University Hospitals Bristol NHS
NHS Foundation Trust

Annual Report

Paediatrics - PTC Core Measures

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Agreement and Approval

PTC Lead Clinician Stephen Lowis

Date 28/09/2012 Signature (agreed via email)

Head of Service for Chemotherapy for the PTC Oonagh McGrath

Date _____ Signature _____

Head of the Hospital Pharmacy Department Steve Brown

Date _____ Signature _____

Review Date

Next report due: July 2013

Versions

Version	Date	Reason	Sign Off
1.0	11/05/10	Draft revision for 2010 Peer Review	
2.0	01/07/11	Draft revision for 2011 Peer Review	
3.0	Aug 12	2012 report produced	28/09/2012

1 Measure Checklist

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11-7B-102	Policy for the place of outpatient chemotherapy delivery	p25		
11-7B-103	Availability of specified regimens/protocols/emergency equipment	p24-25		
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3 Introduction

This report relates to the operational period April 2011 – March 2012. This period has seen a number of issues, challenges and successes as outlined below.

3.1 Key Achievements

Achieved agreement to provide a fully qualified nursing workforce for the wards, improving patient care and administration of chemotherapy. Recruitment in progress to implement this.

Appointed CNS for solid tumour and neuro-oncology MDTs

Patient focus groups held on the role of the keyworker

Achieved JACIE reaccreditation

3.2 Key Challenges

Changes required to processes and protocols in response to amalgamation of units and building work

Bed capacity

Dietetics service

Electronic prescribing

Plan for post graduate specialist oncology nurse training

4 Facilities

4.1 Review of bed occupancy and nurse workload, 2010-2011

An assessment of the workload of ward 34 nurses was made in August 2011. Two assessments of the numbers of staff required for the safe management of the ward were made, using tools which have been developed independently. Data from both analyses is presented.

At the time of the analysis, the nursing establishment was recorded to be as follows:

Current funded nursing establishment for ward 34 is	20.15 wte.
Current actual establishment is	22
Maternity leave	4.69
Annual Leave	3.37
Acute sickness (low)	0.3
Long term sickness absence	nil
Actual establishment after maternity absence	**17.3 wte**

The first analysis of required numbers was made using the PANDA tool, and the second using the suggested formula given in the Improving Outcomes Guidance document.

4.1.1 PANDA dependency tool analysis

This tool identifies patient dependencies, defined as Normal, High dependency and Ward Intensive care. The tool was not created with Oncology patients in mind, but is intended as a generic assessment tool. The calculations below are based on a reduced gearing, derived from the AUKUH tool, and nursing numbers are therefore less than predicted than the original PANDA tool.

Ward 34, with 10 beds open, the following distribution of dependencies was identified:

Normal dependency	0.9%
High Dependency	13.2%
Ward Intensive care (WIC)	85.8%

With these dependencies, the PANDA tool predicts the following requirements for nursing establishment.

Number of beds	WIC	High	Normal	Total numbers
10	18.7	2.4	0.2	**21.3**
9	16.9	2.2	0.1	**19.2**
8	15.0	1.9	0.1	**17.1**
7	13.1	1.7	0.1	**14.9**

6	11.2	1.5	0.1	**12.8**
5	9.4	1.2	0.1	**10.7**

This does not allow for persistent absence or maternity leave. The nursing establishment for ward 34 at that time was therefore sufficient for 8 beds.

4.1.2 Improving Outcomes Guidance (IOG) analysis.

This document follows RCN recommendations, such that qualified registered nurses are required to staff oncology / haematology wards according to the following plan:

The first third of all beds are considered high dependency, requiring 1 nurse for each 2 beds

The remaining 2/3 of beds are to be staffed at 1 nurse for each 3 beds.

Hence, for a ward of between 5 and 10 beds, each shift requires:

Beds	Staff per shift
10	4
9	4
8	3
7	3
6	3
5	2

This calculation is based upon numbers of fully trained nurses, and no allowance is made for maternity or other absence. At least two staff members on each shift are required to be trained to administer chemotherapy.

Calculation of total establishment typically includes an allowance of 23% to allow for leave and sickness. Based on this formula, the following calculation can be made:

Beds	Staff per shift	Establishment
10	4	22
9	4	22
8	3	17
7	3	17
6	3	17
5	2	11

By these criteria, the nursing establishment in August 2011 was sufficient to open 8 beds

During a period of severe shortage of trained nurses in the early part of 2011, ward 34 was closed. When it reopened, beds were limited to 6, and subsequently 8. This was felt to be an appropriate level by most members of staff, although there were many occasions when fewer than three members of staff were on shift.

4.2 BRHC Bed occupancy (11-7B-113,115)

The total numbers of patients admitted under the oncology service has been reviewed for the 12 month period between August 2011 to July 2010. At this time, ward 34 was open to 8 beds (with rare exceptions). The expected allocation for oncology and haematology patients on ward 35 was 4 beds. Ward 35 patients are generally teenagers, although it is possible for younger oncology patients to be nursed on this ward.

Mean occupancy in this period for ward 34 was 93%, and for the nominal 4 beds on ward 35, 83%. Outliers were identified in the hospital on all except 18 days (95%).

Three or fewer beds were occupied on ward 35 on 192 occasions. On all except 14 such occasions, there were outliers in the hospital. Whilst it may be that very young oncology patients were electively cared for on outlying wards in preference to the adolescent ward, this would not be the preferred policy. It is presumed that oncology patients are best managed by oncology-trained nurses. A more likely explanation is that ward 35 was already full with patients from other services, and the fourth oncology bed was not available on these occasions (49% of all days).

There is substantial variability in the total number of oncology patients admitted to the hospital, although there is little evidence of any seasonal variation (see graph). A mean (± SD) of 13.46 ± 2.4 in-patients were present throughout the year.

From these data, it may reasonably be concluded that the nominal allocation of beds (10 on ward 34 and an additional 4 on ward 35) would be sufficient for approximately 65% of the year.

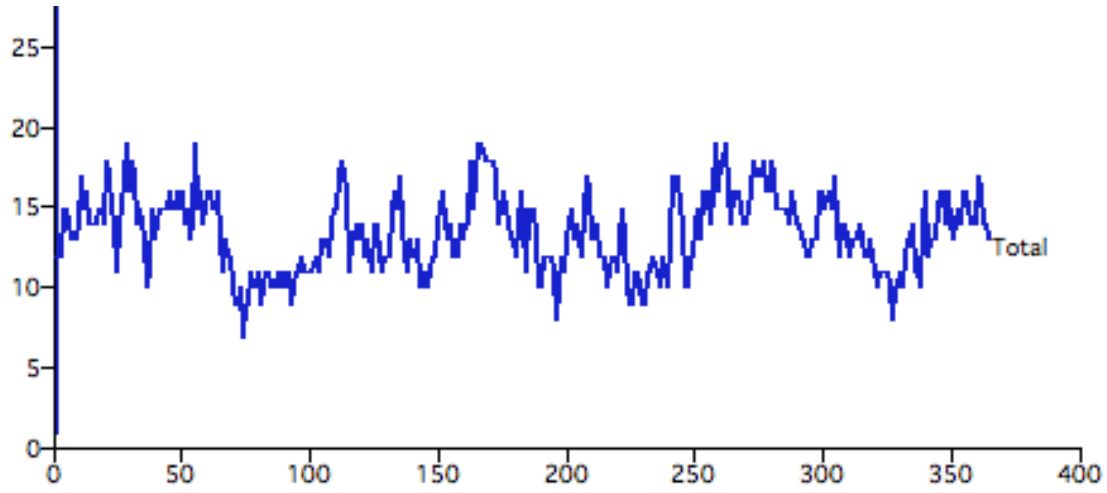

Figure 1. Total bed occupancy according to date of analysis.

Ward	34	35	Outliers	Total
Average	7.44	3.36	2.85	13.46

Minimum	5	1	1	7
Maximum	10	7	8	19
STDEV	0.90	1.51	1.44	2.40

Table 1. Summary occupancy data for oncology patients

5 Workforce (11-7B-125)

Paediatric haematology and oncology has the following time of dedicated support from other health professionals:

Paediatric dietician		0.4	
Physiotherapy	1		
Play specialists		3.2	
Outreach nurses		1.8	
Pharmacists		1	(Haem/Onc)
		1	(BMT)
		1	(Research)
Clinical psychologist	1		
Social worker	1	(Bristol)	

In addition, there are social work teams attached to each POSCU. There is substantial overlap and cross cover by the members of these teams.

There is no dedicated provision of occupational therapy. The hospital has a limited service provided by one Occupational therapist.

At UH Bristol the average annual number of new cases is approximately 120, plus 40 additional BMT patients, an approximate annual average total therefore of 160.

