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Editorial:

Paul C. Hébert and Noni MacDonald

Preparing for pandemic (H1N1) 2009

CMAJ 2009; 181: E102-103E [Full text] [PDF]

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Spain and swine flu

15 September 2009

Tiago Villanueva,
Lisbon, Portugal
Family Medicine Resident, USF AlphaMouro, Algueirão-Rio de Mouro Health Centre Group, Portugal

Send letter to journal:
Re: Spain and swine flu

Email Tiago Villanueva

Spain is the first country in the world where physicians have joined a "common sense and self-control" policy concerning swine flu. The movement started August 10 as an initiative of one of us (JG, www.equipocesca.org). The Spanish Medical Association (representing all Spanish physicians, which amount to around 200,000) joined the position later on (www.cgcom.org) and by the end of August, 40 Spanish blogs (and we're talking of well known blogs belonging to healthcare professionals, which promote Evidence Based Medicine) had joined forces to

promote a "common sense" position regarding swine flu through a coordinated action that started on September 2 (www.gripeycalma.wordpress.com) (1). This means that all of these blogs published the same post simultaneously, and many more (around 150) have joined the cause since then. Other important scientific organizations are supporting the movement of "common sense" as well, such as the Spanish Society of Public Health and Health Administration, and the Spanish Association of Paediatricians thus generating great impact in the Spanish media (TV, newspapers, magazines, radio, social Internet networks, etc...). It is important to raise awareness of the common sense position and reach out to society, in order to counter the campaign of panic, hype and disease mongering that WHO, politicians, media and even corporate interests convey (2). Even though it is a more contagious flu, swine flu is a milder disease than seasonal flu. This means that the enforcement of strict protocols (with its paraphernalia of astronaut-like suits and isolation areas) and of measures such as closing down schools and universities is absurd and reveals lack of common sense, lack of self-control and lack of scientific foundations. The diversion of financial resources towards a minor problem is potentially damaging, because it drains the energy of the health system, and neglects all other important health problems that will continue to afflict society.

Juan Gérvas, Rural General Practitioner, Canencia de la Sierra, Garganta de los Montes (Madrid), Spain jgervasc@meditex.es

Tiago Villanueva, Family Medicine resident, Algueirão-Rio de Mouro Health Centre Group, (Greater Lisbon), Portugal tiago.villanueva@gmail.com

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Conflict of Interest:

None declared

H1N1 vaccine target population differences between countries

20 January 2010

Antonio L. Aguilar-Shea MD PhD, Madrid, Spain

Send letter to journal:
Re: H1N1 vaccine target population differences between countries

Email Antonio L. Aguilar-Shea MD PhD

The outbreak of H1N1 influenza virus infection caused the World Health Organization to raise its pandemic alert to phase 6 and has activated and created protocols for disease control all over the world. As H1N1 spread all over the world the need of a proper vaccination became a concern and once it was created the vaccination campaigns started.

The interpretation of the distribution of the cases of H1N1 flu caused differences on the targeting of the population in the different countries, as it is seen between Spain and the United States of America (US).

The Centers for Disease Control (CDC) by the Advisory Committee on Immunization Practices (ACIP)1 in the US recommended that vaccination efforts focus on:

• pregnant women,

• people who live with, or care for, children under 6 months of age,

• health care and emergency services personnel,

• individuals between the ages of 6 months and 24 years,

• individuals 25 to 64 years of age who are at higher risk for novel H1N1 because of chronic health disorders or compromised immune systems.

The Ministerio de Sanidad y Politica Socilal2 in Spain recommended vaccination of:

• pregnant women,

• health care personnel,

• individuals that work in essential public services such as police, firefighter and penitentiary workers,

• individuals over 6 months of age who are at higher risk for novel H1N1 because of chronic health disorders or compromised immune systems.

The main difference is that in Spain the population over 6 months of age, without any chronic health disorder is not being vaccinated and in the US, of the population between the ages of 6 months and 24 years is being massively vaccinated.

The highest rates of infected individuals in both countries are between 15 and 44 years of age, but in this group there is a very low death percentage. Also, in both countries, the highest mortality rates are among individuals with chronic health disorders (80%). After analyzing the vaccination recommendations, in the US individuals 65 and over years old with chronic health disorders are not being vaccinated and in whom there is a high risk of serious complications due to H1N1 infection3-5.

