# Cervix Cancer Research Network

- Managed by the Gynecologic Cancer Intergroup
- Aim is to promote high quality clinical research
- Literature search was performed to evaluate best practices (slides 2-4)
- Data input required (form developed by the Radiologic Physics Center, Houston, Tx; slides 4-8)
- Participation in a beam measurement program (TLD/OSLD) is required every 2 yrs
- Site visits performed by a audit team from GCIG

# Management of endometrial cancer in Asia: consensus statement from the Asian Oncology Summit 2009

*Siriwan Tangjitgamol, Benjamin O Anderson, Hui Ti See, Chawalit Lertbutsayanukul, Nakarin Sirisabya, Tarinee Manchana, Arunachalam Iancheran, Khai Mun Lee, Siew Eng Lim, Yin-Nin Chia, Efren Domingo, Young-Tak Kim, Chyong-Huey Lai, Ahmad Zailani Hatta Mohd Dali, Wisit Supakapongkul, Sarikapan Wilailak, Eng-Hseon Tay, John Kavanagh*

**Endometrial cancer is one of the gynaecological cancers that carries good overall prognosis because it is often detected at early stages of disease. The International Federation of Gynecology and Obstetrics replaced clinical staging with surgical staging in 1988 and updated the system in 2009. Controversies remain regarding the recommended screening protocol for women with a high risk of endometrial cancer, the role and benefit of retroperitoneal lymph-node dissection, the necessity of ovarian resection, the benefit and type of adjuvant radiation therapy, and the safety of hormone-replacement therapy after treatment. This article reviews the available evidence for optimum management of endometrial cancer and how management strategies can be applied in Asian countries with different levels of health-care resource availability and economic development. An overview of the literature for endometrial-cancer screening, diagnosis, and management is discussed. Consensus statements are formulated on the basis of basic, limited, enhanced, and maximum health-care resource availability, using the framework provided by the Breast Health Global Initiative.**

*Lancet Oncol* 2009; 10: 1119–27

See Reflection and Reaction page 1029

This is the sixth in a series of six consensus statements

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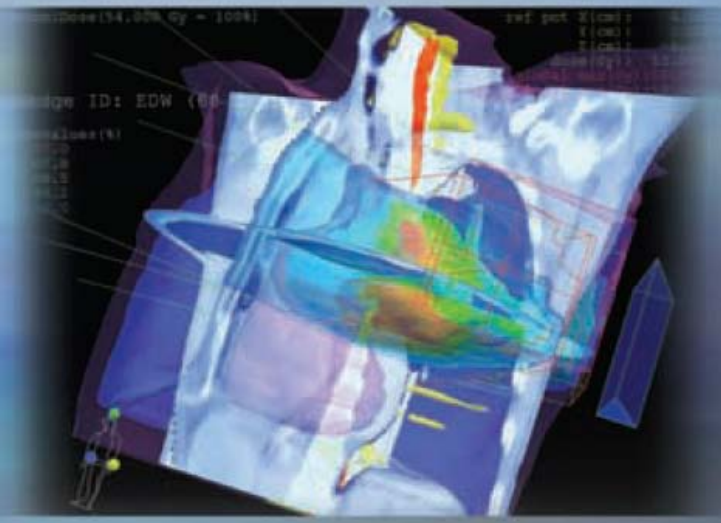
# Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement

Quality Assurance Team for Radiation Oncology (QUATRO)

EFOMP ESTRO IAEA IOMP



IAEA
International Atomic Energy Agency

# Breast Radiation Therapy Guideline Implementation in Low- and Middle-Income Countries

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Complete financial disclosures are presented at the end of this article.

The Radiation Therapy Focus Group: Baffour Awuah, Nuran Senel Bese, Ashwini Budrukkar, Robert W. Carlson, Ahmed Elzawawy, Alexandru Eniu, Anusheel Munshi, and Carlos Perez.

