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The development and evaluation of a community based model for cervical cancer screening based on self-sampling

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HIGHLIGHTS

- Screening and prevention programs world-wide frequently suffer from major cost constraints, poor participation, lost to follow-up, and concerns about sustainability.
- Using Community Based Participatory Research concepts, we designed and implemented a cervical cancer screening model based on self-collection.
- The communities conduct the screening and then the healthcare system can focus resources on the management of the positives.

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ABSTRACT

Objective. To develop and implement a community based model for cervical cancer prevention that allows the communities to manage the screening and the healthcare system to focus resources on evaluation and management of the positives.

Methods. Using self-sampling and the concepts founded in Community Based Participatory Research (CBPR), we progressively developed a model to efficiently reach the women, especially rural communities; and collect the volume of samples needed to support high throughput centralized low cost per case processing.

Results. 8382 eligible women, ages 35 to 59, in 130 rural communities participated. The screening was organized by the local government administration and conducted by the community leaders (CLs). The model used was progressively designed through detailed assessment of key elements at 6 decision points in 26 workshops that were used to train the CLs and the local promoters. The communities were able to accurately conduct the screening; in the final model a local medical worker conducted a 50-minute workshop featuring instructional posters and structured role-play. A manual and a workshop DVD were created for distribution to and implementation by local governments. The average callback rate was 84.3%, without involvement of the local doctors in the management of the positives.

Conclusion. An efficient community based model capable of massive screening events was developed. We believe that the callback rate will be further improved when local doctors are trained in the management of the positives. Many elements impact coverage and further research is needed to define the influence of the identified key variables.

Introduction

Worldwide cervical cancer is the third most common cancer in women, accounting for 13% of all cancers [1]. It is the greatest cancer killer of young women, and the most common cause of death from cancer among women in the developing world [2]. Cervical cancer occurs secondary to viral transformation of the surface (epithelial) cells by high-risk types of the human papillomavirus (HPV), and it is the only gynecologic cancer that can be prevented by regular screening [3,4].

We have well established screening programs in the western world that have effectively reduced the burden of cervical cancer [5,6]. However, they have relied on insensitive screening technologies (cytology) that depend on the long pre-invasive phase of cervical

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carcinogenesis. This requires regular return visits for patients, thereby allowing the screening algorithms to eventually arrive at an accurate diagnosis. World-wide the need for highly sensitive and specific, less infrastructure demanding, screening modalities are sorely needed.

Screening and prevention programs in general, throughout the world, suffer from major cost constraints, poor participation, loss to follow-up, and concerns about sustainability. Over the past 16 years Preventive Oncology International (POI, a 501c3 public charity based in Cleveland Heights, Ohio, USA) and its collaborators have been studying self-collection as a way to reach the medically underserved for cervical cancer screening. In a recent 10,000 patient randomized clinical trial we demonstrated that a self-collected sample, tested for the presence of high-risk HPV, is equivalent in accuracy to a physician obtained endocervical specimen using a PCR based assay [7]. Applied to the majority of the worlds' medically underserved now living in middle income countries, it is no longer necessary to think small, slow, and simple, with poor quality control. It is totally achievable with self-collection to have specimens analyzed by centralized, high-throughput, low cost per case processing. In addition, we now have solid media specimen transport cards, thereby avoiding the logistics of dealing with personal use of alcohol-based liquids, concerns about exposure temperature, and ease of transportation [8].

