Systemic adjuvant therapy for women with early breast cancer

An educational kit for health care professionals practising in regional areas of Australia

Prepared by the Rural Chemotherapy Project Team
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Disclaimer

The workshop program and accompanying materials are designed to provide information on issues associated with the management of women with early breast cancer.

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Information prepared by the National Breast Cancer Centre's Project Team is intended for use only as it is prepared here. The Centre can not be responsible for any alterations made to presentation material.
Foreword

This Kit is a first for the iSource National Breast Cancer Centre (the Centre). It is the result of a close collaboration between the Centre’s Medical Oncology Expert Advisory Group and representatives from the Royal Australian College of General Practitioners and the Cancer Nurses Society of Australia.

This Kit is for use by health services that may wish to conduct educational workshops in their own region. It is designed to provide non-metropolitan health care professionals with an overview of the issues involved in the management of women receiving systemic adjuvant therapy for the treatment of early breast cancer. The materials in this Kit are evidence-based and have been peer reviewed. Furthermore, the materials have been used in five workshops conducted by the Centre in regional areas of Australia and have been shown to improve rural health care professionals’ knowledge and confidence in relation to providing systemic adjuvant therapy to women with early breast cancer.

It is anticipated that the outcomes for regions conducting workshops using this Kit may include:

- improved care for women with early breast cancer, through enhanced service delivery, communication techniques and symptom management
- improved access to quality treatment for women in regional areas and an increased awareness of treatment related issues among health professionals
- benefits for patients who are being treated for other forms of cancer

We would like to thank everyone who has been involved in this project and in the development of this Kit.

Dr Fran Boyle
Chair
Medical Oncology Expert Advisory Group
Rural Chemotherapy Project Team

We thank the members of the Rural Chemotherapy Project Team for their advice and contribution to this project.

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Acknowledgments

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We thank the members of the Rural Chemotherapy Project Team for their advice and contribution to the development of this resource.

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We would also like to thank the following people for their contributions to the development of the presentations in this Kit.

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1 Background

1.1 About the iSource National Breast Cancer Centre

The iSource National Breast Cancer Centre (the Centre) was established in March 1995 by the Commonwealth Government in response to community concerns about the human cost of breast cancer.

The Mission of the Centre is:

To work in partnership with women, health professionals, cancer organisations, researchers and governments, to improve outcomes for women with breast cancer. The Centre will strive to reduce mortality from breast cancer and to improve the wellbeing of women who are diagnosed with the disease.

The Centre has been established to improve breast cancer control by:

- analysing research and making it readily available to women and health professionals
- developing, disseminating and encouraging the adoption of clinical guidelines to improve the diagnosis, treatment and support of women with breast cancer
- providing accurate and accessible information to well women, women with breast cancer, primary care providers and breast cancer specialists
- developing a national monitoring system to provide information about all aspects of breast cancer
1.2 Improving care for women receiving systematic adjuvant therapy for the treatment of early breast cancer

Breast cancer and clinical practice guidelines

Each year in Australia approximately 10,000 women are diagnosed with breast cancer. Breast cancer is the most common cause of death from cancer in Australian women, with around 2600 women dying from the disease each year.

In 1995 the National Health and Medical Research Council (NHMRC) released the Clinical practice guidelines for the management of early breast cancer, and the second edition of these guidelines will be released by the National Breast Cancer Centre in 2001. The aim of the guidelines is to assist health practitioners to make decisions about appropriate health care for specific clinical circumstances by summarising the best available evidence.

Providing systematic adjuvant therapy in rural and remote areas

The Clinical practice guidelines for the management of early breast cancer (2nd edition) indicate that systemic adjuvant therapy, which includes all forms of hormonal manipulation and/or cytotoxic chemotherapy, has the potential to improve survival for women with breast cancer.

Approximately 30% of women diagnosed with breast cancer live in rural or remote areas of Australia and there is increasing pressure for chemotherapy services to be delivered in these areas. While it is reported that systemic adjuvant therapy and follow-up can be provided locally, the provision of such therapy in these regions can present a number of challenges. Many rural and remote regions of Australia do not have a resident medical oncologist, and women with breast cancer who live in these areas may be seen by an oncologist who visits their region or may be required to travel to an oncology clinic for an initial consultation.
General practitioners and nurses working in rural and remote areas may be closely involved and are conveniently located to provide care to women receiving systemic adjuvant therapy. However, it is important for health services to recognise that the preparation, administration and disposal of chemotherapeutic agents may expose health care professionals to cytotoxic waste, and any local service delivery should not be at the expense of the safety and quality of the care delivered. In addition, any complications of treatment may require further management from a medical oncologist, who may be at a distant site. Furthermore, health care professionals in rural and remote areas may experience difficulty accessing the necessary resources, disposal facilities and other services relevant to the care of women with early breast cancer.

**Education for health professionals practising in rural and remote regions of Australia**

Health care professionals involved in the provision of systemic adjuvant therapy need to be kept up to date with current information, including evidence-based clinical practice guidelines, to ensure their care of women with early breast cancer is in accord with best practice.

A survey of general practitioners found that many perceived their training as inadequate to meet the needs of breast cancer patients in the areas of provider communication, health care system needs and interpersonal needs.

Similarly, rural nurses have expressed a need to access relevant information and training. However, it is recognised that this may be limited by a number of factors, including:

- cost (to the employer and employee)
- lack of replacement staff
- family commitments
- lack of time
- inappropriateness of training programs
- lack of information about the availability of programs
- lack of commitment by employers

**Systemic adjuvant therapy for women with early breast cancer**

**Background information**
2 About this Kit

In 2000 and 2001, the iSource National Breast Cancer Centre undertook the Rural Chemotherapy Project to develop an educational workshop program for rural health care professionals who are involved in the provision and/or management of women receiving systemic adjuvant therapy for the treatment of early breast cancer in non-metropolitan regions of Australia.

This project involved the conduct of five workshops in regional areas of Australia in 2000 and 2001, to:

- provide information about best practice to health professionals working in regional areas of Australia
- provide education to health professionals on the issues surrounding the management and supportive care of women receiving systemic adjuvant therapy for the treatment of early breast cancer
- facilitate communication links between general practitioners and nurses with specialist services
- assist health professionals in identifying and providing psychosocial support to women and their families

Using the workshop program detailed in this Kit, participants who attended one of the five workshops held by the Centre demonstrated an increase in knowledge and confidence across all program topics. Feedback received indicated that this workshop format was an effective form of education, and that it provided an opportunity for planning and establishing communication links at the local level.

This Kit has been developed as a result of the Rural Chemotherapy Project and is considered suitable for use by other health services that would like to conduct a workshop in their own region. The workshops provide health care professionals with an overview of the issues involved in the management of women receiving systemic adjuvant therapy for the treatment of early breast cancer.
It should be noted that the workshop program is not intended as a training course for chemotherapy administration. However, the workshop does provide an opportunity to update participants on the latest evidence-based recommendations and information on systemic adjuvant therapy. The workshops also provide an opportunity to enhance networks and establish communication links between all health care providers at the local level.

This Kit contains a recommended workshop program, pre-prepared presentations, suggested reading material for participants and evaluation forms.

The pre-prepared presentations have been developed by Project Team Members and have been peer reviewed.

Source documents for the presentation material include:

- Clinical practice guidelines for the management of early breast cancer, 2nd edition
- Psychosocial clinical practice guidelines: providing information, support and counselling for women with breast cancer
- WorkCover Guidelines for handling cytotoxic drugs and related waste in health care establishments
- Peer reviewed journal articles
3 Workshop organisation

3.1 Workshop participants

The intended audience for the workshops is health professionals (mainly general practitioners and registered nurses) involved in the administration of chemotherapy; those wishing to become involved; and those who have some involvement in the care of women who are receiving chemotherapy for early breast cancer. Other health professionals such as counsellors, social workers, community nurses and hospital managers may also find the program relevant to their work and should be encouraged to attend.

3.2 Key organisers

The local medical oncologist (visiting or resident), local hospital managers, local Divisions of General Practice, local nursing organisations and other supportive care staff should be involved during the planning and coordination of the workshop.

The local medical oncologist (visiting or resident) should be involved in any such workshop being conducted in the local area. As indicated in the attached workshop program, the local medical oncologist plays a key role in the delivery of the program information. Local oncology nurses also play an important role in the conduct and organisation of the workshop program.

3.3 Conduct

The 1½ day workshops conducted by the National Breast Cancer Centre were held over a weekend, either on a Friday evening and all day Saturday or all day Saturday and Sunday morning. The evaluation of the workshops demonstrated that participants preferred the workshop be held on a Friday evening and all day Saturday.
The program has only been evaluated when conducted as a face-to-face workshop and it is therefore recommended that the program be conducted in a face-to-face setting. This format was chosen deliberately, as it encourages participant interaction as well as allowing local networks and communication links to be developed. Other organisers may feel that this program could also be conducted as a series, with the program content covered over a number of weeks, or via a different medium, such as webcasting or videoconferencing. However, the success of such methods has not been evaluated. Regardless of how the workshop is conducted, it is recommended that all components of the workshop program be covered.

