

DELIVERABLE D.T3.2.3

**SIMULATOR TESTING TO IMPORVE ENDOSCOPIST PRACTICE IN
FIELD OF CD**





1. INTRODUCTION

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. In order to obtain appropriate biopsy specimens a clinician performing EGDS must be well trained. Many young clinicians do not have sufficient endoscopic skills. They can acquire this by learning from the books and from available video materials, but mostly practice on real patients. In order to retain good skills an endoscopist must perform many procedures in one year, which in some smaller centres and in paediatric, institutions might be demanding. Simulators are useful in many fields where technical skills are needed (e.g. pilots...). Simulator training cannot be a full substitute for performing endoscopy on real patients; however, it can greatly enhance the learning curve. Clinicians that will not directly diagnose coeliac disease in their practice are not aware of the diagnostic procedures that need to be performed in order to confirm the disease.



2. PILOT PROJECT IDEAS & ESTABLISHED STAKEHOLDER GROUPS

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?*
 - 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.
 - In order to obtain appropriate biopsy specimens a clinician performing EGDS must be well trained.
 - Many young clinicians do not have sufficient endoscopic skills. They can acquire this by learning from the books and from available video materials, but mostly practice on real patients.
 - In order to retain good skills an endoscopist must perform many procedures in one year, which in some smaller centres and in paediatric, institutions might be demanding.
 - Simulators are useful in many fields where technical skills are needed (e.g. pilots...)
 - Simulator training cannot be a full substitute for performing endoscopy on real patients; however, it can greatly enhance the learning curve.
 - Clinicians that will not directly diagnose coeliac disease in their practice are not aware of the diagnostic procedures that need to be performed in order to confirm the disease.

- *Are there preliminary works that the project is based on? What are they?*
 - Colonoscopy simulator has already proved to be a useful training tool at endoscopy training courses.

- *What is the knowledge base behind the project (studies, methods, statistical data etc.)?*

Several studies have addressed the advantages and outcomes of simulator based training in endoscopy.

 - Amiot A, Conroy G, Le Baleur Y, Winkler J, et al. Endoscopic training: A nationwide survey of French fellows in gastroenterology. Clin Res Hepatol Gastroenterol. 2017
 - Walczak DA, Grajek M, Walczak PA, et al. The first homemade colonoscopy trainer. Z Gastroenterol. 2017



- Naur TMH, Nilsson PM, Pietersen PI, Clementsen PF, Konge L. Simulation-Based Training in Flexible Bronchoscopy and Endobronchial Ultrasound-Guided Transbronchial Needle Aspiration (EBUS-TBNA): A Systematic Review. *Respiration*. 2017
- King N, Kunac A, Merchant AM. A Review of Endoscopic Simulation: Current Evidence on Simulators and Curricula. *J Surg Educ*. 2016
- Harpham-Lockyer L, Laskaratos FM, Berlingieri P, Epstein O. Role of virtual reality simulation in endoscopy training. *World J Gastrointest Endosc*. 2015
- Blackburn SC, Griffin SJ. Role of simulation in training the next generation of endoscopists. *World J Gastrointest Endosc*. 2014
- Qiao W, Bai Y, Lv R, Zhang W, Chen Y, Lei S, Zhi F. The effect of virtual endoscopy simulator training on novices: a systematic review. *PLoS One*. 2014
- Wilcox V Jr, Trus T, Salas N, Martinez J, Dunkin BJ. A proficiency-based skills training curriculum for the SAGES surgical training for endoscopic proficiency (STEP) program. *J Surg Educ*. 2014
- *What methods will you / do you plan to use (to motivate stakeholders, to involve lead users, to develop ICT infrastructure, to communicate online etc.)?*
 - We intend to purchase EGDS simulator.
 - We plan to tests its functionality with skilled endoscopists.
 - We plan to design a questionnaire for trainees to assess their pre training knowledge and theoretical skills, as well as their pre training manual skills.
 - Thereafter we will present them with the functionality of the simulator.
 - We will then present several scenarios and let trainees practice on the simulators. We will at the end reassess trainees technical skill and theoretical knowledge, and measure the improvement.
 - Individual and group training will be tested.
 - We intend to involve students, interns, residents and young specialists as well as nurses in training program.
 - We plan to record the training course and provide it online.
 - We plan to design written materials for participants with different scenarios.
 - We plan to design interactive materials for participants with different scenarios



