Forum Risk Management
obiettivo sanità salute
26-29 NOVEMBRE 2024
AREZZO FIERE E CONGRESSI
19

LINEE OPERATIVE PER LA GESTIONE DELLA CRONICITÀ
IL CASO DELLE PATOLOGIE CARDIOMETABOLICHE

DAI MODELLI PRESTAZIONALI ALLA PRESA IN CARICO DEL PAZIENTE

Lo screening pediatrico del diabete tipo 1 e della celiachia

Dott. Flavia Pricci
Dip. Malattie Cardiovascolari, Endocrino-Metaboliche e Invecchiamento
Istituto Superiore di Sanità

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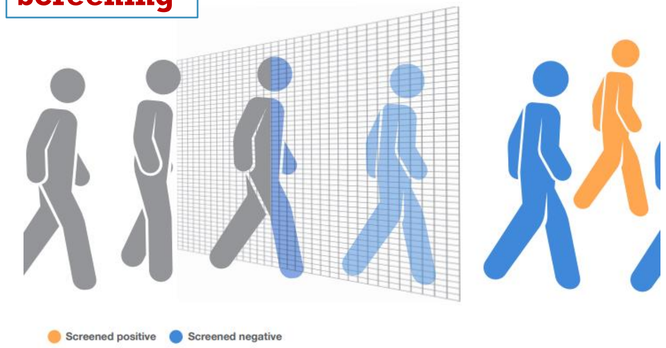
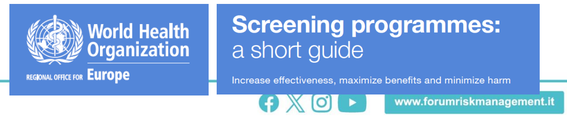
Screening

Lo *screening* ha lo scopo di individuare, in fase precoce e in assenza di sintomi, le malattie presenti in una comunità, permettendo così di giungere ad interventi terapeutici tempestivi in modo da ridurre la mortalità e/o i disturbi legati alla malattia o gli effetti dannosi dei trattamenti somministrati in una fase di malattia avanzata.



Screening programmes: a short guide. Increase effectiveness, maximize benefits and minimize harm. Copenhagen: WHO Regional Office for Europe; 2020. Licence: CC BY-NC-SA 3.0 IGO.
https://iris.who.int/bitstream/handle/10665/330829/9789289054782-eng.pdf



Screening nel diabete tipo 1

Table 4—Wilson and Jungner's guidelines for screening as applied to type 1 diabetes

Principle	Application to screening for type 1 diabetes
1. Identify an important health problem	Type 1 diabetes is one of the most common and consequential chronic illnesses of children but also affects individuals of all ages.
2. There should be an accepted treatment for the condition	Teplizumab was shown to delay the diagnosis of individuals at risk. Other agents are under evaluation.
3. Facilities for diagnosis and treatment are available	Diagnosis and treatment can be done in medical offices.
4. There should be a recognizable latent or early symptomatic period	Stages of progression of type 1 diabetes in those at genetic risk have been defined. High-risk individuals (stage 2) have a 75% risk of diagnosis within 5 years.
5. There should be a suitable test or examination 6. The test should be acceptable to the population	AAs can define risk. Newer technologies to improve prediction are under study. AAs can be measured in many laboratories.
7. The natural history of the condition should be understood	Although many specifics remain uncertain, results from immune therapy trials indicate that type 1 diabetes is due to immune-mediated killing of β-cells.
8. There should be an agreed policy on whom to treat as patients	Children and adolescents, during developmental years, have the highest unmet need.
9. The cost of case finding should be economically balanced in relation to expenditure on medical care as a whole	The lifetime costs for type 1 diabetes after onset in childhood are great, even without the additional costs associated with disease-related complications.
10. Case finding should be a continuing process	Projects across the globe are piloting strategies for case identification.

Guidelines are as described by Wilson and Jungner (64).

