## **Diabetes Management**

Diagnostic Therapeutic Assistance Paths (DTAP) for type 1 Diabetes mellitus: Summary of the Document of the Italian association Medici Diabetologic scientific society



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### ABSTRACT

Young age onset and long-life expectancy of type 1 diabetes mellitus (T1DM) people make it essential to achieve an early, stable and optimal glycemic control to prevent chronic complications and ensure good quality of life.

These goals can only be achieved by having a healthcare organization that guarantees patient equity of access, quality and continuity of care, with an appropriate use of resources.

To make the treatment organization efficient and appropriate, various health systems have implemented Diagnostic Therapeutic Assistance Paths (DTAP). DTAPs aim to share decisionmaking processes and healthcare organization for specific groups of patients on the basis of existing guidelines and in relation to the available resources, during a well-defined period of time.

In Italy, the Italian Association of Diabetologists (AMD) scientific society, in association with Association of Pediatric Endocrinologists and Diabetologists (SIEDP), and voluntary diabetes associations (i.e. Diabetes Italia) developed a national DTAP for T1DM. Five DTAP models were defined, focusing on 5 different disease stages or treatment process: onset of illness or first referral from another diabetes clinic, routine visit in good metabolic control, uncontrolled hyperglycemia, advanced technologies, transition from pediatric to adult diabetes clinic. Objectives, healthcare professionals involved, visits organization, and educational contents for each of these PDTAs are detailed in the core document.

This DTAP will be disseminated through the AMD regional referents to the Regional Healthcare Systems. Each Region will be asked to implement the DTAP through multi-professional working groups, with the participation of regional AMD referents and representatives of Patient Associations.

The DTAP effectiveness will be evaluated using an indicators' system every year.

### Introduction

the last 30 years worldwide and in Italy [1-4].

Type 1 diabetes (T1DM) is one of the most frequent chronic diseases in pediatric age. Different national studies and reports consistently documented an increase in its incidence during According to the T1DM Register (RIDI) [3-4], during the period 1990-2003, the incidence rate of T1DM in Italy was 12.26 per 100,000 person-

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### **KEYWORDS**

- type 1 diabetes
- healthcare organization
- diagnostic
- therapeutic
- assistance paths
- transition

years, being significantly higher in the male gender than in the female one (13.13 vs. 11.35). In addition, the incidence increases as the age group increases and shows a very heterogeneous distribution among the different regions [3-4].

The regional register of Sardinia [5] shows that the pediatric T1DM (0-14 years) incidence is definitely higher than in all the other regions, resulting in 44.8/100,000 person-years in the two decades 1989-2009, with an annual increase of 2.12%.

This increase is related none only to genetic predisposition, but only to environmental factors: short duration of breastfeeding, early weaning with nutritional mistakes that persist in later ages, recurring viral infections, stress, early puberty, etc. [6].

In addition, T1DM affects increasing proportion of immigrate children [7].

In terms of prevalence, T1DM is estimated to represent about 8% of all cases of diabetes with an overall prevalence of 0.3% in Italy [8,9].

The young age onset and the long-life expectancy of T1DM people make it essential to achieve an early, stable and optimal glycemic control to prevent chronic complications and ensure good quality of life. These goals can only be achieved by having a healthcare organization that guarantees patient equity of access, quality and continuity of care, with an appropriate use of resources [8-13].

A particularly complex moment in T1DM life is the transition from the pediatric diabetes center to the center caring for adult patients. In the problematic phase of adolescence, the child must be progressively educated to autonomy in T1DM management, which was physically and psychologically delegated to parents during childhood. The risk of the child not accepting and/or not being able to manage the change and abandoning diabetes care is very high. Literature data document that 30% of boys are lost to follow-up during transition, being exposed to prolonged hyperglycemia [14-20].

To make the treatment organization for any chronic condition efficient and appropriate, various health systems have implemented Diagnostic Therapeutic Assistance Paths (DTAP). DTAPs aim to share decision-making processes and healthcare organization for specific groups of patients on the basis of existing guidelines and in relation to the available resources, during a welldefined period of time.

