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Applies to	Healthcare Facilities and Professionals licensed by HAAD in the Emirate of Abu Dhabi		
Classification	⦿ Public		

1. Purpose

The standard mandates:

1.1 The case mix, eligibility criteria and data reporting requirements for the screening and diagnosis of breast cancer;

1.2 The clinical care to be provided and care pathways consistent with international evidence-based guidelines and best practice and HAAD's breast screening and diagnosis pathway; and

1.3 The services and service specifications to be delivered for breast cancer screening and diagnosis in the Emirate of Abu Dhabi.

2. Scope

2.1 This standard applies to all Healthcare Providers (Facilities and Professionals) licensed by HAAD in the Emirate of Abu Dhabi delivering health services for breast cancer screening and diagnosis, including mobile units.

2.2 For the purpose of this standard, breast cancer screening and diagnosis include the following services:

- 2.2.1 Breast Screening services;
- 2.2.2 Breast assessment and diagnosis; and
- 2.2.3 Familial/ Genetic High risk Assessment.

2.3 This standard refers to females determined as eligible for breast cancer screening services, in accordance with the criteria detailed in this Standard.

3. Duties for Healthcare Providers

3.1 All licensed healthcare providers (Facilities and Professionals) engaged in providing breast cancer screening and diagnosis services must:

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

3.1.2. 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);

3.1.3. In addition to the routine eClaims data, collect and submit to HAAD data on screening visits , outcomes within 2 weeks of the screening date, through the Cancer Screening Form of the *cancer surveillance e- notification system* found on the HAAD website at http://www.haad.ae/haad/tabid/1084/Default.aspx;

3.1.4. Report all screen-detected cancers to HAAD, through Cancer Case Notification Form, of the *cancer surveillance e-notification*, specified in 3.3;

3.1.5. Comply with HAAD policies and standards on managing and maintaining patient medical records, including developing effective recording systems, maintaining confidentiality, privacy and security of patient information;

3.1.6. Comply with the requirements of the HAAD Policy on Cultural Sensitivity; in particular, providers must ensure:

3.1.6.1. That only female radiographers, mammographers or technologists are allowed to perform mammographic examination for women.

3.1.6.2. that the timing of screening appointment for women seeking the service is not delayed due to the limited number of same sex appropriately licensed professionals beyond a few days; and

3.1.6.3. where delays are likely to occur due to limited availability of same sex licensed professionals at the screening facility, or where there are no female radiographer, that the provider communicates this to the patient and refers/recommends that the patient seek screening services from another provider;

3.1.7. Comply with the HAAD requirements for Patient Education and consent: the licensed provider must provide appropriate patient education and information regarding the screening test (physical and mammography) and must ensure that appropriate patient informed consent is obtained and documented on the patient's medical record consistent with the relevant HAAD policies and standard;

3.1.8. Comply with HAAD requests to inspect and audit records and cooperate with HAAD authorized auditors as required by HAAD; and

3.1.9. Comply with HAAD requirements for information technology ("IT") and data management, electronic patient records and disease management systems, sharing of screening and diagnostic test, and where applicable pathology results.

4. Enforcement and Sanctions

4.1. Healthcare providers, payers and third party administrators 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 Sanction)*.

5. Payment for Screening and Diagnosis of Breast Cancer

5.1 Eligibility for reimbursement under the Health Insurance scheme is as follows:

5.1.1 For Thiqa holders reimbursement must be consistent with the HAAD Standard for Thiqa Preventive List available at www.haad.ae ;

5.1.2 For non-Thiqa holders payment must be consistent with the individual's health insurance product/plan.

6. Standard 1 - Clinical Definitions

6.1. Breast Cancer Screening Case mix is the type or groups of patients to be screened, and is defined to include all females aged 20 years and above residing in Abu Dhabi, except where exclusion criteria for mammogram apply;

6.2. Females are excluded from mammogram screening if they:

6.2.1. Have had a bilateral mammogram within the last 12-24 months;

6.2.2. Have had a bilateral mastectomy;

6.2.3. Are pregnant;

6.2.4. Are breast feeding.

6.3. Screening must not be carried out during pregnancy or lactation. Screening can be resumed around 6 weeks after the cessation of breast feeding;

6.4. Screening mammograms are carried out for healthy women, who have no symptoms of breast cancer;

6.5. Diagnostic mammograms are performed to evaluate a breast complaint or abnormality detected by clinical breast examination or routine screening mammogram;

6.6. Clinical breast examination (CBE) involves inspection and palpation of all breast tissue including lymph nodes basins;

6.7. Breast Awareness: women must be encouraged and educate on how to conduct breast self-exam to become aware of the feel and shape of their breasts, so that they are familiar with what is normal for them and to report any changes immediately to her healthcare provider;

6.8. Breast Assessment and Diagnosis: Involves triple assessment through: further imaging, clinical breast exam and Needle biopsy The aim of assessment is to obtain a definitive and timely diagnosis of all potential abnormalities detected during screening;

6.9. Genetic/Familial High Risk Assessment: include genetic counseling by a trained physician with experience and expertise to deliver this service and referral for genetic testing, for women with strong family history or genetic predisposition.

