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# Coaching doctors and nurses to improve ethical decision-making in team: a stepped wedge cluster randomized trial in 10 departments of the Ghent University Hospital.

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Acronym / Protocol code

CODE II-study

Protocol version and date

Version 1.1 February 13, 2026

NCT number

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Coordinating Investigator:	Dominique D. BENOIT Department of Intensive Care Medicine Ghent University Hospital

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## Coaching doctors and nurses to improve ethical decision-making in team: a stepped wedge cluster randomized trial in 10 departments of the Ghent University Hospital

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### Protocol Coordinating Investigator signature page

I certify that I will conduct the study in compliance with the protocol, any amendments, GCP and the declaration of Helsinki, and all applicable regulatory requirements.

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**Date: February 13 2026**

**Signature:**

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## LIST OF ABBREVIATIONS

APPROPRICUS	=	Appropriateness of care in the ICU
CI	=	Coordinating Investigator
CODE	=	COaching Doctors and nurses in Ethical decision-making
CT	=	Clinical Trial Unit
DISPROPRICUS	=	Disproportionate care in the ICUs
DNI-DNACPR	=	Do-not-intubate and do-not attempt cardiopulmonary resuscitation
EC	=	Ethics Committee
EDMCQ	=	Ethical Decision-making Climate Questionnaire
eCRF	=	electronic Case Report Form
EDC	=	Electronic Data Capture
EPD	=	Electronic Patient Dossier
FPI	=	First Patient In
GCP	=	Good Clinical Practice
GDPR	=	General Data Protection Regulation
HIRUZ	=	Health, Innovation and Research Institute UZ Ghent
ICF	=	Informed Consent Form
ICU	=	Intensive Care Unit
LVLS	=	Last Visit, Last Subject
PI	=	Principal Investigator

## 1. Protocol Summary

### 1.1. Title

Coaching doctors and nurses to improve ethical decision-making in team: a stepped wedge cluster randomized trial in 10 departments of the Ghent University Hospital

### 1.2. Protocol specifics

EudraCT number : NA

Sponsor : Ghent University Hospital

### 1.3. Study Type and Study Phase

Stepped wedge cluster randomized study

### 1.4. Aim of the study (including primary endpoints)

The aim of this study is to investigate whether coaching doctors and nurses to enhance ethical decision-making in team during 4 months improves 1) goal-oriented care operationalized via written do-not-intubate and do-not attempt cardiopulmonary resuscitation (DNI-DNACPR) orders in patients potentially receiving excessive treatment during their first hospitalization (first primary objective) and 2) the quality of the ethical climate (second primary objective). Secondary endpoints aims at assessing whether the intervention reduces the burden on patients potentially receiving excessive treatment and their family, clinicians (doctors, nurses and allied health professionals) and the society.

### 1.5. Subjects

- Head of the Department
- Junior and senior doctors
- Nurses and head nurses
- Allied health professionals (psychologists, physical therapists, speech therapists, occupational therapists, social workers, spiritual care providers)
- Patients potentially receiving excessive treatment who did not yet receive a DNI-DNACPR order during their first hospitalization (for rating quality of care / communication and psychosocial well-being)



- Relatives of patients potentially receiving excessive treatment who did not yet receive a DNI-DNACPR order during their first hospitalization (for rating quality of care / communication and psychosocial well-being)

#### 1.5.1. Number of subjects

In total 50 to 75 junior doctors, 50 to 75 senior doctors (including medical head of department), 300 to 500 nurses (including head nurses) and 100 to 200 allied health professionals working in 10 departments of the Ghent University Hospital are eligible for this study and about 350 to 700 adult patients potentially receiving excessive treatment who did not yet receive a written DNI-DNACPR order together with one of their relatives. The participating departments are : Cardiology, Gastro-enterology and Hepatology, General Internal Medicine, Geriatrics, Hematology, Medical Oncology, Neurology, Nephrology (including dialysis unit), Pulmonology and the Medical ICU.

#### 1.5.2. Target group

All clinicians (doctors, nurses and allied health professionals) taking care of hospitalized patients in the 10 participating departments of the Ghent University Hospital are eligible for the intervention. They will be coached with regard to hospitalized patients who are perceived as receiving excessive treatment according to two or more different clinicians in the team. Excessive treatment was initially defined in the DISPROPRICUS and CODE study as treatment that is perceived to be no longer consistent with the expected survival or quality of life ("too much treatment") or that is perceived as being provided against the patient's or relatives' wishes [1-3]. This definition entails thus potentially futile, non-beneficial, inappropriate or even harmful treatments [4,5] which has been estimated to be provided to 33–38% of patients near the end-of-life [6], as well as treatments that are potentially being provided without voluntary and informed consent [4]. Based on the feedback of participants of the CODE study [3], we changed the definition in the current study to "I doubt whether the treatment or treatment limitation code is consistent with the expected survival or quality of life ("too much" or "excessive treatment") or whether the treatment or treatment limitation code is in line with the patient's or relatives' goals. Hereby, we want to reduce the fear of nurses and other health care professionals of blaming doctors [3] and subsequently increase early identification of such patients in the current study.

These patients will subsequently be included for data collection at the patient, relative and societal level. Because "patients who are perceived as receiving excessive treatment according to two or more clinicians" had a probability of surviving with a good quality of life at home at one year of 7% in the large multicenter DISPROPRICUS study [1], these patients will be systematically denominated from now on as "patients potentially receiving excessive treatment" and abbreviated as "PET" throughout the entire protocol for ease of reading.

#### 1.6. Inclusion and exclusion criteria

- doctors

## CODE II study

- inclusion: all junior and senior doctors (including medical head of department) taking care of hospitalized patients in the 10 participating departments of the Ghent University Hospital
- nurses and allied health care professionals
  - inclusion: all nurses (including the head nurses) taking care of hospitalized patients in the 10 participating departments of the Ghent University Hospital
  - inclusion: all allied health care professionals taking care of hospitalized patients in the 10 participating departments of the Ghent University Hospital
- patients and family members
  - inclusion: First hospitalization of PET hospitalized in the 10 participating departments of the Ghent University Hospital who did not yet receive a written DNI-DNACPR order.
  - exclusion:
    - being younger than 18 years old
    - not able to fill in Dutch questionnaires

### 1.7. Study Interventions

- 1) All participating health care professionals will be invited for one interactive session of approximately two hours focusing on the concepts of medical-ethical decision-making, the psychological challenge of dealing with ethically sensitive medical topics, empowering leadership and the importance of “speaking up” within the team. This session will present coaching as a support mechanism for professional development.
- 2) During the intervention coaches and clinicians in charge will be informed of the presence of a PET in their ward by an electronic alert. Every clinician will be invited to provide perceptions of excessive treatment via the EPD. Once a patient is identified by two or more different clinicians, an email will be sent to coaches and the clinicians in charge of the patient.
- 3) The coaching intervention will consist of :
  - a. Doctors and head nurses : individual coaching sessions in self-reflective and empowering leadership and in managing groups dynamics with regard to ethical decision-making in team about PET patients.
  - b. All clinicians : multidisciplinary coaching during work shift hand-overs and structured metareflective sessions on specific themes related to ethical decision-making in team about PET.

#### Focus of the individual coaching

- a) Learning to acknowledge the patient's (and relatives') subjective goals, emotions and values, and separate them from own and colleagues' subjective goals, emotions and values triggered by that situation.
- b) Learning to acknowledge patient's (and relatives'), colleagues' and own spontaneous defensive avoidance strategies in coping with difficult and aversive care-related situations, like end-of-life decisions.
- c) Learning to identify and separate internal avoidance strategies from external barriers to better delineate the responsibilities of each stakeholder in the process.

- d) Learning to cope more effectively with these internal and avoidance strategies and external barriers to enable more appropriate and timely decisions for the benefit of the patient.
- e) Learning to integrate newly acquired insights into an adapted way of thinking and relating with others to establish a sustainable effect with regards to ethical decision-making.
- f) Learning to transfer these insights into empowering leadership behavior which contributes to dialogue during the interdisciplinary meeting.

#### Focus of the team coaching

- a) Learning to acknowledge the patient's (and relatives') subjective goals, emotions and values, and separate them from own and colleagues' subjective goals, emotions and values triggered by that situation.
- b) Learning to acknowledge patient's (and relatives'), colleagues' and own spontaneous defensive avoidance strategies in coping with difficult and aversive care-related situations, like end-of-life decisions.
- c) Learning to identify and separate internal avoidance strategies from external barriers to better delineate the responsibilities of each stakeholder in the process.
- d) Learning to cope more effectively with these internal and avoidance strategies and external barriers to enable more appropriate and timely decisions for the benefit of the patient.
- e) Learning to integrate newly acquired insights into an adapted way of thinking and relating with others to establish a sustainable effect with regards to ethical decision-making.
- f) Learning to transfer these insights into self-steering participative behavior which contributes to dialogue during the interdisciplinary meeting.

#### Quality of the coaching

Coaching and supervision will be done by professionals who are certified by international standards, hold a degree in human sciences and have experience in leadership development. The independent experienced supervisor has a normative, formative and restoring role. The normative role of the supervision aims at monitoring the quality of the coaching methodology and ethical aspects with regard to the study aims. The formative role aims at supporting the coach in further developing and refining his/her skills in general and more specifically with regard to the study aims. The restorative role aims at guaranteeing the energy of the coach and at resolving potential conflicts due to emotional or unconscious dynamics in the clinical team. This will be done in collaboration with the "cell wellbeing" of the Ghent University Hospital, in line with the contracted mandate to securing the ethical boundaries of the supervision.

We refer to the appendix for the detailed methodology

- a) the methodology, used by the coaches during the intervention
- b) the quality assurance process, used during supervision
- c) the references to the international standards

### 1.7.1. Schematic overview of the data collection & interventions

#### a) Schematic overview of data collection

- Department characteristics by head nurse and medical head of department: T0 + T3
- Baseline demographic (age, years pf experience, role...) variables in clinicians (T0 + T3)
- EDMCQ by clinicians (nurses, doctors and allied health care professionals): T0 + T3.
- Daily perceptions of clinicians (nurses, doctors and allied health care professionals): daily during the 14 month study period (between T0 and T3).
- Inclusion of PETs: daily during the 14 month study period (between T0 and T3).
- Datacollection in PETs: during hospitalization (baseline demographic variables, comorbidities, admission reason Euro-QoL 5D and severity of illness, daily NRS and written DNI-DNACPR orders during admission), 3 weeks after discharge (Hospital Consumer Assessment of Health care Providers and System Instrument, Sinclair Compassion questionnaire-Short form, Euro-FS, HADS), from admission up to one year (potentially inappropriate burdensome treatments) and 1 year after hospital admission (mortality, living at home and EURO-Qol 5D) (T4).
- Datacollection in relatives of PETs : 3 weeks after discharge (Hospital Consumer Assessment of Health care Providers and System Instrument, Sinclair Compassion questionnaire-Short form, Euro-FS, HADS and Euro-QODD concerning patient who died in the ward)
- 
- Evaluation of the CODE II coaching intervention in participants via survey: T2.