Before the date of the workshop is set, organisers should be aware of any other conflicting educational events being held.

### 3.4 Venue

Ideally, the venue should be able to provide each participant with a desk and a chair. The workshops conducted by the Centre utilised hospital education rooms, university tutorial rooms or hotel conference rooms. Depending on numbers of participants, a second room may be required for the break-out groups. The workshops conducted by the Centre had an average of 28 participants.

### 3.5 Workshop program

The workshop program was not designed as a certified training program, but rather to educate participants about the issues associated with the use of systemic adjuvant therapy for the treatment of early breast cancer.

While the program focuses on breast cancer, the material presented may also be useful for the management of other cancers.
The recommended program covers the following topics:

- The role of adjuvant chemotherapy in early breast cancer
- Chemotherapy: managing the side effects
- Endocrine therapy
- Safe administration and handling of cytotoxic drugs and their related wastes
- Legal issues
- Communication and psychosocial issue
- Break-out groups to review local practice issues

The recommended program with suggested time allocation is attached. The total workshop program duration is nine hours (excluding breaks).

Socialising time is an important opportunity for improving networks between local and visiting health professionals. A dinner, held at a local restaurant on the evening between the two days of the workshop program, provides further time for participants to discuss issues raised.
### Recommended workshop program

**Systemic adjuvant therapy for women with early breast cancer: issues associated with administration, side effects and communication**

**A workshop for health professionals**

<table>
<thead>
<tr>
<th>Suggested time allocated</th>
<th>Topics</th>
<th>Recommended presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 30 mins</td>
<td>Registration and pre-program evaluation</td>
<td>Workshop organisers</td>
</tr>
<tr>
<td>2. 10 mins</td>
<td>Welcome</td>
<td>Local representative</td>
</tr>
<tr>
<td>3. 10 mins</td>
<td>Presentation of case scenarios</td>
<td>Medical oncologist</td>
</tr>
<tr>
<td>4. 50 mins</td>
<td>The role of adjuvant chemotherapy in early breast cancer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pharmacokinetics</td>
<td>Medical oncologist</td>
</tr>
<tr>
<td></td>
<td>• Drug classes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Dose maintenance issues</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Commonly used regimens — evidence of efficacy?</td>
<td></td>
</tr>
<tr>
<td>5. 1 hr 20 mins</td>
<td>Chemotherapy: managing the side effects</td>
<td>Medical oncologist</td>
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<tr>
<td></td>
<td>• Supportive care</td>
<td></td>
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<tr>
<td></td>
<td>• CSFs</td>
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<tr>
<td></td>
<td>• Antibiotics</td>
<td></td>
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<tr>
<td></td>
<td>• Antiemetics</td>
<td></td>
</tr>
<tr>
<td>6. 30 mins</td>
<td>Endocrine therapy</td>
<td>Medical oncologist</td>
</tr>
<tr>
<td></td>
<td>• Tamoxifen</td>
<td></td>
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<tr>
<td></td>
<td>• Ovarian ablation</td>
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</table>
7. 45 mins  Safe administration and handling of cytotoxic drugs and their related wastes  Trained oncology nurse

8. 50 mins  Legal Issues  Lawyer

9. 1 hr 30 mins  Communication and psychosocial issues  Health professional with communication skills training

10. 1 hour  Break-out groups to:
    • Review current local practice
    • Identify local issues for GPs and nurses
    • Identify areas to develop local protocols
    • Psychological care  Local representatives (eg local oncology nurse, local medical oncologist)

11. 1 hour  • Break-out groups report back and review issues
    • Follow-up plan on issues identified  Local representatives (eg local oncology nurse, local medical oncologist)

12. 15 mins  Post-program evaluation  Workshop organiser

Close
3.6 Delivery of workshop program

Each topic covered in the workshop program should be presented by a suitably qualified health professional. The topics should be presented in an informal lecture style utilising the pre-prepared slides attached. Audience participation, including questions, should be encouraged to build networking opportunities.

It is intended that the program be delivered with assistance from:

- a medical oncologist*
- an oncology nurse
- a psychosocial expert
- a lawyer

* In workshops held by the National Breast Cancer Centre, presentations were delivered by the local medical oncologist and another medical oncologist. Due to the number of medical oncology presentations, it may be useful to consider this approach or alternatively to conduct presentations over a series of weeks.

Presenters at the workshop should be experienced with the presentation topic. For example:

- the local medical oncologist should be familiar with the Clinical practice guidelines for the management of early breast cancer (2nd edition)
- the oncology nurse should be familiar with guidelines for the safe handling of cytotoxic drugs and their related wastes
- the nominated presenter for the communications issues and psychosocial support should have undertaken formal communication training and be familiar with the Psychosocial clinical practice guidelines: providing information, counselling and support for women with breast cancer.

The Centre coordinates communication skills training.

Contact details for the National Breast Cancer Centre
Telephone: 02 9334 1700
Web site: www.nbcc.org.au
• A lawyer, preferably a specialist in occupational health and personal injury, should deliver the presentation about the legal issues associated with the administration of cytotoxic drugs and answer any questions which may arise. The Australian Plaintiff Lawyer's Association (APLA) may be able to assist workshop organisers in identifying appropriate local lawyers.

**Contact details for APLA**

Level 1
128 Chalmers Street
Surry Hills NSW 2010
Telephone: 02 9698 1700

The recommended workshop program attached outlines recommended presenters for each program topic.

### 3.7 Promotion

Extensive promotion of the workshop is required to ensure a high level of participation across the relevant health care professions. It is recommended that the promotion of the workshop commence at least eight weeks prior to the workshop date.

Each organisation, including local Divisions of General Practice, local hospitals and local nursing organisations, should actively encourage their members to participate. Workshop organisers should mail information to key groups and promote the workshop through local newsletters. An example of a promotional flier is attached. Organisers should also seek media involvement to assist with the promotion of the workshop. Workshop organisers may wish to consider a media release closer to the start date of the workshop to promote the workshop as an educational activity in the local area.
Sample promotional flier

Systemic adjuvant therapy for women with early breast cancer: issues associated with administration, side effects and communication

A workshop for health care professionals and workers

The <<name of health area or organisers>> are conducting a workshop for health care professionals involved in the management of women receiving systemic of adjuvant therapy for the treatment of early breast cancer.

The workshop, in conjunction with the local medical oncologist, will be held over 1½ days and will include the following program topics:

- The role of adjuvant chemotherapy in early breast cancer
- Chemotherapy: managing the side effects
- Safe administration and handling of cytotoxic drugs and their related wastes
- Legal issues
- Communication skills
- Identification of local issues

When <<Dates>>
Where <<Location>>
Time <<Hours each day>>
Workshop cost <<If applicable>>
Workshop Dinner <<If being held, location and cost>>
CME <<Number of points if approved by RACGP>>
Contact person <<Name, phone, fax, e-mail>>

To register, please fax this page to <<fax number>>

Name
Occupation
Organisation
Address
Telephone
Facsimile
E-mail

Workshop dinner (if applicable) Yes ❑ Number attending _____ No ❑
### 3.8 Applying for Continuing Medical Education points from the Royal Australian College of General Practitioners

To help encourage the attendance of general practitioners, it is suggested that Continuing Medical Education (CME) points should be applied for from the Royal Australian College of General Practitioners (RACGP). For accreditation to be received, the program must meet the eligibility criteria set by the RACGP. This includes demonstrating that:

- its primary purpose is to improve quality of patient care
- its content demonstrates high clinical and ethical standards
- general practitioners participate in planning
- a learning needs assessment is conducted
- there are clear learning objectives
- the educational activity is evaluated

An evaluation component will also be required (see Section 5 ‘Evaluation’ for suggestions).

**Contact details for the RACGP**

College House  
1 Palmerston Crescent  
South Melbourne Victoria 3205  
Telephone: 03 9214 1414  
Web site: www.racgp.org.au

You will need to allow six weeks for this approval process.

The National Breast Cancer Centre was granted CME points for the conduct of the workshops that were previously conducted using the model included in this Kit. New workshops will be required to submit a new CME application to the RACGP.
3.9 Funding

The cost of coordinating a workshop can be kept to a minimum. Costs incurred may include catering, venue hire (if outside hospital premises), computer projection equipment and material for workshop participants. Costs may also need to cover travel and accommodation expenses for presenters if they do not reside in the local area. Organisations may seek sponsorship from their own organisation or external groups to cover these costs and to avoid having to charge a registration fee for participants.

3.10 Workbook for participants

It is suggested that a comprehensive workbook be available for the workshop participants, which includes:

- a copy of the slides used in each presentation (included in Section 4)
- accompanying literature, including:
  - a copy of the Psychosocial clinical practice guidelines: providing information, support and counselling for women with breast cancer
  - Guidelines for handling cytotoxic drugs and related waste in health care establishments (applicable for Queensland and NSW)
  - related journal articles

Copies of publications by the Centre, such as the Psychosocial clinical practice guidelines, can be obtained via:
Telephone: 1800 624 973
Web site: www.nbcc.org.au

Guidelines for handling cytotoxic drugs and related waste in health care establishments are available in NSW and Queensland:

NSW WorkCover Authority
400 Kent Street
Sydney NSW 2000
Telephone: 02 9267 9652
Web site: www.workcover.nsw.gov.au
Antibiotic guidelines, which include information about the management of neutropaenic sepsis, are available from Therapeutic Guidelines Limited.

