The Role of the Research Coordinator/Nurse in Critical Care Research.

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Introduction- The Overall role of the RC/RN

- The Research Coordinator/Nurse (RC/RN) is an essential member of the Intensive Care Unit (ICU) Research Team and the Irish Critical Care-Clinical Trials Network.
- At St. Vincent's University Hospital we coordinate a number of randomized controlled trials and global observational studies in our ICU (Figure 1). The ICU RC/RN coordinates each step of the study process on the ground.

Previous Studies

STARRT-AKI, PHARLAP, peptic, transfuse, SPICE-EGDS

Current Studies

TEAM ICU, TAME Cardiac Arrest, REMAP-CAP Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

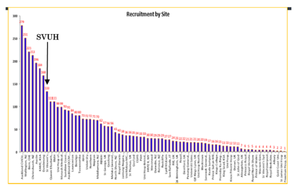
Fig 1. Studies we've previously been involved in and currently coordinate at our site.

- Prior to study commencement we assess study feasibility at our site and apply for ethical approval for the study at our site.
- On a daily basis we screen ICU patients for study eligibility and enrol and randomise eligible patients following discussion with the ICU consultant.
- Another important aspect of our role is education and research dissemination.
- We are responsible for maintaining study documents at our site and archiving studies after completion.

Day-to-day Role of the RC/RN

- Daily we screen patients for inclusion in our clinical trials (Figure 2).
- Following discussion with the ICU consultant suitable patients are randomised into the study.
- ❖ We are currently **the second highest recruiting site** for the TEAM trial worldwide– Prospective Multicentre Phase III RCT of early activity and Mobilisation compared with standard Care in Invasively Ventilated Patients in ICU.
- ❖ In the SPICE III study (study of sedation practices in mechanically ventilated patients) our ICU was the **8th highest recruiting site worldwide** with 133 participants enrolled (Figure 3A) and the **fastest recruiting site** based on patients recruited per week (Figure 3B). This was largely due to the efforts of our ICU staff nurses.

A



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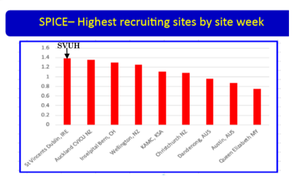

Fig 3. Recruitment rates in the SPICE-III Randomised Controlled Trial. Sites were ranked by total number of participants recruited into the SPICE-III study (A) and by fastest recruiting site based on number of participants recruited per week (B). St. Vincent's University Hospital (SVUH) ICU is highlighted. These figures were taken from the SPICE-III newsletter.

- We speak with families and patients and obtain assent/consent for study involvement.
- We ensure the study protocol is followed and support our nurses, doctors and allied health professionals in delivering the study intervention.
- We are responsible for the data collection and submission including follow-up telephone questionnaires at 6 months and up to 2 years.

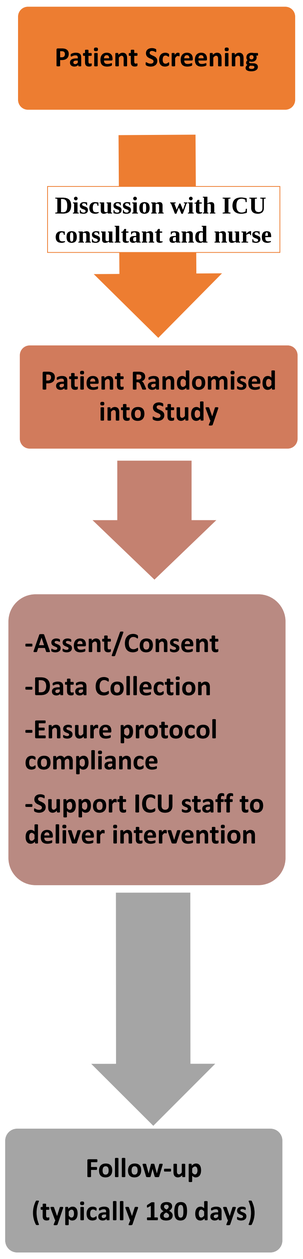

Fig 2. Day-to-day role of the RC/RN.

