



# Evaluating the acceptability of vaccine and vaccination programmes: an individual and public health perspective

Annceny, Les Pensières July 7-9, 2008

## Background and rationale

The introduction of new vaccines in vaccination programmes is based on public health needs, the assessment of the vaccine-preventable burden of disease both medical and social, and the safety and efficacy of the vaccine. This leads to the decision to recommend and fund vaccination programmes. With most vaccines intended to prevent childhood diseases, the success of vaccination policies essentially relied on the public awareness of the severity of the disease to be prevented and the willingness of health care professionals and the parents to actively protect their children against severe diseases.

But, despite recommendations and their proven efficacy or effectiveness, some vaccines remain underused, especially in older age groups. With more and more vaccine targeting new diseases less perceived as life-threatening or intended to adolescents, adults and/or the senior population, new factors will influence the level of implementation of vaccination programmes. They are, to a large extent, linked to the individual perception of the value of being vaccinated. These individual or general attitudes must be thoroughly analysed and understood as they will represent major drivers or barriers to the success of vaccination policies and their public health impact.

The two major players in this field are the health care professionals and the patients themselves, but they can be influenced by others stakeholders in the more and more complex environment of vaccinology. **The concept of acceptability of vaccination** must also be introduced early in the development, regulatory and policy-making processes to introduce new vaccines. It includes not only sociological approaches but will also request the development of specific and validated tools to assess some of the *patient-related outcomes* linked to vaccination that will influence the acceptability of the programme.

The Mérieux Foundation is pleased to organize this meeting as a forum to better analyse and understand what could be the key success factors for the introduction of new vaccines and their adoption by the public at large.

The Foundation welcomes invited scientists, vaccinologists, representatives from industry and international institutions to Les Pensières Conference Center, in Annceny, France, from 7 to 9 July 2008, to attend "**Evaluating the acceptability of vaccine and vaccination, an individual and public health perspective**". Its purpose is to review the general principles leading to the introduction of new vaccines, to analyse the key elements which support the *willingness to vaccinate* by health care professionals and the *willingness to be vaccinated* by the population. This includes reviewing existing ways to assess these elements and the need to develop specific and validated tools, which could be used to support the development and registration of new vaccines, as well as recommendations and implementation of new vaccination programmes. Case studies related to newly introduced vaccines will provide practical examples and contribute to define a general approach.

### The Conference's strategic objectives include:

- ⇒ To identify and understand the key elements underpinning the successful adoption of vaccination programmes by the population;
- ⇒ To analyse the drivers and barriers that lead health care professionals to actively support vaccination policies: the "*Willingness to Vaccinate*";
- ⇒ To analyse the elements that drive the acceptability of vaccination programmes by the target population: the "*Willingness to be Vaccinated*";
- ⇒ To review the assessment methods for such parameters in a way that would be relevant to support policy making processes;
- ⇒ To define a research agenda in this new area of vaccinology.

Each speaker has been asked to specifically address one or more of these objectives in their presentation. There will be a professionally prepared report of the Conference's presentations and discussions including specific responses to the above objectives.

## Monday, July 7, 2008

17h30-18h30	► <b>Registration</b>	
18h30-18h45	<b>Welcome Address</b>	<b>Christophe LONGUET</b>
18h45-19h15	<b>Keynote lecture</b> <i>The principles of vaccine adoption</i>	<b>David SALISBURY</b>

Based on the experience of the recent introduction of several vaccines in the UK, the speaker will review and analyse the key elements that have made the vaccination programmes successfully adopted (key success factors) and the pitfalls health authorities are facing when introducing a new vaccine (reality check).

19h45 ► **Welcome Dinner**

## Tuesday, July 8, 2008

<b>SESSION I</b>	<b>Key elements supporting the introduction of a new vaccine</b> ► <b>Chaired by: David SALISBURY , Nicole GUERIN</b>	
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This session will review in more details some of the elements analysed in the keynote lecture, illustrated by practical examples:

- **Medical needs:** how to make sure that they are identified and properly addressed upfront as part of the development programme of a new vaccine. This includes addressing the epidemiology of the disease and the elements that will have a critical importance in the design of the vaccine (e.g. vaccine strains, formulation...), what will be the meaningful clinical and/or immunological endpoints, and the relevant outcomes to assess early impact of the vaccination programme;
- **Regulatory process:** regulators have the critical role of assessing the quality, safety and efficacy of new vaccines to register them. More and more frequently regulators request the input of expert groups (e.g. Vaccine Working Party at EMEA) and are expected to provide advice that could go beyond the strict technical assessment of a given vaccine and influence the speed of introduction of a vaccine (e.g. risk management plan);
- **The recommendation process:** a more and more transparent evidence-based process for which the role of health technology assessment (HTA) is growing. It is important to understand how health-economics data can be balanced by other parameters like social and ethical values. How the policy-making process is influenced by other stakeholders would also be appropriate to identify.
- **The financing process:** easy access to vaccine is an important factor of the success of a vaccination programme and its acceptability by the population (example of seasonal flu). Reviewing the vaccine financing sources, existing gaps in funding, understanding the different options to fund vaccination programmes would help defining the optimal financing process for a new vaccine and possible alternative approaches.
- **Health infrastructures:** another critical element of the successful implementation of vaccination programmes relates to its "feasibility". This especially includes several issues: will vaccine supply be appropriate? Is or can the new vaccine be administered as part of existing vaccination programmes? Is the health care infrastructure appropriate for running the programme? Will the target population have an easy access to the vaccine?

