

A VOUCHER SCHEME APPROACH TO SCREENING FOR CERVICAL CANCER: THE NICARAGUAN EXPERIENCE

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ABSTRACT

Cervical cancer still kills thousands in developing countries and it is the first cause of mortality amongst adult women in Nicaragua. Although alternatives to the traditional PAP smear are being considered (visual inspection of the cervix, HPV DNA testing, prophylactic HPV vaccination) this remains the only viable screening test for at least another few generations of women living in the developing world.

This technique is not problem free. Screening programmes have notoriously encountered problems in the developed world as well as having failed to significantly reducing mortality in the poorest countries. Like in other Latin American countries the Nicaraguan screening programme has been introduced piecemeal, lacks a sense of direction, coordination and quality control and has by and large, failed to meet its objectives: cervical cancer remaining to date the first cause of death among adult women.

This article reports on an innovative approach to cervical cancer prevention based on a voucher scheme coupled with an External Quality Assurance scheme for cervical cytology. The theory behind the use of vouchers schemes in health is also briefly discussed. The voucher scheme was intended to address a number of shortcomings as seen both in the national screening programme as well as in opportunistic screening done in the private clinics and it was meant to: increase the uptake of screening among poor and high risk-women, improve the quality of cervical cytology; ensure follow-up and effective treatment of precancerous lesions. Vouchers as a tool of health care delivery are particularly appropriate to address shortcomings in a screening programme because: they allow the targeting of beneficiaries, encourage the use of under consumed services and they work best for service packages with predictable costs. The authors conclude that a voucher scheme is a cost effective and efficient way of delivering screening services to some amongst the poorest and most marginalised women in the developing world. However, unless this strategy is adopted by the central government and applied on a large scale, a large chunk of high-risk women will always be left unscreened. Finally, the authors consider the feasibility and utility of using a voucher scheme to deliver prophylactic HPV vaccination once it becomes available to poor and middle income countries.

INTRODUCTION

The Situation in Nicaragua

Nicaragua has, by any standard, a very high mortality rate from cervical cancer: 13.2 per 100,000 women [1] and an age-standardized mortality rate of 22.3 [2]. This is over ten fold higher than the age-standardized mortality rate seen in the USA (2.3) where Human Papilloma Virus is the most commonly sexually transmitted infection [3] and cervical cancer represents a big threat. Even by Latin American standards Nicaragua has one of most serious problems in the region: it is only second to Thaiti in both incidence and mortality rates for cervical cancer [8]. The problem is likely to be worse than these data lead to believe as deaths are largely under reported and there is no population-based cancer registry in Nicaragua to validate data.

As in other developing countries deaths by cervical cancer occurs mostly among poor women [4, 5] who have less access to screening and for whom the catastrophic health costs of treatment often means that this is not available to them. Poor families not only loose the person who is often their primary breadwinner but are left with a number of orphans to care for. The extent of the social and economic costs of this otherwise preventable loss of lives goes well beyond the data shown here.

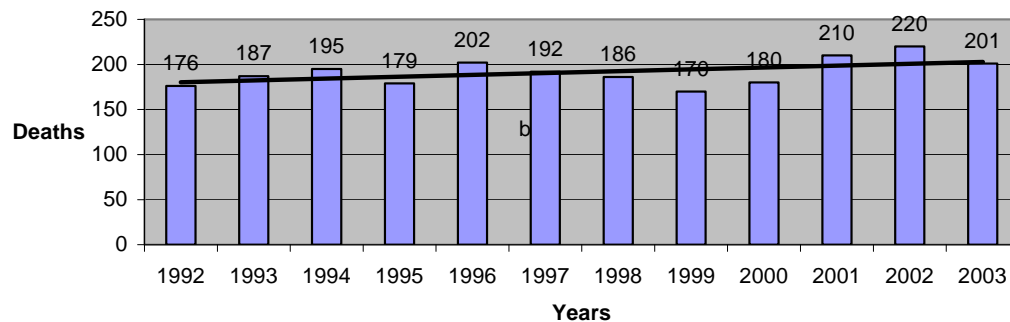


Figure 1. Deaths by cervical cancer in Nicaragua between 1992 and 2003.

Although screening for this disease has been in place for a long time in Nicaragua, this does not appear to have helped reducing incidence or mortality. In fact, in the past 12 years, for which data on mortality for cervical cancer is available, deaths only appear to have increased [6].

Among the biggest constraints of the national prevention programme are: lack of funding and political commitment. Since 2000 the government programme has been in existence officially on paper and has had a director, but there is no funding available: resource allocation at the central level of government is primarily determined by the demand of competing health needs like infectious diseases (mainly Tuberculosis, Malaria and Dengue) maternal and infant mortality and often influenced by donor's priorities. In fact the Nicaraguan Ministry of Health heavily relies on donation from foreign government to increase coverage of screening, rather than allocating money from its own budget (already quite depleted and mainly concerned with restructuring and strengthening the Ministerial

central level and, to a certain degree, secondary health care) [7]. This leaves the fate of the screening programme at the mercy of foreign donor's priorities and rapidly changing international public policies fashions.

Like in other Latin American countries [8] the screening programme in Nicaragua has been introduced piecemeal, lacks both organization and quality control and has failed to meet its objectives. The first among the practical shortcomings of the screening programme is the fact that women at risk of harbouring a pre-cancerous or invasive lesions (older and poorer women) are often left unscreened: screening is done opportunistically both in public services as well as in the private clinics and it is done in conjunction with reproductive health services, thus resulting in younger, low-risk women being tested. According to the national guidelines for the detection and prevention of cervical cancer [3], three or more Papanicolaou per year are necessary for a first timer, after which the frequency of testing can be relaxed but no mention is made to how often. This, again, results in younger and better off women, often with low -grade abnormalities, being screened (and treated) over and over again, a waste of resources which could otherwise be used to detect and treat women with high-grade neoplastic lesions.

The reliability of cytology services is a vital component of a screening programme and one which Nicaragua has disregarded for decades. The limitations of a cytology based screening methods have been recognized and documented [9, 10]. More to the point one has to doubt the efficacy of a programme to save lives when no element of quality control is present. Before the project implemented its own External Quality Assurance scheme for cervical cytology, not much attention was being paid to the accuracy of cytology reading: there is no formal training centre for cytologist in the country and no form of continuous education; many reading centres work without the supervision of a pathologist; internal quality control checks are done sporadically and arbitrarily, if carried out at all; the accuracy of cytology diagnoses varies enormously from one reading centre to another and by and large these are well below internationally accepted standards [11].

