Health Authority – Abu Dhabi			
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1. Purpose

1.1 This standard aims to ensure the delivery of quality and safe clinical care for patients with breast cancer. To do so it sets the requirements for the:

- 1.1.1 minimum standards for the safe and effective management of breast cancer;
- 1.1.2 clinical service specifications;
- 1.1.3 breast cancer care pathway; and
- 1.1.4 data reporting.

2. Scope

2.1 This standard applies to all Healthcare Providers (Facilities and Professionals) licensed by HAAD in the Emirate of Abu Dhabi and providing clinical care and management services for breast cancer.

2.2 For the purpose of this standard, breast cancer management includes the following services; diagnosis, preoperative assessment, treatment, follow up and monitoring.

2.3 The standards has have been adapted from:

- 2.3.1 National Institute for Health and Clinical Excellence (NICE). Early and locally advanced breast cancer: diagnosis and treatment. Publication No 80, Feb 2009;
- 2.3.2 National Institute for Health and Clinical Excellence (NICE). Advanced breast cancer: diagnosis and treatment. Publication No 81, Feb 2009 and
- 2.3.3 National Comprehensive Cancer Network (NCCN). Breast Cancer. Version 2.2011.

3. Duties of Healthcare Providers

All licensed healthcare providers providing breast cancer management services must:

3.1. Provide clinical services and patient care in accordance with this standard, HAAD Policies and Standards, and the laws and regulations of the Emirate of Abu Dhabi.

3.2. Submit data to HAAD via e-Claims in accordance with the HAAD Reporting of Health Statistics Policy and as set out in the HAAD Data Standards and Procedures (found online at www.haad.ae/datadictionary).

3.3. Comply with HAAD policies and standards on managing patient medical records, including developing effective recording systems, maintaining patient records, maintaining confidentiality, privacy and security of patient information; and educating patients on services provided and satisfying the requirements of the patients rights and responsibilities charter.

3.4. HAAD may, at its sole discretion require healthcare providers to report on confirmed new breast cancer cases and specified indicators. Where it does so, providers must comply with these reporting requirements.

4. Enforcement and Sanctions

4.1 Healthcare providers must comply with the terms and requirements of this Standard, the HAAD Standard Contract and the HAAD Data Standards and Procedures. HAAD may impose sanctions in relation to any breach of requirements under this standard in accordance with the [HAAD *Policy on Inspections, Complaints, Appeals and Sanctions*].

5. Standard 1: Clinical Service specifications

5.1. All Healthcare Providers providing breast cancer management services are required to:

5.1.1. Be Licensed by HAAD;

5.1.2. comply with the requirements for a specialized breast care unit, as described at Appendix 1;

5.1.3 follow the HAAD recommended breast cancer pathways, clinical quality indicators and timelines for referral, diagnosis and treatment as stipulated in Appendices 2, 3 and 4, respectively;

5.1.4 comply with the diagnosis procedure and specifications as described in the HAAD Standard for the Screening and Diagnosis of Breast Cancer;

5.1.5 develop, implement and monitor standard operating procedures for the following elements of care:

5.1.4.1 Patient Referral;

5.1.4.2 diagnosis;

5.1.4.3 preoperative assessment;

5.1.4.4 pathology handling and reporting;

5.1.4.5 treatment; and

5.1.4.6 follow up and monitoring.

5.1.5 establish internal audit procedures to demonstrate compliance with this standard and other associated regulatory policies and standards;

5.1.6 ensure availability of audit records to HAAD audit team as evidence of compliance with HAAD Clinical Quality indicators specified at Appendix 4;

5.1.7 ensure management of breast cancer patients by multi-disciplinary teams (MDT) that comprise of the necessary mix of qualified and skilled personnel and staff as stipulated at Appendix 5; and

5.1.8 ensure that all patients with a suspected or confirmed diagnosis of breast cancer have access to a breast care nurse, and psychotherapist if needed, for information and support at the various stages of disease from diagnosis through to treatment and follow up care.

5.2 All Healthcare Professionals participating in the breast cancer diagnosis, treatment, management, and follow up care must:

5.2.1 Be licensed by HAAD;

5.2.2. satisfy the qualifications relevant to their position as defined by the HAAD Professional Qualifications Requirements;

5.2.3 comply with the HAAD Standard for Clinical Privileging framework, including limiting their practice to the skills, competencies and the privileges granted within the particular facility with which they are associated;

5.2.4 participate in continuing medical education; a minimum of 10 hours per year (out of the 25 Category 1 CE hours) must be in the specialty of the physician;

5.2.5 use the clinical standards detailed in this standard as a guide for the minimum care. The treating physician is responsible for deciding the best care options for patient; and

5.2.6 provide patients with clear oral and written information regarding the diagnosis and treatment options and provide psychological support as required.

6 Standard 2: Referral and Diagnosis

6.1 Referral process and criteria

6.1.1 Screening facilities must have a referral system to refer women with abnormal mammogram or recall them for assessment to a specialized breast care unit.

6.1.2 All patients presented with possible or suspected breast cancer signs and symptoms must be referred urgently within 2 weeks, to a specialized breast care unit. The criteria for urgent referral are described at Appendix 6.

6.2 Diagnosis process, procedures and timelines

6.2.1 All patients referred for assessment after initial screening, or after symptomatic presentation, must undergo triple assessment, comprised of:

6.2.1.1 imaging: diagnostic mammogram/ultrasound;

6.2.1.2 clinical exam; and

6.2.1.3 needle biopsy for significant abnormalities. Core needle biopsy (CNB) is the standard procedure to obtain a non-operative diagnosis of breast cancer.

6.2.2 Triple assessment must be completed at a single visit unless there are exceptional circumstances that may necessitate further scheduled visits.

6.2.3 Time interval between the date of pathological diagnosis of breast cancer and the date of therapeutic surgery or other treatment must be less than 4 weeks.

