

UGANDA NATIONAL IMMUNISATION TECHNICAL ADVISORY GROUP POSITION PAPER ON THE PUBLIC HEALTH (AMENDMENT) BILL 2021

Preamble

The government of Uganda committed to the Global Vaccine Action Plan (GVAP) endorsed in May 2012 at the World Health Assembly. One of the recommended actions to help achieve this GVAP goal was that "independent bodies such as national immunisation technical advisory groups (NITAGs) that can guide country policies and strategies based on local epidemiology and cost effectiveness be established or strengthened, thus reducing dependency on external bodies for policy guidance".

NITAGs provide evidence-based recommendations to Ministry of Health, policy makers and program managers, to guide policies and formulate strategies related to vaccines and immunization policy in Uganda. Hence, they aim to promote the adoption of policies based on national priorities, help resist pressure from interest groups like pharmaceutical companies and funding agencies, reinforce the credibility of national vaccine and immunization strategies, and strengthen the ability to secure government or donor funding. NITAGs are consisted of multidisciplinary independent experts and are chaired by an expert independent of the government Immunization Program and are thus able to offer independent bias-free advice.

Uganda established its NITAG through a Ministerial Statement in December of 2014. Uganda's NITAG is composed of eleven (11) core scientists of different specialties supported by eight (8) liaison members as listed in Annex 1. The Uganda NITAG is hosted by the Uganda National Academy of Sciences, an autonomous body of scientists, which exists to promote the acquisition, growth and effective dissemination of scientific knowledge, and to facilitate the use of science in the solution of problems of national interest.

The mandate of the UNITAG is to advice the Government of Uganda, particularly the Ministry of Health, and the general public, on all issues pertaining vaccines and immunisation in Uganda. This Position Paper is submitted in response to the invitation by the Parliamentary Committee on Health to the public to give their comments and proposals with regard to the Public Health (Amendment) Bill filed in Parliament in 2021.

INTRODUCTION

The Uganda National Immunisation Technical Advisory Group (UNITAG) believes that this bill is timely, relevant and very much necessary to address the current COVID-19 crisis and similar health concerns in the future. UNITAG reviewed the proposed amendments in the Bill, particularly vaccination specific clauses and in this position paper, we provide our views and recommendations as detailed below:

COMMENTS AND RECOMMENDATIONS

1. Definition of Public Vaccinator:

Amendment 29 seeks to amend section 27 of the principal act by redefining "public vaccinator" in paragraph "a" to mean the medical officer, and a medical practitioner, and includes a person appointed by the Director General of Health Services or a medical officer to be a public vaccinator"

UNITAG Position:

While we generally support this revision, we feel that it doesn't make explicit the inclusion of vaccinators in the private sector. We therefore propose that a phrase be added at the end of this paragraph to say "this includes vaccinators in the private sector".

In addition, UNITAG recommends that the term "appointed" use in the phrase..... "appointed by the Director General of Health Services or a medical officer to be a public vaccinator" be substituted with the term "assigned" since appointing authority in the health sector lies with the Health Service Commission (Health Service Commission Act, 2001 section 25(2)). Vaccinators are only assigned to vaccinate when the need arises.

2. Rights and Responsibilities

Proposed amendments to sections 45 and 47 of the principal act which call for mandatory vaccination during disease outbreaks and stating that any person who fails or neglects to comply under these sections commits an offence and is liable on conviction to a fine not exceeding two hundred currency points or to imprisonment not exceeding 6 months or, both.

UNITAG Positon:

Vaccination is one of the most effective public health interventions in the world for saving lives and promoting good health. It should however be noted that people may not vaccinate, not because they are averse to it but simply do not have access to the right information and to the vaccines. Indeed, mandatory vaccination can be ethically justified if the threat to public health is grave, the confidence in safety and effectiveness of the vaccine is high, the expected utility of mandatory vaccination is greater than the alternatives, and the penalties or costs for non-compliance are proportionate. However, making vaccination mandatory is not the only way to obtain high vaccination rates and subsequently protect the health of the public.

UNITAG recommends that for the mandatory vaccination to be successful and ethical at the same time, there is need to focus on the responsibilities of the government in terms of providing the immunization services such as: increasing availability and access to the vaccines and vaccination sites, ensuring people get adequate information about the importance of vaccines and immunization, providing the vaccines in a timely manner, facilitating vaccination logistics and related resources such as cold chain systems to ensure vaccines are safe and efficacious, injectable materials, safe disposal mechanisms, trained and qualified health workers, the immunization cards, monitoring and care in case of adverse events following immunization (AEFIs). The roles of the relevant government bodies in ensuring this should be mentioned such as National Medical Stores, National Drug Authority, and Uganda National Expanded Program on Immunization, among others. These will facilitate the public to make informed choices on whether to get vaccinated or not.

