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**Civil society advocacy in the  
introduction of HPV vaccination in  
Europe: an analysis**

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**Le rôle des associations de la  
société civile dans l'introduction de  
la vaccination HPV en Europe : une  
analyse**

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## **Abbreviations**

<b>ECCA:</b>	European Cervical Cancer Association
<b>ECDC:</b>	European Centre for Disease Prevention and Control
<b>ECPC:</b>	European Cancer Patient Coalition
<b>EU:</b>	European Union
<b>EMA:</b>	European Medicines Agency
<b>HPV:</b>	Human Papilloma Virus
<b>NGO:</b>	Non-Governmental Organisations
<b>ONDA:</b>	Osservatorio Nazionale Sulla Salute della Donna
<b>WACC:</b>	Woman Against Cervical Cancer

## **Summary**

Cervical cancer remains the second most common cause of cancer death (after breast cancer) among young women (aged 15–44 years) in Europe. Human papillomavirus (HPV) vaccines represent a major advance in the prevention of this cancer and other HPV-related diseases. The availability of HPV vaccination and cervical cancer screening creates the unique opportunity to combine primary and secondary prevention.

Various types of stakeholders contributed to create a receptive environment for HPV vaccination. The greater involvement of health stakeholders' in vaccination policies meant that new actors rallied the process. Civil society advocacy indeed contributed to focus attention and increase market access of these vaccines both at EU and country level. However, some interest groups also posed a challenge to the introduction of vaccination.

The paper finally argues that civil society advocacy is bound to play a greater role in vaccines' introduction and implementation. Implementation now appears to be the greatest challenge to vaccine uptake. By being rooted in society, civil society groups are in a better position to anticipate and address controversies around vaccination. Should they want to keep a seat at the policy-making table, they will actually have to commit themselves to support public trust and confidence in vaccination policies.

## **Résumé en français**

Le cancer du col de l'utérus reste la deuxième cause de mortalité après le cancer du sein chez la femme jeune (entre 15 et 44 ans) en Europe. Les vaccins contre les papillomavirus humains (HPV) représentent une avancée majeure dans la prévention de ce cancer et des maladies liées à HPV. L'arrivée de la vaccination en complément du dépistage précoce du cancer du col a créé une opportunité unique de combiner la prévention primaire et secondaire.

Divers types d'acteurs ont contribué à créer un environnement favorable à l'introduction de la vaccination HPV. Les associations de la société civile se sont engagées aux côtés des acteurs traditionnels des politiques de santé pour faciliter l'accès au marché de ces vaccins, tant au niveau européen que national. Cependant, certains groupes d'intérêt ont parfois tenté de ralentir ou d'empêcher l'introduction de la vaccination.

Ce mémoire démontrera enfin que les associations de la société civile seront amenées à participer de plus en plus activement à l'introduction et la mise en œuvre des programmes de vaccination. La pérennité de ces programmes dépend en effet de leur mise en œuvre au sein de la population. Ces associations apparaissent comme étant les mieux à même d'anticiper et de gérer les controverses autour de la vaccination. Si elles veulent rester un acteur désormais incontournable des politiques de santé, elles devront s'engager à soutenir la confiance du public.

## I. Introduction

Cervical cancer remains the second most common cause of cancer death (after breast cancer) among young women (aged 15–44 years) in Europe. Each year 38 000 women are diagnosed with cervical cancer, and 17 000 will die from this disease in the 27 European Union (EU) member states, Norway, Switzerland, and Iceland<sup>1</sup>, despite screening for early detection. In virtually 100% of cases, cervical cancer is caused by a virus: the human papilloma virus (HPV), which is also responsible for many other genital diseases.<sup>2</sup>

Screening, or secondary prevention, enables cervical cancer to be diagnosed at an early stage. However, it cannot detect all early lesions and does not prevent HPV infection. Besides, progress has still to be made to improve access to screening and extend screening coverage.

Therefore, the unique opportunity that HPV vaccination represents- a primary line of defence against a common cancer- was early recognized by a wealth of civil society groups, along with the medical and scientific community. But at the same time, other groups sternly and publicly denounced the mandate of HPV vaccines. Some on the grounds that it would promote promiscuity, others that it would derive funding from other health interventions or simply because there are anti vaccine leagues that oppose the introduction of any new vaccine.

Before embarking on the analysis of the role of civil society advocacy in the introduction of HPV vaccination, it is necessary to clarify some key notions.