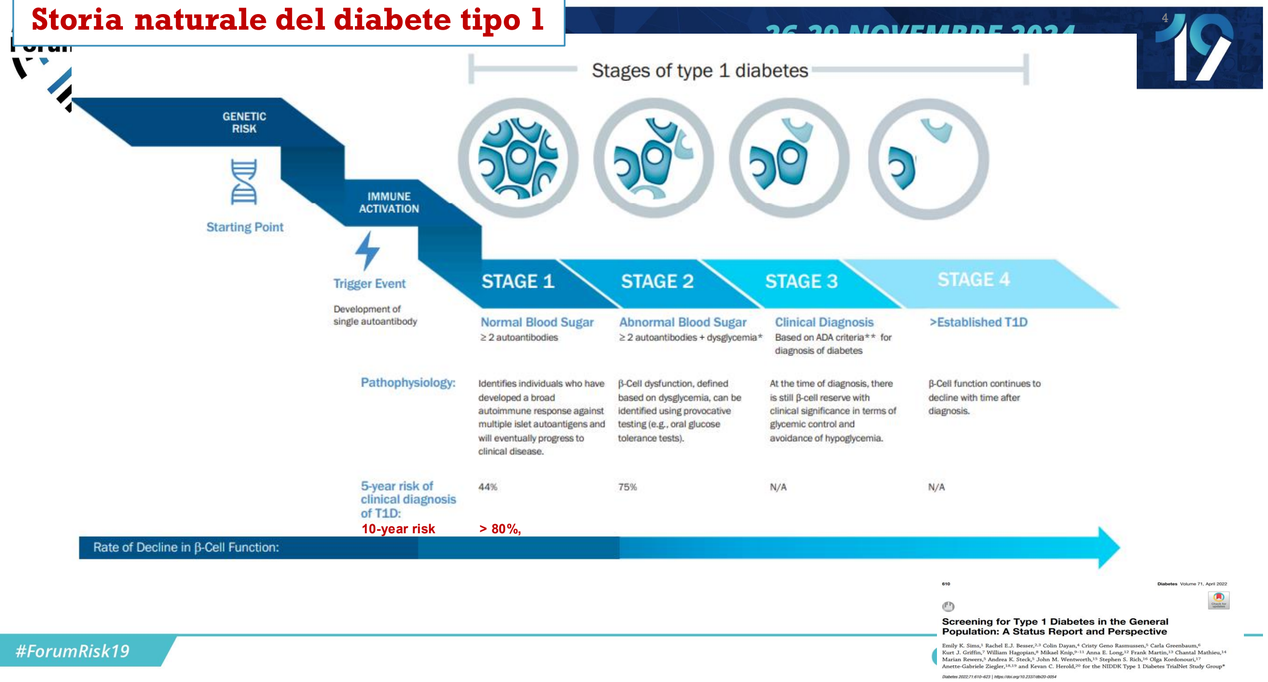

610 Diabetes Volume 71, April 2022

Screening for Type 1 Diabetes in the General Population: A Status Report and Perspective

Emily K. Sims,[1] Rachel E.J. Besser,[2,3] Colin Dayan,[4] Cristy Geno Rasmussen,[5] Carla Greenbaum,[6] Kurt J. Griffin,[7] William Hagopian,[8] Mikael Knip,[9–11] Anna E. Long,[12] Frank Martin,[13] Chantal Mathieu,[14] Marian Rewers,[1] Andrea K. Steck,[1] John M. Wentworth,[15] Stephen S. Rich,[16] Olga Kordonouri,[17] Anette-Gabriele Ziegler,[18,19] and Kevan C. Herold,[20] for the NIDDK Type 1 Diabetes TrialNet Study Group*

Diabetes 2022;71:610–623 | https://doi.org/10.2337/db20-0854

Storia naturale del diabete tipo 1



Screening for Type 1 Diabetes in the General Population: A Status Report and Perspective

Auto-anticorpi nel diabete tipo 1

Table 3—Autoantibodies against islet autoantigens detected in stage 1–3 type 1 diabetes

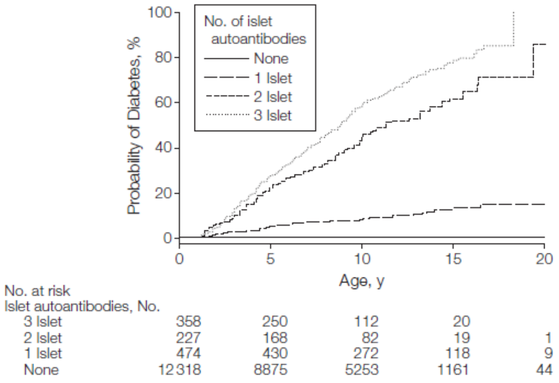
Autoantibody	Islet specificity	Typical characteristics
IAA	Insulin	• Common as a first detected autoantibody in young children (157,158) • Appearance is more common in younger children (159) • Frequency of appearance declines with age • Not informative for individuals treated with insulin, who often develop antibodies in response to injected insulin
GADA	GAD	• Common as a first detected autoantibody in childhood, up until age 15 years (157,158,160) • Adult-onset cases most often present with GADA (161) • Is associated with slower progression to T1D (162) and is often found as a single positive islet autoantibody, especially in adults
IA-2A (also known as ICA512)	Tyrosine phosphatase islet antigen-2	Presence is associated with more advanced islet autoimmunity and faster progression to stage 3 T1D (55,163)
ZnT8A	Zinc transporter type 8, a transmembrane protein in the β-cell granule	Presence can improve risk stratification in individuals with single $GADA^+$, IAA^+, or $IA\text{-}2A^+$ status (164)
ICA	Multiple antigens, undefined	Detected by indirect immunofluorescence on islet cell tissue. While not frequently measured other than in research studies, it does add to risk determination ir the presence of other biochemical autoantibodies

IA-2A, insulinoma antigen-2 autoantibody; ICA, islet cell autoantibodies; ICA512, islet cell autoantigen 512; T1D, type 1 diabetes.


Diabetes Care
American Diabetes Association.
Consensus Guidance for Monitoring Individuals With Islet Autoantibody–Positive Pre-Stage 3 Type 1 Diabetes

80-100% di progressione a diabete di tipo 1 con ≥2 autoanticorpi

Figure 1. Development of Diabetes in Children Stratified for Islet Autoantibody Outcome



No. at risk Islet autoantibodies, No.					
3 Islet	358	250	112	20	
2 Islet	227	168	82	19	1
1 Islet	474	430	272	118	9
None	12318	8875	5253	1161	44

The numbers at risk represent the children receiving follow-up at age 0, 5, 10, 15, and 20 years.

