UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

THE NATIONAL GUIDELINE FOR

BREAST CANCER SCREENING AND DIAGNOSIS

3RD EDITION 2023

NATIONAL BREAST CANCER SCREENING TASK FORCE

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THE NATIONAL GUIDELINE FOR BREAST CANCER SCREENING & DIAGNOSIS

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 requirement for breast cancer screening.

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, providing, breast cancer screening & assessment and diagnosis services; including mobile units.

3. DEFINITIONS

3.1. **Case Mix:** Refer to all females, 40-69 years, determined as eligible for breast cancer screening services, in accordance with the criteria detailed in this guideline.

3.2. **Screening Mammograms:** Are carried out for healthy women, who have no symptoms of breast cancer and negative clinical breast examination.

3.3. **Diagnostic Mammograms:** Are performed to evaluate a breast complaint or abnormality detected by clinical breast examination or routine screening mammogram.

3.4. **Clinical Breast Examination (CBE):** Is an exam conducted by healthcare professional and involves inspection and palpation of all breast tissue including lymph nodes basins.

3.5. **Breast Awareness:** Women, 20 years and older, should be encouraged and educate on how to conduct breast self-exam to become aware of the feeling and shape of their breasts, and to report any changes immediately to their healthcare provider.

3.6. **Breast Assessment and Diagnosis:** 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.

3.7 **1st Degree Relatives:** Parents, siblings, and children

2nd Degree Relatives: Grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings

3rd Degree Relatives: Great-grandparents, great-aunts, great-uncles, great-grandchildren, and first cousins (refer to Appendix 3)

3.8. **Initial Screening:** First screening examination of individual women within the screening program, regardless of the organisational screening round in which women are screened.

3.9. **Subsequent Screening:** All screening examinations of individual women within the screening program following an initial screening examination, regardless of the organisational screening round in which women are screened. There are two types of subsequent screening examinations:

3.9.1. Subsequent screening at the regular screening interval, i.e. in accordance with the routine interval defined by the screening policy (SUBS-R).

3.9.2. Subsequent screening at irregular intervals, i.e. those who miss an invitation to routine screening and return in a subsequent organizational screening round (SUBS-IRR).

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 guideline and in accordance with Policies and Standards, Laws and Regulations of the 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, mammographers 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 15 working days, due to the limited number of same sex appropriately licensed professionals.

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 is no female radiographer, that the provider communicates this to the patient and refers/recommends that the patient seeks 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 this guideline. MOHAP may impose sanctions in relation to any breach of requirements under this guideline.

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 SERVICES SPECIFICATIONS

7.1. Breast Cancer Screening Service

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 referral 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.

7.1.6.2. Establish internal audit policies and procedures and conduct regular audits, monitoring and evaluation to demonstrate compliance with this guideline 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 in Appendix 5.

7.2.3. Comply with breast cancer screening and diagnosis care pathways, clinical quality indicators, and timelines for referral in accordance with Appendices 1, 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 this guideline 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 concerning radiologists and radiographers; to allocate 40% of annual recommended CME for breast imaging.

7.3.3. Conduct breast cancer risk assessment. Detailed history, such as that described in, Appendix 1, must be evaluated and completed, each time a woman 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.

7.3.4. Inform all individuals of the procedures and expected time frame 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. 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 in Appendix 1, including the following activities:

9.1.1. History & risk assessment

9.1.2 Screening mammogram

9.2. Periodical screening must be carried out as specified in breast cancer screening recommendations in 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. Screening mammography must involve two x-ray images for each breast; craniocaudal (CC) and mediolateral oblique (MLO).

9.5. Digital breast tomosynthesis is recommended as adjunct to screening mammogram. for women with high mammographic breast density and to be considered for women at increased risk in accordance with Appendix 2 (References: European Commission initiative on Breast Cancer ECIBC https://ecibc.jrc.ec.europa.eu/recommendations/ 23/3/2023.)

9.6. 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 time frames to receive results.

9.7. 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 (Appendices 1,2).

10.2. Women with abnormal mammogram, who require further assessment and diagnosis must be recalled/referred to Diagnostic Breast Assessment Unit within 15 working days of screening mammogram.

