**ICU Bereavement Follow-up Project**

**Protocol, Version 2, dated 31st May, 2018**

**1. INVESTIGATOR DETAILS AND QUALIFICATIONS**

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On behalf of ICU Bereavement Follow-up Project Team

**2. PURPOSE OF STUDY**

The primary aim of this study is to establish the feasibility of delivering a bereavement service by the Intensive Care Unit (ICU). Secondary aims are to assess the value of feedback received about the end-of-life care and how the service is viewed by family members.

**3. BACKGROUND AND PRELIMINARY STUDIES**

The Royal Adelaide Hospital (RAH) ICU annually has around 300 patients who die during their admission. This accounts for around 30% of all deaths at the RAH. Dying during, or shortly after an ICU admission could potentially add to the existing burden of the dying process to the individual, the families and the health system [1.2]. Providing a bereavement follow-up service may assist in improving end-of-life care for patients, families and the hospital system [3,4,5].

Assessment of empathic practice towards families of ICU patients is a current Australian Council on Healthcare Standards indicator [6]. It is also one of the Australian Commission for Safety and Quality in Health Care essential elements for safe and high-quality end-of-life care [7]. Australian and New Zealand Intensive Care Society (ANZICS) also recommended comprehensive follow-up bereavement aftercare service and emphasized that care of the family even after bereavement is integral part of intensive care [8].

Currently, in Australia, there has not been any published data on bereavement follow-up with telephone interview.

**4. PARTICIPANTS**

The family representative of patients who die in the ICU will be included in the study. They will be excluded if a family representative is not contactable or declines participation.

**5. STUDY PLAN AND DESIGN**

The treating team will refer the patients to the bereavement follow-up service at medical consensus of end-of-life. After the patient’s death, the appropriate family representative will be given a brochure providing bereavement information and a letter outlining the follow-up service (Appendix 1). The 30 minute interview is based on the validated CAESAR tool focused on care around the end-of-life [9]. The responses will be recorded as Likert scores with the option to provide qualitative feedback. The bereavement calls will be made at 4 weeks, by clinicians who are experienced intensive care doctors and nurses. These clinicians are familiar with the intricacies of talking to distressed families. They will complete the follow-up interview. If during the course of this interview contact, they feel the participant is significantly anxious or distressed they will follow the steps below.

The intensive care clinician will ask the study participant if they wish to: (1) talk to the intensive care clinician about the matter, (2) receive the contact details of mental health services (e.g. psychologist or counsellor) in their local area, and/or (3) have the intensive care clinician organise a psychology/counselling appointment for them through their General Practitioner.

For significantly distressed study participants, the intensive care clinician will also contact them again within 72 hours to ensure their wellbeing. During this conversation they will offer to re-provide them with the contact details of the mental health services in their local area, ask them to see their General Practitioner as soon as is practical, and/or offer to make the appointment for them (Appendix 2).

**6. OUTCOMES**

The telephone interview questionnaire will consist of 16 questions in 4 sections. The first section of the questionnaire relates to the care of the patient and support for the family. The second section relates to the communication between ICU and the family. The care of the patient and the discussion around organ donation are covered in the next two sections. The last section consists of open-ended question relating to how the family member feel the end-of-life care can be improved. The telephone interview will not be recorded.

Please see the attached the conversation plan (Version 1, dated 8th Mary 2018) and questionnaire (Appendix 3).

**7. ETHICAL CONSIDERATIONS**

The proposed study is low-risk. The proposal meets all the criteria for Quality Assurance as specified by the National Health and Medical Research Council (NHMRC) in Australia, apart from the intention to publish non-identifiable data,

The family member will be notified of the follow-up telephone interview when the letter and bereavement brochure are provided. They will also be able to opt out at any point before or during the telephone interview.

**8. ANALYSIS AND REPORTING OF RESULTS**

Simple descriptive statistical procedures will be used to calculate means and percentages. The responses for each question will be reported as a percentage of the total number.

All data collected by this project will be kept for a minimum of 7 years, or as otherwise required by regulatory authorities. All study data will be entered into a secure password protected case report form (REDCap). The study participants are allocated a unique identifier by REDCap. A separate re-identification log will be kept on a secure password protected SA Health network drive with access limited to study staff. This is necessary to allow participants to be followed up and to keep study data de-identified. Study related files are kept in a locked cupboard in a secure swipe card access office, with access limited to study related staff only.

It is the intention of the researchers that the data collected by this survey be presented at departmental meetings. Only aggregated data will be presented or published in appropriate critical care journals. All study investigators will approve all presentations and publications.

