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The 2015 global production capacity of seasonal and pandemic influenza vaccine

Kenneth A. McLean^{a,*}, Shoshanna Goldin^b, Claudia Nannei^c, Erin Sparrow^c, Guido Torelli^c

^a University of Edinburgh, Edinburgh, UK

^b Yale School of Public Health, Haven, USA

^c World Health Organization, Geneva, Switzerland

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ABSTRACT

A global shortage and inequitable access to influenza vaccines has been cause for concern for developing countries who face dire consequences in the event of a pandemic. The Global Action Plan for Influenza Vaccines (GAP) was launched in 2006 to increase global capacity for influenza vaccine production to address these concerns. It is widely recognized that well-developed infrastructure to produce seasonal influenza vaccines leads to increased capacity to produce pandemic influenza vaccines. This article summarizes the results of a survey administered to 44 manufacturers to assess their production capacity for seasonal influenza and pandemic influenza vaccine production. When the GAP was launched in 2006, global production capacity for seasonal and pandemic vaccines was estimated to be 500 million and 1.5 billion doses respectively. Since 2006 there has been a significant increase in capacity, with the 2013 survey estimating global capacity at 1.5 billion seasonal and 6.2 billion pandemic doses. Results of the current survey showed that global seasonal influenza vaccine production capacity has decreased since 2013 from 1.504 billion doses to 1.467 billion doses. However, notwithstanding the overall global decrease in seasonal vaccine capacity there were notable positive changes in the distribution of production capacity with increases noted in South East Asia (SEAR) and the Western Pacific (WPR) regions, albeit on a small scale. Despite a decrease in seasonal capacity, there has been a global increase of pandemic influenza vaccine production capacity from 6.2 billion doses in 2013 to 6.4 billion doses in 2015. This growth can be attributed to a shift towards more quadrivalent vaccine production and also to increased use of adjuvants. Pandemic influenza vaccine production capacity is at its highest recorded levels however challenges remain in maintaining this capacity and in ensuring access in the event of a pandemic to underserved regions.

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1. Introduction

Best estimates indicate that seasonal influenza affects 5–10% of the global population each year, resulting in between 250 and 500 thousand deaths [1]. The case fatality rate (CFR) for pandemic influenza can be substantially greater [2]. In the event of an influenza pandemic, the world will require the rapid production and distribution of billions of doses of vaccine in order to meet expected demand and protect the global population [3].

Abbreviations: GAP, Global Action Plan on Influenza Vaccines; EUR, European Region; AMR, Region of the Americas; EMR, Eastern Mediterranean Region; WPR, Western Pacific Region; SEAR, South-East Asia Region; AFR, African Region; LMIC, Low- and middle-income countries.

* Corresponding author at: Centre for Global Health Research, Usher Institute for Population Health Sciences and Informatics, The University of Edinburgh, Teviot Place, Edinburgh EH8 9AG, Scotland, UK.

E-mail address: s1005789@sms.ed.ac.uk (K.A. McLean).

Global pandemic influenza preparedness is dependent on seasonal influenza vaccine production capacity: in the event of an influenza pandemic, vaccine would be produced in facilities that normally produce seasonal influenza vaccine and the capacity of these facilities defines the global capacity to produce pandemic vaccines. Understanding the operational capacity, trends, and limitations for seasonal vaccine production offers a lens through which the global community can assess its pandemic influenza preparedness.

Launched in 2006, the Global Action Plan on Influenza Vaccines (GAP) was a ten year strategy that aimed to significantly strengthen vaccine production capability for effective response to the pandemic influenza threat [4]. Coordinated by the World Health Organization (WHO), the GAP provided a comprehensive strategy to address global scarcities and inequitable access to influenza vaccines. Within the GAP, global attention was directed towards increasing evidence-based seasonal influenza vaccine

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use and growing global pandemic vaccine production as well as promoting research and development for improved vaccines. The overall goal of the GAP is to have enough production capacity to immunize the global population within six months of the transfer of the candidate vaccine virus to manufacturers. Taking into account herd immunity and that a single dose may not provide sufficient protection, this means ensuring equitable access to enough vaccine to immunize 70% of the global population with two doses of vaccine [5,6].

The WHO has continued to perform regular surveys of influenza vaccine manufacturers to compile a projection of global production capacity for both seasonal and pandemic influenza vaccines [6–9]. This article highlights the international progress and projections of seasonal and pandemic influenza vaccine production capacity through analysis of the 2015 manufacturers' survey.

2. Methods

The WHO surveyed 44 vaccine manufacturers with seasonal influenza vaccine production regarding their seasonal and potential pandemic influenza production capacity for 2015. Vaccine manufacturers that participated in previous WHO production capacity information gathering surveys were asked to confirm or amend information previously collected. Vaccine manufacturers responding for the first time completed a Microsoft Excel® questionnaire, a copy of which is included in Appendix A (see supplementary material). For manufacturers who did not respond to the survey, the WHO incorporated data from previous surveys and publically available information including press releases and public statements. All information provided was triangulated for accuracy.

