

STUDY PROTOCOL

Official Title: COLLUTIC_25 – Interprofessional Collaboration in the Cardiac Intensive Care Unit (CICU): An Action-Research Training Project

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1. Introduction

1.2 Background and rationale

Interprofessional collaboration is a crucial factor for improving quality of care, patient safety and organisational efficiency, especially in highly complex clinical-care settings such as Cardiac Intensive Care Units (CICUs/UTICs). However, although the scientific literature acknowledges the benefits of interprofessional education (IPE), it also highlights a lack of structured, validated and transferable educational models for daily clinical practice in these settings.

Systematic reviews and preliminary studies indicate that interventions based on active methodologies—such as simulation and situated learning—can improve communication between professionals, understanding of roles, mutual trust and shared decision-making, with a positive impact on the reduction of clinical errors and an improvement in interprofessional collaboration. Conversely, a lack of interprofessional cooperation is associated with preventable adverse events, poor quality of care and low job satisfaction among healthcare workers.

In response to these critical issues, the proposed study aims to develop, implement and evaluate an innovative educational model to foster interprofessional collaboration among healthcare professionals, built according to an action-research approach and integrated with digital tools to facilitate situated learning and the standardisation of contents.

The research question guiding the study is:

Can a structured interprofessional training programme based on active methodologies improve collaboration among healthcare professionals working in CICU/UTIC settings and contribute to measurable professional and care-related outcomes?

1.3 Research hypothesis

A structured training programme based on action research is more effective than traditional training in improving collaboration among healthcare professionals working in Cardiac Intensive Care Units (UTICs), including physicians, nurses, healthcare assistants (OSS), students and newly hired staff.

1.4 Objectives

1.4.1 Primary objective

To assess the effectiveness of an interprofessional training pathway with an action-research approach in improving, among healthcare professionals working in the CICU/UTIC:

- perception of interprofessional collaboration
- collaborative attitudes
- involvement in shared decision-making
- self-efficacy
- team and professional commitment

1.4.2 Secondary objectives

- To compare over time (T0, T1, 6-month follow-up) the trend of the target variables (collaboration, decision-making, team and professional commitment, self-efficacy).

- To explore potential relationships between socio-demographic variables (age, profession, years of service, gender, academic degree) and educational outcomes.
- To describe the experience of the training pathway from the perspective of students and newly hired staff involved in the project.

1.5 Study design

The study design is longitudinal and prospective and provides for the evaluation of the effectiveness of an interprofessional training pathway through three assessment points: before the intervention (T0), immediately after completion of the programme (T1) and six months later (T2). The evaluation will be carried out exclusively on healthcare professionals who have completed the training and are still working in the unit at the time of the six-month follow-up.

The intervention consists of a training programme specifically designed to improve collaboration among healthcare professionals working in Cardiac Intensive Care Units (UTICs), using active and context-based methodologies.

At each time point the same indicators are collected, including perception of collaboration, attitude towards collaboration, decision-making, team and professional commitment, and self-efficacy. These dimensions constitute the primary outcomes of the intervention and are observed to measure the evolution over time of behaviour and professional perceptions of the staff involved.

The design also takes into account several socio-demographic and professional variables—such as age, gender, years of service, professional role and previous participation in courses on collaboration—that may influence the impact of the training pathway. For students, the degree course (medicine or nursing) and academic year are also recorded. These factors are collected at baseline (T0) and will be used for possible subgroup or adjusted analyses.

Before the start of the training pathway, a detailed guide on how to access the platform will be distributed.

Overall, the design aims to assess not only the immediate effectiveness of the training path but also its sustainability over time, by observing changes in professional behaviours and attitudes six months after the intervention.

2. Methodology: participants, interventions and endpoints

2.1 Study setting

The study will be conducted in the Cardiac Intensive Care Unit (UTIC) of the University Hospital (AOU) of Parma, a highly specialised public teaching hospital integrated with the University of Parma and located in the Emilia-Romagna region, Italy.

The UTIC of the AOU Parma is a high-intensity care setting characterised by multidisciplinary and continuous management of critically ill patients with acute cardiovascular diseases (e.g. acute myocardial infarction, decompensated heart failure, severe arrhythmias). In this context, different professionals work in an integrated way: cardiologists (clinicians, interventional cardiologists, electrophysiologists), nurses, healthcare assistants (OSS), physiotherapists, pharmacists, university students and newly hired staff, whose interprofessional interaction is crucial for quality of care.

2.2 Eligibility criteria

2.2.1 Inclusion criteria

Participants meeting all of the following criteria will be included in the study:

- Healthcare professionals (physicians, nurses and healthcare assistants/OSS) employed in the Cardiac Intensive Care Unit (UTIC) of the University Hospital of Parma.
- Healthcare professionals who have completed the training pathway and are still working in the unit at the time of the six-month follow-up.
- Medical and nursing students who have carried out or are carrying out a clinical placement within the UTIC.
- Ability to use a computer or mobile device, essential for participating in the online training activities (e.g. Moodle, H5P).
- Provision of written informed consent before initiation of any study procedure.

