**ICT CIP – Competitive and Innovation Programme**

United4Health

# UNIversal solutions in TElemedicine Deployment for European HEALTH care

## (Grant Agreement N° 325215)

## Deliverable D3.4
## Intermediate Report on Status of Recruitment
## Version 1.0

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| Author: | Kristian Kidholm, Panos Stafylas, Leo Lewis, Janne Rasmussen |
| Reviewed by: | John Oates |
| Approved by: | Marco d'Angelantonio |
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**Abstract**

This document describes the status of recruitment of patients by both M23 and M27 of project. The report outlines the current figures, the main reasons for delays and issues at each deployment site, as well as overall project and local measures and actions taken to enhance recruitment.

**Key Word List**

United4Health, telemedicine, assessment, recruitment, barriers, solutions

# Executive Summary

This document describes the status of recruitment of patients at both M23 and M27 of project.

As described in the protocol (deliverable D3.1. version 1.5), it was planned to recruit about 12.000 patient in the telemedicine group in the project and about 7.000 patients in the comparison group. In November 2014 (M23), the number of recruited telemedicine patients was 4.086 or 34% of the planned sample. In the comparison group 1.060 or 15% was enrolled.

The main reasons for the low rate of recruitment are technical problems, lack of engagement from the doctors and nurses who do the recruitment, funding problems, and strict inclusion criteria.

The document also contains the latest overview of recruitment to the intervention group from March 2015 (M27). These are included due to the late delivery of the report to demonstrate how recruitment is continuing and the pace increasing.

# Change History

**Version History:**
v0.1    6th March 2015
v0.2    16th March 2015
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**Version Changes**
v0.1    Initial draft by Kristian Kidholm
v0.2    Revisions by Janne Rasmussen
v0.3    Revisions by Leo Lewis
v1.0    Version for issue

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# 1. Introduction

## 1.1 Purpose of this document

This purpose of this document is to describe the status of recruitment at M23 and M27 in the United4Health project.

## 1.2 Glossary

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|---|---|
| **COPD** | Chronic Obstructive Pulmonary Disease |
| **EHR** | Electronic Healthcare Record |
| **WSD** | Whole System Demonstrator (UK project) |

# 2. Background

As described in Deliverable D3.1 version 1.5, United4Health will evaluate selected telemedicine services based on the Renewing Health project. The services selected are:

- Life–long management of diabetes.
- Short-term follow-up after hospital discharge for COPD patients.
- Remote monitoring of congestive heart failure.

Life-long management of diabetes is currently installed in Berlin, Thessaly and Veneto. For the United4Health studies, it will be enhanced with the functionality of patient education and coaching currently installed in North Norway. Within United4Health, this service is planned to be trialled, for a total of 7,410 patients, in:

- Scotland;
- Wales;
- Northwest Moravia;
- Slovenia;
- Campania;
- Calabria;
- South Karelia;
- Central Greece;
- Berlin.

Short-term follow-up after hospital discharge for COPD patients is currently installed in South Denmark. Within United4Health, this service is planned to be trialled, for a total of 2,038 patients, in:

- Scotland;
- Wales;
- Southern Norway;
- Galicia;
- North Norway;
- Berlin.

Remote monitoring of Congestive Heart Failure is currently installed in Thessaly and Veneto. Within United4Health, this service is planned to be trialled, for a total of 1,830 patients, in:

- Scotland;
- Basque Country;
- Northwest Moravia;
- Slovenia;

In general terms, the services are operational, but in regions different from those which will pilot them in United4Health; none of them is currently used in a cross-border multi-centre trial.

The tables below show the planned number of patients in the telemedicine and the comparison groups by region and by pathology according to D3.1 v1.5.

**Table 1: Planned number of telemedicine patients**

| Pathology | New pilots funded by ICT PSP | | | | | New pilots funded from other sources | | | | | Existing Renewing Health partners | | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Scotland (UK) | Basque Country (ES) | Wales (UK) | Southern Norway (NO) | Northwest Moravia (CZ) | Slovenia (SL) | Campania (IT) | Calabria (IT) | Nord Pas De Calais (FR) | Galicia (ES) | North. Norway | South Karelia | Central Greece | Berlin | |
| DM | 1200/4000 | | 400 | 0 | 40 | 400 | 200 | 250 | | | | 150 | 70 | 300 | **7410** |
| COPD | 670/168 | | 200 | 200 | | | | | | 500 | 200 | | | 100 | **2038** |
| CHF | 536/714 | 300 | | | 80 | 200 | | | | | | | | | **1830** |
| HTN | | | | | | | | | 669 | | | | | | **669** |
| Total | 7688 | 300 | 600 | 200 | 120 | 600 | 200 | 250 | 669 | 500 | 200 | 150 | 70 | 400 | 11947 |

