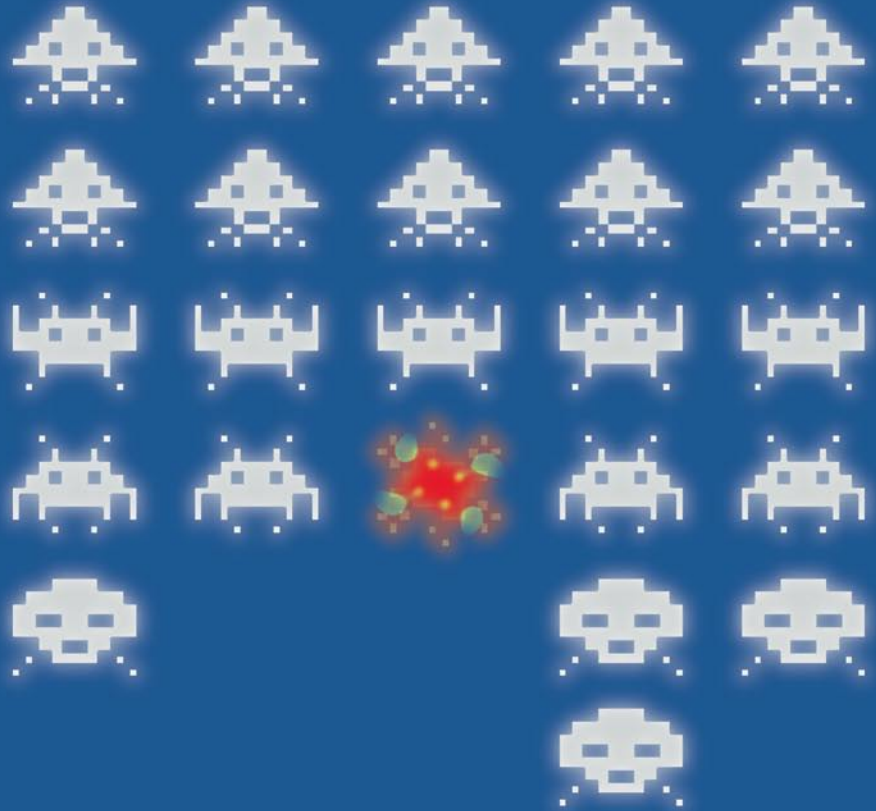




REGIONE AUTONOMA  
FRIULI VENEZIA GIULIA

REGIONAL GROUP FOR IMPROVEMENT  
OF QUALITY IN VACCINATION SERVICES  
IN THE FRIULI VENEZIA GIULIA REGION

Promoting  
improvement  
of quality  
in vaccination  
processes



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## INTRODUCTION

This present document is an account of the dedicated effort being made par excellence by the Regional Health Service, RHS (Servizio Sanitario Regionale, SSR), and gives a clear account of the evolution in vaccination being witnessed in the field of prevention and welfare.

In our Region, great attention has historically been paid to the practice of vaccination, such that very high levels of coverage have been guaranteed over time, and always in line with recommended goals concerning protection of both individual and whole community.

This result places our Region among those best able to apply the plans and recommendations being put in place at national and international level, and has been achieved through the professionalism and untiring work of the entire RHS staff. In particular, major recognition should be given to the central role of doctors, health workers and nurses of the prevention departments of our health agencies heading up the vaccination centres.

The passion and professionalism of these players has had and continues to have a fundamental role in guaranteeing a top-level service for all citizens. The most recent witness to this is precisely the number involved, which is clear demonstration of the effort and intent to systematically guarantee a constant improvement in activities.

An initial programme during the early years of this new millennium targeted vaccination activity under the prevention departments: its hallmark was professionalism and its impact was very largely on organisation. Today, a new instrument is being put forward for continuous improvement in the RHS, which concerns all operators and RHS points involved in vaccination practice in their separate ways.

In brief, this represents a shift from quality sought systematically within an organisational structure (vaccination centres of the prevention departments) to the guarantee given by the RHS to its own users, who in whatever way they interact with the system have the assurance of clear vaccination quality standards.

In other words, this is a framework and further guarantee by which the RHS is able to:

a) offer the best possible responses, whether in day-to-day practice or in emergencies (e.g., risk of pandemics, disasters, etc.),

b) function as an integrated network with regard to exchange of data that is either individual (regarding the citizen) or aggregated (evaluation of local agency and regional population coverage levels),

c) exploit the vaccination event as a “teachable moment” for introducing policies of health promotion and prevention,

d) bring together institutions (RHS, universities), professionals (doctors, health workers, nurses, regional managers), and competences (in hygiene, doctors in general practice and family paediatricians, in nursing and technical management) present in the region, where these goals are relevant.

The fact that this effort in the present programme has also involved doctors in general practice, family paediatricians and hospital health workers who perform vaccinations, is further evidence of the level of maturity and integration of our RHS, which is being built up and strengthened year on year, a matter of great pride to myself and indeed for all of us.

I would in closing like to thank all those who have worked in order to see this programme – under umbrella initiatives of the Ministry of Health’s Centre for Disease Control (Centro per il Controllo delle Malattie) – through to fruition, not least my predecessor Dr. Ezio Beltrame who launched it, but also the staff in my own department, the university academic staff and the health professionals who have all played a part in putting it together.

In conclusion, I wish to give assurance of my full readiness, and that of the entire RHS, to work over the coming years towards putting into operation the recommendations we have set out here.

*Councillor for health and social welfare*

Vladimir Kosic

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# 1

## VACCINATION ACTIVITY AND ITS ORGANISATION IN THE FRIULI VENEZIA GIULIA (FVG) REGION

In the FVG Region, vaccination, in particular of infants, represents one of the public health activities with highest tradition and social impact. In fact, in this context the Region can be described in the following terms:

- for many years, very high levels of coverage, not just for obligatory vaccinations but also for those recommended;
- vaccination services – before legislative decree 502/92 under the public hygiene sectors and now under the departments of prevention – that are well organised and structured, albeit individually for each health agency;
- available vaccination distributed within an integrated network that involves various areas with the same objective: vaccination services referred to departments of prevention, general practitioners, family paediatricians, hospital vaccination services.

Other challenges being taken up by the services and that require abandonment of the old paradigms for provision of infant vaccination include:

- the tendency to go beyond obligatory vaccination;
- a broadening of the population bands reached by vaccination campaigns;
- medicine for travellers;
- health promotion.

The FVG Region's programme for improvement of quality in vaccination services should be considered and interpreted taking into account its regional context; indeed, the programme meets the strong demands of regional bodies to reach this goal, partly as a result of the positive experience accumulated over earlier years (2000-2001).

This present manual, which is based on the first version from 2001, is set out making reference to a number of keywords typifying today's vaccination processes.

In the previous edition, reference was made to keywords that described these services and which are now being reviewed and updated as a result of recent developments in recent years at socio-cultural level and as regards prevention.

**Today's keywords are:****a) Health gains**

Health systems increasingly have to take the lead in promoting correct lifestyles and reducing known risk factors (prevention). In this scenario – commonplace at international level and also sanctioned by recent national health plans – the vaccination itself for both children and adults represents a valuable moment of contact, which aside from the actual vaccination, becomes a “teachable moment”, an opportunity for a range of activities (e.g., counselling on specific issues, health education, etc.) aimed at health promotion.