Seroconversion to Multiple Islet Autoantibodies and Risk of Progression to Diabetes in Children

Anette G. Ziegler, MD
Marian Rewers, MD, PhD
Olli Simell, MD, PhD
Tuula Simell, MPH, PhD
Johanna Lempainen, MD, PhD
Andrea Steck, MD
Christiane Winkler, PhD
Jorma Ilonen, MD, PhD
Riitta Veijola, MD, PhD
Mikael Knip, MD, PhD
Ezio Bonifacio, PhD
George S. Eisenbarth, MD, PhD†

Importance Type 1 diabetes usually has a preclinical phase identified by circulating islet autoantibodies, but the rate of progression to diabetes after seroconversion to islet autoantibodies is uncertain.

Objective To determine the rate of progression to diabetes after islet autoantibody seroconversion.

Design, Setting, and Participants Data were pooled from prospective cohort studies performed in Colorado (recruitment, 1993-2006), Finland (recruitment, 1994-2009), and Germany (recruitment, 1989-2006) examining children genetically at risk for type 1 diabetes for the development of insulin autoantibodies, glutamic acid decarboxylase 65 (GAD65) autoantibodies, insulinoma antigen 2 (IA2) autoantibodies, and diabetes. Participants were all children recruited and followed up in the 3 studies (Colorado, 1962; Finland, 8597; Germany, 2818). Follow-up assessment in each study was concluded by July 2012.

Main Outcomes and Measures The primary analysis was the diagnosis of type 1 diabetes in children with 2 or more autoantibodies. The secondary analysis was the diagnosis of type 1 diabetes in children with 1 autoantibody or no autoantibodies.

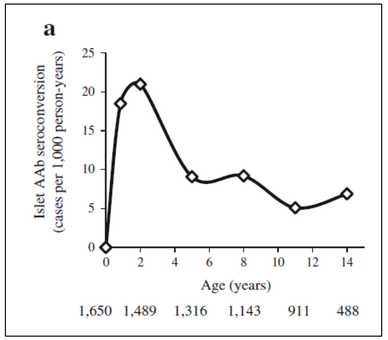
Results Progression to type 1 diabetes at 10-year follow-up after islet autoantibody seroconversion in 585 children with multiple islet autoantibodies was 69.7% (95% CI, 65.1%-74.3%), and in 474 children with a single islet autoantibody was 14.5% (95% CI, 10.3%-18.7%). Risk of diabetes in children who had no islet autoantibodies was 0.4% (95% CI, 0.2%-0.6%) by the age of 15 years. Progression to type 1 diabetes in the children with multiple islet autoantibodies was faster for children who had islet autoantibody seroconversion younger than age 3 years (hazard ratio [HR], 1.65 [95% CI, 1.30-2.09; $P < .001$]; 10-year risk, 74.9% [95% CI, 69.7%-80.1%]) vs children 3 years or older (60.9% [95% CI, 51.5%-70.3%]); for children with the human leukocyte antigen (HLA) genotype *DR3/DR4-DQ8* (HR, 1.35 [95% CI, 1.09-1.68; $P = .007$]; 10-year risk, 76.6% [95% CI, 69.2%-84%]) vs other HLA genotypes (66.2% [95% CI, 60.2%-72.2%]); and for girls (HR, 1.28 [95% CI, 1.04-1.58; $P = .02$];10-year risk, 74.8% [95% CI, 68.0%-81.6%]) vs boys (65.7% [95% CI, 59.3%-

TYPE 1 DIABETES IS A CHRONIC AUTOimmune disease that often manifests during childhood and adolescence.[1] The lifelong requirement for insulin injections and the many complications that follow the diagnosis can be difficult for those affected.[2] Type 1 diabetes usually has a preclinical phase that can be identified by the presence of autoantibodies to antigens of the pancreatic β cells.

Several studies that have performed

Storia naturale e picco di incidenza della sieroconversione per autoanticorpi specifici per il diabete di tipo 1

BABYDIAB Study - BABYDIET Study (First Degree Relatives) (Germany)
1,650 children/152 developed islet autoantibodies



Diabetologia (2012) 55:1937–1943
DOI 10.1007/s00125-012-2472-x

ARTICLE

Age-related islet autoantibody incidence in offspring of patients with type 1 diabetes

A.-G. Ziegler · E. Bonifacio ·
the BABYDIAB-BABYDIET Study Group

TEDDY (First Degree Relatives and General Population HLA risk) (Finland, Sweden, Germany, USA)
8,503 newborn and children/549 (6.5%) developed islet autoantibodies

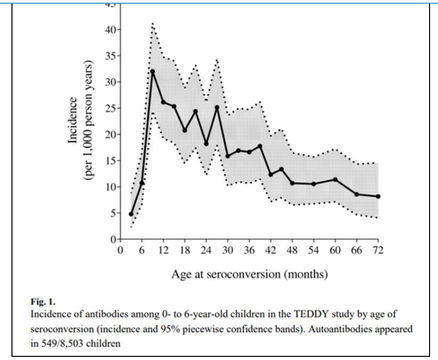


Fig. 1.
Incidence of antibodies among 0- to 6-year-old children in the TEDDY study by age of seroconversion (incidence and 95% piecewise confidence bands). Autoantibodies appeared in 549/8,503 children

Diabetologia. 2015 May ; 58(5): 980–987. doi:10.1007/s00125-015-3514-y.

