

Vaccination strategies for high-risk and fragile populations in Lombardy (Italy): a region-wide assessment of hospital-based models and best practices

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Keywords: Hospital-based vaccinations; life-course immunization; high-risk subjects

Parole chiave: Vaccinazioni intra-ospedaliere; immunizzazione life-course; soggetti ad alto rischio

Abstract

Background. Subjects with selected underlying medical conditions are at higher risk of infection and severe outcomes from vaccines preventable diseases. While most countries adopt life-course approaches to vaccination, high-risk group immunization programmes could maximize individual protection, while contributing to population health. The COVID-19 pandemic stimulated the planning and implementation of successful hospital-based high-risk groups' immunization models. However, in Italy, high-risk subjects' vaccine coverage is not actively monitored at the national or regional level, nor shared guidelines exist yet on hospital-based immunization programmes.

Study Design. The study reports findings from a region-wide assessment of the availability, characteristics, and setting-specific features of hospital-based immunization programmes for high-risk subjects in the Lombardy region.

Methods. Fondazione The Bridge a not-for-profit organization based in Milan, in collaboration with the Prevention Unit of the Lombardy Region Directorate for Welfare, and the University of Pavia coordinated a project aimed at bringing together regional health institutions, key stakeholders, academic experts, scientific societies and patients' associations to assess high-risk subjects' barriers to vaccine uptake and inform preventive programmes and policies. In this context, we designed and implemented a survey to systematically map the existence and characteristics of hospital-based immunization programmes targeting high-risk subjects. The survey was proposed to all 115 hospital medical directions of the Lombardy region.

Results. We collected data from 97 hospital medical directions, with a response rate of 85%. Among respondents, 24% were publicly managed hospitals, 17% were Scientific Institute for Research, Hospitalization and Healthcare (IRCCS) and 59% accredited

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private hospitals. Overall, 51.5% facilities in the Lombardy Region reported to actively administer vaccines to high-risk subjects in hospital settings, the prevalence being 89.6% in public hospitals. Among hospitals where vaccines are actively administered, 46% reported to have centralized vaccines ambulatory clinics, while 54% reported to administer vaccines in the context of inpatient care, within clinical wards. In 14% of hospitals vaccination counselling is carried out at the hospital level, while patients are referred to community services for the vaccine administration, 58% have established clinical pathways and formalized internal procedures to integrate vaccine prevention within the clinical care.

Conclusions. Half of hospital facilities in the Lombardy Region administer vaccines to high-risk patients. Hospital-based immunization models vary widely by vaccines programmes, organizational aspects, vaccines procurement and workforce involved. Identifying best practices and effective models can help tackle current challenges and improve immunization coverage for at-risk groups.

Introduction

Subjects with selected underlying medical conditions are at higher risk of infections and severe outcomes from Vaccines Preventable Diseases (VPDs) (1).

Besides older age, medical conditions including cancer, chronic kidney disease, diabetes, and weakened immune systems increase the risk of severe COVID-19, hospitalization, intensive care unit admission and death (2-6).

Solid evidence is available linking high-risk groups with worse outcomes for other VPDs, including influenza (7,8) and pneumococcal disease (9), as compared to the general population.

While most countries adopt a life-course approach to vaccination, recommending age-specific immunization schedules (10-13), high-risk group immunization programmes could maximize individual protection, while contributing to population health (14-17).

The COVID-19 pandemic has demonstrated the importance of prioritizing high-risk subjects and stimulated the planning and implementation of successful hospital-based high-risk groups immunization models (18-20). In Italy, a life-course approach to vaccination has been introduced since 2017 (21-23). However, vaccine coverage in older populations remains low and below coverage targets (24). Furthermore, privacy limitations reduce the possibility to identify and actively target high-risk subjects with immunization programmes. Also, high-risk subjects vaccine coverage is not actively monitored at the national or regional level (25), nor shared guidelines exist on hospital-based immunization programmes (26, 27). Nonetheless, the hospitals, focal points for the care of subjects with underlying medical conditions, have long been proposed as privileged sites for immunizing (28-30).

Reports suggest that inpatient immunization could represent a crucial opportunity to reach individuals who do not comply with age-related vaccination recommendations (30-32).

In the Lombardy region, as of 2023, *ad hoc* collected data on high-risk subjects immunization show low coverage rates: among oncology patients, only 46.8% were vaccinated against influenza (61.6% considering those over 65), 13.8% against pneumococcus, 3.5% against meningococcus C, and merely 1.3% against herpes zoster. Also looking at diabetic patients, the trend was essentially the same: 46.6% received the influenza vaccine (60.3% considering those over 65), 13.1% the pneumococcal vaccine, 2.8% the meningococcus C vaccine, and 1.2% the herpes zoster vaccine.

In addition, hospital-based immunization models in the region vary widely, and no systematic assessment exist on their characteristic and performances.

In this context, Fondazione The Bridge (see Box 1), supported by the University of Pavia and the Lombardy Directorate General (DG) for Health (Prevention Unit), coordinated a project aimed at bringing together regional health institutions, key stakeholders, academic experts, scientific societies and patients' associations to assess high-risk subjects barriers to vaccine uptake and inform decision making. As part of the project, we conducted a region-wide study to systematically map the availability, characteristics and setting-specific features of hospital-based immunization programmes in the Lombardy Region, pinpointing the best practices and spotting the potential disparities in management approaches among different regional facilities and sectors.

