

Adult Immunization Board - Country meeting:

*Adult Immunization in Italy: successes, lessons learned
and the way forward*

Meeting summary



A collaboration of



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University
of Antwerp

Dr Chloé Wyndham-Thomas (P95)

Meeting objectives :

ITALY

1. **Epidemiology and disease burden** of VPI among adults, **surveillance and control programs**
2. Overview of the healthcare system in Italy and **structure of (adult) immunization programs**
3. Evaluation and **market authorization process** of (adult) vaccines in Italy
4. **Decision-making process/criteria** for inclusion of vaccines in **immunization programs**
5. **Purchase, distribution and financing** of adult vaccines
6. **Organization and delivery of adult vaccination services** in different regions
7. **Recording and reporting of vaccination data**
8. Population's **vaccination demand and acceptance**
9. Strategies and programs to vaccinate **specific adult population groups**
10. **Future prospects and potential solutions** to overcome barriers and enhance adult immunization

To quote Paolo Bonanni “it will be a challenging meeting”

DISCLAIMER

“If you want me to give you a two-hour presentation,
I am ready today.
If you want only a five-minute speech,
it will take me two weeks to prepare.”

Mark Twain

This summary only covers the Italy-focused presentations

1. Epidemiology and burden of selected VPI

ITALY

Surveillance of VPI in Italy:

- Under EU/ECDC umbrella/regulations
- 50 infections/group of diseases
- Central level competence (MoH), supported by Regions & ISS (National Instit. Of Health)
- Two main surveillance systems :
 - **Mandatory notification system of infectious disease (Decree March 7,2022)**
 - List of predefined diseases. Linked to case definition to ECDC.
 - Flexibility : if new (e.g., Mpox), legal instrument is a degree, updates can be fast
 - **Special surveillance systems (coordinated by ISS):**
 - Where with additional data (e.g., laboratory) and requirements are necessary
 - e.g., IBD, arbovirus, measles, Influenza like illness, COVID-19

1. Epidemiology and burden of selected VPI

ITALY

- **SARS-CoV-2**
 - Decrease in severity of cases in time (infection-induced immunity, vaccines, change in variants)
 - Burden of infections remains high (rapid waning of immunity)
- **Influenza-like illness**
 - RespiVirNet: sentinel GP & pediatric network (4% coverage), epidemiological & virological
 - Unusual waves in last 3 years: 2020-21, no circulation → 2022-23 : high impact
 - 2022 -23 : 14 million ILI cases, Influenza in 22% of positive swabs (80% Type A, 92% H3N2)
- **RSV**
 - Impact of COVID-19 : results from Lombardy show high RSV burden in season 2022-2023
 - Increase in susceptible population, particularly in the very young population
- **Future resp. virus surveillance?**
 - Integration of SARS-CoV-2 and RSV into RespiVirNet
 - Waste-water surveillance of multiple pathogens

1. Epidemiology and burden of selected VPIs

ITALY

- **Diphtheria:**
 - European outbreak 22-23 (migrant pop.) : no signal detected in Italy
- **Tetanus:**
 - Italy accounts for 40% of all cases reported to ECDC. 90% are > 65Y
- **Pertussis:**
 - Age distribution different to EU/EAA level (low for >30y): reporting issues in Italy?
- **Invasive pneumococcal disease (IPD) :**
 - Increase till 2017-2018 → related to improvement of notification (identified by comparing to Hospital Discharge Records)
- **Herpes Zoster:**
 - Previous data (2010) in line with current EU rates: 5-10 cases/person years (~150 000 -300 000 cases in Italy?). Association with 50Y+. 1% hospitalised.

2. Healthcare system & structure of (adult) immunization programs - ITALY

- **Italy :**
 - 19 regions, 2 autonomous provinces → 21 Regional Health Authorities
 - 121 local health units, 57 Public enterprises
 - 30 University hospitals, 64 IRCSS (research centers, regional/MoH)
- **History of National Health system:**
 - 1948 -1978: Social insurance system
 - 1978 : Nation Health Service
 - 2001 : Constitutional reform → regional competencies
- **MoH role:**
 - Definition of objectives to reach to improve population health status
 - National health planning
 - Determination of Essential Levels of Assistance (LEA) → to be provided to any resident, uniformly throughout the whole national territory.

