

# Development and evaluation of an influenza pandemic intensive care unit triage protocol

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The Influenza Pandemic ICU Triage (iPIT) study evaluated two intensive care triage protocols, from Ontario and New South Wales, that had been developed to guide the allocation of critical care beds during a major influenza pandemic.<sup>1-3</sup> Both triage protocols excluded patients from the intensive care unit who had medical conditions associated with high predicted mortality rates, on the basis that providing limited resources to patients with a poor probability of survival would deny those resources to patients with a higher probability of survival. The Ontario Health Plan for an Influenza Pandemic (OHPIP) protocol also excluded patients with less severe illness on the basis that these patients were less likely to require ICU resources. The iPIT study found that the OHPIP protocol resulted in a greater increase in ICU bed availability than the NSW protocol.

As we hypothesised that some patients excluded from the ICU by the triage protocols could have mortality rates similar to those of patients not excluded from the ICU, the iPIT study included a planned post-hoc analysis with three objectives.

The first objective was to determine the ICU mortality rates of the patient groups excluded from ICU admission by the individual exclusion criteria contained in the OHPIP and NSW triage protocols. The second objective was to develop an influenza pandemic ICU triage protocol that only excluded patients with the highest and lowest predicted mortality rates. The third objective was to determine the increase in ICU bed availability that resulted from using the new protocol.

## Methods

### Study design

A description of the iPIT study has previously been published.<sup>1</sup> In brief, a prospective evaluation study was conducted in eight adult general tertiary ICUs in NSW and Queensland in the period following the 2009 Australia and New Zealand (H1N1) influenza pandemic in Australia and New Zealand. Each ICU simulated an influenza pandemic scenario over a 6-week period between September 2009 and May 2010. The study evaluated all newly admitted ICU patients who did not undergo elective surgery with the NSW and OHPIP influenza pandemic triage protocols, to determine whether they would have been eligible for admission during

## ABSTRACT

**Objectives:** To develop an influenza pandemic ICU triage (iPIT) protocol that excludes patients with the highest and lowest predicted mortality rates, and to determine the increase in ICU bed availability that would result.

**Design and setting:** Post-hoc analysis of a study evaluating two triage protocols, designed to determine which patients should be excluded from access to ICU resources during an influenza pandemic. ICU mortality rates were determined for the individual triage criteria in the protocols and included criteria based on the Sequential Organ Failure Assessment (SOFA) score. Criteria resulting in mortality rates outside the 25th and 75th percentiles were used as exclusion criteria in a new iPIT-1 protocol. The SOFA threshold component was modified further and reported as iPIT-2 and iPIT-3.

**Main outcome measure:** Increase in ICU bed availability.

**Results:** The 25th and 75th percentiles for ICU mortality were 8.3% and 35.2%, respectively. Applying the iPIT-1 protocol resulted in an increase in ICU bed availability at admission of 71.7% ± 0.6%. Decreasing the lower SOFA score exclusion criteria to ≤ 6 (iPIT-2) and ≤ 4 (iPIT-3) resulted in an increase in ICU bed availability at admission of 66.9% ± 0.6% and 59.4 ± 0.7%, respectively ( $P < 0.001$ ).

