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Welsh Health Specialised Services Committee (WHSSC)

Specialised Services Clinical Access Policy: Enhanced Image Guided Brachytherapy (IGBT) Service for the Treatment of Gynaecological Malignancies

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1. POLICY STATEMENT

The Welsh Health Specialised Services Committee (WHSSC) commissions Image Guide Brachytherapy (IGBT) for the treatment of gynaecological malignancies in line with this policy. Clinicians are requested to take into consideration the indications, patient access criteria and the quality and outcome measures specified in this policy

2. CLINICAL INDICATIONS

Patients with carcinoma of the cervix who are undergoing radical non-surgical treatment (radiotherapy or chemoradiotherapy) who require brachytherapy treatment.

Rarely, selected patients with endometrial or vaginal cancer may also require image guided brachytherapy on an individualised basis.

Gynaecological cancer staging is determined by the clinical extent of the disease and used to guide treatment decisions and prognosis (Figures 1, 2 and 3). [1]

2.1 Staging

Figure 1. Cervical cancer: treatment combinations by stage

Category	Stage	Treatment
Early	IA-IB1 and selected IIA	Womb-sparing surgery or hysterectomy or radiotherapy
Locally advanced	IB2-IVA	Radiotherapy or chemoradiotherapy
Advanced	IVB	Radiotherapy or chemoradiotherapy or chemotherapy

[1] Adapted from the All Wales Guidelines on the Management of Gynaecological Cancers, 2001, the South Wales Cancer Guidelines for Vulva, Endometrium, Ovary and Cervix, 2011 and Hanna, Crosby and Macbeth, Practical Clinical Oncology, Cambridge University Press, 2008

Figure 2. Endometrial cancer: treatment combinations by stage

Category	Stage	Treatment
Early	I-II	Hysterectomy +/- radiotherapy +/- chemotherapy
Locally advanced	III-IVA	Hysterectomy and/or radiotherapy +/- chemotherapy +/- hormonal therapy
Advanced	IVB	Chemotherapy and/or radiotherapy and/or hormonal therapy

Figure 3. Vaginal cancer: treatment combinations by stage

Category	Stage	Treatment
Early	I	Surgery and/or radiotherapy
Locally advanced	II-IVA	Surgery and/or radiotherapy and/or chemotherapy
Advanced	IVB	Radiotherapy and/or chemotherapy

2.2 Cervical cancer[2]

- Inoperable Stage IA1 cervical cancer patients (i.e. those who are unable to have surgery) may be treated definitively with brachytherapy alone.
- Inoperable Stage IA2 - IB1 cervical cancer patients should be treated radically with brachytherapy in conjunction with external beam radiation. Concurrent chemotherapy may be considered at the physician's discretion and based on the presence of high risk features.
- Clinical stage IB2 - IVA cervical cancer should be treated radically with concurrent chemoradiotherapy (or radical radiotherapy alone if unfit for concurrent chemotherapy) followed by brachytherapy. In addition stage IVB cervical cancer where the only site of metastatic disease is within a radical radiotherapy field (e.g. the para-aortic lymph node region) may also be treated with concurrent chemoradiotherapy (or radiotherapy) followed by brachytherapy.
- Stage IVB cervical cancer where the disease has spread beyond a radical treatment volume may be palliatively treated with brachytherapy with or without external beam to decrease the risk of severe hemorrhage or other life-threatening symptoms.

[2] Adapted from the American Brachytherapy Society Cervical Cancer Brachytherapy Task Group criteria for management of cervical cancer

- Patients are treated with brachytherapy regardless of lymph node status, grade, presence of lymphovascular invasion, tumor size, age, or histology. Rarely, medical co-morbidities may prohibit brachytherapy.
- The use of Intensity-Modulated Radiation Therapy (IMRT) or 3D conformal external beam radiation is not a substitute for brachytherapy.