Assuming patients are correctly diagnosed the follow up and treatment of women with abnormalities is a difficult task. The logistic of returning results is not full-proof and rather erratic and the responsibility for following up cases rests entirely with the patient: no tracking or recall system is in place to find cases lost to follow up. Confidence in the public system is often so poor that patients do not even turn up for their Pap smear results, simply assuming these have been lost to the system¹. Management protocols are another sore point in Nicaragua: although the Ministry of Health finally drew one in 2000 [3], its guidelines are very controversial and have been opposed (as well as not implemented) by the most eminent gynecologist in the country. By and large it advocates for very frequent pap smears and for over treatment of pre-cancerous lesions resulting in over-servicing: a strategy the government, with its very limited public funding, can ill afford.

Partly the lack of emphasis on patients' follow up can be blamed on the fact the cervical cancer prevention programme in Nicaragua is still only being considered as screening, not as a comprehensive programme whereby positive patients are seen through the system until the necessary treatment and follow up is provided. No information system is in place that allows the progression (or otherwise) of a patient through the system to be monitored. Finally, the

¹ Project data collected through focus groups and questionnaires with potential target women in Managua, Nicaragua.

great majority of efforts and investments in cervical cancer projects implemented by foreign governments, NGOs and charities have suffered from the same handicap: they all simply concentrated on screening women without making the necessary arrangements to insure follow up and treatment. This highly compromises the ability of a programme to save any lives.

HOW A VOUCHER SCHEME CAN HELP

A voucher is:

A token that can be used in exchange for a restricted range of goods or services, either partially (e.g. as a discount) or in total.

Or put more simply, vouchers are “tied cash”. The “ties” can be in relation to *what* goods the voucher can be exchanged for, but also in relation to *where* the goods can be obtained (i.e. the range of providers may be limited) and *when* they can be obtained (if the voucher has a limited validity). Voucher schemes in health are those where the voucher is used in exchange for health services (such as medical consultations or laboratory tests) or health care consumables (such as drugs).

The basic idea behind vouchers in health is that subsidizing demand among the poor for specific health services of known cost-effectiveness, whilst allowing a competitive market for its provision, will be more beneficial than using those same resources to subsidize supply. Vouchers aim to link subsidies with patient flows, producing incentives at the facility level to increase throughput. In other words, they are a more cost effective way of delivering subsidies through a demand-side mechanism. Typically (and Nicaragua is no exception to this), government intervention in the health sector has taken the form of supply-side subsidies through the creation of a network of publicly owned and operated health facilities and services, either for the population as a whole, or for those unable to afford health insurance and not covered by social security [12]. Supply-side subsidies, which cover some or all of the costs of health service inputs (infrastructure, staff, drugs, equipment) provide little incentive to attract patients or increase productivity. The absence of targeting (restricting benefits to a certain subset of the population) greatly dilutes the impact of public expenditure in health care. Middle class people pay less than they can afford, while the poor often pay more. In addition, the services are consumed by relatively well-off patients with less urgent health needs, undermining both the efficiency and equity of the health system. Demand-side subsidies, on the other hand, create a direct link between the intended beneficiary, the subsidy and the desired output (such as access or utilization). The level of funding received by the provider therefore depends on the outputs produced [12].

Competitive voucher schemes are an extremely flexible tool, but experience in the health sector has to date been quite limited (a few examples described in the literature are [13, 14, 15, 16]) and no experiences exist with voucher schemes for health, which distribute vouchers universally and provide more general access to health care. Vouchers lend themselves particularly well to a cervical cancer screening programme because of their very unique characteristics described below:

- (1) **Vouchers Allow Targeting of Beneficiaries**

They allow funds (governmental or otherwise) to reach a higher proportion of the people meant to be subsidized; when screening for cervical cancer in developing countries this would translate in poorer and older women who are currently excluded from the programme.
- (2) **Vouchers Encourage Use of Under Consumed Services**

Health voucher may encourage people to visit providers they might not otherwise have seen. They are particularly useful for subsidizing services that tend to be under consumed from a social welfare perspective: in this case vouchers are particularly useful because there is no consumer demand from high-risk women for a screening service. By definition screening deals with otherwise healthy women, and poor women who do not feel sick do not tend to seek medical attention simply because they cannot afford nor justify the expense². Vouchers allow this demand to be created.
- (3) **Vouchers Reduce Provider-Induced Demand**

Since they are controlled by the user, vouchers reduce the problems associated with provider-induced demand: women too young to be at risk of harboring a cervical intraepithelial neoplasia or too wealthy to be entitled to subsidized care.
- (4) **Vouchers Work Best for Service Packages of Fixed or Predictable Cost**

Voucher schemes seem to work best when a fixed value can be assigned to the benefits they provide. This makes it easy to reimburse providers, who are given an agreed-upon amount for each voucher they return to the agency. This type of arrangement is possible when the services provided can be specified clearly in advance (e.g. screening by PAP smear, treatment for high grade lesions only, referral of invasive cancer etc.) and each patient receives exactly the same services or the same sets of services according to the diagnosis.
- (5) **Vouchers Increase Client Satisfaction**

In a competitive voucher scheme³ the bearer of the voucher can usually choose a provider. If the voucher covers the full cost of the services or if the cost charged by all providers is the same, the bearer will usually base the choice on perceptions about which provider offers the highest-quality, most convenient and most comfortable service. Providers will raise the quality of their services in order to attract voucher-bearing users. It is possible to create the mixture of providers which would best suit the requirements of the programme: for instance it is possible to chose a mixture of public and private provider and get them to compete amongst each others for clients.

METHODS

² Project data collected through focus groups and questionnaires with potential target women in Managua, Nicaragua.

³ For an exhaustive description of competitive voucher schemes we refer the reader to the book “A Guide to Competitive Vouchers in Health” published by the World Bank ISBN 0-8213-5855-3.

The Nicaraguan voucher programme about to be described has a complex history: it was initially set up in 1999 as a research programme in Nicaragua and Peru and sponsored by the British government aid agency (today DFID, Department for International Development). Because of its success at attracting, reaching, and treating poor, high-risk women it was subsequently funded by the British embassy in Nicaragua, the American government aid agency (USAID); by the DFID a second time (as a six months extension to the original programme); by the Dutch government aid agency and, more recently by a Nicaraguan charity. The configuration of the voucher scheme changed slightly to suit each donor's expectations and differences will be pointed out when deemed necessary. However, the basic features of the programme remained unvaried and are described here:

(a) the target population

this was broadly defined as poor women between the ages of 30 and 65, preferably who had not had a previous PAP in their life. However, no effort was made to exclude women with previous Pap smear because it was assumed that, due to the poor quality of cytology reading, their results was likely to be inaccurate. Although vouchers were meant primarily for supposedly healthy women (i.e. the programme was to emulate a screening programme), those who admitted to have been previously diagnosed with an abnormality were not refused a voucher. One has to be careful when making these decisions because handing out vouchers to women who admit to be positive can potentially represent a problem of adverse selection and jeopardize the financial viability of a programme.

