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Hub-and-Spoke regional system supported by telehealth for managing coeliac disease in Liguria: a mixed-methods survey followed by an observational pilot study

Marco Crocco^{1*†}, Federica Malerba^{1,2†}, Paolo Gandullia¹, Noemi Zampatti², Maria Franca Corona³, Monica Barrani³, Massimiliano Leoni³, Sara Ceresoli^{2,3}, Andrea Gazzolo⁴, Alberto Gaiero⁵, Riccardo Borea⁶, Alessandro Giorgio Lo Curto⁶, Maria Paola Ierardi⁷, Silvia Scelsi⁸, Giuseppe Spiga⁹, Raffaele Spiazzi¹⁰, Renato Botti¹¹ and Marisa Alberti¹⁰

Abstract

Background Due to the need to reorganize the care network for the national screening mandated by law, a new healthcare model was required for the management of coeliac disease. The hub-and-spoke model is a new healthcare organizational system, here we describe its application (supported by telehealth), in the management of pediatric coeliac disease (CD) in Liguria. The results of the pilot phase are presented and the system's strengths and weaknesses discussed.

Methods A mixed-methods survey followed by an observational pilot study was performed. A multiphase approach was used including preparation setting, operative planning and application. The pilot phase involves a single primary center. The reduction of families' expenditure and environmental impact was assessed using the Viamichelin calculator.

Results A regional meeting followed by a survey (specifically developed for this study) and a needs analysis highlighted the priority to have an efficient, up to date and homogeneous model of care assistance throughout the network. A diagnostic and therapeutic care pathway (PDTC) was developed by the regional working group. The project involved 986 Ligurian families and allowed a 90% reduction in the distance traveled by families residing within the pilot center's catchment area, saving €177 and 113 kg of CO₂ on average per family per year.

Conclusions The Gaslini Diffuso hub-and-spoke system for managing CD in Liguria exemplifies a commitment to enhancing healthcare efficiency and patient care, reducing environmental impact and cost for both family and healthcare system.

Keywords Telehealth, Telemedicine, Hub and spoke, Celiac disease, Management; gluten

[†]Marco Crocco and Federica Malerba contributed equally to this work and share first authorship.

*Correspondence:
Marco Crocco
marcocrocco@gaslini.org

Full list of author information is available at the end of the article



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Introduction

Regional healthcare systems are immensely complex and may be affected by (often contrasting) political, economic, social, and epidemiological changes. The need to guarantee universal access to an equitable provision of adequate healthcare services, frequently clashes with the limitations of economic and human resources [1].

Children with special health care needs require health care and related services that exceed the type or amount generally needed by other children [2, 3]. They represent approximately 13%–19% of all children [4], and face an increased risk of frequent medical errors, poor care coordination, and significant challenges for both the health system and their families [4–7]. These adverse outcomes are closely linked to care coordination, which is essential for achieving optimal health outcomes. Consequently, various interventions have been designed to improve the care of children with special health care needs [8, 9]. Coeliac disease (CD) is a chronic autoimmune disease that primarily emerges in childhood and, as a side effect causes significant economic and social hardship for the families involved [10]. The prevalence of CD has rapidly increased over recent decades. However, it remains a disease burdened by a significant diagnostic delay (worsened by SARS-CoV-2 pandemic period) [11] and one which attracts little public attention, in part due to the availability of a highly effective non-pharmacological therapy. A gluten free diet (GFD) impacts the quality of life of patients and their families [12]. In Italy, thanks to a specific national law (called coeliac law), the healthcare system guarantees a partial economic support for the purchase of products specifically formulated for patients with CD. While in other countries, insurance or public health systems usually cover drug therapies, but do not cover the added expense for the non-pharmacological therapy required for treatment of CD, and that added financial burden is placed on families [13].

The management of CD does not typically require surgery, imaging or other advanced technology. Therefore, it is well-suited to a hub-and-spoke model: an organizational health system that offers great potential for efficiently serving patients to optimize the use of human and other resources. This offers the possibility to centralize the most advanced technology and medical expertise (in the hub) while distributing basic services to local secondary sites (spokes). Efficient healthcare strategies can reduce costs while optimizing the use of human and technological resources to provide the best possible care to patients. It is therefore imperative to identify the optimal diagnostic and therapeutic pathways shared by all healthcare facilities to avoid potential discrepancies in the clinical management and support to the families expected in fragmented local healthcare systems compounded with the need for continuous training of staff which in smaller

centers maybe more difficult. A carefully designed hub-and-spoke network meets the needs of patient care and achieves this promoting the efficient use of resources providing improved geographical coverage [14, 15].

The terms telemedicine and telehealth are often used as synonyms, however, telehealth is broader in scope and includes management and delivery of health care, health education and health information services remotely. Telemedicine is a sub-set of telehealth and is composed of a service of remote diagnosis and treatment of patients [16, 17].

The Ligurian pediatric population constitutes 15.3% of the total population (1.550.640) which is primarily distributed along the coastal area (359 km) with a prevalent concentration in the regional capital (Genoa, 841.180) located halfway between the two ends of the region. Over 50% of transportation in Liguria is by private car (50.2% of total transport) [18]. The region is served by a single highway—one of the most congested in Italy—and a single railway, both connecting the various provinces to Genoa. Each provincial health administrative territory has a pediatric department which ensures basic healthcare. The Giannina Gaslini Institute, a pediatric hospital in Genoa with over 500 inpatient beds, serves as a hub for all pediatric sub-specialties. Ensuring homogeneous assistance in an region with these demographic characteristics is a challenge. On 1st July 2022, a decision was taken by the Ligurian regional government (formalized as the ‘Gaslini Diffuso’ project), which gave the Gaslini Hospital a centralized role in managing all pediatric and neonatal services throughout Liguria, this includes four pediatric departments (previously managed by the local health authorities). Two of these being in secondary and two in primary hospitals. Among the objectives of this project there was also an attempt to address the chronic shortage of specialists, in particular pediatricians.