7. Standard 2 –Service Specifications

7.1 Breast Cancer Screening services must:

7.1.1 Comply with HAAD breast cancer screening and diagnosis care pathways, recommendation of breast cancer screening, clinical quality indicators, and time lines for referral in accordance with Appendices 1, 2 and 3 respectively;

7.1.2 Comply with requirement of breast screening unit, detailed in Appendix 4;

7.1.3 Assign a screening program director/coordinator who will be in charge of overall performance, quality assurance of the unit and will be responsible for submitting data on screening visits and outcomes to HAAD through the cancer e- notification;

7.1.4 Have an approved protocol for referral of women with screen detected abnormalities to diagnostic breast assessment unit;

7.1.5 Establish and maintain record of mammogram outcomes audit program to follow up positive mammography assessments and to correlate pathology results with the interpreting physician's findings;

7.1.6 Establish internal quality audit procedures to demonstrate compliance with this standard and other associated regulatory policies and standards; and

7.1.7 Ensure availability of evidence of compliance with HAAD Clinical Quality indicators specified at Appendix 3.

7.2 Breast Assessment and Diagnosis Services

7.2.1 Breast assessment and diagnosis services must be carried out in a Diagnostic Breast Assessment unit. The unit must:

7.2.1.1 Comply with breast cancer screening and diagnosis care pathways, clinical quality indicators, and time lines for referral in accordance with Appendices 1 and 3 respectively;

7.2.1.2 Comply with the requirements of Diagnostic Breast Assessment unit described at Appendix 4;

7.2.1.3Have approved written protocols/procedures for the screening assessment and diagnosis; that clearly define the methods of assessment and the diagnostic pathways for all possible assessment outcomes;

7.2.1.4HAAD recognizes guidance on screening assessment and diagnosis includes: those of the National Comprehensive Cancer Network and, the National Health System (NHS) the National Institute for Health and Clinical Excellence;

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

7.2.1.6 Ensure availability of evidence of compliance with HAAD Clinical Quality indicators specified at Appendix 3;

7.2.1.7 Report breast screening assessment and diagnosis results to HAAD, through the cancer e-nonfiction within 3 weeks of assessment; and

7.2.1.8 Report all screen-detected cancers to HAAD, through Cancer Case Notification Form, of the cancer surveillance e-notification.

8. Standard 3 – Licensed Healthcare Professionals:

8.1 All licensed health professionals involved in the breast cancer screening, screening assessment and diagnosis must:

8.1.1 Satisfy the qualifications relevant to their position as defined by the HAAD Personnel Qualification Requirement;

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

8.1.3 Have knowledge of the principles of breast cancer screening, assessment, diagnosis and management;

8.1.4 Participate in continuing medical education in accordance with HAAD requirements;

8.1.5 Take part in any recognized external quality assessment schemes;

8.2 All units involved in screening and diagnostic activities must ensure the formation of proper multidisciplinary teamwork involving a full range of specially trained

professionals including a radiologist, radiographer, pathologist, surgeon, nurse counselor and medical oncologist/radiotherapist.

9. Standard 5: Breast Screening and Diagnosis Communication

9.1 The woman is central to the screening process. Any communication with her must take into account the need to avoid direct or indirect harm and the requirement to balance benefits against risks.

9.2 Women must be provided with (oral and written) education and information, regarding benefits, risk and limitation of breast cancer screening, and about the screening test, associated procedures and expected timeframes to receive results (consistent with those specified in Appendix 3).

9.3 Adequate attention must be given to the level of literacy, diversity and linguistic requirements of different populations.

10. Standard 4: Breast Cancer Screening

10.1 Breast Cancer Screening must be provided in accordance with the HAAD Breast screening and diagnosis care pathway as provided at Appendix 1, including the following activities:

10.1.1 History & Risk assessment;
10.1.2 Clinical breast exam (Physical exam);
10.1.3 Breast awareness; and
10.1.4 Screening mammogram.

10.2 Periodical screening must be carried out as specified in HAAD Breast Cancer Screening recommendations at Appendix 2.

10.3 Detailed history, such as that described in the cancer screening form, cancer e-notification (Appendix 5) must be evaluated and completed by the screening facility nurse, each time a woman visits for screening. The purpose of that is to identify patient at increased risk and determine the appropriate screening tests or referral to genetic counseling.

10.4 Clinical breast exam (physical exam) must be conducted by a trained physician, who will then refer the woman for a screening mammogram.

10.5 Screening mammography must involve two x-ray images for each breast; craniocaudal (CC) and mediolateral oblique (MLO).

