Ministry of Health of the
Republic of Moldova

Capacity Assessment and Recommendations

for a

National Cervical Cancer Screening Program

in the

Republic of Moldova

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Abbreviations:

AMF	Asociatia Medicilor de Familie / Association of Family Physicians
AMT	Asociatia Medicala Teritoriala / Territorial Medical Association
BSCCP	British Society for Colposcopy & Cervical Pathology
CBE	Clinical Breast Examination
CDR	Centrul Diagnostic Republican / Republican Diagnostic Centre
CIN	Cervical Intraepithelial Neoplasia
CME	Continuing Medical Education
CMF	Centrul Medicilor de Familie / Family Medicine Center
CNAM	Compania Nationala de Asigurari in Medicina / National Health Insurance Company
CNMF	Colegiul National de Medicina si Farmacie / National College of Medicine and Pharmacy
CNMS	Centrul National de Management in Sanatate / National Center for Health Management
CNSP	Centrul National de Sanatate Publica / National Centre for Public Health
CNSRGM	Centrul National de Sanatate a Reproducerii si Genetica Medicala / National Centre for Reproductive Health & Medical Genetics
CQI	Continuous Quality Improvement
CS	Centrul de Sanatate / Health Centre
CSD	Cervical Screening Director
DoM	Date of Manufacture
ECCA	European Cervical Cancer Association / Asociatia Europeana pentru Prevenirea Cancerul de Col Uterin
FIGO	International Federation of Obstetrics and Gynaecology
FTE	Full Time Equivalent (Full Time Salaried Position)
HPV	Human Papillomavirus / Virusul Papiloma Uman
IARC	International Agency for Research on Cancer
IO	Institutul Oncologic / Institute of Oncology
MS	Ministerul Sanatatii / Ministry of Health
MHO	Ordinul Ministerului Sanatatii / Ministry of Health Order
OMF	Oficiul Medicilor de Familie / Family Physician Office
OS	Oficiu de Sanatate / Health Office
PHC	Primary Health Care
QA	Quality Assurance
RCT	Randomised Controlled Trial
RM	Republica Moldova / Republic of Moldova
SCO	Screening Coordination Office
SSO	Societatea Stiintifico-practica a Oncologilor din Republica Moldova / Scientific Society of Oncologists in Moldova
SOP	Standard Operating Procedure
UNFPA	United Nations Population Fund
USMF	Universitatea de Stat de Medicina si Farmacie “Nicolae Testemitanu”/ State University of Medicine and Pharmacy “Nicolae Testemitanu”
WE	Western Europe
WHO	World Health Organisation

1. Introduction

This study was undertaken to analyse the current situation with cervical cancer prevention in the Republic of Moldova (RM) and prepare recommendations for the implementation of a national cervical cancer screening program in the country.

The implementation of new health programs is challenging because health systems are complex adaptive networks composed of multiple interconnected components and with each component having multiple stakeholders. As the cooperation of these stakeholders will be essential to delivering the new program, the implementation process must do more than simply account for the medical or scientific aspects and instead use a holistic approach that accounts for the interests, motivations and alliances of all these stakeholders, and actively involves them in all aspects of the project.[1,2,3]

The implementation of cancer screening programs is particularly challenging because they require the coordinated interaction of multiple health services. Further, the optimal structure for these programs requires the screening tests to be delivered through facilities that are accessible and familiar to the screening population, with subsequent referral to secondary or tertiary care based on the screening test results. In RM, this means that screening should be delivered through the primary health care (PHC) facilities that constitute the largest health network in the country. Therefore, the number of stakeholders involved is very large and complex, as is the range of interests, motivations and alliances that must be accounted for. However, failure to account for this complexity will greatly reduce the chances of achieving the broad base of support that is required for the successful implementation and operation of the screening program.

Of direct relevance to the introduction of a complex health program, Atun and colleagues[4] evaluated primary health care reform in Bosnia and Herzegovina and identified a number of elements that enhanced the adoption and diffusion of these reforms:

- Regular interaction and communication between the innovators and adopters,
- Characterising the interests of the adopters and aligning program benefits with their interests,
- Characterising the interests of the public and aligning program benefits with their interests,
- Ensuring adopters fully understand the benefits that will accrue to all stakeholders,
- Allowing scope for reforms to be adapted to the local context (this was described as “critical” to the diffusion of reforms as it improved adopter ownership and reduced resistance.

These elements directly address the social and political dimensions of the health system by ensuring all stakeholders are fully involved in the design, planning and implementation of the project so:

- The stakeholders’ collective knowledge of the realities of health service delivery in the country are fully accounted for so the new program as well as the implementation process are properly adapted to the local context,
- The stakeholders who must be involved in the implementation and operation of the new program have ownership and an interest in its success,
- Local champions can be identified and provided with support to advocate for proper resourcing of program implementation and operation.

Following this approach, the key steps undertaken in this project were:

- A systematic review of the literature relating to cervical cancer prevention in RM,
- A review of the laws, regulations, national strategy documents, clinical guidelines and protocols relating to the implementation or operation of a cervical screening program,
- Identification and recruitment of all stakeholders with a role to play in the design, planning, implementation or operation of the cervical screening program, and then work with them to:
  - Collect and analyse data about the organisation and capacity of all required services,
  - Estimate the health service capacities needed to operate a national cervical screening program,
  - Prepare a 5-year plan to develop the capacity of the required services.

2. Methods

A systematic review of the literature was conducted to identify all published data on the current status of cervical cancer and its prevention in RM. Given the limited amount of data, broad search terms were used ('cervical cancer, Moldova', 'cancer screening, Moldova' and 'gynecol* oncology, Moldova' in English, Romanian and Russian) to search MEDLINE, the Cochrane Collection and Google. The electronic search was complemented by a manual review of relevant journals: Info-Med; Medical Courier; Bulletin of Perinatology, Public Health, Economics and Management in Medicine; Scientific Annals of the State University of Medicine and Pharmacy "N. Testemitanu"; Bulletin of the Academy of Sciences; Medical Sciences; Akademos. In addition to the literature review, the following sources were consulted for relevant data: the Statistical Yearbook of the Republic of Moldova; the National Center for Health Management; the World Health Organization; the WHO/ICO HPV Information Centre. This process identified 321 articles and reports of potential interest. The abstracts/ introductions/tables of contents for all were evaluated for relevance and 42 were selected for detailed review with relevant data extracted and summarised in this report.

All national strategy documents relating to the development of the health sector were obtained and evaluated to ensure the implementation of a national cervical screening program is consistent with government policy and identify opportunities for coordinating screening program implementation with other objectives to increase benefits for the overall health system.

An extensive analysis was undertaken to identify all organisations and people with a role to play in the design, planning, implementation or operation of the cervical screening program. Individual meetings were held with all stakeholders to introduce the project and obtain their recommendations for the design or implementation of the program, which were used to revise the project proposal. Subsequently, all stakeholders were invited to the 1st Stakeholder Meeting that was held in the Ministry of Health (MoH) on 23 March 2012 to present the revised project proposal, outline the steps that would be required and obtain further feedback from this group to refine the process.

Primary data on relevant health services were collected using 2 questionnaires:

- The Situation Analysis (SA): used to collect information about factors (policies, legislation, guidelines, recommendations, etc.) that will influence the delivery of these health services,
- The Capacity Assessment (CA): used to collect quantitative data on staff, facilities and equipment for these health services.

The questionnaires were distributed to all stakeholders, data were collected from June to November 2012, and data triangulation (stakeholder-stakeholder and stakeholder-literature) was used to identify discrepancies for further investigation.

The 2nd Stakeholder Meeting was held in the MoH on 11 December 2012 to review the results of the SA/CA and resolve inconsistencies or gaps in the dataset, with further work undertaken from January to September 2013 to complete and verify the data set. During this period, 2 people were selected from among the stakeholders to participate in training exchanges with the Irish organised cervical screening program 'CervicalCheck' to develop their knowledge of a) the organisation and management of an organised cervical screening program, and b) the organisation and management of colposcopy services within an organised cervical screening program.

A draft report containing the data summaries and preliminary analyses was prepared and circulated to all stakeholders at the beginning of November 2013 and the 3rd Stakeholder Meeting was held in the MoH on 21 November 2013. At this meeting, the stakeholders collectively reviewed and confirmed the outcomes of the SA/CA, and then divided into groups focused on key elements of the cervical screening program (administration; data collection and analysis; primary health care; pathology and colposcopy) to define the elements of a capacity building program to strengthen these services. The recommendations of the stakeholders are presented in Section 7 and the actions required to achieve them are presented in Section 8.

3. Cancer Screening

3.1 Principles of cancer screening

The objective of cancer screening is to identify the people within an asymptomatic target population who have pre-cancerous lesions that can be removed to prevent the cancers from developing or early stage cancers so their treatment can be started earlier to reduce morbidity and mortality. Therefore, cancer screening is a complex multistep process that includes:

- Identification and characterisation of the screening population,
- Education and promotion among the screening population to raise awareness about the benefits of screening and increase participation,
- Recruitment to screening,
- Counselling each individual, evaluating their personal risk and undertaking the screening test,
- Processing of the screening test,
- Using the screening test result together with the individual's personal history and clinical profile to plan subsequent care:
  - Routine screening recall,
  - Intensive surveillance,
  - Referral to follow-up.
- If referred for follow-up, re-assessment of the individual's risk based on the follow-up results together with the screening test results, personal history and clinical profile to plan subsequent care:
  - Intense surveillance,
  - Referral for local treatment,
  - Referral for cancer treatment.

When considering the implementation of cancer screening programs, a common error is to focus too much on the screening test while neglecting the other parts of the screening process. However, screening programs will only provide substantial reductions in cancer incidence and/or mortality if a large proportion (≥75%) of the target population is regularly screened, all the required services are of high quality and all of the services are efficiently coordinated.[5,6] Until these 3 criteria are achieved, the choice of screening test is largely irrelevant.

While cancer screening programs can provide substantial benefits, it is essential to recognise they can also produce a wide range of harms for the people being screened.[7] These harms are rare in well-organised programs but screening is applied to populations so the absolute number of people affected can still be very large. The harms inherent in breast and cervical screening programs are summarised in Table 1 below.

Table 1: Harms inherent in breast & cervical screening programs	
1	False negative screening test results that provide false reassurance and lead to delays in diagnosis and the initiation of treatment
2	False positive screening test results leading to unnecessary stress, anxiety and invasive diagnostic procedures that carry a high risk of complications
3	Over-diagnosis through the identification of disease with no malignant potential or that would not become clinically relevant during the individual's lifetime
4	Over-treatment through the treatment of disease with no malignant potential or that would not become clinically relevant during the individual's lifetime
5	Substantial unnecessary costs arising from all of the above, which take resources away from services that could otherwise provide greater benefits for the population
6	Adverse pregnancy complications such as premature membrane rupture and premature delivery in women who have been treated for cervical epithelial neoplasia (CIN)
7	Radiation-induced carcinogenesis following mammography, particularly in situations where old and/or poorly maintained mammography machines are used

3.2 Opportunistic vs organized screening

3.2.1 Opportunistic screening

Opportunistic screening occurs when people are screened at their own request or while attending a doctor for other reasons, but there is no system in place to recruit people, monitor their attendance and follow-up, and ensure all the component services are of the highest possible quality.

Opportunistic screening can produce substantial disease reductions but these are seen only in high-resource countries where a large proportion of the target population regularly interacts with the health system, there are established mechanisms for patient referral and follow-up, and the health services are all of high quality. However, opportunistic screening has also been shown to screen women from higher socioeconomic groups too frequently although they are at lower risk of developing cancer while under-screening women from lower socioeconomic groups, minorities, etc. who are at higher risk. This is important because every screening test has an optimal screening age-range and interval that has been set to maximise the benefits and minimise the harms. Therefore, screening too frequently provides little additional protection but does increase the harms, while under-screening obviously provides less protection. As a result, opportunistic screening produces sub-optimal disease reductions, perpetuates or increases health inequalities and wastes health care resources.

3.2.2 Organised screening

In contrast to opportunistic screening, organised screening programs are specifically designed to maximise the benefits while minimising the harms for the population being screened. The principal element of an organised screening program is a central administration with the budget and authority to ensure:

- High and equitable coverage of the target population,
- Adherence to the recommended screening age-range and interval,
- Optimal quality and coordination of all the services involved in the screening program from recruitment to the follow-up and treatment of people having a positive screening test result.

As a result, organised cancer screening programs provide the optimal balance between the benefits and harms, ensure the benefits are equitably delivered across all social strata and deliver the most cost-effective disease reductions. For these reasons, the European Guidelines for Quality Assurance in Cervical Screening (European Guidelines) state that cervical screening should only be provided through organised programs. The fundamental elements of an organised cancer-screening program are summarised in Table 2 below.[5,6]

Table 2: Fundamental elements of a cancer screening program	
1	A stable budget sufficient for the on-going costs of all of the services required to deliver the program
2	A central administration with responsibility for screening policy & for coordinating of all elements in the screening process including recruitment, recall, follow-up, monitoring & continuous quality improvement (CQI)
3	Access to a current database of the target population for recruitment, monitoring & CQI
4	A central screening registry or linked registries to record cervical cytology, colposcopy and histology that can be used for call, recall, tracking of screen positives & CQI
5	Access to a cancer registry for CQI & program audit
6	Evidence-based training standards, clinical guidelines & performance indicators
7	An comprehensive CQI policy covering the entire screening process from initial recruitment to the follow-up & management of people with cervical disease
8	Education programs for the general public & for healthcare professionals
9	Mechanisms to identify & recruit disadvantaged groups within the target population

These elements are all essential to the effective operation of cancer screening programs. Therefore, the suboptimal performance of any one or more of them will reduce both the effectiveness and the efficiency of the program, even to the point where it has no measurable effect on cancer rates but still consumes substantial resources and produces a range of harms.

4. Cervical Cancer

4.1 Background

Globally, cervical cancer is the 3rd most common cancer among women with more than 530,000 new cases and 275 000 deaths every year.[8] Most cases occur in low and middle-income countries where there are no cervical cancer prevention programs. In Europe, about 60,000 women develop and 30,000 women die from cervical cancer every year. Eastern Europe and the Caucasus have substantially higher rates of cervical cancer than Western Europe and this is primarily due to the extensive opportunistic screening or nationally organised screening programs that are available in Western Europe.[9] Cervical cancer affects younger women than other adult onset cancers with the majority of cases occurring between 35-60 years of age. This is a time when most women are working, caring for their families or doing both, so the social impact of cervical cancer is greatly increased because it removes mothers from their families and workers from the economy.

Cervical cancer is caused by any one of ≈15 carcinogenic (or 'high-risk') types of the Human papillomavirus (hrHPV).[10] HPV is a very common sexually transmitted virus and ≤80% of adults will have had an hrHPV infection at some time in their lives. Most infections occur in young people during their first few years of sexual activity with the incidence and prevalence declining thereafter.[11-14] Approximately 90% of new cervical hrHPV infections are cleared naturally by the immune system without any problems and it is only persistent infections that increase the risk of cervical cancer.[15-17]

Both transient and persistent HPV infections can lead to the development of dysplastic *pre-invasive* lesions called cervical intraepithelial neoplasia (CIN). CIN lesions will regress once the HPV infection has been cleared but if the infection persists, the CIN lesions can progress to cervical cancer over a period of ≈10 years.[18-21] There are no treatments for cervical HPV infections but the CIN caused by these infections can be removed using simple and effective outpatient procedures. However, CIN lesions do not cause any clinical symptoms and can only be identified through cervical screening.

4.2 Cervical screening

Among malignant tumours, cervical cancer is the one that can be most effectively prevented by screening. The primary objective of cervical screening is to identify women who have pre-invasive CIN lesions so these can be removed to prevent invasive cervical cancer from developing.[6] Cervical screening will also find asymptomatic cancers but these will be identified in earlier stages than cancers identified on the basis of clinical symptoms so treatment outcomes will be improved and mortality reduced. Well organised screening programs with a 3-5 year recall interval, good quality control and appropriate mechanisms to follow-up and treat all women having a positive screening test can reduce both the incidence and the mortality of cervical cancer by <80%.[22-24]

The conventional test used for cervical screening is the Pap test in which a small sample of cells is collected from the cervix using a spatula or brush, spread on a glass microscope slide and preserved with a liquid fixative. The slide is then sent to the laboratory where it is stained to highlight the cellular structures and it is examined microscopically for any abnormal cells that may indicate the presence of CIN. Several systems are used to classify these cells (Table 3).[25]

Table 3: Classification systems used for cervical cytology

System	Normal → Cancer							
Bethesda	Negative	Infection/ Reactive	ASCUS		LSIL	HSIL		
Bethesda (NEW)	Negative	Infection/ Reactive	ASC-US	ASC-H	LSIL	HSIL		
EU	Negative		Borderline & Mild Dysplasia			Moderate	Severe	In Situ	Invasive
Dutch	Pap 1		Pap 2	Pap 3a1		Pap 3a2	Pap 3b	Pap 4	Pap 5
UK	Negative		Borderline/ HPV	Mild Dyskaryosis		Moderate Dyskaryosis	Severe Dyskaryosis		
WHO	Normal	Atypia		Mild Dysplasia		Moderate Dysplasia	Severe Dysplasia	Carcinoma In Situ	Invasive Carcinoma
Pap	I	II		III			IV		V

Women with a low-grade Pap test result (ASC-US) are usually re-screened with cytology in 6 months or triaged immediately with HPV testing (i.e. women with ASC-US cytology are tested for HPV and referred to colposcopy if HPV positive). Meanwhile, women with higher-grade cytology (>ASC-US) or repeat low-grade cytology are usually referred to colposcopy where the cervix is visualised and any suspicious areas are biopsied to confirm the presence and grade of CIN.

Although the vast majority of HPV infections resolve spontaneously together with their associated CIN lesions, it is currently not possible to distinguish progressive from regressive lesions so all CIN must be carefully follow-up. Higher-grade CIN has a greater oncogenic potential and this has formed the basis of widely used clinical algorithms in which women with ≤CIN1 are re-screened with cytology in 6 months while those with ≥CIN2 are treated to remove the lesion. As a result, cervical cancer screening inevitably produces a substantial amount of overtreatment.[26-28]

In the past, this overtreatment has been seen as a relatively benign consequence of the screening process and a price worth paying to reduce cervical cancer rates. However, a growing body of evidence linking treatment for CIN to a range of pregnancy complications such as premature rupture of the foetal membranes and pre-term deliveries has increased concern about the adverse health consequences of CIN treatments.[29,30] In addition, increased pressure on healthcare budgets has focused attention on the cost of these treatments and their associated complications.

The recognition of these issues has had a strong influence on the design and operation of cervical screening programs in Western Europe and North America over the past 20 years. One priority area has been the replacement of opportunistic screening by organised screening programs to optimise the balance between the benefits and harms of screening while maximising cost-effectiveness.

Another priority area has been the refinement of colposcopy services with the development of evidence-based training curricula, clinical guidelines, standards and CQI procedures to optimise safety for the women and cost-effectiveness for the health system. This is a particularly important issue for Eastern Europe where colposcopy has not been classified as a distinct medical speciality so training curricula and clinical guidelines have been rudimentary or absent. The safety, efficacy and cost-effectiveness of cervical screening are highly dependent on the quality of colposcopy so it is essential that all colposcopists are well trained and work within a strict CQI system.

In addition, a number of new screening tests have been developed to complement or replace the Pap test. The best-characterised of these are liquid-based cytology (LBC) and HPV-testing, and it is important to consider these for use in RM.

4.2.1 Liquid-Based Cytology (LBC)

LBC is a modification of the conventional Pap test in which the cells collected from the cervix are placed directly into a vial of fixative medium instead of being spread on a microscope slide. The vial is then sent to the laboratory where cells are recovered and used to prepare a cell monolayer on a microscope slide that is stained and examined for abnormal cells.[31]

There are many systematic reviews and meta-analyses comparing the performance of LBC to the Pap test,[32-39] with one of the more widely cited studies concluding the sensitivity and specificity of LBC is ≈ equivalent to the conventional Pap test.[40] However, all the studies included in this analysis were conducted in expert laboratories where conditions are not representative of routine practice in many countries. As a result, the benefits of LBC relative to the Pap test are likely to be greater anywhere the cytology is of a lower standard. With regard to other aspects of LBC performance, there is substantial agreement that:[41-43]

- Cytopathologists and cytology screeners consistently prefer LBC because screening and interpretation are facilitated by the uniform presentation of the cervical cells,
- LBC reduces the number of inadequate samples in environments where this is a problem,
- LBC reduces the time required to screen each sample by ≤30%,
- LBC allows additional testing to be conducted on the preservative medium without the need to recall patients (such as HPV, chlamydia, etc.).

All of these characteristics can improve the operational efficiency of cervical screening programs. However, the cost of the reagents, supplies and equipment needed for LBC are higher than for the conventional Pap so it would be important for RM to undertake a cost-benefit analysis to see if the savings achieved through these efficiencies would offset the higher costs.

4.2.2 HPV Testing

As hrHPV infection is a necessary (but not sufficient) cause of cervical cancer, testing for the presence of hrHPV has been proposed as a screening test for cervical cancer. However, because ≈90% of hrHPV infections will resolve spontaneously,[16,17] the detection of hrHPV serves only as a marker of risk and must be followed-up with another test (such as cytology) that has a higher correlation with the presence of clinically relevant CIN. In contrast, because cervical cancer will not develop in the absence of hrHPV infection, a negative hrHPV test result is an exceptionally strong marker for the absence of cervical disease (negative predictive value typically >99.9%) and longer screening intervals have been proposed for hrHPV negative women.

HPV testing is not recommended for screening women under the age of 30 as the prevalence of transient hrHPV infection in this group is too high so a large number of women would need to be followed-up unnecessarily. The prevalence of hrHPV infection is lower in women aged ≥30 so the use of HPV testing for primary screening in this age group is more practical, although it is still necessary to triage hrHPV positive women with cytology or another test.

A number of large-scale, randomised controlled trials (RCTs) have been undertaken to evaluate the performance of hrHPV testing over 2 screening rounds. These studies have demonstrated:[44-48]

- The sensitivity for the detection of ≥CIN2 of a single hrHPV test when used as a stand-alone primary screening test is 1.5-2.0 times higher than either a single Pap or LBC test,
- The specificity and positive predictive value of a single hrHPV test when used as a stand-alone primary screening test are lower than either a Pap or LBC test,
- Using cytology to triage women with a positive HPV test (i.e. women with a positive hrHPV test are subsequently tested with cytology and referred to colposcopy only if the cytology is also positive) improves the specificity and PPV of hrHPV testing so it is ≈ equivalent to the Pap test,
- Over 2 screening rounds, the sensitivity, specificity and PPV of hrHPV testing with cytology triage are ≈ equivalent to the Pap test or LBC, although hrHPV testing identifies CIN earlier,
- The number of inadequate hrHPV tests is lower than the number of inadequate Pap tests.

As for LBC, the studies noted above were conducted within environments where the cervical cytology (either the conventional Pap test or LBC) would have been of very high quality and this will have minimised differences between hrHPV testing and cytology. As a result, the benefits of hrHPV testing relative to cervical cytology are likely to be greater in environments where the cytology is of a lower standard. In addition, these characteristics will affect to operational efficiency of cervical screening programs and it would be important for RM to conduct a cost-benefit analysis to see if the savings achieved through improved efficiencies would offset the higher costs of hrHPV testing.

4.2.3 Additional considerations for the introduction of new technologies in RM

In considering the use of LBC and/or hrHPV testing in RM, the following points should be noted:

- At this time, there are no RM data on the costs of providing a cervical cytology service within an organized cervical screening program, so it would not possible to undertake a reliable cost-benefit analysis of LBC and/or hrHPV testing compared to the conventional Pap test. However, the implementation of an organized cervical screening program in RM will need to be rolled-out in phases so a cost-benefit comparison of these new screening tests could be undertaken during the first phase of program implementation with the new technology then incorporated into later phases if found to be cost-effective,
- Depending on the characteristics of the population, the number of women testing positive for hrHPV is typically ≥2 times higher than the number of women having abnormal cytology requiring

follow-up or referral. There are no reliable hrHPV prevalence data for RM however 3 large studies of women from the general population in Russia report hrHPV prevalence rates of 13.4% to 25.7%.[49,50,51] If the hrHPV positive rate in RM is at the low end of this range (13.4%), it would be 7.3 times higher than the average positive rate of the 11 cervical cytology laboratories submitting data for this analysis and it would be 1.6 times higher than the cytology laboratory with the highest positive rate. Therefore, the capacity to provide cervical cytology for the triage of these women would need to be considered together with the capacity to provide colposcopy for the women who are cytology positive. In addition, there are currently no mechanisms to ensure the quality of these services and it will take a considerable amount of time before they can be implemented.

