

## ORIGINAL ARTICLE

# Suspension of mandatory vaccination and public health preserving: Rovigo Local Health Unit experience after appliance of Veneto regional law 7/2007

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## Key words

Mandatory and recommended vaccinations • Regional Law 7/2007 • Immunization coverage rates

## Summary

*The burden of infectious diseases preventable by vaccination decreased considerably over last decades in all countries provided with effective immunization schedules. Implementation of these programs with new vaccines has started discussion on duality between mandatory and recommended vaccinations. Regional autonomy has allowed the Veneto Region, with introduction of Law 7/2007, to experience suspension of all mandatory childhood vaccinations, replaced by an active and free offer of all vaccines recognized as safe and effective. Coverage's trends and acceptance of invitation are carefully monitored to avoid loss of compliance and reduction of immunized children. The evaluation, performed on population of Rovigo ULSS18 for 2002-2008 birth cohorts (2008 is the first concerned by the change), revealed no fall for previously mandatory vaccinations, but rather a slight increase. Percentage of non-vaccinated children was negligible.*

*The leading cause of non-vaccination to polio was inability to deliver the letter of invitation due to wrong address. An informed dissent was expressed only by a minority (0.9% in 2008 birth cohort).*

*Compliance to immunization offer was elevated both for previously compulsory and recommended vaccinations. Experience of Rovigo ULSS 18 showed that, in a context of already high levels of coverage for recommended vaccinations with optimal organization of immunization services, coverage rates for ex-mandatory vaccines remain unchanged. Further research and reports are required to carefully assess the effect on coverage rates in next birth cohorts, but available data are encouraging. Similar legislative measures can be successfully adopted by other Regions with starting conditions comparable to Veneto Region.*

## Introduction

Vaccinations are an effective prevention tool for maintaining the health of the individual and society as a whole and have significantly increased life expectancy and quality [1, 2]. Smallpox was officially declared eradicated by the World Health Organization (WHO) in 1980, all industrialized countries are considered "polio-free", while other important infectious diseases such as diphtheria, tetanus and hepatitis B reached a significant reduction [3-5], with important benefits for childhood, by the planning of vaccination campaigns and development of national pediatric immunization schedules in many European countries [6, 7].

Strategies adopted by European Union countries to achieve and maintain high immunization rates in target population include compulsory and recommended vaccinations, free of charge and co-payment offer. Some countries have preferred mandatory vaccinations such as France, Greece, Portugal and Italy (for some pediatric vaccines); others, such as the United Kingdom, voluntary decision supported by appropriate service offer, incentive for caregivers and health education. Others, like USA, Canada and Germany, opted for a middle way (no

sanctions for non-vaccination, but need for a certificate of admission to school) [8-10].

According to latest edition of national immunization schedule, Italian children are mandatory vaccinated against polio, diphtheria, tetanus and hepatitis B, while vaccinations against pertussis, measles, mumps, rubella, pneumococcus, meningococcus and invasive forms of *H. influenzae* type B are recommended [11]. This difference is merely theoretical since no coercion is actually performed for parents who express their dissent to compulsory vaccinations.

Accomplishment of mandatory vaccinations and successful extensive immunization programs permitted prevention of many infectious diseases which resulted in lower concern about them while, nowadays, worsening attention to side effects and availability of new vaccines has progressively increased burden of commitment within vaccination policy. Current scenario is also complicated by strongly varied regional framework in immunization schedules (determined by modification of Title V of Constitution), by inadequate information on low risk in terms of safety and significant benefits concerning protection that facilitate activity of antivaccinal groups.

All Italian National Vaccine Plans (NVP), from 2005 to present, notice the opportunity to begin a cultural and social awareness growth to overcome difference between compulsory and recommended vaccinations, inviting to same active offer for both vaccine groups, in favor of a modern approach, based on health education, health promotion and patient self-determination. Regions which possess following characteristics are encouraged to move towards abolition of mandatory vaccinations: an effective information system with well organized vaccines register; adequate immunization coverage; a sensitive and specific surveillance system of communicable diseases, are able to mix corporate/regional data flows; a good system of monitoring vaccine adverse events, are able to ensure appropriate follow up of cases.