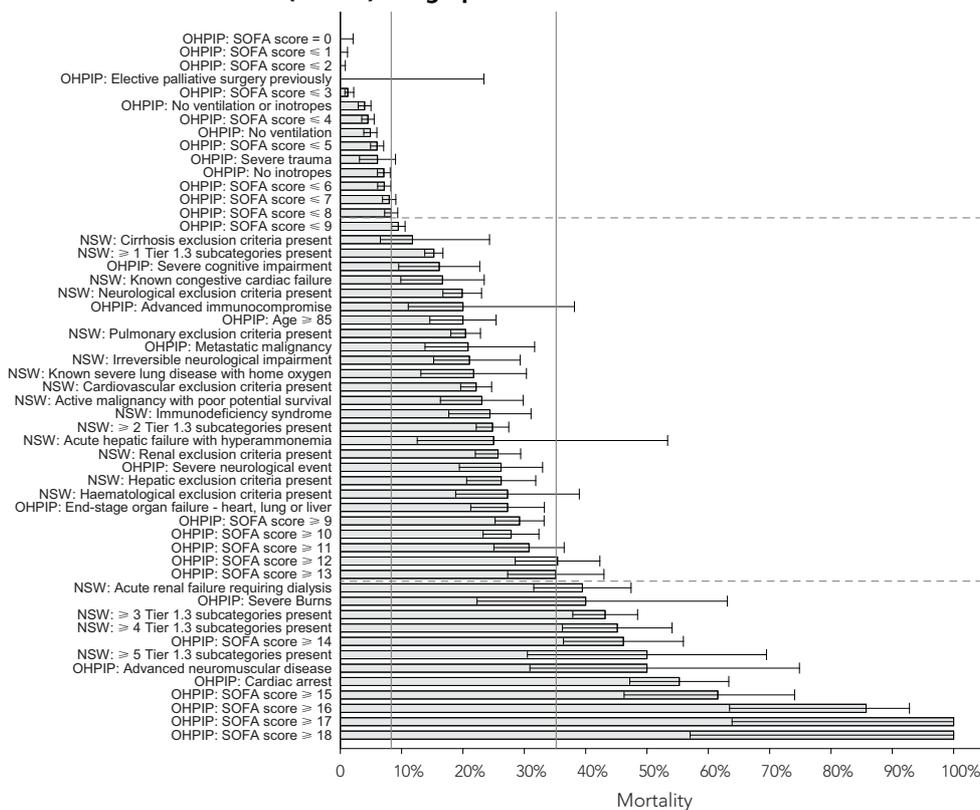
**Conclusion:** The iPIT protocol excludes patients with the lowest and highest ICU mortality, and provides increases in ICU bed availability. Adjusting the lower SOFA score exclusion limit provides a method of escalation or de-escalation to cope with demand.

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an actual pandemic.<sup>1-4</sup> The study did not actually alter patient admission or management. Patients who had elective surgery were excluded as it was expected that during an influenza pandemic all elective surgery would be cancelled. The primary outcome was the increase in ICU bed availability that resulted from the use of each protocol.

In this post-hoc analysis, ICU mortality rates were calculated for all patient groups theoretically excluded from

**Figure 1. Intensive care unit mortality rates of patient groups excluded from the ICU using the individual exclusion criteria and Sequential Organ Failure Assessment (SOFA) score from the New South Wales and Ontario Health Plan for an Influenza Pandemic (OHPIP) triage protocols**



Vertical grey lines and horizontal dotted lines indicate the 25th and 75th percentile (lower and upper quartiles). I-bars indicate standard error.

admission to or who would be discharged from the ICU using the individual exclusion criteria in the NSW and OHPIP triage protocols. ICU mortality rates were also calculated for the patients based on Sequential Organ Failure Assessment (SOFA) score (a scoring system from 0 to 24, where higher scores indicate a greater severity of illness), as used in the OHPIP protocol.<sup>5</sup>

The ICU mortality rate describes how many of the theoretically excluded patients would have died during their ICU stay if they had been admitted to the ICU in accordance with usual practice and the triage protocols were not used. In other words, this measure describes the patients' probability of dying in the ICU under normal circumstances.

From a hierarchical analysis, the 25th and 75th percentiles for ICU mortality were used as exclusion limits for the iPIT-1 protocol. The individual triage criteria from the NSW and OHPIP protocols that resulted in ICU mortality rates outside these exclusion limits were then used as exclusion criteria for ICU admission in the iPIT-1 protocol. An analysis

of the original patient dataset was subsequently performed using the iPIT-1 protocol, and the results compared with the NSW and OHPIP protocols.

