

Making HPV Vaccines Efficient: Cost-Effectiveness Analysis and the Economic Assemblage of Healthcare in Colombia

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Abstract

Cost-effectiveness analysis is a strategy of calculation whose main objective is to compare for making decisions about the best, the most efficient solution (costs vs benefits) to a particular problem. Cost-effectiveness analysis not only provides a framework to compare healthcare interventions which in practice seem incommensurable; it also performs a set of assumptions regarding the nature of healthcare and individuals' behaviour. This article analyses the role of cost-effectiveness analysis as a device to produce value in the introduction of *human papillomavirus* vaccines to Colombia. In different institutional pathways and decision-making scenarios cost-effectiveness has been the key issue that justified the inclusions and exclusions that such technology entails. Cost-effectiveness justified the definition of girls as the population target and the exclusion of boys from the risks and benefits of this technology. Cost-effectiveness analysis has been a key instrument in the sexualising and desexualising of cervical cancer and *human papillomavirus* vaccines through the rationalisation of economic benefits.

Keywords: quantification, HPV vaccines, global health

Introduction

Cervical cancer is strongly associated with the persistent and untreated infection of specific types of the human papillomavirus (HPV). There are currently two vaccines that protect against the HPV types associated with 70% of cervical cancers – Cervarix® manufactured by GlaxoSmithKlein and Gardasil® by Merck. After three years of debate about their cost-effectiveness, in 2012 the Colombian Government introduced Gardasil® into the Colombian Expanded Programme of Immunisation. Since that year, three million girls in Colombia have received the vaccine.

The cost-effectiveness of this intervention was a central concern for health authorities in Colombia. While the security and efficacy of the vaccines were relatively taken for granted, cost-effectiveness was a matter of debate. The cost effectiveness of HPV vaccines has been internationally a contested issue because of the different elements involved in its calculation. They are one of the most expensive vaccines on the market and are an intervention to prevent a disease with an occurrence period of 20–30 years. Moreover, HPV vaccines are 'competing' with cervical

screening programmes, a complex system of diagnosis and treatment of cervical lesions. For the medical community, cervical screening has significantly reduced mortality for cervical cancer in the countries where it has been implemented (developed countries).

The first study used by the Colombian Government to consider the introduction of these vaccines concluded that, at the international prices of that time (2009), a national HPV programme was not cost-effective (UNAL, 2009: 60). Many voices within the medical community expressed disappointment with these conclusions. However, a legal class action led to a reconsideration of the study results by the government. In December 2010, a citizen brought a class action against the Ministry of Health to protect the rights to public health and security that had been breached because of the non-inclusion of HPV vaccines into the mandatory healthcare plan (POS). As result of this class action, the court recognised that the "Right to Public Health" was breached by omission, establishing a deadline of three months after the ruling to complete new cost-effectiveness studies (Council of State, 2012).

At the end of that year, the Ministry of Health contracted a second study concluding that at the international prices of that time (2011), an HPV vaccination programme using Gardasil was cost-effective (UNAL 2011). Accordingly, the National Committee of Immunisation Practices on behalf of the Ministry of Health approved the introduction of Gardasil into the expanded programme of immunisation. Officially, the national vaccination programme against HPV started in August 2012. The President of Colombia Juan Manuel Santos presided over the campaign launch. In 2013, the Colombian Congress approved Act 1626 to support HPV vaccination programmes in the long-term.

How did the Colombian Government come to overturn their original conclusion about HPV vaccines' cost-effectiveness in the space of three years? Different actors tried to influence in the government's decision: courts, medical communities, pharmaceutical companies, and citizens. However, the decision and its argumentation were developed using the language of evidence-based medicine and cost-effectiveness analysis (CEA).

In this case, any attempt to influence the government's decision had to be presented in terms of numbers, evidence and data. For instance, as I present in this article, one of the most significant changes between the studies was the inclusion of genital warts as a public health concern by means of the quantification of its "burden of disease".

This article analyses the role of CEA in the governing of HPV vaccines in Colombia, describing vaccination policy as an assemblage in which quantified entities have an important role in the production of legitimacy. CEA not only provides a framework in which to compare health-care interventions that seem to resist comparison; it also performs values associated with good policy. In the several scenarios in which this policy is constructed, cost-effectiveness has been the key issue that justified the inclusions and the exclusions that such technology entails. This case explores the reception of these calculation devices in a developing country. It aims to contribute to the literature on statistics and CEA in contemporary politics by showing the role of the calculation of the cost-effectiveness of HPV vaccines in its legitimization of the right public health intervention in Colombia.

Following the movement of the numbers and measurements that express cost-effectiveness from technical reports to the immunisation committee, the Colombian Congress and the Council of State, I describe the transformation and malleability of entities that are regarded as objective and stable and the ways in which numbers are intertwined in affective economies. In this process, cost-effectiveness slowly disappears as a matter of concern and other elements such as prices, prevention and women's empowerment gain importance in the public justification of the intervention. I illustrate this argument by analysing the role of the quantification of genital warts' burden of disease in making Gardasil the most cost-effective option and by expanding on the short lives of some numbers once they travel from CEA to public arenas. Cost-effectiveness becomes an icon to justify the inclusions and the exclusions that HPV vaccines entail: the definition of girls as the population target and the exclusion of boys from the risks and benefits of this technology.

