items of potentially valuable IP have arisen from joint work with Universities. The UHB received £394,980 income (net of costs) from successful commercialisation of IP during the financial year of which £197,490 was distributed to UHB employees.

3.0 Research Management and Governance Performance

Reform of the NHS in Wales
During the reporting period of this R&D Annual Report, the reorganisation of the NHS in Wales took place. The restructuring process has inevitably had an impact on the way R&D is managed and governed within the new organisation, with centralisation of management processes to one R&D Office. Whilst the restructuring process has not been completely seamless in terms of R&D management within the primary care setting, at the end of this reporting period, the new UHB is confident that it has robust mechanisms in place to manage and govern both primary and secondary care research within the new organisation.

Governance Structure
The Research Governance Group (RGG) oversees progress made in relation to the RGG Annual Work Programme and the challenges still to be addressed are highlighted to the UHB via the RGG meeting minutes presented quarterly at the bi-monthly Quality and Safety Committee meetings by the Director of R&D. Divisional R&D Leads are responsible for ensuring that research governance issues raised through the RGG are communicated within their areas. The recruitment of additional Research Governance Coordinators is now allowing for a speedier resolution of actions identified by the group.
Medicines and Healthcare products Regulatory Agency (MHRA) Statutory Good Clinical Practice (GCP) Inspection

The MHRA carried out a statutory GCP inspection of the former Trust in December 2007. The response to the MHRA Inspection Report, in the form of a Corrective and Preventative Action Plan, was confirmed as satisfactory in June 2008.

Progress against the MHRA Action Plan continues to be monitored and overseen by quarterly reports to the RGG, and since January 2010 there have been monthly progress meetings with the R&D Director to discuss and prioritise individual responsibilities and agree work plans for achieving the outstanding actions. Whilst cross cover for staff shortages in the commercial trials section of the R&D Office have resulted in some further slippage on the expected timelines for achieving complete regulatory compliance, the R&D Office has been able to make significant progress with addressing the outstanding actions on the MHRA Corrective and Preventative Action Plan.

Following the R&D Office’s submission of the risk-based inspection self assessment questionnaire in June 2009, the MHRA notified the UHB that it had been categorised as a ‘Medium Risk’ organisation. This translates into possible re-inspection at the UHB within 4 years, and hence all outstanding MHRA actions are being treated as high priority, otherwise these could be upgraded to Critical Inspection Findings at the next inspection.

Monitoring and Audit

An internal audit of research governance processes took place between December 2009 and April 2010. The objective of the audit was ‘to evaluate and determine the adequacy of the systems and controls in place for the governance of research undertaken by UHB employees and utilising UHB data, in order to provide reasonable assurance to the UHB’s Audit Committee that risks material to the achievement of system objectives are managed appropriately’. Following consideration of the findings of the audit assignment, it was concluded that the level of assurance given as to the effectiveness of the system of internal control in place to manage the risk associated with the objectives covered in the review, was ‘Adequate Assurance’. Four main risks were identified and the R&D Office was required to produce a Corrective and Preventative Action Plan to address these points.

In order to demonstrate compliance with the Research Governance Framework for Health and Social Care in Wales, a percentage of
ongoing research projects are monitored and audited. Triggered audits and horizontal audits have also taken place when potential issues have been identified.

**Training**
The UHB requires researchers involved in any CTIMP sponsored or hosted by the UHB to demonstrate up to date GCP training (at least every 2 years). The UHB supported 3 half-day GCP training events delivered by external consultants (May 2009, September 2009 and March 2010).

An in-house GCP training programme in modular format (lunchtime seminar series) was developed jointly by the UHB and Cardiff University R&D Offices and the Clinical Research Facility. The first session took place in April 2010. These sessions will be aimed at researchers involved in either CTIMPs or non-CTIMPs.

R&D Office staff and CRF staff also continue to deliver seminars, group and individual training on a number of issues including GCP.

**Progress summary against Forward Plan for April 2009-March 2010**
Of the 21 actions identified on the Report Forward Plan, 18 were achieved or in hand. There were 2 actions that were not progressed and one that was no longer applicable

Note: The full Cardiff and Vale NHS Trust Research and Development Report 2009-2010 is available on request from the R&D Office (258 pages) and was submitted to NISCHR on 24 September 2010

**RECOMMENDATION**
The Committee is asked to:

- **NOTE** the progress made to ensure robust managerial and governance arrangements for Research and Development in Cardiff and Vale University Health Board

**IMPACT ASSESSMENT**

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<tr>
<th>Health Improvement</th>
<th>Trials of new drug, medical device and surgical treatments can lead to health improvements for</th>
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trial subjects. Translational clinical research can lead to improvements in prevention, diagnosis and treatment of disease.

**Workforce**
R&D should lead to evidence based practice by the workforce. The opportunity for staff to carry out R&D should lead to better recruitment and retention of staff.

**Financial**
The report details the use of the £12.5 million NHS Provider Support Funding received from NISCHR

**Legal**
Compliance with legislation governing research including the Medicines for Human Use (Clinical Trials) Regulations 2004, overseen by the Medicines and Healthcare products Regulatory Agency

**Equality**
Consistent with equality legislation

**Environmental**
No impact assessed

### RISK ASSESSMENT

**Clinical/Service**
This report provides an update on the measures in place to ensure robust research governance arrangements. Adequate R&D infrastructure, clinical staff and facilities are required to support R&D

**Financial**
Requirement to demonstrate value for money to NISCHR. Risks relating to Wales wide review of NHS Provider Support Funding

**Reputational**
High performance in R&D is required to maintain the organisation’s reputation locally, nationally and world-wide.

### CONSULTATION AND ENGAGEMENT

N/A

### SOURCES OF INFORMATION & EVIDENCE


Medicines for Human Use (Clinical Trials) Regulations 2004 and Amendment Regulations
AGENDA ITEM 8.3

<table>
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<tr>
<th>DESIGNATED INDIVIDUALS</th>
<th>Clinical Diagnostics and Therapeutics Division</th>
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<tr>
<td>CHAIRED BY</td>
<td>Sheila Harrison, Lead Nurse Patient Experience Division</td>
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<tr>
<td>DATE OF LAST MEETING</td>
<td>3rd August 2010</td>
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KEY AGENDA ITEMS / RISKS TO NOTE

**Designated Individuals**
Reporting routes to the Board needs to be revisited to ensure that existing arrangements are to the satisfaction of what has been agreed with the Human Tissue Authority (HTA).

**Divisional Nurse Support**
This issue will be escalated by the Divisional Manager, to the Nurse Director, in view of the impending move of Sheila Harrison into her new role. Since the meeting, arrangements have been put in place to ensure professional support is provided by the Divisional Nurse for Surgery.

**Blood Safety and Quality Regulations / MHRA compliance issues**
It was not known if feedback from the MHRA had been received as yet following submission of this year’s Blood Compliance Report. Andrew Crowder has assured the Divisional Manager that systems are in place to achieve compliance if the MHRA should return imminently.

**Clostridium difficile action plan**
Further input from directorates to develop the Divisional action plan are required. It was raised that an issue for the Division is the referral of patients for clinical investigations where their infectious status is not communicated, thereby potentially compromising infection control procedures.

**Lessons learnt from a patient identification error in Radiology**
It was clear from the investigation that implementation of procedures for positive patient identification is inadequate. Practical solutions have been identified to strengthen existing processes. It is noted that patient identification issues need revisiting regularly as errors are a recurrent issue. The UHB is non-compliant with the NPSA RRR on patient wristbands.
NCEPOD report on parenteral nutrition practices in the UK, published June 2010
UHB staff contributed to the National working party. The report has been presented to the Specialist Services Division. Dr B Hawthorne is considering the recommendations and actions required by the UHB.

Process for managing MDAs in the UHB
Concern was raised that the current system for managing MDAs in the UHB needs strengthening and interim processes to ensure immediate improvements in the Division were agreed.

Inspections in Radiology, Clinical Engineering and Medical Physics
It was noted that following a Department of Transport inspection and MHRA inspection of a radiopharmacy area in Medical Physics, they have been declared as compliant. HIW are undertaking an IR(ME)R inspection in Radiology at the time of the meeting.

Clinical Risks in Newborn Screening Laboratory
There are staffing and IT infrastructure issues that are contributing to the clinical risks associated with the Newborn Screening Laboratory which receives samples from across Wales.

Policy for Radiographer Reporting of Plain Images in Unscheduled Care
The meeting supported this policy document which aims to promote timely reporting of plain images in Unscheduled Care settings which will improve patient flow.

Clinical governance review of Laboratory Medicine Directorate
Mike Creasy presented the outcomes of a clinical governance review of the directorate. It was identified that implementation of Divisional terms of reference for Quality and Safety groups will assist directorates with strengthening governance mechanisms.

ONGOING WORK / ACTIONS

Incorrect patient identification details on blood samples
Mike Creasy raised concern regarding the volume of samples received that are incorrectly labelled. The data requires further interrogation in order to devise and inform the issuing of an internal safety alert.

Outstanding legacy items
Divisional terms of reference for Quality and Safety groups are awaited in order to improve reporting arrangements; risk registers require updating and a new Chair is still required to replace Sheila Harrison.

