Student Welfare Management Protocol

For the YAM ACT Study
Contents

Duty of Care Procedure ........................................................................................................................ 3
Alert Triggers.............................................................................................................................................3
Response .....................................................................................................................................................3
Other Supports ..........................................................................................................................................4
Figure 1. Flow chart of suicide risk management procedure: YAM Study schools..............................5
...................................................................................................................................................................5
Reporting Adverse Events.................................................................................................................... 6

Estimated number of students who may be identified as at-risk....................................................... 7
**Duty of Care Procedure**

In this study, some survey items indicate a risk of suicide when an individual makes certain response selections. This trial utilises an automatic notification system on the Black Dog Institute research platform, which has been configured to detect and identify students who endorse these responses within the online survey. Where pen-and-paper surveys are administered, this risk screening process is conducted manually by an attending member of the research team. A list of flagged students will be relayed to the lead agency mental health clinician who will meet with the school wellbeing team to manage referrals.

Each of the surveys will be completed during a morning Period early in the week in the presence of the classroom teacher or lead agency staff, and a lead agency mental health clinician. The role of the teacher/agency staff will be to distribute the survey and the role of the mental health clinician will be to communicate information about consent, confidentiality, and the risk flagging procedure to students, and answer any questions relating to the survey items. A flow diagram has been created for an overview of the following steps (Figure 1).

**Alert Triggers**

There are 7 items to identify young people at-risk of suicide for which alerts will be triggered. Alerts will be triggered if the student selects the following responses for:

1. SIDAS Q3 ‘how close have you come to making a suicide attempt’ score ≥ 1 (where 0 = never, 10 = always)
2. SIDAS any item ≥ 7 (yes)
3. SIDAS total score ≥ 15 (where ≥ 25 is indicative of high risk of suicide)
4. ‘Have you ever tried to take your own life’ (yes)
5. ‘When did you try to take your own life’ (during the past month, during the past year)
6. ‘Do you currently have a plan to take your own life’ (yes)
7. PHQ-A total score ≥ 15 (indicative of moderately severe depression)

**Response**

If a student meets any of the above criteria, an automatic email alert will be sent to the lead researcher (for online surveys) or the attending lead agency mental health clinician will manually screen the surveys on site immediately after collection (for pen-and-paper surveys) and pass on the list of flagged students directly to the wellbeing team (e.g., school psychologist, social worker, nurse, youth worker). Immediately after survey screening, the lead agency mental health clinician will receive the list of flagged students, either directly via manual screening the or via email from the lead researcher. The amount of time required to screen surveys is proportional to the number of surveys completed.

The lead agency mental health clinician will meet with the wellbeing team on site the day of survey completion to review the list of flagged students and determine a referral pathway by identifying:

1. Which students are known to be ‘at-risk’ and are currently being supported internally or externally within the school. These students may be able to be managed in-house if recent contact has been made with the student;
2. Which students have not previously been identified as ‘at-risk’ and therefore require immediate risk assessment (and support). If a school has sufficient capacity, these students may be managed in-house with an immediate referral to the school counsellor/psychologist. If the school does not have sufficient support, then the student will be referred to the attending mental health clinician provided by the lead agency for immediate risk assessment and support as required. The amount of time required by lead
agency mental health clinician will be dependent on the number of students flagged and individual school capacity to manage referrals internally.

**Other Supports**

Given the sensitive nature of the surveys, the following steps will be taken to ensure participants are supported throughout the study:

- Schools will be informed of the wellbeing process ahead of time and prepared for the flagging process weeks before survey administration;
- Before students begin the survey, they will be reminded that participation is voluntary and that they can withdraw at any time without consequence. The lead agency mental health clinician will verbally provide instructions for what a student should do if feeling distressed (i.e., let themselves or their teacher know immediately by putting their hand up and/or wait and speak with the teacher, lead agency mental health clinician, or school counsellor if they don’t want other students to know they are not completing the survey).
- Each page of the survey contains a breakout box that instructs students to stop if they are feeling distressed, where to seek help, and the contact details of confidential counselling services.
- A list of supports for students and parents will be available as part of the Parent Information and Consent Form that was emailed to parents.
Figure 1. Flow chart of suicide risk management procedure: YAM Study schools

- Study participant endorses any of the risk items on the student survey
- Research team performs automatic or manual screening immediately after survey completion
- Research team to relay list of flagged students to lead agency mental health clinician immediately after survey screening
- Lead agency mental health clinician to meet with school wellbeing team on site, the day of survey completion, to review flagged list and determine referral pathway according to school protocol
- Lead agency mental health clinician may or may not be required for clinical support, depending on school capacity
Reporting Adverse Events

All adverse events and safety issues will be reported as per the Safety Monitoring Reporting Guidelines for Clinical Trials set out by the UNSW Human Research Ethics Committee (HREC). All events will be reported by Dr Lauren McGillivray to the UNSW Research Ethics Compliance Support Office and notification of UNSW HREC outcomes or decisions will be sent to the Education Directorate and Catholic Archdiocese of Canberra & Goulburn.

<table>
<thead>
<tr>
<th>Type of Event</th>
<th>Example</th>
<th>How</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Event</td>
<td>Mental health related hospitalisation</td>
<td>Adverse Event Form</td>
<td>Within 24 hours of becoming aware of the event</td>
</tr>
<tr>
<td>Adverse Device Effect</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious Adverse Events</td>
<td>Mental health related hospitalisation</td>
<td>Adverse Event Form</td>
<td>Within 24 hours of becoming aware of the event</td>
</tr>
<tr>
<td>Serious Adverse Device Effect Unanticipated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious Adverse Device Effect</td>
<td>Death by suicide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Significant Safety Issue (without an Urgent Safety Measure).</td>
<td>-</td>
<td>SSI notification form</td>
<td>Within 24 hours of becoming aware of the event</td>
</tr>
<tr>
<td>Significant Safety Issue that meets the definition of an Urgent Safety Measure</td>
<td>-</td>
<td>SSI notification form</td>
<td>Immediately after an urgent safety measure has been put in place to eliminate an immediate hazard to a participants’ health or safety.</td>
</tr>
<tr>
<td>Investigator’s Brochure Updates/Addenda</td>
<td>-</td>
<td>Submitted with a Cover Sheet</td>
<td>Annually with the annual safety report, or as required.</td>
</tr>
<tr>
<td>Annual safety report</td>
<td>-</td>
<td>Annual Progress Report</td>
<td>Annual as required by the HREC</td>
</tr>
<tr>
<td>Serious Breach of Protocol</td>
<td>-</td>
<td>Suspected Serious Breach Report Form</td>
<td>Within 24 hours of becoming aware of the event</td>
</tr>
</tbody>
</table>
Estimated number of students who may be identified as at-risk

We estimate that approximately 30% of students completing the first baseline questionnaires may be identified as at-risk according to our pre-determined risk criteria. This estimate is based on preliminary findings from the current NSW trial.