Furthermore, vaccination has for years been a public health measure recognised as efficacious from the scientific point of view, and in the field of primary prevention remains among those measures that have brought the best results, whether historically (e.g., eradication of smallpox), currently (e.g., programme for eradication of poliomyelitis), or for the future, when results are expected in the fight against infectious diseases and, in some case, chronic degenerative diseases.

**b) Operating within a system's logic**

Current social and health frameworks are commonly viewed as pyramid structures, but this representation shows a number of limitations, and indeed the context of vaccination practice also reflects this. The process of vaccination cannot be fully contained within precise organisational and hierarchical structures; the context is evolving and involves increasingly a multiplicity of different actors who dynamically generate complex systems of relationships: the regional policy component, professionals, users and other stakeholders (companies, insurers, and others).

It has therefore become increasingly necessary to give support to the internal consistency and efficiency of the sub-systems within and underpinning the vaccination process; in particular, it is essential to clarify the points where those involved in knowledge management and information management meet those working in management and transfer of this knowledge to the community through counselling.

**c) Centrality of the citizen-user**

As a consequence of the evolution of the social and cultural context vis-à-vis the world of health/disease, the approach that best corresponds to the new demands of the citizen-user is one that is bio-psycho-social, which is designed around the centrality of the person within their course of treatment.

Users and those assisting them have the right to health services that respect their individual needs, preferences and values, as well as their autonomy and independence. In this sense, the right to participate and accompanying responsibility are respected, depending on level of



capacity and preferences, when decisions are being made about treatment or procedures that concern their own life.

As a result, involvement of the citizen necessarily means communication based on shared and accurate information that is relevant and clear, enabling the person concerned to make informed decisions.

This is expressed not only at individual vaccination level, but also takes on wider health policy aspects by involving all organisations representing the citizen, and which can be considered true stakeholders.

The value attributed to the centrality of the user also ensures that all citizens have access to the requisite services, independently of their condition or socio-economic status.

In the social evolution of our national framework, the role of the individual is being shifted gradually centre stage, along with his/her rights to self-determination of informed choices.

In this sense, those operating in vaccination are being increasingly required to extend beyond mere legal obligation, and to build capacity (in professional and organisational terms) to offer vaccination as a teachable moment for information/education that can lead to consensus from the citizen and encourage informed choice.

#### **d) Protecting public health**

One of the challenges facing public health over the next decade is to demonstrate and convince the citizen and the various bodies representing him/her that the measures proposed and accepted are actually necessary rather than just useful, and justify the necessary investment. This demands a targeted effort to systematically produce relationships able to give clear, comprehensible information about results to the citizen and his/her representatives (institutional and otherwise).

In this sense, the vaccination process as generally understood must guarantee homogeneous standards of quality, whether in the planning phase itself at regional level or for the individual vaccination event in all vaccination centres, in the department of prevention, the individual workplace of the general practitioner, family paediatrician, or hospital context.

In this new perspective, the regional system's role takes on strategic significance, as the citizen's guarantor of this process.

#### **e) Safe system offering quality**

The safety of the whole vaccination process becomes extremely relevant in the current context, in which the health environment is strongly oriented towards application of systems for risk analysis and evaluation, and the development of assistance processes where priority is the centrality of the user and his/her safety.

Here, safety is understood to mean the whole set of processes that lead to the elimination/containment of any harm arising from practices designed to improve a treatment's outcome. This context includes 1) the safety that comes directly to the user by virtue of a correctly managed vaccination process, 2) the safety in the operator's behaviour whilst carrying out his/her work, 3) the safety guaranteed to the community as a result of the efficaciousness of the vaccination itself.

Indeed, closely linked to the concept of safety is that of efficacy, that is, the capacity to provide services based on scientific evidence to all who can benefit, at the same time avoiding the provision of services to those who cannot benefit.

In parallel with this, the health organisations must also work in another important direction, building internal capacity to demonstrate whether or not the organisation has reached set targets, in a given context and using available resources. In the specific case, this means that alongside organisation of the individual vaccination itself, an epidemiological surveillance system should also be in place that can demonstrate results achieved in terms of coverage levels, side-effects, diseases prevented, cost-benefits, etc.

In addition, the dimension of education offered at the time of individual contact should also be taken into account.

# 2 ■

## REGIONAL PROGRAMME FOR IMPROVEMENT OF QUALITY IN VACCINATION PROCESSES

At a distance of five years from the start-up of professional accreditation, the FVG Region's Prevention Plan 2005-2007 has now officially laid out a clear working approach for improving quality in vaccination services, thus constituting the formal relaunch of the accreditation project previously put in place under the scientific responsibility of the Chair of Hygiene and Preventive Medicine at the University of Udine.

The development of the project included in the Region's Prevention Plan 2005-2007 is designed to build on the work carried out over recent years by the group of health operators voluntarily participating in the accreditation project of excellent; the goals are to ensure homogeneity in approach and response by all regional vaccination centres, and to ensure the existence of foundations for the process of verifying the quality of a service that is constant over time.

Specifically, the target goals envisaged in the Plan are:

- improve the quality of professionalism, adding better communication skills to competences already built up, with the end-goal of obtaining informed user participation;
- improve the quality of user information as regards scientific content, time dedicated, and respect for cultural differences;
- improve the quality of services in terms of accessibility, high immunitary protection of the population, management of adverse events;
- improve the quality of the information system.

In its most classical sense, accreditation is an instrument for encouraging improvement in quality of service towards excellence, and is not limited to evaluating correspondence to minimum levels, but instead is inclined to encouragement of a process of improvement as widespread as possible within the organisation and its professional employees. Participation in programmes of this type is voluntary and carries no sanctions, while results of inspections remain confidential.

The first version of this manual, from 2001, already set out the basic characteristics determining the process of regional professional accreditation. The positive outcome accrued by this approach is now also allowing better calibration of future plans for continuous improvement, taking as reference point the essential consensus of operators and stakeholders, capacity for

expression of professionalism by those providing the process, the objective of reaching targets of excellence, and adhering to the time-scales involved and respecting gradual phasing.

**The keywords characterising the 2005-2007 programme of improvement described here are therefore:**

**a) Consensus and participation**

The involvement of the professional components is such that the evaluation exercise to be undertaken is based on shared consensus among the professionals concerned – identified either in the role of evaluator or of evaluated.

The professional plays an active role: the formal mandate is issued from a level of regional competence, but the effort of the individual operator is spontaneous and builds on earlier positive experience.

The new group of professionals also views other significant figures as being involved and fully qualified to contribute to continuous improvement of the process: general practitioners, family paediatricians, hospital health professionals.

**b) Professionalism**

Each professional involved in the programme of continuous improvement makes a real and individual contribution to the search for ways to enhance the vaccination process.

It is this context that individuals can put their own know-how and skills to best use.

**c) Excellence**

The programme constitutes an activity promoted by the FVG Region, which has given strong mandate to activate the programme of continuous improvement within prevention activity planning.

The regional system aims to play and maintain a role of leadership in managing this process of improvement; the professional groups are part of this, promoting relationships for exchange and sharing of know-how and skills.

In fact, it is acknowledged that achieving the highest results in health must be based on scientific knowledge and best evidence, but this inevitably depends on the resources available for any context.

**d) Gradual approach**

Undertaking to achieve conformity of requirements and their related in-depth examination and finalisation is pursued gradually, one step at a time, by all levels of the organisation, with priorities given to sectors considered most critical.

# 3 ■

## REFERENCE MODEL

In drawing up this new manual, the relationship between citizen and the Regional Health Service (RHS - Servizio Sanitario Regionale) has been considered central; in this context, regarding the vaccination process, the latter acts as guarantor for the individual citizen and for the community, of homogeneous quality standards in all cases.