T0: Pre-intervention

T1: start of the intervention period (depends on the randomization per team)

T2: end of the intervention period of 4 months (depends on the randomization per team)

T3: end of the study period of 14 months

T4: Post-intervention

\*Patients and their families are asked

- during hospitalization: informed consent and basic characteristics during hospitalization

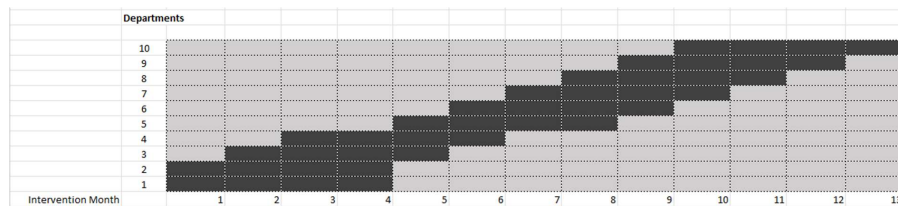
## CODE II study

- 3 weeks after discharge: survey on wellbeing, rating of quality of care, communication and decision-making

\*Patients are asked

1 year after hospital admission: survey on living situation

## b) Schematic overview of stepped wedged protocol (Fig 1)



**Met opmerkingen [DB1]:** Anouska of ruth kunnen jullie hier het nieuwe schema toevoegen ? Met dank

The intervention will be conducted in 10 departments over 14 months. A maximum of 4 departments will be coached at the same time.

## 1.8. Study duration

### 1.8.1. For an individual subject

- Clinicians will be coached during for 4 months (T1-T2)
- Clinicians' daily perceptions: 14 months (T0-T3)
- Head nurses and medical heads of department (for department characteristics): T0 and T3
- PET are surveyed upon admission, 3 weeks and 1 year after hospital discharge
- Family members are surveyed 3 weeks after hospital discharge

### 1.8.2. For the whole study

26 months including 14 months of coaching and the collection of the combined endpoint after one year

## 2. Rationale and background

Because of copyright issues and the fact that the rationale and background of the current are similar to the CODE study, we refer for these chapters to the CODE study protocol and the results that we were published in *Plos One* [2] and *Intensive care Medicine* [3], respectively.

Literature [7-18] and a pilot study performed in 2019 [2] indicate room for enhancing openness to discuss ethical sensitive issues within and between teams, and improving goal-oriented care and decision-making for the benefit of the patient at end-of-life, worldwide and more specifically in Belgium [13,19,20] and in the Ghent University Hospital [2]. The CODE study intervention performed in 2021 suggests already an improvement in goal oriented care operationalized via written DNI-DNACPR in our hospital. In this study, we found a nearly doubling of the incidence in written DNI-DNACPR (from 19.7% to 29.7%,  $p < 0.001$ ) in PET after coaching doctors during 4 months in self-reflective and empowering leadership, and coping with group dynamics [3]. However, we found no improvement in the perception of the quality of the ethical climate by clinicians [3], more specifically by nurses [21] and despite the fact that ethical decision-making is considered a strategic priority in our hospital [3] and an intense communication campaign, clinicians identified a much smaller number of PET during this interventional study than during our observational pilot study in 2019 [2]. Although fading attention for the study over time and visibility of the electronic CODE alert to identify PET was claimed as the main reasons by 75% and 50.7% of the nurses, respectively, 95% expressed the desire to keep on using this alert in the future [3]. This underscores a deeper concern in nurses. More than 40% expressed fear of blaming doctors or skepticism regarding the impact of identifying PET. Nonetheless, 35% acknowledged improvement in interdisciplinary meetings about end-of-life issues since study initiation. These findings together with the incidence of written DNI-DNACPR decisions in the overall study population that remained low after the intervention (3.4%) in comparison to the 1-year mortality (14.5%) highlights the need to additionally coach the entire team in future studies [3]. Indeed, creating a safe climate which enhances inter-professional shared decision-making for the benefit of the patient requires both, specific self-reflective and empowering leadership skills in doctors and head nurses (including the management of group dynamics in the interdisciplinary team) [22,24-31], and confidence in speaking up in nurses and other health care professionals [7,22-25,30-32]. This is what we want to develop with this intervention. These skills will also help clinicians during patient and family meetings which will enable clinicians to better take into account the patient's and family's wishes.

The CODE II study intervention will be compared with the standard of care. Except from a treatment-limitation-decisions guideline which focuses on the legal and deontological framework, no other guideline with regard to ethical decision-making has been implemented at the Ghent University Hospital. Therefore, we expect a high variability in ethical decision-making across wards, as observed in the CODE study. Besides the primary outcomes (written DNI-DNACPR orders and EDMCQ) all factors related to quality of end-of-life care (mortality and survival with a good quality of live at home, satisfaction of the family with regard to communication and end-of-life care...) will be analyzed as secondary outcomes. Since time will be taken into account in our analysis, we will also be able to assess the impact of the number of coaching sessions on these outcomes within and between wards.

## 2.1. Risk/Benefit Assessment

Similarly to the CODE study [2,3], the current intervention is directed towards clinicians whereas the impact of the intervention will be measured at the patients', relatives' and clinicians' levels. Given the consequences of providing excessive treatment at all levels [1-3, 8,9,22] our intervention has a favorable risk to benefit ratio.

1) Only clinicians who are interested to be coached and as such consent to participate will be included in the study. Participating clinicians will be coached by experienced coaches. The coaches will be supervised by a supervisor coach. The intervention is endorsed by the strategic quality cell and the medical council and is therefore completely embedded in the existing Ghent University Hospital structure. The safety, in case of for instance conflicts within the team, will be guaranty by the HR department together with the coach supervisor. Potential conflict with patients or relatives will be management as usual, by the doctor in charge or the head of the department in collaboration with the ombudsperson. Finally, all department heads, head nurses and teams of the 10 participating departments were very enthusiastic about the overall and department specific CODE study results and subsequently the rationale for this intervention during the respective meetings that were organized in Sept 2024-May 2025. They see this intervention as a second real opportunity for personal and team development with regard to ethically distressing situation rather than as a treat.

2) One could argue that this intervention may shorten the patient's life. Firstly, although this may be an issue, it is important to note that the primary intention of this intervention is not to shorten life but to reduce excessive treatment, and as such, suffering of patients with a high risk of dying [2]. By allowing clinicians to express anonymous perceptions of excessive treatment and by explicitly include doubt into the adapted definition of excessive treatment care, we hope that timely identification of patients potentially receiving excessive treatment will improve (sensitivity) on the one hand and that the quality of decision-making will be better guaranty by enhancing reflection and decision-making in team while taking the wishes of patients and relatives into account on the other (specificity). It is also of note that patient's safety increases in such a setting because direct communication and negotiation between doctors and between doctors and nurses will expand. This will enhance fine-tuned decision-making for the benefit of the patient, and will reduce avoidance behavior in complex clinical situations. Secondly, previous interventions aiming at reducing excessive treatment in the field of palliative care, advance care planning or intensive care medicine have shown to increase the quality of life in patients at risk of dying without shortening the survival [32-36]. This was further confirmed in the CODE study. The intervention increased written DNI-DNACPR orders without increasing the one-year mortality in both, PET and the overall patient population [3]. Because of all these reasons we decided to further use written DNI-DNACPR orders as a surrogate maker for goal-oriented care as primary endpoint and consider mortality and survival with a good quality of live at home again as secondary endpoints. Thirdly, treatment-limitation-decisions, at least written DNI-DNACPR orders, aim at clarifying to the patients, relatives and the team what to do in case of deterioration and is therefore also not uniformly associated with mortality [2]. Finally, we decided to power our intervention to detect an increase in written DNI-DNACPR 20% to 40% and not higher, because this would not be a realistic expectation and because 7% of patients potentially receiving excessive treatment are still alive, at home with a good quality of life after 1 year [1].



## 2.2. Limitations

Our study has several limitations. Firstly, the participating wards were not selected at random, which may affect the external validity of our results. However, although we decided to perform this study in wards that were enthusiastic to participate, and hereby already acknowledge room for improving in ethical decision-making, we expect a high variability in ethical decision-making climates across wards as suggested by the high variability in incidence of patients potentially receiving excessive care and written DNI-DNACPR order in the pilot observation [2]. This was confirmed in the CODE study [3]. This will enable us to assess the effect of our intervention across different ethical climates and to make recommendations with regards to our intervention for other departments centers. Secondly, in contrast to a drug which often has a clear biological mechanism, coaching consists of many different techniques which may have different effects in different situations. To minimize this issue our coaches will work according to the guideline in the appendix, which proposes different techniques for different situations. The different techniques and situations will also be collected during the study to perform a post-hoc exploratory analysis (see tertiary endpoints). Thirdly, the effect of the intervention may depend on the skills and experience of the coach. We decided to work with an experienced coaches under supervision of a senior coach to guarantee that across all coaching situations, detailed attention is paid to all relevant aspects of the medical ethical decision-making process, and to leadership as well as productive and counterproductive group dynamics in the team. Finally, the coachability of clinicians might be an issue. Although we acknowledge this potential shortcoming, our aim is to stay as close as possible to the real situation at the bedside. Moreover, based on the satisfaction of the participants and the feedback of the coaches in the CODE study we estimate that few clinicians will be un-coachable in the current study. Therefore, we plan only to perform an intention to coach analysis.

### 3. Objectives

#### 3.1. Primary Objectives

The primary objective of this study is to investigate whether coaching 1) doctors and head nurses individually in self-reflective and empowering leadership and in managing team dynamics and 2) doctors, nurses and allied health care professionals via multidisciplinary coaching during work shift hand-overs and structured case work sessions during 4 months with regard to hospitalized PET improves goal oriented care in comparison with standard of care. The quality of medical ethical decision-making will be assessed *objectively* via the incidence of written DNI-DNACPR orders in PET (first primary endpoint) and *subjectively* via the EDMCQ that will be filled out by the doctors, nurses and allied health professionals in the team (second primary endpoint). This 30-item validated questionnaire consists of 7 main domains or factors: F1 “self-reflective and empowering leadership of doctors”, F2 “open and interdisciplinary reflection”, F3 “not avoiding end-of-life decisions”, F4 “mutual respect within the interdisciplinary team”, F5 “active involvement of nurses in end-of-life care and decision-making”, F6 “active decision-making by doctors”, F7 “ethical awareness”.

These primary objectives can be formalized in the following two study hypotheses:

- The intervention changes the incidence of written DNI-DNACPR order (over the duration of hospital stay) in hospitalized PET without previous written DNI-DNACPR order from 20% (under standard of care) to 40% (in the intervention arm) over the 14-month study period.
- The intervention increases the average EDMCQ score in clinicians (doctors and nurses) by 2.8 points over the 4-month coaching period.

