INMED Scholarly Project.

A Quality Improvement Project for the implementation of elimination of cervical cancer in a Low-Middle Income setting of La Clinica Esperanza in Roatan Honduras

by Susan Aycock MD

+INTRODUCTION

During August 2020 while the world struggled with the COVID19 pandemic, the World Health Organization (WHO) passed a resolution detailing a Global Strategy for elimination of cervical cancer as a public health problem[1].

The Global Strategy states that to reach the elimination threshold of four cases of cervical cancer per 100 000 women a year by the end of the century, countries should reach the following targets by 2030 (the "90–70–90" targets) and maintain them from that point on:

• 90% of girls fully vaccinated with the HPV vaccine by the age of 15

• 70% of women screened with a high-performance test by the age of 35, and again by the age of 45 (i.e., at least twice in their lifetime, a maximum of 10 years apart)

• 90% of women with identified cervical disease receive treatment (i.e., 90% of women with precancer treated and 90% of women with invasive cancer managed.[2]

Currently every nation even the high resource areas fall short in some measure. *The purpose of this project is to develop an actionable plan for a Quality Improvement Project such that a clinic in a low-middle income country (LMIC) can contribute to this WHO goal*. A key component will be to uncover a curriculum that will allow a student to approach mastery of

[1] Chaib, 2021
[2] WHO, Draft, 2020

cervical screening and treatment over the course of a one-month rotation in such a low-middle resource setting.

GENERAL NEEDS ASSESSMENT

According to 2018 statistics, cervical cancer kills more than 311,000 women per year worldwide with the expectation that this number will increase to 400,000 by 2030 without intervention.[3] Approximately 90 % of these deaths occur in medium-low resource areas where cervical cancer is the number ONE cause of cancer deaths in women.[4] In stark contrast, cervical cancer represents less than one percent of cancer deaths of the women living in high resource areas such as USA.[5]

This success in elimination cervical as a public health problem for high resource areas has occurred in the past century. In 1920 Dr Papanicolaou developed the method of screening cervical cells to which his name is attached.[6] He postulated that early detection of abnormal cervical cells and eradication of the same would prevent the development of cervical cancer. His prediction coupled with frequent screening intervals has indeed accomplished this goal in the areas that have the resources to implement this plan.

The next scientific discovery was in 1990 when the association of human papilloma virus (HPV) was identified as an essential co-factor in development of cervical cancer.[7] We have identified over 100 virus types of which 10 are associated with development of cervical cancer especially virus type 16,18, and 45.[8] The combination of HPV detection and typing along with cytological changes of abnormal cervical cells and colposcopic evaluation coupled with treatment has caused the One-Two punch in eradicating cervical cancer as a public health

[3] Chaib,2021
[4] Cheney, 2018
[5] Nat Cancer Institute, stat facts, 2021
[6] Flayton,2019
[7] Nat Cancer Institute, HPV-AND-CANCER,2020
[8] WHO draft ,2020

problem in high resource areas. Are there lessons that can be learned by studying this approach which may extend to the LMIC?

When the method of screening employed in LMIC is the Papanicolaou smear, cervical cells are collected is applied to a glass slide with fixative. Usually there is no provision for HPV testing. Likewise, there is usually no provision for pathology evaluation of Pap smears or cervical biopsies of abnormal findings except in major urban centers. Frequently there is no available treatment of precancerous lesions or cervical cancer either. Where these services are available, they are generally cost prohibitive. Likewise, they often require traveling far distances which is especially burdensome if there are several different steps required for evaluation and treatment. This lack of medical infrastructure, isolation of groups of people, and lack of financial resources are the common themes of most of the low-middle income regions and the reason that cytology screening is not usually appropriate for these areas.[9] [10]

One of the most troubling barriers to elimination of cervical cancer as a public health problem is the basic disregard of the worth of women - especially middle-aged women. Their contribution to the economic development of a country and the stability of the family structure is profound but often underappreciated. The WHO estimates that for every dollar invested in cervical cancer elimination through 2050, $3.20 will be returned to the economy due to workforce participation and a breathtaking $26.00 per dollar invested when the benefits of improved women's health on families, communities , and society as a whole are considered.[11] Only now that this culture of disrespect is recognized on a widespread basis by the 194 countries signing on to the WHO resolution is there hope for the political will and financial backing to conquer this problem[12].

[9] PAHO,2011
[10] Boskey,2020
[11] Chaib,2021
[12] Cheney, 2018

VACCINATION

A Review of the literature reveals that the tools for eradication of cervical cancer already exist! When it comes to primary prevention through vaccination, the twin problems boil down to finances and availability. An HPV vaccine was first approved by the FDA in 2006 though at a high cost.[13,14] Even if cost can be overcome, however, there is currently not a sufficient supply of HPV vaccine for every girl to get a 2-shot series. GAVI, the vaccine alliance for developing countries is currently working on this problem.[15] In June 2020 the HPV vaccine manufacturers pledged to double production in the next few years.[16]

SCREENING

In addressing the second and third strategies, several "screen-and-treat" or "screen-triage-treat" models exist. As mentioned above, the purpose of this project is to develop a Quality Improvement (QI) project for the incorporation of the screen-and-treat component into a pathway for LMIC participation in the WHO goal. The ideal quality improvement project is one where the cost is low, convenience for medical personnel, and acceptability to patients are high, testing results correctly identifies both the affected and unaffected women, and the outcome is measurable.