- **Advocacy** can be defined as "the pursuit of influencing outcomes — including public-policy and resource allocation decisions within political, economic, and social systems and institutions — that directly affect people's current lives".<sup>3</sup> Advocacy groups are therefore "any organization that seeks to influence government policy, but not to govern."<sup>4</sup> This definition includes social movements, and network of organizations.

- **Civil society:** "the part of society that consists of organizations and institutions that help and look after people, their health, and their rights. It does not include the government or the family."<sup>a</sup>
- **Interest groups:** "[their] main characteristic is that they attempt to influence public policy but they do not seek political power."<sup>5</sup>

In this paper, the terms "advocacy groups", "civil society" and "interest groups" will be used equally and interchangeably in order to describe the various organizations that contributed to create - or hamper- a receptive sociopolitical environment for HPV vaccination. These organizations can take the form of patients' groups, women's associations, non-governmental organisations, registered charities, faith-based organisations, social movements or even business associations.

This paper will review the implication of civil society into the introduction of HPV vaccination and then examine its limitations. Finally, it will offer some perspectives for the future.

## **II. Empowered advocacy groups are powerful forces for shaping policy and increasing vaccines' market access....**

In contrast to many vaccine-preventable diseases, there was already awareness of the burden of HPV-related diseases, particularly cervical cancer, at the political, societal, and professional levels prior to the licensing of HPV vaccination. Advocacy from cancer patients groups and multidisciplinary coalitions, some specifically formed around cervical cancer prevention, contributed to greatly speed the introduction of HPV vaccination in Europe.

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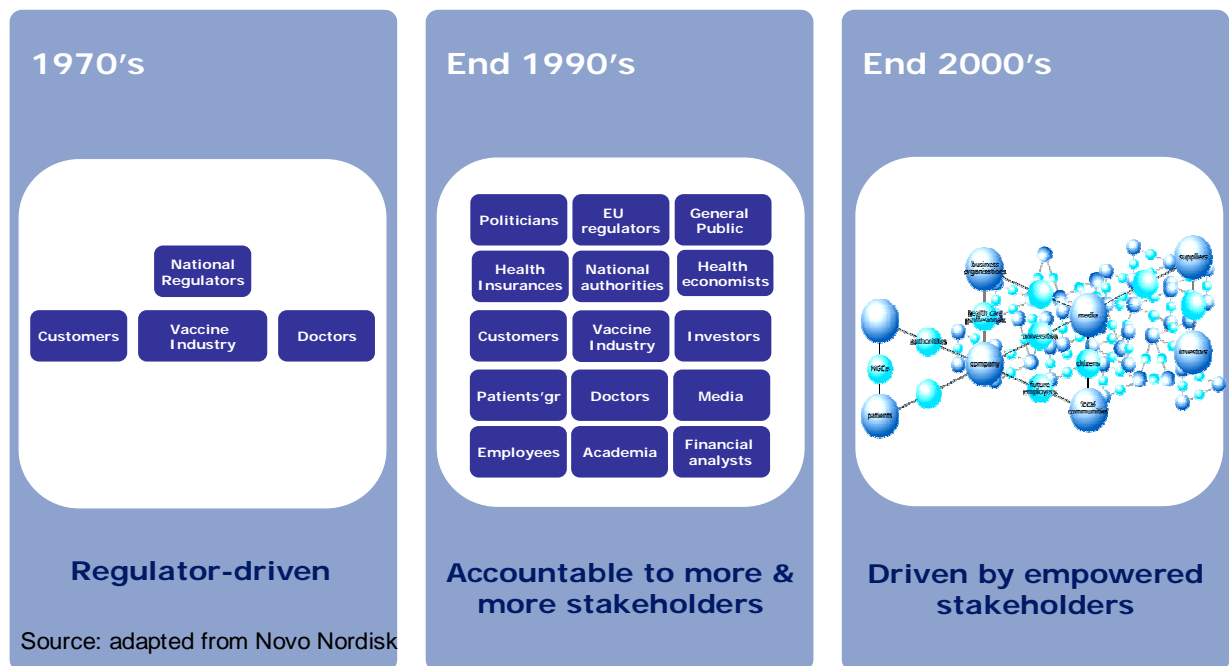
<sup>a</sup> <http://www.macmillandictionary.com/dictionary/american/civil-society> - last access 4 August 2009