The project made no effort to insure that vouchers were not transferred to someone other than the recipient (by donation or sales) on the assumption that an indirect recipient of the voucher was probably in greater need of it than the primary recipient. Often indirect recipients were women with a previous positive Pap smear and were hoping to receive treatment which they could not otherwise afford. However, measures were taken to monitor the potential development of a black market, whereby vouchers are created by someone other than the voucher agency and sold for a profit. Two security measures were put in place: one consisted in numbering vouchers and designing the information system so that it would alert project staff in case a voucher with a numeration other than the one allocated by the project was in circulation. Secondly, as part of the information collected from the patients, a question was asked whether the patient had to pay anything for the voucher (which were otherwise distributed for free). If the number of these cases suddenly increased, an investigation would be carried out.

(b) the package of services which the voucher entitled the bearer to

The programme was meant to have an integral approach to cervical cancer prevention so the voucher was designed to insure that the bearer was entitled to a package of pre-paid services including: screening with PAP, treatment of moderate and high-grade cervical intraepithelial neoplasia (CIN) lesions and follow up of women with low-grade abnormalities. In addition, the voucher secured that the patient would be followed up after six months after receiving any treatment.

So as not to create unrealistic expectations for the patient-to-be, the pre-paid services were clearly specified on the voucher itself. A decision to use exclusively female professionals (nurses) to take Pap smears was taken and also specified on the vouchers, as were a detailed list of clinics contracted by the project where the vouchers bearers could receive these services for free. Finally, the voucher had a sequential number printed on its cover (this was to be the Unique Patient Identifier) and a use by date.



Figure 2. Example of the voucher: the one used in the cervical cancer prevention programme was called GinecoBono

(c) the voucher agency

This was the Central American Institute of Health (Instituto CentroAmericano de la Salud or ICAS), a local NGO which has been experimenting with competitive voucher schemes in Nicaragua for almost 10 years. ICAS has extensive experience in using vouchers to promote Sexually Transmitted Infections (STI) diagnosis and treatment for vulnerable groups with a view to prevent the development of a major AIDS epidemic; it has also used vouchers to improve uptake and quality of care for Sexual and Reproductive Health services for adolescents. In addition ICAS has worked extensively in the past in the area of cervical cancer. This warranted a certain degree of technical knowledge in the area, which turned to be essential in negotiating contracts, management protocols and setting up and supervising quality controls elements.

To a large extent the key to a successful voucher scheme depends on the ability and transparency of the voucher agency. The agency works to link all of the programme components: ICAS is well placed for this role as it does not provide health services itself. No conflict of interest is therefore possible. At the time of implementation of this project, ICAS already possessed the remit, skills and capacity to negotiate and contract health service providers: a key element for the success of a voucher scheme.

(d) the attention to service quality and evidenced based protocol management

ICAS made a substantial effort to insure that the caliber of the services provided were of top quality. This spanned every aspect of the programme, from training nurses to accurately take smear, to setting up an External Quality Assurance (EQA)

scheme for cervical cytology; from monitoring the voucher distribution to training community health workers in doing this. With the assistance of the Scottish External Quality Assurance scheme, ICAS set up and implemented its own EQA scheme based on Proficiency Testing. This scheme was meant to aid in the selection of high performing reliable laboratories to process the project's PAP smears: only laboratories who passed PT and consistently maintained high standards over time were contracted to read the smears. Proficiency Testing was repeated yearly: any decline in the quality of cytology interpretation resulted in a contract being rescinded and a new one signed with a better performing centre.

Agreeing with health care professionals on a patient management protocol was a sore point. At the time the project was first implemented in 1999 there were no national guidelines on this subject and this field in Nicaragua was a real jungle of treatments, often extremely aggressive as well as unnecessary. The project opted for a conservative treatment of low-grade lesions (cytological evidence of HPV and Cervical Intraepithelial Neoplasia grade I), advising for a repeat smear after six months. These patients were given a second voucher and followed up accordingly. Patients with a cytologically diagnosed high-grade precancerous lesions (Cervical Intraepithelial Neoplasia grade II & III and Carcinoma In Situ) were immediately referred to the colposcopic clinic where a single-visit "see and treat" policy [17] was used: women who had a colposcopically diagnosed CIN II or CIN III or Carcinoma *In Situ* underwent a treatment by Large Loop Excision of the Transformation Zone (LLETZ). Histological evidence of clear margins was subsequently sought and if this was confirmed, women were referred for follow up at six months time. Patients diagnosed with invasive cancers were still referred to the project's clinic for colposcopic assessment and if the initial cytology diagnosis was confirmed, they were referred either to the women's' hospital for a hysterectomy or to the national radiotherapy center for radiotherapy or chemotherapy. Often a punch biopsy would be performed as well. All diagnostic tests and specialized ambulatory treatment (cytology, histology, punch biopsy and LLETZ) were free for the voucher bearer (and therefore pre-paid by the project) up to treatment of high-grade precancerous lesions. For women requiring hysterectomy and radiotherapy or chemotherapy an agreement was reached with the central level of the ministry of health whereby in recognition of the fact that voucher bearer were very poor women, no charge would be made to project patients. However, the project agreed to pay for half the value of the necessary tests, the government covering the other half.

(e) the information system

The voucher agency is the one entity ultimately responsible for the smooth operation of the scheme and for securing that women with abnormalities are properly followed up until exclusion from the programme is safe. The project's staff has to be able to monitor the progress of each single patient at any stage of the programme. This was possible thanks to the design of an information system which assigned each patient a unique identifier (i.e. the number of the voucher the women had received): by feeding the programme up-to-date information as collected from the patients' medical records it was always possible to know what procedure a patient had undergone and whether any further treatment was needed. Additionally, the system

would alert the staff if any women had missed her follow up or specialist appointment and a tracking system was set up to (physically) chase up these patients.

When dealing with a voucher scheme with a potential for big numbers and with a variety of service provider, it is essential to insure clinics and specialists are paid according to the services provided as well as insuring that clinical services are actually provided (evidence of attendance and/or treatment). Again, the information system was designed to aid with these tasks. Based on the number of vouchers and clinical records a clinic or specialist would return to the voucher agency, ICAS would reimburse the service provider as per an agreed-upon price. To make sure payment reflected real services provided, the evidence expected from, for instance, a smear taking clinic was: a) the voucher itself; b) patient's medical records; c) a Papanicolaou smear. From a colposcopy clinic the project would expect: a) a colposcopy voucher itself, only given out to positive patients; b) patient's medical records; c) a biopsy, if medical records specified one was taken.