The core features of DTAPs include:

-A clear explanation of the objectives and key elements of care based on scientific evidence, best practices, patient expectations, and their characteristics;

-Easy communication among team members, patients and their families;

-Care process coordination through the definition of roles and responsibilities of the multidisciplinary care team, patients and their families;

-Documentation, monitoring and evaluation of variations and outcomes;

-Appropriate resource identification.

In other words, DTAPs, with respect to a disease or a clinical problem, allow creating a network and identifying the most effective and sustainable care, aiming at improving clinical outcomes (complications prevention) and patient quality of life.

Given these premises and starting from existing local models, the Italian Association of Diabetologists (AMD) scientific society, in association with Italian Association of Pediatric Endocrinologists and Diabetologists (SIEDP), and voluntary diabetes associations (i.e. Diabetes Italia) developed a national DTAP for T1DM, to be implemented in different areas with the aim of improving appropriateness of T1DM care.

### **Materials and Methods**

The document was developed on the basis of the most recent national and international guidelines for T1DM treatment [8-13].

The already available regional or local DTAPs models were also taken into consideration, as well as institutional documents on disease management previously published by AMD [21-30].

Overall, 8 regional DTAPs (Abruzzo, Tuscany, Umbria, Veneto, Friuli Venezia Giulia, Emilia Romagna, Sardinia, Piemonte, Lazio) and 4 local DTAP (Modena, Cuneo, Brescia and Milan-Niguarda Hospital) were identified, reviewed and integrated to provide a national reference model.

The review was carried out by a board of experts including different stakeholders.

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### Results

The review process led to the publication of a document available for free consultation on the AMD website [31]. Main elements are summarized as follows.

### Objectives

DTAP for T1DM describes the care pathway of T1DM patients aged  $\geq$  18 years and aims to:

-Promoting the use of shared and reproducible disease management model in all regions, through the definition of structure and staff requirements and the activation of protocols for referral and follow-up of T1DM patients at the different stages of the disease.

-Ensuring a timely and high quality care to T1DM from the onset of the disease: identification of appropriate therapies and definition of treatment goals, activation of a comprehensive therapeutic educational program, and provision of psychological support to facilitate the disease acceptance and help coping with disease in the social context.

-Avoiding inequities and inequalities though the provision of adequate care also to foreigner or socially vulnerable patients, by understating their different needs and culture.

The 10 call-to-actions identified by DTAP are summarized in **TABLE 1.** 

### Multidisciplinary team definition

The minimum requirements for diabetes services enabling effective and appropriate care to T1DM are detailed in **TABLE 2.** Key mandatory requirements are:

-Presence of a dedicated multi-professional team with well-defined roles and responsibilities in the different disease stages and related DTAP **TABLE 3.** 

-Continuous collection of data on electronic medical records (EMR) for sharing information with all the parties involved in the care process and periodic quality of care assessment.

-Diagnostic and therapeutic care pathways (DTAPs) dedicated to T1DM, accompanied with verified evidence of annual education provided to patients.

#### Differentiated DTAPs by disease phase

AMD has identified 5 DTAP models to be reproduced based on available resources and focused on 5 different disease stages or treatment process:

- Onset of illness or first referral from another diabetes clinic

- Routine visit in good metabolic control
- Uncontrolled hyperglycemia
- Advanced technologies

TABLE 1. Baseline Characteristics by study group.
1. To increase the awareness of gps of early signs for the diagnosis of diabetes, thereby limiting cases of onset with diabetic ketoacidosis (DKA)
2. To intervene during the first hospitalization, from the first days after diagnosis, with a proper education program aimed at sharing the techniques of self-management of the disease with the person with diabetes
3. To standardize hospital pathways for evidence-based care from diagnosis to advanced disease
4. To start, at the time of diagnosis and maintain over time, a nutritional education program for person with T1DM and family members with the support of an expert dietician
5. To provide information on the use of technologies for caring T1DM
6. To provide foreign families with information that takes into account the different socio-cultural characteristics, producing written instructions in the native language
7. To provide psychological support to facilitate the acceptance / understanding of the disease by the person with T1DM and his/her family, personalized over time when needed
8. To favor social and work integration as soon as the clinical conditions allow it
9. To accompany the transition between pediatric and adult diabetes clinic and the transition between pediatrician and general practitioner
10. To encourage contact of people with T1DM with Volunteer Patient Associations