In parallel with the description of this transformation, this article analyses the role of CEA in the production of convoluted relations between sexuality and HPV vaccination. The inclusion of genital warts into the calculation of cost-effectiveness renders visible the sexual character of HPV infection and the hetero-normative assumptions of epidemiologists and health authorities regarding contagion and prevention. In contrast, in public arenas, quantified entities and the reference to cost-effectiveness as a policy value have contributed to “desexualising” cervical cancer. These entities have highlighted the economic and affective benefits of prevention as the focus of the policy.

Numbers production and value in policy

Science and technology studies (STS) and sociology have shown an increasing interest in studying numbers and the effects of quantification in policy and public affairs. Such work can be understood as an extension of the analysis of the production of numbers and mathematical representations in the history of science (Hacking, 1990) and laboratory studies (Latour and Woolgar, 1986). The sociological analysis of quantification has focused on numbers’ practical uses and the ways in which these are related to wider networks of practices (Desrosières, 1998; Espeland and Stevens, 2009; Fourcade, 2011).

Ian Hacking (1990) in *The Taming of Chance* describes the rise of political arithmetic and the genealogy of concepts that have shaped contemporary policy such as probability and evidence. The rise of a quantitative rhetoric is linked with the development of statistics as a governance tool. Indeed, Porter (1995) has described how different professional groups (accountants, engineers, actuaries, economists and statisticians) construct their expert authority around the use of numbers and quantitative models impacting through such ‘technologies of trust’ as public governance. Numerical operations have been used as strategies to soften political controversies and to produce rhetorical objectivity (Porter, 1995: 206).

Different forms of quantification, but in particular statistics, have been adopted as the

language of the modern state. Policymakers know and represent society through numbers and figures; statistics is a key tool in debates, in the assessment of policy choices, and, increasingly, in the evaluation of government performance (Clark, 2005: 404). The integration of quantification as a strategy of governance relies on configurations that are nationally segmented. National regulations, government structures and the history of the relationship between governments and their citizens shape the role of quantification in governance (Jasanoff, 2004). The extensive development and use of information technologies have increased the production of quantified data in different realms of government and have facilitated the execution of convoluted calculations by means of a wide range of software.

Calculation and quantification in policymaking have an important role in the two-way transit of objects from matters of fact to matters of concern (Latour, 2004). Numbers shape data and objects of knowledge as matters of public interest and transform social and political claims in data, figures and ‘objects’ of knowledge:

Modern social institutions spend considerable time and effort measuring what seems un-measurable and valuing what seems beyond valuation in the service of enhancing their own capacities for calculation, crafting new opportunities for profit, or expanding their jurisdictional authority (Fourcade, 2011: 1723).

On the other hand, the economisation (marketisation) of policy has contributed to the development of quantified practices and devices for decision-making. Authors such as Donald MacKenzie (2006), Koray Çaliskan and Michel Callon (2009) and Tiago Moreira (2012b) have demonstrated the role of economics in the shaping of contemporary governance and our understanding of the social and the market through its devices of calculation and practices of quantification. A concept of value shaped by economics has massively dominated contemporary societies. It has influenced “major infrastructures of contemporary life, like housing, circulation, healthcare institutions, etc., many of which play a crucial role in determining our modes of existence” (Kjellberg and Mallard, 2013: 17).

The analysis of valuation involves “unpacking implicit and explicit normative assumptions that are ‘blackboxed’ through different technical infrastructures (Kjellberg and Mallard, 2013: 17)”. A way of unpacking such infrastructures is to follow the transformation of numbers through their circulation from their technical generation to their public display. Numbers are generated by practices of calculation. STS literature (Desrosières, 1998; Callon and Law, 2005; Verran, 2012) has understood numeric calculation as a three-step development, a game of entanglements and disentanglements. When produced as quantified entities, numbers follow a process of ordering, measuring and generalisation. In this process, they are first indices of a partial order, then they become measures of value (symbols), and finally express a naturalised order (icons). As Verran (2012: 65) has noted, understanding the ways in which numbers are produced and transformed is very important in tracing the transformation of contemporary governance.

Verran (2012) argues that in the analysis of the role of numbers in contemporary governance, indices are crucial. An index is a sign in which the relations that constitute it are open and available for changes and reworking: “It is thus in the indexical zone that the three-step epistemic dance of “modern facts” is most easily undone (Verran, 2012: 66)”. The other two types of signs, symbols and icons partially hide or render invisible their own process of production. Symbols can be understood as those types of signs that need a theory, an explicit set of categories, to be meaningful. For instance, those numbers in technical reports that are justified as faithful accomplishments of formulae; these formulae are a set of relations between several abstract concepts. Although the formula does not reveal the material process of producing numbers, it makes explicit the categories that render them.

As Lampland (2010) notes not all the numbers are produced to express a true fact. Actually, “assuming that the effective use of numbers depends upon their veracity obscures crucial social processes at the heart of modernising practice” (Lampland, 2010: 378). The practical value of some numbers relies on the fact that they are ephemeral, temporary and conditional.

I would add that not just false and provisional numbers are unstable. As I present in this article, numbers that are produced with the purpose of expressing ‘reality’ are not particularly meaningful outside specific contexts. The apparent stability of numbers is the result of their transformation in icons. As I present it, the numbers that express the cost-effectiveness of HPV vaccines, although not considered provisional, are regarded as fragile by those responsible for producing them. Such perception of contingency is related not only to the fast changing input data but also to some features of cost-effectiveness as a calculation device in health policy.

Quantification and governance in contemporary healthcare

Different authors (Moreira, 2012a; Reubi, 2013; Wahlberg and Rose, 2015; Adams, 2016) converge in arguing that contemporary healthcare has been transformed by the use of actuarial, managerial and accounting devices of calculation that have promised a more efficient use of scarce resources. Calculation practices such as cost-benefit analysis and CEA have been used to allocate resources and to make trade-offs between drugs, procedures and diseases that previously had been considered not comparable. The development of health currencies based on the quantification of quality of life has made such trade-offs possible.