**Therapeutic Guidelines Limited**
Level 2, 55 Flemington Road
North Melbourne Victoria 3057
Telephone: 1800 061 260
Web site: www.tg.com.au
4 Workshop materials

4.1 Introduction

For each program topic the following material is provided to assist the delivery of the presentation:

- learning objectives for each presentation
- pre-prepared Microsoft PowerPoint 97 slides provided on CD-ROM
- suggested accompanying handout material

Information prepared by the iSource National Breast Cancer Centre’s Project Team is intended for use only as it is prepared here. The Centre can not be responsible for any alterations made to presentation material.

Overviews of each of the topic presentations are given below.

A list of suggested accompanying handout material for each presentation is attached.

The local medical oncologist and/or local oncology nurse/s may also wish to include copies of local policies and procedures, which they may wish to review during the course of the workshop.

4.2 Presentation overviews

Each presentation, in Microsoft PowerPoint 97 format, is provided on the enclosed CD-ROM. A full printed version of each of these presentations is included in this Kit.
• **Case Scenarios**

The workshop program centres on two fictional case scenarios, each focusing on a hypothetical woman living in a rural area (‘Linda’ and ‘Marjorie’). This strategy assists with audience participation throughout the conduct of the workshop. Introductory slides are presented on the case scenarios, and hypothetical questions are presented throughout the remaining workshop presentations.

*Duration:* 10 minutes  
*Recommended presenter:* Medical Oncologist

• **The role of adjuvant chemotherapy in early breast cancer**

This presentation provides background information on chemotherapy. It includes the general principles on the greater efficacy of chemotherapy in tumours of limited size, the general mechanism of action using a scheme of the cell cycle and the specific mechanism of action of the common drugs used in adjuvant chemotherapy for breast cancer. The presentation details clinical trial findings that have been influential in the development of clinical practice guidelines, including the major overview of the Early Breast Cancer Trialists’ Collaborative Group and specific trials addressing questions of chemotherapy dose, optimal drug combinations and combination with tamoxifen. Potential future research trends and novel therapeutic areas are also considered. The series of ‘bicycle slides’ draws an analogy between disrupting the cell cycle and the motion of a bicycle. These slides demonstrate the impact of drugs on the cell cycle and the ability of combinations of drugs to have a more powerful impact on interrupting cell proliferation than any one drug alone.

*Duration:* 50 minutes, including question time.  
*Recommended presenter:* Medical Oncologist
• **Chemotherapy: management of the side effects**

The presentation considers the possible side effects of the chemotherapy, preventative measures, symptom control and treatment. The presentation also identifies medical emergencies and how to alert patients to be aware of these side effects. This is a long but important presentation.

*Duration*: 1 hour 20 minutes, including question time. This duration is recommended as this presentation is usually interspersed with frequent questions and discussion.

*Recommended presenter*: Medical Oncologist

• **Endocrine therapy**

The presentation covers the use of anti-oestrogens (eg tamoxifen), and ovarian ablation in the treatment of early breast cancer, their subsequent possible effects and their management.

*Duration*: 30 minutes, including question time.

*Recommended presenter*: Medical Oncologist

• **Safe administration and handling of cytotoxic drugs and their related waste**

This presentation covers key principles relating to the safe preparation, storage, transport, administration, waste disposal and spill management of cytotoxic drugs and their related wastes. The inclusion of a practical component is also recommended during this presentation, in which a mock-up of a cytotoxic spill is performed and its containment is followed by discussion of the principles outlined in relevant guidelines.

*Duration*: 45 minutes, including question time.

*Recommended presenter*: Oncology Nurse
• Legal issues

This presentation, developed by a lawyer with clinical oncology experience, covers the legal issues associated with the administration of chemotherapy and topics including informed consent, assault and battery, negligence, foreseeability, damages and settlements versus judgements. The presentation also covers examples of case law and responsibilities of health care professionals.

Duration: 50 minutes, including question time.
Recommended presenter: Lawyer

• Communication and psychosocial issues

This presentation was developed in association with the iSource National Breast Cancer Centre’s Psychosocial Expert Advisory Group, and covers issues such as effective communication techniques, screening for concerns, providing emotional support, identifying anxiety and depression, lymphoedema, body image and family support. It is important for the presenter to make this an interactive presentation and to involve participants by asking them about their own experiences as health professionals.

Duration: 1 hour 30 minutes, including question time.
Recommended presenter: Health care professional with communication skills training

• Identification of local issues and development of protocols

This part of the program involves participants taking part in break-out groups and, with the assistance of local representatives, identifying local practice issues that may have been raised during the course of the workshop and facilitating the development and/or enhancement of local protocols and support networks. For participants and presenters, this can be one of the most valuable components of the workshop.
**Breakout groups**

It is suggested that participants should be broken into small groups of up to 10–15 people. A facilitator (eg medical oncologist, oncology nurse, communications expert) in each group should lead discussion regarding local issues that have arisen during the presentations. Such issues may include: development of local policies and procedures; future education for patients and staff; further communication skills training; and development of communication networks. Participants should be encouraged to suggest strategies to solve any problematic issues. A whiteboard is a handy tool here.

*Suggested duration:* 1 hour.

**Reporting back to the main group**

It is suggested that facilitators from the break-out group report back to the main group on the issues discussed during the break-out groups, and identify strategies for dealing with these issues. The main group may wish to nominate representatives to be responsible for actioning the issues identified and a suggested timeline.

*Suggested duration:* 45 minutes.
CASE SCENARIOS

Linda Smith
- 39-year-old woman
- Lives in a rural town
- Married to Bill, a farmer. Assists him with book-keeping
- Two children at primary school:
  - Anna 8
  - Brett 5

Linda’s breast cancer
- She discovers a lump in her right breast
- Presents to her GP
  - ultrasound, mammography – suspicious
- Surgeon does FNAB = malignant cells
- Lumpectomy and axillary dissection performed
- Referred to medical oncologist for consideration of adjuvant therapy

Marjorie Jones
- 55-year-old woman
- Lives on a property 100 km from oncology treatment centre and 30 km from her GP
- Married to Max, a farmer. Assists him with farm work and book-keeping
- Two children
  - Rich 25 – apprentice mechanic
  - Jeff 23 – at Agricultural college
- Postmenopausal
  - was depressed at menopause, improved on HRT

Marjorie’s breast cancer
- She has a mammogram at the caravan and is recalled
- Ultrasound, repeat mammography – suspicious
- FNAB = malignant cells
- Lumpectomy and axillary dissection performed = margins involved with Lobular Carcinoma in Situ
- Mastectomy performed 1 week later
- Referred to medical oncologist for consideration of adjuvant therapy
Learning Objectives

The role of adjuvant chemotherapy in early breast cancer

After this presentation, participants should be able to:

- understand how chemotherapy acts on malignant cells
- identify the differences between key chemotherapy drugs that may be used in the adjuvant setting
- understand the rationale for maintaining dose intensity
- identify future research directions in adjuvant therapy for breast cancer
- understand the indications for chemotherapy for breast cancer in the adjuvant setting

Suggested accompanying handout material

Suggested attached material


Further reading


THE ROLE OF ADJUVANT CHEMOTHERAPY IN EARLY BREAST CANCER

Adjuvare (Latin) = to help

The use of systemic therapy soon after primary local therapy where:
- There is a significant risk of death from tumour
- Death is due to occult metastatic disease
- Effective agents are available
- Acceptable
  - acute toxicity
  - long-term safety
  - cost

Does early breast cancer fulfil these principles?

Risk of Death?
- Stage I Good Prognosis: 10-20% risk of death at 10 years
- Stage II Poor Prognosis: 20-40% risk of death at 10 years
- Stage III Poor Prognosis: 40-80% risk of death at 10 years
- Within stage 1, a poor prognostic subset has been identified
  - size >2cm
  - high histological grade
  - oestrogen receptor negative
  - lymphatic and vascular invasion

Is death due to occult metastatic disease?
- Undetectable blood borne metastases cause relapse in bone, liver, lung, brain
  - even in the absence of node metastases, blood borne spread can occur
- Overt metastatic disease is incurable with current therapies

Microscopic metastatic disease can be successfully treated

- Better perfusion of smaller volume disease
- Less drug resistance
- More favourable kinetics of cell growth
  - higher growth fraction
  - chemotherapy most active in rapidly dividing cells

Tumour growth

- undetectable cancer
- detectable cancer
- Limit of clinical detection
- Host death
Why can't clinical disease be cured?

