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Pandemic influenza preparedness: The critical role of the syringe

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Abstract

In the face of an almost unprecedented threat of a global pandemic of influenza it is imperative that stockpiling of appropriate drugs and devices begin now. One vital device is an appropriate syringe for delivering vaccine. With the potential for millions to be infected and the vaccine supply severely stretched it is imperative that the syringe used to vaccinate waste as little vaccine as possible and thus allow for a maximum number of persons to be vaccinated. Our study tested seven leading candidate vaccine syringes for dosing accuracy, dose-capacity per vial, medication wastage and a battery of ergonomic features. One device, the Flu+^{TM} syringe, proved superior to the others in all important categories, possibly due to its low dead-space volume and its dosing accuracy. The data suggest that switching to this device from any of the others tested would provide between 2 and 19% additional vaccine doses per vial if the current 10-dose vials are used. Extrapolations from this data suggest that many thousands to millions of additional persons could be vaccinated in mass campaigns. Use of a syringe of this type, and the vaccine savings that would accrue, would likely be important in reducing morbidity and mortality in the event of a pandemic of influenza.

Keywords: Influenza; Pandemic; Avian flu; H5N1; Vaccine; Syringe

1. Introduction

Hardly a day passes without a new alarm raised regarding H5N1 avian influenza. Its steady march westward from Asia, its striking case:mortality rate and the expectation that it will soon 'humanize' (become easily transmissible from person to person) are causing tremors throughout the world [1]. At the back of everyone's mind is the question, 'could this become another 1918?' The influenza pandemic of 1918 may well have been the worst catastrophe in human history. The most recent estimates, which now include deaths from India and China, are that as many as a 100 million people worldwide lost their lives [2].

Unlike yearly epidemics, pandemic flu viruses have a predilection for young, healthy persons, whom they attack with astonishing virulence. It was not uncommon in 1918 for a young person to go to bed feeling fine, wake up achy and feverish, be bedridden by noontime and be dead before sundown [3].

Influenza experts have long predicted a 1918-like influenza pandemic from southeastern Asia, the region from which the SARS coronavirus emerged [4,5]. All three influenza pandemics in the last century have come from this region. The 1918 pandemic took 3 weeks to circle the globe in an age without commercial air travel. A pandemic today might take as little as 2 days [6–8]. A recurrence of 1918 would mean 100 million cases of flu in North America alone and an equal number in Europe [4,7]. These would come in two giant waves (if previous pandemics are a guide), the first

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beginning in late fall and the second in spring. Upwards of 2 million deaths could result on each continent [9,10]. The possible toll worldwide is almost unfathomable.

The health-care response during the first days into a pandemic would focus on vigorous, proactive public health measures such as isolation of those infected, closures of schools, the obligatory wearing of masks, gloves and other protective gear and frequent hand-washing [8,11–13]. Anti-influenza drugs, which are currently in short supply, would play a critical role, assuming resistance to them did not develop quickly. The newer Neuraminidase Inhibitors, oseltamivir and zanamivir, would be made available during the first wave to key population groups in countries which have been wise (and wealthy) enough to stockpile [14].

It is axiomatic that a vaccine will not be immediately available, but will take several months to develop with current technology [15,16]. Worldwide there are only a handful of manufacturers [17] who produce the vast majority of influenza vaccines. It would require between 3 and 8 months to produce and release a new influenza subtype vaccine, meaning that no or limited doses of vaccine would be available in the first half year of the pandemic.

Pandemic preparedness involves stockpiling of the key medical supplies known to be needed in the first months of a pandemic (e.g. anti-virals) as well as those that are likely to be in short supply when the vaccine is ready, most critically syringes. The choice of syringe by stockpilers is not merely of academic or financial interest; it will be a major determinant of life or death in a pandemic. Given the scale of need for vaccine and the limited capacity of manufacturers to supply it, shortages will be inevitable. Such will be the outcry for vaccine that officials expect major social and political upheavals [18]. It is therefore of paramount importance to stock a syringe which will reduce vaccine wastage to a minimum and thereby allow the greatest number of persons to be vaccinated. In our experience, discussions on pandemic preparedness often overlook the critical role of the 'lowly' syringe. We continue to do this at our own peril.

This article reports on a study which will inform officials and planners of the public health stakes in their choice of a pandemic syringe for vaccination. It is intended to help them estimate the degree of vaccine wastage/savings they should expect with each potentially stockable device. We provide information for estimating the additional number of individuals who might benefit from vaccination as a function of the device.

The study compared the accuracy and reproducibility of a 0.5 mL dose administered with each of seven device which are being considered as stocking options in pandemic preparedness (Table 1). We compared the total number of 0.5 mL doses obtained from a 10-dose vial (5.0 mL) with the optimal number of 'expected draws'. From this we estimated the number of persons who could be vaccinated with each device per million vials purchased. Finally, we compared the ease and speed of use of each device as determined by users.

2. Materials and methods

2.1. Number of syringes and users

Seventy study syringes per clinician were assessed by five clinicians per site in nine European sites (3150 devices in total). Forty-five clinicians (nurses and physicians) were enrolled at three sites in Poland, three in Sweden and three in the United Kingdom (England, Scotland, Wales) (Table 2). Participating clinicians were required to have at least 6 months of injecting experience and to perform at least five percutaneous injections (intramuscular, intradermal or subcutaneous) per week. Sites varied from academic medical centres to private clinics to regional medical centres and users were felt to constitute a representative sample of injecting health-care professionals.

2.2. Products trialed

At enrollment, each clinician received seven 5 mL vials of sterile saline (Abbott Laboratories, North Chicago, IL, USA); 10 BD Flu+™ 0.25–1 mL variable dose syringes with attached 25 G 1 in. (25 mm) needles (BD, Franklin Lakes, NJ, USA); 10 BD 0.5 mL SoloShot™ IX Auto-Disable Syringes and attached 25 G 1 in. needles; ten 1 mL BD Plastipak™ Luer slip syringes with detached 10 BD Microlance™ 25 G 1 in. needles; 10 BD 2 mL Plastipak™ Luer slip syringes with 10 BD Microlance™ 25 G 1 in. needles; ten 2 mL B Braun Injekt™ Luer slip syringes with 10 detached B Braun Sterican™ 25 G 1 in. needles (B Braun, Melsungen, Germany); ten 1 mL Tyco Monoject™ Luer slip syringes with 10 detached Tyco Monoject™ 25 G 1 in. needles (Tyco, Mansfield, MA, USA); ten 1 mL Terumo™ Luer slip syringes with 10 detached Terumo Neolus™ 25 G 1 in. needles (Terumo, Leuven, Belgium). These devices were chosen based on contacts with pandemic preparedness planners in Europe who

Table 1
Devices tested in current study

Device number	Trade name/description	Dose range (mL)	Needle fixation	Needle gauge (G)	Needle length (in.)	Manufacturer
1	Flu+	0.25–1.0	Attached	25	1	BD
2	SoloShot IX	0.5 (fixed)	Attached	25	1	BD
3	Plastipak Luer slip	0.0–1.0	Detached	25	1	BD
4	Plastipak Luer slip	0.0–2.0	Detached	25	1	BD
5	Injekt Luer slip	0.0–2.0	Detached	25	1	B Braun
6	Monoject Luer slip	0.0–1.0	Detached	25	1	Tyco
7	Terumo Luer slip	0.0–1.0	Detached	25	1	Terumo