Addtions to include in the Bill

- i) Definition of Vaccines by method of approval: There are the regular WHO approved vaccines and vaccines approved under WHO Emergency Use Listing. The WHO Emergency Use Listing Procedure (EUL) is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency¹. Vaacines under EUL have not gone through the full licensure assessment process.
 - UNITAG recommends including a definition of emergency use vaccines in the bill to enable users distinguish between the two types of vaccines.
- ii) Informed consent: The bill should include a clause on informed consent and when it should be applied. Immunization involving vaccines available under Emergency Use Listing triggers an imperative to ensure that individuals receive the information required to support free exercise of meaningful informed choice/consent, with a right to refuse such vaccination for any reason or no reason. This informed consent process should provide individuals with enough information to enable them understand the possible risks and benefits of receiving the vaccine under emergency use and decide whether or not they want to receive the vaccine. Therefore, in the event that one does not consent to receiving an EUL vaccine, they should not be purnished for their decision.
- iii) The rights of the citizens: while the government may have a right to enforce vaccine mandates, the citizens equally have a right to defend themselves. Therefore, the bill should include a clause outlining the rights of the citizen in the event that the government did not fulfil its responsibility to provide the immunization services stated above.
- iv) The bill should include penalties for those engaged in deliberately spreading the wrong/mis-information about vaccines and immunisation and driving vaccine hesitancy.

-

¹ https://www.who.int/teams/regulation-prequalification/eul

- v) The bill should include penalties for negligent health workers who do not administer the available vaccines when the citizens present themselves for vaccination.
- vi) Liability of AEFIs: The Government of Uganda as the the provider of immunisation services should provide fair compensation for damage such as death, severe disability or organ tissue injury, etc., which are abnormal in response to vaccination during the vaccination process or after vaccination.
- vii) The role of the Uganda National Immunization Technical Advisory Group (UNITAG), in advising the Ministry of Health on all matters relating to vaccines and immunization should be included. This has been done in other countries including Kenya² and the United Kingdom³.
- viii) The role of the private sector: UNITAG would like to highlight the crucial role played by the private sector in supporting and implementing immunisation programs and health programs in Uganda as a whole. UNITAG recommends that the Bill should include a clause on the mechanism for private sector engagement in all stages of the policy planning, drafting of implementing rules and guidelines, and more so during the implementation of these healthcare programs and projects.

Conclusion

The Uganda National Immunisation Technical Advisory Group (UNITAG) lauds the initiatives of the Honorable Members of the Parliamentary Committee on Health to further improve the country's healthcare system and infrastructure in light of the ongoing public health emergency caused by COVID-19. However, the current proposed Ammendment Bill needs to be further reviewed and revised, taking into consideration submissions from the various stakeholders.

Signed

Nelson SEWANKAMBO

UNITAG Chair.

² Kenya National Policy on Immunisation page 17. http://e-cavi.com/wp-content/uploads/2014/11/KENYA-NATIONAL-POLICY-ON-IMMUNIZATION-2013.pdf

³ The UK Joint Committee on Vaccination and Immunisation was established under the NHS (Standing Advisory Committees) Order 1981 (SI 1981/597).

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/224864/JCVI _Code_of_Practice_revision_2013_-_final.pdf

Annex 1: UNITAG Membership

No.	Name	Discipline/ Affiliation	Membership
1.	Prof Nelson Sewankambo	Medicine	Chairperson
2.	Prof George B. Kirya	Medicine	Co-Chairperson
3.	Prof. Peter Waiswa	Health Policy	Core Member
4.	Prof John Francis Mugisha	Health Policy	Core Member
5.	Prof. Jesca Lukanga Nakavuma	Vaccinology/ Vaccine Development	Core Member
6.	Prof Sarah Kiguli	Paediatrics	Core Member
7.	Dr. Sabrina Bakeera – Kitaka	Paediatrics	Core Member
8.	Hon Benson Obua Ogwal	Social Sciences	Core Member
9.	Dr. Charlotte Muheki	Health Economics	Core Member
10.	Ms. Diana Kizza	Health Economics	Core Member
11.	Dr Roy William Mayega	Epidemiology	Core Member
12.	Dr Alfred Driwale	Program Manager, UNEPI	Ex-Officio
13.	Dr. Patrice Mawa	Vaccinology/ Vaccine Development	Ex- Officio
14.	Dr. Jesca Nsugwa Sabiiti	Child Health, MOH	Ex-Officio
15.	Dr. Patrick Kadama – Ex-Officio	Civil Society, ACHEST	Ex-Officio
16.	Dr. Emmanuel Mugisha	PATH	Ex-Officio
17.	Dr. Eva Kabwongera	UNICEF	Liaison Member
18.	Dr. Immaculate Ampeire	UNEPI	Liaison Member
19.	Dr. Annet Kisakye – Liaison member	WHO	Liaison Member