The project aimed to outline vaccination services available for high-risk individuals and the models in use, with a specific emphasis on hospital-based approaches. Between June and October 2023, during

Box 1. Fondazione The Bridge

Fondazione The Bridge, is a not-for-profit organization based in Milan, Italy. It acts as a facilitator between healthcare institutions, patient associations, scientific societies, academia, clinical context and industry. The Foundation actively engages in debates and collaborations with institutions and various stakeholders within the healthcare sector. Its aim is to promote health by contributing to research activities, scientific dissemination, advocacy, and comprehensive training programmes aimed at healthcare professionals, policymakers and the general public. Fields of interest encompass healthcare policies – at both regional and national levels –, equity in healthcare, gender health, interaction between environment and human health, mental health, oncological diseases and infectious diseases, with their psychological and physical implications. Within the overarching framework of the “High-risk Subjects Vaccination: a Health Opportunity” project, the Foundation encouraged a dialogue between regional and local authorities regarding the importance of vaccination for fragile individuals at risk for comorbidities or other specific conditions. The goal was to identify current challenges and potential strategic solutions to increase vaccination coverage in the Lombardy Region.



a series of meetings, representatives from hospitals, General Practitioners (GPs), Public Health experts, regional policymakers and patients' associations convened.

Methods

Study setting

In the context of the Fondazione The Bridge, project “High-risk subjects vaccination: a health opportunity” - running between June and October 2023 - the following activities were planned, designed and implemented: 3 scientific seminars, one region-wide focus group with the health directions of all hospitals, a professional communication campaign, a report summarizing the projects' outputs and shared recommendations, and a conclusive public event hosted by the Lombardy Region Health authority.

In particular, the focus group was organized by the Prevention Unit of the Lombardy Directorate General (DG) for Health with the aim of presenting the survey to all hospital health directions and collect qualitative data on the availability and characteristics of local hospital-based immunization services for high-risk groups, as well as public health professionals' experience and opinions on the topic. The outputs from the focus group were used both to calibrate the survey tool, as well as to interpret its findings. Consultation

with experts in the field allowed to retrieve best practices and case studies.

Study design and data collection

We designed and implemented a cross-sectional study to systematically map the availability, characteristics, and setting-specific features of hospital-based immunization programmes in the Lombardy Region. A literature search was conducted using Medline in order to identify existing vaccination hospital-based models, their characteristics and critical aspects. Fondazione The Bridge, the University of Pavia and the Lombardy DG for Health jointly built the survey tool based on inputs and evidence gathered from the literature search, the outputs from the project's seminars, the regional focus group and consultations with experts in the field. Before administration, the survey tool was piloted on three hospital health directions. From September to October 2023, the survey was administered through a dedicated digital platform (IdSurvey) using the computer-assisted web interviewing (CAWI) technique. It was disseminated by the Lombardy DG for health to all the hospital medical directions of accredited regional healthcare facilities. The total sample included 115 Lombardy hospital facilities from both public and private sector. IRCCS were also included. Additionally, telephone interviews were conducted, in order to achieve optimal response rates.

Structure of the survey

The survey tool included a set of questions divided into three primary sections, aiming to explore the existence and organizational aspects of local hospital vaccination models employed in the Lombardy Region. We first retrieved data on site, hospital type (Local Health and Social Care Authorities, IRCCS, other accredited private hospitals) and public/private sector. Then, we asked whether hospital-based immunization services were available for high-risk patients. For those hospitals reporting to have hospital-based immunization services in place for high-risk patients we further inquired the characteristics of hospital immunization models, including:

- where vaccines are administered (within inpatient care/in inpatient wards, or in dedicated in-hospital vaccination ambulatory clinics);
- whether both vaccination counselling and administration are carried out at the hospital level, or only counselling, with patients referred to community services for vaccine administration;
- healthcare personnel involved in high-risk patients' immunization services;
- the availability of hospital-based high-risk patients' immunization clinical pathways and procedures.

A specific section was dedicated to explore in details the existence and characteristics of hospital-based immunization services for diabetic patients, enquiring the role of diabetologists in immunization counselling and administration, timing of immunization status assessment and monitoring for diabetic patients, and the availability of immunization services for diabetic patients' household members and caregivers.

Results

Ninety-seven out of 115 Lombardy hospital facilities participated in the survey, resulting in an overall response rate of 84.3%; distribution was as follows: 23.7% (n=23) publicly managed Local Health and Social Care Authorities (ASST) hospitals, 17.5% (n=17) IRCCS from both public and private sectors and 58.8 (n=57) accredited private hospitals, corresponding to response rates of 85.2% (23 out of 27), 89.5% (17 out of 19) and 82.6% (57 out of 69), respectively (Table 1). Overall, 29 (out of 32) hospitals were affiliated with the public sector, while 68 (out of 83) operated within the private accredited sector, corresponding to response rates of respectively 90.6% and 81.9%.

Availability and characteristics of hospital-based immunization services for high-risk patients

Out of all responders, 51.5% (n=50) of hospitals reported to actively administer vaccines to high-risk subjects. When stratifying by hospital type, in-hospital vaccination was reported to be provided in all ASSTs (n=23, 100%), in 47.1% (n=8) IRCCSs and in 33.3% (n=19) of other private accredited hospitals. In particular, inpatient hospital-based immunization services are provided by 89.6% of public institutions (n=26) and 35.3% of accredited private hospitals (Table 1).

Considering hospitals reporting to provide in-hospital vaccination services for high-risk patients, 54% (n=27) claimed that vaccinations are administered within inpatient care, directly in inpatient wards, while 46% of hospitals (n=23) reported to have established dedicated in-hospital vaccination ambulatory clinics. The distribution of in-hospital immunization sites by

Table 1. Lombardy healthcare facilities participating in the survey: response rate and availability of In-hospital vaccination services for high-risk patients, by hospital type.

