

D.T3.2.7

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

Version 1
5/2019





INTRODUCTION/ D.T3.2.7 - Testin of CD antibodies in school children

The Celiac disease society from Rijeka had a task through work package 3, conduct a pilot project activity- Testing school children on celiac disease. We worked closely with PP4 - Pediatric Clinic of KBC Rijeka related to public procurement of rapid tests for celiac disease, lectures for school principals, teachers and pupil's parents. PP12- Primorje Gorski Kotar County provided support in informing and dissemination activities.

The main objectives of the testing were early detection of celiac disease, prevention of its complications and potentially introducing new celiac disease management with quick test (through primary care).

We did not detect any cases of celiac disease, although we have confirmed 10 IgA deficiencies that may indicate the development of celiac disease in genetically predisposed individuals.

Regardless of this result, we should continue to think about the effectiveness of a quick test and carry out further researches.

We can also conclude that this is a simple method of testing (capillary blood), inexpensively (price of 1 test for a larger amount may be lower than 5 euros), with quick performing (result is obtained through 10 min).

Celiac disease is one of the most common gastroenterological diseases of the present, which still requires long time to be discovered (especially in adults) and patients are a major burden to the health system (with late CD and many other chronic conditions requiring continuous care and treatment). So, we definitely need to be proactive in searching Celiac disease, and one of opportunity still could be rapid test.

It is also one of the conclusion which all partners accepted as a part of Central Europe policy recommendation we recently prepared through Focus IN CD project.



DELIVERABLE D.T3.1.1 REPORT ABOUT PILOT PROJECT IDEAS & ESTABLISHED STAKEHOLDER GROUPS

	Version
Pilot project Start-up description template:	1
TESTING FOR CELIAC DISEASE ANTIBODIES IN SCHOOL CHILDREN	02 2017



1. Pilot Background

Please describe here the background of your pilot in terms of ideas, preliminary actions, plans defined earlier and methods already chosen, etc. Some of the aspects you can tell about are as follows:

- How did the project idea surface?

Celiac disease IS NOT A RARE DISEASE, it is a **complex disorder strongly associated with HLA DQ2 or DQ8 haplotypes (genes) and specific immunological and environmental factors.**

In Europe, the lowest prevalence of celiac disease was recorded in Denmark (0.10: 1000) and the highest in Sweden (3.5: 1000), while in Italy it was recognized as a social illness with a prevalence of 1.5: 100. Celiac disease is a genetically predisposed disease, and in the last decade, the number of patients has increased rapidly. Since its chameleon clinical picture is known, celiac disease can be hidden behind many other autoimmune diseases (**type-1 diabetes mellitus, thyroid diseases, IgA deficiency, Down's syndrome, Turner syndrome, Williams syndrome...**).

Celiac may not be expressed through intestinal symptomatic primary. People could have different disorders: haematological and bleeding disorders, Liver, spleen and pancreatic disorders, Cardiovascular disorders, Neurological problems and others. Therefore, it is necessary to actively seek out among adults and children. With this pilot we want:

Main goals:

1. early detection of celiac disease/ testing of pre-school children on celiac disease (aged: 6-7)
2. detection of potential sufferers and prevent complications of celiac disease

Secondary goals :

1. record the prevalence of celiac disease (given that there is no Registry of patients in our country)
2. possible guidelines for a new management approach to disease detection for a health care professionals

- Are there preliminary works that the project is based on? What are they?
- There are some preliminary works:
- 0) explore of supplier market
- 1) making a public call for procurement of professional rapid tests for celiac disease (blood drop tests)
- 2) Requesting permission from ethical commissions of all competent authorities (University Hospital Center Rijeka, Primorje Gorski Kotar County, Regional Public Health Institution) and school boards.