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...?)*
 - By introducing simulator training, we will improve the knowledge of trainees in the field of gastroenterology who are going to manage coeliac disease in future.
 - General knowledge of coeliac disease management will improve among other HCPs.
 - Better skills of practicing endoscopists and other HCPs will improve the service provided by health care system.

- *What is the approach that makes the project viable and sustainable?*
 - EGDS simulator will remain for future use at Paediatric Gastroenterology Unit at University Medical Centre Maribor.
 - Training courses will be organised on an annual basis for future trainees at the department.
 - Recorded material will remain available for future use.
 - There is continuous need for training in endoscopy with ever-increasing number of patients seeking medical care.

- *What kind of problems are you anticipating and what is your "plan B"-s if something does not turn out as you counted in certain situations?*
 - Demand for high quality training opportunities is high among young trainees.
 - non-participation of individual trainees may occur

- *Will the pilot have cross-regional impacts? Which are they?*
 - We plan to participate at international training courses for young doctors and medical students.
 - We plan to involve other medical partners from other regions to participate at our training courses as both teachers and trainees.

 - We plan to organise courses at our annual international paediatric meeting.

- *Any other aspects you find important.*
 - Simulator training based on our positive experience could become a model of training all young trainees.
 - Better HCPs skills will ensure high quality procedure for all patients.



Partnership			
<i>Please describe your stakeholders and their roles in the pilot project. Insert rows according to your needs.</i>			
Name	Specialization Area	Role in Project	Motivation / Benefits
<i>If you plan to include a certain type of stakeholder but you do not yet know the specific organization, write "[TBD]" (to be determined) in this column.</i>	<i>Healthcare professional/ patient/presentative of NGO/policy maker...</i>	<i>Participating in development phase/participating in testing, communication, evaluation etc.</i>	<i>What is the main motivation of the organization to participate in the pilot project? What will be their anticipated benefits?</i>
1. Medical experts - specialists gastroenterologists	Healthcare professionals	Co-creation, design and implementation of pilot project's main activities	Improved knowledge, better skills, better service
2. Medical students	Healthcare professionals	Participants at training courses	Improved knowledge/better skills
3. Medical experts - nurses	Healthcare professionals	Presenters at trainings and will also have monitoring and support role during training process. Trainees.	Improved knowledge/better skills
4. Coeliac disease society	NGO	Evaluation of training modules	Better service by HCPs who manage patients organized in societies
5. Medical faculty	Higher education	Participating at events	Better knowledge of students, applying simulator training in practical training

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 Relationships	End-user Segments
<ul style="list-style-type: none"> • Project partners (UKC-MB, IRRCS Burlo, KUM, KBC) • Slovenian Celiac society (SDC) • Medical experts (specialists gastroenterologists) • Nurses • Medical faculty 	<ol style="list-style-type: none"> 1. Purchase of EGDS simulator 2. Testing of simulator functionality 3. Preparation of educational materials. 4. Preparation of knowledge assessment 5. Preparation of skills assessment 6. Design of training course for individual trainees 7. Design of training course for groups 8. Evaluation tool to determine knowledge improvement 9. Evaluation tool to determine skills gain 10. Improving of training module 	<ul style="list-style-type: none"> • Development of simulator training course • Improved knowledge • Improved skills • Better service 	<ul style="list-style-type: none"> • Existing mentors will train new mentors • New mentor will guide new patients 	<p>At least 45 participants</p> <ul style="list-style-type: none"> • Students • Residents • Young specialists • Nurses