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

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; especially in non-palpable lesions.

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 in Appendix 6.

11.4. Screening mammograms that require additional assessment tools/imaging should be rated as BI-RADS® 0, 4 or 5 depending on initial evaluation and readers experience.

11.5. Only after full assessment, with additional imaging and/or comparison with prior mammogram; BI-RADS® 1, 2, 4 or 5 can be assigned.

11.6. One final mammogram report to be issued, A synoptic breast imaging report must be used by radiologists containing at least the following information:

- 11.6.1. Interpreting physicians' names
- 11.6.2. Date of examination
- 11.6.3. Patient identification
- 11.6.4. Reason for examination
- 11.6.5. Breast density
- 11.6.6. 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).
- 11.6.7. Final Assessment (BI-RADS®)
- 11.6.8. Detailed recommendations should be included in the report.

12. STANDARD 6: SCREENING OUTCOMES

12.1. All women must be informed about the results of screening within 3 weeks (15 working days) from date of screening mammogram.

12.2. Women with screening mammogram of Normal/Benign (BI-RADS® 1/2), are discharged to routine screening. Screening frequency will follow recommendation specified in Appendix 6.

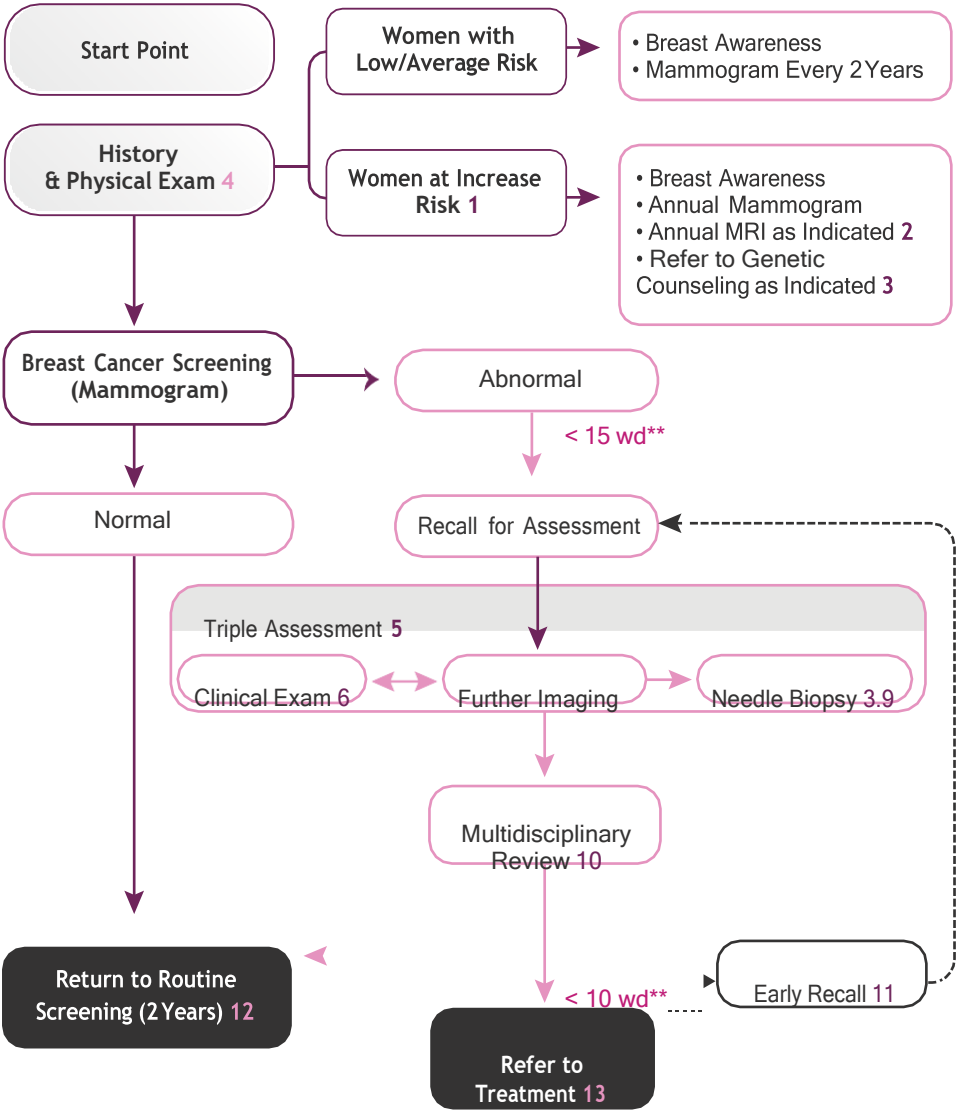
12.3. If a woman requires further assessment for abnormal screening mammogram (BI-RADS® 0) or clinical breast exam, referral must be to a Diagnostic Breast Assessment Unit within 5 days of screening mammogram result.