## **A. The evolution of stakeholders' involvement has transformed vaccination policy-making**

Until relatively recently, the medical "power" was an entrenched part of public health policy. Walt demonstrates in a landmark piece on health policy that physicians were seen to be in "dominant, exclusive, monopolistic positions within the health sector".<sup>5</sup> Their community was the sole provider of information and expertise to the decision-makers on health matters. Third parties had no voice to the debate on drugs or vaccines' introduction. But, notably with the Internet, more and more people started to want to take responsibility of their own health. In a March 2009 issue of the *British Medical Journal*, Joanne Shaw, a prominent figure in the British medical establishment, demonstrated that the "traditional paternalistic relationships between patients and doctors are being undermined in much the same way as the religious Reformation of the 16<sup>th</sup> century empowered the laity and threatened the 1000 year old hierarchy of the Catholic church in Europe. The Reformation had irreversible consequences for Western society; the implications of the healthcare reformation could also be profound." Fiona Godlee, the journal's editor, agrees with her that the shift towards patients' empowerment is "unstoppable".<sup>6</sup>

Beyond patients' empowerment, the vaccines' business also witnessed an evolution of stakeholders' involvement. From a regulatory-driven environment in the 1970s, it went to one accountable to more and more stakeholders (investors, media, health economists, health insurances, academia etc...) at the end of the 1990s. Today, it is one driven by what we can call "empowered" stakeholders. Actually, companies are now not only accountable to a myriad of groups gravitating around the vaccine industry but they are forging new alliances with universities, local communities or NGOs.

## The evolution of stakeholders' involvement in the vaccines' business:



This evolution has also impacted vaccination policy-making, as these new stakeholders manage to get some degree of attention by decision-makers. Actually, the politicians and the media cannot do without interest groups. First, because by building expertise on health matters, interest groups have become pivotal sources of information. Second, specific interest groups like patients' groups or women's associations bring political value and legitimacy when referred to. The media enjoys exploiting the "real-life" angle; patients' stories are always moving, and thus selling. Poland even argues that "we have moved from an evidence-based medicine to a media-based one".<sup>7</sup>

At the political EU level, the notion of empowered stakeholders is now central in several areas. For instance in the draft *Directive on Information to Patients* which recognizes the importance and added value of patients groups, or in or on the *European Transparency Initiative* which aims at registering all interest groups in Brussels. On another level, it is worth noting that some of these groups have enacted their own codes of conduct. For instance, the European Medicines Agency (EMA) consumers and patients' groups' working party has issued an informal code of conduct for its members, and the European Federation of the Pharmaceutical Industry (EFPIA) has issued its binding ethical standards.<sup>8</sup>

These self-regulatory efforts illustrate the evolution of stakeholders' involvement in health policies. These groups have themselves become accountable not only to their constituencies but also to the other health stakeholders.

## **B. Civil society advocacy contributed to focus attention and increase market access of HPV vaccination both at EU and country level**

Policy change may come about because a number of different policy communities initiate action on a particular issue. In the case of HPV vaccination, cancer issues, particularly cancer prevention, were already high on many political agendas, thanks to years of campaigning by the scientific community and cancer associations. So many European and national politicians were open to the idea of supporting the possible adoption of vaccination against a cancer.

The cancer dimension, a new one for vaccination, also meant that a new range of stakeholders entered the arena: patients' groups. Vaccines are for healthy people, and therefore "patients' groups" had never been involved in the vaccine business. But this changed with the major breakthrough in both vaccinology and oncology that HPV vaccination represents.

### **1. At EU level**

Politicians have been encouraged by active support from a number of health associations, specific coalitions and federations of patients' groups. General health associations such as the European Public Health Alliance (EPHA) simply contributed to regularly report on the Commission and governments' efforts to tackle cervical cancer<sup>b</sup>. This kind of proactive monitoring usually pushes policy makers to take action or at least to implement what is already in place. In the case of cervical cancer prevention, the EU had already taken action on screening. Advocacy groups therefore started to lobby for the inclusion of HPV vaccination the 2003 *Council Recommendation on Cancer Screening*<sup>9</sup>.

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<sup>b</sup> <http://www.ephha.org/> - last access 4 August 2009

Organizations such as the European Cervical Cancer Association (ECCA) and the European Cancer Patient Coalition (ECPC) strongly supported the concept of cervical cancer prevention through combined screening and vaccination.

