UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

The National Guidelines For Breast Cancer Screening and Diagnosis

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Adapted from HAAD Standard for
Breast Cancer Screening & Diagnosis 2012

THE NATIONAL CANCER SCREENING INITIATIVE COMMITTEE

Dr. Yousef Al Serkal - Initiative Chair
Assistance Undersecretary of Hospital Sector- MOHAP

Dr. Muna Al Kuwari - Initiative Lead
Assistance Undersecretary of Hospital Sector- MOHAP

Dr. Wedad Al Maidoor - Member
Director of PHC Dubai Medical District- MOHAP

Dr. Jalaa Taher - Member
Manager, Non-Communicable Diseases Department- HAAD

Dr. Salah El Badawi - Member
Health Policy Adviser- MOHAP

Dr. Khawla Al Salman - Member
MCH Specialist- MOHAP

Dr. Amir Khan - Member
Biostatistics & Health Research Department- MOHAP

Dr. Sawsan AL Madhi - Member
Chair, Friends of Cancer Patient

Dr. Abdul Rahman Al Jessmi - Member
Consultant Paediatric Oncologist- DHA

Dr. Amer Al Sharif - Member
Dubai Medical City

Fatima Al Qahtani - Secretariat
Specialized Health Care Department-MOHAP

EDITORS

Dr. Jalaa Taher
Manager, Non-Communicable Diseases Department- HAAD

Dr. Mona El Sebelgy
Consultant Family Medicine - Coordinator In charge of Planning and Evaluation - National Breast Screening Program-MOHAP.

EDITORIAL GROUP: THE NATIONAL BREAST CANCER SCREENING TECHNICAL TASKFORCE

Dr. Jalaa Taher
Manager, Non - Communicable Diseases Department-HAAD

Dr. Mona El Sebelgy
Consultant Family Medicine - Coordinator In charge of Planning and Evaluation - National Breast Screening Program-MOHAP.

Dr. Rola Shaheen
Consultant Radiologist - Al Mafraq Hospital, SEHA

Dr. Nihad Kazim
Specialist Radiologist - National Screening Program for Women & Child- MOHAP

Dr. Latifa Al Awadhi
Coordinator of the National Breast Screening Program, Dubai Preventive Medicine Department Dubai.

Dr. Esaaf Ghazi
Consultant & Acting Head of General Surgery Depart. Dubai Hospital - DHA

Dr. Mona Al Ayyan
General Surgeon - Ras Al Khaima

Dr. Mohamed Abdul Nabbi
Consultant Radiologist- Preventive Medicine - Al Baraha Hospital

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1. PURPOSE

1.1. To stipulate the service requirements to deliver the National Breast Cancer Screening Program in the United Arab Emirates;

1.2. To set out the minimum Clinical Care Standards and frequency for breast cancer screening as per international evidence-based guidelines;

1.3. To set out the case mix, eligibility criteria and data reporting requirements for Breast Cancer Screening; and

1.4. To ensure the population receives quality and safe care and timely referral for diagnosis and/or treatment where appropriate

2. SCOPE

2.1. This Guideline applies to all Healthcare Providers (Facilities and Professionals) in the United Arab Emirates, licensed by Ministry of Health and Prevention (MOHAP), providing breast cancer screening & diagnosis services; including mobile units.

3. DEFINITIONS

3.1. For the purpose of these Guidelines , **Breast Cancer Screening and Diagnosis** include the following services:

3.1.1. Breast Screening services

3.1.2. Breast assessment and diagnosis.

3.2. **Case mix:** refer to all females , 40-69 years, determined as eligible for breast cancer screening services, in accordance with the criteria detailed in these Guidelines

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

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

3.5. **Clinical breast examination (CBE);** is an exam conducted by health care professional and involves inspection and palpation of all breast tissue including lymph nodes basins;

3.6. **Breast Awareness:** women , 20 years and older, should be encouraged and educated on how to conduct breast self-exam to become aware of the feeling 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.

3.7. **Breast Assessment and Diagnosis:** It involve 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.