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/referring physician (at the screening or assessment facilities) to inform women regarding her screening and assessment results. Also, send feedback to referring physician at the primary healthcare clinic.

APPENDIX 1:
BREAST CANCER SCREENING 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 referral to Genetic Counselor is detailed in Table 2.

4. Women with the following criteria should be excluded from screening mammogram: Pregnant, breastfeeding, 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 1.

6. Clinical examination is mandatory for every woman with a confirmed mammographic or ultrasound abnormality that needs needle biopsy.

7. Further imaging usually involves 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 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.

REFERENCES

1. NCCN Clinical Practice Guidelines in Oncology, Breast Cancer Screening and Diagnosis. V.1.2022.

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 2:

NATIONAL BREAST CANCER SCREENING RECOMMENDATION

TABLE 1:

A SUMMARY OFTHE NATIONAL BREAST CANCER SCREENING RECOMMENDATION

Screening Category	Age	Screen Assessment Tools
Women at average risk	• 40-69 years • 70 years and above	• Mammogram every two years • Self-referred
Women at increased/high risk	Age of initiation is individualized according to risk (Table 2)	• Annual mammogram screening • Begin 10 years prior to the youngest affected family member but not prior to 25 years • Consider tomosynthesis • Annual MRI screening - as indicated not prior to 25 years • Referral to genetic counselor for strong familial/genetic predisposition

Adapted from:
NCCN Clinical Practice Guidelines in Oncology, Breast Cancer Screening and Diagnosis. V.1.2022

WOMEN AT INCREASED RISK/HIGH RISK

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

- Previous history of breast cancer.
- Previous treatment with chest radiation at age younger than 30.
- 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

Previous treatment with chest radiation at a young age (between age of 10-30)	Age < 25 years	• Screening begins 10 years after radiotherapy
	Age ≥ 25	• Annual Mammography screening (begin 10 years after radiotherapy but not prior to age of 30 years) • Consider tomosynthesis • Annual MRI screening (begin 10 years after radiotherapy but not prior to age of 25 years)
Strong family history or genetic predisposition**	Age < 25 years	• Referral to genetic risk assessment
	Age ≥ 25 years	•Annual Mammography screening 10 years before the youngest family member but 25 • Youngest family member but not prior to 25
Previous history of breast cancer		Surveillance Protocol • Annual Mammography Screening
Lobular carcinoma in situ (LCIS) or atypical ductal hyperplasia (ADH) or atypical lobular hyperplasia (ALH) on previous breast biopsy		Annual mammogram screening: • To begin at diagnosis of LCIS or ADH/ALH but not prior to age of 25 years • Consider Annual MRI Screening to begin at diagnosis of LCIS or ADH/ALH but not prior to age of 25 years

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

REFERENCE

NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Screening and Diagnosis. V.1.2022.

CRITERIA OF PERSONAL OR FAMILY HISTORY FOR A WOMAN TO BE CATEGORIZED AS HIGH RISK AND TO FOLLOW THE HIGH-RISK PROTOCOL

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

Personal History:

- History of breast cancer.
- History of ovarian cancer.
- Gene mutation: BRCA1, BRCA2, TP 53 or PTEN mutation.
- Previous treatment with chest radiation at age younger than 30.
- Lobular carcinoma in situ (LCIS) or atypical ductal hyperplasia (ADH) or atypical lobular hyperplasia (ALH), on previous breast biopsy.