10.6 Ultrasound breast of the breast is recommended as adjunct to screening mammogram for women with dense breast/s or increased risk in accordance with Appendix 2.

11. Standard 5–Reporting of Screening Mammogram

11.1 A woman must receive a copy of her final mammogram report within 15 working days of the screening mammogram date;

11.2 Double reading of screening mammogram is mandatory. Mammograms must be interpreted by two independent radiologists;

11.3 In case of discordant opinions between two radiologists, either consensus or preferably arbitration using a third expert screening radiologist can be carried out.

11.4 The final assessment must be reported using the FDA-approved Breast Imaging Reporting and Data System (BI-RADS®) Final Assessment Categories as described at Appendix 6.

11.5 A synoptic breast imaging report must be used by radiologist containing at least the following information:

11.5.1 Interpreting physicians' names;
11.5.2 Date of examination;
11.5.3 Patient identification;
11.5.4 Reason for examination;
11.5.5 Breast density;
11.5.6 Description of significant imaging lesions: mammographic characteristics of the lesion; location (in quadrants); distance from the nipple (in mm); and size (maximum diameter in mm);
11.5.7 Final Assessment (BIRADS); and
11.5.8 Recommended next steps.

12. Standard 6- Screening outcomes

12.1 All women must be notified in writing of the result of their screening test. It is the responsibility of the reporting physician at the screening facility to inform and provide a written report to a woman regarding her screening results within 15 working day (3 weeks) of the date of screening test;

12.2 If mammogram is Normal/Benign (BIRADS 1/2), women are discharged to routine screening. Screening frequency will follow recommendation specified in Appendix 2;

12.3 If a woman requires further assessment for abnormal screening mammogram or clinical breast exam, referral must be to a Diagnostic Breast Assessment Unit for further assessment and diagnosis;

12.4 The screening facility must provide women with a printout of HAAD e- Cancer Screening Referral Form. A sample is provided in Appendix 7.

13. Standard 7- Breast Assessment and Diagnosis

13.1 Breast cancer screening must be provided in accordance with the HAAD breast screening, and diagnosis care pathway (Appendix 1);

13.2 Assessment and diagnostic work up of screen detected abnormality is best achieved using the triple assessment:
13.2.1 Imaging; usually diagnostic mammography and ultrasound;
13.2.2 clinical examination; and
13.2.3 image-guided needle biopsy for histological examination, if indicated.

13.3 Cytology alone **must not** be used to obtain a non-operative diagnosis of breast cancer.

13.4 Clinical examination is mandatory for every woman with a confirmed mammographic or ultrasound abnormality that needs needle biopsy and for all women recalled because of clinical signs or symptoms.

13.5 Clinical examination is not mandatory for women whose further imaging is entirely normal.

13.6 Core needle biopsy must be performed under image guidance.

13.7 Clip must be placed at site of biopsy during the procedure of needle sampling to identify the lesion/s location;

13.8 Results of assessments must be evaluated and considered by a multidisciplinary team (MDT). Particular attention must be given to address radiology-pathology correlation;

13.9 Early recall for repeat mammography either in screening or diagnostic settings is not recommended and must never be used as a substitute for inexpert or inadequate assessment.

13.10 Early recall rate must be recorded, monitored and audited;
13.11 Referral of histologically confirmed cancer cases for treatment must be completed within 10 working days of the diagnosis;
13.12 All screen-detected cancers must be reported to HAAD through Cancer Case Notification Form, of the cancer surveillance e-notification, specified in 3.3.

14. Standard 8- Screening women at increased risk

14.1 Details of women who have increased risk of developing cancer are specified in Appendix 2.
14.2 Screening tests and frequency must be in line with specifications detailed in table 2, Appendix 2.
14.3 Criteria of use of MRI as adjunct to mammogram for high risk women are detailed in Appendix 2;
14.4 MRI must be performed in a specialized breast care unit that has a dedicated breast MRI;
14.5 MRI examination must be carried out in day 6-16 of the menstrual cycle and within two weeks of mammography;
14.6 MRI examination must be interpreted by a trained radiologist privileged to provide this service;
14.7 The radiologists interpreting breast MRIs must be:
14.7.1 Experienced in interpreting mammography, and breast ultrasound in order to carry out accurate, clinical comparisons; and
14.7.2 Be able to perform an MRI-guided biopsy.
14.8 Reporting of MRI must use the BI-RADS®) Final Assessment Categories as described at Appendix 6.
14.9 The use of synoptic MRI report is recommended.
14.10 Equipment must be maintained and serviced in accordance with the manufacturers' guidelines and service specifications, and records must be maintained by providers.
14.11 Technologists and medical physicists must perform weekly and annual quality control (QC) tests to assess MRI system performance.