2.2.2 Exclusion criteria

Participants meeting one or more of the following criteria will be excluded from the study:

- Healthcare professionals who do not work in the cardiology setting or who are not employed in the UTIC of the AOU Parma.
- Inability to participate in the training activities or assessment sessions for logistical, organisational or clinical reasons (e.g. planned prolonged absences during the study period).
- Refusal or inability to provide informed consent.

No patients will be involved, as simulations will be conducted with the healthcare professionals participating in the study, after obtaining their consent to take part.

2.3 Interventions

2.3.1 Experimental intervention – Training phase

The training phase of the project consists of an interactive course aimed at healthcare professionals (physicians, nurses and OSS) to improve their ability to recognise and enact effective collaborative practices. Learning is based on the use of **branching scenarios**, created with the H5P software. This approach enables learners to distinguish correct practices and refine their teamwork skills. The course also provides access to additional content on techniques and procedures specific to the UTIC context, curated by expert professionals.

Branching scenarios – Learning scenarios

The branching scenarios reproduce complex and frequent clinical situations that challenge interprofessional collaboration. Each scenario has been designed with particular attention to clinical and organisational details, including:

- the clinical history of the simulated patient and their clinical pathway in the cath-lab and electrophysiology unit, in preparation for a TAVI procedure, with a diagnosis of heart failure (Annex 1);
- vital signs and diagnostic tests;
- available resources;
- clinical objectives and potential critical points.

The structure of each scenario includes:

- definition of a storyline and of the role of the professional involved;
- division into key phases, with information and possible actions, and the related consequences;
- interactive elements that enable the learner to make decisions and interact with characters or objects in the scenario;
- meaningful feedback guiding the learning process;
- multiple paths for a dynamic experience;
- assessment criteria based on the correctness of the responses.

For validation and revision of these scenarios, a team of content experts and educationalists was involved to verify the accuracy, relevance and effectiveness of the material. Pilot tests with sample users were also carried out to collect feedback on usability and clarity, and the necessary modifications were implemented.

Four training pathways are planned, each lasting six months:

1. Cath-lab pathway
2. Electrophysiology pathway
3. Heart failure pathway
4. TAVI pathway

For further details on the structure of the pathways, see Annex 8 “Pathway Sheets”.

Platform and technical implementation

For the management of contents and simulations, the **Moodle Self-PA** platform has been chosen. This platform, specifically designed for the Emilia-Romagna Regional Federation, is an online learning environment dedicated to the continuing education of public administration professionals in the region.

The Federated Regional Moodle Self-PA Emilia-Romagna represents a key resource for strengthening the skills and knowledge needed to face the challenges of the public sector. Thanks to its flexibility and numerous features, it is an effective tool to promote a culture of learning and professional development within the region.

Professionals will be trained to make the best use of the platform’s potential, using interactive tools such as Lessons, Quizzes, Forums, Wikis and SCORM packages. To manage more complex interactions, branching scenarios and virtual tours created with H5P and integrated directly into Moodle will be used.

The technical implementation of the Moodle platform has included:

- configuration of SCORM packages;
- uploading of teaching materials;
- definition of navigation and assessment rules.

Extensive testing was conducted to ensure proper platform functioning, optimal display of contents, consistency of narrative flow and accurate recording of learners’ data.

Documentation and learner guide

A comprehensive documentation set has been produced, including a detailed guide for learners. This guide provides clear instructions on how to use the scenarios, explains the learning objectives and describes the assessment methods (Annex 2). The guide will be distributed before the beginning of the training pathway.

