ENHANCING PALLIATIVE CARE IN INTENSIVE CARE UNITS (EPIC) TRIAL – DESIGN OF THE HEALTH ECONOMIC SUB-STUDY

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EPIC
ENHANCING PALLIATIVE CARE IN INTENSIVE CARE UNITS

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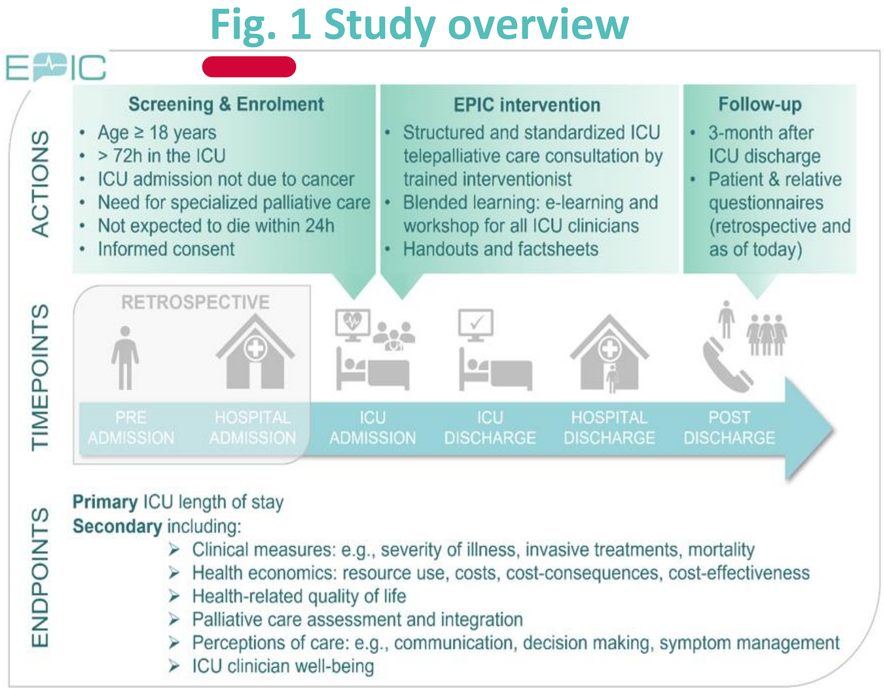
Background EPIC trial

- Aims to assess blended learning and integration of specialized palliative care into intensive care via telemedical consultations.
- Is intensive care unit (ICU) length of stay reduced and care for critically ill non-cancer patients improved?
- We present the design of the health economic sub-study, aiming to evaluate cost implications and cost-effectiveness of the intervention.