15. Standard 9– Genetic/Familial High Risk Assessment

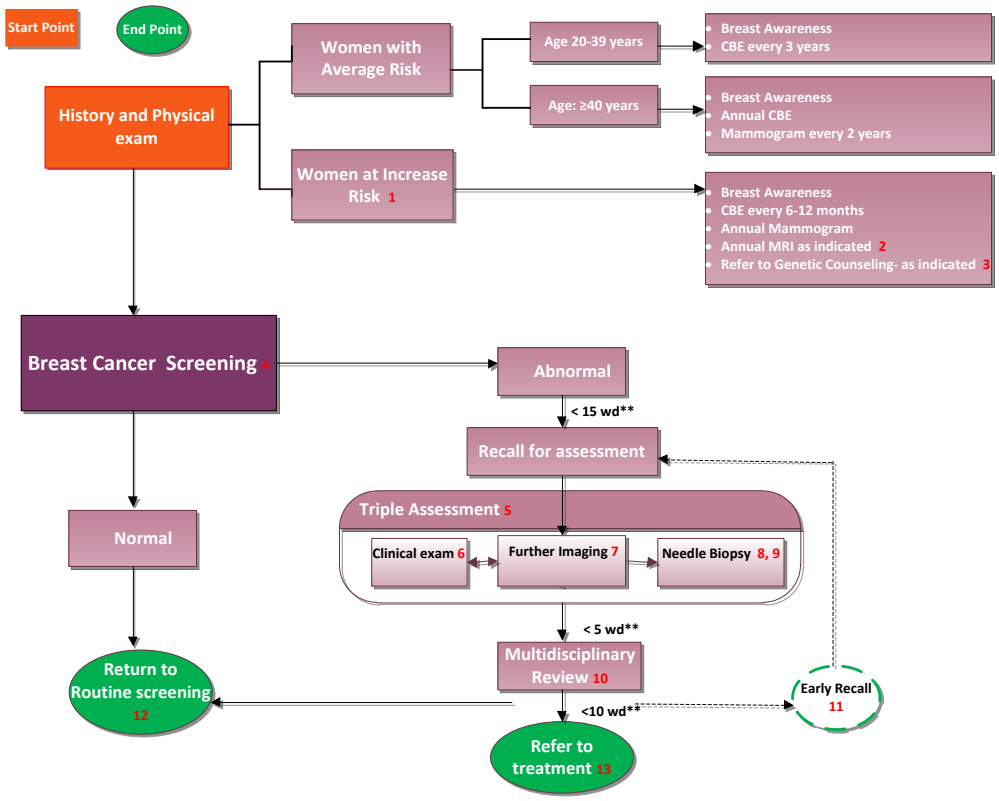
15.1 Women who have strong family history or genetic predisposition to breast cancer as detailed in Appendix 2, must be referred to Genetic Counselor;
15.2 Genetic counseling is highly recommended when genetic testing is offered and after disclosing of results;
15.3 Genetic counseling can be given by a genetic counselor, medical geneticist, oncologist, surgeon, oncologist nurse or other healthcare professional with expertise and experience in genetic counseling who is privileged by the facility to provide counseling;
15.4 Comprehensive gene testing includes full sequencing of BRAC1/2 and detection of large genomic rearrangement. A list of genetic tests to be performed is provided in Appendix 8;
15.5 Women, who have gene mutation, must be managed in accordance with HAAD recognised international best practices and guidelines; including the NCCN guidelines for Genetic/Familial High-Risk Assessment: Breast and Ovary, V.1.2012;

15.6 Screening tests and frequency must be in accordance with the recommendations detailed in table 2, Appendix 2.

Appendix 1

BREAST CANCER SCREENING & DIAGNOSIS PATHWAYS

هيئة الصحة - أبوظبي
HEALTH AUTHORITY - ABU DHABI



Key

1 Women at increased risk of breast cancer are defined in Appendix 2 of the Standard for the Screening & Diagnosis of Breast Cancer.
2 Indication for MRI is stipulated in Appendix 2 of the Standard for the Screening & Diagnosis of Breast Cancer.
3 Criteria for referral to Genetic Counselor is detailed in Appendix 2 .
4 Women with the following criteria should be excluded from screening with mammogram : pregnant, breast feeding, had bilateral mastectomy, and had recent mammogram within 12-24 months, under the age of 40, unless she is at increased risk
5 Triple assessment must be performed in Diagnostic Breast Assessment Unit. Requirement of a Diagnostic Breast Assessment Unit is detailed in Appendix 4
6 Clinical examination is mandatory for every woman with a confirmed mammographic or ultrasound abnormality that needs needle biopsy
7 Further imaging usually involve further diagnostic mammography and/or ultrasound
8 Needle biopsy should be performed under image guidance. Clip placement is done at the time of core needle biopsy to identify lesion location.
9 Cytology should no longer be used alone to obtain a non-operative diagnosis of breast cancer
10 Results of assessments are recommended to be discussed by a multidisciplinary team. Women must be informed about results within 5 working days.
11 Early recall is exceptional screening outcome and should be monitored and audited
12 Screening frequency will follow recommendation specified in appendix 2
13 Referral of histologically confirmed cancer cases to treatment must be made within 10 working days, following diagnosis.
** Working day