At this point a review of the statistical terms of sensitivity and specificity is useful. Sensitivity is the proportion of true positives correctly identified by the screening test. In this situation, if a woman has abnormal cells a highly sensitive test should be positive, and a diseased person will be detected. Conversely, specificity is the proportion of negatives that correctly identifies healthy people such that if a test is negative or normal one can be confident that you do not have the condition. Therefore, the screening test should be the most sensitive

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13 Commissioner, FDA approves,2021
14 WHO draft, 2020
15 Cheney, 2017
16 CCAE, 2021

and if it does not also have a high specificity, the confirmatory or triage test should be more specific to pick up all of the women who are affected but not subject the healthy women to undue worry or treatment[17] This screen and triage concept is used frequently for laboratory detection of disease- usually screen with "reflex" testing. For example, if the initial test for HIV or syphilis are positive but the reflex is negative one can feel confident that you do not have the disease. If both screen and reflex are positive, you do have the disease.

When evaluating the three most common screening tests, cytology (Pap) which was previously described, visual inspection with Acetic acid (VIA), and HPV DNA testing, there was a wide range of accuracy. Regarding cytology, the sensitivities varied from 70-high 80's though specificity was at 95%. VIA showed consistently lower sensitivity at 55-80% but specificity at or above 90%. HPV testing was the all-around winner from a sensitivity perspective in the high 90's with specificity at 85%.[18] [19]

The technique of VIA involves application 5% acetic acid (common white vinegar) to the exposed cervix with a plan to freeze or otherwise ablate the tissue if an abnormal pattern develops.[20] It has been discussed and piloted in low resource areas for a decade.[21] [22] [23] Overall, the technique is well accepted by both patients and providers. It requires only basic medical infrastructure for the initial screening. Cost is only provider time and common table vinegar. The low sensitivity is at least partially offset by the ability to provide same day treatment for abnormal findings and therefore avoiding loss to follow-up as well as loss because of cost. VIA is considered an acceptable screening tool in comparison to no screening at all and carries a

[17] ACCP,2011
[18] ACCP,2011
[19] WHO Guidelines Screening ,2021
[20] Boskey, 2020
[21] Wolford, 2015
[22] Adefuye, 2014
[23] Roger, 2014

38% reduction over 3 years of CIN3+[24]. However, the value of VIA in a screen-triage-treat program lies in its high specificity which makes it a valuable tool for triage when paired with a highly sensitive screen.

HPV screening has become the current gold standard for cervical screening. It demonstrates a 3-year reduction of CIN3+ of more than 77%.[25] High risk HPV (HR HPV) testing has the dual advantages of very high sensitivity and moderately high specificity. When used as a stand-alone test there is a high rate of picking up cervical cancer precursors even though it is paired with a moderately high rate of over treatment since a test positive for high-risk HPV infection detects the necessary co factor but not necessarily abnormal lesions. When it comes to patient acceptability the advent of self-collection of testing swabs has made large gains in the percentage of women submitting for testing in both high resource areas as well as LMIC.[26] Only recently has a Point of Care (POC) testing become available such that same day treatment would be feasible and drop loss to follow-up to zero percent.[27,28] However, the main drawback has been cost. The price usually quoted is $5 per test but this leaves out the infrastructure for testing that requires national or at least broad scale testing such that quantity savings can be achieved. The UNICEF supply catalog quotes 2019 price per HPV test at $10.23 not including capital investment and quotes investment at $21,514 for essential equipment per district[29]. One can easily visualize a national program where widespread HPV self-testing provides the basic screen. For the approximate 6% positive tests[30], a vaginal exam with VIA triage can be followed by ablative treatment when appropriate. It is not hard to imagine the time consumed by 100 vaginal speculum exams for VIA screen as well as the staff

[24] ACCP,2011
[25] ACCP,2011
[26] Yeh TP, 2019
[27] WHO prequalified, 2021
[28] Herqiagen-the CAREHPVtest,2018
[29] PATH, Cervical, 2021
[30] ACCP,2011

time for cleaning the speculums or cost for disposable speculums. In comparison, 100 self-swabs require little provider time except that time required for VIA plus treatment only of the 6/100 positive screens. This HPV screen with VIA triage would be especially beneficial if there was a point of care HPV which allowed a one visit screen-and-treat that would eradicate the loss to follow-up which has to be calculated into any model that requires more than one visit. Think of how difficult follow-up can be even in high resource areas!

At the present time, HPV testing is recommended as the most cost-effective screen for all levels of resource though national support is required in LMIC. VIA can be used as stand-alone as well as a triage method to determine appropriate treatment. Currently all groups working in limited and basic resource areas should have the skills for VIA. The major drawback of VIA has been to identify an effective provider-trainer based educational tool. For this reason, a Curriculum for VIA and ablative treatment (Appendix 1) will be included as a self-contained unit.

