Interreg CENTRAL EUROPE
Focus IN CD
European Union
European Regional Development Fund

ACTIVITY A.T3.2 IMPLEMENTATION OF PILOT PROJECT

D.T3.2.4 IMPROVEMENT OF EARLY DIAGNOSTICS, TESTING METHOD ´IGA T-TG DEPOSITS IN TISSUE SAMPLE´

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.**

Coeliac disease can be diagnosed with combination of different tests. In majority of cases, patients must undergo upper endoscopy – Esophagogastroduodenoscopy (EGDS), whereby biopsy specimens from multiple parts of distal duodenum and duodenal bulb are obtained. Pathologists further examine these samples and determine the degree of intestinal damage typical of coeliac disease. Coeliac disease can be diagnosed with combination of different tests. In majority of cases, the diagnosis can be firmly established with currently available diagnostic tests. However, in some cases the tests can yield unclear or conflicting results. In such cases, clinicians currently cannot reliably diagnose the disease and patients are thus not treated properly. In order to diagnose the disease in these patients new techniques could be used. Determination of early immunological reactions in the intestinal tissue can enable pathologists to determine whether celiac disease specific reaction against gluten is present or not. One such test is the determination of the presence of specific intraepithelial lymphocytes that are specific of coeliac disease (gamma/delta IELs). Another possibility is the determination of coeliac disease specific antibodies in the intestinal tissue itself. Determining tissue deposits of t-TG antibodies was introduced recently and is only used in very few centres worldwide. One of the project partners IRCCS Burlo Garofolo has experience with this method. The aim of this activity was to **apply a new diagnostic method** at University Medical Centre Maribor, which will **improve service in coeliac disease diagnosis**.

In order to introduce this new method we used existing infrastructure in UKC-MB to collect tissue samples with existing endoscopes. We purchased liquid nitrogen containers in which we stored samples form CD patients for further analysis. We purchased small portable liquid nitrogen container for transport of samples within our institution from endoscopy room to storage facility, and a portable freezer for transport of samples to a distant location. This freezer was used to transport samples to collaborate partner IRCCS Burlo Garofolo in Trieste. One of the members of UKC MB project team Dr. Petra Rižnik learnt the technique of t-TG deposits determination in tissues with the help of partner IRCCS Burlo Dr. Tarcisio Not and Dr. Luigina DeLeo. The expertise was then transferred to our institution within which we used existing infrastructure: cryotome for cutting the samples, immunology laboratory to stain the samples, and immunofluorescence method for detecting the positive or negative samples. The results of the staining were compared with other diagnostic methods in patients. Results showed a great concordance with standard diagnostic methods, and proved to be very helpful in selected patients with discrepant standard tests.

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. Introduction of new diagnostic method.	1. Improved diagnostic capacities for celiac disease of University Medical Centre Maribor and Slovenia.
2. Clarification of diagnosis in selected complicated cases.	2. Improved health outcome for patients with difficult diagnosis.
	3. Improved service of health care sector for patients with celiac disease.

3. DEVIATION AND PROBLEMS ENCOUNTERED

- **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 had to make modifications, if yes, describe? Did you had any problems in you pilot implementation? If yes, which was the solution adopted?**

We have encountered few problems during the pilot activity, and adopted necessary mitigation measures.

- Number of samples varied during the duration of the study, however with other activities of the project level of new patients was high enough.
- Lack of skilled personnel within the institution proved to be a minor problem since UKC MB has enough experts who can take over this task.
- Specific steps have to be performed at different locations within the UKC MB, therefore a good coordination of all stakeholders is crucial.
- Obtaining appropriate laboratory material for new technique is an important point, and it is overcome with the help of centre with long experience (IRCCS Burlo Garofolo).

4. 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. Involvement of multidisciplinary team of experts from different units in the UKC MB allowed exchange of expertise.	1. Involvement of larger groups of experts can slow a learning curve. Members of the team with less motivation can jeopardise introduction of novel methods.
2. Cooperation of two partners with different backgrounds and availability of equipment and material enabled faster adoption of new technique.	2.
3. Feedback from other members of multidisciplinary team helped in optimising the method in local settings.	3.

5. FURTHER ACTION PLAN (ACTIVITIES FOR THE FUTURE)

- What are your further activities of the pilot project development,
  - On the local level?
  - Method will be used at the University Medical Centre Maribor in future especially in difficult cases of celiac disease. Methodology will be updated regularly based on new knowledge and reports. New members will be invited to learn the technique. Method will be available for other centres in the region and in the country.
  - On transnational level?
  - Method will be used at the University Medical Centre Maribor in future. It will be updated with the help of the partners form IRCCS Burlo Garofolo, and the data of difficult patients will be exchanged between centres. Results will be presented at international meetings and new techniques will be made available to other centres in neighbouring countries. Trainees form other countries will be presented the technique.

- 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?

Building on an existing infrastructure will decrease the cost of introduction of the new method in the institution and will enable its long-term use. Since UKC Mb serves as a reference centre for coeliac disease this service will provided to other institutions in the region. All the equipment purchased within the project will remain to be used after the project to store samples and to perform analysis.