- All the reagents and equipment for both LBC and hrHPV testing must be purchased outside RM, while the reagents and equipment needed for the conventional Pap test either are or could be made in the country. Therefore, implementing a screening program using the Pap test would keep this money in RM while contributing to the development of the economy. It could also contribute to the equalization of wealth distribution in the country if the manufacturing facilities are either located or established in disadvantaged regions.

On this basis, a logical approach to the introduction of LBC and/or hrHPV testing in RM would be to proceed with the first phase of program implementation based on the conventional Pap test and use this to establish a quality assured cervical cytology screening capacity sufficient for 25%-30% of the anticipated national requirement. In parallel with this, the cost-benefit analyses of the new technologies would be included in the first phase with the outcomes the used to decide about the implementation of the new technologies in subsequent phases as the screening program continues to be rolled out in the country.

4.3 HPV vaccination

Cervical cancer risk can now also be reduced by vaccination against oncogenic Human papillomavirus (HPV) types 16 and 18. There are 2 commercially available HPV vaccines and both can reduce the risk of cervical cancer by ≈75% while simultaneously reducing the number of abnormal Pap tests, CIN lesions and follow-up procedures. HPV vaccination is an important advance in the prevention of cervical cancer but it is still necessary to note:

- Neither vaccine protects against all the HPV types that can cause cervical cancer so cervical screening remains necessary to protect women against cancers caused by these other HPV types,
- The current vaccines provide their optimal protection when given to adolescents before the start of sexual activity and vaccine effectiveness is lower when given to sexually active adults,
- Reductions in abnormal Pap tests, CIN lesions and follow-up procedures will start to be seen when the first vaccinees enter the screening age range. For example, the effects of vaccinating successive age-cohorts of adolescent girls will start to be seen when the first vaccinated cohorts reach screening age with reductions in cervical cancer seen when these women reach their 30s.

In addition, it is important to note that the full benefits of HPV vaccination will only be realised once the majority of the at-risk population (≥80%) has been vaccinated and this has proven difficult to achieve in many countries. In a recent report from the European Centre for Disease Control, the authors noted that of 7 countries for which data were available, only Portugal and the UK had coverage rates of ≥80% while Denmark and Italy ranged from 50–60% and France, Luxembourg and Norway had rates of ≤30%.[52] Further, RM obtained 20,790 doses of the HPV vaccine for 6,930 adolescent girls aged 10-18 (МНО № 722 of 28 October 2010), but the National Center for Public Health reported that only 2.5% of these girls were vaccinated.

HPV vaccination would reduce cervical cancer risk in RM and should be considered as a component of a comprehensive cervical cancer prevention program. However, plans for the implementation of a vaccination program need to include carefully structured educational programs for both health care providers and the public to ensure high recruitment levels can be achieved.

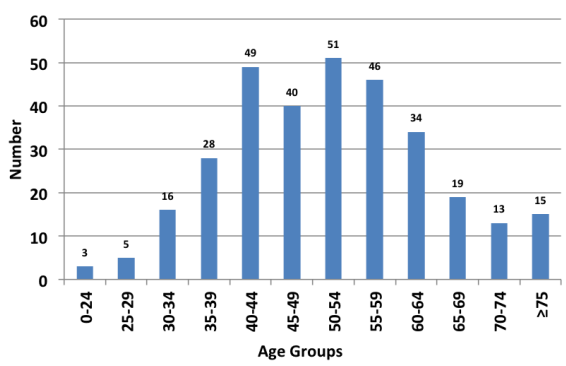
5. Analysis of the Current Situation in the Republic of Moldova

5.1 Cervical cancer in RM

The economic situation in RM over the past 2 decades has not allowed substantial investment in medical or health systems research so reliable data on cervical cancer and its prevention are scarce. Nonetheless, the data that are available indicate that cervical cancer incidence and mortality rates are very high at 17.2 and 7.4 per 100,000 (ASRw) respectively.[53] Meanwhile, a report prepared for the UNDP RM found the incidence of all cancers, including cervical cancer, had increased from 2005 to 2009,[54] with cervical cancer found to be the most common cancer among women in 2011, when it accounted for 39.3% of cancer cases. As in other countries, the majority of cervical cancers occur in middle-aged women with ≈75% of cases occurring in women aged 30-60 (see Figure 1).

Very importantly, the proportion of cervical cancers diagnosed in the later stages (FIGO 3 & 4), when treatment is more complicated, more expensive and less successful, increased from 36.8% in 1990 to 56.1% in 2011, while the proportion of women surviving for 5 years or more decreased from 70.4% in 2000 to 61.5% in 2011.[55] These data are consistent with a lack of effective cervical screening and the consequent diagnosis of most cervical cancers on the basis of clinical symptoms that only appear in the late stages of this disease.

Figure 1: Cervical cancer cases by age group, 2011



5.2 Development strategies

Cervical cancer prevention by screening has been consistently included as a priority in all relevant health sector strategy documents for the past decade, including the examples noted below.

5.2.1 National Reproductive Health Strategy 2005-2015

This strategy includes goals to improve early detection and management of breast and cervical cancers:

- Improve the regulatory framework for the early detection of breast and cervical cancers,
- Improve population access to breast and cervical cancer prevention and diagnosis,
- Increase provision of cytological screening for cervical cancer,
- Train health care providers in the early detection of breast and cervical cancers,
- Raise public awareness of breast and cervical cancer prevention through educational materials and the media promotion.

5.2.2 National Program Against Oncological Diseases 2008-2012

The principal objective of this program was to improve the early detection of cancers to decrease their morbidity and morality. Although not approved, the program included the following strategies:

Strategy 1. Primary prophylaxis:

3. Include the assessment of individual cancer risk and risk-based patient management in PHC.

Strategy 2. Secondary prophylaxis:

3. Modernise and promote cytological screening for cervical cancer detection.

Strategy 3. Staff Management:

1. Improve post-university and CME training in oncology (conforming to European guidelines),
2. Include oncology in the CME requirements for family physicians and paramedical personnel,
3. Introduce cancer screening and cancer risk monitoring in the training of medical staff,
4. Collaborate with European and world centers to support the introduction of primary and secondary methods for cancer prevention and the implementation of new treatment methods.

5.2.3 National Strategy for Prevention and Control of NCDs 2012-2020

The principal objective of this strategy is to reduce the incidence, morbidity and mortality of NCDs. The strategy includes the following:

Section 28. Specific objectives:

6. Provision of the infrastructure needed to manage and care for NCDs,
7. Introduce evidence-based, cost-effective interventions for the primary and secondary prevention of NCDs, with an emphasis on PHC,
8. Increase health service accessibility.

Section 39. Implementation of the Strategy:

1. Short-term strategic priorities (2012-2013)
   c. Strengthen the skills of doctors and nurses and develop a CME program at all levels in the prevention and control of NCDs,
2. Medium-term strategic priorities (2012-2015)
   b. Organize and implement national screening programs for the prevention and early detection of NCDs based on the models applied in the European Union and the USA.

Section 55. International cooperation will be achieved by:

1. Acquisition and implementation of the *acquis communautaire* through the development of partnerships with EU countries to promote the exchange of data, knowledge and experience in the prevention and control of NCDs,
4. Intensification of international cooperation through participation in international fora and development of partnerships with states having relevant experience.

5.3 Legislation, orders and guidelines

A review of the laws, orders and guidelines governing the provision of and access to cervical screening (i.e. the provision of Pap tests) at the PHC level and the treatment of cervical cancer once it has been diagnosed shows they are clear and comprehensive. However, instruments governing the provision of services for the follow-up of women with an abnormal Pap test by colposcopy and biopsy, as well as the treatment of CIN do not exist and need to be implemented to ensure the required services are available and the referral pathways are clearly specified.

In keeping with WHO recommendations, RM legislation specifies that cervical screening and cancer treatment are provided free-of-charge to all women whether or not they are registered for national health insurance with National Health Insurance Company (CNAM). This is particularly important because cervical screening targets women who are healthy so they have no immediately obvious reason to attend for screening. Therefore, imposing a financial barrier would tend to restrict screening attendance to the wealthy (who can afford it) and the well educated (who will be better informed about the future benefits) and thereby contravene government policies regarding the equitable provision of health services in RM.

However, this legislation also specifies that the follow-up of abnormal Pap tests and for the treatment of CIN will be provided free of charge only to women who are registered with CNAM and therefore creates a financial barrier for uninsured women. This situation is likely to be well known to women with a proportion either defaulting from follow-up or choosing not to be screened in the first place because of fears about the cost of these services.

The primary objective of cervical screening is to identify *precancerous* lesions at a stage when they can be easily and safely removed using simple outpatient procedures to prevent cervical cancer from developing in the first place. Therefore, the provision of cervical screening in the absence of services to follow-up, diagnose and treat all women who have a positive screening test is both pointless and unethical.

The instruments affecting the delivery of cervical screening and the treatment of cervical cancers are summarised in Table 4 below with further details provided in Appendices 1 and 2.

Table 4: Summary of current recommendations with supporting legislation, orders & guidelines		
	Recommendation	**Law/regulation/guideline**
1.	The current cervical screening recommendation is that all women aged 25-64 should be screened for cervical cancer using ecto and endocervical cytology once in every 2-year period.	• MHO № 1239/253 of 19 December 2012, "Approving the Methodological Norms for services provided under the unique program of compulsory health insurance for 2013."
2.	All women of screening age are entitled to free cervical screening through PHC services whether or not they are registered with CNAM.	• MHO № 627/163 of 9 September 2010, "Regulations on the registration of population health care facilities that provide PHC within the compulsory health insurance program." • MHO/CNAM № 522/207 of 24 December 2009, "On approving Methodological Norms within the program of mandatory health insurance for 2010."
3.	All PHC clinics in RM must provide breast screening (CBE) and cervical screening (Pap test).	• MHO № 252 of 1 April 2011, "On the Intensification of Prevention in PHC." • MHO № 695 of 13 October 2010, "On Primary Health Care in Moldova." • MHO № 504 of 25 December 2008, "Prophylactic Medical Examination of the Population." • MHO № 1387 of 10 December 2007, "Approval of the Unique Programme of Obligatory Medical Insurance." • MHO № 144/65A of 12 April 2007, "Equipment for PHC Institutions."
4.	All family physicians and nurses must know how to take samples for cervical screening.	• MHO № 695 of 13 October 2010, "On Primary Health Care in Moldova."
5.	Clinical guidelines for taking cervical samples for cervical screening.	• MHO № 722 of 16 July 2012, "On improvement of cytological pathomorphologic services in Moldova."
6.	Guidelines for the referral and follow-up of women with an abnormal screening test.	• 2013 - Precancerous conditions of the cervix: diagnostic issues and behaviour. Chisinau 2013. T Rotari, D Osadcii, N Ghidirim and L Rotaru. • 2012 - Methods of Instrumental Diagnostics in Gynecology. Chisinau, 2012. O Cernetchi and M Stemerg. • 2009 - National Guidelines for the Prevention of Cervical Cancer, Chisinau, 2009. NP Codreanu, VG Friptu, M Statitla and V Cernat.
7.	All women registered with CNAM and a family doctor who have abnormal cervical cytology (clinical group 1A) are entitled to free outpatient follow-up services including colposcopy & biopsy conducted in specialised outpatient facilities. Uninsured women must pay for these services.	• MHO № 1239/253 of 19 December 2012, "Approving the Methodological Norms for services provided under the program of compulsory health insurance for 2013." • MHO/CNAM № 627/163-A of 9 September 2010, "On approval of the Regulation on population registration at health care facilities providing primary health care services under the mandatory health insurance program."
8.	All women registered with CNAM and a family doctor who have precancerous cervical disease (clinical group 1B) are legally entitled to free treatment in specialised outpatient facilities or inpatient services at the Oncology Institute. Uninsured women must pay for these services	• MHO № 1239/253 of 19 December 2012, "Approving the Methodological Norms for services provided under the program of compulsory health insurance, 2013." • MHO/CNAM № 627/163-A of 9 September 2010, "On approval of the Regulation on population registration at health care facilities providing primary health care services under the mandatory health insurance program." • MHO № 348/56A of 24 April 2011 "Approving Methodological Norms for 2011."
9.	All women with histologically confirmed malignant disease (clinical group 2) are legally entitled to free inpatient treatment at the Oncology Institute, whether or not they are registered with CNAM.	• MHO № 1239/253 of 19 December 2012, "Approving the Methodological Norms for services provided under the unique program of compulsory health insurance for 2013."
10.	All women registered with CNAM and a family doctor who have been successfully treated for a malignant disease (clinical group 3) are legally entitled to active monitoring by an oncologist/ gynaecologic oncologist and by a family physician on a quarterly, biannual or yearly basis. Uninsured women must pay for these services.	• MHO № 1239/253 of 19 December 2012, "Approving the Methodological Norms for services provided under the unique program of compulsory health insurance for 2013."
11.	All women registered with CNAM and a family doctor who are living with malignant disease (clinical group 4) are entitled to symptomatic palliative care and pain relief through the Oncology Institute and/or family medicine clinic as required. Uninsured women must pay for these services.	• MHO № 1239/253 of 19 December 2012, "Approving the Methodological Norms for services provided under the unique program of compulsory health insurance for 2013." • MHO № 348/56-A of 24 April 2011, "On approving the Methodological Norms in 2011."
12.	The Oncology Institute has responsibility for the provision and supervision of cervical cytology and pathology services.	• MHO № 722 of 16 July 2012, "On improvement of activity and cytological pathomorphologic services in Moldova".
13.	Cytology/cytopathology work limits.	• MHO № 722 of 16 July 2012, "On improvement of cytological pathomorphologic services in Moldova."
14.	Colposcopy services	• MHO Nr. 1239/253 of 19 December 2012 "Approving the Methodological Norms 2013 a unique program of compulsory health." • Ministry Health Order № 695 of 13 October 2010, "On Primary Health Care in Moldova"
15.	Performance indicators	• MHO/CNAM № 302/70A of 30 March 2012 "Approval of the regulation on the validation of performance indicators"

5.4 Estimated cervical screening population and service requirements

Current recommendations specify that all women aged 25 to 64 should be screened for cervical cancer once every 2 years. According to the 'Anuarul statistic al Republicii Moldova 2011', there were 1.85 million females in RM as of 1 January 2011, with ≈1.031 million women aged 25-64 years. Therefore, using a 2-year screening interval with a maximum participation rate of 75%, a fully operational cervical screening program would require the capacity to screen ≈386,711 women/year (1,031,230 ÷ 2 x 0.75 = 386,711) and a laboratory capacity to process ≈444,720 Pap tests/year (+15% for additional Pap tests due to inadequate samples, follow-up testing, etc.)(see Appendix 3).

5.5 Provision of cervical screening services

5.5.1 Facilities for cervical screening

Effective cervical screening requires a high proportion (≥75%) of the target population to be regularly screened but this will only be achieved if the services are convenient and affordable for women in the target population. In RM, MHO/CNAM № 522/207 of 24 December 2009 specifies:

- All women [in the recommended screening age range] are entitled to free cervical screening through PHC services whether or not they are registered with CNAM.

And MHO № 695 of 13 October 2010 specifies:

- All PHC clinics are required to provide cervical screening services,
- All family physicians and nurses must be able to take cervical samples for Pap tests,
- Colposcopy services for the follow-up of women having an abnormal Pap test should be available through all AMTs, CMFs and CSs.

The PHC responsibilities relevant to the provision of cervical screening services at different levels of the health system in RM are set out in Table 5.

Table 5: Structure of PHC services in RM

Service	Location	Responsibilities
Family Medicine Center/Centrele Medicilor de Familie (CMF) Territorial Medical Association/Asociatia Medicala Teritoriala (AMT)	One per district, located in its capital: • Cat. 1: >80,000 people • Cat. 2: 40,001-80,000 • Cat. 3: ≤40,000 There are 5 AMTs in Chisinau which each have the same status as a CMF: • AMT Botanica • AMT Buiucani • AMT Centru • AMT Ciocana AMT Riscani	• Provides PHC services to the city and additional services to the district • Coordinates all PHC services in the district including the services of the Health Centres, Family Physician Offices and Health Offices, and including services provided by autonomous organisations • Responsible for collecting health data within the district • Responsible for coordinating Continuing Medical Education (CME) for PHC providers in the district • Required to have a: - general medical examination room - family physician's room (which cannot be used for primary screening) - prophylactic gynaecology examination room for the follow-up of abnormal Pap smears (colposcopy, biopsy, etc.) - reproductive health room (which, since 2010, is not to be used for cancer screening)
Health Center/Centrele de Sanatate (CS)	Located in rural areas: • Cat. 1: >11,500 people • Cat. 2: 9,001-11,500 • Cat. 3: 6,001-9,000 • Cat. 4: 4,500-6,000	• Can be sub-divisions of the CMF or autonomous units (coordinated by the CMF) • Provides PHC services & immediate emergency care within their catchment areas • Staffed by ≥3 family physicians and ≥6 family nurses (2-3 family nurses/family physician) • Coordinates the services of Family Physician Offices and Health Offices • Recommended to have a: - family physician's room which can be used for primary screening - prophylactic gynaecology examination room for the follow-up of abnormal Pap smears (colposcopy, biopsy, etc.)
Family Doctor's Office/Oficiile Medicului de Familie (OMF)	Located in villages: • 901-3,000 people	• Are sub-divisions of the CMF or CS • Provide PHC services & emergency care within their catchment areas • Staffed by 1-2 family physicians and ≥4 family nurses • Recommended to have a: - family physician's room - room for prophylactic examinations
Health Office/Oficiile de Sanatate (OS)	Located in small villages: • ≤900 people	• Staffed by a family nurse • Recommended to have a: - family physician's room - room for prophylactic examinations

The network of PHC clinics in Moldova is extensive and easily accessed as evidenced by the number of outpatient contacts/person/year that exceeded the EU average in 2010[56] and by the decreasing number of people who failed to consult a doctor when ill.[57] However, cervical screening targets women who are healthy and with no immediately obvious need to go for screening so statistics on the behaviour of people when they are ill are unlikely to accurately predict the behaviour of women targeted for screening.

5.5.2 PHC staff availability

Staff shortages remain a problem in RM with PHC services currently able to recruit only 88.7% of their staffing needs at the national level but with more severe staff shortages seen in rural areas. Data from the RM National Center for Health Management (CNMS) show that 48.6% of districts have <90% of the recommended staff and 21.6% of districts have <80% (see Appendix 4).[58]

5.5.3 PHC staff training

The effect of PHC staff shortages on the delivery of cervical screening will be compounded by a lack of training among existing staff. For example, cervical screening cannot be provided in 12 villages in the Causeni region because people with the required skills are not available.

The importance of staff training for cervical screening can be overlooked because cervical screening is often viewed only as the taking Pap tests and the taking of Pap tests is viewed as an inherently simple process. However, while the process is simple, it still requires strict adherence to the recommended protocol, with Pap test quality directly linked to the extent of staff training.[59-62] Good training will therefore directly affect program cost-effectiveness by reducing the number of women who need to be rescreened because of an inadequate Pap test. Cervical sampling is now included in training programs for family physicians and nurses but family physicians receive only theoretical information and the practical training is reserved for nurses.

Notwithstanding the importance of training PHC staff to take high quality Pap tests, the Pap test is only a very small part of a cervical screening program and PHC staff must understand all aspects of the program if they are to work effectively within it. Here, it is important to note the women who do develop cervical cancer in countries with screening programs can be divided into 3 ≈equal groups:

- Women who were not screened regularly or at all,
- Women who were screened but had a false negative result,
- Women who had a positive result but failed to complete the follow-up process.

Therefore, ≈2/3 of the cervical cancer cases in screened populations are due to poor recruitment and follow-up. PHC staff have the closest relationships with women in the screening population and can play an essential role in maximising screening attendance and follow-up compliance. Further, because PHC is positioned as the gateway to all other health services in RM, PHC staff should be responsible for organising patient referrals to colposcopy and coordinating these services with each woman's on-going care at the PHC level.

To fulfil these roles, PHC staff must have a good understanding of the entire screening process and also know how to effectively counsel women about the importance of screening, the different Pap tests results, the follow-up procedures and the treatments. Currently, none of this information is included in the training programs or CME materials for either family physicians or nurses, and the monitoring of women as they progress through the screening program is not specified in the responsibilities of PHC staff.

5.5.4 PHC staff certification for cervical screening

Because of the importance of PHC staff to the effective operation of a cervical screening program, many countries with organised screening programs require PHC staff to be certified as having completed an approved training program before they can participate. Adopting this policy in RM would ensure PHC staff understand the operation of the screening program, the referral criteria and pathways, and the counselling needed to maximise recruitment and follow-up compliance.

5.5.5 Clinical guidelines and SOPs for cervical screening procedures conducted in PHC

Cervical screening procedures in PHC are currently specified in MHO № 749 of 30 July 2012 "On Clinical Protocol for Family Doctors – Cervical Cancer." However, these do not account for the operation of an organised cervical screening program and will therefore need to be revised.

5.5.6 Performance indicators, standards and CQI for cervical screening in PHC

RM currently has no nationally approved performance indicators or standards for the cervical screening services delivered through PHC, and there is no CQI program covering these services.

5.6 Cervical cytology (Pap test) screening and diagnosis

5.6.1 Cervical cytology laboratories

MHO № 722 of 16 July 2012 assigns overall responsibility for cytology and cytopathology services to the Institute of Oncology (IO) and lists 16 cervical cytology screening laboratories (IO, Republican Diagnostic Center (CDR), 5 AMTs in Chisinau and 9 regional laboratories). However, as of 1 January 2013, only 12 of these were operational with the other laboratories contracting services from the operational ones.

5.6.2 Cervical cytology laboratory staff availability

RM currently has 15 cytopathologists and 17 cytotechnicians. This number of cytopathologists is likely sufficient to meet both current and future needs, although this will depend on the amount of work they are required to do for other health services. However, the number of cytotechnicians is sufficient to process only 50-60% of the current volume of Pap tests which leads to long delays in the reporting of results and compromises the quality of these services.

5.6.3 Cervical cytology laboratory staff training

For the training of cytopathologists, a mandatory cytopathology residency program was established in 1998 so the people subsequently entering the profession will have completed this residency while those entering at an earlier date will have undertaken an internship program.

For cytotechnicians, there is no formal training program or CME materials for cervical cytology screening and the people currently undertaking this activity in RM will have been trained in general laboratory techniques with subsequent on-the-job training in cytology. This is problematic because cervical cytology screening is highly subjective with the sensitivity and specificity dependent on the training and experience of the cytotechnicians. Therefore, a comprehensive initial training together with regular CME and CQI are essential to achieving and maintaining the performance levels required for cervical screening to be safe and cost-effective.

5.6.4 Certification for cervical cytology screening

RM currently does not recognise cervical cytology screening as a distinct laboratory speciality with a defined curriculum and certification criteria together with CME and recertification requirements. As a result, there is no mechanism to ensure the people undertaking this in RM have the required skills.

5.6.5 Laboratory guidelines and SOPs for cervical cytology screening

RM currently has no national laboratory guidelines or SOPs for cervical cytology screening. In addition, RM has no regulations governing the working practices of cytotechnicians. This is particularly problematic for cervical cytology screening because it is a mentally tiring process with performance decreasing as fatigue sets-in. Therefore, many countries have guidelines limiting the number of Pap tests cytotechnicians can screen per day, and while RM also set a limit in the past (MHO № 68 of 10 March 2005 set a limit of 67 Pap tests/cytotechnician/day or ≈14,500 Pap tests/cytotechnician/year), this order has replaced by MHO № 722 of 16 July 2012, "On improvement of cytological pathomorphologic services in Moldova," that does not set a limit.

In addition to limits on the number of Pap tests screened/day, the European Guidelines[22] have working practice recommendations (see Table 6) that are designed to ensure cytotechnicians will be alert when they are screening cytology specimens so their performance is not compromised. These recommendations address basic human characteristics that will not vary by country so the lack of similar recommendations in RM will be adversely affecting the safety and cost-effectiveness of the cervical screening that is currently being undertaken in the country.