4. DUTIES FOR HEALTHCARE PROVIDERS

All Licensed Healthcare Providers Facilities and Professionals engaged in providing breast cancer screening & diagnosis services must:

4.1. Provide clinical services and patient care in accordance with this Guidelines and in accordance with Policies and Standards, laws and regulations of United Arab Emirates ; including developing effective recording systems, maintaining confidentiality, privacy and security of patient information

4.2. Comply with the federal requirements; laws and policies for Patient Education and Consent. The licensed provider must provide appropriate patient education and information regarding the screening test and must ensure that appropriate patient consent is obtained and documented on the Patient's medical record;

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

4.4. Comply with Federal requirements ; laws, policies and standards 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;

4.5. Comply with relevant policies on Cultural Sensitivity; in particular, providers must ensure:

4.5.1. That only female radiographers, mammographer or technologists

are allowed to perform mammographic examination for women.

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

4.5.3. where delays are likely to occur due to limited availability of same sex licensed professionals at the employing 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;

4.6. Comply with MOHAP requests to inspect and audit records and cooperate with authorized auditors as required ;

4.7. Collect and submit data on screening visits and outcomes, as **per Appendix 1** , to the National Cancer Screening Registry; at MOHAP**.**

4.8. Comply with Federal laws, policies and standards on cancer case reporting and report all confirmed screening –detected cancers to the National Cancer Registry at MOHAP.

5. ENFORCEMENT AND SANCTIONS

5.1. Healthcare providers, payers and third party administrators must comply with the terms and requirements of these Guidelines. MOHAP may impose sanctions in **relation to** any breach of requirements under these Guidelines.

6. PAYMENT FOR SCREENING AND FOLLOW UP OF BREAST CANCER:

6.1. Eligibility for reimbursement under the Health Insurance Scheme must be in Accordance, with local insurance laws for each Emirate.

7. STANDARD 1. CLINICAL SERVICE SPECIFICATIONS

7.1. Breast Cancer Screening services

All licensed **Healthcare Facilities** providing Breast Cancer Screening services must:

7.1.1. Follow best practice for breast cancer screening and diagnosis care pathways and recommendation of breast cancer screening per **Appendix 2,3;**

7.1.2. Adhere to the Clinical performance Indicators and timelines for referral in accordance with **Appendix 4;** and ensure availability of evidence of compliance with these indicators

7.1.3. Comply with requirement of breast screening unit, detailed in **Appendix 5;**

7.1.4. Have an approved protocol for referral of women with screen detected abnormalities for further breast assessment unit or treatment

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. Assign a Breast Cancer facility program coordinator/director who will be accountable to:

7.1.6.1. report and submit screening visits and outcome data, specified in section 4; and

7.1.6.2. establish internal audit policies and procedures and conduct regular audits, monitoring and evaluation to demonstrate compliance with these Guidelines and other associated regulatory policies and standards.

7.2. Breast Assessment and Diagnosis Services

7.2.1. Breast assessment and diagnosis services must be carried out in Diagnostic Breast Assessment unit. These unit must

7.2.2. Comply with the requirements of Diagnostic Breast Assessment unit, described at Appendix 5;

7.2.3. Comply with breast cancer screening and diagnosis care pathways, clinical quality indicators, and time lines for referral in accordance with Appendices 2, 4.

7.2.4. Have approved written protocols for the screening assessment and diagnosis; that clearly define the methods of assessment and the diagnostic pathways for all possible assessment outcomes,

7.2.5. Women who require further assessment must be managed in accordance with internationally best practices and recommended guidelines such those of the National Health System Breast Screening Program (NHSBSP) Clinical guidelines for breast cancer screening assessment or the National Comprehensive Cancer Network (NCCN) Breast Cancer Screening & Diagnosis.