Hospital type	Response rate N (%)	Availability of hospital-based immunization services for high-risk patients N (%)
Local Health and Social Care Authorities (ASST)	23 (85.2%)	23 (100%)
Research and Healthcare Institutes (IRCCS)	17 (89.5%)	8 (47.1%)
Other accredited private hospitals	57 (95%)	19 (33.3%)
Public Sector	29 (90.6%)	26 (89.6%)
Private Sector	68 (81.9%)	24 (35.3%)
Total	97 (84.3%)	50 (51.5%)

hospital type is reported in Table 2. In particular, 73.9% (n=17) of ASSTs, 50% (n=4) of IRCCS and 10.5% (n=2) of other accredited private hospitals reported to have established dedicated in-hospital vaccination ambulatory clinics. Overall, administration in inpatient wards is predominantly observed in the private context (n=20, 83.3%), while the presence of an in-hospital vaccination ambulatory clinic is more common in the public setting (n=19, 73.1%) (Table 2).

In 86% (n=43) of hospitals both vaccination counselling and administration are carried out at the hospital level, on the contrary, in 14% (n=7) of hospitals – all being ASSTs – vaccination counselling is carried out at the hospital level, while patients are referred to community services for vaccine administration.

With reference to healthcare personnel in charge of vaccine administration, 64% (n=32) of hospitals reported that the staff in charge of in-hospital vaccination services for high-risk patients is clinical staff working in wards where patients are hospitalized, in

the rest of the hospitals being from outside inpatients' wards. Healthcare personnel distribution by hospital type and public/private setting is reported in Table 3. In particular, vaccine administration conducted by healthcare personnel within inpatient wards is reported in 52.2% (n=12) of ASSTs and in 50% (n=4) of IRCCSs, whereas it is more frequent among other accredited private hospitals (84.2%, n=16). Overall, administration within inpatient wards is more commonly reported in the private sector (79.2%, n=19) than in the public sector (50%, n=13).

Fifty-eight per cent (n=29) of hospitals reported to have systematized in-hospital vaccination services for high-risk patients in codified clinical pathways and procedures (60.9% of ASSTs, 62.5% of IRCCSs and 52.6% of other private accredited hospitals). In total, codified clinical pathways and procedures for in-hospital vaccination services for high-risk patients are available in 61.5% (n=16) of public and 54.2% (n=13) of private accredited hospitals (Table 4).

Table 2. In-hospital vaccination services for high-risk patients by site, and by hospital type.

Hospital type	Within inpatient care/ in inpatient wards N (%)	Dedicated in-hospital vaccination ambulatory clinics N (%)
Local Health and Social Care Authorities (ASST)	6 (26.1%)	17 (73.9%)
Research and Healthcare Institutes (IRCCS)	4 (50%)	4 (50%)
Other accredited private hospitals	17 (89.5%)	2 (10.5%)
Public Sector	7 (26.9%)	19 (73.1%)
Private Sector	20 (83.3%)	4 (16.7%)
Total	27 (54%)	23 (46%)

Table 3. Healthcare personnel in charge of hospital-based high-risk patients' immunization.

Hospital type	Healthcare personnel from within inpatients' wards N (%)	Healthcare personnel from outside inpatients' wards N (%)
Local Health and Social Care Authorities (ASST)	12 (52.2%)	11 (47.8%)
Research and Healthcare Institutes (IRCCS)	4 (50%)	4 (50%)
Other accredited private hospitals	16 (84.2%)	3 (15.8%)
Public Sector	13 (50%)	13 (50%)
Private Sector	19 (79.2%)	5 (20.8%)
Total	32 (64%)	18 (36%)

Table 4. Presence of hospital-based high-risk patients' immunization clinical pathways and procedures, by hospital type.

Hospital site	Presence of hospital-based high-risk patients' immunization clinical pathways and procedures N (%)
Local Health and Social Care Authorities (ASST)	14 (60.9%)
Research and Healthcare Institutes (IRCCS)	5 (62.5%)
Other accredited private hospitals	10 (52.6%)
Sector	
Public Sector	16 (61.5%)
Private Sector	13 (54.2%)
Total	29 (58%)

Focus on hospital-based diabetic patients' immunization

Among hospitals reporting to have in-hospital vaccination services for high-risk patients, 28% (n=14) have them dedicated to diabetic inpatients, of which 13 ASSTs (56.5%) and 1 IRCCS (12.5%), all affiliated with the public sector.

Of these, 64.3% (n=9) do not identify a specific moment during patient care for assessing their vaccination status, 28.6% (n=4) report to enquire diabetic patients' vaccination status during regular hospital check-ups scheduled with diabetologists, 1 hospital reports the assessment occurs during diabetic patients first hospital medical observation with diabetologists, while none performs diabetic patients' vaccination status evaluation during patients' hospitalization for diabetic complications.

In only 14.3% of hospitals (n=2), counseling and vaccination for diabetic patients are conducted by diabetologists while, in the majority of cases, it is managed by other healthcare professionals. Fifty-seven per cent of hospitals report to periodically monitor diabetic patient vaccination in the context of care and 42.9% (n=6) report to refer to or offer vaccination to patients' household members and caregivers. (Table 5).

Regional focus group outputs and best practices

The qualitative research component of the project included the focus group and consultations with experts in the field to retrieve best practices and case studies. Approximately 60 hospitals participated in the focus group organized by the Prevention Unit of the Lombardy Directorate General (DG) for Health on 2nd October 2023 as a two-hour teleconference chaired by regional health authorities' representatives. Consensus was reached on selected points, including:

The need to raise awareness among clinical specialists on the importance of vaccine preventions among high-risk patients. The role and responsibilities of medical specialists are to be established at the regional and hospital level: specialists should regularly check high-risk patients' vaccination status and recommend selected immunization programmes, if needed. Indeed, missed opportunities for inpatient vaccinations often occur due to clinical specialists' not recommending or not administering vaccines to inpatient high-risk subjects.