7. Standard 3: Pathology- handling, testing and reporting

7.1. Laboratories providing diagnostic services for breast cancer; including testing, reviewing and reporting must:

7.1.1. Comply with HAAD Clinical laboratory Standards in the Emirate of Abu Dhabi;

7.1.2. attain, within 12months from the date of issuance of this standard accreditation by an internationally credible accrediting body (recognized by HAAD such as CAP, ISO 15189(2007), JCI /Lab) for breast cancer. HAAD may, at its sole discretion, consider extension to attain within 18 months from the issuance of this Standard on a case by case basis and taking into account evidence of progress towards accreditation.

7.2. Specimen handling & testing

7.2.1. Specimen Identification and labelling must be in accordance with international evidence based laboratory standards and industry practices; the following information must be recorded as a minimum:

7.2.1.1. Name of Patient (Full name);

7.2.1.2. patient date of birth and/or age;

7.2.1.3. patient gender;

7.2.1.4. medical record number;
7.2.1.5. source of specimen;
7.2.1.6. date of specimen collection;
7.2.1.7. time of specimen collection;
7.2.1.8. time of fixation (time specimen placed in formalin); and
7.2.1.9. relevant clinical information and medical history.

7.2.2. Procedural requirements to be satisfied include:

7.2.2.1. Alignment with procedural requirements of accrediting bodies as detailed in 7.1.2 for procedures and protocols for adequate specimen collection, handling, tumor grading and scoring of predictive markers and communication to healthcare professionals who collect breast specimens;

7.2.2.2. the time of tissue collection (defined as the time that the tissue is removed from the surgical field) and the time the tissue is placed in fixative must be recorded on the specimen requisition to document the cold ischemic time;

7.2.2.3. immediate fixing of all breast tissue specimens, including needle core biopsies, in 10% NBF for no less than 6 hours and preferably no more than 72 hours before processing;

7.2.2.4. immediately placing of needle biopsy specimens in a fixative whose volume is at least 10 times that of the specimen size; and

7.2.2.5. avoidance of frozen sections - especially on small lesions; less than 1 cm in diameter, or non-palpable.

7.3. Histopathology Reporting

7.3.1 A histopathology synoptic reporting format must be used by pathologists containing at least those elements in standards of accrediting bodies as detailed in 7.1.2 for cancer protocols for invasive and DCIS breast cancer.

7.3.2 The report must include at least the following details;

7.3.2.1 Dominant histological type;
7.3.2.2 tumor grade;
7.3.2.3 receptor status on invasive cancer; Estrogen, Progesterone, Human Epidermal Growth Receptor 2;
7.3.2.4 pathology stage (T and N);
7.3.2.5 tumour size for the invasive component;
7.3.2.6 peritumor vascular invasion;
7.3.2.7 distance to nearest surgical l margin; and
7.3.2.8 lymph node status.

8 Standard 4: Preoperative Assessment and staging

8.1 General assessment must include:

8.1.1 Complete Blood Count (CBC);

8.1.2 biochemistry including Liver function test (LFT), alkaline phosphates (ALP) and calcium;

8.1.3 genetic counselling if patient is high risk for hereditary/familial breast cancer by the treating physician and/or appropriately licensed, qualified and privileged health professional; and

8.1.4 prior to chemotherapy fertility counselling for patients who may consider future pregnancies by a consultant or specialist with competencies and privileges in fertility treatment.

8.2 Staging of the breast

8.2.1 Subject to medical necessity, and where other imaging modalities (mammogram and ultrasound) have been conducted and proven to be unreliable or inconclusive, Magnetic resonance imaging (MRI) may be considered as well in the following cases:

8.2.1.1 invasive lobular carcinoma;

8.2.1.2 suspicion of multicentricity;

8.2.1.3 lesions of the breast (i.e., T0N+) not detectable on other clinical or imaging modalities;

8.2.1.4 genetic high risk;

8.2.1.5 women with breast implants;

8.2.1.6 aged less than 40 years;

8.2.1.7 assessment following neoadjuvant treatment; and

8.2.1.8 women with dense breasts.

8.3 Staging of the Axilla

8.3.1 Pre-treatment ultrasound evaluation of the axilla must be performed for all patients being investigated for early invasive breast cancer.

8.3.2 If morphologically abnormal lymph nodes are identified, then ultrasound-guided needle sampling or fine needle aspiration cytology (FNAC) or CNB must be offered.

8.4 Metastatic work up

8.4.1 Metastatic work up is indicated for high risk patient or as directed by signs and symptoms and is not to be routinely performed for early invasive breast cancer, (cT1-2 , N0-1);

8.4.2 The standard imaging modalities include :Chest imaging; X-ray or Computed Tomography (CT) scan;

8.4.2.2 bone scan;

8.4.2.3 abdomen ± pelvis ultrasound (or CT scan, or MRI);

8.4.3 18F-FDG (Fluorodeoxyglucose) PET/CT scan , is considered as a "complementary" imaging modalities in the following high risk patients:

8.4.3.1 Locally advanced breast cancer (stage IIIA, stage IIIB); including inflammatory breast cancer;

8.4.3.2 strong clinical suspicion of stage IV disease; and

8.4.3.3 triple negative breast cancer.

8.4.4 18F-NaF (Sodium Fluoride) PET/CT Bone scan is preferred for high risk patients instead of a conventional bone scan.

9. Standard 5: Surgery to the Breast

9.1. Invasive breast carcinoma

9.1.1 All women with early invasive breast cancer who are candidates for breast conserving surgery must be offered the choice of:

9.1.1.1 Breast conserving surgery (BCS), excision of tumor with clear margins followed by radiotherapy; or

9.1.1.2 modified radical mastectomy.