We decided to use two endpoints because ethical sensitive decisions and the climate in which these decisions are taken are intrinsically connected with each other. Furthermore, it is important to keep in mind that doctors are the only professionals who are medico-legally allowed to take written DNI-DNACPR orders with or without the team (after consent of the patient or relatives) while they represent only 20% of the clinicians that will potentially fill out the EDMCQ.

Both null hypotheses that will be tested express no change (as opposed to change).

We refer to the previous chapter (risk / benefit assessment) for the justification of the primary endpoints.

#### 3.2. Secondary Objectives

The secondary objective of this study is to investigate whether the intervention reduces the burden of patients, relatives, clinicians and costs in comparison to standard of care.

The hypotheses are as follows:

- On patient level
  - No excess 1 year mortality (+ combined endpoint) in PETs who did not yet receive a written DNI-DNACPR order (effectiveness and safety)
  - PETs who did not yet receive a written DNI-DNACPR order feel more involved in decision-making and rate care and communication higher (effectiveness) without impact on their psychological well-being (safety)
  - Improved quality of death and dying as reported by the relative in PETs who did not yet receive a written DNI-DNACPR order who died on the ward (effectiveness)
  - Improved symptom management during hospitalization in PETs who did not yet receive a written DNI-DNACPR order (effectiveness)
  - Less potentially inappropriate and burdensome treatments
    - in PETs who did not yet receive a written DNI-DNACPR order who died on the ward (effectiveness)
    - Less ICU use in the final year of life in PETs (effectiveness)
  - Higher incidence of written DNI-DNACPR orders in all first hospitalizations on the 10 wards (effectiveness) without excess 1 year mortality (safety)
- On family level
  - Improved quality of death and dying reported by and less short-term psychological burden in families of PETS who did not yet receive a written DNI-DNACPR order who died on the ward (effectiveness and safety)
  - Families of PET who did not yet receive a written DNI-DNACPR order feel more involved in decision-making and are more satisfied with care and communication (effectiveness) and report less psychological burden (safety)
- On clinician level
  - Less moral distress due to PET (effectiveness)
  - Better ethical practice and less absenteeism (effectiveness)
  - Less emotional exhaustion and intentional job-leave (effectiveness)
  - Smaller difference in EDMCQ overall and across factors between nurses and doctors.
- On society level

Less hospital costs and use of health resources (hospital and ICU length of stay, number of procedures (such as ventilation, dialysis, CPR, surgical procedures, chemotherapy, radiotherapy, ...), hospital re-admissions, ER visits,...) in PET who did not yet receive a written DNI-DNACPR order and overall patients firstly hospitalized (effectiveness).

### 3.3. Tertiary Objectives

The coach will collect quantitative and qualitative data of the leadership styles of the participating doctors and head nurses. These styles will be used in a sub-analysis to further explore the relationship between leadership style and the primary and secondary endpoints.

In order to evaluate the quality of the implementation of coaching, the participating doctors and head nurses will fill out a user questionnaire

## End Points + Time Points

### 3.4. Primary End Points + Time Points

Our study uses two primary endpoints. The first is a patient-specific endpoint, defined as the occurrence of written DNI-DNACPR code during the first hospitalization, which will be measured in PET who did not yet receive a written DNI-DNACPR order. We focus on this endpoint because of its patient centeredness and of its reliability as an objective endpoint that can easily be collected via the EPD. The second is a health-care provider-specific endpoint given by the EDMCQ score, which will be assessed within 2 weeks (T1) prior and after the intervention period in the specific wards. This endpoint is team-centered and is dependent on the response rate of clinicians.

### 3.5. Secondary End Points + Time Points

#### Patients' level

We use one-year mortality as an endpoint. Because staying at home with a good quality of life is highly valued by patients, the combined one-year patient outcome in this study was defined as dead, not at home or a utility score  $< 0.5$  [1]. For the combined endpoint, Euro-QOL-5D measures health-related quality of life, with possibility of conversion of each health state in a utility index (range -0.1584 to 1.000). This questionnaire measures health in five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [37].

For quality of care and communication and decision-making, we use the Hospital Consumer Assessment of Healthcare Providers and Systems instrument [38], the Sinclair Compassion Questionnaire [39] and the Euro-FS [40].

In the Hospital Consumer Assessment of Healthcare Providers and Systems instrument to measure patient satisfaction in Europe and the US,[38] patients rate their hospitals on a scale of 0 to 10 (best) and patients indicate whether they would recommend their hospital to family and friends.

The Sinclair Compassion Questionnaire is a patient reported experience measure that studies outcomes valued by the patient such as 'feeling heard and understood by their clinician' and 'being valued as a person'. [39]

Euro-FS (European Family Satisfaction in the ICU), which is a validated 18 item questionnaire covering satisfaction with 4 domains: communication, empathy, symptom management and decision-making. [40].

We also use NRS score for pain as objective measure for symptom control during hospitalization. [41].

For well-being 3 weeks after discharge, we use HADS (Hospital anxiety and depression scale) which is a validated 14-item self-report assessment with subscales for anxiety and depression. Each domain has a score range of 0-21 with the following interpretation: 0-7 normal, 8-10 mild, 11-21 moderate to severe [42].

For quality of dying in patients who died on the ward, we use QODD (Quality of dying and death questionnaire). Euro-QODD family is a 14 item questionnaire to allow families to assess patients' quality of dying and death [43].

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For the number of potentially inappropriate and burdensome treatments, we assess ventilation, dialysis, surgery, chemotherapy and radiologic diagnostics in patients who died on the ward and in patients who survived, we assess number of re-admissions and ICU use in the final year of life in patients potentially receiving excessive care [44]

#### Relatives level

For quality of care and communication and decision-making, we use the Hospital Consumer Assessment of Healthcare Providers and Systems instrument [38], the Sinclair Compassion Questionnaire [39] and the Euro-FS [40] (same as patients).

For family well-being/psychological burden 3 weeks after discharge, we use HADS (same as in patients) [42].

#### Clinicians' level

For clinician well-being, we use absenteeism (team-level) and emotional exhaustion and intentional job-leave (individual level) as endpoints. These are frequently used endpoints.

#### Societal level

For hospital costs, we will assess hospital costs by the hospital billing record, and also assess hospital and ICU length of stay as well as number of diagnostic procedures (emergency department visits, hospitalizations, blood analyses, radiological investigations, surgical procedures, and chemotherapeutic and radiotherapeutics treatments)

### 3.6. Tertiary/Exploratory End Points

In order to evaluate the quality of the implementation of coaching, we added process measures based on the RE-AIM implementation framework.

- Reach: inclusion rate of participants in the individual and group coaching + number of coaching sessions
- Efficacy: evolution in scores on self-reflective and empowering leadership, comparison of competencies (self-reflective and empowering leadership and in the management of team dynamics with regard to hospitalized patients potentially receiving excessive care, see appendix) and study outcomes
- Adoption: experiences of doctors and headnurses with the intervention (user experience survey)
- Implementation: experiences and satisfaction with the intervention and the coach, (user experience survey)
- Maintenance: long-term adoption of the intervention (user experience questionnaire)

## 4. Study design

### 4.1. Description of study design

The study follows a stepped wedge cluster randomized trial design, run across 10 different departments of the Ghent University Hospital. All 10 departments will be randomly assigned to start a 4-month coaching period in month  $k=1, \dots, 10$  following a stratified design. The 10 departments will be randomly assigned to start the intervention according to the schematic overview in Figure 1. All departments will be followed in terms of the primary and secondary endpoints over the 14-month duration of the study.

#### End of Study Definition

##### 4.1.1. For an individual subject

The subject has completed the study if he or she has completed all phases of the study, including the last contact via post, email or phone as described in this protocol (see section "9. Study Specific Procedures").

##### 4.1.2. For the whole study

Overall, the end of the study is reached when the last study procedure for the last subject has occurred: last subject, last visit (LSLV).

As soon as the whole study has ended (cfr. the definition above), the EC shall be notified (within 90 days after end of the study, or if the study had to be terminated early, this period must be reduced to 15 days and the reasons should clearly explained).

The summary of the results of the study will be submitted to the Ethics Committee, no later than 1 year after the end of the study.

### 4.2. Estimated duration of the study

#### 4.2.1. For an individual subject

- Clinicians are coached for 4 months (T1-T2); timing of T1 and T2 depend on the department (cfr stepped-wedge randomization)
- Clinicians give daily perceptions of excessive treatment during the whole 14 month study period (T0-T3)
- Head nurses and medical heads of department fill out questionnaire on department characteristics: (T0 and T3)

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- Patients and family:
  - o Inclusion during their first hospitalization
  - o Survey 3 weeks after discharge
  - o Telephone, email or mail survey in patients or one of their relatives in case of incapacity 1 year after hospital discharge

#### 4.2.2. For the whole study

*FPI: T0*

*LSLV: one year after the end of the 14 months study period: T3 + 1 year = 26 months*

## 5. Inclusion and Exclusion Criteria

### 5.1. Inclusion Criteria

- Junior and senior doctors (including medical head of department)
  - Inclusion: all junior and senior doctors taking care of hospitalized patients in the 10 participating departments of the Ghent University Hospital
- Nurses (including head nurses)
  - Inclusion: all nurses taking care of hospitalized patients in the 10 participating departments of the Ghent University Hospital
- Allied health care professionals
  - Inclusion: all allied health care professionals taking care of hospitalized patients in the 10 participating departments of the Ghent University Hospital
- Patients and family members
  - inclusion: hospitalized PET who did not yet receive a written DNI-DNACPR order and their family members

### 5.2. Exclusion Criteria

For doctors, nurses and allied health care professionals there are no exclusion criteria.

For patients and families; persons younger than 18 years and persons who cannot understand Dutch questionnaires are excluded.

#### 5.2.1. Screen failures

Individuals who do not meet the criteria for participation in this study (screen failure) may not be rescreened.



## 6. Target Population

### 6.1. Subjects

#### 6.1.1. Number of subjects and planned recruitment rate

The number of subjects that will be included in this study is:

- Junior and senior doctors (including medical heads of department) : 50 à 75 junior and 50 à 75 senior doctors
- Nurses (including head nurses) : 300 à 500
- Allied health professionals working in 10 departments of the Ghent University Hospital: 100 to 200
- Patients and family members : 350 to 700 PETs who did not yet receive a written DNI-DNACPR order and 350 to 700 family members. Drop-outs will not be replaced. It is expected that overall an accrual rate of 30 patients per month is realistic in the whole study.

#### 6.1.2. Withdrawal and replacement of subjects

Subjects are free to withdraw from participation in the study at any time. A subject must be discontinued from the study if the subject/legal representative of the subject withdraws consent.

The reason why a subject withdraws consent, if given, must be recorded in detail in the electronic Case Report Form (eCRF) and in the subject's medical records. The already gathered subject data should remain in the study database.