TREATMENT

Early treatment has been the key to reducing cervical cancer since the development of the Pap smear. The long prodromal phase from infection with HPV to the development of cancer can last over ten years giving ample opportunity for cure and is the basis of recommendation that the second lifetime screening should not be greater than 10 years following the first.[31] As a physician, I try to follow the mantra, “Don't ask the question if the answer has no bearing on the treatment.” In this setting, screening is useless if there is no effective treatment. The point of screening is to identify the woman in this phase of the disease process that is favorable to both treatment and cure. We currently use either ablative treatments or excisional procedures if ablation is not appropriate.[32] [33]

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[31] WHO draft,2021

[32] Mittal-atlas,2020

The ablative treatment with the longest history in treating cervical cancer precursors is cryotherapy.[34,35] This technique uses a metal tip which is super-cooled using compressed gas to cause a frost bite on the cervix. The damaged tissue sloughs off and heals with an 85% cure rate for precancerous lesions.[36] There are however many regions for which the availability and cost of CO2 or N2O gas as well as inconvenience of transportation of heavy tanks of compressed gas into the field presents a barrier to prompt, local treatment.[37]

In recent years there has been evaluation of thermal ablation as a well-accepted treatment modality with an equal effectiveness to cryotherapy. This technique employs a heated metal tip which when applied to the cervix produces thermal tissue damage which eradicates the cervical cancer precursors. It has the advantage of being easily portable and powered either by rechargeable battery or direct access to electricity.[38]

Both methods of ablation are portable and appropriate for a same day screen-and-treat approach. Both methods have an 85% cure rate for cervical cancer precursors. The techniques are easily mastered by non-physician providers and well tolerated by patients. Detailed instruction about each method is covered in the WHO document, "Atlas of Colposcopy: Principles and Practice".[39] For those lesions that are not appropriate for ablative treatment referral to regional medical centers are made for excisional treatments such as LEEP and cold knife conization. If cancer is suspected by appearance on triage examination or biopsy, then surgical approaches must be considered also requiring referral to regional medical centers.

This preceding discussion details the clinical structures and concepts necessary for a screen-and-treat program but is light on actual provider training. How does a novice proceed to

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[33] Jeronimo,2017
[34] Adefuye,2014
[35] PAHO,2011
[36] ACCP,2011
[37] PAHO,2012
[38] WHO- guidelines thermal, p20,2021
[39] Basu-Atlas,2018

the point of mastery in this screen-and-treat method in a 1-month educational course? The advent of the WHO world strategy for the elimination of cervical cancer as a public health problem has triggered the development of a host of resources to address this goal. The use of these documents has led me to the development of a curriculum to accomplish a one-month educational course (Appendix A). Since it employs WHO sanctioned content it avoids the need for local updating of materials and development of best practices.

Resources for Screen-and-Treat Training: (hyperlinks)

Virtual Course on Comprehensive Cervical Cancer Control (2018)

Atlas of Visual Inspection of the Cervix with Acetic Acid for Screening, Triage, and Assessment for Treatment

Atlas of Colposcopy: Principles and Practice

TARGETTED NEEDS ASSESSMENT

This quality improvement intervention is based on the location of the Roatan Island of Honduras at La Clinica Esperanza where I did my service component of the Diploma in International Medicine and Public Health (DIMPH). This clinic provides excellent care, but currently the rate of effective cervical cancer screening and treatment there is far below the WHO goal. I observed and performed several Paps in the weeks I was there using the method I used at the beginning of my career with a cervix brush and spatula applied to a glass slide and sprayed with a fixative with no opportunity for HPV testing. This contrasts with the liquid-based cytology which can be paired with HPV as a co-test that is usual in high resource areas.[40] However, when I asked about follow-up of abnormal results there was not an easy answer since there is no local pathologist to read the Pap and no local specialist for treatment. Therefore, if

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the Pap is abnormal, several trips to the mainland are required for specialty evaluation prior to determination of appropriate treatment plan and execution of the same. This whole process costs the full month income for the average working-class family. So, it is no surprise that a majority of patients do not present for cervical screening, nor are they particularly encouraged to do so despite the presence of dedicated providers and educators. As I was discussing this dilemma with the Clinic Director, Ms. Peggy Stranges, RN, she challenged me to "come up with" a protocol for effective cervical screening. This challenge set me on the current path of developing a curriculum for VIA training as well as a QI process for incorporating cervical screening and treatment into the fabric of the clinic.

QUALITY IMPROVEMENT

I have brushed over the term Quality Improvement (QI) several times to this point. QI is the process of ongoing cycles of improvement whereby a healthcare system can gradually move from "usual practice" to "best practice" by incorporating specific changes into their culture and thereby improving the health of the community. A QI project for an organization should incorporate all of the stakeholders such that the aim of the project is to determine the goals of the group and to investigate ways to embrace changes and take ownership of them.[41]

La Clinica Esperanza (LCE) is an ideal location for an ongoing quality improvement pilot project since this clinic has a longstanding reputation of striving for excellence. In fact, the pursuit of this project was initiated at the request of the clinic manager, Ms. Peggy Stranges., to "come up with a protocol" for cervical screening. The stakeholders in this arena are at least Ms. Peggy Stranges, the women's health provider, the community health nurse, perhaps the local gynecologist, and even the manager of the local HIV colony. Considering that this is a project that seeks to connect with the WHO initiative, there should be some coordination with the

[41] ARHQ

Honduran Ministry of Health and the Pan American Health Organization (PAHO) cervical cancer initiative.

