How high is a high risk? Prioritising high-risk individuals in an influenza pandemic

Jasper Littmann*

Institute for Experimental Medicine, Christian-Albrechts-Universität zu Kiel, Arnold-Heller-Str. 3, Haus 28, 24104 Kiel, Germany

ARTICLE INFO

ABSTRACT

Pandemic contingency plans frequently define priority groups that are given preferential access to influenza vaccine. One of the most commonly named groups for prioritisation is that of high-risk individuals. However, current models of categorisation are unsatisfactory in a number of ways. It will be argued that existing vaccination strategies fail to adequately define what kind of risks are being considered and how, as well as on the basis of which information, these risks are calculated. Moreover, it will be suggested that existing vaccination strategies fail to specify of what magnitude a risk has to be, in order to be categorised as 'high'. Finally, it shall be argued that a mere focus on the size of a risk factor may lead policy makers to overlook underlying concerns of distributive justice.

1. Introduction

Since there is no effective treatment for influenza, vaccinations constitute the best protection against infection. In cases where the circulating strain of influenza is particularly virulent, the demand for vaccine can be expected to outstrip supply, especially in the early stages of vaccine production [1]. Of course, demand will depend on the expected benefit of the vaccination, as well as perceived risk, and the most recent case of pandemic influenza, the 2009–10 H1N1 virus, offers an example for pandemic influenza, during which the uptake of vaccine was extraordinarily low [2]. Nevertheless, the vast majority of contingency plans for future pandemics operate on the assumption that scarcity of vaccine will ultimately occur and consequently establish priority groups, raising the question who should be vaccinated first in the case of a pandemic [3]. This process of prioritising health care resources is highly complex, and there exists already a substantial body of literature which deals with the fairness of different prioritisation approaches [4–6].

Instead of examining the general process of prioritising health care resource, this paper will focus on a specific aspect that has so far received little attention, namely the definition of a frequently cited priority group, so-called high-risk individuals. In many countries patients considered to be at particular risk during pandemic of seasonal influenza outbreaks are given preferential access to vaccination as soon as it becomes available [7].

The paper will first outline the prioritisation process for the receipt of vaccine during an influenza pandemic, and then consider in greater detail the role of high-risk individuals in this process. It will then be discussed, how inclusion and exclusion criteria for this group are defined, how the process differs between seasonal and pandemic influenza, and why the current practice raises a number of methodological and ethical concerns, paramount to which is the lack of an appropriate threshold value for inclusion in the high-risk category. Finally, the paper will consider, whether or not some risk factors ought to be given special consideration.

2. Priority groups – who is currently included?

In 2011, the World Health Organization (WHO) published a comparative analysis of pandemic preparedness plans in all of its 198 member states [3]. Of these, 119 (60%) had set guidelines for pandemic preparedness that were considered in the study. 108 of these plans included vaccination strategies, of which 73 defined various priority groups [3]. The most commonly named groups were:

(a) Health Care Workers
(b) High-risk groups
(c) Essential Service Workers
(d) Contacts of confirmed infectious patients (early stages of a pandemic)
(e) Avian Influenza Risk Groups (e.g. poultry farmers and veterinary workers)

* Corresponding author.
 E-mail address: j.littmann@iem.uni-kiel.de

(f) Children
(g) Political leaders

Not all pandemic response plans refer to all of these groups, and there are differences in the ranking of respective groups. This variety does not only reflect different levels of detail in contingency planning, but also different goals of vaccination campaigns [8].

The most commonly cited goals are the protection of vulnerable social groups and the protection of social functioning, including the continued functioning of essential services and provision of medical services [9]. These goals can be seen to represent different strategies to reduce morbidity and mortality by ensuring the provision of essential services, the availability of medical care, and a focus on the protection of those most likely to be severely affected by the pandemic [6]. However, detailed inclusion criteria for the relevant prioritised groups are often lacking, and as the rest of the paper will argue, this leads to particular problems in the case of high-risk individuals.

3. High-risk individuals

The prioritisation of high-risk individuals is not only common in contingency plans for pandemic influenza – it also forms part of routine vaccination strategies against seasonal strains [10]. However, establishing who belongs into a high-risk category – and should therefore be prioritised – does not only require epidemiological data on the severity with which certain groups are affected by a strain of influenza. Since the effectiveness of a vaccine may vary between different demographic groups, a priority plan based on high-risk categories should also assess, if the vaccination provides a tangible benefit to those who are to be prioritised [11].