These screening technologies, especially in terms of specificity, will surely continue to improve. However now we need to focus on developing the models that will efficiently reach the women most in need and provide the volume of samples to the centralized laboratories that will enable cost-effective processing. Using self-sampling and the concepts founded in Community Based Participatory Research (CBPR) [9], we believe that systems can be developed that will allow the communities to conduct the screening programs and identify individuals who need further evaluation and possibly treatment. In doing so, the identification of who is abnormal can be removed from the medical model conserving healthcare resources which can then be focused on evaluation and management. Or in other terms, the medical infrastructure can focus on those individuals at highest risk of having disease. In addition, with community involvement in the design of the program (CBPR), we expect that their participation in the "campaigns" and follow-up to be significantly improved. Program sustainability also becomes a simpler problem because of the "campaign" or "event" type model. The sustainability will lie in the community organization (applicable to other programs), management of the central laboratories and the management of the positives by the healthcare system [9]. A community based self-collection model would allow large numbers of patients who are not presently ill, or symptomatic, to avoid traveling long distances and interrupting their daily lives to participate in a preventive healthcare program. Using this community based concept, we began our development of the screening model with two pilot projects in Peru [10–12]. The lessons learned have now been adopted and this report documents the continuation of this work, the Chinese Cervical Cancer Prevention Study (CHICAPS).

Our primary objective was: To develop and implement a community based preventive healthcare model using self-sampling based cervical cancer screening as the target medical intervention. The secondary objectives of the CHICAPS project were to: 1) Acquire increased experience using solid transport media cards; 2) develop an effective specimen transport system (air, truck, etc.); and 3) determine the true impact the lack of histopathological verification of disease has in the screen, triage, and treat model. This manuscript will focus on the primary objective.

Methods

The model development phase and 6 month follow-up of the Chinese Cancer Prevention Study (CHICAPS) took place in Heshan, in Guangdong Province, China. The study was approved by the IRBs of the Cleveland Clinic (Cleveland, Ohio, USA), and Peking University Shenzhen Hospital (Shenzhen, P.R. China), and registered with Clinicaltrials.gov #NCT01524003.

We chose Heshan as the study site because the municipal government was prepared to fund the community work required for a cervical cancer prevention project and was seeking an effective implementation proposal. Hence the community activities in this cervical cancer screening project were sponsored by Heshan Municipal Government and the research funded by the Peking University Shenzhen Hospital, Preventive Oncology International Inc. and BGI Shenzhen (Shenzhen, P.R. China).

Women currently living in the communities were eligible for screening if they were between the ages of 35 and 59 (based on an average later onset of sexual activity in China), had no history of cervical cancer or pelvic radiation, and had not had their uterus and cervix previously removed.

Our primary objective of developing a community based cervical cancer screening model was advanced by identifying key decision points during many training workshops. We integrated our studies with the local officials and their identified local project organizer to conduct a series of workshops designed to educate local community leaders (non-healthcare personnel) about cervical cancer and cervical cancer prevention; and then with their knowledge of their communities develop plans to notify the public about the screening events, teach self-sampling, record research data, collect specimens and report results. We planned to progressively develop the model based on observation and interviews by our staff and evaluation of recorded data.

The decision points for developing our model were not predetermined. We planned for the model to evolve through the individual workshops and screening events, and when we thought we had a model that would work for any size population we considered this phase of our work complete. We made our decisions by studying the "post-workshop practice forms" and by checking the errors made by the CLs and promoters on the research forms they had completed during the actual screening events. Our entire research group would meet after each workshop/screening event and after reviewing the data make modifications to the model. In the end we hoped we could create a community based "Manual of Standard Operating Procedures for Cervical Cancer Screening and Other Healthcare Interventions". This manual could then be provided for local, regional, and provincial government officials and be implemented throughout China as an effective method to bring cervical cancer screening to the vast populations of rural people in China, many of whom are medically underserved.

In order to demonstrate whether the community's assessment of "eligible" among the registered residents in their communities was reliable, we created and conducted a census survey to compare the communities' estimation of the eligible population with an actual door-to-door census survey. We adopted self-sampling to collect the specimens for screening as designed by POI (see Appendix). We categorized the projects' activities as either the "research activities" or the "community activities", which were then conducted only by the research team or the community respectively. Our research staff was strictly forbidden to be involved in the community activities except for providing technical interpretation of the medical issues encountered per the communities' requests. After the final decision point we conducted 2 workshops to test the model. For these two we further separated the research components from the model's essential training components so as to better see and evaluate to final form of the training model.

In order to avoid conflicts with publicly accepted technologies and the local doctors on the effectiveness of the model, we elected for this trial not to involve any local doctors (includes the small "town" and city doctors) in the management phase of the project.