Piedmont, for example, introduced in 2006 a method of simplification of immunization offer, defining priority vaccines (proposed free and in active manner) and all other vaccines (available in health care organizations at cost) obtaining very satisfactory results in terms of agreement [12]. Tuscany, instead, eliminated distinction between mandatory and recommended vaccinations in 2007 and 2010 through Tuscan Vaccine Schedules [13, 14]. Only recently [15] Autonomous Province of Trento started a step-by-step overcoming of compulsory vaccination in children, depending on achievement of provincial immunization coverage percentage not less than that expected by the NVP and in absence of conflicting epidemiological evaluations.

With Regional Law 7/2007 "Suspension of mandatory vaccination for children and adolescents" [16], Veneto Region has suspended obligation of compulsory immunizations for all infants born from 1 January 2008, confirming that they still are included in essential level of assistance and therefore free and actively offered by the Local Health Units (ULSS) and part of immunization schedule, periodically reviewed and approved by the Regional Council in accordance with NVP guidelines. A monitoring plan of vaccination system, shared with Ministry of Health and Superior Institute of Health, must ensure vaccination coverage achieves at least 95% of newborns, otherwise obligation suspension is stopped. President of Regional Council may also come back to previous system, if significant epidemiological events occur or if the content of the document drafted by the Technical Scientific Committee, expressly created, signals an alarm situation with regard to immunization coverage rates.

This paper aims to analyze whether innovations introduced by Veneto Regional Law 7/2007 have modified immunization coverage rates and parents participation in vaccination acceptance. Levels of vaccination coverage achieved in Local Health Unit of Rovigo (ULSS18) at 24 months in children born in 2002-2008 regarding immunizations for which obligation is suspended (including an estimate of non-vaccination against polio percentage and reasons for non-vaccination) and immunization rates for some recommended vaccinations (pertussis, *H. influenzae* B, measles, mumps and rubella) are considered.

For birth cohorts 2006-2011, we assessed percentage of children who have received, within the first year of life, full or partial cycle of vaccination against diphtheria, tetanus, pertussis, hepatitis B to detect possible differences between before and after the appliance of Regional Law 7/2007. Similarly we considered non-compulsory vaccinations against pneumococcus (partial and complete cycle), meningococcal C, measles-mumps-rubella (MMR) and chickenpox (one dose) to examine whether high levels of adhesion to recommended vaccinations were confirmed even after suspension of compulsory vaccination.

## Materials and methods

Records were obtained from two regional forms adopted for monitoring vaccination activities: Model 19 for coverage rates and Enclosure C for immunization acceptance. In both cases adjusted rates were calculated by dividing number of administered doses by number of children born in investigated cohort excluding unreachable (e.g. domiciled abroad and untraceable).