9.1.2 The choice of surgery must be tailored to the individual patient need and choice.

9.1.3 Patients must be fully informed:

9.1.3.1 Of the options and the risks and benefits of radiotherapy; and

9.1.3.2 that further surgery may be required if the margins are positive;

9.1.4 Mastectomy, rather than BCS should be considered in any of the following circumstances:

9.1.4.1 the ratio of the size of the tumour to the breast and the location of the tumour would not result in acceptable cosmesis;
9.1.4.2 there is multifocal/multicentre disease or extensive malignant micro calcification identified by mammogram;
9.1.4.3 there is a contraindication to local radiotherapy (e.g. previous radiotherapy at this site, connective tissue disease, severe heart and lung disease, pregnancy);

9.1.5 For all patients treated with breast conserving surgery, a circumferential or radial margin of greater than or equal to 2 mm should be achieved where possible; smaller margins may be acceptable for deep and superficial margins.

9.1.6 Re-excision should be considered if the margin is less than 2 mm, after discussion of the risks and benefits with the patient.

9.2 Ductal Carcinoma In Situ (DCIS)

9.2.1 Patients with DCIS must have access to breast conserving surgery.

9.2.2 Patients with extensive (>40 mm diameter) or multicentric disease are recommended to undergo a mastectomy.

9.2.3 Intraoperative specimen radiography must be carried out for all cases of DCIS treated by breast conservation surgery.

9.3 Paget's Disease

9.3.1 Breast conserving surgery with removal of the nipple-areola complex is offered as an alternative to mastectomy for patients with Paget's disease of the nipple that has been assessed as localised.

9.3.2 Oncoplastic repair techniques must be offered to maximise cosmesis.

10 Standard 6: Surgery to the Axilla

10.1 Sentinel lymph node biopsy (SLNB)

10.1.1 SLNB is the preferred technique to stage the axilla for patients with: Early invasive breast cancer: and with no evidence of lymph node involvement on ultrasound or a negative ultrasound-guided needle biopsy. SLNB using the combined blue dye/radioisotope technique is a recommended procedure for the majority of patients with early invasive breast cancer.

10.1.3 Axillary staging surgery is not routinely recommended for patients having treatment for DCIS alone.

10.2 Axillary lymph node dissection (ALND)

10.2.1 ALND is the preferred technique for further axillary treatment;

10.2.2 ANLD is offered to patients with early invasive breast cancer who:

10.2.1.1 Have macro metastases or micro metastases shown in a sentinel lymph node;

10.2.1.2 have a preoperative ultrasound-guided needle axillary lymph node biopsy with histologically proven metastatic cancer;

10.2.3. At least10 axillary lymph nodes should be retrieved; and

10.2.4The level of anatomical dissection should be specified.

10.2.5ALND is not offered to patients found to have only isolated tumour cells in their sentinel lymph nodes. (These patients should be regarded as lymph node-negative).

11. Standard 7: Breast Reconstruction

11.1 All patients having treatment by mastectomy must have the opportunity to discuss their breast reconstruction options, including a discussion of risks and benefits of immediate versus delayed interventions and techniques.

11.2 All appropriate breast reconstruction options must be offered and discussed with patients, irrespective of whether they are all available locally.

11.3 Breast reconstruction for mastectomy can be performed at time as the mastectomy "immediate" or following the completion cancer treatment "delayed".

11.4 When post-mastectomy radiation is required, delayed reconstruction is preferred after completion of treatment;

11.5 Subject to the plan coverage and insurance company pre-authorisation, patients treated by mastectomy without immediate reconstruction should be provided with free breast prostheses.

12 Standard 8: Primary Systemic Therapy

12.1 Primary systemic therapy, known as neoadjuvant therapy can be offered to patients any of the following categories of patient:

- 12.1.1 Early invasive breast cancer who is considering breast conserving surgery that is not advisable at presentation;
- 12.1.2 locally advanced but non metastatic; primary systemic therapy precedes therapeutic surgery in order to reduce size of tumor;
- 12.1.3 for elderly or unfit patients for surgery.

13. Standard 9 : Planning of adjuvant treatment

13.1 Adjuvant Therapy Planning

- 13.1.1 Consider adjuvant therapy for all patients with early invasive breast cancer including decision making after discussion of all factors with the patient.
- 13.1.2 Decisions about adjuvant therapy should be made based on assessment of the prognostic and predictive factors, potential benefits and side effects of the treatment.

13.2 Patients must be referred to oncologist promptly after surgery.

13.3 Adjuvant chemotherapy or radiotherapy treatment must start as soon as clinically possible and within 31 days of completion of surgery in patients with early invasive breast cancer.

14. Standard 10: Adjuvant systemic Therapy

14.1 Endocrine Therapy

- 14.1.1 Premenopausal women whose tumours are oestrogen or progesterone receptors positive (ER+/PgR+) should be offered Tamoxifen for 5 years, followed by 5 years of aromatase inhibitor, if menopause is confirmed.
- 14.1.2 In premenopausal women with advanced disease, the combination of Tamoxifen plus ovarian ablation should be offered instead of Tamoxifen alone.
- 14.1.3 Postmenopausal women should be offered aromatase inhibitor as adjuvant therapy for 5 years.

14.2 Chemotherapy

- 14.2.1 Chemotherapy treatment must take into account the following patient factors:
  - 14.2.1.1 Age;

14.2.1.2 stage;
14.2.1.3 performance status using any of the internationally recognized scoring system; and
14.2.1.4 liver, heart and kidney functions.

14.2.2 For patients receiving anthracycline chemotherapy, baseline cardiac function should be assessed in patients with diabetes mellitus, hypertension, smokers or those with underlying cardiac disease. Cardiac function must be assessed before initiating chemotherapy as follows:
14.2.2.1 After 3 cycles of chemotherapy; and
14.2.2.2 at the end of treatment.

14.2.3 Tests recommended for cardiac assessment is multiple uptake gated acquisition (MUGA) scan or echocardiogram.

14.2.4 Docetaxel and paclitaxel are recommended as an option for the treatment of advanced breast cancer where initial cytotoxic chemotherapy (including an anthracycline) has failed or is inappropriate.