IT systems	Structure	Diabetes Team		
IT systems Premises must have furniture, equipment, personal computers and medical devices suitable for the specific activities carried out. In consideration of the amount of data to be managed, an adequate digitalization is needed for secure archiving of essential data and sharing of documents with formats and layouts.Electronic medical record system must allow measurement of upulity indicators of care identified by the AMD annals initiative. Diabetes clinic must be equipped with IT systems to manage (even remotely) data	Structure Premises and spaces must be related to the type and volume of services provided. Presence of a room dedicated to the execution of services that guarantees respect for the user's privacy. Presence of waiting areas dedicated to people with T1DM and for collective educational activities.	are: Professional Education Updated training on epidemiologic and clinical data, new technologies (insulin pumps, continuous blood glucose monitoring), personalized plans, contraception and pregnancy planning in diabetic women of childbearing age, counseling on correct nutrition and physical activity, transition from pediatric to adult centers, diabetes management during hospitalization,	Diabetes Team Patient Education structured therapeutic education, also through educational material; to be provided individually or to groups of patients	Care Care care to be provided according to the required level of care intensity and based on specific skills and responsibilities

TABLE 3. Roles and responsibilities required to T1DM team.						
Diabetologist:	Diabetes nurse	Dietitian	Psychologist			
Assigns the PDTA more appropriate for the patient in that moment	measures weight, height, blood pressure	provides education and training materials on carbohydrates-counting	is responsible of psycho- social evaluation of the patient			
ls responsible of patient care	performs educational reinforcement (insulin administration technique, SMBG, ketonemia, management of hypoglycemia)	check food diary	organizes psychological care based on individual patient needs			
Prescribes medicines, devices, tests	verifies periodically correct use of medical devices	verifies correct use of CHO/ insulin ratio				
Evaluates clinical parameters	verifies any areas of lip dystrophy	verifies skills acquired by the patient				
Revises data downloaded from glucometers, CGM or FGM	downloads glucometer, CGM, or FGM data in electronic medical record or other device					

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Perform an overall clinical assessment of the patient		
Plans follow-up visits		
Decides if patient requires hospitalizations		
Record or is responsible for data recorded in EMR		
Identifies patient educational or psychological needs		
Manages the transition from pediatric to adult diabetes clinic		

- Transition from pediatric to adult diabetes clinic

visits organization and educational contents for each of these PDTAs are detailed in **TABLES 4A-4E.** 

Objectives, healthcare professionals involved,

TABLE 4a. Summa	nry of AMD PDTA in T	IDM PDTA 1: onset (	of T1D or first ac	cess to diabetes clinics.
Goals	Visits scheme	Content of	i visits	Education
To define the health status and to assess the hyperglycemia severity and its treatment.	4/6 accesses within the first 2/4 weeks.	first 2/4 weeks	months from diagnosis	The goal is to get a metabolic balance with the necessary skills acquisition for the intensive insulin therapy self-management.
To realize a diagnostic process to identify any associated pathology.	A variable access number over the next 4-12 months.	Hyperglycemia treatment	Metabolic control stabilization	It takes place over a period of 8-12 months.
Set up the personalized intensive insulin therapy.	Subsequently, the patient enters in routine outpatient checks.	lnsulin therapy – basal bolus regimen	Therapy optimization	The first step aims to transmit starting self- management necessary skills to the subject (survival kit) and requires on average 4 meetings.

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To create a training plan and lead the patient to disease self-management		Typing and identification of any other associated pathology	Acquisition by the patient of an adequate level of autonomy in the therapy management	The next step (other 2/4 meetings) is useful to drive the patient in the exit phase from clinical remission (honeymoon) and reach a stable condition.
To support the patient from a psychological point of view		Beginning of the patient therapeutic educational program	Adequate psychological balance	However, planning and timing are flexible, to be adapted to individual cases.
		Bureaucracy (Exemption for diabetes onset)		At the end of the overall path the patient will have knowledge, skills and competences related to: What is type 1 diabetes Treatment goal, Insulin replacement therapy and drug kinetics, Insulin self-administration, Self- monitoring (capillary and with continuous monitoring system), Correction/prevention of hypoglycemia and possible glucagon use Insulin-dosage modification (correction of hyperglycemia sensitivity factor or correction factor), Diet with fixed CHOs at meals (first phase), CHO equivalent exchange diet (second phase) Carbohydrate counting (third phase, I/CHO ratio),Hyperglycaemia/, intercurrent illness management and ketonemia, Physical activity management ,Awareness of the diabetes impact on every-day life, Tools and strategies for managing recognizing emotions.

