Folkhälsomyndigheten

Work model for changing national vaccination programmes in Sweden

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Innehåll

Summary

In Sweden, national vaccination programmes are regulated through the Communicable Diseases Act (SFS 2004:168) since 1 January 2013. According to the legislation, the Government decides on which diseases should be covered by national vaccination programmes, and the Public Health Agency of Sweden is responsible for developing evidence-based supporting material for these decisions and for issuing supplementary regulations further specifying target groups, number of doses and dose intervals.

To complement and support its mandatory tasks, the Public Health Agency has instituted a *reference group for national vaccination programmes*, composed of representatives of different agencies, professional associations and vaccination service providers. The composition, terms and work processes of the reference group is based on WHO's requirements for a National Immunization Technical Advisory Groups (NITAG), but the members of the reference group are not chosen as individual experts, but rather nominated representatives of their respective organizations.

Proposals for introducing vaccination programmes against new diseases or for making changes to existing programmes can be submitted from different organisations, formally or informally, by the reference group or generated internally at the Public Health Agency. The reference group suggests which investigations should be a priority for the Agency. The final decision to start an investigation is taken by the Director-General as the activity plan of the Agency for the next calendar year is determined.

For each investigation, the Public Health Agency appoints a *working group*. It usually includes analysts from the Agency and external experts chosen based on their specific competence and expertise, following an assessment of their potential conflicts of interest. The working groups develop the supporting material which is needed for proposals to the Government (if it concerns the introduction of a vaccination programme against a new disease) or for a changed regulation (if it is a case of changes to existing programmes). The reference group reviews the material and proposals and submit their viewpoints. The material and proposals are also sent for referral to concerned organizations and a selection of counties and municipalities, and are also open for public comments.

After the proposal has been on referral, the Public Health Agency's Director-General decides on whether to propose a new vaccination programme to the Government or to change the regulations for existing programmes.

If the working group concludes that not all factors and criteria of the legislation have been fulfilled for the disease to be included in a national vaccination programme, they can propose that the Public Health Agency should instead develop non-binding recommendations.

Sammanfattning

Summary in Swedish.

Sedan den 1 januari 2013 regleras nationella vaccinationsprogram av smittskyddslagen (SFS 2004:168) och smittskyddsförordningen (SFS 2004:255). Enligt denna lagstiftning beslutar regeringen om vilka sjukdomar som ska omfattas av nationella vaccinationsprogram. Folkhälsomyndigheten ansvarar för att utarbeta dels underlag för regeringens beslut, dels föreskrifter som närmare specificerar vaccinationsprogrammen (t.ex. vad gäller målgrupper, antal doser och dosintervall).

Förslag på att instifta nationella vaccinationsprogram mot nya sjukdomar eller ändra befintliga vaccinationsprogram kan komma från olika håll, t.ex. från specialistföreningar, intresseorganisationer eller politiker, eller internt från Folkhälsomyndigheten.

En extern referensgrupp stödjer Folkhälsomyndigheten i prioriteringen mellan olika utredningar. När Folkhälsomyndigheten har fattat beslut om vilka frågor som ska utredas tillsätter myndigheten arbetsgrupper bestående av utredare och sakkunniga från Folkhälsomyndigheten samt externa experter utvalda för sin specialistkunskap. Arbetsgrupperna tar fram det underlag (kunskapsunderlag respektive beslutsunderlag) som krävs för att Folkhälsomyndigheten ska kunna lämna förslag till regeringen om ett nytt vaccinationsprogram eller besluta om ändrade föreskrifter (om det är fråga om förändringar av ett befintligt program). Utredningen kan också resultera i att Folkhälsomyndigheten utfärdar rekommendationer för vaccination.

Referensgruppen får under arbetets gång och inför den slutliga behandlingen komma med synpunkter på utredningen och de underlag och förslag som arbetsgruppen tagit fram. Efter att underlagen och förslaget varit på remiss beslutar Folkhälsomyndighetens generaldirektör om förslaget ska lämnas till regeringen eller implementeras genom en föreskriftsändring.