**9. REFERENCES**

1. Wunsch H, Linde-Zwirble W, Harrison D, Barnato A, Rowan K, Angus D. Use of Intensive Care Service during Terminal Hospitalizations in England and the United States. American Journal of Respiratory Critical Care Medicine 2009; 180:875-880.
2. Azoulay E, Pochard F, Kentish-Barnes N, Chevret S, Aboab J, Adrie C, Annane D et al. Risk of Post-traumatic Stress Symptoms in Family Members of Intensive Care Unit Patients. American Journal of Respiratory Critical Care Medicine 2005; 171: 987-994.
3. Milberg A, Olsson E, Jakobsson M, Olsson M, Friedrichsen M. Family Members’ Perceived Needs for Bereavement Follow-up. Journal of Pain and Symptom management 2008; 35(1): 58-69.
4. Warrillow S, Moran J, Jones D. Experience and Outcomes for Relatives of Patients Dying in the ICU: The CAESAR Tool. Journal of Thoracic Disease 2016; 8(7): E611-E614.
5. Cuthbertson S, Margetts M, Streat S. Bereavement Follow-up After Critical illness. Critical Care Medicine 2000; 28(4): 1196-1201.
6. The Australian Council on Healthcare Standards 2015 Intensive Care version 5. Clinical Indicator User Manual.
7. Australian Commission for Safety and Quality in Health Care (ACSQHC) National Consensus Statement: Essential Elements for Safe and High Quality End-of-life Care 2015.
8. ANZICS Statement in Care and Decision-Making at the End of Life for the Critically Ill (edition 1). Melbourne, ANZICS; 2014.)
9. Kentish-Barnes N, Seegers V, Legriel S, Cariou A, Jaber S, Lefrant J, Floccard B. CAESAR: A New Tool to Assess Relatives’ Experience of Dying and Death in the ICU. Intensive Care Medicine 2016; 42:995-1002.

**10. DATE OF PROPOSED COMMENCEMENT AND DURATION**

The study is planned for the duration of one year, commencing June 2018.

**11. SIGNATURES OF INVESTIGATORS**

The Principal Investigator to confirm that the protocol has been read and endorsed.

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**Appendix 1**

Central Adelaide

Local Health Network

Intensive Care Unit

Royal Adelaide Hospital

Critical Care Services

Port Road

Adelaide SA 5000

Health.Bereavement@sa.gov.au

www.health.sa.gov.au

ABN: 96 269 526 412

Dear

On behalf of the Intensive Care Unit at the Royal Adelaide Hospital please accept our sincere condolences on the loss of your loved one. Experiencing bereavement in the ICU is understandably difficult. We hope our team has met the needs of your loved one and your family.

Many families have questions about ‘what happens now?’ To assist you, we have provided some information which you may find useful.

Providing a high standard of care for patients and families at end of life is important to us. Understanding your experience during this difficult time can assist us to continually improve the quality of our care. We welcome any feedback you may have about the care given to you and your loved one.

As part of our commitment, we would like to have a telephone conversation with you in about a month’s time. The caller will be a trained member of our bereavement team and will ask some specific questions regarding the care you and your loved one received and your experience. The call will take about 20 minutes and you can opt out of the call if you wish by contacting us through the email below.

Your feedback is valuable and will inform how we can improve the care given to all families and patients at the end of life.

Sincerely,

The ICU Bereavement follow-up service

Intensive Care Unit Team

Royal Adelaide Hospital

Health.Bereavement@sa.gov.au

**Appendix 2**

For immediate support please refer to one of the following services:

* If you feel you are in immediate danger and cannot keep yourself safe, call 000 or present to your nearest hospital emergency department.
* Ring Lifeline on 13 11 14. This is a 24-hour emergency telephone service.
* Ring the Assessment and Crisis Intervention Service (ACIS) on 13 14 65. ACIS is a 24-hour mental health triage service which can link you in to the appropriate mental health services.
* Please plan a visit to your local GP to discuss any concerns. They will be able to provide you access to ongoing support and counselling through a mental health care plan.

National and local support services:

* Beyond Blue on 1300 224 636. Telephone support is available 24 hours a day, 7 days a week
* Road Trauma Support team of SA on 1800 069 528. Individual and group based support for individuals affected by road trauma including bereavement.
* Anglicare SA on (08) 8131 3400, Monday to Friday 9:00am-5:00pm. Provides grief and loss counselling to families affected by the loss of a loved one

RAH telephone numbers:

* RAH Consumer Advisor on (08) 7074 1377
* RAH switchboard on (08) 7074 0000
* RAH Social Work Department Enquires on (08) 7074 4000

Coroner’s Office:

* (08) 8204 0600 (Ask to speak to social worker for counselling, information and support)

**Appendix 3**

**Bereavement Follow-up Project Questionnaire**

**The following set of questions relate to the 'ICU Team' as a whole - medical, nursing and allied health. How they cared for your loved one and supported you and your family.**

1. How would you rate the overall support you and your family received while your loved one was dying?

1 - Completely unsatisfied/ unhappy

2

3 - Adequate / average

4

5 - Completely satisfied

1. Are there any additional comments you would like to make about the support you received while your loved one was dying?

