Exploring Feasibility of Combined Screening for Coeliac Disease and Type 1 Diabetes in Children: The Italian D1Ce-Screen Pilot Study

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Background

The D1Ce Screen pilot study originates from Italian Law 130/2023, which introduces paediatric screening for presymptomatic type 1 diabetes (T1D) and/or undiagnosed coeliac disease (CD) to support timely diagnosis and prevention of complications. CD affects about 1% of the general population and is often asymptomatic, with ~65% of paediatric cases undiagnosed in Italy.

Aim

To evaluate the feasibility, acceptability, and sustainability of implementing a nationwide screening programme on a smaller scale, assessing critical operational components, such as the active engagement of primary care paediatricians (PCPs), the effectiveness of blood sample collection procedures.

Methods

This multicenter observational study sets out to screen 5,363 children across four Italian regions (Lombardy, Marche, Campania, Sardinia), divided into three age groups (2–2.9, 6–6.9, and 10–10.9 years; the only exclusion is a clinical T1D diagnosis. Voluntary PCPs handle recruitment, consent, questionnaires, and finger-prick blood sampling (Figure 1). CD screening includes TTG IgA/IgG testing (ELISA and LIPS).

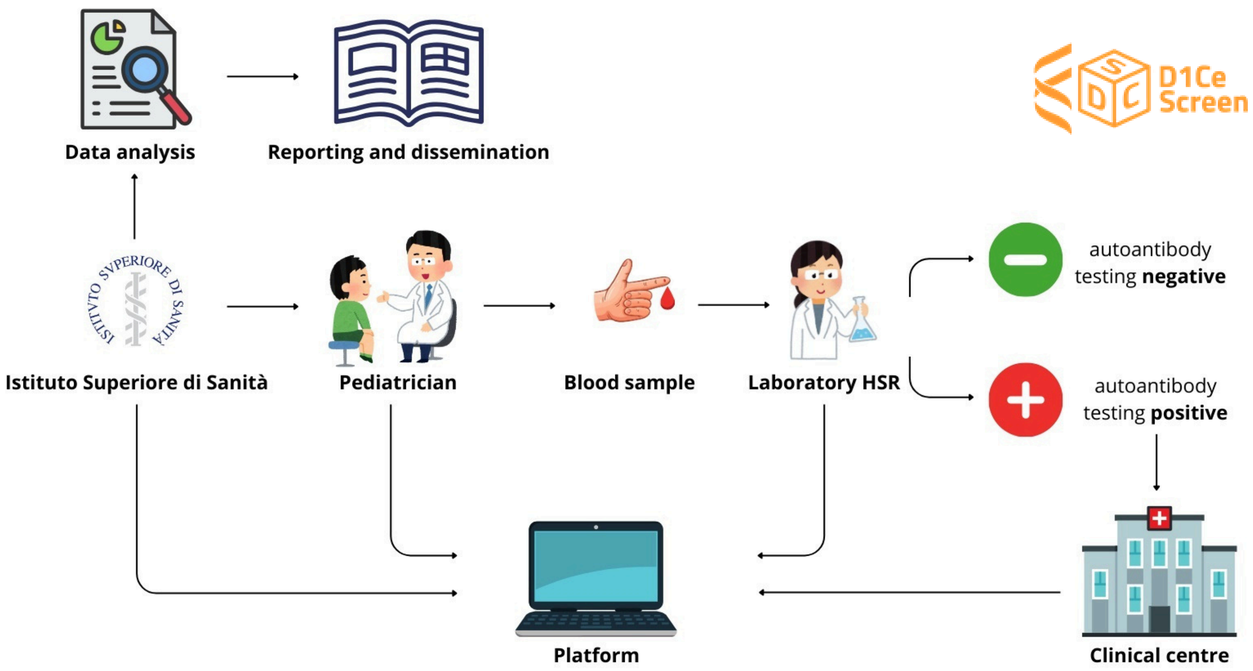


Figure 1. D1Ce Screen workflow.