ITEMS TO RECEIVE OR FOR APPROVAL (Where required)

MINUTES SUBMITTED TO QUALITY & SAFETY COMMITTEE  Yes [  ]  No [  x  ]
DATE OF NEXT MEETING
REPORTING COMMITTEE/GROUP | Thrombosis and Anticoagulation Group
---|---
CHAIR | Dr G Shortland
DATE OF LAST MEETING | 13 July 2010 and 23 September 2010

**KEY AGENDA ITEMS / RISKS TO NOTE**

**Introductions**
This was the Group’s fifth and sixth meetings since the meeting arrangements were refocused earlier in the year; meetings are chaired by the Interim Medical Director and are well attended.

**Progress with Risk Assessment Tools**
Risk Assessment Tools have been agreed for medical, surgical, orthopaedic, trauma and critical care admissions. Obstetric and Spinal risk assessment tools are near completion. Implementation of the risk assessment tools has been variable. Junior doctors have been targeted at the August induction and the process will be reinforced at Divisional level to ensure compliance with the target that by March 2011, 95% of patients will be assessed within 24 hours of admission. Information and risk assessment resources will be accessible to all staff via the clinical portal.

Reporting of ‘outliers’ i.e. clinicians who consider themselves outside of the implementation process and the requirement to audit such practice is to be discussed with Executives and Divisional Directors.

Variance exists in pre-operative prescribing of anti-embolism stockings (AES). Application of the risk assessment process will reduce this variance and ensure appropriate prescribing. Community Pharmacists sought clarification on prescribing of AES which are not and should not be issued routinely upon discharge. However, secondary care does issue AES to relevant exception groups such as varicose vein surgery and gynaecology cases.

Secondary and primary care services are working closely to take forward the pilot of extended thromboprophylaxis in orthopaedics. A number of governance issues have been identified and are in the process of being addressed in order to manage the process safely.
Measuring Compliance
The Group considered the audit process in detail and agreed that a standardised process has to be followed for consistency of recording, reporting and production of high level reports.

It is proposed that small sampling should be undertaken during October 2010. A point prevalence of all adult patients within acute services will be undertaken by junior doctors on a specified day in October 2010 and every third month of each junior doctor rotation thereafter i.e. February and June 2011. The feasibility of providing the audit tool electronically via the portal for both access and reporting is to be explored.

Performance reporting will feature as a standard agenda item in future meetings and will report on the following:
- Small sample audits undertaken October 2010
- Theatreman reports from World Health Organisation (WHO) surgical checklist
- Pulmonary Embolus rates (which are included on the Quality and Safety performance report submitted to the Assembly)
- Divisional progress reports

Spend to Save – Business Case
The business case submitted under Invest to Save was initially unsuccessful and will now be modified for submission to the Executive Board to deliver a 5-day pharmacy-led anticoagulation service and a nurse-led Venous Thrombo Embolism (VTE) diagnostic and treatment service in the UHB. The additional estimated drug costs for thromboprophylaxis (£230K) and the associated impact within the Divisions and the UHB must also be accounted for.

Following an audit of patients with raised INR, key actions were agreed including plans to re-audit later in the year. Raised INR is a component of 1000 lives+ and is now included on the Quality and Safety dashboard.

The proposal for GPs to take on the initiation of warfarin for patients with atrial fibrillation continues to be discussed. However, the issue of recognising prescribing of loading doses as an enhanced service has not been resolved. This will be discussed with Primary, Community ICOP Services.

Representatives attended the Hospital Acquired Thrombosis (HAT) Collaborative meeting 8 June 2010 in Llandrindod Wells, the good progress made at Cardiff and Vale UHB was acknowledged.

Options for funding and publishing a patient information leaflet will need to be
explored. The newly available leaflet produced by EIDO is outside the existing contract arrangement; the leaflet produced internally is favoured. Learning from a recent Rule 43 case will be presented at the next meeting in order to disseminate lessons learnt.

A proposal to purchase D-Dimer reagent will be submitted to the Director of Innovation and Improvement in an effort to reduce a significant number of re-attenders in the Medical Admissions Unit, improve patient outcomes and to realise the revised DVT pathway.

**ONGOING WORK / ACTIONS**

The UK Thromboprophylaxis Forum Regional Meetings 2010 will hold a meeting in Cardiff on Monday 27 September.

Recently Project Manager Support has been lost to this Project following the appointment of the previous post holder to a Directorate Manager post under the UHB reorganisation. The group expressed concern about the senior administrative support required to ensure the initiative progresses and the matter was being taken forward by the Medical Director with the Director of Innovation and Improvement.

**ITEMS TO RECEIVE OR FOR APPROVAL (Where required)**

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<th>MINUTES SUBMITTED TO QUALITY &amp; SAFETY COMMITTEE</th>
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<td>DATE OF NEXT MEETING</td>
<td>8th November 2010</td>
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Introduction
The Group Chair welcomed new members and the Terms of Reference was revisited to confirm the purpose and format of the Medicine & Unscheduled Care Division Quality and Safety Group. Group members will be required to review local policies and procedures in accordance with the UHB guidance.

NPSA – Rapid Response Report Reducing treatment dose errors with Low Molecular Weight Heparins (LMWHs)
This report was reviewed and the need to ensure that all patients are weighed to enable the change in culture of prescribing LMWHs to calculate the required dose. Lead Nurses were requested to review the availability of scales across the Emergency Units and medical wards to enable implementation of this guidance.

Thromboprophylaxis (VTE) Risk Assessments
Dr R Rayment, consultant Haematologist attended the meeting to present the VTE risk assessment and implementation using the All Wales Risk tool, to achieve 95% of patients having a VTE risk assessment within 24 hours of admission. The role of consultants on ward rounds to ensure VTE risk assessments are completed was reinforced. The Division is required to identify an audit lead for VTE to link with Dr Rayment.

Incident, Complaints, Claims update
The Group considered the information provided and the reported trends. Good progress continues with addressing the complaints backlog with the Medical Directorate achieving 100% compliance with the 20-day response target for the last month. The Division has taken a proactive approach to contacting complainants directly to meet with individuals or communicate over the telephone. This is improving satisfaction and has reduced the number of ongoing ‘formal’ complaints. The Division is developing a shared complaints folder with the Corporate Complaints Department to improve complaints tracking (investigating officers, statements, draft documents, final responses and lessons learnt). This will facilitate the sharing of information and tracking.
performance and outcomes.

**WRP Unscheduled Care Action Plan**
The Unscheduled Care Directorate presented the Action Plan identifying good practice and areas for improvement following the 2009/10 Welsh Risk Pool Assessment. Key actions being addressed: revised Escalation policy, development programme to enhance discharge planning. To increase the number of staff trained in adult and paediatric life support. Cross Divisional working to reduce delays in reporting x rays and CT scans. The need for redesign of physical environment. Roll out of SBAR for handover of patients. Nurse Consultant post for Minor Injuries approved. Morbidity and Mortality meetings reinstated in the Directorate. A review of the documentation of pain management is currently under way. D Dimer facilities required and an improved presence of security on site.

**Patient Story:**
Consultant in EU presented a patient story demonstrating the lessons learnt from the admission of a patient presenting with an acute stroke: failings in communication, escalation and handover, length of time spent in EU, delays in CT scan reporting, delays in thrombolysis. The new stroke pathway has now been approved and implemented and improvements have now been achieved with C7 designated the hyper acute stroke ward. The story also related to a recent Rule 43, issued by HM Coroner.

**Divisional and Directorate Risk Registers**
Meetings are arranged to review the format of the current risk registers to migrate to the new format. Key Risks identified by the Unscheduled Care Directorate include:

**Dignity in Care**
The Division has submitted a bid to the Dignity in Care small grants process to develop the skills of nurses on medical wards to deliver care for patients

**Key Risks/Divisional Priorities**
The Divisional Nurse presented an update on key risks, priorities for action within the Division, these were summarised as;

- Workforce/Establishments/Skills Mix in both Nursing and Junior Medical Staff;
- Improving the flow of patients through their care pathways, including planned date of discharge and delayed transfers of care;
- Reduction in Healthcare Associated Infections, priority on C.Dificile;
- Implementing the Quality and Safety PID.
**Corporate Clinical Governance Facilitator Support**
The meeting expressed concern that there would be no back fill when their clinical governance facilitator went on maternity leave this month and would not return until April 2011. The support and guidance provided by the Corporate department was recognised and it was felt the two remaining facilitators will not have the capacity to absorb this role.

**ONGOING WORK / ACTIONS**
The Medical & Unscheduled Care Division Infection Prevention and Control (C diff/HIW) Action Plan has been developed and will be presented at the October Quality & Safety Infection Prevention & Control Group.

**ITEMS TO RECEIVE OR FOR APPROVAL (Where required)**

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AGENDA ITEM 8.6

REPORTING COMMITTEE/GROUP | Surgery Division Quality and Safety Group
CHAIRLED BY | Dr Paul Clyburn
DATE OF LAST MEETING | 3rd September 2010

KEY AGENDA ITEMS / RISKS TO NOTE

1. Compliance with Thromboprophylaxis NICE Guidance CG92
   - Dr Rachel Rayment reported that there is poor compliance with universal risk assessment in many areas, both within the Surgical Services Division and in other Divisions. This is a significant risk to patient safety, as many patients do not receive necessary prophylaxis. In England, a minimum 95% compliance in all areas is mandatory. Failure to meet this target triggers a reduction in tariff and lost revenue. Fortunately, as yet, no such censure exists in Wales.
   - Where poor compliance exists, it is mainly due to a lack of engagement by medical professionals. The Directorates within the Surgical Services Division have been tasked with identifying a nominated person (medical or nursing) to participate with the UHB wide audit of compliance which will be undertaken across the UHB (acute hospitals) on a given day in October. The results of this audit will be shared at the next Divisional Quality and Safety Group.
   - There is also a problem with safe prescribing of extended prophylaxis after discharge. Appropriate selection of patients who would benefit, proper safe protocols, and training of patients to self-administer were some of the problems identified. This is a Health Board wide issue.