About the publication

The Public Health Agency of Sweden is responsible for coordinating the national vaccination programmes. The task includes developing supporting material and conducting assessments on whether new diseases should be covered by national vaccination programmes. The Government then decides on which diseases should be covered. The task also includes to continuously monitor and assess whether the national vaccination programmes comply with the requirements of the Communicable Diseases Act, and suggest any changes deemed necessary.

This report outlines how the Public Health Agency organizes and investigates changes to national vaccination programmes. The main target group of the English version of the report is National Immunization Technical Advisory Groups (NITAGs) and their Secretariats in other countries.

The Swedish original report was developed by Hélène Englund and Ann Lindstrand at the Unit for Vaccination Programmes. Adam Roth and Britta Björkholm participated in the finalization of the report.

The Public Health Agency of Sweden

Johan Carlsson

Director-General

National vaccination programmes

Objectives for national vaccinations programmes

In Sweden, the overall objective of national vaccination programmes is to improve public health by preventing the spread of infections and providing the population with protection against diseases that can be prevented through vaccination. If a defined group in the population is at greater risk of being infected or becoming severely ill from infection, targeted vaccination programmes can be developed to control the disease in the defined risk groups.

The objectives for vaccination programmes against specific diseases may vary depending on the disease and the vaccine's characteristics and may be to either eradicate, eliminate or control the disease. Eradication takes place at the global level and is only possible for certain diseases. If a disease is eradicated, then all countries in the world are free from the disease and there is no longer any source of infection. Elimination may take place at the regional or national level and means that there is no circulation of the pathogen within the region or country, but that the pathogen can be imported from countries where it is still endemic and also cause limited outbreaks. Examples of diseases that are eliminated from Sweden are polio, measles and rubella. If a disease is in the control phase, the pathogen is still circulating in the country, but at the lowest level possible considering the available vaccines. Examples of diseases in the control phase are whooping cough and mumps.

Legal basis for national vaccination programmes

Since 1 January 2013 the national vaccination programmes in Sweden are regulated by the Communicable Diseases Act (SFS 2004:168) §§ 3 a−f and the corresponding Ordinance (SFS 2004:255) §§ 7 a−g. For a national vaccination programme to be possible, the Act requires that there should be a vaccine that can

- be given without prior diagnosis of the disease and
- provide more than short-term immunity against the disease among the entire or parts of the population.

The first point thus excludes therapeutic vaccines from being included in national vaccination programmes.

A communicable disease that fulfils the aforementioned conditions should be covered by a national vaccination programme if the vaccination can be expected to

- effectively prevent the spread of the disease among the population,
- be cost-effective for society, and
- be sustainable based on ethical and humanitarian considerations.

In accordance with the Act, the Government decides on which diseases should be covered by the national vaccination programmes. Since 1 July 2015, the Public Health Agency is responsible for issuing supplementary regulations. These specifically regulate the target groups (age groups,

sexes and risk groups), number of doses and dose intervals.

General and selective vaccination programmes

National vaccination programmes are divided into general and selective vaccination programmes. General vaccination programmes target the entire population, while selective programmes aim to protect a well-defined group with a higher risk of infection or of becoming severely ill.

Supporting material for decisions regarding national vaccination programmes

The Public Health Agency is also tasked with proposing to the Government the changes to national vaccination programmes that the Agency deems necessary. These proposals should include an analysis of the thirteen factors which are listed in the Communicable Diseases Ordinance (SFS 2004:255) § 7 d.

1. the burden of the disease on society, health and medical care as well as individuals
2. the expected impact of vaccinations on the burden and epidemiology of the disease
3. the number of doses that are required to achieve the desired effect
4. the target groups who will be offered the vaccination
5. the safety of the vaccine
6. the effect of vaccinations on the activities of county councils, municipalities, and private health care providers
7. the suitability of combining the vaccine with other vaccines in the national vaccination programme
8. the general public's ability to accept the vaccine, and the effect of the vaccination on attitudes towards vaccinations in general
9. which other accessible, preventive measures or treatments that might be taken or provided as alternatives to vaccinations in a national vaccination programme
10. the vaccination's socioeconomic effects and its expenses and incomes for the State, municipalities, and county councils
11. the opportunities to monitor the effect of the vaccination in the ten above-stated factors and the estimated costs for the State for such monitoring,
12. the need and cost for information initiatives for the population and health care providers
13. medical ethics and humanitarian considerations.

