

The relevance of citizen involvement in Health Technology Assessment.

A concrete application in the assessment of HPV co-testing in the Autonomous Province of Trento

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ABSTRACT

BACKGROUND: Specific programs have been developed in the latest decades to involve patients in Health Technology Assessments (HTAs). However, there are no structured practises in Italy and citizen' perspective is rarely included in HTA reports. Aim of this study is to explore citizen' opinions about cervical cancer screening with Human Papillomavirus (HPV) co-testing in the Autonomous Province of Trento (PAT).

METHODS: Two focus groups were conducted: one with representatives of patients' associations, the other one with women between 31 and 64 years and their family members. Following aspects were investigated: the importance of cervical cancer screening programs; the impact of HPV test on women' and their partners' life; needs, expectations, and critical aspects of the new screening method.

RESULTS: Organised screening programs are very important for all participants. HPV co-testing screening is preferred to cytology for its higher sensitivity, but different opinions came out regarding the longer screening interval after normal HPV and Pap test results. Citizen stressed that correct, clear, and unambiguous information have to be provided to the whole population (men included). A cardinal role plays the patient-doctor relationship in informing and taking care, also emotionally, of women, their partners and relatives in case of positive HPV test.

CONCLUSION: In order to facilitate the introduction of the new screening method, various media must be used to spread clear and unambiguous information, as well as informative and educational meetings with doctors and caregivers. Citizen perspective was included in the report for the Health Trust and played an important role in the decision process.

Key words: patient involvement in HTA, HPV, cervical cancer screening, focus group, citizen perspective

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INTRODUCTION

Patient involvement in HTA

The role of patients in HTA has increased in importance in the latest decades. In the past, patients' views have often been considered anecdotal or biased and their perspective has not been included in HTA [1]. However, it is difficult to consider health technology in isolation from the people who use and understand it [2].

In this study, we use the word '*patient*' meaning all groups of lay people (people who are not healthcare professionals) that may be included in HTA processes. This includes people who have a relevant condition, and people such as family and friends who provide unpaid care for them. It also covers patients organisations, including voluntary sector or non-governmental organisations [3].

Patient involvement in HTA is essential because patients have a unique understanding of what it is like to live with a medical condition and could provide relevant knowledge about intended and unintended effects of using health technologies. Principal advantages of including patients' perspective in HTA reports are:

- an increased accuracy in measuring patients' needs and preferences,
- a better understanding of the impact of technologies in a real-life context and of the quality of life aspects,
- improved quality of assessments, reliability and relevance of reports to the local context [4],
- increased consensus and acceptability of healthcare decisions [5].

Though various benefits, structured practices of patient involvement are only rarely implemented. A survey on HTA Agencies highlights '*a stark difference between real and ideal situations*' in term of level of patients' involvement in HTA [4].

In our analysis we examined articles, websites, and HTA reports of HTAinternational's members, looking for structured patient involvement programs. Only few agencies involve systematically patients in their HTA processes. The most evolved programs are implemented by the *National Institute for Health and Care Excellence* (NICE) [3] and the *Canadian Agency for Drugs and Technologies in Health* (CADTH) [6].

The first program enables patients to participate individually or in groups. Individuals can become lay member in HTA committees. Both individuals and groups can send written memories regarding specific technologies through an appropriate template. A specific team called "*The Patient and Public Involvement Programme*" supports the whole process [7].

The CADTH patient involvement program is part of the *Common Drug Review* (CDR). Only groups of patients or patient organisations can provide written memories to the CDR through the template on the CADTH website. Individuals who wish to provide inputs are encouraged to work with a patient group to have that group include the information in its submission. After the registration in the template, e-notification can be subscribed to be advised per e-mail of pending and receiving drug submissions [8]. In Italy, no systematic involvement program is implemented at the moment, though some organisations are approaching this initiative (e.g. Cittadinanzattiva).

Aim of this study is to explore patients' perspective regarding a specific technology (HPV co-testing) and to integrate it into an existing report for the healthcare decision makers. In particular, the Provincial Healthcare Trust is appraising the opportunity to introduce HPV screening for women between 31 and 64 years in the PAT. An HTA report on this topic was published in 2012, where technical, economical, organisational, and ethical implications were investigated [9]. However, no patient input process was implemented at the time.

