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Acronym	BabyLux
Project n.	620996

D 5.4 REPORT ON TRAINING OF END-USERS

Work Package	WP5
Lead Partner	IRCCS Ca’ Granda (9 IRCCS)
Contributing Partner(s)	1 PoliMi, 3 ICFO, 5 HP, 8 Rh-Neo, 9 IRCCS Ca' Granda.
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Document history

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1. Executive Summary

The aim of this deliverable is to describe the training of clinical partners in using the two BabyLux demonstrator devices.

The delay in training sessions is attributed to the delay in device delivery to the hospitals.

Training sessions were differentiated according to different types of end users with different expectations: 1. Doctors and nurses of the Neonatal Unit involved in the project (8 Rh-Neo and 9 Ca' Granda); 2. project staff end-users.

In section 2, the description of the different types of training are presented.

Section 3 describes additional activities performed at 9 IRCCS Ca' Granda using existing solutions to improve practical and theoretical knowledge preparatory to BabyLux technology.

In section 4 main feed-back from end-users have been summarized.

A conclusion for the future work is given in section 5.

2. Training session for clinical end-users

We have differentiated two types of end-users according to different expectations and needs.

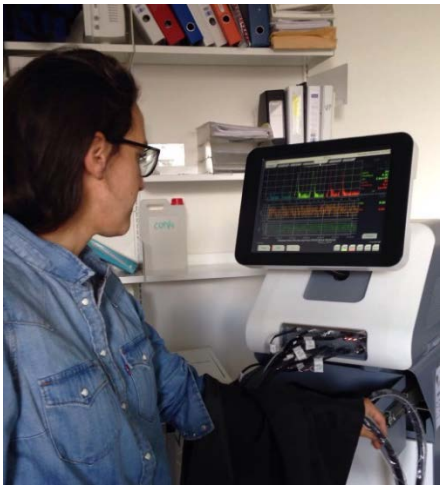
2.1. Doctors and nurses of the Neonatal Unit involved in the project.

Educational material for lectures addressed to both doctors and nurses have been prepared. Lecturers covered basis of neonatal cerebral oxygenation, physical principles of the BabyLux solution, its safety measures and functioning, advantages to other commercial oximetry devices; all the materials were shared between the two clinical partners. Partners 1 PoliMi, 3 ICFO, 5 HP gave a substantial contribution providing the material for the comprehension of physical basis of TRS and DCS systems; it was done in the clearest way, as many doctors and nurses are not aware of spectroscopy applied to neonates.

2.2. Project staff end-users.

Site investigators from the clinical partners (8 Rh Neo and 9 IRCCS Ca' Granda) had trained with the first and the second demonstrator in Copenhagen and in Milan at M30 and M32 respectively.

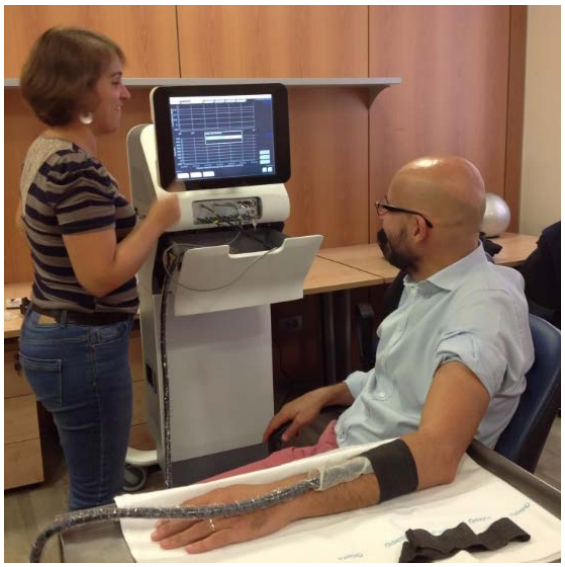
a. The first demonstrator arrived in Copenhagen at M30. The training focused on practical handling and operation of the BabyLux device and performed the first measurements in newborn infants supported by the staff of 3 ICFO (Fig. 1-3). Two investigators from Milan came to Copenhagen for few days at M30. A main objective was to insure homogeneous acquisition of data and to use the same solutions to solve challenges mainly with the software and the probe in their current configuration at M30 through creation of standard operation procedures for performing measurements. Safety instructions were repeated for clinical staff involved in measurements on newborns.



Figures 1-3. Training for end-users in Copenhagen at M30.

b. The second demonstrator arrived in Milan at M32. The clinical partners were trained with support from partner 3 ICFO and 1 PoliMi (Fig. 4-5). The software of the second device has been updated with minimal changes compared to the first device. For this reason standard operation procedures for performing measurement were updated. Clinicians searched for the best solution to ensure newborn skin protection; instructions for preparation of the probe (based on the use of a ultrasound cover and ultrathin hydrocolloid dressing) were shared between the two clinical partners. In Milan all preliminary measurements were performed together with staff of 1 PoliMi. Safety instructions were repeated for clinical staff involved in measurements on newborns, in particular obstetricians, nurses and midwives.

Probe preparation for measurement on newborn babies



Figures 4-5. Training for end-users in Milan at M32.

Additional activities started in Milan at M23 and were prolonged throughout Y3 with the purpose of training doctors and nurses in cerebral monitoring (NIRS and aEEG)

of preterm and term newborns in Neonatal Intensive Care Unit. Neuro-monitoring of newborn infants is not a standard of care in the NICU of Fondazione Ca' Granda and for that reason we decided to improve NICU operators training, starting from the existing solutions. Doctors and nurses used standard NIRS (INVOS) and amplitude-integrated EEG to raise awareness of cerebral events and to get used to handle neonatal head with the most experience and care. Moreover, the use of INVOS helped the NICU staff to better understand the rationale and the aim of BabyLux technology. Until M32 practical activities were done only with existing devices for brain monitoring due to the unavailability of BabyLux devices in hospital (Figures 6-7).

Figures 6-7. Practical activities for small group in Milan at M25 (existing solutions).

In order to improve compliance of clinicians to Good Clinical Practice (GCP), a GCP course was organized in Milan at M27 on ISO14155 and Italian Statement on clinical research with medical devices.

3. Feedback from the clinical end-users:

From the beginning of the study, engineers and manufacturers get end-users involved in the comprehension of BabyLux technology and its practical application. NICU staff was involved and clinical staff accepted the study with interest.

The functioning of the device resulted to be intuitive: it has a quite lasting battery and an easy touch screen. BabyLux is a self-standing and transportable device and the probe seemed quite long to reach the patient in a cot in a comfortable way.

However, during the period of training, BabyLux devices showed also some manufacturing defects. (of the software, of the capable sensor, of the probe and the laser itself). Therefore, the training was stopped many times for fine tuning of the device and in order to look for new solutions together with manufacturers and engineers.

For this reason, clinicians could never work without the support of engineers; working together, they found the solutions for most of the problems and became ready to get safe and good-quality measurements.

Moreover, clinicians involved in the project were able to check the quality of the signal while measuring in order to optimize data acquisition.

5. Conclusions and future work

In conclusion:

- Doctors and nurses of both hospitals have learnt theoretical and practical basis of BabyLux technology, they know the aim of the study and the details of clinical settings.

- Staff end-users became confident with the device and able to get measurements. Despite this, they still need the support of engineers (3 ICFO at 8 RHNeo and 1 PoliMi at 9 IRCCS) to find solutions to sudden device problems and for the interpretation of the data.

Next steps are:

- To increase the number of doctors able to use the device;

- To use the experience in training to guide the manufacturers for ameliorating the friendliness of the device.