The 6 year incidence of diabetes-associated autoantibodies in genetically at-risk children: the TEDDY study

Jeffrey P. Krischer[1], Kristian F. Lynch[1], Desmond A. Schatz[2], Jorma Ilonen[3,4], Åke Lernmark[5], William A. Hagopian[6], Marian J. Rewers[7], Jin-Xiong She[8], Olli G. Simell[9], Jorma Toppari[9,10], Anette-G. Ziegler[11,12,13], Beena Akolkar[14], Ezio Bonifacio[15], and the TEDDY Study Group*

Controllo metabolico e episodi di chetoacidosi negli individui screenati per DT1

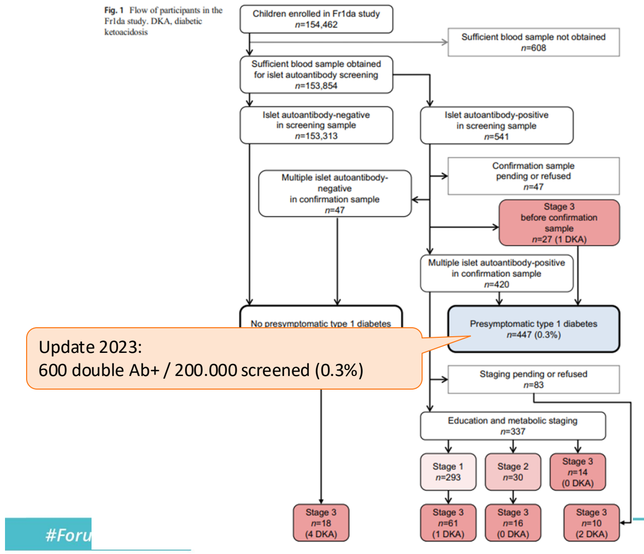
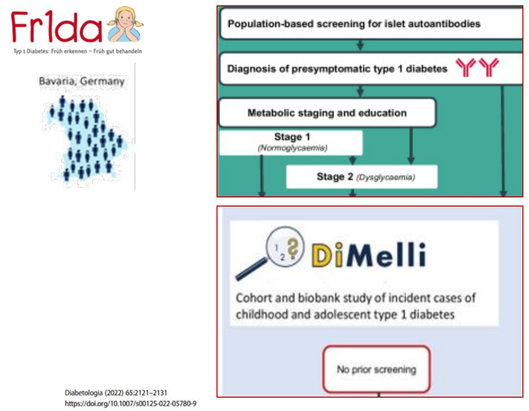


Fig. 1 Flow of participants in the Fr1da study. DKA, diabetic ketoacidosis

Update 2023:
600 double Ab+ / 200.000 screened (0.3%)



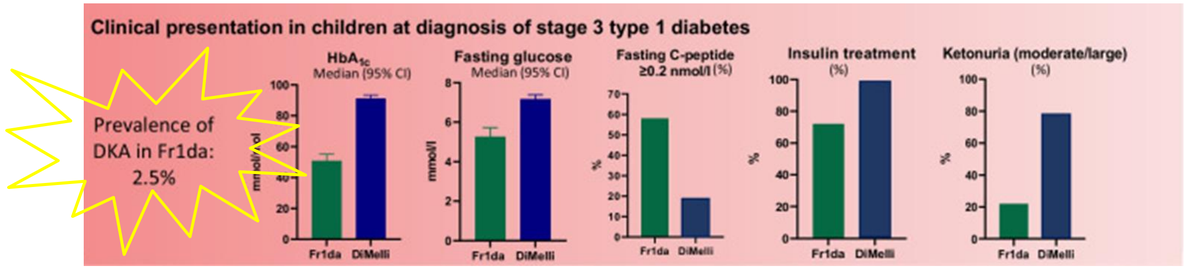
Diabetologia (2022) 65:2121–2131
https://doi.org/10.1007/s00125-022-05780-9

ARTICLE

Progression likelihood score identifies substages of presymptomatic type 1 diabetes in childhood public health screening

Andreas Weiss[1,2] · Jose Zapardiel-Gonzalo[1,2] · Franziska Voss[1] · Manja Jolink[1] · Joanna Stock[1] · Florian Haupt[1,2,3] · Kerstin Kick[1] · Tiziana Welzhofer[4] · Anja Heublein[1] · Christiane Winkler[1,2,3] · Peter Achenbach[1,2,3,4] · Anette-Gabriele Ziegler[1,2,3,4] · Ezio Bonifacio[2,5,6] · for the Fr1da-study group

Controllo metabolico e episodi di chetoacidosi sono drasticamente ridotti negli individui screenati per DT1



At stage 3 diagnosis, children previously diagnosed with presymptomatic type 1 diabetes had a low rate of DKA and had lower HbA_{1c} and fasting blood glucose levels, higher fasting C-peptide level, and a lower incidence of ketonuria and insulin treatment compared with children without a previous early-stage diagnosis

Clinical benefit of screening for early-stage type 1 diabetes was not affected by a family history of type 1 diabetes or diagnosis during the COVID-19 pandemic

How might this impact on clinical practice in the foreseeable future?

