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Criteria aimed at assessing the end of a shortage in the supply of blood or blood components caused by an influenza A (H1N1) pandemic

5 May 2010

1. INTRODUCTION AND ISSUE

On 25 November 2009, the Superior Health Council (SHC) received a letter from the Cabinet of the Minister of Social Affairs and Public Health, which was followed by a note from the Federal Agency for Medicines and Health Products¹ on 30 November 2009. The latter concerned the criteria and methodology to use in assessing the risk of a shortage of blood donations caused by an influenza A(H1N1) pandemic.

The Royal Decree of 6 December 2009, which transposes European Directive 2009/135/EC into Belgian law, states that "*l'avis du Conseil Supérieur [de la Santé] précise notamment l'ampleur du risque de pénurie, ou de la pénurie réelle de sang ou de composants sanguins*" (i.e. the advisory report of the Superior Health Council clarifies, in particular, the extent to which there is a risk of shortage or an actual shortage of blood or blood components) and the SHC "*décrit également les critères et la méthodologie utilisés pour évaluer cette nécessité*" (i.e. also describes the criteria and the methodology used to assess this need). This Decree further stipulates that "*Le Roi fixe la date [...] dès qu'il constate, après avis du Conseil Supérieur de la Santé, que les quantités de sang et de composants sanguins disponibles atteignent de nouveau un niveau suffisant*" (i.e. the King sets the date (...) as soon as He notes that the available blood and blood component supplies reach sufficient levels again and after having received the advice of the Superior Health Council). The recommendations and conclusions issued on this subject by the SHC (2009) had not tackled the latter point because it was considered to be less urgent.

The impact of a pandemic on transfusion needs and the supply of blood components is difficult to assess and unpredictable (Zou, 2006; WHO-BRN, 2007; Zimrin & Hess, 2007; AABB, 2009; EBA, 2009). As this is a critical factor in our healthcare system, the SHC had recommended that an emergency plan be implemented in order to prepare for such a shortage (SHC, 2007; SHC, 2009). The SHC recommendations aim at optimally co-ordinating the hospitals' demand for blood components with their delivery by the blood establishments. All the recommended accompanying measures were communicated to the healthcare establishments (FPS-PHFCSE, 2009).

In contrast, this advisory report tackles the criteria that make it possible to lift the measures that were implemented as a result of a shortage in the supply of blood and blood components due to an influenza A(H1N1) pandemic.

¹ Letter from Ms. S. Maes, Cabinet of the Minister of Social Affairs and Public Health, of 25/11/09, followed by a note from Mr. L. Muylle, of the Federal Agency for Medicines and Health Products (reference: FAGG/80737) of 30/11/09, addressed to Mr. A. Pauwels, SHC Coordinator.

In order to provide an answer to the question, an *ad hoc* working group was set up which included experts in blood transfusion.

2. CONCLUSION

The SHC advises that the date from which the available quantities of blood and blood components may be considered to reach sufficient levels again should be obtained by calculating the number of weeks between the moment when a risk of shortage was declared and that when the supply of red cell concentrates (all blood groups taken together) reached optimal levels again and extending this period by the same number of weeks.

3. ELABORATION AND ARGUMENTATION

3.1 Methodology

This advisory report is based on the assessment of epidemiological findings regarding the influenza A(H1N1) pandemic that raged in the autumn of 2009, as well as on the opinion of the experts.

3.2 Elaboration

The European Commission Directive 2009/135/EC of 3 November 2009 allows temporary derogations to certain eligibility criteria for whole blood and blood component donors in case of a risk of shortage directly caused by the influenza A(H1N1) pandemic (SANCO, 2009).

It is worth recalling that according to estimates, the overall national supply that is required to provide the Belgian hospitals with red cell concentrates amounts to 10,000 concentrates (all blood groups taken together) (SHC, 2009).