Table 6: Working practice recommendations for cervical cytology screening laboratories[22]

- Each period of continuous screening should be ≤2 hours,
- Total time spent on primary screening/day should be ≤6 hours,
- Each laboratory should process ≥15,000 Pap tests/year so cytotechnicians are regularly exposed to the full range of abnormal cytology,
- Each laboratory should have ≥4 cytotechnicians to enhance collaborative learning, ensure service provision during holidays, sick-leave, etc.

5.6.6 Performance indicators, standards and CQI for cervical cytology screening

Currently, there are no performance indicators or standards for cervical cytology screening, and there is no CQI program covering this service.

5.7 Colposcopy for the follow-up of abnormal Pap tests and the treatment of CIN

5.7.1 Colposcopy clinics and staff

MHO № 695 of 13 October 2010 requires all AMTs, CMFs and CSs to have the facilities, staff and equipment to conduct:

- Preventive gynaecologic procedures (including breast and cervical screening),
- Related additional diagnostic procedures (colposcopy and biopsy),
- Related therapeutic interventions (LEEP, cryotherapy, laser or diathermic electro-conisation).

In common with the majority of Eastern European countries, RM does not recognise colposcopy as a distinct medical speciality. As a result, there is a limited number of colposcopists (≈ 5) who are self-trained or obtained specialist training in a foreign country and most of these people are based in Chisinau. Outside Chisinau, gynaecologists are aware their colposcopy knowledge and skills have not kept pace with developments in Western Europe and therefore believe the safety of their patients is best served by referring them to the specialists at the IO in Chisinau.

5.7.2 Colposcopy training and certification

RM currently has no nationally approved training curriculum or certification requirements for colposcopists. High quality colposcopy is essential to ensure the safety and cost-effectiveness of cervical screening, but the quality of colposcopy is largely dependent upon highly subjective clinical judgements that take training, practice and experience to optimise.

As a result, many Western European countries have developed comprehensive training programs and certification criteria together with CME and recertification requirements to ensure colposcopists have the necessary skills. Certification with CME and periodic recertification are now prerequisites to practicing colposcopy in many countries where these requirements have produced enormous improvements in the outcomes of their cervical screening programs. The adoption of similar policies in RM will be required to ensure the quality of colposcopy supports the safe and cost-effective operation of a cervical screening program.

5.7.3 Clinical guidelines and SOPs for colposcopy

RM currently has no nationally approved clinical guidelines or SOPs for the clinical procedures required to follow-up abnormal Pap tests or treat CIN.

5.7.4 Performance indicators, standards and CQI for colposcopy

RM currently has no nationally approved performance indicators or standards for colposcopy, and there is no CQI program covering these services.

5.7.5 Health insurance coverage for colposcopy

While cervical screening and cancer treatment are available free of charge to all Moldovan women whether they have health insurance or not, the follow-up of abnormal Pap tests and the treatment of CIN is free of charge only for women who do have health insurance. As noted in Section 5.2, this will adversely affect referral compliance as well as screening recruitment while increasing disparities in health service provision because this effect will be greater among disadvantaged communities.

5.8 Treatment of cervical cancer

All cancer treatment in RM is undertaken at the IO in Chisinau. MHO № 1239/253 of 19 December 2012 specifies that all Moldovan citizens are entitled to free cancer treatment and palliative care whether or not they are registered with CNAM.

5.9 Quality assurance and CQI

Improving the quality and efficacy of medical services are specified priorities in the RM National Health Policy 2007-2021, the RM Health System Development Strategy 2008-2017 and the CNAM Institutional Development Strategy 2013-2017. However, CQI policies and programs have not yet been implemented for any of the services involved in cervical screening. This is of concern because many aspects of the cervical screening process are based on highly subjective clinical judgements and it will not be possible to ensure the quality of these services without an effective CQI program.

5.10 Cervical screening registry

RM currently has no cervical screening registry or mechanisms to collect and analyse the data that is required to effectively manage a cervical screening program. CNAM does have a database of all people registered for health insurance (currently ≈80% of the population of RM[63]) that includes the details needed to establish eligibility for cervical screening, together with mechanisms for the collection and analysis of data from all contracted health institutions. However, these data and analyses are for monitoring contractual obligations and calculating provider payments so much of the data needed for screening program management is not currently being collected.

5.11 Cancer registry

The Moldovan National Cancer Registry is based in the IO where it has access to data on all cancers diagnosed in RM because all suspect cancer cases are referred to the IO for diagnosis and treatment.

5.12 Private sector provision of health services

RM government policy encourages private sector provision of health services so private capital can be accessed for expanding health services, increasing consumer choice and introducing competition to stimulate improvements in service quality. However, private provision of cervical screening can be problematic because of the subjective nature of decisions about further investigations, follow-ups and treatments that will produce profits for the clinics. Therefore, the guidelines, SOPs, performance indicators, standards and mandatory CQI participation for both public and private clinics will be even more important to ensure the appropriateness as well as the quality of patient care.

A further consideration is that while some women will choose to be screened in the private sector, a proportion of these women will not be able to afford the more expensive follow-up procedures or treatments and will return to the public sector for these services. Therefore, strict application of the measures noted above to both the public and private sectors will be required to ensure women returning to the public sector meet the recommended referral criteria. In addition, each woman's screening history will be required for follow-up or treatment decisions and additional costs will be incurred by the public sector if this information is not available. As there is little incentive for private clinics to provide this information, requiring all cytology, colposcopy and pathology results from both public and private clinics to be reported to the screening registry would ensure this information is readily available when it is needed by any clinician.

6. Assessment of Current Capacities in the Republic of Moldova

6.1 Provision of cervical screening services

The data collected in the capacity assessment indicate that 365,676 women were screened in RM during 2012, which equates to ≈70.9% of the estimated 515,615 women who should be screened annually according to the current recommendations of biennial screening for women aged 25-64. These data also indicate that 137,280 women underwent cervical screening in Chisinau, which is ≈117.7% of the estimated annual cervical screening requirement for this municipality (Appendix 5).

As coverage levels ≥70% have been achieved only by a limited number of well organised screening programs in high-resource countries, ≈70.9% is unlikely to reflect the true screening coverage in RM and these results are likely to have been influenced by one or more of the following:

- Women outside the target screening age range (25-64 years of age) are being screened,
- Women are being screened more frequently than the recommended 2-year screening interval,
- Women from other cities and towns are travelling to Chisinau to be screened due to:
  - Lack of local services
  - Patient preference (lack of trust in local services, belief the services in Chisinau are better, etc.)

These data also indicate that 91.0% of Pap tests were taken in CMFs (56.6%) and CSs (34.4%) with only 9.0% taken in OMFs and OSs. This is relevant because convenient access to screening services is key to achieving the high recruitment needed for screening to effectively reduce cancer rates. Therefore, fully utilising the existing network of clinics would greatly facilitate the operation of a screening program and the cause(s) of this imbalance need to be identified.

The availability of equipment and facilities does not appear to be a substantial factor because much of the required equipment (vaginal speculums and cervical sampling kits) is provided as disposable plastic-ware and all PHC clinics reported they had sufficient supplies to meet demand. In addition, all clinics reported a sufficient number of gynaecology chairs, light sources and examination rooms. However, a number of clinics reported these were very old so poor quality equipment or facilities in the smaller clinics may be influencing patient choices.

PHC staff shortages are likely to be a factor as these are more severe in the rural and remote communities where OMFs and OSs predominate. Further, as noted above, the problem of staff shortages will have been compounded by a lack of training for the existing staff as seen in the Causeni region where a lack of people with the required skills in the villages requires women go to the Causeni CMF or to Chisinau for screening.

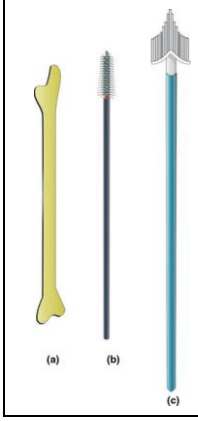
Patient preferences are also likely to be a factor as several nurses reported that women in smaller towns and villages do not want to be screened locally because of doubts about maintaining confidentiality within these small communities and therefore prefer to go to another town.

A particularly important finding of the capacity assessment is a substantial proportion of cervical samples are being taken using Volkmann curettes. This device is not recommended for cervical sampling as it does not sample the full cervical transformation zone and will therefore miss lesions that should be identified and followed-up. A review of cervical sampling devices published in 2007 concluded the most effective devices are:[64]

- The extended tip spatula (Figure 2a)
- A combination of a spatula and the endocervical brush (Figure 2b)
- The cervical broom (Figure 2c).

It is therefore strongly recommended that the use of Volkmann curettes be phased-out as quickly as possible and that PHC staff be trained to use one or more of these recommended devices.

Figure 2: Cervical Sampling Devices



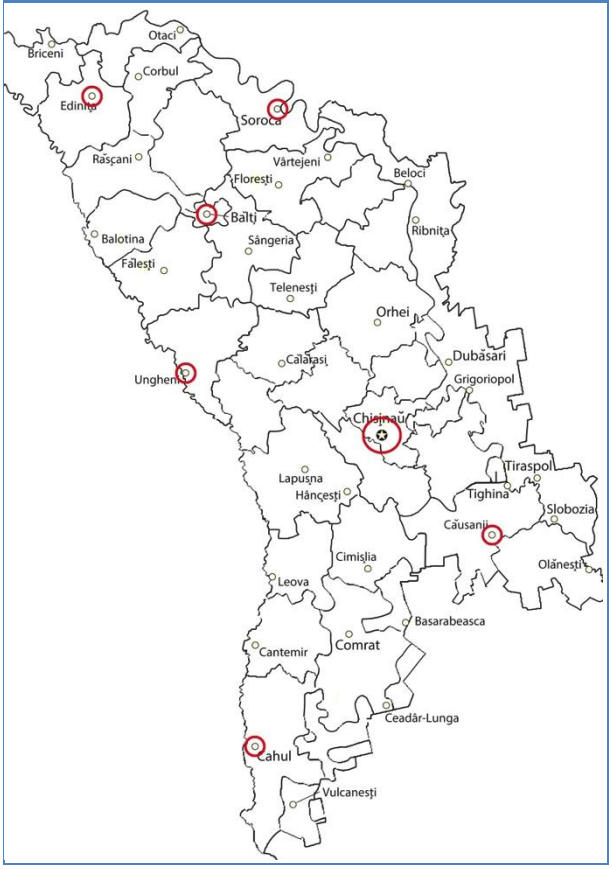
6.2 Cervical cytology screening and diagnosis

Of the 16 cervical cytology laboratories listed in MHO № 722 of 16 July 2012 (IO, CDR, 5 Chisinau AMTs, and 9 regional laboratories), only 12 were operational as of 1 January 2013 with 6 located in Chisinau and the rest located in other larger centers (see Table 7 and Figure 3).

Table 7: Laboratories processing Pap tests

	Laboratory	Status	Volume
1	IO	Operational	63,238
2	CDR	Operational	42,911
3	AMT Botanica	Operational	26,840
4	AMT Buiucani	Not operational➔AMT Centru	-
5	AMT Centru	Operational	37,954
6	AMT Ciocani	Operational	20,268
7	AMT Riscani	Operational	16,076
8	Anenii Noi	Not operational➔IO & RDC	-
9	Balti	Operational	42,130
10	Basarabeasca	Not operational➔IO & RDC	-
11	Briceni	Stopped 2013. Now contracts services from Edinet	-
12	Cahul	Operational	35,128
13	Causeni	Operational, based in the IMSP Spitalul Raional Causeni	12,477
14	Cimislia	Not operational➔IO	-
15	Drochia	Not operational➔RDC	-
16	Edinet CMF, IMSP Hospital	Operational, based in the IMSP Spitalul Raional Edinet	17,357
17	Glodeni	Not operational➔Balti	-
18	Leova	Not operational➔IO, RDC & Cahul	-
19	Singerei	Not operational➔Balti	-
20	Soroca	Operational	25,169
21	Ungheni	Operational	35,698
22	Orhei	Not operational	-
23	Hincesti	Not operational	-
24	Comrat	Not operational	-

Figure 3: Geographical distribution of operational cervical cytology laboratories in RM



The current number of cytopathologists and cytotechnicians in RM is presented in Table 8. This number of cytopathologists is likely sufficient to meet both current and future needs, depending on the amount of work produced by other health services. However, the number of cytotechnicians is not sufficient to meet current demand. If the limit of 67 Pap tests/cytotechnician/day previously set by MHO № 68 of 10 March 2005, was enforced together with the European Guideline recommendations set out in Table 6 above, the screening of 365,676 women would require a minimum of 29 cytotechnicians working in a maximum of 7 laboratories.

Table 8: № of cytopathologists and cytotechnicians

	Laboratory	Volume	Cytopathologist	Cytotechnician
1	IO	63,238	4	5
2	CDR	42,911	2	2
3	AMT Botanica	26,840	1	1
4	AMT Centru	37,954	1	1
5	AMT Ciocani	20,268	1	1
6	AMT Riscani	16,076	1	1
7	Balti	42,130	1	1
8	Cahul	35,128	1	1
9	Causeni	12,477	1	1
10	Edinet	17,357	1	1
11	Soroca	25,169	1	1
12	Ungheni	35,698	1	1

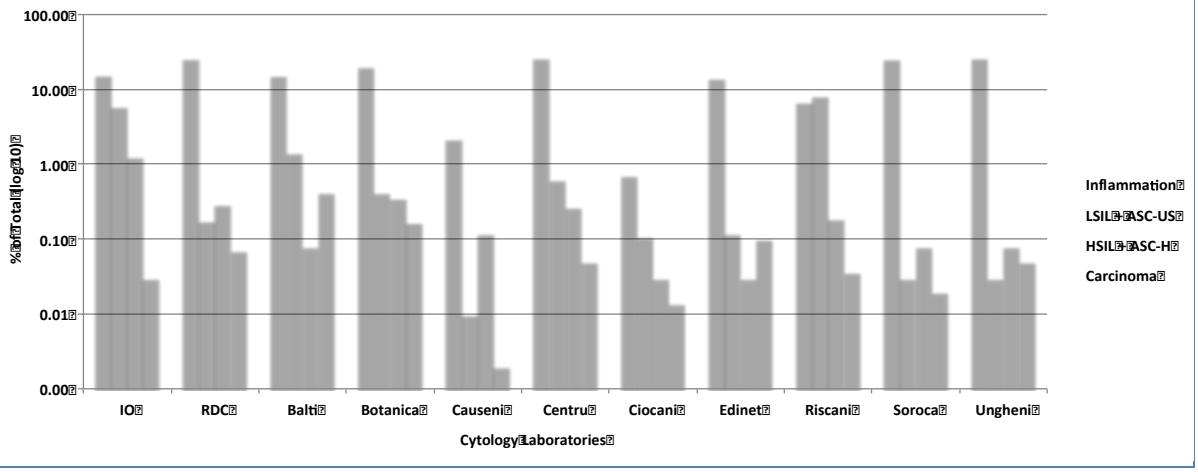
Therefore, at best, RM has ≈60.0% of the staff required to process the current number of Pap tests with the majority of the cytotechnicians working alone in small laboratories that have neither the test volume nor the staff numbers required to ensure service quality. As a result, the current structure and staffing of the cervical cytology laboratory network in RM will be compromising the safety and cost-effectiveness of cervical screening.

No data were available to directly assess the quality of the cervical cytology services in RM. However, examination of the Pap test results from 11 of the 12 operational laboratories identified a number of issues that require further investigation (see Table 9 and Figure 4)

Table 9: Proportions of Pap test results reported during 2012

	England	IO	RDC	Balti	Botanica	Causeni	Centru	Ciocani	Edinet	Riscani	Soroca	Ungheni
Normal	90.6%	77.25%	73.29%	82.70%	78.84%	97.61%	66.79%	98.47%	85.60%	84.57%	81.43%	81.43%
Inflammation	-	15.53%	26.18%	15.36%	20.19%	2.23%	27.00%	0.72%	14.21%	6.80%	25.68%	26.68%
LSIL + ASC-US	5.7%	5.92%	0.18%	1.44%	0.42%	0.01%	0.63%	0.11%	0.12%	8.40%	0.03%	0.03%
HSIL + ASC-H	1.1%	1.27%	0.29%	0.08%	0.36%	0.12%	0.27%	0.03%	0.03%	0.19%	0.08%	0.08%
Carcinoma	0.07%	0.03%	0.07%	0.42%	0.17%	0.002%	0.05%	0.01%	0.10%	0.04%	0.02%	0.05%

Figure 4: Proportions of Pap test results reported during 2012



As illustrated in Figure 4, there are large variations between laboratories in their Pap test results. As this variation has no obvious biological basis, contributing factors are likely to include the lack of:

- A nationally approved cervical cytology training curriculum and certification criteria,
- Nationally approved cervical cytology laboratory guidelines and SOPs,
- A mandatory national cervical cytology CQI program.

Another issue is the high rate of inflammatory Pap tests that also varies widely between the laboratories. Inflammatory Pap tests can have a number of causes and high rates can be expected in some populations but the wide variation between laboratories that are serving similar populations indicates this is also likely to be related to education, guidelines/SOPs and CQI.

Finally, the HSIL rates are very low, even in comparison to well-screened Western European populations, and these rates also vary widely between laboratories. Inflammation can influence HSIL rates by masking diagnostic cells but this does not appear to be the only factor influencing these results as the laboratory with the lowest HSIL rate also has the lowest inflammatory rate. Therefore, other factors will be involved and a principal contributor is likely to be the use of Volkmann curettes for cervical sampling. As noted above, Volkmann curettes are not recommended for cervical sampling because they do not effectively sample the cervical transformation zone and will therefore miss clinically relevant lesions.

6.3 Colposcopy and the follow-up of women having abnormal screening results

The capacity assessment found that 39 clinics have a total of 55 colposcopes with 35 of these known to be of recent manufacture (≥2000). In addition 29 clinics have equipment for the treatment of CIN including 35 diathermic electroconisation (DEC) units, 12 LEEP units and 4 cryotherapy units although only 4, 1 and 0 of these units respectively are of recent manufacture (see Table 10 and Appendix 7). Assuming the units for which no DoM data were provided are all manufactured <2000, these data indicate that RM has quite a few (35) relatively new colposcopes, although there are very few recently manufactured units for the treatment of CIN (1 LEEP unit and 4 DEC units).

However, interviews with gynaecologists in practice found that most believe their patients are best served by referring them to the colposcopy specialists in Chisinau for the following reasons:

- Awareness their colposcopy knowledge and skills have not kept pace with developments in WE,
- Lack of clear clinical guidelines and SOPs,
- Lack of appropriate equipment or facilities.

As noted above, requiring women to travel to a distant colposcopy clinic is known to reduce attendance and this is likely a principal cause of the low follow-up rates in Cahul, Falesti and Straseni where only 7.4%, 14.5% and 18.5% respectively of women referred to colposcopy actually attended.

Finally, no data were provided on the training and qualifications of the (few) clinicians who are doing cervical surgeries. A number of studies have linked treatments for CIN to a range of adverse pregnancy complications such as premature rupture of membranes, pre-term deliveries, etc.[29,30] which cause unnecessary morbidity for women and costs for the health system. The safety and efficacy of CIN treatments are directly linked to clinician training so further information about training levels will be required to design educational programs.

Table 10: Colposcopy services and equipment

	Colposcopy	Cervical Surgery	Colposcope	LEEP	Cryotherapy	DEC*
IO	✔	✔	1x1990 3x2007 1x2010	5x1979	0	5x1979
AMT Botanica	➔IO	➔IO	3xDoM	3xDoM	3xDoM	2xDoM
AMT Buiucani	➔IO	➔IO	1xDoM	0	0	1x1981
AMT Centru	➔IO	➔IO	1xDoM 2x2010	0	0	1xDoM
AMT Ciocani	➔IO	➔IO	1x2002	0	0	1x1981
AMT Riscani	➔IO	➔IO	1x1984 1x1987 1x2003 1x2010	0	0	1x1975 1x1978 1x1982 1x2010
Balti CMF	➔IO	➔IO	1x1971 1x2003	0	0	0
CS Briceni	➔IO	➔IO	1x1998	0	0	1x1984
Donduseni CMF	➔IO	➔IO	1x2005	0	0	1xDoM
Sudarca CS	➔IO	➔IO	1x1998	0	0	1x2009
Drochia CMF	➔IO	➔IO	1xDoM	0	0	1xDoM
Edinet CMF	➔IO	➔IO	1x2004	0	0	1x1984
Falesti	➔IO	➔IO	1x2000	0	0	0
Floresti	➔IO	➔IO	1x2004	0	0	0
Glodeni	➔IO	➔IO	1x1988 1x2003	1xDoM	0	1xDoM
Ocnita	➔IO	➔IO	1x2007	0	0	0
Riscani CMF	➔IO	➔IO	1x2003	0	0	0
Singerei Noi CS	➔IO	➔IO	1x2003	0	0	1x1990
Soroca CMF	➔IO	➔IO	1x2005	0	0	1xDoM
Anenii Noi CMF	➔IO	➔IO	1x2004	0	0	1xDoM
Calarasi CMF	➔IO	➔IO	3x2003	?	0	1x1976
Pirljolteni CS	➔IO	➔IO	0	0	0	1xDoM
Criuleni CMF	➔IO	➔IO	1x2004	0	0	0
Hincesti CMF	➔IO	➔IO	1x2006	0	0	0
Ialoveni CMF	➔IO	➔IO	1xDoM	0	0	1xDoM
Nisporeni OS	➔IO	➔IO	1x2007		0	1xDoM
Orhei CMF	➔IO	➔IO	1xDoM	0	0	1xDoM
Teleseu CS	➔IO	➔IO	0	0	0	1xDoM
Rezina CMF	➔IO	➔IO	1x2006			
Straseni	➔IO	➔IO	1xDoM	0	0	1xDoM
Telenesti	➔IO	➔IO	1xDoM	0	0	0
Ungheni CMF	➔IO	➔IO	1x2000	?	0	1xDoM
Basarabeasca CMF	➔IO	➔IO	1xDoM 1x1984	1x1983	0	1x1983
Cahul CMF	➔IO	➔IO	1x2004	0	1xDoM	0
Cantemir CMF	➔IO	➔IO	1x2005	0	0	0
Causeni CMF	➔IO	➔IO	0	0	0	1xDoM
Cimislia CMF	➔IO	➔IO	1x2005	0	0	1xDoM
Leova	➔IO	➔IO	0	0	0	1x2009
Stefan-Voda CS	➔IO	➔IO	1x2005	1x2011	0	1x2009
Taraclia CMF	➔IO	➔IO	1x2011	0	0	0
Comrat CMF	➔IO	➔IO	1x2006	1x1979	0	0
Copceac CS	➔IO	➔IO	1x1987	0	0	0
Vulcanesti CMF	➔IO	➔IO	1x2005	0	0	0
		Totals:	52	10	3	35
		Totals ≥2000:	34	2	?	3

6.4 Summary of capacity assessment findings

A key finding of this capacity assessment was that 365,676 women had a Pap test in 2012. This is a very considerable number of women. However, it is essential to recognise this screening is being done without the resources needed for the follow-up of abnormal Pap tests, the treatment of CIN or the administrative and QA systems required for it to be safe and cost-effective. Therefore, the cervical screening currently undertaken in RM will produce suboptimal reductions in cancer rates but will still comsume substantial health care resources. In addition, it will produce an unnecessarily high degree of harm for women through an excessive number of false negative results leading to delayed diagnoses of cancer and false positive results leading to needless stress, follow-up procedures and treatments.

This situation is not due to any failure on the part of the people involved in the delivery of the screening services who are doing the best they can within the existing structures. Instead, it is because circumstances in RM since the collapse of the Soviet Union have prevented the health services from keeping pace with developments in screening program structures and systems that have occurred in other countries. Therefore, the solution is to move forward with implementing these structures and systems as quickly as possible but with the priority being the improvement of the existing services, not the recruitment of more women to screening.

7. Recommendations for Implementing an Organised Cervical Screening Program

A principal component of this project was the identification and active involvement of all relevant stakeholders to ensure the outcomes are well adapted to the RM health system and the people who will be responsible for delivering the cervical screening services have ownership of the program with an interest in its success.