6 Training

6.1 Nurse Training Competencies

6.1.1 Ward 34 (11-7B-116-118)

Name	WTE	Post/ Band	Peer Review Level	Module	IV/central line competency	Febrile neutropenia competency	Blood transfusion competency	Chemo Competent	Onc Emergencies	Long term F/U	Radio therapy
Suzanne Allman	1	Sister Band 7	External	UWE	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Nicky O'Leary	1	SSN Band 6	External	UWE Degree Paed Onc	yes	yes	Yes	yes	Yes	Yes	Yes
Sarah Fay	0.92	SSN Band 6	External	Cardiff Degree	yes	yes	Yes	yes	Yes	Yes	Yes
Charlotte Higby	0.46	SN Band 5	External	UWE	yes	yes	Yes	yes	Yes	Yes	Yes
Karina Kay (mat leave)	(0..46)	SN Band 5	External	UWE	yes	yes	Yes	yes	Yes	Yes	Yes
Jaydene Davies	0.92	SN Band 5	External	UWE 2011	yes	yes	Yes	yes	Yes	Yes	Yes
Zoe Coppin	0.61	SN Band 5	External	UWE 2009	yes	yes	Yes	yes	yes	yes	yes
Natalie England	1	SN Band 5	External	UWE 2009	yes	yes	yes	yes	Yes	Yes	Yes
Emma Bevan	0.61	SN Band 5	Internal Full	No	yes	yes	Yes	yes	Yes	Yes	Yes
Kirsty Porter	1	SN Band 5	Internal Full		yes	yes	Yes	yes	Yes	Yes	Yes
Claire Fagan	1	SN Band 5	Internal Full		yes	yes	Yes	Yes	Yes	Yes	Yes
Loshini Reed	0.82	SN Band 5	Internal Full		yes	yes	Yes	yes	Yes	Yes	Yes
Olivia Lines	1	SN Band 5	Internal Full	Cardiff	yes	yes	Yes	yes	Yes	Yes	Yes
Rachel Price	0.92	SN Band 5	Internal Full	(UWE 2012)	yes	yes	Yes	yes	Yes	Yes	Yes
Amanda Harper	1	SN Band 5	Internal foundation		Yes	Yes	Yes	working	No	No	No

Lizzy Palmer	**1**	**SN Band 5**	**Internal Foundation**		**Yes**	**Yes**	**Yes**	**working**	**No**	No	No
Rachel Bailey	**1**	**SN Band 5**	**Internal Found'n**		**yes**	**yes**	**Yes**	**No**	**Yes**	Yes	Yes
Deborah Moir	**1**	**SN Band 5**	**Internal Foundation**		**Yes**	**Yes**	**Yes**	**No**	No	No	No
Laura Stokoe	**1**	**SN Band 5**	**Internal Foundation**		**Yes**	**Yes**	**Yes**	**No**	Yes	Yes	Yes
Leah Roberts	**1**	**SN Band 5**	**External**	**UWE**	**Yes**	**Yes**	**Yes**	**Yes**	Yes	Yes	Yes
Amy Whittaker	**1**	**SN Band 5**	**Untrained (started Sept 2012)**		**No**	**No**	**No**	**No**	No	No	No

6.1.2 Ward 35 (11-7B-116-118)

Name	WTE	Post/ Band	Peer Review Level	Module	IV/central line competency	Febrile neutropenia competency	Blood transfusion competency	Chemo Competent	Onc Emergencies	Long term F/U	Radio therapy
Sarah Johnson	**1**	**Sister Band 7**	**Internal Full**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Yvonne Stacey	**0.5**	**SSN Band 6**	**External**	**UWE**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Alicia Daniels	**1**	**SSN Band 6**	**Internal Full**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Rebecca Williams	**1**	**SSN Band 6**	**Internal Full**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Brian Riley	**1**	**SSN Band 6**	**External**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Claire Allan	**1**	**SN Band 5**	**Internal Full**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Marcia Neville	**0.92**	**SN Band 5**	**External**	**UWE**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Rachel Mealing	**1**	**SN Band 5**	**External**	**UWE**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Claire Bhurton	**0.92**	**SN Band 5**	**Internal Full**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Julia Bossina	**0.46**	**SN Band 5**	**External**	**UWE**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Laura Clifford (Leave)	**0.4**	**SN Band 5**	**Internal Full**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**

Rebecca Eagle	0.92	SN Band 5	Internal Full		Yes	Yes	Yes	Yes	Yes	Yes	Yes
Tamsin Eschle (Bank)		SN Band 5	Internal Full		Yes	Yes	Yes	Yes	Yes	Yes	Yes
Laura Gapper	0.7	SN Band 5	Internal Full		Yes	Yes	Yes	Yes	Yes	Yes	Yes
Rebecca Morgan	0.31	SN Band 5	Internal Foundation		Yes	Yes	Yes	No	Yes	Yes	Yes
Alice Parham	0.5	SN Band 5	Internal Foundation		Yes	Yes	Yes	No	Yes	Yes	Yes
Hannah Purcell	1	SN Band 5	Internal Full		Yes	Yes	Yes	Yes	Yes	Yes	Yes
Carolyn Waldron	1	SN Band 5	Internal Full		Yes	Yes	Yes	Yes	Yes	Yes	Yes
Viv Winterbottom	0.31	SN Band 5	Internal Full		Yes	Yes	Yes	Yes	Yes	Yes	Yes
Nonnie Thresher	1	SN Band 5	Internal Foundation		Yes	Yes	Yes	working	No	No	No
Victoria Tarr	1	SN Band 5	Internal Foundation		Yes	Yes	Yes	No	No	No	No
Mark Newlands	1	SN Band 5	Internal Foundation		Yes	Yes	Yes	No	No	No	No
Alana Allen	1	SN Band 5	Internal Foundation		Yes	Yes	Yes	No	No	No	No
Rebecca Griffiths	1	SN Band 5	Awaiting training Sept 2012		No	No	No	No	No	No	No
Kirsty Newberry	0.62	NA Band 3	untrained		No	No	No	No	No	No	No
Rhys Wynn-Jones	1	NA Band 3	untrained		No	No	No	No	No	No	No
Christine Power	1	NA Band 2	untrained		No	No	No	No	No	No	No
Emily Delaval	1	NA Band 2	untrained		No	No	No	No	No	No	No

6.1.3 Oncology Daybeds (11-7B-119-121)

Name	WTE	Post/ Band	Peer Review Level	Module	IV/central line competency	Febrile neutropenia competency	Blood transfusion competency	Chemo Competent	Onc Emergencies	Long term F/U	Radio therapy
Sue Fackrell	1	Sister Band 7	External	UWE	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Helen O'Keefe	**1**	**SSN Band 6**	**External**	**UWE**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Sheila Fox	**1**	**SSN Band 6**	**External**	**UWE Adult**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Catherine Lee	**0.25**	**SN Band 5**	**Internal: Full**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Lynn Fogg	**0.5**	**SN Band 5**	**External**	**UWE**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Helen Wilcox	**0.29**	**SN Band 5**	**Internal:Full**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Judith Carroll	**1**	**SN Band 5**	**Internal: Full**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Andrea McCotter	**1**	**SN Band 5**	**Internal:Full**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Rachel Dungy	**1**	**SN Band 5**	**Internal Full**		**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Jennifer Vincent	**0.8**	**NA Band 2**	**Untrained**		**No**	**No**	**No**	**No**	**No**	**No**	**No**

Note that this facility is dedicated to treatment of Oncology patients and is not open when not delivering chemotherapy.

6.1.4 Senior Nurse and CNS

Name	Nursing position	Training Level	Oncology Qualifications or Study Days	IV/central line competency	Febrile neutropenia competency	Blood transfusion competency	Chemo Competent	Oncology Emergencies	Long Term F/U	Radio-therapy
Helen Morris	Lead Nurse	External	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ruth Elson	Band 7 CNS	External	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Caroline Lyons (mat leave)	Band 7 CNS	External	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Wendy Saegenschnitter	Band 7 Education	External	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ken Hull	Band 7 CNS	External	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Selena Peters	Band 7 Research	External	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Charlie StJohn-Gifford	Band 6 Research	External	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Nicki Thorne	Band6 Research	Internal full	No	Yes	Yes	Yes	No	Yes	Yes	Yes

6.2 Senior Nurses

Training levels for senior nurses specified in the Operational Policy met the specified training levels of External in all cases.

6.3 Ward 34

	Band 7 Total in post (WTE) % trained	**Band 6** Total in post (WTE) % trained	**Band 5** Total in post (WTE) % trained	**Total Registered staff** Total in post (WTE) % Trained	**Band 2/3 unregistered** Total in post (WTE)
Total number of staff	1 (1)	2 (1.92)	18 (15.72)	21 (18.64)	0
External	1 (1) 100%	2 (1.92) 100%	6 (4.84) 30.8%	9 (7.76) 42%	
Internal: Full	-	-	6 (5.35) 34%	6 (5.35) 29%	
Internal: Foundation	-	-	5 (5) 32%	5 (5) 27%	
Other	0	0	1 (1) 6%	1 (1) 5%	

The facility has a total head count of 21, representing 18.64 whole time equivalents. Currently 95% of all registered nursing staff are trained to a minimum of “internal foundation ” level. The one remaining staff member is untrained but only started in September 2012, so is undergoing training to internal foundation level.

Achievements against PTC standards are:

- 95% of all ward nursing staff are trained to Internal Foundation level
- 100% of Band 6 (and over) staff are trained to External level.

Ward 34 plans to have a minimum staffing level of 3 registered and 1 unregistered on each day shift with a minimum of 2 chemotherapy givers that are trained to a minimum of “full internal” level. For night shifts a minimum of 2 registered and 1 unregistered nurses with a minimum of 1 chemotherapy giver trained to a minimum of “full internal” is planned. An example of the rota can be found in Appendix 1- Nursing Off Duty on page 46.

6.4 Ward 35

	Band 7 Total in post (WTE) % trained	**Band 6** Total in post (WTE) % trained	**Band 5** Total in post (WTE) % trained	**Total Registered staff** Total in post (WTE) % Trained	**Band 2/3 unregistered** Total in post (WTE)
Total number of staff	1 (1)	4 (3.5)	19 (15.44)	24 (19.94)	4 (3.62)
External	0 (0%)	2 (1.5) 42%	3 (2.38) 15%	5 (3.88) 19%	

Internal: Full	1 (1) 100%	2 (2) 57%	11 (6.25) 40%	13 (11.6) 58%	
Internal: Foundation	-	-	6 (4.81) 31%	3 (1.92) 9%	
Other	0	0	1 (1) 6%	1 (1) 5%	

The facility has a total trained head count of 24, representing 19.94 whole time equivalents. Currently 95% of all registered nursing staff are trained to a minimum of “internal foundation ” level. One staff member joined in September 2012 and is currently undergoing training.