- 3) Requesting written consent for parents
 - 4) communication with schools (Headmasters), school boards and parents' councils: presenting the entire project, presenting the pilot project and its activities, benefits or communication with Health Care Institution will be enough in order to pass on further information to general practitioners (systematic examinations of pre-school children) ...
 - 5) communication with the media in order to promote the project / media activities
 - What is the knowledge base behind the project (studies, methods, statistical data etc.)?
1. **Conceição-Machado ME, Santana ML, Silva Rde C, Silva LR, Pinto EJ, Couto RD, Moraes LT, Assis AM. Serologic screening of celiac disease in adolescents. Rev Bras Epidemiol. 2015;18(1):149-56. doi: 10.1590/1980-5497201500010012. Epub 2015 Mar 1.**
 2. **Kårhus LL1, Thuesen BH, Rumessen JJ, Linneberg A. Symptoms and biomarkers associated with celiac disease: evaluation of a population-based screening program in adults. Eur J Gastroenterol Hepatol. 2016 ;28(11):1298-304. doi: 10.1097/MEG.0000000000000709.**
 3. **Leonard MM1, Fogle R2, Asch A2, Katz A2. Screening for Celiac Disease in a Pediatric Primary Care Setting. Clin Pediatr (Phila). 2016;55(3):214-8. doi: 10.1177/0009922815593879. Epub 2015 Jul 6.**
 4. **Horwitz A1, Skaaby T, Kårhus LL, Schwarz P, Jørgensen T, Rumessen JJ, Linneberg A. Screening for celiac disease in Danish adults. Scand J Gastroenterol. 2015;50(7):824-31. doi: 10.3109/00365521.2015.1010571. Epub 2015 Feb 17.**
 5. **Rosén A, Sandström O, Carlsson A, Högberg L, Olén O, Stenlund H, Ivarsson A. Usefulness of symptoms to screen for celiac disease. Pediatrics. 2014;133(2):211-8. doi: 10.1542/peds.2012-3765. Epub 2014 Jan 13.**
 6. **Alessandrini S, Giacomoni E1, Muccioli F. Mass population screening for celiac disease in children: the experience in Republic of San Marino from 1993 to 2009. Ital J Pediatr. 2013;39:67. doi: 10.1186/1824-7288-39-67.**
 7. **Sandström O1, Rosén A, Lagerqvist C, Carlsson A, Hernell O, Högberg L, Ivarsson A. Transglutaminase IgA antibodies in a celiac disease mass screening and the role of HLA-DQ genotyping and endomysial antibodies in sequential testing. J Pediatr Gastroenterol Nutr. 2013;57(4):472-6. doi: 10.1097/MPG.0b013e31829ef65d.**
 8. **Almazán MV, Ortega E, Moreno Torres R, Tovar M, Romero J, López-Casado MÁ, Jáimez L, Jiménez-Jáimez J, Ballesteros A, Caballero-Villarraso J, Maldonado J. Diagnostic screening for subclinical celiac disease using a rapid test in children aged 2-4. Pediatr Res. 2015;78(3):280-5. doi: 10.1038/pr.2015.98. Epub 2015 May 21.**
 9. **Hariz MB, Laadhar L, Kallel-Sellami M, Siala N, Bouraoui S, Bouziri S, Borgi A, Karouia F, Maherzi A, Makni S. Celiac disease in Tunisian children: a second screening study using a "new generation" rapid test. Immunol Invest. 2013;42(4):356-68. doi: 10.3109/08820139.2013.770012.**

We can say that a similar pilot did not take place in our country, especially when we are talking about screening of children's (pre)school population. Our country does not have a Patient registry -adults and children with celiac disease. When we talk about celiac patients then we use European and world statistics about the prevalence of celiac disease.



- What methods will you / do you plan to use (to motivate stakeholders, to involve lead users, to develop ICT infrastructure, to communicate online etc.)?

First contact will be made with the Public Health Care Institution to exchange all information about Pilot. Then we will provide:

- meeting with school Head masters
- project and pilot presentation for school boards
- project and pilot presentation for parent councils
- project and pilot presentation for the children

... and about celiac disease and special gluten free needs, its frequency among the general population, complications of disease, about the consequences of untreated celiac disease and its late detection.

Presentations will be provided by PP6 (About society, what is celiac disease/gluten dangerous, why is important early detection, everyday life with CD, what is our special need, expectation from the system, peers, friends, teachers, families...), PP4 (what is CD, why CD can be so dangerous, where can we find it and why are we looking for...), PP12 (programme presentation- Interreg CE, importance of including in this Pilot project, dissemination, help with the adoption of new contributions which will be made through this Pilot project, which should ensure a more balanced and efficient care of celiac disease patient- recommendation). We should also prepare short communication with psychologist (if will be needed) - communication focus on society without violence and discrimination, tolerance of diversity, provision of peer support, volunteering - empathy development.

At least, ethical commissions that should approve the project implementation and recommendations of public health institutions should certainly have a positive influence on parents' decisions to allow their children to participate in the project.





2. Pilot Objectives

Please describe here the objectives of your pilot in terms of what the pilot project plans to achieve at the project's end and by what means. Some of the aspects you can tell about are as follows:

- What are the main outputs of the pilot project (service, process, new management approach, new knowledge...)
 - **newly discovered patients**
 - **the frequency of illness**
 - **new management approach-recommendation** (maybe the number of discovered patients will point out the need for a new approach to detecting celiac disease: screening of the general population - children -in regular primary care at the preschool check up).