HPV screening test: Characteristics and HTA results

HPV is the most common sexually transmitted infection worldwide. Most HPV infections are harmless and clears spontaneously within one-two years but persistent infections with high-risk HPV (especially type 16 and type 18) can cause cancer of the cervix, vulva, vagina, anus, penis, and oropharynx [10,11]. Various years are needed for the infection to evolve into cancer. Although both men and women can be infected, cancer in men is very rare [10].

To date there are various prophylactic vaccines, but no effective therapeutic ones [10]. For this reason, screening programs have high importance in preventing cervical cancer. In

PAT, a prophylactic vaccine program for girls up to 11 years [12] and an organised cytology screening for women between 18 and 60 years have been implemented. However, evidence demonstrated that HPV screening can be more effective than cytology [9].

For what concerns the clinical aspects, HPV co-testing can detect more high-grade precancerous lesions, enables higher accuracy and reproducibility, and more extended screening intervals (from three to five years) (Tab. 1) [9]. Undesired effects are limited to the lower specificity of molecular tests, that can determine overtreatment in young women. For this reason it is recommendable to continue using cytology for women up to 30 years. For women between 31 and 64 years the new screening protocol has to be organised as illustrated in Fig. 1. A pilot program on this population target took place in the period 2011-2012.

According to the economic evaluation, a single round of HPV testing is more expensive than cytology. However, the longer interval between two negative tests leads to lower overall costs. Looking at the organisational aspects, the most relevant problems are related to the necessity of triage, to the

protocol's complexity and to the conversion of cytology lecture activities. Thus, the analysis of HPV tests have to be aggregate in few big laboratories. Regarding social and legal aspects, appropriate communication of test results and of the implications of a positive test should be granted. However, no concrete exploration of patients perspective was done at that time.

METHODS

Two different focus groups [13] with the same structure were implemented.

Exponents of four patients' associations - Tribunal of Patients' Rights, Coordinamento Donne di Trento (*Women Union Trento*), Coordinamento donne delle Associazioni cristiane dei Lavoratori Italiani (*Women Union of the Catholic Association of Italian Workers*), Associazione Città Aperta (*Open City Association*) - were invited to the first session. In the second one, participants were selected within the target population of HPV test and their potential caregivers (e.g. husbands, children, etc.).

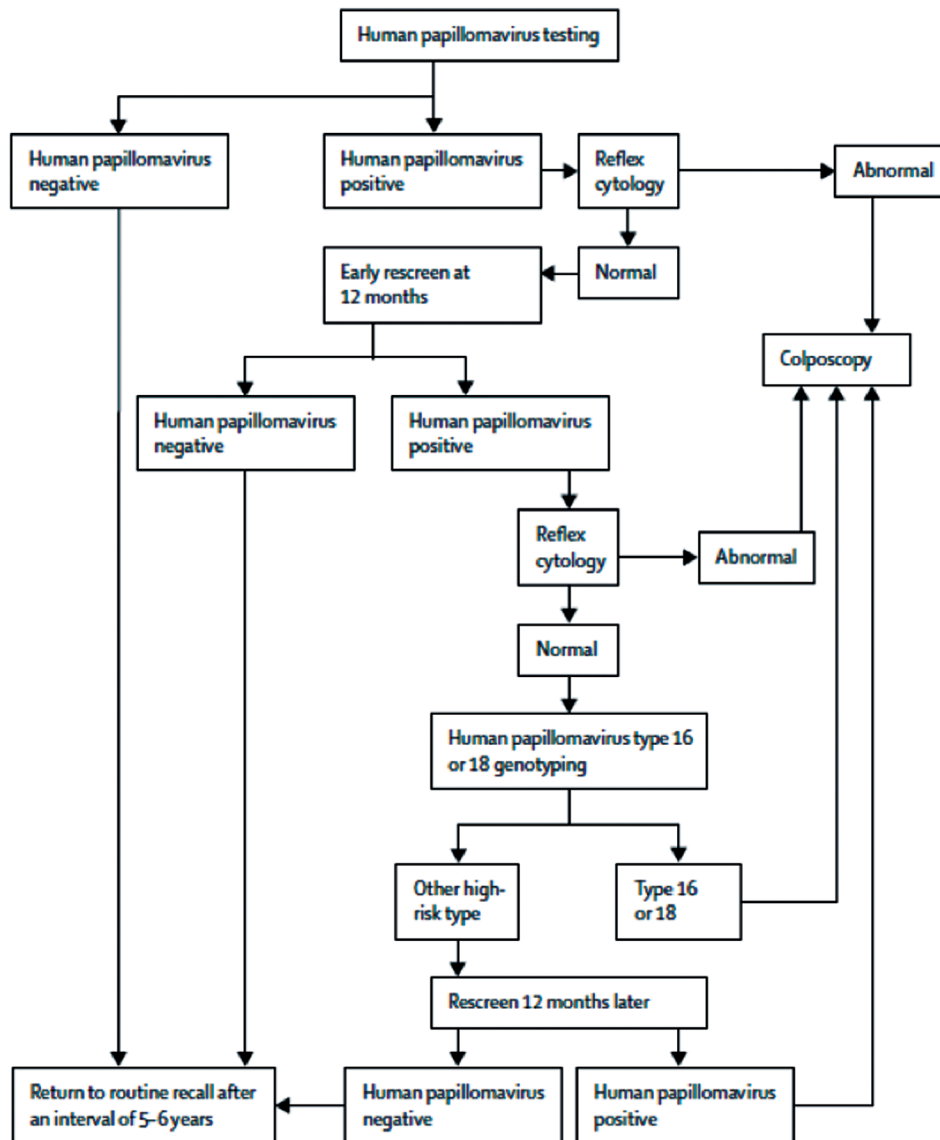
We expected different discussion topics between the two sessions. In the first one we