Differences in the Programme According to the Donor

Each one of the donor who supported the cervical cancer programme, aside from an interest in saving lives, had its own private agenda and priorities which the project had to take into account and try to accommodate. This often meant lengthy negotiations with all the parties involved but a solution beneficial to all was always found. Donors' requirements translated in modifications in three areas: 1) the method of voucher distribution; 2) the geographical location selected for the target population; 3) the clinics where Paps were taken. Under the original programme set-up funded by the British Government, vouchers were sold to patients at a subsidized rate (to see if this could be financially self sustainable⁴), PAPs were taken in private clinics whose staff had been trained by ICAS and paid for by the project. The voucher bearer could choose among a number of them, according to their preference for location, perceived quality of services, quality of attention. A social marketing campaign was mounted in Managua to advertize the package of preventive and curative services marketed under the name of GinecoBono. These vouchers were sold either directly from the voucher agency or by pharmacies who had signed a contract to do so for a small marginal profit. The voucher name, format or content never changed after this initial configuration. The project also insisted in maintaining the right to choose the laboratory that would process and read the Paps as well as the colposcopy clinic. This decision was made so as to be able to insure the highest quality of services where it most mattered.

In 2000 the project obtained a small donation by the British Embassy in Managua to purchase 1,000 vouchers at the cost of US\$10 each. The embassy requested that these were distributed in a mining area of difficult access in the North of Nicaragua (Siuna) where the Embassy had previously supported the work of a British NGO: Health Unlimited. Work was

⁴ The idea behind this was to charge for the voucher an amount similar to the cost of a Pap smear in a private clinic (US\$7.00), but to include in the package of services follow up and treatment for women with cervical abnormalities. This would basically be a small insurance the woman would purchase. Because the health services were effectively purchased at a lower cost by the project (through negotiation and bulk purchase) the extra money charged for the voucher would serve to cover the cost of follow up and treatment of positive patients.

carried out here in collaboration with Health Unlimited staff who distributed the vouchers and took the smears to some of the poorest and hardest to access communities the project came across, and although the logistic of this project was at times challenging to say the least⁵, the services provided were of the same high quality as the ones offered to women in the capital. In 2001, the USAID funded the purchase of 10,000 vouchers for a total of US\$100,000. This donor requested of the programme to work with a network of local clinics (Profamilia) which USAID was supporting: voucher were distributed by Profamilia's community health workers. It was agreed that Profamilia did not distribute vouchers to its existing patients but tried to look for those older women who had never been screened or who had not had a Pap smear recently. This suited Profamilia too because it provided a chance to increase their clientele. Smears were taken in Profamilia's clinics at a negotiated cost to the project. The areas chosen where those were Profamilia had a clinic. DFID and the Dutch Cooperation subsequently sponsored the programme with the purchase of 10,000 vouchers each. These donors simply requested that the project worked in collaboration with the Nicaraguan MoH and tried to strengthen its own existing system. Vouchers were therefore symbolically donated to the Ministry and ICAS agreed to provide the package of services anywhere in the country where the MoH would require them, provided that the contracting of health service provision (smear taking, reading and treatment) was left in the hands of the voucher agency. In 2005 a local Nicaragua charity called Fundacion Ortiz Gurdian purchased 18,000 Vouchers which it donated to the MoH to strengthen its cervical cancer prevention programme. This donation has been received at the time this article was being written, so work on it is in progress and no result can yet be presented. At all time during the duration of the programme, the possibility of a direct vouchers sale to either clients or third party purchaser remained open . Through this mechanism two small direct purchases were made: one from ICAS's own sex worker programme and the second by the Nicaraguan Buddhist Association. Details of these will be discussed later.

HOW A VOUCHER SCHEME WORKS

A cervical cancer voucher scheme works in the way shown in Figure 3.

The process begins with the transfer of funds to a voucher agency (1). Vouchers are then produced by a voucher agency (ICAS) and distributed to a target population, either by the agency itself (2a) or to third party organizations (2b) who in turn distributes them to sections of the target population with which they have particularly close links (2c). The voucher is taken by the recipient to a health service provider of his or her choice (3) and used as payment for a Papanicolaou smear. Health service providers can be private clinics, NGO clinics, health centers or health posts, depending on the contracts stipulated. The service providers return the vouchers to the voucher agency (4), along with the patient=s medical records and her

⁵ Health Unlimited nurses travelled miles on mule-back to reach some isolated households whose women, according to their records, had never been screened for cervical cancer. Pap smears were taken directly at women's houses, even if not in the best of conditions. Slides had to be flown out of the nearest town (Siuna) so as to be assessed by the project's laboratory in Managua; (there was no laboratory in the whole region), and results had to be flown back in. Women requiring specialized care had to travel for two days to come to the capital city.

cytology, which then pays the providers a sum agreed in advance for each of the vouchers returned (5). The voucher agency reports the program outputs and outcomes back to the government or donor providing the subsidies.

This would be the working of a voucher scheme for patients with negative results. Patients with a positive result receive a second voucher according to the severity of their diagnosis: either a second GinecoBono for a follow up Pap smear in six month, or a Colposcopy voucher which entitled them to a specialized visit at the colposcopy clinic contracted by the project. The second voucher is handed out at the time of collecting their Pap smear results and the patient is given an indication of what she should expect in the near future. If required, an appointment with the gyneco-oncologist is made there and then and a big effort is made to motivate the patient to attend.