### IMMUNIZATION COVERAGE RATES

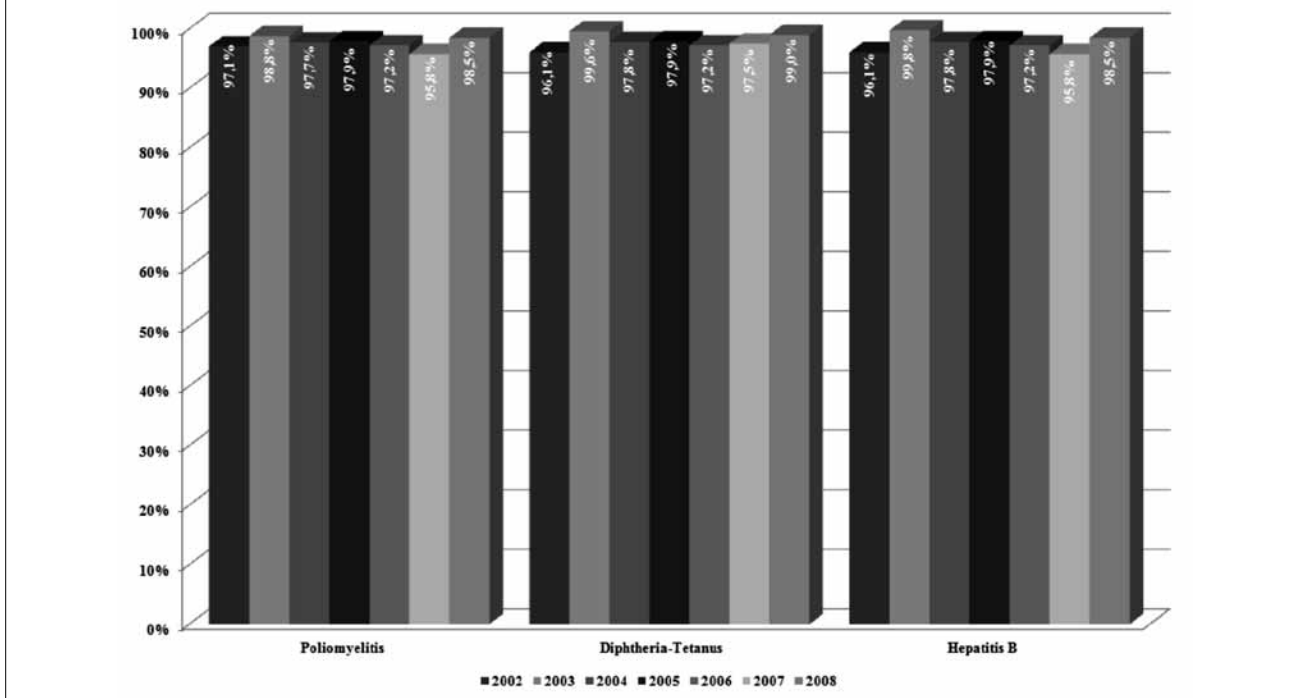
Data on immunization coverage were collected from annual survey form (so called Model 19) that each ULSS annually transmit to Veneto Region in order to assess coverage rates. Years from 2004 to 2010 were considered, therefore, vaccination coverage refers to birth cohorts 2002-2008 (2008 birth cohort is the first affected by the suspension of immunization compulsoriness). According to regional directives, we examined immunization coverage at 24 months as the number of completed vaccinations in children born two years before the year of reference. Coverage rates at 24 months were assessed as well as for previously mandatory vaccines (polio, diphtheria, tetanus and hepatitis B) as for those against pertussis, *H. influenzae* B (HiB), measles, rubella and mumps.

In addition, qualitative analysis of reasons for polio non-vaccination was performed.

### COMPLIANCE TO VACCINATION PROPOSAL AFTER SUSPENSION OF OBLIGATION

Trends in immunization offer acceptance were calculated from regional form, called Enclosure C, that each ULSS send to Department Prevention Services - Promotion and Development of Hygiene and Public Health of Veneto Region twice a year (March 31 and September 30) in order to strictly monitor vaccination compliance. Number of doses administered to newborns divided in cohorts, according to three previous semesters are recorded, e.g. the detection of 30 September 2011 considered separately children born in the first half of 2010, those born in the second half of 2010 and those born in the first half of 2011 in order to assess vaccines received within 6, 12 and 18 months from birth respectively. Presented data relate to three doses of hexavalent and anti-pneumococcal vaccines

Fig. 1. Rovigo ULSS18 coverage rate at 24 months for formerly mandatory vaccinations (birth cohorts 2002-2008).



and first dose of measles, chickenpox, rubella, mumps and meningococcal C vaccines in the period September 2007- September 2011.

## Results

Coverage percentages at 24 months for the vaccines for which suspension of compulsory immunization was introduced are shown in Figure 1. For each vaccination and for each birth cohort considered, 95% coverage, set by Region as goal, was always exceeded. For birth cohort 2008 percentage of vaccinated children, that under mandatory tended to decrease, showed an increase compared to previous birth cohort, reaching 98.5% for polio and hepatitis B and 99% for diphtheria-tetanus.