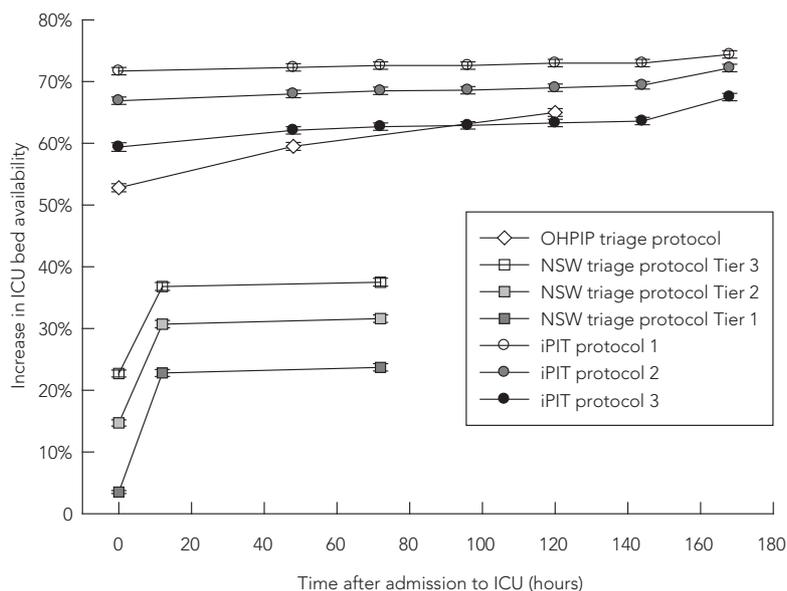
The primary outcome was the increase in ICU bed availability. This was defined as the proportion of the total bed-days available spent by patients in the ICU after the triage protocol had excluded them from admission or discharged them from the ICU. The assumption was that patients excluded or discharged from the ICU early would have their remaining bed-days available for use by other patients. The primary outcome was therefore calculated by subtracting the theoretical ICU length of stay following the use of the triage protocols from the actual ICU length of stay for each patient, then expressing the sum total for all patients as a proportion of the total ICU bed-days available.

### Statistical analysis

The Kolmogorov–Smirnov test and histogram approach were used to test for the normality of the ICU mortality distribution of the individual exclusion criteria. As the ICU mortalities were found not to be normally distributed, the 25th and 75th percentile (lower and upper quartiles) were used to determine the exclusion limits for the new triage protocol.<sup>6</sup>

Increase in ICU bed availability was calculated as a percentage of the number of beds available per ICU per day (± standard error). Standard error was calculated using the binomial method where the sample size was ≤ 30. Bed availability results were compared using Yates' continuity-corrected  $\chi^2$  test. Statistical analysis was performed by an independent statistician using Microsoft Excel 2003 (Microsoft Corporation, Redmond, Wash, USA); SPSS, version 17.0 (IBM, Armonk, NY, USA); and Confidence Interval Analysis, version 1.2 (BMJ Publishing Group, London, UK).

**Figure 2. Cumulative increase in intensive care unit bed availability using the Influenza Pandemic ICU Triage (iPIT) protocols 1, 2 and 3, the New South Wales triage protocol (Tiers 1, 2 and 3) and the Ontario Health Plan for an Influenza Pandemic (OHPIP) triage protocol**



There were significant differences in the increase in ICU bed availability between all triage protocols at admission (Yates' continuity-corrected  $\chi^2$  test;  $P < 0.001$ ) and within all three iPIT protocols when comparing admission to compulsory discharge at 7 days (iPIT-1 protocol,  $P = 0.002$ ; iPIT-2 and iPIT-3 protocols,  $P < 0.001$ ). I-bars indicate standard error.

## Results

Of the 1262 patients admitted to the ICUs, 457 (36.2%) were excluded due to elective surgery. The 805 (63.8%) patients who did not have elective surgery were all evaluated using the NSW and OHPIP triage protocols. These patients occupied 76.7% (4350 bed-days) of the total available bed-days. The ICU mortality rate for the 805 study patients was 11.7% (94 deaths).

