Session 5 - Adult Vaccination in Italy in specific population groups

7 December 2023

Immunocompromised
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ASSENZA CONFLITTO D'INTERESSE

La Sottoscritta Laura STICCHI, in qualità di relatrice, ai sensi dell'art. 3.3 sul Conflitto di Interessi, pag. 18,19 dell'Accordo Stato-Regione del 19 aprile 2012, per conto del Provider dichiara che negli ultimi due anni ha avuto rapporti anche di finanziamento con soggetti portatori di interessi commerciali in campo sanitario:

- MSD vaccini
- Pfizer vaccini
- GSK vaccini
- Sanofi Pasteur vaccini
- Sequirus
- Merck
- Astra Zeneca
- Aj Vaccines
- Novavax

Vaccine recommendations

- **What are specific vaccine recommendations or schedules (if any) for this population in Italy? If applicable, how have these recommendations changed over time?**

VACCINATION and IMMUNODEFICIENCY

Two main questions…

Is it safe ?

Is it effective ?

HOST FACTORS

-Nature of immunodeficiency
-Degree of immunosuppression
-Response to immunization
-Susceptibility to infection

→Vaccine benefit
→**Recommendations**

VACCINE FACTORS

Italian National Immunization Plan (PNPV 2023-25)

	Cardiov.	Resp.	Diab.	Renal	Liver	Pregn.	Aspl.	IC	SOT cand.	HIV <200	HIV >200	HSCT
MMR												
Var												
Zoster (RZV)				Chronic renal failure and on dialysis								
dTpa												
Flu												
Pneum												
Hib												
Men												
HBV												
HAV												

Contraindicated

Recommended

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Italian National Immunization Plan (PNPV 2023-25)
Shingles (Zoster)

At 65 years of age

Vaccination is also recommended for :

- Subjects with diabetes mellitus
- Subjects with cardiovascular disease, excluding isolated hypertension, following risk assessment
- Subjects with COPD and bronchial asthma

It is recommended for the following additional conditions, only with the recombinant adjuvanted vaccine (RZV) use:

- Subjects with congenital/acquired immunodeficiency or candidates for immunosuppressive therapy
- Subjects with chronic renal failure and on dialysis
- Subjects with relapses or particularly severe previous incidents of Shingles

Italian National Immunization Plan (PNPV 2023-25)

HPV

HPV: 2 or 3 doses based on age. The catch-up vaccination is recommended for women up to 26 years of age, also using the appropriate opportunity of the call to the first screening for the prevention of cervical cancer. For men, it is up to 18 years of age including if they have not previously been vaccinated or have not completed the vaccination schedule.

	2 mesi	3 mesi	4 mesi	5 mesi	6 mesi	10 mesi	12 mesi	14 mesi	5 anni	11 anni	13 anni	18-59 anni	50-64 anni	60 anni	65 anni	66 anni e più
Esavalente: Difterite, Tetano, Pertosse, Poliomielite, Epatite B, Haemophilus influenzae di tipo b (DTPa-IPV-HBV-Hib)																
Rotavirus (RV)	i															
Pneumococco coniugato (PCV)															ii	
Meningococco B (MenB)								iii								
Morbillo, Parotite, Rosolia, Varicella (MPRV o MPR+V)							iv									
Meningococco ACWY (MenACWY)							v									
Difterite, Tetano, Pertosse, Poliomielite (DTPa-IPV/dTpa-IPV)									vi		vii					
Papillomavirus (HPV)										viii						
Difterite, Tetano, Pertosse adulto (dTpa)												ix				
Influenza (FLU)[x]					x									xi		
Herpes Zoster (HZV)															xii	
Pneumococcico polisaccaridico 23-valente (PPSV23)																xiii

Le colonne fino a 13 anni si riferiscono a singoli accessi, considerando quindi le relative co-somministrazioni.

Vaccinazione raccomandata per età

It is also recommended for:

- Women who have been treated for CIN2+ or higher grade injuries. Vaccination will possibly be administered before treatment or subsequently, up to a maximum of three years from treatment.

- Subjects with HIV infections

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DGPRE-P

Ministero della Salute

DIREZIONE GENERALE DELLA PREVENZIONE SANITARIA
Ufficio 5 - Prevenzione malattie trasmissibili e profilassi internazionale

Italian COVID-19 vaccine recommendations

OGGETTO: indicazioni e raccomandazioni per la campagna di vaccinazione autunnale/invernale 2023/2024 anti COVID-19.