National Immunization Technical Advisory Groups

National vaccination programmes entail major investments for the State and health care and therefore there is a need for formalized and comparable processes for assessments and decisions. Over the years independent national committees, referred to as 'National Immunization Technical Advisory Groups' (NITAGs) have formed in different countries with both similar and varying structures and assignments (1-4). The tasks of a NITAG may include

- recommending (changes to) vaccination programmes
- recommending prevention measures
- conducting risk-benefit analyses
- providing advice on implementation of vaccinations
- conducting external environment monitoring
- monitoring vaccination programmes
- identifying knowledge gaps
- creating information materials and guidance
- recommending further research.

The NITAG work of many countries includes producing evidence-based supporting materials through a systematic review and assessment of available data.

Process indicators for NITAGs

In 2009 the WHO developed six process indicators for NITAGs to monitor the development regionally and globally. These include:

1. Terms of reference outlining the mandates and frameworks for the work of NITAGs.
2. Establishment through legislation or other official regulation, as a sign of the Government's support.
3. Representatives from at least five different areas; paediatrics, public health, communicable diseases, epidemiology and immunology are highlighted as particularly important.
4. Meetings at least once per year.
5. Agenda and relevant supporting material sent at least one week before each meeting.
6. That members submit written declarations of conflicts of interest.

In May 2012, the World Health Assembly (WHA) of the United Nations adopted a Global Vaccine Action Plan (5). A target within the action plan is for all member states to have NITAGs that fulfil the afore-mentioned six indicators by 2020.

Reference group for national vaccination programmes

In Sweden, the Public Health Agency is responsible for many of the assignments described above that a NITAG can have: developing evidence-based supporting materials on whether new diseases should be covered by national vaccination programmes, monitoring and assessing whether the national vaccination programmes fulfil the requirements and, if not, suggesting or independently implementing changes to the programmes regarding target groups, number of doses, intervals between doses, etcetera.

To complement its mandatory tasks, the Public Health Agency instituted a reference group for national vaccination programmes in 2016 as a consultative body. The group's assignments are to

- support the Public Health Agency in identifying necessary changes to national vaccination programmes, for example, concerning new diseases, or the number of doses, dose intervals, age and risk groups concerned,
- support the Public Health Agency in prioritizing the proposed changes to national vaccination programmes,
- review and comment on supporting materials and proposals which the working groups have developed, so that all relevant aspects are included and correctly described, and
- promote support for the Agency's work in terms of the national vaccination programmes.

The group does not develop supporting materials, make decisions on national vaccination programmes or issue recommendations. No voting occurs.

Representation in the reference group

The reference group is comprised if representatives of the following agencies, organizations and areas of work:

- The Medical Products Agency
- The National Board of Health and Welfare
- National Society for School Nurses
- Swedish Association of Local Authorities and Regions, SALAR
- Swedish Association of Midwives
- Swedish College of General Practice
- Swedish Society for Clinical Microbiology
- Swedish Society for Communicable Disease Prevention and Control
- Swedish Society of Infectious Diseases
- Swedish Society for Obstetrics and Gynaecology
- Swedish Paediatric Society
- The Society for School Doctors

- Paediatric health care

The composition of the reference group is based on WHO's requirements for a NITAG and includes medical expertise in areas such as paediatrics, public health, infectious disease, epidemiology and immunology, but also representatives for child and school health care, general medicine and maternal care. Thus, the reference group reflects reflect the breadth and the different functions that are affected by vaccination issues in the country. An important difference in comparison to other NITAGs is that the members are not part of the reference group as individual experts, but rather as representatives of their respective organizations.

The Public Health Agency solicits nominations for one representative and one substitute from each organization. Each nominated person should present a declaration of conflicts of interest. These are reviewed by the chair and secretary of the reference group, with support from the Agency's legal department, if necessary. If no conflicts are present, the head of the Department of Communicable Disease Control and Health Protection appoints the members for a period of three years.

The members do not receive any compensation for their involvement in the reference group, as it is considered part of their ordinary positions. The Public Health Agency however pays for necessary costs for travels that arise in conjunction with the meetings.