2. Rapid Response Report NPSA/2009/RRR004: Preventing delay to follow up for patients with glaucoma:
   - Claire Nelson reported the practical problems of complying with this RRR. IT infrastructure is inadequate and the potential workload is unmanageable with current resources. Solutions to this problem are being addressed through the Operational Performance Group.

3. Surgical marking and laterality audit:
   - We continue to receive reportable incidents/near misses of wrong site of surgery. Not all specialties are marking the correct site of surgery in
the prescribed manner.
- Presentation of a laterality audit performed end of 2009 could not take place because of annual leave and has been deferred to next meeting.
- We wish to highlight this as an ongoing problem that is being addressed.

4. **White residue on theatre sterile equipment:**
   - Despite difficulties in irradiating the residue, its sterility residue has been confirmed.
   - The situation continues to be evaluated.
   - Further details are contained in attached briefing note on theatre tray related issues

### Ongoing Work / Actions

Numbers refer to above

1. Discussion with Directorates to explore barriers to clinician engagement.
   Engagement with the UHB Acute Hospital Audit assessing compliance with the Risk Assessment tool for VTE prevention.
2. Presentation of laterality audit at Directorate CG meetings.

### Items to Receive or for Approval (Where Required)

<table>
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<tr>
<th>Briefing note on theatre tray related issues (Appendix 1)</th>
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<tr>
<th>Minutes Submitted to Quality &amp; Safety Committee</th>
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Briefing note on theatre tray related issues at Cardiff and Vale University Health Board

A further meeting was held on Friday 20\textsuperscript{th} August 2010, to consider and review the reported ongoing problems with Cardiac Surgery Instrument Trays and the related impact on activity.

A cross section of staff representing Cardiac Surgeons, Theatres, HSDU, Welsh Health Estates, Directorate, Divisional and Corporate Executive Management were present.

The meeting was Chaired by Dr Graham Shortland, Interim Medical Director.

The meeting primarily was to consider the ongoing report of recurring small amounts of fine black particulate matter (FBPM) being deposited on Cardiac Theatre tray liners following sterilisation processes and the impact this was having on patient related activity, staff and reputational image.

The Divisional General Manager outlined progress to date with all actions taken since the incident was first reported in May 2010. The meeting was also apprised of the recent media interest which occurred during the week a related consequence of further cancelled/postponed theatre activity due to discarded trays.

Referenced as Appendix 1, is a summary of the last detailed update submitted to UHB Executives and WAG.

The Divisional Manager outlined the ongoing problems which were summarised as follows;

- Cardiac Trays were still being rejected due primarily to the instruction of a ‘Zero’ tolerance approach relating to any discovered ‘black bits’ in all except emergency activity, this was continuing to impact on planned surgery

- The current checking processes were based on provocative testing which had developed and become more aggressive as the management response to the issues progressed

- Whilst very positive progress had been made over the 3 months since the reported problem, despite everyone’s best efforts, it
had not been possible to eliminate completely the issue of small amounts of fine particulate matter (black bits) being discovered on trays. However, it should be noted that external advice from WHE and SMTL confirm that all HSDUs (to a greater or lesser extent), experience this and whilst it cannot be eradicated assurance was provided that sterility was not an issue and that there was no material risk.

- The risk assessment processes needed to balance the internal checking procedures with the risks associated with patients whose procedures were being cancelled, these included inpatients and those patients not able to be admitted to hospital for their procedures.

- The impact on patients and staff needed to be appropriately balanced within related risk assessment processes.

- The impact on professional and organisational reputation should not be understated.

In response and in addition to what is outlined above, from the July update, the UHB has;

- Good staff interaction and cross departmental support between operating theatres and HSDU

- Daily 10 am meetings in place with primary focus on Patient Safety

- Independent external ‘expert’ advice considers the response and actions taken by the UHB to be exemplary. The overriding view is that instrument trays are sterile.

- An additional £200k of new instrumentation has been procured

- 5 new washer disinfectors (state of the art) installed and commissioned

- The HSDU refurbishment programme continues to progress at pace

- Agreement reached to also replace sterilisers
Appendix 1

- Patient Safety Friday Board Member Walkround to HSDU and Theatres was well received by staff and also informed better understanding of the related issues

Way Forward

- The UHB would with immediate effect, revise its checking protocol to reflect the progress that has been made since the incident was first reported in May 2010, the external expert advice confirming trays to be sterile, and balancing the associated risks of lost activity on patient safety

- Aligned to the above, Peter O’Keefe and the Divisional Management team would as a matter of some urgency, produce guidance relating to fine black particulate matter (FBPM) on tray liners and seek external expert advice on the suggested way forward and confirm that proceeding to use trays for surgery presents a negligible risk to patient safety

- UHB Executive informed by the work of the Group including external ‘expert’ advice to endorse the approach outlined within this update

Dr Graham Shortland
Interim Medical Director

Ian Morris
Divisional Manager, Surgery Services

Nicola Ryley
Divisional Nurse, Surgery Services

20th August 2010
Appendix 1 to Surgery Q&S Report  
Quality and Safety Committee  
12 October 2010

Appendix 1

Briefing note on theatre tray related issues at Cardiff and Vale University Health Board

This paper seeks to provide a description of theatre tray related issues at Cardiff and Vale University Health Board and actions taken to address the reported issue and maintain services.

- The incident commenced on the 26th May when the water-logging and water-marking of theatre trays at the University Hospital of Wales led to the disruption of lists and the cancellation of cardiac cases.

- The water-logging was quickly resolved and has not recurred.

- The risks associated with the water-marking of trays was considered by a Multi-Disciplinary Group (MDG) later that day, with representation including surgeons and the UHB Infection Control Doctor. It was agreed that this did not constitute a microbiological risk as the trays were sterilised, process controls were satisfactory and the trays themselves were intact.

- The next week two further issues emerged, a sticky residue on instruments and a white powdering on trays and instruments

- The MDG was extended to include input from the UHB QA Pharmacists, Welsh Health Estates (WHE) and the Surgical Materials Testing Laboratory (SMTL)

- The MDG adopted the following strategy in seeking to address these issues:
  o Identify the residue and powder to trace the potential source and subsequent interventions
  o Following the review of processes and checks on process controls, the trailing of interventions to eliminate the problems

- The sticky residue was resolved first, following a switch from blue to white tray liners. The blue liners are industry standard and had been used at the University Hospital Llandough without incident for many years
Appendix 1

- The white powder was resolved in the third week when the detergent used was switched from the pH neutral one used for many years without incident to an alkaline detergent. Process tests had identified that it was the washer phase that was associated with white powdering, not the sterilisation process. Though not scientifically proven, it is considered probable that the hardening of the UHB water supply led to the white powdering of instruments, which was resolved by the detergent switch.

- Laboratory testing was undertaken as part of investigation and on occasions was potentially misleading, for example when the white powder was initially identified as a phosphate. Subsequent tests confirmed that the overwhelming majority of issues were associated with calcium carbonate deposits, derived from the water supply.

- At all stages there has been assurance regarding the sterility of instruments.

- Initially in an effort to maintain cardiac surgery, trays were sourced from local hospitals but these failed local QA checks. Efforts were also made to source trays from Cardiac Centres, though these were unsuccessful for logistical reasons.

- In response to the disruption to cardiac surgery, the incident was reported to WAG as a Serious Adverse Incident on the 9th June.

- The focus on theatre instruments led to the very close inspection of trays, with inevitable ascertainment bias.

- In the views of WHE and SMTL, the UHB theatre trays were of comparable quality to those at HSDUs across Wales.

- Cardiac surgery resumed on the 11th June

- The theatre tray inspection procedure was continually updated in response to emerging findings and risk assessments

- It has subsequently become apparent that a fifth issue has emerged, with intermittent black bits appearing on theatre trays.
This resulted in the cancellation of four cardiac surgery cases on the 1st and 2nd July.