TABLE 1

SIMILARITIES AND DIFFERENCES BETWEEN THE TWO SCREENING PROTOCOLS		
	PRIMARY SCREENING WITH PAP-TEST	PRIMARY SCREENING WITH HPV TEST
WHAT IS INVESTIGATED	tumour cells in the cervix	HPV in cells' DNA
TEST TYPE	cytological - analysis of cells' morphology	molecular - DNA analysis
ANALYSIS METHOD	lecture with the microscope by the technician	automatic analysis with a specific machine
SENSITIVITY	less sensitive	more sensitive
SPECIFICITY	more specific	less specific
INTERVAL AFTER A NEGATIVE TEST	three years	five years
INTERVAL AFTER A POSITIVE TEST WITH NEGATIVE TRIAGE	new Pap-test after six month	new HPV test after one year
HOW IS THE SAMPLE TAKEN	smear from the uterine cervix	
TYPE OF SCREENING	organised (with invitation letter) as well as spontaneous	
COMMUNICATION OF THE RESULTS	letter and (eventually) meeting with the gynaecologist	

FIGURE 1

FUTURE SCREENING PROTOCOL: PRIMARY SCREENING WITH HPV TEST^a



expected the group focused especially on the perspective of patients' associations regarding the introduction of the new screening method as well as on the role that patients' associations and other media could play. In the second one, we expected the discussion to be focalised on the personal opinions about HPV co-testing and on how the Provincial Healthcare Trust could minimize its impact on citizen' lives.

At least 15 people for each session were called and invited. The main selection criteria were: age (31 – 64 years) and to live in the PAT.

We enrolled also men because we supposed that not only women' life could be influenced by the change in the technology, especially when talking about sexually transmitted virus.

We submitted the participants a small questionnaire in order to match all selection criteria and to grant homogeneity in education level and profession.

Four women and one man took part in the first session. Each patients' association was represented by at least one member. Three more persons accepted the invitation but had

TABLE 2

INTERVIEW GUIDE	
	TIME
Information session	60 min
Introduction and presentation of the interviewer and of the participants	20 min
Question 1 <i>Do you think that it is important to participate to a cervical cancer screening? Why?</i>	15 min
Question 2 <i>Do you think that the life of the woman, of the couple and/or of the family can be influenced by the decision to take part to the HPV screening? If yes, how?</i>	20 min
Question 3 <i>Do you have any needs regarding the screening?</i>	20 min
Question 4 <i>If you should compare the two screening test (HPV test and Pap test), can the HPV test better or worse meet your needs? How? Do you see any critical aspects?</i>	15 min
TOT.	1h 30 min

left before the focus group started. Eight women and one man took part in the second session. Informed consent was obtained in writing.