A subject will be considered lost to follow-up if he or she cannot be reached one year after hospital discharge by the study site staff.

The following actions must be taken if a subject fails to return to the clinic for a required study visit:

- Before a subject is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the subject (where possible, 3 telephone calls or by contacting the general practitioner). These contact attempts should be documented in the subject's medical record or study file.
- Should the subject continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

### 6.2. Method of recruitment

- All departments within the Ghent University Hospital who participated to the CODE study were invited to participate to the current CODE II study during team meetings organized in 2024-2025 aimed at discussing and reflecting about the general and local CODE study results and the impact of providing excessive treatment for patients,

relatives and clinicians in our hospital. All 10 departments acknowledge room to further improve goal-oriented care in our hospital and were enthusiastic to participate to this study.

- Junior and senior doctors (including medical heads of department)
  - all junior and senior doctors taking care of hospitalized patients in the 10 participating departments of the Ghent University Hospital will be informed about the study on their medical staff meeting, we will give our contact details in order to ask individual questions after the meeting
  - those who give informed consent will be included in the study
  - by means of coaching, participants get the opportunity for personal growth, which is the only (but important) incentive
- Nurses (including head nurses) and allied health care professionals
  - Inclusion: all nurses and allied health care professionals taking care of hospitalized patients in the 10 participating departments of the Ghent University Hospital will be informed about the study on their staff meetings, we will give our contact details in order to ask individual questions after the meeting
  - those who give informed consent will be included in the study
  - there is no financial incentive, from former studies (APPROPRICUS, and DISPROPRICUS and CODE study) we learnt that nurses were very eager to give their anonymous perception about the ethical climate and their perception of excessive treatment (when they feel safe). Furthermore by means of interprofessional coaching, participants get the opportunity for personal growth, which is the only (but important) incentive
- Patients and family members
  - inclusion: adult PET who did not yet receive a written DNI-DNACPR order (or their legal representative in case of incompetence) identified as potentially receiving excessive treatment will be asked informed consent by the treating physician to fill-out survey 3 weeks after discharge and to be contacted 1 year after discharge. They will be asked to indicate 1 family member to be contacted.
  - That family member will be asked informed consent also during hospitalization
  - There is no financial incentive for study participation
  - The investigator or designee will make every effort to regain contact with the subject after 1 year to collect living situation 1 year after discharge (where possible, 3 telephone calls or by contacting the general practitioner).

Since our intervention is completely embedded in the hospital, we will be able to count on the communication department of the Ghent University Hospital to empower clinicians to participate by means of posters, flyers and multimedia.

### 6.3. Screening

Every patient that is identified by clinicians as potentially receiving excessive treatment.

## 7. Study Specific Procedures

### 7.1. Recruitment

- Junior and senior doctors (including medical heads of department)
  - all junior and senior doctors taking care of hospitalized patients in the 10 participating departments of the Ghent University Hospital will be informed about the study on their medical staff meeting, we will give our contact details in order to ask individual questions after the meeting
  - they are free in how they accept the offered individual and group coaching
  - they will each be given an electronic link to fill-out the RED-CAP [46] EDMCQ at T0 and T3 online and are free to participate or not
  - filling-out the daily perceptions will be seen as consent to participate
- Nurses and allied health care professionals
  - all nurses and health care professionals taking care of hospitalized patients in the 10 participating departments of the Ghent University Hospital will be informed about the study on their nursing staff meeting, we will give our contact details in order to ask individual questions after the meeting
  - they are free in how they accept the offered individual and group coaching
  - they will each be given an electronic link to fill-out the RED-CAP EDMCQ at T0 and T3 online and are free to participate or not
  - filling-out the daily perceptions will be seen as consent to participate
- Patients and family members
  - All PETs who did not yet receive a written DNI-DNACPR order (or their legal representative in case of incompetence) will be asked informed consent by the treating physician to fill-out survey 3 weeks after discharge and to be contacted 1 year after discharge. They will be asked to indicate 1 family member to be contacted.
  - That family member will be asked informed consent also during hospitalization
  - There are no financial incentives for study participation
  - The investigator or designee will make every effort to regain contact with the subject after 1 year to collect living situation 1 year after discharge (where possible, 3 telephone calls or by contacting the general practitioner).

### 7.2. Randomisation/blinding

Randomisation of the 10 departments will be performed by the Ghent University Department of Applied Mathematics, Computer Science and Statistics based on a random number generator in the software R. As in nearly all stepped wedge designs, the nature of the intervention is such that it cannot be blinded to health care providers. However, patients will be blind to the intervention.

### 7.3. Overview of collected data

OUTCOME DOMAIN	OUTCOMES	INSTRUMENT	DATA SOURCE	TIMING OF MEASUREMENT
<b>ETHICAL DECISION-MAKING (PRIMARY ENDPOINTS)</b>				
DNI-DNACPR INCIDENCE	Time from 2PET to written DNI-DNACPR		Chart extraction	Post discharge
TEAM PERCEPTION OF ETHICAL CLIMATE	Ethical decision-making climate	EDMCQ	Nurses, doctors and allied health care professionals	T0 and T3
<b>PATIENT-CENTERED OUTCOME IN ALL PATIENTS</b>				
LIVING SITUATION AT 1 YEAR	(Time from 2PET to) survival, QOL and place of residence in survivors	Euro-QOL-5D + survey	Patient or family by telephone call email of mail	1 year after discharge
QUALITY OF CARE, COMMUNICATION AND DECISION-MAKING	Pain	NRS	Chart extraction	Post-discharge
	Symptom management	Euro-FS adapted for the patient (part	Patient discharged alive	3 weeks after discharge
	Symptom management	Euro-FS (part 1)	Family	3 weeks after discharge
	Quality of communication and decision-making	Euro-FS adapted for the patient (part 2), Sinclair Compassion Questionnaire VAS	Patient discharged alive	3 weeks after discharge
WELL-BEING AFTER DISCHARGE	Anxiety and depression	HADS	Patient discharged alive	3 weeks after discharge
<b>IN PATIENTS WHO DIED ON THE WARD</b>				
QUALITY OF DYING	Quality of dying	Euro-QODD	Family	3 weeks after discharge
	Potentially inappropriate treatments at EOL		Chart extraction: ICU stay, surgery, chemotherapy, radiotherapy	Post-discharge
OUTCOME DOMAIN	OUTCOMES	INSTRUMENT	DATA SOURCE	TIMING OF MEASUREMENT
<b>FAMILY OUTCOME</b>				

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<b>IN PATIENTS WHO WERE DISCHARGED ALIVE</b>				
<b>WELL-BEING AFTER DISCHARGE</b>	Anxiety and depression	HADS	Family	3 weeks after discharge
<b>QUALITY OF COMMUNICATION AND DECISION-MAKING</b>	Quality of communication and decision-making	Euro-FS (part 2), Sinclair Compassion Questionnaire and satisfaction VAS	Family	3 weeks after discharge
<b>IN PATIENTS WHO DIED ON THE WARD</b>				
<b>WELL-BEING AFTER DISCHARGE</b>	Anxiety and depression	HADS	Family	3 weeks after discharge
<b>QUALITY OF COMMUNICATION AND DECISION-MAKING</b>	Quality of communication and decision-making	Euro-FS (part 2), Sinclair Compassion Questionnaire and satisfaction VAS	Family	3 weeks after discharge
<b>HEALTHCARE COSTS</b>				
	Cost of the intervention			
	Payer's hospitalization cost		Hospital billing record	Post-discharge
	Hospital (and ICU) length of stay and diagnostics		Chart extraction	Post-discharge
	Hospital re-admission rates after discharge		Patient or family by telephone call, email or mail	1 year after discharge
<b>WELL-BEING OF HEALTH CARE PROFESSIONALS</b>	Emotional Exhaustion and Intention to leave job		Nurses and physicians	T0 and T3
<b>TEAM WELL-BEING AND PERFORMANCE</b>	Absenteeism		Department Heads and Head Nurses	T0 and T3

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OUTCOME DOMAIN	OUTCOMES	INSTRUMENT	DATA SOURCE	TIMING OF MEASUREMENT
<b>PROCESS MEASURES</b>				
NUMBER OF COACHING SESSIONS)			Survey (by coach)	During intervention
SELF-REFLECTIVE AND EMPOWERING LEADERSHIP SKILLS		Survey on quality of self-reflection	Coach	During intervention
			Survey (user experience by doctors and headnurses)	T2

#### 7.4. Schematic overview of the data collection & interventions

<b>Procedures</b>				
	Inclusion during hospitalization	3 weeks post-discharge	Follow-up 1 year after hospital admission	4 months : start according to cluster randomization at department level
Informed consent	X			
Survey		X	x	
Coaching				x

## 8. Statistical Considerations

### 8.1. Sample size calculation

The outcome(s) on which the sample size calculation is based upon are the incidence of written DNI-DNACPR and the EDMCQ.

For written DNI-DNACPR code, analysis will be based on a logistic mixed effect model in PET who did not yet receive a written DNI-DNACPR order. The model will allow for a random intercept to account for between-department variability, a fixed coaching effect from time of initiation onwards and for a linear period effect, even though no such effects are expected. Based on such analysis, a Monte Carlo power evaluation (with 10000 simulations) showed that under the considered randomized design, a Wald test at the 5% significance level delivers 77.2% power to detect an intervention effect when data are available for 3 DNIR-naïve PET per department per month (over a period of 12 months) (or 61.1% when data are available for 2, and 87.4% when data are available for 4 DNI-DNACPR naïve patients), if the risk of written DNIR order by the end of hospital stay in PET patients increases from 20% before to 40% after intervention; with 2 PETs identified in 6% of patients [3]. Independently from each other, respectively the scientific experts in the field of coaching and the experienced coach of our steering committee estimated that a 4 month intervention would be required to detect an effect in the team and at least 5 individual and 5 group coaching sessions to detect an effect at the individual level.

The above calculation amounts to a total of 6000 patients, of which 360 (i.e., 6%) patients identified with at least 2 perceptions of excessive treatment over a 14 month period. In the above power analysis, we considered a design in which all participating departments are randomly assigned to start a 4-month coaching intervention in either month 1, 2, 3, ... or 7 following the previously described design. Moreover, we assumed an intra-class correlation of 0.025. This means that for 95% of hospital departments, the risk of written DNI-DNACPR order in PET who did not yet receive a written DNI-DNACPR order lies between 12% and 31% before intervention, and between 27% and 54% after intervention.

For the EDMCQ, the sample size calculation was based on linear mixed models for the change in EDMCQ score after versus before the intervention, including a random intercept to account for between-department variability. Based on such analysis, a Monte Carlo power evaluation (with 10000 simulations) showed that a Wald test at the 5% significance level delivers 89% power to detect an intervention effect when data are available for 5 health care providers per department, if the EDMCQ score increases on average with 2.8 units. For this, we assumed an intra-department correlation of 0.14 and a total standard deviation of 5.03.