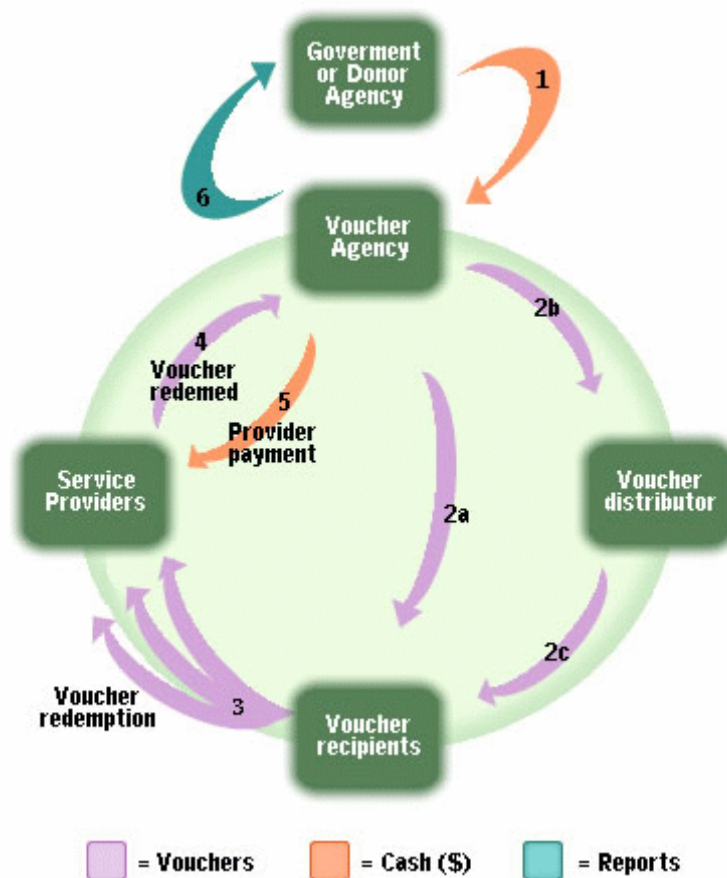


Figure 3. ICAS's cervical cancer voucher scheme.

The voucher agency contracts health care providers through competitive tenders, trains them, implements best practice protocols and monitors the distribution of vouchers by third parties. The voucher recipients choose a provider who compete for clients and whose services are paid according to the number of vouchers they receive. Quality is monitored rigorously and only the best providers are retained in the schemes'

RESULTS

Voucher Distribution and Redemption

Table 1 summarizes the voucher distribution and redemption of the entire programme so far. For convenience this is organized by the funding which has been received by the project, because this is what it has shaped the programme over time. The reason why in some of the cases the number of vouchers distributed is actually higher than the number of vouchers purchased is because when the utilization rates seemed low and women were taking a while to come forward for a Pap smear, a redistribution of extra vouchers was done so as to assure a minimum total redemption rate of at least 50%. Vouchers had an expiry date printed on them and it was possible to calculate how many of the distributed vouchers would not have been redeemed.

Because vouchers are such flexible tools of health care delivery and they can entitle the bearer to endless configuration of services and/or payment methods, comparison of redemption rates with our data is difficult because there is nothing in the international literature of vouchers and health that has a similar pre-paid, flexible package of services. The most logical comparison can be made with a similar cervical cancer prevention programme, based on screening of high risk women through a voucher scheme, done by ICAS in El Salvador. An assumption was made in El Salvador that utilization rates would be around 50% and the aim with this project was to screen 10,000 rural, poor women over three years. 20,000 vouchers were distributed and 9,048 (45%) were eventually redeemed⁶, a slightly lower redemption rate than the Nicaraguan programme's average (52%). Comparisons with ICAS's other two vouchers schemes in Nicaragua are also possible because, although the services provided are different, the ideas behind it and methodology of distribution are roughly the same. The ICAS sex workers project in Nicaragua, aimed at increasing access to sexual health services for female sex workers and populations vulnerable for STI/HIV. This has now been running for 10 years and their results show [18] that an average of 46% of voucher recipients attend an initial consultation. The ICAS adolescent programme, aimed at improving the uptake and quality of sexual and reproductive health care for adolescents (also in Nicaragua) had utilization rates ranging from 23% for girls to 15% for boys [19]. These lower uptake rates reflect the difficulties in getting poor adolescent to take an interest in the planning of their sexual life. However, the adolescent programme's aim was to provide a certain number of sexual and reproductive consultations to adolescent regardless of how many vouchers needed to be distributed to achieve this target.

⁶ Project data available on request from ICAS at www.icas.net

Table 1. Distribution and utilization of cervical cancer prevention vouchers according to institutional funding.

	Original programme funded by DFID	British Embassy Donation	ICAS=s sex worker project	Nicaraguan Buddhist Association	USAID Donation	DFID Donation	Dutch Government Donation	Total
No. vouchers Purchased/donated	1727 (purchased)	150	363	100	10000	10000	10000	32340
No. voucher distributed	1727	150	372	172	10651	9810	12839	35721
No. vouchers redeemed	972	150	328	91	6379	4985	5518	18423
Utilization rate	56%	100%	88%	53%	60%	51 %	43%	52%
Geographical area of distribution	Managua Tipitapa Leon San Marco Granada Esteli Sebaco Matagalpa Ocotal	Siuna		Oriental market in Managua & Boaco	Wherever Profamilia has a clinic who needed strengthening, (all over Nicaragua)	Siuna and province Mulukuku and province	Tipitapa Ticuanetepe Masaya (three small town in the proximity of Managua)	
Voucher distributors	Pharmacies & NGO clinics	Health unlimited (a British NGO)	ICAS=s sex workers project	ICAS=s staff at market & Aventhis Health	Profamilia=s community health workers	MoH local staff in Siuna Two NGO groups, one in Siuna and one in Mulukuku	MoH local staff	
Clinics where smears were taken	A mixture of private & NGO clinics, and public and private hospitals	Health Unlimited staff	Private clinics contracted by the sex worker projects	Two private clinics, one in Managua and one in Boaco	Profamilia=s clinics all over Nicaragua	Public health centres and posts; one NGOs clinic in Siuna and one in Mulukuku	A mixture of public and private clinics, predominantly public health centres	

In the case of the cervical cancer, the rate at which distributed vouchers are used depends on a number of things, first among which it reflects how well the distribution process was made: how persuasive the health workers have been at convincing the women that a) they needed a Pap smear and b) this package of services was a chance they could not miss because it provided treatment as well as screening. The utilization rate also reflects how good or poor the selection of target population was, how easy it was for women to access the selected clinics and, where patients had a choice, the selection of clinics available for Pap smear. For instance, in the most isolated area the project reached, Siuna, all the vouchers purchased were distributed and used. Health Unlimited was extremely committed to reach women in this rural area. In addition, because smears were actually taken at the time of voucher distribution, there was no chance for non-redemption. Smears were taken there and then because these women lived in such isolated communities that, Health Unlimited staff believed, they would have never come to the main town for a Pap smear. The collaboration with the ICAS's sex worker programme also had an unusually high utilization rate. However, this data does not reflect real utilization because the Pap smear using the GinecoBono were taken from sex workers who had already come forward to the clinic to use a different type of voucher for the prevention and treatment of Sexually Transmitted Infections: this voucher included a Pap smear which the project decided to contract out to the cervical cancer one. The lowest utilization rates are found in the 100 vouchers purchased by the Nicaraguan Buddhist Association (30%). These vouchers were distributed directly by ICAS's staff to women in the Oriental Market in Managua. This is the biggest market in Nicaragua and the place where by far the cheapest goods can be found. Sellers here work seven days a week and even with that they struggle to make a living. The low utilization rates probably reflect a) the low priority these women place on their health vs. the opportunity costs of lost sales; and b) lack of insight on the part of the project into these women's priorities and lives. Perhaps efforts should have been made to contract a clinic within the market itself so that ease of accessibility could have been insured. Alternatively, vouchers should have simply been destined to women who were more likely to use them. Of the original voucher distribution within this cooperation, only 30 (30%) vouchers were actually used. A second redistribution of 72 vouchers was done by a different NGO (Aventhis Health) that had requested a voucher donation in a small rural area of Boaco. Utilization rates here were higher (53%) and in line with expectations.