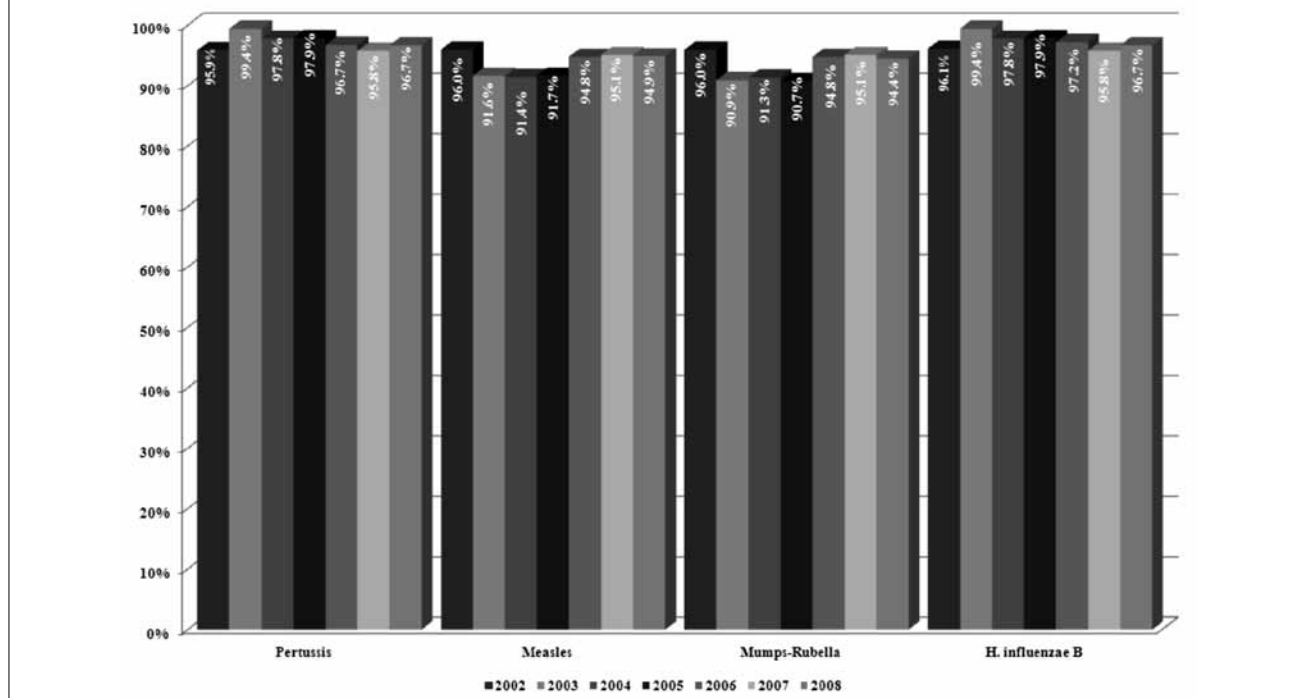
Figure 2 refers to formerly recommended vaccinations. The percentage of children vaccinated against pertussis and HiB at 24 months after birth was always fully satisfactory and, in the first cohort affected by the suspension of obligation, amounted to 96.7%. Measles, mumps and rubella vaccinations, that in cohort 2002 recorded a coverage of 96%, has shown, over the years, a marked reduction, however, in recent years percentage of vaccinated children has increased to 94.9% for measles and 94.5% for mumps and rubella.

The motivations of non-vaccination against polio at 24 months after birth are indicated in Figure 3. The leading cause was the inability to contact parents and deliver invitation to vaccination because they moved abroad, do not have a fixed address or are untraceable. Exemptions for health reasons have been sporadic and did not occurred after 2005.

Since 2007, standard definitions to define several types of vaccination postponement have been broadened considering also vaccination delay. Proportion of children actually defaulting vaccination (having expressed an informed dissent) was a minority, but the percentage showed an increasing trend from 0.2% in 2002 cohort to 0.9% in 2008 cohort.

Suspension of compulsory vaccination requires a closely monitoring of the compliance to immunization offer. Data collected every six months, before and after suspension of compulsory vaccination, are reported in Table I. The monitoring do not have the purpose of determine vaccine coverage, that can be estimated on consolidated data at 24 months of life, but to evaluate performance of immunization activities on cohorts of newborns to make a comparison over time and between ULSS (benchmarking), therefore it should not concern the detection of percentages slightly lower than 95% even for previously mandatory vaccinations. Proportion of children receiving hexavalent vaccine has always been elevated and a steady increase, more pronounced for the third dose, has been recorded. In all measurements, the percentage of vaccinated children has reached levels ranging from acceptable (90-94%) and desirable ( $\geq 95\%$ ). Vaccination against pneumococcal presented a comparable situation, with a more marked rise for third dose passing from 33% in September 2007 to 64% in September 2011. Percentage of children vaccinated against meningococcal (offered from the thirteenth month) was stable around 90%. Measles-mumps-rubella and chickenpox vaccinations starting from very lower rates of acceptance (respectively 72.3 and 67.3%) showed an increase, reaching levels fairly above 80%, always remaining within a not satisfactory range.

