**Thames Valley and Wessex Radiotherapy Network**

# Radiotherapy Protocols

## Cervical Cancer

This document is the standardised Thames Valley and Wessex Radiotherapy Network **Cervical Cancer** treatment protocol developed collaboratively by the Cervical Cancer Protocol Working Group:

| Trust | Clinician | Physicist | Radiographer |
|---|---|---|---|
| Oxford University Hospitals NHS Foundation Trust | Dr Amanda Horne<br>Dr Sally Trent<br>Dr Claire Mortimer | David Polley<br>Sriram Padmanaban | Loryn Caulfield |
| Portsmouth Hospitals University NHS Trust | Dr Maja Uherek<br>Dr Radwa Ahmed | Wojciech Polak<br>Sarah Wilby | Alison Ormerod |
| Royal Berkshire Hospitals NHS Foundation Trust | Dr Helen O'Donnell | Jo Jones | Lisa Revans |
| University Hospitals Dorset NHS Foundation Trust | Dr Rachel Wilkinson<br>Dr Joanne Parkinson<br>Dr Matt Roberts | Emma Wesley<br>Sreelish Kariyarambath | Gillian Thomas |
| University Hospitals Southampton NHS Foundation Trust | Dr Vicky McFarlane<br>Dr Luke Bennett<br>Dr Hannah Beckett<br>Dr Cristiana Alzamora | Iulianna Craciun<br>Aaron Huckle | Rosemary Sharp<br>Julie Calvert |

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# Contents

## 1. Primary Objective and Scope

To summarise the planning and treatment of patients receiving external beam radiotherapy for cervical cancer for use in Radiotherapy Centres in the Thames Valley and Wessex Radiotherapy Network. Please see the separate brachytherapy consensus document. Where FIGO staging has been utilised in this document, this references the FIGO staging of cancer of the cervix uteri (2018)[1].

## 2. Indications

### Inclusion Criteria

**Radical treatment**

- FIGO stage IB3-IVA.
- Selected FIGO stage IVB cases where optimal local control is achievable and appropriate.
- Selected FIGO stage IB1-2 cases where adjuvant treatment following radical hysterectomy is likely or predictable
- Selected FIGO stage IB1-2 cases where the patient is unfit for surgery
- Histologically confirmed diagnosis of cancer of the cervix

**Adjuvant treatment**

Per British Gynaecological Cancer Society (BGCS) Cervical Cancer Guidelines: Recommendations for Practice[2].

**Adjuvant radiotherapy** – any two of the following:

- Lymphovascular space invasion (LVSI)
- Deep stromal invasion (i.e. greater than 1/3 of the stroma)
- Large tumour size (>4cm)

**Adjuvant chemoradiotherapy** – any of the following:

- Pathological lymph nodes
- Parametrial invasion
- Positive resection margins
- *Consider in patients with close resection margins i.e. <2mm*

Patients who have had surgery for cervical cancer and require adjuvant radiotherapy/chemoradiotherapy should be treated according to the protocol for adjuvant endometrial cancer.

### Exclusion Criteria

- Disease too large to encompass within a radical radiotherapy field

## 3. Pre-Radiotherapy Investigations & work-up

- Clinical examination +/- examination under anaesthesia (EUA)
- MRI pelvis
- PET-CT
- CT C/A/P
- Bloods – FBC, U&Es
- Formal NM EDTA if borderline renal function and planned for concurrent cisplatin
- Offer referral to local fertility services if child-bearing age for consideration of egg harvesting.
- If positive lymph nodes >4cm are identified, consideration should be made to consider surgical dissection of these nodes prior to definitive chemoradiotherapy.
  - Nodal metastases extending beyond the level of the renal hilum
  - Poor performance status
  - Severe co-morbidities precluding radical treatment

## 4. Therapeutic Schema

**Neoadjuvant chemotherapy**
The results of the GCIG INTERLACE[3] study appear to demonstrate that those patients who undergo 6 weeks of neoadjuvant chemotherapy prior to definitive chemoradiotherapy have a 5-year progression-free survival (73% vs 64%) and overall survival (80% vs 72%) advantage compared to those who had no neoadjuvant treatment in the cohort studied. The chemotherapy schema is as follows:

- **Carboplatin (AUC2) & paclitaxel (80mg/m$^2$) delivered intravenously on a weekly basis for 6 weeks**
- **Radical (chemo)radiotherapy to be commenced in week 7 at standard schedule**

All subgroups appeared to benefit from induction chemotherapy and adherence to chemoradiotherapy was high in both trial groups. However PET-CT staging was used in only 25% of patients and those with suspected para-aortic lymph node involvement were excluded. Additionally, the trial mostly predated more modern external beam radiotherapy and brachytherapy techniques in use today which have had a positive impact on patient survival and local control. The patient cohort who will benefit from neoadjuvant chemotherapy is therefore unclear however its use should be considered.