- What kind of problems are you anticipating and what are your "plan B"-s if something doesn't turn out as you counted in certain situations?
 - **schools may not want to express interest for participating in the project**
 - **parents may not want to expose their children to testing for celiac disease**
 - **children may not want to be tested**

- To avoid this, we have decided to carry out educational-info workshops about celiac disease, complications of illness, consequences of untreated celiac disease.
- Raising awareness of the disease and highlighting important facts about the illness should ensure a positive response and parents' decision to participate in the project.
- Presentation of a non-invasive test for celiac disease - a blood drop - should also help with the parents' consent.
- Prevention, early disease detection, non-invasive method, support of medical pilots, support of CD patients-suffers- to raise awareness of health protection and prevent potential complications-are the main facts we will negotiate for participation.

It is very important to choose the right approach for children to explain why they will be included into this testing. So we will consult with a psychologist (presentation mode) or invite a psychologist to participate in the explanation. In that context, we will talk with hospital psychologist or a psychologist from school which will be involved in the project.



Will the pilot have cross-regional impacts? Which are they?

- Pilot activities and achievements will be transferred to other regions and countries through our participation at transnational events
- Pilot activities and achievements will be transferred to our regional friendship CD societies in Slovenia, Serbia and Bosnia after the end of the project as well as in all partner countries
- Public Health Care Institution and Children Hospital from our capital city- Zagreb, this year will also organized testing for 2000 preschool children on celiac disease, so we are going to exchange all information about. That means that together we will have representative sample of 3 500 preschool children.

Any other aspects you find important ?

- It is important to emphasize that if we discover child (who potentially suffered from celiac disease), has multiple benefits cause we will continue with actively searching celiac disease in his/her family. This is certainly way of active searching for celiac disease, since we know about its genetic predisposition and its high prevalence rate. We must keep on mind relation between celiac disease and associated illnesses and start to think about people health also about the health system costs.
- **The Association-PP6 is Pilot coordinator for CRO partners - pilot activities will also be provide by PP4 and PP12 (medical work, dissemination). We will test about 1500 pre/school children. We also agreed that the sample of children would be between 6 and 7 years old.**
- We should prepare educational CD workshops for school workers and children (if will be needed). We should also share a booklet about celiac disease (facts, information about CD - "Thousand faces of celiac disease") which we had prepared in our previous project in cooperation with specialists from University Hospital Centre Rijeka.**



Focus IN CD

3. Partnership

Please describe your stakeholders and their roles in the pilot project. Insert rows according to your needs.

Name	Specialization Area	Role in Project	Motivation / Benefits
<i>If you plan to include a certain type of stakeholder but you don't</i>	<i>Healthcare professional/ patient/presentative of NGO/policy</i>	<i>Participating in development phase/participating in testing,</i>	<i>What is the main motivation of the organization to participate in</i>



<i>yet know the specific organization, write "[TBD]" (to be determined) in this column.</i>	<i>maker...</i>	<i>communication, evaluation etc.</i>	<i>the pilot project? What will be their anticipated benefits?</i>
<p><i>University Hospital Center Rijeka: doctors, laboratory workers, psychologist</i></p>	<p><i>Health care professionals</i></p>	<p><i>Participating in testing and evaluation, communication</i></p>	<p>Motivation: active searching for celiac disease</p> <p>Benefits: early detection of the disease , preventing complications of the CD, data base</p>
<p><i>Primary schools- TBD</i></p>	<p><i>Educational institutions</i></p>	<p><i>Participating in testing</i></p>	<p>Motivation: care about children health- only a healthy child is a child capable of learning and fulfilling his daily tasks, support for medical pilot research, support celiac patients and raise awareness of celiac disease</p> <p>Benefits: detection of possible health problems, prevention of illness complications</p>
<p><i>CD Society</i></p>	<p><i>NGO</i></p>	<p><i>Implementation, communication, testing and evaluation, dissemination</i></p>	<p>Motivation: to point that celiac disease is not a rare disease in the general population, possible new approach to detecting celiac disease: screening of children in regular medical examination at the time of enrollment in the first grade of primary school</p>



			<p>Benefits: Early detection of the disease diminishes its complications and raises the quality of life, the basis for further work and projects that will upgrade this database, raise awareness, new celiac disease management approach in the health care system</p>
<p>Primorje Gorski Kotar County-Administrative Department for Education/ Department of Health ; The City of Rijeka-the same departments</p>	<p><i>Local/regional public authority</i></p>	<p><i>Communication, approving the pilot project to be implemented in a particular school, dissemination</i></p>	<p>Motivation: to support the work of the association , help in discovering potential patients, provide them with care and reduce future costs in the healthcare system</p> <p>Benefits: obtaining relevant data about the frequency of celiac disease in The City of Rijeka and area and further planning about mananing</p>
<p>Regional Public Health Institution</p>	<p><i>Public service provider</i></p>	<p><i>communication</i></p>	<p>Motivation: to support CD society work, detection of potentially disabled children and prevention of illness</p> <p>Benefits: healthy population, prevention of disease in the general population is a fundamental principle of the work of public health institutions at all</p>