ALLEGATO 2

Elenco gruppi di Persone a cui viene raccomandata la vaccinazione di richiamo con il nuovo vaccino aggiornato:

- Persone dai 6 mesi ai 59 anni di età compresi, con elevata fragilità, in quanto affette da patologie o con condizioni che aumentano il rischio di COVID-19 grave, quali:

VACCINE RECOMMENDATIONS FOR HOUSEHOLD MEMBERS OF IMMUNOCOMPROMISED PATIENTS

- Flu
- Meningococcal vaccines
- MMR-Var
- Anti SARS CoV-19

Highly immunocompromised patients should avoid handling diapers of infants who have been vaccinated with rotavirus vaccine for 4 weeks after vaccination.

Immunocompromised patients should avoid contact with persons who develop skin lesions after receiving VAR or ZOS until the lesions clear.

Vaccine strategies and services

- What strategies and services are in place to ensure that this population receives the necessary vaccinations?

- How is Italy coordinating efforts with local health departments and community organizations to improve vaccination efforts for this group? What support is provided to address the unique needs of this population? What can be improved?

Italian National Immunization Plan (PNPV 2023-25)

PROMOTE INTERVENTIONS IN HIGH RISK POPULATIONS, FAVORING AN APPROACH FOCUSED ON THE CITIZEN/PATIENT NEEDS

- Vaccination promotion to fragile subjects within **the clinical care path** (e.g. hospitalization, outpatient visits, home care, assistance at local social-health and social-welfare structures, etc.) with the involvement of healthcare workers (GPs/PLS, Specialists).
- Moving to a **proactive approach** for a patient-focused vaccination process, at both the hospital and local level.
- The **PDTA of chronic patients** (e.g. diabetes, heart failure, renal failure, etc.), identified as at risk of infection and serious forms of vaccine-preventable infectious pathologies should integrate specific vaccination programmes. Also, access to the Vaccine Registry which is a database that records and tracks vaccinations that must be available to anyone and any time including but not limited to for specialists, hospitals and local staff.

Italian National Immunization Plan (PNPV 2023-25)

PROMOTE INTERVENTIONS IN HIGH RISK POPULATIONS, FAVORING AN APPROACH FOCUSED ON THE CITIZEN/PATIENT NEEDS

- **Subjects in outpatient follow-up for pathology or who enter the hospital on an inpatient basis should be given the opportunity and encouraged to be vaccinated on these occasions.**

- It is also recommended to involve specialists both in hospitals and in the local areas such as diabetes centres, dialysis centres, transplant centres, oncology-haematology centres, cardiology centres, second level screening centres. for cervical cancer, pulmonology, rheumatology, gastroenterology clinics, etc. in the promotion of vaccination,

- Where it is not possible to provide the necessary vaccinations directly by the service in charge of the patient for the specialist pathology, it is essential **to facilitate the booking** and address activities of the patient themselves at the territorial vaccination centers.

- It is important for all specialists, both hospital and local, to verify that their patients have been vaccinated at the time of taking charge, **indicating in the patient's clinical documents** (for example the discharge letter), the recommendation to carry out the vaccinations required for the risk condition.

Vaccine strategies and services

- What is the current vaccination rate among the target group? Are vaccination rates increasing or decreasing?
- What are the key challenges in vaccinating this population in Italy?

Vaccine coverage for recommended vaccines among splenectomised patients in Apulia, South Italy: a retrospective cohort study

Francesco Paolo Bianchi, Pasquale Stefanizzi, Antonio Di Lorenzo, Eustachio Cuscianna, Silvio Tafuri , Cinzia Annatea Germinario

1650 subjects living in Apulia have undergone splenectomy

Table 2 Vaccine coverage (%) per immunisation prophylaxis and age class of patients

Age class (years)	Anti-meningococcal B (2 doses)	Anti-meningococcal ACYW135 (2 doses)	Anti-pneumococcal (PCV13+PPSV23)	Anti-Hib	Seasonal influenza vaccine*
0–17 (n=77)	39 (50.7%)	32 (41.6%)	16 (20.8%)	30 (39.0%)	37 (48.1%)
18–64 (n=812)	288 (35.5%)	273 (33.6%)	254 (31.3%)	282 (34.7%)	396 (48.8%)
65+ (n=687)	160 (23.3%)	132 (19.2%)	155 (22.6%)	163 (23.7%)	342 (49.8%)

*At least one seasonal influenza shot after splenectomy.
PCV13, 13-valent conjugate anti-pneumococcal vaccine; PPSV23, 23-valent polysaccharide anti-pneumococcal vaccine.