The increasing use of QALY (quality adjusted life years) and DALY (disability adjusted life years) has recently attracted the interests of scholars – from anthropology, sociology and science studies – who have perceived that metrics have an important role in the shaping of the contemporary governance of global health. Some of these works have analysed the normative assumptions behind the design of these metrics (Kenny, 2015; Wahlberg and Rose, 2015) arguing that they show a deeper transformation in epidemiological rationality and the governing of life. Other works (Moreira, 2012b; Adams, 2016) have emphasised their role in the economisation (Adams, 2016) of healthcare. For them, QALY and DALY are key elements in the organisation of global health according to principles from the market. These scholars are concerned with the side effects of

7quantification in the provision of “health for all” (Adams, 2016).

The use of these techniques and metrics shows the tensions and particularities of what McGoey and colleagues (2011) have called global health complex; that is, an increasing globalised understanding of health risk accompanied by the involvement of new actors in international health policy advocating for standardisation, efficiency and business-like strategies of assessment and intervention. Such complexity echoes a global assemblage (Ong and Collier, 2005) in which standards and other “global forms” are concrete elements in the configuration of local and specific objects:

The relationship among the elements in an assemblage is not stable; nor is their configuration reducible to a single logic. Rather, an assemblage is structured through critical reflection, debate, and contest (Collier, 2006).

The governing of healthcare by numbers could be understood as an assemblage of metrics, national governments, international institutions and material infrastructures.

This configuration is deeply entangled with other transformations in global and public health such as its pharmaceuticalisation (Biehl, 2012; Mamo and Epstein, 2014) and new engagement with local and national forms of citizenship and regulations (Ecks, 2008; Biehl and Petryna, 2011). An emphasis on quantified and measurable health outcomes has privileged those interventions that can demonstrate their value through clinical trials and CEA. Drugs perform particularly well in this valuation framework, while more holistic approaches have serious problems in reporting their impact and effectiveness in the language of quantification (Adams, 2016). On the other hand, the rise of a quantified regime of valuation in healthcare has produced tensions, conflicts and new relationships with other valuation frameworks such as the law (Foucarde, 2011: 1733). Stefan Ecks (2008) has described the surge of new forms of strategic mobilisation of legal resources by pharmaceutical companies, in which they pretend to be “good citizens” that advocate for patients and citizens’ rights. Other authors (Biehl and Petryna, 2011; Maldonado, 2017) have

described the clash between representations of health as a “Right” and as a matter of calculation and a commodity. In countries such as Brazil (Biehl and Petryna, 2011) and Colombia (Maldonado, 2017) patients have had to appeal to courts in order to get access to prescribed medicines, often in direct opposition to economical valuation about their cost-effectiveness.

How do we approach the assemblages where these devices operate? I argue that a comprehensive study of the quantification (Fourcade, 2011) in healthcare policy asks why and how numbers are produced and in which assemblages they are produced and circulate (Çaliskan and Callon, 2010; Fourcade, 2011). This analysis is necessary in order to follow the production and circulation of information between documents, tracking the transformation of data and numbers, their disentanglement from the calculation spaces in which they are produced and their re-entanglement in new texts by new institutions. I have analysed the technical studies produced by consultants for the Colombian Ministry of Health, memoranda and regulation. Additionally I have interviewed the members of the Committee of Immunisation practice and the experts that developed those studies. This exercise can be understood as reverse engineering. I have traced papers and documents that are quoted as references to support particular claims and data, and I have re-enacted some calculations in order to understand the origin and use of some of these results. Although cost-effectiveness is invoked as the main framework for understanding the social and economic value of HPV vaccines, as I show, the metrics that render visible such value do not travel through these different institutional settings.

CEA as calculation practice depends on the disentanglement of technologies and procedures from their contexts of use in healthcare; these entities are ordered in a calculative space in which they will be transformed and translated into new entanglements as results. In the case of CEA the calculative space will be defined by formulae. A formula is a symbolic representation of the relation between entities that have been quantified. In the same way in which tables and rankings tell stories about modes of ordering, hierarchies, inclusions and exclusions, formulae as calculative

spaces enact rules, assumptions and narratives about the entities that are calculated. This article is an analysis of how methods perform reality, in this case how CEA as a methodology of comparison and valuation produces an assemblage between health, economic value, sexuality, risk, cervical cancer and HPV vaccines.

Assembling cost-effectiveness: numbers, courts and viruses

CEA allows the identification and monetisation of the costs and benefits of a programme. It relates costs to specific measures of effectiveness. CEA is a well-established technique to support decision making in health policy; it has a long tradition in Europe and North America, and in the past decade it has been increasingly used in developing countries. This practice has demanded the development of particular health measurement units such as the year lost life (YLL), the life year gained (LYG), QALY and DALY. These units act as health currencies in the sense that they are used as quantified and interchangeable measures of the value of healthcare interventions in terms of human life (Moreira, 2012b). Health currencies complete the work done by monetary estimations in the calculation of cost-effectiveness, which is a ratio between costs expressed in money and benefits in terms of human life and quality of life.