The Wyoming Department of Health delineates a five-step process for developing a medical QI project which is used below as a framework for this particular situation.[42]

1. The first step in establishing a project in QI is to identify an area of improvement.[43] In this case, at least the initial target is set by the cervical screening challenge. We have identified that cytology is the "usual practice" at LCE. If we are to move to "best practice" of screen-and-treat it will require education of the providers in the techniques of Visual Inspection with Acetic acid (VIA) as well as therapies for treatment as determined to be appropriate by the committee. This is where the Curriculum for VIA that follows in Appendix A will be appropriate.

2. The second stage of the QI project is to determine what processes can be modified to improve outcomes.[44] We must first assess a baseline of data for the clinic looking to verify how many women have been screened, by which method, and at what ages. In addition, it would be important to determine if any treatment was indicated or utilized. There are several techniques that could be used. If there is an electronic medical record that uses diagnostic codes, such as z12.4 for screening for malignant cervical cancer, or a computerized billing system that could pull out Pap smear payments then these could be used to identify client services. A computer analysis would be much more convenient than pulling a certain percentage of charts by hand to search for evidence of cervical screening.

   If these techniques are not feasible, the WHO has tabulated a current Cervical Cancer Profile for each of the member nations. The Honduras profile (*hyperlink)* states that 6 in 10 women have been screened for cervical cancer in the last 5 years and 75% claim to have

[42] Wyoming DOH, 2017
[43] Wyoming DOH, 2017
[44] Wyoming DOH,2017

been screened at least once in their life.[45] This profile for Honduras states that there is currently no national cervical cancer screening program and leaves blank the primary screening test utilized. There is a PAHO document from 2010 providing a "rapid assessment in 12 countries of Latin America" which states that Honduras *does* have a national program and that the screening method is Pap smear. In fact, all of the Central American countries covered in this report use Pap as the primary screening method though a few lists VIA as a secondary method.[46] There have been some pilot programs in Honduras using VIA[47] but no sustained efforts. Several other sources discuss the use of Pap as the preferred screening method but, not surprisingly, detail the roadblocks of difficult follow-up both from a travel aspect as well as locating women that need treatment.[48] [49]

If this current profile sheet is used as the baseline of the percentage of women who attend LCE who have been screened for cervical cancer, it would be prudent to try to verify the statistics with at least a survey of the women coming through the clinic. This should consist of only a few questions to determine the awareness of cervical cancer and their reception to a screening protocol. Example: 1) Do you know anyone who has/had cervical cancer? 2) Have you ever had a Pap smear? At what age or how long ago? 3) Would you like to be screened and treated for an infection before it turns into cancer? 4) What would keep you from being screened?

3. Develop and execute effective strategies to improve quality. The specific actions to achieve the QI goals should follow the SMART mnemonic[50].

    *Specific: understandable in lay terms--- "We are starting a program to help women avoid and treat cervical cancer."

[45] WHO cervical cancer profile ,2021
[46] PAHO,2010
[47] CCA,2012
[48] Pryor R., 2017
[49] Dartmouth, 2022
[50] The Mind, smart assessed 2021

*Measurable: quantifiable on a scale--- how many women who attend LCE have been screened twice in their life for cervical cancer and treated if appropriate. We discussed above methods of determining quantifiable statistics for this topic.

*Attainable: realistic goals considering the resources---When it comes to provider training, there should be no barriers to achieving 100% compliance since the GOALS AND OBJECTIVES in the Curriculum for VIA are laid out for completion in a one-month window (see Appendix 1) and the resources are readily available on-line.

There are two web-based documents informative for clinical staff. The first is appropriately named "Atlas of Visual Inspection of the Cervix with Acetic Acid for Screening, Triage, and Assessment for Treatment" [51] It proceeds through clinical background of cervical structure both throughout the lifespan of a woman as well as following infection with HPV. Then follows a "large repository" of cervical images before and after treatment with acetic acid showing normal findings, abnormal findings suggestive of cervical precancers, and ending with slides displaying the usual appearance of adenocarcinoma of the cervix.

The second web-based document is "Atlas of Colposcopy: Principles and Practice."[52] The components that are most applicable in this setting are the sections on treatment which detail the steps of cryotherapy and thermal ablation as well as the expected risks and benefits of the same.

The Pan American Health Organization (PAHO) Virtual Course on Comprehensive Cervical Control document is an important baseline of knowledge for each of the committee members.[53] This document provides the scientific background of normal cervical changes that happen throughout a woman's life and as well as the changes that happen as a result of HPV

[51] Mittal S, Atlas, assessed 2021
[52] Basu P, Atlas ,2017
[53] PAHO,2018

infection. It provides a programmatic approach to each of the WHO targets beginning with primary prevention of HPV vaccination, secondary prevention of screening for cervical abnormalities and treatment of precancerous lesions. Lastly it describes the steps of tertiary prevention by treatment of curable cancers and palliation for incurable cancers. Any person who successfully completes the training will receive a certificate.

