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Vaccines to promote and protect sexual health: Policy challenges and opportunities

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ABSTRACT

Vaccines aim to improve the well-being of everyone and are seen as a public health success story in the prevention and control of communicable infections. However, decisions to use vaccinations are not without controversy, and the introduction of vaccines targeting sexually transmitted infections (STIs) is particularly contentious. In this paper we investigate the underlying policy challenges and opportunities for rolling out STI vaccines. Looking in detail at the experience of delivering HPV vaccine, we explore the lessons that can be learnt, including policy and human rights dimensions, for future STI vaccine introduction and scale up. Policies arise from the interaction of ideas, interests and institutions. In the case of HPV vaccine, ideas have been particularly contested, although interests and institutions have impacted on policy too. A review of human rights in relation to STI vaccine policies highlights the specific needs and rights of adolescents, and the paper details concepts of consent and evolving capacity which can be used to ensure that adolescents have full access to health interventions. Policy options for vaccines include mandatory approaches – and these have been utilized in some settings for HPV vaccines. The paper argues, and outlines the rationale, against adopting mandatory STI vaccine policy approaches. The paper concludes by identifying policy opportunities for introducing new vaccines targeting STIs.

1. Introduction

While vaccination programmes aim to improve the well-being of everyone and are seen as a leading public health success story in the prevention and control of communicable infections, decisions to use vaccinations are not without controversy from a public health perspective. Vaccines can be expensive, efficacy is sometimes questionable, and public trust can be fragile. In this paper we explore some of the underlying policy challenges and opportunities for rolling out vaccines which aim to prevent sexually transmitted infections (STI) and contribute to the improvement of sexual and reproductive health more generally. Looking in detail at the experience of delivering a specific STI vaccine (against human papilloma virus, HPV), we explore the lessons that can be learnt, including from human rights considerations, for policies concerned with future STI vaccine introduction and scaling up. We focus particularly on the needs and rights of adolescents since this is the age group targeted for HPV vaccines and likely to be the focus of future STI vaccines. The paper recommends strategies for addressing the potential barriers to introducing vaccines targeting STIs.

2. Human papilloma virus

Human papilloma virus (HPV) is sexually transmitted, and incidence rates are at their highest shortly after the onset of sexual activity [1]. In 2002, HPV contributed to approximately 5% of all cancers globally [2] – a figure which increases in some low- and middle-income countries and settings (estimated to be 14.2% in sub-Saharan Africa and 15.5% in India [3]). Prevention of some of the 530,000 cases of cervical cancer, and 80,000 cases of cancers of the penis, vulva, vagina, anus and oropharynx [2], which occur annually throughout the world, has become more feasible since the development of HPV vaccines targeting oncogenic virus subtypes. One of the main HPV vaccines available also protects against viral subtypes associated with the development of some cases of genital warts [4] – thus decreasing the burden of disease associated with this common condition. Maximum prevention efficacy against cervical cancer is achieved by targeting the vaccine at the pre-sexual exposure age group, and in most settings this will be the young adolescent years (usually ages 9–13) [5,6]. HPV vaccination is not a stand-alone effort in the prevention and control of HPV, however,

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and WHO recommends additional secondary and tertiary prevention interventions including regular cervical cancer screening for women in selected age groups and access to treatment for women and men diagnosed with cancers [7].

Targeting vaccines against sexually transmitted infections (STIs) at young age groups may offer an opportunity to "catalyze a life course approach" to promoting and protecting sexual health [7], but is also fraught with challenges. In the next section we explore some of the policy options for vaccine programmes, and consider how these may be modified for this particular age group and for infections transmitted through sexual exposure.

3. Policy options for vaccine programmes

Public health interventions are, in general, based on principles of utilitarian goals [8] – i.e. actions designed to positively and maximally contribute to the well-being of everyone equally. Additionally, according to international human rights standards, everyone, without discrimination, has the right to the highest attainable standard of health [9–11]. All people also have the right to enjoy the benefits of scientific progress [12], including in relation to needed vaccines. Vaccines are seen as a "public good" – in that they are non-rival and [ideally] non-excludable, there are positive externalities associated with consumption, and negative externalities associated with non-consumption [13]. Vaccines of proven efficacy should therefore be available to everyone.

Vaccination programmes are seen as a public health success story in the control of communicable infections. So successful that they are ranked at number 3 in the global "best buys" in development [14]. In general, vaccine programmes enjoy a large degree of public and policy support.