7.2.6. Establish internal audit procedures to demonstrate compliance with these Guidelines and other associated regulatory policies and standards;

7.3. All licensed Healthcare Professionals participating in breast cancer screening & diagnosis must:

7.3.1. Have knowledge of the principles of breast cancer screening, assessment, diagnosis and management.

7.3.2. Participate in continuing medical education and take part in any recognized external quality assessment schemes

7.3.3. Conduct breast cancer risk assessment. Detailed history, such as that described in, Appendix 1, must be evaluated and completed, each time an women visits for screening. The purpose of this is to identify risk status , as per risk categories specified in **Appendix 2** and referral women to appropriate screening tests or

7.3.4. Inform all individuals of the procedures and expected timeframe to be screened and to receive results;

7.3.5. Ensure that the outcome of screening for breast Cancer is reviewed by a multi-disciplinary team involving a full range of specially trained professionals including a radiologist, radiographer, pathologist, surgeon, nurse counselor and medical oncologist/radiotherapist.

7.3.6. Follow up and timely referral of women with abnormal results to further assessment or treatment.

8. STANDARD 2: RECRUITMENT FOR SCREENING

Women eligible for breast cancer screening may be recruited by the healthcare facilities, through the following:

8.1. Targeted invitation

8.1.1. All facilities providing Breast cancer screening & diagnosis services must establish an invitation system to ensure identification , successful participation and retaining of eligible population;

8.1.2. Targeted invitation may be established via an electronic or manual invitation system;

8.2. Opportunistic

8.2.1. New physician consultation for related or unrelated reason or;

8.2.2. Engagement in a health promotion campaign

9. STANDARD 3: BREAST CANCER SCREENING

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

9.1.1 History & Risk assessment;

9.1.2 Clinical breast exam (Physical exam); and

9.1.3 Screening mammogram.

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

9.3 Detailed history, such as that described in Appendix 1, 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.

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

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

9.6 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

9.7 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

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

10. STANDARD 4- BREAST ASSESSMENT AND DIAGNOSIS

10.1 Breast cancer assessment and diagnosis must be provided in accordance with the clinical care pathway and timelines for referral (Appendix 2, 4);

10.2 Women with abnormal mammogram , who require further assessment and diagnosis must be recalled/referred to Diagnostic Breast Assessment unit within 5 working days of screening mammogram Date.

10.3 Assessment and diagnostic work up of screen detected abnormality is best achieved using the triple assessment:

- 10.3.1 Imaging; usually diagnostic mammography and ultrasound;
- 10.3.2 clinical examination; and
- 10.3.3 image-guided needle biopsy for histological examination, if indicated.
- 10.3.4 Cytology alone must not be used to obtain a non-operative diagnosis of breast cancer.
- 10.3.5 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.

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

10.5 Core needle biopsy must be performed under image guidance.

10.6 A clip must be placed at site of biopsy during the procedure of needle sampling to identify the lesion/s location;

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

10.8 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.

10.9 Early recall rate must be recorded, monitored and audited;

11. STANDARD 5–REPORTING OF SCREENING MAMMOGRAM

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

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

11.3 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.

11.4 All screening mammograms that require additional assessment should be rated as BIRADS 0. Only after full assessment , with additional imaging and or comparison with prior mammogram; BIRADS 3-5 can be assigned

11.5 One final mammogram report to be issued, A synoptic breast imaging report must be used by radiologists 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 informed about the results of screening within 3 weeks (15

working days) of the date of screening mammogram.

12.2 Women with screening mammogram Normal/Benign (BIRADS 1/2), are discharged to routine screening. Screening frequency will follow recommendation specified in Appendix 3;

12.3 If a woman requires further assessment for abnormal screening mammogram (BIRADS 0) or clinical breast exam, referral must be to a Diagnostic Breast Assessment Unit within 5 days of screening mammogram date ;

12.4 Women must be notified with assessment results within 5 days of assessment tests.

12.5 At the end of the screening, women must be provided with one final written mammogram report.

12.6 It is the responsibility of the radiologist (at the screening or assessment facilities) to inform women regarding her screening and assessment results. Also, send feedback to referring physician at the primary health care clinic.