The need for establishing coordinated models within hospital settings, in collaboration with community services. It is crucial to ensure coordination and alignment between community and hospital prevention delivery strategies and resource allocation. For instance, not all hospitals have the capacity to vaccinate high-risk individuals on-site. A system enabling hospital specialists to directly book vaccination appointments at the community level would make the system more efficient. In this sense, the development of a regional digital booking platform that grants access to all actors involved in care and prevention would be crucial.

The importance of integrating primary prevention strategies within existing diagnostic and therapeutic pathways (PDTAs) for high-risk conditions management, starting from the hospital setting. To date, several hospitals have implemented specific pathways for managing selected chronic diseases. However, almost none of these include assessment patients' vaccination status or vaccine administration as part of their management.

Consultation with experts in the field allowed to retrieve best practices and case studies on in-hospital vaccination services for high-risk patients from selected hospitals, including Fondazione IRCCS Policlinico San Matteo in Pavia (see Box 2).

Table 5. In-hospital vaccination pathways for diabetic patients.

In-hospital vaccination pathways for diabetic patients	
	N (%)
Hospital type	
Local Health and Social Care Authorities (ASST)	13 (56.5%)
Research and Healthcare Institutes (IRCCS)	1 (12.5%)
Other accredited private hospitals	0 (-)
Sector	
Public	14 (53.8%)
Private	0 (-)
Total	14 (28%)
Timing of immunization status assessment	
Not Identified	9 (64.3%)
First hospital visit with the specialist medical observation with diabetologists	1 (7.1%)
Scheduled Check-ups with diabetologists	4 (28.6%)
Hospitalization due to disease complications	0 (-)
Healthcare personnel in charge of vaccination	
Diabetologist	2 (14.3%)
Other healthcare personnel	12 (85.7%)
Patient vaccination status monitoring	
Yes	8 (57.1%)
Caregiver vaccination	
Yes	6 (42.9%)

Box 2. Best practices in in-hospital vaccination services for high-risk patients: the case of Fondazione IRCCS Policlinico San Matteo in Pavia.

Fondazione Policlinico San Matteo, based in Pavia, is a IRCCS and one of the largest university hospitals in the Lombardy Region. Since 2017, a dedicated in-hospital vaccination ambulatory clinic has been established with the purpose of vaccinating healthcare professionals and inpatients belonging to high-risk categories: individuals with chronic diseases (e.g., diabetes, cardiovascular diseases), immunocompromised subjects (e.g., pre-transplant candidates, patients with asplenia) and their caregivers, oncological and haematological patients, older adults, at-risk women of childbearing age, premature infants and neonates with chronic conditions.

For each clinical area, an operational protocol has been shared with specialists: this involves assessing the vaccination status of the inpatient or at-risk individuals and administering the recommended vaccines within the hospital ambulatory clinic. The in-hospital vaccination ambulatory clinic for high-risk adult individuals is located inside the medical department within the infectious disease clinic. Women of childbearing age and pregnant women, as well as infants and children, receive vaccinations inside the mother and child department (within the gynecology, neonatology, and pediatric clinics, respectively). Infectious disease consultation is provided before administration.

The ambulatory management is interdepartmental, jointly directed by the hospital medical direction and the Healthcare Infection Control Practices Advisory Committee. Coordination with local authorities enables vaccines procurement. Between 2017 and 2022, over 3200 high-risk patients have been vaccinated, this providing a successful example of in-hospital vaccination model for high-risk patients which can not only inform the planning, implementation and monitoring of regional and local models, but also be scaled up to derive regional and national guidelines.

Discussion

Hospital-based immunization is an effective approach to intercept high-risk individuals and increase vaccine uptake in those at higher risk of infection and severe outcomes from vaccines preventable diseases (17–19, 25–27). Hospital-based immunization complements community immunization programmes towards infectious diseases' prevention and control and is a metric of hospitals' quality of care (34). We conducted a region-wide assessment of the availability, characteristics, and setting-specific features of hospital-based immunization programmes for high-risk subjects in the Lombardy Region, collecting data from nearly 100 healthcare facilities. Overall, half of the hospitals in the region have hospital-based immunization services for high-risk patients with large heterogeneity in terms of vaccinal programmes, organizational aspects, vaccines procurement and workforce involved.

Within the regional landscape, some interesting findings emerge from our analysis. First, hospital-based vaccination pathways for high-risk patients are predominantly set up within the public sector, with almost 90% of public hospitals providing immunization to high-risk patients, as compared to roughly one in three private accredited hospitals. Second, hospital-based immunization is provided either directly in inpatient wards, or in dedicated in-hospital vaccination ambulatory clinics. While overall in the region hospitals are almost evenly distributed between these two models, public-private differences exist with dedicated hospital-based ambulatory clinics being more prevalent in the public sector, and immunization within inpatient care, directly in inpatient wards, more prevalent in private accredited hospitals. Indeed, in private accredited hospitals high-risk patients' immunization is almost entirely organized within different clinical wards: vaccinations are predominantly administered within inpatient wards, employing healthcare personnel from the same setting (i.e. de-centralized model). On the contrary, in the public sector, the predominant model is centralized around dedicated immunization ambulatory clinic managed outside single clinical wards by public health specialists. Both models have been described in the literature, outlining strengths and weaknesses (18, 35, 36). During the COVID-19 pandemic, centralized hospital-managed and wide-collaborative immunization services have been implemented with the aim of efficiently absorbing larger vaccination volumes in a more effective and timely manner. In those centralized hospital-based models, vaccination is managed by both physicians and nurses (standing

order policies) (37), the hospital pharmacy interacts with involved parties through specific electronic applications and electronic medication administration record (38, 39), and infectious disease consultation is available for patient counselling, regardless of the admitting ward (40, 41).