CEA is a powerful tool in policymaking because it translates different objects and realms into a quantified language whose “value” is perceived as highly visible: money. As Pinch and colleagues noted, the success and credibility of such technique “lie[s] in their ability to continually trade between the worlds of facts and figures and worlds of words and politics” (Pinch et al., 2000: 24). Such capacity to mediate between practices and artefacts has extended their use in contemporary policy. Additionally, CEA enacts future scenarios for policy imaginaries and practices. This is important to decision makers because the benefit and costs of programmes are not limited to the present; on the contrary they are calculated and defined into the future. Economic and health benefits are projected into the future; the current scenario matters because it is perceived as a stage in the enactment of the future (Adams et al., 2009).

Although CEA valuation might be considered as a corollary of the expansion of bureaucratic-legal rule in contemporary democracies, the reception and justification of this tool is related to specific nation-state assemblages. Different countries justify the practice and implement it in a special way (Fourcade, 2011: 1733). In the United States, for instance, cost-benefit methods are widely spread and are perceived as a normative instrument of good democratic governance; while in countries such as France, they are more openly perceived as technocratic contraptions rather than accountability tools (Fourcade, 2011). As I present in this article, CEA in Colombia has been recently introduced into health policy and is perceived as a novel instrument by policymakers that would improve decision-making, increasing the efficiency of policy.

The formula behind a CEA seems quite simple: “typically, analysts subtract costs from benefits to obtain the net benefits of the policy (if the net benefits are negative, they are referred to as net costs)” (Cellini and Kee, 2010: 494). In practice, this is far from simple. Even when the effectiveness is assumed, as in this case¹, epidemiologists and health economists have to undertake a painstaking process to estimate the costs and to translate clinical trials’ effectiveness in terms of populations. In this case, the epidemiologists from Universidad Nacional evaluated the cost-effectiveness of an HPV-vaccine programme. The unit cost of vaccinating one person was known and the probabilities of contagion, transition to cancer and death were estimated from epidemiological data and were calculated in terms of cohorts. The total cost was calculated by multiplying the costs of treatment of one person by the numbers needed to achieve herd immunity in a hypothetical cohort. The expected health yield of such an intervention is expressed in disability health adjusted units (DALY).

These elements are constructed in a transmission dynamic model, usually a Markov chain. The model aims to predict the burden of HPV related diseases in several treatment scenarios: non-intervention, cervical screening only, vaccination only and vaccination and screening. In the model the population is stratified by HPV type and age. Papillomavirus types were split into two groups

for cervical cancers (type 16, type 18 and other low-risk types) and one group for genital warts (type 6 and type 11).

This kind of epidemiological modelling can be understood as a systematic review in movement. The parameters are selected from an evaluation of technical and scientific literature. The probabilities of transition between states, the demographical composition of the cohort, the incidence and prevalence of HPV infection, cervical lesions, genital warts and cancer come from literature and national statistics. The modelling intends to recreate the development of the disease according to the specificities of the 'Colombian epidemiological profile'. Such specificity relies on the origin and location of the input data.

As I noted previously Universidad Nacional developed two studies to determine the cost-effectiveness of HPV vaccines (See table 1). Study 1 (UNAL, 2009) focused on defining the burden of cervical cancer and HPV infection in Colombia,

and in assessing the potential impact of a bivalent HPV vaccine (HPV 16 and 18) in the reduction of the incidence of cervical cancer. In this study, the CEA is based on LLY. DALYs are used to express the burden of the disease but not to determine cost-effectiveness. This study concluded that the most cost-effective strategy is cervical screening and HPV vaccination combined. However, at the international prices offered to the Colombian Government in 2009 (US\$25 per shot) a vaccination programme would be too expensive. The costs are higher than the cost-effectiveness threshold of one GDP per capita. Consequently, the Committee of Immunisations (NCIP) decided to postpone the introduction of these vaccines.

This study is extremely careful in declaring the limitations and contingencies of the analysis. It notes the lack of official data about the national incidence and prevalence of cervical cancer and HPV infection by types. It is stated, moreover, that the frequency of HPV 16 and 18 oscillates

Table 1. Summary of the cost-effectiveness studies of HPV vaccines in Colombia developed by Universidad Nacional

Institution (author)	Universidad Nacional	Universidad Nacional
Year	2009	2011
Perspective	Society and Healthcare System	Society and Healthcare System
Vaccine	Bivalent	Bivalent (BV) Quadrivalent (QV)
Disease measured	CIN 1, 2, 3 and cervical cancer	Cervical cancer, CIN 1, 2, 3 and genital warts
Population	Girls 14 years old	Girls 12 years old
Compared with	Screening programme and non-intervention	Screening programme (Pap-test)
Source and data	Bogota cohort, Pueblo Rico Antioq study	Bogota cohort, Mexico
Outcome measure	DALY	DALY
ICER (Incremental cost-effectiveness ratio)	\$1.028,02	ICER/DALY: BV: \$5.314 (\$11.354) QV: \$5.193
Threshold	\$7.400 (Int. dollars) (GDP/per cap)	\$6,294 (US\$) (GDP/per cap) max: (GDP/per capX3)
Protection duration	Life-long (life exp: 85 years old)	Life-long (life exp: 76 years)
Cost vaccine course	\$25 (Int. dollars)	BV: USD \$13,48 (x3) QV: USD \$15,15 (x3)
Screening pattern	annually at 1st two visits (neg. results) then triennial (1-1-3)	annually at 1st two visits (neg. results) then triennial (1-1-3)
Vaccine coverage rate	70%	
Screening coverage rate	50%	
Vaccine efficacy	100%	BV 99% QV 99%
Money	International dollar	US dollars
Conclusion	Non-cost-effective	Both are cost-effective

Source: UNAL, 2009, 2011.

between 52% and 64% in the Colombian female population. More importantly, the study does not “take into consideration the burden of disease produced by genital warts because these lesions are benign and there is no consensus about the degree of disability they produce” (UNAL, 2009: 44).