2.3 Other gynaecological cancers

- Occasionally, patients with endometrial cancer cancer who are medically unfit for surgery may require brachytherapy.[3]

- Vaginal cancer is rare and brachytherapy is not covered by national guidelines but brachytherapy may form part of its treatment.[4]

3. CLINICAL ASSESSMENT

All patients who are scheduled to have brachytherapy will be assessed by a consultant clinical oncologist and a consultant anaesthetist

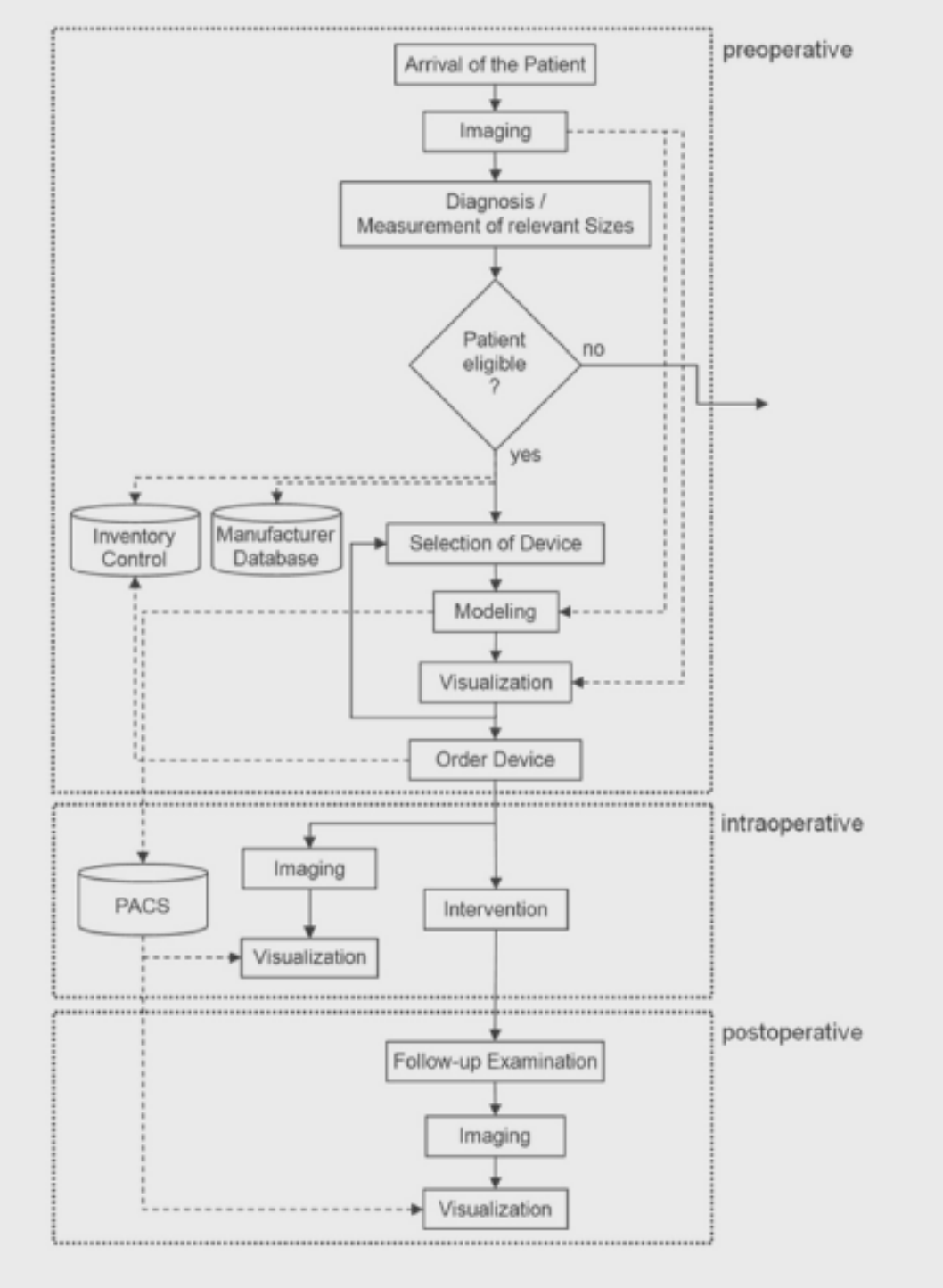
The clinical practice of brachytherapy is well characterized using five components:

1. Applicator Choice and Insertion Techniques;
2. Imaging Protocol;
3. Contouring Protocol;
4. Treatment Planning;
5. Dose; and
6. Fractionation (shown in Figure 4).

[3] Nag et al., 2000. The American Brachytherapy Society recommendations for high-dose-rate brachytherapy for carcinoma of the endometrium. Int J Radiat Oncol Biol Phys, 48: 779-90.

[4] Beller et al., International Federation of Gynaecologic Oncology Annual Report, 2003.