Linda’s pathology report
Infiltrating ductal carcinoma
- 2.5 cm diameter
- high grade
- oestrogen and progesterone receptor negative
- margins of lumpectomy clear
- 15 axillary nodes negative

Marjorie’s pathology report
Infiltrating lobular carcinoma
- 3 cm diameter
- moderate grade
- oestrogen and progesterone receptor positive
- margins of lumpectomy unclear, residual LCIS at mastectomy
- 2/20 axillary nodes positive (apical node clear)

Linda’s initial questions
- What is her prognosis? (estimated survival at 5 and 10 years)
- Will any additional treatment significantly improve her survival?
- Will any additional treatment significantly reduce her risk of local recurrence?
- Where can treatment be given?
- Will treatment make her hair fall out?

Marjorie’s initial questions
- What is her prognosis? (Estimated survival at 5 and 10 years)
- Will any additional treatment significantly improve her survival?
- Will any additional treatment significantly reduce her risk of local recurrence?
- Where can treatment be given?
- Will treatment make her hair fall out?

Does effective systemic therapy exist in early breast cancer?
Supported by Level 1 evidence
1. Combination chemotherapy
2. Hormone manipulation in receptor positive disease
   - ovarian ablation/suppression
   - Tamoxifen
Is chemotherapy tolerable?

• Acute toxicity
• Long-term safety
• Cost
  – for node positive patients, chemotherapy is one of the most cost-effective interventions in current medical practice
  – it has been estimated to cost US$1000 per QALY (quality adjusted life year)

Principles of chemotherapy

• Cancer cells must be sensitive to the agent
• Drugs must reach the malignant cell
• If a drug is phase specific it must be given frequently enough to be present when the majority of cells are cycling
• Malignant cells must be destroyed before resistance develops
Mitotic inhibitors
eg Taxanes

Mechanism of action
• Binding to tubulin to prevent depolymerisation of the spindle Act in M phase

Topoisomerase inhibitors
eg Doxorubicin

Mechanism of Action
• Act in S phase

Anti-metabolites
eg 5FU, Methotrexate

Mechanism of action
• Inhibition of DNA and RNA synthesis by either inappropriate purine or pyrimidine synthesis
  • Act in S phase

Alkylating agents
eg Cyclophosphamide

Mechanism of action
• Cross-linking of DNA and single strand breaks by covalent linking of reactive metabolites that are electron deficient
  • Act in G/M and G1/S phases
Combination chemotherapy
• Active single agents
• Toxicities
  – different type
  – different time
• Act in different parts of cell cycle
• Different mechanism of action
• Synergism

Chemotherapy: effect on outcome

<table>
<thead>
<tr>
<th>Overall survival</th>
<th>Age</th>
<th>Relative risk reduction</th>
<th>Nodal status</th>
<th>Absolute difference at 10 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>15%</td>
<td>Node negative</td>
<td>1.7%</td>
<td></td>
</tr>
<tr>
<td>&lt;50</td>
<td>12%</td>
<td>Node positive</td>
<td>2.4%</td>
<td></td>
</tr>
<tr>
<td>50-69</td>
<td>11%</td>
<td>Node negative</td>
<td>0.3%</td>
<td></td>
</tr>
<tr>
<td>Node positive</td>
<td></td>
<td></td>
<td>0.4%</td>
<td></td>
</tr>
</tbody>
</table>

Data from Early Breast Cancer Trials' Collaborative Group, 1998

Clinical practice guidelines for the management of early breast cancer (2nd edition)

• Moderately prolonged (several months) combined chemotherapy is recommended, as it is more effective than single agent therapy and than treatment lasting less than one month.

• Anthracycline-containing regimes are superior to cyclophosphamide, methotrexate and 5-fluorouracil (CMF) for both recurrence-free survival and overall survival at the increased risk of alopecia, cardiac toxicity and febrile neutropenia.

Dose intensity is important to outcome in adjuvant cytotoxic therapy, at least in dose ranges achievable without colony stimulating factor (CSF) support.
The role of dose adjuvant chemotherapy

- Dose reductions below the maximally tolerated range without growth factors are harmful
- Two- to four-fold dose increases for cyclophosphamide do not improve outcome
- There are threshold doses for doxorubicin and epirubicin for optimal efficacy

Randomised trials of adjuvant HDCT for primary breast cancer – 3 Year OS

<table>
<thead>
<tr>
<th>Author</th>
<th>HD</th>
<th>OS</th>
<th>ST</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hortobagyi</td>
<td>58</td>
<td>77</td>
<td></td>
<td>0.271</td>
</tr>
<tr>
<td>Rodenhuis</td>
<td>85</td>
<td>78</td>
<td></td>
<td>0.837</td>
</tr>
<tr>
<td>Peters</td>
<td>79</td>
<td>80</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Bergh</td>
<td>76</td>
<td>80</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Redenhuis</td>
<td>NS</td>
<td>NS</td>
<td></td>
<td>0.31</td>
</tr>
</tbody>
</table>

Tamoxifen alone or with chemotherapy for postmenopausal women with ER+ breast cancer

<table>
<thead>
<tr>
<th></th>
<th>TAM</th>
<th>TAM+CAF</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-yr DFS</td>
<td>67%</td>
<td>76%</td>
<td>0.0001</td>
</tr>
<tr>
<td>Proportional reduction: 27%; absolute: 9%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-yr OS</td>
<td>79%</td>
<td>84%</td>
<td>0.01</td>
</tr>
<tr>
<td>Proportional reduction: 24%; absolute: 5%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tamoxifen Plus (F) AC for postmenopausal women with ER+ breast cancer - 5Yr DFS

<table>
<thead>
<tr>
<th>Study</th>
<th>Tamoxifen</th>
<th>Tamoxifen + chemotherapy</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSC 39321 b-16</td>
<td>61%</td>
<td>68%</td>
<td>0.01</td>
</tr>
<tr>
<td>SWOG 8814</td>
<td>67%</td>
<td>76%</td>
<td>0.0001</td>
</tr>
</tbody>
</table>
How do we decide?

• Assess absolute risk
  – eg node negative, >2cm, ER negative, high grade, young age
• Determine absolute benefit of therapy
• Assess potential toxicity of therapy
  – eg cardiac disease
• Discuss logistics
• Discuss risk/benefit ratio to patient
• Negotiate an acceptable compromise

The basic adjuvant choices

<table>
<thead>
<tr>
<th>ER-</th>
<th>ER+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation</td>
<td>Observation</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>Endocrine therapy</td>
</tr>
<tr>
<td>Combined therapy</td>
<td></td>
</tr>
</tbody>
</table>

Linda’s recommended therapy

• ER -ve, node -ve, grade III tumour
• Chemotherapy improves survival
  – 4 cycles at 3 week intervals, IV day 1
  – doxorubicin and cyclophosphamide
  – given at the local clinic
• Radiotherapy reduces local recurrence
  – takes 6 weeks (Monday – Friday)
  – given in major centres
• Her hair will fall out

Marjorie’s recommended therapy

• ER +ve, node +ve, large tumour
• Chemotherapy improves survival
  – 6 cycles at 4 week intervals
  – cyclophosphamide orally 14 days
  – methotrexate, 5FU IV day 1 and 8
  – given at the local clinic
• Tamoxifen improves survival
  – 5 years, 20 mg/day. Oral tablet
• Her hair will fall out gradually, maybe not completely

Effects of optimal therapy on breast cancer mortality

<table>
<thead>
<tr>
<th>Treatment modality</th>
<th>Reduction in odds of death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local therapy</td>
<td>10%</td>
</tr>
<tr>
<td>Tamoxifen</td>
<td>30%</td>
</tr>
<tr>
<td>Anthracycline-based</td>
<td>20%</td>
</tr>
<tr>
<td>chemotherapy</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>50%</td>
</tr>
</tbody>
</table>

Research trends

• Who needs therapy?
  – biological markers of aggressiveness
    – eg HER2 oncogene expression
  – detection of circulating tumour cells
• Therapies based on tumour biology
  – preventing bone metastases with bisphosphonates
  – antibodies to oncogenes (Herceptin)
  – anti-angiogenic agents
  – new hormones
  – vaccines
Learning Objectives

Chemotherapy: managing the side effects

After this presentation, participants should be able to:

- understand how to manage febrile neutropenia
- understand how to manage stomatitis
- understand the association between diarrhoea and febrile neutropenia
- recognise fatigue
- assess the time to onset of side effects after chemotherapy
- prevent nausea and vomiting

Suggested accompanying handout material

Suggested attached material


CHEMOTHERAPY
MANAGING THE SIDE EFFECTS

• Nausea and vomiting
• Stomatitis
• Diarrhoea
• Myelosuppression
• Alopecia
• Skin reactions
• Fatigue
• Cognitive changes
• Long-term side effects

Nausea and vomiting

The goal of anti-emetic therapy is to prevent vomiting beginning with the initial cycle of chemotherapy
• Improve quality of life
• Improve compliance
• Prevent anticipatory and refractory nausea and vomiting

Nausea and vomiting

Prognostic factors
• Treatment-related
  – chemotherapy agent, dose, schedule
• Patient-related
  – gender
  – age
  – prior chemotherapy
  – ethanol consumption
  – other (eg opiates)

Nausea and vomiting

3 syndromes
• Acute emesis (<24 hours)
• Delayed emesis (24-96 hours)
  – eg cisplatin/carboplatin - mechanism unknown
  – 5HT-3 antagonists no better than other agents
• Anticipatory emesis
  – conditioned response in patients with poorly controlled nausea and vomiting
  – best treatment is prevention
  – lorazepam/anxiolytics/behavioural interventions