The SHC recommended that a risk of serious shortage or an actual shortage directly caused by the influenza A(H1N1) pandemic should be notified as soon as one of the following situations occurs (SHC, 2009):

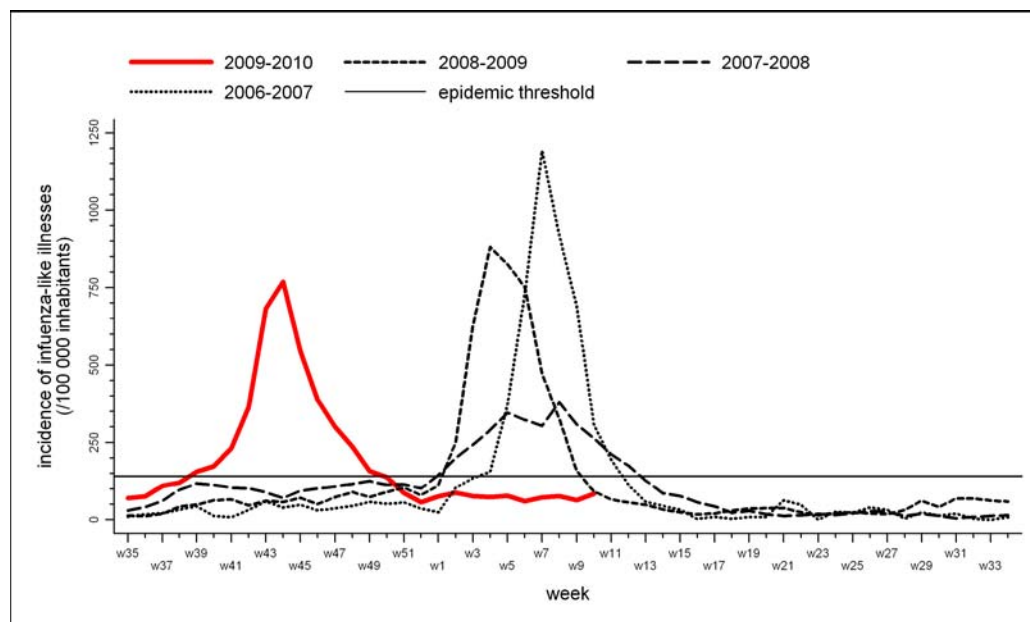
- the weekly incidence of influenza-like illnesses reaches 200 per 100,000 population, with 30 % of the samples testing positive for the A(H1N1) virus (*risk of shortage*);
- the supply level drops to the critical threshold of 5,000 red cell concentrates of all blood groups taken together (*real shortage*);
- the supply level drops to the critical threshold of 2,500 red cell concentrates of group O (*real shortage*).

In order to issue an advisory report regarding the date on which these temporary derogations can be withdrawn, the SHC takes the view that various scenarios can interfere with the simple observation that supply levels are once again above the critical thresholds.

- 1) The incidence of influenza-like illnesses can evolve as a clearly delimited epidemic outburst, like the one that was actually observed in the autumn of 2009 (Fig. 1). Nevertheless, there is no certainty over the manner in which an influenza pandemic will progress. As a result, outbursts with transient drops that may be mistaken for the end of an epidemic cannot be ruled out;
- 2) Depending on its virulence (Clifford et al., 2009) and attack rate (Kamp et al., 2010), the pandemic wave can have a much stronger impact on the supply levels than that observed so far. As regards an attack rate such as that of the "Spanish flu", Kamp et al. (2010) anticipate a drop in blood donations that is six times greater than that estimated to have

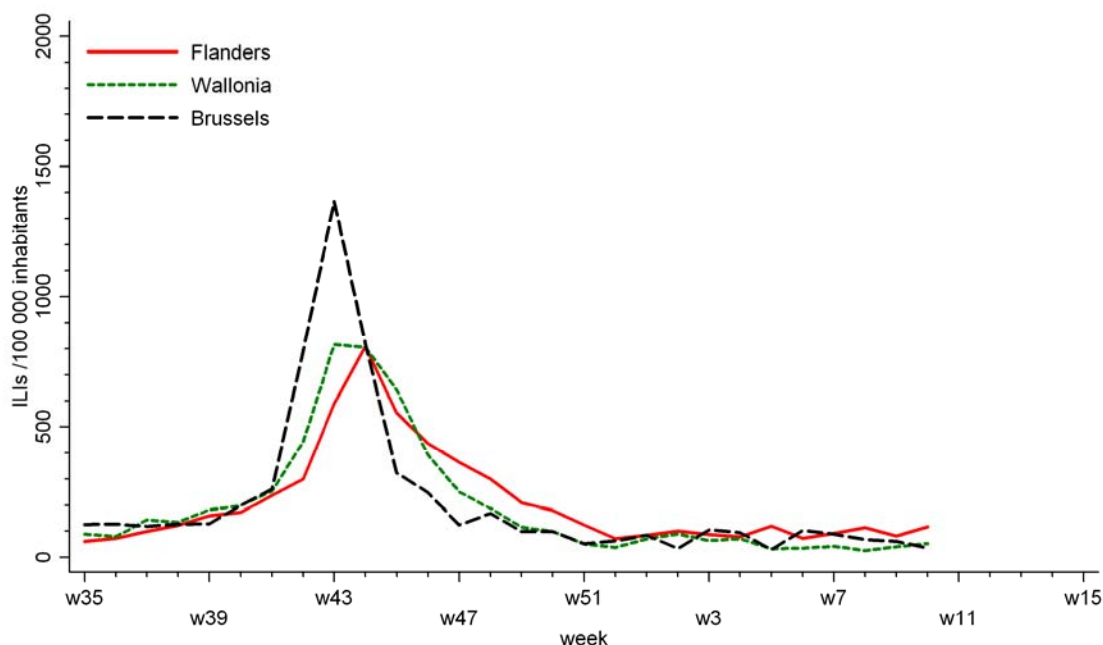
been caused by the A(H1N1)2009 virus. Though unpredictable, the impact on healthcare establishment supply levels could make itself felt even after the incidence has fallen below the epidemiological threshold again;