The class action against the non-inclusion of HPV vaccines in public funded programmes culminated in the Council of State’s intervention. The court assessed Study 1 (UNAL, 2009), rejecting its conclusions and demanding important changes. The court argued that the study should be updated because since 2008 statistics could have changed: “Moreover, it is possible that the biologics (vaccines) have had some changes which could have a different effect regarding their cost-effectiveness” (Council of State, 2012: 44). For the court, another limitation of this study was that it only covered HPV effects in women and not in men; and “there is no analysis of the potential impact of HPV vaccines in other types of cancer” (Council of State, 2012: 44). As a consequence, the court ordered a new study that should include an analysis of cost-effectiveness of HPV vaccines in the prevention of other cancers in men and women. The court set a deadline of three months for the new study. If vaccines are found to be cost-effective according to the new framework, the ministry must include them in the Expanded Programme on Immunisation (EPI). The result is well known; in July of 2012, the Ministry of Health made public the introduction of HPV vaccines into the programme.

Despite the Council of State’s ruling, very few criteria and parameters changed in the second study (UNAL, 2011). After three years most of technical and data limitations are the same. Study 2 extends the analysis of the burden of disease to other cancers related to HPV infection. Nevertheless, these data come from literature reviews; most of them are statistical estimations based on trials, but not official data. The study remains focused on cervical cancer and the cost-effectiveness of strategies for its prevention and treatment. However, it introduces two important changes. It offers a comparison between both the vaccines that entered the market: tetravalent (Gardasil) and bivalent (Cervarix) and calculates

the impact of genital warts, always, in combination with cervical screening. These changes will reconfigure the analysis, enhancing the value of Gardasil, which finally was integrated into the national programme of immunisation in 2012. The second study becomes the main source of evidence provided by the Ministry of Health for the Congress of Colombia in the discussion about the inclusion of boys into the vaccination programme.

Although the second study was strongly supported in public by the committee of immunisation practices, during the interviews some of the members expressed concerns with the ways in which data were selected and the subtle influence of the manufacturers of Gardasil. Such members complained about the exclusion of two studies published in *The Lancet Oncology* regarding the higher cross-protective efficacy of Cervarix. Cross-protective efficacy is the development of immunity against other types of oncogenic HPV that are not the primary target of the vaccine. This factor would have increased the efficacy of Cervarix as against Gardasil, potentially changing the CEA results. This discussion illustrates the role of companies in shaping these calculations but also the difficulty of presenting evidence about their involvement in policy. Despite this concern, once the decision was made public, committee members have maintained public consensus regarding the cost-effectiveness of Gardasil.

The production of numbers by CEA shows us the plasticity of quantified entities, their power and their temporality. In what follows, I will briefly illustrate this argument by analysing the role of the quantification of genital warts’ burden of disease in making Gardasil the most cost-effective option and by expanding on the short lives of some numbers once they travel from CEA to public arenas. Cost-effectiveness becomes an icon to justify the inclusions and the exclusions that HPV vaccines entail: the definition of girls as the population target and the exclusion of boys from the risks and benefits of this technology. This exemplifies the role of quantification in the reconfiguration of disease through the rationalisation of economic benefits. In this case, CEA is key to the sexualising and desexualising of cervical cancer and HPV vaccines.

Genital warts and DALYs: Assembling matters of concern through economic valuation

Epidemiology had noted cervical cancer displayed a profile similar to STDs (Bosch et al., 2002: 246). During the second half of the twentieth century research about cervical cancer was focused on finding a cause linked to STD; syphilis, gonorrhoea and herpes simplex virus type 2 (HSV2) were hypotheses. Even sperm was considered as a possible cause of cervical cancer, known as the “male factor” (Reid et al., 1978; Reynolds and Tansey, 2009). The definition of cervical cancer as an STD and of vaccination as a tool of prevention shaped the models and the studies to define the cost-effectiveness and pertinence of HPV vaccines.

In CEA, HPV vaccines have been understood as prevention tools for cervical cancer. Reference to other cancers related to HPV infection – such as throat and anal cancer – is marginal in policy-makers’ discourses and technical reports. Just one other disease has been rendered visible in the discussions about HPV vaccination: genital warts. The consideration of genital warts as a public health concern has been controversial. For years, this condition was considered benign and has become a “health” problem only during the last ten years, in close connection with the molecular design of Gardasil (HPV 6 and 11). Protection against genital warts became an advantage for Gardasil regarding its competitor Cervarix. In parallel with the licencing of Gardasil, in several countries the economic analysis of the burden of genital warts was undertaken to show the possible impact of this vaccine in terms of cost reduction for healthcare systems (Hillemanns et al., 2008).

In Colombia, regional health authorities have claimed genital warts are a serious clinical issue, particularly in those towns and provinces affected by war. The army medical service reported to the immunisation committee that genital warts are a common condition in male soldiers. The political and clinical interest in genital warts contrasts with the lack of studies and epidemiological data about their incidence, costs and treatment. This problem is not exclusive to Colombia; information about the incidence, prevalence and treatment costs of genital warts is relatively scarce compared to the

data about other maladies associated with the HPV infection. Even the study used as “evidence” to define the parameters of the cost-effectiveness model in relation to genital warts (Hillemanns et al., 2008) notes the difficulties of gathering information about genital warts in Germany, where the study was conducted. This research team decided to calculate the incidence and costs of genital warts in Germany through the analysis of a statistically representative sample.

