Pan Birmingham NHS
Cancer Network

Guideline for Expectant Mothers and those trying to conceive involved in the administration of and/or the care of patients receiving chemotherapy/monoclonal antibodies

Version History

Version	Date Issued	Brief Summary of Change
1.0	Oct 2006	Endorsed by the Governance Committee
1.1	11/03/08	Prepared for review and re formatted
1.1	17/03/08	Endorsed by the Chemotherapy Network Site Specific Group
1.2	16/03/2011	Reformatted by Rachel Loveless
1.3	08/08/2011	Taken the Chemo NSSG. Document agreed and members offered an additional 2 week window to request changes.
1.4	22/09/11	Reviewed by Frances Shaw
1.5	22/09/11	Comments from Frances Shaw integrated
1.3	16/11/11	Reviewed and updated by Frances Shaw
1.4	06/12/11	Prepared for discussion by Guidelines Sub Group
1.5	14/12/11	Reviewed and endorsed by Guidelines Sub Group and sent to Elaine Spellman for final review
1.6	28/12/11	Reviewed and updated by Elaine Spellman
2.0	28/12/11	Endorsed by Guidelines Sub Group

Date Approved by Network Governance	**December 2011**

Date for Review	**December 2014**

Changes between Versions 1 and 2

No specific changes between versions 1 and 2.

1 Scope of the guideline

1.1 This guideline has been produced to support clinical areas where chemotherapy is administered to ensure safe practice for pregnant workers (and those trying to conceive) working in areas where chemotherapy/monoclonal antibodies are administered. It is based on the evidence and research available.

1.2 Clinical areas where chemotherapy/monoclonal antibodies are administered are predominantly staffed by women of child bearing age making it an important area to have clear guidance. [11, 16]

2 Background

2.1 Many Antineoplastic drugs have mutagenic, teratogenic and carcinogenic properties [7, 8, 13] however; the associated potential risk to chemotherapy administrators is unclear.[2, 13, 16] There are currently no clear guidelines for measuring cytotoxic exposure with the validity of airborne testing, current biological (blood test for full blood count) and internal dose (urine samples) measures and their safe levels being unclear when exposure is long term and low dose.[7, 13, 16] With no conclusive evidence as to their benefit, the use of biological or Internal Dose markers is not suitable for routine use in clinical practice settings.[1, 7, 13, 16, 17] These findings form the basis for the use of Personal Protective Equipment (PPE) [1, 7, 12, 13, 16, 17]

2.2 Some studies have suggested an association between occupational exposure to cytotoxics and adverse events in pregnancy, [4, 13] however, the evidence of detrimental health effects relating to cytotoxic exposure and related effects in workers in general is far from clear. [1, 17] One study collating evidence from studies between 1966-2004 found no significant association for the risks of stillbirths or congenital malformations; however a small associated risk was identified with spontaneous abortion.[4]

2.3 However, the relevance of earlier studies on current practice is questionable.[11, 16, 17] Higher levels of exposure have been frequently identified in the 1980's when the associated risks of cytotoxic exposure in general were less known and therefore the use of PPE and isolators were less frequent; often with nurses mixing up chemotherapy drugs on the ward without any protection at all.[11, 16, 17]

2.4 Other studies which contradict these findings (with no increased risk identified) conclude that this was due to the use of PPE, appropriate staff training and the correct risk assessments strategies being in place, [11] with a study of 374 patients showing that receiving chemotherapy in the second and third trimesters appears to be safe[11], the greatest risk to the unborn child being in the first three months when cell division and differentiation are most prolific.[11]

2.5 Guidelines for pharmacy staff involved in the preparation and reconstitution of chemotherapy agents are clear and recommend that staff involved in these activities should be removed from these duties during pregnancy [2, 11] Guidelines for associated risks relating to the preparation and reconstitution of monoclonal antibodies are less clear, however, as the risk are unknown we recommend that the same policy should apply in these instances.