### 8.2. Type of statistical methods

Analysis of the incidence of written DNI-DNACPR order will be based on logistic mixed effects models with random intercept to account for between-department variability, assuming a constant coaching effect from the start of coaching onwards and allowing for linear period effects. The coaching effect will be reported as the odds ratio of having a written DNI/DNACPR order in any study month for patients treated in departments where coaching had already been implemented versus those where it had not. This effect may be diluted because of spillover effects from clinicians who have been previously coached (when they worked in a different department) as well as a learning effect of the coaching sessions (which do not immediately

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attain their full effect). A secondary analysis will therefore include, in each month prior to the end of the coaching period, a variable that expresses the average percentage of total coaching sessions previously attended by clinicians in the department. The coaching effect in this secondary analysis can be defined as the odds ratio of having a written DNI/DNACPR order in any study month for patients treated in departments where all clinicians attended all coaching sessions versus where no clinicians have received coaching. Additional secondary analyses will allow for arbitrary (possibly non-linear) period effects and adjust for patient admission characteristics to correct for random imbalances between randomized arms.

Analysis of the change in ECDMQ score will be based on linear mixed effects models for the change in ECDMQ score, including a random intercept to account for between-department variability. A secondary analysis will additionally adjust for characteristics of health care providers measured prior to coaching to correct for random imbalances between randomized arms.

For secondary endpoints, the analysis of continuous endpoints will be based on linear mixed models and the analysis of dichotomous endpoints on logistic mixed models, each time including a random intercept at the ward level to account for between-department variability. Analyses at the patient level will additionally include a fixed (linear) effect of time to correct for period effects.

### 8.3. Statistical analysis team

Analysis of the primary and secondary endpoints will be done by the Department of Applied Mathematics, Computer Science and Statistics of Ghent University (responsible: Prof. Stijn Vansteelandt).

### 8.4. Interim analysis

No interim analysis is planned.



## 9. Data handling

### 9.1. Method of data collection

Subjects that are included in the study, will be assigned a unique study number upon their registration in REDCap [46]. The subject identification list will be safeguarded by the site. The name and any other directly identifying details will not be included in the study database.

#### 9.1.1. Case Report Form

An electronic data capture (EDC) system, i.e. REDCap, will be used for data collection. Data reported on each eCRF should be consistent with the source data. If information is not known, this must be clearly indicated on the eCRF. All missing and ambiguous data will be clarified.

Only the data required by the protocol are captured in the eCRF. The eCRFs and the database will be developed, based on the protocol. The final eCRF design will be approved by the Coordinating Investigator.

All data entries and corrections will only be performed by study site staff, authorized by the investigator. Data will be checked by trained personnel (data manager) and any errors or inconsistencies will be clarified. The investigator must verify that all data entries in the eCRF are accurate and correct.

REDCap is provided and maintained by Vanderbilt University; a license for use was granted to the Health, Innovation and Research Institute (HIRUZ). REDCap is a web-based system [46].

The study site staff is responsible for data entry in REDCap.

### 9.2. Data storage

The data is accessed through a web browser directly on the secure REDCap server. The server is hosted within the UZ Gent campus and meets hospital level security and back-up requirements.

Privacy and data integrity between the user's browser and the server is provided by mandatory use of Transport Layer Security (TLS), and a server certificate issued by TERENA (Trans-European Research and Education Networking Association). All study sites will have access to REDCap. Site access is controlled with Internet Protocol (IP) restriction.

### 9.3. Archiving of data

The investigator and sponsor specific essential documents will be retained for at least 10 years. At that moment, it will be judged whether it is necessary to retain them for a longer period, according to applicable regulatory or other requirement(s).

### 9.4. Access to data

The investigators and institutions involved in the study will permit audits and regulatory inspections (including provision of direct access to source data and documents). Login in REDCap is password controlled. Each user will receive a personal login name and password and will have a specific role which has predefined restrictions on what is allowed in REDCap. Furthermore, users will only be able to see data of subjects of their own site. Any activity in the software is traced and transparent via the audit trail.

## 10. Monitoring/Auditing/Inspection

### 10.1. Monitoring

Not applicable

### 10.2. Inspection

This study can be inspected at any time by regulatory agencies during or after completion of the study. Therefore access to all study records, including source documents, must be accessible to the inspection representatives. Subject privacy must be respected at all times, in accordance to GDPR, GCP and all other applicable local regulations.

### 10.3. Non-compliance policy

Sponsor and all investigators agree to take any reasonable actions to correct protocol or other non-compliances/violations noted during inspection. All non-compliances must be documented on the correct deviation log by the study team that is kept available at any time for inspection purposes.

Subject, site and sponsor non-compliances must be reported in the CRF. In case a (potential) critical non-compliance is detected, the sponsor should be contacted within 1 business day of awareness and the escalation procedure should be started.

Under emergency circumstances, deviations from the protocol to protect the rights, safety or well-being of human subjects may take place without prior approval of the sponsor and the EC.

### 10.4. Serious breach to GCP and/or the protocol

A 'serious breach' means a breach likely to affect to a significant degree the safety and rights of a subject or the reliability and robustness of the data generated in the clinical study.

Any deviation of the approved protocol version that has a major impact on the subject safety and/or rights, data integrity and/or study conduct should be clearly documented on the applicable deviation log and will be communicated with the Coordinating Investigator, HIRUZ CTU and possibly the EC.

Please contact HIRUZ CTU asap in case of a serious breach: [hiruz.ctu@uzgent.be](mailto:hiruz.ctu@uzgent.be) and/or +32933320500.

Early determination of the study may be necessary in case of major non-compliance.

## 11. Ethical and legal aspects

### 11.1. Good Clinical Practice

The study will be conducted conform the latest version of the ICH-GCP guidelines, creating a standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical studies that provides assurance that the data and reported results are accurate and that the rights, integrity and confidentiality of study subjects are protected.

### 11.2. Informed Consent

Eligible subjects may only be included in the study after providing written (witnessed, if needed) Ethics Committee-approved informed consent, or, if incapable of doing so, after such consent has been provided by a legally acceptable representative(s) of the subject. Informed consent must be obtained before conducting any study-specific procedures (as described in this protocol).

Prior to entry in the study, the investigator must explain to potential subjects or their legal representatives the study and the implication of participation. Subjects will be informed that their participation is voluntary and that they may withdraw consent to participate at any time. Participating subjects will be told that their records may be accessed by competent authorities and by authorized persons without violating the confidentiality of the subject, to the extent permitted by the applicable law(s) and/or regulations. By signing the Informed Consent Form (ICF), the subjects or legally acceptable representatives are authorizing such access.

After this explanation and before entry to the study, written, dated and signed informed consent should be obtained from the subject or legally acceptable representative. The ICF should be provided in a language sufficiently understood by the subject. Subjects must be given the opportunity to ask questions.

The subject or legally acceptable representative will be given sufficient time to read the ICF and to ask additional questions. After this explanation and before entry to the study, consent should be appropriately recorded by means of either the subject's or his/her legal representative's dated signature or the signature of an independent witness who certifies the subject's consent in writing. After having obtained the consent, a copy of the ICF must be given to the subject.

In case the subject or legally acceptable representative is unable to read, an impartial witness must attest the informed consent.

Subjects who are unable to comprehend the information provided can only be enrolled after consent of a legally acceptable representative.

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The following information should be added to the electronic patient dossier (EPD):

- which version of the ICF was obtained
- who signed the ICF
- if sufficient time has been given to consider participation into the study
- which investigator obtained ICF with the date of signature
- if a copy was provided to the patient
- start and end of participation in the study

### 11.3. Approval of the study protocol

#### 11.3.1. General

The protocol has been reviewed and approved by the Ethics Committee of the Ghent University (Hospital).

#### 11.3.2. Protocol amendments and urgent safety measures

Any significant change or addition to the protocol can only be made in a written protocol amendment that must be approved by the Ethics Committee.

Only amendments that are intended to eliminate an apparent immediate safety threat to patients may be implemented immediately.

Notwithstanding the need for approval of formal protocol amendments, the investigators are expected to take any immediate action, required for the safety of any subject included in this study, even if this action represents a deviation from the protocol. These actions should always be notified to the sponsor.

### 11.4. Confidentiality and Data Protection

All study data will be handled in accordance with the law on General Data Protection Regulation (GDPR) and institutional rules (in Belgium: in accordance with the Belgian laws dated on 30 July 2018 and 22 August 2002).

The collection and processing of personal data from subjects enrolled in this study will be limited to those data that are necessary to fulfill the objectives of the study. These data must be collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data privacy protection laws and regulations.

Appropriate technical and organizational measures to protect the personal data against unauthorized disclosures or access, accidental or unlawful destruction, or accidental loss or alteration must be put in place. Sponsor and site personnel whose responsibilities require access to personal data agree to keep the identity of subjects confidential.

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Site personnel informs the subject about the processing of personal data and direct access for the investigator/institution to his or her original medical records (source data/documents) for audit, EC review and regulatory inspection. The subject is also informed about the transfer of the data to other entities, if applicable.

All data will be pseudonymised. Pseudonymisation is the responsibility of the PI. Pseudonymisation can be done by the PI or any other investigator appointed by the PI and legally authorized to do so (therapeutic relationship with the participant). The key for encryption and decryption of pseudonymized data is kept by the PI and other investigators authorized by the PI. Data is processed in an electronic, secure database (REDCap), in accordance with the technical and organizational security measures of the Ghent University Hospital.

Privacy and confidentiality of data generated in the future on stored samples will be protected by the same standards applicable to all other clinical data.

### 11.5. Liability and Insurance

The sponsor has taken a no fault insurance for this study (applicable in Belgium), in accordance with the relevant legislation (article 29, Belgian Law of May 7, 2004).

Sponsor: Ghent University Hospital

Insurance Details: Allianz Global Corporate & Specialty, Uitbreidingstraat 86, 2600 Berchem, Belgium, tel: +32 33 04 16 00

Policy number: BEL001889

## 12. Publication policy

This study will be registered at ClinicalTrials.gov, and results information from this study will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals.

The local investigators are responsible for recruiting patients according to the inclusion and exclusion criteria, collecting informed consent and empowering teams to provide PETs during the entire 12 months study period together with the study nurse, coach, communication department of the Ghent University Hospital and the principal investigators.

Similarly tot the CODE study, all local investigators who fulfill the authorship requirements will be coauthor of at least one of the principal publications. In case the journal does not allow a high number of coauthors (members of the steering committee + local investigators of 10 wards), co-authorship will be divided among the first main publications. Local investigators may subsequently become first authors of publications on CODE II study sub-analyses once the initial main results have been published.

Professional medical writers will not be hired. Every person who collaborated with this study outside the steering committee and the list of local investigators will be acknowledged in the publications. Funding will be acknowledged appropriately.