- The MDG consider that the “black bits” are residual blood, which has been on instruments for some time (months/years)

- It is considered that the more aggressive alkaline detergent is resulting in the more effective cleaning of instruments, but is resulting in long standing residue being displaced (hence the “black bits”)

- WHE and SMTL reported that this phenomenon occurs in all HSDUs (to a greater or lesser extent), and as such cannot be eradicated they provided assurance that sterility was not an issue and that there was no material risk

- For cardiac instruments, the UHB has sought to overcome this through:
  
  o Fast-tracking instruments to HSDU following use (avoiding instruments drying out)
  o Ultra-sonicating instruments prior to fine cleaning
  o Enhancing fine cleaning of instruments prior to washer/disinfection
  o Accelerating the replacement of instruments

- Cardiac surgery proceeded as planned on the 5th July

- To assess risks associated with the more recent phenomenon, a meeting of the UHB Medical Director, Divisional Director (Surgery) and the Clinical Director (Cardiothoracic Services) is planned for Thursday 8th July, including input from Dr Mike Simmons (Director, NPHS and previous WAG Decontamination Medical Lead)

- Throughout the UHB has adopted a cautionary principle, based on risk assessment and the maintenance of patient safety

- No material disruption has been experienced with other specialties, or at UHL or the Dental Hospital
Appendix 1

- The MDG has supported the management of the incident throughout and has reviewed lessons learnt with the objective of sharing lessons learnt with HSDUs across Wales

- The UHB are undertaking an evidential review of the actions and decisions made in relation to the incident

Ian Morris
Divisional Manager, Surgery Services

Nicola Ryley
Divisional Nurse, Surgery Services

5th July 2010
ATTENDEES:
Paul Clyburn Chair
Nicola Ryley Vice Chair
Cathie Steele Clinical Governance Facilitator
Sharon O’Brien Manager, Resuscitation Service
Tony Turley CD, Surgical Support Services
Tina Bayliss DM, Ophthalmology/Head & Neck
Claire Nelson DM, General Surgery, Urology
Jyothi Srinivas Clinical Governance, Anaesthetics
Yvonne Hyde Infection Control
Gillian Edwards LN, Trauma & Orthopaedics

IN ATTENDANCE FOR ITEM 3.2.1
Rachel Rayment Consultant Haematologist
Lisa Franklin Practice Development Nurse – General Surgery/Urology
Helen Luton Practice Development Nurse, T&O

PART 1: PRELIMINARIES

<table>
<thead>
<tr>
<th>ACTION</th>
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<tbody>
<tr>
<td><strong>1.1 Welcome and Introductions</strong></td>
</tr>
<tr>
<td>Paul Clyburn welcomed colleagues to the meeting and introductions were made around the table.</td>
</tr>
</tbody>
</table>

| **1.2 Apologies for Absence** |
| Apologies were received from Ian Morris, Sue Mogford, David Scott-Coombes, Ceri Harris, Linda Walker, Simon Rogers, Richard Hughes, Richard Whiston, Robert Williams, Anne |
### Appendix 2

<table>
<thead>
<tr>
<th>AAppendix 2</th>
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</thead>
<tbody>
<tr>
<td>Hiscocks, Alun Tomkinson, Alena Ball, Chris Williams and Michelle Mason-Gawne</td>
</tr>
</tbody>
</table>

#### 1.3 Approval of the minutes of meeting held 07 May 2010

The Minutes were approved as a correct record.

#### 1.4 Matters Arising

The action log from the above meeting was received and the following noted:

- **Minute 10/16 of 7/5/10**: Use of Betadine Solution in Surgical Cavities. Assurance was received that Directorate Risk Assessments were in the process of completion in conjunction with Pharmacy.
- **Minute 10/27 of 7/5/1**: Footwear Decontamination in Theatres. Linda Walker had taken a paper to the UHB Decontamination Group.
- **Minute 10/27 of 7/5/10**: NPSA/2009/RRR004 – Preventing Delay for Follow up to patients with Glaucoma. An agenda item
- **Minute 10/29 of 7/5/10**: C.difficile. Nicola Ryley referred to the Divisional Action Plan, and urged that Directorate Action plans should have team ownership. David Scott-Coombes had communicated with CDs. Yvonne Hyde confirmed that the audit was pharmacy and microbiology led.
- **Minute 10/38 of 7/5/10**: Clinical Equipment Strategy Group funding. Nicola Ryley confirmed that this had been added to the Divisional Risk Register.

#### 1.5 To receive and approve the Surgery Division Quality and Safety Group Terms of Reference

The following was noted:

- DMs are to attend
- Sub groups would be revisited in line with the new Divisional structure
- Policies and Procedures – it was confirmed that the Group can ratify Procedures and Guidelines, but NOT Policies.
Cathie Steele advised that the TOR mirrored the UHB TOR, and should be mirrored down to Directorate Q&S groups. Paul Clyburn would write to each Directorate, requesting assurance at the next Divisional Q&S meeting that schedules of meetings were in place. A report from each Directorate meeting would be required at Divisional Q&S.

### 1.6 Legacy Statement from Surgery Service Group Clinical Governance Committee

It was confirmed that relevant issues had been fed to other Divisions. The remainder (Betadine and Laterality issues) were being addressed.

## PART 2: SAFETY AND QUALITY

### 2.1 Standards for Healthcare in Wales – representation at UHB Planning Group

It was confirmed that Claire Nelson, and Gillian Edwards would represent the Division. The UHB was awaiting WAG guidance, but in the interim Directorates should carry out self assessment against the 28 Standards.

### 2.2 Alerts and other Safety Notices

#### 2.2.1 NPSA/2009/RRR004 - Preventing Delay for Follow up to patients with Glaucoma

Claire Nelson confirmed that a paper would be presented at Operational Performance Group on 6th September. A WAG funding community pilot had run for a limited time. The UHB funding for a key IT system had been withdrawn. The Directorate had attempted to cease new patient appointments to allow follow-ups to be addressed, but this could take years. Cathie Steele requested that an update be provided within the Divisional report to the next UHB Quality and Safety Committee.

#### 2.2.2 NPSA/2009/RRR005 - Minimising risks of Suprapubic Catheter insertion (Adults Only)

Owen Hughes to provide a written update.
### 2.2.3 NPSA/2009/PSA004 - Safer spinal (intrathecal) epidural and regional devices
Paul Clyburn provided an overview of the relevant procedure and equipment. An All Wales working group was in the process of evaluating available equipment. Paul Clyburn had formed a UHB working group. Compliance by 1 April 2011 was dependent on the outcome of the Wales working group and on manufacturers.

### 2.2.4 NPSA/2009/RRR007 - Reducing the risks of tourniquets left on after finger and toe surgery
A verbal or written update to be provided by David Scott-Coombes.

### 2.2.5 NPSA/2010/RRR010 - Early complications after gastrostomy
Cathie Steele reported that Maria Roberts had provided an update. Alun Tomkinson was progressing.

### 2.2.6 NPSA/2010/RRR011 - Checking Pregnancy before surgery
Being progressed.

### 2.2.7 NPSA/Patient safety Alert - WHO Surgical Safety Checklist
Tony Turley reported variable % compliance. Jyothi Srinivas cited an instance of laterality error, with Cathie Steele providing a further example. It was confirmed that Neurosurgeons do not mark. Nicola Ryley noted that Sarah Plummer was pursuing this with Neurosurgery.

### 2.2.8 MDA (2010) 040 - All chest drains when used with high-flow, low-vacuum suction systems (wall mounted)
Tony Turley provided clarification on areas where this was a problem. Cathie Steele confirmed
that the MDA had been sent to Directorates who should respond to the Health and Safety Committee confirming that this has been actioned. Tony Turley advised that Directorates should be asked if they are confident that patients with chest drains can be managed and what their back up plan was, or to refer to an expert. Each Directorate to provide a position statement to Paul Clyburn (via Edwina Shackell confirming compliance with the MDA.

PART 3: STRATEGIC DIRECTION AND SERVICE DEVELOPMENT

3.1 Key Messages from Board/ Committees/ Groups

3.1.1 UHB Quality and Safety Committee 17 August 2010. Cathie Steele informed colleagues of the key message around NPSA and Alerts. A Chairman’s Report from this meeting will be required within the next 2 weeks.

3.1.2 Decontamination Group 28 June 2010 Cathie Steele summarised the key issues. Nicola Ryley updated colleagues on the Theatre Tray position. Porton Down, WHE and Public Health had been consulted and the risk was defined as Low. Detailed notes are available and would be circulated. Nicola Ryley and David Scott-Coombes had met with Cardiac Surgeons the previous week. The Main Theatres teams and Sterile Services were to be commended.

3.1.3 C. difficile Task and Finish Group – Directorate Improvement Plans. Nicola Ryley reinforced full team Directorate engagement with momentum being maintained. Particular reference was made to the disappointing commode audit.
Yvonne Hyde informed colleagues that each case of *C. difficile* was highlighted to the surgeon in order that lessons were learnt.

### 3.1.4 Infection Control Group 05 August 2010

The Group was advised that Ian Morris will be the Surgery Division representative. Minutes would be shared with the Surgery Q&S Group.
3.2 Evidence Based Practice – NSF/NICE/NCEPOD/National Reports etc

3.2.1 NICE CG92 – UHB Implementation

Dr Rachel Rayment presented an overview of the NICE Guidance, which relates to Venous Thromboembolism (VTE), and highlighted the significant mortality rate associated with this condition. Administration of appropriate thromboprophylaxis reduces mortality by 60%. The Chief Medical Officer in 2005 had directed that all patients be assessed for risk of VTE. 2008 NICE Guidance, updated in 2010, encompasses all hospital patients. The CMO directed that a Theatre Group Committee be set up in each organisation. The Cardiff and Vale Committee had been in place for 4-5 years but with limited progress.

In 2009/2010, compliance guidance was revised and relaunched by the Theatre Group Committee. It was noted that in England, compliance is tariff linked, requiring evidence that all patients are risk assessed, whereas in Wales, there is a commitment to achieve 95% assessment compliance by April 2011, but no punitive measures yet applied. Particular clinical areas, therefore, do not take ownership of the target, (eg T&O where compliance is 50%). There were 2 components to consider:

1. straightforward assessment of patient for risk of thrombosis
2. ensuring that the risk of giving thromboprophylaxis will not cause harm, ie even if low molecular heparin is administered according to patient weight and renal function (linked also to age).

Dr Rayment reported that feedback from clinicians had been received stating that completion of the form was time consuming. It was acknowledged that the document was
Appendix 2

detailed, but the tick box style facilitated quick completion. The form also enabled an audit of practice within the organisation, and was embedded in the surgical admission pathways.

Audit was currently being undertaken single handedly. Following organisational restructuring, there was no co-ordinator for the organisation; Divisions were therefore responsible for auditing compliance. One day in October 2010 would be identified when the process would be initiated, with all wards on all sites audited by an FP1 or FP2 on each ward.