14.3 Biological Therapy

14.3.1 Trastuzumab is offered as an adjuvant treatment following surgery, chemotherapy, and radiotherapy to women with:
14.3.1.1 Human epidermal growth receptor 2 (HER2) positive and axillary lymph node positive breast cancer; or
14.3.1.2 HER2 positive lymph node negative tumours greater than or equal to 1 cm;

14.3.2 Assessment of cardiac function must be carried out before starting treatment with Trastuzumab and every 3 months while on Trastuzumab.

15. Standard 11: Adjuvant Radiotherapy

15.1 Radiotherapy after Breast conservative therapy

15.1.1 This is offered to patients with:
15.1.1.1 Early invasive breast cancer who have had breast conserving surgery with clear margins; or
15.1.1.2 DCIS following breast conserving surgery.

15.1.2 Radiotherapy is not offered after mastectomy to patients with:
15.1.1.3 DCIS; or
15.1.1.4 early invasive breast cancer who are at low risk of local recurrence (for example, age above 70 years, lesions less than 5mm, grade 1 or 2 who are lymph node-negative).

15.2 Radiotherapy after Mastectomy

15.2.1 Adjuvant chest wall radiotherapy is offered to patients with early invasive breast cancer after mastectomy and at a high risk of local recurrence.
(Patients at a high risk of local recurrence include those with four or more positive axillary lymph nodes or involved resection margins).

15.3 Dose Fractionation

15.3.1 Use external beam radiotherapy giving 45-50Gy in 1.8 - 2 Gy per fraction or 42.5 Gy per 2.66 Gy per fraction.

15.3.2 All dose schedules are given 5days per week, for 5 weeks.

15.4 Breast Boost

15.4.1 An external beam boost is offered to the site of local excision to patients with early invasive breast cancer and a high risk of local recurrence, following breast conserving surgery with clear margins and whole breast radiotherapy.

15.4.2 If an external beam boost to the site of local excision following breast conserving surgery is being considered in patients with early invasive breast cancer, inform the patient of the side effects associated with this intervention, including poor cosmesis, particularly in women with larger breasts.

15.5 Radiotherapy to Nodal Areas

15.5.1 Adjuvant radiotherapy is not offered to :

15.5.1.1 The axilla or supraclavicular fossa for patients with histologically negative lymph node; and

15.5.1.2 to the axilla after ALND for early invasive breast cancer.

15.5.2 Adjuvant radiotherapy is offered to:

15.5.2.1 The supraclavicular fossa for patients with early invasive breast cancer and histologically positive axillary lymph nodes.

15.5.2.2 to the internal mammary chain for patients with early invasive breast cancer who have had 4 or more histologically positive axillary lymph node.

16. Standard 12: Managing of complications

16.1 Lymphoedema

Patients must:

16.1.1 Be informed about the of risk lymphoedema and given verbal/ written information before making a decision about surgery and radiotherapy;

16.1.2 given advice on how to prevent infection or trauma; and

16.1.3 have rapid access to lymphoedema care service/physiotherapy.

16.2 Arm mobility

16.2.1 Breast units should have local guidelines written and agreed with the physiotherapy department for postoperative physiotherapy regimens.

16.3 Menopausal symptoms

16.3.1 Patients must be offered information and counselling about the possibility of early menopause and menopausal symptoms associated with breast cancer treatment.

16.3.2 HRT must be discontinued in women diagnosed with early breast cancer.

16.3.3 HRT (including estrogen/progestogen combination) is offered only in exceptional circumstances to women with early breast cancer who have severe menopausal symptoms, and when the woman has been fully informed about the associated risks.

17. Standard13: Follow-up

17.1. Periodic history and physical examination must be performed every 4 to 6 months for 5 years, and then annually.

17.2. Mammography should be performed annually.
17.3. Mammography should not be offered for the ipsilateral soft tissues after mastectomy.
17.4. Ultrasound or MRI should not be offered for routine post-treatment follow up in patients who have been treated for early invasive breast cancer or DCIS.
17.5. Women on Tamoxifen must have an annual gynecology assessment if uterus is present.
17.6. Women on aromatase inhibitors or who have ovarian failure must have assessment for bone health with a bone mineral density determination at baseline and periodically thereafter.

18. Standard 14: Monitoring

18.1. 18F-FDG PET/CT scan may be considered in patients with loco-regional recurrence or metastasis when conventional study is judged by the treating physician (consultant or specialist level) to be insufficient for the clinical management of the patient to detect "presence and location" as well as to determine the extent of residual disease, recurrence or metastasis.
18.2. 18F-FDG PET/CT may be considered at 6monthly interval for initial period of 2-3 years with increasing interval in imaging after this time period according to medical necessity.
18.3. 18F-FDG PET/CT may be considered subject to the judgment of the treating physician (consultant or specialist level) during the course of treatment to monitor the response of a "primary and metastatic" breast cancer when a change in therapy is contemplated and according to medical necessity.

19. Standard 15: Advanced breast cancer; diagnosis , monitoring and treatment

19.1. Imaging assessment

19.1.1. The presence and extent of visceral metastases is assessed using; X-ray, or ultrasound, CT scans or MRI.
19.1.2. The presence and extent of metastases in the bones of the axial skeleton is assessed using CT scan or MRI or bone scan.
19.1.3. X-rays of symptomatic bones; long and weight bearing bones abnormal on bone scan.
19.1.4. MRI is performed to assess bony metastases if other imaging is equivocal for metastatic disease or if more information is needed.
19.1.5. PET-CT should only be used to make a new diagnosis of metastases for patients with breast cancer whose imaging is inconclusive but not diagnostic of metastatic disease.

19.2. Pathology Assessment

19.2.1. The ER and HER2 receptor status is assessed at the time of disease recurrence if receptor status was not assessed at the time of initial diagnosis. In the absence of tumor tissue from the primary tumor, and if feasible, obtain a biopsy of a metastasis to assess ER and HER2 status.

19.3. Systemic therapy

19.4. Endocrine therapy

19.4.1.1. As first-line treatment for the majority of patients with ER-positive advanced breast cancer; or
19.4.1.2. for patients who have been treated with chemotherapy as their first-line treatment, following the completion of chemotherapy.

