

# Proposed Ordinal Outcome

## ASCOT Data

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## Background

Proposed outcome of moderate and severe for federated platform: *Severe and Moderate: 90-day mortality + 28-day OSFDs*. The scale proposed was:

- -1: Dead by 90 days
- 0: 28 Organ support days (0 organ support free days)
- 1-28: Number of organ support free days
- 29: Receive >10 days of oxygen, no organ support
- 30: Receive 3-10 days of oxygen, no organ support
- 31: Receive 1-3 days of oxygen, no organ support
- 33: Never receive oxygen or organ support

Aim to investigate this outcome in the ASCOT data.

A few comments:

- I assumed 33: *Never receive oxygen or OFS* should be 32: *Never receive oxygen or OFS*
- I assumed 1-3 days is inclusive, so that:
  - 31 is {1, 2, 3} days on oxygen, no organ support
  - 30 is {4, 5, ..., 9, 10} days on oxygen, no organ support
  - 29 is {11, 12, ..., 27, 28} days on oxygen, no organ support
- I used death at 28 days rather than 90 days due to readiness of the outcome, wouldn't be too much more to actually look at day 90, but will be much more missingness (25 unknown status) with few additional known deaths (6), and have not performed quality/consistency checks of day 90 dataset to date
- in ASCOT we only have daily data collected on the index admission, so after discharge we don't know duration of organ support/oxygen if readmitted. So the following data is based on the index admission only. Readmissions appear to be few.

Per email correspondence, in terms of the daily WHO scale:

- 1-4: no oxygen and no organ support
- 5: oxygen
- 6.3: oxygen
- 6.1, 6.2, 6.4: organ support
- 7: organ support
- vasopressor/inotropic use: organ support

Oxygen days were counted as any day where WHO scale was at least 5. Organ support days were counted as any day where WHO scale was 6.1, 6.2, 6.4, 7, or which had vasopressor/inotropic use.

Variables used from the daily dataset:

- StudyPatientID
- DD\_StudyDay
- DD\_ParticipantDailyStatus
- DD\_O2
- DD\_O2VasopressorsInotropes

From the day 28 dataset:

- StudyPatientID
- D28\_PatientStatusDay28

## Outcomes

### All Platform Participants

Figure 1 presents the ordinal outcome for all platform participants. In total,

- 1588 randomised without study withdrawal
- 544 (0.34) participants had at least 1 day where oxygen was received.
- 113 (0.07) participants had at least 1 day where organ support was received.
- 50 (0.03) participants had died by day 28.
- 1040 (0.65) participants received no oxygen and no organ support.