The management of CD was chosen as one of the first projects of the new integrated organization due to the high prevalence of CD in children undiagnosed and the need to reorganize the care network for the national screening mandated by law [19, 20]. The Regional Reference Center (RRC) for CD (Gaslini Institute– Genoa) was given responsibility for drawing up the implementation plan.

This paper presents the experience of implementing the Giannina Gaslini Institute hub-and-spoke system “Gaslini Diffuso” to manage the diagnosis and follow up of pediatric CD in the Liguria region. The hub-and-spoke organization design is described and its strengths and weaknesses discussed, facilitating other healthcare providers to adopt this model while avoiding some of the pitfalls we encountered.

Material and methods

In order to implement a hub and spoke system for the management of pediatric CD in the Liguria region, a mixed-methods survey with an explanatory sequential design using a multistage and participatory approach was conducted, followed by an observational pilot study.

The combination of financial benefits (lower costs), professional development and a desire to offer improved services to their patients are, if properly implemented, effective tools for encouraging active participation and commitment to the project goals.

The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Regional Ethics Committee (Liguria: 133/2024—DB id 13,773, 29/04/2024). Written consent to participate was obtained from all of the participants/families in the study.

Preparation setting

In January 2023, a regional meeting was organized by the RRC involving all the healthcare providers (pediatric gastroenterologists with clinical and endoscopic experience in CD, family and hospital pediatricians, diabetologist, nutritionists, dieticians, endocrinologists, dermatologists) and stakeholders represented by the Associazione Italiana Celiachia– Liguria, to update them on the latest

scientific evidence on the diagnosis and treatment of CD and its complications.

A complete survey of local (human and technological) resources was performed in hub and spokes pediatric departments including pediatricians and the department heads. This review phase mapped also patient care: what actually happens to a "typical patient" within the original hospital care organization. The first step in building a diagnostic and therapeutic care pathway (PDTC) was a needs analysis to better understand the problems, weaknesses and areas for improvement. In this phase, reviewing the existing status was also extremely useful. A survey was created for this purpose (see Additional file 1. Survey of local resources and patient care.). The variability and heterogeneity of performance across various active centers were assessed by a survey completed by medical staff.

Operative planning

A Regional working group was formed, led by the Gaslini Children hospital's health management. Figure 1 (Preparation setting, operative planning and application of Giannina Gaslini Institute hub-and-spoke system for managing coeliac disease in Liguria) summarizes the various organizational steps.

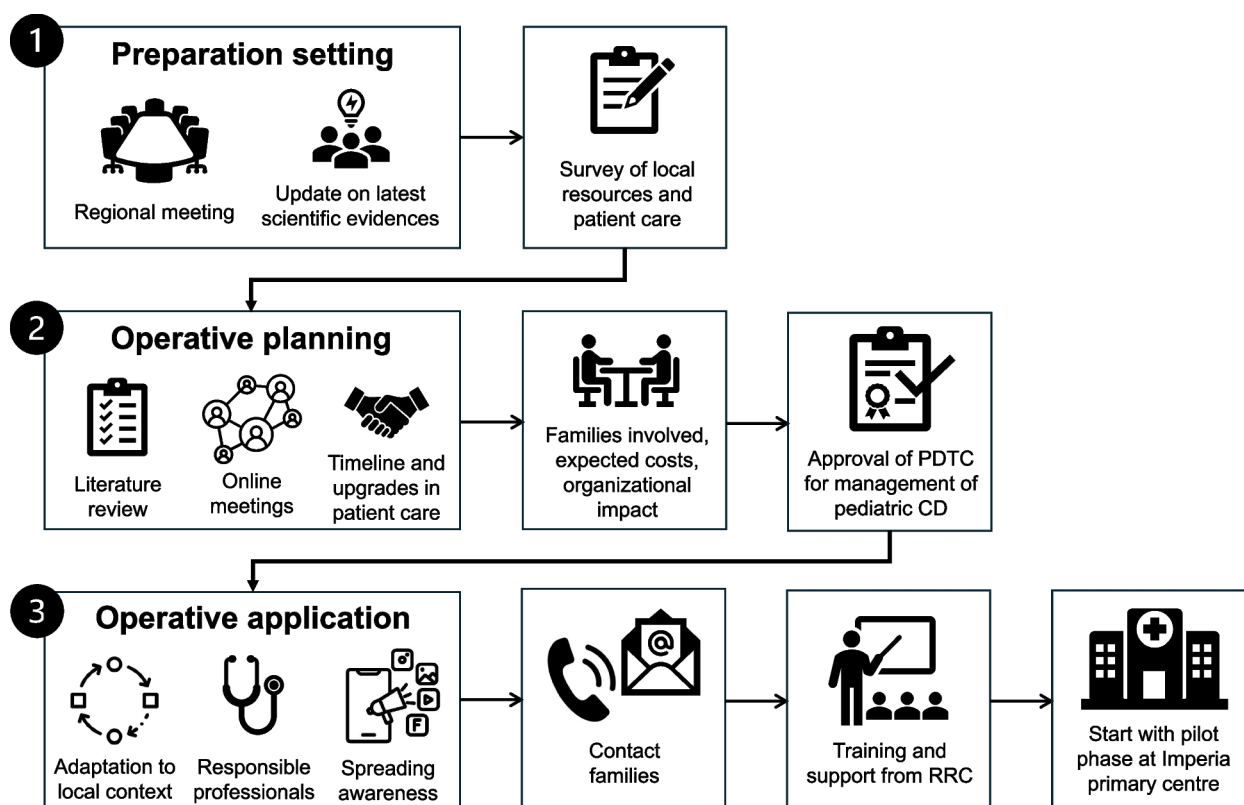


Fig. 1 Flow chart of decision-making and organizational processes. Preparation setting, operative planning and application of Giannina Gaslini Institute hub-and-spoke system for managing coeliac disease in Liguria. CD = coeliac disease; PDTC = diagnostic and therapeutic care pathway; RRC = Regional Reference Center

The availability of up to date high-quality guidelines was reviewed by the CD team of RRC (M.C. and F.M.). The literature review research strategy used was the following: (coeliac disease[Title]) AND (guideline*[Title]). We included papers identified as guidelines on the diagnosis of CD published in the last 5 years, independently of the methodology used for the guideline development.