Pap Smear Results and Patients Treated

A brief word on nomenclature: the nomenclature adopted for reporting gynaecological cytopathology results was the British Society for Clinical Cytology (BSCC) one [20]. This terminology was introduced in the programme through the EQA scheme: because the first few sets of slides used for the Proficiency Testing were brought to Nicaragua from Scotland, the same nomenclature had to be used for reporting on test slides. It was quickly realized that the BSCC nomenclature allowed to get around the problem of categorizing all smears showing inflammation or changes remotely consistent with HPV infection as positive and was therefore adopted for cytopathology reporting throughout the programme. Local pathologist and cytologist in fact have a tendency of seeing HPV-associated changes

practically everywhere⁷. Under the BSCC terminology smears showing HPV changes are coded as negative if the nuclear changes are less than dyskaryosis. The term “dyskaryosis” was translated into “dysplasia” in Spanish. Thus the category reported below as Low-Grade Lesions or Low-Grade Squamous Intraepithelial Lesions (LSIL) DO NOT include cases with cellular changes consistent with HPV infections only.

Table 2. Cytology results (expressed as crude umbers and percentages) in each diagnostic category per programme and faith of patients.

	Original programme funded by DFID	British Embassy Donation	ICAS=s sex worker project	Nicaraguan Buddhist Association	USAID Donation	DFID Donation	Dutch Government Donation	Total
Low-Grade Lesions (CIN I) + Borderline*	40 (4.11 %)	2 (1.33%)	39 (11.89 %)	8 (8.79 %)	193 (3.02 %)	136 (2.73 %)	176 (3.19 %)	594 (3.22 %)
High-Grade Lesions (CIN II, CIN III & Carcinoma In Situ)**	24 (2.47 %)	2 (1.33 %)	6 (1.83 %)	1 (1.10 %)	64 (1.0 %)	63 (1.26 %)	42 (0.76 %)	202 (1.1 %)
Invasive cancer**H	3 (0.31%)	0	0	0	10 (0.16 %)	13 (0.26 %)	4 (0.07 %)	30 (0.16 %)
Deaths (during duration of each programme)	1	0	0	0	4	2	0	7

* Cytology results

** Results confirmed histologically.

HOf the 30 cases of invasive cancers diagnosed, two of them were of glandular origin

The highest prevalence of low-grade lesions was detected amongst patients from the sex workers programme (11.9%). This is hardly surprising given that these women have high rates of sexually transmitted infection and re-infections due to the nature of their work. The prevalence of their high grade lesions (1.83%), although higher than most other programmes, is not dramatically different from other groups (average prevalence of high-grade lesions being 1.1%). These women are regularly screened by the ICAS sex worker programme and treated when found positive for cervical abnormalities. The group where high grade lesions were highest is the one where women had to purchase the GinecoBono, this was the very first programme funded by DFID: , under this programme configuration the voucher was sold directly to the patient. In this case we probably witnessed what economists call “adverse selection”: that is some of the patients who probably already knew they had a cervical abnormality purchase the voucher to obtain the free treatment. The same can be said for the prevalence of invasive cancer: 0.31% of cases were diagnosed in this subgroup of patients

⁷ Experience with Proficiency Testing slides showed that local professionals have a tendency to associate any type of inflammatory changes with HPV associated changes: PT slides cannot, by definition, include any case of borderline nuclear change (ASCUS or AGUS). Even with this knowledge, local professionals reported HPV associated changes in the great majority of positive and negative test smears.

who opted for purchasing the GinecoBono package of services. Adverse selection can be a problem if it destabilizes the financial sustainability of the programme by spending a large proportion of the money aimed at paying for screening on treatment. However, this was not the case of this programme and in fact all the money spent in treatment were actually recovered by the direct voucher sales, as well as the money spent in screening⁸. On the other hand, it is very likely that purchasing the GinecoBono was the only hope these women had of ever receiving treatment. So a small number of free riders was not necessarily a bad thing and the project complied with its objectives and the promises it made during the social marketing campaign, as well as saving the lives of the 24 women harboring high-grade lesions and the two patients who had invasive cancer. The third patient in this group who was diagnosed with invasive cancer sadly died soon after the diagnosis was made. Her cancer was at a very advanced stage and her family admitted having purchased the voucher as a last resource in the hope to obtain treatment. Looking at these results in terms of value for money (cost effectiveness, cost per life saved etc.) invested in the programme, the Dutch government probably saved the least lives for monetary investment made. The prevalence of high-grade lesions is the lowest as it is the prevalence of invasive cancers (not taking into account the three programmes with less than 500 smears taken: too few patients to pick up an invasive cancer). This is most probably due to the poor selection of target population made by the central level of the MoH. Two of the town selected (Ticuantepé and Masaya) are actually reasonably wealthy by Nicaraguan standards. These locations are also close to the capital city Managua and many people residing here commute to the capital for work. Women probably prefer to use the health services in the capital where there is more choice of service providers rather than being restricted, as the project was offering within this collaboration, to the local public health centers. The challenge of reaching out to very poor and marginalized women was therefore a hard one. However, since the MoH insisted the project covered these geographical areas because it felt that not enough smears were being taken here, ICAS simply complied with its commitment to take the GinecoBono package wherever it was requested of.

