

SARS-CoV-2 Genomic surveillance activities in Italy

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Influenza virological surveillance in Italy: NIC/ISS and the INFLUNET Laboratory Network



The Influnet Laboratory Network

N. 21 peripheral Laboratories

1. Bolzano, Trentino-Alto Adige
2. Torino, Piedmont
3. Milano, Lombardy
4. Pavia, Lombardy
5. Padova, Veneto
6. Trieste, Friuli-Venezia Giulia
7. Genova, Liguria
8. Parma, Emilia-Romagna
9. Firenze, Tuscany
10. Perugia, Umbria
11. Roma, Catholic Univ., Lazio
12. Bari, Apulia
13. Sassari, Sardinia
14. Palermo, Sicily
15. Roma, Spallanzani Hosp., Lazio
16. Bologna, Emilia-Romagna
17. Pisa, Tuscany
18. Ancona, Marche
19. Pescara, Abruzzo
20. Napoli, Campania
21. Cosenza, Calabria



+ 5 newly enrolled peripheral Laboratories for the 2022/23 season

1. Trento, Trentino-Alto Adige
2. Aosta, Aosta Valley
3. Campobasso, Molise
4. Potenza, Basilicata
5. Matera, Basilicata

The Influnet Network has been recently geographically extended to cover the entire national territory, with a total 26 laboratories located in all the Italian Regions.

The early detection of viral variants, their characterization and tracing as a critical component of the pandemic response

Italy has defined and implemented a sequencing strategy of SARS-CoV-2

- To optimize sequencing and obtain data that may guarantee a continuous flow of information (on which the early identification of new variants is based)
- To obtain a high precision estimation of the prevalence of viral variants

Sequencing strategies for identification and monitoring of SARS-CoV-2 variants in Italy

Two independent collection flows

(MoH circular 0017975-17/03/2022)

Weekly structured sequencing, where targeted sampling does not overlap with random sampling

Periodic (monthly flash surveys)

High-precision
prevalence estimation

Random sampling

Carried out on an agreed day of the month and statistically calibrated to intercept variants that circulate, in each macro-region, with a prevalence 0.5-1%, at a confidence level of 95%.

Continuous

Real-time monitoring of
circulating viral genotypes and
early warnings issue

Targeted sampling

Statistically calibrated to intercept variants that circulate, at national level, with a prevalence $>0.25\%$, at $>90\%$ probability, by considering 1.000 sequences per week, regardless from the estimated number of cases.

Categories:

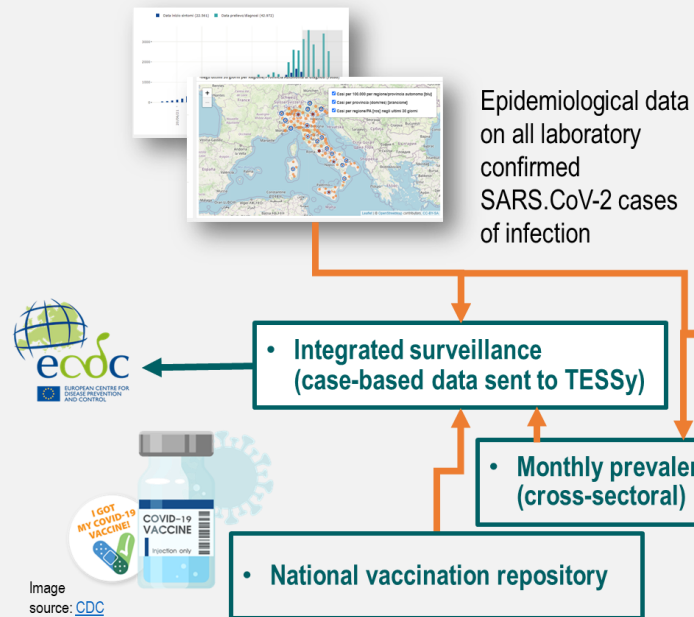
1. hospitalized subjects;
2. subjects at ICU;
3. reinfected subjects;
4. immunocompromised;
5. subjects returning from targeted countries;
6. atypical manifestations.