Figure 4. Example Work Flow for IGBT including Follow Up Examination (from Egger 2013).[5] Specific centre may vary slightly from this model.



[5] Egger, 2013. Springer Plus, 2: 395

3.1 Treatment planning[6]

Dosimetry should be performed every time applicators are inserted to assess doses to the targets as well as the normal tissues, even if fixed geometry applicators are used. Failure to perform dosimetry can result in exceeding the normal tissue tolerance of the organs at risk.

Planning target volume:

- Point A should be reported for all cases regardless of the imaging modality utilised;
- For institutions that utilize MRI, GTV for the cervix, high-risk CTV of the cervix plus tumour extension at the time of brachytherapy, intermediate-risk CTV of the cervix plus tumour extension at the time of diagnosis as defined by the GEC-ESTRO recommendations. Point A must always be reported, as should the D90, V100 and D2cc to the rectum, bladder and sigmoid/bowel;
- For institutions that utilize CT, the width of the cervix and any parameterial extension should be contoured (HR-CTV-CT). The superior border of the cervix should extend at least 1 cm above either the uterine vessels identified by IV contrast, or the location where the uterus begins to enlarge. If these cannot be identified, a height of 3 cm should be contoured for the cervix;
- Delineation of target volumes to be performed after insertion of tandem and vaginal applicators or interstitial applicator on images in the treatment planning computer;
- Treatment planning for intracavitary applications should be performed after brachytherapy insertion and prior to treatment;
- A pre-implant scan before the procedure may be performed for interstitial cases to assist with proper catheter placement;
- Image-based volumetric information shall consist of CT, and/or MRI using contiguous slice acquisition with slice thicknesses < 3 mm;
- Organs at risk to be contoured (including bladder, rectum, and sigmoid/bowel) are defined at the time of brachytherapy;
- DVH information is used for assessment of coverage of the target and dose to organs at risk;
- Reporting: Standard parameters reported in the GEC-ESTRO recommendations include the D2cc for the organs at risk; D90 and V100 for tumour.

3.2 Post-insertion assessment

3.2.1 Imaging

[6] Adapted from American Brachytherapy Society Guidelines, 2012

T2-weighted MRI should be used for organs at risk (OARs) delineation and targeting in image-based cervical cancer brachytherapy.

CT imaging may also be required for accurate geometric reconstruction of the applicators.

4. TREATMENT

4.1 Dosimetry

- Recommended prescription dosimetric parameters that should be met or exceeded;
- Target coverage D90 should equal 100% of prescription
- D2cc to the sigmoid/bowel = 70-75Gy$_{\alpha/\beta3}$ and D2cc to the rectum=70-75 Gy $_{\alpha/\beta3}$. A D2cc to the bladder = 90-95 Gy$_{\alpha/\beta3}$.

Dose homogeneity:

- The importance of dose homogeneity is unclear.
- Efforts should be made to spare the bladder, rectum, and sigmoid/bowel.

4.2 Recommended prescription

The recommendations for implementing Image Guided Brachytherapy in the UK state that the minimum EQD2 dose to Point A and/or D90 should be 75-80Gy $_{\alpha/\beta10.}$ The GEC-ESTRO and ABS recommendation is for a tumour EQD2 85-90Gy$_{\alpha/\beta10}$ – RCR states that this is higher than doses traditionally used in the UK and should be applied with caution in association with detailed attention to OAR doses and careful monitoring of morbidity rates.

Current practice in Velindre Cancer Centre is to give an EQD2 dose of 74.6Gy$_{\alpha/\beta10}$ to Point A. There are plans for dose escalation to be carried out in line with the UK recommendations in the future.

4.3 Timing

High-dose-rate brachytherapy commences after EBRT of usually 45Gy in 25 fractions (+/- boost to high risk areas). Brachytherapy may be initiated earlier, during the external beam at the discretion of the treating consultant.

4.4 Intraoperative procedure

- Standard brachytherapy procedure consists of dilating the cervical os. Ultrasound guidance may assist with applicator placement;
- Tandem and ovoid, tandem and ring or tandem and cylinders for intra-cavitary applications are inserted free hand;
- Hollow interstitial needles, if used, are inserted either freehand or with template or ultrasound guidance (e.g., template or guide holes in a ring applicator) for interstitial applications;
- Radiographic CT and/or MRI imaging to assist with dose prescription.