Achievements against PTC standards are:

- 95% of all registered ward nursing staff are trained to Internal Foundation level
- 33% of Band 6 (and over) staff are trained to External level.

Ward 35 plans to have a minimum staffing level of 4 registered and 1 unregistered on each day shift with a minimum of 2 chemotherapy givers that are trained to a minimum of “full internal” level. For night shifts a minimum of 3 registered and 1 unregistered nurses with a minimum of 1 chemotherapy giver trained to a minimum of “full internal” is planned.

6.5 Oncology Daybeds Staffing

	Band 7 Total in post (WTE) % trained	**Band 6** Total in post (WTE) % trained	**Band 5** Total in post (WTE) % trained	**Total Registered staff** Total in post (WTE) % Trained	**Band 2/3 unregistered** Total in post (WTE)
Total number of staff	1 (1)	2 (2)	6 (4.04)	9 (7.04)	1 (0.8)
External	1 (1) 100%	2 (2) 100%	1 (0.5) 12%	4 (3.5) 55%	
Internal: Full	-	-	5 (3.54) 88%	5 (3.54%) 44%	
Internal: Foundation	-	-	-		
Other	0	0	0		

The facility has a total registered head count of 9, representing 7.04 whole time equivalents. Currently 100% of all registered nursing staff are trained to a minimum of “internal foundation ” level.

Achievements against PTC standards are:

- 100% of all unit nursing staff are trained to Internal Foundation level
- 100% of Band 6 (and over) staff are trained to External level.

ODB plans to have 4-5 registered nurses and 1 unregistered nurse on each shift with a minimum of 2 chemotherapy givers that are trained to a minimum of ‘full internal’ level.

The facility only provides day case chemotherapy and is not open for delivery of non chemotherapy services.

7 Chemotherapy

7.1 Records of unlisted regimens

A record is kept of unlisted regimens used, in accordance with policy as outlined in the Operational Policy. Please see Appendix 2 on page 50 for the list of uses in 2011-July 2012.

7.2 Chemotherapy Trainer (11-7B-146)

The chemotherapy nurse trainer is Wendy Saegenschnitter. The nurse chemotherapy has been involved in ongoing study from 1992 to 2006. She began chemotherapy delivery in 1994, attaining a professional chemotherapy qualification in 1995. Professional qualifications in nursing of children were attained in 2003. Teaching and assessment qualifications were attained in 2006.

7.3 Staff Authorised to Prescribe Chemotherapy (Nursing) (11-7B-147)

Nursing staff are authorised in the delivery of chemotherapy when the have completed cytotoxic training, the chemotherapy workbook and chemotherapy competency.

7.3.1 Ward 34 chemo competencies

Name	Cytotoxic Study Day	Chemo Workbook	Competent
Claire Harrison	Feb 2008	Yes	Yes
Nicky O'Leary	May 2011	Yes	Yes
Sarah Fay	Nov 2005	Yes	Yes
Zoe Coppin	May 2009	Yes	Yes
Charlotte Higby	Dec 2010	Yes	Yes
Karina Kay	May 2010	Yes	Yes
Jaydene Davies	Feb 2009	Yes	Yes
Natalie Nolan	Sept 2008 (Sept 11)	Yes	Yes
Emma Bevan	Dec 2008	Yes	Working
Elizabeth Knott	Sept 2010	Yes	Yes
Kirsty Porter	Sept 2010	Yes	Yes
Claire Danks	Sept 2010	Yes	Working
Loshini Reed	Dec 2010	Yes	Yes
Olivia Sparey-Tottle	May 2009	Yes	Yes
Vicki Oram	Sept 2009	Yes	Yes
Rachael Price	Sept 2009	Yes	Yes
Jane Matthews	Mar 2011	Yes	Working
Rachel Bailey	Sept 2011		
Jennifer Platt	Sept 2011		

7.3.2 Ward 35 chemo competencies

Name	Cytotoxic Study Day	Chemo Workbook	Competent

Sarah Johnson	Sept 2009	Yes	Yes
Yvonne Stacey	Dec 2008	Yes	Yes
Alicia Daniels	May 2010	Yes	Yes
Rebecca Williams	May 2010	Yes	Yes
Brian Riley	May 2011	Yes	Yes
Rebecca Eagle	Sept 2008	Yes	Yes
Rachel Mealing	May 2009	Yes	Yes
Nicola Davies	Dec 2009	No	No
Laura Clifford	Dec 2009	Yes	Yes
Matt Nelmes	Oct 2009	Yes	Yes
Hannah Purcell	May 2010	Yes	Yes
Claire Bhurtun	May 2010	Yes	Yes
Rebecca Eagle	Sept 2010	Yes	Yes
Claire Allan	Sept 2010	Yes	Yes
Laura Gapper	Sept 2010	Yes	Yes
Alice Parham	Dec 2010	No	No
Carolyn Waldron	Sept 2009	Yes	Yes
Tamsin Eschele	Sept 2009	Yes	Yes
Marcia Neville	Sept 2009	Yes	Yes
Julia Bossina	May 2009	Yes	Yes
Viv Winterbottom	Sept 2008	Yes	Yes
Rebecca Morgan	April 2010	No	No

7.3.3 Day Beds chemo competencies

Name	Cytotoxic Study Day	ChemoWorkbook	Competent
Sue Fackrell		Yes	Yes
Helen O'Keefe		Yes	Yes
Sheila Fox	May 2009	Yes	Yes
Caroline Roberts		Yes	Yes
Catherine Lee		Yes	Yes
Lynn Fogg		Yes	Yes
Helen Wilcox		Yes	Yes
Judith Carroll		Yes	Yes
Andrea McCotter		Yes	Yes
Leah Roberts	Feb 2008	Yes	Yes
Rachel Dungy		Yes	Yes

7.4 Staff Authorised to Prescribe Chemotherapy (Medical) (11-7B-150)

Name of Prescriber	Designation	Date Authorisation given	Valid until

John Moppett	Consultant	17/01/06	Ongoing
Michelle Cummins	Consultant	08/06/05	Ongoing
Helen Rees	Consultant	01/11/07	Ongoing
Anthony Ng	Consultant	01/04/07	Ongoing
Stephen Lowis	Consultant	08/06/05	Ongoing
Mike Stevens	Consultant	01/11/04	Ongoing
Rachel Cox	Consultant	01/05/07	Ongoing
Oliver Tunstall Pedoe	Consultant	16/03/10	Ongoing
Balveer Kaur	Staff Grade	30/08/05	Ongoing
Rachel Dommett	Registrar	15/12/09	01/01/12
Hugh Bishop	Registrar	6/10/09	01/01/12
Anthony Penn	Registrar	22/9/09	01/01/12
Pam Venkatachalam	Registrar	13/10/09	01/01/12
Raj Battacharyyra	Registrar	01/11/04	01/01/12
Rebecca Palmer	Clinical Fellow	7/10/08	Ongoing
Jamie Cargill	Nurse medical prescriber	16/10/09	Ongoing

8 Pharmacy Services (11-7B-158,159)

8.1 External Radiopharmacy, Production, QC and WDL Audit (Licensed)

Safeguarding public health

RESTRICTED - COMMERCIAL

Ms S E HEPBURN
UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION
THE PHARMACY
BRISTOL ROYAL INFIRMARY
BRISTOL
AVON
BS2 8HW

4th August 2010

Ref: INSP GMP_GDP PMU 12893_270710_T1

Subject: **MEDICINES ACT 1968**
MANUFACTURER'S LICENCE NO. MS, MIA (IMP) 12893
WHOLESALE DEALER'S LICENCE NO. WL 12893

Dear Ms Hepburn

May I thank you and your colleagues for the courtesy and co-operation shown to Mr Ellison and me during the inspection of your premises at Bristol on 27th July 2010.

During the inspection a number of failures to comply with the principles and guidelines of good manufacturing/distribution practice were observed and these are listed in the Appendix to this letter. A reference to the EU Guide is included for the deficiency classified as major.

This list comprises of those deficiencies made on the day together those carried over from the previous inspection on 17th – 19th May 2010.

Please reply within 28 days, giving your proposals for dealing with these matters, together with a timetable for their implementation. It would be helpful if the response was structured as follows:

1. Restate the deficiency number and the deficiency as written below.
2. State the proposed corrective action.
3. State the proposed target date for the completion of the corrective action(s).
4. Include any comment that the company considers appropriate.
5. An electronic version via e-mail.

Yours sincerely

Michael Woodhall
Senior GMP Inspector

Direct line 01707 299138
Email:michael.woodhall@mhra.gsi.gov.uk

Medicines and Healthcare products Regulatory Agency

Safeguarding public health

MHRA

File Ref: INSP GMP_GDP PMU 12893_270710_T1
Inspection date: 27th July 2010
Company: UHB NHS FOUNDATION TRUST

FAILURES TO COMPLY WITH THE GUIDE TO GOOD MANUFACTURING/DISTRIBUTION PRACTICES

1. CRITICAL

None

2. MAJOR

2.1 The measures designed to reduce the risk of mix up of non sterile materials in the unit were deficient in that:-

2.1.1 The storage and segregation of materials was not in accordance with the labelling on shelves and presented a risk of mix up.