<p><i>Parents</i></p>	<p><i>General public</i></p>	<p><i>communication</i></p>	<p><i>Motivation: at first, children which will be directly involved, - potential patients, health prevention; citizens will be reached through social media and media presentations- new knowledge Benefits: disease prevention, raise awareness about disease, encouraging an active healthcare</i></p>
<p><i>Croatian Ministry of Health</i></p>	<p><i>National public authority</i></p>	<p><i>communication</i></p>	<p><i>Motivation/Benefits/ vision: Protecting, preserving and improving the health of the population through the protection of public health, early detection of disease risk, disease prevention, treatment and rehabilitation.</i></p>



4. Business Model Canvas

Please summarize your project plan and approach model described above in this table. Write bullet points in each cell of the table

Key pilot Partners	Key Activities	Value Proposition of the pilot (what is the benefit ?)	End-user (patient) Relationships	End-user (patient) Segments
<ul style="list-style-type: none"> • PP6- NGO (Celiac disease society Rijeka) • PP4 -Health care professionals(University Hospital Centre Rijeka) • PP12-regional authority (Primorje- Gorsky Kotar County) • Educational institutions- primary schools (TBD) • Regional Public Health Institution • Ministry of Health 	<p>1.Gathering data about suppliers and types of tests for celiac disease in Croatia</p> <p>2. Preparing documents for the Ethics Committee (Brief description of the research, Notice for parents / guardians to participate in the research consent form for participation in the research Parent questionnaire)</p> <p>3. A public call and a contractor's choice</p> <p>4. Communication with local authority, public health institution and schools about permitting (compile a communication letter for the school,</p>	<ul style="list-style-type: none"> • Early detection of the disease diminishes its complications and raises the quality of life • obtaining relevant data about frequency of celiac disease in the Primorje Gorski Kotar County • detecting possible other/releted health problems • healthy population (If new patients will be discovered, their brothers, sisters and 	<p>Self-service/help/management ?</p> <p>Co-creation process with end-users</p> <ul style="list-style-type: none"> • personal data record • testing on celiac disease • data processing - positive / negative result • Further referral to hospital treatment if result is positive (specialist gastroenterologist) - Rapid test does not have 100% probability • notice of family screening on CD 	<p>Young/old/ specific target group</p> <ul style="list-style-type: none"> • (pre)school children between 6 and 7 years old • girls and boys



	<p>information letter for parents...)</p> <p>5. Educational workshops and presentations of the project and pilot activities, also CD, importance and benefits of testing , presentations for the school boards, parents, children (to be determined)</p> <p>6. Testing- screening school children</p> <p>7. Evaluation</p> <p>8. Promotion and raising awareness</p> <ul style="list-style-type: none"> • Media promotions- facebook, TV, radio, web portal • T-shirts for the children which will be involved in testing • gluten free products (food) for children 	<p>parents will also be notified with family screening on celiac disease)</p> <ul style="list-style-type: none"> • reducing the costs of the health system if disease is detected on time • new management approach for celiac disease (recommendation) 		
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	<p>which will be involved in testing</p>			
	<p>Key Resources</p> <p>1. Human</p> <p>Coordination, presentation, evaluation- PP6</p> <p>Testing, coordination and presentation, evaluation (doctors, lab workers)-PP4</p> <p>Dissemination-PP12</p> <p>2. Financial</p> <ul style="list-style-type: none"> • PP6, PP4, PP12; staff cost-?? <p>3. Material cost</p> <p>rapid tests- 8.400 eur</p> <p>cotton wool</p> <p>alcohol</p> <p>gloves</p> <ul style="list-style-type: none"> • T-shirts- 6.000 eur • gluten free products-?? 		<p>Communication channels ?</p> <p>-personal contact</p> <p>- ICT tools</p> <p>-social media</p> <p>-working group</p>	
<p>Cost Structure</p> <p>Pilot development coordination costs</p>	<p>Revenue Streams</p>			



Maintenance costs / later after the project will end	
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5. Preliminary work plan

Please give a time plan of how you plan to proceed with your pilot project. Define the main stages and milestones of the workflow. Insert rows according to your needs.