Family History:

- One 1st degree female relative with
  - breast cancer diagnosed < 50 y
  - ovarian cancer at any age
  - Bilateral breast cancer where the first diagnosed < 50 y
- Two or more first-degree relatives, with breast cancer
- One of first-degree or second-degree relative diagnosed with breast cancer or ovarian cancer at any age
- One first-degree male relative with breast cancer at any age
- Having a first-degree relative with gene mutation (BRCA1, BRCA2, TP 53 or PTEN)

REFERENCES:

1. NICE, familial breast cancer. V.1.2022
2. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Screening and Diagnosis. V.1.2022

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.

CRITERIA TO MERIT REFERRAL FOR GENETIC RISK EVALUATION[2]

- Ovarian cancer
- Male breast cancer
- Personal history of three or more of the following (especially if diagnosed before age of 50 and can include multiple primary cancers in the same individual)
- Breast cancer
- Colon cancer
- Diffuse gastric cancer
- Pancreatic cancer
- Prostate cancer
- Thyroid cancer
- Brain tumors
- Endometrial cancer
- Adrenocortical carcinoma
- Melanoma
- Sarcoma
- Leukemia
- Kidney cancer
- Hamartomata's polyps of GI tract

AN INDIVIDUAL WITH A BREAST CANCER DIAGNOSIS MEETING ANY OF THE FOLLOWING:

- A known mutation in a cancer susceptibility gene within the family (BRCA1/2, TP 53 or PTEN).
- Early-age-onset breast cancer ≤ 45.
- Triple negative (ER-, PR-, HER-) breast cancer and age ≤ 60.
- Two breast cancer primaries in a single individual.
- Breast cancer at any age, and
    - > one close blood relatives with breast cancer 50 years, or
    - > one close blood relative (1st or 2nd or 3rd degree) with invasive ovarian cancer at any age, or
    - > two close blood relative with breast cancer, prostate cancer and/or pancreatic cancer at any age.
    - Personal history of pancreatic cancer at any age.

AN INDIVIDUAL WITH NO PERSONAL HISTORY OF CANCER BUT WITH:

- A close relative with any of the following:
  - > 2 breast cancer primaries in a single individual.
  - > 2 different individuals with breast cancer primaries from the same side of the family maternal or paternal with at least one diagnosed before 50.
  - Ovarian cancer
  - Male breast cancer
  - First-or second-degree relative with breast cancer ≤ 45 years
    - Family history of three or more of the following (especially if diagnosed before age of 50 and can include multiple primary cancers in the same individual).
    - Breast cancer
    - Colon cancer
    - Diffuse gastric cancer
    - Pancreatic cancer
    - Prostate cancer
    - Thyroid cancer
    - Brain tumors
    - Endometrial cancer
    - Adrenocortical carcinoma
    - Melanoma
    - Sarcoma
    - Leukemia
    - Kidney cancer
    - Hamartomata's polyps of GIT

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

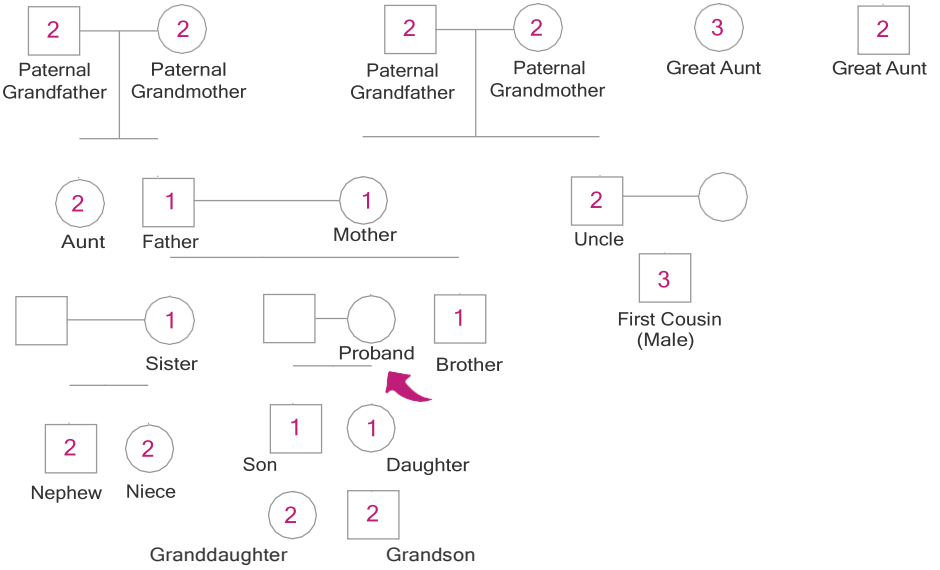
REFERENCES:

1. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Screening and Diagnosis. V.1.2022.

2. The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovary. V.1.2022.

APPENDIX 3:

PEDIGREE: FIRST, SECOND- AND THIRD-DEGREE RELATIVES OF PROBAND



1st degree relatives: Parents, siblings, and children.

2nd degree relatives: Grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings.

3rd degree relatives: Great-grandparents, great-aunts, great-uncles, great-grandchildren, and first cousins.

APPENDIX 4:
NATIONAL BREAST CANCER SCREENING CLINICAL PERFORMANCE INDICATORS

Clinical Quality Indicators	Definition	Calculation	Acceptable Level		Desirable Level
1. Participation rate	Percentage of women 40-74 years who have a screening mammogram (calculated biennially) as a proportion of the eligible population	Number of women screened at least once (per 2 years period)/ Target population (1st & 2nd year populations averaged from census/forecast)*100	> 70%		> 75%
2. Retention rate	The estimated percentage of women 40-74 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	< 7-10%
			At subsequent screening	Auditable outcome	> 5-7%
5. Early recall rate	Proportion of women undergoing a technical repeat screening examination	[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 screens detected /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 screens]*1,000	At initial screening		> 5 Per 1,000
			At subsequent screening		> 3 Per 1,000
8. In situ cancer detection rate	Number of ductal carcinoma in situ (DCIS) detected per 1,000 screens	[Number of DCIS detected /Number of screens]*1,000	At 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 tumor ≤ 10mm/Total number of invasive tumors]*100	Initial screening		≥ 20% 25%
			Subsequent screening		≥ 25% ≥ 30%
10. Invasive cancer detection rate	Number of women with diagnosis of invasive breast cancer after a normal screening within 12 & 24 months of 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)		< per 10,000
			Within the second year (12-23 months)		12 per 10,000
11. Time interval	- Screening mammography & result within 15 working days (wd)			95%	> 95%
	- Screening & offered assessment within 5 working days (wd)			90%	> 90%
	- Assessment & issuing of results within 5 working days (wd)			90%	> 90%
	- Non-operative (needle) biopsy & result within 5 working days (wd)			> 90%	100%

**Refer to reference 2 for calculation.

REFERENCES:

1. European guidelines for quality assurance in breast cancer screening and diagnosis. Update3.2023.

2. Public Health Agency of Canada. Report from the Evaluation Indicators Working Group. Guidelines for Monitoring Breast Screening Program Performance. Update. 2022.

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 MOHAP.

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 manufacturer's 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 1000 screening mammograms 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, assessment processes, referrals and outcomes.

6.2. Maintain record 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 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. Physic-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	BI-RADS® Score	Description	Definition
3340F	0	Incomplete. Need Additional Imaging	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, continue biannual screening mammography (for women 40 & older).
3342F	2	Benign	Benign (non-cancerous) finding, same statistics & plan of follow-up as level 1. This category is for cases that have a finding that is characteristically benign such as cyst of fibro adenoma.
3343F	3	Probably Benign	Probably benign finding, there is less than 2% chance if cancer, additional examinations done to clear the situation at once.
3344F	4	Suspicious 4A AB 4C	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. 4A: Finding with a low suspicion of being cancer (> 2% & ≤ 10%). 4B: Finding with an intermediate suspicion of being cancer (> 10% & ≤ 50%). 4C: Finding of moderate concern of being cancer but not as high category 5 (> 50% & < 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 category 4 & 5, the percentage of category 5 abnormalities that will be cancer may vary between 75% & 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.

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