19.4.2. Chemotherapy is offered as first-line treatment for patients with ER-positive advanced breast cancer whose disease is imminently life-threatening or requires early relief of symptoms because of significant visceral organ involvement, providing they are fully informed of the risks of toxicity.

19.4.3. Trastuzumab is discontinued at the time of disease progression outside the central nervous system. It is not to be discontinued if disease progression is confined within the central nervous system alone

19.4.4. Managing complications

19.4.4.1. A breast cancer multidisciplinary team should assess all patients presenting with uncontrolled local disease and discuss the therapeutic options for controlling the disease and relieving symptoms.

19.4.4.2. Bisphosphonates is considered in patients newly diagnosed with bone metastases, to prevent skeletal-related events and reduce pain.

19.4.4.3. External beam radiotherapy is used in a single fraction of 8Gy to treat patients with bone metastases and pain.

19.4.4.4. Surgery is offered followed by whole brain radiotherapy to patients who have a single or small number of potentially resectable brain metastases, a good performance status and who have no or well-controlled other metastatic disease.

20. Standard 16: Breast cancer during pregnancy and post partum period

20.1. Diagnosis

20.1.1. Diagnosis of pregnant women with suspected cancer is similar to non-pregnancy associated breast cancer (refer to section 6 of this standard);

20.1.2. Mammography, when performed must be performed with shielding.

20.2. Preoperative assessment and staging

20.2.1. For node negative T1-2 tumors: perform CBC, LFT and renal function test and chest X-ray with shield;

20.2.2. for node positive, or T3 tumors: in addition to the above tests, perform ultrasound abdomen, plus MRI for thoracic or lumbar spine

20.3. Treatment

20.3.1. Mastectomy is the common therapeutic surgical procedure. BCS is a possible alternative, if radiotherapy can be delayed to the post partum period and there is no negative impact on survival.

20.3.2. Surgery is performed at 25 weeks of gestation or after. Obstetrical and prenatal specialist must be on site and immediately available in the event of precipitous delivery of viable fetus.

20.3.3. Considerations and selection of optimal local and systemic therapy are similar to non-pregnancy associated breast cancer (refer to section 14 & 15 of this standard). However, selection and timing of chemotherapy, endocrine therapy and radiation therapy is different for the pregnant patient, and must follow the specific details below:

20.3.3.1. Chemotherapy must not be administered in first trimester of pregnancy;

20.3.3.2. chemotherapy must not be administered after week 35 of pregnancy or within 3 weeks of planned delivery;

20.3.3.3. postpartum chemotherapy is the same for non-pregnancy associated breast cancer(refer to section 14.2 of this standard);

20.3.3.4. endocrine therapy and radiotherapy must not be administered during any trimester of pregnancy; and

20.3.3.5. the use of Trastuzumab is contraindicated during pregnancy.

20.3.4. The use of blue dye for SLNB is contraindicated in pregnancy; radio labeled sulfur colloid appears to be safer for SLNB.

Standard 17– Payment for Breast Cancer diagnosis and treatment under the Health Insurance Scheme

The cost of Breast Cancer diagnosis and treatment, including surgical intervention and breast prostheses, is covered by the Thiqa Health Insurance scheme for UAE Nationals.

21.2 For non-Nationals, the cost of Breast Cancer diagnosis and treatment is covered under the patient's health insurance plan; however, is subject to:

21.2.1 Patient's Plan terms and conditions;

21.2.2 high-cost medical condition six months waiting period; and

21.2.3 Insurance company pre-authorisation for admissions, CT/PET Scan and breast prostheses.

21.3 Coding for Breast Cancer diagnosis, treatment and related care services must be done using the codes classification defined in the Coding Manual published by the HAAD Clinical Coding Steering Committee, and in compliance with e-Claim requirements.

21.4 Charges for Breast Cancer diagnosis, treatment and related care services shall be in accordance with the Standard Provider Contract negotiated rates, and in compliance with the Mandatory Tariff pricelist and HAAD Claims and Adjudication Rules.

Appendix 1. Requirements for a Specialized Breast Care Unit.

In order to be authorized facility to provide breast cancer management; diagnosis, treatment, and follow up, the Specialized Breast care Unit must fulfil the following requirements.
A unit is a group of specialists in breast cancer, not necessarily be a geographically single entity; however the separate buildings must be within reasonable proximity to allow multidisciplinary working.

Summary of required resources and training

I. PERSONAL	Mandatory	Recommended
1. Designated breast Surgeon		
Two nominated specialist breast surgeons specially trained in breast disease. Each of whom must carry out personally primary surgery on at least 15 newly diagnosed cancers per annum	M	
To be breast dedicated the surgeon has to spend at least 30% of his/her working time in breast disease	M	
The surgeon must participate in diagnostic, new patient and follow up clinics, and audit activities		R
They should also participate in MDMs		R
The surgeon should be able to undertake basic reconstruction, when required, and oncoplastic surgery		R
Training of breast surgeon should comply with the guidelines on the standards for the training of specialised health professionals dealing with breast cancer http://www.eusoma.org/doc/Guidelines_on_the_standards_for_the_training_of_specialised_health_professionals_dealing_with_breast_cancer.pdf	M	
The Specialized Unit must make arrangement with at least one nominated plastic surgeons with special interest in breast reconstructive techniques	M	
2. Breast Radiologist		
There must be at least two nominated specialist breast radiologists	M	
Each of them must read a minimum of 1000 mammography cases per year	M	
To be breast dedicated the radiologist must spend at least 20% of the working time in breast	M	