The low incidence of H1N1 in the elderly population is managed differently between the countries with the understanding of an immune protection of this population, even though the experience of seasonal flu has demonstrated a high incidence of death among the infected elderly population6.

To my understanding, the individuals at any age with chronic health disorders can benefit from an early vaccination, including over 65 years of age. The guidelines and the recommendations are no more than recommendations in clinical practice and the physicians must individualize on each patient on the understanding of the patient as a whole. Common sense must be present in making these decisions.

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Conflict of Interest:

None declared

Buddy System Design for Physician Pandemic Coverage Planning

20 October 2009

Thomas Ungar

Send letter to journal:
Re: Buddy System Design for Physician Pandemic Coverage Planning

Email Thomas Ungar

As part of pandemic flu planning. clinical departments across Canada are creating physician coverage plans. Our hospital department of psychiatry created a buddy system coverage model to meet this challenge. Our department considered a number of design solutions.[1] The larger hospital's initial design approach was to look at assigned duties and inventory physican skills sets, and to then create a coverage schedule. As a clinical chief in consultation with our department's physicians we felt this was an overly cumbersome, time consuming and complex approach. Some of the other clinical departments have enhanced their existing on call structure, creating second and third on call rosters. Our psychiatric department settled on a Buddy system design (see attatched with names changed). We paired physicians with a buddy, leveraging physician goodwill and personal sense of loyalty to eachother. Buddy pairs were created taking in to account clinical capacity and skill sets. Physicians covering inpatients were paired with those who primarily cover outpatients so as to not overwhelm any one inaptient physican and thus slow inpatient flow. Physicans who provide consultation to ICU and other high acuity work were paired with a buddy who generally provides lower acuity duties. If ill, step one, a physican can call their buddy. It is then the buddy's duty to cover, and triage their own duties as needed, or to do the phone calling to arrange for others to cover. This alleviates an ill physician from having to phone around. Clinical triage priority principles were set to help guide workload triage decisions prioritizing ICU and Emergency room, then inpatient and general consultations, then day programs, then routine outpatient work. In step two, each buddy pair has another assigned buddy pair, with adequate clinical skills capable of covering each other, to go to next. Step three of the algorithm goes to the wider active staff then consulting staff lists. Physican's must start alphabetically with the name following theirs for a fair distribution of coverage requests. The algorithm is colour coded at each decision step. The plan has been well accepted by the department's physician group. We hope that sharing our experience and example of a buddy system is of help to others needing to meet this challenge.

Dr. Thomas Ungar MD, M.Ed, CCFP, FCFP, FRCPC, DABPN Associate Professor, University of Toronto Chief of Psychiatry and Medical Director Mental Health Program, North York General Hospital North York, Ontario

Reference

1. Brown, T. Design Thinking. Harvard Business Review. June, 2008, p.85-92.

Conflict of Interest:

None declared

T helper type immune response and H1N1 related SIRS

18 September 2009

Vivian C McAlister
University of Western Ontario

Send letter to journal:
Re: T helper type immune response and H1N1 related SIRS

Email Vivian C McAlister

Much of the journalism concerning H1N1 influenza virus continues the simplistic infectious disease model that it is a virulent virus which can be managed with hand washing and vaccination.1 H1N1 declared itself almost as soon as it was identified. At the same time that large numbers of deaths occurred in Mexico, other countries experienced mild cases. Further clues became evident later. Severe complications and deaths were later seen in specific groups: pregnant women and aboriginal communities. The infectious disease model suggests that lower standards of living and medical care explain these disparities.

A more plausible explanation is available. The response to H1N1 may be one of two types: severe inflammatory response syndrome (SIRS) versus mild influenza. It has been known for years that distinct populations behave differently after organ transplantation. Hispanic populations behave more like first-nation Americans than like Spaniards who conform to the European pattern.2 One of the mechanisms proposed for this difference is the type of immune response mustered. There is evidence that the ratio of type 2 T-helper (Th2) responders to type 1 T-helper (Th1) responders is higher in aboriginal populations than in those of European stock.3 Rejection after transplantation is a Th1 response and if such a response occurs in a pregnant woman rejection, or miscarriage, of the haplo- identical foetus would result. Conversion from the normal Th1 state to Th2 is thought to be required for a successful pregnancy.4 Is the development of SIRS with H1N1 a Th2 phenomenon and could it explain the susceptibility of pregnant women and aboriginal or Mexican populations to this complication? The cytokines produced in the Th2 response have been implicated the development of SIRS.5 The type of immune response a person has on contact with H1N1 determines the outcome and it may be that a Th2 or similar response heralds severe complications.