The new model was drawn up setting out from two reference points:

1. the concept of network, taken as the collection of RHS points/hubs (its own and/or under contract to it – “convenzionati”) offering the vaccination process to the citizen, where:
  - a. **hubs** may be individual actors or organisational units;
  - b. the hubs/points are interconnected through joint membership of the RHS and by virtue of the role of public health service which the individual processes assume when considered as one whole;
  - c. the network **limits** are set by making reference to the RHS but recognising that each hub can also belong to other networks;
  - d. hubs/points that provide the process can also exist outside the RHS, but precisely by virtue of public health service these will increasingly have to belong to the network;
  - e. each hub may have **different responsibilities** (including hierarchical) but only the network as a whole can guarantee homogeneity in performance;
  - f. as with each network, the vaccination system also has **operational properties that** represent the system dynamics; examples are languages, codes, values, targets, planning, control, etc.
2. the concept of process, where this is a collection of actions, actors, and instruments operating in synergy to obtain a specific result (performance) – in our case to guarantee standards to the individual and to the community that are qualitatively and quantitatively both homogenous and high-level.

The parties constituting the network in our case are: the department of prevention, with its own internal structures (vaccination centres); general practitioners (GPs) and family paediatricians (FPs); the vaccination services that provide the service within the health structures, mainly for

employees; groups of stakeholders in vaccination policies; regional bodies that put policy into practice (Figs. 1,2).

Fig.1

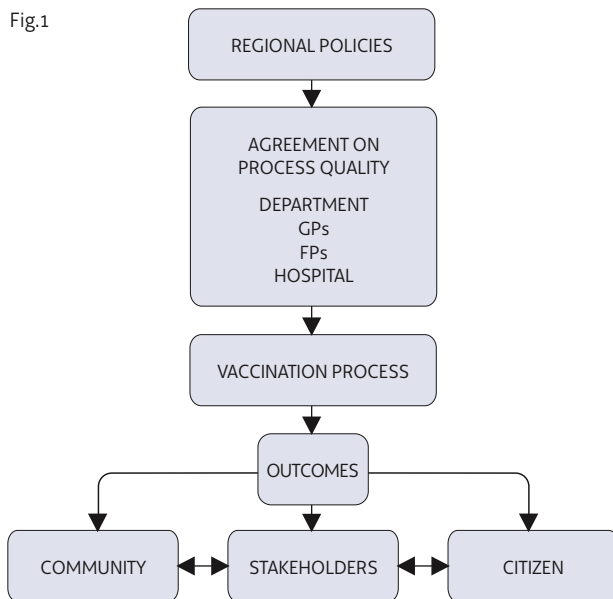
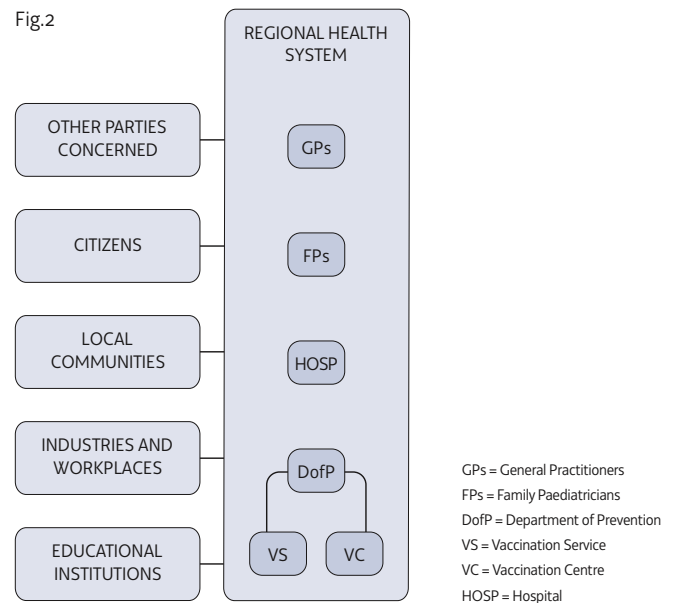


Fig.2



As described under the National Vaccine Plan 2005-2007 (Piano Nazionale Vaccini 2005-2007), various levels of responsibility are involved in defining and implementing an immunization programme, and only by integrating them optimally can positive results (good process performances) be obtained in terms of functioning of services, interaction with the population, and impact on the incidence of infectious diseases.

Each of these components, at their various levels and degrees of involvement, takes on its own responsibilities vis-à-vis vaccination policy and process, starting out from the regional body that defines the reference rules and stands as the guarantor for the community as a whole, right through to the outlying vaccination centre and to the individual professional carrying out the specific work of user

# 4.

## INTRODUCTION TO THE MANUAL

Setting out from the concepts illustrated, with reference always to the user at the centre of the model, the manual has been set out under the following chapters:

- 1. Policies and leadership:** The policies and strategies for immunisation within a (regional) community require the identification of various levels of responsibility that are inter-coordinated to ensure positive results in terms of functioning of services, impact on incidence of infectious and chronic degenerative diseases, and population health gains. In all activities of prevention, the professional figure features as a major actor.
- 2. Prevention and education:** Prevention and health education are elements that are essential and characteristic of the efforts required if health gains are to be achieved. Vaccination policies and the vaccination process have traditionally been among the best known and best rooted instruments in the context of prevention, and can be considered teachable moments, where it is possible to go beyond the procedure itself, to inform and educate about risk factors and correct lifestyles.
- 3. Safety and quality:** Safety and quality go hand in hand in any process of assistance. Available evidence shows that guaranteeing quality and safety requires an approach that integrates all those involved in the vaccination process, acting as a de facto indicator that the whole system is operating well.
- 4. Vaccination process:** This includes all phases of planning, right through to verification of the results of the vaccination activity, including responsibilities, necessary resources, time-scales and target results.
- 5. Information management:** The management of information should include all information that is relevant and useful to the information requirements of the regional health system and of the user.
- 6. Performance:** Accrediting a process that involves various different professionals and organisational levels means breaking down the system's overall performance into the various process phases and their individual performances, then building up an overall assessment.

**7. Emergencies:** Those involved in vaccination, whether individual or services, may be required to handle three different types of emergency situation: pandemics, natural disasters and bio-terrorism (e.g. smallpox). Handling these emergencies requires a network of professionals and services involved in the vaccination process (Fig. 3).

Fig.3

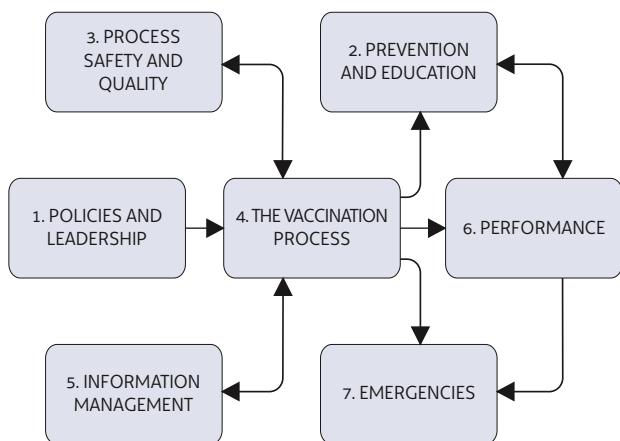
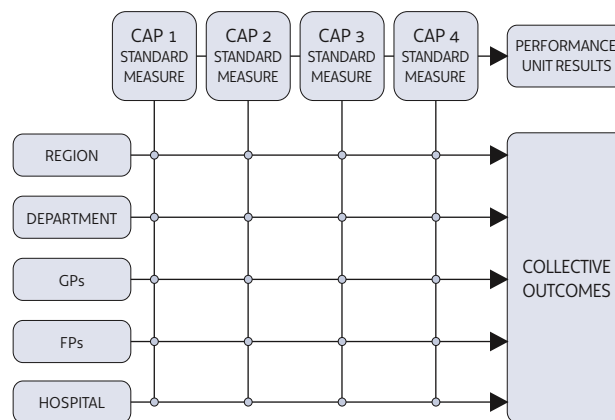


Fig.4

APPLICATION OF THE MANUAL TO THE VACCINATION PROCESS



The relevant standards are given under these main headings; within each of them are the “evaluation factors” along with the possible evidence requested.