Third, we report suboptimal coordination between the hospital and the community level, with public hospitals experiencing difficulties in referring high-risk patients to community services for vaccines administration after hospital immunization counselling. Based on our findings, a noticeable gap between hospital and the territorial context emerges: only a few facilities assess the vaccination status of the patient at the hospital level and plan administration of vaccines at the territorial level, all being within the public sector; indeed, based on consultations with regional experts, it has been observed that an effective communication between the two levels is often lacking. Furthermore, a system enabling hospital specialists to directly consult the vaccination status of the patient and to schedule the vaccination appointments at the community level, is strongly required. Fourth, less than 60% of hospitals have systematized in-hospital vaccination services in codified clinical pathways and procedures. Still, virtuous case studies were retrieved, such as Fondazione IRCCS Policlinico San Matteo that stands out - within the regional context - as a noteworthy example of internal process structuring and external integration with the community level. Several successful hospital-based vaccination models structured around *ad hoc* designed internal procedures are described in the literature (27, 42–44), for example adopting checklists during medical history assessments to evaluate high-risk individuals' vaccination status (45).

Vaccination is not currently included in the protocols for managing chronic patients in regional healthcare facilities. In the section of the study dedicated to investigating pathways for diabetic patients, the majority of hospitals reported not to have identified a specific stage for assessing patients' vaccination status. Only a few healthcare facilities considered specialist check-ups as an opportunity for preventive interventions and the management of disease-related complications in hospitals does not actually encompass an evaluation of the patient's vaccination status. Furthermore, a scant proportion of facilities point out hospital medical specialist as a crucial actor in patient vaccination status assessment and counseling; however, available literature emphasizes how missed opportunities often result from clinical specialists either

not recommending or not administering vaccines to high-risk subjects on the spot (30, 46).

Overall, we portray a scenario in which preventive assessment is not taken into account in the overall evaluation of high-risk patients during their transition through the hospital setting. A more effective preventive strategy could involve incorporating the assessment of vaccination status within clinical pathways for chronic conditions established by regional facilities.

Our study has both strengths and limitations. It is the first systematic and comprehensive region-wide mapping of hospital-based immunization practices and models for high-risk patients. It has been conducted in collaboration with regional health authorities and within the wider framework of the Fondazione The Bridge project to promote high-risk subjects' preventive strategies. In addition, it includes findings from both quantitative and qualitative methods. Inputs were provided by both clinical and public health experts, scientific societies, patients' associations, and civil society. Last, but not least, the high response rate guarantees that our findings are representative of the Lombardy region. Study limitations include those inherent to the cross-sectional study design. It will be important to repeat the survey again in the future so as to collect prospective data and monitor in-hospital immunization protocols' advancements for all the hospitals of the Region. In addition, data may be affected by misreporting. However, telephone interviews were conducted on top of questionnaire self-administration to improve data quality. Another detail that could have worsened the situation: we stratified data by hospital type and public/private setting, but we did not consider hospital size, which could have allowed us to weight data by number of beds or wards.

In conclusion, hospital vaccination models for high-risk individuals are only partially implemented in the Lombardy region and exhibit considerable heterogeneity: a certain disparity between public and private contexts seems to emerge, particularly regarding organizational features and coordination with territorial primary healthcare services. We raise awareness on the need of promoting hospital-based immunization for high-risk subjects and better coordinate, complement and integrate hospital and community vaccine services. In addition, more attention should be paid to prevention in chronic patients' hospital management. This cannot be achieved without involving and empowering clinical specialists and structuring and systematizing preventive aspects in clinical care journey.

In a context where vaccination coverage among high-risk individuals appears alarmingly low, both at regional and national level, a public health response becomes increasingly urgent. New vaccination technologies will broaden the pool of eligible high-risk individuals, significantly expanding potential coverage. Furthermore, exploration into new combined formulations will aim to efficiently vaccinate more people using fewer resources. The role of public health will be to set up new organizational models to fully leverage upcoming new models, practices and technologies, aiming to reach an increasingly larger proportion of the population. As of today, thanks in part to the drive of pandemic, new models have been tested and, in some cases, begun to permeate the organizational structures of the hospital facilities in the Lombardy region. However, a better response is needed in order to significantly increase coverage among vulnerable patients.

While further investigation is required to identify, adapt and scale-up models that can serve as a benchmark for preventive management of high-risk individuals within the hospital setting, our findings provide regional policymakers with insights into current practices evaluation and will inform the planning, implementation and monitoring of innovative prevention models.

Conflicts of interest

None declared

Acknowledgments

The authors would like to thank all scientific societies and patient association members who contributed to the project.

Riassunto

Strategie per la vaccinazione di soggetti fragili e ad alto rischio in Regione Lombardia (Italia): una valutazione dei modelli e delle best-practices di immunizzazione intra-ospedaliera

Background. Soggetti con condizioni mediche sottostanti sono a maggior rischio di sviluppare complicanze gravi da malattie prevenibili con vaccino. Mentre la maggior parte dei paesi adotta approcci vaccinali *life-course*, programmi vaccinali targettizzati su soggetti fragili potrebbero massimizzare la protezione individuale, contribuendo nel contempo a tutelare la salute della popolazione. La pandemia di COVID-19 ha dato impulso alla pianificazione e all'implementazione di modelli di immunizzazione intra-ospedaliera per le categorie a rischio. Tuttavia, in Italia, la copertura vaccinale per soggetti fragili non viene attivamente monitorata a livello nazionale o regionale e non esistono linee guida condivise per i programmi di immunizzazione ospedaliera.

Disegno dello studio. Lo studio, di tipo cross-sectional, vuole indagare la presenza e le caratteristiche dei modelli vaccinali ospe-

dalieri per soggetti fragili implementati nelle strutture di ricovero e cura in Regione Lombardia.