Determinants of influenza vaccination among solid organ transplant recipients attending Sicilian reference center

Vincenzo Restivo, Giovanni Vizzini, Alessandra Mularoni, Cinzia Di Benedetto, Santi Mauro Gioè & Francesco Vitale

Thirty one **(37.8%)** out of 82 solid organ transplant recipients were vaccinated against influenza.

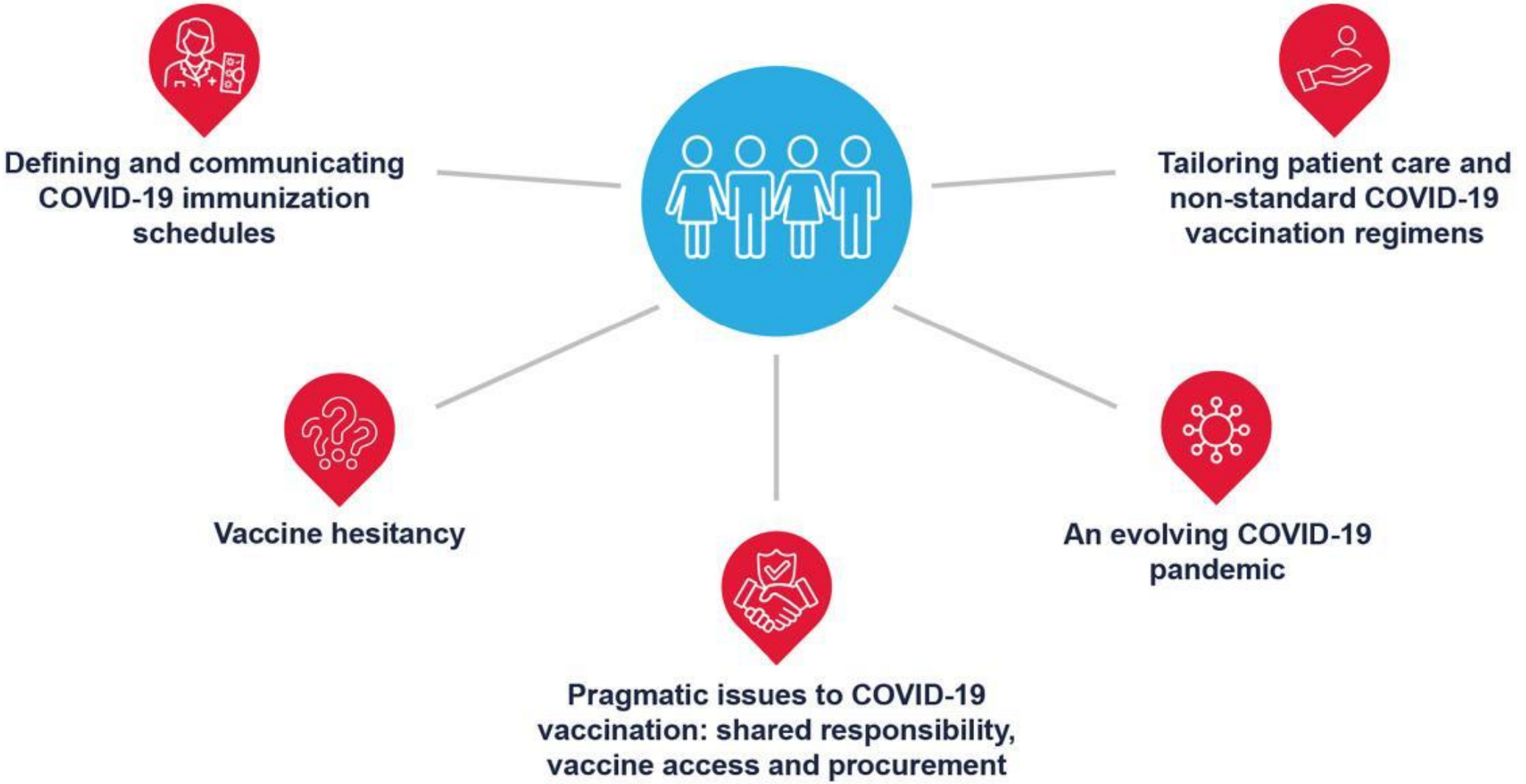
Table 1. Demographics and clinical characteristics of SOT recipients attending RC during 2014–2015 influenza season.