2.1.2 Naming conventions including trade names were not consistently applied. There was no document to confirm the translation between trade name and pharmacopoeial name used on batch documentation.

The company confirmed that it had already taken action since the last inspection and would include an update as part of this response.

EU Guide: - 5.7, 5.12, 5.13 & 5.29.

3. OTHER

3.1. There was no Technical Agreement available to detail the roles and responsibilities for Dr Munton and Dr Harrowing.

3.2. The management and control of validation of the electronic document management system was lacking as evidenced by:-

3.2.1. There was no validation plan to describe the approach to be taken.

3.2.2. Procedures to describe the use of the system had not been issued. (The company confirmed that this had now been rectified).

3.2.3. There was no documented sign off of the system to signify the acceptability of use in the live environment.

Medicines and Healthcare products Regulatory Agency

3.3. Quality control testing was deficient in that:-

3.3.1. The Out Of Specification (OOS) procedure did not stipulate the need for supplementary data to be used to justify the acceptance of a passing retest e.g. there was no historical trend analysis of results, no investigation into the raw materials used etc.

3.3.2. The control of microbiological testing was deficient in that:-

3.3.3. Environmental monitoring results within the sterile manufacturing unit are not considered as part of the batch release process.

3.3.4. The documents relating to environmental plate locations had not been reviewed in compliance with specified date (Jan 08).

3.4. The Quality Management System (QMS) had a number of omissions as specified below:-

3.4.1. There was no definition of exception within the procedure. (The company confirmed that this had now been rectified).

3.4.2. The mechanism for capture of complaint information as received was not defined. (The company confirmed that this had now been rectified).

3.4.3. There was evidence that forms are not controlled as part of the Quality Management System.

3.4.4. The stated review period of 5 years for TSE certification is not in line with expectations and is considered excessive.

3.4.5. Changes to product codes had not resulted in the corresponding change to product specification.

3.5. Production activities were deficient in that:-

3.5.1. The storage of goods in the corridor of the PMU presented a risk of mix-up. In addition there was a noted inconsistency between the colour specified on the batch sheet and those in use for the bins.

3.5.2. There were a number of manual changes on the batch sheet without the appropriate authorisation.

3.5.3. The printer procedure does not cover all print operations.

3.5.4. There was no documented reason for the Ondansetron reprint observed at the time of the inspection.

3.5.5. There was no procedure for the electronic control of labels including a consideration of the impact of future clinical trial requirements.

It was noted that there seemed to be a high number of reprints including confusion regarding the use of an off line label as first pulled. The response should include a plan for reducing the occurrence of reprints.

3.6. There was no procedure relating to the verification of new suppliers or customers. In addition, there were no regular rechecks on the bona fide status of existing suppliers or customers.

3.7. The procedures and documentation for operations conducted under the MIA(IMP) licence was incomplete in that:-

3.7.1. There was no documented evaluation concerning products to be handled, specifically concerning the risks of cross contamination, given that common equipment and facilities are employed.

3.7.2. There was no procedure to describe required checks on bioavailability and the derivation of expiry date when over encapsulation is performed.

3.7.3. The Technical Agreement reviewed had been amended in the unit after signature by the Contract Giver with no further joint authorisation.

3.7.4. The Technical Agreement did not include a consideration of retention samples.

3.7.5. There was no evidence in the file regarding the provision of a sample label following the request by MHRA CTD. In addition the file was not structured to facilitate document retrieval and review.

3.7.6. The documentation was not clear regarding responsibilities for Adverse Event management and the control of comparators.

4. COMMENTS

4.1. The company will submit a variation to the appropriate licences for the QC move to Southmead. Other changes previously discussed will be incorporated at this time.

4.2. As part of the introduction of the proposed electronic system the company should review the naming of materials within different systems with the aim being a consistent approach.

4.3. The unit agreed to include a justification for the current system for non sterile component traceability.

4.4. The inspectors agreed to consider the licence requirements for Callington Road hospital storage.

4.5. Feedback from the unit regarding eye protection in GradeB/Grade A operations will be discussed with other inspectors.

4.6. The benefits of the use of the Periodic Quality Review template (Chapter 1) for conducting an annual review of QMS were discussed.

4.7. The inspector understands that the unit are planning to conduct a risk assessment aimed at justifying the removal of the coarse filtration unit on the water line as a result of leakages.

4.8. Labelling requirements will be confirmed for the MS products (POM/CD/ NON IMP). The unit should not use the IMP licence number for non IMP studies.

4.9. The reason for the omission of "Trading As" on the licence will be investigated.

4.10. Bar codes on final products were discussed. Information regarding current situation at national level will be sought.

4.11. The company should include in their response plans to address the apparent gaps in microbiological expertise at the unit.

8.2 External Radiopharmacy, Production, QC and WDL Audit – Remedial Actions (Licensed)

1. The following points were raised during the inspection of Pharmacy Production May and July 2010. (Production / QC)

Item	Action	Lead
2.1 The Quality Management System 2.1.1 (4) Investigations in PMU failed to consistently consider and document the implications on other batches or related systems	Consider with the change control process (follow on from events deviation) wait until feedback from MW July 27th	Complete (this was prior to CAPA being in place)
3.1 Laboratory Operations		
3.4.1 There is no procedure for checks following engineering work to ensure the acceptability of equipment/facilities prior to the resumption of their use	Fridge CAPA 954: SH to check with dispensary as to whether the ice-spy alarm sounds every 20 mins if alarm is not acknowledged. Pop-up alarm on dispensary base unit? Pop alarms not sounding as base unit defaulted to no scouts in zone. Reset	SH complete
3.5 Controls on place for environmental monitoring		
3.5.1 There is no specific requirement for reporting timescales from the contract lab; a period of one month for a swab was observed	-Chemical/physical analysis-raw material/finished product-test within 1 wk of receipt? -TPN sample- 1 month? (QA-retrospective)	Technical agreement in place with timescales. Decided not to have 2nd contract lab named on license as not going to use regularly
4.2 The inspector recommended that the PMU should use risk assessment methodology for proposed increases in capacity and the current labelling operation	Calendar for Validation master plan. Diary based system? VMP appendix have not been signed off.	Electronic/calendar system to remind department of when PPMs are due being trialed in RP. CM Increased capacity – will use risk assessments Labelling operation changed as result of non sterile review

Category	Issue	Action	By	Date / Urgency	Comment/update
None					
2.1 The measures designed to reduce the risk of mix up of non sterile materials in the unit were deficient in that:					

2.1.1	The storage and segregation of materials was not in accordance with the labelling on shelves and presented a risk of mix up				Complete
3.1.	There was no Technical Agreement available to detail the roles and responsibilities for Dr Munton and Dr Harrowing.	SH to speak to SB to write to Andrew Davis SH to ask TM if he knows of any QP's	SH	Oct '10	Mark Santillo- Torbay only local QP(IMP). No response regarding technical agreements from Peter Harrowing. SH to follow up
3.2	**The management and control of validation of the electronic document management system was lacking as evidenced by:**				
	1.There was no validation plan to describe the approach to be taken	Retrospective validation to be carried out	SH	Dec '10	o/s
	3.There was no documented sign off of the system to signify the acceptability of use in the live environment	To be carried out once the validation has been completed	SB	Dec '10	o/s
3.3	**The control of microbiological testing was deficient in that:-**				
3.3.2 3.3.3	Environmental monitoring results within the sterile manufacturing unit are not considered as part of the batch release process.	To be added to generic final product specs	NT NT	Dec '10 Dec '10	Complete
3.5	**Production activities were deficient in that:-**				
3.5.1	The storage of goods in the corridor of the PMU presented a risk of mix-up. In addition there was a noted inconsistency between the colour specified on the batch sheet and those in use for the bins.	1. Part of non-sterile review Sept '10 2. System will be reviewed in 12-18 months and will implement change then	RW RW	Mar '11	Non-sterile review now complete. Changes implemented, less reprints seen and less congestion in corridor. Worksheets to be changed and progress reviewed as part of QMS
3.5.2	There were a number of manual changes on the batch sheet without the appropriate authorisation.	Part of non-sterile review Sept '10	RW	Mar '11	
3.5.3	The printer procedure does not cover all print operations.	SOP to be generated for checking label-authorisation.	RW	Dec '10	Complete
3.5.4	There was no documented reason for the Ondansetron reprint observed at the time of the inspection.	SOP to be generated for checking label-authorisation.	RW	Dec '10	Complete
3.5.5	There was no procedure for the electronic	*It was noted that there seemed to be a high*	RW	May '11	Software re-configured and printing

	control of labels including a consideration of the impact of future clinical trial requirements	*number of reprints including confusion regarding the use of an off line label as first pulled. The response should include a plan for reducing the occurrence of reprints.* SH to ask MW to elaborate	 o/s	New Episys system	parameters altered. Staff had training. SOP for re-prints to be generated. Waiting on the outcome on the worksheet decision
3.9	There was no procedure relating to the verification of new suppliers or customers. In addition, there were no regular rechecks on the bona fide status of existing suppliers or customers.	Sops – new suppliers check license – checklist template (Jo resp), approval going onto EDS; Customers checklist template – bona fidae (TB/AC – ok TC,SB,JS resp); regular recheck for both customers – April 2011	JS JS/BS	Sop draft Oct test Jan2011 MHRA revoke list	Supplier approval SOP in place (Mar 11) Need to validate existing customers start with Specials – licence check, SLA- (BM)PASA
Comments					
4.1	The company will submit a variation to the appropriate licences for the QC move to Southmead. Other changes previously discussed will be incorporated at this time.	SH to check with inspector	SH		Complete
4.3	The unit agreed to include a justification for the current system for non sterile component traceability.	Container date	SB		o/s
4.4	The inspectors agreed to consider the licence requirements for Callington Road hospital storage.	Waiting on feedback			Complete (not required)
4.5	Feedback from the unit regarding eye protection in Grade B/Grade A operations will be discussed	Waiting on feedback			Complete (not required)
4.6	The benefit of the use of the Periodic Review Template (Chapter 1) for conducting an annual review of the QMS were discussed	SH and CA had meeting- need to have second meeting	CA/SH	Nov '10	Initial meeting held. 2nd one to be timetabled
4.7	The inspector understands that the unit are planning to conduct a risk assessment aimed at justifying the removal of the coarse filtration unit on the water line as a result of leakages	Risk assessment to be carried out RW to do SOP change for washing equipment for rinsing with water for irrigation	RW	Dec '10	Complete
4.9	The reason for the omission of "Trading As"	Waiting on feedback			Email reminder sent Dec 2010

	on the license will be investigated	UB Pharmaceuticals			Feb 11 – no response
4.10	Bar codes on final products were discussed. Information regarding current situation at national level will be sought	Waiting on confirmation			For information
4.11	The company should include in their response plans to address the apparent gaps in microbiological expertise at the unit	Training sessions for staff-17th and 18th August and 17th September 2010			Training took place 17/18th Sept More training to be given to staff?