**Table 2: Planned number of patients in the comparison group**

| Pathology | New pilots funded by ICT PSP | | | | | New pilots funded from other sources | | | | | Existing Renewing Health partners | | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Scotland (UK) - Scenario 1 | Basque Country (ES) | Wales (UK) | Southern Norway (NO) | Northwest Moravia (CZ) | Slovenia (SL) | Campania (IT) | Calabria (IT) | Nord Pas De Calais (FR) | Galicia (ES) | North. Norway | South Karelia | Central Greece | Berlin | |
| DM | 1200 | | 400 | | 40 | 400 | 200 | 125 | | | | 100 | 70 | 250 | **3585** |
| COPD | 670 | | 200 | 85 | | | | | | 500 | 50 | | | 80 | **1985** |
| CHF | 536 | 300 | | | 80 | 200 | | | | | | | | | **1516** |
| HTN | | | | | | | | | 0 | | | | | | **0** |
| Total | 2406 | 300 | 600 | 85 | 120 | 600 | 200 | 125 | 0 | 500 | 50 | 100 | 70 | 330 | 7086 |

# 3.     Status of recruitment

The enrolment of patients in the intervention group was originally planned to start between 1st November 2013 and 31st January 2014 according to site capability. The plan was also to continue until 1st April 2015, or until the target population was recruited.

However, due to the fact that the development of a common protocol took much longer than expected, and because of technical issues and delays in the procurement of the necessary equipment, the start of the recruitment has in practice been significantly delayed in most of the deployment sites.

The status of recruitment at M23 (November 2014) and M27 (March 2015) is described in the tables below.

## 3.1     Recruitment overview at M23

As the tables show, 34% of the telemedicine patients were recruited in November 2014. Some regions, Slovenia, Calabria, Central Greece and Berlin, have recruited more than 60% of the patients, but others lag considerably behind. There is also some variation among the pathologies, since 37% of the diabetes patients are included, but only 13% of the patients with chronic heart failure are included.

**Table 3: Number of telemedicine patients recruited at M23**

| Pathology | New pilots funded by ICT PSP | | | | | New pilots funded from other sources | | | | | Existing RENEWING HEALTH partners | | | | Total |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Scotland (UK) | Basque Country (ES) | Wales (UK) | Southern Norway (NO) | Northwest Moravia (CZ) | Slovenia (SL) | Campania (IT) | Calabria (IT) | Nord Pas De Calais (FR) | Galicia (ES) | North. Norway | South Karelia | Central Greece | Berlin | |
| DM | 1744 | | 102 | | 14 | 334 | 0 | 206 | | | | 50 | 45 | 272 | **2767** |
| COPD | 26 | | 48 | 27 | | | | | | 220 | 2 | | | 85 | **408** |
| CHF | 53 | 33 | | | 39 | 117 | | | | | | | | | **242** |
| HTN | | | | | | | | | 669 | | | | | | **669** |
| **Total** | 1823 | 33 | 150 | 27 | 53 | 451 | 0 | 206 | 669 | 220 | 2 | 50 | 45 | 357 | 4086 |
| **% Target** | 24% | 11% | 25% | 14% | 44% | 75% | 0% | 82% | 100% | 44% | 0% | 33% | 64% | 89% | **35%** |

In the comparison group, 1.060 patients have been enrolled, corresponding to 15%. However, this is only a minor problem, since data on patients in the comparison group are available in the local databases and registers, and just need to be collected and inserted into the central database of the project. (The central database is described in deliverables D3.2 and D3.3).

**Table 4: Number of patients enrolled in the comparison group at M23**

| Pathology | New pilots funded by ICT PSP | | | | | New pilots funded from other sources | | | | | Existing RENEWING HEALTH partners | | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Scotland (UK) | Basque Country (ES) | Wales (UK) | Southern Norway (NO) | Northwest Moravia (CZ) | Slovenia (SL) | Campania (IT) | Calabria (IT) | Nord Pas De Calais (FR) | Galicia (ES) | North. Norway | South Karelia | Central Greece | Berlin | |
| DM | 0 | | 20 | | 0 | 158 | 0 | 103 | | | | | | 220 | **501** |
| COPD | 26 | | 74 | 0 | | | | | | 220 | 2 | | | 70 | **392** |
| CHF | 6 | 51 | | | 0 | 110 | | | | | | | | | **167** |
| Total | 32 | 51 | 94 | 0 | 0 | 268 | 0 | 103 | 0 | 220 | 2 | 0 | 0 | 290 | **1060** |

## 3.2 Recruitment overview at M27

The table below provides the updated patient recruitment figures following the revision to the scientific protocol and additional recruitment strategies collated and shared between deployment sites.