References:
1. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Screening and Diagnosis. V.1.2011.
2. NHS . Clinical Guidelines for Breast Cancer Screening Assessment. NHSBSP Publication No 49.2010
3. the National Health System (NHS) Cancer Screening Programmes. Technical Guidelines for Magnetic Resonance Imaging for the Surveillance of Women at Higher Risk of Developing Breast Cancer. NHSBSP PUBLICATION NO 68. 2012
4. The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovary. V.1.2012

Cancer Control & Prevention- Non Communicable Disease Department- Public health and Policies-
Health Authority- Abu Dhabi. Updated in June, 2012

Appendix 2-HAAD Breast Cancer Screening Recommendation

Table 1: A summary of HAAD Screening Recommendations [1]

Screening Category	Age	Screen Assessment tools
Women at average Risk	20 – 39 years	• Breast Awareness • Clinical Breast Exam every three years
	≥ 40 years	• Breast Awareness • Clinical Breast Exam yearly • Mammography every two years
Women at increased Risk		• Breast Awareness • Clinical Breast Exam every 6-12 months • Annual Mammography screening • Annual MRI screening - as indicated • Referral to genetic counselor –for strong familial/genetic predisposition

Adapted from: NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Screening and Diagnosis. V.1.2011

Women at Increased Risk [1]

A woman is considered at higher risk of developing breast cancer if she has one or more of the following criteria:

- Previous treatment with chest radiation at a young age (between age of 10-30)
- Previous history of Breast
- Lobular carcinoma in situ (LCIS) or Atypical ductal hyperplasia (ADH) on previous breast biopsy
- Strong family history or genetic predisposition
- Women who have a life time risk of 20-25% as defined by models largely dependent of family history
- 5-years risk of developing invasive breast cancer of ≥ 1.7 % in women aged ≥35 (per Gail model)

Table 2: HAAD Screening Recommendations for women at Increased Risk [1]

Screening Category	Age	Screen Assessment tools
Previous treatment with chest radiation at a young age (between age of 10-30)	Age < 25 years	• Breast Awareness • Annual Clinical Breast Exam
	Age ≥25	• Breast Awareness • Clinical Breast Exam every 6-12 months • Annual Mammography screening (begin 8-10 years after radiotherapy or age > 25 years, whichever come last) • Annual MRI screening
Strong family history or genetic predisposition	Age < 25 years	• Breast Awareness • Annual Clinical Breast Exam • Referral to genetic consoler
	Age ≥25 years	• Breast Awareness • Clinical Breast Exam every 6-12 months • Annual Mammography screening • Annual MRI screening • Referral to genetic consoler
Previous history of Breast		• Clinical Breast Exam every 6-12 months in the first 5 years, annually thereafter. • Annual Mammography screening
5-years risk of developing invasive breast cancer of ≥ 1.7 % in women aged ≥35 (per Gail model)		• Breast Awareness • Clinical Breast Exam every 6-12 months • Annual Mammography screening
Lobular carcinoma in situ (LCIS) or Atypical ductal hyperplasia (ADH) on previous breast biopsy		
Women who have a life time risk of 20-25% as defined by models largely dependent of family history		• Breast Awareness • Clinical Breast Exam every 6-12 months • Annual Mammography screening • Annual MRI screening

Criteria of use of MRI as adjunct to mammogram for high risk women [1]

- Having BRCA 1, 2 mutation
- Having a first degree relative with BRCA 1, 2 mutation
- Having a life time risk of 20-25% or more
- Received chest radiation between age 10-30
- Carry or have a first degree relative who carries mutation in TP 53 or PTEN genes

Criteria for Genetic Risk Evaluation [2]

<u>An affected individual with one or more of the following:</u>

- Early –age- onset breast cancer
- Triple negative (ER -, PR-, HER-) breast cancer
- Two breast cancer primaries in a single individual
- Breast cancer at any age and
    - ≥ one closed blood relative with breast cancer≤ 50 years, or
    - ≥ one close blood relative with epithelial ovarian cancer at any age, or
    - ≥ two close blood relative with breast cancer and/or pancreatic cancer at any age
    - A combination of breast cancer with one or more of the following: thyroid cancer , sarcoma, adrenocortical carcinoma, endometrial cancer, pancreatic cancer, brain tumors, diffuse gastric cancer, dermatological manifestation and /or macrocephaly, leukemia/ lymphoma on the same side of family (especially if early onset)
- Ovarian cancer
- Male breast cancer

<u>An affected individual with a family history of one or more of the following:</u>