2. The following points were raised during the inspection of radiopharmacy

Category	Issue	Action	By	Date / Urgency	Comment/update
1. **None**					
2. **None**					
3.1 Estates / equipment: The maintenance of the facility and equipment within the radiopharmacy was lacking in that:					
3.1.1	There was no procedure to describe the requirement for the authorisation of work on critical equipment, including checks on the completion of work to ensure that the equipment or facility is suitable for return to use.	Add authorisation of work, including checks on the completion of work to ensure that the equipment or facility is suitable for return to use to SOP 25.1 (planned maintenance). This SOP will reflect the critical equipment log (3.1.3) sign-off (who can sign off equipment will be risk rated) Full review of SOP 25 (Equipment maintenance)	SB /SH /MP /MD	Feb '11	Reviewed 17.8.10. Discussed that it will be better to do this across the board with Estates and production. Feb 11 – progressing via ppm meetings
	It was noted at the time of the inspection that the changes to the BMS software had not been formally assesses including a consideration of potential re-validation requirements.	Seek to obtain documentation from installers and set levels. Document BMS status before and after any changes made.	SH/ MP/ MD	Feb '11	Folder given to Radiopharmacy from Schneider with process map of BMS, print-out of set points. Agreed; log would be recorded after each visit and if changes are made the new set-point will be printed out. Training session for RP staff- Richard (Schneider)
3.1.2	There was no agreed plan between Estates and the department for the maintenance of the facility and equipment including an	Agree timescales and escalation at next ppm. Maintenance schedule to be standing agenda item for ppm meetings	CA to email Di to get	Sept/ Oct '10	SB to give list of ppms to Estates. Need to agree the acceptable period for ppms to be done after

	escalation procedure in the case of a deviation from agreed timescales.		timescales Discuss 4th Nov with Estates		their due date and also to see if ppms are currently overdue. Outlook folder to alert RP staff when ppms due.
3.1.3	There was no logbook available for the major or critical equipment recording to include calibration, maintenance and repair operations including dates and identity of people who carried these operations out. (It was noted that the absence of a suitable logbook full details of equipment outages had not been recorded although for the incident reviewed it was accepted that a CAPA had been raised)	Start use of Critical equipment log to record all relevant issues/actions relating to critical equipment. To be discussed with named estates officer at next ppm (17 June 2010)	SB/ SH/ MD/ MP	July '10	SB generated critical equipment log. CA to email to other departments. SB to put permit to work and equipment log as annex in SOP
3.2	**Documentation within the radiopharmacy was inadequate in that:**				
3.2.1	There was no controlled list of approved suppliers for the materials received as part of the goods receipt checking procedure. The unit should include consideration of the inclusion of the material status i.e. licensed or unlicensed as a trigger for additional check.	List to be generated	CM	July '10	Approved supplier list and SOP generated.
3.2.2	Checks on the correctness of the dispensing record are not formally included as part of the batch release process	Include in SOP 6.3- Checker to do final checks for batch release and end session. Change to format of worksheet to include a formal final release sign off (also to incl. QC.)	DK	July '10	SOP updated Worksheet updated to include final sign off.
3.3	**Environmental monitoring was unsatisfactory in that:**				
3.3.2	There was no clear link between the organism identification and the investigation conducted	Review of EM documentation/ SOP within dept	MP/ SH/ SB/ CM	Jan '11	Complete Dec 2010 SOP to be issued
3.3.3	For the environmental result reviewed no plate id had been conducted (in contravention to the procedure); the CAPA had not commented on this failing.	Review of EM documentation/SOP within dept.	MP/ SH/ SB/ CM	Jan '11	Complete
3.3.4	The technical agreement with the Regional	Revised SLA to be agreed with the Regional	SH/NT	Aug '10	In place

	Quality Control Laboratory did not include timelines for result notification. Thus was the subject of a previous observation	Quality Control Laboratory			
3.3.5	The procedure for the environmental monitoring have not been included as part of the documentation project and therefore access and updating requirements appeared not to have been considered	Review of EM documentation/SOP within dept.	MP/ SH/ SB/ CM	Jan '11	Complete
3.3.6	There was no complete record of the temperature range within incubators used for the environmental monitoring.	Icespy probe to be installed	SH	End July 2010	Complete
4. Comments					
4.1	The inspector discussed with the company the requirement to include the drain condition as part of the maintenance programme for the HVAC system.	Add to 4 weekly PPM schedule list and review of SOP.	SB/MD	Asap to check drains Sept for SOP review	In place
4.2	The inspector will discuss with colleagues the requirement for wholesale dealing license for radiopharmaceuticals not manufactured within the facility				
4.5	A discussion was held regarding the work currently being formulated by the UK Radiopharmacy Group with respect to the QC testing requirements for radiopharmaceuticals manufactured under a Special's license. Once the output from this group had been reviewed and agreed with the inspectorate it is the expectation that these minimum requirements will be compiled with the absence of a valid justification to deviate. The unit should therefore plan any necessary equipment acquisitions with these requirements in mind.	Awaiting outcome from UKRG July '10	SB/ LH/ SH	Aug '10	Still waiting on outcome Due publication April 2011

8.3 External Parenteral Services Unit Audit (Unlicensed)

An inspection of the Parenteral Services Unit was carried out on 24th August 2010, by Trevor Munton (Regional Quality Assurance Pharmacist). The overall risk assessment was Low." The outcomes of the audit (159) are in the QMS. A paper copy can be made available for checking. Agenda / Minutes of Quality Meeting to discuss remedial action is as follows

8.4 External Parenteral Services Unit Audit Remedial Actions

United Bristol Healthcare NHS Trust - Parenteral Services and Quality Control

Quality Management System: Agenda and Minutes - 21st December 2010

Agenda: **1. Review of minutes and matters arising** **2. EL 97(52) inspection** **3. Environmental monitoring** **4. PPM schedule and building work**	5. SOPs – HZ, ACD and SH to set up dates 6. Audits - action points 7. New products 8. Product development / product changes 9. Health and safety - nil	**10. Validation** **11. Deviation reports** **12. Complaints** **13. AOB**	**Present:** OM, SH, CA and SP Apologies: AG Items in bold discussed

No and Item	Comments and Action	By	Complete
1. o/s actions	1. 48hr TPN stability –waiting for approval	1. OM	
	2. Poor response Amercare around sorting engineer visit – checked contract no time specified. To consider when renewing. Note: TM chairing and om on NHS isolator user gp. Keep as reminder for when annual contract will be set up	2. OM	
	3. Surface sampling (high in hatch cylcophosphamide). 1µg/100cm^2 = 1000nanograms/100cm^2. Regional QC Lab-10 times higher that the USP limit .PSU to work within limits of detection of our test. SH to check what HZ has snet	3.SH to confirm with HZ	
	4. Process for identifying fat strength and bag should be consistent, SOP written and followed by all staff putting Rx through. SOP waiting for approval	4. OM	
	5. OOS SOP for swabs, particles, PN content + sterility, validation bags, operator validations drafted . 2 fails then klericide (ie check previous results and if cleaned no further clean needed). SOP for comments HZ and OM Is it on the DMS?	5. SP	
	6. No overage in TPN fat preparations? Nationally mixture of exact volumes and overages. Capital equipment likely to be agreed. OM to look at feasibility of process & equipment to use including switch to LFC for tpn April once capital	6. Test new	