Metodi. Fondazione The Bridge, organizzazione non profit con sede a Milano, in collaborazione con l'Unità di Prevenzione della Direzione Generale Welfare di Regione Lombardia e l'Università di Pavia ha coordinato un progetto volto a riunire istituzioni sanitarie regionali, principali stakeholder, esperti accademici, società scientifiche e associazioni di pazienti per valutare le barriere all'adesione delle campagne vaccinali dei soggetti ad alto rischio, proponendo programmi e politiche preventive. In questo contesto, abbiamo progettato e implementato una survey con l'obiettivo di mappare sistematicamente la presenza e le caratteristiche dei programmi regionali di vaccinazione intra-ospedaliera rivolti a soggetti ad alto rischio. Il questionario è stato somministrato a tutte le 115 direzioni sanitarie ospedaliere delle strutture di ricovero e cura accreditate di Regione Lombardia.

Risultati. Sono stati raccolti dati da 97 strutture, con un tasso di rispondenza dell'85%. Il 24% delle risposte è pervenuto da direzioni sanitarie di ospedali pubblici, il 17% da Istituti di Ricovero e Cura a Carattere Scientifico (IRCCS) e il 59% da strutture private accreditate. Complessivamente, il 51.5% delle strutture di Regione Lombardia ha dichiarato di somministrare attivamente vaccini a soggetti ad alto rischio, con una prevalenza dell'89,6% nel settore pubblico. Tra le strutture dove vengono attivamente somministrati vaccini nel contesto ospedaliero, il 46% riporta di aver allestito ambulatori dedicati alla vaccinazione, mentre il 54% ha indicato che la somministrazione dei vaccini avviene in reparto nel contesto della degenza. Nel 14% delle strutture il counselling vaccinale avviene a livello ospedaliero ed i pazienti sono indirizzati alle strutture territoriali per ricevere la vaccinazione. Meno del 60% delle strutture dichiara di aver adottato procedure interne per la sistematizzazione e l'integrazione dei servizi preventivi vaccinali nei percorsi di cura dei soggetti fragili.

Conclusioni. Circa la metà delle strutture ospedaliere di Regione Lombardia somministra vaccini a soggetti fragili. I modelli di vaccinazione intra-ospedaliera variano ampiamente in base ai programmi vaccinali, al contesto organizzativo e al personale coinvolto. L'individuazione e condivisione di best practices e modelli virtuosi di vaccinazione in ospedale può contribuire ad aumentare le coperture nei soggetti fragili in Regione Lombardia.

References

- Kolobova I, Nyaku MK, Karakusevic A, Bridge D, Fotheringham I, O'Brien M. Burden of vaccine-preventable diseases among at-risk adult populations in the US. *Hum Vaccines Immunother*. 2022 Nov 30;**18**(5):2054602. doi: 10.1080/21645515.2022.2054602. Epub 2022 Apr 21. PMID: 35446725.
- Centers for Disease Control and Prevention (CDC). Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals. 2023. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html> [Last accessed: 2023 Dec 15].
- Rosenthal N, Cao Z, Gundrum J, Sianis J, Safo S. Risk Factors Associated With In-Hospital Mortality in a US National Sample of Patients With COVID-19. *JAMA Netw Open*. 2020 Dec 10;**3**(12):e2029058. doi: <https://doi.org/10.1001/2020.29058>. PMID: 33301018.
- De Giorgi A, Fabbian F, Greco S, Di Simone E, De Giorgio R, Passaro A, et al. Prediction of in-hospital mortality of patients with SARS-CoV-2 infection by comorbidity indexes: an Italian internal medicine single center study. *Eur Rev Med Pharmacol Sci*. 2020 Oct;**24**(19):10258–66. doi: https://doi.org/10.26355/eurrev_202010_23250. PMID: 33090437.
- Dominguez-Ramirez L, Rodriguez-Perez F, Sosa-Jurado F, Santos-Lopez G, Cortes-Hernandez P. The role of metabolic comorbidity in COVID-19 mortality of middle-aged adults. The case of Mexico. *Epidemiology*. 2020 Dec. doi: <https://doi.org/10.1101/2020.12.15.20244160>.
- Rovida F, Esposito GL, Rissone M, Novelli V, Cutti S, Muzzi A, et al. Characteristics and outcomes of vaccinated and nonvaccinated patients hospitalized in a single Italian hub for COVID-19 during the Delta and Omicron waves in Northern Italy. *Int J Infect Dis*. 2022 Sep;**122**:420–6. doi: 10.1016/j.ijid.2022.06.028. Epub 2022 Jun 22. PMID: 35750265.
- Poland GA, Hall LL, Powell JA. Effective and equitable influenza vaccine coverage in older and vulnerable adults: The need for evidence-based innovation and transformation. *Vaccine*. 2019 Apr;**37**(16):2167–70. doi: 10.1016/j.vaccine.2019.02.076. Epub 2019 Mar 20. PMID: 30902480.
- World Health Organization (WHO). Influenza (Seasonal). 2023. Available from: [https://www.who.int/news-room/fact-sheets/detail/influenza-\(seasonal\)](https://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal)) [Last accessed: 2023 Dec 15].
- Centers for Disease Control and Prevention (CDC). Pneumococcal Disease: Risk Factors and How It Spreads [Internet]. 2023. Available from: <https://www.cdc.gov/pneumococcal/about/risk-transmission.html#:~:text=Young%20children%20and%20older%20adults,adults%2065%20years%20or%20older> [Last accessed: 2023 Dec 15].
- Scognamiglio F, Fantini MP, Reno C, Montalti M, Di Valerio Z, Soldà G, et al. Vaccinations and Healthy Ageing: How to Rise to the Challenge Following a Life-Course Vaccination Approach. *Vaccines*. 2022 Feb 28;**10**(3):375. doi: 10.3390/vaccines10030375. PMID: 35335007.
- Tate J, Aguado T, Belie JD, Holt D, Karafillakis E, Larson HJ, et al. The life-course approach to vaccination: Harnessing the benefits of vaccination throughout life. *Vaccine*. 2019 Oct;**37**(44):6581–3. doi: 10.1016/j.vaccine.2019.09.016. Epub 2019 Sep 23. PMID: 31558327.
- Philip RK, Attwell K, Breuer T, Di Pasquale A, Lopalco PL. Life-course immunization as a gateway to health. *Expert Rev Vaccines*. 2018 Oct 3;**17**(10):851–64. doi: 10.1080/14760584.2018.1527690. PMID: 30350731.
- Burioni R, Odone A, Signorelli C. Lessons from Italy's policy shift on immunization. *Nature*. 2018 Mar;**555**(7694):30–30. doi: 10.1038/d41586-018-02267-9. PMID: 32094876.
- Kang SJ, Jung SI. Age-Related Morbidity and Mortality among Patients with COVID-19. *Infect Chemother*. 2020;**52**(2):154. doi: 10.3947/ic.2020.52.2.154. PMID: 32537961.
- Djharuddin I, Munawwarah S, Nurulita A, Ilyas M, Tabri NA, Lihawa N. Comorbidities and mortality in COVID-