**Table 5: Number of telemedicine patients recruited at M27**

| Pathology | New pilots funded by ICT PSP | | | | | | New pilots funded from other sources | | | | Existing RENEWING HEALTH partners | | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Scotland (UK) | Basque Country (ES) | Wales (UK) | Southern Norway (NO) | Northwest Moravia (CZ) | Slovenia (SL) | Campania (IT) | Calabria (IT) | Nord Pas De Calais (FR) | Galicia (ES) | North. Norway | South Karelia | Central Greece | Berlin | |
| DM | 65/2400 | | 123 | | 21 | 300 | 10 | 232 | | | | 50 | 62 | 295 | **3558** |
| COPD | 128 | | 79 | 60 | | | | | | 332 | 4 | | | 92 | **695** |
| CHF | 88 | 73 | | | 44 | 117 | | | | | | | | | **322** |
| HTN | | | | | | | | | 669 | | | | | | **669** |
| Total | 2681 | 73 | 202 | 60 | 65 | 417 | 10 | 232 | 669 | 332 | 4 | 50 | 62 | 387 | **5244** |

From M23 to M27, the project has increased the recruitment by 1.158 patients to 44% of total target.

# 4. Reasons for lack of recruitment

The problems with recruitment of patients were the main focus of the Project Assembly in Cosenza in October 2014. For instance, several sites reported in advance of the meeting that recruitment for COPD service was difficult due to the acute and vulnerable condition of the patients during an admission to hospital for exacerbation. Consequently, project management organised a presentation and discussion with a COPD telemedicine nurse from Region of Southern Denmark in order to understand their approach to recruitment, as it was understood that they had very high participation from their patients during Renewing Health and in the subsequent operation of the COPD telemedicine service they offer at OUH Odense University Hospital and Svendborg Hospital. In addition, special sessions at the meeting were arranged with the purpose of discussing just the recruitment situation and problems at the Assembly.

At the Assembly, a number of reasons were presented by the deployment sites. In many of the regions, the inclusion criteria of the protocol (D3.1) were considered a main obstacle, because many of the patients screened did not fulfil all criteria, and therefore were not included. Again, it was also reported as a problem to recruit patients during an admission for exacerbation for the COPD service, as specified by the protocol; the refusal to participate rate was high.

Other reasons for the lack of or slow pace of recruitment are summarised in the table below. As the table shows, technical problems have been the reason for the problems in Scotland and the Basque Country. In Scotland, lack of funding has also been a problem for a wider use of the telemedicine services, as they are aiming for system-wide and transformational change through sustainable telehealth solutions. Considering the size of these sites' share of the total recruitment target, their delay and slow recruitment has an evident impact on the overall project numbers.

In Wales, Northwest Moravia and South Karelia, the problem has been a lack of engagement by the doctors and nurses, who in practice were asked to recruit the patients. In other regions, the problems have been delay in implementation due to a much more complicated process of procurement than expected. Finally some regions have reported that a large percentage of the patients refused to use the telemedicine services they were offered.

**Table 6: Additional reasons for low level of recruitment**

|  | **Diabetes** | **COPD** | **CHF** |
|---|---|---|---|
| **Scotland** | Delays in development of software for integration between monitoring devices and SCI-DC. | Lack of sufficient funding for telehealth technology in relation to target numbers. | Lack of sufficient funding for telehealth technology in relation to target numbers. |
| **Basque Country** | ///// | ///// | Delay in integration of telehealth data into EHR. |
| **Wales** | Poor GP practice participation. | Recruitment of inpatients proving to be problematic due to acuity of patient and medical ward staff turnover. | ///// |
| **Southern Norway** | ///// | Late implementation of the telehealth service. | ///// |

| | Diabetes | COPD | CHF |
|---|---|---|---|
| **Northwest Moravia** | Delay in implementation of telehealth service has resulted in doctors being reluctant to recruit patients. Some patients are not able to use the touch-screen telehealth devices. | ///// | Delay in implementation of telehealth service has resulted in doctors being reluctant to recruit patients. Some patients are not able to use the touch-screen telehealth devices. |
| **Slovenia** | No problems with recruitment. | ///// | No problems with recruitment. |
| **Campania** | Due to local organisational problems, recruitment has not been initiated. | ///// | ///// |
| **Calabria** | No problems with recruitment. | ///// | ///// |
| **Galicia** | ///// | Delay in implementation. | ///// |
| **North Norway** | ///// | Delay in implementation. | ///// |
| **South Karelia** | Poor interest by nurses upon whom recruitment is dependent. | ///// | ///// |
| **Central Greece** | No problems with recruitment. | ///// | ///// |
| **Berlin** | No problems with recruitment. | No problems with recruitment. | ///// |

**Note**: the situation and reasons listed in Table 6 are based on the discussion and feedback received in Cosenza, October 2014. It therefore does not necessarily reflect the situation at the year end or Y2 review date.