	known. Meeting Thur June 3rd with SB, OM, MP, SH and RW about allocation of capital for equipment and type of equipment i.e. isolator or LFC? Tender out for isolators. AG and HZ to look at Baxa repeater pump validation PP0065. HZ spoke to Barbs- for batch production it needs calibration before each volume. Before each lipid PSU would need to calibrate equipment. HZ to speak to rep also. Lipid will pend if we have an appropriate delivery system otherwise fill by hand. Validation of Baxa pump with water, tolerance too tight and problems occurring. *SP to check what TPN fats could have gone into TPN bags last month* 7. Difficult to trend CAPA data as all in free text. DK to work with CM + AG on drug name trending Jan 10. 8. SH intro AG to Alison Webber (Trobay micro) re pseudomonas. AG to speak to Tony about turn-around time for id's. Send all ids to same place for consistency. AG spoke to Tony- RQCL will charge £10 per ID- Path lab-charge 50p. SH to speak to Bovis lend Lease 9. Take software out of critical equipment 14.3 SOP-OM to sign approve	system in Jan 7. DK to start in Jan 11 8. SH 9. OM	
2. EL (97) 52 audit + 6	See page 3 EL(97)52 2009 reviewed dec 09 **11.3** Unit participates in national CIVA reporting. SH spoke to Richard Batemen .He would prefer data to fit parameters. What we do not have is Grade of staff that identified issue and grade of staff involved in issue. They combine actual and potential harm. SH to pull off report for PSU and send to R.B. for him to look through. **12.5** Considering re-use of returns when med management tech in post–use ice-spy or calibrated data loggers, Disposable devise for containers-don't confirm temperature in transit but have time awareness. How do we capture that time reliably? OM to speak to other departments in relation to re-use and cold chain validation. –Mark still looking into this. MHRA very strong about cold chain validation so it needs to be robust, **EL (97) 52- August 24th 2010:** **Chemo care:** SH to speak to Maria about trials and oral/iv studies, decrease iv dose is started cyclosporine. Maria to check if we have a robust system **Aseptic processing:** Risk assessment to be carried out for the movement of vials from A to D to A Grade Rooms. Decision made on risk assessment to re-use vials or not. Ask at next Regional QC day what other departments do (do they keep them in the isolator)? **Monitoring:** Change to plate laying- long weekends lay for 2 hours and then go to QC for incubation NT to find out the validated time that plates can be laid for. If normal plates can be used use these if not use thick plates. On Fridays lay plates for the whole session and incubate plates on the Monday (for 4 days) SP to arrange a specific box to store the plates in the store room over the weekend Staff to be informed of change of practice- enter opening and closing times on plates	SH OM SH/MP HZ-011 SP SP	o/s o/s on-going

	SP to contact NT to find out information about the drying out of plates (Cherwell) AG to change settle plate spreadsheet to include the times laid/action limits etc.-o/s Change Control to be done **Transport:** Cold chain of items going to Whitchurch clinic-data logger to be put into delivery of chemo and results recorded- Patients were cancelled twice when SP was going to do temp monitoring- to do in Jan 11	SP/NT AG SP SP	
3. EM	• Continuous particle monitoring to be carried out in PSU. Carry out in additions TPN A278 & accufuser in four point isolator. Do monitoring in new isolators when they arrive. To be carried out Sept '10 along with routine particle monitoring. AG did in Dec for additions to aqueous phase but Lasair battery dies before additions of fats. To do fats in Jan 11 • Humidity loggers in clean room: 2 days CR1 (Wed/Thur), 2 days CR2 (Sat/Sun) and 2 days CR3 (Mon/Tue). Keep note of where they are positioned and the length of time. Do people being present (Mon-Fri) have an effect vs weekend? OM chase Estates	AG OM	
4. PPM + deviation	• Fluid dynamic and computer monitoring was carried out as part of the risk assessment for the Terrell St. demolition. Highlighted at risk areas with a south westerly wind and wind in the opposite direction. SH to show pictures to PSU staff-end Jan 11 before demolition begins • Terrell St Demolition: No changing to scrubs will take place, clogs only in graded areas, goods/people cross over, do swabs on outer packaging once before demolition and one after demolition • Bag up cardboard once removed • Tacky mats- 1 by lift and 1 at main door (one at BHOC main entrance) • Monitoring- 2 new particle counters and 3 new air samplers • Bovis Lend Lease to visit every 2 weeks and do random check of air flow Contingency plan for PSU and production: staff validations, work load, sing different equipment, change procedures- do concurrent validations. PSU and Production to discuss contingency plans in Jan 11. CA to arrange date.	SH All CA	
5.	• Nil		
6.	• Frequency and content of internal audits changing- 10 weekly audits to be carried out on different areas –SP and CA to out together content of audits and schedule	SP/CA	
7.	• Nil		
8.	• Regional QC lab- establishing stability indicating method for busluphan. HZ sent 3 vials busluphan, worksheets (concentration + diluents) and SOP to BH. 24-48 hours. SH to check with Tony. SH to look at SOP 14-update again including contract and stability changes. SH and OM to look at SOP together.- Issues with the reliability of the test method. RQCL to go ahead with test and a decision will be made on the result	SH to check	o/s

	• Supplied v small dose of ganciclovir for SCBU with overage needed in syringe as vol lost in line. Check what due with ambisome-SH • Pemetrexed-shelf-life- keep 1 weeks of ready-made Pemetrexed (or if patient cancelled- represent clinical dose) Need 2 x 25ml- 50ml twice for shelf-life test. If theis does not work, use vial (£1000) second option • Paclataxel-Marc send SH email 20th Oct • Docetaxel-contract changes (from 2 vials to one vial)	SH-o/s SH	o/s
9.	• Shield gloves- Operators are happier to stick with the Berner gloves rather than the Helapet gloves. More expensive black gloves available-weigh up cost of discarding Berner gloves and cost of a more expensive "stronger" glove. SP to speak to HZ	SP	
10.	• SP to upload VMP onto the DMS		
11-12 CAPA	• CAPA overview – see sep. report. (Aug-Nov vs Jun-Aug) with picking error most frequent, then equipment 2nd and documentation 3rd. • 974 – fire door open in prep (OM follow up action 1223)	OM OM	
13 AOB	• Monthly reports- HZ to look at the page in front of file. Need to review it. Possibility of using an outlook calendar to ensure that reports are in, in a timely manner. Shared folder-make them electronic? The turn -around time from Regional QC lab is a factor. • Three babies died of septicaemia caused by Enterobacter cloacae contaminated TPN. It would appear that the root cause is now firmly established as a hairline crack in a bottle of amino acid solution which lead to the bottle being contaminated prior to use (though not visibly so). • Comments (3rd Nov) to be put forward for a say in the future of regional QC testing centres; there are the 2 regional QC (ie testing) centres (north – based at NBT, Southmead; south – based at Torbay) each with a regional QA pharmacist. Is this what we want/need in the future? What do we in UHBristol need to be able to ensure we can provide our patients with medicines suitable for intend use. • **Date of next meeting: PSU QMS –9th Feb 2011.**	SP HZ	SP to send SH a report monthly

EL(97)52, 2009 (risk management; Rx validation; facilities; doc; personnel + training; starting materials; storage + dist)

No	Acceptance criteria	Result	Comments/Action	By	Status	Status
1	Prescription validation	CMOS	Out of date chemo protocols on AWS network	OM	Ongoing	Add to trust risk register
7	Storage + distribution	CMOS	Fridge mapping	HZ/ABG		Map in use for 24 hrs

Chemo (Apr08)

No	Acceptance criteria	Result	Comments/Action	By	Date + status
4.5	Operational characteristics of key equipment are confirmed in writing as part of planned preventative maintenance	CMOS	Check got for check of automix	OM/SP	HZ check with company in Jan2010
5.1	SOPs written for all processes and equipment are issued, approved and reviewed by suitably qualified staff.	CMOS	add VMP and reference to trust's intrathecal policy	OM	Dec08
5.3	Master batch manufacturing records formula/worksheets written and approved by suitably qualified staff	CMOS	Good validation programme in place for training and documenting this. Consider using a condensed version for re-validation	AM	Oct08
11.3	The unit participates in the national CIVA error reporting scheme	CMOS	Need to check – done in house not reported nationally	SH	May08. Spasmodic Mark chemo, Alex TPN
12.2	Storage in the pharmacy is validated, mapped where necessary and routinely monitored eg refrigeration	CMOS	Check mapping is part of MVP.	SP/ABG	Jul08
12.3	Storage on the wards is validated and routinely monitored	CMOS	Rolling programme (TPN) needs to also cover chemo Wd 34 done 4 hours to get to <8'C. Check 3/52	SP/AM	Start Jul08
12.5	Returned product must have a known history and a valid shelf-life and be assessed for re-use by a suitably qualified person	CMOS	Only used for same patient. Need to check if this is the case for items sent to wards or just if not dispatched from PSU. Add 6.2 not reused	AM/LOR	May08
12.7	There is an SOP for returns	CMOS	No specific SOP, but now under review	OM	Apr2010

TPN (Jan09)

No	Acceptance criteria	Result	Comments/Action	By	Date + status
1.6	Risk is considered when allocating product shelf-life	CMOS	Yes but currently no SOP outlining expiry allocation	OM	
2.7	Any deviations from validated processes	CMOS	See 2.4		

	must be recorded and assessed by the responsible pharmacist				
2.8	Trust policy statement available for aseptic and unlicensed products	CMOS		SBrown	
4.5	Operational characteristics of key equipment are confirmed in writing as part of planned preventative maintenance	CMOS	Automix	SP	
4.7	Where appropriate equipment if tested against performance criteria for compliance with appropriate guidelines and standards	CMOS	May find it easier if have checklist for comparing ppm/calibration reports against	SP	
5.1	SOPs written for all processes and PPM + servicing of equipment & premises	CMOS	Need to include MVP (acceptance criteria + dates)	SP	
6.1	An agreed and defined management structure including a named responsible pharmacist for section 10	CMOS	In place but SOP and training record does not include authorised pharmacists	OM	
6.8	Records of continuing staff training	CMOS	Ltd update. Programme in place for 2009		
7.20	Clothing cleaned appropriately and monitored	CMOS	Check if change process accessed (nb rooms = grade C)	ABG/SP	
8.4	Procedures reflect current standards of aseptic practice and technique	CMOS	Consider standardising operator methods used for in-process checks	SH/OM	
8.11	Suitable technical agreements are in place	CMOS	HPA expired Jul08	SH	
9.4	Cleaning procedures are regularly validated particularly when hazardous material is present	CMOS	No surface sampling currently carried out in rooms/hatches (grade A swabs post clean)	SP	
10.1	All starting materials used are licensed. If a 'specials' is used C of A are available	CMOS	Check c of A for Zinc, selenium, Calcium, potassium chloride + phosphate; sodium acetate, iron	SH	
10.3	Raw material specifications are written incl container specifications	CMOS		ABG	
12.2	Storage in the pharmacy is validated	CMOS	Need to temp map the fridges	ABG	

