دائـــرة الـصـحـــة
DEPARTMENT OF HEALTH

Document Title:	Department of Health Standard for the Cervical Cancer Screening Program		
Document Ref. Number:	DOH/CCSC/SD/1.0	**Version:**	1.0
Approval Date:	08 May 2018	**Effective Date:**	13 May 2018
Last Reviewed:	August 2012	**Next Review:**	August 2021
Document Owner:	Cancer Prevention and Control Section, NCD, Public Health Division		
Applies to:	All Licensed Healthcare Providers in the Emirate of Abu Dhabi participating in DOH's Cervical Cancer Screening Program		
Classification:	⦿ Public		

1. Purpose

1.1 This standard mandates the clinical service specifications and data reporting for DOH's Cervical Cancer Screening Program in the Emirate of Abu Dhabi;

1.2 It specifies the clinical care pathway and minimum service standards and specifications to ensure that women screened for cervical cancer receive quality and safe care and timely referral for diagnosis and/or treatment.

2. Scope

2.2. This Standard apply to all Healthcare Providers (Facilities, laboratories, Professionals) licensed by DOH in the Emirate of Abu Dhabi who are participating in DOH's Cervical Cancer Screening Program.

2.3. Participating Healthcare Providers are to provide the following services as applicable based on their license category:

2.3.1. Risk assessment and physical examination;

2.3.2. Specimen collection and preparation of adequate cervical smear;

2.3.3. Handling and reporting of cervical smears; and

2.3.4. Follow up and referral.

2.4. Follow reporting terminologies defined by DOH as per appendix 1.

3. General Duties of the Health care Providers

All licensed and eligible healthcare providers participating in DOH's Cervical Cancer Screening Program must:

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

3.2. Submit data to DOH via e-Claims in accordance with the DOH Reporting of Health Statistics Policy and as set out in the DOH Data Standards and Procedures (found online at www.haad.ae/datadictionary);
3.3. Comply with relevant DOH Policies and Standards with special attention to:
3.3.1. Policies and standards on 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;
3.3.2. Policies and standards on managing patient medical records including developing effective recording systems, maintaining patient records, maintaining confidentiality, privacy and security of patient information; and educating patients on services provided and satisfying the requirements of patient informed consent and patient rights and responsibilities charter;
3.3.3. DOH Data Standards and Procedures.
3.4. Comply with DOH's requests to inspect and audit records and cooperate with DOH authorized auditors as required by DOH; and
3.5. Comply with requirements for information technology (IT) and data management including sharing of screening/diagnosis and where applicable, pathology results, electronic patient records and disease management systems;

4. Enforcement and Sanctions

4.1 Healthcare providers, professionals and laboratories participating in the DOH's Cancer Screening Program must comply with the terms and requirements of this Standard.
4.2 Health care providers must comply with the DOH Standard Provider Contract.
4.3 DOH may impose sanctions in relation to any breach of requirements under this standard in accordance with the [DOH *Policy on Inspections, Complaints, Appeals and Sanctions*].

5. Payment Mechanism

Eligibility for reimbursement under the Health Insurance scheme is as follows:
5.1. For Thiqa holders, reimbursement must be consistent with the DOH Standard for Thiqa Preventive List of Interventions available at www.haad.ae; and
5.2. For non-Thiqa holders, payment must be consistent with the individual's health insurance product/plan.