A draft of a new PDTC for hospital management of CD in pediatric cases was discussed in two online round table meetings involving the RRC for CD (Gaslini– Genova), the health management of the Gaslini Liguria project and the heads of the Ligurian pediatric departments involved.

Following online meetings a multiphase timeline plan was established and potential improvements in patient care identified. The number of families involved in the project was estimated by the Regional Authorities and detailed in a report submitted to the Italian Parliament [19]. The expected costs and organizational impact on the hospital were estimated by the Gaslini Children hospital's quality team. The final document (PDTC for the management pediatric CD) was submitted to the hospital's Quality Control Chief (G.S.) and subsequently endorsed by the Medical Director (R.S.).

Operative application

The working group evaluated the adaptation of the guidelines to the local context to define the best clinical and managerial practices to implement an "ideal pathway". This was necessary to ensure that daily practice would reflect current recommendations and available evidence. The PDTC had to define not only "what" interventions should be carried out in relation to specific clinical situations, but also establish: "who" were the responsible professionals; "how" the procedures were to be applied; "where" the various procedures were to be performed and "when" (the clinical timing to be respected).

Internal communication services (internal website, training courses, mailing lists, social networks, etc.) were used to spread awareness regarding the new PDTC.

The operational application of PDTC began with a pilot phase aimed at evaluating the applicability of the new healthcare model. It was necessary to identify critical areas, such as the inability to implement new procedures and/or the need to improve them before the PDTC could become fully operative. The pilot phase involves a single primary center (Imperia children's department) between November 2023 and January 2024 (3 months). The CD team of RRC provided the training and support necessary for the healthcare personnel involved. Local families with children or adolescents (below 18 years old) were contacted by email or phone to explain the project and give them the opportunity to transfer the follow up activities to the center close to their place of residence. The first outpatient evaluation was carried out jointly by

the coeliac team of RRC and the pediatrician of the center involved.

For the analysis of the reduction of families' expenditure and environmental impact, the Viamichelin calculator (www.viamichelin.it) was used. A Euro 5 city car was chosen as the reference, being the most popular car model owned by Italian families.

Results

The project is estimated to involve approximately 986 Ligurian families globally and around 200 families from outside the region. Preliminary data on the pilot phase (involving 40 patients) showed that less than 6% of families chose not to transfer preferring instead to continue the follow up in the tertiary center. Therefore, 38 families were enrolled in the pilot program.

Preparation setting

In a regional meeting organized by RRC for CD on 23rd January 2023 the state of the art of CD and gluten disorders in pediatric patients was discussed with national experts in CD and 98 pediatric specialists involved in the management of CD in Liguria. The open issues and possible solutions were also discussed in the meeting and by email in the following months with representatives of the patient association as stakeholders (Associazione Italiana Celiachia—Liguria).

A subsequent survey undertaken in September 2023 (pediatric department heads $n=5$; pediatricians from spoke and hub hospitals, $n=10$) mapped the diagnostic pathway of a suspected CD. The differences in the management of pediatric CD between the different centers were notable. In Liguria, 2 secondary centers (Savona and La Spezia pediatric departments) performed the diagnosis and follow up, including potential and seronegative CD, undertaken (in Savona) by an endocrinologist and (in La Spezia) by two pediatricians. In the province of Imperia there had never been a service dedicated to CD patients who were standardly referred to the tertiary center (Gaslini Institute of Genova). In another health care zone (corresponding to Lavagna pediatric department) the CD follow up center had closed during SARS-CoV-2 pandemic period. Three different types of transglutaminase kits were being used across the 5 centers and diagnosis was based on three different protocols. The discrepancies became even more evident when the methods of diagnosis were analyzed. In the secondary centers the Italian Health Ministry protocol for CD 195/2015 (based on ESPGHAN 2012 guideline [21]) and a personalized protocol (including human leukocyte antigen (HLA)) were being used. While, in the tertiary center ESPGHAN 2020 guideline was, and still is, applied [22]. Endoscopic examinations were performed in patients over 14 years old in two centers and on those over 3 years old in one.

The tertiary center had a CD team dedicated to taking care of patients including endoscopy examination in children and adolescents. Finally, five different IT programs were in use for the clinical charts and reports. The lack of dietitians with experience in pediatric CD in the various spokes was already known.

Operative planning

The needs analysis identified as a priority the need to have an efficient, up to date and homogeneous model of care assistance in all the centers. The literature search on guidelines for CD undertaken in September 2023 identified 8 records in PubMed, 3 of which were suitable for pediatric patients: European Society Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) guideline [22], European Society for the Study of Coeliac Disease (ESsCD) [23] and Italian societies of gastroenterology [24]. All three applied the same ESPGHAN criteria for the diagnosis in pediatric cases, therefore ESPGHAN criteria was adopted for the CD Gaslini PDTC.

In two round table meetings the Regional working group discussed and, after minor revisions, approved (on October 20, 2024) the draft PDTC proposed by RCC for CD.

The RCC for CD and the heads of Pediatric departments involved were given responsibility for the implementation of the PDTC. The expected results were reported in the document (Fig. 2. Aims and expected results of diagnostic and therapeutic pathway for managing CD in the spokes). The various contexts in which

PDTC should be applied, the clinical timing to be respected and the description of specific procedures to adopt in suspected new cases of CD in childhood with related responsibility for the different levels of care were detailed in the text and graphically illustrated in a flow chart (Fig. 3. Flow chart to adopt in suspected new cases of coeliac disease in childhood with related responsibility for the different levels of care).

The PDTC was organized as a multistep approach. In order to facilitate communication between all the centers and to standardize reporting for families and family pediatricians, the first step was to standardize the terms used for CD and other gluten disorders, the Oslo definitions and terms were adopted [25]. Marsh-Oberhuber [26] and Corazza-Villanacci [27] classification was used for the histological report. To facilitate communication between different centers the clinical charts and reports were standardized using the same electronic tool (Galileo software, Noemalife, Bologna, Italy) and made accessible from all sites.