Nausea and vomiting

Non-pharmacological measures
• Clear fluids prior to chemotherapy
• Bland foods, served at room temperature
• Small amounts frequently
• Avoid food with strong odours
• Diversional (eg read a book, watch TV, gentle exercise) and relaxation techniques (relaxation tapes, meditation)
Nausea and vomiting

Pharmacological measures
• Depends on emetogenic potential of the chemotherapy being administered
  – low potential
  – medium potential
  – high potential

Nausea and vomiting

Low emetogenic potential (eg Fluorouracil, taxanes)
• Simple antiemetics
  – metoclopramide
  – prochlorperazine
  – give pre chemotherapy and 6hr prn post chemotherapy
  – 5HT-3 antagonist only if patient experiences refractory nausea and vomiting

Nausea and vomiting

Medium emetogenic potential (e.g. CMF / AC)
Consider:
• Pre chemotherapy
  – 5HT-3 antagonist iv or oral
    plus dexamethasone
• Post Chemotherapy
  – 5HT-3 antagonist orally for 48 hrs
  – metoclopramide and prochlorperazine po prn
    or prochlorperazine suppositories

Other useful medication for consideration
• For refractory vomiting/unable to tolerate oral medication, example
  – lorazepam (can be given orally or sublingually)
  – prochlorperazine suppositories
SEEK ADVICE IF SIMPLE MEASURES NOT WORKING

Nausea and vomiting

• Very few patients need to be admitted for control of emesis
  
  • Prevention is the key

Case studies

Linda
• Has severe vomiting on D3 post cycle 1 of doxorubicin, cyclophosphamide
• Has taken ondansetron 8mg po bd for 4 doses, plus metoclopramide 10mg po tds, but still vomiting
• Keeping some fluids down and not significantly dehydrated

How would you manage?
Linda
• In day ward for cycle 2. Begins to vomit while chemotherapy being administered

How would you manage?

Marjorie
• Calls you on day 10 of first cycle of chemotherapy with problem of nausea.
• Felt OK first few days, then persistent, low-grade nausea despite taking anti-nausea medication

How would you manage?

Stomatitis
Why?
• Rapidly dividing cells

Which drugs?
• Doxorubicin, cyclophosphamide and 5-fluorouracil

Secondary infection?
• Herpes
• Candidiasis

Stomatitis
Prevention
• Ice to suck at time of 5-FU chemotherapy
• Properly fitted dentures
• Soft toothbrush, non-alcoholic mouthwash (eg chlorhexidine) after meals
• Avoid spicy foods, serve food at room temperature
• Maintain good nutrition

Stomatitis
Treatment
• Non-alcoholic mouthwash (eg. Benzydamine, chlorhexadine)
• Analgesia
  – may be required for moderate to severe
  – stomatitis
  – lignocaine viscous
  – morphine if severe
  – cocaine mouthwash if severe
  – seek advice
• IV rehydration

Stomatitis
• Do not start next chemotherapy cycle until resolved
• May require a dose reduction or extra preventative measures

CONSULT MEDICAL ONCOLOGIST
**Marjorie**
- Develops significant stomatitis day 6 of second cycle. Can eat with difficulty and fluids OK
- What drugs may have caused it? Differential?
  - How would you manage this cycle?
  - How would you manage next cycle?

**Diarrhoea**
- Caused by destruction of normal rapidly dividing cells of GIT
- Certain chemotherapy agents more likely eg 5-FU, methotrexate
- Risks include dehydration, ARF
- If correlates with neutropenia, higher incidence of bacteraemia

**Diarrhoea**
**Treatment**
- Increase fluid intake – IV if necessary
- Eliminate dairy products, high fibre foods
- Check electrolytes if severe (?K suppl)
- Rule out infection- stool culture
- Antidiarrhoeals- loperamide/lomotil
- Warn about fever

**Diarrhoea**
- Withhold further chemotherapy until resolved
- May require dose reduction

**CONSULT MEDICAL ONCOLOGIST**

**Myelosuppression**
- Stem cell suppression
  - alkylating drugs (cyclophosphamide)
- Suppression of proliferating committed cells (granulocytes and platelets)
  - majority of chemotherapy drugs
- Erythroid suppression
  - cisplatin
- Minimal suppression
  - hormones

**Myelosuppression**
**Neutropenia**
- Nadir at 7 to 14 days
- Bacterial infections mostly opportunistic normal flora
- Report T>38°C = medical emergency
- Encourage good personal hygiene
- No dental procedures
- No rectal medication/procedures
- Prophylactic use of G-CSF in subsequent cycles
**G-CSF**

- To avoid dose delays/dose reductions in subsequent cycles
- S-100 reimbursement
  - ‘patients with certain malignancies being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission’ eg adjuvant chemotherapy breast cancer
- Start day after chemotherapy, give for 7 – 10 days; once daily dose subcutaneously

**Myelosuppression**

**Thrombocytopenia**

- Nadir may be later D14 – D21
- Avoid aspirin
- Avoid invasive procedures including IM injections
- Soft toothbrush; avoid dental floss
- Consider OCP/progestogen if heavy menstrual bleeding

**Anaemia**

- May take 2 or more months to develop
- Fatigue, dyspnoea
- Consider concomitant Fe deficiency
- Generally avoid transfusion in the adjuvant setting
- Prophylactic use of erythropoietin under investigation

**RECOMMENDATIONS**

- Do not proceed with chemotherapy unless
  - neutrophils >1.5
  - platelets >100
- If considering dose delay or dose reduction,
  CONSULT MEDICAL ONCOLOGIST

---

**Linda**

- Unwell d10 cycle 1. Temp 38.5°, feels hot and cold, presents to GP surgery

  **How would you manage?**

- Within 2 hours of admission to local hospital BP is 75 systolic and SaO2<90% room air

  **How would you manage now?**

**Neutropaenic sepsis**

- Resuscitation
- Cultures esp. blood
- Empiric antibiotics intravenously
  - gentamicin plus
    - cefazidime
    - or cefepime
    - or imipenem
    - or ticarcillin plus clavulanate
  - vancomycin if high risk of Gram positive organism eg central line, hospitalised

Antibiotic Guidelines Version 11
**Alopecia**

A major concern for many patients

- Will it happen?
  - almost universal with doxorubicin and taxanes
  - less common CMF
  - affects head more than other areas
- When will it happen?
  - approx 3 – 4 weeks, often preceding scalp tenderness

**Alopecia**

How long will it last?

- Begins to grow back straight away
- Often more fine (downy) initially
- Can be different in texture or colour

**Alopecia**

Prevention/minimisation

- Mild shampoo and conditioner
- Avoid excessive shampooing
- Avoid hairdryers/perms/highlights etc

**Skin reactions**

- Flare reaction
- Extravasation with necrosis
- Generalised erythema/urticaria
- Photosensitivity
- Radiation recall

**Linda**

- Her hand is painful and red at the site of the drip

Is this normal? What would you tell her to do?

**Fatigue - following treatment for breast cancer**

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>% fatigued</th>
<th>Time post treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 1991</td>
<td>172 [breast]</td>
<td>76</td>
<td>2-15 years</td>
</tr>
<tr>
<td>2. 1997</td>
<td>21 [breast]</td>
<td>73</td>
<td>6 months</td>
</tr>
<tr>
<td>3. 1997</td>
<td>419 [breast &amp; other]</td>
<td>78</td>
<td>6 weeks to 1 year</td>
</tr>
<tr>
<td>4. 1998</td>
<td>61 [breast]</td>
<td>68</td>
<td>15 months</td>
</tr>
<tr>
<td>5. 2000</td>
<td>1957 [breast]</td>
<td>35</td>
<td>1-5 years</td>
</tr>
</tbody>
</table>
Algorithm for the evaluation & management of cancer-related fatigue

Evaluation of fatigue characteristics
[severity, onset, duration, impact]

Evaluation of predisposing factors
[physiologic, psychological]

Correction of potential aetiologies: depression, pain, anaemia, sleep disorder, other

Symptomatic treatment: pharmacologic, non-pharmacologic

Management of post treatment fatigue

Non-pharmacological interventions
- Patient related
- Patient education
- Exercise
- Modification of activity & rest patterns
- Stress management and cognitive therapies
- Adequate nutrition & hydration

Pharmacological interventions
- Two randomised trials demonstrate QOL benefit for use of rHu-epo

Other short-term side effects
- Angina (5FU)
- Arrhythmias
- Psychological
- Anorexia
- Constipation
- Weight gain
- Cognitive changes
- Renal impairment
- Tissue necrosis

Specific side effects of taxanes
- Paclitaxel, docetaxel
  - myelosuppression
  - peripheral neuropathy (cumulative)
  - nail changes
  - capillary leak/fluid retention (eg peripheral oedema, pleural effusions – not to be confused with disease progression!)
  - myalgias, arthralgias
  - hypersensitivity reactions (acute allergic type reaction or pulmonary infiltrates)
- Steroid premedication

Long-term side effects
- Premature menopause
- Infertility
- Pulmonary
  - Teratogenesis
  - Second malignancies
  - Radiation recall
  - Cardiac

Cardiac toxicity
- Dose limiting toxicity of anthracyclines
  - doxorubicin
  - epirubicin
  - mitoxantrone
- May be idiosyncratic
- Can occur several months following completion of treatment
- Medical oncologist will recommend regular monitoring during treatment
- ACE inhibitors effective
Learning Objectives

Endocrine therapy

After this presentation, participants should be able to:

- understand the evidence to support ovarian ablation
- understand the mechanism of action of tamoxifen
- understand the side effects of tamoxifen
- optimise their management of the side effects of endocrine therapy

Suggested accompanying handout material

Suggested attached material


Further reading


ENDOCRINE THERAPY

Tamoxifen

Ovarian ablation

Oestrogen

Progesterone

Nucleus

Ovarian ablation – premenopausal ER/PR +

Tamoxifen – pre and post-menopausal ER/PR+

The stick in the jaws of the crocodile...