- 19 patients. *Gac Sanit.* 2021;**35**:S530–2. doi: 10.1016/j.gaceta.2021.10.085. PMID: 34929892.
16. Colaneri M, Asperges E, Calia M, Sacchi P, Rettani M, Cutti S, et al. Despite Vaccination: A Real-Life Experience of Severe and Life-Threatening COVID-19 in Vaccinated and Unvaccinated Patients. *Vaccines.* 2022 Sep 16;**10**(9):1540. doi: 10.3390/vaccines10091540. PMID: 36146618.
17. Cook TM, Roberts JV. Impact of vaccination by priority group on UK deaths, hospital admissions and intensive care admissions from COVID-19. *Anaesthesia.* 2021 May;**76**(5):608–16. doi: 10.1111/anae.15442. Epub 2021 Feb 11. PMID: 33572007.
18. Perrone PM, Biganzoli G, Lecce M, Campagnoli EM, Castrofino A, Cinnirella A, et al. Influenza Vaccination Campaign during the COVID-19 Pandemic: The Experience of a Research and Teaching Hospital in Milan. *Int J Environ Res Public Health.* 2021 May 30;**18**(11):5874. doi: 10.3390/ijerph18115874. PMID: 34070763.
19. Freiser D, Roca M, Chung T, Bhakta T, Winston LG, Ortiz GM. The Evolution of a Hospital-Based Covid-19 Vaccination Program for Inpatients. *NEJM Catal.* 2022 Jan 19. Available from: <http://catalyst.nejm.org/doi/10.1056/CAT.21.0340> [Last accessed: 2023 Dec 15].
20. Lecce M, Biganzoli G, Agnello L, Belisario I, Cicconi G, D'Amico M, et al. COVID-19 and Influenza Vaccination Campaign in a Research and University Hospital in Milan, Italy. *Int J Environ Res Public Health.* 2022 May **26**;19(11):6500. doi: 10.3390/ijerph19116500. PMID: 35682083.
21. Di Pietro A, Visalli G, Antonuccio GM, Facciola A. Today's vaccination policies in Italy: The National Plan for Vaccine Prevention 2017–2019 and the Law 119/2017 on the mandatory vaccinations. *Ann Ig.* 2019;**31**(2 Suppl 1):54–64. doi: 10.7416/ai.2019.2277. PMID: 30994164.
22. Odone A, Signorelli C. When vaccine hesitancy makes headlines. *Vaccine.* 2017 Mar;**35**(9):1209–10. doi: 10.1016/j.vaccine.2015.11.051. Epub 2015 Dec 2. PMID: 26657186.
23. Ferro A, Odone A, Siddu A, Colucci M, Anello P, Longone M, et al. Monitoring the web to support vaccine coverage: results of two years of the portal VaccinarSi. *Epidemiol Prev.* 2015;**39**(4 Suppl 1):88–93. PMID: 26499422.
24. Italian Ministry of Health. Italian influenza vaccination coverage. 2023. Available from: <https://www.salute.gov.it/portale/influenza/dettaglioContenutiInfluenza.jsp?id=679&area=influenza&menu=vuoto> [Last accessed: 2023 Dec 15].
25. Italia Longeva. La mappa della fragilità in Italia. 2022; Available from: https://www.italialongeva.it/wp-content/uploads/2022/04/indagine-2022_italialongeva.pdf [Last accessed: 2023 Dec 15].
26. Mihalek AJ, Russell CJ, Hassan A, Yeh MY, Wu S. National Inpatient Immunization Patterns: Variation in Practice and Policy Between Vaccine Types. *Hosp Pediatr.* 2021 May 1;**11**(5):462–71. doi: 10.1542/hpeds.2020-002634. Epub 2021 Apr 5. PMID: 33820809.
27. Bryan MA, Hofstetter AM, Ramos D, Ramirez M, Opel DJ. Facilitators and Barriers to Providing Vaccinations During Hospital Visits. *Hosp Pediatr.* 2021 Oct 1;**11**(10):1137–52. doi: 10.1542/hpeds.2020-004655. PMID: 34556537.
28. Fedson DS, Houck P, Bratzler D. Hospital-Based Influenza and Pneumococcal Vaccination: Sutton's Law Applied to Prevention. *Infect Control Hosp Epidemiol.* 2000 Nov;**21**(11):692–9. doi: 10.1086/501716. PMID: 11089652.
29. Anderson EJ, Kao C, Yildirim I. Hospitalization Is an Underutilized Opportunity to Vaccinate for Influenza. *Mayo Clin Proc.* 2019 Mar;**94**(3):377–9. doi: 10.1016/j.mayocp.2019.01.012. PMID: 30832785.
30. Dexter PR, Perkins SM, Maharry KS, Jones K, McDonald CJ. Inpatient Computer-Based Standing Orders vs Physician Reminders to Increase Influenza and Pneumococcal Vaccination Rates: A Randomized Trial. *JAMA.* 2004 Nov 17;**292**(19):2366. doi: 10.1001/jama.292.19.2366. PMID: 15547164.
31. McFadden K, Seale H. A review of hospital-based interventions to improve inpatient influenza vaccination uptake for high-risk adults. *Vaccine.* 2021 Jan;**39**(4):658–66. doi: 10.1016/j.vaccine.2020.12.042. Epub 2020 Dec 21. PMID: 33357955.
32. Norman DA, Danchin M, Van Buynnder P, Moore HC, Blyth CC, Seale H. Caregiver's attitudes, beliefs, and experiences for influenza vaccination in Australian children with medical comorbidities. *Vaccine.* 2019 Apr;**37**(16):2244–8. doi: 10.1016/j.vaccine.2019.02.077. Epub 2019 Mar 15. PMID: 30885511.
33. McFadden K, Heywood A, Dyda A, Kaufman J, Seale H. Minimising missed opportunities to promote and deliver immunization services to middle and older age adults: Can hospital-based programs be a solution? *Vaccine.* 2021 Jun;**39**(26):3467–72. doi: 10.1016/j.vaccine.2021.05.027. Epub 2021 May 20. PMID: 34024659.
34. Joint Commission. Specifications Manuals. 2020. Available from: http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx [Last accessed: 2023 Dec 15].
35. Berger RE, Diaz DC, Chacko S, Louh I, Wheaton C, Ipolitti C, et al. Implementation of an Inpatient Covid-19 Vaccination Program. *NEJM Catal.* 2021 Sep 15;**2**(10):CAT.21.0235. doi: 10.1056/CAT.21.0235.
36. Odone A, Fara GM, Giammaco G, Blangiardi F, Signorelli C. The future of immunization policies in Italy and in the European Union: The Declaration of Erice. *Hum Vaccines Immunother.* 2015 May 4;**11**(5):1268–71. doi: 10.1080/21645515.2015.1019980. PMID: 25806425.
37. Shevlin J. A systematic approach for increasing pneumococcal vaccination rates at an inner-city public hospital. *Am J Prev Med.* 2002 Feb;**22**(2):92–7. doi: 10.1016/s0749-3797-(01)00408-1. PMID: 11818177.
38. Gerard MN, Trick WE, Das K, Charles-Damte M, Murphy GA, Benson IM. Use of Clinical Decision Support to Increase Influenza Vaccination: Multi-year Evolution of the System. *J Am Med Inform Assoc.* 2008 Nov 1;**15**(6):776–9. doi: 10.1197/jamia.M2698. Epub 2008 Aug 28. PMID: 18756001.