The clinical presentation of children at the onset of stage 3 type 1 diabetes could be improved by prior diagnosis of presymptomatic type 1 diabetes through population-based screening

Diabetologia (2023) 66:1633–1642
https://doi.org/10.1007/s00125-023-05953-0

ARTICLE

Children diagnosed with presymptomatic type 1 diabetes through public health screening have milder diabetes at clinical manifestation

Sandra Hummel[1,2,3,4] · Johanna Carl[1] · Nadine Friedl[1] · Christiane Winkler[1,2,3] · Kerstin Kick[4] · Joanna Stock[1] · Franziska Reinmöller[4] · Claudia Ramminger[1] · Jennifer Schmidt[1] · Dominik Lworsky[1] · Sonja Braig[1] · Desiree Dunstheimer[1] · Uwe Ernst[5] · Eva-Maria Gerss[6] · Leonie Weber[7,8] · Nicole Nellen-Hellmuth[7,8,9] · Susanne Brämswig[10] · Marina Sindichakis[11] · Stefanie Tretter[11] · Anja Lormann[12] · Ezio Bonifacio[2,3,4,13] · Anette-G. Ziegler[1,2,3,4] · Peter Achenbach[1,2,3,4] · for the Fr1da Study Group

Prospettive future

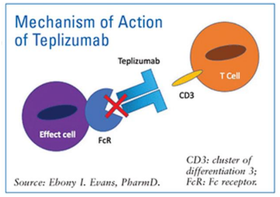
	Teplizumab		Placebo	
	n TD1 free	Mesi (media)	n TD1 free	Mesi (media)
60 mesi	25/44 (56%)	48,4	9/32 (28%)	24,4
72 mesi	22/44 (50%)	59,6	7/32 (22%)	27,1

Teplizumab (TZIELD™): Key Points

A CD3-directed monoclonal antibody (humanized IgG1κ) that is being developed by Provention Bio, Inc. for the treatment of T1D

Received its first approval on 17 November 2022 in the USA

Approved to delay the onset of Stage 3 T1D in adults and pediatric patients aged 8 years of age and older with Stage 2 T1D



PER LA PRIMA VOLTA IN ITALIA DISPONIBILE TEPLIZUMAB PER USO COMPASSIONEVOLE

DIABETE TIPO 1: SCREENING BIMBI RIDUCE DEL 94% RISCHIO DI GRAVI COMPLICANZE

Novembre 11, 2024

La chiave per evitare la chetoacidosi, la più grave e temibile complicanza del diabete di tipo 1, a volte addirittura fatale, è la diagnosi precoce. A dimostrare l'importanza di individuare i bimbi a rischio prima [...]

Drugs (2023) 83:439–445
https://doi.org/10.1007/s40265-023-01847-y
ADISINSIGHT REPORT

Teplizumab: First Approval

Susan J. Keam[1]

Teplizumab in Type 1 Diabetes Mellitus: An Updated Review

Citation: *touchREVIEWS in Endocrinology.* 2023;19(2):22–30

Simran Thakkar,[1] Aditi Chopra,[1] Lakshmi Nagre

Legge 130/2023

SERIE GENERALE

Spediz. abb. post. - art. 1, comma 1
Legge 27-02-2004, n. 46 - Filiale di Roma

Anno 164° - Numero 226

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SOMMARIO

LEGGI ED ALTRI ATTI NORMATIVI

LEGGE 15 settembre 2023, n. 130.

Disposizioni concernenti la definizione di un programma diagnostico per l'individuazione del diabete di tipo 1 e della celiachia nella popolazione pediatrica. (23G00140) . . . . . Pag. 1

DECRETO DEL PRESIDENTE DELLA REPUBBLICA 31 agosto 2023

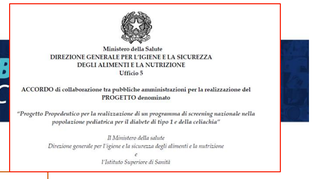
Scioglimento del consiglio comunale di Besate. (23A05245) . . . . . Pag. 4

DECRETI, DELIBERE E ORDINANZE MINISTERIALI

Art. 1
Programma di screening nazionale per diabete di tipo 1 e celiachia

- 1. Al fine di **prevenire l'insorgenza di chetoacidosi in soggetti affetti da diabete di tipo 1 e di rallentare la progressione della malattia** mediante l'impiego delle terapie disponibili, nonché' di effettuare la **diagnosi precoce della celiachia**, con decreto del Ministro della salute, da emanare entro centoventi giorni dalla data di entrata in vigore della presente legge, previo parere della Conferenza permanente per i rapporti tra lo Stato, le regioni e le province autonome di Trento e di Bolzano e sentite le associazioni maggiormente rappresentative delle persone affette da diabete di tipo 1 e da celiachia e dei loro familiari e le fondazioni di rilevanza nazionale operanti in materia, è adottato un programma pluriennale di screening su base nazionale nella popolazione pediatrica per l'individuazione degli anticorpi del diabete di tipo 1 e della celiachia, da avviare a decorrere dall'anno 2024. Lo schema di decreto di cui al primo periodo è sottoposto al parere delle competenti Commissioni parlamentari, che si esprimono entro il termine di trenta giorni dalla data della sua trasmissione, decorso il quale il Ministro della salute può comunque procedere.
- 2. Per l'attuazione del programma pluriennale di cui al comma 1 è autorizzata la spesa di 3,85 milioni di euro per ciascuno degli anni 2024 e 2025 e di 2,85 milioni di euro annui a decorrere dall'anno 2026, a valere sulle risorse del fondo di cui al comma 530 dell'articolo 1 della **legge 29 dicembre 2022, n. 197,** come **rifinanziato** ai sensi dell'articolo 4 della presente legge.