Receptor

Tamoxifen

Oestrogen

Side effects of endocrine therapy

- Premature menopause
  - short-term symptoms of hormone withdrawal
  - long-term health effects

- Tamoxifen
  - anti-oestrogenic side effects
  - oestrogenic side effects
  - other side effects

Early Breast Cancer Trials’ Collaborative Group, 1996

Early Breast Cancer Trials’ Collaborative Group 1998
Tamoxifen

Anti-oestrogenic side effects

- Hot flushes
- Cessation of menstruation
- Reduced libido
- Vaginal dryness
- Vulval irritation
- Hair thinning
- Cognitive deficits

Oestrogenic side effects

- Fatty liver, hepatitis
- Endometrial polyps, endometrial cancer
- Thromboembolic disease

Other side effects of tamoxifen

- Retinal crystals, macular oedema (high dose)
- Enhanced cataract formation
- Transient reduction in white cell count
- Transient reduction in platelet count
- Interacts with warfarin – dose adjustment required

Other benefits of tamoxifen

- Reduced local recurrences of cancer
- Reduced incidence of cancer in the other breast
- Reduced deaths from cardiovascular disease
- Improved cholesterol profile in post-menopausal patients
- Reduced osteoporosis, especially in the spine

Managing hot flushes

- Avoid precipitants
  - alcohol, coffee
  - spices
  - overdressing
- Clonidine
- Progesterone
- SSRI’s (venlafaxine)
- ? Short-term HRT (clinical trial currently)
- ? Relaxation / meditation

Managing vaginal dryness

- Prevention
  - moisturiser
  - avoid washing with soap
- Treatment
  - non-absorbed oestrogens
  - lubricant for intercourse
  - exclude candidiasis
Other consequences of early menopause

**Osteoporosis**
- Baseline bone density
- Exclude thyroid disease
- Moderate alcohol
- Weight bearing exercise
- Calcium / vitamin D intake
- Consider bisphosphonates if rapid fall in bone density
- Progesterone

Current research trends

- Pre-menopausal
  - reversible ovarian ablation with LHRH agonists
  - combined hormone blockade
- Post-menopausal
  - aromatase inhibitors
- Reducing side effects of hormonal disruption
  - safety of HRT (HABIT study)
Learning Objectives

Safe administration and handling of cytotoxic drugs and their related wastes

After this presentation, participants should be able to:

• identify the safe level of exposure to cytotoxic drugs
• understand the occupational health and safety issues surrounding the preparation of cytotoxic drugs
• identify the personal protective equipment required for the administration of cytotoxic drugs
• understand the requirements for the safe transportation of cytotoxic drugs
• identify the risks of administration of vesicant cytotoxics
• record and report employee exposure to cytotoxics
• demonstrate the procedures for managing a cytotoxic spill
• demonstrate the safe handling of oral cytotoxics

Suggested accompanying handout material

Suggested attached material


**Further reading**


SAFE ADMINISTRATION AND HANDLING OF CYTOTOXIC DRUGS AND THEIR RELATED WASTES

Legislation
1. Occupational health and safety act 1983
2. Dangerous goods act 1975
3. Workers compensation act 1987 as amended
5. The Poisons Act 1966
6. The Nurses Act
7. The Therapeutic Goods Act
8. The Trade Practices Act

Factual / Regulatory issues
Professional responsibility:
• Standards
• Regulations
• Guidelines
• Competencies
• Quality assurance/codes of practice
• Documentation as evidence
• Professional associations role

Guidelines
Examples
• Workcover
• EPA Guidelines
• NHMRC
• Department of Health
• SHPA
• Therapeutic Goods Administration

What are the risks?
• Mutagenic
• Carcinogenic
• Teratogenic
• Occupational exposure - inhalation of aerosols, drug particles, skin absorption, ingestions and needlestick injury

Managing the risks
• Reduce the occupational exposure
  – handling procedures
  – specialised equipment
  – personal protective equipment (PPE)
  – training and education of the worker
**Preparation of cytotoxic drugs**

- Facilities
  - cytotoxic suite
  - accredited training
- Personal Protective Equipment
  - gowns
  - gloves
  - goggles, face shields
  - masks
  - overshoes

**Administration of cytotoxic drugs**

- Personal Protective Equipment
- Parenteral
- Non parenteral
- Patient Transport

**Storage and transport of cytotoxic drugs**

- Storage
  - signage
  - double bagged, heat sealed
  - rigid walled container / Refrigerator
  - dedicated area - spill containment and management
- Transport of the Drug

**Spill management**

- Spill Containment
  - contain spill
  - remove all persons not involved in management of spill
  - restrict access
  - use spill kit/absorbent materials
- Reporting
  - log of staff involved in preparation, administration of chemotherapy should be kept
  - spill register

**Management of waste**

- Identification, Segregation, Containment
- On Site transport
- Off site Transport
- Waste disposal

**Extravasation**

- Immediate complication unique to chemotherapy
- Consequences
- Prevention
- Local policy regarding management
Learning Objectives

Legal issues

After this presentation, participants should be able to:

- identify the elements of negligence necessary to substantiate a damages claim
- understand the standard of proof necessary in civil proceedings at Common Law, versus the standard of proof necessary to bring a claim in the Workers Compensation Court
- understand that informed consent is based upon the 'self-determination principle'

Suggested accompanying handout material

Suggested attached material


Further reading

Australian Nursing Federation Competency Standards for the Advanced Nurse.


Breen v. Williams (6 September 1996), High Court of Australia, Justices Brennan, Dawson, Toohey, Gaudron, McHugh, and Gummow JJ.


The College of Law, Seminar Papers, Medical Negligence Litigation, 1996.

Legal issues

- Informed consent
- Assault and battery
- Negligence (civil and criminal)
- Forseeability
- Damages
- Settlements v. Judgements
- ADR
- Conciliation and arbitration
- Forum shopping

Law of Torts

- Crooked conduct/ a wrong
- An act or omission which causes harm to a determinate person, whether intentionally or not, being the breach of a duty arising out of a personal relation or contract, and which is either contrary to law, or an omission of a specific legal duty, or a violation of an absolute right
- A civil wrong for which the remedy is a common law action for unliquidated damages, and which is not exclusively the breach of a contract, or the breach of a trust or other merely equitable obligation

Consent

- Acquiescence
- Agreement
- Voluntary, expressly, impliedly, voluntary waiver, abandonment
- Negated by fraud
- Volenti non fit injuria
  - that to which a man consents cannot be considered an injury
  - the consent must be real, given without fear, force, fraud

Consent

- Legal Justification Principles
  1. Bodily integrity to be protected against invasion by others and
  2. Failure to gain consent (with recognised exceptions) may constitute an assault
- Battery
  - all direct damages are recoverable
- Negligence
  - damages foreseeable

Informed consent

- Patients’ rights
  Hunter v. Handley 1955
  - In diagnosis and treatment there is scope for differing opinions
  - Test of negligence on the part of the health provider is ‘whether he/she has been proved to be guilty of such failure as no health provider of ordinary skill could be guilty of if acting with ordinary care’
Informed consent

Roe v. Ministry of Health
- Must have regard to environment in which health providers work
- Must be a duty of care at all times
- Not negligence that which is only misadventure

Cassidy v. Ministry of Health
- Vicarious liability doctrine
- Applies to hospital and health-related doctrine

Lister v. Romford Ice
- Vicarious liability of employers for their employees

Haynes v. Harwood
- There is no consent where a man acts under the compulsion of a legal or moral duty
- Mere knowledge of a risk does not amount to consent. The maxim is volenti non scienti
- Unfair contract terms act 1977 S. 2 (3)

Rogers v. Whittaker
- Plaintiff has onus of proof to show that had she known and understood certain risks then she would have made a materially different decision as to what was consented to
- Failure to warn
- Failure to inform
- Role of the MDU to have case read down failed
- Bolam principle discarded