	<p>Key Resources</p> <p>1. Human</p> <ul style="list-style-type: none"> project partners, health care professionals, students <p>2. Financial</p> <ul style="list-style-type: none"> PP2 UKC MB 		<p>Communication channels?</p> <ul style="list-style-type: none"> Written material Video material 	
<p>Cost Structure</p> <p>Purchase of simulator</p> <p>Pilot development coordination costs: distribution of working hours</p> <p>Publishing of written education material</p> <p>Publishing of video material</p>		<p>Revenue Streams</p> <p>Not planned</p>		

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. Purchase of EGDS simulator	UKC-MB	Purchase of simulator	October 2017
2. Selection of training mentors	UKC-MB	Two mentors enlisted	February 2018
3. Testing of simulator functionality	UKC-MB	Functionality tested	February 2018
4. Assessment of knowledge	UKC-MB	Assessment tool designed	March 2018
5. Assessment of skills	UKC-MB	Assessment tool designed	March 2018
6. Training course design	UKC-MB, Medical faculty, Coeliac disease society	Training course design	March 2018



3. Training material	UKC-MB, Medical faculty	Written and video material	May 2018
4. Training	UKC-MB, Medical faculties from Europe, Regional hospitals	Training courses for groups	March and April 2018
5. Training	UKC-MB, Medical faculty, Other hospitals	Training course for individuals	From April 2018 onwards
6. Evaluation	UKC-MB, Coeliac disease society, Other hospitals, Medical faculty, other medical faculties	Evaluation tool	March 2018

3. IMPLEMENTATION OF PILOT PROJECT - Pilot Status

Report 1

The activities in development and implementation of the pilot action in which we tested positive/negative effects of using EGDS Simulator in daily CD procedures/practice were continued. Several workshops for potential stakeholders were organised. Participants were able to learn and practice their skills with EGDS (esophago-gastro-duodenoscopy) simulator within the activity. All participants were provided a written material with detailed description of functionality of endoscopes. They were also provided with the material in which indications and contraindications as well as with benefits and risks of EGDS procedure were presented.

We purchased new equipment - light source and image video processor, which improved the quality of the training.

Workshops were designed for established and younger HCPs of different profiles from Slovenia and other countries. At least one of the skilled endoscopists was responsible for teaching future HCPs.

Participants were residents of paediatrics, interns, students of Medical schools as well as students of nursing schools.

Participants of the workshops expressed high level of satisfaction with the training.

Plans

We plan to continue with the training activities in the next period both individually as well as in small groups. We also plan to publish a supportive material for HCPs with an animated video and brochure about endoscopic procedures.



4. 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. Clinicians who will not directly diagnose coeliac disease in their practice are not aware of the diagnostic procedures that need to be performed in order to confirm the disease. In order to obtain appropriate biopsy specimens a clinician performing EGDS must be well trained. Many young clinicians do not have sufficient endoscopic skills. They can acquire this by learning from the books and from available video materials, but mostly practice on real patients. In order to retain good skills an endoscopist must perform many procedures in one year, which in some smaller centres and in paediatric institutions, might be demanding. Simulator training cannot be a full substitute for performing endoscopy on real patients; however, it can greatly enhance the learning curve. Several studies have addressed the advantages and outcomes of simulator based training in endoscopy.

To improve skills of HCPs who are working with patients with gastrointestinal problems including CD we purchased an EGDS simulator alongside with light source and video processor for existing endoscopes at UKC MB. Initial step was testing of the functionality of simulator by skilled endoscopists performing procedure in real patients. Dr. Tomaž Krenčnik and Dr. Jernej Dolinšek together with endoscopy nurses Erika Macur and Gordana Rudelič tested the equipment. They agreed that the simulator closely resembled real situation. Thereafter short instructions for trainees undergoing the training were developed by Dr. Petra Rižnik. Within these instructions, basic principles of endoscopy procedures were introduced as well as technical specifications of endoscopes. Indications and contraindications for the procedure were presented. Basic endoscopy techniques were also presented. An interactive lecture was prepared for trainees with several scenarios described in more detail.