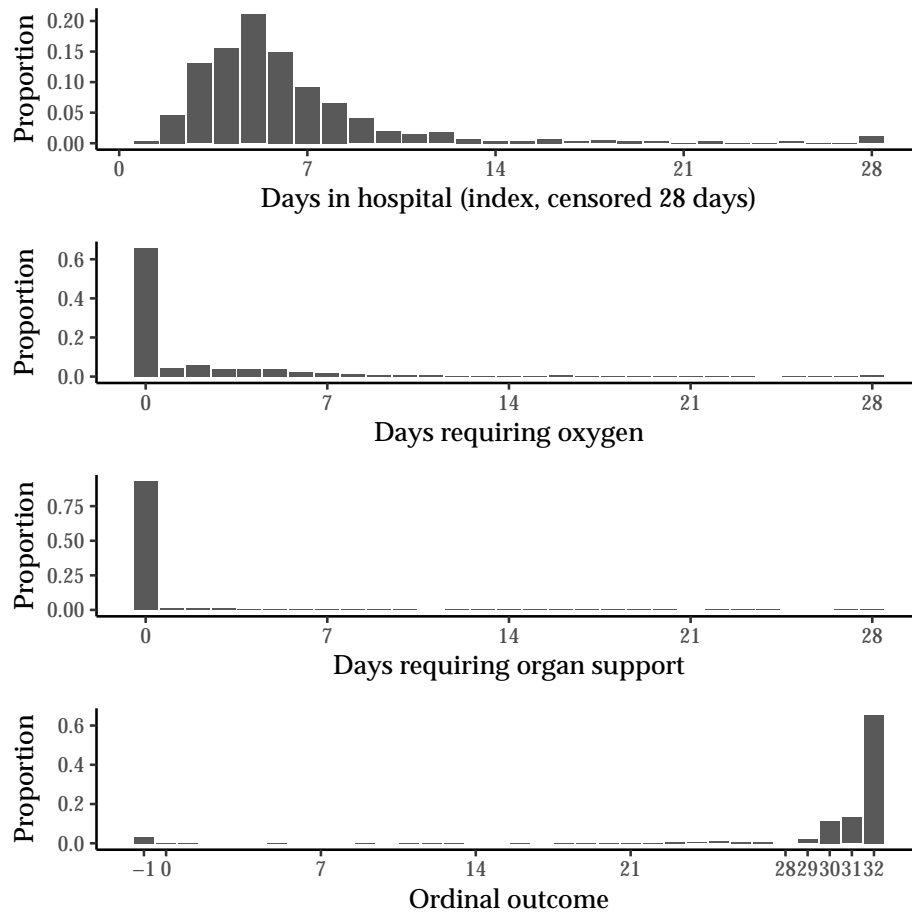


Figure 1: Distribution of days in hospital, days requiring oxygen, days requiring organ support, and the proposed ordinal outcome, for all platform participants. Note that scales vary.

## Australia/New Zealand

Figure 2 presents the ordinal outcome for Australia and New Zealand platform participants only. In total,

- 177 randomised without study withdrawal
- 145 (0.82) participants had at least 1 day where oxygen was received.
- 48 (0.27) participants had at least 1 day where organ support was received.
- 1 (0.01) participants had died by day 28.
- 32 (0.18) participants received no oxygen and no organ support.

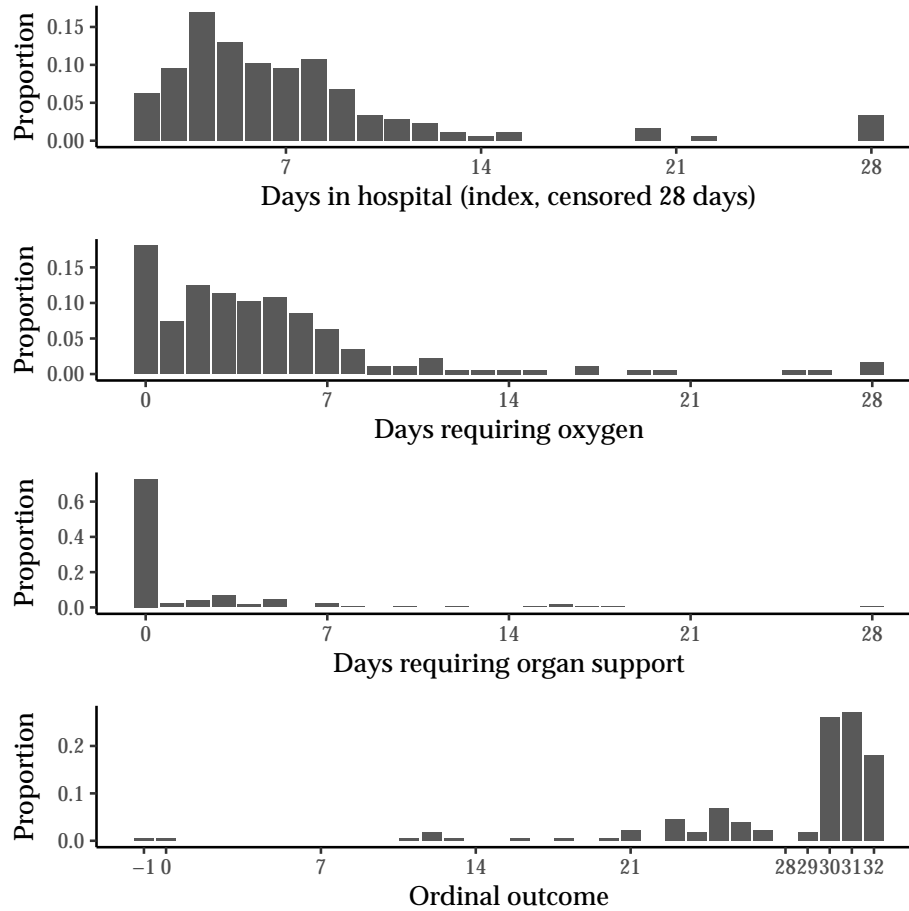


Figure 2: Distribution of days in hospital, days requiring oxygen, days requiring organ support, and the proposed ordinal outcome for Australia and New Zealand participants. Note that scales vary.