

Session 5 - Adult Vaccination in Italy in specific population groups

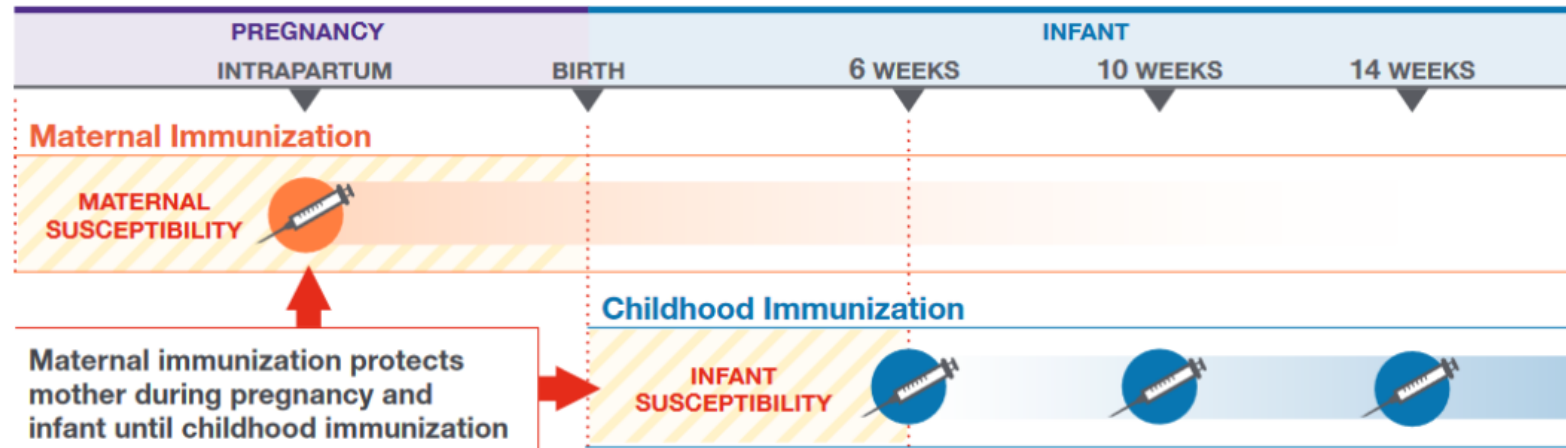
5.3 - Pregnant women

Angela Bechini



7 December 2023

Maternal immunization



Lackritz EM, et al. Maternal immunization safety monitoring in low- and middle-income countries: a roadmap for program development. Bill & Melinda Gates Foundation and Global Alliance to Prevent Prematurity and Stillbirth (GAPPS), 2017.

Vaccination during pregnancy strengthens the mother's immunity and allows the transfer of maternal antibodies to the unborn child in utero through the placenta or, after birth, through breast milk. For newborns, maternal passive antibodies provide essential protection during a “**window of vulnerability**” when children are too young to get their own vaccinations.

Vaccine recommendations in pregnancy in Italy and schedule

- In Italy vaccinations during pregnancy are offered free of charge in accordance with the **National Immunization Plan (NIP) 2023-25**, issued in August 2023.

- **Tdap** vaccination of the woman is recommended and should be offered in the third trimester (ideally around the 28th week, in a range from the 27th to the 36th week) of each pregnancy (even if a vaccination was given in the previous year or if the woman is up to date with Tdap vaccine boosters).

- Tdap vaccination is also recommended for those living with newborns.

- **Influenza** vaccination is now recommended at any time of pregnancy

- **COVID-19** vaccination is also recommended according to the National Strategic Vaccine Plan for Prevention of SARS-CoV-2 Infections and Updating Circulars.

LEA:
ESSENTIAL
LEVEL OF
ASSISTANCE

Vaccine recommendations: brief history of maternal vaccination in Italy

Influenza/Tdap/COVID-19

Influenza vaccination was recommended for **the first time** to women who will be in their 2nd or 3rd trimester of pregnancy at the beginning of the flu season

It is recommended to **fully inform both general practitioners and gynecologists/obstetricians** about the opportunity to offer **vaccination free of charge** to this category.