**Concurrent chemotherapy**
- **Cisplatin 40mg/m$^2$ (recommended to be capped at 70mg) delivered weekly.** Contraindicated if CrCl <60ml/min, significant hearing impairment or co-morbidities preclude administration. Monitor FBC, U&Es, $Mg^{2+}$ weekly.
- **Carboplatin AUC 1.5-2 can be delivered weekly if CrCl <60ml/min.**

**Radical radiotherapy (followed by HDR brachytherapy)[4]**
- 45Gy in 25 fractions delivered over 5 weeks to the pelvis +/- para-aortic strip (PTV45)
- 55Gy in 25 fractions delivered over 5 weeks as a simultaneous integrated boost to positive lymph nodes within the true pelvis (PTV55)

- 57.5Gy in 25 fractions delivered over 5 weeks as a simultaneous integrated boost to positive lymph nodes outside of the true pelvis (PTV57.5)
- Please see separate HDR brachytherapy document for subsequent therapy (aiming EQD2 >85Gy to the HR-CTV D90)
- Treatment, including HDR brachytherapy, should be completed within 56 days of initiation and ideally no longer than 50 days (category 1).

**Radical or salvage radiotherapy (No HDR brachytherapy)**
In cases where patients are either unfit or unwilling to undergo brachytherapy, techniques should be individualised while respecting OAR tolerances. In these cases, consideration should be made to consider referrals to centres for SABR boost. Alternatively, simultaneous integrated boosts to the primary or two-phase plans can be considered. Suggested solutions may include:

- 45Gy in 25 fractions to the pelvis +/- para-aortic strip with a simultaneous integrated boost of 57.5-60Gy in 25 fractions to the primary and lymph nodes (respecting OAR tolerances).
    - Aiming for 60Gy/25# to pelvic nodes and 57.5Gy/25# in para-aortic nodes
- 45Gy in 25 fractions to the pelvis +/- para-aortic strip followed by a subsequent phase II boost to the primary. Suggested 1.8Gy-2.0Gy doses over 8-10 fractions.

**Adjuvant radiotherapy**

- 45Gy in 25 fractions delivered over 5 weeks to the pelvis +/- para-aortic strip (PTV45)

**Adjuvant radiotherapy with residual/unresected positive lymph nodes**

- 45Gy in 25 fractions delivered over 5 weeks to the pelvis +/- para-aortic strip (PTV45)
- 60Gy in 25 fractions delivered over 5 weeks as a simultaneous integrated boost to unresected positive lymph nodes within the true pelvis (PTV60), where vaginal vault brachytherapy is not planned.
- 57.5Gy in 25 fractions delivered over 5 weeks as a simultaneous integrated boost to residual positive lymph nodes outside of the true pelvis (PTV57.5)
- Please see separate HDR brachytherapy document for subsequent therapy (consider vaginal vault brachytherapy if positive or close margins i.e. <2mm)

**HDR brachytherapy**

- This is covered separately in the consensus brachytherapy – please review this document for the therapeutic schema.

**Retreatment**
In very select circumstances re-irradiation could be considered. It depends on the expected prognosis and there being no suitable alternative treatment. The risk and benefits must be discussed and documented within a peer group and fully discussed with the patient. Prescription may vary and should consider time elapsed from previous treatment, the use of chemotherapy, previous surgery, associated comorbidities, BED to points of interest (including from prior brachytherapy) and evidence of radiation sequelae. SABR or brachytherapy may be most suitable.
Patients having re-irradiation should ideally be added to an appropriate national audit.

## 5. Pre-Treatment: Patient Simulation and Immobilisation

**Pre-planning:**
Patients should be counselled on the importance of bladder and bowel preparation for treatment planning and delivery. Local protocols should be employed to promote

hydration, comfortable bladder filling and regular emptying of bowels. This may include a local drinking protocol, regular laxatives or micro-enemas.