4.5 Post-treatment evaluation[7]

- PET evaluation at 3 months has shown to be prognostic. The use of PET imaging at time points other than 3 months should be considered on an individual basis in line with the WHSSC policy on PET-CT. MRI at 3-6 months can determine response to treatment;
- Physical examination for recurrence or complications is necessary;
- Quality of life and patient satisfaction should be considered;
- Post-treatment biopsy may be needed to rule out recurrence.

5. RELATIONSHIP WITH OTHER POLICIES AND SERVICE SPECIFICATIONS

This document should be read in conjunction with the following policies and services specifications:

- CP50 PET-CT Clinical Access Policy
- All Wales Policy: Making Decisions on Individual Patient Funding Requests

The policy should also be read in conjunction with:

- Velindre NHS Trust. Delivering Quality, Care and Excellence. Service, Workforce and Financial Framework 2011/12 - 2015/16.
- Implementing Image-Guided Brachytherapy for Cervix Cancer in the UK. The Royal College of Radiologists, ISBN 978-1-905034-36-9 Ref No. BFCO(09)1, April 2009.
- Radiotherapy Services in England 2012. Department of Health Cancer Policy Team, 6th November, 2012.
- Recommendations from Gynaecological (GYN) GEC-ESTRO Working Group (I): Concepts and terms in 3D image based 3D treatment planning in cervix cancer brachytherapy with emphasis

[7] Adapted from American Brachytherapy Guidelines, 2012

on MRI assessment of GTV and CTV. Radiotherapy Oncol 2005; 74:235-245. Haie-Meder C, Pötter R et al.

- Recommendations from gynaecological (GYN) GEC-ESTRO working group (II): Concepts and terms in 3D image-based treatment planning in cervix cancer brachytherapy-3D dose volume parameters and aspects of 3D image-based anatomy, radiation physics, radiobiology. Radiotherapy Oncol 2006;78:67-77. Pötter R, Haie-Meder C et al.

6. DEFINITIONS

Brachytherapy Radiotherapy can be divided into external beam radiotherapy (EBRT) and internal radiotherapy, frequently referred to as brachytherapy. Unlike EBRT, brachytherapy involves placing a radiation source internally near to, or into, the target tissue. The precise, conformal approach of brachytherapy allows radiation to be delivered directly to the target area, while sparing surrounding healthy tissues and structures.