Information about HPV was provided to the participants. Two different information moments were planned:

- the users' information of "Le 100 domande sul test HPV" (*"The 100 questions on HPV test"*) [11] prepared by GISCi (Italian Group of Cervical Cancer Screening) were sent to the participants at least ten days before each session;
- immediately before the focus group we organised a one-hour session with an expert, where topics related to HPV (virus, vaccine, test nature and procedure) were discussed and further clarification were provided.

The facilitator was Mrs. Vivori because of her experience in conducting focus groups. She did not have any relationship to the participants.

An interview guide with key questions was developed (Tab. 2). Following topics were examined:

- the importance of cervical screening;
- which implications HPV test could have on women' and their caregivers' life;
- what are patients' needs about screening methodology;
- a comparison between the actual screening program and the new one.

Both sessions lasted one and a half hour,

they were digitally recorded and notes were taken. Records were then transcribed, and data were analysed and interpreted. After that, a feedback regarding the results of the study was sent to the participants.

RESULTS

1. The importance of cervical cancer screening programs

Everybody agreed that cervical cancer screening programs are very important and everyone should participate. However, some potential barriers were highlighted. Some exponents of patients' associations noticed that some women could have a general negative approach towards screening programs. Some people in both sessions also noted that some women may feel uncomfortable because the focus is on the most intimate part of their body. Another major obstacle is the behaviour of the partner. In particular, partners do not always support the woman in the screening decision and in its implications or do not want to be involved.

"Men tend to delegate, and to ignore, women' problems. [...] They say "it is woman's stuff", like they do not want to get involved in it"

Furthermore, the participation to the screening program as well as the communication of results can lead to arguments and anxiety within the couple. However, in the first session one person noted that in any case woman's

health comes in first place, so the partner's reaction should not impede the participation to the screening.

Scarce information diffusion about cervical cancer screening, HPV and its characteristics was also complained. Specific problems arise in communicating with people from foreign countries. One representative of patient associations said: *"I see various fliers in Arabic and it is a good thing. However, you maybe give them to someone that cannot read!"*

2. Influence of the HPV screening program on women' and their caregivers' life

The possible impact of the HPV test results regards the emotive and psychological sphere of the woman and her partner's life, especially in stable couples. This is due to the possible accuses of betrayal regarding who wants to be tested for HPV, and regarding both woman and her partner, in case of positive HPV test. This problem does not occur in cytology screenings because the Pap test does not look for a sexual transmitted virus.

According to the group of potential users, the long latency period of HPV makes it difficult to understand when a woman could have been infected. Furthermore, the presence of the virus or, in worst cases, of the cancer is a way more relevant problem for the couple than the betrayal. For these reasons, if a positive test leads firstly to an argument, in a second time this would be replaced by the necessity of removing the infection. Also when deciding to be tested for a sexual transmitted virus, the importance of taking care of one's health prevails to the rumours that could arise. Thus, the participation to the screening will not be undermined. In addition, the initial negative impact can be reduced if correct information about HPV is provided.

"It can surely create problems in the family. [...] yes, there will be an argument about that, but then, if the test is positive, we have to face the problem [...] and the problems are others!"

3. Needs regarding the new cervical cancer screening program

Especially in the first session, some participants highlighted that the screening test should be

as precise as possible in identifying infected cells. Furthermore, the relationship between gynaecologist and patient plays an essential role. The creation of an high level of trust and confidence between the two parts is necessary to enhance the participation to the screening. Moreover, gynaecologists and general practitioners should provide their patients with all information needed and take care of them also with regard to psychological and emotional implications. Both focus groups highlighted that doctors are often not able or have not enough time to take properly care of their patients. Consequently, patients are afraid to ask for further information and their needs cannot be completely fulfilled.

Another fundamental aspect stressed in both focus groups is the necessity of providing information. First of all, information should be correct, clear, and easy to understand. Using a clear language is very important, so that the explanation is easily understood independently of patients' educational level.