If the Honduras profile statistics are confirmed that 6/10 women have been screened at least once in their life,[54] then it could be realistic that the initial goals could be to actually achieve the WHO percentages of 7/10 women screened twice in their life between the age of 30-50 years.

When the QI program is expanded in future cycles to include the remaining strategies for elimination of cervical cancer, the addition of HPV screening for improved secondary prevention will prove to be the greatest "stretch" goal. It is the one that will require national coordination for the provision of HPV testing capital outlay and maintenance in the absence of some large charitable grant to the Bay Islands of which Roatan is the largest. In 2020, the WHO introduced a document called "Step-by-Step, Introducing and Scaling-up testing for HPV as part of the Comprehensive Program to Prevent and Control Cervical Cancer" which details both the need and "how to" for this most difficult part of the screening strategy[55].

When it comes to vaccination for primary prevention, then coordination of the national program will again be needed to achieve realistic goals. Since the Ministry of Health has already committed to the addition of HPV vaccine to the national program as stated in the Honduras profile[56], it will surely be a realistic goal to achieve 90% vaccination rate because of the support of GAVI suppliers. Fortunately, Honduras already has in place a very effective program for mass pediatric vaccination described to me by the community health nurse which

54 WHO, CC profile-Honduras, 2021
55 WHO, Introducing, 2020
56 WHO, CC profile-Honduras, 2021

does achieve such a 90% rate for nationally approved vaccinations.

Treatment of cervical lesions that are not appropriate for local ablation either because of the size of the lesion, the shape of the cervix, or the potential for cancerous changes will require coordination with regional centers. LCE already has such usual referral paths. Reaching 90% treatment of these complicated lesions will place a cost on the national healthcare system since few individuals would be able to afford surgeries, chemotherapy, radiation treatments.

There is however another type of treatment for advanced cancers which would be appropriate for a local medical provider such as LCE. Palliative treatment is another phase of tertiary prevention of crippling effects of cervical cancer and is the second part of the third strategy to achieve 90% treatment of invasive cancer. Each provider or medical location is encouraged to acquire the skills to manage terminal cancer pain with low-cost narcotics and home visits from community health nurses.

*Relevant: actions address the identified target ---staff education and training are key to initiating improved rates of cervical screening and treatment. Additionally, community engagement and education are key to the success. At LCE, there exists a system of "las promotoras" who are already involved with community groups especially in regard to children but also women's health. Additionally, there should be ongoing monitoring of the individuals screened and which ones required treatment with the necessary follow-up or even referral to the national cancer registry. One of the relevant targets for achieving effective treatment is to find a funding mechanism for the treatment equipment. It may be that the clinic has enough cash buffer such that the relatively small capital outlay for treatment of approximately $1500 USD is reasonable. Otherwise, it strikes me that if the first cryogun or thermal gun can be acquired by charitable contributions through the La Clinical Esperanza newsletter or by a "go-fund-me" page then the ongoing replacement could be funded through several mechanisms such as students who come to LCE for the purpose of learning this VIA technique. In addition, this

clinic has a policy of charging patients a modest price for services and the cost of HPV testing ($10 USD) is equal to the ($10 USD) cost of the Pap. VIA alone or as a triage for HPV screening is very cost effective as is the ablative treatments.

*Timely: allotted timetable--- goals could be completed on quarterly or annual basis. The initial goal of provider training should be accomplished within the first quarter with recognition that there should be some time designated in the usual work week to accomplish this goal. By the end of the second quarter the statistics of history of patient cervical screening by the mechanisms detailed above of chart reviews or in person survey should be complete. As the process goes on additional quarterly and annual goals should be delineated.

4. Track performance and outcome.[57] As previously mentioned, the weak link of the project is the determination of baseline of cervical screening such that the analysis of ongoing results is initially tenuous but becomes stronger as the QI committee can compare progressive results. This is where quarterly marks can provide guidance about the effectiveness of the whole process. It may turn out that different tools for acceptance of screening are needed. For example, if the community health nurse was not initially included in the project, it may be determined that her involvement is critical to the overall success of widespread screening to reach the goal of 70% of all women screened twice in their life between 30 – 50 years old.

5. Determine results to spur broad quality improvement. The committee should meet at least quarterly to assess the progress of interim goals including documentation of education for clinicians and maintenance of cervical screening/treatment records for patients being sure to contribute any cancer diagnoses to the national cancer data bank. As the first annual cycle ends, the committee should decide on the success of each action as it applies to stated goal of

[57] Wyoming DOH,2017

improving screening and treatment for the elimination of cervical cancer. This analysis will help both with the local achievement at the clinic as well as broader implications for spreading these tactics beyond their boundaries.