disease		
They should also participate in MDMs		R
They must attend audit meetings		R
Training of breast radiologist should comply with the guidelines on the standards for the training of specialised health professionals dealing with breast cancer http://www.eusoma.org/doc/Guidelines_on_the_standards_for_the_training_of_specialised_health_professionals_dealing_with_breast_cancer.pdf	M	
3. Breast Pathologist		
The Specialized Unit must have at least one lead pathologist plus an additional one or two, depending on the Unit size.	M	
They should be responsible for all breast pathology and cytology	M	
To be breast dedicated a pathologist must spend approximately 20% of his/her working time in breast disease	M	
Pathologists must attend audit meetings.		R
They should also participate in MDMs		R
Training of breast pathologist should comply with the guidelines on the standards for the training of specialised health professionals dealing with breast cancer http://www.eusoma.org/doc/Guidelines_on_the_standards_for_the_training_of_specialised_health_professionals_dealing_with_breast_cancer.pdf	M	
4. Medical Oncologist		
The Specialized Unit must have a medical oncologist. Medical Oncologist should be physically present in the unit when chemotherapy or immunotherapy is administered to supervise chemotherapy and manage any side-effects.	M	
To be dedicated he/she has to spend around 20% of working time in breast cancer	M	
He/she must attend audit meeting	M	
They should also participate in MDMs		R
They must attend audit meetings		R
Training Medical Oncologist should comply with the guidelines on the standards for the training of specialised health professionals dealing with breast cancer http://www.eusoma.org/doc/Guidelines_on_the_standards_for_the_training_of_specialised_health_professionals_dealing_with_breast_cancer.pdf	M	

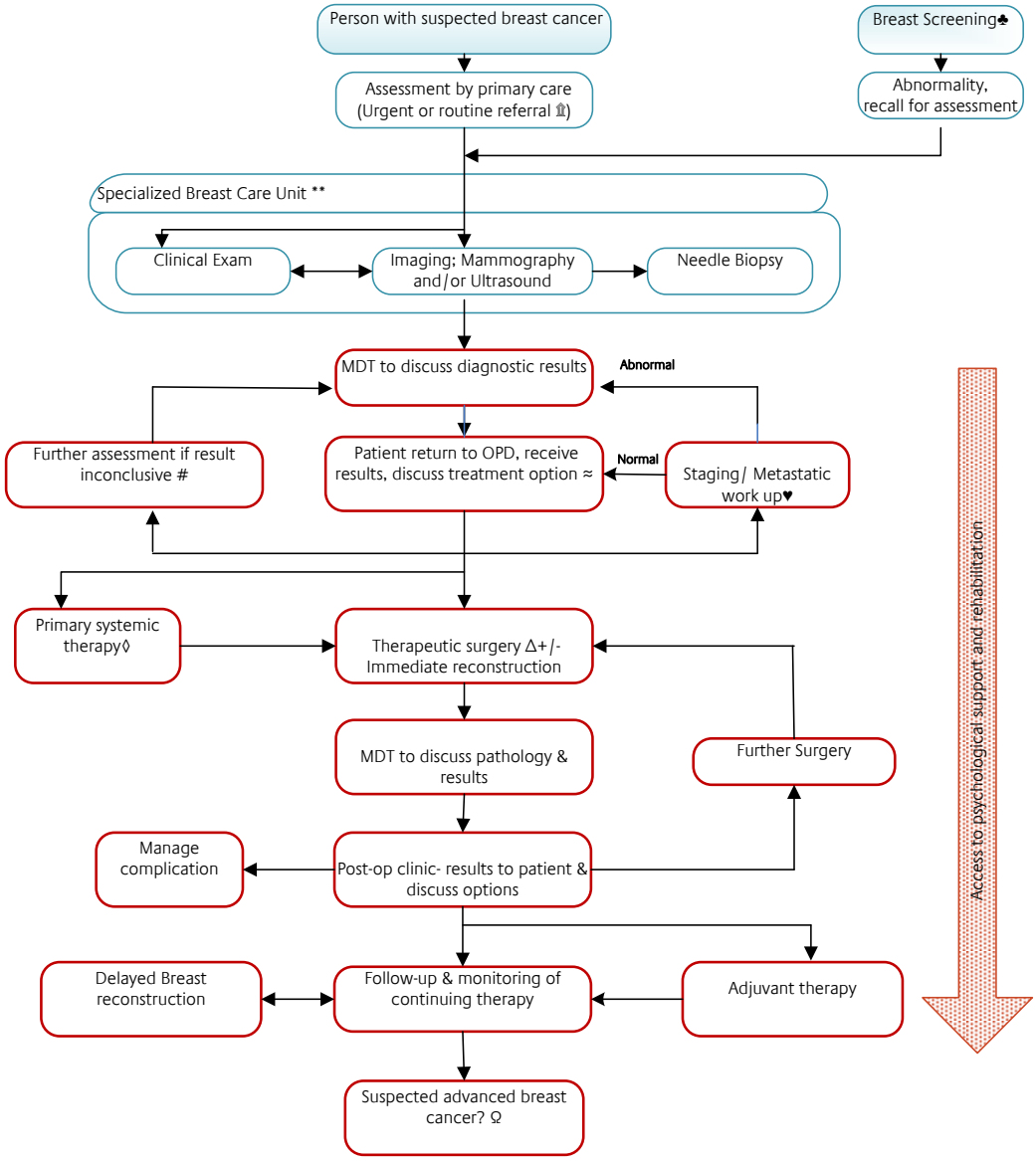
5. **Radiation Oncologist**	M	
The Specialized Unit must have a radiation oncologist dedicated to breast cancer	M	
To be dedicated he/she has to spend around 20% of working time in breast cancer	M	
He/she must attend audit meeting		R
They should also participate in MDMs		R
Training of breast radiation oncologist should comply with the guidelines on the standards for the training of specialised health professionals dealing with breast cancer http://www.eusoma.org/doc/Guidelines_on_the_standards_for_the_training_of_specialised_health_professionals_dealing_with_breast_cancer.pdf	M	
6. **Breast care nurse**	M	
At least two breast care nurses are needed per breast care Unit	M	
To be dedicated he/she has to spend around 20% of working time in breast cancer	M	
They must be available to counsel and offer practical advice and emotional support to newly diagnosed patients at the time the diagnosis is given, so as to further explain treatment plans.	M	
They should also participate in MDMs		R
Breast care nurse must attend audit meeting		R
Training of breast radiation oncologist should comply with the guidelines on the standards for the training of specialised health professionals dealing with breast cancer http://www.eusoma.org/doc/Guidelines_on_the_standards_for_the_training_of_specialised_health_professionals_dealing_with_breast_cancer.pdf	M	
II. RESOURCES	**Mandatory**	**Recommended**
1. The Specialized Unit must be in possession of: mammography Unit, stereotactic biopsy attachment and/or dedicated prone biopsy table, ultrasound equipped with a high-frequency linear probe >=10MHz	M	
2. The Specialized Unit must have at least 2 radiographers performing each 20 mammograms per week	M	
3. The Service must be equipped with: processors, microtomes, staining machines and immunostainers	M	
4. The minimum equipment must include at least two megavoltage units, a simulator and a computerized 3D planning system	M	