6. Cervical Cancer Screening Program- Specifications for Facilities:

Facilities participating in DOH's Cervical Cancer Screening Program must:
6.1. Be Licensed by the DOH;
6.2. Fulfill the eligibility criteria for a cervical cancer screening Program participating facilities in accordance with Appendix 2 and approved by DOH as eligible cervical cancer screening program facilities;
6.3. Comply with DOH cervical cancer screening care pathways, clinical quality indicators and time lines for referral in accordance with Appendices 3, 4 and 5 respectively;
6.4. Assign a screening program coordinator responsible for submitting data on screening visits and outcomes to DOH, who will fulfill the responsibilities in accordance with Appendix 6;
6.5. Collect and submit data on screening visits and outcomes within 3 weeks of the screening date, to DOH through the Electronic Cancer Screening Notification (e-*cancer notification*) that can be accessed at: [https://www.haad.ae/haad/tabid/1084/Default.aspx];
6.6. Report all screen-detected cancer cases to DOH, through Cancer Case Notification Form, of the e-*cancer notification*, specified in 4.2;

6.7. Maintain records for screening tests and outcomes;
6.8. Establish internal audit procedures to demonstrate compliance with this standard and other associated regulatory policies and standards;
6.9. Ensure availability of evidence of compliance with the Cervical Cancer Screening Program Clinical Quality indicators specified in Appendix 4 including:
  6.9.1. Collection and preparation of adequate cervical smear;
  6.9.2. Handling and transporting of specimens to DOH Licensed clinical laboratories;
  6.9.3. Have an approved protocol for referral of women with abnormal results or physical examination to a diagnostic or treatment centers.

7. Cervical Cancer Screening Program- Specifications for Laboratories:

Laboratories participating in DOH Cervical Cancer Screening Program must:

7.1. Be Licensed by the DOH;
7.2. Comply with the applicable elements of the Screening Program and other DOH clinical quality indicators in accordance with Appendix 4 and ensure availability of evidence of compliance with these indicators such as laboratory records required for accreditation purposes;
7.3. Comply with the DOH Clinical Laboratory Standards;
7.4. Attain accreditation by an international body recognized by the DOH; such as, CAP- ISO 15189(2007), or JCI /Lab;
7.5. Participate in an international external proficiency test by all personnel involved in screening and reporting Pap test;
7.6. Establish internal audit procedures to demonstrate compliance with this standard and with other associated regulatory policies and standards;
7.7. Develop, implement, and monitor policies and standard operating procedures for management of smears in accordance with DOH Clinical Laboratory standards.

8. Cervical Cancer Screening Program- Specifications for Healthcare professionals:

Health professionals participating in the DOH's Cervical Cancer Screening Program must be:

8.1. Licensed by the DOH;
8.2. Comply with the clinical standards detailed in this Standard to provide the most appropriate care, taking responsibility for deciding the best care options for managing cervical cancer cases;
8.3. Provide women with culturally and socially relevant education on women's' health and with information (oral and written) regarding the screening benefits and limitations of cervical screening, potential outcomes and next steps that may be required for care management.
8.4. Participate in continuing medical education (CME) in accordance with DOH requirements;

9. Cervical Cancer Screening Program- Screening tests and frequency

9.1. Screening tests:

9.1.1. Papanicolaou test, (also called Pap test). Liquid based cytology (LBC) is the accepted standard method for Pap test specimen collection.
9.1.2. HPV test, as co-testing, for women age of 30 years and above. Only FDA HPV approved tests are the accepted test for screening

9.2. Frequency of screening:

The frequency for repeat screening for average risk, symptom free women is:

9.2.1. Every three years for women aged 25-29 years.

9.2.3. Every 5 years for women 30-65 years.
9.2.4. Annually for women who are immune-compromised due to disease or medication.

10. Cervical Cancer Screening Program-Service Specifications:

10.1. Eligibility for Screening Criteria

10.1.1. All sexually active women (past or present), symptom free, aged 25- 65 years residing in the Emirate of Abu Dhabi, except where exclusion criteria for screening apply.