The mission of ECCA is to raise awareness of cervical cancer and its prevention among members of the general public, healthcare professionals and public health decision-makers in Europe<sup>c</sup>. 100 institutional members (cancer societies, medical associations, research organisations and patient groups) from 34 countries are represented.

ECCA developed a three-step approach to put and maintain cervical cancer vaccination on the EU political agenda. First, it started by producing educational materials on cervical cancer and its means of prevention, translated and distributed throughout Europe. In order to do this, it developed a Europe-wide network of researchers, clinicians and academics to provide a solid intellectual foundation for these education programs. Second, it developed a network of cancer societies, medical associations, patients' groups for them to be involved directly in the running of these programs and to perform advocacy at local level. And third, under the presidency of a former Member of the European Parliament, Ms. Mel Read, ECCA changed gear and started lobbying at EU political level. The association developed a network of European and national politicians to keep cervical cancer prevention on the parliamentary agendas. One of the key moments in cervical cancer prevention is now the European Cervical Cancer Prevention Week, with a Summit held in the European Parliament every year on the 3rd week of January. It gathers the whole European cervical cancer "community", ranging from politicians to country patients' groups.

This three-step approach proved successful as we will see below, but mostly at EU institutional level. So far, despite its efforts, ECCA has not managed to have the same success at country level. Possibly because ECCA is largely funded by industry; and its sponsors' competing interests did not facilitate putting vaccination on the various countries' agenda.

ECCA was largely aided in its advocacy by a federation of patients' groups: the European Cancer Patients Coalition (ECPC)<sup>d</sup>. ECPC concentrated good part of its efforts on the EU level to tackle cervical cancer more forcefully. For instance, ECPC established in 2006 a forum for the members of the EU Parliament (the MEPs), called MEPs Against Cancer (MAC).

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<sup>c</sup> <http://www.ecca.info/webECCA/en/> - last access 4 August 2009

<sup>d</sup> <http://www.ecpc-online.org/> - last access 4 August 2009

MAC became "the" cancer forum in the EU Parliament and several questions on cervical cancer were posed to the Commission by its members<sup>e</sup>. These questions are like the ones asked in national assemblies; the Commission must answer to them. By being involved in all cancer initiatives across Europe (at EMEA level, Commission's level or national level through its members), ECPC maintained a steady pressure on policy makers. As a result, ECPC is among the "founders" of the new cancer Commission's initiative: the *European Cancer Partnership Against Cancer* that will be launched in the 2009 fall. Cervical cancer is listed among the priorities.

Further to these active advocacy efforts, a European Parliament resolution on "*Combating Cancer in the European Union*" was adopted with an amazing majority (621 voices in favour) calling to "reinforce actions in favour of vaccination against cervical cancer"<sup>10</sup>. The same year, the Council issued conclusions on reducing the burden of cancer, and stated that "the development of prophylactic vaccines against some carcinogenic viruses has opened up a new area in cancer prevention". Finally, the Parliament requested "specific policies to be developed for cervical cancer" in the "*White Paper: Together for Health: A Strategic Approach for the EU 2008-2013*"<sup>11</sup>. These documents came in support of the national recommendations and contributed to push countries lagging behind.

The WACC Foundation (Women Against Cervical Cancer) did not lobby directly at European institutional level, but developed another type of European-wide advocacy. By forging an alliance between scientists, key opinion leaders, patients and political representatives in countries, WACC created an original European advocacy coalition.

WACC was started by a gynaecologist who used his experience with a French patients' group (called 1000 Femmes 1000 Vies), and now comprises more than 50 advocacy groups and women's health associations<sup>f</sup>. Its goal is to harness the power of local associations and provide them with readily available advocacy tools. To develop these and manage the network, a European task force mostly made up of health care professionals has been created.

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<sup>e</sup> ECCA had also set up a MEPs group on cervical cancer, very active in preparing the Cervical Cancer Prevention Week

<sup>f</sup> <http://www.eurogin.com/2008/wacc/organizations.html> - last access 4 August 2009

A number of other organizations contributed, to a lesser extent, to shape policy and increase market access of HPV vaccination. Efforts going on in other parts of the world, such as the US, influenced European decision-makers. For instance, a group of US female legislators (Women in Government) greatly emphasized awareness of cervical cancer in and outside the US<sup>g</sup>. They distributed in Europe an "international toolkit" recapping the key steps to be followed in any awareness campaign (see graph below). Let's note the importance of building coalitions and cooperating with other community-based organizations. WIG demonstrates here that no one organization can raise awareness on its own. A "virtuous circle" must be established and maintained to be successful.