The guarantee of quality within the network lies in the definition of the context of application of each standard and evaluation element. There is in fact variation that depends on the role played within the network of responsibility, such that not all hubs are concerned with all measurable elements, but each hub has its own list of elements it has to guarantee (Fig. 4).

In this edition of the manual, as in the previous version, it has been decided not to introduce a weighted evaluation of each individual measurable element and standard: the goal is not to make a listing or identify a cut-off below which to “close down” or “restructure” the hub; instead, partly encouraged by earlier results, the aim is to promote a culture of continuous improvement, partly on the basis of previous results. By not giving different weightings, all elements are actually set at the same level, therefore demanding even greater effort.



# 5.

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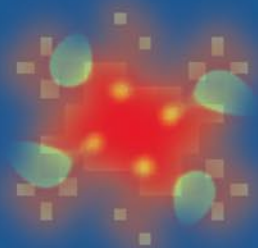
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# CHAPTERS AND STANDARDS



# 1

## POLICIES AND LEADERSHIP

The policies and strategies for immunisation within a (regional) community require the identification of various levels of responsibility that are inter-coordinated to ensure positive results in terms of functioning of services, impact on incidence of infectious and chronic degenerative diseases, and population health gains.

Those working within a (regional) system in positions of responsibility and guidance are required to offer efficacious leadership, that is, bringing a good mix of skills and know-how to relationships with people and working groups, understanding the various responsibilities and powers individuals hold, understanding the environment and context, in defining strategies of action and behaviour to channel management and use of resources towards set targets.

Vaccination policies form part of a large chapter on prevention, and should be understood as a process that goes beyond the simple administration of the vaccine. For an advanced health system, these policies need to be oriented such that at every point of a system where the process is in operation, certain characteristics are guaranteed:

- a) consistency with prevention strategies, their planning, management and monitoring;
- b) integration with all stakeholders (internal and external);
- c) process quality and safety.

All prevention activities involve the professional component very markedly. The vaccination process is no exception, and in particular is very much influenced by the knowledge, communication skills and drive of the health professionals involved, who need to be motivated, well trained and fully updated about the programme and its objectives.

## STANDARD 1

The responsibilities at the various phases of the process are identified, including definition of policies, management aspects, means of participating.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor					
1.1	The prevention and health promotion programmes are set out at the various levels in line with those at higher levels (local health agency, territorial and regional policy level)	National and regional vaccination plans	REG	LA	HOSP	DEP	GPs	FPs
			●	●	●	●	●	●
1.2	Those in charge of the processes at the various levels of the Regional Health Service have been identified	Evidence of the identification, plans, regulations, formal duties	REG	LA	HOSP	DEP	GPs	FPs
			●	●	●	●	●	●
1.3	Mandates for application of vaccination policies are defined at every organisational level	Deliberations, plans, minutes, formal information	REG	LA	HOSP	DEP	GPs	FPs
			●	●	●	●	●	●
1.4	Modalities and levels of integration with parties (internal and external) most involved in providing vaccinations are described	Agreements, planning documents on service networks, conventions	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●	●	●
1.5	The actions and related pathways set up to satisfy the system needs are included in the definitions of the process goals	Local health agency plan, requests for facilities or devices necessary	REG	LA	HOSP	DEP	GPs	FPs
			●	●	●	●	●	●
1.6	Those responsible determine the resource requirements and define the relative budget on an annual basis	Local health agency meeting minutes, budgetary charts, plans	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
1.7	Availability, access and use of documents regulating the process are guaranteed to all operators involved	Local health agency plans, internal documentation, regulations for the vaccination session	REG	LA	HOSP	DEP	GPs	FPs
			●	●	●	●	●	●

### NOTE

REG = regional level;  
 LA = local health agency;  
 HOSP = hospital level;  
 DEP = department of prevention level;  
 GPs = General Practitioners;  
 FPs = Family Paediatricians



## STANDARD 2

There is an organisation set up for planning and managing the vaccination process.

	<b>Evaluation factors</b>	<b>Possible evaluation evidence</b>	<b>Level of applicability of evaluation factor</b>					
			REG	LA	HOSP	DEP	GPs	FPs
<b>2.1</b>	Planning of activities at the various levels is set out	Programme time-scale, local health agency plan	●	●	●	●	●	●
<b>2.2</b>	The levels of responsibility and functions of the working team members are established	Local health agency documentation, official internal procedures		●		●	●	●
<b>2.3</b>	Those in charge define the organisation envisaged for provision of the vaccination process	Organisational chart			●	●		
<b>2.4</b>	The modalities for providing the vaccination process are specified	Guidelines, protocols, organisation of the service			●	●		

### STANDARD 3

There is a programme for improving quality, based on monitoring and evaluation.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor					
			REG	LA	HOSP	DEP	GPs	FPs
3.1	Those in charge have access to data and information for managing and improving the various phases of the process	Reports on progress of the vaccination campaigns, annual, six-monthly, etc	●			●		
3.2	Those in charge monitor the results and performance in their own areas of responsibility	Progress and analysis, reports from users and operators, clinical indicators		●		●		
3.3	A system is set up for regular monitoring of the progress of the programmes, based on assessment of process indicators and results	Programme for improving quality	●	●	●	●		
3.4	Those in charge incorporate these activities into the programme for improving quality (local health authority, regional...)	Reports on vaccination campaigns, comparison with previous years	●	●	●	●		
3.5	There is an internal system and it is applied	Presence of formal documentation of an audit carried out at least annually	●		●	●		
3.6	User expectations and satisfaction are examined; these data are used as input to a programme for improving quality	Data on user satisfaction and analysis of these data, meetings with user associations, the various stakeholders			●	●	●	●
3.7	Staff expectations and satisfaction are examined; these data are used as input to a programme for improving quality	Data on staff satisfaction and analysis of these data, verification meetings with service personnel, meeting minutes, ad hoc interviews			●	●	●	●

## STANDARD 4

There is a staff management policy that determines training requirements, incentivises the involvement of operators, and utilises their skills.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor					
			REG	LA	HOSP	DEP	GPs	FPs
4.1	The process for placing newly hired staff is set out	Procedure for placing new staff			●	●		
4.2	The frameworks for priority staff training are defined	Training plan	●		●	●	●	●
4.3	At least one activity relevant to training/ updating for each operator is recorded each year	Training courses, certifications, planning to meet training needs			●	●	●	●
4.4	Those in charge encourage communication and integration among internal parties involved in provision of the vaccination process	Encouragement of group working, communication protocols, meetings, etc.			●	●		
4.5	Staff members are involved in defining the goals and in development of the service programmes	Meeting minutes			●	●		
4.6	The service staff members are aware of the existence of the progress towards the targets	Meetings, distribution of reports, internal communications			●	●		
4.7	Those in charge assess staff performance	Contract, evaluation forms			●	●		

# 2 ■

## PREVENTION AND EDUCATION

Prevention and health education are elements that are essential and characteristic of the efforts required if health gains are to be achieved.