08h30-08h50	<i>The medical needs</i>	<b>Paolo BONANNI</b>
08h50-09h10	<i>Discussion</i>	

09h10-09h30	<i>The regulatory process</i>	Nora DELLEPIANE
09h30-09h50	<i>Discussion</i>	
09h50-10h10	<i>The recommendation process</i>	Claire Anne SIEGRIST
10:10-10:30h	<i>Discussion</i>	
10:30-11:00h	<i>Coffee Break</i>	
11h00-11h20	<i>The financing process</i>	Patrick LYDON
11h20-11h40	<i>Discussion</i>	
11h40-12h00	<i>Public health infrastructures</i>	Michel ZAFFRAN
12h00-12h20	<i>Discussion</i>	
12h20-14h00	<i>Lunch</i>	

<b>SESSION II</b>	<b>Anticipating successful vaccine adoption: the Willingness to Vaccinate</b> ▶ <b>Chaired by: Zuliqar BHUTTA ,</b>
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Recommendations and funding of vaccination programmes as well as the appropriate infrastructure to ensure access and delivery of the vaccine to the end users are not sufficient to ensure its successful implementation. Acceptance, or better "adoption", of the policy and of the vaccine by those in charge of advising the target population and/or administering the vaccine is essential. This "willingness to vaccinate" is critical when one knows that health care professionals are the most trusted adviser by the patients.

The session will:

- analyse the elements that will influence the health care provider in her/his willingness to vaccinate;
- review the methodological approaches to evaluate this behavioural aspects;
- analyse the key components of successful advocacy programmes aimed at ensuring the acceptability of vaccination programmes by health care providers,
- and address the role of scientific and professional societies in supporting vaccination policies and providing guidance to their health care professionals.

These aspects of the successful adoption of vaccination programmes will be illustrated by the recent introduction of HPV vaccination.

14h00-14h20	<i>The role of health care professionals in the acceptability of vaccination programme</i>	Adam FINN
14h20-14h40	<i>Discussion</i>	
14h40-15h00	<i>Assessing the willingness to vaccinate: methodological approaches</i>	Patrick KLEIN
15h00-15h30	<i>Discussion</i>	
15h30-15h50	▶ <i>Coffee Break</i>	
15h50-16h10	<i>Advocacy programmes to support the willingness to vaccinate</i>	John GRABENSTEIN
16h10-16h25	<i>Discussion</i>	

16h25-16h45	<i>Ensuring the Willingness to vaccinate: the role of professional societies</i>	Jean Pierre MICHEL
16h45-17h00	<i>Discussion</i>	
17h00-17h20	<i>Case study: HPV vaccination</i>	Sergio PECORELLI
17h20-17h40	<i>Discussion</i>	

19h00 ▶ *Dinner*

## WEDNESDAY, July 9, 2008

<b>SESSION III</b>	<b>Anticipating successful vaccine adoption: the Willingness to be Vaccinated</b> ▶ <b>Chaired by: S. L. ROSENTHAL , Daniel SALMON</b>	
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Recommendations and funding of vaccination programmes as well as the infrastructure to ensure access and delivery of the vaccine to the end users are not sufficient to ensure its successful implementation. Acceptance, or better, "adoption" of the policy and of the vaccine by the target population is essential. This rather new dimension in vaccinology needs to be understood and properly addressed by those in charge of conducting vaccination policies.

The session will:

- analyse the elements that will influence the consumer acceptance and result in the willingness to be vaccinated;
- review the methodological approaches to evaluate this social or personal behavioural aspects;
- analyse the key components of successful advocacy programmes, i.e. that the vaccination is the right answer to a given situation,
- and address the role that some "third parties", such as patient groups and parents can play in vaccine adoption.

These aspects will be illustrated by the recent introduction of zoster vaccination.

08h30-08h50	<i>Consumer acceptance: a new dimension in vaccinology</i>	Joanne YARWOOD
08h50-09h10	<i>Discussion</i>	
09h10-09h30	<i>Assessing the Willingness to be vaccinated: social and behavioural aspects</i>	Bonita STANTON
09h30-09h50	<i>Discussion</i>	
09h50-10h20	▶ <i>Coffee Break</i>	
10h20-10h40	<i>Ensuring Willingness to be vaccinated: the content of advocacy programmes</i>	W. ORENSTEIN
10h40-11h00	<i>Discussion</i>	
11h00-11h20	<i>Ensuring Willingness to be vaccinated: the role of Parents</i>	Loretta BRABIN
11h20-11h40	<i>Discussion</i>	
11:40-12:00	<i>Case study: Zoster vaccination</i>	Robert JOHNSON
12h00-12h20	<i>Discussion</i>	
12h20-14h00	▶ <i>Lunch</i>	

**SESSION IV****How to assess the acceptability of vaccination by the vaccinees: the concept of Patient Related Outcomes****►Chaired by: Thomas SZUCS**

This session will first address the concept of "patient-related outcomes" (PRO), defined as the impact a given event will have on the acceptability or rejection of the vaccine by the patient. This includes the perception of adverse events, or injection techniques that could paradoxically be better accepted than expected based on their usual assessment of severity or intensity.

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<b>14h00-14h20</b>	<b><i>The concept of patient related outcomes (PRO) and its measurements</i></b>	<b>Benoît ARNOULD</b>
<b>14h20-14h40</b>	<b><i>Discussion</i></b>	
<b>15h00-15h20</b>	<b><i>Role of PRO in vaccination process</i></b>	<b>Carla DIAS BARBOSA</b>
<b>15h20-15h40</b>	<b><i>Discussion</i></b>	
<b>15h40-16h15</b>	<b><i>Concluding Remarks</i></b>	<b>Luc HESSEL</b>
<b>16h:15</b>	<b>►End of the meeting</b>	