Within Surgery, elective hip and knee patients, amongst others, should be assessed going home on Low Molecular Heparin, or appropriate anticoagulant as prescribed in Orthopaedics. Dr Rayment strongly emphasised that engagement of Consultants and Senior Nurses was crucial in raising awareness of the assessment requirement.

Lisa Franklin referred to her own and Helen Luton's work. They had found no consultant ownership of assessment forms; moreover, had met with animosity and resistance. Consultants were checking that TEDS were provided, but were not completing the VTE assessment. Compliance was extremely poor. Cathie Steele cited a recent incident which, a few months hence, would have been dealt with under Coroner’s Rule 43.

Lisa Franklin reported that nursing staff were placed in a vulnerable position. Clarification was necessary on nurses’ position regarding Clexane administration in a situation where TEDS had been supplied to an existing patient who had not been risk assessed. The advice received was that the nurse has to feel confident that the patient does not have a contraindication to TEDS and Clexane. How should nurses be advised? Nicola Ryley asked
this to be escalated to David Scott-Coombes, Divisional Director. Gillian Edwards confirmed that VTE assessment had been discussed in T&O. Lisa Franklin however noted that because this issue is being raised by nursing staff, it was not being taken seriously. Paul Clyburn perceived the solution as one of authority and leadership of consultants. Tony Turley confirmed that this was part of the performance dashboard and reiterated that the worst performing directorates must reach 95% compliance. Rachel Rayment highlighted that there a lack of infrastructure, due to organisational financial constraints, for auditing the outcome, and currently no data to populate the dashboard. It was acknowledged that discussions had taken place, but this had not been translated into action. It was not expected that consultant compliance would improve in the absence of audit. Cathie Steele requested that each Directorate provide her with a named F1 or F2 to pilot the audit tool. It was then the Division and Directorates' responsibility to name one person on the day in October to complete the audit. Paul Clyburn noted that the lack of medical involvement in some areas needed to be addressed. He will discuss the way forward with David Scott-Coombes. It was confirmed that Thromboprophylaxis was included on the WHO Checklist as a single component. Tony Turley proposed adding a new box in Theatreman for thrombosis assessment. Cathie Steele asked that Trauma and General Surgery provide a named F1 or F2 for the audit tool to trial the tool. Cathie Steele noted that Alun John and Simon White are responsible for thromboprophylaxis. Paul Clyburn will speak to Sandeep Hemmadi regarding T&O. Cathie Steele queried whether compliance with the dashboard was a matter for the CD to monitor performance.
A discussion following regarding administration of Clexane, summarised as follows:

- A Pilot in abdo/pelvic cancers and urology had moved to gynaecology
- T&O patients were sent home on Clexane, but nurses had not been taught how to train patients to self administer.
- Patients need blood HIP test after 7-10 days.
- Inconsistent administration of Clexane in Trauma.
- Of 100 patients discharged on Clexane, 1/3 were hip fracture which was acceptable. 2/3 were lower leg casts, spending 5-6 weeks on Clexane.
- Home visits to administer Clexane constituted a significant workload for District Nurses.
- Data from elsewhere suggests 80-85% of patients should be able to self administer.
- A need for clarity on who should receive extended prophylaxis
- Guidelines required now in Trauma on which patients will require extended prophylaxis so that nurses can teach patients.
- A paper had been prepared for Divisional Nurses and the Nurse Director on the education of nurses on how to train patients to self administer; the pathway, when agreed, would be piloted in T&O.
- Lack of engagement with medical staff
- Rachel Rayment confirmed that her team were participating in the F1 and F2 core training programme.
- The Medical Director, (Chair of the Thromboprophylaxis Committee) had cascaded the information but there remained a lack of engagement.

- Rachel Rayment confirmed that extended prophylaxis was not at present on the assessment form.

PC/TT
It was reiterated that project management had been removed; there was a lack of corporate “sign up” due to financial constraints.

It had not been possible to engage with the Medical Director. Paul Clyburn and Tony Turley (in his AMD role) would discuss with the Medical Director.

3.3 Statutory Compliance e.g. Licences
Colleagues should make Cathie Steele/Paul Clyburn aware of any of the above in their area.

PART 4: ORGANISATIONAL PERFORMANCE AND EFFECTIVENESS

4.1 Clinical Incidents, Complaints, and Claims update

4.1.1 Clinical Incident Report
Cathie Steele reviewed the Quarter 1 Report, including incidents reported to Regional Office or under investigation. A brief resumé of reported incidents was given:
Ref: 10092217 – retained swab. Key message: if any member of theatre team has concerns, these must be vocalised.
Ref: 10099124 – retained needle in spine. A report will be brought to the next meeting.
Ref: 10099123 and 10091410 – patient confidentiality.

Cathie Steele advised colleagues of the new WAG guidance regarding categories of incident:
- ‘Serious Incident’
- ‘No Surprises Incident’.
It was expected that Serious Incidents be investigated and reported on within two months.

Coroner’s Rule 43: Paul Clyburn clarified that the Coroner can write to any public organisation and make recommendations, copied to the Lord Chancellor, and available publicly. Responses are required within 56 days.
| 4.1.2 **Internal Safety Notice – Prevention of retained swabs, needles, and instruments**  
To be emailed out today |
| 4.1.3 **Ensuring confidentiality of data.** Patient data continued to be lost, particularly handover sheets. |
| 4.1.4 **Complaints Report**  
4.1.5 **Claims Update**  
Cathie Steele advised that the Complaints Report and Claims Update would in future be included with the Incident Report. |
| 4.1.6 **Pressure Ulcer Prevention**  
*Claim Ref CN/UHW/711 and Claim Ref CN/UHW/961* – deferred in the absence of Rhiannon Joseph. |
| **4.2** **Exception reports from Directorates/Working Groups**  
4.2.1 General Surgery, Urology and Vascular |
| 4.2.2 Head & Neck, Maxillo Facial and Ophthalmology |
| 4.2.3 Theatres & Anaesthetics, SSU, Day Surgery & Endoscopy and Sterilisation Services |
| 4.2.4 Trauma and Orthopaedics  
Each Directorate confirmed that there was nil to report. Paul Clyburn will arrange to meet with Directorate teams in the next few weeks regarding governance. |
| **4.3** **Project Initiation Document (PID)**  
Cathie Steele noted that the dashboard was in the early stages of development, with the objective of preventing multiple requests for the same data. |
| **4.4** **1,000 lives**  
4.4.1 **Directorate Updates**  
Gillian Edwards, Trauma & Orthopaedics, confirmed that 3 out of 6 areas had moved forward with Transforming Care, with information regularly displayed in |
patient/staff/visitor areas. A4 was participating in the Skin Bundle with B2; Urology would be next. Jyothi Srinivas highlighted that the Sepsis Care Bundle was not being adhered to across the organisation.

<table>
<thead>
<tr>
<th>4.5</th>
<th>Policies and Procedures</th>
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<tbody>
<tr>
<td>Cathie Steele advised that these could be brought to the Group, e.g. Sedation Policy was being taken to the next UHB Quality &amp; Safety Group.</td>
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### PART 5: GOVERNANCE

<table>
<thead>
<tr>
<th>5.1</th>
<th>Divisional and Directorate Risk Registers</th>
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<tr>
<td>Melanie Westlake had been invited to the Surgery Divisional Management Team meeting, which was currently being rearranged.</td>
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<thead>
<tr>
<th>5.2</th>
<th>Safeguarding</th>
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<tr>
<td>Nil to report</td>
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<tr>
<th>5.3</th>
<th>Audit</th>
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<tr>
<td>5.3.1 Laterality Audit – presentation of findings – deferred in the absence of Alena Ball.</td>
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<tr>
<th>5.4</th>
<th>Rule 43s and Inquests</th>
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<tr>
<td>5.4.1 Rule 43 Summary Report – to be brought to the next meeting</td>
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<tr>
<th>5.4.2 Forthcoming Inquests</th>
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<tr>
<td>It was noted that the Coroner was increasingly calling junior staff, F1s and F2s and that there was a need to ensure that full information is available in advance and that staff are appropriately supported prior to attending Inquest. Cathie Steele advised that in light of this, case managers were now appointed for each case. Welsh Health Legal Services are available to meet with staff pre-inquest. Colleagues were asked to contact Cathie Steele if they became aware of any staff called to Inquest. There followed a brief discussion around the shortcomings in documentation by junior medical staff. In response to a question from Jyothi Srinivas, Cathie Steele confirmed that junior staff undertook training in</td>
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Appendix 2

documentation as part of their induction.

5.5 **Research & Development**
Confirmation is to be obtained that Wyn Lewis is the Divisional Representative.

ES

**PART 6: DATES OF NEXT MEETING**
Friday 05 November 2010, 8-10 am in the Council Room, UHW

**PART 7: URGENT BUSINESS**

7.1 **To consider any urgent issues**
None reported

**PART 8: AGREED MESSAGES FROM THE DIVISIONAL QUALITY AND SAFETY GROUP**

8.1 **To agree messages to be issued and actions to be progressed**

1. Glaucoma
2. Thromboprophylaxis
3. White residue – theatre trays
4. Laterality – neuro marking

Paul Clyburn asked colleagues to consider how to move forward to improve quality and safety, and for Directorates to feed into this in a meaningful way. Cathie Steele proposed including feedback from Patient Safety Friday visits – it was agreed that this would be positive if issues could then be resolved on the front line.
AGENDA ITEM 8.7

<table>
<thead>
<tr>
<th>REPORTING COMMITTEE/GROUP</th>
<th>Safeguarding Children Steering Group (SCSG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHAIREDBY</td>
<td>Mandy Rayani</td>
</tr>
<tr>
<td>DATE OF LAST MEETING</td>
<td>23rd September 2010</td>
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### KEY AGENDA ITEMS / RISKS TO NOTE

#### Information Sharing
Lack of secure email between partnership agencies: unable to share critical information electronically which impacts on issues relating to domestic abuse, safeguarding children and looked after children. Delay in receiving information puts both child and professionals at risk.