The virulence of influenza should not be determined by its rate of transmission but by the ratio of the two types of immune response it engenders. Immunity should not be measured by a general response to vaccine but by the cytokine profile generated. Vaccination should not be measured by the reduction in incidence of H1N1 but by the protection it gives against the development of SIRS. Aluminum hydroxide adjuvant boosts the general immune response to influenza vaccine but the increase is predominantly of the Th2 type which, in mice at least, does not confer immunity to influenza.5 It is to be hoped that a reduction in incidence of H1N1 influenza with vaccination will compensate for any change in the rate of H1N1 related SIRS. Science would have been preferable to hoping-for-the -best but it is too late for that now.

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Conflict of Interest:

None declared

Swine flu, specialists versus generalists

17 September 2009

MIGUEL A. GARCÍA-PÉREZ
Family physician. National Confederation of Physicians' Trade Unions (CESM). Spain.

Send letter to journal:
Re: Swine flu, specialists versus generalists

Email MIGUEL A. GARCÍA-PÉREZ

I think it's important to consider the particular point of view that each professional practice confer to its practitioners. Intensivists have developed a very partial but justified view of the swine flu, because of their exposure to severe very critical patients affected by the pandemic

flu. But it occurs in a context of millions of mild episodes of the same disease, so the 'critical view', by itself, is not the real view of the whole question.

In the editorial 'Preparing for pandemic (H1N1) 2009' (1), the first editorialist seems to be affected by this bias, as it has been similarly ascertained from the Australian experience (2). He is an intensivist, and this can be the reason for a position so opposed to that of the Spanish generalists, who are successfully campaigning for a prudent consideration of the pandemic managing in Spain(3,4).

I have also seen the same bias in our Trade Union discussions to reply to some of the initial Spanish plans in front of the flu (5). The views are different between intensivists and generalists, and we must build effective strategies in a global view of the pandemic, attending to their different features. That is the reason for our recommendation to Spanish health authorities: prudence and preparedness for alternative scenarios.

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Conflict of Interest:

None declared

RE: The H1N1 vaccine race: Can we beat the pandemic?

15 September 2009

 Elwyn Griffiths
Director General, BGTD

Send letter to journal:
Re: RE: The H1N1 vaccine race: Can we beat the pandemic?

Email Elwyn Griffiths

Health Canada has the greatest respect for the Canadian Medical Association Journal as a source of expert information and opinion for health professionals and Canadians on health care issues. That is why we were disappointed by the August 31, 2009, CMAJ editorial The H1N1 vaccine race: Can we beat the pandemic? It aired unsubstantiated concerns about the regulatory approval process that Health Canada - Canada's national vaccine regulator - has adopted for the H1N1 pandemic vaccine.

What concerns us most about the editorial is that the CMAJ did not make an effort to contact Health Canada to determine the facts about and the rationale for the regulatory path we have chosen. Health Canada would like to set the record straight on the claims made in the CMAJ editorial, in particular the following:

All vaccines made available to Canadians are subject to a strict authorization process which is conducted by Health Canada. However, there are unique challenges associated with the development and regulatory evaluation of a pandemic influenza vaccine. Influenza pandemics are caused by novel strains of virus that have not previously circulated in humans. Since vaccine manufacturing cannot begin until the actual pandemic strain has been isolated, the time available between the completion of vaccine manufacturing and the need to begin immunization campaigns may be very short.

For this reason both Health Canada and the Public Health Agency of Canada have been proactively preparing for an influenza pandemic for several years. The Canadian Pandemic

Influenza Plan has built in a balance between the need for speed in getting a vaccine to Canadians with gathering as much information as we can on vaccine safety and effectiveness. A key component of this preparatory work has been a close collaboration with the contract vaccine manufacturer to complete much of the process necessary for the evaluation of a pandemic vaccine in advance of the declaration of an actual pandemic.

In this pre-pandemic period, Health Canada focused regulatory activity on review of a potential pandemic or "mock" (H5N1) vaccine produced by the manufacturer. This enabled Health Canada to validate the contract manufacturer's production process, and review results from both animal and human studies with the mock vaccine. During this period the safety and effectiveness of the proposed adjuvant to be used with the vaccine was assessed by both Health Canada and other regulatory authorities worldwide.