Results

PCPs participating were 429 and 309 filled the dedicated questionnaire (Figure 2). Enrolled children were 5535, with 5045 (94,1%) within the target age range (Figure 3). Samples suitable for analysis (adequacy for at least one assay) accounted for 89% of the total collected. Preliminary results revealed that, out of a total of 4,944 samples, 2,8% tested positives for TTG IgA (of which 33% positives also for TTG) and (1,1%) were borderline for IgA (Figure 4). A higher prevalence of CD in females (59,8%) was reported.

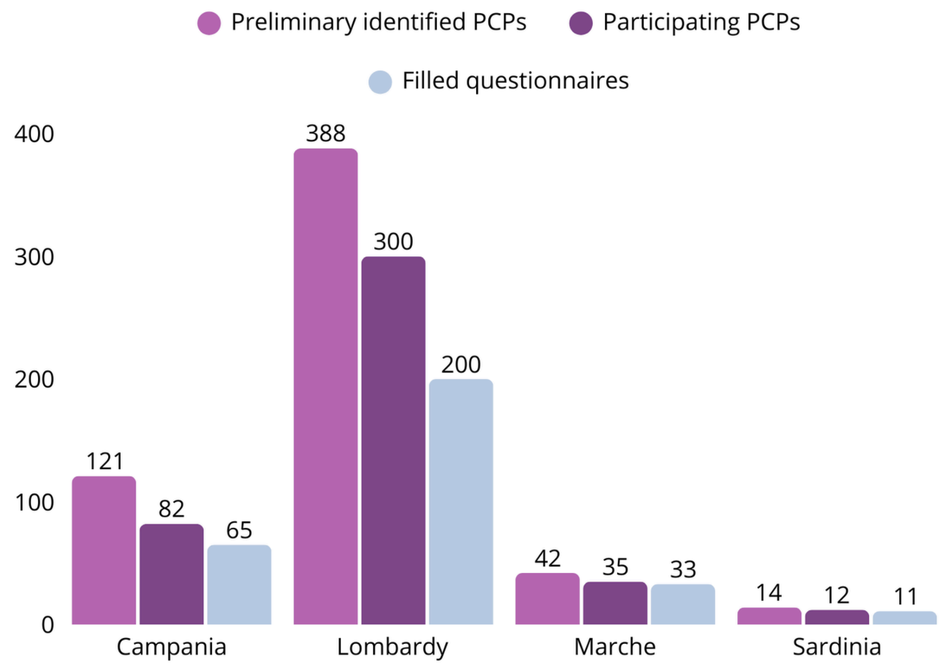
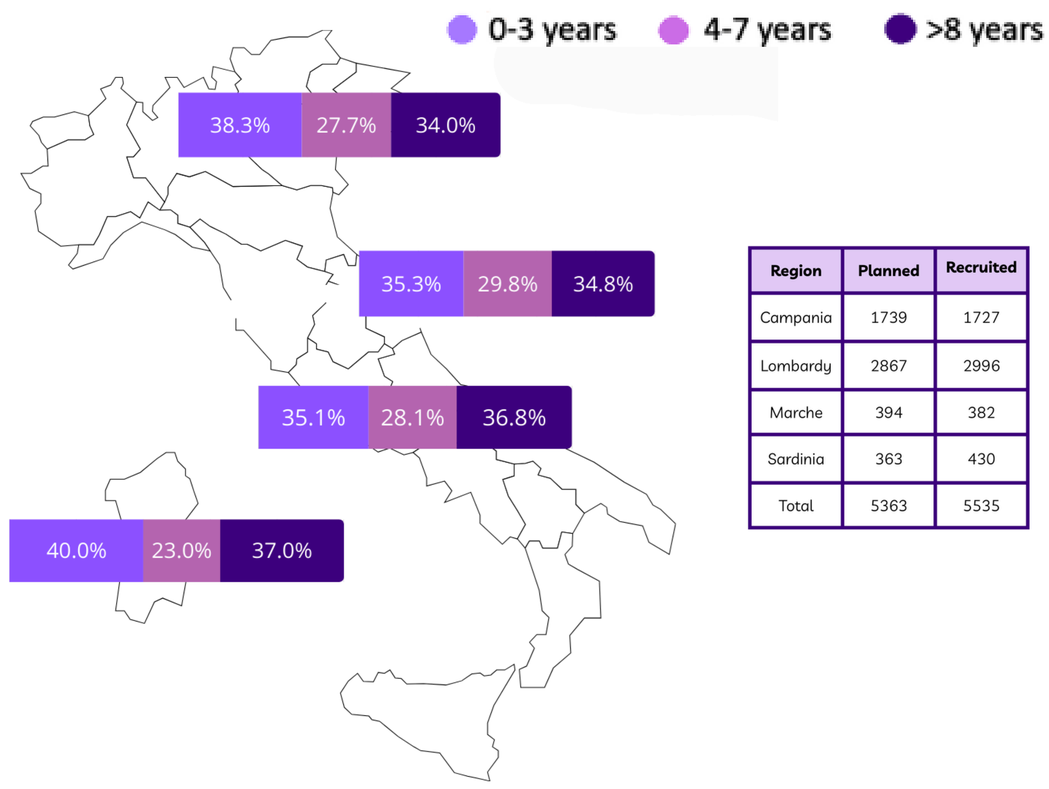