		Total N (%-IQR)	Vaccinated against influenza (n = 31), N (%-IQR)	Unvaccinated against influenza (n = 51), N (%-IQR)	p
Sex	Male	60 (73.2)	26 (43.3)	34 (56.7)	0.088
	Female	22 (26.8)	5 (22.7)	17 (77.3)	
Age		49.8 (46.6–52.0)	53.6 (48.6–50.5)	47.5 (43.4–51.6)	0.063
Country of origin	Italian	79 (96.3)	31 (39.2)	48 (70.8)	0.169
	Other	3 (3.7)	0 (0)	3 (100)	
School level	Nothing	3 (3.7)	2 (66.4)	1 (33.3)	0.128
	Primary	23 (28.0)	11 (47.8)	12 (52.2)	
	Secondary	27 (32.9)	12 (44.4)	15 (55.6)	
	College	19 (23.2)	3 (15.8)	16 (84.2)	
	University	10 (12.2)	3 (30.0)	7 (70.0)	
Employment status	Employed	40 (48.8)	8 (20.0)	32 (80.0)	0.004
	Retired	31 (37.8)	18 (58.1)	13 (41.9)	
	Unemployed	11 (13.4)	5 (45.5)	6 (54.5)	
Smoking habits	Never	43 (52.4)	12 (27.9)	31 (71.1)	0.132
	Not for 10 y	16 (19.6)	7 (43.7)	9 (56.3)	
	Yes	23 (28.0)	12 (52.2)	11 (47.8)	
ILI for 3 last seasons	Yes	35 (42.7)	8 (22.8)	27 (77.2)	0.016
Source of information about influenza vaccination	General Practitioner	29 (35.4)	12 (41.4)	17 (58.6)	0.022
	Reference center physician	19 (23.2)	16 (84.2)	3 (15.8)	
	Parents/friends	4 (4.9)	2 (50.0)	2 (50.0)	
	Other physician	5 (6.1)	1 (20.0)	4 (80.0)	
Vaccination against pneumococcus	Yes	17 (20.7)	11 (64.7)	6 (35.3)	0.010
Performed transplant	Liver	34 (41.5)	13 (38.2)	21 (61.8)	0.653
	Heart	9 (11.0)	4 (44.4)	5 (55.6)	
	Heart and kidney	1 (1.2)	0 (0)	1 (100)	
	Lung	22 (26.8)	9 (40.9)	13 (59.1)	
	Kidney	15 (18.3)	4 (26.7)	11 (73.3)	
	Liver and kidney	1 (1.2)	1 (100)	0 (0)	
Medical history	Bronchopulmunary diseases	26 (31.7)	13 (50.0)	13 (50.0)	0.121
	Cardiovascular diseases	60 (73.2)	24 (40.0)	36 (60.0)	0.498
	Diabetes	25 (30.5)	10 (40.0)	15 (60.0)	0.786
	Chronical renal failure	25 (30.5)	8 (32.0)	17 (68.0)	0.473
	Immunosuppressive diseases	1 (1.2)	0 (0)	1 (100)	0.433
	Chronic hepatitis	31 (37.8)	12 (38.7)	19 (61.3)	0.895
	Leukemia/lymphoma	3 (3.7)	0 (0)	3 (100)	0.169
	Solid tumor	9 (11.0)	4 (44.4)	5 (55.6)	0.663
	Other diseases	51 (62.2)	18 (35.3)	33 (64.7)	0.548

Table 2. Multivariate analysis of factors associated with influenza vaccine uptake among SOT recipients during 2014–2015 influenza season.

	OR	95% CI	
Sex (Male Vs. Female)	2.5	0.5	12.0
Age (per year increase)	1.0	0.9	1.1
Worker (Yes Vs. No)	0.4	0.1	2.5
Retired (Yes Vs. No)	1.3	0.1	11.8
ILI for 3 previous seasons (Yes Vs. No)	0.4	0.1	1.3
Vaccination against pneumococcus (Yes Vs. No)	7.0	1.4	34.4
Influenza vaccination information by Reference Center physician (Yes Vs. No)	53.4	7.2	394.8
Influenza vaccination information by General Practitioner (Yes Vs. No)	4.6	0.9	22.9