Progetto propedeutico per la realizzazione di un programma di screening nazionale nella popolazione pediatrica per il diabete di tipo 1 e la celiachia - *D1Ce Screen*


Ministero della Salute
DIREZIONE GENERALE PER L'IGIENE E LA SICUREZZA DEGLI ALIMENTI E LA NUTRIZIONE
Ufficio 5

ACCORDO di collaborazione tra pubbliche amministrazioni per la realizzazione del PROGETTO denominato

"Progetto Propedeutico per la realizzazione di un programma di screening nazionale nella popolazione pediatrica per il diabete di tipo 1 e della celiachia"

Il Ministero della salute
Direzione generale per l'igiene e la sicurezza degli alimenti e la nutrizione
e
l'Istituto Superiore di Sanità

Scopo

Evidenziare per lo screening nazionale per il diabete tipo 1 e la celiachia:

- sostenibilità da parte del SSN
- potenzialità
- criticità organizzative
- costi-benefici

Responsabili scientifici

Flavia Pricci (ISS - Dip MACA)
Olimpia Vincentini (ISS - Dip SANV)
Giuseppe Plutino: Ministero della Salute

Referenti scientifici

Emanuele Bosi (HSR) per il diabete tipo 1
Carlo Catassi (Univ Marche) per la celiachia
Valentino Cherubini (Univ Marche) per i centri clinici
Antonio D'Avino (FIMP) per il pediatri di libera scelta

ISTITUTO SUPERIORE DI SANITÀ

D1Ce Screen

D1Ce Screen - Disegno dello studio

26-29 NOVEMBRE 2024
AREZZO FIERE E CONGRESSI
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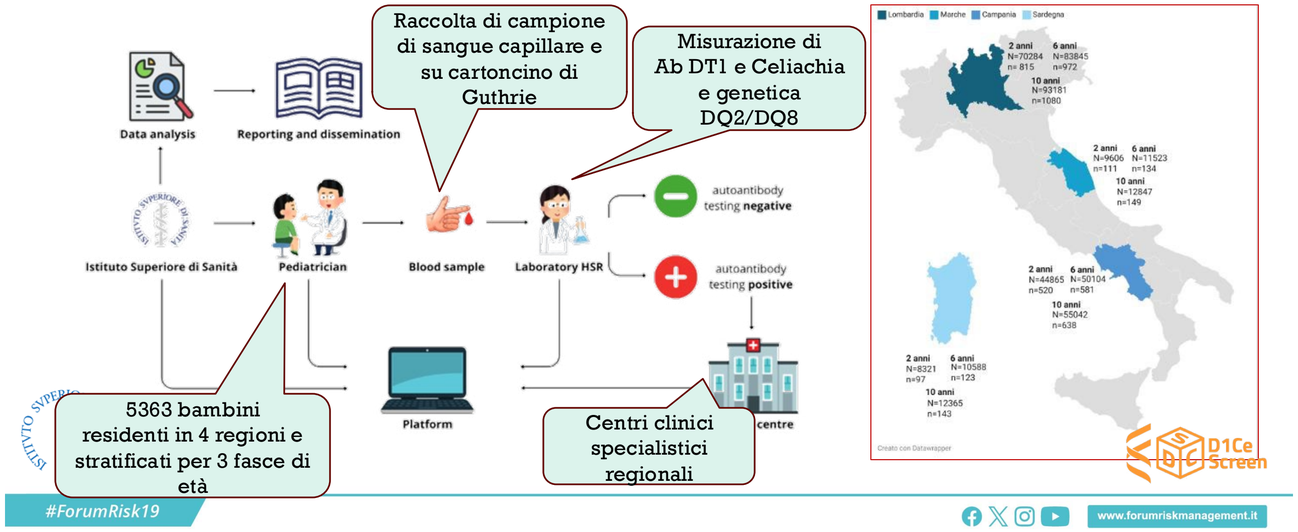
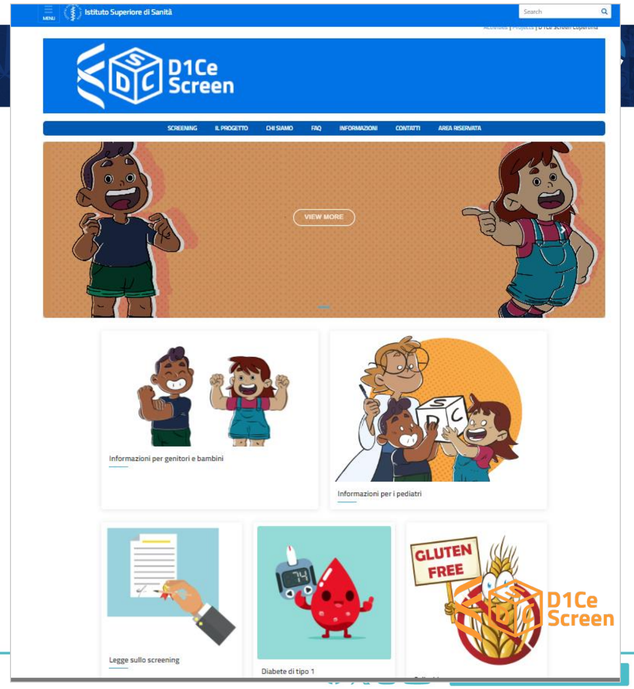
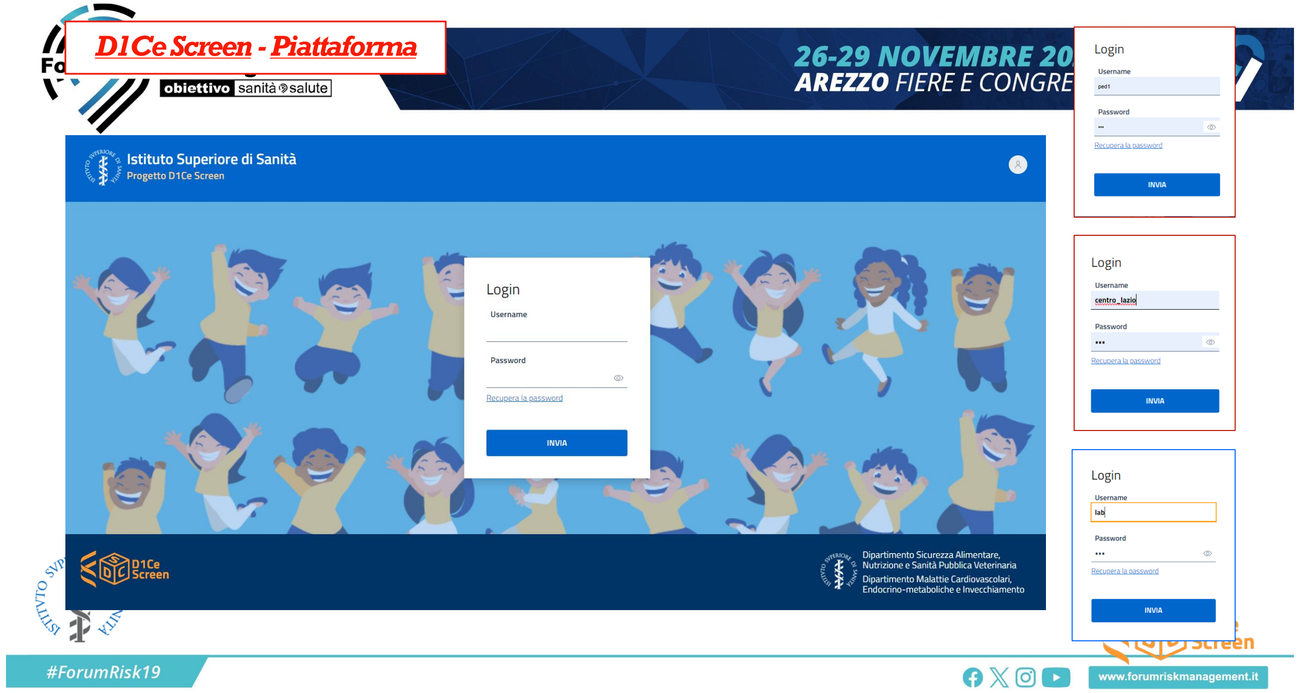