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TABLE 4	1	routine visits i	n people with T1D	M and satisfacto	ry glycemic con	trol.
Goals of PDTA	Visits scheme		Content	of visits		Education
	Visits	Every 3-4 month	n people with T1D Content Once year 1 outpatient visit with the dietician is desirable Examination of the peripheral pulses and search for vascular murmurs and determination of the Windsor index Evaluation of the pressure sensitivity loss to the monofilament of 10 g and of the vibratory sensitivity using tuning forks on the back 20 of the big toe, preferably inserted in a structured	of visits Every 2-5 years from diagnosis Fundus oculi should be performed 5 years after the diabetes diagnosis and then be repeated every 2 years in the retinopathy absence. Lower limb arterial Doppler if Winsor test<0.9 (if normal it can be	In case of unsatisfactory glycemic control complications development, the diabetologist will: Therapy modification	
and chronic complication development, Monitor the metabolic compensation progress over time. Plan periodic follow-ups to identify the chronic complication development early and, if present, monitor their evolution and response to the therapy optimization.	Visits are performed according to Italian Standards for Diabetes Mellitus Care 2018.	Outpatient visits in stable conditions, in the absence of developmental complications: BP and weight measurement Laboratory tests: HbA1c	scoring system (after 5 years of illness) together with cardiovascular reflex tests Laboratory tests: total cholesterol, HDL cholesterol, HDL cholesterol, non- HDL cholesterol triglycerides, LDL cholesterol calculated with the Friedewald formula (unless the triglyceridemic is>400mg/dL for which direct determination becomes necessary), albuminuria (if duration of diabetes>5years), serum creatinine (to estimate glomerular filtration rate and stage disease). Instrumental tests: Screening for the possible presence of silent ischemic heart disease must only be performed in patients with a high probability of silent IC pre-test with exercise ECG	re-evaluated after 3-5years). Cardiovascular Tests for the Vegetative Neuropathy identification are particularly useful: in the presence of vegetative dysfunction symptoms and signs, in the presence of high cardiovascular risk or micro and macroangiopathic complications, before major surgery, in the preparation of a physical activity program, in diabetics with a history of poor glycemic control, and in the presence of asymptomatic hypoglycemia.	in-depth blood chemistry and instrumental tests and/or specialists visits In the event that periodic outpatient	If necessary, interventions by the psychologist and participation in group training meeting can also be provided.

Goals of PDTA	Visits scheme	Content of visits	Education
			Topic: Treatment goals
To transmit to the person the necessary skills for self- management	2-3 (or more) visits every 15-30 days (intensive path)	Check glycemic trend from self-monitoring data download	Insulin replacement therap and drug kinetics
			Insulin self-administration
			Blood sugar levels self- monitoring
		Check correct tools use, adherence to therapies, knowledge level of diabetes self-management	Hypoglycemia correction prevention and possible glucagon use
			Insulin dosage modification (correction o hyperglycemia sensitivity factor or correction factor
		Identification of	Snacks management
		personalized solutions to specific needs Planning of subsequent meetings based on patient needs	Management of hyperglycemia/intercurrer disease and of ketonuria/ ketonemia