Current Challenges for COVID-19 Vaccination Among Immunocompromised Populations

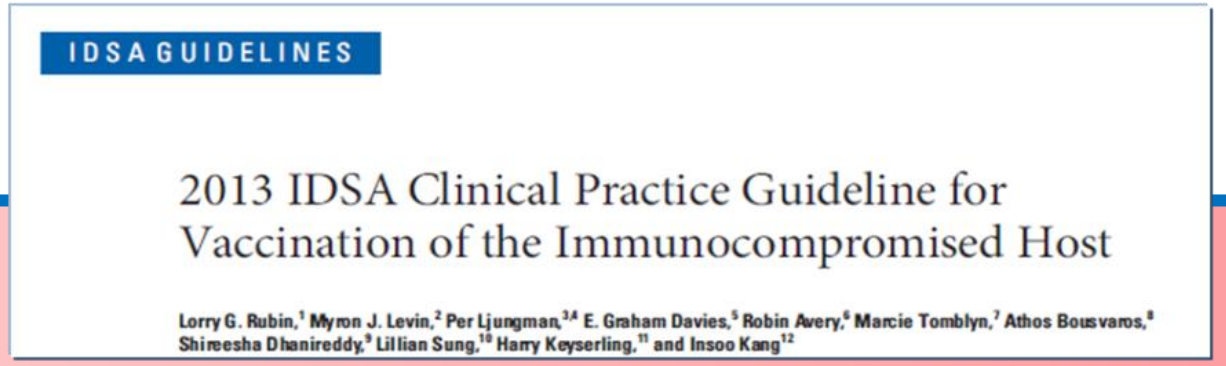


Bonanni P et al., 2023

Succes stories / projects

- **Are there notable successes or best practices in this population that have improved vaccination rates or delivery? What are the future goals and initiatives to improve vaccination in this target group.**

Suboptimal Vaccine Coverage in immunocompromised patients


IDSA GUIDELINES

2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host

Lorry G. Rubin,[1] Myron J. Levin,[2] Per Ljungman,[3,4] E. Graham Davies,[5] Robin Avery,[6] Marcie Tomblyn,[7] Athos Bousvaros,[8] Shireesha Dhanireddy,[9] Lillian Sung,[10] Harry Keyserling,[11] and Insoo Kang[12]

1. Specialists who care for immunocompromised patients share responsibility with the primary care provider for ensuring that appropriate vaccinations are administered to immunocompromised patients (strong, low).

2. Specialists who care for immunocompromised patients share responsibility with the primary care provider for recommending appropriate vaccinations for members of immunocompromised patients' household (strong, very low).

con avallo di

Responsibility of defining the operational proposals for vaccination of fragile adults

PROPOSTE OPERATIVE PER LA VACCINAZIONE DEI SOGGETTI ADULTI FRAGILI/IMMUNOCOMPROMESSI

Società Scientifiche proponenti: SIMIT- Società Italiana Malattie Infettive e Tropicali, SItI- Società Italiana Igiene, Medicina Preventiva e Sanità Pubblica

Con l'avallo delle seguenti Società Scientifiche: AMD- Associazione Medici Diabetologi, IG-IBD Italian Group for the study of Inflammatory Bowel Disease, SID- Società Italiana Diabetologia, SIGE - Società Italiana di Gastroenterologia ed Endoscopia digestiva, SIGG- Società Italiana Geriatria e Gerontologia, SIMG- Società Italiana Medicina Generale, SIR- Società Italiana Reumatologia

Panel di esperti coinvolti nella stesura del documento: Massimo Andreoni, Andrea Buda, Paolo Bonanni, Agostino Consoli, Riccardo Fornengo, Giovanni Gabutti, Roberto Gerli, Francesco Landi, Claudio Maria Mastroianni, Alessandro Rossi

OPERATIONAL PROPOSALS FOR VACCINATION OF FRAGILE/IMMUNOCOMPROMISED ADULTS

Drawing the attention of medical specialists to the national and international recommendations of the relevant Scientific Societies, regarding the vaccinations that must be recommended to their patients.

Creation of ad hoc vaccination paths for fragile/immunosuppressed subjects, where the local public health maintains the overall governance of the vaccinations provided but can make use of the organizational and operational support of GPs and specialists

For that, it is considered essential to overcome some barriers that currently hinder the paths mentioned as soon as possible:

Procurement of vaccines by Hospitals/Health Care Residences (RSAs)/Specialist or General Medicine Clinics
Access to the Vaccination Registry by Hospital Institutions/Health Care Residences (RSAs)/Specialist or General Medicine Clinics

Raise awareness about the problem of vaccination of these subjects to the Health Management Area of Hospital/Welfare Institutions so that they have the organizational measures necessary to deal with this need within their Institutions and collaborate with the Prevention Departments to remove the barriers

IMPORTANT TAKE-AWAYS

- ✓ Immunization in patients with immunocompromised conditions is a life-saving act, but the vaccination coverage in these populations is largely suboptimal;
- ✓ Overall lack of homogeneity (in terms of immune response to vaccination/outcomes) among fragile populations.
- ✓ Raising awareness of the importance of vaccination is needed


Thank you!