No pandemic plan that the author is aware of attempts to exhaustively define inclusion criteria for a high-risk category. However, common denominators across many pandemic preparedness plans are that high-risk individuals are elderly (usually 65 or older) and/or have a previous medical condition which makes them more prone to becoming severely ill [9]. There does not appear to be a general consensus which medical conditions warrant prioritisation and summaries of conditions that increase the risk of individuals to be severely affected by influenza are usually only categorised in broad terms. The WHO, for example, defines high-risk individuals as those with "underlying diseases such as cardiovascular, pulmonary, metabolic or renal disease, or [people who are] immunocompromised" [3]. In addition to these medical factors, certain demographics are frequently included in pandemic prioritisation plans, including children (over six months) and pregnant women, as well as people who live in nursing homes [3]. Studies have also suggested a link between some lifestyle factors and the risk of contracting a severe case of influenza, notably smoking and obesity [12–14]. The WHO recognised this during the H1N1 pandemic, when if recommended that obese persons with a BMI > 35 ought to be given priority in receiving pandemic vaccine as well [15].

There are, in essence, four questions which the current practice of defining high-risk individuals raises. The first relates to the nature of the risk. Given the numerous conditions and characteristics that confer a 'high risk' status, we may wonder what people in this category are actually at risk of. The second question which will be raised here is how, and on the basis of what information, risks for different groups are assessed at the beginning of a pandemic. The third question concerns the magnitude of risk differentials, and how much larger a risk has to be, in order to become 'high', compared to a 'normal' risk. Finally, we may wonder if all risk factors are equally deserving of prioritisation, or if in some instances we

have good reason to place particular emphasis on the protection of a specific, vulnerable group.

4. At risk of what?

Being a high-risk individual implies that the nature of that risk (as well as its magnitude) can be specified, or at least estimated with some degree of confidence. However, it is noteworthy that not all high-risk groups are necessarily at risk of the same thing (nor, as we shall later see, do they face risks of similar magnitude). Germany's Robert Koch Institute,[1] for example, recommends the vaccination of high-risk individuals during an influenza pandemic and defines such individuals as persons with "an increased risk of exposure (outside the workplace), of falling ill, or of suffering complications" [16]. In this definition alone, there are three dimensions of risk: exposure, the chance of falling ill, and potential complications. All three are likely to affect different groups and carry very different implications. School children, for instance, face a particularly high-risk of exposure, but are not commonly included in the group of high-risk individuals [17]. On the other hand, those with a particularly high chance of developing complications, such as those with severely compromised immune systems, are likely to face a lower risk of exposure due to fewer social interactions, and it has been suggested that the most effective vaccination strategy to protect high-risk individuals may actually be to focus on the immunisation of vectors, rather than particularly vulnerable populations because the overall spread of an influenza epidemic or pandemic can better be controlled this way [18]. Pandemic contingency plans should therefore specify which kinds of risks prioritisation they are sensitive to in the case of prioritising some groups for immunisation.

A second concern related to the type of risk that specific groups face is the measurement of such risks in the first place. Probably the most commonly used proxy for measuring complications during the course of an influenza pandemic or epidemic is hospitalisation [19]. However, this measure may overstate the seriousness of complications, especially in patient groups for whom physicians are more likely to err on the side of caution. This applies in particular to pregnant women and potentially also children – a fact that vaccination recommendations have recognised, but are currently unable to sufficiently account for [19]. On the other hand, outcome measures such as hospitalisation may also underestimate the severity of complications in some instances. For example, evidence suggests that obese patients with a BMI > 30 are not at higher risk of being hospitalised upon contracting influenza, but *do* face a higher risk of being admitted to intensive care because they are more likely to need a ventilator [19]. In yet other instances, study results suggest that those who are morbidly obese (BMI > 40) are both more likely to be hospitalised *and* more likely to die from influenza [12].

High-risk individuals can thus be at greater risk of hospitalisation, of requiring intensive care, of death, or of all three, yet pandemic vaccination strategies do not normally distinguish between these kinds of risks. Of course, this may simply be due to the fact that they are all considered to be relevant, but if this is the case, such assumptions are merely implicit, and it would also appear that if no further distinction between different risk groups is made, these risks are treated as equally important. We shall later return to this point.

5. Assessing risks *ex ante*

Pandemics present policy makers with the challenge of making decisions under extreme uncertainty. Part of this uncertainty is to

---

[1] The Robert Koch Institute is Germany's central federal institution responsible for disease control and prevention.