The second step was to define the symptoms and signs suggesting CD screening in childhood patients or requiring evaluation in the RCC even where CD serology has tested negative. To reduce possible discrepancies, allow comparison and reduce cost, all centers make use of the same standardized TTG IgA kit [28, 29]. Anti gliadin deamidated IgG and TTG IgG kits were recommended in cases of IgA deficiency. The HLA was limited to first family members, potential and seronegative CD.

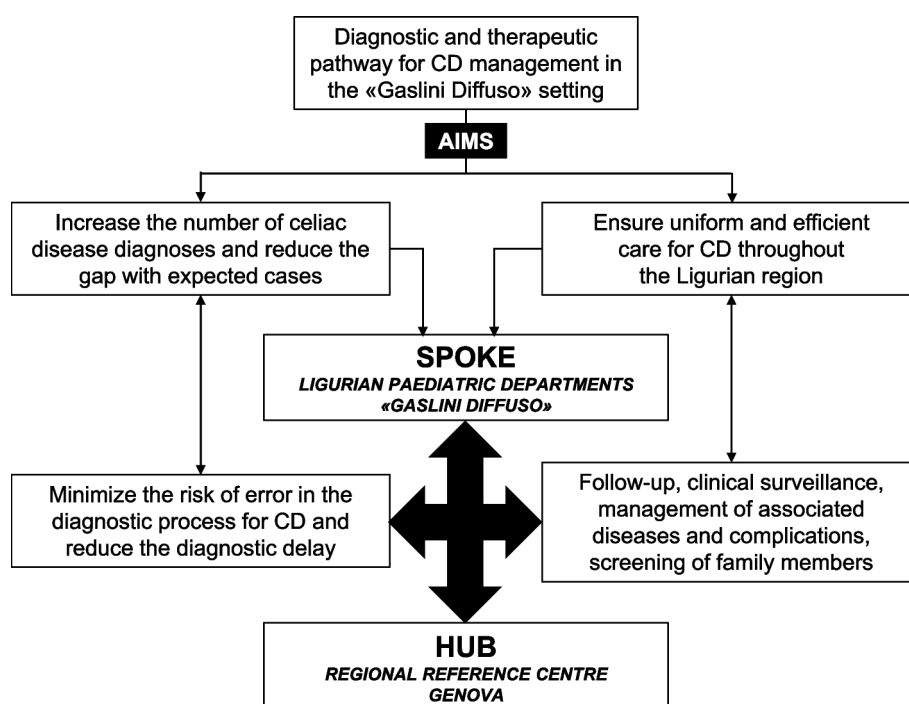


Fig. 2 Aims and expected results of diagnostic and therapeutic pathway for managing coeliac disease (CD) in spokes

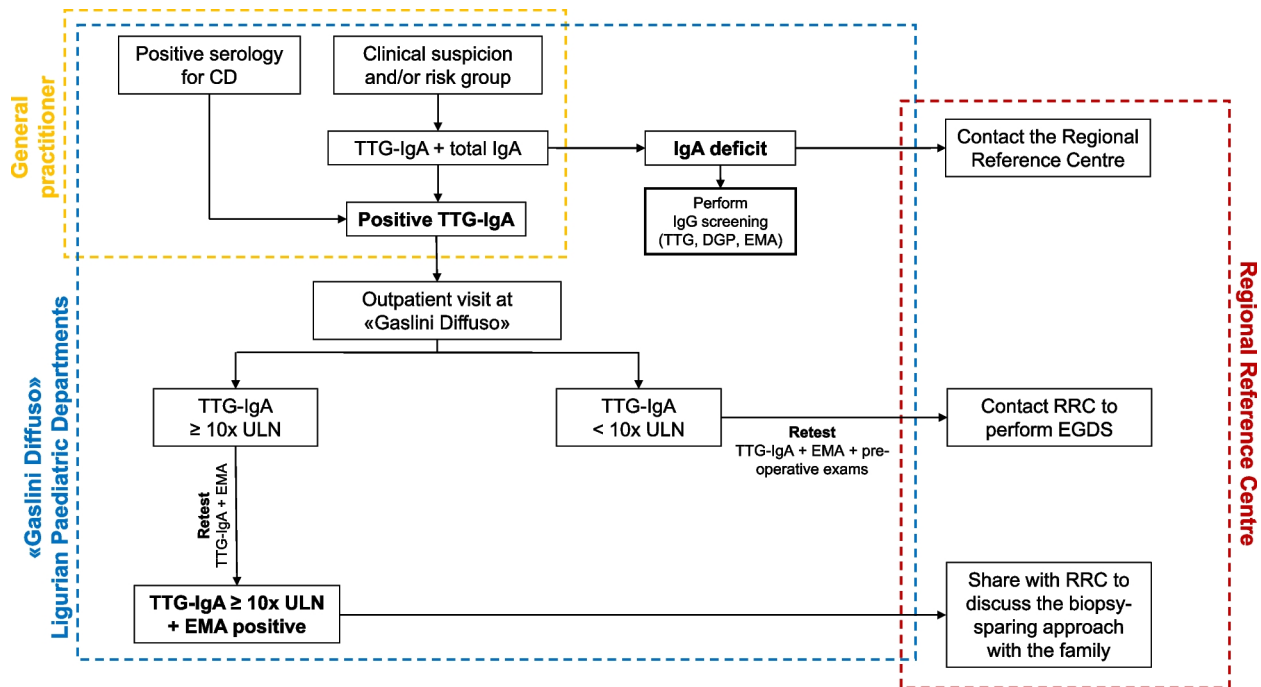


Fig. 3 Algorithm for suspected new cases of coeliac disease in childhood in Liguria. Flow chart to adopt in suspected new cases of coeliac disease in childhood with related responsibility for the different levels of care. Adapted from ESPGHAN Guideline [21]. CD = coeliac disease; DGP = anti deamidated gliadin (ELiA GliadinDP IgG, Phadia AB, Uppsala, Sweden); EGDS = esophagogastroduodenoscopy; EMA = anti endomysium; TTG = anti transglutaminase (ELiA Celikey kit, Phadia AB, Uppsala, Sweden)