10.1.2. Women are excluded from screening if:

10.1.2.1. They have received a total hysterectomy for benign indications; or

10.1.2.2. They are over 65 years, (if the last three previous smears were negative).

10.1.3. Women who have had subtotal hysterectomy (preserving the cervix) or hysterectomy due to cervical cancer or precancerous condition should continue to have cervical screening; and

10.1.4. Screening recommendations remain the same regardless of whether or not they have received the HPV vaccination.

10.2. Recruitment to screening

Recruitment of eligible women for screening can be made through:

10.2.1. Targeted invitation from the eligible screening facilities.

10.2.2. Opportunistic by:

10.2.2.1. Approaching women who are enrolled in other existing screening programs; e.g. breast cancer);

10.2.2.2. Physician consultation for related or unrelated reason; or

10.2.2.3. As an outcome of a health promotion campaign.

10.3 Risk assessment and physical examination

10.3.1 Women must receive adequate information regarding the screening, Pap test procedure and expected outcomes and timeframe to receive results.

10.3.1 Detailed history must be taken to assess risk and frequency of repeating screening, including at least:

10.3.2 Menstrual status (LMP, hysterectomy, pregnant, postpartum, use of contraceptive or hormone therapy);

10.3.3 Previous screening, results of screening, (negative, abnormal or positive) and any previous treatment, (biopsy, chemotherapy, radiotherapy or surgery;

10.3.4 Immune-compromised status due to diseases (including HIV) or medication;

10.3.5 Full clinical examination must be performed including visual inspection of the cervix.

10.4 Specimen collection and preparation of adequate Pap test

10.4.1 The following categories of DOH Licensed healthcare physicians are eligible to perform a Pap test:

10.4.2 Licensed gynecologists and obstetricians; and

10.4.3 Physicians already privileged to do so by their institution.

10.4.4 Eligible Physicians must:

10.4.4.1 Complete the required form with relevant clinical information in accordance with Article 9. 1.2;

10.4.4.2 Collect and manage specimens in accordance with the facility internal policies and procedures and DOH Standards.

10.4.5 Smear taking must be avoided in the following circumstances and women must be advised when to return for a pap test:

10.4.5.1 Menstruation, blood loss, breakthrough bleeding;

10.4.5.2 Vaginal inflammation/ infection;

10.4.5.3 Pregnancy (Unless a previous smear was abnormal and in the interim the woman becomes pregnant, then the follow-up smear must not be delayed).

10.5 Cytology smear handling and reporting

Clinical Laboratories handling and reporting of cytology specimens and cytology smears testing must:

10.5.1 Manage cervical cytology smears and perform the cytopathology testing as indicated and in accordance with the specifications of the DOH Clinical Laboratory Standards, including without limitation "Processes for Laboratory Specialties" and "Cytopathology of the HAAD Clinical Laboratory Standards".

10.5.2 Make final reports of cervical cytology smear using the Bethesda System (The Bethesda System for Reporting Cervical Cytology).

10.5.3 The report must be verified by a pathologist for all abnormal and reactive cases, while negative cases can be verified by licensed cytotechnologist using standard synoptic reporting format and containing minimum elements consistent with those of internationally Reputable accrediting bodies.

10.5.4 The report must minimally include the following details:

10.5.4.1 Patient's name;

10.5.4.2 Age/date of birth;

10.5.4.3 Menstrual status (LMP, hysterectomy, pregnant, postpartum, hormone therapy);

10.5.4.4 Relevant clinical information such as if the patient has previously had a positive test or had other types of cancer, etc.

10.5.4.5 Specimen Description (source).

10.5.5 The reporting pathologist is the professional responsible for confirming the positive cancer results.

10.5.6 Reports for Specimen adequacy and Cytological findings must be returned to the referring physician at the screening center within 8 working days of receiving the specimen.

10.5.7 The DOH may, at its discretion, conduct third-party independent quality assurance testing of laboratories providing cervical smear laboratory test service. Where it does so, providers must comply with DOH's direction and cooperate with the DOH appointed party.

10.6 Screening outcomes and referrals

10.6.1 All women must be notified in writing of the result of their screening tests.

10.6.2 It is the responsibility of the physician at the screening facility to notify and provide a written report to a woman regarding her screening results within 21 days (3 weeks) of the date of specimen taken.