The data converge in the monthly bulletin

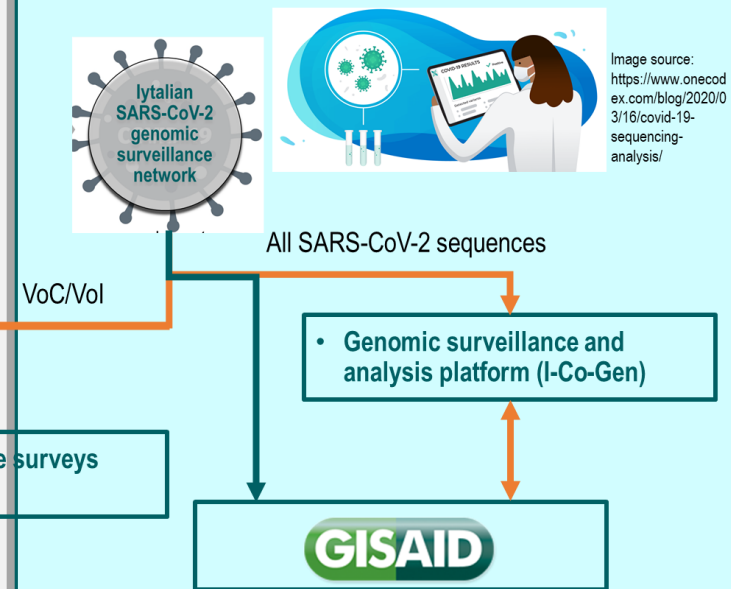
“Prevalenza e distribuzione delle varianti
di SARS-CoV-2 di interesse per la Sanità
Pubblica in Italia”

Objectives of the microbiological national surveillance component

Accurately **monitor the prevalence and spread** of circulating variants and support **epidemiological and genomic virological characterisation**



Detect novel or emerging VOCs and VOIs in a timely fashion



The network

- Currently, the **Italian genomic laboratory network** involves 69 laboratories across all of the 21 Italian Regions and Autonomous Provinces in the country, coordinated at central level by ISS.
- **A dedicated national collaborative infrastructure:** sequence data are collected in the ISS managed national repository called “I-Co-Gen” (Italian COVID-19 Genomic), accessible to all peripheric laboratories, where the sequences are uploaded, analyzed, and verified for completeness and timeliness. After a quality review and integration, all consolidated data are transferred to the public genomic repository *GISAID* for data sharing. *Early warning* for new variants and new mutations of concern are provided.
- Data and analyses produced using this approach enable prompt restitution of the information in the form of publicly available **reports** (e.g. flash survey reports: <https://www.iss.it/en/web/guest/ricerca?categoryId=5616545>) and **open data** (e.g. https://www.epicentro.iss.it/coronavirus/open-data/covid_19-iss.xlsx).