Reference group meetings

The reference group should meet at least once a year, but usually meets twice a year, in spring and autumn. If required, extra meetings can be held physically or through telephone conferences.

The Head of the Agency's Unit for Vaccination Programmes convenes and chairs the meetings. Usually the reference group's Secretary and other analysts from the Unit also participate in the meetings. Other representatives from the Agency, for example, from working groups and the microbiology units from the Department of Microbiology, participate in the meetings if needed. External experts may also be invited.

The Secretary of the group develops an agenda following suggestions and viewpoints from the group members and chair, and decisions taken at previous meetings. Minutes from the meetings are published on the Public Health Agency's website (https://www.folkhalsomyndigheten.se/).

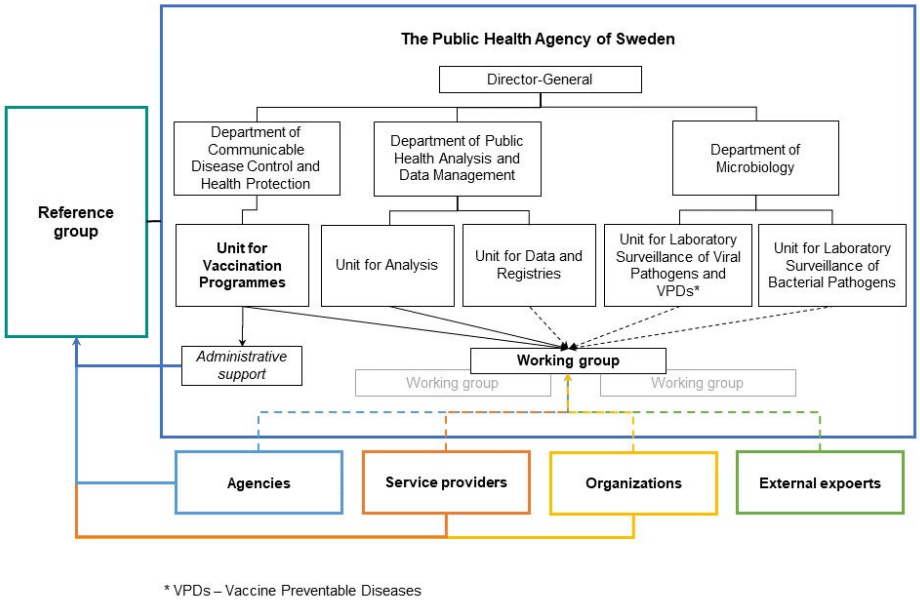
Administrative support

The Unit for Vaccination Programmes at the Public Health Agency provides the reference group with administrative support. This includes planning the agenda and convening meetings, gathering and distributing supporting materials, writing meeting minutes, and meeting and travel arrangements.

Work model for changing vaccination programmes

The process for developing proposals for changes to the national vaccination programmes presented below follow the main targets, indicators and principles developed by WHO. The model has been modified in accordance with the tasks, mandates and decisional hierarchy of the Public Health Agency of Sweden.

Figure. Schematic overview of the work model's organization (working groups, reference group and administrative support).



* VPDs – Vaccine Preventable Diseases

1. Soliciting proposals for changes

Proposals may refer to

- introduction of the vaccination programmes against diseases which were previously not covered by national vaccination programmes
- changes to existing vaccination programmes.

Proposals can be submitted from different organizations, formally or informally, or generated internally at the Public Health Agency. The Agency actively solicits proposals in preparation of the annual status report for the Government (as per § 7 b of the Communicable Disease Ordinance), and during meetings with the Agency's Reference Group for National Vaccination Programmes.

The Unit for Vaccination Programmes compiles the received proposals.

2. Compilation of supporting material

The secretary from the Public Health Agency's Unit for vaccination programmes assesses if the proposals fulfil the two fundamental conditions in the legislation. A supporting material is then compiled with existing data regarding each proposal including, current incidence and burden of the disease, whether the disease is covered by recommendations for vaccination by WHO or whether targets for elimination have been adopted, and whether regional vaccination programmes have been introduced in Sweden.