Radiation therapy plays a critical role in the management of breast cancer and often is unavailable to patients in low- and middle-income countries (LMCs). There is a need to provide appropriate equipment and to improve the techniques of administration, quality assurance, and use of resources for radiation therapy in LMCs. Although the linear accelerator is the preferred equipment, telecobalt machines may be considered as an acceptable alternative in LMCs. Applying safe and effective treatment also requires well trained staff, support systems, geographic accessibility, and the initiation and completion of treatment without undue delay. In early-stage breast cancer, standard treatment includes the irradiation of the entire breast with an additional boost to the tumor site and should be delivered after treatment planning with at least 2-dimensional imaging. Although postmastectomy radiation therapy (PMRT) has demonstrated local control and overall survival advantages in all patients with axillary lymph node metastases, preference in limited resource settings could be reserved for patients who have $\geq$4 positive lymph nodes. The long-term risks of cardiac morbidity and mortality require special attention to the volume of heart and lungs exposed. Alternative treatment schedules like hypofractionated radiation and partial breast irradiation currently are investigational. Radiation therapy is an integral component for patients with locally advanced breast cancer after initial systemic treatment and surgery. For patients with distant metastases, radiation is an effective tool for palliation, especially for bone, brain, and soft tissue metastases. The implementation of quality-assurance programs applied to equipment, the planning process, and radiation treatment delivery must be instituted in all radiation therapy centers. ***Cancer* 2008;113(8 suppl):2305–14.** © *2008 American Cancer Society.*

**KEYWORDS: breast cancer, radiation therapy, implementation, quality assurance.**

Radiation therapy plays an essential role in the multimodal treatment of breast cancer, depending on the stage of the disease. It has a major impact on local tumor control for early and locally advanced disease, and effective and safe radiation therapy can improve overall survival rates as well.[1-3] Radiation therapy also is an

# GCIG/CCRN SOPs (site visits)

1) Sites which are not members of a GCIG member research group may be facilitated to join launched GCIG cervix cancer studies by joining the CCRN initiative.

2) Certain steps/requirements must be met to join the CCRN initiative:
   a. Lead group study chair to inform GCIG/CCRN of potential site(s) and provide contact information;
   b. CCRN Chair and GCIG Chair must approve potential site(s) and authorize visits;
   c. Potential site will receive pre-qualifying questionnaire (p-q q);
   d. Pre-qualifying questionnaire to be completed and returned; reviewed by CCRN QA;
   e. Following approval of p-q-q, site visit will be scheduled;
   f. Site visitor(s) will perform QA checks as per CCRN QA Checklist;
   g. Lead group study chair will be notified of CCRN QA approval;
   h. Lead group will then initiate study specific local activation requirements.

3) By nature of GCIG membership, sites within GCIG member groups do not require CCRN QA.

4) Additional trial-specific QA requirements are the responsibility of the lead group.

5) Each GCIG study requiring CCRN QA visits will be allotted $xxxx. USD for this purpose only.

6) Each authorized CCRN QA visitor will be reimbursed upon receipt of GCIG Expense Claim Form with attached receipts, boarding passes, etc.

**OVERSIGHT**: independent committee receives reports from trial-specific IDMCs.

# RPC Questionnaire

Facility Questionnaire
(Demographics and Technical Survey)

**All textboxes are editable**. Please review the data below verifying its correctness. If data is missing or changes are required, please make the modifications or additions. Use the appropriate Button to periodically register your changes. **Please make sure to click the Submit the Facility Questionnaire button at the end of the form to verify that the information is correct to the best of your knowledge and to close out the form.** **Note: Please fill in as much as you can and submit. You can always fill out the rest or make changes at a later time.*

General Institution Information

RTF# Institution Name: **1001**
Last Accessed: Address
CTEP/NCI Id#:
Today's Date City 06-Feb-2012
FL Country USA Zipcode 33952 State
9416276465 Extension: Fax: Telephone:
Degree:Person submitting this form -
Phone Email

*If you are participating in the RPC QA program, please confirm the TLD/OSLD and billing address form* TLD/OSLD and Billing Address

List the **primary** individuals responsible for general question regarding clinical trials and dosimetry compliance (OSLD/TLD monitoring) for NCI sponsored clinical trials.

| | First Name | Last Name | |
|---|---|---|---|
| Degree:**Physicist** - | Bob | Duerkes | |
| rduerkes@rtsx.com Phone 9416276465 Email | | | |
| Fax | | | |
| Degree:**Research Associate:** - | | | |
| Phone Email | | | |
| Fax | | | |
| Degree:**Dosimetrist** - | | | |
| Phone Email | | | |
| Fax | | | |
| Degree:**Radiation Oncologist** Dr. | Daniel | Doseretz | M.D. |
| Phone Email | | | |
| Fax | | | |