APPENDIX 1

NATIONAL CANCER SCREENING REGISTRY DATA REQUIREMENT: SCREENING VISITS AND OUTCOME

Patient Information			
First Name		Emirates ID Number	
Middle Name		Medical File Number	
Last Name			
Gender		DOB	
Nationality		Emirates of residence	
Marital status		City of residence	
BMI		Mobile Number	

Screening History			
Registry Status?	New/Registered	Method of recruitment	Invited for screening
			Walk in
			With appointment
Date of Last Screening test performed (anywhere)		☐ CBE	Date
		☐ Mammogram	Date
		☐ Pap test	Date
		☐ Colonoscopy /FIT	Date

Reproductive Health History			
Parity (number deliveries)?		Age at birth of rst child?	
Had uterus removed (Hysterectomy)?	Y/N	If yes, Reason for hysterectomy?	
Current use of oral contraceptive pills	Y/N	If ever, total duration in years?	

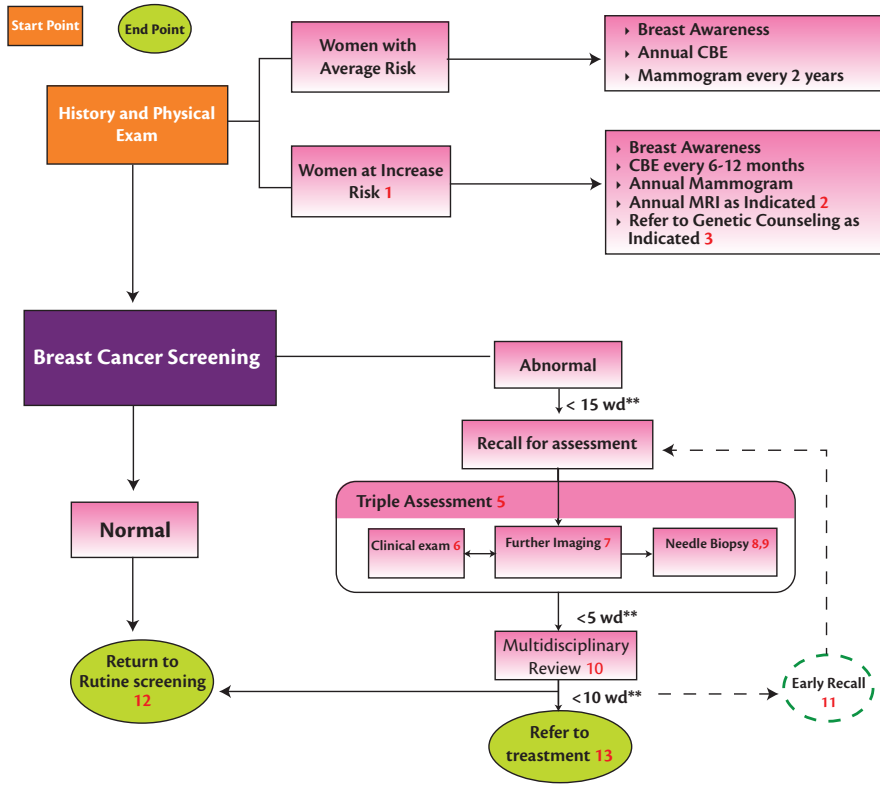
Personal Health History	
Personal history of the following conditions. Tick if appropriate	☐ Breast or ovarian cancer
	☐ ADH/ALH/LCIS on previous breast biopsy or surgery
	☐ Previous treatment with chest radiation (at age <30)

Family History			
Family history of cancer in rst 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 2

BREAST CANCER SCREENING & DIAGNOSIS PATHWAYS



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 refererral to Genetic Counselor is detaliled 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 Assesment 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 blopsy.
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 locations.
9. Cytology should no longer be used alone to obtain a non-operative diagnosis of breast cancer.
10. Result of assessments are recommended to be discussed by a multidisciplinary tem, 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.
2. NHS Clinical Guidelines for Breast Cancer Screening Assessment, NHSBSP Publication No 49.
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.
4. The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology, Genetic /Familial High-Risk Assessment: Breast and Ovary.