Fig. 2. Rovigo ULSS18 coverage rate at 24 months for formerly recommended vaccinations (birth cohorts 2002-2008).



## Discussion and conclusions

Regional autonomy has allowed, in healthcare sector, the undertaking of an important initiative of Public Health such as that started by Veneto Region with the promulgation of Regional Law 7/2007 that, overcoming the dichotomy between mandatory and recommended vaccinations, meets the growing demand of citizens for self-determination in choices regarding their health by introducing a legislative action with a European outlook. The debate on recommended or mandatory vaccinations has also collected conflicting opinions because it raises several ethical issues. The possibility for Regions to independently determine vaccination schedule and introduce new vaccines and methods of promotion has created a national framework strongly non homogeneous which could have a negative impact on immunization programs and, apparently, does not ensure equal access

to immunization. Furthermore, at first sight, the comparison between countries that only recommend certain vaccinations and countries that force them does not seem to show remarkable differences [17, 18].

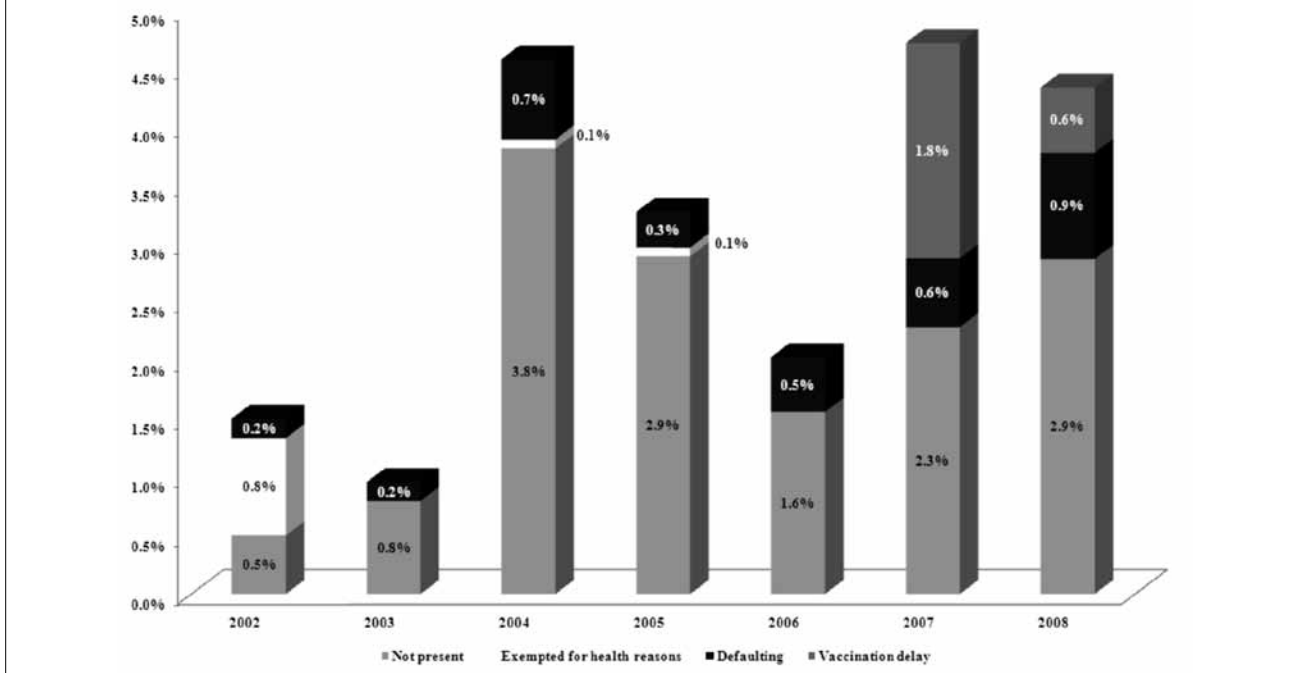
The experience of Rovigo ULSS18 showed that, in a context of already high levels of coverage for recommended vaccinations, rates for ex-mandatory immunizations remain unchanged. Results obtained in the 2008 birth cohort, the first involved in the suspension of the obligation, showed that no loss of coverage occurred for previously mandatory vaccines, in fact coverage rates moved from values ranging from 95-97% in previous birth cohorts to 98.5 for poliomyelitis and hepatitis B and to 99 for diphtheria and tetanus in 2008 birth cohort [19]. Obviously available data on a single birth cohort are too limited to express a judgment of full validity of the Regional Law, therefore it will be necessary to continue to monitor levels of vaccination coverage and offer compliance in order to

Tab. I. Compliance to vaccines offer.