2. Healthcare system & structure of (adult) immunization programs - ITALY

■ MoH → Legislation

- Law/decrees: Mandatory vaccination (see later, specific topic), COVID-19: National Strategic Vaccine Plan for Prevention of SARS-CoV-2 ; List of YF vaccination centers
- Plans : National Vaccine plan, Polio eradication plan, Polio preparedness and response plan, Measles and congenital rubella elimination plan,
- ‘Circular letters’: E.g., yearly Circular for prevention and control Influenza E.g., Mpox interim guidance and description of logistics

■ Regional Health authorities :

- Autonomous in operating strategies → responsible for planning, financing, organizing and implementing vaccination services following the national immunization plan
- Ability to legislate on health issues, respecting the general principles
- Determination of further LEA to be provided uniformly at regional level
→ immunization plan can be extended, if regionally financed
- Responsible for promoting vaccination (mandatory and non-mandatory)

3. Market authorization process

EUROPE (ITALY)

Three regulatory pathways

- **Centralized procedure**, Mutual recognition procedures, De-centralized (national)
 - Obligatory for a series of products, incl. biotechnological processes, e.g., recomb DNA,
 - In practice, most vaccines go through this procedure
 - EMA, EU commission gives formal approval
 - 1 trade name, common labelling, defined procedure and maximum time limit
- Price/reimbursement & recommendations for use are defined and tailored at (sub)national level

Requirements for authorization :

- Vaccine efficacy and safety : gold standard Phase III CT
- If already authorized: comparative vaccine or relative efficacy versus licensed vaccine
- Alternative : immune correlates of protection, immuno-bridging, control human infection models
- Safety at least 3000 individuals and followed 6 months (at least 2)
- Plans for Post marketing surveillance to be set early on (ECDC-EMA vaccine monitoring plan)

4. Decision-making process/criteria for inclusion of vaccines in immunization programs - ITALY

▪ **Calendario Vaccinale per la Vita (Life time Vaccination Calendar)**

- The Board of the Lifetime Vaccination Calendar represents a unique alliance of scientific societies and professional associations: 4 societies SItI, SIP, FIMP, FIMMG (> 50 000 physicians)
- Created to propose the 'ideal' vaccination schedule' based on scientific evidence of efficacy, effectiveness and safety : From 0 – 100 years old
- Its proposal were taken as the backbone of the National Vaccination Plan 2017- 19, one of the most complete vaccination offers available internationally
- The Board of the Calendario Vaccinale per la Vita has published its proposals in the international literature, to make them known, and to offer inspiration for possible similar initiatives
- It constitutes a recognized player in setting up vaccination strategies by Italian health authorities
- Will continue to propose the best possible vaccination offer for all ages of life

4. Decision-making process/criteria for inclusion of vaccines in immunization programs - ITALY

- **National Immunization plan :**
 - All vaccines included in the plan = LEA
 - free of charge , financed by National Health Fund (Statutory financing system) for entire resident population (MoH, Ministry of Economy and Finance)
 - New plan Approved August 2023 - Changes :
 - Immunization schedule can be changed annually, while the plan can last longer
 - Introduction of monoclonal antibodies (mAb) for preventive purposes
 - Key role of Departments of Prevention (NHS) for planning and co-coordination of campaigns
 - Use of pandemic experience (extension of administration sites, e.g., hospitals, pharmacies)
 - Critical issues with 2017-2019 plan: targets of vaccination coverages not reached especially in adolescents and adults. High regional differences, Organisational differences (active call, IT systems), and strong power of Antivax in some regions
 - Adaptation of goals (e.g., Improve communication, vaccination in high-risk groups and of highly vulnerable groups for social and economic conditions)