As part of this process, the 3rd Stakeholder Meeting was held in the RM Ministry of Health on 21 November 2013 to review the outcomes of the capacity assessment and define the key elements of the capacity building program needed to strengthen the health services required for the delivery of a cervical screening program. The key elements identified by the stakeholders at this meeting were:

- Establish an administrative structure with overall responsibility for the implementation and operation of the cervical screening program.
- Prepare and publish cervical screening policy documents and service specifications including:
  - Cervical screening service policy,
  - Cervical screening CQI policy.
  - Cervical screening service specification.
- Review and revise legislation and orders affecting the delivery of health services required for the delivery of a cervical screening program to ensure compatibility with screening program operation.
- Design and implement the cervical screening registry:
  - Review and revise data collection by CNAM to include the data required for screening program management,
  - Review and revise data transfer mechanisms to meet the needs of the screening program.
- Increase PHC (family physicians and nurses) capacity for cervical screening:
  - Prepare a standard national cervical screening curriculum and certification criteria for PHC staff,
  - Review/revise/prepare clinical guidelines and SOPs for all cervical screening procedures conducted in PHC,
  - Review and revise facilities and equipment specifications,
  - Review/revise/define evidence-based performance indicators and standards,
  - Design and implement educational modules for university/college and CME programs,
  - Establish a PHC outreach training service for PHC staff in practice,
  - Design and implement a cervical screening CQI system for PHC.
- Increase cervical cytology laboratory capacity:
  - Undertake a full inventory of all cervical cytology screening laboratories,
  - Undertake external quality assessments of all cervical cytology screening laboratories,
  - Prepare nationally approved curriculum and certification criteria for cervical cytology screening,
  - Review laboratory specialist classifications and revise to include cervical cytology screening,
  - Prepare laboratory guidelines and SOPs for all cervical cytology laboratory procedures,
  - Review and revise facilities and equipment specifications,
  - Define evidence-based performance indicators and standards,
  - Review and revise the structure of the existing laboratory network based on the inventory, external quality assessments, new guidelines, SOPs and standards,
  - Design and implement a training facility for cervical cytology screening,
  - Design and implement a cervical cytology CQI system,
  - Undertake cost-benefit analyses of new technologies for cervical screening.
- Increase colposcopy and cervical surgery capacity:
  - Prepare a nationally approved curriculum and certification criteria for colposcopy,
  - Revise medical specialist classifications to include colposcopy as a defined medical speciality,
  - Prepare clinical guidelines and SOPs for all procedures undertaken in the colposcopy clinic,
  - Review and revise facilities and equipment specifications,
  - Define evidence-based performance indicators and standards,
  - Design and implement a training facility for colposcopy and cervical surgery,
  - Design and implement a colposcopy CQI system.

7.1 Support for the implementation of a cervical screening program

A number of Western European (WE) countries have developed very high-quality cervical screening programs and the ECCA has established relationships with several of these programs to share their expertise for the development of cervical screening in Eastern Europe. To accommodate the complexity of screening program implementation and the time required for these programs to become embedded within the health system, these partnerships have been designed as long-term collaborations that include:

- Training exchange visits to the WE cervical screening program where the trainees will work directly with the people who are responsible for the day-to-day delivery of the services,
- The provision of program documentation including screening policies, service specifications, clinical/laboratory guidelines and SOPs, facility and equipment specifications, training curricula and certification criteria, CQI system specifications, etc. together with help to adapt these documents for use in the trainee's home country,
- Visits by WE trainers to the trainee's country to review service delivery in practice and work with local experts to refine program implementation or operation,
- On-going trainer-trainee interaction with monitoring of service performance and further intervention as required to address issues as they arise.

RM could obtain substantial support for the establishment of a cervical screening program through these collaborations. However, a potential problem is the majority of cervical cytology in RM is processed using the Romanowski technique and its use for this purpose is largely restricted to the countries of the former Soviet Union. Elsewhere in the world, including Western Europe, the majority of cervical cytology is processed using the Papanicolaou technique. This is an important point as the 2 techniques use different processes and interpretations so laboratories specialised in one technique would not be able to effectively train cervical cytology screeners from laboratories using the other technique.

Therefore, RM would need to switch to the Papanicolaou technique to take full advantage of these partnerships with Western European cervical screening programs, while remaining with the Romanowski technique would restrict opportunities for laboratory technical training exchanges to countries of the former Soviet Union where most of the cervical cytology services are similar to or worse than the services in RM.

An additional consideration with switching to the Papanicolaou technique is the laboratory processing is completely different so costs would be incurred for the purchase of laboratory equipment and the renovation of facilities. However, these costs are not substantial and a proportion of these costs would be required for updating the laboratory network regardless of which technique is being used.

The implementation of a cervical screening program in RM will require staff training, equipment purchases, facility refurbishment and the creation of a cervical cytology training capacity to meet initial and on-going requirements, with a substantial part of this expenditure directly linked to the laboratory technique. Therefore, deciding to switch technique at a later date would require the re-training of laboratory staff together with the replacement of laboratory equipment and facility alterations to accommodate the new technique.

7.2 Cervical screening program administration

7.2.1 The screening coordination office

RM does not currently have an organization with the expertise, authority and mechanisms to coordinate the health services involved in cervical screening or to monitor women as they move through the program.

These duties are the responsibility of the Screening Coordination Office (SCO) and the establishment of the SCO is therefore a prerequisite to the implementation of a screening program in RM. The principal actions undertaken by the SCO are set out in Table 11.

Table 11: Screening Coordination Office activities

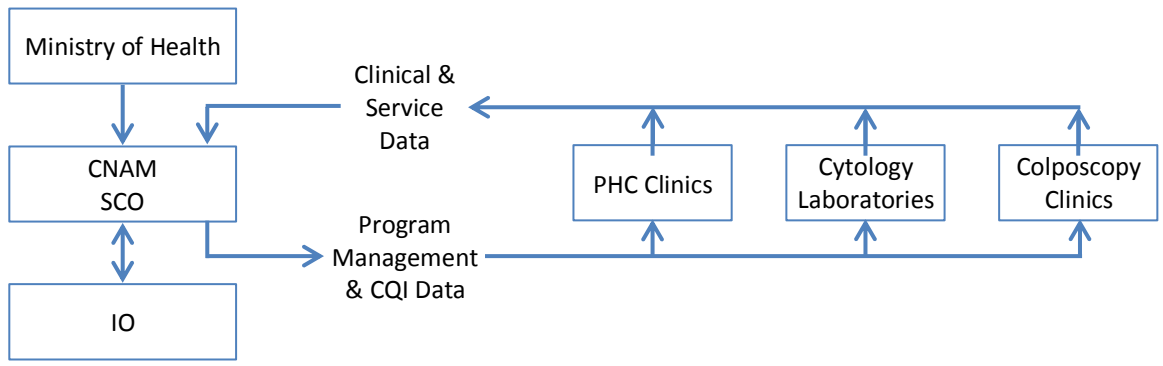
- Regularly review and update the cervical screening service specification and operational guidelines,
- Implement, operate and maintain the cervical screening registry,
- Send service providers the data they need to coordinate patient referrals and ensure referral compliance,
- Operate the CQI programs and intervene as required to continuously improve service quality,
- Work with the USMF and IO to coordinate CME programs so they effectively support the CQI process,
- Design and implement public educational programs to raise awareness of cervical cancer prevention and encourage screening program attendance,
- Undertake actions to identify under-screened/unscreened women and implement programs to increase attendance,
- Work with the Ministry of Health, CNAM, USMF and relevant professional groups to facilitate the regular review and updating of training standards, certification criteria, clinical guidelines and SOPs, performance indicators and standards for each of the services involved in the screening process,
- Regularly monitor and evaluate all aspects of screening program performance, and intervene as required,
- Prepare and publish reports on screening program performance for the MoH, CNAM and other interested organisations,
- Interact with other health services as required to ensure efficient program operation (i.e. cancer registry),
- Interact with other governmental departments and nongovernmental organisations as required to ensure intersectoral cooperation for cancer prevention (such as the Department of Education for the inclusion of cancer prevention in secondary school health curriculums).

As seen in Table 11, cervical screening program management is primarily an administrative exercise, although it still requires a thorough understanding of the clinical services that are required to deliver the program. In addition, the SCO requires a regular flow of data to and from all of the component health services (see Appendix 8) and therefore needs access to mechanisms for the secure transfer of these data. In RM, relevant expertise, responsibilities and facilities are split between 2 organisations:

- CNAM:
  - Responsible for contracting all public sector health services with contracts setting terms of service provision, performance indicators and performance-based payments,
  - Database of all people registered for health insurance (currently ≈80% of the population of RM[63]), including details required to establish eligibility for cervical screening,
  - Mechanisms for the collection and analysis of data from all contracted health institutions.
- Institute of Oncology:
  - Clinical expertise in cancer screening, treatment and palliative care,
  - Responsible for all cytology laboratories, including staff training and service quality,
  - Location of the largest cervical cytology screening laboratory in RM (≈65,000 Pap tests/year),
  - Location of the largest colposcopy clinic in RM (≈15,000 patients/year),
  - Location of the cancer registry.

Therefore, the functions of the SCO must also be shared between these 2 institutions with CNAM having responsibility for hosting the SCO, data transfers and facilitating screening program operation through the terms of health center contracts, while the IO would act in a consultative capacity to provide expertise as required for program operation (see Figure 5).

Figure 5: Organisational structure of the cervical screening program



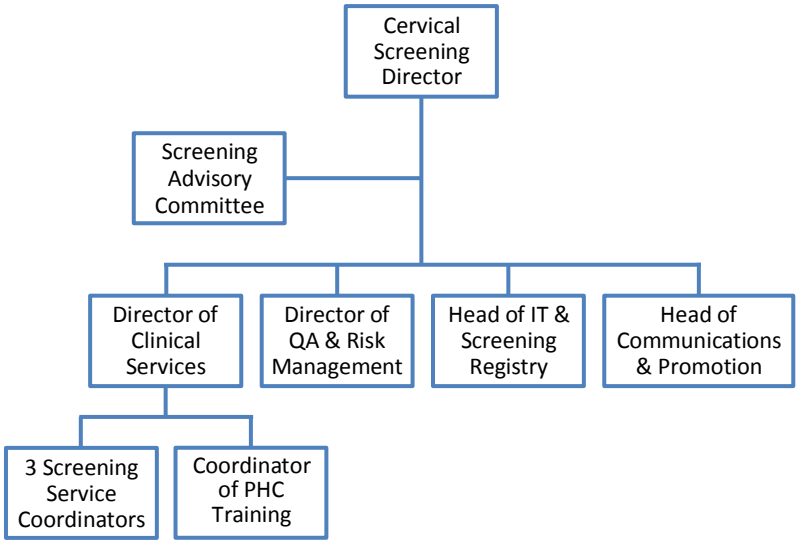
7.2.2 Screening coordination office staff

Effective management of a fully operational national organised cervical screening program in RM will require substantial human resources. However, many of these people will be employed by the health services involved in the delivery of the screening program rather than by the SCO, while staff employed directly by the SCO can be increased as the program is expanded.

In the short-term, the immediate need is for the appointment of the SCO core staff, starting with the Cervical Screening Director (CSD) who would then take responsibility for recruiting the other staff.

The principal staff positions and relationships are set out in Figure 6, with summary job descriptions and the key skills/qualifications set out below.

Figure 6: Screening Coordination Office staff organogram



7.2.2.1 Cervical Screening Director

The Cervical Screening Director is the person who will have overall responsibility for costs, service delivery and quality of the cervical screening program when operating and should therefore also have overall responsibility for the implementation of the program.

This position requires a medically qualified professional with clinical experience in some or all of the health services involved in cervical screening (PHC, cytology, colposcopy and cervical surgery, gynae-oncology) and the administration of a cancer screening service or similar public health program. This experience should be from RM as a detailed knowledge of the RM health system will be essential. In addition, fluency in English is required as the Cervical Screening Director will need to communicate with a wide range of organisations in WE to facilitate training exchanges.

7.2.2.2 Director of Clinical Services

The Director of Clinical Services will have overall responsibility for coordinating the clinical services involved in cervical screening (i.e. colposcopy and the clinical procedures conducted by PHC staff for the cervical screening program), and ensuring these services comply with the Cervical Cancer Prevention Policy, Cervical Screening CQI Policy and relevant international recommendations.

This position requires a medically qualified professional with training and clinical experience in colposcopy, together with a detailed knowledge of the provision of clinical services within the RM health system. In addition, fluency in English is required as the Director of Clinical Services will need to communicate with a wide range of organisations in WE to facilitate training exchanges.

7.2.2.3 Director of Quality and Risk Management

The Director of Quality and Risk Management will have overall responsibility for developing the cervical screening program QA/CQI policy and ensuring it is fully and continuously implemented at all levels of the program.

This position requires professional qualifications in health service quality and/or risk management together with experience in the quality management of health services in RM.

7.2.2.4 Head of IT and Screening Registry Management

The Head of IT and Screening Registry Management will have overall responsibility for the design, implementation and operation of the cervical screening registry and related IT systems.

This position will require specialist qualifications and experience in database design, operation and maintenance as well as the collection, verification and analysis of confidential personal health data.

7.2.2.5 Head of Communications and Cervical Screening Promotion

The Head of Communications and Cervical Screening Promotion will have overall responsibility for informing, educating and encouraging women to participate in the cervical screening program.

This position will require specialist qualifications in health communications and/or health psychology, together with a detailed knowledge of the factors that may influence screening recruitment in RM.

7.2.2.6 Coordinator of PHC Training

The Coordinator of PHC Training will be responsible for all CME training of PHC staff and will be involved in the development of the curriculum and certification criteria for family physician residency, nurse training and CME programs. In addition, this position will be responsible for managing the PHC outreach training service staff required to train the 7,190 PHC staff currently practicing in RM.

This position requires a good knowledge of PHC service delivery within the RM health system, obtained through a nurse training program with subsequent PHC clinical experience in both urban and rural settings. Good communications skills or teaching experience together with personnel management experience is also required.

7.2.2.7 Screening Service Coordinators

A cervical screening program requires the efficient coordination of 3 key services: PHC, cytology/ cytopathology and colposcopy. A Screening Service Coordinator is therefore required for each service to be their single point of contact with the screening program and to maintain regular communications with each service to identify and resolve performance issues as they arise.

Each of these positions requires a good knowledge of targeted service, obtained through nurse or laboratory technician training programs together with practical experience in the RM health system. Very good organisational, communications and problem solving skills are also required.

7.2.3 Advisory Committee

The cervical screening program requires the effective coordination of the component health services but this will not be possible unless the program can continuously adapt to the changing needs of each service. In addition, the cervical screening program requires high coverage of the target population and this will not be achieved unless the program effectively addresses the needs and concerns of these women. Therefore, an Advisory Committee should be established to facilitate communications with *and* between these stakeholders. The Advisory Committee should include representatives from:

- MoH
- CNAM
- National Center of Health Management
- National Center of Public Health
- National Council for Evaluation and Accreditation in Health
- IO
- USMF
- League of Doctors of RM
- Health Workers Trade Union 'Sanatatea'
- Assoc. of Gynaecologists of RM
- Assoc. of Pathologists of RM
- Assoc. of Family Physicians of RM
- Assoc. of Nurses of RM
- NGOs/CSOs representing health, women's health, cancer patients, etc.
- Development partners: WHO, UNFPA
- Representative(s) from an established cervical screening program in WE.

The Advisory Committee should be established by a Ministerial Order as an independent body that can provide objective advice on the operation of the cervical screening program and the Cervical Screening Director should attend every meeting to facilitate communications between the Committee and the program. The Advisory Committee should meet at least 4 times per year during the piloting and implementation of the cervical screening program, or more frequently if required.

7.2.4 Screening registry

Effective cervical screening program management requires the timely collection and analysis of data from all component services, together with prompt return of the information service providers need for patient management. The screening registry is the tool used to achieve this.

The screening registry should be located in CNAM as it already has established mechanisms for the collection of data from all contracted health care institutions together with the IT expertise that will be required for the development of the screening registry. However, the CNAM IT system was established primarily for monitoring contract compliance and calculating provider payments so much of the data required for screening program management is not currently collected and the software will need to be modified accordingly. The data, sources and analyses required for cervical screening program management, as recommended by the European Guidelines,[22] are set out in Appendix 10.

Model specifications for cervical screening registries (and possibly the associated software) can be obtained from Western European screening programs together with support for adaptation to RM.

7.3 Primary health care

7.3.1 PHC staff numbers

In keeping with other evaluations of RM PHC services, this assessment found that PHC staff shortages remain a problem, particularly in rural and remote communities. PHC staff recruitment is not part of this project, which instead focuses on increasing PHC screening capacity by ensuring all PHC staff have the skills required to effectively support the operation of the cervical screening program.

7.3.2 PHC staff training and certification

As noted in Section 5.5.3, PHC staff must have a good understanding of all aspects of the cervical screening process, but this information is not currently included in the training programs or CME materials for either family physicians or nurses. Therefore, family physician residency and CME programs, together with nurse training and CME programs need to be revised to include the full range of information required for these people to work effectively as members of the team that will deliver the cervical screening program (see Table 12).

Table 12: Educational modules for PHC staff

Modules
• The cervical screening process & the structure of cervical screening programs • Operating the cervical screening registry (submitting data, checking patient records, receiving results, etc.) • Patient reception, registration & data recording • Patient counselling, communications & stress management techniques • Patient confidentiality • History taking and assessment of individual cervical cancer risk • Routine vs high-risk cervical screening algorithms • Anatomy, physiology & pathology of the vulva, vagina and cervix • Clinical examination the vulva, vagina and cervix • Obtaining cervical samples, preparing microscope slides & laboratory submission pathways (theoretical) • Pap test results, interpretation, counselling, follow-up/referral criteria & colposcopy referral pathways • Colposcopy/biopsy results, interpretation, counselling, referral criteria & referral pathways for treatment • Performance indicators and CQI • Failsafe & audit procedures

Examples of training curricula with certification criteria can be obtained from Western European screening programs together with support for their adaptation to RM.

Because of the central role that PHC staff play in supporting the operation of the screening program and acting as the interface between the screening program and the public, PHC staff should be required to complete an accredited training course before they can participate in the program. However, the introduction of this requirement should be accompanied by incentives to motivate compliance such as additional payments, provision of IT equipment, facilities refurbishment, etc.

7.3.3 Outreach training for PHC staff in practice

Data from the RM National Center for Health Management for 2011 show there are 1,853 family physicians and 5,337 family practice nurses working in 1,328 clinics (37 x CMF; 263 x CS; 623 x OMF; 405 x OS) across RM. However, none of these people have received formal training about the operation of organised cancer screening programs or their role within these programs, so they will all need training to ensure they have the knowledge and skills to support effective program operation.

As the majority of PHC staff will have neither the time nor the money to travel to a distant center, the training must be delivered through an outreach service that uses a combination of online or print materials and classes conducted in regional centers. The training program can then be scheduled to remain one step ahead of the phased implementation of the screening program to ensure the PHC staff have access to the training that is required for them to participate.

Here it is worth noting that, once established, this outreach training service could be used to deliver many other training programs to PHC providers and can therefore contribute to the strengthening of the overall health system.

7.3.4 Regulatory changes

MHO № 695 of 13 October 2010 states only that family physicians and nurses are required to take Pap tests. This order should be changed so the full range of duties noted above are clearly specified among the responsibilities of PHC staff.

7.3.5 Evidence-based clinical guidelines and standard operating procedures for PHC

Evidence-based clinical guidelines and SOPs for each step in the screening process are essential to ensure each of the component services will produce the expected outcomes and are effectively integrated into the operation of overall screening program. Clinical guidelines and SOPs are also integral to the standard training curricula, certification criteria, performance standards and CQI processes. Clinical guidelines and SOPs relevant to cervical screening in PHC are set out in Table 13.

Table 13: Cervical screening clinical guidelines and SOPs relevant to PHC
• Service provider operation of the cervical screening registry • Counselling women about the benefits and drawback of cervical screening, • Assessment of cervical cancer risk and identification of women at increased risk, • Obtaining cervical samples, preparing the microscope slides and submitting them to the laboratory, • Pap test results, interpretation, counselling, follow-up/referral criteria and colposcopy referral pathways, • Colposcopy/biopsy results, interpretation, counselling, follow-up/referral criteria and treatment referral pathways.

Examples of clinical guidelines and SOPs can be obtained from Western European screening programs together with support for their adaptation to RM.

7.3.6 Facility and equipment specifications

As cervical screening targets healthy women with no pressing need to attend for screening, good quality facilities that provide women with a pleasant experience are essential for achieving recruitment targets. Therefore, the RM cervical screening Director of Clinical Services should work with the National Council for Evaluation and Accreditation in Health to review the specifications for PHC clinics and revise them if required to support the effective operation of the program.

7.4 Cervical cytology screening

7.4.1 Cervical cytology laboratory and staff numbers

The capacity assessment found that RM has ≈60.0% of the staff required to process the current number of Pap tests, with the majority of these people working alone in small laboratories that do not have the Pap test volume or staff numbers required to ensure the quality of these services.

Therefore, the first priority for cervical cytology in RM must be to objectively assess the existing laboratory network and implement any measures that are required to ensure the quality of these services is sufficient to deliver safe and cost-effective cervical screening. These actions include:

- Prepare an inventory of each laboratory to characterize the quantity and quality of their facilities, equipment and staffing levels relative to the number of Pap tests being processed,
- Conduct an external assessment of the quality of cytology services in each laboratory,

Then, the inventory data and external assessment outcomes can be used to:

- Prepare a plan for restructuring the laboratory network to have a smaller number of larger laboratories that each have the Pap test volume and staff numbers required to provide a high-quality service. In addition, this process will allow the laboratory network to be structured to accommodate the future introduction of new technologies such as liquid-based cytology, HPV testing, HPV vaccination, etc. and thereby facilitate their implementation as and when they are found to be cost-effective within the RM health system,
- Design and implement targeted training programs as required to improve the skills existing staff.

In parallel with the laboratory evaluations and staff training, measures should be taken to enforce compliance with the recommended screening age-range and interval to bring the number of Pap tests more into line with the current laboratory capacity, while simultaneously concentrating the existing resources on the women who will benefit most from cervical screening. The simplest way to achieve this is to restrict payments for PHC clinics and cytology laboratories to Pap tests taken from women who comply with the recommendations. This approach was used in Norway when they launched their organised cervical screening program and the volume of Pap tests declined by 35% within the first year. However, enforcing the screening age-range and interval must be accompanied by information to PHC staff explaining why these restrictions are required so they can provide clear advice to women in their catchment areas.

The number of Pap tests could be further reduced by restricting the screening age range to 30-59 years or by lengthening the screening interval to 3 years. However, once strict compliance with the age range and interval recommendations has been achieved, changing them in the future and achieving strict compliance with the new recommendations will be very difficult. Therefore, RM should just focus on ensuring the current recommendations are followed.

The actions outlined above will help to improve the quality of cervical cytology services in the short term but the number of cytotechnicians will still need to be increased in the longer-term. Based on the limit of 67 Pap tests/cyto-technician/day and the European Guidelines,[22] the estimated number of cytotechnicians and laboratories for different coverage levels is set out in Table 14.

Table 14: Estimated number of cytotechnicians & laboratories by level of population coverage

Coverage %	Est. № Pap Tests/Year	Min № Cytotechnicians	Max № Laboratories
35	198,512	14	4
45	255,229	17	5
55	311,947	21	6
65	368,665	25	7
75	425,382	29	8

However, these estimates for the number of cytotechnicians are based on the recommended *minimum* numbers for a program with well-trained and experienced staff, working in well-resourced laboratories that have clearly defined laboratory and administrative procedures. Therefore, until the laboratories in RM reach a similar position, the number of staff required will be considerably higher.

Further, the estimates for the number of laboratories are maximums so a smaller number of larger laboratories would still comply with the recommendations. In this regard, concentrating cervical cytology services into 3-4 laboratories would simplify CQI, provide economies of scale and facilitate the introduction of new technologies. However, decisions about the number of laboratories also need to consider the effect of specimen transport on reporting times, clinician-laboratory interaction and security of supply if unforeseen events force the closure of one or more laboratories.