Ideally, decisions about whether and how to employ vaccines should be based on scientific evidence concerning parameters such as burden of preventable disease, vaccine efficacy and cost-effectiveness. In practice, however, vaccine policies are subject to the routine 'politics' of decision-making which are driven by the classical triad of policy-making, namely the ongoing interaction among ideas, interests and institutions [15] – which can at times be conflictual. This interaction essentially captures the notion that policy processes are not necessarily or only driven by empirical evidence [16], but are also subject to the distribution of power and the values held by those involved in policy decisions [17].

Ideas, in the form of evidence, arguments and frames, testimony and personal anecdote – often based on underlying values and beliefs – influence all policy, including those governing vaccines. Relevant ideas shaping vaccine policy may include analysis of trial results, consideration of appropriate modes of delivering a vaccine, attitudes to whom, when, and where within in a given jurisdiction a vaccine ought to be delivered, and resonance with local cultural norms. The balance or contest between the concepts of utilitarian public health goals and human rights standards represents a thread throughout the decision-making process for vaccine policies [18]. Critical ideas may also involve decisions around who has the right to decide whether or not an individual receives a vaccine – the individual themselves, the State, parents or other competent guardians.

Interests are defined by what an individual or institution stands to gain or lose from a decision. In the case of vaccine policies, interests may be driven by treasury or finance ministry considerations of resource availability and future cost-savings, competing programmes within health ministries, by individual preferences to be protected from potential health risks, considerations of public good [13], and/or the pursuit of industry profit [19].

Institutions, while often considered the 'ways things are done' or the 'rules of the game' in any particular policy setting, can also be considered the organizations which have some influence over policy adoption (or not) and successful implementation (or failure). In the case of vaccine policy, these include stakeholders ranging from technical norm setters, such as the WHO, to social norm setters, such as the media or religious groups, vaccine manufacturers, agencies delivering routine immunization or campaigns, medical and nursing associations who may have a stake, and civil society organizations representing 'target' populations. Institutional norms and capacity may determine vaccine policy outcomes – for example, the flexibility of institutions to adapt and incorporate new vaccines (e.g. introducing a new childhood vaccine into current national guidelines), or to provide sites for vaccine delivery (e.g. delivering publicly funded vaccines through the school system [20]). The success or failure of a vaccine policy will depend on the outcome of ongoing interactions between all these many factors [21].

Vaccines targeting sexually transmitted infections, and focused on adolescents, introduce particularly potent variables into policy spaces. Ideas and norms around adolescent sexuality and the promotion and protection of adolescent sexual health in particular, are especially contested. However, interests (particularly commercial interests) and institutions have also been seen to be active and influential in vaccine policy. In the specific case of HPV vaccine, dilemmas around decision making on delivery of vaccines, including the capacity of adolescents to make informed decisions around vaccine acceptance, have added to an already heady mix of mandatory versus voluntary vaccine policies [22], perceptions of profiteering [19], and concerns about vaccine safety and efficacy [23]. As a result, the introduction of this vaccine targeting an infection (HPV) transmitted through sex has been highly problematic in a number of settings – as we explore below. Nonetheless, there is an increasing demand for information about the vaccine and accessible and affordable services to deliver it.

In the following sections we review the introduction of HPV vaccines in a variety of settings in order to examine what lessons can be learnt for future vaccines targeting STIs. We focus predominantly on the battle of ideas around HPV vaccines, but refer to entrenched interests and stakeholder institutions where these have influenced policy.

4. Ideas relevant to STI vaccine policies – applying human rights principles

Human rights laws and principles apply directly in the provision of HPV vaccines. The right to the highest attainable standard of health requires governments to progressively take steps necessary to make services accessible and available, without discrimination, to the maximum of their available resources, and to reduce health inequities [24]. Given the problems with alternative STI prevention measures, such as screening programmes [25], the benefits of vaccine programmes (in conjunction with other public health approaches) become more clear: vaccines may place considerably fewer demands on health systems than other interventions, by utilizing established infrastructure, logistics networks and information systems of immunization service delivery [22]. Moreover, studies indicate that HPV vaccines, if made available and accessible to adolescent girls in developing countries, would help prevent a large proportion of cases of cervical cancer in the next decade [26] – and may reduce the burden of other cancers and genital warts too.

Thus, the benefits of HPV vaccines are clear from a human rights perspective, and similar arguments about efficacy and cost effectiveness would need to be made for future STI vaccines. However, vaccines specifically targeted at young adolescents (as