8.5 Computer generated Prescriptions

Chemocare: Protocol Status July 2011						
Agreed List Protocols	**Status In BCH**	**Agreed to Put on Chemocare**	**Protocol Put on Chemocare**	**Signed off and ready to go live**	**Running Live on Chemocare**	**Any Issues**
EsPhALL (Version 5 - Feb 2010)	Open					
INTERFANT - 06 (Version 4.0 21st July 2010)	Open 06/01/09					
UK ALLR3 (Version 5 - May 2009)	Open randomisation halted 21/12/07					
AML 17 (Version 5)	Open					
UK ALL 2003 (Version 7 - Aug 2009) + CYP ALL Interim guidelines	Closed 30/6/2011	Yes	Yes	Yes	Yes	Mercaptopurine alternate day dosing - use pre-printed charts as Chemocare is unable to process alternate day dosing. UKALL 2011 agreed to run on chemocare, but not all issues resolved.
UK ALL 2003 (Version 4 - Flowsheets)	Closed 30/6/2011	n/a	n/a	n/a	n/a	n/a
MATURE B FAB LMB 96	Guidelines from 23/07/03					
EuroNet PHL - C1- Hodgkins Lymphoma (Version 3- 3rd Aug 2010)	Open 07/05/09	Yes	Yes	No		
MINI BEAM	Not a study					
LPD	? No ethical approval					
Treatment of Intracranial Germ Cell Tumours	No ethical approval					

LGG2 (LOW GRADE GLIOMA)Version 3 (UK Supplement Version 4)	Open 23/09/06					
Infant Ependymoma	No ethical approval					
EURAMOS 1 (Appendix A ver 2 Dec 2008 /Appendix B ver 3 Apr 2011)	Open 12/06/06	Yes	No	No	No	Protocol is live in PSU. Need to copy, check and sign validation documents.
EURO EWINGS 99 (Version 3a 14th September 2010)	Open	Yes	Yes	No	No	
EpSSG RMS 2005 (Version 2.0 August 2010)	Open 21/08/06					
EpSSG NRSTS 2005 (Version 3.0 September 2009)	Open 21/08/06					
H R Neuroblastoma (October 2010)	Open	Yes	Yes	No	No	Cis-retinoic acid - use pre-printed sheets as Chemocare unable to process protocol?
WILMS 2001 (Version 5 25 August 2010 / amend 10 Sept 2010)	Open	Yes	Yes	No	No	
SIOPEL 6 (Version 3 -- 19th August 2010)	Open 28/01/09					
TISSUE BANK (Version 3.0 10th January 2011)	Open 06/06/08					
Large Cell Anaplastic Lymphoma	Closed 24/06/09					

Supplementary Protocol	Inserted into ALCL99 folder					
AML 15 (FLAG Ida arm closed to recruitment 08/05/2007)	Closed 05/01/09					
AML 15 Paediatric Guidance Variations for Children Version 4 Aug 2007						
Hodgkins 2002 02	Closed					
Large Cell Anaplastic Lymphoma	ALCL 99 Closed 06/09					
ALCL - Relapse	Closed to recruitment 29.07.09					
NHL T-CELL	Closed 19/12/2008					
SIOP EPENDYMOMA 99	Closed 31/03/08					
MEDULLOBLASTOMA	Closed 31/12/06					
HART High Risk Metastatic Medulloblastoma(Vers 3) & Standard Risk PNET 4 (Vers 2)	Closed 02/06/08--31/07/07					
INFANT PNET	Closed 06/11/03					
MMT 98 - Met RHABDO	Closed 19/11/04					
HART for ST PNET	Closed 25/11/2008					
EUROPEAN INFANT 99	Closed 30/06/04					
SIOP > 1 yr Unresectable	Closed 09/02/07					
Relapsed WILMS	Closed 27/11/2008					
Hepatoblastoma - SIOPEL 3 (Amended Oct	Closed 31/12/06					

2004)						
SIOPEL 4 + guidelines for standard care(Siopel 3)	Closed to recruitment 20/08/09					
Extra Cranial Germ Cell Tumours (GC111)	Closed to recruitment 09/09					
HLH 94	Closed					
HLH 2004	Closed to recruitment					
LCH III	Closed to recruitment 02/10/07					
RETINOBLASTOMA-Guidelines ver 1.0-05/05	Closed to recruitment 29/07/09					
Childhood Tumour and Leukaemia Bank. Version 3.1	Susp Reopened as Tissue Bank					

Appendix 1 Nursing Off Duty

1.1 Ward 34

Dec Jan 2010		Sun	Mon	Tue	Wed	Thu	Fri	Sat	Sun	Mon	Tue	Wed	Thu	Fri	Sat	Sun	Mon	Tue	Wed	Thu	Fri	Sat	Sun	Mon	Tue	Wed	Thu	Fri	Sat
WARD 34		6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	1	2
SR Harrison	7		E	D	M	D				D	D		M	D		D	E	E	M						E	M	D	D	
SN O'Leary	6		AL		AL		N			AL		M	D	N		N			D	D	D						D	N
SN Hull	6						D	D	D	N			D	D	D			M	D						N	N	N	N	
SN Gilbert	5	D				E				D	D											D							N
SN Higby	5		D											D		D							D						D
SN Darton	5	N	N			D	D		D		N	N					D	D			N	N				D			
SN Coppin	5	D		N	N	N				AL		AL		AL				N	N					D	D	N	N		
SN Nolan	5	D		D	D	SD	N				D		SD				N			D	D		N	N	N				
SN Dungey	5	D	D	D								D	D		D	D		D		E				D	D		D	D	
SN Bevan	5	N					D	N	N			D		D	N	N				N			D			D	D		
SN Knott	5		N					D	D		N			N						D			D	D					
SN Porter	5		D		D	D				D	D	N	N				D		N			D	D		D		D		
SN Reed	5			D	D			D				D			D			D	E			D	N			D			
SN Jackson	5	AL					AL	N	N		AL		E			D	N			L				N			D		E
SN Sparey-Tottle	5		AL	N	N	N		AL		N					D				D		D			D	D			N	N
SN Price	5		AL		AL		AL			D		D	N	N	N			D	D		N	N							D
SN Oram	5		AL		AL		AL			AL		AL		AL			D	N	N	N						D	D		D
HCA Cole	2				D	D	D			AL		AL		AL		N	N	N				D	N	N			N		
HCA Gaze	2		N	N	N			D	D		N	N	N				D				D		D	D		D			
CNS Wendy											?D							?D											
CNS Jamie					?D																								
CNS Ruth			?E																										
CNS Flo																													
DAYS		4	3	4	3+1	3+1	3+1	3+1	3+1	4	4	4	3	4	4	4	3+1	4	4	3	3+1	3+1	4+1	4+1	4	4+1	4	4	4
EARLIES			1			1							1				1	1	1	1					1				1
LATES			0										0							1									
NIGHTS		2	2+1	2+1	2+1	2	2	2	2	2	2+1	2+1	2+1	3	2	2+1	2+1	2+1	3	2	2	2	2+1	2+1	2	2	2	2+1	3
CHEMO DAY		4	2+e	3	1+m	2+e	2	1	2	2	3	1+M	3+M	3	2	3	1+E	1me	2+M	2+e	2	1	1	2	2+e	1+m	1	3	2
NIGHTS		1	1	1	1	1	2	0	0	1	1	1	0	1	0	1	1	1	1	0	1	1	1	1	2	2	2	1	1
IV DAY																													
NIGHTS																													