### Analysis of NSW and OHPIP protocols

The ICU mortality rates for the patient groups excluded from the ICU by the individual triage criteria in the NSW and OHPIP triage protocols are shown in Figure 1. The ICU mortality rates for the 53 triage criteria ranged from 0 to 100%. The 25th and 75th percentiles for ICU mortality were 8.3% and 35.2%, respectively.

The lowest mortality rates were seen in patients who did not require mechanical ventilation, did not require inotropes or vasopressors, had sustained severe trauma (defined as an Injury Severity Score  $> 15$ ),<sup>7,8</sup> had received palliative surgery earlier in their hospital admission, or had a SOFA score at admission  $\leq 8$ . Excluding these patients increased ICU bed

availability by 27.7%, 53.2%, 10.4%, 0.6%, and 61.8%, respectively. There were 675 (83.9%) patients with SOFA scores  $\leq 8$ .

The highest mortality rates were seen in patients with acute renal failure requiring dialysis, severe burns, cardiac arrest, a SOFA score  $\geq 14$ , or who had three or more NSW Tier 1.3 exclusion criteria present. Excluding these patients increased ICU bed availability by 3.2%, 1.3%, 3.9%, 3.7% and 9.6%, respectively. There were 26 (3.2%) patients with SOFA scores  $\geq 14$ .

### Influenza pandemic ICU triage protocol

The iPIT-1 protocol is detailed in Appendix 1. Patients would only be admitted to the ICU if they required invasive ventilation, or cardiovascular support with inotropes or vasopressors; they had not received palliative surgery during their hospital admission; they did not have severe trauma, acute renal failure requiring dialysis, severe burns, cardiac arrest or advanced neuromuscular disease; and they did not have an admission SOFA score  $\leq 8$  or  $\geq 14$ .

Using the iPIT-1 protocol to theoretically triage patients from the original dataset resulted in an increase in ICU bed availability of  $71.7\% \pm 0.6\%$  at admission, with 755 (93.8%) patients being excluded.

Applying the study results, a 17-bed general ICU would expect to make available 12 beds using the iPIT-1 protocol at admission, whereas the OHPIP protocol would make 9 beds available, and the NSW protocol would make 0.5–4 beds available, depending on which tier was used.

### Further protocol development

As a SOFA score at admission  $\leq 8$  resulted in the single largest increase in ICU bed availability of any individual criteria, the iPIT-1 protocol was altered to determine the effect that lowering the SOFA score exclusion criteria would have on this. The altered protocols were the same, except the iPIT-2 protocol excluded patients at admission who had SOFA scores  $\leq 6$ , and the iPIT-3 protocol excluded patients with SOFA scores  $\leq 4$ .

At admission, the iPIT-2 and iPIT-3 protocols resulted in an increase in ICU bed availability of  $66.9\% \pm 0.6\%$  and  $59.4\% \pm 0.7\%$  respectively, with 709 (88.1%) and 625 (77.6%) patients being excluded.

### Additional discharge criteria

The view of the authors was that a triage tool should also place limits on the duration of patient stay in the ICU. Two

additional discharge criteria were added to the iPIT protocols. These are detailed in Steps 8 and 9 of the iPIT-1 protocol in Appendix 1.

The first criteria discharged patients from the ICU between Day 2 and Day 6 once they had been removed from mechanical ventilation, as this was regarded as a principal reason for ICU admission. The second was a compulsory discharge of all patients on Day 7 from the ICU, regardless of clinical condition, as this was regarded as a reasonable maximal duration of admission during a major pandemic that necessitated the use of triage protocols. The increase in bed availability using the iPIT protocols, with the NSW and OHPIP protocols shown for comparison, is shown in Figure 2.

## Discussion

Our study demonstrated that increases in ICU bed availability could be achieved using an alternative influenza pandemic ICU triage protocol that excluded patients with the lowest and highest predicted ICU mortality rates. The iPIT-1 protocol made more ICU beds available than the NSW and OHPIP protocols. Decreasing the lower SOFA score exclusion limit resulted in less patients being excluded, providing a potential method for altering ICU bed availability as demand for critical care services changes in a pandemic.