National Immunization Plan
2012-2014

Influenza in 2nd or 3rd trimester of pregnancy and **Tdap** vaccine :
Essential Level of Assistance

2005-2006
Winter season

2010-2011
Winter season

2012-2014

2017-2019

Influenza annual Circular Letter from the Ministry of Health recommend Influenza vaccination

Influenza
Essential Level of Assistance

National Immunization Plan
2017-2019

How have these recommendations changed over time?

Vaccine recommendations: brief history of maternal vaccination in Italy Influenza/Tdap/COVID-19

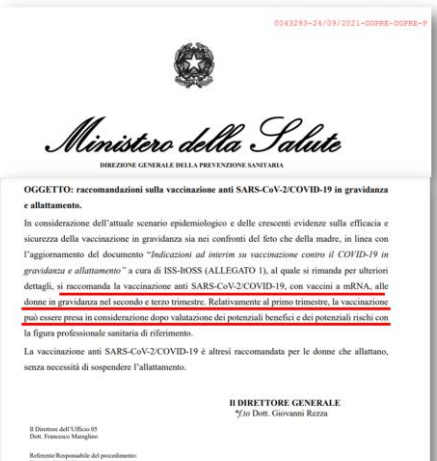
Circular 2018 prot. n. 0023831-07/08/2018 on recommended vaccinations for childbearing age and pregnant women (flu and Tdap in the 2nd-3rd trimester of pregnancy)



2018
August

2019
November

Circular prot. n. 0035309-04/08/2021 COVID-19 vaccines are not contraindicated during pregnancy



2021
August

2021
September



Circular 2019 prot. n. 0033045-12/11/2019 on recommended vaccinations for childbearing age and pregnant women (flu at any time of pregnancy and Tdap in the 2nd-3rd trimester of pregnancy)

Dedicated National strategic Vaccine Plan for Prevention of SARS-CoV-2 Infections (Decree of the Ministry of Health) and Updating Circulars

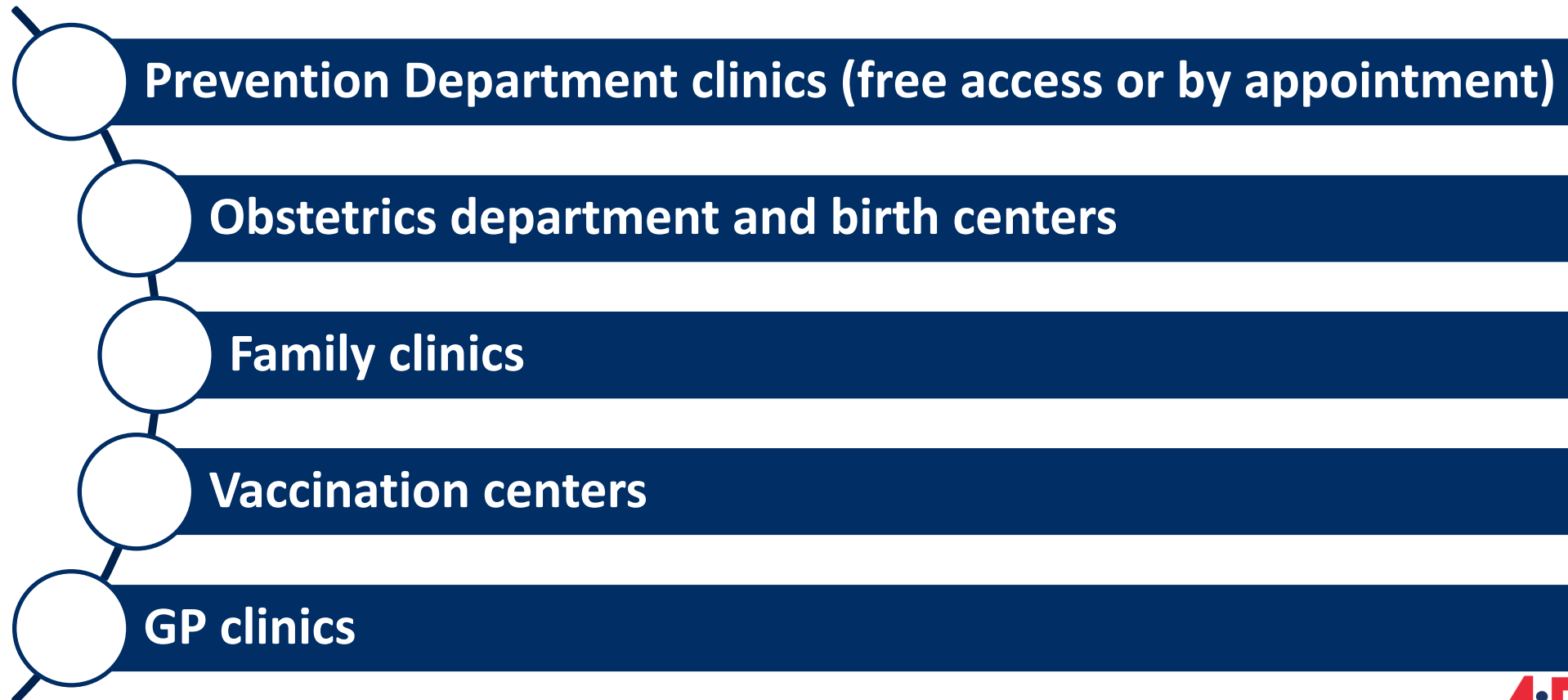
Circular 2021 prot. n. 0043293-24/09/2021 COVID-19 mRNA vaccines recommended in the 2nd-3rd trimester of pregnancy