The most recent WHO document from July 2020 that spells out the whole process is "The Global Strategy to Elimination Cervical Cancer as a Public health problem"[58]. In addition to the background information, it discusses each target individually including the secondary prevention methods of screening and treatment of cervical precancers. The final module of the paper is titled "Surveillance, Monitoring, and Evaluation". It covers the topics of programming monitoring, performance indicators, result indicator, and impact indicator. Each of these are directly applicable to goals for QI projects. The tools of sensitivity and specificity that we reviewed at the initial discussion of screen-and-treat will continue to be important as the QI committee proceeds through the research on screening methodologies. A pattern for such a process is spelled out in a QI format in the WHO document about scaling up testing for HPV in the section concerning Cervical cancer screening methodologies.[59]

[58] WHO, Global, 2020
[59] WHO Introducing ,2020

Figure 2. Screening methodologies

Another outstanding resource for quality improvement goals and tools is the Cervical Cancer Action for Elimination (CCAE) network of eight organizations that initially came together in 2006 for the fight against cervical cancer. It was restructured in 2019 to support the WHO global strategy with the stated goal to "facilitate the exchange of best practices in research, innovation, and learning for impactful interventions."[60] Its web site is laid out in such a manner to achieve strategies for each of the WHO targets which of course includes screening and treatment of precancers.

Additionally, one of the member organizations of CCAE is PATH which is a global organization that works to eliminate health inequities by developing and scaling solutions to these health problems by combining the expertise of many specialties to include science and technology.[61] The PATH group has developed an interactive excel-based model to evaluate

[60] CCAE,2020
[61] PATH

scenarios for scaling up effective screening and treatment of cervical precancer. The benefit of Quality Improvement is that it provides a tool for decision making that varies according to screening and treatment approaches. The screening approach varies by 1) VIA alone, 2) HPV alone, 3) HPV +VIA triage, and 4) HPV + enhanced triage. The treatment scenario varies by 1) single visit approach for screen-and-treat, 2) hospital treatment which requires a second visit to go to the local hospital, 3) district treatment requiring further travel and less availability of treatment devices, and 4) hybrid static-mobile situations where treatment can be delivered by mobile units to screening sites. As each of these variables is manipulated, the cost and effectiveness can be compared and incorporated into a QI program.

Resources for Quality Improvement (hyperlinks)

The Global Strategy to Eliminate Cervical Cancer as a Public Health Problem

Cervical Cancer Action for Elimination – CCAE

PATH Excel-based Model of S&T for Cervical Precancer

In Summary, a potential timetable for this QI project would look something like this: Q1 All key stakeholders should complete the PAHO self-learning program in the first quarter. This would include administrative personnel, community health nurse, pediatrician/ medical director, community resource people such as the local gynecologist, as well as the clinicians at LCE. The clinical staff should also aim to complete the Atlases for VIA and treatment during this first quarter. Obviously, the education process can and should begin as soon as the commitment is made but the training cannot be completed until there is an instrument for treatment either cryogun or thermal ablator and preferably both types of equipment. There is nothing to stop providers from trying their hand at VIA as a prelude to Pap screening while they

are completing their training. Certainly, there is nothing to stop triage of an abnormal Pap by VIA whether it is a historical finding or a current Pap. Likewise, VIA could be incorporated into the Pap process as an additional screening method with the explanation that LCE is converting to a new improved process to replace the Pap. They should discuss with their patients the coming changes of HPV screening with VIA triage as a cost-effective improvement over the current "usual" treatment.

Q1-2 Survey of charts /or questions addressed to women who are already associated with LCE in order to assess statistical baseline of and reception to screening by the end of the second quarter. This can be accomplished by "front office" registration staff passing out a written form if appropriate to the person on check-in and collected at discharge. This information may also be collected by the providers during routine visits. Chart review would be under the medical records staff – or even utilizing visiting students and nurses. This information will be used both to verify the National data sheet regarding prevalence of cervical screening and make a contact list for widespread coverage of the LCE patients for screening and treatment.

Q2-3 Once a complete understanding of the program is accomplished by the community health nurse, a series of education sessions should be organized for "las promotoras" so that they will be able to take this information on cervical screening as well as HPV vaccination back to their communities. At this time the community women can be recruited for the improved screening process. During this second and third quarters the pediatrician will also be discussing prevention of cervical cancer with the mothers and mentioning the screen-and-treat program for women 30-50 years old. This assumes that the HPV vaccine is actually readily available from the national vaccine bank.

Q3-4 Once the LCE staff are comfortable with VIA for screening followed by appropriate treatment, then LCE will be prepared to host visiting students who want to learn this skill set in a one month on site program. (See the attached curriculum guide.)

Q?? Addition of HPV screening is heavily dependent on the national timeline. I recommend that a designated person at LCE stay in contact with Dr. Jacqueline Figueroa the cervical cancer champion at the Honduras Ministry of Health. It is desirable, however, that the providers and patients be comfortable with VIA and treatment at the local level before adding the increased complexity of HPV screening. The ideal situation would be that both the patients and providers are anticipating the arrival of improved screening.

CONCLUSION

Quality Improvement is an ongoing process like the steps of the “yellow brick road leading to the city of Oz”. The path that leads from the challenge to “come up with a protocol” for

effective cervical screening, to the ultimate goal of achieving the WHO Global Strategy of elimination cervical cancer as a public health problem by 2030 will engage many cycles.

I think it is fair to say that the WHO and associated organizations have provided a host of materials to achieve the elimination of cervical cancer as a public health problem. The key now is for local organizations such as La Clinica Esperanza, mission-based groups such as INMED and, educational groups especially those residency programs with a global health track to incorporate the skills such as VIA into their quality improvement programs for the incorporation of best practices for the Global Strategy.