2.6 As pregnancies are often unplanned or unknown for several weeks the emphasis should therefore be to ensure safe practice **at all times for all staff** [11, 17] caring for patients receiving chemotherapy. With provision of the correct dermal protection and up to date risk assessments reducing the risks of exposure within the clinical area to a minimum, normal work can continue [2, 11]. If required individuals should be referred to Occupational Health to discuss specific concerns.[2, 11] The Health and Safety Executive Guidance recommends that as safe levels of these drugs cannot be ascertained, exposure should be avoided or reduced to 'as low a level as is feasibly possible'[11] Consideration should be given to areas of perceived high risk e.g. sluice room.[11]

2.7 There is a need to ensure standardised practice to ensure staff safety and consistency of practice across the Network.

2.8 The main areas to consider are:

a) risk assessment.
b) education and training.
c) PPE.

3 Risk assessment

3.1 **It is the responsibility of the employer** to ensure 'so far as is reasonably practicable the health, safety and welfare at work of all his employees', and a 'written statement of the policy with respect to health and safety at work'[6] to include:

a) 'the provision and maintenance of plant and systems of work that are, so far as reasonably practicable, safe and without risk to health.'[6]

b) 'arrangements for ensuring, so far as reasonably practicable, safety and absence of risks to health in connection with the use, handling, storage and transport of articles and substances.' [6]

c) 'the provision of such information, instruction, training and supervision as is necessary to ensure, as reasonably practicable, the health and safety at work of his employees.'[6]

d) ‘so far as is reasonably practicable as regards any place of work under the employers control, the maintenance of it in a condition that is safe and without risks to health and the provision and maintenance of means of access to and egress from it that are safe and without such risks.’[6]

e) ‘the provision and maintenance of a working environment for his employees that is, so far as reasonably practicable, safe, without risks to health, and adequate as regards facilities and arrangements for their welfare at work.’[6]

3.2 It is the responsibility of the employee:

a) ‘to take reasonable care of himself and of other persons who may be affected by his acts or omissions at work.’[6]

b) ‘as regards any duty or requirement imposed on his employer or any other person by or under any of the relevant statutory provisions, to co-operate with him so far as is necessary to enable that duty or requirement to be performed or complied with.’[6]

c) attend any training provided to ensure they are aware of the potential risks and follow recommended precautions.

3.3 Comprehensive risk assessment in all relevant clinical areas and is essential to identify specific risks and decide what controls are needed in line with Health and Safety at Work Act 1974 [6]and COSHH to minimise that risk. [3, 5, 17]
Risk assessments should be reviewed annually.

4 COSHH 8 step requirements as follows:

a) assess the risk. [3, 5.]
b) decide what precautions are needed. [3, 5]
c) prevent or adequately control exposure. [3, 5]
d) ensure that control measures are used and maintained. [3, 5]
e) monitor the exposure [3, 5] (Occupational Health referral for significant exposure [7]).
f) carry out appropriate health surveillance [3, 5] (no current indication for routine surveillance [1, 7, 13, 16, 17]).
g) prepare plans to deal with accidents, incidents and emergencies. [3, 5]
h) ensure employees are properly informed, trained and supervised. [3, 5]

5 Education and training

5.1 The main identified areas that affect the risk of exposure include drug handling, frequency and duration of handling, potential for absorption, PPE and work practices [1, 13] with the main routes of exposure being inhalation and skin contact/absorption.