7. CLINICAL CODING

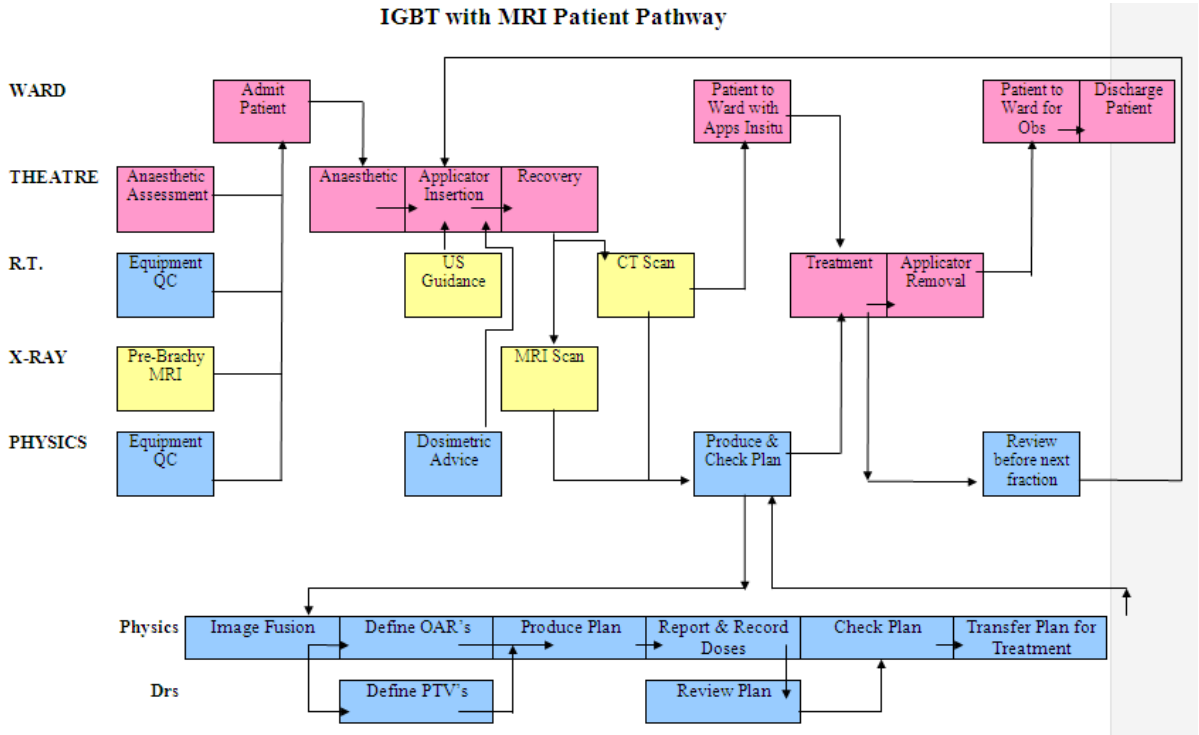
OPCS 4

X65.2 Delivery of a fraction of intracavitary radiotherapy
Y35.4 Introduction of radioactive substance into organ for brachytherapy NOC
Z45.1 Cervix uteri

ICD-10

In addition an ICD-10 code from category C53. e.g. Malignant neoplasm of cervix uteri is assigned.

8. PATIENT PATHWAY



9. EXCLUSIONS

9.1 General

Unfit to undergo the procedure for example if they have severe breathing problems meaning that they are unable to lie flat for several hours.

Absolute contraindications to radical treatment[8]

- Prior pelvic radiotherapy with brachytherapy
- Life expectancy < 6 months

[8] American Brachytherapy Society Guidelines, 2012

10. CLINICAL OUTCOME AND QUALITY MEASURES

The Provider must work to written quality standards and provide monitoring information to the lead purchaser. Providers are expected to comply, as a minimum, with the following:

10.1 Quality indicators

- IRMER Regulations
- Departmental Quality Control

The Image Guided Brachytherapy Implementation Group, under the auspices of the Radiotherapy Development group working in conjunction with the Gynaecological Site Specific Team will monitor quality criteria including serious incidences, concerns received, lessons learned and action plans which will include:

10.2 Clinical Outcomes

The improvement in local control with image guided brachytherapy has been established by the University of Vienna who monitored outcomes over a 20 year period. The introduction of image guided brachytherapy to level 4 resulted in an increase in local control of around 20%.

10.3 Clinical audit

The Gynaecological Site Specific Team which oversees the audit programme for the gynaecological team will include IGBT in its annual programme and will monitor local tumour control.

10.4 Patient experience

Providers should use a validated patient experience tool for monitoring patient experience on, as a minimum, an annual basis (e.g. CAREs tool (http://www.caremeasure.org/)

Patient experience will be included in the departmental audit programme.

10.5 Quality of life

Quality of life using e.g. the QOL–EQ VAS tool will be monitored during routine follow up.

11. EQUALITY IMPACT ASSESSMENT

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

12. GLOSSARY OF ACRONYMS

3D	Three dimensional
α/β3	Alpha Beta Ratio at 3 Gy
α/β10	Alpha Beta Ratio at 10 Gy
ABS	American Brachytherapy Society
CT	Computed Tomgraphy
CTV	Clinical Target Volume
D2cc	Minimum dose received by 2 centimetres cubed
D90	Minimum dose received by 90% of the volume
EBRT	External Beam Radiotherapy
EQD2	Equivalent Dose at 2Gy
EQIA	Equality Impact Assessment
GEC-ESTRO	Group Europeen de Curietherapie – European Society for Radiotherapy and Oncology
GTV	Gross Tumour Volume
Gy	Gray
GYN	Gynaecology
HR-CTV	High Risk Clinical Target Volume
IGBT	Image guided brachytherapy
IMRT	Intensity Modulated Radiation Therapy
IRMER	Ionising Radiation (Medical Exposure) Regulations
IV	Intravenous
MRI	Magnetic Resonance Imaging
OAR	Organs at risk
PACS	Picture Archive and Communication System

PET	Positron Emission Tomography
PET-CT	Positron Emission Tomography – Computed Tomography
QC	Quality Control
QOL-EQ VAS	Quality of Life Questionnaire Visual Analogue Scale
RCR	Royal College of Radiologists
UK	United Kingdom
US	Ultrasound
V100	Volume receiving 100% of the dose
WHSSC	Welsh Health Specialised Services Committee

13. REFERENCES

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