Fig. 1. Evolution of the incidence of influenza-like illnesses (IPH, 2010).



- 3) The incidence distribution can vary from one region to another and its impact will be handled with varying degrees of success by the different healthcare establishments (Fig. 2);

Fig. 2. Regional distribution of the incidence of influenza-like illnesses during the autumn 2009 A(H1N1) epidemic (IPH, 2009).



- 4) In previous reports, the SHC (SHC, 2007; SHC, 2009) insisted that the hospitals' emergency plans should include measures aimed at further increasing blood saving and enhancing the judicious use of blood components on the basis of good transfusion practices (SHC, 2010). Particular attention should be paid to platelet supplies, taking into account the fact that they have a short shelf-life and that it is difficult to postpone treatment for patients with haemato-oncological disorders, who are usually immunodeficient (CSS, 2009; Fontaine et al., 2009; NHS, 2009);
- 5) The influenza wave may be followed by a period during which particular efforts are typically required for the recruiting of donors (holiday departures, family reunions during the festive season) or by another epidemic. Thus, the return to sufficient supply levels for blood components could be jeopardised, with transfusions that had to be postponed during the pandemic requiring appropriate supplies at a later stage.

For all these reasons, the SHC takes the view that the date from which the available quantities of blood and blood components may be considered to reach sufficient levels again is obtained by calculating the number of weeks between the moment when a risk of shortage was declared and that when the supply of red cell concentrates (all blood groups taken together) reached optimal levels again and extending this period by the same number of weeks. When there is no *real shortage*, the date is set at the moment when the criteria for an epidemic are no longer met (cf. SHC, 2009; IPH, 2009).

Taking into account the lack of perspective and the uncertain evolution of the A(H1N1) pandemic, the recommendations and conclusions in this advisory report must be adapted according to the evolution of the situation.

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5. COMPOSITION OF THE WORKING GROUP

All experts joined the working group *in a private capacity*. The names of the experts of the Superior Health Council are indicated with an asterisk*.

The following experts were involved in drawing up this advisory report:

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The following expert was consulted:

MUYLLE Ludo* (blood, tissues and cells – UA; UZA; FAMHP).

This working group was chaired by Ms. Véronique DENEYS, the scientific secretary was Mr. Roland HÜBNER.

About the Superior Health Council (SHC)

The Superior Health Council is a federal body that is part of the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC takes no decisions on the policies to follow, nor does it implement them. It does, however, aim at giving guidance to political decision-makers on public health matters. It does so on the basis of the most recent scientific knowledge.

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, members of scientific institutions), 200 of whom are appointed experts of the Council. These experts meet in multidisciplinary working groups in order to write the advisory reports.

These advisory reports are submitted to the Board. Once they have been endorsed, they are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.css-hgr.be). Some of them are also communicated to the press and to target groups among healthcare professionals.

The SHC is also an active partner in developing the EuSANH network (European Science Advisory Network for Health), which aims at drawing up advisory reports at the European level.

In order to receive notification about the activities and publications of the SHC, you can subscribe to the mailing-list and/or an *RSS-feed* via the following link: <http://www.css-hgr.be/rss>.