7.4.2 Training and certification for cervical cytology screening

Because cervical cytology screening relies on the subjective assessments of the cytotechnicians, comprehensive initial training together with CME and strict CQI are essential to achieving and maintaining a safe and cost-effective service. Therefore, in addition to the priority actions listed above, the implementation of a cervical screening program in RM will require:

- Preparation of a cervical cytology screening training curriculum with certification criteria,
- Designation of cervical cytology screening as a distinct laboratory specialty with a defined training curriculum and certification criteria together with CME and re-certification requirements,
- Design and implementation of a comprehensive cervical cytology CQI program,
- Establishment of a cervical cytology screening training facility that will:
  - Train new cytotechnicians to meet the needs of the screening program as it expands and the on-going needs of the program as people retire, change jobs, etc.
  - Run CME courses to update and maintain the skills of the existing workforce,
  - Support the cervical cytology CQI program with targeted training interventions.

In RM, the USFM has responsibility for medical training curricula and examination/certification criteria, while the IO has responsibility for cervical cytology services, including staff training and service quality. The IO also has the largest cervical cytology screening laboratory (≈65,000 Pap tests/year) and the greatest concentration of cytology expertise. Therefore, a cervical cytology screening training facility should be established as a partnership of these institutions with the USFM responsible for the curriculum and certification, and the IO responsible for delivering the program.

If RM changes to the Papanicolaou technique, a partnership could be established between the USFM, IO and a foreign cervical cytology screening training facility as described in Section 7.1. Language differences could be a problem with foreign training exchanges but should be manageable as much of the training focuses on visual recognition while communication could be facilitated by selecting one or more bilingual trainees who can interpret for the group.

7.4.3 Designating cervical cytology screening as a distinct laboratory specialty

The quality of the cervical cytology service will directly influence the safety and cost-effectiveness of the screening program so it is essential to ensure all staff have the required training and skills. Therefore, cervical cytology screening should be designated as a distinct laboratory speciality with a defined curriculum, CME requirements, certification/recertification criteria and certification being mandatory to work in the field. Doing this would not only ensure the quality of cervical cytology services in RM, but also increase the credibility of these services in the eyes of the public, thereby helping to attract people to work in this field and facilitate the recruitment of women to be screened.

7.4.4 Evidence-based laboratory guidelines and standard operating procedures

Evidence-based laboratory guidelines and SOPs for each step in the processing and analysis of Pap tests are essential to ensure these services produce the expected outcomes and are effectively integrated into the operation of the screening program. Laboratory guidelines and SOPs are also integral to the standard training curricula, certification criteria, performance standards and CQI processes. The laboratory guidelines and SOPs relevant to cervical cytology screening, cytopathology and histopathology are set out in Table 15.

Table 15: Cervical cytology, cytopathology and histopathology laboratory guidelines and SOPs
• Sample receipt and laboratory processing of cervical cytology, • Service provider operation of the cervical screening registry • Primary screening of cervical cytology, • Diagnosis of the cytological abnormalities identified in screening, • CQI of cervical cytology, • Sample receipt and laboratory processing of cervical biopsy specimens • Evaluation of cervical biopsy specimens • Clinico-Pathological Correlation (CPC)/Multidisciplinary Team (MDT) Meeting Guidelines.

Examples of clinical guidelines and SOPs can be obtained from Western European screening programs together with support for their adaptation to RM. However, this should be coordinated

with the cytology training described in Section 7.4.2 so the techniques and procedures taught to the trainees will be the same as the ones that will be adapted for use in RM.

7.4.5 Laboratory facility and equipment specifications

The laboratory environment and equipment are also important factors influencing the quality of cervical cytology screening. Therefore, the RM National Council for Evaluation and Accreditation in Health should be supported to review the facility and equipment requirements for cytology laboratories and revise them if required to comply with the European Guidelines.[22]

7.4.6 Cost benefit analyses of new technologies

As noted in Section 4.2.3, new technologies such as LBC and hrHPV testing could provide substantial benefits for cervical screening in RM but there are currently insufficient data to conduct the required cost-benefit analyses. Therefore, the initial phase of screening program implementation should use the conventional Pap test but include these cost benefit comparisons with the outcomes used to make decisions about the inclusion of LBC and/or hrHPV testing in subsequent phases.

7.5 Colposcopy

7.5.1 Colposcopy clinic and staff numbers

Currently, 23 clinics offer colposcopy for the follow-up of abnormal Pap tests and 17 clinics offer treatment for CIN. In addition, data for 2011 indicate there were 562 gynaecologists registered in RM. However, in common with most Eastern European countries, RM does not recognise colposcopy as a distinct medical speciality so there is a limited number of colposcopists (≈ 5) who are self-trained or obtained specialist training outside RM, and most of them are based in Chisinau.

Estimates of the colposcopy clinic and staff requirements for a cervical screening program in RM can be based on the guidelines prepared by the English National Health Service and the British Society for Colposcopy and Cervical Pathology (BSCCP) regarding the practice of colposcopy (see Table 16).[65,66] Using these recommended timings and a mix of appointment types, each colposcopy clinic should be able to accommodate ≤18 colposcopies per day (2 sessions of 3-3.5 hours per day with 9 colposcopies per session) or ≈3,960 colposcopies per clinic based on 220 working days per year (see Table 17).

Table 16: BSCCP colposcopy recommendations

Colposcopy clinic facilities	• A private area with changing facilities, • Toilet facilities specific for the clinic, • A room specifically for colposcopy procedures, • A recovery area that is separate from the waiting room.
Colposcopy clinic staff	• A designated colposcopy clinical lead, • A second colposcopist, • 2 nurses: – 1 registered nurse (RN) with training in colposcopy procedures and patient counselling and who is without other outpatient duties, – 1 nurse for support of the patient • 1 clinical assistant who is present in the colposcopy room throughout every procedure (can be the RN noted above) • Adequate clerical support for the effective operation of the clinic.
Minimum appointment times	• New referral: 20 min • New high-grade referral: 30 min • Return for treatment: 20 min • Follow-up examination: 10 min

However, colposcopy referral is based on cervical cytology results and the distribution of results in RM is likely to change once the training and CQI programs have been implemented. Therefore, these estimates have been based on data from the Irish National Cervical Screening Program that was launched in September 2008 so the statistics come from a relatively unscreened population that will be more representative of RM during the early years of program implementation:

- A 1st colposcopy referral rate of 8.5%,
- A 72.5% uptake of colposcopy,
- Each 1st referral will generate an average of 1.7 follow-up colposcopy appointments,
- Each colposcopy clinic will be open for 220 days/year and conduct 3,960 colposcopies/year,
- Each colposcopy clinic will be staffed by 2 colposcopists, 2 nurses and 1 administrator.

Table 17: Estimated number of colposcopy clinics &staff by level of population coverage									
Coverage (%)	People Screened	1st Referrals	Follow-Up Appts.	Total Appts.	Colposcopy Clinics	Colpo-scopists	Registered Nurses	Other Nurses	Admin Staff
35	198,512	16,874	28,685	33,030	8	17	8	8	8
45	255,229	21,694	36,881	42,467	11	21	11	11	11
55	311,947	26,515	45,076	51,904	13	26	13	13	13
65	368,665	31,337	53,272	61,341	15	31	15	15	15
75	425,382	36,157	61,468	70,778	18	36	18	18	18

In considering the estimates presented above, it is very important to remember they are based on the recommended *minimum* numbers for a program with well trained and experienced staff working in well-resourced clinics that have clearly defined clinical and administrative procedures. Therefore, until RM reaches a similar state, the number of colposcopies/clinic/ day will be considerably lower so the number of clinics and staff required will be considerably higher. On this basis, RM should plan to develop the colposcopy capacity required for 75% coverage as quickly as possible so all women requiring follow-up during the early years of program implementation can be quickly seen without overburdening the newly trained colposcopists. Then, colposcopy capacity will progressively increase as the clinicians gain experience and this should accommodate the increased demand that will accompany the rollout of the screening program.

The implementation of a cervical screening program in RM will therefore require the:

- Preparation of a colposcopy training curriculum with certification criteria,
- Designation of colposcopy as a distinct medical specialty with a defined curriculum, CME requirements and certification/re-certification criteria,
- Design and implementation of a comprehensive colposcopy CQI system,
- Establishment of a colposcopy training facility that will:
  - Train new colposcopists to meet the needs of the screening program as it expands as well as the on-going needs of the program as clinicians retire, etc.
  - Run CME courses to maintain workforce skills,
  - Participate in the colposcopy CQI program by undertaking targeted training interventions to resolve quality issues that are related to staff skills.

7.5.2 Colposcopy training and certification

7.5.2.1 Colposcopy specialists

Primary responsibility for colposcopy training and certification in RM would be with the USFM, although the IO has the largest colposcopy clinic (≈15,000 patients/year) and the greatest concentration of colposcopy expertise. Therefore, a colposcopy training program would need to be established as a partnership of these 2 institutions with the USFM responsible for the curriculum, theoretical training and certification, while the IO would be responsible for the clinical training.

RM can access substantial colposcopy expertise through partnerships with Western European organisations and the British Society of Colposcopy and Cervical Pathology (BSCCP) has developed exceptional training programs for both the practice as well as the teaching of colposcopy. However, the clinical component of these programs would only be available to RM gynaecologists who also hold a passport from Romania or another EU country. As this is unlikely to be a problem, a collaboration should be established between the USFM, the IO and the BSCCP. As the theoretical training is conducted in groups and much of the clinical training would be restricted to 1 trainee with the instructor, it would not be feasible to have one member of the group translate for the others. Therefore, the trainees will need to have a good knowledge of English.

7.5.2.2 Colposcopy nursing staff

As noted in Section 7.5.1, nursing staff are essential to the smooth running of colposcopy clinics and the cost-effective use of the colposcopists' time. The BSCCP recommends that each colposcopy clinic should have ≥2 nurses with one of these being a registered nurse who has also undertaken training in both colposcopy procedures and patient counselling.

The shortage of colposcopy capacity in RM creates a substantial barrier to the implementation of a cervical screening program. Therefore, introducing a training program that provides nurses with the skills to effectively support colposcopists in the clinic would help to overcome this barrier by increasing the number of patients each colposcopist could see per clinic session. The development of this training program could be included within the partnership described in Section 7.5.2.1.

7.5.3 Designating colposcopy as a distinct medical specialty

The quality of colposcopy will directly influence the safety and cost-effectiveness of the screening program so it is essential to ensure all colposcopists have the required training and skills. Therefore, colposcopy should be designated as a distinct medical speciality with a defined curriculum, CME requirements, and certification/recertification criteria, and with certification being mandatory to work in the field. In parallel with this, the RM MoH should officially recognise BSCCP certification as equivalent to national certification so people trained in the UK will not need to be recertified in RM.

7.5.4 Evidence-based clinical guidelines and standard operating procedures

Evidence-based clinical guidelines and SOPs for each step in the colposcopic evaluation and treatment are essential to ensure these services achieve the expected outcomes and are effectively integrated into the operation of screening program. Clinical guidelines and SOPs are also integral to the standard training curricula, certification criteria, performance standards and CQI processes. The clinical guidelines and SOPs relevant to colposcopy are set out in Table 18.

Table 18: Colposcopy clinical guidelines and SOPs
• Counselling women about abnormal Pap tests and colposcopy procedures,
• Service provider operation of the cervical screening registry
• Colposcopic evaluation of the cervix
• Colposcopically directed cervical biopsy
• Treatment of CIN: surgical techniques including cryocautery and excision
• Treatment of recurrent CIN
• Follow-up after colposcopy: duration, frequency, follow-up cytology
• Management of glandular abnormalities
• Clinico-Pathological Correlation (CPC)/Multidisciplinary Team (MDT) Meeting Guidelines,
• CQI for colposcopy.

The development of clinical guidelines and SOPs for RM can also draw upon work done in other countries. However, this should be coordinated with the colposcopy training described in Section 7.5.2 so the techniques and procedures taught to the trainees will be the same as the ones that will be adapted for use in RM.

7.5.5 Colposcopy facility and equipment specifications

As colposcopy has not been classified as a speciality in RM, the facility and equipment specifications relating to the provision of colposcopy services will not reflect the revised clinical guidelines, SOPs and performance standards recommended above. Therefore, the RM cervical screening Director of Clinical Services should work with the National Council for Evaluation and Accreditation in Health to review these specifications and adapt them to comply with revised procedures.

7.6 Evidence-based performance indicators and standards

Performance indicators and standards for many health services in RM have already been established. However, because there are no organised cancer screening programs in RM, these indicators and standards do not include key aspects of 'program performance' that are required to optimise safety, quality and cost-effectiveness. Therefore, the RM cervical screening Director of Clinical Services should work with the Council for Evaluation and Accreditation in Health to review and revise relevant indicators and standards. The cervical screening performance indicators and standards recommended in the European Guidelines are presented in Appendix 11.

8. Actions for Implementing an Organised Cervical Screening Program

8.1 Establish the Cervical Screening Coordination office

Actions	Time-Frame	Lead	Partners
Prepare CSO budget & obtain approval.	Yr 1 : Mo 1	CNAM	
Obtain authorisation to hire SCO core staff.			
Prepare job descriptions for the core SCO staff: • Cervical Screening Director (CSD), • Director of Clinical Services (DCS), • Director of Quality & Risk Management (DQA), • Head of IT & Screening Registry Management (H-IT), • Head of Communications & Cervical Screening Promotion (H-Comm) • Coordinator of PHC training (C-PHC).	Yr 1 : Mo 1	CNAM	IO ECCA
Recruit SCO core staff.	Yr 1 : Mo 2-6	CNAM	

8.2 Establish relationships for training exchange programs

Actions	Time-Frame	Lead	Partners
Organise RM government delegation visit to the principal partner country: • 2 senior Members of Parliament, • Minister of Health, • Ministerial Clinical Specialists • Director General CNAM, • Director, Institute of Oncology, • CSD.	Yr 1 : Mo 1-6	MoH	CNAM IO CSD ECCA
Undertake government visit to the principal partner country	Yr 1 : Mo 6		

8.3 Initiate training exchange visits for SCO core staff

Actions	Time-Frame	Lead	Partners
Organise initial training exchange visits to the cervical screening program in the principal partner country where the SCO core staff can work directly with their counterparts in the WE screening program: • Cervical Screening Director (CSD), • Director of Clinical Services (DCS), • Director of Quality & Risk Management (DQA), • Head of IT & Screening Registry Management (H-IT), • Head of Communications & Cervical Screening Promotion (H-Comm) • Coordinator of PHC training (C-PHC).	Yr 1 : Mo 1-6	CSD	ECCA
Undertake training exchange visits	Yr 1 : Mo 6-9	CSD	ECCA

8.4 Establish the National Advisory Committee

Actions	Time-Frame	Lead	Partners
Prepare terms of reference for the cervical screening program Advisory Committee.	Yr 1 : Mo 1-2	MoH	CNAM IO
Obtain Ministerial Order to establish the Advisory Committee.	Yr 1 : Mo 1-2		
Appoint Advisory Committee members.	Yr 1 : Mo 2-6		
Convene quarterly meetings of the Advisory Committee during the planning and piloting of the cervical screening program.	Yr 1 : Mo 6,9,12 Yr 2 : Mo 3,6,9,12 Yr 3 : Mo 3,6,9,12	MoH	CNAM IO CSD
Convene biannual meetings of the Advisory Committee during the implementation of the cervical screening program.	Yr 4 : Mo 6,12 Yr 5 : Mo 6,12 Yr 6 : Mo 6,12 Yr 7 : Mo 6,12 Yr 8 : Mo 6,12	MoH	CNAM IO CSD

8.5 Maintain the involvement of the stakeholder group

Actions	Time-Frame	Lead	Partners
Monitor activity within the health sector to identify additional organisations with an interest in cervical screening and recruit to the stakeholder group.	Continuous	CSD	Advisory Committee
Deliver all cervical screening program reports to the members of the stakeholder group.	Continuous	CSD	
Convene annual meetings of the stakeholder group for years 1-5 (and continue if requested)	Yr 1 : Mo 12 Yr 2 : Mo 12 Yr 3 : Mo 12 Yr 4 : Mo 12 Yr 5 : Mo 12	CSD	ECCA

8.6 Prepare & publish policy documents

Actions	Time-Frame	Lead	Partners
Identify & obtain examples of Cervical Cancer Prevention & Cervical Screening CQI policies from training exchange partner countries.	Yr 1 : Mo 1-6	CSD	DCS DQA ECCA
Convene the first AC meeting to: • Review the current situation with cervical cancer & its prevention in RM • Review the options for prevention & assess compatibility with: – Existing capacities – Health sector development plans • Discuss & agree the key elements of the RM Cervical Cancer Prevention & Cervical Screening CQI policies, • Prepare drafts RM policies & submit to the AC for amendment or approval, • Submit the final version to the MoH for approval.	Yr 1 : Mo 6	MoH	
Review existing National policy documents relating to any aspect of cervical cancer prevention & amend or repeal as required to ensure consistency with the RM Cervical Cancer Prevention & CQI policies.	Yr 1 : Mo 6-12	CSD	

8.7 Implement the cervical screening registry

Actions	Time-Frame	Lead	Partners
Work with WE partners to obtain copies of their cervical screening registry specifications & adapt these to RM for the preparation of the specification for the RM cervical screening registry together with the related IT systems.	Yr 1 : Mo 6	H-IT	National Center for Health Management CNAM-IT WE Partner
Review legislation, regulations & guidelines relating to the: • Electronic collection, storage & transfer of personal medical information, • Service provider requirements for the collection, recording and/or reporting of the data required for the operation of the cervical screening program. Identify any barriers to the effective operation of the screening registry & propose revisions as required.	Yr 1 : Mo 6-12	H-IT	National Center for Health Management CNAM-IT
Develop a survey tool to assess: • Service provider IT requirements, • Service provider training requirements to ensure effective utilisation of the screening registry. To be combined with surveys of service provider knowledge & awareness of organised cervical screening program operation & CQI.	Yr 1 : Mo 6	H-IT	CNAM-IT WE partner
Undertake survey of service providers and analyse the results	Yr 1 : Mo 6-8	H-IT	CNAM-IT WE partner
Identify other health sector IT projects, assess compatibility/complementarity with the screening registry project & negotiate partnerships if appropriate.	Yr 1 : Mo 6-12	H-IT	MoH CNAM-IT
Prepare the cervical screening registry implementation budget & obtain approval.	Yr 1 : Mo 10-12	H-IT	CNAM-IT WE partner
Prepare a plan for the phased rollout of the cervical screening registry. To be coordinated with the phased rollout of the PHC training service as well as the development of the cytology laboratories & colposcopy services.	Yr 1 : Mo 10-12	H-IT	CNAM-IT WE partner
Together with the C-PHC, prepare a training module to teach service providers about the operation of the screening registry to be included in the PHC outreach training service.	Yr 1 : Mo 10-12	H-IT C-PHC	WE partner
Implement the required modifications to the CNAM database, develop the SCO interface to perform the required operations & establish connections with the cancer registry as well as the death registry.	Yr 1 : Mo 10-12	CNAM-IT	H-IT
Initiate phase 1 of the screening registry roll-out in 2 rayons to: • Test & refine the screening registry IT systems • Evaluate service provider registry training program & modify as required. To be coordinated with the phased rollout of PHC training as well as the development of the cytology laboratories & colposcopy services.	Yrs 2 - 3	H-IT	CNAM-IT WE partner
Undertake quarterly progress reviews of phase 1 and revise the plan as required.	Yr 2 : Mo 3,6,9,12 Yr 3 : Mo 3,6,9,12		
Continue subsequent phases of the rollout of the cervical screening registry as part of the overall rollout of the cervical screening program with quarterly reporting to the CSD.	Yrs 4 - 8	H-IT	CSD CNAM-IT WE partner
Undertake 6 monthly progress reviews of the cervical screening registry rollout. To be combined with meetings of the Advisory Committee.	Yr 4 : Mo 6,12 Yr 5 : Mo 6,12 Yr 6 : Mo 6,12 Yr 7 : Mo 6,12 Yr 8 : Mo 6,12	H-IT	

8.8 Increase PHC capacity for cervical screening

Actions	Time-Frame	Lead	Partners
Establish a training exchange partnership with a cervical screening program in WE.	Yr 1 : Mo 1-6	CSD	ECCA
Work with the WE partner to obtain copies of documents relating to the provision of cervical screening services in PHC, & to adapt these to RM for the preparation of: • PHC clinical guidelines & SOPs for screening procedures, • PHC screening performance indicators & standards, • PHC facilities & equipment specifications, • PHC screening CQI policy & specification, • Service specification for cervical screening procedures conducted in PHC.	Yr 1 : Mo 6-9	DCS	MoH PHC Dept. NCEAH CNAM USMF Assoc. Fam-Phys Assoc. Nurses WE partner
Based on the adapted PHC screening CQI policy & specification, design & implement the PHC screening CQI program. To be coordinated with the development of the screening registry to ensure the required data are collected & analyses are performed.	Yr 1 : Mo 8-12	DQA	DCS H-IT WE partner
Review legislation & regulations relating to the delivery of cervical screening procedures by PHC staff, identify any barriers to the effective operation of the screening program & propose revisions as required.	Yr 1 : Mo 8-12	MoH Primary Care Dept.	DCS
Review CNAM contract conditions for PHC facilities & revise to comply with the new facilities, equipment & service specifications.	Yr 1 : Mo 8-12	DCS	CNAM
Review methodological norms for PHC providers under CNAM contract & revise to comply with new guidelines, SOPs, performance indicators, etc.			
Develop a survey tool to assess service provider knowledge & awareness about the operation of organised cervical screening programs. To be combined with surveys of service provider IT & training requirements.	Yr 1 : Mo 6	C-PHC	Assoc. Fam-Phys Assoc. Nurses WE partner
Undertake survey of service providers and analyse the results	Yr 1 : Mo 6-9		
Identify other health sector development projects, assess compatibility/complementarity with the PHC training & negotiate partnerships if appropriate.	Yr 1 : Mo 6-12	C-PHC	MoH PHC Dept. Assoc. Fam-Phys Assoc. Nurses
The C-PHC will visit the WE partner country to • Undertake their PHC training program, • Adapt their PHC training curriculum & educational materials to RM.	Yr 1 : Mo 6-7	C-PHC	CSD ECCA
Based on the adapted PHC training documents, the training exchange visit, the revised PHC clinical guidelines, SOPs, indicators & standards, & the survey results, define the structure, content, teaching methods, educational materials, evaluation & certification procedures for: • The family physician residency & nurse training programs, • The PHC outreach training service.	Yr 1 : Mo 7-8	C-PHC	MoH PHC Dept. USMF DCS Assoc. Fam-Phys Assoc. Nurses WE partner
Design & produce the educational materials for the training of PHC staff including printed materials, teaching models, presentations, web-based distance-learning modules, etc.	Yr 1 : Mo 8-9	C-PHC	USMF Assoc. Fam-Phys Assoc. Nurses WE partner
Prepare the PHC training budget & obtain approval.	Yr 1 : Mo 10-12	C-PHC	CNAM
Work with the USMF & nursing college to implement cervical screening training modules into their programs.	Yr 1 : Mo 10	C-PHC	USMF Nursing College
Prepare job descriptions for the PHC outreach training service staff & undertake recruitment.	Yr 1 : Mo 10	C-PHC	CSD CNAM
Train the outreach training service staff.	Yr 1 : Mo 10-12	C-PHC	
Introduce measures requiring PHC staff to complete the training course as a prerequisite to participating in the cervical screening program. To be coordinated with the pilot projects & the cervical screening program rollout.	Yr 1 : Mo 10-12	MoH	CNAM
Initiate phase 1 of the rollout of the PHC outreach training service in 2 rayons to evaluate the training program & modify as required. To be coordinated with the rollout of the screening registry as well as the development of the cytology laboratories & colposcopy services.	Yrs 2 - 3	C-PHC	DCS Assoc. Fam-Phys Assoc. Nurses WE partner
Undertake quarterly progress reviews of phase 1 & revise plans as required.	Yr 2 : Mo 3,6,9,12 Yr 3 : Mo 3,6,9,12	C-PHC	CSD DCS
Continue the phased rollout of the PHC outreach training service so the training & certification of PHC staff is coordinated with the screening program rollout & development of cytology & colposcopy services.	Yrs 4 - 8	C-PHC	CSD DCS
Undertake 6 monthly progress reviews of the PHC outreach training service. To be combined with meetings of the Advisory Committee.	Yr 4 : Mo 6,12 Yr 5 : Mo 6,12 Yr 6 : Mo 6,12 Yr 7 : Mo 6,12 Yr 8 : Mo 6,12	C-PHC	