2. How would you rate the attention your loved one received during their ICU stay?

1 - Completely unsatisfied / unhappy

2

3 - Adequate / average

4

5 - Completely satisfied

2. Are there any additional comments you would like to make about the support your loved one received whilst in ICU?

3. How do you feel that your loved one's dignity was maintained during their ICU stay?

1 - Without appropriate dignity / disrespectfully

2

3 - Adequate / average

4

5 - With complete dignity and respect

3. Are there any additional comments you would like to make about how your loved one's dignity was maintained?

4. Was your loved one's pain well controlled throughout the ICU stay?

1 - Completely unsatisfied / unhappy

2

3 - Adequate / average

4

5 - Completely satisfied

4. Are there any additional comments you would like to make about your loved one's pain management during their ICU stay?

**The following questions relate to communication between you, your family and the ICU Team.**

5. Do you feel you were given enough opportunity to discuss your loved one’s wishes, as well as, your own preferences with the ICU team?

1 - Completely unsatisfied / unhappy

2

3 - Adequate / average

4

5 - Completely satisfied

5. Are there any comments you would make about the opportunity to discuss your loved one's wishes, as well as your own preferences, with the ICU team?

6. Were you satisfied with the quality or nature of the communication between you and the doctors in ICU?

1 - Completely unsatisfied / unhappy

2

3 - Adequate / average

4

5 - Completely satisfied

6. Do you have any additional comments about the quality of the communication between you and the doctors in ICU?

7. Were you satisfied with the quality or nature of the communication between you and the nurses in ICU?

1 - Completely unsatisfied / unhappy

2

3 - Adequate / average

4

5 - Completely satisfied

7. Do you have any comments about the quality or nature of the communication between you and the nurses in ICU?

8. Before your loved one died, were you clearly informed that they were dying?

1 - Unaware, a complete surprise

2

3 - Death discussed and aware

4

5 - Discussed in detail, with a description of the expected process

8. Do you have any comments about being informed (or not) about their dying?

**The following questions relate to the medical treatment your loved one received whilst in the ICU.**

9. Were you satisfied with the quality of medical care received by your loved one in the ICU?

1 - Very unhappy / significantly concerned

2

3 - Happy / not concerned

4

5 - Very happy / impressed

9. Do you have any other comments about the quality of medical care received by your loved one?

10. Did your loved one, or the family, refuse any of the suggested medical treatments whilst in ICU?

Yes

No

10. Do you have any comments about any of the suggested treatments offered in ICU, particularly why any may have been refused?

11. Do you believe the ICU Team may have gone too far or used unnecessary treatments in caring for your loved one?

1 - All treatments were appropriate. More could have been done.

2.

3 - All treatment was appropriate. What could be done was

4

5 - Treatment went beyond the patient's wishes and prolonged suffering unduly or was intrusive

11. Do you have any comments on how far the ICU Team went in the treatment given to your loved one?

12. Were you present when your loved one died?

Yes

No

12. Do you have any comments about being present (or not) when your loved one died?

13. Were you given sufficient time and opportunity to say goodbye and express important feelings to your loved one?

1 - No. Inadequate time and/or opportunity

2

3 - Yes, but only just adequate

4

5 - Yes. More than sufficient time and opportunity

13. Do you have any comments about being able to say goodbye and express important feelings to your loved one?

**The following questions relate to the discussions around and process of Organ Donation.**

Was organ donation raised as a possibility for your loved one?

Yes

No

With respect to the concept of organ donation, who raised this topic in discussion “first”?

One of the senior doctors in ICU (Cons/SR)

One of the junior doctors in ICU (Reg)

One of the nursing staff in ICU

One of the medical/nursing staff outside of ICU

Within the family, prior to any medical discussion

14. How did the possibility of donation affect you and your family?

1 - Very uncomfortable / unnecessary stress at a difficult time

2

3 - No real effect. A part of the overall process

4

5 - Very comfortable. A positive experience

14. Do you have any comments about organ donation being raised as a possibility for your loved one?

**Final comments and/or suggestions.**

15. What suggestions would you have as to how we might improve the care we offer to patients and families at the end of life?

16. Do you have any suggestions or comments on this follow-up service?