The numerical enactment of genital warts became the key element in the differentiation and added value of Gardasil in the analysis of cost-effectiveness. Genital warts are presented as a quantified burden of disease expressed in DALY. DALY as a measurement unit of disability was considered the right tool to value the burden of a disease whose outcomes were not fatal. It allows a more visible differentiation between vaccines to be produced (see Tables 2 and 3). In terms of deaths avoided by vaccination, the performance of both vaccines was impressively similar. According to the second study (UNAL, 2011), if tetravalent vaccine is compared with no intervention, in a cohort of 450,000 women this vaccine avoids 8,783 deaths from the 9,593 deaths that could happen without any intervention. In the same scenario, bivalent vaccine avoids 8,785 deaths. In contrast, when DALYs are introduced the gap between vaccines is rendered visible. Tetravalent vaccine prevents 1,054 DALYs (bivalent vaccine 1,013 DALYs). Although this difference is not very wide (41 avoided DALY), it is still greater than the gap in terms of the reduction of mortality.

DALY is calculated through a set of weightings defined in relation to the disability that a disease produces. In the second study from Universidad Nacional (UNAL, 2011) such weightings are taken from the *Victorian Burden of Disease Study* (VSG, 2001) (see Table 4). These weightings assign an important burden of disability to terminal stages of cervical cancer (up to 0.95 on a scale where 1 is death) and to the consequences of early treatment (0.43).

Although these data come from a context of healthcare attention completely different from the Colombian one, they are widely accepted by public health experts as an approximate measure of the effects of the disease on human function. On the contrary, the nature of genital warts as

Table 2. Incremental cost-effectiveness of HPV vaccination in Colombian women, taking into account genital warts. Base case

	Costs/US\$	Increment costs	LLY	LYG	DALYs	Avoided DALYs	ICER: US\$/LYG	ICER: US\$/DALYs
Non-intervention	7,495,699		9,593		11,453			
Screening	56,114,451	48,618,752	1,191	8,402	1,506	9,947	5,787	4,888
Screening + Bivalent	62,754,454	55,258,755	808	8,785	1,054	10,399	6,290	5,314
Screening + Tetrav.	61,712,199	54,216,500	810	8,783	1,013	10,440	6,173	5,193

Source: (UNAL, 2011).

Table 3. Incremental cost-effectiveness of HPV vaccination in Colombian women, taking into account genital warts. Competitive analysis

	Costs US\$	Increment costs US\$	LLY	LYG	DALYs	Avoided DALYs	ICER: US\$/LYG	ICER: USD/DALYs
Non-intervention	7,495,699		9,593		11,453			
Screening	56,114,451	48,618,752	1,191	8,402	1,506	9,947	5,787	4,888
Screening + Tetrav.	61,712,199	5,597,748	810	381	1,013	493	14,692	11,354
Screening + Bivalent	62,754,454	1,042,244	808	2	1,054	-41	21,128	Dominated

Source: (UNAL, 2011).

a disease with an important burden has been contested. There is no defined weighting for this condition within the technical literature about burden of disease (WHO, 2012; VSG, 2001). As I noted previously, even Universidad Nacional's first study pointed out that such condition is a "benign" infection.

In the second study, data are not provided about the assigned weight of genital warts in the calculation of DALY. Nevertheless, if the calculations are re-enacted it is possible to note that the disability value assigned is very low; just 41 DALYs are assigned to 8,410 episodes of genital warts.

Because genital warts are not a fatal condition it is possible to estimate that the assigned disability weight was 0.0048. This weight is slightly higher than the lowest weighting assigned to a disease by the Victorian Burden of Disease (VSG, 2001), which is the long-term effect of moderate burns. The concern for the disease burden of genital warts is a consequence of the introduction of HPV vaccine and the claims of added value of Gardasil. Even within the immunisation committee, tetravalent critics argued that the genital warts burden was part of the strategy of Merck to add value to its vaccine.

Table 4. Disability weightings associated with cervical cancer

Cervix Cancer		
Diagnosis and primary therapy	0.430	Provisional weight based on Dutch weights
State after intentionally curative primary therapy	0.200	Provisional weight based on Dutch weights
In remission	0.200	Provisional weight based on Dutch weights
Disseminated carcinoma	0.750	Provisional weight based on Dutch weights
Terminal stage	0.930	Dutch weights for end-stage disease

Source: UNAL, 2011.

The consequences of introducing genital warts into the national immunisations committee's calculations were very significant. First, they increased the value of HPV vaccines, because of the estimated costs and burden of disease that could be prevented through vaccination. Second, they constituted a differential between vaccines. Only Gardasil prevents against cervical cancer and genital warts. Third, the emphasis on genital warts not only increased the value of the tetravalent vaccine (Gardasil); at the same time, it overshadowed the possible impact of this vaccine on other cancers most of them related to non-heteronormative sexualities.

In the technical reports, the tables that summarise the results of modelling – as calculative spaces – preserve some of the contingency of these calculations. In particular, they render visible the narrowness of the difference and the effort of raising genital warts as a matter of public health. However, once these data are moved from technical reports to the technical committee, such contingencies and indexicalities (Verran, 2012) disappear. The different elements that are displayed in the calculative spaces of the CEA are reordered in a coherent and linear narrative whose conclusion is the selection of tetravalent vaccine (Gardasil) as the right tool. As is noted in the minutes of the NCIP:

In a cohort of 430.859 women, 9.137 cases of cervical cancer and 8.410 episodes of genital warts can happen without any intervention. Cervical cancer could cause 6.436 female deaths. The Colombian cervical screening programme would avoid 3.744 deaths. Any alternative to vaccination is cost-effective compared with non-intervention. However, in a competitive analysis, screening plus bivalent vaccine are dominant alternatives. Meanwhile, tetravalent vaccination plus screening is the most cost-effective option, being under 1 GDP per capita (ICER: US\$2395 per DALY) (Ministry of Health, 2012a. SGC-F03 3 May 2012).