#### Training
Safeguarding children training for independent contractors: awaiting Review of safeguarding children arrangements within health by Professor Mansel Aylward.

#### Vetting and Barring
Members of Safeguarding Children Steering Group (SCSG) being Criminal Records Bureau checked. All Wales group to review consistency of practice in relation to Vetting and Barring; to feedback to next meeting.

#### Sexual Assault Referral Centre
Service provided for children and young people in Cardiff and Vale of Glamorgan. High number of referrals in July/August, 90 in total, with 45% < 18 years old. Need identified to develop managed clinical network to include Aneurin Bevan and Cwm Taf: meeting arranged 1.10.10 to discuss. Public Health Wales(PHW) Specification for medical assessment of child sexual abuse to be considered by Children and Women Division.

#### Standards for Healthcare in Wales 17/11
Awaiting response to submission for Healthcare Standard(HCS)17. Away day to develop model for safeguarding children and vulnerable adults within UHB organisation, and response to HCS 11 for next year.
Response to Healthcare Inspectorate Wales (HIW) report October 2009: Safeguarding and protecting children in Wales updated and to be sent to HIW.

Serious Case Review (SCR) presentation given by Named Nurse Safeguarding Children
- Cardiff Local Safeguarding Children Board (LSCB): 2 Serious case reviews representing 3 families concluding: to be presented at next meeting. 1 SCR ongoing, 1 new SCR agreed and 1 being considered
- Vale LSCB: 1 SCR ongoing, 1 new SCR agreed and 1 being considered
- 2 out of county SCRs being conducted where children were treated within the UHB.
- Themes identified include Sudden Infant Death Syndrome and co-sleeping, (child death review panel draft recommendations to be discussed with Welsh Assembly Government), neglect, maternal mental health, and communication between hospital based and community based teams when child is an inpatient.

Safeguarding children training
- Terms of reference for Training subgroup ratified with minor changes, with clarification of representatives from the Divisions.
- Training needs analysis: beginning to receive data on training figures of UHB staff collated on Electronic Staff Record. This can be linked to identify training needs within Divisions and professional groups.
- Face to face Level 2 training to be updated. E learning programme (level 2) for health professionals developed by Postgraduate Deanery and UHB to be launched soon.

Monitoring and Review (M&R)
- Terms of reference for M&R subgroup ratified with minor changes, with clarification of representatives from the Divisions.
- Future audits identified for workplan.
- Young person escalation policy identified through clinical incident to be reviewed by child health.
- Dashboard being developed to include clinical incidents, and complaints: discussion around appropriate data collection.
- Response to children presenting with child protection concerns in injured children to Emergency Unit: pathway developed by child health and unscheduled care agreed at meeting, to be implemented.
Local Safeguarding Children Boards (LSCB)
- Section 28 audit for Cardiff LSCB being completed.
- Consideration of merger between Cardiff and Vale LSCBs.
- LSCB audit subgroup chaired by Named Nurse Safeguarding Children identified the need for improved core group working, recommending specific multiagency training involving health professionals.
- LSCB protocols and guidance agreed at SCSG, which need to be implemented in UHB:
  - Discharge of vulnerable children from hospital
  - Multiagency protocol on children who go missing.

ONGOING WORK / ACTIONS
Lack of secure email between partnership agencies.
Need identified to develop managed clinical network to include Aneurin Bevan and Cwm Taf: meeting arranged 1.10.10 to discuss.
Away day to develop model for safeguarding children and vulnerable adults within UHB organisation planned for 19/10/10.
Children’s Right’s day November 17th within UHB. Children’s Commissioner will be in attendance to raise awareness.
Serious case review work plan.
Training work plan being developed to include training needs analysis.
Future audits identified for inclusion in this work plan.

ITEMS TO RECEIVE OR FOR APPROVAL (Where required)

| MINUTES SUBMITTED TO QUALITY & SAFETY COMMITTEE | Yes [ ] No [ X ] |
| DATE OF NEXT MEETING | To be confirmed |
**AGENDA ITEM 8.8**

<table>
<thead>
<tr>
<th>REPORTING COMMITTEE/GROUP</th>
<th>Specialist Services Division Quality and Safety Group Report</th>
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<tbody>
<tr>
<td>CHAIRCED BY</td>
<td>Carys Fox, Divisional Nurse</td>
</tr>
<tr>
<td>DATE OF LAST MEETING</td>
<td>8th September 2010</td>
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### KEY AGENDA ITEMS / RISKS TO NOTE

**Patient Story**
Carys Fox read an anonymised letter of complaint from a patient’s wife describing the poor nursing care provided to her husband and inadequate adherence to infection control procedures, amongst other issues. The letter was complimentary towards medical staff. The complaint is under investigation but there are clear and immediate issues to address.

**Terms of Reference**
It was acknowledged that the Divisional Terms of Reference for the Quality and Safety Groups have been agreed at Committee level and will be adopted by the Division at the next meeting.

**Latest NPSA RRRs, NICE guidance and MDAs**
The latest alerts from the NPSA, NICE and MHRA were raised. NICE guidance on chronic heart failure and transient loss of consciousness are being reviewed by the Cardiothoracic Directorate. An MDA on neurosurgical sponges will be addressed by Neurosciences.

**Clostridium difficile and antibiotic stewardship**
There was significant discussion about these issues and Dr Robin Howe led the debate as to improving compliance with antibiotic prescribing as one mechanism to improve the C diff situation. It was noted that the Medical Director has written to directorates requiring that they focus attention on C diff issues at the September 2010 directorate Quality and Safety meetings. The importance of robust housekeeping is significantly reinforced by the Division as being fundamental in the control of infection.

**Thromboprophylaxis**
Dr Gareth Scholey discussed his role as Divisional representative on the Thromboprophylaxis and Anticoagulation Group which is driving forwards...
improvements with thromboprophylaxis. A UHB document to promote thromboprophylaxis management has been devised but it is acknowledged that some directorates may have specific needs to incorporate. Directorates are requested to submit local documents for consideration by the UHB group.

**Clinical Incident Investigations**

A number of incidents that are under investigation in the Division were discussed in order to determine progress with the investigations. The lessons learnt from a number of other incidents were raised including safe administration of amiodarone; improved prescribing of aspirin and clopidogrel; appropriate storage of patient identifiable information.

**Safe Sedation Policy**

It was noted that some directorates need to discuss compliance with this policy with the policy author, namely Cardiothoracic and Nephrology & Transplant.

**ONGOING WORK / ACTIONS**

**Data security**

Directorates are requested to re-review their processes for security of patient identifiable information in view of recent breeches.

**ITEMS TO RECEIVE OR FOR APPROVAL (Where required)**

'Draft' Minutes of the Group Meeting held on 8th September 2010.

| MINUTES SUBMITTED TO QUALITY & SAFETY COMMITTEE | Yes [✓] | No [ ] |
| DATE OF NEXT MEETING | 28th October 2010 |
SPECIALIST SERVICES DIVISION
QUALITY AND SAFETY GROUP
MINUTES
8th September 2010  08-10:00 hrs
Venue: Council Room, UGF/A Block, UHW

In Attendance:

Carys Fox, Divisional Nurse, Specialist Services Division (Chair)
Maria Roberts, Clinical Governance Facilitator
Gina Gwynne, Directorate Manager, Haematology, Clinical Immunology & Genetics
Noreen Lewis, Senior Nurse, Haematology
Vincent Cain, Unison
Orla Morgan, Acting Senior Nurse, Critical Care
Gemma Ellis, Consultant Nurse, Adult Critical Care
Sanjoy Shah, Locum Consultant Intensive Care
Richard Anderson, Consultant Cardiologist
Karen Jones, Associate CNS, Infection, Prevention Control
Jenny Thomas, Clinical Director, Neurosciences
Catherine Wood, Directorate Manager, Neurosciences
Helen Hortop, Directorate Manager, ALAS
Lynda Jenkins, Senior Nurse, Cardiothoracic
Gareth Scholey, Consultant, Critical Care
Jessica Castle, Directorate Manager, Cardiac and Critical Care
Darrell Baker, Pharmacist
Sarah Matthews, Senior Nurse, Nephrology & Transplant
Sian Griffin, Consultant Nephrologist
Robin Howe, Microbiologist

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<tr>
<th>PART 1: PRELIMINARIES (Chair)</th>
<th>ACTION</th>
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<tr>
<td>Patient Story</td>
<td>CF informed the group that this meeting and future meetings will</td>
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commence with a patient story, where lessons can be learnt and awareness raised.