1.2 Ward 35

Jan/Feb 2010	31	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
Grade Staff Name	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S
N7 Willsher Megan									Da		Ma		E	Da		Da		MD	L	Da			Da		Ma	E	SD	
N7 Johnson Sarah		DO	DO	MD	Da		Da	N	DO	DO	MD	Da	Da	DO	DO	DO	AL	AL	AL	DO	DO		DO	DO	MD	Da	Da	
N6 Milton Jemma	N	DO		N			N	N		DO	Da	Da	Ma	DO	DO			Da	Da		Da		Da	Da		Da		DO
N6 Daniels Alicia	N	N				Ma			N	N	N				Da	Da			Da	Da	DO			Da	DO		N	N
N6 Stacey Yvonne				OD	MD	DO		DO	DO	DO	Da		DO	DO	DO	DO	DO	AL	MD	DO	Da	Da	DO	DO	AL	DO	DO	DO
5b Allan Claire	DO	N	N			Da	DO	DO	DO	DO	AL	AL	AL	DO	DO	Da		Da	Da			N	N				Da	Da
5b Clifford Laura	DO	DO	N	N	N	DO	DO	DO	DO	Da	Da			Da	Da		Da	Da		Da	DO	DO	DO	SD	Da			Da
5b Nelmes Matthew			Da	Da		Da	DO	AL	AL	DO	DO	DO	Da	N	N				DO	N	N			N	N			N
5b Mealing Rachel	DO		AL	SD	SD	N			SD	AL	DO	N	N		DO		Da	SD		N	N	N					Da	N
5b Gapper Laura	DO	ML	ML	ML	ML	ML	DO	DO	ML	ML	ML	ML	ML	DO	DO	ML	ML	ML	ML	ML	DO	DO	ML	ML	ML	ML	ML	DO
5a Swann Hannah	AL	DO	DO	AL	DO	DO	AL	DO	DO	N	N	N		DO	DO	N	N	N			Da	Da			Da	Da	DO	DO
5b Bhurtun Claire	Da	DO	Da	N	DO	DO	Da	Da	DO	Da	N	DO	DO	DO	Da	DO	Da	N	DO	DO	DO	Da	DO	Da	N	DO	DO	DO
5a Williams Rebecca	DO	Da	Da		SD		Da		SD	Da			Da			N	N	N					Da		Da	N		
5a Williams Rebecca													N															
5A Parham Alice	Da	Da		Da	DO		DO	N	N	N				Da	DO	DO	AL	SS	AL	AL	DO	DO	N	N				
5a Eagle Rebecca	DO	Da		Da	Da			Da	Da			Da	Da		N	N		DO	DO	DO	DO	DO	AL	DO	AL	DO	AL	DO
N4 Rea Helen	N	N	N				Da	Da	Da			Da					N	N	N				Da		N			
5b Neville Marcia	Da				Da	Da			Da			N	N	DO	DO	AL	AL	AL	DO	DO	DO		N	N	N			Da
5b Davies Nicola		DO	DO	DO	DO	DO	DO	DO	AL	AL	DO	DO	DO	DO	DO	AL	AL	DO	DO	DO	DO					N	N	
5b Eschle Tamsin		AL	AL					AL			AL							AL					AL			AL		
5b Bossina Julia	DO	DO	ML	ML	DO	DO	DO	DO		ML	ML	DO	DO	DO	DO	DO	ML	ML	DO	DO	DO	DO	DO	ML	ML	DO	DO	DO
5b Waldron Carolyn	N				N	N	N	DO					N	N	N				N	N	N	DO	AL	AL	AL	DO	DO	DO
5b Waldron Carolyn																											N	
5b Winterbottom Vivienne			N						N					DO	DO	AL	DO	DO	DO	DO	DO					N		
5b Morgan Rebecca						N								N					N								N	
N2 Power Christina	Da			Da	Da	Da				Da	Da			Da	Da	Da						N	N	N				Da

Jan/Feb 2010	31	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
N4 Southcott Nathan	DO	Da	Da				Da	Da	DO		Da	Da		Da	DO		Da		Da	Da	DO	DO				N	N	N
N2 Delaval Emily		Da			Da	Da		Da				N	N	N				Da			Da	Da		Da	Da		Da	
N2 Williams Charlotte	DO	AL	Da	Da		AL	DO	DO	DO	DO	Da	DO	DO	Da	DO	DO	Da			Da	Da	Da				Da		DO
N3 Newberry Kirstie	Da			N	N		DO	DO	Da	Da			Da		Da			Da	Da				Da		Da	Da	DO	DO
N2 Abbasi-Kia Matina	AL	DO	DO	DO	DO	AL	AL	AL	DO	DO	DO	DO	AL	AL	DO	Da		DO	N	N	N			Da			Da	Da
5a Roberts Leah																												
C2 Parsons Deb	DO	DO	DO	DA	DA	DA	DO	DO	DO	DO	DA	DA	DA	DO	DO	DO	DO	DA	DA	DA	DO	DO	DO	DO	DA	DA	DA	DO
C2 Sparks Pat	DO	DA	DA	DA	DO	DO	DO	DO	DA	DA	DA	DO	DO	DO	DO	DA	DA	DA	DO	DO	DO	DO	DA	DA	DA	DO	DO	DO
HK Robinson Pat	DO	DA	DA	DA	DA	DA	DO	DO	DA	DA	DA	DA	DA	DO	DO	DA	DA	DA	DA	DA	DO	DO	DA	DA	DA	DA	DA	DO
N8 Armstrong Judith																			E									
N7 Cargill Jamie																												
5b Eley Kelly									N													N						
N6 Goodman-Carter Hannah																												
N7 Hewitt Helen																												
N7 Marriage Deborah																												
5b Thompson Hayley							N																					
5b Traub Clare																					E							
5b Turton Anthony			DY																									

1.3 Oncology Day Beds

Day Beds Rota Aug-10	Mon 16th	Tues 17th	Wed 18th	Thurs 19th	Fri 20th		Mon 23rd	Tue 24th	Wed 25th	Thurs 26th	Fri 27th
SR S Fackrell	MD	W	SD	DO	W		W	MD	W	DO	LW
SSN H O'Keefe	W	W	DO	EW	LW		W	C	DO	W	LW
SSN S Fox	DO	C	W	AL	AL		DO	EW	W	W	LMD
SN C Roberts				W						W	
SN H Wilcox											
SN L Fogg	EW						W				
SN C Lee					LW						AL
SN A McCotter	AL	AL	AL	AL	DO		AL	AL	AL	AL	DO
SN J Carroll	W	W	W	DO	LW		W	W	W	DO	TO
SN L Roberts	AL	AL	AL	AL	DO		DO	W	W	EW	W
SN R Dungey	W	EW	W	W	DO		EW	W	D0	W	W
SN J Boere			EW						EW		W
NA E Perrett											
NA J Vince	8~4	8~4	8~4	8~4			8~4	8~4	8~4	8~4	
Students **Bank Staff** LUCY FLO Jo Neal **TOTALS**	4+1	4 + 1	4+1	W 4+1	4		5+1	4+1	5+1	5+1	5

Tues 17th - Sue Wd38 9.45
Wed 18th - Sue Coporate Clinical Update 8.20-16.30
Tues 24th - Sue Wd38 10.00
Wed 25th Chemo Group Meeting
Thurs 26TH Cover Jamie Clinic

Appendix 2 Off Protocol Prescribing (11-7B-135)

Anonymised record of off protocol prescribing January 2011-July 2012

Consultant	Indication	Protocol
Steve Lowis	GIST	Nilotinib
Michelle Cummins	Relapsed AML	M-FLANG
John Moppett	SECONDARY AML	European relapsed AML protocol
Oliver Tunstall	ALL	Based on ALL 2003/ALL 2011
John Moppett	ALL	Based on ALL 2003/ALL 2011
Steve Lowis	PTLD	UKCCSG 2005 lymphoproliferative disorder guidelines
Michelle Cummins	ALL	Based on ALL 2003
Mike Stevens	Retinoblastoma	Agreed with Birmingham. Relapsed Sept 2011 then onto JOE protocol (retinoblastoma guidelines)
Oliver Tunstall	AML downs	AML downs protocol ML-DS 2007
John Moppett	ALL	Based on ALL Interim guidelines + nelarabine/cyclophosphamide/etoposide & Protocol MA (UKALL 2011)
Rachel Cox	Relapsed Ewing's sarcoma	Irinotecan temozolomide
Rachel Cox	Infant medulloblastoma	Irinotecan temozolomide. Then TMZ single agent 200mg/m2 from Oct 2011
Anthony Ng	Burkitts Lymphoma	R-ICE
Oliver Tunstall	AML downs	AML downs protocol ML-DS 2007. Protocol agreed Oct 2011
Michelle Cummins	Molecular relapse of ALL post transplant	Fludarabine + Vinc&dex (UKALL maint)
Helen Rees	Hepatoblastoma in end stage renal failure (on HD)	Based on SIOPEL 4 - cisplatin over 1 hour (no pre hydration). Then dialysis 2 hours later.
Steve Lowis	ATRT (relapse)	Intraventricular etoposide (based on prev treatment)
John Moppett	AML (M6) - 6week old 2.5kg	Based on AML17 paed guidelines - cytarabine 1/4 dose then added daunorubicin 1/2 dose on day 7 and 9 only.
Steve Lowis	Refractory Osteosarcoma	Gemcitabine/Docetaxel
Consultant	Indication	Protocol
Steve Lowis	GIST	Nilotinib
Oliver Tunstall	TAM	Low dose cytarabine x 2 cycles
Michelle Cummins	ALL	Thioguanine replacing 6MP for a tolerance trial. Previously on 12.5% maintenance, so starting dose of 12.5% x thioguanine dose of ALL97 (100% = 40mg/m2)
Helen Rees	Colorectal Cancer	XELOX/CAPOX (ASWCS protocol)
Steve Lowis	Diffuse Bcell Lymphoma (16yrs)	R-EPOCH - recommended by Amos Burke. Includes Vincristine infusion - exception to IT policy

Rachel Cox	Relapsed Ewing's sarcoma	Gemcitabine/Docetaxel (same as Mary Collard)
Oliver Tunstall	Autoimmune haemolytic anaemia	Bortezomib - recommended and funded from GOS
Rachel Cox	Infant medulloblastoma	Oral etoposide
Oliver Tunstall	ALL	Based on ALL Interim guidelines + nelarabine/cyclophosphamide/etoposide & Protocol MA (UKALL 2011)
Michelle Cummins	JMML	Oral 6MP 50mg/m2 as per EWOG MDS guidelines
Helen Rees	Diffuse Bcell Lymphoma (16yrs)	REPOCH
Steve Lowis	Refractory RMS	VIT (based on VIT 2011 trial protocol)
Helen Rees	Synchronous localised orbital rhabdomyosarcoma & choroid plexus carcinoma	Alternating IVA/CyCE/IVE
Maaz Ata	Relapsed Osteosarcoma	Gemcitabine and Docetaxel with Mepact (Oxford MDT approval and exceptional funding arranged) for treatment in Taunton