10.6.3 If the test outcome is normal, the woman is discharged to routine screening as per frequency mentioned in this Standard.

10.6.4 If the test outcome is unsatisfactory, it must be repeated within 6-12 weeks, treating infection, if present, as indicated.

10.6.5 If the Pap test outcome is abnormal (cytology showed intraepithelial lesions or

malignancy and/or HPV positive), the woman's test should be managed according to Appendix 3.

10.6.6 If a suspicious visible abnormality is identified during visualization of the cervix, the woman must be referred immediately to a Gynecologist oncologist without receipt of her test results.

10.6.7 If a woman requires referral for colposcopy or treatment, the physician must make the referral to an appropriately DOH licensed healthcare professional, privileged to provide the specialty/oncology service. Timelines for referral should be in compliance with Appendix 5

Appendix 1

Definitions

Term	Definition
The Bethesda system (TBS)	is a system for **reporting cervical** or vaginal **cytological** diagnoses, used for **reporting** Pap smear results., The name comes from the location (**Bethesda**, Maryland) of the conference that established the system of reporting
HPV	Human papilloma virus
HPV co-testing	Is a test is done along with the pap test in women aged 30 years and above, to screen for a high-risk HPV viral types. Only FDA approved test are accepted
ASC-US	Atypical squamous cells of undetermined significance. It is a finding of abnormal cells in the tissue that lines the outer part of the cervix
ASC-H	Suspicious for high grade dysplasia
LGSIL or LSIL	Low-grade squamous intraepithelial lesion
HGSIL or HSIL	High-grade squamous intraepithelial lesion
AIS	Adenocarcinoma in situ
AGC	Atypical Glandular Cells

Appendix 2

Eligibility Criteria for a Facility to Participate in DOH's Cervical Cancer Screening Program

1. General

In addition, to the requirements of this standard the healthcare facility must fulfill the following criteria:

1.1 Plan capacity to match the demand for screening and the facility capacity.

1.2 Allocate appointment slots for cervical cancer screening linked to the DOH online booking system (when available).

1.3 Have available adequate equipment to provide safe and quality screening;

1.3.1 Send cervical cytology smears only to DOH licensed Laboratories that meet the requirements of this standard; and

1.3.2 Ensure patient privacy, comfort and confidentiality at all times.

2. Human Resources

2.1 The core team must include at least:

2.1.1 A program coordinator;

2.1.2 A licensed Physician, Gynecologist or Obstetrician, physician privileged to deliver cervical screening care and services;

2.1.3 A licensed nurse for each clinic with a minimum of 2 years of experience in Gynecology or obstetric nursing.

2.2 Training of licensed health professionals must be delivered using CME/CPD courses accredited by DOH CME department at http://www.haad.ae/cme/ including

2.2.1 For physicians; training for Pap smear taking in accordance with international evidence based training standards and guidelines.

3. Registration as DOH - Screening facilities

Facilities meeting DOH cervical cancer screening requirements should follow DOH facilities' registration process:

3.1. Establish communication with cancer control team as per DOH (HAAD previously) circular

3.2. Fill service provision form

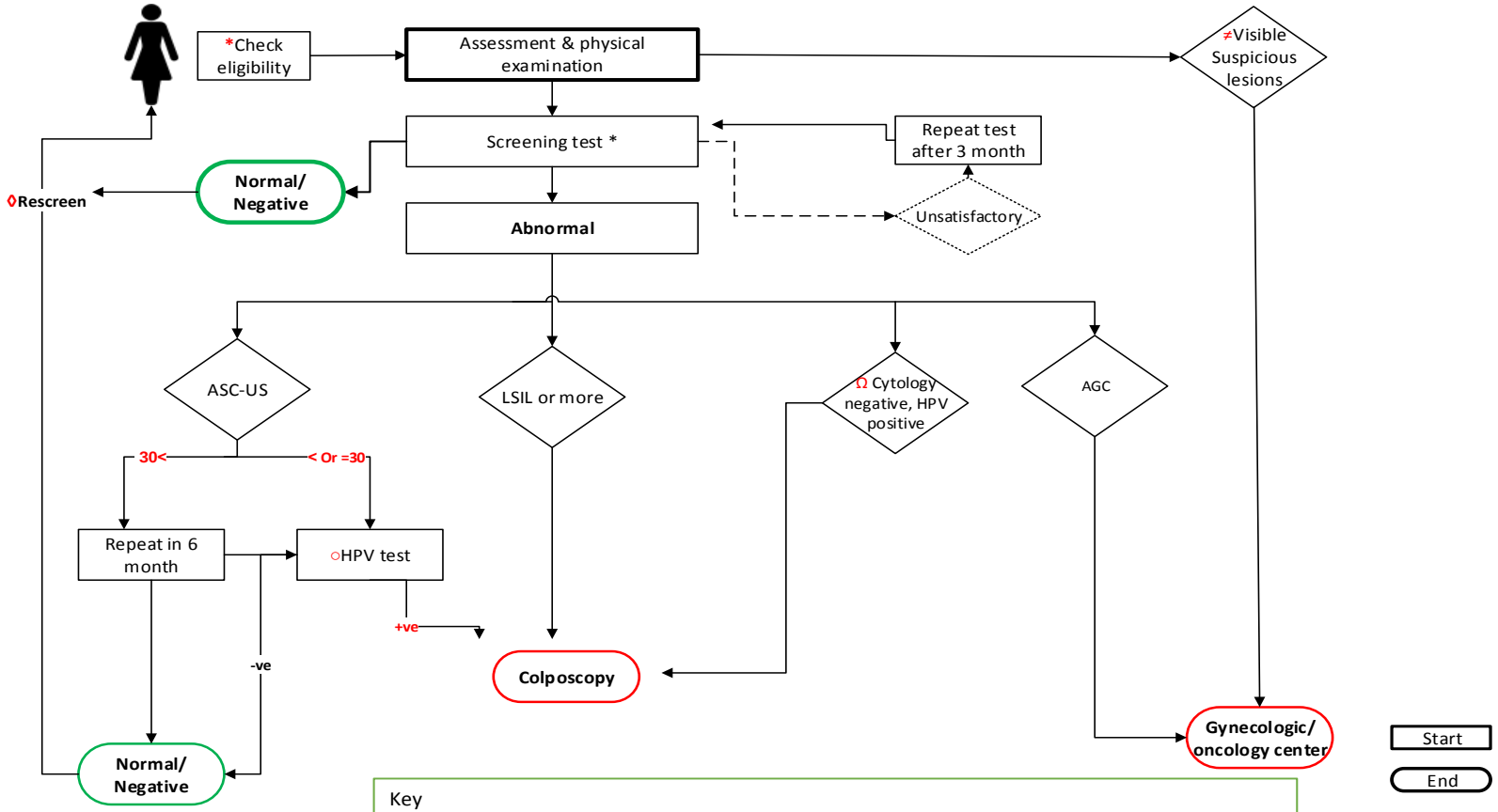
3.3. Return filled form back to cancer control team

3.4. 4 Wait until receive confirmation from cancer control team upon DAMAN approval and starting date

3.5. Receive user name and password for data reporting after orientation secession with cancer team

3.6. Commence screening and reporting of screening data to DOH

Appendix 3: Cervical cancer screening care-pathway



Key

*Screen as per screening guidelines women 25-29 years with cytology, women 30—69 years with cytology and HPV as co-testing

◊Rescreening interval for 25- 29 every 3 years, for 30-65 every 5 years

○HPV ttest is done as triage for women ≥25 and co-testing for women ≥30

≠Women with suspicious visible lesions should be refer immediately to Gyna/oncologists