Now that the human influenza A (H1N1) 2009 virus has emerged as the pandemic virus, the manufacturer has initiated production of a vaccine against this strain. Due to the extensive evaluation of the vaccine conducted in the pre-pandemic phase, and careful ongoing planning since the pandemic was declared, the decision to authorize the vaccine can be finalized upon receipt and assessment of updated quality assurance information on the vaccine manufacturing process and data from a small clinical trial to show that the H1N1 vaccine produces an adequate immune response in humans. These remaining data requirements are in fact similar to what is required each year to support a seasonal strain change. The bottom line is that although we are treating this vaccine as a new product, which it is, the extra work involved in the authorization was largely completed before this current pandemic was declared. Furthermore, as the regulatory review of the adjuvant has already been completed as part of the review of the H5N1 vaccine, no additional data on the adjuvant itself is being asked for by Health Canada. Our remaining evaluation activities are focussed on the H1N1 antigen component of the vaccine.

Health Canada is working in extremely close collaboration with the United States Food and Drug Administration, the European Medicines Agency and Australia's Therapeutic Goods Administration as well as other agencies around the world and their respective public health officials. The comment in the article about these jurisdictions pursuing a separate "fast -track" licensure of non-adjuvanted vaccine does not reflect our understanding of their approaches which are discussed via weekly teleconferences amongst the agencies. While some differences in approach to licensure exist amongst countries due to the legislative frameworks under which they operate, the scientific approach to licensure of pandemic vaccine in these countries is similar. Furthermore, we are working with our international partners to monitor the safety and effectiveness of the vaccine following authorization and to ensure timely communication of any potential adverse events following immunization.

In summary, there will be no delay in getting a pandemic influenza vaccine to Canadians due to regulatory requirements. Health Canada is working closely with the manufacturer to review proposed production timelines for Canada and we will be ready to make a decision on the authorization of an adjuvanted and a non-adjuvanted pandemic vaccine as soon as one becomes available and a public health determination has been made to use one, the other, or both.

Yours sincerely,

Dr. Elwyn Griffiths

Director General, BGTD

Conflict of Interest:

None declared

Have the CDC been crying wolf?

15 September 2009


Byron Hyde

Send letter to journal:
Re: Have the CDC been crying wolf?

Email Byron Hyde

Influenza has always been a serious illness and for many a deadly one. The press seems to remember the great influenza epidemic of 1919 that reputedly killed millions. However the press appears to have forgotten the epidemic of 1889 that I have good reason to remember. The 1889 influenza epidemic reputedly killed more North Americans than the 1919 epidemic. My great grandparents died within a day of each other in 1989, leaving my grandfather who was then 12 to raise his 11 year old brother and 6-year- old sister. So it is understandable that the public and the medical community should be concerned about the so-called Mexican Swine Flu now referred to as H1N1. However, how real is this danger or is it simply advertising for the benefit of a few companies that produce and sell influenza immunizations?

I do not mean in anyway to suggest that H1N1 and any influenza A or B infections are not of serious concern but there is something that simply does not make sense to me. If my memory is correct then in the last many years, certainly the last 10-15 years the CDC (Centers for Disease Control) in Atlanta have issued annual warnings to the public and to physicians the danger of influenza killing well in excess of 10,000 people a year, every year, in the USA.

In fact after a fast review of the Internet I was able to come up with the figures from the August, American Journal of Epidemiology out of Johns Hopkins, one of the best medical schools in the world, a figure of 41,400 cases a year dying from 1979 to 2001, presumably in the USA.

So what is the underlying annual message we receive from CDC? You must truck out to your local physician and get your flu shot or risk being very dead. Many of my physician friends have questioned these enormous figures and felt it was simply promotion to assist the pharmaceutical industry in selling a huge amount of medications and immunizations to the various governments in one fell swoop.

I am working in Italy at the moment, and the press is going crazy about a single child who just died from the swine flu H1N1. As of September 2009 the number of individuals who have died in the USA due to H1N1 is so far reported to be 37 during the past year and the media has gone out of its mind reporting on this plague that is about to come upon us.

This raises several questions: Has the CDC simply been crying wolf for the last many years as I suspect? What is the problem with H1N1, if they have been telling the truth? Should we not be congratulating ourselves that instead of 41,400 deaths this year we have only had 37 deaths, due to H1N1?