4. Decision-making process/criteria for inclusion of vaccines in immunization programs - ITALY

- Immunization schedule

Calendario Nazionale Vaccinale per età

	2 mesi	3 mesi	4 mesi	5 mesi	6 mesi	10 mesi	12 mesi	13/14 mesi	5 anni	6 anni	11 anni	12-18 anni	19-59 anni	50-64 anni	60 anni	65 anni	66 anni e più
Esavalente: Difterite, Tetano, Pertosse, Poliomielite, Epatite B, Haemophilus influenzae di tipo b (DTaP-IPV-HBV-Hib)	■					■											
Rotavirus (RV)	■	■	1														
Pneumococco coniugato (PCV)	■					■										2	
Meningococco B (MenB)	■	■	3					■									
Morbillo, Parotite, Rosolia, Varicella (MMRV o MMR+V)							4		■								
Meningococco ACWY (MenACWY)							5					■					
Difterite, Tetano, Pertosse, Poliomielite (DTaP-IPV/dTap-IPV)									6			7					
Papillomavirus (HPV)											8						
Difterite, Tetano, Pertosse adulto (dTaP)															9		
Influenza (FLU)								10									11
Herpes Zoster (HZV)																12	

■ Vaccinazione raccomandata per età

Nota Bene: i mesi e gli anni di vita si intendono compiuti. Esempi: la prima dose DTaP-IPV-HBV-Hib può essere offerta a partire da 2 mesi compiuti, ovvero a partire dal 61* giorno di vita; la dose di richiamo DTaP-IPV-HBV-Hib a 10 mesi, ovvero a partire dal 301* giorno di vita, ecc.

4. Decision-making process/criteria for inclusion of vaccines in immunization programs - ITALY

■ NITAG :

- 3rd NITAG since 2021, Chair Prof. Carlo Signorelli, +29 members
- Independent board, secretary is part of MoH, appointed by MoH (Decree),
- Actions: advisory for NVP, advisory for Circolari on immunization strategies
- Hearings of stakeholders (companies, professional associations, boards)

- Proposal New National Immunization schedule 2024 :
 - 3 working groups: schedule update, vaccines in high-risk pop, vaccines in workers and travellers (not included in LEA)
 - Issues under discussion :
 - Anti COVID-19 in national schedule
 - Anti-men B vaccine in adolescents
 - Anti RSV immunisation (mAb and vaccines) in adults (and children)

5. Purchase, distribution and financing of adult vaccines

	Lombardia (N-ITALY)	Tuscany (C-Italy)	Puglia (S-ITALY)
PROCUREMENT	Regional Public Tenders ARIA Spa	Regional Public Tenders ESTAR	Regional Public Tenders INNOVA Puglia
ASSESSING DEMAND	Prevention Unit of DG Welfare	Historical numbers, NVP, population data. Challenge to identify risk groups	Historical numbers versus vaccine coverage targets
DISTRIBUTION	ASST (local social health authority), can buy vaccines directly from vaccine company (winner of tender)	ESTAR distributes to ASL (Local Health Care Units) and to public/private pharmacies	ASLs (n=6) order vaccines from those regionally procured
FINANCING BODIES	Government (LEA) Other : Co-financing (e.g. Men B)	Government (LEA) Other : Regional (e.g. work-related vaccines) or Patient Co-financing	Government (LEA) No Co-funding
Sustainability	Not commented	Not commented	Challenges for high priced new vaccines
Role Health insurance	Not commented	Not commented	None
Role employer	Not commented	Not commented	Very limited (e.g., Flu, travel)
IMPROVEMENT STRATEGIES	Not commented	Draw dedicated budget for innovative drugs and request additional National funds; Identify and address barrier; Dev. relationships with all stakeholders	Expanding role to Pharmacy Consensus meetings with Stakeholders