The details of the information we intended to collect in order to develop and evaluate the model are found in the Appendix.

Statistics

As the primary goal of this project is the development of a community facilitated screening program, and the primary outcomes

are process outcomes, power calculations are not necessary. This study aims to implement a novel community based public health program. Outcomes to be collected, tabulated and evaluated include the community work (participants' demographics, specimen labeling, and completion of research specific forms), effectiveness of self-collection instructions, call-back rate, and barriers to program implementation. Since the rates of the "eligible" women are continuous variables as a percent of the registered residents for the "door to door" census and a promoter, we examined the relationship by calculating the correlation between the actual census and the estimation by the local promoters for the communities of Taoyuan and Longkou. Percentage calculations and correlations were performed in Excel 2010, using a significance level of 0.05.

Results

Between November 2011 and July 2013, 8382 women between the ages of 35 and 59 who were eligible for screening gave consent for participation in the community screening events and thereby participation in CHICAPS. They were enrolled through a community based screening model organized by the Heshan government administration and conducted by the community leaders (CLs) with the technical assistance of the research team. By the end 26 workshops had been held to train the CLs and the local promoters. The final training model was created through detailed assessment of the research team's modifications at 6 decision points. These results will report the developed "methods" for future community-based screening.

In conducting CHICAPS, we demonstrated that the local project organizer of the community preventive health event must meet 2 requirements: 1) there must be an existing linkage between the local organizer and the target communities; and 2) the local organizer has the human and financial resources required by the screening model for the conduct of community based screening. In China, the government will always be involved as the local organizer. Therefore in CHICAPS, the governments of the target towns, the primary level of administration under the China administration system, were identified as the organizers of the project. The local governments had the highest public trust, since no powerful NGOs were operative in the region. They were directly linked with the communities where the screening events were to take place. They were capable of providing necessary resources required for the conduct of the projects. In addition, the community screening must be conducted by the CLs with the assistance of some promoters and the support of the local project organizer and as we learned the local gynecologists. The CLs must be identified to be the persons who are respected and selected by the community members to be in charge of the public healthcare. They must not only be trusted members of the community, but eager and willing to do something that benefits their communities.

It is important to emphasize that both the organizer and promoters are roles in our model but not job titles in the communities. The organizer may actually be any person who is able to meet the requirements needed as the organizer. (A village leader can be the organizer if a small village wanted to screen their women with their own resources). Clearly it would be most efficient if the organizer (person or organization/government) could influence multiple counties.

We determined that the most important resources that need to be provided by the government (most effective organizer in China) are: 1) computerized demographic data for identification of the target population; 2) funding to support the community work; and 3) a medical facility and gynecologists qualified according to the local regulations, for evaluation and management of women testing positive.

We ultimately engaged the town hospital in each of the 8 towns involved in the screening and a municipal level hospital to be an additional resource for evaluation and management of participants whose screening tests are positive. The town hospitals which had a gynecologist were the lowest level medical facility qualified legally and practically (close to villages) to conduct management of the positives. However, as stated earlier for research reasons during CHICAPS, management was standardized by our research team physicians from the Peking University Shenzhen Hospital.

Prior to the workshops, a planning meeting that included the research team, the local government organizers, and the CLs from the target communities was held. This proved to be critical, since the enthusiasm of the leadership, and especially the community leaders, was identified by the research team as one of the prime determinants for a successful community screening event. Therefore, we identified this "pre-workshop meeting" as the first step of the model as shown in Table 1.

Table 1 provides an overview of the community model we developed and specifically shows the identified 8 key components, along

Table 1
Overview of the community based preventive healthcare model (cervical cancer): Lists and describes the key elements that are designed to be adaptable to other cancer prevention and early diagnosis strategies. CL = community leader.