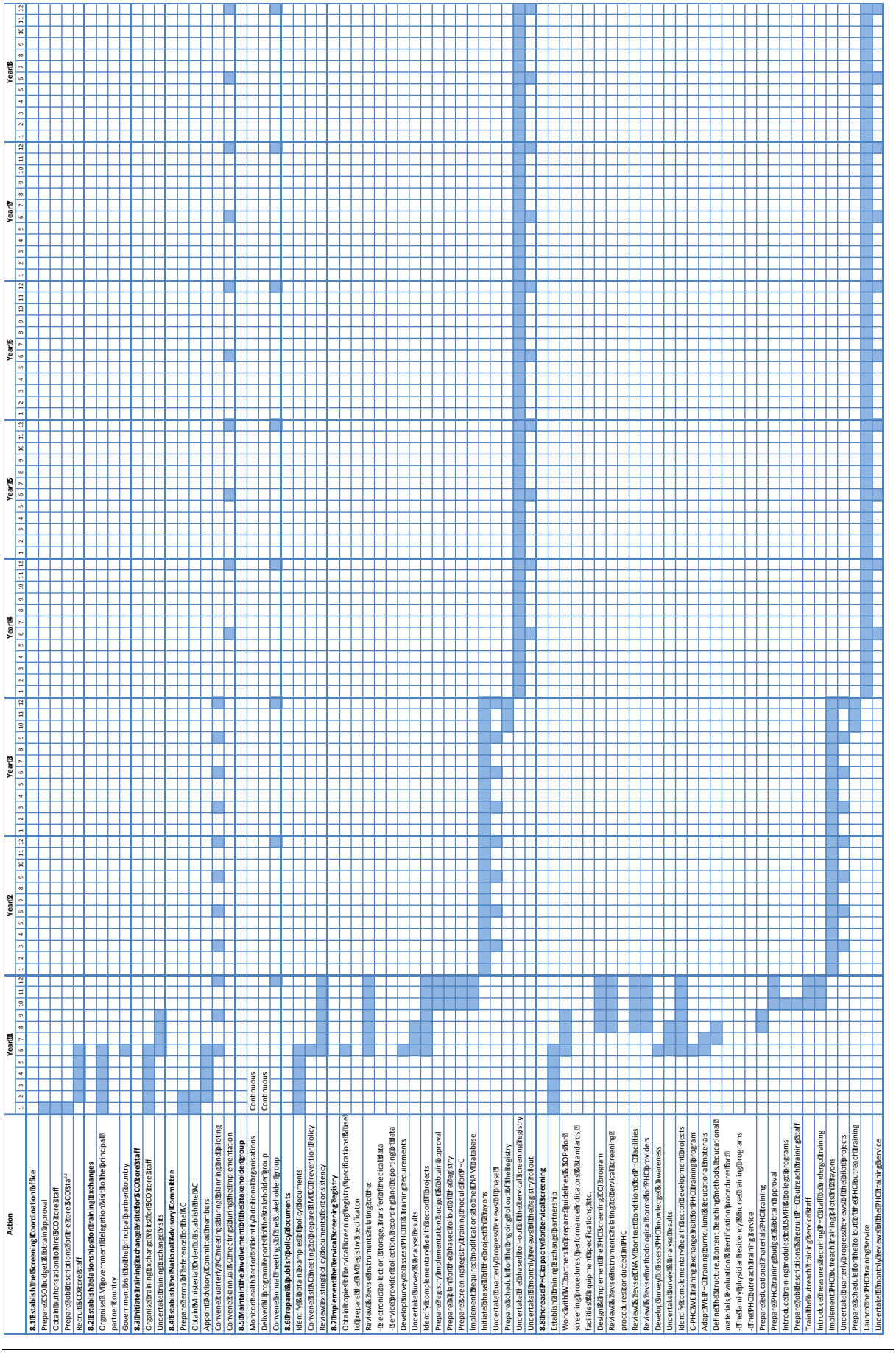
8.9 Increase cervical cytology & cytopathology capacity

Actions	Time-Frame	Lead	Partners
Introduce measures to ensure compliance with the recommended cervical screening age range & screening interval to reduce the volume of Pap testing.	Yr 1 : Mo 1-6	MoH CNAM	
Prepare inventory of each laboratory to characterize the quantity & quality of the facilities & equipment as well as staff number, qualifications & ages.	Yr 1 : Mo 6-9	IO	MoH Path Comm. CSD
Establish training exchange partnerships with a cervical screening program in WE.	Yr 1 : Mo 1-6	IO USMF	CSD ECCA
Work with the WE partner to undertake an external quality review of each cervical cytology laboratory	Yr 1 : Mo 6-9	IO	CSD WE partner
Work with WE partners to obtain copies of documents for the provision of gynae cytology, cytopathology & histopathology & adapt these to RM for the: • Cervical cytology & gynae pathology laboratory guidelines & SOPs, • Cervical cytology & gynae pathology performance indicators & standards, • Cervical cytology & gynae pathology CQI policy & specification, • Cervical cytology & gynae pathology facilities & equipment specification, • Service specification for cervical cytology & gynae pathology, • CPC/MDT Meeting Guidelines.	Yr 1 : Mo 6-9	IO	MoH-Path Comm. NCEAH Assoc. of Pathologists CSD ECCA WE partner
Based on the adapted cervical cytology & gynae pathology CQI policies & specifications, design & implement the RM cervical cytology & gynae pathology CQI programs. To be coordinated with the development of the screening registry to ensure the required data are collected.	Yr 1 : Mo 8-12	DQA	DCS H-IT WE partner
Review legislation, regulations guidelines relating to the delivery of cervical cytology & gynae pathology, identify any barriers to the effective operation of the screening program & propose revisions as required.	Yr 1 : Mo 8-12		
Based on these documents & the inventory results, prepare a plan & budget for the reorganisation of the RM cervical cytology service & obtain approval.	Yr 1 : Mo 10-12	IO	CSD CNAM
Work with a WE partner to create a RM nucleus of expertise in cervical cytology screening & cytopathology using the Papanicolaou technique: • A WE cytopathologist will visit RM to review the provision of cervical cytology & work with RM experts to prepare plans for: – The phased introduction of the Papanicolaou technique, – Converting the IO cervical cytology laboratory to the Papanicolaou technique with a capacity of 100,000 Pap tests/year, – Establishing a cervical cytology training facility within the IO laboratory, • While work is being done on the IO laboratory, 2 cytopathologists & 7 cytotechnicians will go to the WE partner country to: – Be trained in Papanicolaou cytopathology & cervical cytology screening, – Adapt the WE training curricula & certification criteria to RM, – 1 of the RM trainees will receive additional training in cytology CQI, – 1 of the RM trainees will receive additional training in managing cervical cytology laboratories as part of an organised cervical screening program. • The WE cytopathologist will travel to RM together with the RM trainees to: – Provide support with introducing the Papanicolaou technique & CQI, – Monitor the quality of services during the initial phase of operation. • The WE cytopathologist will travel home but maintain contact with the RM staff to monitor performance indicators & intervene as required. • The WE cytopathologist will travel to RM to support the RM staff in conducting a full quality review of the IO laboratory. This will service both to assess service quality & to reinforce the skills of the RM staff.	Yr 1 : Mo 6-12	IO USMF	CSD ECCA WE partner
Work with the WE partner to establish a cervical cytology screening training facility in the IO: • RM trainees will work with the WE trainers to adapt their training program & teaching materials to RM, • Once the Papanicolaou technique has become routine in the IO laboratory, the WE cytopathologist will travel to RM to support the staff: – Running the first RM cytology training session using Papanicolaou staining, – Reviewing & revising the cervical cytology screening training program.	Yr 1 : Mo 6-12	IO USMF	CSD ECCA WE partner
Prepare schedule for the training & certification of cytotechnicians. To be coordinated with the plan for reorganisation of cervical cytology services in RM, the implementation of the cervical screening pilots & the phased rollout of the cervical screening program.	Yr 1 : Mo 11-12	IO USMF	CSD
Work with the WE partner to plan and implement cost-benefit analyses of new technologies, evaluate results & revise implementation plans as required.	Yr 2 : Mo 1-12 Yr 3 : Mo 1-8		
Review & revise relevant instruments to designate cervical cytology screening as a distinct laboratory specialty with a defined training curriculum & certification criteria together with CME & re-certification requirements.	Yr 1 : Mo 11-12 Yr 2 : Mo 1-2	MoH CNAM	CSD
Launch the cervical cytology screening training program with: • Biannual reporting to the IO & CSD, • Periodic progress reviews & modification of the program and/or schedule.	Ongoing as required	IO USMF	CSD CNAM
Work with the WE partner to establish a cervical cytopathology training facility in the IO: • RM cytopathologists will work with the WE partners to adapt their cytopathology training program & teaching materials to RM, • The WE cytopathologist will travel to RM to: – Support the RM cytopathologists to run the first cervical cytopathology training session based on the Papanicolaou technique & evaluate trainees, – To participate in a CPC/MDT with the colposcopy service.	Yr 1 : Mo 7-12	IO USMF	CSD ECCA WE partner

8.10 Increase colposcopy capacity

Actions	Time-Frame	Lead	Partners
Prepare an inventory of each colposcopy facility to characterize the quantity & quality of their facilities & equipment as well as staff number, qualifications & ages (gynaecologists, nurses & admin).	Yr 1 : Mo 6-9	MoH CNAM	DCS
Establish a training exchange partnership with a cervical screening program in WE.	Yr 1 : Mo 1-6	IO USMF	CSD DCS ECCA WE partner
Work with the WE partner to obtain copies of documents relating to the provision of colposcopy services & adapt these documents to RM for the preparation of: • Colposcopy clinical guidelines & SOPs, • Colposcopy facility & equipment specifications, • Colposcopy performance indicators & standards, • Colposcopy service specification, • Colposcopy CQI policy & specification, • CPC/MDT Meeting Guidelines.	Yr 1 : Mo 6-9	DCS	ECCA WE partner
Based on the adapted colposcopy CQI policy & specification, design & implement the RM colposcopy CQI program. To be coordinated with the development of the screening registry to ensure the required data are collected & analyses are performed.	Yr 1 : Mo 8-12	DQA	DCS H-IT WE partner
Review legislation, regulations guidelines relating to the delivery of colposcopy services, identify any barriers to the effective operation of the screening program & propose revisions as required.	Yr 1 : Mo 8-12		
Based on the inventory results, prepare a plan & budget for the phased development of colposcopy services in RM & obtain approval.	Yr 1 : Mo 10-12	DCS CSD	MoH CNAM
Work with the WE partner to create a RM training facility for colposcopists & for colposcopy nurses in the IO: • 3 RM gynaecologists (who also have a Romanian/EU passport) will attend the WE partner's training courses for colposcopy practice & for the teaching of colposcopy, • 1 of the RM trainees will undertake an additional training exchange to learn about colposcopy CQI methods & procedures, • 1 of the RM trainees will undertake an additional training exchange to learn about colposcopy service management & the effective coordination of these services with the operation of a cervical screening program, • WE partner colposcopy trainers will visit RM & work with RM trainees to: – Evaluate the IO colposcopy facilities & prepare plans for the establishment of a national training facility for colposcopists & colposcopy nurses, – Review the WE partner's colposcopy training curricula, teaching materials, examination methods & certification criteria & adapt these to RM. • Once the facilities have been prepared, WE partner colposcopy trainers will return to support RM staff: – To run the first training sessions for both colposcopists & colposcopy nurses, & to evaluate the trainees, – To refine the colposcopy training programs. • The WE partner colposcopy trainers will maintain contact with the RM colposcopists to: – Include them by video-conference in CPC/MDT meetings, – Provide advice & support as required, – Monitor performance indicators to identify problems as they arise & recommend remedial action, • The WE partner colposcopy trainers will travel to RM to support the RM staff in conducting a full quality review of the IO colposcopy services. This will both assess the quality of these services & reinforce RM staff skills for undertaking quality reviews of other RM colposcopy clinics in the future.	Yr 1 : Mo 6-12	IO DCS	CSD ECCA WE partner
Prepare schedule for the training & certification of colposcopists & colposcopy nurses. To be coordinated with the plans for development of colposcopy services & the reorganisation of cervical cytology services & the phased rollout of the cervical screening program.	Yr 1 : Mo 11-12	DCS	CSD IO USMF
Review & revise relevant instruments to designate colposcopy as a distinct medical specialty with a defined training curriculum & certification criteria together with CME & re-certification requirements,	Yr 1 : Mo 11-12 Yr 2 : Mo 1-2	MoH	CSD DCS
Launch the colposcopy training program with: • Biannual reporting to the IO & CSD, • Periodic progress reviews & modification of the program and/or schedule as required.	Ongoing as required		

8.11 Implementation actions Gantt chart



Action
Year1
Year2
Year3
Year4
Year5
Year6
Year7
Year8
8.9 Increase Cervical Cytology Capacity
Enforce data compliance with the screening age range and interval
Undertake an inventory of cervical cytology laboratories
Establish a training exchange partnership
Undertake external quality review of RM cytology laboratories
Work with the WE partners to prepare guidelines & SOPs
performance indicators & standards; TCQI policy & specification
facilities & equipment specification & services specifications, etc.
Design & implement the cytology & pathology TCQI programs
Review & revise instruments relating to the delivery of gynae
cytology & pathology
Prepare plan & budget to reorganise gynaecytology services
Develop RM expertise in the Papanicolaou technique:
WE cytopathologists visit to RM
RM staff training in WE partner country
RM staff training in the cervical cytology TCQI
RM staff training in the cervical cytology laboratory management
WE cytopathologists visit to RM to support Pap introduction
WE cytopathologists ongoing TA monitoring
WE cytopathologists visit to RM to support full TA review
Establish RM cervical cytology screening facility:
- Work with the WE cytopathologists to adapt cytology
screening programs and teaching materials to RM
- WE cytopathologists visit to RM to support the first cytology
training session, assess results & revise programs as required
Prepare & schedule for training cytotechnicians
Designate cervical cytology screening as a distinct specialty
Launch the full cervical cytology screening service
Undertake cost-benefit outcomes review & planning required
Undertake monthly review of the training service
Establish a cervical cytopathology training facility:
- Work with the WE cytopathologists to adapt their
cytopathology training programs & materials to RM
- WE cytopathologists visit to RM to support the first Pap
cytopathology training, assess results and revise program
Launch the full cervical cytopathology training service
Ongoing basis
Required
8.10 Increase Colposcopy Capacity
Undertake an inventory of colposcopy facilities
Establish a training exchange partnership.
Work with WE partners to prepare clinical guidelines & SOPs
facility & equipment specifications; performance indicators &
standards; service & specification; etc.
Design & implement colposcopy TCQI program
Review & revise instruments relating to the delivery of
colposcopy services
Prepare plan & budget to develop colposcopy services
Establish a RM colposcopy training facility:
- RM staff training in colposcopy practices & teaching
- RM staff training in colposcopy TCQI
- RM staff training in colposcopy service management
- WE trainers visit to RM to support the development of
facilities, training curricula, teaching & materials, etc.
- WE trainers visit to RM to support the first training, assess
results & refine the program
- WE trainers ongoing monitoring
- WE trainers visit to RM to support full TA review
Designate colposcopy as a distinct medical specialty
Prepare & schedule for training colposcopists
Launch the full colposcopy training service
Undertake monthly review of the training service

Appendix 1: Legislation & orders affecting cervical screening	
Law/regulation	**Provisions dealing with cervical screening**
1995	
RML № 411-XIII of 28 March 1995	Article 3 specifies preventive health care as a fundamental principle to ensuring public health.
1997	
MHO № 200 of 19 August 1997, “On primary health care reform in Moldova”	Guarantees all Moldovan citizens access to PHC services
GD №1134 of 9 December 1997, “On the development of primary health care”	Guarantees people’s access to PHC services and specified measures for improving the quality of PHC services.
1998	
MHO №163 of 21 May 1998, “On reforms of primary health care physician profiles"	Specifies measures to accelerate reform of the health system and facilitates the introduction of a new form of PHC. Appendix 3 includes examinations for breast and cervical cancers within the specified duties of family physicians.
GD № 1269 of 25 December 1998	Approves the national program to fight cancer for 1998-2003.
1999	
MHO № 57 of 1 March 1999, "On the improvement of cytology."	
2001	
RML №185-XV of 24 May 2001, “On reproductive health and family planning"	Article 7(1) states, "Everyone has the right to receive reproductive health care services and family planning services"
2002	
GD № 156 of 11 February 2002, “On the approval of the organization and funding of actions and events that promote healthy lifestyles and reduce the risk of disease.”	
GD № 594 of 14 May 2002, “On the approval of the regulation on carrying out preventive measures (screening) for early detection of disease.”	
MHO № 141 of 29 May 2002	Approved additional programs for control and prevention of reproductive tract cancers and established specific measures to combat breast and cervical cancers including: • Create a special educational program on the prevention of breast and cervical cancers for gynaecologists, doctors and nurses in PHC, • Create multidisciplinary teams of oncologists, surgeons, cytologists and radiologists for the 1^{o} and 2^{o} prevention of breast and cervical cancers, • Increase availability of cytology screening as for the prevention of cervical cancer and improve cytology quality assurance measures, • Increase family physician participation in breast and cervical cancer prevention.
Guidelines for Oncology Prophylactic Checks of the Female Population in Moldova. Prof D Sofroni d.h.s.m., Dr V Cernat d.h.s.m.; Dr I Lazarev d.h.s.m., Dr I Iacovlev d.h.s.m., Prof N Godorogea d.h.s.m. and Dr L Sofroni d.s.m.	Recommends: • Annual preventive gynecological examinations for all women aged ≥20 and for sexually active women aged < 20. • Pap test once every 2 years for all women aged ≥ 20, taken by CMM nurse, midwife or doctor. In women aged <20, a Pap test is indicated only in the case of visible cervical pathology.
2005	
MHO №68 of 10 March 2005, "On measures directed to improve cytology services."	Establishes the Republican Cytology Laboratory within the IO with authority for national cytology services delivered through laboratories located in regional medical institutions: SR Cahul, SR Causeni, SR Edinet, SR Hincesti, SR Orhei, SR Soroca, SR Ungheni, Department of Health for the Municipality of Chisinau, Department of Health for the Municipality of Balti, Department of Health for the Municipality of Gagauzia
GD № 913 of 26 August 2005, “Approval of the National Reproductive Health Strategy for 2005-2015”	Approves the National Reproductive Health Strategy (see below for details of the strategy)
2006	
MHO № 46 of 31 January 2006, "On the organization in the IMSP Republican, a subdivision for the monitoring and evaluation of medical services."	Created a new organisation for the monitoring and evaluation of health services including those provided by the IO: • Monitor and evaluate the quality of medical services delivered in medical institutions at the municipal and district levels • Advise on monitoring and data collection to medical institutions
MHO № 425 of 12 October 2006, “On the creation of municipal Reproductive Health Offices and Women's Health Centres”	Introduces the reorganisation of family planning and reproductive health services, with clinics required to provide more services including: • Primary and secondary preventive measures for cancer of the reproductive organs in women • Diagnostic services for the prevention of breast and cervical cancer • Cytologic screening to detect precancerous & cancerous lesions • Counselling women with precancerous processes
2007	
GD № 886 of 6 August 2007, "On the approval of the National Health Policy 2007-2021"	Approves the National Health Policy 2007-2021 which includes provisions for the prevention of non-communicable diseases (see below for details)

Appendix 1: Legislation & orders affecting cervical screening	
Law/regulation	**Provisions dealing with cervical screening**
GD №1387 of 10 December 2007, "On the single program of mandatory health insurance"	Established a national health insurance mechanism with responsibility for funding all public health care services in RM. The health insurance regulations specify that: • Primary care services will include annual prophylactic medical examination for all persons aged 18+ years, • Prophylactic examinations, in accordance with MoH regulations, include CBE and a gynaecological examination with a Pap test.
2008	
MHO № 504 of 12 October 2008, "On medical prophylactic examination of the population"	Specifies that prophylactic medical examinations are the responsibility of PHC doctors and must include: • Yearly preventive gynecological examination for all women aged ≥15, • A Pap test every 2 years for all women ≥20 years of age, • CBE every year for women of all ages.
2009	
MHO/CNAM № 522/207 of 24 December 2009,	Extends annual prophylactic medical examinations conducted in PHC to all Moldovan citizens, whether or not they are registered with CNAM, starting in 2012. Paragraph 26 states, "Prophylactic examinations, including early detection of breast and cervical cancer (CBE and Pap test), are to be provided for all people registered with a GP, established by legislation in force."
2010	
Ministry Health Order № 695 of 13 October 2010, "On Primary Health Care in Moldova"	Specifies that: • Primary care services can be conducted in: family physician centres, health centres (including autonomous health centres), family physician cabinets, health offices, • Family physicians must be able to perform cervical pathology screening with cytology smear collection and interpretation of the results of the cytological analysis; perform screening for mammary gland pathology, • Nurses must be able to perform gynecological examinations and take Pap tests, • The facilities note above must have a gynaecological examination couch and vaginal speculums.
MHO № 722 of 28 October 2010	Authorises HPV vaccination for the female population aged 10 to 18 years. (20,790 doses of Gardasil were received for the vaccination of 6,930 girls. ≈2.5% of the target population was vaccinated.)
2011	
2011 - The MoH - draft regulations for preventive examinations conducted in gynecological cabinets.	Specifies: • Procedure for conducting CBE, • Procedure for examining the cervix and taking a Pap test, • Minimum equipment required to conduct the examinations (vaginal speculums, vaginal spatula for taking Pap tests, forceps, colposcope), • Qualifications (minimum training requirements) for health workers conducting screening examinations.
MHO № 550 of 30 June 2011, "On Approval the National Clinical Protocol for Cervical Cancer Prevention"	Approves the National Clinical Protocol for Cervical Cancer Prevention. (Amended 4 October 2011)
MHO №743 of 4 October 2011, "On amending and repealing certain orders of the Ministry of Health."	Approved a new list of prophylactic medical examinations of the population including ecto and endocervical cytology once every 2 years for all women aged 20+.
2012	
MHO/CNAM № 302/70A of 30 March 2012, "On approval of medical service performance indicators."	Sets-out PHC performance indicators including: • Providing a preventive gynecological examination with cytology sampling once in every 2 year period for each woman registered on the GP list, • Payments to GPs are based on validation of the performance indicators and are paid "per service."
MHO № 722 of 16 July 2012, "On improvement of activity and cytological pathomorphologic services in Moldova."	Recommends the organisational structure of cytology services and confirms authority of the Republican Cytology Laboratory in the IO over all national cytology services.