Each manufacturer was asked to report and/or confirm the estimated maximum total production capacity for 2015 (in millions of doses) of seasonal (Northern and Southern hemisphere) and, if applicable, monovalent pandemic influenza vaccine. Taking this information into consideration, this model forecasted future potential pandemic influenza production capacity. The projection method took into consideration whether the seasonal influenza vaccine was trivalent (with the three predicted strains most likely to circulate): in this case the maximum seasonal production capacity was multiplied by three within the model. In the case of tetravalent seasonal influenza vaccines (with the four predicted strains most likely to circulate) the potential maximum pandemic influenza vaccine production capacity was obtained by multiplying the seasonal capacity by four. For manufacturers with registered pandemic vaccines containing adjuvants the manufacturing capacity was determined by multiplying the seasonal capacity in terms of monovalent doses at 15 µg by the dose-sparing afforded by the adjuvant.

Thirty-five manufacturers (80%) responded to the survey. Manufacturers were approached to clarify when there was a significant conflict among the numbers declared by the manufacturer in terms of production capacity and the previous or publicly available numbers, and the relevant changes were made to the final figures.

Data was aggregated by WHO region to preserve individual manufacturer confidentiality. Furthermore, due to the multinational nature of some of the biggest manufacturers and the way data was reported, the summary information is presented as an aggregated global total.

3. Results

3.1. Seasonal influenza vaccine production capacity

In 2015, the global seasonal influenza production is determined to be 1.467 billion doses compared to 1.504 billion doses reported

in 2013 [9] and 1.420 billion doses in 2011 [6]. Compared to 2013, this represents a reduction of 37 million doses. This reduction results from several manufacturers either having reduced their capacity or having put their facilities on hold and a subsequent decrease in production at these manufacturers totalling 96 million doses. Fortunately, this is partially offset by a few new manufacturers having established manufacturing processes with a combined capacity of 59 million doses. Fig. 1 details the evolution of global seasonal influenza production capacity from 2011 to 2015.

The majority of production capacity is from manufacturers in high income countries. Thirteen manufacturers are located in lower-middle income countries with a combined capacity of 200 million doses of seasonal influenza vaccine and four manufacturers are in upper-middle income countries with a combined capacity of 250 million seasonal vaccine doses. The remaining 1017 million seasonal vaccine doses are from manufacturers in high income countries.

In the region of the Americas (AMR), one large-scale facility has started production since 2013 resulting in an approximate 40 million increase in seasonal vaccine production capacity in this region. However, one manufacturer reported a reduction in capacity of 60 million doses, and another a reduction of 6 million. These reductions are a function of reduced demand and not an infrastructural change to the facility. However, they do negatively impact the global capacity since these manufacturers have effectively decreased their egg procurement and in the event of a pandemic the egg supply they had previously would not be guaranteed. There is therefore a net decrease in this region of 26 million doses of seasonal vaccine. The impact on pandemic capacity is slightly mitigated by the fact that some of these manufacturers have transitioned from trivalent to tetravalent vaccine. In these cases the same seasonal capacity corresponds to a 33% increase in pandemic capacity as extrapolated from total hemagglutinin production.

In the European region (EUR), over the last three years three small to medium sized manufacturers have put their production on hold, resulting in a reduction of approximately 30 million doses of production capacity. The manufacturers have indicated that this hold is temporary following either refurbishment of their facilities, a change to tissue culture-based technology, or a new market strategy following change in ownership. There is therefore a net decrease of 30 million doses in the region compared to data from previous years. Several of the manufacturers in this region have transitioned from trivalent to tetravalent which means that this small decrease in seasonal capacity does not negatively impact the pandemic capacity.

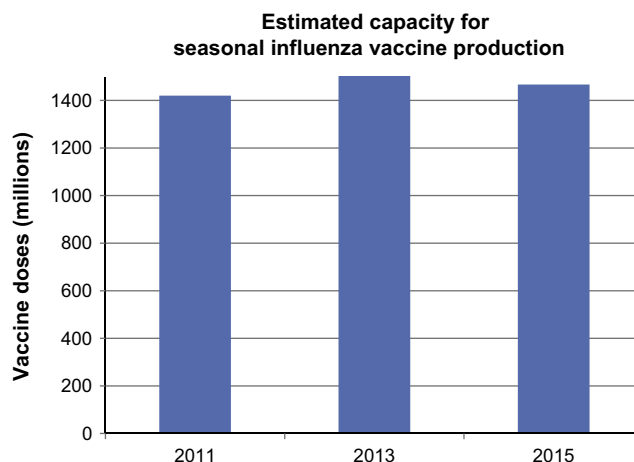


Fig. 1. Global seasonal influenza vaccine capacity, year 2011–2015.

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