### TABLE 4c. PDTA 3 routine visits in people with T1DM and satisfactory glycemic control.

Goals of PDTA	A 4 use of techno Visits scheme	logy in T1D care.	t of visits		Education
		Transition from multiple daily insulin injections (MDI) to continuous sub- coutaneous insulin infusion (CSII) and stabilization of therapy	Short follow-up visits (based on patient needs)	Long-term follow-up	The collective modality for education an verification may be used Group meetine managed by the doctor / nurse dietician when the priority educational objectives are addressed:Lev and correctne of basal and higher functio
Acquisition of batient skills and competences that ensure the appropriate technology use of: • Continuous glucose monitoring (real time or intermittent) • Insulin pump therapy (CSII) • integrated system therapy (Sensor Augmented Pump therapy - SAP) /hybrid ystems/artificial pancreas	of care" and "Recommendations on the technologies use, AMD SID 2018 group". The beginning of CSII e/o SAP therapy is carried out routinely in the day hospital regimen or complex outpatient activity depending on the organization of the facility. The verification of the facility. The verification of patient requirements is a key aspect: given the speed of evolution, the indications for	<ul> <li>injection therapy to continuous infusion and/or integrated system involves the following activities:</li> <li>1. Technical training and positioning of the pump/ infusion set</li> <li>2. Setting of infusion therapy (passage from multi- injection to continuous infusion, definition of basal and bolus);</li> <li>3. Start of therapy with capillary blood glucose monitoring, basal infusion check/correction, meal bolus check;</li> <li>4. Optimization of infusion therapy up to the achievement of patient complete autonomy in the therapy management both in terms of basal and higher functions;</li> <li>5. In the case of SAP it is necessary to acquire both specific theoretical notions and practical skills such as:</li> <li>Positioning training</li> <li>Sensor operation (calibration, setting, alarms, etc.)</li> <li>Data use (immediate, intermediated, retrospective information)</li> <li>Data download and analysis (dedicated software use)</li> <li>Finally, it will be necessary to agree on the number of sensors to be used (intermittent and continuous)</li> </ul>	After the therapy start, the patient is monitored with close checks, until the infusion therapy is optimized and autonomy is achieved in the therapy management, both in terms of basal and higher functions	Once the therapy initiation/ stabilization process has been completed, the patient restarts routine clinics and re- evaluated on an outpatient basis at a variable rate according to his clinical/ training needs. According to the needs identified during the interview and the visit, the necessary educational interventions are planned and/or carried out.	Hypoglycemi treatment an prevention Behaviors in ca of unexplaine hyperglycemi and intercurre illness Interruptions of treatment Managemen of unusual situations In ca of SAP: corree management the monitorin system, amou of informatio usage. The periodic verification is carried out b the various team membe on the basis of their skills eve in separate moments and must have a maximum two year frequence

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TARI E 4e. PDTA 5 t	ransition from paed	liatric to adult diab	5	le selentine society
Goals of PDTA	Visits scheme		of visits:	Education
Start the transition		First visit	After 1 year	
process for young	When the diabetes	The patient is	, itel i jeu	
people with DM1 by	pediatrician (DP)	accompanied to the	After the first year, the	
the age of 18 with	recognizes that	first visit at ADC by	transition team fills in	
a homogeneous	transition age	the DP. The joint visit	the "Follow-up form",	
care pathway that	is approaching,	is carried out with	with verification	Educational sessions
involves interaction between the health	in a climate of	evaluation of any active problem and a	of the degree of	are aimed at verifying progresses in:patient
professionals involved	collaboration and	personal care plan is	achievement of	progresses in:patient
in the treatment	communication with	drawn up with shared	objectives identified	maturity
plan (pediatric	the family and the	objectives between	in the first visit, while	matanty
diabetologists	young patient, he/she	the two diabetes	the patient fills in the	
and for adult,	begins to propose the	teams and transcribed	"Satisfaction question	
nurses, dieticians,	path of transition.	in a standardized	on the transition".	
psychologists)		"Follow-up form".		
	A joint meeting with			
	the patient, family			
	and both diabetes			
Ensuring young	teams is organized.			
people with T1DM	After the first			
that the care transfer	meeting, the young patient continues to	This plan will	All collected	
to the adult center	be followed at the	accompany the	questionnaires in a	
takes place following	pediatric diabetes	patient during 1 year	certain timeframe are	patient knowledge of
an organized and	clinic, but participates	at the CDA. The child	discussed in periodic	illness and necessary
gradual process from	in the annual	can start the self-care	dedicated meetings	treatments
the pediatric center. The transfer process	meetings organized	follow-up at the ADC	between pediatric	
is evaluated and	by the adult diabetes	according to the personal care plan	and adult teams	
initiated according to	center (ADC), until in			
the local reality.	a condition of stable			
,	metabolic control the			
	DP decides that the			
	patient is ready to transition.			
	At this point the DP			
	fills in a standardized			
	Transition Form and			
To ease accessibility to adult centers for	sets an appointment			
young people with	for the first visit			
DM1 by providing	of the patient to			
specifics paths and	the ADC. Cultural,			
relationships with	sporting, scholastic			
diabetes team of both	interests, manual			
centers.	skills, friendship and			
	parental networks should also be			
	specified,			
Ensure the	· · · · · · · · · · · · · · · · · · ·			
appropriateness of				
the services useful	Compatibly with			
for the young	the service needs,			
people with T1DM	the ADC organizes a			
management through				
the establishment	to welcoming the			
of an access that replaces the Day	patient in transition and identifies the staff			
Hospital regime but	responsible for him/			
ensures a "protected"	her reception among			
care setting	the two teams. It			
(applicable for the	is also possible to			
first 5 years after the	involve other young			
transition) Implement	patients who have			
tools at a regional	already made the			
level to identify adult	transition and who			
centers suitable	are willing to share			
for welcoming and	their experience			
managing young				
people.				