The committee concludes based on this analysis that “in a competitive scenario and taking into consideration genital warts without cross effective protection, the vaccination with tetravalent is the most cost-effective strategy. ICER: US\$1.348/DALY” (Ministry of Health, 2012a. SGC-F03 3 May 2012: 10).

The enactment of genital warts in DALY was the differential element that defined the selection of the tetravalent vaccine (Gardasil) as the right tool for EPI in Colombia. Curiously, DALYs and genital warts, main actors in CEA, will be rendered invisible in the movement of data and matters of fact towards more public arenas: media, Congress and vaccination campaigns. Other numbers, particularly prices, will surge as the quantified entities express the value of HPV vaccination. Cost-effectiveness will be detached from its numerical expressions to become a word, an icon of the calculations that legitimised the selection of this vaccine.

Icons, prices and the affective entanglements of calculation

In November 2012, the Congress of Colombia asked the Ministry of Health for a technical concept about Bill 260 of 2012. The bill had suggested “the National Government must guarantee the free and mandatory vaccination against HPV for all boys and girls between 9 and 12 years old”. Based on the second study (UNAL, 2011) the Ministry of Health argued that the vaccination of boys is not cost-effective.

In the technical concept (memorandum) presented by the Ministry of Health to the Congress of Colombia, the legitimacy of the current vaccination programme is supported through data about the costs of the current treatment of cervical cancer and genital warts and the savings that HPV vaccine could generate:

Universidad Nacional estimated that the costs of observation of a female cohort for genital warts are US\$5.8 million, US\$1.0 million for CIN I (Low risk), US\$24 million for CIN II and III and US\$13.4 million for cervical cancer at any stage. The additional costs of prevention and treatment of this disease are US\$117.6 million per year (Ministry of Health, 2012b: memo 201221102384491).

However, in this memorandum the cost-effectiveness of the Colombian vaccination programme is not explained using measurements of cost-effectiveness such as ICER or DALY, neither are the numbers to calculate the effect of vaccinating boys provided. Instead, the Ministry of Health

presents a selection of key papers in which it is argued that the vaccination of boys is not cost-effective (Figure 1).

From these studies data or figures are not selected; the studies themselves are evidence of the loss of cost-effectiveness in HPV vaccination by extending the programme to boys. The Ministry of Health notes the vaccination for boys is not recommended because “such strategies are more cost-effective when they are focused on women to the extent that boys are protected by the herd effect” (Ministry of Health, 2012b: 1).

This last claim from the Ministry of Health materialises the inclusions and exclusions produced during the different entanglements and disentanglements that cost-effectiveness calculations entail. The promise of extended protection to boys through the herd effect from girls’ vaccination renders visible the heterosexual sexualising of HPV vaccines. Nevertheless, as I have shown before, such sexualising is limited only to decision making and experts’ arenas. In media and vaccination campaigns, the Ministry of Health and the EPI have tried explicitly to de-sex HPV vaccines, presenting them as an anticipated treatment against cervical cancer and as a means of empowering girls. Genital warts and the debate about cost-effectiveness, key factors in the process of decision-making, will go into the shadows as “technical details”. Meanwhile, cervical cancer and gender inclusion will be integrated into the presentation of the vaccine in public arenas and media.

Once the committee’s decision is enacted, DALYS, formulae and tables disappear. The decision will be justified in public arenas using

disentangled data about the impact of cervical cancer in public health and the reduction of female mortality that the HPV vaccines promise. Although cost-effectiveness will continue as a source of political legitimacy, its presence becomes iconic in the sense defined by Verran (2012) regarding numbers. That is, the category and the measurement unit are treated as indistinguishable. Numbers and figures about the cost of the HPV vaccine, and its estimated impact on the reduction of cervical cancer, are read as evidence of the effectiveness of this technology without any further discussion about the meaning of these elements and the ways in which they were calculated. Cost-effectiveness justified the definition of girls as the population target and the exclusion of boys from the risks and benefits of these drugs.

New numbers are attached to these accounts. The campaign “Haría lo que fuera” sponsored by Merck suggested a trade-off between daughters’ health and lives and the potential (economic) costs to guarantee their protection. This campaign was online between 2011 and 2014 (Maldonado, 2017). The campaign Haría lo que fuera [Everything I can] offers mothers a scenario of calculation in which the benefits and costs of protecting their daughters’ health should be evaluated. The campaign entangles data about cervical cancer risk and HPV infection, testimonial footage about women’s future plans and “dreams” and mothers’ care and responsibility. Although an explicit price is absent from this campaign, the value of HPV vaccine is enacted in relation to the pricelessness of health and the moral duty of affording HPV vaccines despite their price. Another example is the political advertisement produced by the

The quoted papers are (this is the bibliographic notation used in the memo):

“Evaluating Human Papillomavirus Vaccination Programs” in: *Emerging Infectious Diseases*, 10 (11) Nov., 2004;

“The value of including boys in an HPV vaccination programme: a cost-effectiveness analysis in a low-resource setting”;

WHO position paper about the introduction of HPV vaccines (2009):

“Population-wide vaccination against human papillomavirus in adolescent boys: Australia as a case study”.