The potential for a worker to suffer adverse events from hazardous drugs increases with the amount and frequency of exposure and the lack of proper working practices.[13]

Education and training of staff is the key to ensure that staff understand the risks of exposure associated with cytotoxics and the precautions they should take when handling them.[7, 17] Staff should not handle cytotoxic drugs or waste unless they understand the risks and appropriate techniques for avoiding exposure.[12]

5.2 Education and training should be provided on to all staff in the clinical area relating to:

a) the potential health risks of cytotoxics.[8, 10].
b) sources of up to date relevant information.[10]
c) routes of exposure.[8, 10]
d) the relevant risk assessments for the clinical area.[10]
e) safe practices when administering chemotherapy. [8, 10]
f) safe disposal of cytotoxic waste.[8, 10]
g) PPE and required precautions.[8, 10]
h) disposal of excreta and other bodily fluids.[8, 10]
i) changing bed linen.
j) dealing with emergency procedures I.e. spillage, extravasation, anaphylaxis [8,10].

5.3 Educational training should be ongoing and staff competency should be demonstrated and documented.[8, 10]

5.4 Staff should also ensure that they keep up to date with any changing practices[13] and realise that they work as a team and as such have a responsibility for their own and others safety.[10]

6 Personal protective equipment (PPE)

6.1 PPE should be provided by the employer when adequate control of exposure cannot be achieved; the choice of PPE based on the risk assessment carried out under COSHH and should provide adequate protection for its intended use.[3, 5, 7, 12, 13, 16, 17] The employer should also ensure adequate training about the use of PPE.[7]

With the use of appropriate PPE and risk assessment administration of cytotoxics during pregnancy may continue.[2]

6.2 Current evidence that the PPE used should include:

a) disposable powder free latex or nitrile* (*except with etoposide) gloves and manufacturer guidance if any followed.
b) staff should also ensure they wash their hands thoroughly before and after use of gloves[12].
c) plastic apron[2, 7, 10,12,13, 16, 17].
d) specific equipment in spillage kit when required in this instance[12].

6.3 Staff should ensure they are aware of the hazards of the drugs that they are handling, the equipment and the local and national policies and procedures to prevent exposure[7, 12, 13, 16, 17]

7 Recommendations

a) local (Trust) policies and should be available for the training and competencies required as well as the operational arrangements to ensure safe practices. Staff should be informed of these policies on induction and where they can be located.
b) Network policies for the training and competencies required as well as the operational arrangements to ensure safe practices should be developed and adopted at Trust level.
c) during induction staff should be informed of all relevant policies and risk assessments and sign to say they have been informed of them and understand them **(see appendix 1)**.
d) staff should have access to relevant literature[11].
e) staff should receive annual based training update as agreed by individual Trust Lead Chemotherapy Nurse
f) confirmation of relevant training should be obtained from the employee **(see appendix 2)**.
g) with appropriate risk assessment in place **(see appendix 3)** nursing staff trying to conceive or throughout pregnancy may continue to administer chemotherapy[2].
h) the evidence available suggests that staff can work safely delivering chemotherapy/monoclonal antibody treatment during the first trimester but should be offered the option to refrain from chemotherapy/monoclonal antibody administration during the first trimester (i.e. first 12 weeks) of pregnancy if they have a particular concern. This must be after discussion and agreement by the OHD and their line manager. This may require deployment elsewhere in the department or within the Trust during this period [2, 7,11].
i) chemotherapy/monoclonal antibody administration should continue as normal during the second and third trimesters of pregnancy for those

wishing to refrain from chemotherapy administration during the first trimester of pregnancy. There is no evidence of any associated risks following the first trimester of pregnancy[11].

j) due to the potential increased risk of dermal contact and inhalation relating to spillage, pregnant workers should refrain from involvement in spillage clean-up if possible[11].

k) staff should be encouraged to inform their line manager if they are trying to, or thinking about trying to conceive, so early Occupational Health referral can be made and appropriate support provided. Risk assessment should be conducted at this point for all workers. We recommend that the risk assessment include administration of boluses, administrations of infusion, spillage, extravasation, use of PPE and disposal of excreta.

l) Occupational Health referrals should be made for all staff trying to conceive or when the employer is first informed of pregnancy to discuss any specific concerns[11].

m) Occupational Health referrals should be made for any staff member wishing discuss any concerns they have regarding chemotherapy/monoclonal antibody administration during pregnancy or whilst trying to conceive [7, 11].

n) if an employee has a particular concern which is not allayed by the Occupational Health Department and wishes not to administer chemotherapy/monoclonal antibodies throughout pregnancy, alternative duties should be offered.[11] However, this may result in redeployment for the duration of the pregnancy if appropriate duties are not available.