In order to get an idea of whether the project reached a cross section of the population aimed at (i.e. one at high risk) it would be interesting to interpret these result by looking at the incidence and prevalence of pre-cancerous and cancerous lesions in Nicaragua. However this is practically impossible (see introduction). The next best data available for comparison belongs to the *Guanacaste project* in Costa Rica [21] for whom cytology results are available for a randomly chosen group of 8582 women of the Guanacaste province. It seems safe to assume that the health system and epidemiological situation in Guanacaste at the time the study was carried out posses similar characteristics to the current situation in Nicaragua which makes a comparison of our data feasible. Firstly, there exist similarities in the study population: women in the Guanacaste province of Costa Rica have a high incidence of invasive cervical cancer (average annual incidence rate in the past 10 years =33 cases per 100,000 women [21]). The age standardized mortality rate in Nicaragua is 22.3 deaths per 100,000 women [1]. Secondly, given these high rates of cervical cancer and the fact that Guanacaste is right on the border Costa Rica shares with Nicaragua, it is probably safe to assume that the epidemiological profile in terms of cervical precancerous and cancerous lesions of the women in the two studies is similar. Finally, shortcomings in the health system performance are also similar and possibly partially the cause of such high cervical cancer

⁸ Financial details of the project are not presented here.

incidence rates: in Guanacaste the coverage of the national screening programme, although provided under the universal health /care system, has traditionally been low and the target population generally restricted to women attending family planning and prenatal care clinics. The laboratories have limited quality control systems and there are difficulties in the follow-up and referral of cases detected [22]. Under the study situation, however, heavy investments were made in quality control related issues in both countries: this should further diminish confounding and allow for a more reliable comparison of data with the Nicaraguan project. The Guanacaste study smears were read three times: once by local cytopathologists in Costa Rica with conventional cytology reporting results with the modified Bethesda System; the second time the same smears were analyzed using PapNet technology and the third time images were sent for reporting to a senior cytotechnologist at The Johns Hopkins University, Baltimore. The results reported here correspond to those of the first reading, done by local Costa Rican cytopathologists with conventional Pap smear technique.

Table 3. Comparison of results expressed as crude numbers and percentages between the Nicaraguan and the Costa Rican projects.

	No. in voucher programme	No. in Herrero et al.	Prevalence of diagnosis in voucher programme	Prevalence of diagnosis in Herrero et al.
All diagnosis	18423	8582	-	-
Negative	17594	7131	95.5 %	83 %
Low-Grade Lesions	594	950	3.22 %	2.2%
High-Grade Lesions	202	128	1.1 %	1.5 %
Invasive cancer	30	12	0.16 %	0.14%

To facilitate comparison with the results from Herrero's study, the age specific prevalence rates of Nicaragua were standardized to the Guanacaste population according to the 1984 Costa Rican National Census, on the bases of which the selection of sample study was made in Costa Rica. By doing this we are therefore assuming that the population in Nicaragua has the same age-distribution as the population in Guanacaste in 1984.

Table 4. Age-standardized prevalence rates of pre-invasive cervical lesion and cancer of the cervix in the Nicaraguan project and the Costa Rican study. The Nicaraguan age-specific results were standardized to the Guanacaste according to the 1984 census.

	Voucher program	Herrero et al.
Low-Grade Lesions	4.61	2.2
High-Grade Lesions	1.07	1.5
Invasive cancer	0.06	0.14

The percentage of Low-Grade lesions diagnosed by our study (3.22%) is slightly higher than the Herrero's one (2.2%) but this may reflect the fact that in our programme Borderline results were included into the diagnostic category of LSIL whilst Herrero's presents these data separately (8.9% of ASCUS)[21]. When looking at the age standardized prevalence rates

in table 4, this situation is even more pronounced. Conversely the percentage of High-Grade Lesions reported by Herrero is slightly higher than the voucher programme's one: 1.5% vs. 1.1% as from Table 3 and 1.5 vs. 1.07 when looking at the age-standardized prevalence rates of these lesions in Table 4. Although the percentage of invasive cases of cancer seems to appear higher in the Nicaraguan study than the Costa Rican one (0.16% in Nicaragua vs. 0.14% in Costa Rica), when looking at the age-standardized prevalence rates things are reversed (0.06 in Nicaragua vs. 0.14 in Costa Rica), even taking into account the fact that the median age of our patients diagnosed with invasive cancer (47) was higher than the women in Herrero's study (39.5 years of age).

It appears that the prevalence rate of invasive cervical cancer in the Guanacaste population is higher than in Nicaragua. However, these comparisons are hard to make because whilst the Costa Rican study tested a random sample of the population well defined in a geographical area, the Nicaragua project tested women scattered all over the country and who either came forward voluntarily for a Pap smear or who were invited for one by health workers involved in the voucher distribution. Concentrating the resources for screening in one single region or area of Nicaragua would have allowed for a better base for comparison and for learning something about the real prevalence of cervical precancerous and cancerous lesions. However financial constraints imposed by donors' priorities made this impossible. Having said that, the aim of the project was never to learn the real prevalence of precancerous and cancerous lesions but to use a voucher scheme to reach and treat poor, high risk women through a comprehensive package of services which would include treatment as well as screening. Was the project successful at this? Unfortunately the project socioeconomic data and information regarding the existence of a previous smear is reliable only for a subgroup of the women screened. Because these questions were asked by contracted nurses in the public and private sector of different institutions all over the country, control over the reliability of information was beyond the project reach. Often questions regarding patients socio-economic status were omitted because nurses felt this would be embarrassing for the women to answer. This was not, after all, a study. A different way of looking at whether the project was successful at reaching poor, high risk women is to look at the prevalence of life threatening lesions and/or geographical areas reached. It has already been mentioned how the selection of a central and relatively wealthy location for the distribution of the vouchers donated by the Dutch Government resulted in a low prevalence of high-grade lesions and invasive cancers as well as the second lowest utilization rates of the vouchers distributed (43%, see table 2). Things went much better in the case of Siuna and Mulukuku, screening was carried out on marginalized (at least geographically) and rather poor women, largely previously unscreened⁹. These results highlight the importance of a careful selection of the target population when publicly subsidized services are offered. They also show that although the commitment of health workers to seek out the neediest potential patient is important (see Siuna where 100% utilization rate was achieved thanks to very a group of very dedicated professionals), a certain self selection on the side of the potentially high-risk patients seems to be at work. These decisions have important implication for use of public money and for who makes the decision. Donors, with their priorities and fast changing public health fashions, are not necessarily the best placed in order to do this. This role should ideally be played by public health leaders and the MoH. However, in the case of the Dutch

⁹ Data collected by Salud Sin Limite personnel.

Cooperation, the MoH did not necessarily pick the most needy geographical areas but the ones where the public services themselves were failing: Ticuantepe, Masaya and Tipitapa had low coverage and low service uptake according to the MoH. What they probably did not realize is that these women simply travel to the capital for private, better quality health services.