ΩAll negative cytology with positive HPV test refer to colposcopy specialized centers

Appendix 4

Cervical Cancer Screening Program -Clinical Quality Indicators

Quality Indicator		Acceptable level	Desirable level
Coverage			
Retention Rate	Percentage of eligible women re-screened within three years after a negative Pap test in a 12-month period.	40%	50%
Cytology Performance Indicators			
Specimen Adequacy Unsatisfactory proportion	Percentage of Pap tests that are reported as unsatisfactory in a 12 month period	4.7%	1.3
Screening test results Negative	Percentage of women by their most severe Pap test result in a 12-month period.	90%	97%
System Capacity Indicators			
Cytology Turn Around Time 2 weeks	The average time from the date the specimen is taken to the date the finalized report is issued over a 12-month period.	>80%	>90%
Time to Colposcopy	Percentage of women with a positive Pap test (HSIL+/ASC-H) who had follow-up colposcopy within 3, 6, 9 and 12 months subsequent to the index Pap test.	80%	88%
Follow – up			
Biopsy Rate	Percentage of women with a positive screening test result (HSIL+/ASC-H) who received a histological diagnosis in a 12 month period	To be determined	11%

Cytology-Histology Agreement	Proportion of positive Pap tests with histological work-up found to have a pre-cancerous lesion or invasive cervical cancer in a 12 month period A.	To be determined	
Outcome Indicators			
Pre-Cancer Detection Rate	Number of pre-cancerous lesions detected per 1,000 women who had a Pap test in a 12-month period.	To be determined	7.1 per 1000

Appendix 5

Cervical Cancer Screening Program - Timeframes for Appointments

Cytological pattern	Priority	Appointment
HSIL or greater	Urgent	1-2 weeks
LSIL	soon	2-4 weeks
ASC-US/ ASC-H	Routine	4-8 weeks

Appendix 6

Responsibilities of the Facility Cancer Screening Program Coordinator

The healthcare facility cervical cancer screening program coordinator must:

1.1. Be a licensed healthcare professional;

1.2. Have comprehensive and high quality knowledge in cervical cancer as a disease and its prevention;

1.3. Be responsible for:

1.3.1. Recruitment of eligible women;

1.3.2. Follow up and tracking of screening results to ensure the timeliness and completeness of follow-up;

1.3.3. Assessing relationships between planned care and approved protocols for care;

1.3.4. Assessing women's' needs for support to remove barriers to screening and follow-up;

1.3.5. Developing and promoting recall systems that include reminders to patients as appropriate; and

1.3.6. Submitting data on screening visit and outcomes to DOH via the [cancer screening e-notification system].

References:

NHS Cervical Screening Program
https://www.bsccp.org.uk/assets/file/uploads/resources/NHSCSP_20_Colposcopy_and_Programme_Management_(3rd_Edition)_(2).pdf

The American Cancer Society Guidelines for the Prevention and Early Detection of Cervical Cancer
https://www.cancer.org/cancer/cervical-cancer/prevention-and-early-detection/cervical-cancer-screening-guidelines.html

Performance Monitoring for cervical Cancer Screening Programs in Canada
http://www.phac-aspc.gc.ca/cd-mc/cancer/pmccspc-srpdccuc/pdf/cervical-eng.pdf

Ontario Cervical Screening Guidelines
https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=13104

NCCN cervical cancer screening guidelines
https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=13104

ACOG-cervical cancer screening guidelines
https://www.acog.org/Patients/FAQs/Cervical-Cancer-Screening

Implementation of cancer screening in the European Union (2017)
https://ec.europa.eu/health/sites/health/files/major_chronic_diseases/docs/2017_cancerscreening_2ndreportimplementation_en.pdf
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2826099/

European guidelines for quality assurance in cervical cancer screening
http://screening.iarc.fr/doc/ND7007117ENC_002.pdf