"I have not known about HPV since two years ago. [...] I had never heard it before. When I heard it, I was shocked because [...] in the test results I read [...] "HPV", but I thought "HIV"!!! [...] Then I read one more time [...] "Human Papillomavirus"... what is that?"

Secondly, congruent, coherent and unambiguous information should be granted. In addition, it should be spread through different media. Particularly, in both sessions someone complained about the different information they received from the gynaecologist and the information provided before the focus group.

"Where was I infected?" The gynaecologist said "You could have been infected in the swimming pool...", but as I read in the material... it is not true!"

Thirdly, information should be addressed not only to women but also to men. This would:

- increase patients' consciousness regarding the HPV,
- facilitate the way to approach the test, and
- reduce the impact of possible positive HPV results in the family context.

In addition, following factors were also considered very important for the new cervical cancer screening program to be successful: the use of invitation letters, the way and time of the results' communication, the necessity to raise also young people' awareness of the HPV test and vaccine.

4. HPV Test and Pap test: A comparison

Higher sensitivity of HPV test. In both sessions the higher sensitivity and, consequently, the better capability of HPV test to identify infected cells was considered as a great advantage. Some people underlined that it should be emphasized when providing information about the new screening method, especially in the transition phase.

Longer intervals after a positive HPV test. Particularly in the first session, a long discussion took place regarding the waiting time between a positive HPV test combined with negative cytology. Longer intervals could lead to anxiety in women' and in the couple's life. However, some participants underlined that anxious moments are part of everyone's life and have to be faced.

"There is anxiety, until it is over, there is anxiety [...] and I do not think that it could be eliminated. It happens and it is part of the life"

Representatives of patients' associations stressed that gynaecologists and doctors play an essential role in reducing the possible anxiety. They have to provide all information in a clear and comprehensible way. In addition, they should approach the woman with empathy and reassure her regarding the possible steps that follow the first screening test.

Longer intervals after a negative HPV test. Different opinions about this aspect emerged in both sessions. While some persons saw it as an advantage (*"fabulous! If you can do it every five years, I think that it is very good!"*), for other persons it is too long. This confirms the degree of compliance noted in other studies [14].

Negative opinions are principally due to the fear that the identification of the infection fails because of an error in the smear. Consequently, HPV would develop in cancer and it is already too late when somebody notices that.

"I think five years are too long [...] unfortunately you heard about women that got a tumour also after the screening and nobody knows why [...] maybe it eluded the screening..."

However, various persons acknowledged that the decision regarding screening protocols has to be up to healthcare specialists and not to patients. For this reason, if researches formulated specific guidelines, they have to be followed.

Some participants of the second session proposed to fix a shorter interval in the first phase of the new screening, so that people can get used to it. In a second time, the period could be extended to five years.

5. Final opinions and recommendations

The final opinion was that HPV screening should get at least the same or higher acceptance than the cytology screening, if correct information is provided. In particular, the exponents of patients associations made following proposals to reduce the impact of critical aspects:

- clear, correct and unambiguous information has to be provided through various media (internet, web 2.0, television, formative meetings in libraries, information diffusion through patients associations). A simple and attractive language could help to awake citizen' consciousness regarding the new screening;
- gynaecologists, general practitioners, and health workers have to be educated in order to develop an empathetic approach in communicating with patients (e.g. through informative and educational courses);
- more formative meetings and focus groups should be planned before the start of the new screening program;
- the message that the HPV test has an higher sensitivity has to be widely spread in order to increase the trustworthiness towards the new screening program.

DISCUSSION

Patient involvement enabled healthcare decision makers to consider specific implications of the introduction of the HPV co-testing screening in the PAT. The study outlined following aspects of citizen perspective:

- cervical cancer screening is very important and it is essential to raise consciousness within the whole population;
- clear, correct and unambiguous information about HPV is crucial and

has to be addressed to both women and men;

- the role of gynaecologists and general practitioners is very important in informing correctly and reassuring the patient, especially in case of positive HPV test;
- representatives of patients' associations also considered the implication of the HPV test on foreign citizens, especially on Muslims. They were also more proactive in providing recommendations to reduce the impact of the new screening;
- potential users focused principally on the impact of HPV on woman's, her partner's and her family's life. Moreover, following topics were stressed: the importance of organised screening programs, the need of unambiguous information as well as of a clearer and more comprehensible language.