2.4 Endpoints

Description of endpoints, instruments, measurement units and frequency

- **Attitudes towards interprofessional collaboration**
 - Instrument: *Jefferson Scale of Attitudes toward Physician–Nurse Collaborative Relationships (JSAPNC)*.
 - The instrument consists of 5 dimensions: (1) shared education, (2) teamwork, (3) caring vs. curing, (4) nurse autonomy, (5) physician autonomy. It includes 15 items on a 4-point Likert scale from 1 = “strongly agree” to 4 = “strongly disagree”.
- **Perception of collaboration**
 - Instrument: *Nurse–Physician Collaboration Scale (NPCS)*.
 - The scale consists of 3 dimensions: (1) joint participation in the care-related decision-making process; (2) sharing of patient-related information; (3) cooperativeness. It includes 20 items on a 5-point Likert scale (1 = always, 2 = usually, 3 = sometimes, 4 = rarely, 5 = never).
- **Decision-making**
 - Instrument: *Collaboration and Satisfaction with Care Decisions (CSACD)*.
 - The tool measures collaboration between physicians and nurses in decision-making about patient care in relation to a specific patient. It consists of 8 items: the first seven measure interaction, and the last measures satisfaction with the decision-making process, on a 5-point Likert scale from “strongly disagree” to “strongly agree”.
- **Team and professional commitment**
 - Instrument based on items adapted from Ellemers et al. (1995), Cadinu & Reggiori (2002) and Le Blanc et al. (2010).
 - Total of 17 items: 12 items for **professional commitment** (e.g. “In general, I am happy to be part of my professional category”) and 5 items for **team commitment** (e.g. “I am satisfied to be a member of this unit/team”), on a 5-point Likert scale from 1 = strongly disagree to 5 = strongly agree.
- **Self-efficacy**
 - Instrument: “Personal accomplishment” subscale of the *Maslach Burnout Inventory (MBI)*, Italian adaptation by Vanin & Castelli (2003) and Sirigatti & Stefanile (1993), based on Maslach & Jackson (1981).
 - Composed of 5 items evaluating perceived competence and personal accomplishment at work, using a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). Example item: “I feel very competent in my work.”

Data collection for these endpoints will occur at three time points: before the start of the training (T0), at the end of the training (T1), and six months after completion of the programme (T2).

2.5 Study duration

The study will start after approval of this protocol by the Ethics Committee and authorisation by the Directorate of Health Professions, and will continue for 24 months.

2.6 Sample size

A convenience sample will be used, consisting of professionals who agree to participate in the training process (planned: physicians: 5; nurses: 30; OSS: 8; nursing students: 5; medical students: 5).

2.7 Recruitment

On the training days, the Principal Investigator or a delegate will present the project and request informed consent from physicians, nurses, OSS, medical students and nursing students affiliated with the UTIC of the University Hospital of Parma.

3. Methodology: data collection, management and analysis

3.1 Data collection

Data collection will take place at three distinct time points for each participating healthcare professional. Data will be collected via the Moodle Self-PA platform, after each participant has provided informed consent. Before accessing the platform, the information sheet and consent form will be provided. Subsequently, the professional will be able to access the questionnaire through the link provided. At the end of the questionnaire, a code will be requested for cross-matching, which must be generated as follows: initial of the mother's first name, mother's year of birth in four-digit format, and participant's own year of birth, also in four-digit format. Assessments will be carried out in three phases: before the start of the training pathway, at the end of the training and six months after completion of the pathway. The first assessment (T0) will take place before the start of the training event, the second (T1) at the end, and the third (T2) six months after the conclusion of the training event. The instruments used for attitudes, perception of collaboration, decision-making, team/professional commitment and self-efficacy are those described in section 7.4. Before starting the study, adequate training on the use of the scales and instruments will be provided to the assessors. The data sheets generated via the dedicated Moodle platform, accessible only to professionals participating in the study, will then be processed. These pseudo-anonymised data will be accessible exclusively to the Principal Investigator and their delegates and will be stored on a password-protected personal computer of the University Hospital of Parma. In case of a data breach, the folder path will be changed and the members of the study team indicated in the protocol will be asked to change their password.

3.2 Data analysis

- **Reliability and validity:** At T0, T1 and T2 Cronbach's alpha and McDonald's omega will be calculated for each (sub)scale. Where appropriate, the factor structure will be confirmed through confirmatory factor analysis (CFA) with assessment of measurement invariance (configural → metric → scalar) prior to longitudinal comparison.
- **Data preparation and quality:** data cleaning, coding, reverse-scoring of items; exploration of missing data, outliers and distributions (histograms, Q-Q plots); inspection of floor and ceiling effects; documentation of the data dictionary.
- **Descriptive analysis and responsiveness:** descriptive statistics for T0, T1 and T2 (mean, SD, median, IQR) for total and subscale scores. Suggested graphs: spaghetti plots (individual trajectories), box/violin plots and mean lines with 95% CI over time. Responsiveness to change: calculation of Cohen's d (T1–T0; T2–T0; T2–T1) and Standardized Response Mean (SRM) as indices of change, with interpretation according to literature conventions; where possible, definition/search of MCID.
- **Main analysis – Linear mixed models (LMMs):** For each outcome, a linear mixed model will be used with time as a within-subject factor.
 - Dependent variable: continuous outcome score.
 - Fixed effects: Time (T0 as reference; levels T1, T2).
 - Random effects: random intercept for participant; if data allow, random slope for Time.
 - Covariance structure: unstructured or AR(1) for equally spaced measures; REML estimation.
 - Planned contrasts: T1–T0 (immediate effect), T2–T0 (maintenance), T2–T1 (decay/maintenance).
 - Effect measures: standardised β , marginal and conditional R^2 ; conversion to d from LMM estimates with 95% CIs.