### Structured therapeutic education in DTAP for T1DM patients

Patient education is pivotal for any T1DM therapeutic strategy; therefore, educational sessions must be integrated within the DTAP, with topics related to the disease stage.

The educational activity involves the whole team (doctor, nurse, dietician, and psychologist) who must operate in a coordinate and consistent manner according to documented protocols; training records must be saved in the patient EMR.

Therapeutic education requires specific operators training relating not only to content but also to methodologies and relational skills.

For each type of educational intervention, there are protocols that outline the essential elements for the delivery of an effective education [32, 33] based on active listening and person-centered (and/or caregiver-centered) approach.

Consistently with health pedagogy fundamentals [32], each educational activity must be structured according to:

-Educational diagnostics (who is the patient, what does he/she know? What does he/she believe? What does he/she expect? What does he/she need?)

-Definition of educational objectives (patient knowledge and skills)

-Choice of methods (relevant, consistent and sustainable by the organization)

-Definition of key points for disease status verification and verification tools.

Patient educational support must be conceived as a continuous process to be modulated over time also according to patient's specifications, needs and attitudes. It is desirable that the diabetes clinic be able to plan both individual and group sessions, based on educational contents. Group session (even in residential mode) represents a precious methodology both in terms of time and human resources and intervention effectiveness. In fact, peer interaction has been shown to be extremely effective in adults learning and behavior modifications. AMD selected the contents of the educational sessions to be implemented within the different DTAPs **TABLE 3**.

### DTAP effectiveness evaluation

Since many years, AMD has promoted a monitoring and continuous care improvement initiative (AMD Annals) which has led to a progressive care quality improvement [34]. Periodical evaluation of a pre-defined set of process and outcomes indicators assessed on routine clinical data recorded in EMRs has represented an integral part of the activity promoted by the AMD network for over 15 years.

On the same line, effectiveness of the implemented DTAP will be evaluated using predefined volume, process and outcome indicators **TABLE 5.** The goal for each indicator will be: "equal or higher than the national average (AMD Annals)" and/ or "increase of own result compared to the previous year".

TABLE 5: List of pre-defined quality of care indicators to measure the effectiveness of PDTAs.					
Indicators of activity volume	Process indicators	Intermediate outcome indicators			
Total registered patients with T1DM	Proportion of patients with at least 1 evaluation in the previous 12 months of:	Mean (standard deviation) HbA1c			
Total patients with at least one visit per year	HbA1c	% patients with HbA1c <7.0%			
% first visits / first access	blood pressure	% patients with HbA1c >9.0%			
Total educational interventions performed	Renal function (creatinine or albuminuria)	% patients with LDL < 100 mg/dl			
Total educational interventions for counting CHOs performed	Lipid profile	% patients with blood pressure < 140/90 mm/Hg			

-Choice of contents (essential)

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No. of patients in therapy with insulin pump or sensor-augmented pump (SAP)	Retinopathy	% patients with blood pressure >= 140/90 mm/Hg
No. of patients who have performed pump training or SAP and have applied it	Cardiopathy (ECG)	
	Diabetic foot	

### Discussion

Improving the quality of T1DM care by differentiating the DTAPs according to the disease stage is a goal agreed by all T1DM stakeholders.