Other Personnel - List everybody who will be involved with clinical trial

| Salutation | First Name | Last Name | Occupation | Email | Phone | | |
|---|---|---|---|---|---|---|---|
| Mr. | Klaus W. | Buzzi | Physicist | | 941-627-6465 | Edit | Delete |
| Dr. | Daniel | Doseretz | Chief Oncologist | | | Edit | Delete |
| - | Bob | Duerkes | Physicist | | | Edit | Delete |
| - | Bob | Duerkes | Chief Physicist | rduerkes@rtsx.com | 9416276465 | Edit | Delete |
| Ms. | Teresa | Fischer | Physicist | | | Edit | Delete |
| Ms. | Linda | Flegel | Billing | | | Edit | Delete |
| - | Timothy | Gao | Physicist | | | Edit | Delete |

Please enter any extra personnel on the next line then hit Insert

Insert Clear

Cooperative group membership

| Study Group | Study Group Number | | |
|---|---|---|---|
| CALGB | | Edit | Delete |
| GOG | 96 | Edit | Delete |

Please enter extra study group on the next line then hit Insert

Insert Clear

Delivery Resources

| Vendor | Model | Serial No | In-house Designation | Photon Energies | Electron/ Proton Energies | Last TLD Report | MLC | IMRT Capability | IGRT Capability | Click Edit to view more... |
|---|---|---|---|---|---|---|---|---|---|---|
| Varian | Clinac 2100C | 946 | | 6, 18 | 6, 9, 12, 16, 20 | 12/27/2010 | | | | Edit Delete |
| Varian | Trilogy | 1112 | | 6, 10, 10 | 6, 9, 12, 15, 18, 22 | 12/27/2010 | | | | Edit Delete |

Insert a new record

## External Beam Planning Resources

| Vendor-Model | Version | Calculation Algorithm | Heterogenity correction used? | Beam To Phantom? | Computer Used for | Installed Date? | Click Edit to view more... |
|---|---|---|---|---|---|---|---|
| CMS - XiO | | | ☐ | ☐ | | | Edit Delete |

Insert a new record

## Brachytherapy Planning Resources

| Vendor - Model | Version | Computer Used For | Installed Date | |
|---|---|---|---|---|
| Please enter any extra Brachytherapy Planning Resources on the next line then hit Insert | | | | |
| | | ☐ ☐ ☐ LDR HDR PDR | | Insert Clear |

IMRT or 3DCRT

1. TREATMENT POSITIONING VERIFICATION FOR 3DCRT or IMRT

How do you verify field positioning relative to the patient's anatomy (check all that apply)?

☐ Bat ultrasound ☐ CT ☐ KV Imaging
☐ MV Ortho ☐ MV Port
☐ Other:

How often is positioning verification done?

○ First treament only ○ Daily ○ Weekly
○ Other:

2. VERIFICATION OF DELIVERED DOSE FOR 3DCRT

Describe the method(s) used to conduct a check of the dose and monitor unit calculations generated by the 3DRTP system:

Are your 3DCRT treatments monitored by a record and verify system? ○ Yes ○ No

3. VERIFICATION OF DELIVERED DOSE FOR IMRT

How do you verify that the treatment unit delivers the planned dose for individual patients

a. Absolute dose

○ Point(s) Measurement
○ Radiographic (e.g. EDR2, XV) film
○ Diode array (eg. Mapcheck)
○ Ion chamber array (e.g. MatrixX)
○ Other:

b. Dose Distribution with:

○ Radiographic (e.g. EDR@, XV) film
○ Radiochromic film
○ Diode array (e.g. MapCheck)
○ Ion chamber array (e.g. MatrixX)
○ Other

c. What type of phantom do you use for QA:

☐ Anthropomorphic phantom
☐ Geometric phantom

d. What agreement betweeen planned and measured doses for individual patients is considered acceptable at your institution? +/-

e. Are your monitor unit calculations checked by an independent program?