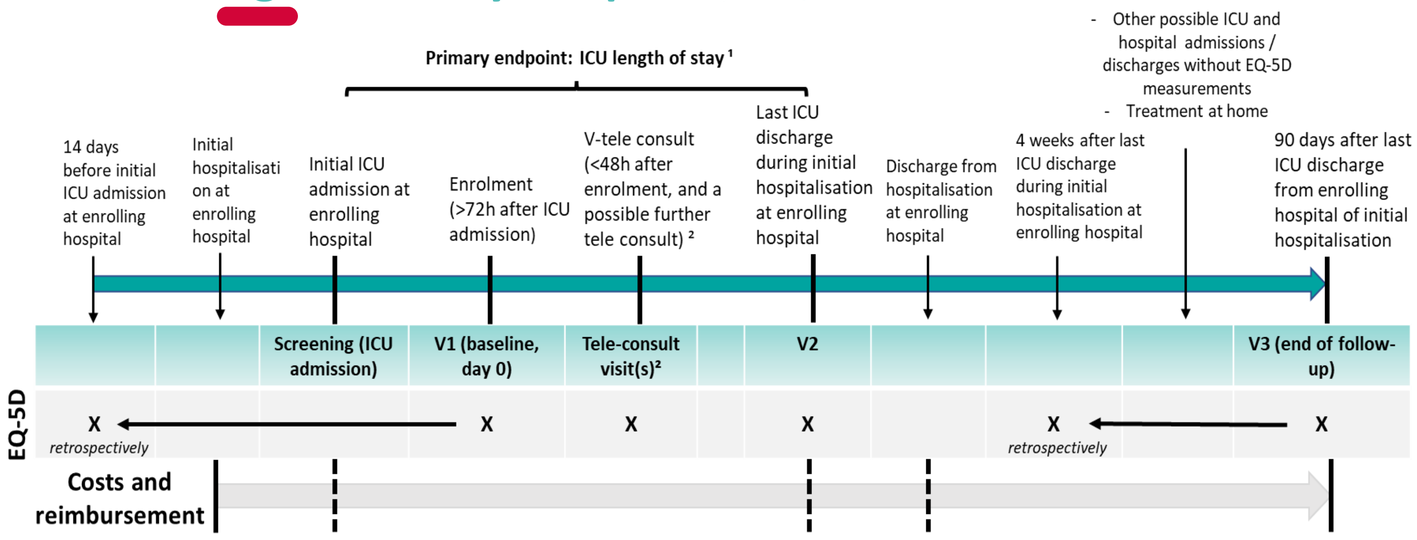
Fig. 1 Study overview



Methods

- EPIC is a European, stepped-wedge cluster randomised trial conducted in 7 clinical centers and 30 multidisciplinary intensive care units in 5 European countries (Greece, Czech Republic, Italy, Israel, and Germany). Each clinical center is a "hub" that provides specialist consultations to 2 to 5 more distant intensive care units, which act as "satellite centers".
- N=2001 patients anticipated. Enrolment since October 2024. Last patient last visit expected September 2027.
- The intervention includes early and high-quality access to palliative care through
  (a) telemedical consultations by experts from external institutions specialized in palliative care provided to ICU staff
  (b) training of ICU staff in basic palliative care
  (c) use of checklists for early identification of eligible patients and structured recording of palliative care needs.
- Health economic data collection items were determined and tailored-to-purpose through literature review, consultations with consortium experts and financial departments of participating centres.
- Cost and value for money of the complex intervention compared to standard care will be studied from healthcare system, societal and institutional perspectives. The latter will consider reimbursements and costs at the hospital level.
- Given challenges of interpreting standard cost-effectiveness metrics (costs per quality-adjusted life year gained) in our setting, costs will also be related to other trial outcomes in a cost-consequence analysis.

Fig. 2 Primary endpoint, EQ-5D and cost measurements



[1] The primary endpoint is defined as the total number of consecutive and/or non-consecutive ICU days from the start to the end of the initial hospitalisation at the enrolling hospital. It can include several ICU stays at the enrolling hospital during the initial hospitalisation (same or different ICUs consecutively or with a normal ward stay in between).
[2] Intervention group only
Please note that
- the order of some time-points in the above graph might be different in reality (e.g. "discharge from enrolling hospital" might be after "4 weeks after last ICU discharge during initial hospitalisation at enrolling hospital")
- together with the EQ-5D questionnaire, information on patient's consciousness/unconsciousness is collected

ICU = intensive care unit, V = visit

Results

- Health-related quality-of-life (HRQoL) is assessed using appropriate language versions of the EQ-5D-5L questionnaire, completed by patients or proxies. A mixture of retrospective and current-day EQ-5D-5L measurements covers the period from 14 days before ICU admission to 3 months post ICU discharge (see Figs. 1 & 2). Follow-up data is collected during telephone interviews from surviving patients and/or patients' relatives including HRQoL, use of health services and resources.
- Given variability in reimbursement and accounting systems in the five recruiting countries, collection of patient-level and reimbursement data, and site-level unit cost data, is being pursued as consistently as feasible.
- Patient-level cost and billing data are provided by hospital administrations. Variables collected at the patient level will cover reimbursements and real costs for the period from start of index hospitalization to 3-month follow-up (including flat-fee reimbursement codes if applicable) (Fig. 2).
- Medical resource use data, including relevant admission and discharge dates, are extracted from clinical information systems by study staff (until the end of index hospitalization), or self-reported by patients and relatives (from end of index hospitalization to the 3-month follow-up). This information will be combined with unit costs from publicly accessible, external sources or hospital administrations.
- Information on productivity losses and informal care is also self-reported.
- The costs of the intervention will be estimated considering the cost of telemedicine technology (based on information from centres and/or technology providers), staff time (for training, palliative care consultations) and staff costs per unit of time, by relevant profession.
- Data monitoring quality checks are defined and ongoing, as a basis for corrective action if required.

Conclusions

- We have implemented a pragmatic, feasible strategy for health economic data collection in a complex trial setting.
- Ensuring data quality and completeness requires continuous monitoring to identify needs for corrective action.
- The economic findings may help identify barriers to palliative care integration and facilitate larger-scale implementation.

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