Several workshops were organised during the implementation phase of the pilot project. Two approaches were used. Group training was organised at conferences such as Meeting of Slovene paediatricians with participation of HCPs already performing endoscopy procedures in their institutions and at Skills lab meeting of future HCPs coming from Central European Medical faculties. Group session was also organised for students of Faculty for Health Sciences of University of Maribor. Another approach was individual training of students of Medical Faculty of University of Maribor. These students were also exposed to real patient endoscopic procedures and were able to compare it with simulator experience. Specialists, residents, interns, medical students, nurses, and students of nursing school attended courses organised within the pilot activity. Regardless of the approach used, all participants were highly satisfied with the training and gained knowledge. As organisers of these courses, we were able to acknowledge great **improvement in theoretical knowledge** about the rationale of endoscopic procedures in patients with gastrointestinal disease, as well as **improvement of technical skills** of participants already performing endoscopies in their institutions. A tutorial video was developed for HCPs. As all the participants were also presented with materials, regarding celiac disease management we also recorded **improved knowledge about celiac disease management** of participants.

EGDS simulator will remain at Paediatric Gastroenterology Unit at University Medical Centre Maribor for future use. Training courses will be organised on an annual basis for future trainees at the department. Recorded material will remain available for future use.



5. 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. Knowledge about the performance of EGDS.	1. Improved skills of practicing endoscopists.
2. Better knowledge about indications and contraindications for EGDS.	2. Timely appointment for endoscopy of patients who need endoscopic procedure such as CD patients.
3. Better knowledge about diagnostic procedures in celiac disease management.	3. Improved service of health care sector for patients with celiac disease.

6. DEVIATION AND PROBLEMS ENCONTERED

- In case your outcomes are different from the planned, please explain 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 not encountered any major problems during the pilot activity.

Some problems were anticipated and mitigation measure were adopted efficiently.

- When larger groups were registered for a training event participants were split in smaller groups and more than one station was organised with involvement of more teaching staff.
- When students attending had time constraints individual phases of training were split in different days.
- Lack of interest by students was overcome by blending of interactive and individual approach, which stimulated higher degree of involvement of participants.



7. 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 participants from different backgrounds and with different knowledge allowed exchange of different views and enabled the introduction of more personalized themes in the training.	1. Involvement of larger groups can slow down a learning curve, and can allow lower involvement of individuals with less motivation.
2. Simultaneous involvement of doctors and nurses enabled better communication between themselves, which is crucial in real settings.	2.
3. Constant feedback by participants during interactive lessons and during training improved the teaching capabilities of teachers.	3.

8. FURTHER ACTION PLAN (ACTIVITIES FOR THE FUTURE)

- What are your further activities of the pilot project development,
 - > On the local level?
 - > Simulator will remain at the Department of Paediatrics of University Medical Centre Maribor for future use by trainees. Medical students, residents and young specialists from Slovenia will be practicing at simulator. All written and other supporting material will be regularly updated, and will be distributed to new trainees.
 - > On transnational level?
 - > Simulators will remain at the Department of Paediatrics of University Medical Centre Maribor for future use by trainees. Participants from neighbouring countries will be invited to participate in training sessions organised at different international events in Maribor. Trainees that regularly visit Department of Paediatrics at the University Medical



Centre Maribor will be involved in training as well. All written and other supporting material will be regularly updated, and will be distributed to new trainees.

>

- 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?

As described above the simulator will remain operational at the Department of Paediatrics of University Medical Centre Maribor. All supporting materials will be regularly updated with new knowledge and developments in the field of gastrointestinal endoscopy. Members of the teaching staff will attend *train the trainers* courses in order to improve skills in training and will be included in the international endoscopy-training network.