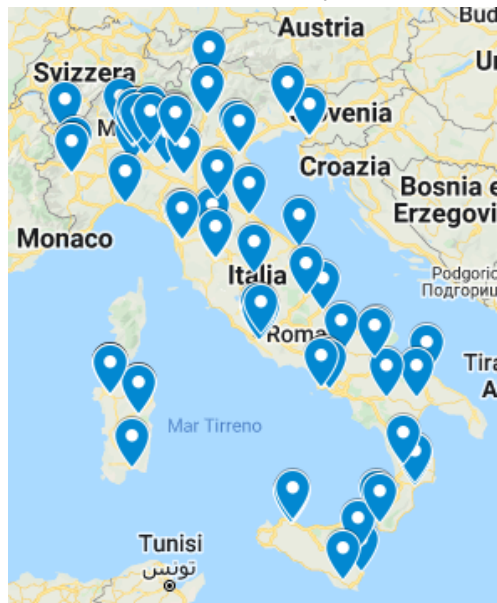
Italian SARS-CoV-2 Sequencing Network

I-Co-Gen platform

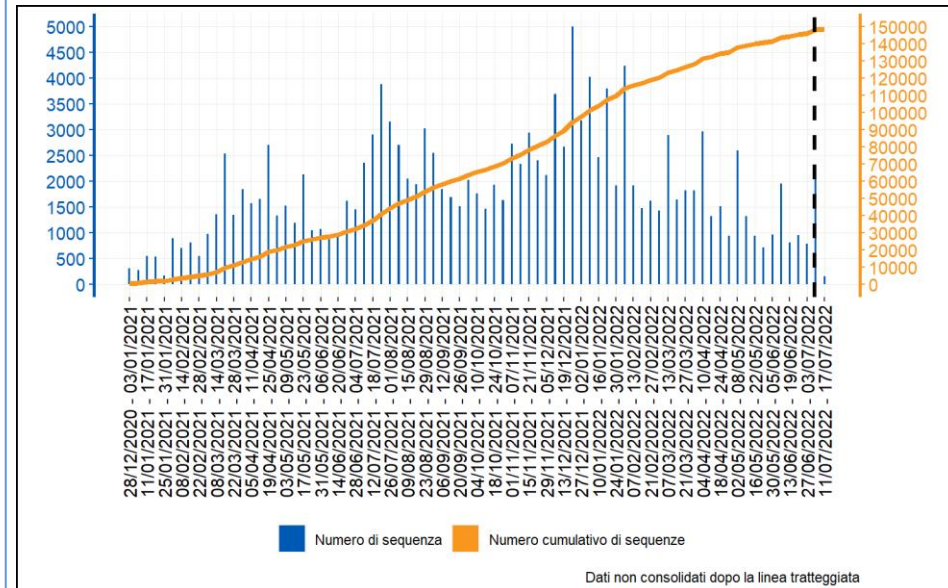


Collaborative infrastructure for the **collection, analysis, early warning and international sharing (GISAID)** of sequencing data with adequate quality standards

The network comprises 69 laboratories located throughout the country



Based on the last published report, more than **165,000 sequences** have been collected