○ no ○ yes

# Facility Questionnaire
# Delivery Resources

**RTF_NO:** 1001

**For Cervical Cancer treeatment only - Please answer the following 7 questions**

1. For how many patients have you used IGRT for cervical cancer in the past 12 months:

2. With what frequency do you use IGRT?
   - ○ Each Fraction
   - ○ First 5 fractions and once weekly thereafter
   - ○ Other

3. Do you perform a second IGRTstudy after the patient's position is adjusted?
   - ○ Yes
   - ○ No

4. What tolerance levels (in mm) are used for x, y, and z adjustments of the patient's position?

5. What are your rotational tolerances before repositioning the patient?

6. If the system has a robotic couch, what are your tolerance levels for the rotational corrections?

7. Who approves the changes at the time of treatment?
   - ○ Therapist
   - ○ Radiation Oncology
   - ○ Physicist
   - ○ Other

Update Cancel

## General Institution Information 1

| | |
|---|---|
| Name of Institution: | |
| Contact Person for CCRN: | E-mail Address: |
| Address: | Phone Number: |
| | Fax Number: |

## General Institution Information 1

| |
|---|
| Please check the type of membership being considered:<br>☐ General CCRN ☐ Trial specific ☐ Provisional |
| Average number of NEW cancer patients seen in the hospital/institution per year: |
| Average number of NEW GYN cancer patients seen in the hospital/institution per year: |
| Average number of NEW Cervix cancer patients seen in the hospital/institution per year: |
| |

| | |
|---|---|
| Name of the clinical study: | |
| Contact Person for study : | E-mail Address: |
| Address: | Phone Number: |
| | Fax Number: |

## Site Resources [if any of these resources are off-site, please explain]

| | | |
|---|---|---|
| Routine Hematology | ☐ Yes | ☐ No |
| Routine Biochemistry | ☐ Yes | ☐ No |
| Routine Anatomical Pathology | ☐ Yes | ☐ No |
| Specimen storage facility (long term) | Y | N |
| Designated gyne. Pathologist | Y | N |
| Any specialized pathological services : (Please describe) | | |
| Transfusions facility | ☐ Yes | ☐ No |
| Critical Care facility | ☐ Yes | ☐ No |
| Radiology Facilities: | ☐ Yes | ☐ No |
| Plane X-Ray | ☐ Yes | ☐ No |
| Ultra-sound | ☐ Yes | ☐ No |
| CT | ☐ Yes | ☐ No |
| MRI | ☐ Yes | ☐ No |
| PET | ☐ Yes | ☐ No |
| PET/CT | ☐ Yes | ☐ No |
| Dedicated gyne. Radiology specialist | Y | N |
| Other (notes): _____ | | |
| IT facility/support | ☐ Yes | ☐ No |
| eMail available during working hrs? | ☐ Yes | ☐ No |
| Access to PC for Doctors, Technologists, Data Managers and Nurses? | ☐ Yes | ☐ No |
| Is your facility capable of digital data exchange? | ☐ Yes | ☐ No |

## Clinical Trial Operations

Does your site have a Clinical Trials Unit? ☐ Yes ☐ No

Do you have a team that can manage a GCIG study at your site? Y N

Primary Principal Investigator: _____

Research Nurse: _____

Data Manager: _____

Designated research Pharmacist: _____

On-Site Monitor: _____

If you join a GCIG study, do you have a trained data manager? ☐ Yes ☐ No

If you do not have a qualified data manager, how do you plan to perform data management at your institution? :

Do you have prior experience with electronic data entry (web-based CRFs): _____

Do you have a secure on-site storage area for clinical trial data: _____

Do you have a secure on-site pharmacy area for clinical trial agents: _____

Does your site have regular Tumour Board review/meetings for Gyne cancers? _____

In how many oncology clinical trials has your site participated over the past 5 years: _____

In how many cervical cancer clinical trials has your site participated over the past 5 years: ___

Has your site participated in multi-center clinical trials: _____(national or international)

Has your site agreed to be the National Sponsor (ethics and regulatory) for your country? ____

If so, have you signed a clinical trial agreement with the lead group? _____

If not, have you signed a clinical trial agreement with the national sponsor? _____

Is your site able to abide by standard ethical, regulatory, and safety reporting requirements? Please **attach** a short summary of the Ethics and Regulatory approval processes at national, regional and site levels, including reference to initial approval, protocol amendments, annual reporting and safety reporting requirements. Please also provide documentation of ICH GCP education and practice on site.