The third step defined the roles of the hub and spokes. The PDTC identified two primary centers as responsible for the follow up of non complicated CD, supporting general pediatricians in case of doubts about CD screening and subsequent diagnostic approach, updating local health and social workers on CD. Two secondary centers were also given responsibility for diagnosis and follow-up of CD including the most common clinical complications (transitory low adherence to GFD, type 1 diabetes mellitus and thyroiditis with pediatric endocrinologists). The tertiary center was confirmed as RRC for CD and given responsibility for diagnosis and follow-up of all patients in the province of Genoa, diagnosis and follow-up of all regional patients with potential, seronegative or refractory CD, and all complicated cases referred by primary or secondary centers (i.e. persistent low adherence to GFD or low quality of life, not responding to GFD, poly-autoimmunity) as well as keeping the network, local health and social workers updated on all issues and changes related to CD. The endoscopic organization was left unchanged, but complex cases requiring a second histological evaluation were centralized to RRC for CD. In accordance with ESPGHAN guidelines [21], it was recommended that those “spokes”, which do not have a pediatric gastroenterology service with expertise in CD, share their cases with the RRC for CD before confirming the biopsy sparing diagnosis or referring patients for endoscopic examination. Telemedicine was introduced to

allow consultation between the family and the two centers (hub and spoke).

The fourth step suggested a practical diagnostic approach to various possible scenarios in the new clinical hub and spoke setting. The working group evaluated the adaptation of the content of the ESPGHAN guidelines [21] to the local context to define best professional and managerial practice and design an “ideal pathway”. In particular flow diagrams were designed for patients with clinical suspicion of CD or CD risk group, CD serology positive for incidental findings, discrepant serology in the second diagnostic step, esophagogastroduodenoscopy.

The fifth step was to reorganize the follow up program adapting it to recent national and international guidelines [24, 30–32] (Fig. 4. Flow chart to follow up of coeliac disease in childhood), reducing unnecessary blood tests and introducing routine evaluation of quality of life through a validated questionnaire [33]. A telehealth solution was implemented including regular educational meetings (educational therapy group) on GFD for families of newly diagnosed patients, and monitoring the quality and adherence to GFD.

Despite the involvement of an increased number of medical staff (part time: 1 medical doctor in the RRC and 2 pediatricians in the primary spokes), the overall cost (€50,215.00 per year for the additional salary of a newly hired junior pediatrician) and organizational impact on the centers involved were estimated to remain

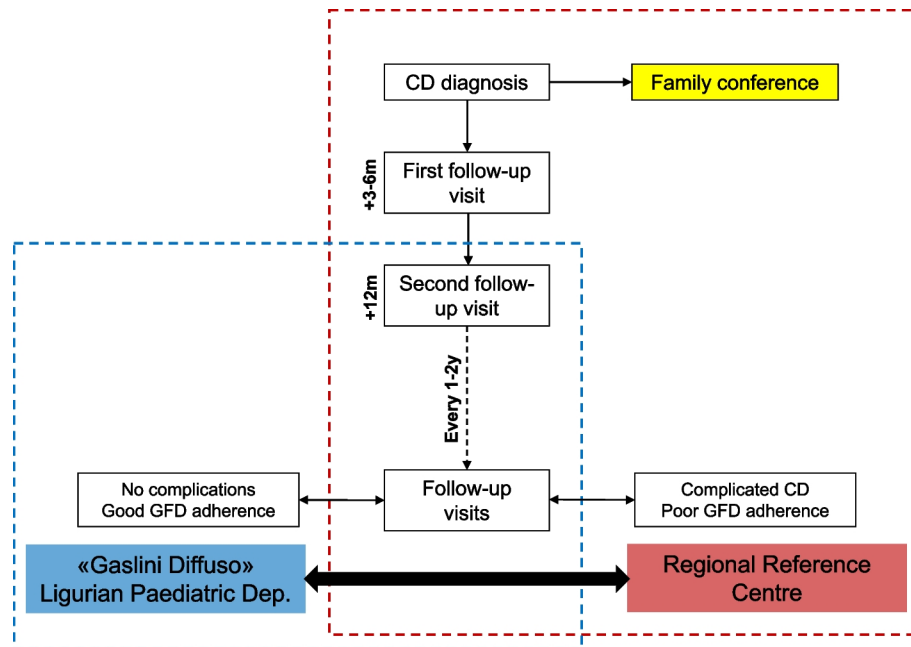


Fig. 4 Algorithm for follow up of coeliac disease in childhood in Liguria. Flow chart to follow up of coeliac disease in childhood. CD = coeliac disease; GFD = gluten free diet

unchanged, this thanks to improvements in the efficiency of the process. These savings include a reduction in the cost of biochemical analysis for diagnosis (in the diagnosis phase, a preliminary analysis established the savings as €636 per patient in the spokes) and follow up, optimization of outpatient visits, implementation of telehealth and more effective utilization of human resources. Overall, the use of telemedicine increased by 35%. This, combined with the improved distribution of patients from other provinces, the number of outpatient visits in the hub was reduced by 33% optimizing human resource utilization. The increase in the overall number of outpatient visits and teleconsultations has led to an increase in higher reimbursements provided to hospitals by the healthcare system.

Operative application

To disseminate information regarding the PDTC a meeting was scheduled in every center involving hospital staff, pediatricians and family doctors. Eighteen months after the initial regional meeting, a national meeting with the presence of experts in CD was held to update all the pediatric specialists involved in the management of CD (pediatric gastroenterologists, family and hospital pediatricians, diabetologists, nutritionists, dieticians, endocrinologists, dermatologists, residents in pediatrics and gastroenterology) on the latest developments in treating and diagnosing CD and gluten disorders. An email newsletter was regularly sent by RCC to all medical staff providing updates and continuous training initiatives on CD.

The pilot phase involved the province furthest (Imperia) from the RCC (Fig. 5. Hub-and-Spokes centers for the management of coeliac disease in Liguria), which had not previously been supported by a CD center. A pediatrician from the primary center was provided with training by the specialists of the RCC, through attendance at the tertiary center, this included endoscopy, theoretical lessons, attendance at the pediatric gastroenterology unit and the CD outpatients department (where diagnosis and follow up of CD are carried out). Moreover, due to the need to transition patients gradually while continuing to train the pediatrician (for a period of at least 18 months) patients visits to the primary center are being conducted jointly with a CD specialist from the RCC. Twenty patients resident in this province and previously followed by the RCC were transitioned to the new center each month. In the first three months only two of the sixty eligible families refused to transfer to the primary center.