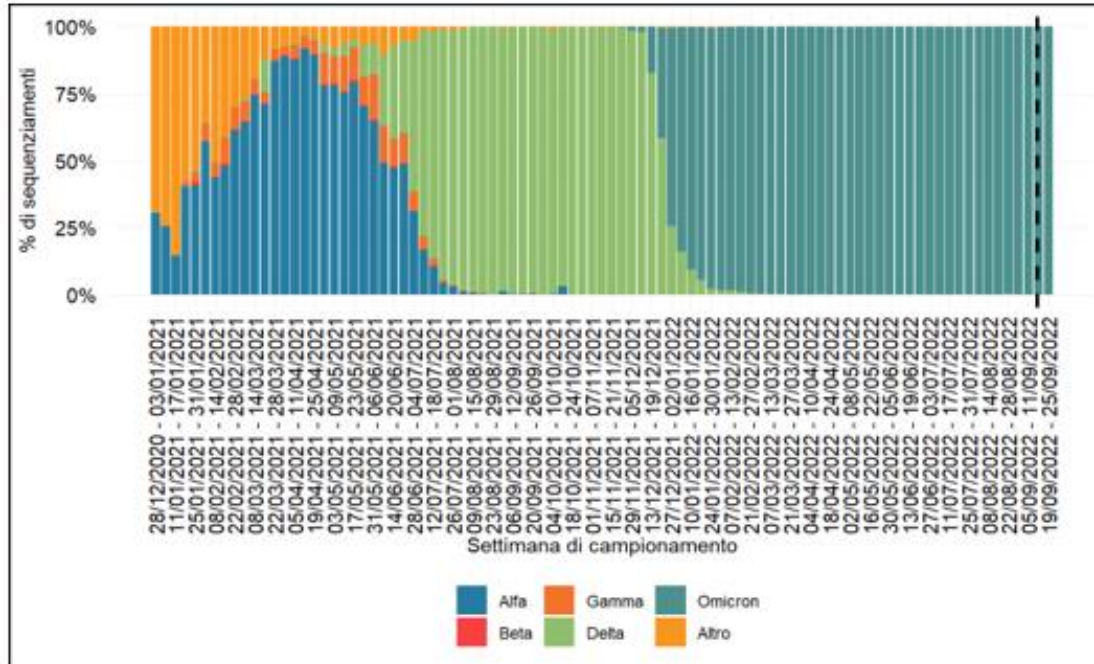


<https://www.epicentro.iss.it/coronavirus/sars-cov-2-monitoraggio-varianti-rapporti-periodici>

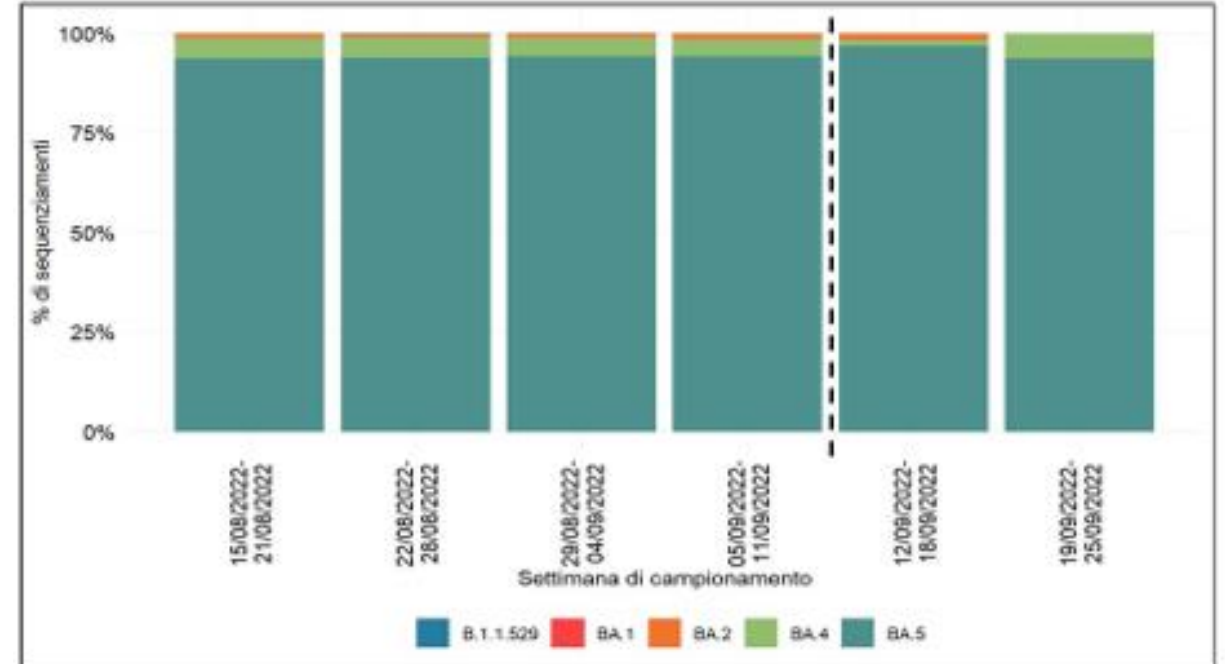
To support the network and make it stable, financial support is provided in accordance with art. 34bis, L. 23 July 2021, n. 106 (and subsequent amendments)

Analysis of Sars-CoV-2 sequences deposited in the I-Co-Gen platform

(last update 26 September 2022)



"Altro": Includes sequences associated with other variants / lineages and unclassifiable sequencing



Each lineage include the identified sub-lineages.