	Sept 2007	Mar 2008	Sept 2008	Mar 2009	Sept 2009	Mar 2010	Sept 2010	Mar 2011	Sept 2011
Hexavalent vaccine (dose 1)*	93.5	95.3	95.9	96.1	94.6	95.5	98.0	96.0	94.9
Hexavalent vaccine (dose 2)	94.4	94.8	95.2	96.9	96.9	96.4	96.0	97.3	97.2
Hexavalent vaccine (dose 3)	90.8	92.5	91.8	95.6	94.5	93.7	92.4	93.0	95.3
Pneumococcal vaccine (dose 1)	88.2	94.1	93.3	93.5	93.2	92.9	95.9	95.4	94.0
Pneumococcal vaccine (dose 2)	87.8	92.3	93.1	93.9	94.9	94.5	94.0	95.9	95.2
Pneumococcal vaccine (dose 3)	33.2	38.5	36.5	54.6	61.2	45.9	59.0	54.6	64.1
Meningococcal vaccine	89.2	91.7	89.1	93.7	90.9	87.2	90.1	90.1	92.2
Measles-Mumps-Rubella	72.3	75.2	78.3	84.3	84.3	78.4	83.0	82.6	84.9
Chickenpox	67.3	71.8	67.7	74.5	75.4	72.7	78.7	78.5	81.8

\* Hexavalent vaccine contains poliomyelitis, diphtheria, tetanus, pertussis, hepatitis B, H. influenzae B vaccines.

Fig. 3. Percentage of children at 24 months not vaccinated against polio according to motivation that led to non-vaccination (birth cohorts 2002-2008).



Not present includes domiciled abroad, nomads, homeless, not traceable.

highlight situations of deviation from expected value before warning situation occurs.

Opponents of this law consider that liberalization in the field of immunization poses a threat to consolidated practices of Public Health with the risk of decreasing vaccine coverage and increase the number of cases of infectious diseases easily preventable. However, first monitoring data are fully encouraging and demonstrate that there were no changes with regard to coverage, while acceptance of immunization offer remained constant for ex-mandatory and was even growing for ex-recommended vaccinations. In that regard, it should be noted that the legislative measure adopted by Veneto provides for a constant monitoring of vaccination coverage and compliance to invitation, a rigorous epidemiological surveillance of infectious diseases for which the requirement of vaccination is suspended, and immediate suspension of the Regional Law 7/2007 when coverage levels fall below the established threshold or in case of significant epidemiological events related to the disease for which the vaccination requirement is suspended.

The developed delivery system of vaccinations appears able to allow the suspension of mandatory vaccinations without risk to coverage, continuing to ensure a strong adhesion to all available vaccinations, as it is characterized by some essential elements: a strong degree of integration of vaccination services with pediatricians and family physicians; active and free offer of all vaccinations recognized as safe and effective; computerized immunization database that allows rapid recovery of non-adhesion to first call; the remarkable cultural

maturity reached by population that is constantly affected by actions of counseling and health education.

These observations support the conclusion that similar legislative measures can be adopted with comparable success, as advocated by NVP 2012-14, also in other Italian Regions, provided that they possess specific starting conditions: high levels of immunization coverage, ability to ensure an effective vaccination offer system, continuous monitoring of membership, a rapid recovery of any non-compliance based on dialogue and information.

The introduction of compulsory vaccination suspension law in Veneto Region has allowed experiencing a Public Health setting established on self-guided individual choice in making decisions regarding health, creating a modern and efficient vaccine service. Further research and reports are required to carefully value whether the choice between compulsory and voluntary vaccination takes effect on coverage rates.

In conclusion a healthcare system should promote and actively offer all vaccinations approved as safe, effective and with a positive public health impact. However decision about proposal for vaccine strategies should be elaborated in agreement with organizational features of vaccination services combined with traditional and cultural habits. Trust on health authorities will lead to more compliance with recommendations producing not only benefits for health of citizen but also enhancing their awareness on this issue and support the overall effectiveness of vaccination programs through the herd immunity effect.

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