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D1Ce screen: a pilot feasibility project of the Italian paediatric national screening programme for type 1 diabetes and coeliac disease

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Background and aims: The D1Ce Screen pilot study stems from the Italian Republic Law 130/2023 introducing the screening for pre-symptomatic type 1 diabetes (T1D) and/or undiagnosed coeliac disease (CD) in the general paediatric population using autoantibody measurement on capillary blood. Early detection aims to mitigate the complications associated with late or missed diagnosis of these diseases on affected individuals and the healthcare system. Primary objective is to assess, on a smaller scale, feasibility, acceptability and sustainability of a nationwide screening program within the Italian National Health Service. Specifically, D1Ce Screen assesses operational aspects, including the involvement of primary care paediatricians (PCPs), blood sample collection accuracy and acceptability for families measuring anxiety, depression and quality of life through three existing validated questionnaires.

Materials and methods: This is an observational multicenter study to screen a sample of 5,363 children across four Italian regions (Lombardy, Marche, Campania, Sardinia), distributed into three classes of age (2-2.9, 6-6.9, and 10-10.9 years), corresponding to reported peaks of seroconversion for these diseases. Screening is conducted by voluntary PCPs, responsible for recruitment of participants, administration of informed consents and questionnaires, execution of blood drawing by finger prick, capillary blood collection and sample shipment. Specific T1D and CD autoantibodies are measured in capillary samples by ELISA and LIPS, with comparative evaluation. In addition, HLA DQ2 and DQ8 HLA typing for CD susceptibility is performed on dried blood spot (DBS).

Results: PCPs initially accepting invitation to participate were 565, with 428 (75.7%) completing the study. Enrolled children were 5534, with 5044 (91.1%) within the target age range and 490 in other ages (Table 1). The gender distribution was 49.4% females and 50.6%

males. Samples suitable for analysis (adequacy for at least one assay) accounted for 89% of the total collected. All DBS samples were suitable for HLA typing. Questionnaires were administered to more than the 2% target families

Conclusion: The D1Ce Screen pilot supports feasibility of the national program. The active involvement of PCPs, a high participation response by families, and an efficient capillary blood sample collection were the key factors for success. These preliminary results support the potential for large-scale implementation of the paediatric screening program for T1D and CD within the Italian National Health Service

Regions	Age (yr)					Total	Planned	% Planned
	2 +1	6 +1	10 +1	Out of range	In range			
Campania	468	536	498	224	1502	1726	1739	86,37
Lombardy	824	936	1050	186	2810	2996	2867	98,01
Marche	113	123	127	19	363	382	394	92,13
Sardinia	96	126	147	61	369	430	363	101,65
Total	1501	1721	1822	490	5044	5534	5363	

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C-peptide as a predictor for diabetes onset in patients with possible insulin autoimmune syndrome

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Background and aims: The onset of hypoglycemia as a consequence of impaired insulin secretion might be considered a sign of future impaired glycemia regulation. The aim was to investigate the significance of autoimmunity in patients with hypoglycemia, and the possible presence of insulin autoimmune syndrome (IAS). IAS is commonly present in patients with other autoimmune diseases such as thyroid disease. The role in the development of prediabetes [impaired glucose tolerance (IGT) or impaired fasting glucose (IFG)] or diabetes (DM) was also studied.

Materials and methods: Non-diabetic patients presenting with repeated hypoglycemia were included in the study. Insulinoma was excluded based on prolonged oral glucose tolerance test (OGTT) and 48-hour fasting test. IGT was diagnosed if 2-hour plasma glucose (PG) concentrations were 7.8 to 11.1 mmol/L and IFG if the FPG was ≥ 6.1 mmol/L and the 2-hour PG was < 7.8 mmol/L. OGTT was performed over an 8-10 mo period during 5 yrs. Antibodies (Abs) to antigens of the pancreatic islet beta cells (ICA), glutamic acid decarboxylase Abs (GAD), thyroid Abs: thyroid peroxidase Abs and thyroglobulin Abs, fasting and postprandial insulin and C-peptide, insulin resistance (IR), and other metabolic syndrome parameters were determined in