Not consolidated data after the dotted line

<https://www.epicentro.iss.it/coronavirus/sars-cov-2-monitoraggio-varianti-rapporti-periodici>



www.iss.it/malattie-infettive



The flash surveys on SARS-CoV-2 variants in Italy

Laboratories have the task to collect positive COVID-19 samples distributed across five macro-areas, defined according to the Eurostat

The sample size is calculated to have the statistical power to detect a prevalence of 1%, with 0.8% error within each macro-area, based on the number of cases notified on the day of the survey.

The collected samples are then sequenced and the genomes are uploaded into I-Co-Gen platform and the final results in terms of lineages and sublineages are communicated to the MoH and ISS to calculate the prevalence and, finally, write a report.

The prevalence estimates at national level are obtained as the average prevalence in the different Regions / PPAA weighted by the number of regional cases notified in the day of the survey.

A mathematical framework was used to estimate the relative transmissibility of competing SARS-CoV-2 variants of concern, taking as case study the co-circulation of Alpha and Gamma in Italy at the beginning of 2021.

Based on two genomic surveillance surveys conducted across the whole Italian territory on 18 February and 18 March 2021, it was showed that the Alpha variant was already dominant on 18 February in a majority of regions/AP (national prevalence: 54%) and had almost completely replaced historical lineages by 18 March (dominant in all regions/AP, national prevalence: 86%). At the same time, a substantial proportion of cases of the Gamma variant on 18 February, almost exclusively in Regions of central Italy was identified.

RESEARCH

Co-circulation of SARS-CoV-2 Alpha and Gamma variants in Italy, February and March 2021

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Tracking the progressive spread of the SARS-CoV-2 Omicron variant in Italy, December 2021 - January 2022.

Paola Stefanelli, Filippo Trentini, Daniele Petrone et al.

(accepted for publication Eurosurveillance, preprint in MedRxiv)

- The results of **three quick genomic prevalence surveys** conducted biweekly in Italy between December 6, 2021, and January 3, 2022. were used to estimated prevalence of Omicron and combine with data gathered by the Italian Integrated Surveillance System to assess the impact of the variant spread on the overall circulation of SARS-CoV-2.
- The results shows that Omicron became dominant across the Italian territory **in less than one month**, significantly increasing SARS-CoV-2 transmission.

The screenshot shows the medRxiv preprint server interface. At the top left is the medRxiv logo with the tagline 'THE PREPRINT SERVER FOR HEALTH SCIENCES'. To its right are logos for CSH Cold Spring Harbor Laboratory and BMJ Yale. A navigation menu includes 'HOME | SUBMIT | FAQ | BLOG | ALERTS / RSS | ABOUT'. A search bar is present with a magnifying glass icon and the text 'Advanced Search'. Below the navigation is a 'Previous' and 'Next' navigation bar. The main content area features the article title, authors (Paola Stefanelli, Filippo Trentini, Daniele Petrone, Alessia Mammone, Luigina Ambrosio, Mattia Manica, Giorgio Guzzetta, Valeria d'Andrea, Valentina Marziano, Agnese Zardini, Carla Molina Grane, Marco Ajelli, Angela Di Martino, Flavia Riccardo, Antonino Bella, Monica Sane Schepisi, Francesco Maraglino, Piero Poletti, Anna Teresa Palamara, Silvio Brusaferrero, Giovanni Rezza, Patrizio Pezzotti, Stefano Merler), the Genomic SARS-CoV-2 National Surveillance Working Group, and the Italian Integrated Surveillance of COVID-19 Study Group. A DOI link is provided: <https://doi.org/10.1101/2022.01.27.22269949>. A disclaimer states: 'This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.' Below the disclaimer are social media sharing icons for comment, email, print, and tweet. A navigation bar includes 'Abstract', 'Full Text', 'Info/History', 'Metrics', and 'Preview PDF'. The abstract text begins: 'The SARS-CoV-2 variant of concern Omicron was first detected in Italy in November 2021. Data from three genomic surveys conducted in Italy between December 2021 and January'. On the right side, there is a 'Download PDF' button, an 'Email' button, a 'Share' button, and 'Citation Tools'. A 'Tweet' button is also present. Below these is a section for 'COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv', a 'Subject Area' dropdown menu set to 'Infectious Diseases (except HIV/AIDS)', and a 'Subject Areas' section.