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## 13. Appendices

### 13.1. Appendix 1: Coaching protocol

#### Coaching & Intervention Protocol

The intervention that is central to this study consists of implementing individual and group coaching sessions with multidisciplinary teams in a hospital context. The individual sessions will be organised for doctors and head nurses. For doctors they will aim at facilitating self-reflective and empowering leadership, and at improving medical doctors' competence in managing team dynamics with regard to ethically sensitive medical topics, in line with the theoretical framework elaborated by Van den Bulcke et al. This framework starts from the point of view that doctors need first to collect detailed information to be able to take in all conscious a decision for the benefit of the patient. Although, this seems obvious, previous studies suggest that doctors (unconsciously) prefer to remain prognostically uncertain rather than to gather the information that is required to reduce uncertainty and to effectively take decisions in the team (Palda 2005, Piers 2014). This information may be objective or subjective, and may come directly or indirectly from the patient, relatives, clinicians or any other party. All upfront clinicians may and will have potential important information about the patient, regardless of their role, knowledge or experience (Curtis 2010, Van den Bulcke 2018, Moynihan 2021, Michalsen 2019). To obtain all that information, the doctor in charge of the patient needs to empower clinicians to speak up while guarantying a safe environment. This enables to shift from pure knowledge and experience driven discussions often led by the doctor solely, to participative knowledge, experience and value driven reflection in team (Van den Bulcke 2018); however, sharing viewpoints or questioning authority might often be felt as taking an interpersonal risk. That is also why head nurses will receive individual coaching too, as they are often the primus inter pares between the doctor and the clinicians team. For head nurses the individual coaching will aim at two main themes: processing the impact of their role in the system in which they operate and offering them a structural sounding board where they can develop opportunities to strengthen their facilitative role. The group sessions will aim at lowering a feeling of interpersonal risk by fostering a culture of open speech where participating clinicians feel at ease to contribute to the conversation. People's perceptions of the consequences of taking interpersonal risks inhibits psychological safety and a culture of speaking up. Therefore, it is imperative to create a psychologically safe space as it plays a vital role in helping people overcome barriers to learning and change in interpersonally challenging work environments. (Edmondson 2014, 2016). Apart from reducing avoidance and tension in teams, and indecision in doctors, sharing emotions and values stimulates a sense of meaning, and thus ethical awareness and well-being in the team. This collective awareness enriches the ethical decision-making process for the benefit of the patient and supports the doctor to effectively communicate decisions on patient care (Van den Bulcke 2018).

#### Study Focus

A key systems-psychodynamic hypothesis guiding the intervention is that ethically sensitive medical topics are inherently anxiety provoking. They confront professionals with death and

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suffering, with uncertainty and powerlessness in aversive situations, and with the prospect that decisions and actions might have an aggravating impact on aversive situations. Such confrontations have a shocking effect and provoke mixed feelings. Shame, pity, compassion and guilt might come to the fore, but the bottom-line reaction to death and decay is desperate anxiety.

In her seminal psychodynamic studies on how medical professionals work, Menzies Lyth (1988, p. 43-88) described that if this elementary anxiety is not faced and worked through, all kinds of dysfunctional defences ruin collaborations and undermine thoughtful medical ethical decision-making. Working through means that challenging situations are faced and discussed in plain but respectful terms, such that the complexity of the situation is acknowledged, and affective reactions are contained in the interactions between professionals, patients and families. Dysfunctional defensive reactions in their turn come to the fore as people avoid thoughtful deliberation about sensitive medical topics, and shy away from such situations, e.g. by avoiding close commitment to patients, fleeing in depersonalized and neutral interactions, focusing on technical details in treatments only, emotional unresponsiveness, or scheduling no time to address worries and concerns in team meetings.

Given this challenge, the coaching sessions will aim at helping the team to work through ethically sensitive medical topics and to facilitate a culture of open speech, defined within the context of empowering leadership.

In this study, coaching is implemented with a dual focus: 1) helping medical doctors and head nurses to address ethically sensitive issues in multidisciplinary teams and to optimise their decision process for the benefit of the patient and leadership for the team; 2) helping all members of the multidisciplinary team to address ethically sensitive issues by processing known group defence mechanisms so to stimulate their contribution to the collective decision-making process.

Four coaching interventions of 4 months will be conducted in 10 internal medicine and neurology wards over a period of 12 months. During that period individual - and team coaching will take place in self- reflection and self-regulation with regard to ethical decision-making in patients potentially receiving excessive care and in coping with group dynamics in the multidisciplinary team, with the intention to achieve following specific objectives.

### Objectives for the individual coaching

- a) Learning to acknowledge the patient's (and relatives') subjective goals, emotions and values, and separate them from own and colleagues' subjective goals, emotions and values triggered by that situation.
- b) Learning to acknowledge patient's (and relatives'), colleagues' and own spontaneous defensive avoidance strategies in coping with difficult and aversive care-related situations, like end-of-life decisions.

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- c) Learning to identify and separate internal avoidance strategies from external barriers to better delineate the responsibilities of each stakeholder in the process.
- d) Learning to cope more effectively with these internal and avoidance strategies and external barriers to enable more appropriate and timely decisions for the benefit of the patient.
- e) Learning to integrate newly acquired insights into an adapted way of thinking and relating with others to establish a sustainable effect with regards to ethical decision-making.
- f) Learning to transfer these insights into empowering leadership behaviour which contributes to dialogue during the interdisciplinary meeting.

#### Objectives for the team coaching

- a) Learning to acknowledge the patient's (and relatives') subjective goals, emotions and values, and separate them from own and colleagues' subjective goals, emotions and values triggered by that situation.
- b) Learning to acknowledge patient's (and relatives'), colleagues' and own spontaneous defensive avoidance strategies in coping with difficult and aversive care-related situations, like end-of-life decisions.
- c) Learning to identify and separate internal avoidance strategies from external barriers to better delineate the responsibilities of each stakeholder in the process.
- d) Learning to cope more effectively with these internal and avoidance strategies and external barriers to enable more appropriate and timely decisions for the benefit of the patient.
- e) Learning to integrate newly acquired insights into an adapted way of thinking and relating with others to establish a sustainable effect with regards to ethical decision-making.
- f) Learning to transfer these insights into self-steering participative behaviour which contributes to dialogue during the interdisciplinary meeting.

#### **Focus one**

In 2018 Van den Bulcke and colleagues reviewed literature on medical ethical decision-making and based on psychometric research of a newly constructed questionnaire (EDMCQ) they discerned seven key domains that make up a medical ethical decision-making climate: (1) self-reflective and empowering leadership by physicians; (2) practice and culture of open multidisciplinary reflection; (3) culture of not avoiding end-of-life decisions; (4) culture of mutual respect in the multidisciplinary team; (5) active involvement of nurses in end-of-life care and decision-making; (6) active decision-making by physicians; and (7) practice and culture of ethical awareness. In this study, we will focus on coaching doctors and head

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nurses in self-reflective and empowering leadership, which by itself will have an effect on all other factors in the team (Vandenbulcke 2018, Benoit 2023, 2024).

The coachee will be invited to have individual coaching sessions. By stimulating open speech and reflection on ethically sensitive medical topics, like disagreements on interventions, difficulties in taking EOL decisions, or challenges of dealing with conflicting opinions in the doctor-patient relationship, the intervention will intend at strengthening their capacities to reflect and communicate about difficult decisions in uncertain circumstances and to guide their multidisciplinary teams in dealing with such topics.

### Focus two

The teams will be assisted through two parallel group interventions: the team coach facilitating the work shift hand-over by clinicians and the team coach facilitating structured metareflective sessions on specific themes related to ethical decision-making by multidisciplinary teams. Similar to the individual coaching sessions, stimulating open speech and reflection on ethically sensitive medical topics, like disagreements on interventions, challenges of dealing with conflicting opinions in the team, emotional pressure by anxiety provoking events, the intervention will intend at strengthening participating health workers' capacities to reflect and communicate about difficult decisions in uncertain circumstances.

### Interventions

#### Intervention one: Individual coaching for doctors and head nurses

##### Session focus

In hospital teams doctors and head nurses typically occupy a leadership role. It is under their responsibility that crucial decisions are taken and that team dynamics take shape. Our intervention aims at supporting them in effectuating an empowering leadership style. As Kets de Vries (Kets de Vries, 2014) indicates, "Empowering concerns the leader's ability to delegate authority to others. An empowering leader involves others in the decision-making process thereby indicating his or her high expectations and confidence in them. An empowering leader also works to minimise secrecy and to create an open and transparent environment. He or she also tolerates mistakes and failures as part of the learning process."

The session will focus on discussing: (a) challenges and opportunities in dealing with ethical and medical dilemmas; (b) challenges and opportunities in relating with colleagues and team, and with patients and families; (c) challenges and opportunities in taking up an empowering leadership role. The coach will aim at increasing awareness and efficacy in dealing with these topics and transferring these into leadership behaviour, starting from a collaborative relationship with the coachee.

##### Method

Each time that at least two clinicians of the team for which a doctor is responsible indicates that for one the patients under treatment they are facing an ethical dilemma in the direction of

“too much treatment”, respectively the doctor and the head nurse will be invited for an individual coaching session.

Generally speaking, individual coaching is a form of “leadership development where a leader has a series of contracted and confidential conversations with a coaching psychologist or development expert. It is a form of organisational learning through one-to-one conversations, which facilitates development for an individual” (de Haan, Molyn & Nilsson, 2020, p. 2). The input coachees typically bring to coaching session can cover a spectrum of themes varying between personal dynamics influencing or disturbing work situations, dilemmas and difficulties related to their work setting or exploring opportunities for growth. During coaching “coachee and coach collaborate to assess and understand the coachee and his or her leadership developmental tasks, to challenge current constraints while exploring new possibilities, and to ensure accountability and support for reaching goals and sustaining development” (Ting & Hart, 2004, p. 116). It is supporting someone to adapt his/her relationship to a specific reality. Often an individual cannot overcome the issue by him-/herself as some variables are unknown and require multiple learning loops to understand specific internal and external dynamics which inhibit our performance (Heifetz, 1997). Since furthermore, “because of the personalized nature, the high confidentiality, and the possibility for deep understanding and challenge, coaching seems to work at relational and personal depths” (de Haan, Gray & Boneywell, 2019, p. 586).

The individual coaching we implement will start from the principles described by Kets de Vries (2006, 2007) and de Haan (2008, 2014, 2019).

Kets de Vries’ coaching methodology is based on the combination of two concepts: a psychodynamic perspective and a systemic perspective. This is defined as the ‘clinical paradigm’, a conceptual framework that builds on psychoanalytical concepts and techniques and which considers the dynamics of organisational behaviour (Kets de Vries, 2006). He argues that leadership behaviour is driven by the interplay between conscious and unconscious processes, the so-called ‘inner theatre’ – the roles we have developed over the course of life and which permanently influence our thinking. Therefore, this coaching methodology intends to help the leader make sense of the invisible deeper thoughts, feelings, motives and anxieties that influence his/her cognitive processes such as decision-making and daily leadership behaviour.