Appendix 2: Guidelines & protocols affecting cervical screening	
Strategy/guideline	**Provisions dealing with cervical screening or cancer**
2002	
Guidelines for Prophylactic Oncology Checks of the Female Population in Moldova. Sofroni D, Cernat V, Lazarev I, Iacovlev I, Godorogea N and Sofroni L.	Recommends a Pap test once every 2 years for all women aged ≥20, taken by a nurse, midwife or doctor. For women aged <20, a Pap test is indicated only in case of visible cervical pathology.
2005	
The National Reproductive Health Strategy for 2005-2015	Sets priority areas within the health system for improvement including: • Improve the legal framework to facilitate the early diagnosis of breast and cervical cancers, • Increase public access to diagnostic services for the prevention of breast and cervical cancer, • Improve cytology screening for precancerous lesions and cervical cancer, • Provide training in the early detection of breast and cervical cancer to health care providers and specifically to obstetrician-gynaecologists and nurses in rural areas, • Public health education programs to increase public awareness about preventing breast and cervical cancers, • Targets for cervical screening in which the detection rate of cervical cancers in stage 0 will exceed 25.0% and stages I-II will exceed 45.0%.
2007	
National Health Policy 2007-2021 (approved by GD № 866 of 6 August 2007).	Specifies provisions for promoting healthy lifestyles and the prevention of non-communicable diseases.
The Early Detection of Cancer and Precancerous Conditions as Performance Indicators for Family Physicians. CNAM 2007	Set the number of Pap tests conducted as the indicator for the provision of preventive gynaecological examinations with cytology sampling.
2008	
National Program Against Oncologic Diseases in Moldova 2008-2012 (not approved)	Recommended • Annual detection of cancer and precancerous lesions with the support of family doctors, regional oncologists and medical specialists. • Modernizing and popularizing cytology screening for cervical cancer, • Implementation of new methods of pathomorphological detection.
2009	
National Guidelines for the Prevention of Cervical Cancer. Authors: Codreanu NP, Friptu VG, Stratila M, Cernat V.. Chisinau 2009	Recommended: Preventive gynecological examinations, including the Pap test, for all women aged 25-65, once every 3 years for women aged 25-49 and once every 5 years for women aged 50-65. (Was not approved by gynaecology scientific council.)
2010	
National Health System Development Strategy 2008-2017	This strategy specified: • Primary care services could be conducted in Centrele Medicilor de Familie, Centrele de Sanatate, Oficiile Medicului de Familie and Oficiile de Sanatate. • Family physicians must be able to: - Perform cervical screening with Pap smear collection and be able to interpret the results, - Perform breast screening. • Primary care nurses must be able to perform gynecological examinations including the taking of Pap tests, • Facilities conducting PHC must have the equipment required to conduct breast and cervical cancer screening including a gynaecological examination couch and vaginal speculums.
2011	
National Cervical Cancer Clinical Protocol (Approved by the MH in 2011, revised in 2013)	This states: • PHC institutions are responsible for primary cervical cancer prevention by HPV vaccination of girls aged 11-12 and for the education of girls aged 11-12 about cervical cancer prevention (i.e. safe sex, etc.) • Cervical cancer screening should be conducted once every 2 years for women aged 25-64 • In case of precancerous lesions of the cervix, patients should be directed to the district oncologist or directly to Institute of Oncology
2012	
Clinical Standardized Protocol “Cervical Cancer” , approved by the MHO №749 of 30.07.2012	This states: • Pap test for women aged 25-64 each 2 years • Referral to specialist for medical and surgical treatment of precancerous lesions

Appendix 3: Female population at 1 January 2011 & projected cervical screening requirement										
			Women Screened/Year Coverage Level				Pap Tests/Year (+10%) Coverage Level			
	Total № Females	Women Aged 25-64	45%	55%	65%	75%	45%	55%	65%	75%
Chisinau	418,435	233,300	52,493	64,158	75,823	87,488	57,742	70,573	83,405	96,236
Chisinau	352,291	196,422	44,195	54,016	63,837	73,658	48,614	59,418	70,221	81,024
Codru	6,254	3,487	785	959	1,133	1,308	863	1,055	1,247	1,438
Cricova	4,558	2,541	572	699	826	953	629	769	909	1,048
Durlesti	9,752	5,437	1,223	1,495	1,767	2,039	1,346	1,645	1,944	2,243
Singera	4,187	2,334	525	642	759	875	578	706	835	963
Vadul lui Voda	2,544	1,418	319	390	461	532	351	429	507	585
Vatra	1,802	1,005	226	276	327	377	249	304	359	414
Chisinau-villages	37,047	20,656	4,648	5,680	6,713	7,746	5,112	6,248	7,384	8,520
North	529,406	295,173	66,414	81,173	95,931	110,690	73,055	89,290	105,524	121,759
Balti	80,406	44,831	10,087	12,328	14,570	16,812	11,096	13,561	16,027	18,493
Balti	77,760	43,355	9,755	11,923	14,091	16,258	10,730	13,115	15,500	17,884
Balti-villages	2,646	1,475	332	406	479	553	365	446	527	609
Briceni	39,533	22,042	4,959	6,061	7,163	8,266	5,455	6,668	7,880	9,092
Briceni	5,198	2,898	652	797	942	1,087	717	877	1,036	1,195
Lipcani	2,940	1,639	369	451	533	615	406	496	586	676
Briceni-villages	31,395	17,504	3,938	4,814	5,689	6,564	4,332	5,295	6,258	7,221
Donduseni	24,083	13,428	3,021	3,693	4,364	5,035	3,323	4,062	4,800	5,539
Donduseni	5,714	3,186	717	876	1,035	1,195	788	964	1,139	1,314
Donduseni-villages	18,370	10,242	2,304	2,817	3,329	3,841	2,535	3,098	3,662	4,225
Drochia	47,212	26,324	5,923	7,239	8,555	9,871	6,515	7,963	9,411	10,858
Drochia	10,690	5,960	1,341	1,639	1,937	2,235	1,475	1,803	2,131	2,459
Drochia-villages	36,523	20,363	4,582	5,600	6,618	7,636	5,040	6,160	7,280	8,400
Edinet	43,688	24,359	5,481	6,699	7,917	9,134	6,029	7,368	8,708	10,048
Edinet	9,697	5,406	1,216	1,487	1,757	2,027	1,338	1,635	1,933	2,230
Cupcini	4,005	2,233	502	614	726	837	553	676	798	921
Edinet-villages	29,986	16,719	3,762	4,598	5,434	6,270	4,138	5,057	5,977	6,897
Falesti	47,782	26,641	5,994	7,326	8,658	9,990	6,594	8,059	9,524	10,989
Falesti	8,669	4,833	1,087	1,329	1,571	1,812	1,196	1,462	1,728	1,994
Falesti-villages	39,113	21,808	4,907	5,997	7,087	8,178	5,397	6,597	7,796	8,996
Floresti	46,800	26,094	5,871	7,176	8,480	9,785	6,458	7,893	9,328	10,764
Floresti	8,008	4,465	1,005	1,228	1,451	1,674	1,105	1,351	1,596	1,842
Ghindesti	988	551	124	151	179	207	136	167	197	227
Marculesti	1,040	580	130	159	188	217	144	175	207	239
Floresti-villages	36,764	20,498	4,612	5,637	6,662	7,687	5,073	6,201	7,328	8,455
Glodeni	32,250	17,981	4,046	4,945	5,844	6,743	4,450	5,439	6,428	7,417
Glodeni	6,096	3,399	765	935	1,105	1,275	841	1,028	1,215	1,402
Glodeni-villages	26,154	14,582	3,281	4,010	4,739	5,468	3,609	4,411	5,213	6,015
Ocnita	29,565	16,484	3,709	4,533	5,357	6,181	4,080	4,986	5,893	6,800
Ocnita	4,901	2,733	615	751	888	1,025	676	827	977	1,127
Otaci	4,480	2,498	562	687	812	937	618	756	893	1,030
Frunza	896	500	112	137	162	187	124	151	179	206
Ocnita-villages	19,288	10,754	2,420	2,957	3,495	4,033	2,662	3,253	3,845	4,436
Riscani	36,540	20,373	4,584	5,603	6,621	7,640	5,042	6,163	7,283	8,404
Riscani	6,995	3,900	877	1,072	1,267	1,462	965	1,180	1,394	1,609
Costesti	1,305	728	164	200	236	273	180	220	260	300
Riscani-villages	28,240	15,745	3,543	4,330	5,117	5,905	3,897	4,763	5,629	6,495
Singerei	47,821	26,663	5,999	7,332	8,665	9,999	6,599	8,065	9,532	10,998
Singerei	7,475	4,168	938	1,146	1,355	1,563	1,032	1,261	1,490	1,719
Biruinta	2,150	1,199	270	330	390	450	297	363	429	495
Singerei-villages	38,195	21,296	4,792	5,856	6,921	7,986	5,271	6,442	7,613	8,785
Soroca	51,405	28,661	6,449	7,882	9,315	10,748	7,094	8,670	10,246	11,823
Soroca	19,149	10,677	2,402	2,936	3,470	4,004	2,642	3,230	3,817	4,404
Soroca-villages	32,445	18,090	4,070	4,975	5,879	6,784	4,477	5,472	6,467	7,462
Center	544,088	303,359	68,256	83,424	98,592	113,760	75,081	91,766	108,451	125,136
Anenii Noi	42,547	23,722	5,338	6,524	7,710	8,896	5,871	7,176	8,481	9,785
Anenii Noi	4,403	2,455	552	675	798	921	608	743	878	1,013
Anenii Noi-villages	38,144	21,267	4,785	5,849	6,912	7,975	5,264	6,433	7,603	8,773
Calarasi	40,188	22,407	5,042	6,162	7,282	8,403	5,546	6,778	8,011	9,243
Calarasi	8,262	4,607	1,036	1,267	1,497	1,727	1,140	1,393	1,647	1,900
Calarasi-villages	31,926	17,800	4,005	4,895	5,785	6,675	4,406	5,385	6,364	7,343
Criuleni	37,354	20,827	4,686	5,727	6,769	7,810	5,155	6,300	7,446	8,591
Criuleni	4,241	2,365	532	650	769	887	585	715	845	975
Criuleni-villages	33,113	18,462	4,154	5,077	6,000	6,923	4,569	5,585	6,600	7,616
Dubasari-villages	17,917	9,990	2,248	2,747	3,247	3,746	2,472	3,022	3,571	4,121
Hincesti	61,732	34,419	7,744	9,465	11,186	12,907	8,519	10,412	12,305	14,198
Hincesti	8,501	4,740	1,066	1,303	1,540	1,777	1,173	1,434	1,694	1,955
Hincesti-villages	53,231	29,679	6,678	8,162	9,646	11,130	7,346	8,978	10,610	12,243

Appendix 3: Female population at 1 January 2011 & projected cervical screening requirement										
			Women Screened/Year Coverage Level				Pap Tests/Year (+10%) Coverage Level			
	Total № Females	Women Aged 25-64	45%	55%	65%	75%	45%	55%	65%	75%
Ialoveni	50,343	28,069	6,315	7,719	9,122	10,526	6,947	8,491	10,035	11,578
Ialoveni	7,874	4,390	988	1,207	1,427	1,646	1,087	1,328	1,569	1,811
Ialoveni-villages	42,469	23,679	5,328	6,512	7,696	8,880	5,860	7,163	8,465	9,767
Nisporeni	33,868	18,883	4,249	5,193	6,137	7,081	4,674	5,712	6,751	7,789
Nisporeni	7,402	4,127	929	1,135	1,341	1,548	1,021	1,248	1,475	1,702
Nisporeni-villages	26,465	14,756	3,320	4,058	4,796	5,533	3,652	4,464	5,275	6,087
Orhei	65,468	36,502	8,213	10,038	11,863	13,688	9,034	11,042	13,049	15,057
Orhei	17,420	9,713	2,185	2,671	3,157	3,642	2,404	2,938	3,472	4,006
Orhei-villages	48,048	26,789	6,028	7,367	8,707	10,046	6,630	8,104	9,577	11,051
Rezina	26,773	14,928	3,359	4,105	4,851	5,598	3,695	4,516	5,337	6,158
Rezina	6,872	3,831	862	1,054	1,245	1,437	948	1,159	1,370	1,580
Rezina-villages	19,902	11,096	2,497	3,052	3,606	4,161	2,746	3,357	3,967	4,577
Straseni	46,472	25,911	5,830	7,125	8,421	9,716	6,413	7,838	9,263	10,688
Straseni	10,333	5,761	1,296	1,584	1,872	2,160	1,426	1,743	2,060	2,376
Bucovat	662	369	83	101	120	138	91	112	132	152
Straseni-villages	35,477	19,781	4,451	5,440	6,429	7,418	4,896	5,984	7,072	8,159
Soldanesti	22,170	12,361	2,781	3,399	4,017	4,635	3,059	3,739	4,419	5,099
Soldanesti	3,891	2,170	488	597	705	814	537	656	776	895
Soldanesti-villages	18,278	10,191	2,293	2,803	3,312	3,822	2,522	3,083	3,643	4,204
Telenesti	37,397	20,851	4,691	5,734	6,776	7,819	5,161	6,307	7,454	8,601
Telenesti	4,133	2,304	518	634	749	864	570	697	824	951
Telenesti-villages	33,264	18,547	4,173	5,100	6,028	6,955	4,590	5,610	6,630	7,650
Ungheni	59,170	32,990	7,423	9,072	10,722	12,371	8,165	9,980	11,794	13,608
Ungheni	19,202	10,706	2,409	2,944	3,480	4,015	2,650	3,239	3,828	4,416
Cornesti	1,361	759	171	209	247	285	188	230	271	313
Ungheni-villages	39,909	22,251	5,007	6,119	7,232	8,344	5,507	6,731	7,955	9,179
South	276,536	154,184	34,691	42,401	50,110	57,819	38,161	46,641	55,121	63,601
Basarabeasca	15,038	8,385	1,887	2,306	2,725	3,144	2,075	2,536	2,997	3,459
Basarabeasca	6,438	3,589	808	987	1,167	1,346	888	1,086	1,283	1,481
Basarabeasca-villages	8,601	4,795	1,079	1,319	1,558	1,798	1,187	1,451	1,714	1,978
Cahul	64,646	36,044	8,110	9,912	11,714	13,516	8,921	10,903	12,886	14,868
Cahul	20,565	11,466	2,580	3,153	3,726	4,300	2,838	3,468	4,099	4,730
Cahul-villages	44,082	24,578	5,530	6,759	7,988	9,217	6,083	7,435	8,787	10,138
Cantemir	31,400	17,507	3,939	4,814	5,690	6,565	4,333	5,296	6,259	7,222
Cantemir	3,000	1,673	376	460	544	627	414	506	598	690
Cantemir-villages	28,400	15,835	3,563	4,355	5,146	5,938	3,919	4,790	5,661	6,532
Causeni	47,073	26,246	5,905	7,218	8,530	9,842	6,496	7,939	9,383	10,826
Causeni	10,149	5,659	1,273	1,556	1,839	2,122	1,401	1,712	2,023	2,334
Cainari	2,346	1,308	294	360	425	491	324	396	468	540
Causeni-villages	34,578	19,279	4,338	5,302	6,266	7,230	4,772	5,832	6,892	7,953
Cimislia	31,405	17,510	3,940	4,815	5,691	6,566	4,334	5,297	6,260	7,223
Cimislia	7,228	4,030	907	1,108	1,310	1,511	997	1,219	1,441	1,662
Cimislia-villages	24,178	13,480	3,033	3,707	4,381	5,055	3,336	4,078	4,819	5,561
Leova	26,954	15,028	3,381	4,133	4,884	5,636	3,719	4,546	5,373	6,199
Leova	5,461	3,045	685	837	990	1,142	754	921	1,088	1,256
Iargara	2,405	1,341	302	369	436	503	332	406	479	553
Leova-villages	19,088	10,643	2,395	2,927	3,459	3,991	2,634	3,219	3,805	4,390
Stefan Voda	36,022	20,084	4,519	5,523	6,527	7,532	4,971	6,075	7,180	8,285
Stefan Voda	4,359	2,430	547	668	790	911	601	735	869	1,002
Stefan Voda - villages	31,663	17,654	3,972	4,855	5,738	6,620	4,369	5,340	6,311	7,282
Taraclia	22,144	12,347	2,778	3,395	4,013	4,630	3,056	3,735	4,414	5,093
Taraclia	7,465	4,162	936	1,145	1,353	1,561	1,030	1,259	1,488	1,717
Taraclia-villages	14,679	8,185	1,842	2,251	2,660	3,069	2,026	2,476	2,926	3,376
UTA Gagauzia	80,511	44,889	10,100	12,345	14,589	16,833	11,110	13,579	16,048	18,517
Comrat	12,675	7,067	1,590	1,943	2,297	2,650	1,749	2,138	2,527	2,915
Ciadir-Lunga	11,537	6,432	1,447	1,769	2,091	2,412	1,592	1,946	2,300	2,653
Vulcanesti	8,532	4,757	1,070	1,308	1,546	1,784	1,177	1,439	1,701	1,962
UTA Gagauzia-villages	49,824	27,780	6,250	7,639	9,028	10,417	6,875	8,403	9,931	11,459
Total	1,849,558	1,031,230	232,027	283,588	335,150	386,711	255,229	311,947	368,665	425,382

Appendix 4: Health facility staffing levels in 2011 (% of required staff levels)					
District		PHC	Hospitals	Specialists	Total
Comrat	≥95.0%	100.00	96.20	86.10	87.40
Drochia		98.60	97.60	95.50	97.70
Ceadir-Lunga		97.80	88.20	92.70	84.60
Edinet		97.10	97.00	95.20	96.80
Chisinau		96.30	95.50	94.50	94.10
Donduseni		95.00	99.20	97.30	96.80
Singerei	90% - <95%	94.60	98.30	78.30	91.60
Balti		94.50	99.00	92.10	95.40
Riscani		94.10	91.60	91.50	92.70
Ialoveni		93.80	94.50	89.80	88.30
Ocnita		93.30	91.20	93.20	93.40
Soroca		93.10	95.60	88.60	93.20
Anenii Noi		92.30	98.30	90.60	89.50
Taraclia		92.10	93.60	76.20	83.20
Telenesti		90.90	88.00	84.50	83.00
Vulcanesti		90.50	78.00	79.40	78.20
Straseni		90.40	98.20	77.20	83.50
Briceni		90.20	85.50	82.30	87.30
Dubasari		90.10			81.40
Glodeni	80% - <90%	89.70	84.80	79.00	85.50
Cahul		89.10	82.40	83.60	83.20
Calarasi		88.80	88.20	79.20	81.50
Floresti		87.50	93.70	85.70	90.20
Soldanesti		85.80	89.70	91.30	82.50
Ungheni		82.90	88.20	89.80	80.40
Basarabeasca		82.40	96.10	80.60	82.90
Criuleni		82.00	82.50	86.20	81.00
Cimislia		81.50	85.60	77.50	75.90
Causeni		81.00	91.10	87.20	78.70
Stefan Voda	<80%	76.50	95.70	70.70	76.40
Orhei		74.20	91.30	94.80	82.40
Leova		73.00	99.20	80.80	77.10
Falesti		72.50	97.40	68.70	76.40
Hincesti		71.90	91.90	99.60	81.30
Rezina		71.70	91.00	94.70	79.40
Nisporeni		70.90	89.10	56.60	68.70
Cantemir		52.50	86.60	59.90	62.80

Appendix 5: Estimate eligible number vs. reported number of women screened/year							
	Est. Annual Target Population	Reported № Women Screened/Yr				Coverage of Target Population	Comments
		CMF/ AMT	CS/ CDC	OMF	OS		
Chisinau Central	98,211						
AMT Botanica		12,000					Own lab – 26,840 Paps/yr
AMT Buiucani		13,200	19,200				Cytology →AMT Centru
AMT Centru		26,400	26,400				Own lab – 40,054 Paps/yr
AMT Ciocana		10,800	9,600				Own lab – 20,400 Paps/yr
AMT Riscani		14,400	5,280				Own lab – 16,076 Paps/yr
Codru	1,743						
Cricova	1,271						Cytology →AMT Centru
Durlesti	2,719						Cytology →AMT Centru
Singera	1,167						
Vadul lui Voda	709						Cytology →AMT Centru
Vatra	502						Cytology →AMT Centru
Chisinau-villages	10,328						
Chisinau	116,650	76,800	60,480			117.7%	
North							
Balti	22,415	5,760				25.7%	Own lab – 42,130 Paps/yr
Balti	21,678	3,600					
Balti -villages	738		960	1,200			
Briceni	11,021	3,360				30.5%	→Edinet
Briceni	1,449	3,360					
Lipcani	820						
Briceni-villages	8,752						
Donduseni	6,714	5,448				81.1%	
Donduseni	1,593	4,800					
Donduseni-villages	5,121		480	120	48		
Drochia	13,162	6,720				51.1%	
Drochia	2,980	4,800					
Drochia-villages	10,182		960	960	0		
Edinet	12,179	11,280				92.6%	Own lab – 17,346 Paps/yr
Edinet	2,703	7,200					
Cupcini	1,117		3,600	480	0		
Edinet-villages	8,360						
Falesti	13,320	2,880				21.6%	→CDR
Falesti	2,417	1,440					
Falesti-villages	10,904		960	480	0		
Floresti	13,047	3,480				26.7%	→CDR
Floresti	2,232	2,400					
Ghindesti	275		960	120	0		
Marculesti	290						
Floresti-villages	10,249						
Glodeni	8,991	7,200				80.1%	→CDR, Balti
Glodeni	1,699	2,400					
Glodeni-villages	7,291		2,400	2,400	0		
Ocnita	8,242	4,320				52.4%	
Ocnita	1,366	1,920		240	0		
Otaci	1,249		1,920	240	0		
Frunza	250						
Ocnita-villages	5,377						
Rascani	10,187	9,840				96.6%	→CDR
Rascani	1,950	4,800					
Costesti	364		2,400	2,640	0		
Rascani -villages	7,873						
Singerei	13,331	8,640				64.8%	→ Balti
Singerei	2,084	5,280	960	720	480		
Biruinta	599		1,200				
Singerei-villages	10,648						
Soroca	14,330	9,780				68.3%	Own lab – 25,158 Paps/yr
Soroca	5,338	7,200					
Soroca-villages	9,045		2,400	180	0		
Center							
Anenii Noi	11,861	3,180				26.8%	→IO
Anenii Noi	1,228	2,400					
Anenii Noi-villages	10,634		720	60	0		
Calarasi	11,204	2,424				21.6%	
Calarasi	2,303	2,400					
Calarasi-villages	8,900			24	0		
Criuleni	10,413	1,140				11.0%	
Criuleni	1,182	1,200					
Criuleni-villages	9,231		240		0		

Appendix 5: Estimate eligible number vs. reported number of women screened/year							
	Est. Annual Target Population	Reported № Women Screened/Yr				Coverage of Target Population	Comments
		CMF/ AMT	CS/ CDC	OMF	OS		
Dubasari-villages	4,995	2,880	240	240	0	67.3%	
Hincesti	17,209	5,040				29.3%	
Hincesti	2,370	4,800					
Hincesti-villages	14,840		240	0	0		
Ialoveni	14,034	5,040				35.9%	
Ialoveni	2,195	3,840					
Ialoveni-villages	11,839		960	240	0		
Nisporeni	9,442	9,600				101.7%	
Nisporeni	2,064	4,800					
Nisporeni-villages	7,378		2,400	1,920	480		
Orhei	18,251	6,000				32.9%	→CDR
Orhei	4,856	2,400					
Orhei-villages	13,395		720	1,680	1,200		
Rezina	7,464	9,600				128.6%	→CDR
Rezina	1,916	6,000					
Rezina-villages	5,548		720	1,920	960		
Straseni	12,955	1,440				11.1%	
Straseni	2,881	1,200					
Bucovat	184		240	0	0		
Straseni-villages	9,890						
Soldanesti	6,180	5,760				93.2%	
Soldanesti	1,085	1,440					
Soldanesti-villages	5,096		2,400	720	1,200		
Telenesti	10,425	6,000				57.6%	→CDR
Telenesti	1,152	3,360					
Telenesti-villages	9,273		720	1,920	0		
Ungheni	16,495	7,680				46.6%	Own lab – 35,698 Paps/yr
Ungheni	5,353	6,000					
Cornesti	379		960	480	240		
Ungheni-villages	11,126						
South							
Basarabeasca	4,192	3,360				80.2%	→IO
Basarabeasca	1,795	1,200					
Basarabeasca-villages	2,398		720	720	720		
Cahul	18,022	6,840				38.0%	Own lab – 38,128 Paps/yr
Cahul	5,733	6,000					
Cahul-villages	12,289		720	120	0		
Cantemir	8,754	12,000				137.0%	
Cantemir	836	7,200					
Cantemir-villages	7,917		2,400	2,400	0		
Causeni	13,123	5,520				42.1%	Own lab – 12,477 Paps/yr
Causeni	2,829	4,800					
Cainari	654		480	240	0		
Causeni -villages	9,640						
Cimislia	8,755	7,680				87.7%	→IO
Cimislia	2,015	2,400	1,200	720	720		
Cimislia-villages	6,740		1,200	720	720		
Leova	7,514	3,000				39.9%	→IO, RDC, Cahul
Leova	1,522	2,400					
Iargara	670		480	72	48		
Leova-villages	5,321						
Stefan-Voda	10,042	8,400				83.7%	
Stefan-Voda	1,215	2,400					
Stefan-Voda - villages	8,827		3,600	2,400	0		
Taraclia	6,173	2,676				43.4%	
Taraclia	2,081	1,920					
Taraclia-villages	4,092		480	240	36		
UTA Gagauzia	22,445	12,048				53.7%	
Comrat	3,534	5,520					
Ciadir-Lunga	3,216	3,600	2,400	0	0		
Vulcanesti	2,379	480	24	24	0		
UTA Gagauzia-villages	13,890						
Total	**515,615**	**206,640**	**125,544**	**26,400**	**6,852**	**70.9%**	
		365,676					