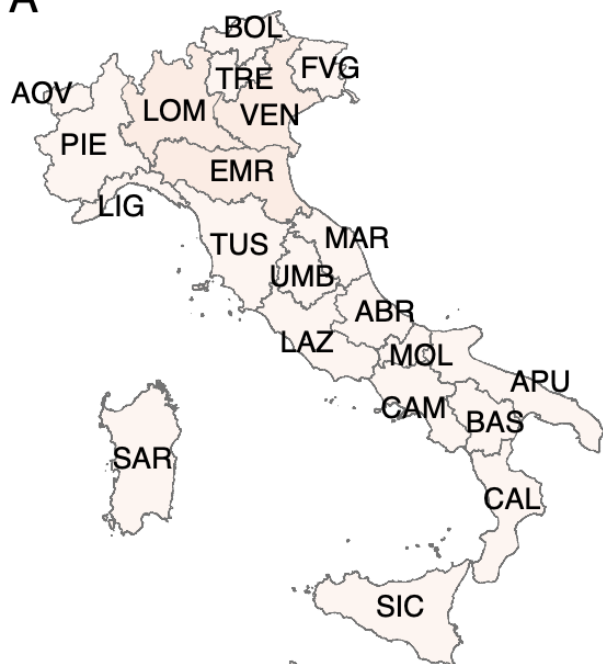
Dec 6, 2021

Dec 20, 2021

Jan 3, 2022

Jan 17, 2022

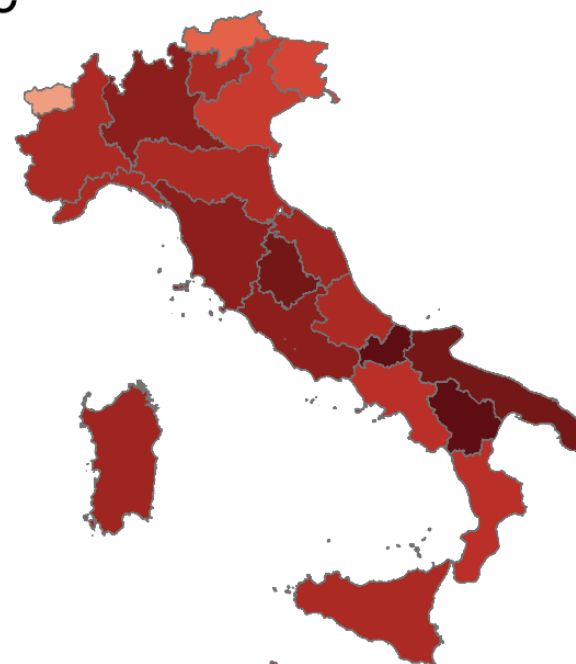
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