- Assumptions/diagnostics: normality of residuals and homoscedasticity; graphical inspection and robust tests in case of violations.
- Covariates (recommended): age, seniority, profile (physician, nurse, OSS, student/new hire), concurrent educational exposures.
- Interactions: Time × Profile; Time × Seniority, to analyse differential impacts.
- Clustering: if relevant (e.g. shifts/teams), addition of a group-level random effect.

3.3 Data protection and confidentiality

Data will initially be collected using paper forms (see annex) and then entered into an electronic database by the PI or a delegate. The electronic quantitative data file will be accessible only to the Promoter and their delegates and stored on password-protected company computers. Data will be pseudo-anonymised. In the event of a confirmed breach, the folder path will be changed and the members of the study group indicated in the protocol will be asked to change their password.

4. Monitoring

Quality monitoring of the study, given that the promoter is the University Hospital of Parma itself, will be carried out by the Quality Assurance (QA) unit, part of the Clinical and Epidemiological Research Unit, as specified in the Clinical Monitoring Regulation (protocol no. 0024107 of 04/06/2024).

5. Ethical considerations and communications

Informed consent will be obtained from all healthcare professionals involved, including medical and nursing students, in accordance with current regulations. For this research protocol and its related informed consent documents, a request for approval will be submitted to the local Ethics Committee in order to verify scientific adequacy and full compliance with ethical and research regulations protecting participants.

5.1 Ethical approval and study start

The study will be conducted in accordance with this protocol and will start only after Ethics Committee approval and subsequent authorisation by the General Directorate. Health Professions Directorate will be informed before the beginning of the study. Data for research purposes will be collected on a voluntary basis.

5.2 Gantt chart

The protocol includes a Gantt chart (page 21 of the original document) detailing responsibilities and estimated duration for all phases: drafting of the protocol, ethics approval, scenario development and validation, Moodle platform development and testing, recruitment and consent, data collection at T0–T1–T2, training delivery, data digitisation and analysis, quality monitoring, report writing and dissemination of results over a 24-month period.

5.3 Protocol amendments

Any modifications to this protocol will be promptly communicated by the PI to the Ethics Committee and to the participants.

5.4 Informed consent

Informed consent will be obtained by the PI or a delegate when healthcare professionals and medical/nursing students first enter the UTIC unit.

5.5 Confidentiality

Data collection sheets, initially in paper format, will subsequently be digitised and will be accessible only to the PI and delegates, stored on password-protected computers of the University Hospital of Parma. Paper forms will be destroyed after digitalisation.

Data will be pseudo-anonymised. In the event of a confirmed breach, the folder path will be changed and the study team members listed in the protocol will be asked to change their password.

5.6 Conflict of interest

Members of the research group declare that they have no conflicts of interest or financial interests of any kind related to this protocol.

5.7 Data access

Access to the study data will be strictly limited to the Principal Investigator and their delegates. Data will be anonymised before analysis. Anonymised raw data will be stored in a secure database on a server of the University Hospital of Parma, protected by password and accessible only to the Principal Investigator and their delegates.

5.8 Dissemination policy

At the end of the study, the research group will assess the most appropriate modes of dissemination of the results. In particular, publication of one or more articles in peer-reviewed journals will be considered. In addition, the organisation of a dedicated educational event for professionals internal and external to the University Hospital and the University of Parma will be evaluated, with the aim of sharing the evidence produced and promoting a culture of interprofessional collaboration in CICU/UTIC settings.

5.9 Expected results / Impact of the study

The success of this project will be evaluated based on the effectiveness of the training intervention on the perception of collaboration and attitudes towards teamwork.

The following results are hypothesised at the end of the intervention:

- **Improved perception of collaboration:** an improvement in perceived interprofessional collaboration among the professionals involved is expected.
- **Positive change in attitudes:** an increase in mean scores on questionnaires assessing attitudes towards collaboration, reflecting a greater propensity to work jointly for the patient's benefit.
- **Increased knowledge and skills:** participants are expected to show greater awareness of the importance of interprofessional collaboration and to acquire new skills to address barriers to teamwork.
- **Development of a "community of practice":** the project is expected to foster the creation of a stable network among professionals, who will continue to exchange knowledge and collaborate even after the end of the study, consolidating a lasting culture of collaboration within the UTIC.
- **Strengthening of team cohesion:** participants are expected to report increased trust and confidence in group dynamics, a greater sense of synergy in daily work and a reduction in communication inefficiencies, resulting in better interprofessional collaboration and a stronger sense of team—essential for the complex management of patients in Cardiac Intensive Care.
- **Increased professional commitment:** the experience of effective collaboration and the perception of contributing meaningfully to shared goals are expected to strengthen participants' professional

commitment, leading to higher job satisfaction and a reduction in stress and burnout factors related to communication, as well as a stronger sense of value and identification with their role within the team.

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