APPENDIX 3

NATIONAL BREAST CANCER SCREENING RECOMMENDATION

Table 1: A summary of the National Breast Cancer Screening Recommendations [1]

Screening Category	Age	Screen Assessment tools
Women at Average Risk	20-39 years	• Breast Awareness
	40-69 years	• Breast Awareness • Clinical Breast Exam yearly • Mammography every two years
Women at Increased /High Risk	Age of initiation is individualized according to risk (table 2)	• 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.1.2014

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 age younger than 30
- Previous history of Breast Cancer
- Lobular carcinoma in situ (LCIS) or Atypical ductal hyperplasia (ADH) or Atypical lobular hyperplasia (ALH), on previous breast biopsy
- Strong family history or genetic predisposition

Table 2: National 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. Screening begin 8-10 years after radiotherapy
	Age ≥25	• Breast Awareness • Clinical Breast Exam every 6-12 months • Annual Mammography screening (begin 8-10 years after radiotherapy or age > 40 years, whichever comes first) • Annual MRI screening
Strong family history or genetic predisposition **	Age < 25 years	• Breast Awareness • Annual Clinical Breast Exam • Referral to genetic counselor
	Age ≥25 years	• Breast Awareness • Clinical Breast Exam every 6-12 months • Annual Mammography screening – as indicated Ω • Annual MRI screening – as indicated • Referral to genetic counselor
Previous history of Breast Cancer		• Clinical Breast Exam every 6-12 months in the first 5 years, annually thereafter. • Annual Mammography screening
Lobular carcinoma in situ (LCIS) or Atypical ductal hyperplasia (ADH) or Atypical lobular hyperplasia (ALH) on previous breast biopsy		• Breast Awareness • Clinical Breast Exam every 6-12 months • Annual Mammography screening. • Screening begin at diagnosis

**** (Screening and assessment of women with genetic /familial high risk is individualized and should be in accordance with recognized international guidance; such as NCCN guidelines 2)**

Ω (Screening mammogram is not recommended before age of 30 years)

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
- Received chest radiation between age 10-30
- Carry or have a first degree relative who carries mutation in TP 53 or PTEN genes

Indication of Strong family history or genetic predisposition to merit referral for Genetic Risk Evaluation 2:

Individual with a breast cancer diagnosis with one or more of the following:

- 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
    - Personal or family history of three or more of the following (especially if early onset): pancreatic cancer, prostate cancer, sarcoma, adrenocortical carcinoma, brain tumors, endometrial cancer, thyroid cancer, kidney cancer, dermatologic manifestations and or macrocephally, hamartomatous polyps of gastrointestinal tract, diffuse gastric cancer
- Ovarian cancer
- Male breast cancer

An individual with no personal history of cancer with a family history of one or more of the following:

- ≥ Two Breast cancer 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

- Personal or family history of three or more of the following (especially if early onset): pancreatic cancer, prostate cancer, sarcoma, adrenocortical carcinoma, brain tumors, endometrial cancer, thyroid cancer, kidney cancer, dermatologic manifestations and or macrocephally, hamartomatous polyps of of gastrointestinal tract, diffuse gastric cancer
- A known mutation in breast cancer suitability gene within the family
- Male breast cancer

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

References:

1. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Screening and Diagnosis. V.1.2014.
2. The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovary. V.2.2014

APPENDIX 4

NATIONAL BREAST CANCER SCREENING CLINICAL PERFORMANCE INDICATORS

Clinical Quality Indicators	Definition	Calculation	Acceptable level		Desirable level
1. Participation rate	Percentage of women 40-69 years who have a screening mammogram (calculated biennially) as a proportion of the eligible population	[Number of women screened at least once (per 2-year period) / Target population (1st & 2nd year populations averaged from census/ forecast)] *100	>70%		> 75%
2. Retention rate	The estimated percentage of women 40-69 years who are re -screened within 30 months of their previous screen.	Kaplan-Meier Method **	Auditable outcome		> 75%
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	Auditable outcome	<10-15%
			At subsequent screening	Auditable outcome	<7-10%
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%

Clinical Quality Indicators	Definition	Calculation	Acceptable level		Desirable level
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
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 (wd)		95%		> 95%
	- Screening and offered assessment within 5 working days (wd)		90%		> 90%
	- Assessment and issuing of results within 5 working days (wd)		90%		> 90%
	- Non-operative (needle) biopsy and result 5 working days (wd)		>90%		100%

** Refer to Reference 2 for calculation

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 5

REQUIREMENT FOR BREAST SCREENING AND DIAGNOSIS SERVICES A. REQUIREMENT FOR BREAST SCREENING UNIT

1. General

1.1. 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 MoH;

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.