BT v. Dr Oei
- HIV Case
- Role of MDU: not tested

What the doctor should tell the patient
- The patient’s diagnosis
- What the treatment/operation entails, its gravity, the reasons for it, and what it will achieve if successful
- Any material risks of the operation other than commonly known risks
- Alternative to the treatment or the 'do nothing' alternative
- The potential benefits and material risks of alternatives
- Who will conduct the treatment and where it will take place
- Permission to ask questions
- Allow the patient to seek a second opinion

Consent exceptions
- Capacity
- Age
- Emergency life saving procedures
- Guardianship cases v. Parental refusal
- Changes to the mental health act

Cases
- Schloendorf v. Society of N.Y. Hospital
  - Self determination principle to refuse treatment despite “benefits” to having treatment
- Re C
- B v. Croydon Health Authority
Australia

• Insufficient documentation can lead to the overriding of patients rights

• Justice Cordoza in Re C held in the words of C ‘I would rather die with two feet than live with one’

Trespass

Assault
• A tort consisting of an act of the defendant which caused the plaintiff reasonable fear of an infliction of a battery on him by the defendant

• Unlawful laying of hands on another person

Battery
• Actual touching or striking of another in a rude, insolent, angry or revengeful manner

Case
• Letang v. Cooper
  – Trespass to a person occurs when the act or conduct complained of is intentional or the result of negligence

Negligence

• Duty of care

• Breach of duty by act or omission

• Damages directly related to the breach

• Doctrine of reasonable foreseeability

• Standard of proof
  – Civil v. Criminal

Tai v. Hatzistavarov- Appeal Court NSW
• Where there are gaps in the health care system, the patient must not be left to bear the cost

Burnett v. Kalakerinos
• Held for plaintiff – failure to follow up

Potential for litigation

Employer
• Occupational exposure or related injury

• Guidelines, standards, or statutes ignored

Patient
• Informed consent not given

• Wrong drugs given

• Wrong concentrations of drugs given

• Administrative accidents

• Drug adjustments not attended in light of severe neutropaenia or infection

• Poor monitoring of patients between courses or during courses

• Poor management of side effects

• Unaccredited staff administration of drugs under the direction/acquiescence of hospital administrators and/or private practices

• Accredited practitioners , accredited negligently
  – Rule v. Lutheran hospitals
  – Park North General Hospital v. Hickman

Mitigation of damages awarded to employees

• Failure of the employee to take due care of themselves and others for the maintenance of health and safety

• Failure to comply with clinical training competencies

• Failure to renew competency accreditation

• Failure to demonstrate adequate theoretical competence of the drugs they handle or their interaction with other drugs
Learning Objectives

Communication and psychosocial issues

After the presentation, participants should be:

• able to identify risk factors for adverse psychological outcomes in women with breast cancer
• able to identify communication strategies that enhance disclosure
• able to identify pharmacological and non-pharmacological approaches to the management of anxiety and depression
• aware of practical issues that cause concern for women with early breast cancer, and should have identified resources in their local area to address these
• able to identify issues of body image and sexuality, and potential approaches to management

Suggested accompanying handout material

Suggested attached materials


COMMUNICATION AND PSYCHOSOCIAL ISSUES

COMMUNICATION
• association between doctors’ communication skills and patient satisfaction
  Ong et al. 1995
• communication techniques affect psychological adjustment
  Roberts et al. 1994
• commonest complaint by patients is that doctors do not listen to them
  Meryn 1998

SCREENING FOR CONCERNS
• Identify risk factors
• Ask about general emotional wellbeing
  • specifically about
    - anxiety
    - depression
    - relationships
    - body image and sexuality
    - practical issues eg prosthesis
    - intrusive thoughts about the cancer

WHAT COMMUNICATION TECHNIQUES ARE EFFECTIVE?
• Empathy and active listening
• Open-ended questions
• Encouraging questions
• Checking understanding
• Giving clear information in a variety of formats
• Staging and repeating information

PATIENT DISCLOSURE
Patient is more likely to disclose significant information when clinicians:
• Use open questions
• Use questions with a psychological focus
• Clarify psychological aspects of patients’ response
• Make empathic statements
• Make educated guesses

Maguire, Booth et al. 1996
Maguire, Faulkner et al. 1996
Risk for adverse psychosocial outcomes

Factors associated with increased risk:
- Younger
- Single, separated, divorced or widowed
- Children of <21 years old
- Economic adversity
- Perceived poor social support
- Poor marital or family functioning
- History of psychiatric problems
- Cumulative stressful life events
- History of alcohol or other substance abuse

Providing emotional support

- Appropriate counselling improves the wellbeing of women with breast cancer
  
  Level I

- Discussing feelings with a member of the treatment team or counsellor can decrease psychological distress
  
  Level I

- Specialist breast nurses enhance early recognition of social support needs and decrease psychological distress
  
  Level II

When to treat psychological concerns

- Disruption to the person’s functioning
- Interferes with relationships
- Impacts on ability to understand or comply with treatments
- Suffering of the patient

Proportion of each group with clinically significant anxiety & depression

Marjorie

- Marjorie is feeling shaky and nauseated when she arrives at the clinic for treatment
- She is also sleeping poorly

How would you approach this situation?
Psychological care: anxiety

• Anxiety is estimated at 12% – 30% for women with breast cancer
• Symptoms include:
  – heightened physical arousal, agitation & anger
  – sleep disturbance
  – impaired concentration & decision making
  – anticipatory nausea
• Severe anxiety includes: panic attacks, treatment phobias, pervasive worry

Psychological care: asking about anxiety

• Incorporate specific questions about anxiety into the general interview about psychological wellbeing
• Intrusive or difficult to manage anxiety problems should be offered specialist assessment
• Keep the treatment team informed
• Cognitive and behavioural techniques can be effective, as can certain medications

Anxiolytics

• Benzodiazepines
  – premedicate before chemotherapy with lorazepam
  – longer term consider diazepam (beware long half-life)
  – oxazepam safest in liver disease
  – withdraw slowly
• Neuroleptics in extreme agitation
• Antidepressants for mixed anxiety/depression

Linda

• At the end of the treatment instead of feeling better, Linda is fatigued and teary

How would you best assist her to cope with this situation?

Psychological care: depression

• Approximately 5% – 20% of women with breast cancer experience major depression
• Symptoms include:
  – feelings of hopelessness, guilt and worthlessness
  – low or flat mood, loss of interest in previously enjoyable things
  – anorexia, insomnia, anergia, weight loss (sometimes difficult to separate from treatment side effects)

Psychological care: asking about depression

• Be alert for signs of clinical depression
• Routinely ask about, and document any risk factors
• Clarify depth of mood disturbance, and the frequency and length of these experiences
• Sensitively explore suicidal thoughts, their frequency, any plans and access to means
• Refer to psychologist/psychiatrist for further assessment; urgently if suicidal ideation
**Interventions and their impact**

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<thead>
<tr>
<th>Type</th>
<th>Teaches and encourages</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive behavioural</td>
<td>Problem solving, reframing attitudes, coping with stress and anxiety, approaching problems more effectively, gradual adaptation to fears</td>
<td>Level I, Level II, Level III</td>
</tr>
<tr>
<td>Supportive Psychotherapy</td>
<td>Expression of emotions, a sense of support through empathic listening and encouragement</td>
<td>Level I, Level II</td>
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</tbody>
</table>
| Psycho-educational    | Enhances understanding of:  
  - Breast cancer  
  - Treatment options  
  - Adjustment & coping  
  - Diet & health behaviours  
  - Available services | Level I, Level II, Level III |

**Pharmacotherapy**

- Target specific symptoms which are troubling the patient
- Beware potential for side effects
- Risk of exacerbating medical problems
- Potential for drug interactions
- Start low – go slow

*Belles & Stoudmire 1999*

**Tricyclics**

- Highly effective antidepressants
- Sedation of the agitated depressed patient  
  - reduce anxiety, insomnia
- Potentiates opioid analgesia  
  
  *Brettart 1992*
- CVS side effects
- Anticholinergic side effects  
  - dry mouth exacerbates mucositis  
  - constipation
- Lethal in overdose

**Selective serotonin reuptake inhibitors (SSRIs)**

- Effective antidepressants
- Less sedation than TCAs
- Fewer autonomic effects
- Safer in overdose
- Often single tablet dosing

**Adverse effects**

- Headache, dizziness
- Nausea, loose stools or constipation
- Insomnia
- Sweating, dry mouth, tremor
- Anxiety, restlessness
- Sexual dysfunction

**Adverse effects**

- Drug interactions especially warfarin, carbamazepine, TCAs and antipsychotics
- Prozac has a long half-life with active metabolites
- Strongly protein-bound – increase levels digoxin, cisplatin
Marjorie

- Max won’t look at her mastectomy scar
  She doesn’t like it either

  Is this normal? What can be done?

What is body image?

- Complex thoughts and feelings about our bodies
- Includes body size, shape, form and posture
- Includes intellectual and emotional aspects
- Involves comparison with social norms
- Self-esteem and body image are intimately related to sexuality

Body image and sexuality

- 33% of women have sexual difficulties 12 months post-mastectomy vs. 8% of controls  
  Maguire et al 1978
- Body image better after BCT  
  Lee et al 1992
- Perception of lower support after BCT  
  Levy et al 1989

Factors influencing sexual adjustment

- The woman and her situation
- The diagnosis and disease stage
- Surgical treatment
- Radiotherapy
- Chemotherapy
- Induced menopause

Linda

- Bill has become withdrawn and won’t talk
  How can he be helped?