The key steps to be followed in an awareness campaign, from Women In Government's Best Practices:



Source: adapted from Women in Government International Toolkit

<sup>g</sup> <http://www.womeningovernment.org/> - last access 4 August 2009

WIG also partnered with ECCA. A United Nations organization, UNIFEM (the United Nations Development Fund for Women) also organized a landmark event in Brussels to convince decision-makers to better tackle cervical cancer and introduce vaccination both in developed and developing countries. Finally, other international coalitions<sup>h</sup> kept working through social media and other web-based tools to raise awareness on the issue.

## **2. At country level**

Various interest groups contributed to focus attention and increase market access of HPV vaccination.

### **a. Patients' groups**

They have been the most active ones advocating for the introduction of HPV vaccination. Long before HPV vaccination was mentioned in the media, a UK patients' group was already working on cervical cancer prevention. Jo's Trust offered British women trusted information on the topic and continuous support in their cancer journey<sup>i</sup>. So when primary prevention started to make the news, Jo's Trust immediately grasped the opportunity and started campaigning in the UK and Ireland (and subsequently at EU level). Thanks to regular events organized for decision-makers but giving the floor to patients, Jo's Trust managed to establish a broad base of support for HPV vaccination. Vaccination was finally introduced in the UK in June 2008.

In France, we already briefly mentioned 1000 Femmes, 1000 Vies<sup>j</sup>. It is a charity composed of patients, but it was originally created by a gynaecologist. 1000 Femmes, 1000 Vies owes its name to the fact that every year 1000 women die of cervical cancer in France. There again, once HPV vaccination hit the news, the group started campaigning for a joint approach between secondary and primary prevention. Thanks to the complementarities between patients' pressure and support from the scientific board, 1000 Femmes, 1000 Vies made its voice heard in the debate. However, the organization only succeeded because it managed to connect patients with an existing medical network. In the absence of any well-known champion that can publicly support the cause, the link between experts and patients becomes

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<sup>h</sup> <http://www.cervicalcanceraction.org/home/home.php> - last access 4 August 2009

<sup>i</sup> <http://www.jotrust.co.uk/> - last access 4 August 2009

<sup>j</sup> <http://www.1000femmes1000vies.org/> - last access 4 August 2009

the only actionable one to influence policy. This is a model that was then reproduced at European level with the creation of the WACC network, uniting professionals and their patients in the same battle.

In Greece, Germany, Estonia, Portugal, Bulgaria, Norway, Sweden or Spain, **cancer leagues** and national cancer patient organizations played a key role in establishing a base of support for policy makers, rather than putting hard pressure on them. Long-lasting relationships between these groups and decision-makers helped maintain the momentum of the introduction of HPV vaccines.

#### **b. Women's associations**

They also played an important role in the advocacy for HPV vaccination. Small associations like<sup>k</sup> "Regards de Femmes" in France, but which belong to larger networks (such as the European Women's Lobby<sup>l</sup>, a powerful European federation) or political women's movements like Vrouw en Maatschappij<sup>m</sup> in the Flanders region in Belgium contributed to "educate" women across Europe on cervical cancer and the means to prevent it. In France, vaccination is given on demand with 65% of the cost of the vaccine covered by national health insurance started sexual for those aged 14-23. In Belgium, national recommendations propose: a) Vaccination of 1 cohort females between 10-13 to be undertaken within a school-based programme and b) Vaccination of virgin females aged 14-26 to be proposed by physicians.<sup>n</sup> Vrouw en Maatschappij subsequently supported the implementation of a school based vaccination programme in Flanders. The Flemish government plans the launch in 2010 for girls aged 12.

In Italy, the Osservatorio Nazionale sulla salute della Donna (ONDA) an Italian observatory on women's health, set up a nation-wide advocacy campaign on cervical cancer<sup>o</sup>. ONDA deployed various types of tools, ranging from senate hearings to distribution of leaflets in the metro. It thus managed to create awareness on the topic, both at political and lay public level.