5. The Specialized Unit must make arrangement with at least one nominated plastic surgeons with special interest in breast reconstructive techniques. The Specialized Unit should advise and where necessary treat benign disease.	M	
6. If the radiotherapy unit is not available within the hospital, the Specialized Breast care Unit must have an agreement with a radiotherapy service and the radiotherapist must attend MDMs at the Unit.	M	
7. If Medical Oncology unit is not available within the hospital, the Specialized Breast care Unit must have an agreement with a medical oncology unit and the medical oncologist must attend MDMs at the Unit	M	

Appendix 2

Early and Locally Advanced Breast Cancer Pathways

هيئة الصحة - أبوظبي
HEALTH AUTHORITY - ABU DHABI



Key

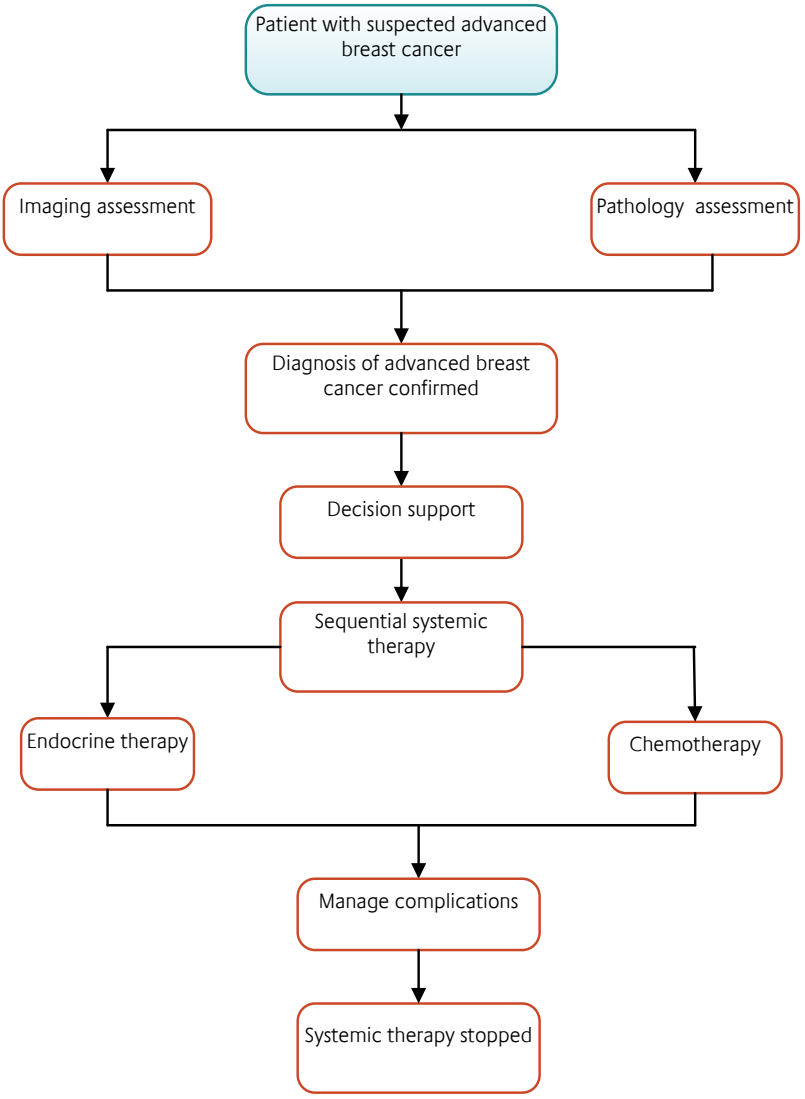
🏛 Urgent referral should be seen with two weeks. Criteria for urgent referral are described in appendix 5 of this Standard.
** Requirement for specialized breast care unit is described in appendix 1of this Standard.
# Include repeat core biopsy/open surgical biopsy/MRI
♥ Not all patient require staging,
≈Initiation of therapeutic surgery or other treatment must be within 4 weeks from date of pathological diagnosis of breast cancer
ΔTherapeutic surgery could include Breast conservative,(WLE), mastectomy and axilary staging (SLNB, sampling or clearance).
◊ For elderly or unfit patient, surgery may not be appropriate, for locally advanced but not metastatic breast cancer primary systemic therapy precedes therapeutic surgery to reduce size of tumor.
Ω Refer to advance breast cancer pathway, Appendix3.