39. Cohen ES, Ogrinc G, Taylor T, Brown C, Geiling J. Influenza vaccination rates for hospitalised patients: a multiyear quality improvement effort. *BMJ Qual Saf.* 2015 Mar;24(3):221–7. doi: 10.1136/bmjqs-2014-003556. Epub 2015 Jan 29. PMID: 25633277.
40. Peterson S, Taylor R, Sawyer M, Nagy P, Paine L, Berenholtz S, et al. The Power of Involving House Staff in Quality Improvement: An Interdisciplinary House Staff–Driven Vaccination Initiative. *Am J Med Qual.* 2015 Jul;30(4):323–7. doi: 10.1177/1062860614532682. Epub 2014 May 9. PMID: 24814939.
41. Gianfredi V, Pennisi F, Lume A, Ricciardi GE, Minerva M, Riccò M, et al. Challenges and Opportunities of Mass Vaccination Centers in COVID-19 Times: A Rapid Review of Literature. *Vaccines.* 2021 Jun 1;9(6):574. doi: 10.3390/vaccines9060574. PMID: 34205891.
42. Smith JG, Metzger NL. Evaluation of Pneumococcal Vaccination Rates After Vaccine Protocol Changes and Nurse Education in a Tertiary Care Teaching Hospital. *J Manag Care Pharm.* 2011 Nov;17(9):701–8. doi: 10.18553/jmcp.2011.17.9.701. PMID: 22050395.
43. Lawson F, Baker V, Au D, McElhaney JE. Standing Orders for Influenza Vaccination Increased Vaccination Rates in Inpatient Settings Compared With Community Rates. *J Gerontol A Biol Sci Med Sci.* 2000 Sep 1;55(9):M522–6. doi: 10.1093/gerona/55.9.m522. PMID: 10995050.
44. Middleton DB, Fox DE, Nowalk MP, Skledar SJ, Sokos DR, Zimmerman RK, et al. Overcoming Barriers to Establishing an Inpatient Vaccination Program for Pneumococcus Using Standing Orders. *Infect Control Hosp Epidemiol.* 2005 Nov;26(11):874–81. doi: 10.1086/502511. PMID: 16320983.
45. Bawa T, Smith D, Andreeva D, Vaidya S, Kruja B, Farrell T, et al. Inpatient COVID-19 vaccination rollout: Improving access to vaccination. *Clin Med Lond Engl.* 2022 Sep;22(5):461–7. doi: 10.7861/clinmed.2022-0132. PMID: 36507810.
46. Dallagiaco G, Allora A, Salvati S, Cocciolo G, Capraro M, Lamberti A, et al. Type 1 Diabetes Patients' Practice, Knowledge and Attitudes towards Influenza Immunization. *Vaccines.* 2021 Jun 29;9(7):707. doi: 10.3390/vaccines9070707. PMID: 34210044.

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