D1Ce Screen - Materiale divulgativo

D1Ce Screen - Sito web

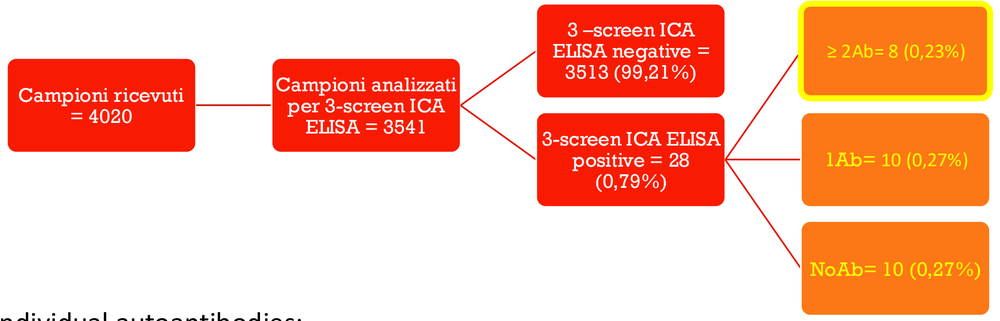


D1Ce Screen - Piattaforma



D1Ce Screen - Risultati preliminari Arruolamenti

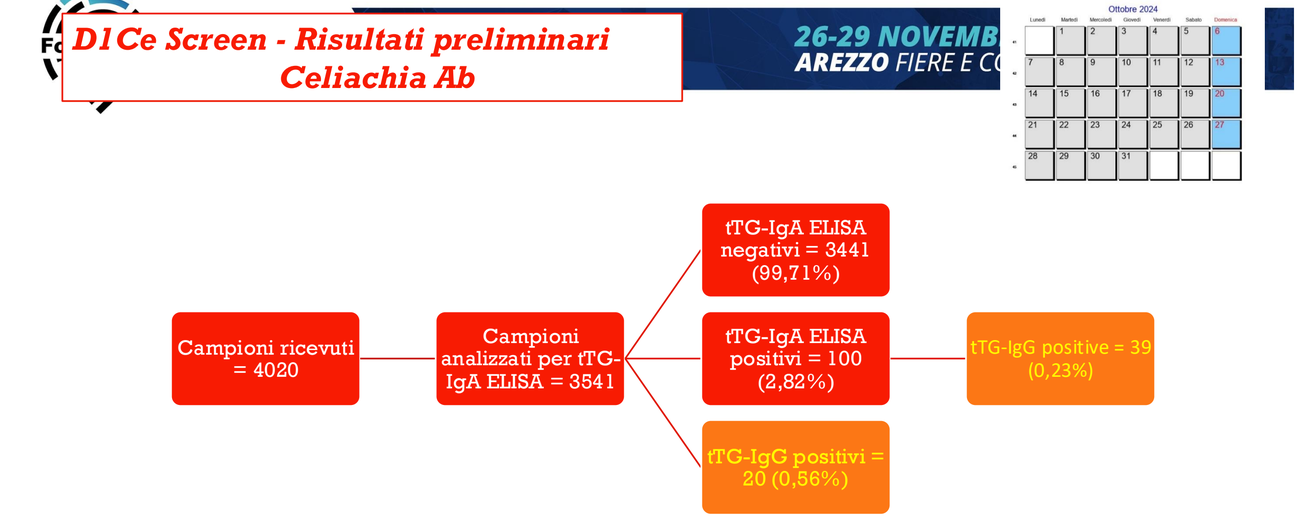
D1Ce Screen - Risultati preliminari DT1 Ab



Individual autoantibodies:

GADA 16 (0,45%), ZnT8A 9 (0,25%), IA2A 4 (0,1%), IAA 3 (0,08%)

D1Ce Screen - Risultati preliminari Celiachia Ab



Procedure di follow-up per DT1

obiettivo sanità salute

Follow-up and monitoring programme in children identified in early-stage type 1 diabetes during screening in the general population of Italy

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TABLE 1 Follow-up and monitoring programme for children at risk of type 1 diabetes identified through anti-islet autoantibody screening in Italy.

Age, years	3 months	6 months	9 months	12 months	Follow-up
Programme for children at-intermediate risk (pre-stage 1, S-iAb Pos)					
2-2.9	Random glucose or FBG, HbA1c, Ab, education, psychological support	Random glucose or FBG, HbA1c, Ab, education, psychological support	Call from the nurse	Random glucose or FBG, HbA1c, Ab, education, psychological support	• If S-iAb continues with follow-up every 6 months • If M-iAb and normoglycaemia, monitoring as for stage 1 • If S- or M-iAb plus dysglycaemia, monitoring as stage 2 • If Neg Ab continues as a National Screening Program[a]
6-10.9	Call from the nurse	Random glucose or FBG, HbA1c, Ab, education, psychological support	Call from the nurse	Random glucose or FBG, HbA1c, Ab, education, psychological support	• If S-iAb continues with follow-up every 6 months • If M-iAb and normoglycaemia, monitoring as for stage 1 • If S- or M-iAb plus dysglycaemia, monitoring as stage 2 • If Neg Ab continue as National Screening Program[a]
Monitoring children in stage 1 (M-iAb Pos and normoglycaemia)					
2-2.9	Random glucose or FBG, HbA1c, Ab, education	Random glucose or FBG, HbA1c, Ab, education, psychological support, 14d-CGM	Call from the nurse	Random glucose or FBG, HbA1c, Ab, education, psychological support, 14d-CGM	• If M-iAb and normoglycaemia, monitoring as stage 1 • If M-iAb plus dysglycaemia, monitoring as stage 2
6-10.9	Call from the nurse	Random glucose or FBG, HbA1c, Ab, education, psychological support, 14d-CGM	Call from the nurse	Random glucose or FBG, HbA1c, Ab, education, psychological support, 14d-CGM	• If M-iAb and normoglycaemia monitoring as stage 1 • If M-iAb plus dysglycaemia, monitoring as stage 2
Monitoring children in stage 2 (M-iAb Pos and dysglycaemia)					
2-10.9	FBG, HbA1c, CGM, education, psychological support	FBG, HbA1c, CGM, education, psychological support	FBG, HbA1c, CGM, education, psychological support	FBG, HbA1c, CGM, education, psychological support	• Decision on when to start insulin treatment and/or refer the child to research protocols

Note: Dysglycaemia: FBG 100-125 mg/dl or HbA1c 5.7%-6.4% or percentage time >140 mg/dl at 14d-CGM >10%. Education: information and leaflets for the prevention of diabetic ketoacidosis. Psychological support: discussion with the child and parents about the possibility of the appearance of clinical signs of type 1 diabetes, burden, and opportunities.

Programma di screening nazionale per DT1 e Celiachia

- ✓ Dal 1 gennaio 2025, le 21 Regioni e Provincie autonome si faranno carico dell'organizzazione dello screening
- ✓ Finanziamento totale di quasi 4.000.000 di Euro per ciascuno degli anni 2025 e 2026
- ✓ Determinazione degli aplotipi DQ2/8 alla nascita
- ✓ Dosaggio degli anticorpi del DT1 a 2-3 e 5-7 anni
- ✓ Dosaggi degli anticorpi della Celiachia a 5-7 anni nei soggetti predisposti in base al test genetico
- ✓ L'ISS manterrà il coordinamento del programma di screening ed effettuerà l'elaborazione dei dati totali da presentare annualmente all'Osservatorio, costituito presso il Ministero della Salute

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