Phase Title & Description	Participating Stakeholders	Milestones	Planned Date
<i>Give the title and/or short description of the phase (identification process, focus group meeting, survey, testing... etc.).</i>	<i>According to the Partnership table above. You can write "All" if all of the stakeholders participate in the Phase.</i>	<i>Describe the milestone that you plan to achieve at the end of the phase</i>	<i>Planned date of milestone</i>
1. GATHERING DATA ABOUT SUPPLIERS (Information about RAPID TEST)	PP6, PP4	To find the most favourable purchase of high sensitivity tests on celiac disease	October, November 2017
1. PREPARATION WORK MATERIAL FOR COMMUNICATION	PP6 PP4 PP12	Communication letter, request for the Ethical Board, presentations, parent's confirmation etc...	November, December 2017
2. PREPARATION AND IMPLEMENTATION - CALL FOR PUBLIC PROCUREMENT	PP4	Supplier selection, communication, documents administration	January, February, March 2018
3. PR ACTIVITIES	PP6, PP4, PP12	we will publish all activities through social networks, we will also arrange TV and radio presentations	May, September, December 2018
4. MEETINGS/PRESENTATIONS	PP6, PP4	obtain approval for pilot activities, arrange sequence and activity dynamics	January - till the end of Pilot 2018



5. IMPLEMENTATION OF PILOTS	PP6,PP4,PP12	Pilot project presentations, pilot activities, celiac disease, research benefits	September 2018
6. TESTING	PP4	Screening school children on CD with rapid (quick) test - from the droplet of blood	September, Oct 2018
7. EVALUATION	PP4, PP6	Preparing report	December 2018
8. DISSEMINATION	PP6,PP4,PP12	informing the Ministry of Health, local and regional authorities about the results of the Pilot Project as well as the general public	December 2018

ACTIVITY A.T3.2 IMPLEMENTATION OF PILOT PROJECT

Pilot Status Report 1

Version 1
03 2017





1. Pilot Status According to Objectives defined in D.T3.1.1

- Short description, if pilot development activities are implemented according to objectives set-up in the framework of D.T3.1.1
- Did the development process contribute to any additional new objectives?
- Did the team discover that any of initially set-up objective would not be reachable and please explain reasons/circumstances?

Pilot project- Screening school children on CD- develop according to objectives set up in the framework of D.T3.1.1..

Development process didn t contribute to any new objectives.

At this moment while we are doing communication with schools, everything that team set up as initially objectives seems to be reachable. We can only highlighted different ways that schools wanted to be inform about the pilot project (presentation, lecture or short information on first parent meetings + writing information).

Also, we were looking for additional information and permission from Ministry of Science and Education and Central Education Agency to enter the school space for testing purposes (in progress to have a document).

2. Activities implemented so far

- Please provide short description of activities implemented so far and explain the progress in developing and testing of pilot solution

After we finished with preparation of all documentation for testing and got Ethical improvement, we also ended up with purchase of rapid tests and had several presentations about Pilot project activities where we informed primary school principals and our stakeholders about main goals and importance of testing on CD.

On September Society had meeting with PP4 and PP12 where we agreed about current activities. Our stakeholder- Public Health Institution-Department of School Medicine sent to us a list of primary schools and children enrolled in the first grades, so we proceeded a documentation and the whole information about testing to their mail addresses and right now we are in part of communication and preparation to go into schools and have meetings with parents in order to provide presentation or lecture about Pilot.



We are planning to visit primary schools, do needed communication with parents and take parental approvals (in progress, closed with 15 OCT) and after all set up dates for testing children (through OCT and NOV, closed with 15th DEC).

PR activities we plan at time when we will do testing.

We also agreed about T-shirt design for the purpose of giving children some "project present". At this moment we are waiting for 3 offers to choose the most favorable.

We can conclude that so far everything is going according to plan.

3. Changes in stakeholder's partnership

STAKEHOLDERS NO LONGER PARTICIPATING

Name	Reason for leaving
-	-

NEW STAKEHOLDERS

Name	Specialization Area	Role in Pilot Project	Motivation / Benefits
Ministry of Science and Education of the Republic of Croatia	Science and education	- giving the necessary permission to enter the school space for the purpose of conducting the test	- cooperation with the Ministry of Health and other specialized institutions (hospitals and societies) for the prevention and protection of children's health, information exchange, support for scientific research