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<sup>k</sup> <http://www.regardsdefemmes.com/> - last access 4 August 2009

<sup>l</sup> <http://www.womenlobby.org/site/hp.asp?langue=FR> - last access 4 August 2009

<sup>m</sup> <http://www.vrouwenmaatschappij.be/index.asp> - last access 4 August 2009

<sup>n</sup> And the cost of vaccination for females aged 12-18 is covered by the government but subject to a co-payment of €0.80 per dose.

<sup>o</sup> [http://www.ondaosservatorio.it/en/malattie\\_neurodegenerative.asp](http://www.ondaosservatorio.it/en/malattie_neurodegenerative.asp) - last access 4 August 2009

Today, HPV vaccination is provided free of charge to girls aged 12 through local health centres with direct invitation by letter, in most Italian regions (in some regions, more cohorts are included)<sup>12</sup>.

Hence, the environment that these various interest groups established in Europe definitely provided a base of support for policy makers. They derived legitimacy and encouragement from it. Of course, a number of other elements played a key role in the introduction of HPV vaccination programs. The rapidity with which EMEA approved the dossier surely placed a responsibility on governments to accelerate their recommendations and funding decisions. The feedback loop between EU institutions and countries at technical level and political level also facilitated market access. Scientific societies mobilized themselves very early and contributed to maintain the momentum. Finally, one must not forget that it was "robust data generated by research specifically targeted to public health needs that has convinced the various stakeholders to advocate, license, recommend and fund [HPV] vaccination".<sup>13</sup>

### **III. ...But civil society advocacy can also be damaging to the introduction of vaccination programs**

Most interest groups present in the cancer and women's health field actively supported the introduction of HPV vaccination, despite the somewhat limited extent of their perimeter. However, a number of groups, some backing very different types of causes, endangered the introduction of HPV vaccination.

## **A. Civil society advocacy can hamper policy shaping and market access**

4 main types of arguments have been put forward by interest groups against HPV vaccination.

### **1. Promotion of promiscuity**

Although research has shown that that sexual and reproductive health education does not promote sexual activity or promiscuity<sup>14</sup>, conservative groups and faith-based organizations actively campaigned against HPV vaccination. This was mostly the case in the US, where they saw it as a licence to engage in premarital sex. For instance, a conservative group called Traditional Values Coalition consistently opposed HPV vaccination in the US. In England, school-based surveys showed that some parents also worried about promiscuity<sup>15</sup> and the Catholic Church tried to cast doubt over the merits of primary prevention for that reason<sup>P</sup>. However, health authorities were quick to react and contributed to defuse the argument.

### **2. Safety**

This has been the prime concern of various interest groups. "Usual suspects" in any vaccination debate came to the fore. Anti-vaccine movements, such as the National Vaccination Information Centre (NVIC), Judicial Watch (both US associations) or the French Ligue Nationale Pour la Liberté des Vaccinations keep trying to put doubts on the safety of HPV vaccines<sup>16</sup>. For instance, NVIC merely did crude cut and paste from the VAERS database in the US<sup>Q</sup>, and did not account for the differences in dosing or the amount of doses distributed. In the UK, Jabs, a support group for people who believe that they have been damaged by vaccines, pointed out to anecdotal evidence stretching back to the introduction of the Cervarix vaccine<sup>17</sup>. In the Netherlands, the Dutch Association of Critical Vaccination, an anti-vaccine group set up in 1994, has been accused by the Director of the Dutch Institute of Public Health of damaging women's health by spreading false claims<sup>18</sup>. Some parents' associations also echoed concerns on vaccines' side effects.

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<sup>P</sup> Some Catholic schools even banned girls from having cervical cancer jabs.

<sup>Q</sup> The VAERS database is the US federal Vaccine Adverse Events Reporting System

In Spain, further to the hospitalization of 2 girls in the province of Valencia following vaccination with HPV, a parents' association was created. La Asociación de Afectadas por el Virus de la Papiloma (AAVP) is now advocating for a moratorium on HPV vaccination<sup>19</sup>.

### 3. "Aggressive" awareness campaigns

Some interest groups like the Associació de Dones de les Illes Balears per a la Salut (ADIBS), a women association from the Balearic Islands in Spain, launched advocacy campaigns denouncing industry's advertising and "aggressive marketing"<sup>20</sup>. For instance, ADIBS sent a petition to be signed by all Spanish members of the EU parliament asking for a moratorium. They also put up a presentation to be disseminated through social media, like You Tube. In Germany, health care professionals expressed concern in the media, while women and patients' groups did not partner with them. 13 health scientists launched a *Manifesto* calling to put an end to "misleading information" on the efficacy of HPV vaccination. Awareness campaigns conducted by the vaccine manufacturers were found "highly tendentious". Subsequently, an *Alliance Against Misinformation and Manipulation* was launched by the president of the Berlin medical association<sup>21</sup>.