6. Organization and delivery of adult vaccination services

	Lombardia (N-ITALY)	Tuscany (C-Italy)	Puglia (S-ITALY)
VACCINE ADMINISTRATION	ASST (n=27), GP, Pediatricians, Hospitals, LTCF, Community Homes, Pharmacists	ASLs (n=3, children and adults), GP (adults mostly), Pediatricians, Occupational medicine, Pharmacists (Covid/Flu, adult)	GPs , PH vaccine centers (PCV/Zoster), University hospitals (2x), Pharmacies : new (COVID-19), limited
RECORDING, REPORTING, ACCURACY	Methods not commented. But vaccine coverage data publicly available	SISPC, communicates with National Registry. Accuracy/completeness though alerts and mandatory fields	Regional database : Software accessible to GPs (others on demand). Communicates with National registry , but not completely integrated Issues for denominator data for risk pop.
OUTREACH PROGRAMS	Homeless vaccination, community homes. Vaccine project for Diabetic patients . n-hospital campaigns (Zoster - cancer). Open day free vaccinations	Two open days for HPV vaccinations	Not commented
PROMOTING ACCEPTANCE	Portal for Vaccine communication	Tailored communication and campaigns, engagement GP/pharma	Not commented
SUCCESS STORIES	COVID-19 vaccination: by Pharmacists 46%, ASST 28%, GP 17%	COVID vaccination : vaccination centers, booking system etc	COVID-19 vaccination: initial coverage Influenza adult vaccine rates Mandatory vaccination in HCW

7. Recording and reporting of vaccination data

ITALY

MONITORING VACCINE COVERAGE

National Vaccine REGISTRIES

- National Vaccine Registry : 2017-2018 (with mandatory law)
 - Aim to tracks vaccination. Collect and exchange with international institutions
 - Data fed by regions and autonomous provinces : personal info, vaccine data, lack of vaccination
 - Quarterly basis
- National Vaccine Registry COVID-19 : 2022-2021
 - Daily basis, dashboard : by vaccine type, risk group, age group

Other Data sources

- Flu vaccination registration system
- ISTAT multipurpose survey on households (self-reported vaccinations)
- “PASSI” : specific database monitoring trends of risk factors/preventive measures at local level

7. Recording and reporting of vaccination data

ITALY

MONITORING VACCINE EFFECTIVENESS

- Retrospective cohort study :
 - COVID-19 : fiscal code allowed link COVID-19 vaccine and the SARS-CoV-2 surveillance data from the National Integrated surveillance system
 - Post-marketing COVID-19 Vaccine effectiveness e.g., age-groups, brand-specific
- Case-control study: test negative controls
- Screening methods: proportion of vaccinated subjects among those presenting the disease
 - Tuscany, Men C outbreak, VE 77%

Frequent updates on vaccination coverage and effectiveness in adults are a crucial resource for policy making and strategies aimed at improving overall public health outcomes

7. Recording and reporting of vaccination data

ITALY

MONITORING SAFETY/PHARMACOVIGILANCE - Mandate of AIFA : Agenzia Italiana Del Farmaco

- Adverse event of following immunization (AEFI) = Untoward medical event after vaccination
 - Vaccine product related , quality defect, immunization error, anxiety related, co-incidental
- AEFI rates with non-COVID-19 vaccines: 78/100 000 doses, most are mild (severe 3.6/100 000 doses)
- AEFI rate COVID-vaccines: 97/100 000 doses, mostly related to mRNA vaccines
- CovidVaccineMonitor.eu : EMA funded, prospective surveillance, 16 EU countries.
 - Active surveillance via a web-app (smartphones), collecting solicited & unsolicited safety events
 - 2982 persons participated in Italy: Local events and non severe systemic were all higher with Spikevax. Unsolicited events were the same across vaccine types
- Pregnancy and breastfeeding :
 - Perceived risks and benefits on deciding on COVID-19 vaccination
 - MAGNOLIA: serious game application (n=125, Health literacy)
 - Request for shared choices with professionals and information on safety

8. Population's vaccination demand and acceptance

- ITALY

Vaccine confidence project: results from EU (focus on Italy)

- Biannual survey tool to monitor trends in vaccine confidence → good predictor of uptake
- ITALY :
 - Better than EU average for % agreeing that vaccines are important/safe/effective/compatible, only exceptions perception for HPV and MMR, close to EU average .
 - In HCW: vaccine confidence is lowest for Flu and COVID-19 in pregnant women.
 - No Socio-demographic factors influencing vaccine confidence. The vaccine confidence age gap : Age groups 45y + on MMR are importance and safe compared to younger groups