If the CDC have been telling the truth in previous years, then H1N1 would appear to be no problem at all. If they are lying, why are they lying? Does it mean that individuals at CDC are in the pay of the pharmaceutical companies or simply that they are disseminating fear due to no reason other than their own incredible foolishness? How are these annual statistics kept and how real are they?

The real question is, does anyone have access to a direct statistic from CDC, with a person’s name attached to it, discussing the reputed thousands dying every year from influenza A and B in the USA? At present, the 2008-2009 H1Ni epidemic appears to be as big a fiasco as the last swine flu epidemic in the USA where, if my memory serves me, only one known death from influenza A, Swine Flu occurred and how many millions of influenza immunizations were given to the frightened public that year? How well do we keep data concerning the adverse effects of these same immunizations every year where there appears to be a virtual black-out of information? What is the true cost of immunizing fear?

Byron M. Hyde MD

American Journal of Epidemiology November 30 2006

 Mortality due to Influenza in the United States—An Annualized Regression Approach Using Multiple-Cause Mortality Data Jonathan Dushoff1,2, Joshua B. Plotkin3, Cecile Viboud2, David J. D. Earn4 and Lone Simonsen5

The total number of deaths attributed to influenza by our surveillance model (41,400 per year from 1979 to 2001) is similar to that found in other studies (11, 13, 14). The fact that our estimate of the mortality burden of influenza, based on our conservative methodology, is similar to earlier estimates provides support for classical assumptions about the role of

influenza in seasonal excess mortality. Our estimates are not consistent, however, with much lower estimates from authors who attribute most excess winter deaths to cold (3, 27) or with much higher numbers that can be inferred from cohort studies (2, 4–6, 14).

Conflict of Interest:

None declared

Increased sedative and antibiotic use in H1N1 ICU Patients

14 September 2009

Alfred Gin

Send letter to journal:
Re: Increased sedative and antibiotic use in H1N1 ICU Patients

Email Alfred Gin

On June 11, 2009, the WHO raised the pandemic alert level to 6 marking the first pandemic of the 21st century.1 Although the majority of cases of swine origin H1N1 (soH1N1) influenza A appear to be of mild to moderate severity, severe cases requiring admission to the intensive care unit (ICU) have been reported around the globe. In Canada, as of August 15, 2009, 275 cases requiring admission to the ICU with confirmed soH1N1 infection were reported to the Public Health Agency of Canada.2 At the Health Sciences Centre Winnipeg in Winnipeg, Manitoba, 27 patients were admitted to the adult medical ICU (MICU) with confirmed H1N1 respiratory failure between April 23 and June 30th, 2009. Patient demographics of the Winnipeg ICU cohort were similar to 10 soH1N1 reported cases in Michigan.3 Both patient populations suffered from severe ARDS and required prolonged ventilatory support. We observed substantial increases in the use of sedative agents and empiric antibiotics during this recent outbreak in our adult MICU. To ascertain the increase in medication use, we compared utilization data for fentanyl, midazolam, piperacillin-tazobactam, cefotaxime, levofloxacin and vancomycin for our fiscal quarter from April 1 to June 30, 2009 to the same time period in 2008. Total volume dispensed for each drug in our MICU was obtained from the Pharmacy's Cerner Millennium information system. Compared to the same quarter in 2008, fentanyl and midazolam utilization increased 166% and 333% respectively due to increased sedation requirements. Piperacillin-tazobactam, levofloxacin and vancomycin use increased by 43%, 131% and 56% respectively compared to the same quarter. To put the impact of soH1N1 on sedative and antibiotic use in the adult MICU into perspective, the amount of midazolam, fentanyl, piperacillin- tazobactam, levofloxacin and vancomycin use in 3 months in our adult MICU was equal to 104%, 62%, 31%, 34% and 37% of the total used in the previous 12 months. As part of pandemic planning and capacity building, we encourage pharmacists, clinicians and pandemic planners to consider the amount of sedation and antimicrobials necessary to care for soH1N1 patients in the ICU. In addition, we encourage institutions to report their experiences to assist in soH1N1influenza A pandemic planning and management.

Alfred Gin, PharmD, FCSHP Anand Kumar, MD Ryan Zarychanski MD, FRCPC Nick Honcharik, PharmD, FCSHP

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3. Centers for Disease Control. Intensive-care patients with severe novel influenza A (H1N1) virus infection - Michigan, June 2009. MMWR Morb Mortal Wkly Rep 2009;58:749-52.

Conflict of Interest:

None declared