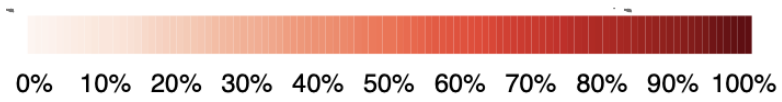
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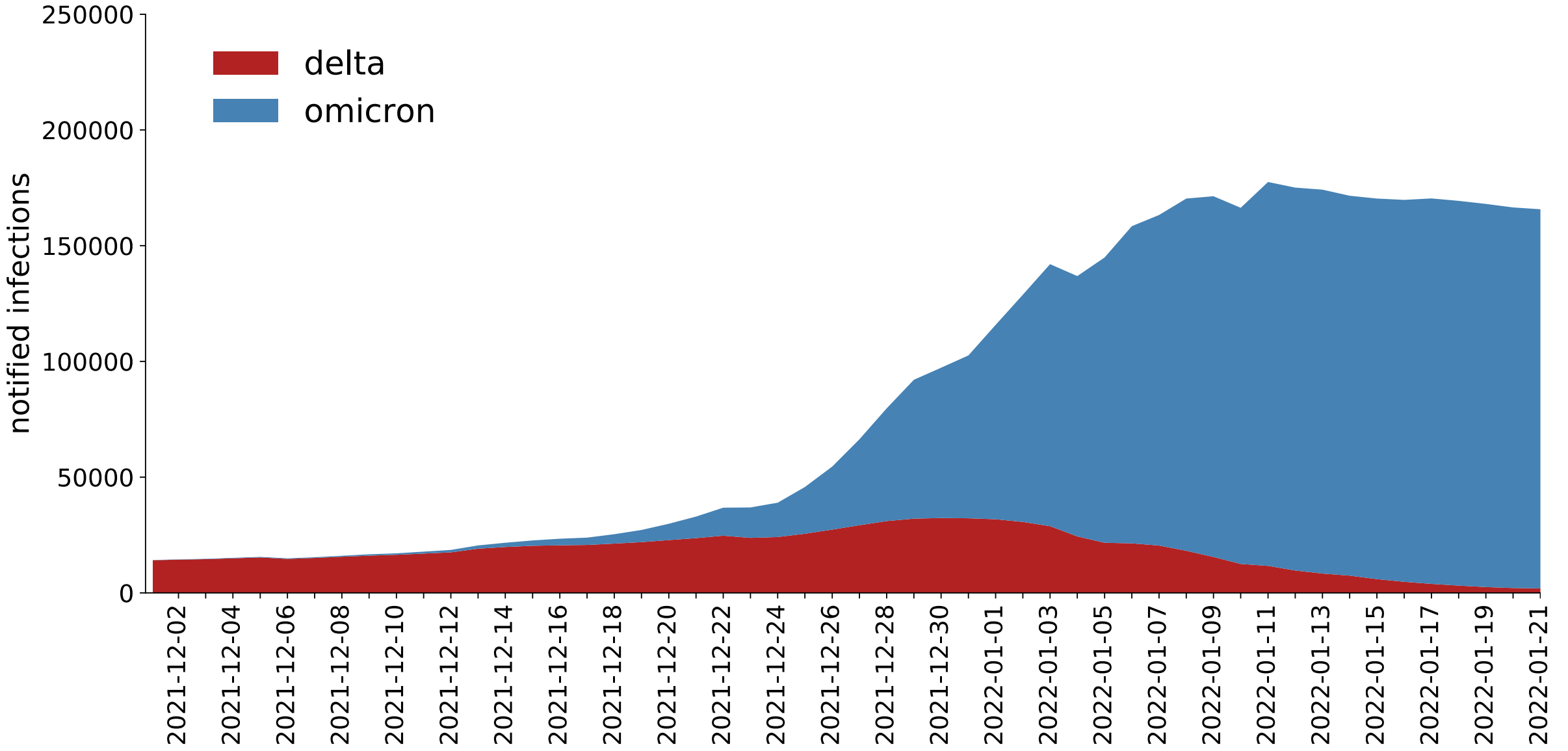