Vaccination policies and the vaccination process have traditionally been among the best known and best rooted instruments in the context of prevention, and can be considered teachable moments, where it is possible to go beyond the procedure itself, to inform and educate about risk factors and correct lifestyles.

The action of vaccination is understood as a process that has a 'before', a 'during' and an 'after'. It is an action that is not simply a medical-health issue, but also a moment of individual, family and also social time: it addresses the individual, but implies a background family, and at the same time is designed to achieve a result in public health for the whole community.

In the field of preventive activity, in particularly that of vaccination, the relationship between health operators and persons/citizens is changing, with a shift towards models that accent participation, where the aim is to inform and persuade the person concerned to adopt choices and behaviour proven to be able to bring about health gains.

It is therefore essential that the Regional Health Service – through its various actors (regional directorate, regional health agency, local health and hospital agencies, departments of prevention, GPs, FPs) – communicate with its own community (individual users and institutions more generally) through suitable forms of information and communication that take account of requirements, whether or not explicitly stated.

In this sense, it is particularly necessary to know how to operate in today's growing multi-ethnic and multi-cultural society, and to be able to tackle common cultural issues.

## STANDARD 1

Operators have the cultural instruments for involving the user and persuading him/her to play an active role in the decision-making process.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
1.1	There is evidence that all staff dedicated to vaccination activity participate every six months in meetings to gather and exchange information about the characteristics of the population served	Evidence of participation in meetings on the topic	REG HOSP DEP GPs FPs ● ● ● ● ●
1.2	There is evidence that all staff dedicated to vaccination activity participate regularly in meetings in which topics relevant to vaccination activity (changes to the vaccination calendar, new vaccines, etc.) are discussed	Meeting minutes	REG HOSP DEP GPs FPs ● ● ●

## STANDARD 2

Service staff members have access to well-organised up-to-date scientific material and activity data.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
2.1	All staff have access to national, regional and local health agency reference documentation regarding vaccination activity	Prevention plans, guidelines, scientific material	REG HOSP DEP GPs FPs ● ● ● ● ●
2.2	All staff have access to internet, to consult official websites regarding vaccinations (NIV - Italian vaccination network, etc.)	Access to PC, passwords, shared documentation system	REG HOSP DEP GPs FPs ● ● (●) (●)

(●) not obligatory in this first phase

### STANDARD 3

All staff put in place the process of vaccination counselling.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
3.1	Operators are given orientation for management of counselling	Respect of the regulations and attachments	REG HOSP DEP GPs FPs ● ● ● ●
3.2	There is evidence of regular retraining in vaccination counselling	Training plan and evidence of participation	REG HOSP DEP GPs FPs ● ● ● ●
3.3	The duration of the contact allows times long enough for counselling in terms of vaccination typology and calendar (in any case not less than 10 minutes)	Scheduling	REG HOSP DEP GPs FPs ● ● ● ● ●

### STANDARD 4

Health promotion campaigns are carried out for users where envisaged under health agency plans.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
4.1	Health promotion and prevention programmes - promoted by the department of prevention and the health agency - expect user involvement	Evidence of user involvement in the health prevention programmes	REG HOSP DEP GPs FPs ● ● ● ● ●
4.2	There is easy access to active programmes for the user	Internet information content	REG HOSP DEP GPs FPs ● ●
4.3	There is evidence of information initiatives carried out by the service for specific population targets (e.g., pregnant women)	Internet information content	REG HOSP DEP GPs FPs ● ●

# 3 ■

## SAFETY AND QUALITY

Safety and quality go hand in hand in any process of assistance. The aim is to avoid errors and deviations in the system. This requires action to be taken at the various levels within the system, taking into account all components that can directly or indirectly bring about a malfunction or error, and that could harm the person receiving the service.

Today it is required that the service can be shown to have reached its targets, or else to have sought the best possible solutions to the problems presented.

Available evidence shows that guaranteeing quality and safety requires an approach that integrates all those involved in the vaccination process, acting as a de facto indicator that the whole system is operating well.

## STANDARD 1

The working environments are suitable for the type of service being provided, the characteristics and number of users attending, and meet the minimum organisational needs as well as the requirements for safeguarding privacy and safety.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
1.1	There is a waiting room, for use as a pre-vaccination waiting area and for post-vaccination monitoring	Building plan, specifications of the areas	REG HOSP DEP GPs FPs ● ● ● ●
1.2	The waiting room is also designed to be suitable for children, with both a play-area and a more private section with baby-changing facility	Presence of suitable areas	REG HOSP DEP GPs FPs ● ●
1.3	Separate washrooms/toilet facilities are available for users and staff, as well as for the disabled where required by regulation	Presence of separate washrooms/toilet facilities for users and staff and/or disabled	REG HOSP DEP GPs FPs ● ● ● ●
1.4	The room is ventilated and has adequate lighting	Presence	REG HOSP DEP GPs FPs ● ● ● ●
1.5	Floors and walls are washable and can be disinfected	Presence	REG HOSP DEP GPs FPs ● ● ● ●
1.6	There is a suitable system for hand-washing (non-manually-operated washbasins or hand-rub)	Presence of suitable facilities	REG HOSP DEP GPs FPs ● ● ● ●
1.7	There is a bed with safety rail	Presence of suitable equipment	REG HOSP DEP GPs FPs ● ●
1.8	There are work surfaces and/or trolleys are present	Presence of suitable furnishing/equipment	REG HOSP DEP GPs FPs ● ●
1.9	There is an separate area for use as a changing room	Presence of suitable areas	REG HOSP DEP GPs FPs ● ●
1.10	There are separate spaces/rooms for storage of clean and soiled materials	Presence of suitable areas	REG HOSP DEP GPs FPs ● ● ● ●



## STANDARD 2

Safety laws in force are observed regarding prevention of risks in the working environment and protection of those accessing the services (users, operators, visitors).

	<b>Evaluation factors</b>	<b>Possible evaluation evidence</b>	<b>Level of applicability of evaluation factor</b>					
<b>2.1</b>	Instructions are present both outside and inside to enable users to gain access and find their way around	Presence	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
<b>2.2</b>	Facilitated access, free from architectural barriers	Presence	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
<b>2.3</b>	Programmes are in place to ensure all occupants of the structure are provided protection from fire, smoke and other emergencies	Training process for fire regulations, certifications, signs	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
<b>2.4</b>	The plan sets out all necessary procedures to be activated in the case of emergency (interventions for prevention, alarms, management of critical phases, evacuation where necessary)	Management of fire emergencies, signs with escape routes, location of extinguishers, etc.	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
<b>2.5</b>	The fire/smoke safety management plan is tested regularly, including the various devices for alarm-raising and extinction; the results are documented	Documentation of regular maintenance of extinguishers, hydrants, etc.	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
<b>2.6</b>	Availability of the minimum set of drugs and facilities as set out under the vaccination session regulations for dealing with health emergencies	Presence of drugs and facilities	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
<b>2.7</b>	Staff are trained and know the role each must assume in the case of technical and/or health emergency	Training course certifications	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●	●	●