Steps	Components	Time frame	Tasks	Materials available
1	Community engagement	10 days before Step 4	1) Seek community interest (support) 2) Identify the CL of the community	Instruction sheet and the operation manual
2	Advertisement and community notification	10 days before initiating sampling	1) Video advertisement on TV 2) Public notification with posters 3) Personal notification with core information sheet	Public advertisement video Public notification poster Personal information sheet
3	Training for the local doctors	Any day before Step 4	Training the local doctors for: 1) Meaning of a positive test 2) Management options and techniques	(Under development)
4	Training for the CLs and promoters	Complete in 2 h (before the sampling days)	1) Instruction 2) Encouragement 3) Promoters to estimate no. of eligible and available women; also decide the final day for screening.	Training program manual Posters Kits for self-sampling
5	Sampling days	Allow 8–10 days	1) CLs and promoters instruct the women 2) CLs collect completed samples	Instructions on the kit Personal information (envelope) Removable bar code (ID)
6	Collection of completed specimens	Maximum of 10 days after sampling begins (Step 4)	Transfer the specimens from the community to the central laboratory	
7	Report results to community (for the patients)	Depends on the testing period for a certain no. of specimens.	1) Paper report for each women returned to community 2) Doctors available for consult provided 3) Encourage positives to visit clinic for management	Paper report Guidelines for positives
8	Call-back for evaluation and management	Arrange evaluation as soon as possible after results reported	1) First contact by community 2) Second effort by local doctor 3) Management by standard of care	

Table 2
Key roles in the community based model.

Role	Criteria for identification
The organizer	An official from a local organization with an established relationship with the target communities. He/she is able to locate the human and financial resources needed for the community-based screening model.
The community leader trainer	A local health worker (doctor, nurse, public health) with good communication skills and enthusiasm for the community-based screening model. He/she will be trained using the operation manual, the course DVD and a training workshop.
The community leader (CL)	A respected community member who has been selected by the community via an official election, in charge of public healthcare. In addition to being a trusted member of the community, they must be eager and willing to do something that benefits their community.
The promoter	A community woman who is widely trusted and known to be "always willing to help."

with their time frame, the specific tasks involved and the current status of the materials we identified as necessary and have developed as of time this manuscript was prepared. Table 2 lists and describes the key roles within the model.

We have demonstrated through CHICAPS that this model is successful in the following functions:

1) Teaching the government to efficiently use its resources to conduct a community based screening event
2) Teaching the CLs and the promoters to get patient information, label the specimens and follow the procedures correctly
3) Teaching the rural women to collect their own specimen correctly.

Table 3 summarizes the evolution of the training model at the 6 decision points used in the development of the model. As seen in Table 3, the key decision points occurred just after 1st Chinese workshop, then after 4th, 5th, 16th, and the 24th. The key changes in the length of the workshop, the principal trainers, the critical attendees, how information was presented (posters and role play), and post-workshop practice are listed.

The work of the CLs and promoters tabulated at the 6 decision points for accuracy averaged 96.5% for patient demographics (range 90.7%–99.5% among the villages), 100% for specimen labeling, and 90.2% for the research forms (range 78%–94.6%).

Table 4 shows the callback rate (% of patients testing hrHPV positive who returned for evaluation and management) at each of the decision points which overall averages 84.3% (range 71.4%–100%). We observed lower rates in communities closer to the cities (where the women had other options), and especially if the CLs were less enthusiastic to promote in their villages.

Initial estimations of coverage in the many villages varied from a high of 80% to a low of 30%. To identify whether the CL's or the promoter's estimation is reliable in identifying the eligible residents in the communities, a 10% random sample was selected in 2 communities and is reported after a house to house survey. The Pearson's correlation coefficients were 0.84 and 0.64 in Taoyuan and Longkou respectively. These results suggest that the promoters' estimation will be a reliable method to use in the future for the estimation of coverage.

Discussion

The primary objective of this project has been to develop and implement a community based preventive healthcare model using self-sampling based cervical cancer screening as the target medical intervention. To accomplish this goal we have spent more than 16 years studying and understanding self-sampling technologies and how to make them as accurate as a direct (physician obtained) endocervical specimen [7,13–16]. After combining a simple brush ("Just for Me", POI, Hong Kong Ltd.), with an inexpensive high-risk HPV assay for centralized processing (SEQHPV, BGI Shenzhen, China) [17], we then added the POI FTA card (collaboration with GE Healthcare, Piscadaway, NJ, USA) for ease of transport [18]. Then first in Peru and continuing in China we begin the process to develop a community based preventive healthcare model. Then within this model we developed the "training model" so local organizers could effectively guide the community based screening programs.