PILOT development and testing

WP title	Pilot development and testing
<p>Please describe the progress in the current reporting period and explain how partners were involved in the activities (who did what).</p>	<p>After sending an info letter to primary school principals, to their mail addresses with complete information about CD testing and all necessary permissions (Ethics committee and the permission of the Ministry of Science and Education), we have been started individual visits to each school to hold a lecture about celiac disease and present the Pilot project activity. So far, we have visited 30 schools and we have conducted the tests in 8 schools (the total number of children is 390).</p> <p>PP4 was involved as a partner executor (implementation of CD testing with rapid tests) and performing an expert lecture about disease.</p> <p>PP12- was partly involved in communication with schools and several presentation activity (planned for dissemination activities)</p>
<p>Please describe and justify any problems and deviations including delays from the work plan as presented in the application form and the solutions found</p>	<p>We have noticed several problems during the implementation of this pilot project.</p> <p>1) Primary schools in our county have classes with a small number of children enrolled in first grade ad1) so we have to go through a large number of schools which certainly slow down our work</p> <p>2) Parents are motivated to participate in the project if they are given a lecture about celiac disease and have an opportunity for discussion ad2) so we go to each individual school, hold a lecture, present a project and have discussion. When the information was forwarded only as written info through the teacher, the parents response was not satisfactory or did not exist at all.</p> <p>3) Our county covers the coast, the islands and the mountainous area. Due to the equity distribution, but also as a request of our partner PP12, which highlighted the opportunity for as many children from different parts of the county to get a chance to participate in this health preventive program, we decided to give extra effort to organize lectures and testing in the mountainous and island parts of county.</p> <p>4) A medical team organization ad4) medical staff is not available all the time and takes additional time for the organization</p> <p>All above are reasons why we asked to extend the implementation of the pilot project (in Vienna). We certainly need to be prolonged and March 2019 is our new proposal deadline.</p> <p>We will also let you know about the total number of children we will be achieve in the next period, as the activity will stop in the period from 20 December to 15 January. due to duration of winter school holidays.</p>



<i>Deliverable title / D.T3.1.1</i>	<i>Report about pilot project ideas and established stakeholders groups</i>
Deliverable description (in the AF)	Progress Reports Deliverable Description
<i>Report will include short description about each of the 10 project ideas and involved stakeholders who will co-create the pilot solution. It will present the existing needs and challenges as well as potential benefits of pilot development.</i>	
<i>Deliverable title/ D.T3.2.1</i>	<i>Preparation of common pilot methodology</i>
Transnational dimension of development and implementation of pilots, transferability of results and assessment of end results will be ensured with common methodology, prepared upon experience of projects: CE CENTRALAB, MED MEDLAB, Alpine Space OPEN ALPS	
<i>Deliverable title/ D.T3.2.2</i>	<i>Mentoring service for newly diagnosed patients (LP MOM)</i>
Report about 10 included newly diagnosed CD patients in tested mentoring service, since newly diagnosed CD patients are faced with many challenges in the transition to a lifelong strict diet.	
<i>Deliverable title/ D.T3.2.3</i>	<i>“Simulator testing to improve endoscopist practice in field of CD (PP2 UKC - MB)</i>
Practice report about positive/negative effects of using Simulator in daily CD procedures/practice.	
<i>Deliverable title/ D.T3.2.4</i>	<i>Improvement of early diagnostics, testing method “IgA t-Tg deposits in tissue sample” (PP2 UKC-MB)</i>
Report about results using improved early diagnostic methods 'IgA t-Tg deposits in tissue sample' on 10 patients.	
<i>Deliverable title/ D.T3.2.5</i>	<i>Improvement of diagnostics, with testing 3 methods to improve CD practise (PP4 KBC Rijeka)</i>
Report about results, testing 3 new methods (fecal alpha -1-antitrypsin, fecal elastase -1 and calproteins tests) to improve CD management practice.	
<i>Deliverable title/ D.T3.2.6</i>	<i>Detecting and managing CD patient within a “cohort of super allergic population” (PP5 - UNITS)</i>
Action plan for intervention will be implemented in a sample of patients with severe allergies.	
<i>Deliverable title/ D.T3.2.7</i>	<i>Testing of CD antibodies in school children (PP6 - UOCPGŽ Rijeka)</i>



Report for approximately 400 school children (a representative sample) for presence of CD specific antibodies with a rapid tests and report about possible newly detected patients. Pilot will be implemented in cooperation with KBC Rijeka.	
<i>Deliverable title/ D.T3.2.8</i>	<i>Improvement of diagnostic of atypical CD patients (PP7 IRCCS)</i>
Preparation of report about results and experience in detection and diagnostic of atypical patients (which differ from known standard diagnostic procedures).	
<i>Deliverable title/ D.T3.2.9</i>	<i>Implementation and testing of new service to improve transition from paediatric to adult health care (PP8 - KUM)</i>
(Pilot activity: KUM PP8) Preparation of report about results and experience introducing new service - guided transition of CD patient from paediatric to adult health care.	
<i>Deliverable title/ D.T3.2.10</i>	<i>Evaluation and follow up of family members (PP10 HP)</i>
Report about results related to testing an open-access service for accepting new family members of diagnosed patients, starting before birth.	
<i>Deliverable title/ D.T3.2.11</i>	<i>Testing of real life environment use of gluten free offer in restaurants (PP9 HCS)</i>
Report about control results of compliance with following gluten-free rules in restaurants offering 'gluten-free' food.	
<i>Deliverable title/ D.T3.2.12</i>	<i>Report about pilot project implementation</i>
Report will include description of the pilot design and its development, together with the information about the testing of the pilot in real environment. It will include the information about the end-user feedback and possible modifications.	
<i>Deliverable title/ D.T3.3.1</i>	<i>Transnational transferability plan of pilot solutions</i>
Upon exchange of needs of participating regions, transnational transferability plan will be prepared to transfer best solutions among project participating regions.	
<i>Deliverable title/ D.T3.3.2</i>	<i>Pilot project recommendations for transfer to other users/regions</i>
Based on a feedback from pilot stakeholder group and end users, pilot project recommendations will present development process, experience and results related to	



pilot projects to other possible users within the consortium and within the region.