**Positioning & immobilisation:**
Supine position and immobilised using local pelvic immobilisation devices with foot and knee support

**Simulation:**

- Two planning scans are required in the bladder full and empty states.
- Patients will be scanned from at least the top of T10 to 2-4cm below the ischial tuberosities.
- Bladder full scan should be acquired with a bladder volume of 200-400mls. Volume may be tested with an initial scouting CT or bladder scanner. This image set is acquired with intravenous contrast (unless contraindicated) to visualise the pelvic vessels. Oral contrast may be employed to help visualise the small bowel.
- Empty bladder scan is acquired without intravenous contrast.
- The diameter of the rectum should be ≤4cm in any direction. Further attempt at CT planning should be sought if rectum is outside of this tolerance. If persisting distention, consideration should be made to increase the posterior margins to the CTV.

## 6. Tumour Motion

- The position of the uterus can be markedly variable in relation of bladder filling and bowel distention. To account for this, at least 2 planning CTs with full and empty bladder is employed. Later in the contouring guidance, the posterior margin of the CTV is increased to compensate for variable filling.
- On treatment daily CBCT should be employed to aid set-up.
- All centres should aim to adopt a 'Plan of the day' approach for delivery of treatment, as recommended by the RCR Consensus Statements.

## 7. Treatment Planning

| Conventional contour nomenclature and description | Suggested ProKnow nomenclature |
|---|---|
| **GTV:** Gross tumour volume (at diagnosis) | GTVp |
| **HR-CTV (full):** High Risk CTV (bladder full) | CTVp_HR_full_4500 |
| **LR-CTV (full)**: Low Risk CTV (bladder full) | CTVp_LR_full_4500 |
| **HR-CTV (empty):** High Risk CTV (bladder empty) | CTVp_HR_empty_4500 |

| | |
|---|---|
| **LR-CTV (empty):** Low Risk CTV (bladder empty) | CTVp_LR_empty_4500 |
| **HR-CTV (for CBCT):** HR-CTV (full) + HR-CTV (empty) to aid radiographers in soft tissue matching using CBCT | CTVp_HR_4500 (OR ITVp_HR_4500?) |
| **ITV-T:** ITV-Tumour combining LR-CTV volumes from full & empty (+/- diagnostic) scans | ITVp_4500 |
| **GTV-N**: GTV-(involved) Nodes | GTVn |
| **CTV-N**: CTV-(involved) Nodes | CTVn_xxxx (in case of >1 node prescribed the same dose please add numbers in order from superior to inferior e.g. CTVn1_5500, CTVn2_5500) |
| **CTV-E**: CTV-elective nodal areas at risk of microscopic spread | CTVe_4500 |
| **PTV45** | PTVpen_4500 |
| **PTV55-57.5** | PTVn_xxxx (in case of >1 node prescribed the same dose please add numbers in order from superior to inferior e.g. PTVn1_5500, PTVn2_5500) |

Organs at risk

- **Bladder**
- **Rectum**
- **Sigmoid**
- **Bowel**
- **Femoral heads**
- **Kidneys** – if para-aortic fields also included
- **Spinal cord/column**

## 8. Volume Outlining

Outlining guidelines have been adapted from the EMBRACE II trial protocol[5] and 'an Atlas of the Pelvic Lymph Node Regions to Aid Radiotherapy Target Volume Definition[6]'.

**STEP 1: Outlining primary:**

- **GTV** = Outline all visible tumour (using all available imaging, ideally with fused planning MRI)

- **HR-CTV** = GTV + entire cervix

- **LR-CTV** = HR-CTV + 5mm anterior margin, 10mm posterior margin. Then manually extended to include parametria, entire uterus, 20mm uninvolved vagina. If the pelvic sidewall or mesorectum is involved, add a 20mm margin to the HR-CTV.

| **Borders of parametria** | **Definition** |
|---|---|
| Superior | Fallopian tube or broad ligament/Uterine artery enters uterus |
| Inferior | Levator ani/pelvic floor muscles |
| Anterior | Posterior bladder or posterior border of external iliac vessels |
| Posterior | Mesorectal fascia and uterosacral ligaments |
| Lateral | Medial internal obturator/piriformis muscle/ischial ramus i.e. Pelvic sidewall |
| Medial | Cervix |

- The HR-CTV & LR-CTV is completed on the full, empty and (if applicable) diagnostic MRI images and labelled accordingly.

- **ITV-T** = Combine the LR-CTV_full and LR-CTV_empty (& LR-CTV_diagnostic if available)

- **HR-CTV (for CBCT)** = Combine the HR-CTV on full and empty bladder scans to aid CBCT, for the purpose of aiding on-set decisions such as soft tissue matching.