Generally, our model can be divided into 3 parts: 1) Identifying the specific target communities and deciding the right persons to assume the roles in the model. 2) Training the local doctors in management of the positives (a future project that was not done in CHICAPS). 3) Recruitment, teaching self-collection and avoiding mistakes in specimen labeling (the CL/Promoter workshop). The community model is then integrated with processing specimens in a centralized laboratory. We strongly believe that all the parts in our model are applicable anywhere in the world regardless of ethnic/cultural background. The individual variation will be related to who are the right persons to assume the roles we have identified in the model.

There are a few of the model components that require further discussion. First, the identification of a qualified local organizer is absolutely essential. The Heshan administration was the organizer of this project. In China the organizer will always be the government, but it was also the organizer because it met the requirements for the organizer. In other countries there may be opportunities for more flexibility. Any organization such as a church, NGO or especially a hospital that meets the requirements can be the organizer. For along with providing the human and financial resources, it is with their enthusiastic support that the individual communities are engaged, the community leaders

Table 3
Stages in the development of the training model demonstrating the training courses: decision points in model development; duration: length of courses; teachers: the directors of the courses; attendees: who was asked to attend (CL = community leader); posters: if used and how many; role play: did it include structured dialog (questions) based on actual screening events; and practice: did attendees have an opportunity to practice what they learned in the course.

Courses	Duration	Teachers	Attendees	Posters	Role play	Practice
3 (2 in Peru, 1 in China)	2 1/2 days–2 days	Prof. (professional)	CLs & promoters	NO	Attendees No structure	No
3	1 day–3 h–1 h	Prof.	CLs & promoters	Yes (7)	Team No structure	Yes
1	1 h	Prof.	CLs	Yes (7)	Team No structure	No
11	1 h	Prof.–local	CLs & promoters	Yes (7)	Team Structure	No
8	50 min	Local	CLs	Yes (7)	Team Structure	Yes
2 (final model)	50 min	Local	CLs & selected promoters	Yes (6)	Team Structure	Yes

Table 4
Call-back rates at every decision point of the development of the model.

Decision points	I	II	III	IV	V	VI
No. of positives (HPV)	38	47	90	219	106	40
No. of positives managed	38	43	77	187	77	33
Rate	100.0%	91.5%	85.6%	85.4%	72.6%	82.5%

(CLs) identified, and the energy and enthusiasm built so that the project can be successful. The most ideal situation to maximize the enthusiasm of the community is when the organizer and the conductor of the project are the same group of persons, but generally this will not be the case. Thus, the initial engagement with the communities by the local organizers hopefully will generate excitement among the CLs to perform their key coordinating roles. If this first step is not successful, everything that follows becomes more difficult and will result in the community receiving less than maximal benefit from the preventive healthcare opportunity.

A tremendous amount of work by the research team was focused on the training model. We viewed it as our mark on the entire program. The training model as detailed in the manual, and demonstrated in an accompanying DVD, hopefully will provide a clear guide for future local organizers. When we did our final evaluation we discovered that we could identify 6 time points where we made the major decisions about the training model.

After the first training workshop, our team realized that our original design for the workshop (a 2 1/2 day program) was not working well. This was primarily due to two problems: We failed to gain the attendees' full attention so that they could concentrate on the workshop information, and the length of the workshop was clearly beyond their attention span. Also some attendees could not finish the training program because they had to leave at a certain time for housework and other jobs outside the home. It is not surprising that the CLs and the promoters in these communities have many roles in their lives, making them unable to stop for even a half-day, let alone 2–2 1/2 days. In fact it became clear that it was hard for them to stay in the workshop for more than 2 h. Consequently, we needed to change our teaching methods if we hoped to accomplish our goals within a time frame that could hold their attendance and attention.