The distance traveled by families residing in Imperia has been reduced by approximately 90%, saving €43 and 27.4 kg of CO₂, per family, per trip [34]. Considering that in the first year of diagnosis, on average, families made 4 trips to Genoa (1 for the diagnosis, one immediately after diagnosis for a discussion on diet, 1 for the check-up at 4–6 months and one for the check-up at 12 months) while with the new care system, they make three trips to the local “spoke” center (Imperia) and two teleconsultations. Therefore, in the first year of diagnosis, the savings calculated for each family involved in the pilot project amount to €177 and 113 kg of CO₂.

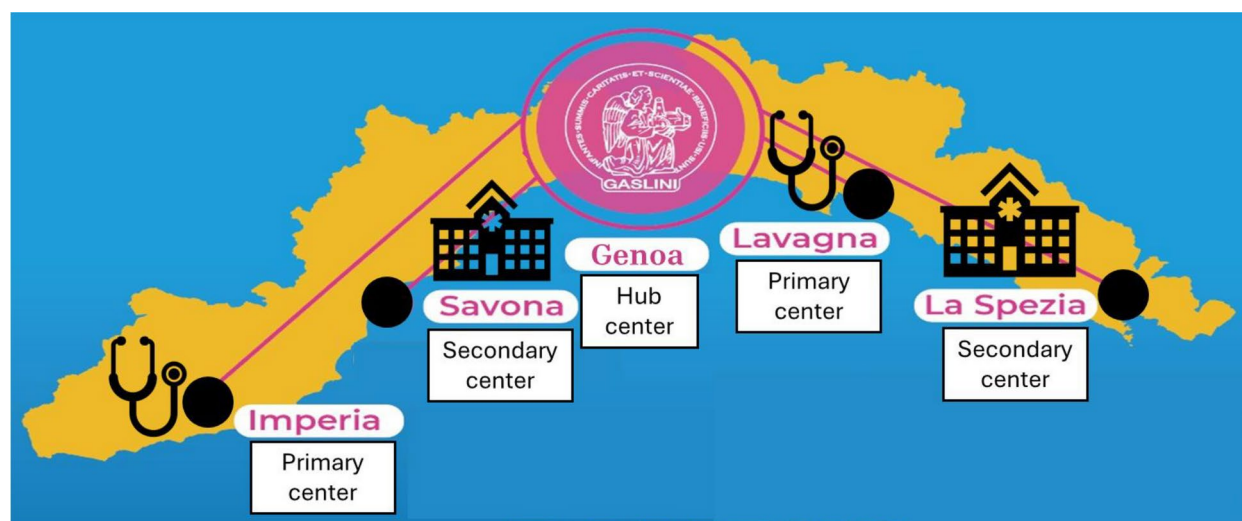


Fig. 5 Hub-and-Spoke centers for the management of coeliac disease in Liguria

Moreover, in the first 3 months of the project some aspects of the plan were being introduced while the pilot phase was in progress, in particular centralization of complex cases. Two patients with potential CD and 2 patients with persistent positivity to TTG IgA testing were referred to RCC from secondary centers. In both potential CD a Marsh Oberhuber type 3 villous atrophy was confirmed after repeating the endoscopic examination. The other two families had low adherence to GFD, in one case due to voluntary gluten ingestion by the patient (adolescent) and, in the other case, related to gluten contamination during meal preparation. In depth follow ups were scheduled to verify compliance with GFD, and support from a psychologist and dietician was proposed.

All spoke centers may refer patients to RCC for a second opinion on histologic samples or to benefit from the new advanced techniques based on a double immunohistochemistry for the determination of intestinal anti-transglutaminase antibodies (TTG) IgA deposits on formalin-fixed paraffin-embedded biopsies that could help eliminate doubts regarding diagnosis in case of the unavailability of frozen tissue [35].

In part thanks to improving telehealth assistance, new services (i.e. dietician support) previously only available in the tertiary center were extended to all patients. Informational interviews with newly diagnosed patients and their families regarding CD and dietary therapy with a pediatric gastroenterologist and dietician are now available via group videoconference. Moreover, support group meetings are scheduled monthly, they include patient association members, caregivers (families, teachers, babysitters, etc.), patients with a new diagnosis of CD and any patients in follow-up who request to participate. In the first two support group meetings 35 of the 40

families invited agreed to participate. Ten televisits were scheduled, most of them in suspected cases to explain the diagnostic approach (i.e. the need for endoscopic examination or the possibility to adopt a biopsy sparing approach) or to clarify doubts regarding GFD, in a small number of cases they were used to share blood test results with patients.

Discussion

The implementation of the Gaslini Diffuso hub-and-spoke system, known as "Gaslini Diffuso", to manage pediatric CD in Liguria reflects a forward-thinking approach to address the complexities of modern health systems. To the best of our knowledge, this is the first description of a hub and spoke system managing CD in pediatric patients. The project was facilitated by a previous regional political decision to unify the management of the pediatric departments of the Liguria region. This political choice currently represents a unique situation in Italy and aiming to address the challenges of the Italian healthcare system (i.e. fragmented healthcare system, disparate data infrastructure, and poor interoperability between different regions and hospitals) [36].

The new healthcare model represents an evolution of co-management-centered models, which targeted and structured complex care interventions. It aims to streamline and enhance the care and support provided to patients with chronic diseases, such as CD [37, 38]. It substitutes the previous organization characterized by differing diagnostic and follow up approaches with an efficient, effective, and homogeneous approach designed to better exploit the advanced technology and expertise at the hub (Gaslini Institute—Genova), while at the same time ensuring that basic services are distributed geographically through primary and secondary centers. The

introduction of telehealth services, including telemedicine, educational sessions and support group meetings, has enhanced patient and caregiver engagement while optimizing resource utilization.