Mixed-methods study on HCW vaccine confidence :

- Rational : HCW vaccine confidence influences self-vaccination and vaccination of patients
- ITALY: Nursing, midwives and HCPs were less confident.
- **Lack of trust** in health authorities and in information provided. Likelihood to recommend COVID-19, but **lower for HPV, MMR**. Less comfortable to communicate on **safety and in particular adjuvants**

8. Population's vaccination demand and acceptance

- ITALY

Actions to counteract hesitancy and increase acceptance and coverage rates:

- Parental Vaccine hesitancy in Italy 2016 (mandatory vaccination, ISS) : 3130 questionnaires: 83.7% pro vaccines, 15.6% hesitant, <1% anti vaccine

10 Actions to counteract vaccine hesitancy, recommendations Italian Society of Public Health

- National multidisciplinary **working group, monitoring** of vaccine hesitancy, **tools, good practices, training** and promoting knowledge on hesitancy, risk communication, behavioral, **promoting collaborations, community engagement, infodemiology**
- Successfully included in new NVP, both as an objective and strategy, with a specific chapter on framework for vaccine communication
- Rebuilding trust : e.g., online tools, reliable references.
- Reliable references : regional websites : *VaccinarSi*
- Infodemiology : social media monitoring is essential, to pick up signals

8. Population's vaccination demand and acceptance

- ITALY

The law on compulsory vaccination in Italy: an update after 2 years

- Before 2017 : Four mandatory vaccines: polio, diphtheria, tetanus, hepatitis B
- Veneto Region stopped mandatory vaccination in 2007 : vaccine coverage dropped
- 2017 Measles epidemic → Italy and Romania put under trial at WHO
- Law Decree 2017 : 10 mandatory vaccines for 0-16y : + Hib, pertussis, measles, mumps, rubella, varicella
 - Catch-up of unvaccinated children
 - Enforce penalties: Children not vaccinated cannot be enrolled in nursery/school; parental fines
 - Challenges : political discussions, organization, 1% antivax-obstacles, regional differences
- Positive impact :
 - Everyone talking about vaccines, high impact, media took clear position in favor
 - Importance of monitoring vaccine coverage.
 - Vaccine coverage from 2016 - 2022, Italian average:
 - Mandatory : Polio 93% → 95%; MMR 87% → 94% ;
 - Non mandatory : Pneumococcal : 88% → 91% HPV (coverage 15y, males) : 18% - 56 %

9. Strategies/programs to vaccinate specific adult populations

	OLDER ADULTS	HCW	PREGNANCY
SPECIFIC RECOMM.	Flu, PCV, HZ, Tdap Circular 23/24 : High dose or adjuvanted flu vaccines	Flu, HBV, MMR, Varicella, Tdap (BCG) Circular- Seasonal COVID-19	Tdap 3rd Trim, each pregnancy Flu (any time) Circular - COVID-19 2nd or 3rd Trim.
STRATEGIES	Multiple strategies at regional and local administrative district, focusing on hospital setting and Influenza vaccine campaign	At work?, Proximity vaccination, territorial vaccination unit or GPs	Prev. department clinic, Obstetrics department and birth center, Vaccination centers , (GP clinics)
VACCINATION RATES	Flu : below the 75% target (56%), decreasing over time, No good national data for Pneumococcal or HZ, but estimated at <30% & 5-12%, COVID-19 5th dose : 3.4- 18.9%	No official national data , Higher for vaccines with individual perceived risk	No Official National data, No denominator data, Regional level : Tdap highest
CHALLENGES	Lack of training, Regional differences	Lack of coordination	Vaccination pathway
SUCCESS STORIES	PROVAX: vaccinated end of hosp. stay Emilia-Romana: information on vaccination needs in discharge letter	COVID-19 : 94% for primary.	Palermo : Educational intervention in childbirth classes
FUTURE GOALS	Insert vaccination in specialist guidelines; Other sites	Incentives to Flu vaccine (paid vacation day), On site Hospital Unit, Encourage departmental competition	Vaccination pathways, Free access, HCW awareness, Outreach campaigns (diff languages)