- Her libido is reduced and she experiences vaginal dryness after chemotherapy induced menopause
  How can this be managed?

What about partners?

- Levels of distress comparable to the woman  
  Northouse & Swain 1987
- Fear about the woman dying  
  Goy 1984
- Changes in domestic roles and responsibilities  
  Zahnis et al 1991
- Reluctance to seek professional assistance  
  Glasdem et al 1996
- Satisfaction with partner support influences the woman’s adjustment  
  Pistrang & Barker 1995
## Promoting family coping
- Information about the impact on partners and children
- Involvement of family in provisioning of information
- Identification of disorder in partners
- Challenging ‘positive thinking at any cost’
- Challenging ‘+conspiracies of silence’

## Promoting sexual adjustment
- Enhancing communication
- Discussing expectations
- Education about the physiological impact of menopause
- Use of a water-based lubricant
- Specific couple-therapy provides benefit

**Christensen 1983**

## Linda
- Her children ask if she is going to die like another child’s mother at the school did

**What should she tell them?**

## What about children?
- Guilt and distress about impact on children
- Increased psychological risk for those women who have higher numbers of young children

**Bloom & Kessler 1994**

- Response depends on developmental stage
  - young children guilty and anxious
  - middle children need information
  - adolescents especially vulnerable

## Practical issues
**Evidence**
- There are benefits in discussing:
  - costs for diagnosis and treatment
  - the cost, availability and types of prostheses
  - breast reconstruction
  - travel and accommodation
  - lymphoedema management

## Marjorie
- Marjorie has swelling in her arm and it is causing her considerable pain

**What would you tell her?**
Lymphoedema

Symptoms
- Heaviness
- Arm pain
- Swelling of arm or hand
- Restricted mobility
- Carpal tunnel syndrome
- Poor healing
- Susceptibility to infection

Management
- Exercise
- Massage
- Bandaging
- Compression garments
- Care with
  - infection
  - surgery
  - venepuncture
  - blood pressure monitoring

Practical issues
- Ask how practical issues are influencing treatment decisions
- Provide information about likely costs, financial assistance and support services
- Provide information regarding the cancer support organisations and contact numbers
- Offer to refer the woman to a social worker for assistance with practical issues
5 Evaluation

The workshops conducted by the National Breast Cancer Centre included an evaluation component to test the effectiveness of the workshop model. Organisers who apply for CME points will need to include an evaluation component.

The evaluation questions developed by the Centre are attached, and workshop organisers may wish to use a similar model to evaluate their own workshop.

Workshop participants were asked to complete the knowledge and confidence questionnaire:

- before the workshop
- immediately after the workshop
- at 12 week follow-up

Statistical analysis was conducted on the knowledge and confidence questionnaires to test for pre- and post-workshop changes.

Participants were also surveyed at the close of each workshop about the relevance to their work of the presentations in the workshop program, the proficiency of the presenters, the quality of the presentation and the usefulness of accompanying material in the workbook provided.

Follow-up surveys conducted 12 weeks after each workshop investigated the impact of the workshop on participants' practice.
**EVALUATION**

Knowledge and confidence questionnaire  
(Pre-workshop, post-workshop and at 12-week follow-up)

Please indicate whether you are a:  
- Nurse  
- GP  
- Other (please specify) _____________________

### The role of adjuvant chemotherapy in early breast cancer

| Please tick (✓) |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| **Very low**    | **Low**         | **Moderate**    | **High**        | **Very high**   |

1. **Please rate your knowledge of the following:**

   a. How chemotherapy acts on malignant cells

   b. The differences between key chemotherapy drugs that you may use in the adjuvant setting

   c. Rationale for maintaining dose intensity

   d. Research directions in adjuvant therapy for breast cancer

2. **Please rate your confidence in relation to the following:**

   a. Understanding the indications for chemotherapy for breast cancer in the adjuvant setting

### Chemotherapy: managing the side effects

| Please tick (✓) |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| **Very low**    | **Low**         | **Moderate**    | **High**        | **Very high**   |

1. **Please rate your knowledge of the following:**

   a. Management of febrile neutropenia

   b. Management of stomatitis

   c. Association between diarrhoea and febrile neutropenia

   d. Recognition of fatigue

2. **Please rate your confidence in relation to the following:**

   a. Assessing the time to onset of side effects after chemotherapy

   b. Prevention of nausea and vomiting
### Legal issues

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<thead>
<tr>
<th>Please tick ✓</th>
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<th>Low</th>
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<tr>
<td>a  The elements of negligence necessary to substantiate a claim against you</td>
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<td>b  The standard of proof necessary in civil proceedings at Common Law versus the standard of proof necessary to bring a claim in the Workers Compensation Court</td>
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<td>c  That informed consent is based upon the 'self-determination principle'</td>
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### Safe administration and handling of cytotoxic drugs and their related wastes

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<td>a  Safe level of exposure to cytotoxic drugs</td>
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<td>b  OH&amp;S issues surrounding the preparation of cytotoxic drugs</td>
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<td>c  Personal protective equipment required for the administration of cytotoxic drugs</td>
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<td>d  The requirements for the safe transportation of cytotoxic drugs</td>
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<td>e  The risks of administration of vesicant cytotoxics</td>
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<td>f  Recording and reporting employee exposure to cytotoxics</td>
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2. **Please rate your confidence in relation to the following:**

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<td>a  Procedures for managing a cytotoxic spill</td>
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<td>b  The safe handling of oral cytotoxics</td>
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<td>Communication issues</td>
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<td>a Communication techniques/strategies to facilitate disclosure</td>
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<td>b Psychological consequences of a breast cancer diagnosis</td>
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<td>c Psychological consequences of breast cancer treatment</td>
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<td>d Risk factors for adverse psychological outcomes</td>
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<td>e The evidence for effectiveness of psychological interventions</td>
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<td>2. Please rate your confidence in relation to the following:</td>
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<td>a Identifying and managing anxiety in women with breast cancer</td>
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<tr>
<td>b Identifying and managing depression in women with breast cancer</td>
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<td>c Discussing body image and sexuality concerns</td>
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<td>d Assisting partners and children to access support</td>
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<td>a Evidence to support ovarian ablation</td>
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<td>b Mechanism of action of tamoxifen</td>
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<td>c Mechanism of side effects of tamoxifen</td>
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<td>2. Please rate your confidence in relation to the following:</td>
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<tr>
<td>a Managing side effects of endocrine therapy</td>
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</table>

Thank you
EVALUATION

Please indicate whether you are a:

- Nurse
- GP
- Other (please specify) _____________________

1. For each presentation, how would you rate the following?

<table>
<thead>
<tr>
<th>Please rate each as follows:</th>
<th>Relevance to your work</th>
<th>Proficiency of the presenter</th>
<th>Overall quality of presentation</th>
<th>Usefulness of accompanying handouts in workbook</th>
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<tr>
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<tr>
<td>a The role of adjuvant chemotherapy in early breast cancer</td>
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<td>e Communication issues</td>
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<td>F Endocrine therapy</td>
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<td>G Identification of local issues and local adaptation of guidelines</td>
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2. Any other comments?

______________________________________________________________________________
______________________________________________________________________________
EVALUATION

1. To what extent did the program provide information that was new to you?
   - not at all
   - a little
   - mostly
   - a lot

2. What did you learn that was new?

3. What changes to your clinical practice will you attempt as a result of what you may have learnt today?

4. What barriers to those changes do you anticipate?

5. What strategies might you use to overcome them?

6. What specific benefits do you anticipate for your patients as a result of what you may have learned today?

7. What further learning needs have you identified as a result of today?
12- WEEK FOLLOW-UP EVALUATION

Please indicate whether you are a: Nurse □  GP □  Other □ (please specify) ___________

1. What changes to your practice have you attempted as a result of attending the chemotherapy workshop (site)?
___________________________________________________________________________
___________________________________________________________________________

2a. What barriers, if any, have you encountered in these attempts to change practice?
___________________________________________________________________________
___________________________________________________________________________

2b. What strategies have you used to overcome these barriers?
___________________________________________________________________________
___________________________________________________________________________

3. What further learning needs regarding chemotherapy have you identified since the workshop?
___________________________________________________________________________
___________________________________________________________________________

4. What further educational strategies related to chemotherapy management have you undertaken as a result of attending the workshop?
___________________________________________________________________________
___________________________________________________________________________

5. What further actions in terms of changing practice have you planned?
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

6. What are your current arrangements for communicating with the visiting or resident medical oncologist?
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

7. Would you say that your communication with the visiting or resident medical oncologist since the workshop has:
greatly improved □  improved □  remained unchanged □  deteriorated □

8. Are you now involved in the management of more women with early breast cancer than you were before the workshop?
Yes □  No □  Don’t know □
References


5. Rural Oncology Sub-Committee. Provision of oncology services to rural and remote regions of Australia. Medical Oncology Group of Australia (in preparation).