CF read out an anonymised letter from a patient’s wife detailing her husband’s stay 9 week stay in hospital. The letter had been read out at Nursing and Midwifery Board also but it transpired that the complaint related to this Division. The letter raised concern with the fact that her husband had been left in the same clothes he was admitted in for up to 30 hours without any nurses offering or attempting to change his clothes. The family had to ask for his feet to be looked at and for him to be given pyjama bottoms to wear. When asked, the nurses did help, but the question was raised as to why did she need to ask for help? The letter went on to say that the patient’s wife found the nursing care of her husband to be generally poor, with a fellow patient having to give water to her husband as the nurses had failed to do so. They found barrier nursing to be inconsistent. There was also an issue raised of the nursing station, where the nurses were reported as standing around chatting in groups of 4/5. The letter proposed that the nursing station should be abolished, so that the nurses spend more time on the ward caring for the patients. It was suggested that there was a lack of leadership, supervision and compassion. Care from medical staff was praised.

CF noted that this case was still being investigated and that she will feedback at the next meeting. She asked that directorates consider the issues from this complaint as it is acknowledged that other areas and Divisions have received similar complaints.

1.1 Welcome and Introductions
The group introduced themselves in light of the new posts which commenced on the 1st September 2010.

1.2 Apologies for Absence
Apologies were received from Zaheer Yousef, Robert Williams, Sacha Coodye, Rafael Chavez, Andrea Richards, Stephen King, Annie Procter, Rachel Barry, Chris Fegan and Andrea Edwards.

1.3 Minutes of the previous meeting to agree and matters arising
The minutes were agreed as an accurate record, subject to one amendment on the attendance list.

Matters Arising:
- Item 2.1 - MR confirmed that Catherine Wood is happy to be the Divisional representative for the Health Care Standards Planning Group.
- Item 2.3 - Darrell Baker confirmed that all NPSA RRRs are considered by the Safer Medicines Practice Group. Corporate work to address compliance is underway, much of which comes under the auspices of 1000 Lives also. There is a related RRR on high risk injectable medicines but stability of the medicines is an issue that requires further consideration. CF confirmed that she had spoken to the relevant department and that the RRR on safer administration of insulin was included on junior doctor training. It was further noted that Claire Gill is the Divisional representative on the Safer Medicines Practice Group.
- Item 3.3.1 - LJ confirmed that the skin bundle implementation on C5 had been very successful and was now ready to be rolled out in other areas across the directorate.

**PART 2: SAFETY AND QUALITY**

<table>
<thead>
<tr>
<th>2.1</th>
<th>Feedback from Quality and Safety Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR noted that the minutes are not yet available on the intranet/internet and that this is not a meeting she would normally attend but she is aware that the Divisional Terms of Reference have been agreed. CF will send out the TOR and they will be signed off at the next meeting. It has also been agreed that the Divisions will submit a Chair’s report to the Quality and Safety Committee as part of assurance mechanisms.</td>
<td>CF</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>2.2</th>
<th>NPSA Rapid Response Report issued 26.08.2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of over infusion of intravenous fluid* and medicines in neonates</td>
<td></td>
</tr>
<tr>
<td><a href="http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=75519">http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=75519</a></td>
<td></td>
</tr>
<tr>
<td>CF informed the group that this is for information only since it relates to neonates.</td>
<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>2.3</th>
<th>NICE guidance issued August 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://guidance.nice.org.uk/Date/2010/August">http://guidance.nice.org.uk/Date/2010/August</a></td>
<td></td>
</tr>
<tr>
<td>CF noted that Attachment 2 described the NICE guidance issued in August 2010. Two relevant issues to the Division this month are Chronic heart failure and Transient loss of consciousness.</td>
<td></td>
</tr>
</tbody>
</table>
RA informed the group that Zaheer Yousef is working on the Chronic Heart Failure guidance and compliance is largely in place.

RA noted that Peter O'Keefe is working on the transient loss of consciousness guidance.

2.4 **Medical Device Alerts issued August 2010**

[http://www.mhra.gov.uk/Publications/safetywarnings/MedicalDeviceAlerts/CON070967](http://www.mhra.gov.uk/Publications/safetywarnings/MedicalDeviceAlerts/CON070967)

CF noted that a neurosurgical sponges alert in theatres (sponges manufactured by Codman) had been issued on the 19th August. JT will look at this from the directorate’s perspective.

PART 3: STRATEGIC DIRECTION AND SERVICE DEVELOPMENT

3.1 **Clostridium difficile / Antibiotic Stewardship**

Dr Robin Howe updated the group.

RH noted that the Health Board has not performed well over the last few years in relation to the AOF targets and C difficile. The Health Board still has one of the highest C difficile rates in Wales in 2009 and the rates are still increasing, therefore the Health Board has requested a C difficile action plan, of which one element is Antibiotic Stewardship. RH confirmed that studies have shown that 1/3 of antibiotic use is inappropriate in the acute setting and therefore if antibiotic use is improved then C difficile rates should improve. It has been agreed that the antibiotics that have a higher risk of causing C difficile will no longer used. An antibiotic policy has been produced that will avoid these agents. The key issues are controlling when people start on antibiotics and how long they are prescribed for. RH noted that as there are often no diagnostic specimens taken, there is no supporting information which means that decisions can not be made as to whether to stop using antibiotics or to carry on. RH also noted the role of junior medical staff and antibiotic prescribing unsupervised during on call periods. RH confirmed that the Divisional responses to the action plan did not include anything on antimicrobial use. Sticky labels have also been produced for prescribing antimicrobials in order to promote more focussed thought on what is being prescribed and why. RH commented however that there has been patchy uptake of the stickers so far. DB noted that in the last meeting the availability of stickers was raised as an issue, however 5,000 have been printed...
and they can be ordered through Oracle now. DB further advised that the ultimate aim was to incorporate antimicrobial use onto a revised All Wales drug chart.

GE commented that the stickers are a good idea, but that there was a lack of clarity when they were introduced, as there was no education or training. RH commented that he thought that the cascading of this information would come through the Divisional structure. GE noted that they do have a plan and structures in place but that it will take time to embed new practice and culture with which SS concurred. It was suggested that education and audit would help.

JT commented that pharmacist stewardship is key but it is acknowledged that this impacts on staff resource available. RA commented that another factor that should be taken into account is that the guidance came out in July when a lot of people are on annual leave but DB was of the view that it is now September and implementation remains below expectation.

RA raised that robust communication is key. MR noted that the C difficile Task and Finish group were looking at a communication strategy and that it needs to be fed back where communication has not been robust. RH identified that it was hoped that the consultant body could ‘police’ this. CF sought assurance that each directorate is discussing this locally in detail. Cardiothoracic and Nephrology & Transplant directorates need to submit local plans. MR noted that a letter has gone out from the Medical Director requesting that this issue is discussed at the September 2010 clinical governance rolling session.

JT advised that she is still not receiving data from Dylan Hill and CF will discuss this again with him. RH raised a study which took place last year with input from Clinical Governance staff which identified that problems for patients often arise when their antibiotic use is chaotic such as on 4 or more antimicrobials and on multiple courses. RH suggested that looking at use of PPIs would also be useful as this is an issue coming to the fore but it is noted that the majority of patients are commenced on this in Primary Care settings.

DB referred to a flowchart that is available to assist with antibiotic management in C difficile but it was determined that this needed to
be recirculated as the group were not familiar with it.

CF asked the group if the hand hygiene audit results were being displayed as agreed at the last meeting. Not all areas are auditing and displaying results and LJ confirmed that Cardiothoracics will look at this today.

KJ informed the group that an additional red sticker is also available to prompt doctors to identify the severity of C difficile infection. There was some discussion about the implementation of another sticker but RH confirmed that severity scoring the infection is an important part of prescribing appropriate treatment. CF requested that Directorates add this to the agenda at local control meetings also.

CF raised the issue of bed cleaning that was discussed at the last meeting and noted that Rachel Barry had arranged a training session on B4N which Cardiothoracics attended. CF informed the group that the Hill-Rom Nurse Advisor will come and speak to Directorates about their bed cleaning if required.

3.2 Thromboprophylaxis in the Division

CF noted that Dr Gareth Scholey is the Thromboprophylaxis Divisional representative. GS informed the group that the UHB has signed up to Thromboprophylaxis as a non-negotiable quality standard following publication of the relevant NICE guidance.

GS advised that the UHB-wide Thromboprophylaxis and Anticoagulation Group has devised clinical risk-assessment tools that must be implemented. This Division is problematic as some of the specialty areas will have specific needs meaning the generic tools need further work. He reported that he re-designed the tool for use in Critical Care which was accepted by TAG. Therefore, it is highlighted that each specialty will need to consider their own practices and applicability of the generic tool. An audit will be undertaken by TAG to assess the baseline of practice. Patient information leaflets regarding this subject matter are available. It is advised that directorates identify a lead to take this forwards locally.

PART 4: ORGANISATIONAL PERFORMANCE AND EFFECTIVENESS

4.1 Clinical incidents under investigation - update

MR referred to attachment 4 and summarised the 6 serious
incidents that occurred within the Specialist Services Division March – August 2010.

Reference 10093702 refers to a patient who collapsed post pancreas transplant. George Findlay asked Paul Clyburn to carry out a separate review to ensure the systems in Nephrology & Transplant robustly examined the case. MR has been in discussion with Dr Clyburn recently to bring this case to a close. SG noted that there were concerns about delays in getting blood from Blood Bank. Initial investigation identified that access to blood in an emergency had not been included in the porter training. This issue is fairly regularly raised and Blood Bank have had telephone recording equipment installed so that there is an audit trail of what was requested and when.

Reference 10093409 – this incident occurred in 2002, whereby a patient had a pacemaker inserted but a swab was retained. The investigation by Linda Walker was completed some time ago but an incident review meeting to address arising issues is needed. The directorate should be in a position to feedback at the next meeting.