## Radiation Therapy Treatment Record

1. **Typically recorded daily doses**

| | |
|---|---|
| Tumor: ☐ Yes ☐ No | |
| dmax (give dose): | ☐ Yes ☐ No |
| Critical Organs (Specify): | |
| Treatment plan signed by Radiation Oncologist prior to treatment: ☐ Yes ☐ No | |
| Other (Specify): | |

2. **Typically recorded daily doses for brachytherapy (using T&O)**

| |
|---|
| Describe the prescription volume or point: |
| Dose to critical normal tissue calculated for each treatment: ☐ Yes ☐ No |
| Dose calculation signed by physicist / dosimetrist and physician prior to treatment: ☐ Yes ☐ No |
| Other (Specify): |

3. Does your institution have capability of electronic submission of treatment plans? ☐ Yes ☐ No

4. You may be asked to provide a sample copy of daily treatment record.

**External Beam Radiation Therapy: Basic Requirements (low and high resource settings)**

1.) Dosimetry audit (remote monitoring program to evaluate beam output) at least every two years (either via IAEA or RPC), Yes ____ No___
(provide most recent date of participation __/__/__).
2.) Image guidance or port films obtained +/- weekly Yes ____ No___
3.) Physician visits documented weekly for trial patients Yes ____ No___
4.) Protocol specific knowledge assessment completed Yes ____ No___
5.) All fields must be filmed (simulation preferred). Yes ____ No___
6.) 2D therapy is permissible as well as Cobalt teletherapy. Central axis dosimetry is recommended (not mandatory for the lowest resource settings).

**External Beam Radiation Therapy: Additional items for high resource settings**

1.) Onsite review visits by physicists/physician to each participating country/cooperative group/site to assess GCP
2.) Dosimetric review of first two cases and +/- 20% of cases from each institution
Yes ____ No___
3.) For IMRT, independent dosimetry check (eg phantom study) must be performed and centers must be credentialed thru an independent body (RPC, IAEA, other entity), and data must be evaluable. Yes ____ No___

**Brachytherapy: Basic Requirements**

1.) Source activity documentation Yes ____ No___
2.) Brachytherapy resources: activity traceable to standard Yes ____ No___
3.) Dose calculation method Describe _____

**Brachytherapy: Additional items for high resource settings**

1.) All procedures must be simulated

## Radiation Therapy Quality Assurance

| |
|---|
| 1.Specify QA program in existence at facility to verify equipment performance. (Brief details of parameters and frequency of checks) |
| 2. What is the procedure used for ensuring accuracy of each individual patient's initial dose calculations (timer/monitor units)? |
| 3. Who is responsible for RT chart review and how often is this done? |
| 4. How often are portal and/or verification films taken for each patient? |
| 5. How often are patients reviewed by physicians during treatment? |

## Clinical Management Information

An anonymized sample medical record should be collected / submitted for review.

Does your site's medical record contain the following information in easily accessible format?

| |
|---|
| 1. Site and histological diagnosis? ☐ Yes ☐ No |
| 2. Copy of the original histology and operative reports? (surgical specifics) ☐ Yes ☐ No |
| 3. Staging or other quantitative information related to the diagnosis? ☐ Yes ☐ No |
| 4. Treatment policy / statement and treatment intent? ☐ Yes ☐ No |
| 5. Specific medication and chemotherapy information? ☐ Yes ☐ No |
| 6. Copy of the original laboratory and radiological investigations? ☐ Yes ☐ No |
| 7. Informed consent signed by the patient accepting treatment? ☐ Yes ☐ No |
| 8. Do you have the ability to follow patients and conduct assessments/investigations according to protocol specified schedules (minimum: post-treatment every 6 months for 2 years and there after based on protocol specified time-periods)? ☐ Yes ☐ No<br><br>Including on-site monitoring: ☐ Yes ☐ No<br><br>(In low resource settings, documentation of phone call confirmation of vital status by an eye witness [eg: GP] would be acceptable). |
| 9. Other (site-specific note):<br>_____ |
| If you have answered NO to any of these questions would you be able to include the above information in patients' medical records and/or modify your procedures? ☐ Yes ☐ No |

### Clinical Management: Basic Requirements

1.) Surgical QA will be trial specific and assessed by the lead group.
2.) Chemotherapy or targeted drug treatment information must be recorded in the medical record and available for review (dates, drugs, doses, dose modifications & reasons, etc).
3.) Documentation of GCP recommended
4.) Documentation of adverse event reporting.
5.) Assuring FollowUp capabilities (it is recommended that 2-4 charts in this disease site for the past 4 years be evaluated and length of follow up assessed).

### Clinical Management: Additional items for high resource settings

1.) Vital status determined by physician visit.