Follow-up

- As many of our studies involve follow-up with recruited patients, follow-up telephone questionnaires are performed with patients typically at Day 180 post randomisation or as per study protocol.
- Follow-up is performed by a blinded member of the research team.
- Each member of the research team is trained to perform follow-up.
- These follow-up questionnaires are an essential part of each study which assess how the patient is doing, answer key study questions and involve more patient-centred outcomes such as quality of life.

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Education

- Another important aspect of our role is education, training and research dissemination (Figure 4).
- We provide GCP training, study specific research training and quarterly research updates to staff.
- We provide research updates to non-consultant hospital doctors (NCHDs) and support them in carrying out their own research.
- We provide study updates and disseminate study newsletters and results particularly through our research board in the ICU.
- We also support staff nurses to attend conferences.

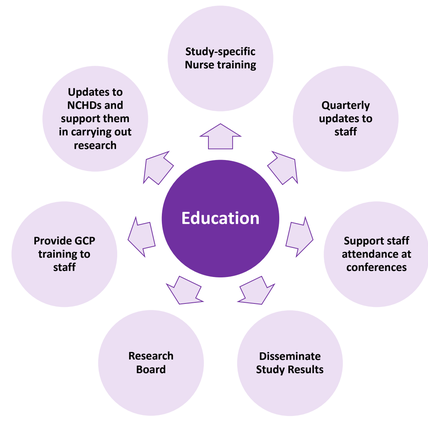

Fig 4. Education as part of the ICU RC/RN role.

Collaboration- Internationally and closer to home: The Irish Critical Care Research Coordinators Group

- International, national and local collaboration are all important to the coordination of our ICU research studies (Figure 5).
- We collaborate internationally on many of our studies in particular with the Australian and New Zealand Intensive Care-Research Centre (ANZIC-RC).
- We collaborate with sites throughout Ireland through the Irish Critical Care-Clinical Trials Group (ICC-CTG).
- We have recently establish a Research Coordinators Group within the Irish Critical Care-Clinical Trials Network (ICC-CTN) and ICC-CTG.
- This group supports collaboration between ICU RCs within Ireland and a main aim of this group is to provide advice, support and share research tools. This group will meet 1-2 times annually.
- Locally, we collaborate with ICU staff and the ED department on a daily basis.
- Our research involves a multidisciplinary team including nurses, doctors, dietician, pharmacist and physios so it is important we communicate and collaborate with all ICU staff members.

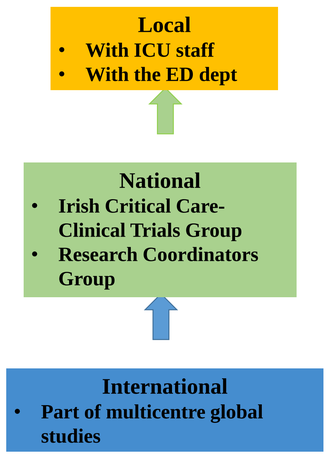

Fig 5. Types of Collaboration. International, national and local collaboration are all required for the coordination of our ICU research studies.

Study Tools

- In order to ensure a study runs smoothly we generate a number of study tools to facilitate patient enrolment, data collection and the running of the study (Figure 6).
- These tools are designed to support and aid in the running of the study and improve study visibility.
- These include study packs, trial posters, lanyards, pocket cards and stickers.

A

B

C

Fig 6. Examples of study tools.
A study pack (A), a study lanyard with information on the study and inclusion and exclusion criteria (B) and study stickers (C).

Conclusions and Future Direction

- In St Vincent's University Hospital ICU the ICU Research coordinator is an essential member of the research team who coordinates all aspects of a number of clinical studies.
- This role involves screening, randomisation, consent, data collection and patient follow-up on a day-to-day basis.
- Education, research and training and collaboration internationally, nationally and locally are important aspects of this role which truly involves multidisciplinary communication.
- The future directions are to further expand the studies we run in the ICU, further develop ICU research in Ireland and the continued development of the Irish Critical Care Research Coordinators group with an overall aim to improve outcomes of the critically ill.