Quality Issues

Although the project spent a substantial proportion of its time and funding on quality related issues, the high quality of services offered was never a selling point when promoting the voucher package to potential patients. Non-medical persons are generally unaware of the importance of good technical quality of care: nobody in the general population in Nicaragua would ever think of doubting the accuracy of smear interpretation. Nevertheless, the implication of such a big investment in improving service quality have been far reaching. The process of setting up the External Quality Assurance scheme for cervical cytology and the results of Proficiency Testing is described at length elsewhere [11]. This scheme became so popular that it was eventually implemented at the national level in collaboration with the MoH. Thanks to its accreditation and certification scheme, EQA is currently working to insure that purchasers of cytology reading services in Nicaragua are aware of the quality of work of the laboratory they are contracting. The extensive training given to nurses on smear taking has also gone a long way towards ameliorating quality in existing services and towards changing old fashioned customs: in the private and NGO clinics gynecologist would normally take the PAP smears, an expensive use of their specialized time. The project imposed, through contract specification, that nurses should be taking smears, so as to insure a) that female professionals did this task; and b) that the cost of smear taking was affordable to the project were a fee for this had to be paid (i.e. in the private sector). In the public sector nurses would normally take smears but without any formal training on this matter and with not much attention paid to the process of collecting, labeling, fixing and storing an adequate specimen. Through numerous workshops over the duration of the project 136 health professionals were trained in the theory and practice of smear taking. This valuable professional knowledge and practice is something that will remain with the Nicaragua health professionals and hopefully translate into better practice of smear taking and handling outside the project activities.

Cost Effectiveness of the Programme

Under the initial project configuration, where women were expected to purchase the voucher at a subsidized price, the cost-effectiveness of the project lied in a pre-paid insurance scheme whereby negative women were basically subsidizing positive ones. Financially, this worked even with a small degree of adverse selection in progress. Subsequently, when funding were offered by donors to target poor, high risk patients and vouchers were being distributed for free to women, cost-effectiveness came from a sectorial investment in health, by targeting subsidies to poor, high risk women and specifically by subsidizing demand among the poor for specific health services of known cost-effectiveness, whilst allowing a competitive market for its provision. Because screening high risk patients for cervical cancer

is a cost-effective measure in itself, and because the existing system (based on the traditional supply-side mechanism) is largely failing to do so, vouchers for the detection and treatment of pre-cancerous lesions aimed at a well defined target population do seem indeed to be a cost effective intervention for donors and local government alike to invest in.

CONCLUSION

The cervical cancer voucher scheme showed that it could solve some of the difficult problems faced by conventional health programmes and allowed to (a) target and reach the poor and most needy; (b) subsidize only cost-effective interventions (i.e. best practice, evidence based); (c) involve both private and public sector service providers; (d) use competition to minimize costs and maximize quality; and (f) broaden poor peoples choices for health care. Vouchers removed financials barriers; guided voucher bearers to available providers; instigated trust that bearers would be treated (and not refused) and receive the type of care they needed. Vouchers versatility and flexibility allowed different configuration to be adopted to suite donors and purchasers of vouchers alike.

By and large the project's objective of finding an affordable way to improve the coverage, screening, test accuracy and follow-up of cytological abnormalities for cervical cancer prevention in a developing country was met. However, the problem of efficient and effective prevention of cervical cancer on a national level in a low income country remains. Despite the few hundreds of lives saved by this project, many more women are dying in Nicaragua from this preventable and curable diseases. The real question should then be: would the modality of a voucher scheme coupled with a quality assurance scheme for cervical cytology allow, if adopted on a national level, to dramatically reduce mortality and morbidity from this disease? And if so, who would be best placed and have the capacity of running a voucher scheme at a national level? Ultimately the responsibility for a cervical cancer prevention programme rests with the Ministry of Health and until a political and financial commitment is made on the part of the government, Nicaraguan women and their families will sadly continue to carry the burden of this disease. A reliance on donations from foreign government will go as far as the ability and commitment of the people running those limited funds go, and will stop there. The national screening programme needs to be restructured, more attention needs to be paid to the targeting of the high risk patients and a functional tracking and follow up system needs setting up. A focus on the quality of services provided is paramount as it is the collaboration with the private sector which today is responsible for a big proportion of the screening which takes place. The ministry of finance needs to make a commitment towards this too and break this circle of dependence from foreign donors. One element of this voucher programme that the MoH seems to have taken up and made some effort to implement at a national level has been the External Quality Assurance scheme for cervical cytology. But the funding to run this are still provided by the project itself, as well as all the technical know-how.

No experiences exist with voucher schemes for health, which distribute vouchers universally and provide more general access to health care. A voucher based screening programme would be logistically complex and expensive to run on a regular base for the entire adult female population of a country. It appears that voucher schemes may not be a

substitute for health systems that can offer a comprehensive range of services to entire populations. However, in order to get public subsidies to high priority and/or difficult-to-reach populations for the provision of clearly defined packages of cost-effective services voucher schemes seem to be a highly feasible way. Vouchers could help in specific situations, in geographically remote areas for instance or in particularly hard to reach groups of the population (i.e. for cultural or religious belief). An interesting and innovative prospective for the use of vouchers in the prevention of cervical cancer could be feasible when vaccination for HPV becomes available to poor and middle income countries. Vouchers would offer a perfect opportunity to deliver both therapeutic and prophylactic vaccination with all the added advantages of the intrinsic vouchers characteristics: allow effective and efficient targeting, improve service quality, increase equity in access to health services, increase service use by vulnerable groups, etc. Prophylactic vaccination, if intended for adolescents, could be coupled with a social marketing campaign aimed at young people and their parents with the objective of creating acceptability. Vaccination coverage could be monitored through National Birth Registry in collaboration with schools to insure a wide participation. The existence of a redeemed voucher would be a guarantee that the vaccination had taken place and a centralized registry of this could be kept, as opposed to vaccinations cards (used for infants) currently in the hands of patients which often end up lost. The use of a voucher scheme for the delivery of therapeutic vaccination to women with cervical lesions would be of even greater potential for a developing country like Nicaragua where tracking and follow up systems are so poor. Simply making use of the existing institutional infrastructure, one can envisage all the screening facilities, private and public, to hold a number of follow up vouchers entitling the bearer to therapeutic vaccination at an appointed health facility: as the patient is diagnosed with an abnormality, assuming the test result is reliable, she is given a follow up voucher and encouraged to seek vaccination. Back to the real world we are reminded that, though a variety of clinical tests on prophylactic and therapeutic vaccines against HPV are recently being developed worldwide, it will take at least from 5 to 10-years time to have them available on the market [23] and probably a lot longer for developing countries to be able to afford these. The reality is that until these vaccines become available early detection and treatment via organized screening programme remains the strategy of choice. Countries like Nicaragua need to restructure and strengthen their existing programme: vouchers can help in some situations, but are no substitute to a national cancer prevention programme.

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