Figure 1. Memorandum 201221102384491. Technical concept from Ministry of Health to Colombian Congress about Bill 260 of 2012

“Movimiento Independiente de Renovación Absoluta” MIRA (<https://www.youtube.com/watch?v=uRBuBBnzkm>), one of the political parties involved in the promotion of HPV vaccination through the Colombian Congress. This material gathers many elements that have shaped the discourse of politicians and government about HPV vaccines, including anticipation and citizen rights.

This advertising was produced for the election of Congress in 2014. In the commercial, two references are used to enhance the value of vaccination. One is a girl writing ‘dreams’ in her diary. Professional and personal success (becoming a doctor and getting married) are complemented by an expectation of good health, in this case being free of cervical cancer. Then the message is directed to parents: they should consent to vaccination in order to protect their daughters’ dreams. HPV vaccination became a key element in assuring professional and personal success based on ‘contemporary’ ideals of being a woman: a powerful amalgam between being a mother, a wife and a successful professional.

The other reference in the advertising is the price of the vaccine expressed as the amount of money saved by the families through State intervention. The amount saved is COP800,000 for three doses; this figure is presented with reference to the Act 1626 [2013] that guarantees free HPV vaccination. Finally, the video finishes with the MIRA party’s logo. The figure of COP800,000 (US\$264) is particularly meaningful in a context in which the minimum wage is COP616,000 (approx. US\$200 per month) and measurements of poverty are based on individual income. According to the Colombian National Department of Statistics (DANE) the poverty threshold for 2012 was COP202.083 per month. This context highlights the role of pricing (economic value) in the enhancement of the (social and affective) value of public vaccination. In this material, through explicit reference to the market price of the vaccine, politicians are connecting economic value to care and parental protection. HPV vaccines are portrayed as an affective and economic investment.

Conclusion

CEA as a device of calculation involves the disentanglement of entities and its reordering in a new calculative space. Prices, technologies, populations and health technologies are disentangled from other contexts and reordered through the rules and dynamics enacted in formulae. CEA has been particularly important in contemporary decision making for its capacity to transform a political process of selection of alternatives of healthcare into an ‘objective’ calculation. Such movement of objects requires the development of languages that facilitate the translation and commensurability of (in)commensurable entities. In the case of healthcare, measurement units such as DALY, QALY and LLY have the role of quantifying the effects of technologies and drugs in terms of improvement in quality of life.

The introduction of HPV vaccines in Colombia is a good case in which to trace the ways that these calculation practices are reshaped locally. CEA not only provides a framework to compare healthcare interventions that seem to resist comparison; it also performs values associated with good policy such as objectivity and efficiency. In the several scenarios in which HPV vaccination is presented, cost-effectiveness has been the key argument that justified vaccination as the right intervention for the Colombian population. Additionally, the numbers generated by these practices of calculation are entangled in affective economies. In Colombia, these numbers have enacted representations of care and have contributed to the development of convoluted relations between sexuality and HPV vaccination.

The inclusion of genital warts in the calculation of cost-effectiveness contributed to rendering visible HPV infection as a sexually transmitted disease. At the same time, it reinforced heteronormative assumptions about HPV contagion that are inscribed in the models. Because the epidemiological models are centred in cervical cancer, they only recreate scenarios of contagion and prevention based on heterosexual transmission of the virus. The model assumes that men are protected from HPV infection by the herd immunity of the female population, excluding men who have sex with men from the calculation.

CEA has a very important role in the presentation of particular diseases as public health concerns and in rendering visible the value of healthcare procedures and technologies. In Colombia as in other countries, genital warts became a public concern through the production of numbers about its burden of disease and the economic costs of their treatment. Measurement units such as DALY have an important role in the expert characterisation of this condition. Epidemiologists use DALY to express the subtle public health benefits of genital warts prevention. Nevertheless, these metrics are useful in very limited contexts. Beyond expert arenas, DALY is not used to express cost-effectiveness. In more public arenas, some numbers, figures and papers become icons. They are themselves presented as the evidence that legitimates decision making without reference to the data and the involvements that they encompass.

Other numbers such as prices have an important role in the development of public narratives about care and responsibility in HPV vaccination. Public campaigns have involved narratives about reciprocity, costs and care, in which price has operated as an element to enhance and highlight the responsibility of parents to their daughters, healthcare providers to their patients and governments to its citizens. From the perspective of public vaccination programmes, vaccines are perceived to be interventions by the State. These narratives have reproduced practices of government in which rights are understood as gifts; such style of governing has characterised many of the Colombian State's actions.

This case has shown how interest in cost-effectiveness is restricted to experts' discussion and committees' decisions. In public arenas, cost-effectiveness as an argument loses its rhetoric appeal and is overshadowed by concerns about price and care. The main interest for health authorities in public arenas seems to be to show the benefits of prevention and to desexualise cervical cancer. The connections between sexuality and HPV vaccination are avoided by health authorities in order to prevent potential public resistance to vaccination, particularly among conservative groups that perceive it as encouraging early sexual relations.

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Note

- 1 HPV effectiveness is assumed. This is a black box that I will not open in this article. There are more than 100 types of HPV, of which almost 20 types are considered as oncogenic. HPV vaccines protect against two types (16 and 18) associated with 90% of cases; however the incidence of this infection varies geographically. HPV 16 and 18 are the most prevalent types in Europe and North America. The committee and the studies in Colombia assume the vaccines are safe and effective. They attribute an effectiveness of 99% to the calculation.