ACTIVITY A.T3.2 IMPLEMENTATION OF PILOT PROJECT

Pilot project Final Report

Version 1
03 2017





1. RESULTS ACHIEVED ACCORDINGLY TO OBJECTIVES

- **Please review the objectives you have set up in your D.T3.1.1 description, in the Status report Phase 1 and describe activities and results achieved by your pilot. Give an overview of the processes that are part of your pilot project.**
- After all the prerequisites have been met; 1) obtaining the approval of the Ethical Hospital Committee and the Ministry of Education for the implementation of the Pilot project activity in elementary schools of our area; 2) the procurement of the rapid tests; 3) the main presentation of the Pilot project for principals of primary schools (Primorje- Gorski Kotar County, 5th May 2018)) we were ready for implementation of testing school children on celiac disease.
- The implementation of the Pilot Project has been actively started since September 2018. with intensive communication aimed at elementary schools (via mail and phone). After the arrangements for holding meetings with parents, we gave professional lectures on celiac disease and related illnesses, also at the same time held presentations about the Interreg CE program and the Pilot project "Testing the school children on celiac disease".
- We passed through (Association and Hospital, PP6 and PP4, occasionally and PP12) 33 primary schools, realized about 66 outings on the 3 micro-regions of our county (mountains area of Gorski Kotar, coast and islands). We went to each school at least twice (in some schools we went out three times because of the different timing of school tuition); at first because principals had to approve school attendance and to show first interest in project implementation and for parents who had to sign approvals and the second time for CD testing to be implemented.
- We tested a total of 1478 children with non-invasive rapid celiac test and recorded 10 IgA deficits, which were not diagnosed as a positive celiac disease patients in a further diagnostic protocol in the Hospital (anti-transglutaminase antibodies).
So, we can conclude that through the set goals of this project; discovering new patients, prevalence of disease and new recommendation for a possible new approach to disease detection, we did not find/confirmed an increased celiac prevalence rate / celiac suspect, we have not confirmed any new celiac disease patient.
Further, we conclude that we recorded 10 IgA deficiencies which points to the risk group of children who can develop celiac disease if they have a genetic predisposition to the disease.
- As secondary conclusions, it is important to note that through this Pilot Project, in directly communication with parents we informed about the many health issues of their children concerning food allergies and even problems related to gluten consumption, also dermatological skin changes. Almost in every class we detected children below average body weight and lower growth for which there was a possible suspect on disease (as well known CD symptoms), but this type of testing did not give positive results on that suspects.



- Further we noticed that children parents (which are between 30-40 years old) have the presence of many autoimmune diseases that are mentioned in relation to celiac disease (thyroid disease, diabetes, rheumatoid arthritis ...which they shared with us after given lecture about CD).
- Because of the presence of such health issues, parents were positive in decision to test children on CD. So, we can also conclude that parents as well as school workers were very interested in health topic, they recognized their health issues related to CD, they pointed out problems of their children and gave us big support for CD testing. We offered them a new knowledge about CD.

2. ADDED VALUE OF THE DEVELOPED & TESTED PILOT SOLUTION IN YOUR REGIONAL ENVIRONMENT

- **Please describe shortly, what is the gained added value for the end-user of pilot service solution**

ADDED VALUE for END-USER	
Short term effects	Long-term effects
1. New knowledge	1. New knowledge about celiac disease and related disorders
2. testing on CD/health check/ possibility to discover disease and other related conditions	2. Public raising awareness
3. possibility to exchange opinion with health care professionals	3. Further cooperation with educational institutions (workshops for kitchen workers and teachers about CD and special food requests)
	4. Further cooperation with schools with related topics/related projects/prevention and health protection

- **In case your outcomes are different from the planned, please give an explanation of the reasons and formulate your modified results achieved. Was your planned model working or did you have to make modifications, if yes, describe? Did you have any problems in your pilot implementation? If yes, which was the solution adopted?**
- The producer of rapid test (Biocard) declares very high sensitivity and specificity of the test so we decided to use it. We did not find any patient with CD although we expected it because every year in Pediatric department of our hospital there are at least 3-5 newly diagnosed children from Primorje-



Gorski Kotar County. There are no epidemiological data on CD incidence and prevalence in Croatia. It is to be questioned are our results real picture of CD prevalence in our territory, less than in other parts of the Europe, or there is problem with rapid test. It can be concluded that new and more detailed researches need to be done. We have noticed several problems during the implementation of this pilot project but we adapted very fast and made quick answer to situation. Implementation of CD testing was lasted five months just because we needed to go twice to every school.