Care objectives can only be pursued through healthcare models able to respond to diabetes patient global needs, in the different disease phases, establishing, in a standardized and measurable way, roles and objectives of the individual components of the care relationship.

The proposed DTAP offers an organic response to the care fragmentation in order to improve the appropriateness and clinical efficacy, combining it with required resource homogenization and optimization at the regional level.

The proposed DTAP follows the patient from the disease onset, to the transition from pediatric to adult center, to the elderly, spanning from metabolic control to uncontrolled hyperglycemia phases. Key aspects of each phase are considered, including therapeutic goals, visit schemes, therapeutic education, patient satisfaction and appropriate use of devices.

Nowadays, in Italy a few and heterogeneous DTAPs dedicated to T1DM have been implemented at the local level.

### Conclusion

This DTAP will be disseminated through

the AMD regional referents to the Regional Healthcare Systems. Each Region will be asked to implement the DTAP through multi-professional working groups, with the participation of regional AMD referents and representatives of Patient Associations.

The DTAP effectiveness will be evaluated using the indicators system every year.

This DTAP will be revised in the light of new scientific evidence that may become available and in any case within a maximum time of 5 years.

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### **Duality of Interest**

No conflict of interest

### **Author Contributions**

GLP and PDP wrote the manuscript; all authors were involved in the paper revision and approval.

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#### References

- Diaz-Valencia PA, Bougnères P, Valleron AJ. Global epidemiology of type 1 diabetes in young adults and adults: a systematic review. BMC Public Health. 15(1):255 (2015)
- Mayer-Davis EJ, Lawrence JM, Dabelea D, et al. Incidence trends of type 1 and type 2 diabetes among youths, 2002–2012. N Eng J Med. 376(3):1419-1429. (2017)
- Bruno G, Maule M, Merletti F, et.al. Age-periodcohort analysis of 1990-2003 incidence time trends of childhood diabetes in Italy: the RIDI study. Diabetes. 59(9): 2281-2287. (2010)
- 4. Carle F, Gesuita R, Bruno G, et al. Diabetes incidence in 0- to 14-year age-group in Italy: a 10-year prospective study. Diabetes Care. 27(12): 2790-2796 (2004)
- Casu A, Pascutto C, Bernardinelli L, et al. Type 1 diabetes among sardini an children is increasing: the Sardinian diabetes register for children aged 0-14 years (1989-1999). DiabetesCare.27(7): 1623-1629 (2004)
- Giwa AM, Ahmed R, Omidian, et al. Current understandings of the pathogenesis of type 1 diabetes: Genetics to environment. World J Diabetes. 11(1): 13-25 (2020)
- 7. Ji J, Hemminki K, Sundquist J, et al. Ethnic differences in incidence of type 1 diabetes among second-generation immigrants and adoptees from abroad. J Clin Endocrinol Metab. 95(2): 847-850 (2010)
- 8. Standard Italiani AMD-SID per la cura del diabete mellito 2018
- 9. Hanas R, Donaghue K, Klingensmith G, et al. Global IDF/ISPAD Guideline for diabetes in childhood and adolescence. International Diabetes Federation.1-28. (2011)
- 10. National Institute for Health and Care Excellence (Great Britain). Type 1 diabetes in adults: diagnosis and management. National Institute for Health and Care Excellence (NICE); 2015.
- 11. Chamberlain JJ, Kalyani RR, Leal S, et al. Treatments of type 1 diabetes: synopsis of the 2017 ADA Standards of Medical Care in diabetes. Ann Intern Med. 167(7): 493-498 (2017)
- 12. APEG-ADS: National Evidence-Based Clinical Care Guidelines for Type 1 Diabetes in Children, Adolescents and Adults (2011)
- 13. Chiang JL, Maahs DM, Garvey KC, et al. Type 1 Diabetes in Children and Adolescents: A Position Statement by the American Diabetes Association. Diabetes Care. 41(9): 2026-2044 (2018)

