

ACTIVITY A.T3.2 IMPLEMENTATION OF PILOT PROJECT

Deliverable D.T3.2.12 Report about pilot project
implementation





1. RESULTS ACHIEVED ACCORDINGLY TO OBJECTIVES

Description of deliverable

Report will include description of the pilot design and its development, together with the information about the testing of the pilot in real environment.

This work package (**WP3**) named “**Pilot development and testing**”, was aimed to implement and improve health care and social models for subjects with celiac disease in terms of innovative clinical diagnostic practices during clinical medical activities, better mentoring service for celiac patients in the long run of the gluten-free diet therapy, simplify procedures for screening programs in pediatric age.

Definition of all pilot actions and regional pilot stakeholder groups and was done during the first phase of the project (A.3.1 Identification of pilot services and creation of pilot stakeholders' groups).

The pilot actions are summarized in table1

D.T3.2.2 Mentoring service for newly diagnosed patients (LP MOM)

D.T3.2.3 Simulator testing to improve endoscopist practice in field of CD (PP2 UKC MB)

D.T3.2.4 Improvement of early diagnostics, testing method 'IgA t-Tg deposits in tissue sample' (PP2 UKC MB)

D.T3.2.5 Improvement of diagnostics, with testing 3 methods to improve CD practice (PP4 KBC Rijeka)

D.T3.2.6 Detecting and managing CD patient within a 'cohort of super allergic population' (PP5 Units)

D.T3.2.7 Testing for celiac disease antibodies in school children (PP6-UOCPGŽ Rijeka).

D.T3.2.8 Improvement of diagnostic of atypical CD patients (PP7 BURLO).

D.T3.2.9 Implementation and testing of new service to improve transition from paediatric to adult health care (PP8 KUM)

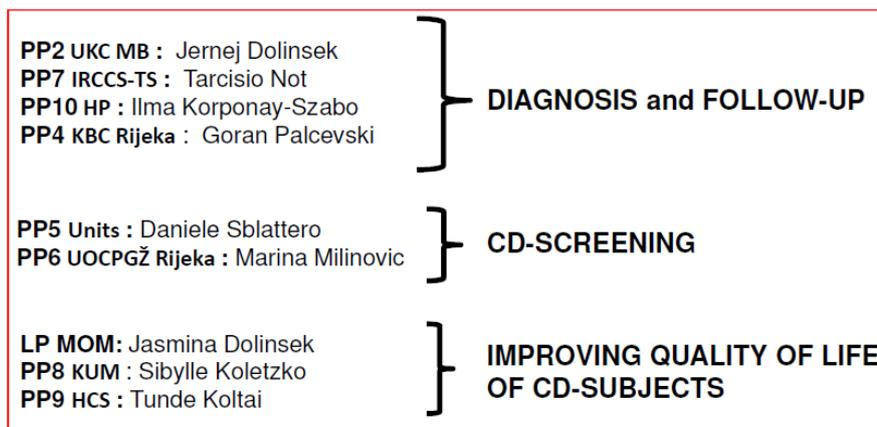
D.T3.2.10 "Evaluation and follow up of family members" (PP10 HP).

D.T3.2.11 Testing of real life environment use of gluten free-offer in restaurants (PP9 HCS).

Tab.1 *List of pilot projects developed during this work package*

After the definitions of Pilots the **Activity A.3.2 Development and testing of pilots** cover the operative part of the project and was done from **February 2018 to April 2019**

In order to be more productive, better coordinate the partners' work and encourage interactions between them pilots were grouped into three homogeneous themes (Tab.2).



Tab.2 The three main themes in which the pilot projects have been divided.

A summary of the main results for each of the pilot is reported here. All details can be found in individual pilot report from D.T3.2.2 to D.T3.2.11

A. Diagnosis and Follow-up.

D.T3.2.4 Improvement of early diagnostics, testing method 'IgA t-Tg deposits in tissue samples

D.T3.2.8 Improvement of diagnostic of atypical CD patients

In this theme a new immunological methodology on intestinal biopsy was applied on a large scale to identify anti-intestinal transglutaminase antibodies in atypical cases of celiac disease characterized by a normal intestinal mucosa and with low pathological concentrations or even absence of typical serum CD auto-antibodies. The use of this immunological assay allowed us to identify and diagnose as CD-patient individuals that would not have been diagnosed with celiac disease with the current diagnostic criteria. The PP2 and PP7 partners shared 100 subjects and diagnosed 20 subjects with atypical celiac disease. Furthermore, a close collaboration was implemented between the two partners to spread this immunological technique to other Italian and Slovenian pediatric gastroenterology units. The stable presence of stakeholder medical (pediatricians and adult gastroenterologists) groups on this specific field will allow the continuity of the knowledge acquired during several scientific meetings. Of interest, the results obtained during the project were published (*Gastrointest.Endosc.*2018;88:521) or presented at international meetings (ESPGHAN meetings 2018, 2019).

D.T3.2.5 Improvement of diagnostics, with testing 3 methods to improve CD practice

To simplify and make the diagnosis of celiac disease less invasive, the partner PP4 developed a series of fecal analyzes to identify the best marker capable of identifying subjects with CD. These



analyses did not allow to identify one or more markers capable of identifying subjects with CD, however also in this study several Croatian working groups were involved, and the general knowledge of this disease was improved.