2. Invitation system

2.1. Operate a successful personalized invitation system and/or a promotional campaign as well as an organized system for re-inviting all previously screened women

3. Mammography equipment:

3.1. Specifications must meet recognized standards such as the MQSA final rule published by the FDA;

3.2. Subject to regular radiographic and physicist quality-controlled tests, in concordance with MQSA rule.

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 have had at least 40 hours of training specific to the radiographic aspects of mammography , and

4.2. Regularly participate in External Quality Assessment Schemes and radiographic update courses.

5. Radiologists

5.1. Must have at least 60 hours of training specific to mammography.

5.2. Must read mammograms from a minimum of 400 screening mammogram annually. Have centralized reading or, in a case of a decentralized programmer, centralized double

5.3. This radiologist must take full responsibility for the image quality of the mammograms reported and ensure that where necessary images are repeated until they are of satisfactory standard. The number of all repeated examinations should be recorded

6. Referral, assessment and feedback

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

6.2. Maintain record of, mammogram results, referrals m 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 BREAST ASSESSMENT /DIAGNOSTIC UNIT

1. General

1.1 Perform at least 2,000 mammograms a year.

1.2 Be able to perform physical examinations and ultrasound examinations as well as the full range of radiographic procedures. Provide cytological examination and/or core biopsy

1.3 sampling under radiological (including stereotactic) or sonographic guidance.

1.4 Monitor data and feedback of results.

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

2. Physico-technical

2.1. Have dedicated equipment specifically designed for application in diagnostic mammography e.g. mammography system with magnification ability and dedicated processing, and be able to provide adequate viewing conditions for mammograms.

2.2. Have dedicated ultrasound and stereotactic system and needle biopsy device for preoperative tissue diagnosis.

2.3. Comply with specifications of recognized standards such as the MQSA final rule published by the FDA

3. Radiographers

3.1. The radiographers, technologists or other members of staff performing the mammographic examination must have had at least 40 hours of training specific to the radiographic aspects of mammography and regularly participate in External Quality Assessment Schemes and radiographic update courses. These persons must be able to perform good quality mammograms. There should be a nominated lead in the radiographic aspects of quality control.

4. Radiologists

4.1. Employ a trained radiologist, i.e. a person who has had at least 60 hours of training specific to mammography and who in volume reads at least 1,000 mammograms per year.

5. Pathology support

5.1. Have organized and specialist cyto / histopathological support services.

6. Multidisciplinary activities.

6.1. Participate in multidisciplinary communication and review meetings with others responsible for diagnostic and treatment services.

APPENDIX 6

BI-RADS® FINAL ASSESSMENT CATEGORIES

CPT II Evaluation Code	BIRADS Score	Description	Definition
3340F	0	Incomplete. 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 bi annual screening mammography (for women 40 and older).
3342F	2	Benign	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	Probably benign finding, there is less than 2% chance of cancer. Usually receives a 6 month follow-up mammogram; followed by additional examination until long term stability. There may be occasion where biopsy is done instead. (patient preference or overriding clinical concerns)

CPT II Evaluation Code	BIRADS Score	Description	Definition
3344F	4	Suspicious 4 A 4 B 4 C	Suspicious abnormality. Findings do not have the classic appearance of malignancy, but are sufficiently suspicious to justify recommended biopsy. Carry 2%-95% chance of being malignant finding. 4 A: finding with a low suspicion of being cancer (>2% and ≤ 10%) 4 B: finding with an intermediate suspicion of being cancer (>10% and ≤ 50%) 4 C: Finding of moderate concern of being cancer but not as high category 5 (>50% and <95%)
3345F	5	Highly Suggestive of Malignancy.	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 those are being imaged prior to definitive treatment; assure that treatment is completed.

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