**STEP 2: Outlining involved nodes (if applicable)**:

- **GTV-N**: Outline all involved lymph nodes using information from PET-CT, MRI and planning CT. Consider non-avid nodes >1.0cm in short axis and those with irregular morphology (e.g. rounded, loss of fatty hilum). Label each by number (e.g. GTV-N1, GTV-N2 etc. starting at the most superior positive node).

- **CTV-N** = GTV-N +3-5mm margin. Edit off bone. Label each CTV corresponding to GTV number (e.g. CTV-N1).

**STEP 3: Outlining elective nodal regions**:

The elective nodal volume should encompass pre-sacral, internal iliac, external iliac and obturator lymph node groups. Common iliac lymph nodes should also be included ('large pelvis') unless the patient meets all of the following 'low-risk' features (otherwise termed 'small pelvis'):

- Tumour size <4cm
- FIGO stage IA-IB or IIA1
- Squamous cell carcinoma
- No uterine invasion

The inguinal lymph nodes should be included in the event of extensive vaginal involvement (may be defined by lower third involvement, but this is up to the discretion of the clinician). Para-aortic lymph nodes should be included in the event of positive para-aortic lymph nodes, ≥1 common iliac or ≥3 pelvic lymph nodes.

- **Vessels** = The superior extent of the vessels is determined by the risk-group:
    - Small pelvis: Bifurcation of the common iliac vessels
    - Large pelvis: Bifurcation of the aorta
    - Para-aortic field: Level of the renal veins

  The vessels should be outlined until the level of the top of the femoral heads.

- **CTV-E** = Vessels + 7mm margin in the anterior, posterior and lateral directions. The volume is then manually edited to exclude bone and muscle. The volume is then adjusted using the following instructions:
    - Para-aortics (if included): Manually expand the volume postero-laterally to cover the vertebral body and left para-aortic area.
    - Pre-sacral: Using a 10mm rollerball, contour anterior to the sacrum and connect the bilateral pelvic nodal groups. Do not include the sacral foramina. Continue this down to the bottom of S2 or until the pyriformis muscle becomes visible.
    - Common iliacs: Extend the field posteriorly and laterally to the vertebral body and psoas.
    - Internal & external iliacs: As the volumes separate, connect the ipsilateral internal and external iliacs along the pelvic sidewalls with a 17mm rollerball.
    - If treating positive external iliac lymph nodes, use a 15mm rollerball anterior to the external iliac artery as lymph nodes may be found more distally.
    - Obturators: Below the level of the internal and external iliac vessels, continue to employ a 17mm rollerball along the pelvic sidewall. Ensure muscle is excluded. Continue the volume inferiorly until the obturator vessels exit the obturator foramina.
    - Inguinal (if included): The inguinal lymph nodes should be drawn as a 'compartment'. The superior extent is where the external iliac vessels leave the pelvis. The inferior extent is at the bottom of the lesser trochanter. The lateral aspect is the ventral fascia of the ileopsoas and sartorius muscles. The posterior border is ventral fascia of the pectineus muscle. The anterior border is 5mm below the skin surface. The medial border should be at least 20-25mm medial to the inguinal vessels.
    - Note, the majority of inguinal nodal recurrences are found in the anteromedial aspect of the compartment[7].

- Inclusion of CTV-N: Finally, ensure that the CTV-N is included within the CTV-E.

**STEP 4: Combining tumour and nodal volumes and creating PTVs:**

Once these nodal volumes have been outlined, combine the margins from the CTV-E and ITV-T to create a volume called **ITV45.**

- **PTV45** = ITV45 + 5mm margin.
- **PTV55-57.5 (with n-number if more than one node with the same dose level)** = CTV-N + 5mm margin.

## 9. Dose Calculation and Plan Evaluation

### Organs at Risk (OARs) Limits

#### PLANNING AIMS FOR TARGETS AND ORGANS AT RISK

With a prescription dose of 45Gy to PTV45, and 55-57.5Gy to PTV-N (#) if applicable, delivered in 25 fractions, the dose volume constraints for organs at risk (OAR) summarized in table below need to be met.
Note that these OAR constraints are based on the PTV definition with a 5mm ITV to PTV margin.