Next to intrapersonal dynamics, the leader is also influenced by interpersonal dynamics. A leader takes up distinct formal and informal roles in various social constructions that affect his/her intrapsychic life. This implies that decision-making behaviour is undoubtedly influenced by the interpretation of these interactions. Finally, leaders also act according to organisational expectations, often derived from formal rules and so-called ‘organisational myths’, i.e. normative narratives that indicate how people should collaborate. As Kets de Vries (2006, p. 308) indicates, “subjection to these myths may come at the cost of personal responsibility and independence”.

De Haan’s coaching methodology is based on a relational model, in which the working alliance between coach and coachee is seen as a predictor of present and future leadership effectiveness (de Haan, Gray & Boneywell, 2019, p. 585). De Haan describes relational



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coaching as a dual active effort. On the one hand the coach is requested to understand all leadership dynamics from the perspective of the relationships the coachee is involved in, being previous, current and in-the- moment relationships. On the other hand the coach helps the coachee to make his/her professional relationships as strong and productive as possible – considered from the perspective of the coachee. Consequently, the coach needs “to explore regularly with the coachee how the relationship is progressing” (de Haan, 2008, p.53).

Research shows that “professional coaches who specialize in the coaching profession perceive more typical nondirective and client-centred coaching behaviours over time”. It is argued that coaches “have a wide array of behavioural responses at their disposal and as they mature, they will reflect on which of their interventions to use” (de Haan & Nilsson, 2017, p. 328). This might imply that starting from a client – centred approach requires the coach to apply a wider portfolio of potential responses and methods. By becoming more skilful over time, this will provide greater flexibility to design approaches specific to the individual (Cox, Bachkirova, Clutterbuck, 2010, p.419-420). However, this also means that the coach will always influence the conversation, both intentionally and unintentionally, by every contribution to that conversation. The coachee, as second element in the relationship, will equally bring a plethora of variables into the conversation. “An orderly, well-controlled conversation is out of the question; there are simply too many variables” (de Haan & Burger, 2014, p. 15). Consequently, de Haan argues it is the coach’s responsibility to keep a window onto the coachee’s contribution to the conversation because the coachee’s issues are data and material to work with. And it is the reciprocal relation, where coach and coachee explore the map of experiences in the moment, that defines the foundation of the coaching work.

### Objectives

Each coaching session will consist of an in-depth discussion of the decision-making process around the case of the patient of which an alert was given.

The coach invites the coachee to describe and discuss:

- The currently challenging situation
- Perceived subjective reactions by him-/herself and others (patient, family, colleagues) to the situation
- Perceived challenges in the mutual communication about the situation, whereby attention is paid to characteristics of the own communication style and the style of the others involved
- Perceived challenges in the medical ethical decision process in the challenging situation, whereby attention is paid to differences and similarities in goals and values between all parties involved

By discussing these topics, the coach aims at addressing and fostering insight in:

- Avoidance reactions in how the coached doctor and head nurse, their team, and the patient and their family cope with the challenging situation

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- Helping and obstructing relational patterns in relation to the team as well as in relation to the patient and his family
- Own communicative style
- Own decision-making style
- Own strengths and weaknesses at the level of empowering leadership

Depending on the challenging situation and the coachee's style and trajectory the coach will direct sessions towards:

- Acknowledging and gaining insight in avoidance reactions, relational patterns, communicative processes, decision making processes and empowering leadership
- Confronting the coachee with processes he/she fails to acknowledge
- Reflecting with the coachee on dealing with and intervening upon such processes

#### **Success indicators, to be rated post - intervention by the coach**

1. The intervention was based on the procedural alert. If not, please specify the trigger.
2. The coachee became more aware of his/her subjective reaction to the uncertainty of the prognosis.
3. The coachee became more aware of his/her subjective reaction to the anticipated decision.
4. The coachee shared his understanding about the doubt of others in relation to the described therapy.
5. The coachee gave proof through specific comments of insight into the perspective of the patient.
6. The coachee gave proof through specific comments of insight into the perspective of the family.
7. The coachee gave proof through specific comments being able to separate internal avoidance strategies from external barriers.
8. The coachee described an increased insight on dealing with conflict.
9. The intervention took place in an appropriate coaching setting (i.e. confidential, discrete, serene, not be pressured by time...).
10. We were able to process multiple learning loops which fostered the coachee's thinking.
11. The coachee demonstrated his/her ability to implement newly acquired insights during the interdisciplinary meeting.
12. The coachee described empowering leadership skills applied during the interdisciplinary meeting.

#### Intervention two: facilitation of interprofessional reflection on patient cases

##### **Session focus**

A work shift hand-over is a moment in which a collection of possible perceived pressures might arise at both the team ending their shift as well as the team starting their shift. The team handing over is still processing data from their shift experience, doesn't want to forget anything for the hand-over, is aware the work is about to end, is moving into a transitional

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zone of 'work' ending and 'not-work' starting, all in which an authority figure is present. The team starting the work shift is equally still processing data from the not-work world they just left, is moving into a transitional zone of 'not-work' ending and 'work' starting, doesn't want to miss anything during the hand-over, is under time pressure as patients are waiting, all in which an authority figure is present.

The team coach will focus on facilitating a conversation in which: (a) challenges and opportunities in exchanging complex data occur; (b) challenges and opportunities in relating with colleagues and team occur; (c) challenges and opportunities in speaking up during a time - pressured moment occur. The team coach will aim at increasing awareness and efficacy in dealing with these topics starting from a collaborative relationship with all attendees.

### Method

Over a period of 16 weeks with 2 à 3 interventions per week, a team coach will facilitate the hand-over of the clinician team. The team coach will be randomly allocated from the pool of team coaches, always different from the individual coach, so to avoid reciprocal contamination of findings between the individual work and the work with the team.

The team facilitation we implement will start from the principles described by Ancona & Bresman (2007, 2023) and Edmondson (2014, 2016).

It is first important to coin a definition of team within the context of the research. Organisations use a variety of types of teams. Team type may vary in different ways: they might be spread across several dimensions, being cross-functional as opposed to single-function, being time-limited or enduring over longer periods of time, being manager-led or self-led. The teams we are working with hold following attributes: a collection of several disciplines, attendance based on working shifts, connected to the world outside the team through different stakeholders (family, social services, compliance systems, specialty disciplines). We firstly argue that the composition and purpose of the concerned teams can be defined as an X-team. "X-teams combine internal focus with a strong orientation toward external outreach and learning." Consequently, the team is not a closed circle but has a more permeable boundary. "X-team members are active in crossing team boundaries and bringing others in." (Ancona & Bresman, 2023). A second argument to define the concerned teams as X-teams is the changing circumstances to which these teams are permanently exposed. Teams face changes to (1) the power structures in which teams operate, (2) the structure of knowledge with which they work, and (3) the structure of tasks they perform. (Ancona & Bresman, 2007).

As findings suggest, psychological safety is essentially a group-level phenomenon in which group defence mechanisms might influence the primary task of the team. "Some of this variance can be attributed to supervisor behaviours, which convey varying messages about the consequences of taking the interpersonal risks associated with behaviours such as admitting error, asking for help, or speaking up with ideas." (Edmondson, 2014). On top, those on the front line of providing critical human services often feel less psychologically safe. Especially in health care where team-based efforts focused on learning can "be

thwarted by the challenge of speaking up across status lines. When such status differences are not overcome, errors and other service delivery problems can happen.” (Edmondson, 2016). The team coach intends to foster psychological safety through facilitation of the hand-over by stimulating open speech. “Team psychological safety is defined as a shared belief that the team is safe for interpersonal risk-taking. It should facilitate learning behaviour in work teams because it alleviates excessive concern about others' reactions to actions that have the potential for embarrassment or threat, which learning behaviours often have.” (Edmondson, 1999). Therefore, the team coach uses in-the-moment experiences to help understand inhibitors of a culture of open speech. By speaking to what was happening in the conversation it will contribute to providing insight and to upskilling the conversation techniques of the clinicians.

## Objectives

The team coach will facilitate the hand-over to achieve following objectives:

- **Fostering a blame-free environment** by creating a climate where clinicians feel safe to report concerns, near misses, or uncertainties without fear of blame or retribution.
- **Encouraging questions and clarifications** by actively prompting team members to ask questions or clarify uncertainties, regardless of role or seniority.
- Actively inviting participation from less vocal members to avoid dominance by a few voices, in line with inclusive communication.
- **Acknowledging external inputs by inviting to** integrate relevant updates from external units and consider family or patient-reported concerns.
- *Reducing power dynamics and enhancing inclusive collaboration* by inviting input from all attending team members, especially nurses, junior doctors, and other health staff.
- Empowering distributed leadership by enabling team members to take the lead on different aspects of the conversation or decision-making, fostering shared responsibility and adaptability.
- Reflecting on what was difficult or unusual during the shift and what the team learned to build a *learning culture and team cohesion*.
- Encouraging proactive discussion of anticipated challenges for the next shift (e.g., potential discharges, difficult families, critical cases) to **promote anticipation and adaptability**.
- **Fostering a psychologically safe culture of co-owned improvement** by soliciting feedback on the hand-over process itself and iterate improvements collaboratively.

## Success indicators, to be rated post - intervention by the coach

1. Team members *openly asked clarifying or probing questions without hesitation, regardless of seniority*.
2. *Each expressed concerns or uncertainties about patient care, even if it involved potential errors or ambiguous situations*.
3. *All contributed to the discussion - not just the most senior staff*.

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4. Team members **built on each other's input** by referencing and developing the ideas or observations of others, showing active listening and shared problem-solving.
5. *Team members admitted knowledge gaps or uncertainty without embarrassment or defensiveness.*
6. *Body language showed openness - eye contact, nodding, relaxed postures - rather than disengagement or tension.*
7. *Updates or insights from other departments (e.g., lab, radiology, specialists) were shared and brought into the conversation.*
8. The team discussed expected changes in patient status, potential risks, and contingency plans for the upcoming shift – without perceived judgement of others.
9. *Different team members led parts of the hand-over depending on their role or knowledge, rather than waiting for hierarchy to guide the conversation.*
10. Team members could express fatigue or emotional impact (e.g., after a difficult case) *without stigma or shutdown.*
11. The group occasionally reflected on how they worked together during the previous shift - what went well and what could be improved.
12. Team members *suggested ways to improve the hand-over process itself, and authority was receptive to them.*

Intervention three: facilitation of structured metareflective sessions on specific themes related to ethical decision-making with multidisciplinary teams

### Session focus

Medical professionals are confronted with death and suffering, with uncertainty and powerlessness in aversive situations, and with the prospect that decisions and actions might have an aggravating impact on those aversive situations. Such confrontations have a shocking effect and provoke mixed feelings. Shame, pity, compassion and guilt might come to the fore, but the bottom-line reaction to death and decay is desperate anxiety. As described by Menzies Lyth (1988): if elementary anxiety is not faced and worked through, all kinds of dysfunctional defences ruin collaborations and undermine thoughtful medical ethical decision-making.