APPENDEX A: CURRICULUM FOR VIA AS A TOOL FOR THE ELIMINATION OF CERVICAL CANCER AS A PUBLIC HEALTH PROBLEM

GOALS AND OBJECTIVES

The main goal of this curriculum is to provide a tool to implement WHO sanctioned content that a student of at least 4th year medical school or advanced nursing degree can wield to achieve competency in screening and early treatment of cervical abnormalities in a low resource setting by1-month term. It could also serve the local Women's Health provider and local midwives. For this audience a significant portion should be available in the local language. Portions of the curriculum would be of use to community health workers as well as program managers. The flexibility of the curriculum provides for this wide range of interests and experience level.

There are three specific objectives to lead to this goal:

1) A student will describe general knowledge about cervical cancer prevention and control prior to beginning or by the first week of the rotation.

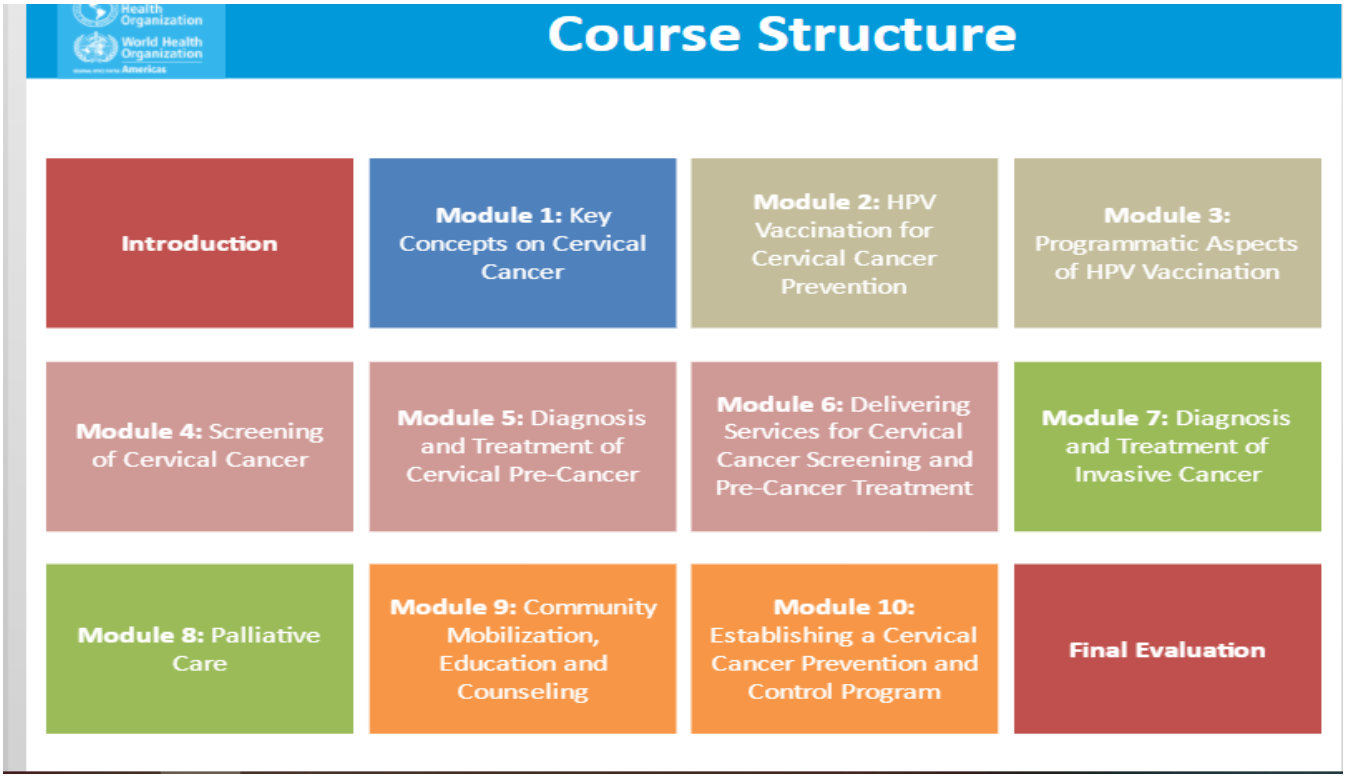
2) The student will explain how the visual inspection of the cervix with acetic acid is effective for screening, triage, and assessment for treatment by the end of the second week of the rotation.

3) The student will demonstrate the correct technique for cryotherapy and/or thermal ablation to the cervix by the end of the rotation.

EDUCATIONAL STRATEGIES

The source of the curricular materials is primarily from existing WHO sanctioned content which increases the likelihood that the materials are both appropriate to the stated goal of elimination of cervical cancer as well as easy to update as best practices evolve. The

foundation of the curriculum is "Virtual Course on Comprehensive Cervical Cancer Control (2018)" available on the Virtual Campus for Public Health and sponsored by both the World Health Organization as well as the Pan American Health Organization.[62] This is a self-learning program that uses a virtual teaching platform that consists of ten modules progressing through the above-mentioned course objectives.