Monitoring of the guideline

Adherence to the Network guidelines may from time to time be formally monitored.

Author of Version 1

Rachel Hodges — Oncology Clinical Nurse Specialist, Heart of England NHS Foundation Trust

Author of Version 2

Frances Shaw — Pharmacist, Heart of England NHS Foundation Trust

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Approval Signatures

Pan Birmingham Cancer Network Governance Committee Chair

Name: Karen Deaney

Signature: Date:

Pan Birmingham Cancer Network Manager

Name: Karen Metcalf

Signature  Date December 2011

Pan Birmingham Cancer Network Site Specific Group Chair

Name: Frances Shaw

Signature:  Date December 2011

Appendix 1

Chemotherapy Safety Training - on commencing post

I confirm that I am aware of the location of the relevant Local and Network Policies relating to Chemotherapy and Monoclonal Antibodies and have received information and safety training relating to:

Topic	Date	Trainers Signature	Trainees signature
Managing Cytotoxic Spillage			
Managing Cytotoxic Extravasation			
Safe disposal of Cytotoxic waste (i.e. chemotherapy bags/syringes)			
Safe disposal of cytotoxic excreta			
Changing bed linen			
Use of Personal Protective Clothing			
Other-please state:			

Appendix 2

Chemotherapy Safety Training - at disclosure of pregnancy

I confirm that I am aware of the location of the relevant Local and Network Policies relating to Chemotherapy and Monoclonal Antibodies and have received information and safety training relating to:

Topic	Date	Trainers Signature	Trainees signature
Managing Cytotoxic Spillage			
Managing Cytotoxic Extravasation			
Safe disposal of Cytotoxic waste (i.e. chemotherapy bags/syringes)			
Safe disposal of cytotoxic excreta			
Changing bed linen			
Use of Personal Protective Clothing			
Other-please state:			

I have also received the following:

Risk assessment conducted			
Occupational Health referral			
Access to relevant Policies and information folder			

Appendix 3 - (adapted from Christie's) to be adapted to Trust Risk Assessment procedures Health & Safety Risk Assessment Form

Hazard	Risk *	Present Control Arrangements	Required Action	Date Reviewed
26. **Risk of Foetal damage/malformation due to the regular exposure to cytotoxic chemotherapy of pregnant staff or those planning future pregnancies** **Cytotoxic chemotherapy can be mutagenic, teratogenic and carcinogenic if regular contact with the drugs are made**	**L x C =R*** **1 x 3 = 3**	• **Training for all grades in safe handling, administration and disposal of cytotoxics** • **Correct Personal protective equipment must be worn** • **Needleless IV systems provided to prevent accidental Ct inoculation** • **Safe working practices devised and enforced at all times** • **Safe disposal of cytotoxic waste enforced and correct containers provided** • **Spill kits & clean up guidelines provided** • **No eating/drinking in areas where CT drugs are reconstituted, stored, administered or disposed of** • **Update policies and guidelines for all aspects of cytotoxic handling provided and enforced** • **Regular IV practices review for all staff** • **Regular risk assessment and review of equipment and control arrangements**	**Maintain a safe environment at all times not just due to pregnancy** **Extra caution when disposing of contaminated body fluids** **Extra caution when dealing with cytotoxic spills/avoid if possible** **Occupational Health Department input/support**	

		• **Risk assessment and review for all expectant mothers** • **Expectant and nursing mothers do not work in pharmacy aseptics** • **No nursing medical staff to reconstitute cytotoxics at any time**		