Dose constraints for EBRT for N0 and N1 patients. (Updated dose constraints of EMBRACE II study protocol version 1.0.)

| P | **No lymph node involvement** | | **Involved lymph nodes** | |
|---|---|---|---|---|
| | Hard dose constraints | Soft dose constraints | Hard dose constraints | Soft dose constraints |
| PTV45 | V42.75> 95%<br>Dmax < 107% | V42.75= 95% | V42.75> 95% | V42.75= 95%<br>Dmax < 107% for helper structure:<br>PTV45 – (PTV-N(#) + 1 cm) |
| ITV45 | Dmin>95% | | Dmin>95% | |
| **CTV-HR +10mm** | | Dmax < 103% | | Dmax < 103% for helper structure:<br>CTV-HR+ 10 mm – (PTV-N(#) + 1 cm) |
| **PTV-N(#)** | | | D98% > 90% of prescribed LN dose<br>Dmax < 107% of prescribed LN dose | D98% = 90% of prescribed LN dose |
| **CTV-N(#)** | | | D98% > 100% of prescribed LN dose | D50% > 102% of prescribed LN dose |
| Bowel | Dmax < 105% (47.3Gy) | V40Gy < 250 cm3*<br>V30Gy < 500 cm3* | Dmax < 105%<br>in regions outside 10–15mm from PTV-N | When no para-aortic irradiation:<br>V40Gy < 250 cm3*<br>V30Gy < 500 cm3*<br>For para-aortic irradiation:<br>V40Gy < 300 cm3*<br>V30Gy < 650 cm3*<br>Dmax < 57.5Gy** |
| Sigmoid | Dmax< 105% (47.3Gy) | | Dmax< 105% (47.3Gy)* | Dmax < 57.5Gy** |
| Bladder | Dmax < 105% (47.3Gy) | V40Gy < 60*<br>V30Gy < 80* | Dmax < 105%<br>in regions outside 10–15 mm from PTV-N | V40Gy < 60%*<br>V30Gy < 80%* |
| Rectum | Dmax < 105% (47.3Gy) | V40Gy < 75%*<br>V30Gy < 95%* | Dmax < 105%<br>in regions outside 10–15 mm from PTV-N | V40Gy < 75%*<br>V30Gy < 95%*<br>Dmax < 57.5Gy** |
| Spinal Cord Canal | Dmax < 48Gy | | Dmax < 48Gy | |
| Femoral Heads | Dmax < 50Gy | | Dmax < 50Gy | |
| Body | Dmax < 107% | | Dmax < 107% | |
| Kidney | Dmean < 15Gy | Dmean < 10Gy | Dmean < 15Gy | Dmean < 10Gy |
| Transposed Ovaries | Dmean<8 Gy | Dmean < 5 Gy | Dmean<8 Gy | Dmean < 5 Gy |
| Duodenum | V55<15cm3 | | V55<15cm3 | |

References:

| | |
|---|---|
| The EMBRACE II study: The outcome and prospect of two decades of evolution within the GEC-ESTRO GYN working group and the EMBRACE studies (https://pmc.ncbi.nlm.nih.gov/articles/PMC5862686/ ) *Soft constraints which can be used as optimisation constraints as they are not based on clinical evidence. The constraints are not supposed to be fulfilled by all patients, but rather by ~70-80% of the patients. | |
| ICRU report83 | Dmax /Dmin can be replaced with D0.1cc /D0.1% and D99.9% |
| Retained from local protocols | ** OAR Max dose Planning constraint |

## 10. Treatment Delivery & Verification

- For all fractions of VMAT treatments, the Radiographers treating MUST ensure the gantry will not collide with the patient or couch during the treatment.
- Daily on-line CBCT image guidance

## 11. Supportive care

- Patients should receive weekly on-treatment reviews by an appropriately trained medical professional to manage ongoing toxicity. This may include Oncologists, Advanced/Consultant Radiographers, Treatment Radiographers, radiotherapy specialist nurses or Gynaecology Clinical Nurse Specialists.
- Patients should undergo weekly blood tests with FBC, U&Es, LFTs and Mg2+ to assess suitability for chemotherapy delivery each week.

## 12. Follow-up after treatment

- **6 week post-treatment r/v:** Review of toxicities
- **3 month r/v:** Clinical review with interval MRI or PET-CT
- **Year 1:** 3-4 monthly clinical reviews with CT at 1 year
- **Year 2:** 3-4 monthly clinical reviews with CT at 2 years
- **Year 3:** 6-monthly review with CT at 3 years
- **Years 4-5**: 6-12-monthly clinical reviews

Ideally all centres should have access to a ‘late effects of radiotherapy’ service. This is a multidisciplinary approach to addressing the late gastrointestinal, urological and sexual effects as well as addressing premature menopause, lymphoedema, psychological needs and nutrition following radiotherapy.

## Appendix 1: References


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