- 14. Peters A, Laffel L, American Diabetes Association Transitions Working Group. Diabetes care for emerging adults: recommendations for transition from pediatric to adult diabetes care systems: a position statement of the American diabetes association, with representation by the American College of osteopathic family physicians, the American Academy of paediatrics, the American association of clinical endocrinologists, the American osteopathic association, the centers for disease control and prevention, children with diabetes, the endocrine Society, the International Society for Diabetes care. 34(11):2477-2485. (2011)
- 15. The Endocrine Society. Managing the transition of care for patients with type 1 diabetes .
- 16. The National Alliance to Advance Adolescent Health. Got Transition .
- 17. Cadario F, Prodam F, Bellone S, et al. Transition process of patients with type 1 diabetes (T1DM) from paediatric to the adult health care service: a hospital-based approach. Clin Endocrinol (Oxf). 71(3): 346-350 (2009)
- 18. Vanelli M, Caronna S, Adinolfi B, Chiari G, Gugliotta M, Arsenio L. Effectiveness of an uninterrupted procedure to transfer adolescents with Type 1 Diabetes from the paediatric to the adult clinic held in the same Hospital: Eight-Year experience with the Parma Protocol. Diabetes Nutr Metab. 17(5): 304-308 (2004)
- 19. Jaser SS, Yates H, Dumser S, et al. Risky business: risk behaviors in adolescents with type 1 diabetes. Diabetes Educ. 37(6): 756–764 (2011)
- 20. Colton PA, Olmsted MP, Daneman D, et al. Eating disorders in girls and women with type1 diabetes: A longitudinal study of prevalence, onset, remission, and recurrence. Diabetes Care. 38(7): 1212-1217 (2015)
- 21. Piano Nazionale sulla Malattia Diabetica 2012, Ministero della Programmazione Sanitaria-Commissione zionale Diabete. Approvato in conferenza Stato – Regioni il 6 Dicembre 2012
- 22. Organization of care for patients with diabetes in hospital and on the territory: AMD, SID, SIEDP, OSDI; ITALIAN HEALTH POLICY BRIEF, June 2012
- 23. La presa in carico della persona con Diabete tipo 1: la formazione del paziente al centro di un modello assistenziale per il diabete e le malattie metaboliche. JAMD 2017, 20: 177-184 (2017)
- 24. Documento di Consenso Transizione dei Giovani con Diabete Mellito verso l'età adulta: passaggio dal pediatra al medico dell'a- dulto

Gruppo di Studio SIEDP-AMD-SID. Il Giornale di AMD. 13: 159-168 (2010); Il Diabete. Vol. 23 (2011)

- 25. Noto G. I Profili di Assistenza per le malattie croniche: il modello Diabete Mellito – a cura di AMD – Milano Springer Verlag 2007
- 26. Grid for the assessment of appropriateness of the Diagnostic Therapeutic Assistance Pathways (PDTA) for Diabetes Mellitus. A check list for assessing appropriateness of integrated Management Pathways (PDTA) for Diabetes, J AMD Vol 20, (2017)
- 27. Maffettone A, Rinaldi M, Botta A. L'organizzazione di una unità operativa di diabetologia ospedaliera secondo i criteri di governo clinico: i PDTA. Il Giornale di AMD. 18(2): 142 (2015)
- Orlandini D, Fava D, De Bigontina G. Manuale di accreditamento delle strutture diabetologiche

   A cura di AMD – Springer 2007
- 29. Circolare n. 13/2015: "Linee di indirizzo per un uso appropriato dei dispositivi medici per l'autocontrollo e l'autogestione":
- 30. ASST Grande Ospedale Metropolitano Niguarda. Aggiornamento percorso per l'applicazione e la gestione del microinfusore di insulina nel paziente diabetico tipo 1 a cura di: ASST Grande Ospedale Metropolitano Niguarda
- 31. Gruppo di studio AMD DT1. Percorso Diagnostico Terapeutico Assistenziale per la Gestione della Persona Adulta con Diabete Tipo 1.
- 32. Albano MG, Crozet C, d'Ivernois JF. Analysis of the 2004-2007 literature on therapeutic patient education in diabetes: results and trends. Acta Diabetol. 45(4): 211-219 (2008)
- 33. Assal JP, Jacquemet S, Morel Y. The added value of therapy in diabetes: the education of patients for self-management of their disease. Metabolism. 46(12): 61-64 (1997)
- 34. Rossi MC, Candido R, Ceriello A, et al. Trends over 8 years in quality of diabetes care: Results of the AMD Annals continuous quality improvement initiative. Acta Diabetol. 52(3): 557-571 (2015)