How have these recommendations changed over time?



Vaccine strategies and services - 1

□ Place of administration



Vaccine strategies and services - 2

Personnel involved



Gynaecologists referred their patients directly to the Prevention Department to carry out vaccinations which are administered by healthcare assistants and nurses, while those carried out in hospitals are carried out by nurses.

Vaccine strategies and services - 3

- **Organization of the offer**
- The **promotion of vaccinations** in pregnancy is guaranteed as part of **birth support program or antenatal courses**. Vaccinations to pregnant women are offered **FREE OF CHARGE** in accordance with the NIP 2023-25.

There are different strategies in the Italian Regions:

- **Direct and free access to the Prevention Department and Vaccination centers of the LHA:** pregnant women can access the clinics without any appointment and can be vaccinated immediately, once a week in some LHA
- **Appointment via Unified Booking Center (CUP), the centralized computerized system for booking healthcare services, dedicated agenda (*frequently*)**
- **In case of hospitalized patients, vaccination is carried out in hospital (*rarely*)**

Vaccine strategies and services - 4

- All regions offered the recommended vaccinations
 - **Influenza**
 - **Tdap**
 - **COVID-19**

- **What support is provided to address the unique needs of this population?**
 - Informative material available in different languages
 - Training courses for HCWs involved in the vaccination of pregnant women
 - Free access to vaccinations
 - Dedicated agenda for appointments to the vaccination centers

Vaccine strategies and services - 5

- **What are the key challenges in vaccinating this population in Italy?**
 - The activation of dedicated vaccination pathways (Diagnostic Therapeutic Assistance Path – PDTA)

Rarely Italian regions have in place a dedicated pathway for the vaccination of pregnant women. Some regions are working on the implementation of these pathways between gynaecologists and the Public Health Services or creating a vaccination center for risk groups in hospital setting which can be directly accessed by pregnant women after routine visits.

- **What can be improved?**
 - The monitoring of administered vaccinations in pregnancy

Vaccine strategies and services - 6

- Data on **vaccination coverage** among pregnant women at the national level **is not available**. Thus, it is impossible to estimate whether vaccination rates are increasing or decreasing after the adoption of strong recommendations.
- Since 2017/2018 a **National Vaccination Registry** (NVR) was introduced by the Ministry of Health.
- NVR was available to regions **from the first quarter of 2019** to transfer their data through the Regional Vaccination Registry. This is not an automatic procedure!
- **At the end of 2020** in the NVR the “**Pregnancy Status**” was added as an **optional field** (not mandatory). This field indicates whether the person who received the COVID-19 vaccination (or other vaccinations) is a pregnant woman. The allowed values are: 0 – Not pregnant woman; 1 - Pregnant woman; 2 – Woman who does not exclude pregnancy.