Adopted from NICE Pathways, October 2011. http://pathways.nice.org.uk/pathways/early-and-locally-advanced-breast-cancer

Appendix 3

Advanced Breast Cancer Pathways

هيئة الصحة - أبوظبي
HEALTH AUTHORITY - ABU DHABI



Adopted from NICE Pathways, October 2011. http://pathways.nice.org.uk/pathways/advanced-breast-cancer

Appendix 4 - Quality Indicators in Breast Cancer Care

Clinical Quality Indicators	Minimum standard	Target standard
Diagnosis		
1. Completeness of the Triple assessment		
1.1. Proportion of women with breast cancer who preoperatively underwent 1.1.1. Clinical exam 1.1.2. Imaging; mammogram/ultrasound	90%	95%
1.2 Proportion of patients with breast cancer (invasive and in situ) who had pre-operative diagnosis	80%	90%
2. The ratio of benign to malignant diagnoses, based on definitive pathology report (surgery only).	1:2	1:4
3. Completion of prognostic/predictive characterization		
3.1 The proportion of invasive cancer cases with primary surgery for which the following prognostic /predictive parameters have been recorded in the pathology report. • Dominant histological type; • Tumour grade; • Receptor status on invasive cancer (Estrogen, Progesterone, HER2); • Pathology stage (T and N); • Tumour size for the invasive component; • Peritumor vascular invasion; • Distance to nearest surgical l margin; and • Lymph node status	95%	98%

3.1 The proportion of non-invasive cancer cases with primary surgery for which the following prognostic /predictive parameters have been recorded in the pathology report. • Dominant histological type • Tumor grade; • Size in mm, • Distance to nearest surgical l margin	95%	98%
4. Time interval between date diagnosis of breast cancer and date of therapeutic surgery or other treatment must be within 4 weeks.	>75%	>90%
Surgery		
5. The proportion of cancers patients to be discussed by the multidisciplinary team (MDT)	90%	99%
6. Appropriateness of Surgical approach		
6.1. The proportion of cancers patients with invasive cancer who received single breast operation, (excluding breast reconstruction)	80%	90%
6.2. The proportion of cancers patients with DCIS (ONLY) cancer who received single breast operation.	70%	90%
6.3. The proportion of cancers patients with invasive cancer and a clinically negative axilla (+US±FNA/CNB) who had SLNB	90	>95%
6.4. The proportion of cancers patients with invasive cancer and ALND performed with at least 10 lymph nodes examined	95%	98%
7. Time interval between completion of surgery and start of adjuvant chemotherapy or radiotherapy must be within 31 days in patients with early invasive breast cancer	>75%	>90%
Radiotherapy		
8. Appropriateness of Surgical approach		
8.1. The proportion of cancers patients with invasive cancer (M0) who received postoperative radiotherapy after surgical resection of the primary tumour and appropriate axillary staging/surgery in the frame work of BCS	90%	95%

8.2. The proportion of cancers patients with involvement of axillary nodes (≥ pN) who receive post-mastectomy radiotherapy.	90%	95%
Systemic treatment		
9. Appropriateness of endocrine therapy		
9.1. The proportion of patients with endocrine sensitive invasive cancer who received hormone therapy,	80%	90%
9.2. The proportion of patients with ER - ,PgR – cancers who didn't received hormone therapy.	98%	100%
10. Appropriateness of chemotherapy and other medical therapy		
10.1. The proportion of patients with ER- (T>1cm or Node +) cancer who received adjuvant chemotherapy, out of total of same diagnosis	80%	90%
10.2. The proportion of patients with Node+ or Node – T≥1cm HER2+ cancer treated with chemotherapy and who had adjuvant trastuzumab, out of total of same diagnosis.	80%	90%
10.3. The proportion of patients with HER2+ cancer treated with adjuvant chemotherapy and who had adjuvant trastuzumab, out of total of same diagnosis who had trastuzumab	95%	100%
10.4. The proportion of patient with inflammatory cancer or locally advanced carcinoma who had neoadjuvant chemotherapy out of total of same diagnosis	90%	95%
Follow up		
11. Proportion of asymptomatic patients who undergo routine annual mammographic screening and clinical evaluation every 6 months for in the first 5 years after the operation.	95%	99%

Appendix 5: The Breast Cancer Multidisciplinary team

The Breast Cancer Multidisciplinary team (MDT) is a group of experts with a specialist role in the diagnosis, treatment and management of patients with breast cancer. The team comprises doctors, nurses and other healthcare professionals who manage the treatment of breast cancers. The core Breast cancer MDT consist of the following

- Designated breast Surgeon
- Radiologist
- Pathologist
- Medical Oncologist
- Radiation oncologist
- breast care nurse

The role of the breast care team

The team as a whole should be responsible for planning care in a seamless way so that each patient receives prompt and appropriate care throughout the process of diagnosis and treatment, up to and including the period when palliation may be needed. The team must maintain close contact with all other professionals who are actively involved in supporting the patient or carrying out the treatment strategy decided by the core team. These include the following:

- GPs/primary care teams
- Palliative care specialist/team
- Breast radiographer
- Psychiatrist/clinical psychologist
- Social worker
- Plastic surgeon
- Clinical geneticist/genetics counsellor
- Physiotherapist/lymphoedema specialist
- Nominated orthopaedic surgeon with expertise in management of bone metastases Neurosurgeon
- Occupational therapist

Team meetings

The team should meet at least weekly to discuss, in confidence, newly referred patients with a suspected or confirmed diagnosis of breast cancer. The MDT meetings offer a forum for the team members to plan and agree a recommended program of treatment specific to individual patient needs. This approach ensures that all necessary investigations are carried out as quickly as possible and the best available treatment is offered. Treatment options are then discussed with the patient and their family at the same or subsequent meetings.

Appendix 6- Criteria for Urgent Referral to Specialized Breast Clinic

Urgent referral (within two weeks):

- Patients aged 30 or over with a discrete lump in the breast.
- Patients with breast signs or symptoms which are highly suggestive of cancer.

These include:

- Ulceration
- Skin nodule
- Skin distortion
- Nipple eczema
- Recent nipple retraction or distortion (< 3 months)
- Unilateral nipple discharge which stains clothes

Conditions that require referral, not necessarily urgent:

Breast lumps in the following patients, or of the following types:

- Discrete lump in a younger woman (age < 30 years)
- Asymmetrical nodularity that persists at review after menstruation
- Abscess
- Persistently refilling or recurrent cyst
- Intractable pain which does not respond to simple measures such as wearing a well-fitting bra and using over-the-counter analgesics such as paracetamol.