### 4. Cost

This has mostly been an issue for governments, in charge of funding vaccination programs. But some interest groups, like ADIBS in Spain, criticized the cost of the vaccine and the profit made by industry. In Germany, where the vaccine is particularly expensive due to wholesalers' and pharmacists' mark-ups and taxes, cost has been a big issue. In addition, the cost-effectiveness of HPV vaccination has been fiercely debated, notably by the Manifesto leaders.

## **B. Civil society advocacy's power finds its limitations**

There are inherent limitations to the influence of civil society groups.

First of all, the importance of traditional actors in healthcare policy setting remains high. Because sound scientific data is the basis of any decision in the field, the opinion of scientific experts counts a lot. Scientific societies and key healthcare leaders still have an easier access to decision makers than civil society groups, notably because they sit in government committees in charge of issuing recommendations. Besides, a number of scientific associations, at EU or country level, produced guidelines on HPV vaccination that guided decision makers. This being said, one must remember that alliances between experts and civil society groups are now considered one of the most successful advocacy approaches with decision makers.

As any other lobby, civil society groups can be seen as bending public policy towards their own interests and can make the business of governments more difficult. Competition between these groups is indeed fierce - be it for media exposure, political power or money. All these groups vie to attract funding. Without appropriate resources, it is indeed difficult to effectively focus attention on a given cause. The issue is even more acute for patients' groups. They must balance their sources of funding, between industry's and public's funding, in order not to be accused of partiality.

Fragmented health regimes across Europe do not help interest groups to extend their influence. For those groups powerful at country level, it is very difficult to "export" their influence because recommendation and funding of vaccination programs is a national competency. There is an EU-wide licensure by the EMEA but following the "subsidiarity" principle, each country may develop national recommendations, and then funding must be found, either from the public or private sector or both. For interest groups active at European level, the challenge remains the same: they can have an important role in shaping policy and focussing attention, but when it comes to funding, their influence greatly diminishes.

Finally, the limitations to civil society's influence can be illustrated by the absence of a real "champion" for the cervical cancer cause. At country level, a few well-known celebrities committed themselves (such as actress Katarina Stenberger in Austria) but no one really embodied the cause. The only public figure that conducted a desperate fight for awareness was the *Big Brother* celebrity Jade Goody in the UK. But she decided on her own to herald the cause after having being diagnosed with cervical cancer<sup>22</sup>.

#### **IV. Future perspectives: civil society advocacy is bound to play a greater role in vaccines' introduction and implementation**

After the assessment of civil society advocacy in the introduction of HPV vaccination programs in Europe, we would like to offer here some thoughts on the future of this movement in vaccinology.

Among the various types of interest groups, patients' groups are now playing a more and more central role in health policy setting. A European Charter of Patients' Rights was established in 2002 by a group of European citizens' and consumers' organizations, led by ACN (Active Citizenship Network).<sup>f</sup> A European patient' rights' day has even be launched, with 80 events organized across Europe in 2009. The Directive on Patients' Rights and other EU initiatives on the topic encompassed in the "*Europe for Patients*" campaign illustrate that EU policy makers now take them seriously. This campaign now provides a global framework for a wealth of health policy projects, which must aim at providing better healthcare for all in Europe.<sup>s</sup>

Patients' empowerment is bound to continue growing also because people will always pay more attention to emotional stories than to cold scientific statistics, be it for drugs or for vaccines. Patients' groups bring health matters closer to the lay public and benefit from an immediate sympathy. Patients now seek more control over their options and how they can prevent future diseases; they look for feedback from other patients<sup>23</sup>. It is also bound to be growing because both industry and policy makers are striving to put patients in the centre of health care, not the disease anymore.