- On the one hand, we had the opportunity to choose the easiest way to give an information through primary school physicians (in period of systematically examining related to children for the first grade) to avoid duplicate going to schools (which has created additional effort and extended duration of the pilot project).

On the other hand, with our stay among the parents and given lectures about CD/ presentations of the Program and the Pilot Project, we have made huge raising of public awareness (parents of children, teachers, principals of the institution, as well as other public through the media that followed us: national and regional newspapers, TV and radio).

1) Primary schools in our county have classes with a small number of children enrolled in first grade so we have to go through a large number of schools what certainly slowed our work but also gave us opportunity to screen situation much better on wider area of our county.

2) Parents were motivated to participate in the project only if they were given a lecture about celiac disease and have an opportunity for discussion, so we went to each school, held a lecture, presented a project and had discussion. While information was forwarded only as a written info through the teacher, the parents response was not satisfactory or did not exist at all. It gives us conclusion about parent's need that health topic should always be presented as complete professional information (information about CD testing which was providing by principals or teachers didn't give expected results with approvals; that was the reason we asked to prolong our work).

3) Our county covers the coast, the islands and the mountainous area. Due to the equity distribution, but also as request of our partner PP12, which highlighted the opportunity for as many children from different parts of the county to get a chance to participate in this health preventive program, we decided to give extra effort to organize lectures and testing in the mountainous and island parts of county. Such kind of observation has enabled us to meet a wider social community, to different social and cultural features , as well as the ability to meet the health problems of people from different geographical areas of our county.

- 4) A medical team organization - additional efforts were needed to equip the medical team to do testing because of schools in different geographic areas of our county.



3. LESSON LEARNED RELATED TO CO-CREATION OF PILOT SOLUTIONS WITH ENGAGED STAKEHOLDERS

- Please describe what were the benefits and setbacks related to co-creation of pilot project with stakeholders.

LESSONS LEARNED	
Benefits	Setbacks
1. positive and relatively fast correlation	1. a small number of children enrolled in the first grade/ which increased the number of school tours
2. interest in the subject/ prevention and health protection	2. dislocation of schools in the county/3 micro-regions/more effort in planning implementation
3. adaptability and teachers' support in preparing children to extract blood	3. organization of a permanent medical team
4. media interest for the pilot project and its results	

4. FURTHER ACTION PLAN (ACTIVITIES FOR THE FUTURE)

- What are your further activities of the pilot project development,
 - On the local level ?

The results of the Pilot project will be presented to the local authorities. Regarding to that results we will not make recommendation for mass screening using fast celiac tests because we did not prove its presence although we have proven secondary goal; IgA deficiency among the children's population. It points to the possibility of increased development of primary intestinal infections, but also of celiac disease if a person has a positive genetic predisposition to develop this disease.

We have definitely proved that cooperation with educational institutions can be achieved in the implementation of pilot projects; that parents have an interest in participating in the health prevention program of their children's health by non-invasive methods; that they are interested in health education; and that there is an interest of the public (also media) to monitor such projects and to participate in raising awareness of different needs, as celiac disease also request.



On transnational level ?

Our work and results will be presented in Poland through our activity related to WP4.

- **How did you plan to ensure sustainability to your pilot? Have you plan any action for the maintenance/follow up/development of the actions implemented, after the project ends?**

We can say that this Pilot Project was of multiple benefit, although we did not confirm any celiac disease (considering that out of ten children with IgA deficiency, four of them had access to further hospitalization, no celiac disease was confirmed, the other six children so far have not responded to further processing). We will resume calls to risky patients to respond to further diagnostic protocol, which was also presented to parents as a part of our activity in some needed cases.

This research was carried out according to the manufacturer's instructions and in our case did not prove successful in terms of certifying celiac disease, but we certainly do not exclude the possibility of further research by this method since many data showed usefulness of rapid test. and its possibility/usefulness to reduce health system costs.

We need to keep on mind that rapid tests are still cheaper (1 rapid test could be order for less than 5 euro), simplest (don't need to be done in laboratory), quicker (need up to 10 minutes to have a result) than blood testing from vein. Certainly we need to do more pilot researches to make final decision.

Nevertheless, the most important result is in raising the awareness of the illness in the general population. It can make easier everyday life of the people with CD, with more understanding for their needs, and it can be expected that people will seek medical help in different conditions that can be related to CD and actively search for CD testing.