We quickly learned the attendees' concentration and their ability to remember key information improved with the use of teaching posters. We demonstrated that the posters are determinative in not only graphically showing the necessary information, but also in focusing the attention of the non-medically educated attendees. This resulted in a much better understanding of the course materials, shortened the required length of the workshop from 2 1/2 days to 50 min, and provided a structure for the trainers. Furthermore, the posters can be printed in smaller size and provided to the community for their reference.

The teacher for the workshop was a professional teacher early in the model development in large part so that we could control some variables in the beginning. But eventually it became a role for a local healthcare worker who could learn the material in the training manual, speak the local dialect and had the trust and confidence of the local women. We wavered some as we tried to identify the key trainees (likely hoping that they could be only the promoters), but eventually settling on the CLs and selected promoters (selected by the CL according to their needs of assistance and their identification for the promoter according to the requirements).

The development of a script based structured role-play also added tremendously to the retention of the course content by the attendees [19]. The script was based on frequent questions or points of confusion that has occurred during previous training sessions and during the screening events. In addition the opportunity to practice after the workshop such things as interview skills to determine eligibility, and proper labeling and completion of the study forms was very well received by the CLs and promoters.

Once the sampling begins in the communities, the days allowed should be sufficient for all who are available to participate. Although samples obtained during a menstrual period should be valid, most women would prefer to obtain the sample at a time other than during their menstrual flow. An adequate sampling time or possibly 2 time intervals will also benefit those who live only a portion of the lives within the community where they are registered.

We were very impressed by the work the communities did in handling the research forms and most importantly the proper labeling of the specimens, which demonstrated that that aspect of the training model worked well. We considered the ability to properly label the specimens as key since after this study when the research elements drop out, the distribution of the sampling kits and the proper labeling and specimen identification will remain. Clearly the communities understood the importance of specimen identification and performed extremely well in this task. The forms and the issues of labeling seem simple to virtually anyone who has worked in healthcare, or any organized office setting or industry. However, for most of the community women, the tasks we asked them to do were as foreign as their "fish farming" would have been to us, and they performed admirably.

Since specimen processing by the laboratory can be done in less than 1 week [17], it is critical to provide results to the patients and have positives managed as quickly as possible while the entire program is still fresh in their minds. Any delay between delivery of the test results and the positive management will result in patients being lost to follow-up [20,21]. Under these circumstances and in the future with the engagement of the local doctors (enabling a flexible time frame for positive management), the coverage, callback rate, and follow-up should be greatly improved. As mentioned in the Methods section we made the decision not to involve the local physicians in order to avoid conflicts with established methods and to better control the evaluation and management phase of the CHICAPS project. We believe we achieved those goals but on balance, the benefits of this decision were out-weighed by the negative effects incurred during the screening phase on enrollment and then during follow-up for evaluation and management. Consequently, we currently have under development a training course for local physicians that will emphasize primary HPV screening, self-collection, the meaning of a positive test, and current management options and techniques.

To understand how the model can result in a massive screening event, consider a "pass the message on" type model. Once the workshops are organized by the local organizer, each may have 25 CLs in the class. They contact any local village promoters they need to assist them, and then the appropriate women in the villages are easily reached. As an example: 40 workshops train 1000 CLs who may work with several promoters and very easily more than 100,000 women are screened.

An assessment of coverage we believe is an important parameter for any screening program [22,23]. CHICAPS by design, was balanced heavily toward model development and implementation and not toward maximizing coverage. Two major obstacles were actually built into CHICAPS that we came to realize were counter to testing the model for coverage. First we selected Heshan because we were invited, and they had the funds to manage the local screening costs. However, the local hospital with responsibility for women's health in Heshan had conducted several cervical cancer screening programs in the past 3 years, but the towns could not provide us with an accurate record of who has been screened. Therefore, a portion of the population in the villages that we screened and used to develop our model had been screened within the past 3 years. This may have been the most important reason for the lower enrollment in CHICAPS although it was difficult to quantitate. The screening opportunity was simply not as unique as it could have been in a more medically underserved setting, such as in many of our prior technology development studies [13,16,24]. Therefore, we do not believe that the comparatively lower coverage in CHICAPS is related to the model design. Second, as

previously mentioned, the intentional exclusion of the local doctors clearly had a negative influence on coverage.