The supporting material serves as a basis for discussions regarding prioritization of investigations and a systematic or complete literature review is not required at this stage. If there is supporting material from the prioritization process of previous years, this can be used with necessary updates or supplementations.

3. Prioritization

The reference group discusses the proposals (new and previously submitted ones) annually and suggests which investigations should be a priority for the Public Health Agency. The high priority investigations are published on the Agency's website and included in the annual status report to the Government.

Proposals that are not considered to be a priority remain on the list and might come in question for investigation at a later time, i.e. if new scientific evidence has become available, or if the burden of disease or the cost of the vaccination has changed. At each prioritization event, all proposals are considered.

4. Decision to investigate

The Unit for Vaccination Programmes at the Public Health Agency manages all investigations concerning vaccination programmes. The head of the unit decides which and how many proposals to investigate in conjunction with the Agency's annual activity planning for the upcoming year. The Director-General takes the final decision, as the final activity plan is determined.

5. Appointment of a working group

For each investigation, the Public Health Agency appoints a working group. It includes two analysts from the Unit for Vaccination Programmes, which also serve as the project managers for the investigation and convenes the working group. They develop a preliminary plan for the investigation, highlighting the need for different competences. Usually also other analysts and subject-matter experts from the Agency are invited, such as epidemiologists, statisticians, microbiologists, health economics and communicators, as well as external experts and analysts from e.g. the Medical Products Agency. The external experts are appointed by the Agency based on their specific competence and known expertise within the relevant subject, following an assessment of their potential conflicts of interest, and compensated for their hours worked.

The responsibility of the working group is to develop the necessary supporting material for the relevant change. The working group should have a scientific approach throughout the process and their considerations should be evidence-based, which includes performing systematic reviews and considering all available data and recommendations.

6. Investigation

Depending on whether the proposal refers to a disease that is currently not covered by a national vaccination programme or a change to an existing vaccination programme, the subsequent steps will be different.

6 a. Investigation of a vaccination against a disease which was not previously covered by a national vaccination programme

Methods

The investigation concerning a new vaccination programme should include an analysis of the applicable factors listed in the Communicable Diseases Ordinance (SFS 2004:255) § 7 d.

In terms of burden of the disease, a structured summary of national data should primarily be made and used as supporting material. If this is not possible, a systematic literature review should be performed where the emphasis should be placed on data from countries with similar population, social, health and medical care structures as Sweden. Published systematic reviews can be used as supporting material if they are up-to-date and relevant for the question at hand, and a complete literature review is then not necessary. If required, a supplementary literature review can be performed.

Data on available vaccines (their efficacy, effectiveness, safety and suitability of combining with other vaccines) can be supplied by the Medical Products Agency, EMA as well as relevant product summaries for relevant vaccines. Data may also be obtained from systematic reviews or from countries that have already performed similar investigations.

GRADE, the system for grading of evidence, and a meta-analysis can be performed for the effect and safety of the vaccination if required, but if this has previously been published then such a systematic review can be used, supplemented with an AMSTAR assessment of the overview's quality.

A survey on attitudes should be conducted if required in order to investigate the target group's acceptance of the vaccine. Furthermore, it is investigated how the proposal would affect activities of county councils, municipalities, and private actors through, for example, interviews or surveys, or the knowledge of the experts in the working group.

The expected impact of the vaccination in the target group or population can be analysed with epidemiological modelling.

Based on the gathered data, a health economics assessment is performed which covers expenses and incomes for the State, municipalities and county councils. Both direct and indirect costs are included, and the analysis takes on a societal perspective.

Alternatives to vaccination and the opportunities to monitor the programme are identified and described by the working group. The working group also assesses the need for information

initiatives and develops a plan for monitoring and calculates the costs for these.

All the gathered data are compiled in one or more knowledge bases, written in Swedish or English. The working group then gathers to perform a medical ethics assessment, based on the guidance issued by the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) on the evaluation of methods in health care (6). Thereafter the Swedish National Council on Medical Ethics (SMER) are asked for their opinion, based on the preliminary medical ethics assessment done by the working group.