Vaccine coverage available at regional (or local level)

- ❑ In Tuscany data extraction from the Regional vaccination registry reported the number of women not excluding pregnancy, in pregnancy and in post-partum (update to November 2023*).
- ❑ **Denominators are not available to calculate vaccine coverage** for COVID-19, flu and Tdap vaccines in pregnant women, but we can assume a pregnant woman for each newborn, and we can estimate a crude vaccination coverage for COVID-19, influenza and Tdap from 2021 to 2023*.
- ❑ Newborns in Tuscany were **on average 22,500** each year in the years 2021 - 2023*.

| Denominazione vaccino - Denominazione vaccino | | COVID-19 | Anti Difterica | Influenza | Pertussis | Anti Tetanica |
|--|-----------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Denominazione categoria rischio | Anno somministrazione | Numero somministrazioni | Numero somministrazioni | Numero somministrazioni | Numero somministrazioni | Numero somministrazioni |
| Woman who does not exclude pregnancy | 2021 | 244 | - | - | - | - |
| | 2022 | 119 | - | - | - | - |
| | 2023 | 27 | - | - | - | - |
| Pregnant woman | 2021 | 1.147 | - | - | - | - |
| | 2022 | 774 | - | - | 1 | 1 |
| | 2023 | 208 | - | - | - | - |
| Pregnant woman at the beginning of the epidemic season or woman in post-partum | 2021 | - | - | 1.746 | - | - |
| | 2022 | - | 1 | 2.148 | 1 | 1 |
| | 2023 | - | - | 1.444 | - | - |
| Pregnant woman | 2021 | - | 8.952 | 1 | 8.941 | 8.958 |
| | 2022 | - | 8.599 | 1 | 8.598 | 8.608 |
| | 2023 | - | 7.926 | - | 7.925 | 7.932 |

Handwritten annotations in blue:

- For COVID-19: 6.2% (2021), 3.9% (2022), 1% (2023)
- For Anti Difterica: 5% (2021), 3.4% (2022), 0.9% (2023)
- For Influenza: 8% (2021), 9.8% (2022), 6.6% (2023)
- For Anti Tetanica: 41% (2021), 39.4% (2022), 36.4% (2023)

Newborns in Tuscany:

1st January 2020: 23,220; 1st January 2021: 22,427

1st January 2022: 22,654; 1st January 2023: 21,834

Vaccine coverage available at regional or local level (Tuscany) - 1



Article

Descriptive Observational Study of Tdap Vaccination Adherence in Pregnant Women in the Florentine Area (Tuscany, Italy) in 2019 and 2020

Benedetta Bonito ¹, Daniela Balzi ², Sara Boccalini ¹, Paolo Bonanni ¹, Giovanna Mereu ², Maria Grazia Santini ² and Angela Bechini ^{1,*}

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Aim: To describe for the first time the rates of adherence to Tdap vaccination by pregnant women in the Local Health Agency - Tuscany Center (provinces of Florence, Prato, Empoli and Pistoia), the socio-demographic characteristics and the determinants of Tdap vaccination adherence.

The data was collected for the years **2019 and 2020**.

The population of pregnant women for the year 2019 included **10,072 women** residing in the LHA of TC.

Vaccine coverage available at regional or local level (Tuscany) - 2



Article

Descriptive Observational Study of Tdap Vaccination Adhesion in Pregnant Women in the Florentine Area (Tuscany, Italy) in 2019 and 2020

Benedetta Bonito ¹, Daniela Balzi ², Sara Boccalini ¹, Paolo Bonanni ¹, Giovanna Mereu ², Maria Grazia Santini ² and Angela Bechini ^{1,*}

The vaccination coverage rate for Tdap was **43% in 2019** and **47.3% in 2020**.

Probable "SARS-CoV-2 pandemic effect" which significantly increased the perception of the risk of contracting vaccine-preventable diseases. Lower rates of vaccination coverage than other European countries have been observed (e.g. Belgium: 64%; UK: 50% - 62%).

Determinants for greater adherence to vaccination were: **Italian citizenship of both parents, older age and higher educational level of the mother, and reduced number of previous births/abortions.**