9. Strategies/programs to vaccinate specific adult populations

	Immunocompro.	Migrants	Young adults (HPV)	Travellers
SPECIFIC RECOMM.	Aspl, IC, SOT, HIV, HSCT, HMM Defined in NEW NVP: Zoster recomb. Vaccine, HPV (HIV+); Circular : COVID-19 (6m+)	Children : according to age (NVP) Adults: polio, MMR, varicella, Tdap, Hep B	Free of charge in women with CIN 2+ ; Free catch up during first screening (25y)	After consultation; Routine vaccinations ; Hep A in VFR's children (free) , Hep B-DTP(P)-MMR
STRATEGIES	Clinical care pathway Proactive approach	NEW NVP, strategy to reduce inequalities; to implement	Not commented	One dedicated "travel clinic" per ASL No real efforts/policy
VACC. RATES	No National level data, No denominator. Sub local/Region studies in subgroups	Specific studies : Flu in HR patients, PASSI: Rubella in women, COVID-19 → lower uptake in uptakes	Not commented	No denominator data, not a specific group in registry. Roughly 50% are see pre travel, <20% if VFR
CHALLENGES	e.g., COVID-19 : evolving pandemic, vaccine hesitancy, communication,	Cultural, linguistic, contact and invitation, health service access, mistrust	Not commented	COVID-19 = total disruption Travel medicine not a recognized discipline
SUCCESS STORIES	Sitl and Simit, operational proposals for vacc of IC	AcToVax4NAM : newly arrived migrants; Co-created Tools	SPERNAZA: HPV vacc after (pre) cancer lesions	Rabies vaccine Catch up vaccinations
FUTURE GOALS	Involvement of Specialists (IDSA); Facilitate booking; info in discharge letter, Access to NVR	Multidisciplinary approach, easy access, incl. civil societies/Social services, strengthen NVR (on the move)	Research on vaccination timing - RCT trials NOVEL, HOPE9 (9 Italian centers)	Vaccinology formally taught, Travel medicine recognized as discipline, Denominators

STRENGTHS

ITALY

- Lifetime vaccination planner, National Vaccination Plan
 - Vaccines in NVP are Free of charge (LEA)
 - Mandatory vaccinations & positive impact on coverage
- Multiple success stories/ best practices at regional level
 - e.g., Lombardy: extension of vaccination by pharmacies; Veneto : Zoster 50% in 65y+;
 - e.g., In risk groups - PROVAX program, AcToVax4NAM
- COVID-19 :
 - Uptake and monitoring, post-marketing surveillance (safety/effectiveness), administration sites/strategies
- Vaccine vigilance system

CHALLENGES

ITALY

- Fragmentation of NHS → complexity, regional disparities (inequalities), Arlequin effect
- Economical issues :
 - National health Fund : only 5% for prevention.
 - Since 2017, budget for vaccination, but also for innovative drugs (competitive) ;
 - High Expenditure : high due to regional tenders and organizations
- Adults are not prioritized
- Campaigns, insufficient, need to be targeted
- Stock of vaccines and order system
- Reporting of VPI, gaps in data (e.g., pertussis, zoster)
- Regional registries not fully integrated with National Vaccine registry
- Vaccine coverage. Lack of data in specific risk groups and denominator issues.
- Vaccine hesitancy : 15%, strategy defined in new NVP
- Changing demographics, ageing population
- Hard-to-reach populations : e.g., migrants



10. FUTURE PROSPECTS AND POTENTIAL SOLUTIONS

ITALY

- Better prioritization of vaccination strategies in the adult population
- Collect and learn from best practices and organizations in successful regions, tailored to local needs
- Increase vaccine site: pharmacists, other
- Structuring of campaigns
- Knowledge - Vaccine literacy, training of HCW
- More regulation on a National level strategy
- Improve access (time, booking)
- Multisectoral approach
- Collaboration between primary care (in restructure, family nurse) and hospitals
- Role of scientific societies
- Translation of statements and identified solution into action
- Improve denominators, to improve vaccine coverage data