Appendix 6: Cervical cytology laboratory staffing & results

Laboratory	Status	Cyto-technicians	Cyto-pathologists	Pathologists	Specimens/yr
Institute of Oncology	Operational	**5 x FTE**	**5 X FTE**	-	Result / № / % Normal 48,854 77.25% Inflammation 9,818 15.53% ASC-US 2,574 4.07% AGC 136 0.22% ASC-H 384 0.61% LSIL 1,168 1.85% HSIL 286 0.45% Carcinoma 18 0.03% **Total 63,238 100.0%**
Republic Diagnostic Centre	Operational	**3 FTE**	**3 FTE**	-	Result / № / % Normal 31,451 73.29% Endocervicoză 830 1.93% Inflamation 10,400 24.23% AGC ND ND LSIL (+ASC-US) 76 0.18% HSIL (+ASC-H) 124 0.29% Susp. Carc. 8 0.02% Carcinoma 22 0.05% **Total 42,911 100.0%**
AMT Botanica	Operational	**1 x FTE**	**0.5 FTE**	-	Result / № / % Normal 21,162 78.84% Endocervicoză 1,605 5.97% Inflamation 3,815 14.21% AGC - LSIL (+ASC-US) 113 0.42% HSIL(+ASC-H) 98 0.36% Susp. Carc. 47 0.17% Carcinoma - **Total 26,840 100,0%**
AMT Buiucani	Not operational, contracts services from AMT Centru				
AMT Centru	Operational	**2 x FTE**	**2 x FTE**		Result / № / % Normal 26,753 66.79% Inflamation 10,816 27.00% AGC 15 0.03% LSIL (+ASC-US) 238 0.59% HSIL (+ASC-H) 110 0.27% Carcinoma 22 0.05% **Total 37,954 100.0%**
AMT Ciocani	Operational	**1 x FTE**	**0.5 FTE**		Result / № / % Normal 20,088 98.47% Inflamation 147 0.72% ASC-US 10 0.04% AGC ND ND LSIL 12 0.05% HSIL (+ASC-H) 8 0.03% Carcinoma 3 0.014% **Total 20,268 100.0%**
AMT Riscani	Operational	**0.5 FTE**	**1 x FTE**		Result / № / % Normal 13,597 84.57% Endocervicoză 1,090 6.80% Inflamation 1,340 8.33% AGC ND ND LSIL (+ASC-US) 11 0.68% HSIL (+ASC-H) 32 0.19% Carcinoma 6 0.037% **Total 16,076 100.0%**
Anenii Noi	Not operational. Contracts services from the IO & RDC?				
Balti	Operational	**4.5 FTE**	**1 FTE**		Result / 2012 / % Normal 34,833 82.76% Trihomoniaza 349 0.8% Endocervicoză 1,149 2.7% Inflamation 4,975 11.8% AGC - LSIL (+ASC-US) 608 1.44% HSIL (+ASC-H) 35 0.08% Susp. Cr. 148 0.35% Carcinoma 33 0.07% **Total 42,130 100.0%**

Appendix 6: Cervical cytology laboratory staffing & results

Laboratory	Status	Cyto-technicians	Cyto-pathologists	Pathologists	Specimens/yr
Basarabeasca	Not operational. Contracts services from the IO & RDC?				
Briceni	Stopped operations in 2013				
Cahul					Cytologies: 35,128
Causeni	Operational	**1 FTE**	**1 FTE**	**1 FTE**	
Cimislia	Not operational. Contracts services from the IO				
Drochia	Not operational. Contracts services from the RDC				
Edinet	Operational	**1 FTE**	**1 FTE**		
Glodeni	Not operational. Contracts services from Balti				
Leova	Not operational. Contracts services from the IO & RDC				
Singerei	Not operational. Contracts services from Balti				
Soroca	Operational	**1 FTE**	**1 FTE**		
Ungheni	Operational	**1.25 x FTE**	**1 x FTE**		
Comrat	Not operational				

Result	№	%
Normal	12,180	97.61%
Endocervicoză	154	1.23%
Inflammation	125	1.00%
ASC-US	ND	ND
AGC	ND	ND
ASC-H	ND	ND
LSIL	--	--
HSIL	15	0.12%
Carcinoma	3	0.002%
Total	**12,477**	**100.0%**

Result	№	%
Normal	14,848	85.6%
Inflamation	2,387	13.8%
Endocervicoză	78	0.45%
ASC-US	17	0.09%
AGC	ND	ND
ASC-H	ND	ND
LSIL	5	0.03%
HSIL	5	0.03%
Susp. Carc.	11	0.06%
Carcinoma	6	0.03%
Total	**17,357**	**100.0%**

Result	№	%
Normal	20,486	81.43%
Inflamation	2,803	11.14%
Endocervicoză	1.829	7.27%
ASC-US	ND	ND
AGC	ND	ND
ASC-H	ND	ND
LSIL	16	0.03%
HSIL	26	0.08%
Susp. Carc.	-	-
Carcinoma	9	0.02%
Total	**25,169**	**100.0%**

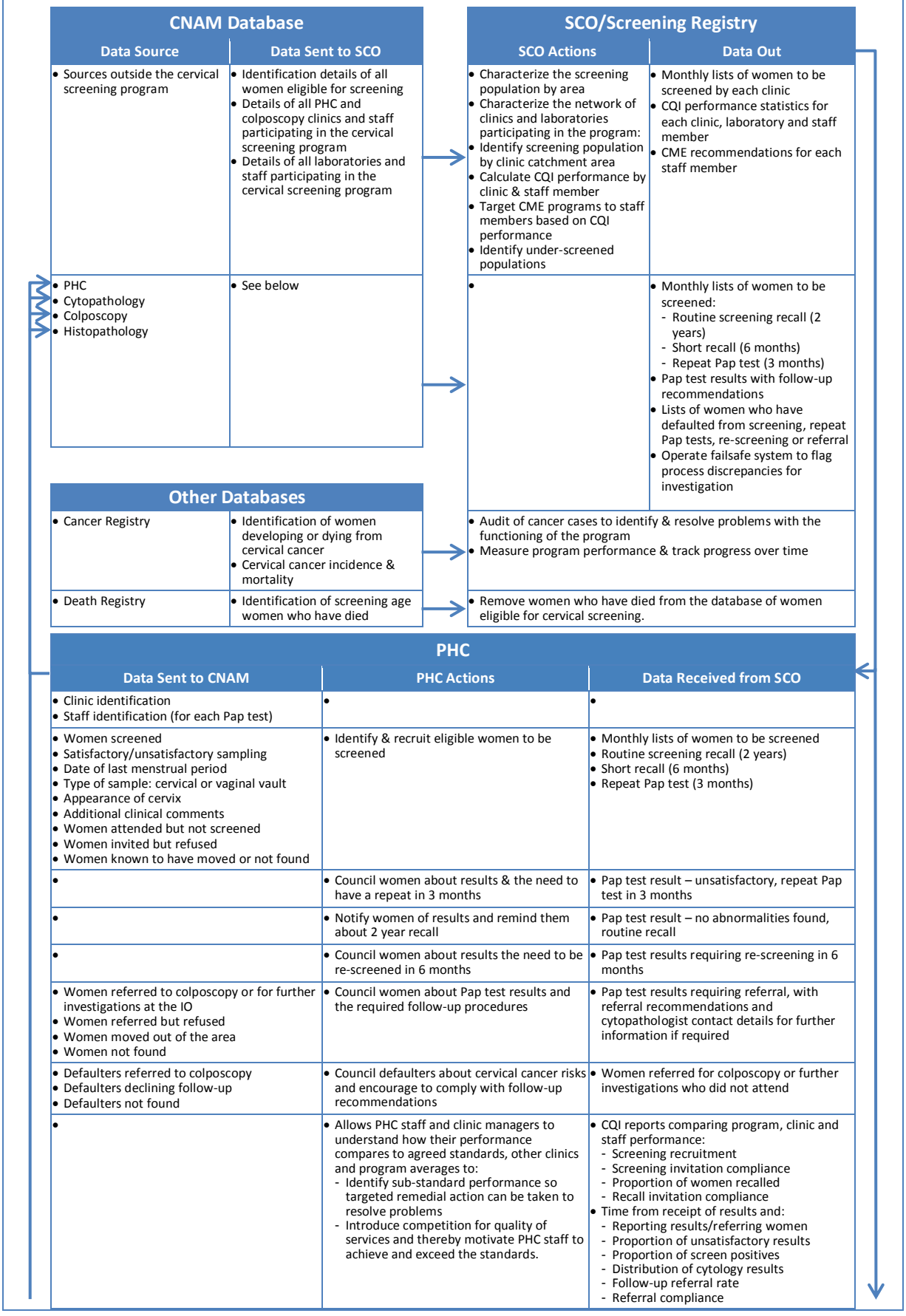
Result	№	%
Normal	29,070	81.43%
Inflamation	3,976	11.14%
Endocervicoză	2,596	7.27%
ASC-US	ND	ND
AGC	ND	ND
ASC-H	ND	ND
LSIL	10	0.03%
HSIL	27	0.08%
Susp. Carc.	11	0.03%
Carcinoma	8	0.02%
Total	**35,698**	**100.0%**

Appendix 7: Services & equipment for follow-up of abnormal Pap tests & cervical surgery													
	Colposcopy	Cervical Surgery	Gynaecological Couch	Vaginal Speculums	Endocervical Speculums	Biopsy Forceps	ECC Curette	Forceps	Autoclave/steriliser	Colposcope	LEEP	Cryo	DEC
Chisinau													
Institute of Oncology	✔	✔	5	D	0	10	7	-	5xDoM	1x1990 3x2007 1x2010	5x1979	0	5x1979
AMT Botanica	➔IO	➔IO	4	D	0	3	1	-		3xDoM	3xDoM	3xDoM	2xDoM
AMT Buiucani	➔IO	➔IO	1	D	-	2	1	T 5 NT 5 Sp 10	1xDoM	1xDoM	0	0	1x1981
AMT Centru	➔IO	➔IO	2	D	-	2		T 32 NT 8	2x1989	1xDoM 2x2010	0	0	1xDoM
AMT Ciocani	➔IO	➔IO	1	D	-	2	1	T 5 NT 5 Sp 10	1x1980 1x2006	1x2002	0	0	1x1981
AMT Riscani	➔IO	➔IO	3	D	-	3	0	0	3x1988 1x2008 4x2009	1x1984 1x1987 1x2003 1x2010	0	0	1x1975 1x1978 1x1982 1x2010
North													
Balti CMF	➔IO	➔IO	2	L: 16 M: 24 S: 2	0	0	0	0	0	1x1971 1x2003	0	0	0
Briceni CMF	➔IO	➔IO	2	D	0	0	0	0	0	1x1998	0	0	1x1984
Lipcani	➔IO	➔IO	7	D	0	0	0	0	0	0	0	0	0
Donduseni CMF	➔IO	➔IO	1	?	30	0	0	0	1xDoM	1x2005	0	0	1xDoM
Sudarca CS (Donduseni)	➔IO	➔IO	7	D	0	0	0	0	1x2009	1x1998	0	0	1x2009
Drochia CMF	➔IO	➔IO	1	D		8	2	T 5 NT 5 Sp 2		1xDoM	0	0	1xDoM
Edinet CMF	➔IO	➔IO	4	D	0	0	0	0	0	1x2004	0	0	1x1984
Falesti CMF	➔IO	➔IO	3							1x2000			
Floresti CMF	➔IO	➔IO	0	L 20 M 30 S 20	0	0	0	0	0	1x2004	0	0	0
Glodeni CMF	➔IO	➔IO	2	L 13 M 46 S 349	0	2	2	T 2 NT 7	1xDoM 1x2009	1x1988 1x2003	1xDoM	0	1xDoM
Ocnita CMF	➔IO	➔IO	1	L 10 M 15 S 10	0	0	0	0	1x2009	1x2007	0	0	0
Riscani CMF	➔IO	➔IO	1	D	0	0	0	0	1x2003	1x2003 (NF)	-	-	-
Singerei Noi CS	➔IO	➔IO	1	L 10 M 20 S 30	0	0	0	10	0	1x2003	0	0	1x1990
Soroca CMF	➔IO	➔IO								1x2005			1xDoM
Center													
Anenii Noi CMF	➔IO	➔IO	1	D	0	0	0	0	-	1x2004		0	1xDoM
Calarasi CMF	➔IO	➔IO	2	L: 20 M: 50 S: 20	0	10	10	0	0	3x2003		0	1x1976
Pirljolteni CS	➔IO	➔IO	1	L 30 M 23 S 12	0	0	1	0	0	0	0	0	1xDoM (NF)
Criuleni CMF	➔IO	➔IO	0		0	0	0	0	0	1x2004			
Dubasari CMF	➔IO	➔IO											
Hincesti CMF	➔IO	➔IO	1	D	0	0	0	0	0	1x2006 (NF)	0	0	-
Ialoveni CMF	➔IO	➔IO								1xDoM			1xDoM

Appendix 7: Services & equipment for follow-up of abnormal Pap tests & cervical surgery													
	Colposcopy	Cervical Surgery	Gynaecological Couch	Vaginal Speculums	Endocervical Speculums	Biopsy Forceps	ECC Curette	Forceps	Autoclave/steriliser	Colposcope	LEEP	Cryo	DEC
Nisporeni CMF	➔IO	➔IO	1	D	0	20	10	0	0	1x2007		0	1xDoM (NF)
Orhei CMF	➔IO	➔IO	1	D	0	0	0	0		1xDoM			1xDoM
Teleseu CS	➔IO	➔IO	1										1xDoM (NF)
Rezina CMF	➔IO	➔IO	-	-						1x2006 (NF)			
Straseni CMF	➔IO	➔IO	2	L: 2 M: 2 S: 2						1xDoM			
Soldanesti CMF	➔IO	➔IO											
Telenesti CMF	➔IO	➔IO		-						1xDoM			
Ungheni CMF	➔IO	➔IO	1	D	0	0	0	0	1x2012	1x2000		0	1xDoM (NF)
South													
Basarabeasca CMF	➔IO	➔IO	2	L 7 M 13 S 3	0	0	0	0	0	1x1984 (NF) 1xDoM	1x1983	0	1x1983
Cahul CMF	➔IO	➔IO	1	0	0	0	0	0	0	1x2004		1xDoM	
Cantemir CMF	➔IO	➔IO	1	D	1	0	0	0	1x2003	1x2005	0	0	0
Causeni CMF	➔IO	➔IO	0	-	0	0	0	0	0	0	0	0	1xDoM
Cimislia CMF	➔IO	➔IO	1	D	0	0	0	0	4	1x2005	0	0	1xDoM
Leova	➔IO	➔IO	1	D	0	0	0	0	0	0	0	0	1x2009
Stefan-Voda CMF	➔IO	➔IO	3	L 12 M 15 S 10	0	0	0	T 5 NT 5 Sp 10	0	1x2005	1x2011	0	1x2009
Taraclia CMF	➔IO	➔IO	2							1x2011			
UTA Gagauzia													
Comrat CMF	➔IO	➔IO	1	-	0	0	0	0	1xDoM	1x2006	1x1979	0	
Ceadir-Lunga CMF	➔IO	➔IO	9	D	0	0	0	0	0	0	0	0	0
Copciac	➔IO	➔IO	1	D	0	0	0	0	1xDoM	1x1987	0	0	0
Vulcanesti CMF	➔IO	➔IO	2	D	0	0	0	0	2xDoM	1x2005	0	0	0
									Total:	55	12	4	35
									≥2000	32	1	0	4
									≥2000NF	3	0	0	0
									<2000	9	7	0	15
									DoM?	11	4	4	16

DEC: Diathermic electroconisation
D: Disposibles
L, M, S: Large, Medium, Small
T, NT, Sp: Toothed, Non-toothed
NF: Not functional

Appendix 8: Screening registry data requirements and flows



Appendix 8: Screening registry data requirements and flows

Cytopathology

Data Sent to CNAM	Use	Data Received from SCO
• Laboratory identification • Staff identification (for each Pap test) • Specimen type • Squamous cell results • Endocervical cell results • Other/non-cervical cell analysis • Follow-up recommendations	• Anticipate sample receipt and initiate tracing of Pap tests that do not arrive at lab • Investigate and resolve failsafe notices • Allows laboratory staff and managers to understand how their performance compares to agreed standards, other laboratories and program averages to: - Identify sub-standard performance so targeted remedial action can be taken to resolve problems - Introduce competition for quality of services and thereby motivate laboratory staff to achieve and exceed the standards.	• Pap tests taken and date sent to lab • Previous Pap test results • Date of last menstrual period • Type of sample: cervical or vaginal vault • Appearance of cervix • Additional clinical comments • Failsafe notices to be investigated • CQI reports comparing program, laboratory and staff performance: - Time from receipt of Pap test to reporting of results - Proportion of unsatisfactory results - Proportion of positives - Distribution of cytology results

Colposcopy & Cervical Surgery

Data Sent to CNAM	Use	Data Received from SCO
• Clinic identification • Colposcopist identification • Appointment attendance • [illegible]Extent of lesion • Colposcopic opinion • [illegible]Biopsy taken (yes/no) • Biopsy result • Follow-up recommendations	• Anticipate patient appointment and initiate tracing of defaulters • Ensures access to referral Pap test result and related clinical information • Investigate and resolve failsafe notices • Allows colposcopy staff and clinic managers to see how their performance compares to agreed standards and other clinics: - Identify sub-standard performance so targeted remedial action can be taken to resolve problems - Introduce competition for quality of services and thereby motivate staff to achieve and exceed the standards.	• Women referred and date of referral • Referring clinic/clinician identification • Referral Pap test result and/or clinical indications • Pap test history • Additional clinical comments • CQI reports for colposcopy clinic and staff performance: - Time from referral to appointment - Biopsy rate - Proportion of women treated after screen detected CIN1 - Proportion of women treated after screen detected ≥CIN2 - Proportion of women having a hysterectomy after screen detected CIN - Positive predictive value of colposcopy referral - Distribution of histology results - Cancer incidence after treatment for CIN

Histopathology

Data Sent to CNAM	Use	Data Received from SCO
• Specimen adequacy • Margin status • Histology result • Pathologist's recommendations	• Anticipate patient appointment and initiate tracing of defaulters • Ensures access to required clinical information • Investigate and resolve failsafe notices • Allows laboratory staff and managers to understand how their performance compares to agreed standards, other laboratories and program averages to: - Identify sub-standard performance so targeted remedial action can be taken to resolve problems - Introduce competition for quality of services and thereby motivate laboratory staff to achieve and exceed the standards	• Specimen referred and date of referral • Referring clinic/clinician identification • Colposcopic opinion and clinical details • CQI reports: - Time from receipt of sample to reporting of results - Proportion of unsatisfactory results - Proportion of positives - Distribution of histology results

Appendix 9: Minimum data reporting requirements	
Facility	**Data**
PHC – Pap test submission[67]	• Patient surname • Patient forename • Patient surname at birth and any previous surnames • Patient address + postcode • Patient correspondence address (if different from registered address) • Patient date of birth • Patient health insurance number • Clinic name, address and registration number • Staff name and registration number (the person who took the cervical sample • Date of last menstrual period • Type of sample: cervical or vaginal vault • Appearance of cervix: normal, suspicious, or not seen • Confirmation that the cervix was fully visualised and a 360° sample was taken • Previous Pap test results • Additional clinical comments
Cytopathology	• Specimen type • Squamous cell results • Endocervical cell results • Other/non-cervical cell analysis • Follow-up recommendations
PHC – Colposcopy referral	• Referral indication: abnormal screening cytology; abnormal smear after colposcopy; clinically suspicious cervix; suspicious symptoms; other • Cervical cytology: no cytology; negative (normal cytology); inadequate; ASC-US; ASC-H; AGUS; LSIL, HSIL; ? invasive cancer; ? glandular neoplasia
Colposcopy & Cervical Surgery[68]	• Attendance: attended; defaulted (cancelled by patient in advance; cancelled by patient on the day; cancelled by clinic; did not attend - no advance warning; arrived late; left without being seen) • Extent of lesion: ectocervix; extends into endocervical canal (upper limit seen); extends into endocervical canal (upper limit not seen); extends onto vagina • Colposcopic opinion: - Cervical: no cervix; normal; HPV/inflammatory/benign; CIN low grade; CIN high grade; invasion; other; not performed - Vaginal; normal; HPV/inflammatory/benign; VaIN low grade; VaIN high grade; invasion; other; not performed • Biopsy: no biopsy; punch biopsy (cervix; vagina); multiple punch biopsies (cervix; vagina); excisional biopsy; wedge biopsy (diagnostic loop) • Follow-up recommendations: discharge; colposcopy follow-up; treatment; cancer treatment; other • Treatment Method: no treatment; ablation (cold coagulation; cryotherapy; diathermy; laser); loop/laser excision; extended loop; knife cone; hysterectomy; other • Analgesia: no analgesia; local analgesia; general anaesthesia • Complications: additional haemostatic technique needed in addition to the treatment method; admission to hospital • Follow-up recommendations: discharge; colposcopy follow-up; treatment; cancer treatment; other
Histopathology (biopsy, excised tissue)	• Biopsy adequacy: satisfactory; unsatisfactory • Histology: unsatisfactory/inadequate; normal (no HPV or cervicitis); HPV or cervicitis; CIN 1; CIN 2; CIN 3; invasive squamous (Ia1); invasive squamous (Ia2); invasive squamous (Ib+); CGIN; invasive adenocarcinoma; VaIN 1; VaIN 2; VaIN 3; invasive vaginal carcinoma, • Margin status (not applicable to punch biopsies): incompletely excised at endocervical margin; completely excised at endocervical margin; excision status not specified; not applicable

Appendix 10: Performance indicators for cervical screening[22]		
	Indicator	Calculation
1	Program extension/coverage calculated regionally and nationally	N° targeted women in catchment area / N° targeted women in the region or country
2	Program recruitment during the screening interval, stratified by 5 year age groups	N° women screened in the screening interval / N° targeted women living in catchment area
3	Compliance to invitation (within six months after the end of the screening interval)	N° invited women screened / N° women invited
4	Proportion of eligible women recalled within the screening interval	N° women recalled / N° women eligible for recall
5	Compliance to recall invitation (within six months of the end of the screening interval)	N° recalled women screened / N° women recalled
6	Time (in working days) between: • screening test and reporting of result to patient • positive screening test result and offer colposcopy appointment • colposcopy appointment and reporting of results to patient • colposcopy/biopsy result and offer of appointment for treatment	
7	Pap tests/woman screened (include only the initial Pap test, not repeat tests such as those conducted after unsatisfactory tests or for follow-up)	N° Pap tests in the interval / N° women screened in the interval
8	Proportion of women requiring repeat Pap tests (calculate for initial screening appointment & recall screening appointment)	N° women requiring repeat Pap / N° women screened
9	Compliance with repeat Pap testing (calculate for the initial screening appointment & recall screening appointment)	N° women having repeat Pap / N° women referred for repeat Pap
10	Proportion of screen positive women (calculate for the initial screening appointment & recall screening appointment)	N° women with a positive Pap / N° women screened
11	Distribution of cytology results (calculate for the initial screening appointment & recall screening appointment)	N° of each cytological diagnosis / N° women screened
12	Referral rate to colposcopy (calculate for the initial screening appointment & recall screening appointment)	N° women referred to colposcopy / N° women screened
13	Compliance with referral to colposcopy (Calculate for 3 months after referral, 6 months after referral and by referral cytology)	N° women attending colposcopy / N° women referred to colposcopy
14	Biopsy rate (calculate for the initial screening appointment & recall screening appointment)	N° women having a biopsy / N° women having colposcopy
15	Proportion of women treated after screen detected CIN1	N° women with CIN1 treated / N° women with CIN1
16	Proportion of women treated after screen detected ≥CIN2	N° women with CIN2/3 treated / N° women with CIN2/3
17	Proportion of women having a hysterectomy after screen detected CIN	N° women with CIN having a hysterectomy / N° women with CIN
18	Positive predictive value of colposcopy referral (Calculate overall and for referral cytology, initial screening appointment, recall screening appointment & for grade of CIN)	N° women with ≥ CIN1 / N° women referred to colposcopy
19	Distribution of histology results (Calculate for histology result, initial screening appointment & recall screening appointment)	N° women with CIN+ / N° screened women
20	Cancer incidence after normal cytology (Calculate for interval from index cytology and by cancer morphology)	N° women having cancer after normal cytology / N° person-years of screened women for same period after normal cytology

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