Though the formative meeting and the information material provided, we received various requests for clarification regarding HPV. This reflects the complexity of the topic and it is essential to provide more information about it.

In conclusion, the concrete citizen involvement not only confirmed the issues of the previous HTA report, but also lead to an in-depth discussion of those aspects, as well as to several useful recommendations. For this reason, it played a crucial role in the assessment of HPV primary screening in the PAT.

In particular, the results of citizen involvement were integrated in the existing HTA report and were include in the Provincial Committee resolution n. 1173 of 14 July 2014, that introduced the HPV primary cervical cancer screening in the PAT. According to this resolution the Provincial Healthcare Trust started various informative and educational meetings with doctor, caregivers, and citizen.

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References.

- [1] Facey KM, Hansen HP. Patient-focused HTAs. *International Journal of Technology Assessment* 2011; 27:273-4.
- [2] DACEHTA - Danish Centre for Health Tecnology Assessment. *Health Technology Assessment Handbook*. Denmark: National Board of Health, 2008; <http://sundhedsstyrelsen.dk/~media/COED080616D7410E8B6020B903AD0339.aspx> Accessed [6 March 2015]
- [3] NICE - National Institute for Health and Care Excellence. www.nice.org.uk Accessed [5 May 2015]
- [4] European Patients' Forum. Patient involvement in health technology assessment: An interim report on EPF's survey with HTA Agencies in Europe. [Online]. 2012 <http://www.eu-patient.eu/whatwedo/Initiatives/> Accessed [11 May 2014].
- [5] Danner M, Hummel JM, Volz F, van Manen JG, Wiegard B, Dintsios CM, et al. Integrating patients' views into health technology assessment: Analytic hierarchy process (AHP) as a method to elicit patient preferences. *International Journal of Technology Assessment in Health Care*. 2011; 27:369-375.
- [6] CADTH - Canadian Agency for Drugs and Technologies in Health. www.cadth.ca. Accessed [12 May 2014].
- [7] NICE - National Institute for Health and Care Excellence. <http://www.nice.org.uk/getinvolved/patientandpublicinvolvement/ppipinvolvementprogramme.jsp> Accessed [12 May 2014].
- [8] CADTH - Canadian Agency for Drugs and Technologies in Health. GUIDE - Patient group input to the Common Drug Review at CADTH. 2012 http://www.cadth.ca/media/cdr/cdr-pdf/Guide-Patient_Group_Input_to_CDR_final_e.pdf Accessed [15 May 2014].
- [9] Ronco G, Confortini M, Maccallini V, Naldoni C, Segnan N, Sideri M, et al. HTA REPORT - Uso della citologia in fase liquida nello screening dei precursori del cancro del collo uterino (Use of liquid-based cytology for cervical cancer precursors screening). *EPIDEMIOLOGIA & PREVENZIONE* 2012; 36 Suppl 2:e1-33.
- [10] Crosbie EJ, Einstein MH, Franceschi S, Kitchener HC. Human papillomavirus and cervical cancer. *Lancet* 2013; 9890:889-99.
- [11] GISCI - Gruppo Italiano Screening del Cervicocarcinoma. Le 100 domande sul test HPV (The 100 questions on HPV test). www.osservatorionazionalecreening.it 2013 Accessed [16 May 2014].

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- [12] APSS - Azienda Provinciale per i Servizi Sanitari. www.apss.tn.it 2012 Accessed [16 May 2014].
- [13] Morgan DL, Krueger RA. The focus group kit. Thousand Oaks: Sage Publications, 1998.
- [14] Giorgi Rossi P, Baldacchini F, Ronco G. The possible effects on socio-economic inequalities of introducing HPV test as primary test in cervical cancer screening programs. *Frontiers in oncology* 2014; 20:1-11.
- [15] Tjørnhøj-Thomsen T, Hansen HP. Knowledge in health technology assessment: Who, what, how? *International Journal of Technology Assessment in Health Care* 2011; 27:324-9.