### STANDARD 3

A good management programme is in place for equipment used and facilities present.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor					
3.1	There is documentation that equipment used is compliant with legislation	Documents certifying that the equipment is compliant with legislation (CE mark)	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
3.2	There is an official ordinary maintenance programme for the equipment	Certification of regular maintenance, annual, six-monthly, etc.	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
3.3	Monitoring data for the equipment maintenance programme are collected	Certification of regular maintenance, annual, six-monthly, etc.	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
3.4	The central structures have refrigerators fitted with minimum and maximum temperature monitoring systems (temperature recorder) and alarm system, and connected to a back-up generator	Presence of refrigerator with back-up battery	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
3.5	Peripheral structures have a refrigerator fitted with minimum and maximum temperature monitoring systems	Presence of refrigerator, minimum and maximum temperature with regular recording	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●	●	●
3.6	The electricity, water and other basic utility plants undergo regular inspection and maintenance when running correctly, and where necessary repaired	Presence of extraordinary maintenance documentation	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		
3.7	Instructions are given for how to request necessary interventions falling outside standard programmes	Written procedure for ordinary and extraordinary maintenance	REG	LA	HOSP	DEP	GPs	FPs
				●	●	●		

### STANDARD 4

A policy for prevention of work-related risks and for operator protection is clearly in place.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor					
			REG	LA	HOSP	DEP	GPs	FPs
4.1	There is documentation on the regular assessment of work-related risks	Risk assessment, etc.			●	●		
4.2	There is documentation showing that operators are informed, trained and have experience regarding these risks and how to prevent them	Training courses on safety (biological, chemical risk, etc.)		●	●	●	●	●
4.3	Operators have personal protection devices specific to the risks they are exposed to, and use them in their work environments	Training certification, application of personal protection devices on the basis of the training courses			●	●		
4.4	A policy of prevention of accident from biological risk and action to take in case of incident has been defined	Procedures			●	●		

## STANDARD 5

There is a system for monitoring, surveillance, control and prevention of events that threaten the safety of users and staff.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
5.1	Maintenance of the cold chain at all points of vaccination provision (including outside the service) is guaranteed	Presence of refrigerator with back-up battery and presence of portable refrigerator or similar, cold-chain maintenance plan, etc.	REG HOSP DEP GPs FPs ● ● ● ●
5.2	There is evidence that the vaccination process undergoes risk analysis, and that this analysis has led to improvements in the areas considered priority	Evidence of the analyses and interventions carried out	REG HOSP DEP GPs FPs ● ●
5.3	There is a specific procedure for managing expired vaccines	Specific procedure	REG HOSP DEP GPs FPs ● ● ● ● ●
5.4	Measures and procedures are in place for preventing risk of infection (adoption of standard precautions, including additional precautions where envisaged, procedures for correct hand-washing)	Presence of hand-washing protocols and the execution of these protocols, protocols for disposal of single-use material	REG HOSP DEP GPs FPs ● ● ● ●
5.5	Monitoring includes data about incidents and accidents occurring at the service (incident reporting) and these data are used as part of a programme for improving risk management	Existence of a reporting model, notification and analysis of the adverse events	REG HOSP DEP GPs FPs ● ●

# 4.

## THE VACCINATION PROCESS

In this manual, the vaccination process includes all phases of planning, right through to verification of the results of the vaccination activity, including responsibilities, necessary resources, time-scales and target results.

The creation of a documentation system in this sense represents the reference framework where procedures and protocols figure as instruments for reducing variability in behaviour and improving the safety of the process.

It follows that written procedures should be sought, possibly gathered in a manual available to all operators.

In this context, the regulations for the vaccination session, endorsed by the Friuli Venezia Giulia Region, represent a key instrument.

The process is split into: pre-vaccination phase; vaccination phase; post-vaccination phase.

### PRE-VACCINATION PHASE STANDARD 1

There is a documentation system for the specific activities related to the working processes of the vaccination service.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
1.1	The procedures give clear indication of the author	Verification of each procedure	REG HOSP DEP GPs FPs ● ● ● ● ●
1.2	The procedures give the date of the first version and any subsequent updates	Verification of each procedure	REG HOSP DEP GPs FPs ● ● ● ● ●
1.3	The procedures contain any relevant bibliographic references (regulatory and/or guidelines) to support the descriptions	Verification of each procedure	REG HOSP DEP GPs FPs ● ● ● ● ●
1.4	The procedures are officially endorsed at levels envisaged	Deliberation, endorsement by the person in charge as indicated	REG HOSP DEP GPs FPs ● ● ● ● ●
1.5	The procedures have been distributed to the operators	Documents transmitted, meeting minutes	REG HOSP DEP GPs FPs ● ● ●

## STANDARD 2

The policy for vaccine procurement is clearly defined.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
2.1	Vaccine procurement is consistent with policies set out at regional and local health agency level	Decrees, regional health agency regulations	REG HOSP DEP GPs FPs ● ● ●
2.2	There is a budget drawn up annually for vaccine procurement that is consistent with the regional and local health agency goals	Budgetary charts	REG HOSP DEP GPs FPs ● ● ●
2.3	For the various different types of vaccine, procurement procedures set out definition of quality standards	Written procedures regarding quality standards	REG HOSP DEP GPs FPs ●
2.4	The vaccine quality standards are defined by the service staff taking into account the best available scientific evidence	Written report	REG HOSP DEP GPs FPs ● ●
2.5	The supply of vaccines anticipates interaction between those expressing the need for vaccines and those in charge of procurement (including the Centro Servizi Condivisi regionale, the Region's Common Services Centre, where envisaged)	Specific procedure	REG HOSP DEP GPs FPs ● ● ●

## STANDARD 3

There is a procedure for planning and organising the vaccination session.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
3.1	The procedure sets out the description of obligatory and recommended vaccinations	National and regional instructions	REG HOSP DEP GPs FPs ● ● ● ● ●
3.2	The procedure sets out the distribution of vaccinations for children and adults	National and regional instructions	REG HOSP DEP GPs FPs ● ● ● ● ●
3.3	The procedure sets out the management of the calls	Procedure	REG HOSP DEP GPs FPs ●
3.4	The procedure sets out the management of failures	Procedure	REG HOSP DEP GPs FPs ●
3.5	The procedure describes the cases and modalities for carrying out counselling and protection for international travellers	Circulars, scientific documentation	REG HOSP DEP GPs FPs ●

## VACCINATION PHASE STANDARD 4

The organisational context for provision of the vaccination is defined, as are the responsibilities of the operators involved.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
4.1	The vaccination session regulations approved by the Region are available in the workplace	Presence of the regulations	REG HOSP DEP GPs FPs ● ● ● ● ●
4.2	The doctor is present within the structure where the vaccination session is being held and intervenes to handle cases as required by the professional operator	Presence as required under the regulations	REG HOSP DEP GPs FPs ● ● ● ●
4.3	The professional operator has been formally tasked with the vaccination activity and can be identified	Internal selection and presence of identification, service uniform	REG HOSP DEP GPs FPs ● ●
4.4	Before beginning the vaccination session, the professional operator makes the necessary preparations and carries out due controls in accordance with requirements set out under the regional regulations	Procedure as under the regulations	REG HOSP DEP GPs FPs ● ● ● ●
4.5	The professional operator carries out unequivocal identification of the party to be vaccinated	Regulations respected	REG HOSP DEP GPs FPs ● ● ● ●
4.6	The professional operator carries out pre-vaccination counselling	Regulations respected	REG HOSP DEP GPs FPs ● ● ● ●
4.7	The professional operator follows the procedures envisaged for carrying out vaccination	Regulations respected	REG HOSP DEP GPs FPs ● ● ● ●
4.8	The professional operator enters the data about the person vaccinated into the regional computer system (personal data, type of vaccine, doses to administer at a later date, when to administer them)	Data in the regional computer system inspected	REG HOSP DEP GPs FPs ● ●
4.9	The professional operator is trained in first aid and cardio-pulmonary resuscitation procedures	Certification for participation in BLS and PBLIS courses	REG HOSP DEP GPs FPs ● ● ● ●