Success stories / projects (Sicily – Palermo) - 1

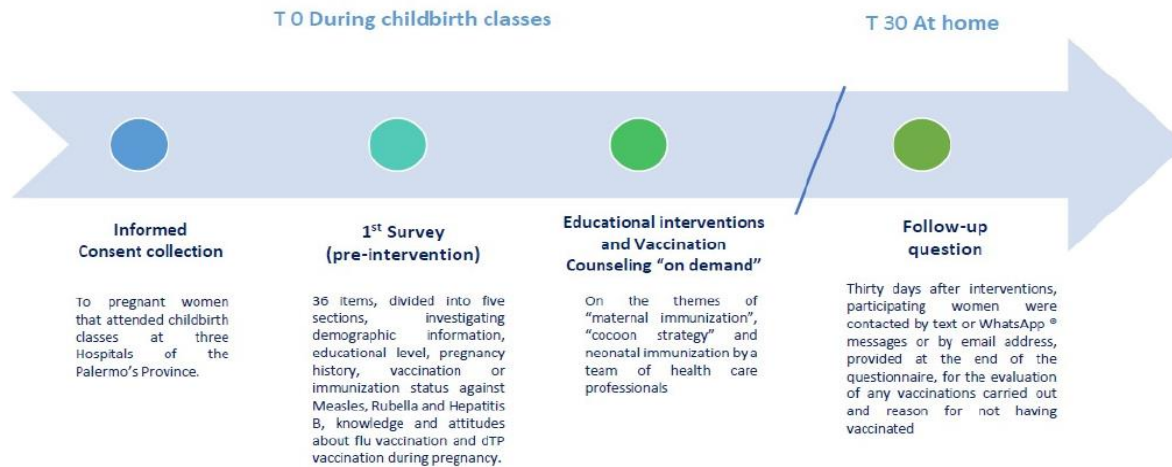


Figure 1. Timeline of the study design at T0 (during childbirth classes) and at T30 (pregnant women participating from home).

Among the 201 responding pregnant women, after the Educational intervention:

- 47.8% received influenza vaccination
- 57.7% received Tdap vaccination
- 64.2% received at least one of the recommended vaccinations.

The main reasons reported for vaccine refusal were: fear of adverse events (47.6%), vaccinations were not recommended by gynaecologist/obstetrician (43.4%) and, only for influenza vaccination, the intervention was conducted outside the seasonal influenza vaccination campaign (9%).

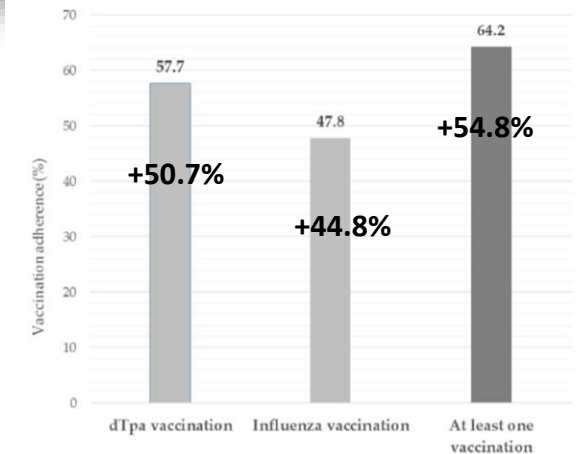
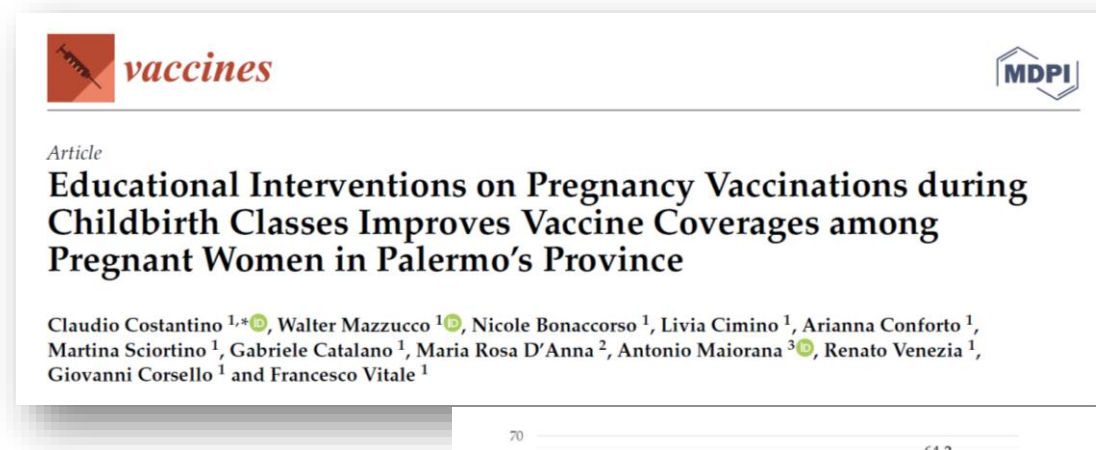


Figure 2. Adherence (%) to recommended vaccinations during current pregnancy following the counseling intervention, among the 201 pregnant women responding to the follow-up questions.