# 5.    Recruitment enhancing measures to date

Over the course of Y2 of the project, various measures have been taken at overall project level to enhance recruitment. The table below shows what the actions were taken and what the outcome has been seen to date.

**Table 7: Recruitment enhancing measures done at overall project level to date**

| Action | Level | Outcome |
|---|---|---|
| Overview/status of recruitment<br><br>Collecting recruitment projectory figures from all deployment sites to assess scale of the delay / recruitment problem. Sites were asked to indicate forecast recruitment figures based on:<br>- timeframe for recruitment as per protocol (D3.1) and original project lifetime (M36)<br>- with additional six months to recruit in (M42)<br>- with additional twelve months to recruit in (M48) | Consortium | Assessment of status against original target, extent of delay, and possible time needed to complete targets, which project management team could use to discuss contingency actions with local sites and possible extension needed to reach the numbers.<br><br>As many sites were very delayed, and recruitment started late, this was done at different stages (summer '14 and winter '14/15) in order to account for recruitment problems once live as well. |
| Sharing of lessons learned<br><br>Facilitating lessons learned on recruitment, actions taken to overcome obstacles, and solutions implemented to enhance recruitment between deployment sites through e.g. Midterm Workshop, Project Assemblies and meetings. | Consortium | Deployment sites have oversight of which actions others have taken to overcome challenges, and assess if appropriate / possible for them or not. |
| Project Management resources<br><br>Increased project management resources, as new project manager from HIM SA (responsible for operational project management) has taken post. | Consortium | Closer contact with deployment sites in order to monitor status and discuss problems and solutions at both local level and across sites. Transfer of local deployment site measures has taken place through one2one conversations with project manager and deployment site representatives. |
| Review of protocols<br><br>Based on discussion of experiences and lessons learned from deployment sites, elements of the protocols that were seen to make recruitment difficult and slow were opened up for discussion and mutual agreement on changes (deployment sites and scientific committees approval). | Consortium | Has increased recruitment for COPD, as it is now possible to recruit patients up to seven days after their admission, meaning they are not in such an acute and vulnerable condition as during admission. Recruitment has picked up since this change was introduced. |

| | | |
|---|---|---|
| Clinical dissemination and involvement<br><br>Through dissemination and communication, different efforts have been made to raise awareness and involve clinicians both in local activities as well as general discussions on telehealth at European level | Consortium | Clinical disengagement has been a problem; raising awareness of telemedicine / telehealth can support the wider domain across Europe. E.g. U4H had a dedicated session at the European Congress on e-Cardiology & e-Health (29-31 October, 2014).<br><br>Through the UPAB, the project is able to involve at policy level key clinical associations and federations. |
| | Deployment site | At local level, e.g. Scotland has put in place a contractual framework for clinical lead across all sites in Scotland for each pathology, setting conditions, funding, etc, so that the clinical lead is able to prioritise the work and is free from regular commitments to attend to U4H tasks across multiple deployment sites in Scotland. |
| | Deployment site | Wales has struggled with GP engagement despite efforts to inform and engage. Posters in GP offices have been set up to encourage patients themselves to inquire about the service, and also information about service presented at different GP and nurse forums. |
| Additional recruitment sources | Deployment site | In the Basque Country, an additional site has been brought in, which has enhanced recruitment. Also Wales has engaged additional hospitals (from 1 to 4). |
| Ensuring sufficient funding | Deployment site | Telehealth equipment, maintenance and etc is still relatively expensive, especially at large scale. Scotland's ambitions for deployment through U4H (>7000 patients) has proven only to be achievable through substantial additional funding from other sources. Through the national Technology Enabled Care (TEC) Programme, the seven U4H sites in Scotland have obtained funding to help support its U4H goals. |

# 6. Conclusion

As described in the protocol (deliverable D3.1 version 1.5), it was planned to recruit 11.947 patients in the telemedicine group and 7.086 patients in the comparison group.

In November 2014, the number of recruited telemedicine patients was 4.086 or 34% of the planned sample. In the comparison group 1.060 or 15% was enrolled.

The main reasons for the low rate of recruitment are technical problems, lack of engagement from the doctor and nurses who do the recruitment, funding problems and strict inclusion criteria.

Locally and at project level, measures were taken to enhance recruitment. In a four month period, from November 2014 to March 2015, recruitment went up by 1.158 patients to 44% of total target.