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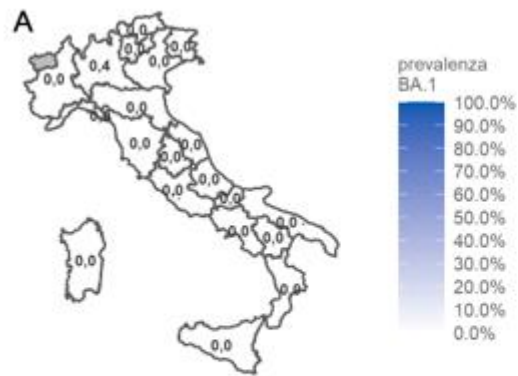
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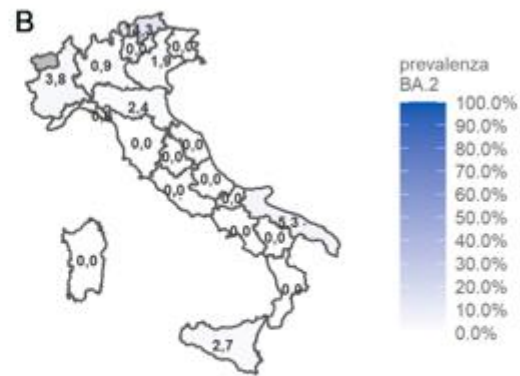


Prevalence estimate from the most recent "flash survey" (September 6, 2022)

<https://www.epicentro.iss.it/coronavirus/sars-cov-2-monitoraggio-varianti-indagini-rapide>



prevalenza nazionale variante BA.1: 0,06%

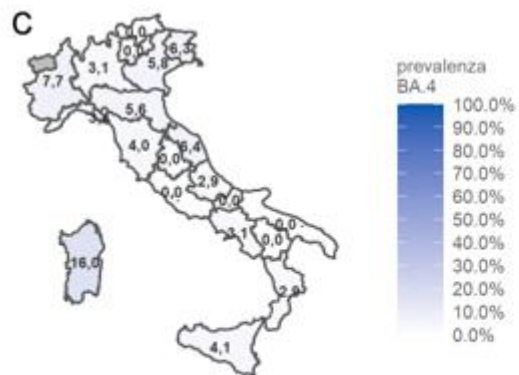


prevalenza nazionale variante BA.2: 1,11%

Variante Omicron 100% (range: 100% - 100%)

| | | |
|---------------|-----------------------|-------------|
| 0,21% | (0% - 0,4%) | BA.1 |
| 1,11% | (0% - 14,3%) | BA.2 |
| 4,41% | (0% - 16,0%) | BA.4 |
| 94,41% | (84,0% - 100%) | BA.5 |

Each BA.n lineage include the identified sub-lineages.



prevalenza nazionale variante BA.4: 4,41%



prevalenza nazionale variante BA.5: 94,41%

Genomic surveillance in Italy

Weaknesses

- ❖ Inability to collect and sequence enough positive samples in the community suitable for genomic surveillance (use of antigenic tests).
- ❖ Delay between sample collection and the upload of sequences on the national genomic surveillance platform I-Co-Gen in same epi weeks.
- ❖ Difficulty in ensuring high quality of patient data in terms of completeness and data sharing at local level.

Strengths

- ❖ Sequence data collected and managed by a unique central facility accessible to all peripheric laboratories and ISS, where the sequences are uploaded, analyzed and verified for completeness and timeliness.
- ❖ Early warning periodically added and/or revised for new variants o mutations of concern.
- ❖ Data and analyses produced using a standardized approach, enabling prompt restitution of information in the form of publicly available reports and open data.
- ❖ Continuous stimulating collaborations in place within the Italian genomic laboratory network and ISS.

What about the next phase?

- SARS-CoV-2 will likely continue to circulate and new variants may emerge.
- Immune escape mutations may be selected, replacing previous circulating variants, due to the selective pressure of vaccine-induced and natural immunity.
- In the perspective of an integrated surveillance of respiratory viruses, this system will not only be maintained but eventually implemented to integrate influenza and other respiratory pathogens (RSV) as a useful by-product of the efforts made to counteract the COVID-19 pandemic in the country.

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