Many elements in fact have the potential to impact coverage and it is very difficult for the organizer to control all the variables. We believe that the key solution to eliminate the negative impact from multiple sources is maximizing the enthusiasm of the conductors (the CLs and promoters). The simple way may be for the organizers to develop a plan to compensate the conductors for their time inputs. In CHICAPS, in order to identify the key elements impacting the model implementation, as a research team we decided not to pay for the community work, although we were asked for time compensation. We were aware that most of the CLs and promoters received some funding from the local organizers for participating in workshop. We believe that the promoters in only a few villages were compensated for their community work by their CLs or their village committees. Developing a clear method and scale of compensation may actually be the most efficient way to quickly and effectively accomplish the screening. We come to this conclusion because we noticed that some of the most enthusiastic CLs and promoters created very high coverage and had a good callback rate in their villages. We need more research to demonstrate whether a time-input/compensation mechanism works consistently and what is the best financial mechanism.

The callback rate was another area that was affected by our decision to exclude the local doctors. Although the callback rate of 84.3% is good in these rural settings [10,15,26], we are confident that, by maximizing the enthusiasm of the CLs and promoters together with educating and then involving the local doctors in the management phase of the screening campaigns, the callback rate will be improved significantly. Callback for positive management we feel should always be conducted first by the community and then if the community fails to convince the woman to return for evaluation and management, the next contact should come from the local doctors.

In the future, prior to the screening event, a name-list of the community women who are eligible should be in hand, if one wants to properly evaluate the effectiveness of the model. As our census evaluation demonstrated this appears to be easy information to come-by since the promoters demonstrated a “good to excellent” correlation with our door to door census survey. This information can also be used by organizers to decide when an appropriate time would be to repeat the screening event for a particular group of communities. Coverage will also be easier to evaluate if in the future large screening campaigns the organizer can coordinate with the central laboratory and keep detailed records for who has participated in the screening programs when they are offered.

In most settings, establishing a new model is always easier if nothing currently exists. If an old system, even one that is labor intensive and resource expensive, needs to be dismantled to build a new, it often takes years, a generation of caregivers, and there are major obstacles created by those benefitting from the old system. Current cervical cancer screening systems used in China are mostly cytology based. This is problematic since cytology skills are not widely available and the needed infrastructure is not in place to allow a cytology based system to serve the vast rural populations in China. In addition a cytology system is insensitive [25], and due to the labor intensive interpretation of the slides, and the needed callback infrastructure, it is slow, and difficult to apply to large populations. CareHPV was developed to be a low cost, low tech HPV test to be used to reach the medically underserved of the world [26–28]. However, application has been slow with many delays of actual implementation although multiple pilots still continue. It is also not high throughput and the final per patient cost is still unknown. Unaided visual inspection with acetic acid (VIA), is often touted as the life-saving “see and treat” screening method for many medically underserved regions of the world. It does lend itself to see and treat, but it is also slow, insensitive, and misses at least 50% of the high grade lesions [26]. It has been shown to reduce cancers, with a labor intensive repeated door to door effort, and clearly requires a “best we can do under the circumstances” mentality [29,30].

The strength of this study is the gradual development of our goals over many small trials by the careful attention to the effectiveness of the elements; and the research team's willingness to follow the results and modify plans accordingly. The study's major drawback is the lack of involvement by the local community doctors and the consequences that resulted in enrollment and follow-up.

Conflict of interest statement

Jerome L. Belinson MD over the past 17 years has received support in kind (reagents and testing) and funds for direct support and research, under the auspices of Preventive Oncology International Inc., from Hologic Inc., Qiagen, Gen-Probe, Merck Inc., BGI Shenzhen, and GE Healthcare.

The other authors declare that they have no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ygyno.2014.01.006.

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