- ≥ Two Breast primary , either in one individual or two different individual from the same side of the family Maternal or paternal
- ≥ One ovarian cancer primary from side of family maternal or paternal
- First -or second –degree relative with breast cancer ≤45 years
- A combination of breast cancer with one or more of the following: Thyroid cancer, sarcoma, adrenocortical carcinoma, endometrial cancer, pancreatic cancer, brain tumors, diffuse gastric cancer, dermatological manifestation and / or macrocephaly. or leukemia /Lymphoma on the same side of family (especially if early onset)
- A known mutation in breast cancer suitability gene within the family
- Male breast cancer

N. B. Maternal and paternal sides of the family must be considered independently for familial pattern of cancer.1st degree: mother, sister, daughter, brother, father- 2nd degree: grandmother, aunt, niece, nephew

References:

1. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Screening and Diagnosis. V.1.2011.
2. The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovary. V.1.2012

Appendix 3 - HAAD Breast Cancer Screening Clinical Quality Indicators

Clinical Quality Indicators	Definition	Calculation	Acceptable level		Desirable level
1. Participation rate	Percentage of women who have a screening mammogram (calculated biennially) as a proportion of the eligible	[Number of women screened at least once (per 2-year period) / Target population (1st & 2nd year populations averaged from		>70%	>75%
2. Retention rate	The estimated percentage of women who are re-screened within 30 months of their previous			>75%	95%
3. Technical repeat rate	Proportion of women undergoing a technical repeat screening examination	[Number of women undergoing a technical repeat / Number of women screened]*100		<3%	<1%
4. Abnormal Recall rate	Proportion of women recalled for further assessment	[Number of recalls due to abnormal screens / Number of women screened]*100	At Initial screening	<15%	<10%
			At subsequent screening	<10%	<7%
5. Early recall rate	Proportion of screened women subjected to early recall following diagnostic assessment	[Number of subjected for early recall / Number of women screened]*100		<1 %	0%
6. Positive Predictive Value	Proportion of abnormal cases with completed follow-up found to have breast cancer .	[Number of screen detected cancers / Number of abnormal screens with complete work-up] *100	At Initial screening		>5%
			At subsequent screening		>6%
7. Invasive cancer detection rate	Number of invasive cancers detected per 1,000 screens.	[Number of invasive cancers detected/ number of screen] *1000	Initial screening		>5 per 1,000
			Subsequent screening		> 3 per 1,000

Clinical Quality Indicators	Definition	Calculation	Acceptable level		Desirable level
8. In Situ Cancer Detection Rate	Number of in ductal carcinoma in situ (DCIS) detected per 1,000 screens.	[Number of DCIS detected/ number of screen] *1000	Initial screening		>0.4 per 1,000
			Subsequent screening		>0.4 per 1,000
9. Invasive Cancer Tumor Size	Proportion of invasive screen-detected cancers that are <10 mm in size	[Number of invasive tumors ≤10mm / Total number of invasive tumors] *100	Initial screening	20%	≥25%
			Subsequent screening	≥25%	≥30%
10. Interval cancer detection rate	Number of women with a diagnosis of invasive breast cancer after a normal screening within 12 AND 24 months of the screen date.	[Number of cancers detected in the 0-12 month interval after a normal screening episode / Total person-years at risk (0-12 months post screen)]*10,000	Within the first year (0–11 months)		< 6 per 10,000
			Within the second year (12–23 months)		12 per 10,000
11. Time Interval	-Screening mammography and result within 15 working days		95%		> 95%
	-Screening and offered assessment within 5 working days		90%		> 90%
	-Assessment and issuing of results within 5 working days		90%		> 90%
	-Non-operative (needle) biopsy and result 5 working days		>90%		100%

Reference:

1. European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth Edit. 2006
2. Public Health Agency of Canada. Report from the Evaluation Indicators Working Group. Guidelines for Monitoring Breast Screening Program Performance. Second Edition. 2007

Appendix 4 – Requirement for breast screening and diagnosis services

A. Requirement for Breast Screening Unit

1. General

1.1. Assign a screening program director/coordinator to be in charge of overall performance, quality assurance of the unit and will be responsible for submitting data on screening visits and outcomes to HAAD through the cancer e-notification;
1.2. Perform at least 1,000 mammograms a year.
1.3. Be able to perform risk assessment, physical examinations and screening mammogram
1.4. Monitor data and feedback of results. Keep a formal record of mammogram results, assessment processes and outcomes.
1.5. Establish and maintain records of mammogram outcomes;
1.6. Develop and implement an audit program to follow up positive mammography assessments and to compare pathology results with the interpreting physician's findings. Develop an action plan to manage any adverse findings.
1.7.

2. Invitation system

2.1. Develop and implement a personalized invitation system and/or a promotional campaign as well as a planned and structured system to re-invite all previously screened women.