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<sup>f</sup> <http://www.activecitizenship.net/> - last access 4 August 2009

<sup>s</sup> [http://ec.europa.eu/health-eu/europe\\_for\\_patients/policies\\_actions/index\\_en.htm](http://ec.europa.eu/health-eu/europe_for_patients/policies_actions/index_en.htm) last access 4 August 2009

Patient-centred healthcare has very practical implications in vaccinology. For instance, the American College of Physicians (ACP) and the Infectious Diseases Society of America (IDSA) have advised their members at the end of 2008 to "discuss and review their adult patients' vaccination status and either vaccinate them or provide a referral for recommended vaccines". They consider that the "patient-centered [...] model of care – which in coordination with the other components of the health care delivery system is the future of health care – will help to increase immunization rates among adults."<sup>24</sup>

Civil society advocacy will become more and more important for the new vaccines in the pipeline, such as the ones against *Staphylococcus aureus* and *Clostridium difficile*. Healthcare associated infections (also called nosocomial infections) are directly responsible for approximately 37 000 deaths annually and contribute to a further 110 000 across the EU<sup>†</sup>. Global patients' organizations of course seized the issue. Patient safety<sup>‡</sup> is for instance a strategic priority for the European Patient Forum (EPF), and EPF is a member of the European Commission's Patient Safety Working Group. Other interest groups such as Health Action International (HAI), a European network of consumers, public interest NGOs and health care providers, have reached out to the EU Parliament for support<sup>25</sup>.

Upcoming therapeutic vaccines in the cancer area have also gotten the attention of cancer patients' groups. In many situations these vaccines will need to be integrated optimally with current therapies that are used for various cancer indications. Patients' groups will probably not only lobby for the introduction of these new vaccines, but will also pay attention also to the synergy between vaccine and chemotherapeutic approaches.

It is also worth remembering that the vaccines market is forecasted to be the fastest growing sector in the pharmaceutical market. As the "classical" pharmaceutical sector has to overcome more and more hurdles (generics, counterfeiting etc.), it provides less funding to interest groups. A growing number of these groups are turning their attention to vaccines, as they realize that funding opportunities may appear.

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<sup>†</sup> <http://ecdc.europa.eu/> - last access 4 August 2009

<sup>‡</sup> Patient safety is defined as freedom for a patient from unnecessary harm or potential harm associated with healthcare.

Finally, a new dimension for civil society advocacy is emerging with the implementation of HPV vaccination programs. As Hutt writes, "Ultimately, the final challenge for a new vaccine is not only its inclusion into national programmes, but above all the adoption of the policy by the public and its political/economic sustainability"<sup>26</sup>. One must remember that the successful implementation of vaccination policies relies upon two basic approaches. First, the support of stakeholders in charge of implementing the programme has to be secured (the « willingness to vaccinate »). Second, the programme must also be supported by the vaccinees and those who influence them (the « willingness to be vaccinated »)<sup>27</sup>.

Now that HPV vaccination programs are in place in the majority of European countries, the issue has become more complex. HPV vaccination is faced with an accumulation of controversies, which are damaging citizens' confidence in the program. This happens with the introduction of any new vaccine<sup>28</sup>, and the lesson learnt is that the continuing commitment of all stakeholders who have supported the introduction of vaccination is paramount. "Success in public health relies on public trust", notes Wynia<sup>29</sup>. Therefore, advocacy groups have to play their part and must start performing bottom-up advocacy to retain their stakeholders' and the public's confidence in HPV vaccination programs. The sustainability of these programs depends upon this.

## V. Conclusion

As we strived to demonstrate in this paper, civil society advocacy definitely contributed to the introduction of HPV vaccination programs in Europe, despite its inherent limitations and the challenges posed by a number of interest groups.

Nevertheless, the introduction of the program was only the first act in the play.

Any vaccination program is indeed doomed if it fails to acknowledge the importance of consumer acceptance. Civil society groups will therefore have to devise new means to overcome the challenge of implementation, to ensure the long-term success of this extraordinary public health tool. By being rooted in society, these groups are better positioned to anticipate and address controversies around vaccination.

To keep a seat at the policy-making table, they are now expected to go beyond education and awareness and commit themselves to support public trust and confidence in vaccination policies.

Finally, lessons from the HPV experience will benefit the AIDS community. This experience actually provides an unprecedented opportunity for civil society groups to inform future access strategies and implementation mechanisms for an AIDS vaccine. There are indeed many areas of common concern to both vaccines, from the population targeting and delivery strategies to the complex messaging that is required (for both HIV and HPV, a vaccine will not replace related efforts)<sup>30</sup>. While it will be some years before the development of an effective AIDS vaccine, the opportunity for advocacy groups to participate in and support HPV vaccines introduction will help plan the delivery of a future AIDS vaccine.

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