Figure 2. Participating PCPs and filled questionnaires.



Region	Planned	Recruited
Campania	1739	1727
Lombardy	2867	2996
Marche	394	382
Sardinia	363	430
Total	5363	5535

Figure 3. Distribution of enrollments by region and age groups (including out of age range) - percentage of the regional total.

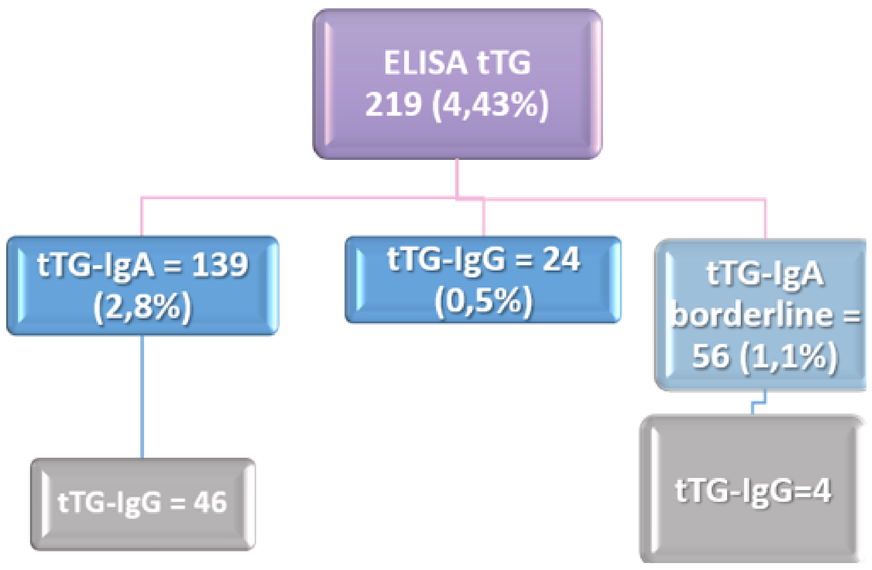


Figure 4. Results for TTG IgA and IgG autoantibodies for celiac disease

Conclusions

The D1Ce-Screen pilot study demonstrates the feasibility of implementing a nationwide screening program for CD and T1D within the Italian National Health Service. Key success factors included the strong engagement of PCPs, high family participation and the effective use of capillary blood sampling. These results support the scalability of a paediatric screening strategy at the national level.. Participants positive for CD specific autoantibodies will be followed up at the CD specialized center to confirm diagnosis allowing a timely dietary intervention.