Reference 10098245 – This incident is being managed by Surgery Services Division but is raised now as it relates to Neurosciences. The patient was booked for a left sided craniotomy however the surgeon started surgery on the right side. The investigation is progressing well. It has been identified that there is reluctance on occasion to use the surgical safety checklist in some areas.

Reference 10098610 – this refers to a case of Legionella on B4. This incident was reported to WAG and the media. Reports coordinated by Dr Eleri Davies have gone to WAG and the Health & Safety Executive.

Reference 10099127 – A patient in cardiac theatres was having coronary artery bypass grafts but an error occurred during the operation when the aortic clamp remained in situ. The patient was without adequate circulation for some time and died in Critical Care several weeks after the incident. The patient’s death has been reported to the Coroner and the inquest will be challenging for those involved. Ian Lane is the Investigating Officer and the investigation is progressing well.

Reference 10102298 – this refers to a data protection issue in
Critical Care. GE advised that Nick Stallard is the investigating officer who will feedback in due course.

4.2 **Amiodarone incident / Cardiothoracics (Incident ref 10098253)**

RA informed the group of an incident where Amiodarone bolus was given in an inappropriate manner. RA noted that the administration of Amiodarone as a bolus has been more common place than it should be. RA commented that this incident has given an opportunity to highlight how it should be given and referred to Attachment 5. RA stated that outside of cardiac arrest, Amiodrone should never be given as a bolus. Attachment 5 states that it should be given in an appropriate manner and that it must be given by a central line which has been formulated into a guidance document by Peter O’Callaghan. This guidance will be cascaded through the Medicines Management Group. DB noted that the Medicine Division has discussed this in their Divisional meeting and that it had been disseminated through a newsletter into ward areas. It is also available on the intranet. MR suggested that the guidance is put into the UHB format and uploaded to the relevant intranet page, however DB declined this saying that the document would become too cumbersome. Electronic links to the document would be available via existing pharmacy routes.

4.3 **Aspirin and clopidogrel issues / Cardiothoracics**

RA informed the meeting of an incident where a coronary angioplasty took place on a patient where a particular type of stent was required. Stents are used for various timeframes and so the anticoagulation issues differ. In this case, the patient was given only one month prescription instead of one year. The patient had another heart attack when the stent blocked off and died after numerous medical interventions. The patient had a particularly complex history. This has been investigated thoroughly. The investigation identified issues such a legibility of prescription, communication mechanisms with the GP and quality of patient carried POMs/green cards. DB confirmed that the TTH is now written in full i.e. 1 month instead of 1/12.

DB further highlighted that work is underway with IHC regarding electronic discharge. Over the next 6 months the electronic discharge communication system should be implemented. It was noted that this incident led to a review of the POMs green cards which has been agreed by NMB.
4.4 **Losses of patient identifiable data**
CF noted that this was discussed in length at the last meeting. It was agreed that the Divisional Manager would support staff that require Wales.nhs.uk email addresses.

CF informed the group of an incident shortly after the last meeting where patient identifiable information was found in some toilets on UHB premises. Luckily the mislaid papers were found by member of staff. NL reported that the issue has been dealt with and handover sheets are no longer printed for use. CF requested that Directorates raise awareness that patient identifiable information is not to be taken off the premises, must be kept in a secure place with adequate access to confidential / shredding facilities.

### PART 5: GOVERNANCE

#### 5.1 Safeguarding
CF noted that there were 3 POVA cases reported at the last meeting;
- one has been closed – no case to answer;
- one will legally close soon after case the conference;
- one is still ongoing.

#### 5.2 Safe Sedation Policy
CF noted that this Policy was written by Dr Sara Rees, Consultant Anaesthetist. The policy states that Non Anaesthetists should only perform conscious sedation and any deeper levels of sedation require the presence of an anaesthetist who has the skills and training.

It is believed that this policy is still out for consultation and has not yet been formally ratified. JC noted that the policy has been circulated within the Cardiology department mainly and there is an impact on the directorate as sedation to the point of no eyelash response is undertaken. It was agreed that Peter O’Callaghan needs to discuss this with Dr Sara Rees as soon as possible as patients shouldn’t be anaesthetised to such a low level without an Anaesthetist present.

NL reported that following discussion with Jonathan Kell, the use of midazolam in bone marrow aspirate is possible but seldom used.

In Nephrology and Transplant, Rob Bradley has reviewed the document and will link with SG and Dr Rees.
5.3 **Single Sex Hospital Accommodation**

CF noted that this was a significant issue for every clinical area within the Health Board following revised guidance from WAG. Anne Smith is leading on this in the UHB. There has been concern about the level of non-compliance. This issue needs to be resolved by March 2011 and includes day units and Critical Care areas. NL raised concern that the refurbishment plans show a reduction in cubicles. CF confirmed that the second plan option had actually increased the number of cubicles and bathrooms, which should help.

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**PART 6: DATES OF FUTURE MEETINGS**

6.1

<table>
<thead>
<tr>
<th>DATE</th>
<th>TIME</th>
<th>VENUE</th>
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<tbody>
<tr>
<td>Thursday 28&lt;sup&gt;th&lt;/sup&gt; October 2010</td>
<td>8-10am</td>
<td>Library Seminar Room, A2, UHW</td>
</tr>
<tr>
<td>Thursday 16&lt;sup&gt;th&lt;/sup&gt; December 2010</td>
<td>8-10am</td>
<td>Council Room, UHW</td>
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<tr>
<td>Thursday 27&lt;sup&gt;th&lt;/sup&gt; January 2011</td>
<td>8-10am</td>
<td>Library Seminar Room, A2, UHW</td>
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**PART 7: URGENT BUSINESS**

7.1 **To consider any urgent issues/Directorate exceptions**

None to report.

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**PART 8: AGREED MESSAGES FROM THE DIVISIONAL QUALITY AND RISK GROUP**

8.1 **To agree messages to be issued and actions to be progressed**

- Directorates to discuss and consider in their Q&S meetings their C difficile plans and antibacterial stewardship. Feed back to the Divisional Q&S meeting is required.
- Divisions to submit their C difficile plans by close of play today if not already done so.
- Directorates to discuss Thromboprophylaxis Management – identify leads/champions and forward to Gemma Williams who will inform Gareth Scholey.
- Directorates to review processes for data security.
AGENDA ITEM 8.9

REPORTING COMMITTEE/GROUP | Infection Prevention and Control Group (IPC)
CHAIRED BY | Ruth Walker, Nurse Director
DATE OF LAST MEETING | 9th September 2010
KEY AGENDA ITEMS / RISKS TO NOTE

**Theatre Blues:**
The IPC Group supported the proposal that Theatre Blues should not be worn outside the Theatre suite and recommended that this should be taken forward in consultation with staff groups.

**Lead for CJD risk assessment:**
A Lead for CJD risk Assessment has been agreed.

**Terms of Reference for IPCG:**
Revisions were suggested in relation to the community elements of Healthcare Associated Infections.

**Legionella Incident Report:**
A report on the Legionella Incident on Haematology was considered. The report details all actions taken. No further clinical cases of legionella related to the water outlets in the UHW have been detected. Revisions to water sampling and monitoring arrangements have been made and a water outlet flushing regimen has been established on high risk units which will be disseminated across the organisation. Monitoring of the actions will be taken forward by the Legionella group which reports to the IPCG.

**Clostridium difficile; AOF Target and Task group:**
The monthly report from the WHAIP team, Public Health Wales for August 2010 shows that Cardiff and Vale UHB remains red against the target of 20% reduction in C. difficile vs. baseline data from 2008 – 2009.
Divisional plans have been developed and will be monitored through the task group. A task group meeting on the 10th September was convened to discuss plans with Divisional Nurses. A revised reporting structure for the improvement plans was agreed.
The implementation of the new antimicrobial policy was discussed. It was
agreed that divisional implementation plans should be clear about the actions needed to fully implement the policy.

**Presentations received at the IPC Group Meeting:**
A presentation was received from the Neonatal Unit with regard to infection rates. Repeat audits of the unit had found that a cluttered environment may be a contributory factor. The de-cluttering programme / Patient Experience teams will be asked to review the situation on the unit.

A presentation was given on reducing Healthcare Associated Infections on the renal and critical care units. Both units have introduced improvements in bed and patient equipment cleaning, for example commodes and patient washbowls. Issues around sharing best practice were discussed.

**Local and National HCAI surveillance:**
As noted above, the Health Board is not meeting its targeted reduction in C. difficile rates. MRSA bacteraemia rates are currently lower than last year. Infection Rates for surgical site infections in both orthopaedics and obstetrics (C-section) are reducing as the compliance with the programmes increases. Further action will need to be taken to improve surveillance to the 95% compliance required in the AOF.

**ONGOING WORK / ACTIONS**
- Formally appoint CJD lead for risk assessment.
- Support the re-structuring of the C. difficile operational group and monitoring of divisional improvement plans.
- Agree Terms of Reference at next meeting.

**ITEMS TO RECEIVE OR FOR APPROVAL (Where required)**
It has been agreed that the ICG can ratify Infection Control related Procedures and Guidelines, with Policy and Strategy taken to the Quality and Safety Committee with a recommendation for approval.

<table>
<thead>
<tr>
<th>MINUTES SUBMITTED TO QUALITY &amp; SAFETY COMMITTEE</th>
<th>Yes [ ]  No [ x ]</th>
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<tbody>
<tr>
<td>DATE OF NEXT MEETING</td>
<td>4th November 2010</td>
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