## STANDARD 5

There is a specific procedure for each type of vaccine.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
5.1	The procedure specifies the instructions for the vaccination	National and regional instructions, scientific documentation	REG HOSP DEP GPs FPs ● ● ● ●
5.2	The procedure specifies case-history and assessment of the anti-body titres	Regulations, procedures (case-histories, check-list..)	REG HOSP DEP GPs FPs ● ● ● ●
5.3	The procedure specifies the vaccination calendar	National and regional instructions	REG HOSP DEP GPs FPs ● ● ● ●
5.4	The procedure specifies the contraindications	Vaccination session regulations and attachments	REG HOSP DEP GPs FPs ● ● ● ●
5.5	The procedure specifies the possible interactions	Vaccination session regulations and attachments	REG HOSP DEP GPs FPs ● ● ● ●
5.6	The procedure specifies the vaccine inoculation sites	Local health agency procedure	REG HOSP DEP GPs FPs ● ● ● ●
5.7	The procedure specifies the doses to be administered	Technical information sheets	REG HOSP DEP GPs FPs ● ● ● ●
5.8	The procedure specifies that the user shall have access to specific information material for each individual vaccine, explanation of the incidence of adverse reactions and of the risk-benefit relationship of the vaccinations, in order that informed consent can be given	Technical information sheets	REG HOSP DEP GPs FPs ● ● ● ●
5.9	The procedure specifies that informed consent shall be expressed/given	Vaccination session regulations and attachments	REG HOSP DEP GPs FPs ● ● ● ●



## POST-VACCINATION PHASE

### STANDARD 6

The person being vaccinated is guaranteed post-vaccination assistance.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
6.1	The professional operator who has carried out the session undertakes post-vaccination health surveillance as described under the regulations	Verification of behaviour in accordance with the vaccination session regulations	REG HOSP DEP GPs FPs ● ● ● ●
6.2	The professional operator provides information and advice about any possible post-vaccination side-effects, as well as information material as set out under regulations attachment E)	Verification of behaviour in accordance with the vaccination session regulations	REG HOSP DEP GPs FPs ● ● ● ●

### STANDARD 7

On completion of the vaccination session, full clean-up of the workplace is ensured.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
7.2	The provisions of procedures for waste collection and disposal are applied	Existence of procedure, verification that behaviour matches content	REG HOSP DEP GPs FPs ● ●
7.3	The provisions of procedures for environmental health and equipment are applied	Existence of procedure, verification that behaviour matches content	REG HOSP DEP GPs FPs ● ●
7.4	The provisions of procedures for environmental health and equipment are applied	Existence of procedure, verification that behaviour matches content	REG HOSP DEP GPs FPs ● ●
7.5	The provisions of procedures for regular checking of all drugs, stock and materials subject to expiry are applied	Existence of procedure, verification that behaviour matches content	REG HOSP DEP GPs FPs ● ●

# 5.

## INFORMATION MANAGEMENT

The management of information concerning the vaccination process should include all information that is relevant (e.g., regarding internal processes, and service performance) and useful to the information requirements of the regional health system and of the user.

It is important that the service:

- expresses its own information requirements,
- gives the sources of the data and information,
- specifies the processing applied to these data,
- indicates the system for transmission and reporting.

The information system should therefore allow for assignment of responsibility in the management and use of the data, the type of data, description of data flows, accessibility levels, provisions for protection and checking of the data.

In examining the information system architecture and characteristics of the databases, it is essential that attention be given to application of the minimal security measures as set out under regulations in force.

The process concerning service information demands not only management of data used internally, but also takes account of the whole field of information of interest to the user.

In addition, the service organisation and type of offer guaranteed as regards usefulness to the citizen should be given: type of service given, times, places and means of provision, as well as means of service call-up/alerts. This should be consistent with the standards of **Chapter 2** Prevention and Education and **Chapter 7** Emergencies.

### STANDARD 1

There is a user manual for the SIR (sistema informativo regionale, regional computer system) vaccination line that sets out access procedures for:

	<b>Evaluation factors</b>	<b>Possible evaluation evidence</b>	<b>Level of applicability of evaluation factor</b>
<b>1.1</b>	Data recording and management	Online manual	REG HOSP DEP GPs FPs ● ● ● ●
<b>1.2</b>	Management of calls	Online manual	REG HOSP DEP GPs FPs ●
<b>1.3</b>	Management of the store	Online manual	REG HOSP DEP GPs FPs ●
<b>1.4</b>	Recording of adverse reactions	Online manual	REG HOSP DEP GPs FPs ●
<b>1.5</b>	Calculation of immunisation coverage	Online manual	REG HOSP DEP GPs FPs ● ●

### STANDARD 2

There is evidence of application of security measures regarding data privacy.

	<b>Evaluation factors</b>	<b>Possible evaluation evidence</b>	<b>Level of applicability of evaluation factor</b>
<b>2.1</b>	People in charge and working on data-processing are officially nominated	Names written down in official document	REG HOSP DEP GPs FPs ● ● ● ● ●
<b>2.2</b>	All operators authorised to work on data-entry are provided with personal passwords	Existence of the passwords	REG HOSP DEP GPs FPs ● ● ● ●
<b>2.3</b>	Printed documents are protected from external access	Lockable cupboards and archives	REG HOSP DEP GPs FPs ● ● ● ● ●
<b>2.4</b>	Official instructions exist regarding how to access and release data and certificates in full respect of privacy	Names written down in accordance with regulations	REG HOSP DEP GPs FPs ● ● ● ● ●

### STANDARD 3

The data are entered in to the SIR (regional computer system) in real-time, or at least systematically and promptly.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
3.1	Operators are able to access vaccination data in real-time	Presence of SIR (regional computer system), paper-based archive	REG HOSP DEP GPs FPs ● ● ● ●
3.2	Operators are able to enter/manage vaccination data in real-time (during a day)	Presence of SIR (regional computer system) – daily printing or other	REG HOSP DEP GPs FPs ● ●
3.3	GP/FP operators forward vaccination data promptly (maximum one month) to the department	Forwarding of certifications	REG HOSP DEP GPs FPs ● ●

### STANDARD 4

Adequate and complete information about the vaccination service and activity are available to the user.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
4.1	Information s available to the user (paper-based, online, etc.)	Website, illustrative leaflets, etc.	REG HOSP DEP GPs FPs ● ● ● ●
4.2	The user is informed about how the service is organised: opening times, waiting times, telephone contacts	Service charter, booklets, PR office (Ufficio Relazioni con il Pubblico), website	REG HOSP DEP GPs FPs ● ● ● ●
4.3	There is a vaccination information booklet, and this is issued at birth	Presence of the booklet	REG HOSP DEP GPs FPs ●

# 6

## PERFORMANCE

Accrediting a process that involves various different professionals and organisational levels means breaking down the system’s overall performance into the various process phases and their individual performances, then building up an overall assessment.