3. Mammography equipment:

3.1. Equipment specifications must meet HAAD recognized standards such as the Mammogram Quality Standards Act (MQSA) published by the FDA;
3.2. Equipment must be subject to periodic Quality Control (QC) tests, as specified by the MQSA for screen-film systems and by the manufacturer for full-field Digital Mammography (FFDM) system including:
3.2.1. Radiographic QC tests, by mammographers, radiographers or technologists trained in Mammography; and
3.2.2. Medical Physics compliance QC tests at installation and at least annual thereafter, by a HAAD licensed qualified Medical Physicist.
3.3. Equipment must be maintained and serviced in accordance with the manufacturers' guidelines and service specifications, records must be maintained by providers.

4. Radiographers

4.1. Radiographers, mammographers or technologists performing the mammographic examination must:
4.1.1. Have had at least 40 hours of training specific to the radiographic aspects of mammography; and
4.1.2. regularly participate in External Quality Assessment Schemes and radiographic update courses.

5. Radiologists

5.1. Radiologists must:

5.1.1. Have at least 60 hours of training specific to mammography;

5.1.2 read mammograms from a minimum of 400 screening mammogram annually; and

5.1.3 have centralized reading or, in a case of a decentralized programmer, centralized double reading;

5.1.4 take full responsibility for the image quality of the mammograms reported;

5.1.5 ensure that where necessary images are repeated until they are of satisfactory standard and document all repeated examinations.

6. Referral, assessment and feedback

6.1. Keep a formal record of mammogram results, assessment processes, referrals and outcomes.

6.2. Maintain records of mammogram results, referrals, assessment processes and outcomes.

6.3. Have an approved protocol for referral of women with screen detected abnormalities to diagnostic breast assessment unit

B. Requirement for a Diagnostic Breast Assessment Unit

1. General

1.1 The unit must:

1.1.1 Perform at least 2,000 mammograms a year;

1.1.2 Be able to perform physical examinations and ultrasound examinations as well as the full range of radiographic procedures;

1.1.3 Provide cytological examination and/or core biopsy;

1.1.4 Provide sampling under radiological (including stereotactic) or sonographic guidance;

1.1.5 Monitor data and feedback of results; and

1.1.6 Keep a formal record of mammogram results, assessment processes and outcomes.

1.1.7 Have a nominated lead in the radiographic aspects of quality control.

1.1.8 Have a multidisciplinary team who participate in regular review meetings with all team members responsible for diagnostic and treatment services.

2. Physico-technical

2.1. The unit must:

2.1.1. Have dedicated equipment specifically designed for application in diagnostic mammography e.g. mammography system with magnification ability and dedicated processing;

2.1.2. be able to provide adequate viewing conditions for mammograms;

2.1.3. have dedicated ultrasound and stereotactic system and needle biopsy device for preoperative tissue diagnosis; and

2.1.4. comply with specifications of HAAD recognized standards such as the MQSA final rule published by the FDA.

3. Staff performing mammographic examination

3.1. The radiographers, technologists or other members of staff performing the must:

3.1.1. Have had at least 40 hours of training specific to the radiographic aspects of mammography;

3.1.2. regularly participate in External Quality Assessment Schemes and radiographic update courses;

3.1.3. be able to perform good quality mammograms.

4. Radiologists

4.1. The unit must:

4.1.1. Employ a trained radiologist, i.e. a person who has:

4.1.1.1. At least 60 hours of training specific to mammography; and

4.1.1.2. who reads at least 1,000 mammograms per year.

5. Pathology support

5.1. The unit must:

5.1.1. Have organized and specialist cyto/histopathological support services who can demonstrate compliance with HAAD Clinical Laboratory standards.

Appendix 5: e- Cancer Screening Form

For information only, the web-based "Cancer Screening Form" must be completed, available on http://www.haad.ae/haad/tabid/1084/Default.aspx;

Patient Information			
First Name		Emirates ID Number	
Middle Name		Medical File Number	
Last Name			
Gender		DOB	
Nationality		Emirates of residence	
Occupation		City of residence	
Education		Mobile Number	
Marital status			
Weight (kg)		Height (cm)	

Reason for current visit			
Reason for current visit	☐ Breast Screening	☐ Cervical screening	☐ Colorectal cancer
Registry Status?		Method of recruitment	
Date of Last Screening test performed (anywhere)		☐ CBE	Date
		☐ Mammogram	Date
		☐ Pap test	Date
		☐ Colonoscopy	Date

Reproductive Health History			
Parity (number deliveries)?		Age at birth of first child?	
Age at menarche?		If married, Age at first marriage	
Menopausal status?		If yes, Age at menopause?	
Had uterus removed (Hysterectomy)?	Y/N	If yes, Reason for hysterectomy?	
Had ovary removed (oophorectomy)?	Y/N	If yes, Reason oophorectomy?	
Current use of oral contraceptive pills	Y/N	If ever, total duration in years?	