The working group's assessment

Based on the knowledge bases and the ethical assessments, the working group then performs an assessment of each of the 13 criteria. The knowledge bases and assessments are summarized in a decision base, written in Swedish and for use primarily by the government of Sweden. The target groups and dose schedule of the vaccination programme are specified and the state of evidence, benefit-risk balance and other advantages and disadvantages are presented. Finally a balanced assessment is performed concerning whether the investigation speaks for or against the introduction of a new vaccination programme, considering the three factors listed in 3 e § of the Communicable Diseases Act, i.e. if the vaccination can be expected to

- effectively prevent the spread of the disease among the population,
- be cost-effective for society, and
- be sustainable based on ethical and humanitarian considerations.

Sometimes the working group concludes that not all factors have been fulfilled for the disease to be included in a national vaccination programme. Then the working group can instead propose that the Public Health Agency should develop non-binding recommendations for vaccination against the disease, for the entire population or certain target groups. The disease can come in question for consideration for a national vaccination programme again, at a later time, if circumstances have changed. Then the proposal is added to the list under point 1 again, and prioritized with the help of the reference group. If a new investigation starts, existing supporting material should be used as far as possible and supplemented as required.

Presentation for the reference group

The status and preliminary results of each ongoing investigation are presented for the reference group during the regular meetings, and the opinions of the group are asked for. The knowledge and decision bases are also sent to the members of the reference group for review and their viewpoints. The reference group is specifically consulted on whether it agrees with the investigation's assessment of how the vaccinations could impact their respective activities.

Presentation for the Director-General

The results of the investigation, the assessment and proposed vaccination programme is presented to the Public Health Agency of Sweden's Director-General who decides on whether or not to endorse the proposal and if knowledge and decision bases can be sent for referral.

Referral

If the Director-General endorses the proposed vaccination programme, the material is sent for referral to the Medical Products Agency, the National Board of Health and Welfare, The Dental and Pharmaceutical Benefits Agency, a selection of municipalities and county councils, as well as other concerned agencies and organizations, both professional and non-governmental. The referral is also open, which means that all agencies, organizations, companies and individuals can reply, not only the invited ones.

The project managers then compile the received referral replies. If needed, the knowledge base is revised or supplemented, and the proposed vaccination programme modified.

Decision to propose a national vaccination programme

The revised vaccination programme proposal and the viewpoints of the referral bodies are finally reported to the Director-General who decides whether the proposal and decision base should be sent to the Government.

6 b. Investigation on changes to existing vaccination programmes

Proposals on changes to existing national vaccination programmes may entail new or changed target groups, for example age, sex or risk groups. In these cases, most of the thirteen factors of the Communicable Diseases Ordinance need to be considered. The proposals may also cover the number of doses, intervals between doses or other factors that the Public Health Agency may regulate through its regulations. If this is the case, only selected factors that are important for the relevant change will be analysed and the focus will be on differences in relation to current programmes, for example, concerning impact on health care and any changes to costs.

In other aspects, the process is similar to investigations concerning new vaccination programmes: a working group is appointed, supporting material developed and sent to the reference group for review and viewpoints and reported to the Director-General. For this type of investigation, the working group's final product is a proposal for regulations. If the proposal is approved, the supporting material is sent for referral, revised if required and reported again to the Director-General who will decide on changes to the regulations. The regulations are then formulated in accordance with the Agency's regular procedures.

If the Public Health Agency wants to make changes to existing programmes, which entail significant cost increases, the Government's consent for the regulations should be obtained. Such changes could for instance include an increased number of target groups or doses.

7. Summary and publication of supporting material

Irrespective of which investigation is conducted and at what stage the investigation ends, the developed supporting material and conclusions is published on the Public Health Agency of Sweden's website.

Acronyms

AMSTAR - A Measurement Tool to Assess Systematic Reviews

EMA - European Medical Agency

GRADE - Grading of Recommendations Assessment, Development and Evaluation

NITAG - National Immunization Technical Advisory Group

SALAR - Swedish Association of Local Authorities and Regions

SBU - Swedish Agency for Health Technology Assessment and Assessment of Social Services

SFS - Swedish Code of Statutes

SMER - The Swedish National Council on Medical Ethics

WHA - World Health Assembly

WHO - World Health Organization

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