It also includes the diagnosis, treatment and palliative care of cervical cancer in order to include all components of the WHO targets. The student will work through this course in either English or Spanish as a flipped classroom structure prior to arriving in Honduras or at least within the first week of the month-long program.

At this point the student is equipped with the foundation to proceed with practical instruction about screen and treat procedures. That student should be able to utilize the ASCO (American Society of Clinical Oncology) Guidelines put out in 2016 in the form of readings of

[62] Pan American Health Organization, 2018

Algorithms Packet[63] and resource stratified clinical guidelines by the end of the second week.

In addition, the International Agency for Research on Cancer (IARC) which is an arm of the World Health Organization, has organized two web-based atlases both of which are available in multiple languages. The first is "Atlas of visual inspection of the cervix with acetic acid for screening, triage, and assessment for treatment."[64] It includes theoretical background of Visual Inspection with Acetic acid (VIA) as implied in the self-explanatory title as well as a "large repository" of before and after acetic acid cervical images with interpretation. This information is additionally used as determination of eligibility for ablative treatment. The student should be able to describe the technique of VIA and discuss management of women with an abnormal screening test by the end of the third week. This atlas is appropriate for a stand-alone practical guide.

The second web-based document is "Atlas of Colposcopy: Principles and Practice" which details many standard treatments for precancerous lesions to include detailed instructions on treatment by cryotherapy.[65] The student should be able to demonstrate correct freezing technique on a piece of uncooked meat by the end of the third week as well as discussing possible side effects and complications. There is an obvious advantage of this learning unit if the location has a colposcope which could be used by the more advanced student for analysis of the abnormal screen whether VIA or abnormal HVP screen. In addition, there is a Women's Health provider on the staff of the clinic who could use this information as a second step evaluation for problems a student may identify.

The last component of the training consists of a simulation model called "The Visualize Trainer" which is a low-cost training model that was first built in 2013 to aide midwives in

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63 Jeronimo et al, 2017
64 Mittal, 2020
65 Basu, 2017

Ghana in learning to perform VIA.[66] It consists of a box with an artificial vagina into which the student must insert a speculum, provide some kind of external light source, and apply acetic acid to a card. This card demonstrates the before and after cervical pictures in response to the acetic acid and provides an electronic feedback mechanism. As is often true of simulated learning, this mechanism combines several skills sets in order to be more comfortable when faced with a real patient.

At this point the student will coordinate with local faculty for supervised clinical experience. The faculty will help determine which group of women may be appropriate for screening with a concentration on those individuals whose resources would otherwise preclude screening and treatment.

EVALUATION AND FEEDBACK

The evaluation and feedback of the project will take several forms. The foundation "Comprehensive Cervical Cancer Control" has integral evaluation and immediate feedback for each of the ten modules consisting of ten multiple choice questions and a discussion forum as well as a final test consisting of 40 questions. A 70% pass is required for successful completion of the course as well as being awarded a certificate issued by the Pan American Organization. The self-contained feature makes this portion of the total program particularly appropriate for use by program managers who may not desire the technical application component but need to know how to establish a local or regional Cervical Cancer Prevention and Control Program. In addition, this foundation provides the knowledge base for continued improvement as best practices evolve and technical improvements allow for improved HPV detection.

A similar though not as extensive immediate feedback mechanism exists for the Atlas of VIA. The last of three sections consists of a quiz on randomly selected cases where the student

[66] Young, 2013

will have to interpret them and submit responses. The correct results will immediately be revealed for self-assessment of competency. There is no corresponding certificate of completion.

The *Atlas of Colposcopy* lacks a feedback mechanism but is much more appropriate for the specialized needs of the individual learner and should be discussed with the local faculty to determine appropriate preceptor evaluation. Familiarity with the broad scope of treatment for cervical abnormality is helpful at any level of provider competency for patient instruction especially if there is a need for referral. The basic student however will achieve her/his overarching goal of competency in VIA by completing the extensive sections on treatment by cryotherapy and thermal ablation. The more advanced student would also benefit from the discussion of colposcopic examination.

As the evaluation mechanism for the whole course, I chose the single-group, posttest-only design [67]. This method is consistent with the need for a cost effective and simple mechanism that can be used to document proficiency and elicit suggestions for improvement.

The format will consist of a survey on a scale of 1-5 with one being poor and 5 being good. These scaled questions are congruent with the previously stated measurable objectives. In addition, several open-ended questions provide feedback for improvement of the learning experience:

1) Can you explain the general concepts of cervical cancer prevention and control?1-5

2) How well did this course explain how VIA functions for screening, triage, and treatment?1-5

3) How confident do you feel that you can use VIA and treatment in any low resource area?1-5

4) What was the weakest section of your learning experience?

5)What was the strongest section of your learning experience?

6) What recommendations do you have to improve this course?

[67] Thomas, Kern, Hughes, and Chen, 2016

The last portion of evaluation for the individual learner is for local “faculty” to give a summative assessment of the student and ask for any clarification of the survey answers. This should result in certification of the student’s competence and ability to join the battle for cervical cancer elimination!!

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