In examining this initiative, it is crucial to draw parallels with other successful hub-and-spoke models to better appreciate the potential benefits and challenges. One notable example of a successful hub-and-spoke system is that used in emergency health [39–41]. For example, the Cleveland Clinic's Heart and Vascular Institute centralizes advanced cardiac care and surgery at the main campus (the hub) while establishing spokes in surrounding communities for routine cardiovascular services and patient follow-up [42, 43]. Similarly, Gaslini Diffuso centralizes specialized services at the Giannina Gaslini Institute in Genoa while guaranteeing appropriate levels of expertise in the spokes, thereby improving patient outcomes by ensuring a seamless continuum of care between hub and spokes.

A pilot phase in a primary center (Imperia) allowed the evaluation of the new system identifying potential areas for improvement. Preliminary data confirmed that this model is replicable in other healthcare systems, also for chronic diseases. The results indicate a high acceptance rate for the new system, which is significantly less expensive both economically and in terms of time for family and healthcare system, whilst also reducing environmental pollution.

The success of such a project is dependent on a careful preparation phase involving a comprehensive analysis of the available human (interested in being involved in the project) and technological resources, a needs analysis to identify areas of possible improvement and a strategy to adopt a uniform clinical approach, reorganizing all the elements of the system and reducing costs where possible. A critical aspect shared by these hub-and-spoke models is the emphasis on standardized protocols [44], these facilitate consistent care delivery, reduce variations among different centers and contribute to improved patient outcomes. In the Gaslini Diffuso initiative, the development of the PDTC in collaboration with the involved stakeholders, served as a guide to align diagnosis and management of pediatric CD, addressing discrepancies in the management and diagnosis procedures observed during the needs analysis. Sharing knowledge from the hub across the network ensures a homogeneous assistance in all the spokes over time. Centralizing to the hub the complex medical services facilitates maintaining high levels of human skills and technology. The hub-and-spoke system, therefore, represents a more efficient organization ensuring improved assistance and reducing cost of care compared to a system replicating operations across multiple sites [15, 45].

The hub-and-spoke model also enhances an institution's ability to adapt as needs evolve. It is highly scalable since the design facilitates expansion initiatives with spokes that may be "added" if the volume of demand becomes excessive for the existing spokes [39, 46]. Conversely, in situations where the particular needs served by individual spokes decline, resources can be reduced. Those resources can then be redirected to other elements of the network or, perhaps, used to introduce new spokes in areas with growing need. The central hub also functions as primary repository for system-wide data, facilitating seamless access to both historical and real-time data on patient volume and flow, serving as an invaluable resource for strategic planning. Proactive planning reduces waiting time for patients and the risk of congestion of a spoke. The cost and organizational impact assessment indicates potential benefits in terms of efficiency, reduced costs for biochemical analysis, and improved utilization of human resources. However, the lack of independent cost assessments may have biased our results.

Despite the significant advantages of our hub-and-spoke model, there are inherent risks linked to the system which need to be carefully managed. The rapid referral of appropriate patients to the hub center should be a focus of attention to ensure that a potential reluctance of healthcare personnel to delegate clinical activities reduces the systems efficiency. Similarly, the transfer of patients who can be adequately managed by the spokes should take place as expeditiously as the family's agreement allows. There is also a risk of spoke "overextension" due to a large number of satellites causing excessive distance between hub and spoke thereby reducing the benefits of the system, this problem may be only partially overcome by telehealth. Due to the particular geography of Liguria, characterized by limited transport infrastructure and isolated mountain communities, transportation disruption could be critical to guaranteeing an efficient continuum of care and transfer to hub where necessary. Higher volume of bureaucratic and organizational work at the hub may also generate the risk of reducing the quality of care in more complex cases. This issue remains unresolved due to the insufficient availability of qualified professional personnel. Some bureaucratic processes have been automated to reduce dependency on human resources, such as the implementation of electronic diaries equipped with barcode recognition devices. However, low engagement and the routine nature of tasks at the spokes may contribute to staff dissatisfaction. This risk materialized one year after the project's inception, when one of the two pediatricians at a primary center in Imperia expressed a desire to withdraw from the project due to personal reasons. The training of additional pediatricians ensured that the center's operations continued

without disruption. Staff participating in the project received financial incentives, with their contributions acknowledged through higher performance-related salary scores.

The hierarchical organization necessary to guarantee uniformity of care associated with the hub and spoke system might result in the impression of the lack of autonomy. These “limitations” of the activities for the healthcare personnel employed in the spokes may reduce the desire to work in these centers. Political decisions are required to strike a balance between the need of institutions for operational efficiency and the priorities of local politics or patients to have services available in peripheral areas. Apart from establishing effective communication across all facilities in the hub-and-spoke network, mitigating the risk of staff dissatisfaction requires ensuring suitably skilled administrators manage the satellite facilities. This implies promoting a positive culture within the involved institutions and effectively transmitting it throughout the network. Staff across the system should periodically rotate between hub and spokes for a constructive exchange of knowledge and to promote cohesion and collaboration between the various actors in the network. Collaboration in scientific research work and economic rewards linked to the improved productivity of the system (also considering the aforementioned disadvantages of the system) could help guarantee a positive and collaborative staff.

In our system the integration of telemedicine was one of the key points contributing to the success of the project, being used for patient assistance, education and support group meetings. It is also an important contributing factor to containing costs and improving health outcomes, enhancing organizational productivity and allowing assistance to rural and remote areas. Patients can easily obtain online clinical assistance eliminating geographical barriers. A full standardized electronic medical chart shared between the centers plays a pivotal role in this integration, enabling efficient communication and information exchange. The expansion of telemedicine services to both in- and out-patients helps reduce transfers and permits patients to remain in their local communities, as also demonstrated in other diseases [47, 48]. The support group meetings empower patients to play an active role in their healthcare [49, 50]. Telemedicine is a time and cost saving tool, specialists can assist more patients using telehealth, reduce the time and cost of patient education programs [51, 52] and also provide ongoing education for all the network staff. Telemedicine also reduces healthcare costs and impact for the families involved reducing travel, loss of income due to absences from work and minimizing impact on children's education [53]. Finally, integration of telehealth helps in reducing environment pollution [54, 55].