Success stories / projects (Sicily – Palermo) - 2

Are there notable successes or best practices in this population that have improved vaccination rates or delivery?



Article

Educational Interventions on Pregnancy Vaccinations during Childbirth Classes Improves Vaccine Coverages among Pregnant Women in Palermo's Province

Claudio Costantino ^{1,*}, Walter Mazzucco ¹, Nicole Bonaccorso ¹, Livia Cimino ¹, Arianna Conforto ¹, Martina Sciortino ¹, Gabriele Catalano ¹, Maria Rosa D'Anna ², Antonio Maiorana ³, Renato Venezia ¹, Giovanni Corsello ¹ and Francesco Vitale ¹

During pregnancy, the combination of correct information and consistent recommendations provided by HCWs can be considered to be one of the strongest predictive factors, increasing the chances of adherence to highly recommended vaccinations during pregnancy and the involvement of gynaecologists and obstetricians

To increase vaccination adherence during pregnancy the permanent inclusion of educational interventions by teams of trained healthcare professionals, during pre-partum courses, on the topic of maternal immunization, but also on the importance of the cocoon strategy should be extended to the national level.

Educating and training gynaecologists and obstetricians on vaccination themes could further improve in future vaccines adherence during pregnancy.



SWOT ANALYSIS

Strengths

Adequate and complete regulations, strong national and regional recommendation, training courses and vaccination offer through antenatal courses. Different HCWs involved in vaccinations pathways.

Weaknesses

Absence of agreements/protocols/procedures that standardize the path and agreement between operators (gynaecologists and PH specialists). Non-uniform protocols on the regional territory. Different training courses in different LHA and non-homogeneous offer on the national territory.

Opportunities

Some good and effective practices to be implemented. Antenatal courses as training places. Vaccination in hospital (gynaecology departments) or hospital vaccination clinics, vaccination through GPs. Possible inclusion of a gynaecology representative in the Vaccine Regional Technical Group to strengthen maternal immunization vaccination policies.

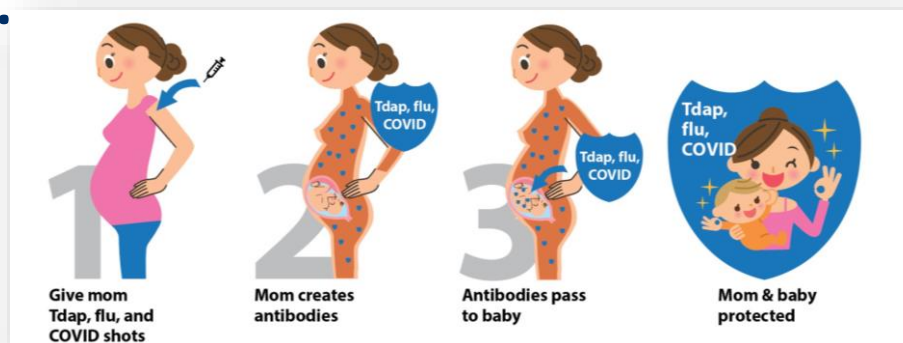
Threats

Possible health inequalities in the access to vaccination due to staff shortages in vaccination services, difficulties in offering free access. It is often not possible to identify migrant women or women of low socio-economic and low educational level who do not attend antenatal courses or who limits visits during pregnancy to a minimum.

Conclusion

What should be the future goals and initiatives to improve vaccination in this target group?

- The implementation of dedicated vaccination pathways to facilitate the adherence to recommended vaccinations and to future available vaccinations (e.g. RSV)
- The extension of free access to vaccination clinics/centers for pregnant women
- The sensibilization of all HCWs involved in the vaccination process of this target group
- The importance of an adequate communication and outreach campaigns, informative materials and FAQs available in different languages to break down possible cultural barriers.



Thank you for your attention!

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The **FIND MY VACCINE** webpage:
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for the **Italian CITIZEN** but also for the
HEALTHCARE OPERATOR

to identify the recommended vaccinations based
on the personal characteristics of the
subject/patient

Autori: Sara Boccalini, Angela Bechini, Marco del Riccio, Alessandra Ninci, Paolo Bonanni