D.T3.2.10 "Evaluation and follow up of family members"

Of extreme clinical utility in daily clinical practice was the study coordinated by the partner PP10 in collaboration with partners PP2 and PP8 to identify the time window in which children at CD-risk (i.e. family members of CD-patients) develop celiac autoimmunity to diagnose CD early. The results obtained on a large number of subjects (1007 children) have shown that the time window in which these children develop the CD-autoimmunity is between 3 and 9 years. This information (which will be presented at ESPGHAN meeting 2019) is important to maintain high attention in performing CD-serological screening in this time period so as to avoid diagnostic delay. This observation together with the previous ones can be included in CD diagnostic and follow-up guidelines for improving the medical care of this condition.

D.T3.2.3 Simulator testing to improve endoscopist practice in field of CD

Finally, to consolidate this work group to improve the CD diagnosis, a course in digestive endoscopy was developed and implemented using a simulator that was first used within the partner PP2 and also at the partner PP5. This training activity will be regularly updated with new knowledge in the field of gastrointestinal endoscopy at the department of pediatrics of the University Medical Center Maribor.

B. CD-screening.

In this theme two pilot actions have been carried out: the aim was to promote mass screening in countries where the CD prevalence is unknown and a second one was to prove that subjects with severe food allergy are a group at CD risk and that they could take advantage of screening.

D.T3.2.7 Testing for celiac disease antibodies in school children

In the first case a screening was organized among elementary school children and proceeded to screening by means of a rapid blood drop test to measure anti-transglutaminase antibodies. No positive subjects have been found and no new cases of celiac disease have been diagnosed in this cohort of subjects. However, the project has made it possible to raise awareness about this disease for many parents and health authorities on this condition.

D.T3.2.6 Detecting and managing CD patient within a 'cohort of super allergic population'

In the second pilot case, it was have confirmed that a specific population of patients (super allergic) have a higher risk of CD (9/120, 7.5%) in comparison to the general population (1%)(this new data will be presented at ESPGHAN meeting 2019). This will lead, by the help of HCPs and

stakeholders, to share new CD-diagnostic guidelines. The availability of guidelines acquired by the pilot clinical and diagnostic experience will allow to diffuse the knowledge and the application of the screening procedure for CD diagnosis by other working groups so to become a hopefully standard diffuse procedure.

C. Improving quality of life of CD-subjects.

In this theme three pilot actions have been carried out:

helping the transition of CD-patients from adolescence to adulthood care system; mentoring service for newly CD-diagnosed patients to improve management of their health and at the same time provide opportunities for patients to help others facing similar challenges; improving the knowledge of the CD diagnosis and treatment procedures in real life environment, and the legal rules and regulation for gluten-free food in general and especially in the catering.

D.T3.2.9 Implementation and testing of new service to improve transition from paediatric to adult health care (PP8 KUM)

Generally, the transition from pediatric to adult care should be a collaborative process involving patients, their parents or caregivers, general physician and the dietician. Of interest, the celiac passport was prepared and proposed (Fig.1) to record all the clinical and laboratory evaluations from the diagnosis and during the follow-up by the patient and the family physician. This document, created in collaboration with the German celiac association, will be a tool that can guarantee continuity of health-care even during the transition phase from the pediatrician to the general physician or adult gastroenterologist, who will have the opportunity to verify and discuss with the patient what has been done up to now.

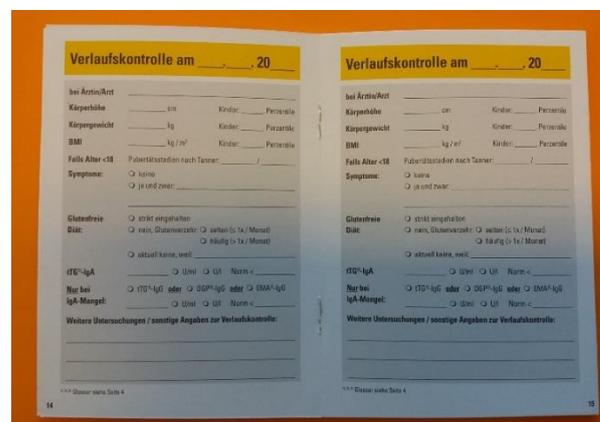


Fig.1 Example of a celiac passport, on which to record the patient's clinical and laboratory information. This document will describe how the diagnosis was made and what symptoms the patient suffered before the diagnosis. The clinical effects of the gluten-free diet and the compliance to the diet will be reported.



In the context of a teenager who is facing the transition from pediatric to adult care, work-shops have been proposed to improve their independence from their parents for better managing the daily gluten-free-diet. To do this, a practical path was organized to facilitate the preparation of original gluten-free dishes, and with the support and involvement of the German, Slovenian and Hungarian celiac societies. In general, this path has received great interest from the teenagers who participated to these workshops and social events.

D.T3.2.11 Testing of real-life environment use of gluten free-offer in restaurants (PP9 HCS).

Of interest, it was the activity to make the food outside the home safe for celiacs by promoting contact with restaurateurs and producing cooking manuals for celiacs. This activity allowed to organize groups of volunteers able to continue this important dissemination activity even after the conclusion of the present project.

D.T3.2.2 Mentoring service for newly diagnosed patients (LP MOM)

In this actions new celiac disease service puts the patient in the center, gives him support, helps him to better cope with the disease in the first year, to better manage their condition, to gain knowledge and skills, to reduce problems, risks, diet compliance, psychological disorders, complication. Furthermore, improvement of CD society service - standardised education protocol offers CD society a tool to improve their services. The final aim was a better quality of life of chronic celiac disease patients