The performances explored here are represented by the outcomes of the vaccination process, both quantitatively (output) and qualitatively, such as impact on health and distribution to all those concerned.

### STANDARD 1

There is evidence that the service activity meets the health goals set by the department of prevention.

	<b>Evaluation factors</b>	<b>Possible evaluation evidence</b>	<b>Level of applicability of evaluation factor</b>
<b>1.1</b>	Total immunisation coverage levels and levels specific for the vaccine are given	Service report, official documents	REG HOSP DEP GPs FPs ● ● ● ● ●
<b>1.2</b>	The morbidity levels of all vaccine-preventable infectious diseases are given	Report notifying infectious diseases	REG HOSP DEP GPs FPs ● ● ●
<b>1.3</b>	There is evidence that data on incidence of vaccine-preventable diseases are reported to the operational services	Meetings, reports, evidence	REG HOSP DEP GPs FPs ● ●
<b>1.4</b>	Service performance indicators are comparable	Summary reports	REG HOSP DEP GPs FPs ● ● ●
<b>1.5</b>	Intra-agency performances are assessed and compared for individual vaccination centres – CRM (codici regionali medici, GP/FP regional registration no.)	Report	REG HOSP DEP GPs FPs ● ● ● ●

## STANDARD 2

There is evidence that parties not responding to direct calls are contacted by the vaccination centre.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
2.1	The reasons for failure to respond to the call are analysed	Service report	REG HOSP DEP GPs FPs ● ● ● ● ●
2.2	Cases of non-consent to vaccination are analysed and interpreted, and trigger mechanisms for reassessment of the vaccination policies of the service	Service report	REG HOSP DEP GPs FPs ● ● ●

## STANDARD 3

Adverse reactions are constantly monitored.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
3.1	There is evidence that those administering vaccines are facilitated in communicating the adverse reactions	Procedure for communication methods	REG HOSP DEP GPs FPs ● ● ● ● ●
3.2	The adverse reactions are regularly analysed and communicated to the structures concerned (regional, national and European notification structures)	Adverse reactions report	REG HOSP DEP GPs FPs ● ● ●

## STANDARD 4

A report on the activity of the service is drawn up.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
4.1	A progress report is produced at least annually, giving a summary and describing progress towards objectives	Report	REG HOSP DEP GPs FPs ● ● ●
4.2	The report covers data regarding immunisation coverage, morbidity and mortality for diseases and adverse reactions to the vaccine	Report	REG HOSP DEP GPs FPs ● ●
4.3	The report is distributed without delay to service operators, local health agency structures, GPs/FPs and those with whom the service deals (stakeholders)	Evidence of the communications, report, internet site (letter of transmission, meetings, etc.)	REG HOSP DEP GPs FPs ● ●

## STANDARD 5\*

User satisfaction is evaluated.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
5.1	The user or family members has the possibility of making comments/ observations about the activity of the service	Forms to complete - box for their collection	REG HOSP DEP GPs FPs ● ● ● ●
5.2	Complaints/comments by the user are regularly analysed and interpreted by the operators	PR office (Ufficio Relazioni con il Pubblico)	REG HOSP DEP GPs FPs ● ●
5.3	Regular investigations are carried out into service user satisfaction	Analytical report, questionnaires, telephone surveys	REG HOSP DEP GPs FPs ● ●
5.4	The results of the investigations trigger processes of service improvement	Project for improving quality	REG HOSP DEP GPs FPs ● ●

## STANDARD 6\*

The atmosphere within the service is regularly assessed, as an indicator of the level of satisfaction of its operators.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
6.1	Recorded satisfaction of operators in their own work and the work they carry out regarding organisation of the service in which their activity is carried out	Regular meeting minutes	REG HOSP DEP GPs FPs ● ●
6.2	There are indicators for measuring level of satisfaction, and they are being used	Evidence (absences, participation)	REG HOSP DEP GPs FPs ● ●
6.3	Where problems come to light, there are documented initiatives for improving the situation and verifying the results	Meeting minutes	REG HOSP DEP GPs FPs ● ●
6.4	There is evidence of application of staff reward systems	Incentives, updates, recognition	REG HOSP DEP GPs FPs ● ●

\* See also Chapter 1 Policies and Leadership and 3 Safety and Quality, which should be read in conjunction with these tables.

# 7

## EMERGENCIES

Those working in vaccination, whether individual or services, may be required to handle three different types of emergency situation:

- pandemics
- natural disasters
- bio-terrorism (e.g. smallpox).

Handling these emergencies requires a network of professionals and services involved in the vaccination process. Actors participating in the network are not just part of the health services, but also of other sectors such as civil defence.

Communication within the network is an important factor, and allows its participants to know what events may occur, when and how to activate the network (define an activation code, for example), and how to operate in a coordinated way.

Management of vaccine-preventable emergencies also requires management of communication with the media, provision of information and raising public-awareness on what should be done to control the event (definition of a communication plan, choice of spokesperson).

Efficacious emergency management requires effective and regular training in methods for network activation. Overall, each “professional and service” actor must know:

- the flows and pathways for giving notification of situations arising;
- how to access clinical and preventive diagnostic information;
- what guidelines to adopt for coherent management of the event.

In addition, each actor must undergo regular training, including staff practice exercises.



## STANDARD 1

The department of prevention has a plan for handling a vaccine-preventable emergency.

	<b>Evaluation factors</b>	<b>Possible evaluation evidence</b>	<b>Level of applicability of evaluation factor</b>
<b>1.1</b>	There is a regional plan for infectious emergencies, which involves the main actors such as hospitals, prevention departments, GPs or FPs	Regional emergency plan	REG HOSP DEP GPs FPs ●
<b>1.2</b>	The department of prevention/ vaccination service keeps updated and makes available lists of priority and complication risk group categories to be vaccinated in case of emergency/ pandemic	Up-to-date list of categories at risk (the elderly >65 years, the immuno-suppressed, health workers, schools, institutes, military structures, etc.)	REG HOSP DEP GPs FPs ● ● ●
<b>1.3</b>	An inventory is available of spaces within the health agency, of staff who will administer the vaccine in the case of emergency/pandemic	Local health agency internal spaces	REG HOSP DEP GPs FPs ● ● ●
<b>1.4</b>	There is an organisational plan for identifying vaccine storage procedures	Plan and inventory	REG HOSP DEP GPs FPs ● ● ●

## STANDARD 2

There is evidence that the service forms part of a network of structures and professionals set up to manage vaccine-preventable emergencies.

	Evaluation factors	Possible evaluation evidence	Level of applicability of evaluation factor
2.1	Department of prevention is authorised to access the databases of infectious diseases, hospital discharge sheets, mortalities	Access to databases, presence of authorisation	REG HOSP DEP GPs FPs ●
2.2	Up-to-date list available of all GPs, FPs and up-to-date list of hospital doctors in the territory concerned, with relevant addresses, telephone, fax numbers and e-mail addresses	Full list of addresses	REG HOSP DEP GPs FPs ●
2.3	The reference laboratories for diagnosis of individual pathologies have been identified	Procedure and list of laboratory with the special reference examinations	REG HOSP DEP GPs FPs ● ● ●
2.4	This is an alert plan that includes communication in case of emergency to structures hierarchically above or below the vaccination centre	Communication, alert plan	REG HOSP DEP GPs FPs ● ● ● ● ●
2.5	There is a plan to ensure rapid deployment by health operators of services for managing public health interventions	Presence of the plan	REG HOSP DEP GPs FPs ● ●



May 2008 Edition