Given this challenge, the structured metareflective group sessions will aim at helping the team to: (a) discern which sensitive themes were currently affecting the team; (b) reflect on how the team is currently facing or avoiding difficult questions and discussions concerning these topics; (c) evaluate each own's role and strategies in facilitating or obstructing open reflection; (d) reflect on how the team is dealing with the emotional distress that ethically sensitive medical topics provoke.

### Method

Over a period of 4 months with 1 intervention per month, a team coach will facilitate structured metareflective group sessions based on experienced cases during the last month. The team coach will be randomly allocated from the pool of team coaches, always different

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from the individual coach, so to avoid reciprocal contamination of findings between the individual work and the work with the team.

The team facilitation we implement will start from four principles of the field of Systems Psychodynamics.

The structured metareflective group sessions will consist of involved practitioners from different areas of expertise yet having participated in either individual coaching upon alert or team coaching during the work shift hand-over. Consequently, all potential attendees might have experienced similar challenges.

Firstly, like all human beings, the clinician is individually subject to varying degrees of unconscious defences such as repression, minimisation, and denial of negative emotions and thoughts. These responses are particularly reinforced in the face of death, suffering, uncertainty, and a sense of powerlessness in distressing situations. Such defences serve to help us make sense of recurring difficult experiences and protect us from confronting painful realities we may wish to avoid. However, they can also distort our perception of reality and hinder our capacity to absorb new insights about ourselves and the world around us (Steiner, 2017, p. 54). By helping clinicians making sense of their unprocessed defences, the team coach intends to ease possible pain.

Second, clinicians operate in rotating teams. "People stretched across many teams face issues of fragmented attention, task switching, conflicting demands, and work overload. These, in turn affect their individual cognitions, behaviours, and performance as well as both learning and productivity at the team and organisational levels." (Mortensen and Gardner, 2017). Next to this reality, the clinicians' team is subject to group behaviour, as researched by Bion. Bion identified two modes of group functioning: the *work group*, focused on the task, and the *basic assumption group*, driven by unconscious emotional needs (e.g. dependency, fight-flight, pairing). In practice, a facilitator trained in Bion's theory can observe when a team deviates from task-focused behaviour - for example, when members avoid responsibility (dependency) or scapegoat others (fight-flight). However, individuals are often unaware of those phenomena, which contribute to the separation of their stated intentions from their hidden agendas. "The hidden agendas of the individuals within the group collectively make up the latent (covert) aspects of group behaviour." (Armstrong, Sher, Lawlor, 2022, p. 122). By naming and addressing these phenomena, the team coach helps the group return to productive engagement. This enhances team effectiveness, psychological safety, and decision-making under pressure.

Third, all involved practitioners in the study belong to the same institution. It is argued that unconscious processes within institutions can hinder change because institutions, as collective entities, develop structures and routines not only to fulfil their primary tasks but also to manage underlying anxieties. These unconscious dynamics often manifest as resistance when change threatens established norms and the psychological equilibrium of the organisation. Therefore it is important trying to recognize and address these hidden forces in order to facilitate effective transformation. (Obholzer A., 1987). By exploring unconscious factors and helping them to surface, the team coach supports the clinicians in better navigating change and avoiding the pitfalls of unacknowledged resistance.

Fourth, as any individual operating in an organisation, clinicians are subject to social defences. 'Social defences are "collective arrangements, such as an organisational structure, a work method, or a prevalent discourse, created or used by an organisation's member as a protection against disturbing affect derived from external threads, internal conflicts, or the nature of their work."' (Petriglieri, 2010, p. 47). By helping clinicians making sense of their social defences, the team coach intends to lower the individual anxiety and consequently to contribute to a higher mental well-being.

It is the primary task of the team coach to help attendees exploring their unconscious and invisible psychodynamic processes and structures within the context of their organisation's internal and social dynamics. "A well-trained developmental coach should at least be able to develop hypotheses and interventions both at an individual level as well as a group level." (Compernelle T., in Kets de Vries, M., Korotov, K., Florent-Treacy, E., 2007, p.35). The main focus is to support the group in progressing with the task by enhancing the quality of their interactions (Thornton, 2016, p. 38). It is also of utmost importance for the team coach to monitor consistently focus on the primary task to avoid the abuse of power and "to keep at a relative minimum the occurrence and spread of basic assumption activity." (Obholzer A., Zagier Roberts V., 2019, p.55). Consequently, the team coach needs to be aware of their own anxieties, being able to observe for themselves what actually goes on, apart from what is stated and then be able to reflect on the significance of what has been observed.

## Objectives

The team coach will facilitate the structured group reflection to support attendees in:

- **Recognising unconscious individual defence mechanisms** (e.g., repression, denial, minimisation) in their responses to distressing clinical experiences.
- Understanding how unacknowledged negative emotions can distort perception and hinder personal and professional development.
- **Reflective group dialogue on emotionally charged clinical events** by exploring the emotional undercurrents of recent clinical cases.
- Recognizing group patterns such as dependency, fight-flight, and pairing, and consequently the group return to task-focused work.
- Identifying how institutional routines and structures may produce social defences and unconsciously serve to avoid anxiety, and how this undermines learning.
- Applying systems psychodynamic thinking to formulate a working hypothesis **about unconscious dynamics at individual and group levels.**
- **Maintaining focus on the primary task in group facilitation** through techniques to help the group stay focused on their collective task, resisting distractions or unconscious diversions.
- **Applying ethical awareness in managing group dynamics and facilitator power** through reflection on their own use of authority, managing the tension between containment and control to avoid misuse of power.
- **Using self-as-instrument in observing and interpreting group processes** by cultivating the ability to observe their own emotional reactions and use them as data in understanding and intervening in group dynamics.

**Success indicators, to be rated post - intervention by the coach**

1. **Participants** contributed to reflective conversations with honesty and vulnerability, particularly around emotionally charged clinical experiences.
2. **Participants** showed sensitivity in how they express opinions or take initiative, balancing assertiveness with attentiveness to group safety and boundaries.
3. **Participants** demonstrated an ability to notice and articulate emotional discomfort (e.g., anxiety, frustration) without immediately resorting to defensive responses.
4. **Participants were** able to articulate collective behaviours such as avoidance (fight/flight), dependency, or undue optimism (pairing).
5. **Participants** described their connection between their unprocessed emotional experiences and specific impacts on clinical judgement, learning, or interpersonal behaviour.
6. **Participants** critically reflected on organisational norms, taken-for-granted routines, or structures that may unconsciously act as barriers to emotional insight or learning.
7. **Participants** offered thoughtful interpretations of group or individual behaviour, by means of testing these hypotheses through observation and discussion.
8. **Participants** described changes in clinical, interpersonal, or team behaviours by referring back to insights from prior sessions and indicated how these have influenced their clinical or interpersonal conduct.



### Quality assurance

To secure the quality of the intervention the coach will work under the guidelines of the Ashridge Code of Conduct (see appendix).

The quality of the coaching we implement will be also supervised by an independent third-party supervisor; governed by ethical standards and principles as adopted from de Haan (de Haan, 2019). Five moral foundations which support integrity in coaching and research were applied: (a) independence to guard the physician's and clinician's autonomy; (b) informed consent so the physician/clinician knows what he/she is getting involved in; (c) confidentiality to safeguard the physician/clinician; (d) respect and diversity to allow multiple voices and perspectives and care about vulnerable parties; (e) integrity and trust to comply with legislation and to handle data in an ethical way.

This supervisor has a normative, formative and restoring role (Proctor, 2006). The normative role of the supervision aims at monitoring the quality of the coaching methodology and ethical aspects with regard to the study purpose. The formative role aims at supporting the coach in further developing and refining his/her skills in general and more specifically about the study purpose. The restorative role aims at guarantying the energy of the coach and at resolving potential conflicts due to emotional or unconscious dynamics in the team.

Coaching Supervision is about ensuring high quality coaching provision and takes the form of ongoing meetings between the supervisor and the coach. One way of looking at the process of supervision is provided by the Seven-eyed model (Hawkins and Shohet, 2000). Originally developed for use with psychotherapists and counsellors, it is now being applied to coaching and mentoring. It describes the 7 areas that supervision can focus on:

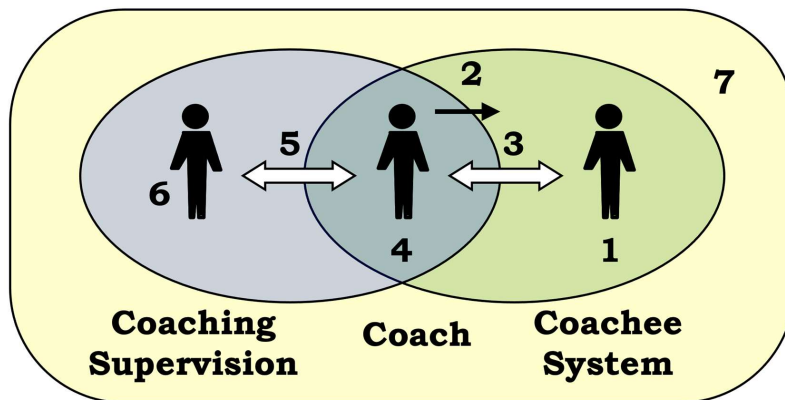
1. The coachee: The focus is on the coachee's situation – the case the coachee wants help with, how they present the issues and the choices they are making.
2. The coach's Interventions: The focus is on the interventions the coach made, how and why they made them, and what else they might have done.
3. The relationship between the coach and coachee: The focus is on neither the coach nor the coachee but on the conscious and unconscious interactions between the two of them, so that the coach develops a better understanding of the dynamics of the coaching relationship.
4. The coach: The focus is on the coach's own experience as an instrument for registering what is happening beneath the surface of the coachee's system.
5. The supervisory relationship: The focus is on what the coach has absorbed from the coachee's system and how it may be playing out in the relationship between coach and supervisor.
6. The supervisor's self-reflection: The focus is the supervisor's "here and now" experience with the coach and how this can be used to shed light on the coach/coachee relationship.
7. The wider context: The focus is on the wider organisational, social, cultural, ethical, and contractual context within which the supervision is taking place.

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In focusing on areas 1-3, the supervision is concerned with reflecting on the coaching session itself – its content, the interventions made, and the dynamics of the coaching relationship.

In areas 4-6, the supervision is concerned with the coaching session as it is reflected in the here and now experience of the supervision session.

The value of this model is that it maps the areas that supervision can focus on, making it easier to ensure that we have covered the ground.



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