The use of telemedicine experienced significant growth during the SARS-CoV-2 pandemic period and seems to be able to solve many problems linked to traditional healthcare systems [56]. In the near future, telemedicine may contribute to improving healthcare systems, through innovative patient focused care models. However, some disadvantages of telehealth need to be considered [57]. One of the limits is the absence of a complete physical examination to support diagnosis and treatment. Furthermore, although there is a lack of evidence in this field [58], certain critics of telehealth have expressed concern about its potential negative impact on continuity of care. They argue that online interactions lack the “personal touch” and can involve greater risk since virtual providers may not have access to crucial contextual information. Technical difficulties may also be encountered by physicians and patients, including a lack of technological proficiency (particularly among older adults) and inadequate internet bandwidth in rural or under served regions. Providers must be vigilant about understanding such risks and the potential liability and legal implications including informed consent, practice standards and protocols, supervision requirements for non-physician providers. Furthermore, inconsistent and varying regulations regarding privacy and regulatory standards could represent a bureaucratic burden that impacts clinical activity and constitutes a barrier. Another potential barrier to effective telehealth practice is the safety of data transmission and storage by the telehealth systems which depends, in part, on providers' and patients' attitudes towards digital security.

Surveillance of outcomes will be conducted over a minimum of three years in both the hub and spokes by monitoring the registry of new diagnoses, waiting list numbers and times for visits (including televisits), quality of life assessments, and adherence to the gluten-free diet over time. A significant proportion of healthcare providers in our sample may have led to a predominance of clinicians' perspectives in our findings. The project did not incorporate the perspectives of family members and older patients in the design and implementation of the new healthcare system. These aspects will be explored in future research, which will evaluate the project's outcomes, with model revisions scheduled at least every three years. Increased collaboration with key stakeholders (patients, families, and policymakers) will be essential to address emerging gaps in care and establish best clinical practices that ensure the delivery of high-value care for children with CD.

Conclusions

The Gaslini Diffuso hub-and-spoke system supported by telehealth for managing CD in Liguria exemplifies a commitment to enhancing healthcare efficiency and patient

care while limiting cost and reducing environmental pollution. Our hub-and-spoke organization design is highly adaptable, practically any regional health system, regardless of its size or mission, could replicate it to achieve its many benefits. However, challenges remain, and the success of such systems hinges on ongoing evaluation and adaptation, in particular great attention must be paid to aligning processes and information standards, while also paying close attention to the limits and risks of telehealth, and to maintaining staff operational cooperation levels and morale high. The ongoing success of the Gaslini Dif-fuso organization, or any equivalent system, depends on continued collaboration, innovation, and a patient-cen-tric focus which is essential for its long-term success.

Future research should focus on the long-term out-comes of the hub-and-spoke model in various regions and healthcare settings. Comparative studies could explore the model's efficacy in managing other chronic diseases, assessing patient satisfaction, adherence to treatment, and overall health outcomes including various dimensions of quality of care (i.e., safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity). Additionally, further investigation into the cost-effec-tiveness and scalability of telehealth-supported models in different demographic and geographic contexts would provide valuable insights for broader implementation.

Abbreviations

TTG	Anti-transglutaminase antibodies
CD	Coeliac disease
PDTC	Diagnostic and therapeutic care pathway
ESsCD	European Society for the Study of Coeliac Disease
ESPGHAN guideline	European Society Paediatric Gastroenterology, Hepatology and Nutrition
GFD	Gluten free diet
HLA	Human leukocyte antigen
RRC	Regional Reference Center

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12913-025-12459-5>.

Supplementary Material 1.

Acknowledgements

The authors thank the Associazione Italiana Celiachia Liguria APS for their cooperation with this study.

Authors' contributions

Conceptualization and methodology M.C., F.M.; project administration and execution M.F.C., M.B., M.L., S.C., A.I.G., A.N.G., R.B., A.G.L.C., M.P.I. validation, P.G., M.A.; writing—original draft preparation, M.C., F.M., N.Z., S.S., R.S., G.S., R.B.; supervision, P.G. and M.A.; funding acquisition, P.G. All authors have read and agreed to the published version of the manuscript.

Funding

This research received no external funding.

Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The protocol was approved by the Regional Ethics Committee (Liguria: 133/2024—DB id 13773, 29/04/2024). Informed consent to participate was obtained from all of the participants/parents in the study.

Consent for publication

Written informed consent for publication of the patient's clinical details was obtained from the patients/parents.

Competing interests

The authors declare no competing interests.

Author details

¹Pediatric Gastroenterology and Endoscopy Unit, IRCCS Istituto Giannina Gaslini, Genoa 16147, Italy

²Department of Neuroscience, Rehabilitation, Ophthalmology, Genetics, Maternal and Child Health (DINO GMI), University of Genova, Genoa, Italy

³UOC Pediatria e Neonatologia La Spezia, IRCCS Istituto Giannina Gaslini, La Spezia 19121, Italy

⁴UOC Pediatria e Neonatologia Lavagna, IRCCS Istituto Giannina Gaslini, Lavagna 16033, Italy

⁵UOC Pediatria e Neonatologia Savona, IRCCS Istituto Giannina Gaslini, Savona 17100, Italy

⁶UOC Pediatria e Neonatologia Imperia, IRCCS Istituto Giannina Gaslini, Imperia 18100, Italy

⁷UOSD Centro Nutrizionale, IRCCS Istituto Giannina Gaslini, Genoa 16147, Italy

⁸UOC Direzione Delle Professioni Sanitarie, IRCCS Istituto Giannina Gaslini, Genoa 16147, Italy

⁹UOC Governo Clinico, Direzione Sanitaria, IRCCS Gaslini, Genoa 16147, Italy

¹⁰UOC Direzione Sanitaria, IRCCS Istituto Giannina Gaslini, Genoa 16147, Italy

¹¹UOC Direzione Generale, IRCCS Istituto Giannina Gaslini, Genoa 16147, Italy

Received: 28 July 2024 / Accepted: 19 February 2025

Published online: 18 March 2025

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