Current use of hormonal replacement therapy		Y/N	If yes, total duration in years?		
Personal Health History					
Smoking History					
Personal history of the following conditions. Tick if appropriate			☐ Breast biopsy		
			☐ Atypical Ductal Hyperplasia on breast biopsy		
			☐ Breast implants (still present)		
			☐ Mastectomy		
			☐ Lumpectomy (for breast cancer)		
			☐ Breast radiation		
Personal history of cancer?		Y/N			
If yes,	type of cancer	☐ Left	☐ Right	☐ NA/Unknown	Age at diagnosis
	type of cancer	☐ Left	☐ Right	☐ NA/Unknown	Age at diagnosis
Family History					
Family history of cancer in first or second degree?			Y/N		
If yes, type of cancer		Relation	Cancer type	Age at diagnosis	
		Relation	Cancer type	Age at diagnosis	
		Relation	Cancer type	Age at diagnosis	
Current Screening outcomes					
CBE done		y/N	If yes, result of CBE		
Mammogram done		Y/N	If yes, date?		
			If No, reason for refusal?		
Mammogram report (BIRADS)			Date patient notified with report		
Recommended Next Step					
Patient referred to other hospital		Y/N	Date patient referred?		

Appendix 6-BI-RADS® Final Assessment Categories

CPT II EVALUATION CODE	BIRADS SCORE	DESCRIPTION	DEFINITION
3340F	0	Need Additional Imaging Evaluation	The mammogram or ultrasound didn't give enough information to make a clear diagnosis; follow-up imaging is necessary and/or prior Mammogram for comparison
3341F	1	Negative	Negative, there is a 5/10,000 chance of cancer being present. Continue annual screening mammography (for women 40 and older).
3342F	2	Benign Finding	Benign (non-cancerous) finding, same statistics and plan of follow-up as level 1. This category is for cases that have a finding that is characteristically benign such as cyst or fibroadenoma (see below for more detail).
3343F	3	Probably Benign Finding Short Interval Follow-Up Suggested	Probably benign finding, there is less than 2% chance of cancer. Usually receives a 6 month follow-up mammogram; most level 3 abnormalities do not receive biopsy.
3344F	4	Suspicious Abnormality . Biopsy to be Considered	Suspicious abnormality. Most category 4 abnormalities are benign but may require biopsy since this category can be malignant in 25-50% of cases.
3345F	5	Highly Suggestive of Malignancy. Appropriate Action must be taken	Highly suggestive of malignancy. Classic signs of cancer are seen on the mammogram. All category 5 abnormalities typically receive biopsy and if the biopsy results are benign, the abnormality usually receives re-biopsy since the first biopsy may not have sampled the correct area. Depending on how individual radiologists differentiate between category 4 and 5, the percentage of category 5 abnormalities that will be cancer may vary between 75% and 99%.
3350F	6	Known Biopsy Proven Malignancy	Lesions known to be malignant that are being imaged prior to definitive treatment; assure that treatment is completed

Appendix 7

e-Cancer Screening (Referral Form)

For information only - this form can be printed directly from the cancer surveillance e-notification after completing the "Cancer Screening form".

Cancer Screening ID:

Patient & Facility Information	
Facility Name	
First Name	
Last Name	
Date of Birth	
Nationality	
Emirate I.D.	
Marital status	

Mammogram Report	
Recommended next step	
Referred? Yes/No	
Date of referral	

Appendix 8- Genetic Tests

Available genetic tests for the patient or her affected family member(s) that may be recommended by the Cancer Genetics professional based on to the assessment:

Disease	Gene	Method
BRCA1 & BRCA2 Hereditary Breast and Ovarian Cancer	BRCA1	Sequencing
BRCA1 & BRCA2 Hereditary Breast and Ovarian Cancer	BRCA1	Deletion/duplication analysis
BRCA1 & BRCA2 Hereditary Breast and Ovarian Cancer	BRCA2	Sequencing
BRCA1 & BRCA2 Hereditary Breast and Ovarian Cancer	BRCA2	Deletion/duplication analysis
Li-Fraumeni Syndrome	TP53	Sequencing
Li-Fraumeni Syndrome	TP53	Deletion/duplication analysis
Cowden Syndrome	PTEN	Sequencing
Cowden Syndrome	PTEN	Deletion/duplication analysis
CHEK2-Related Susceptibility to Breast Cancer	CHEK2	Sequencing
CHEK2-Related Susceptibility to Breast Cancer	CHEK2	Deletion/duplication analysis
RAD51C-Related Familial Susceptibility to Breast-Ovarian Cancer	RAD51C	Sequencing
RAD51C-Related Familial Susceptibility to Breast-Ovarian Cancer	RAD51C	Deletion/duplication analysis
BARD1-Related Susceptibility to Breast Cancer	BARD1	Sequencing
BARD1-Related Susceptibility to Breast Cancer	BARD1	Deletion/duplication analysis

BRCA1 and BRCA2 Sequencing are the most commonly ordered genetic tests for High risk patients