The largest increases in ICU bed availability resulted from the exclusion of the large number of patients with low predicted mortality rates. Using ventilation or cardiovascular support as exclusion criteria accounted for a third of the increase in bed availability. Excluding patients on the basis of a low SOFA score accounted for another third. Excluding patients with high predicted mortality rates resulted in much smaller increases in bed availability due to the smaller numbers of patients.

It is difficult to compare individual triage criteria mortality results between studies. There are many studies documenting mortality rates for specific individual clinical conditions; however, there are no publications comparing the ICU mortality rates of the clinical conditions used as exclusion criteria in the NSW or OHPIP triage protocols. Mortality rates can vary between institutions due to the complexity of the medical conditions, patient volume, quality of care, referral patterns and data management methods.<sup>9</sup> Though SOFA-based models have been used extensively to predict mortality, they still require further validation.<sup>10</sup>

The ethics of public health differ from usual clinical ethics, as the common good is promoted over protecting individual autonomy.<sup>11</sup> As a result, the principles that guide resource allocations in disaster settings have been utilitarian in nature, where the objective is to do the greatest good for the greatest number of people. From an intensive care medicine perspective, this aim has been interpreted as maximising the

number of patients who survive to hospital discharge.<sup>11</sup> The iPIT protocols partially address this issue by excluding patients who are less likely to survive if provided with ICU level care, or who are likely to survive anyway if ICU level care is not provided. However, a detailed discussion regarding the ethics of triage is beyond the scope of this article.

Our study demonstrates the potential efficacy of an alternative influenza pandemic triage protocol, and provides health care policymakers with more information to develop influenza pandemic policies. These results are likely to be applicable and generalisable in Australia and possibly in countries with similar health care systems.

The strength of this study was its multicentre design; in general, adult, tertiary ICU settings, that would carry the majority of the burden in an actual pandemic. It had a large sample size, complete data collection and used existing protocols already available in the public domain.

A major limitation of this study was the derivation of data and evaluation of the new influenza pandemic protocols during a non-pandemic setting. Conducting the study during an actual pandemic may have provided different results due to different ICU admission, discharge and management patterns. Also, the criteria used in the NSW and OHPIP protocols excluded patients based mainly on organ failure and arbitrary clinical criteria. Many criteria did not have strict definitions and interpretation was left to the discretion of the treating physician. The study did not determine whether other clinical criteria, such as major emergency cardiovascular surgery, should also be represented in an influenza pandemic protocol. Finally, because the study did not actually change patient management, the actual outcomes for excluded patients remain unknown.

The study was conducted as a theoretical evaluation, and it is important that its results are validated in real pandemic conditions. There are likely to be many difficulties associated with actually applying triage mechanisms in the field.

Larger studies are also needed to verify the mortality rates of the patients excluded by the individual triage criteria. The triage protocols need to be evaluated in different medical jurisdictions, and triage priorities in non-adult patients need to be considered. Further research needs to determine whether triage protocols can be further improved, and whether such restrictive measures are actually acceptable to the community.

## Conclusion

When tested in a non-influenza pandemic setting, our alternative influenza pandemic ICU triage protocols provided increases in ICU bed availability, while excluding patients with the lowest and highest ICU mortalities. The increase in ICU bed availability was greater than that found in the NSW and OHPIP triage protocols. Altering the lower SOFA score exclu-

sion limit provides a potential method of escalating or de-escalating an influenza pandemic ICU triage protocol to cope with changes in demand for critical care resources.

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## Competing interests

None declared.

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**Appendix 1. Influenza Pandemic ICU Triage (iPIT-1) protocol****Step 1: inclusion criterion**

Only admit patients requiring invasive ventilation or inotropes/vasopressors

**Step 2: exclusion criteria 1**

Exclude the patient if they have any of the following conditions:

- A. Elective palliative surgery
- B. Severe trauma

**Step 3: exclusion criteria 2**

Exclude the patient if they have any of the following conditions:

- A. Acute renal failure requiring dialysis
- B. Severe burns with any two of the following: age > 60 years; > 40% of total body surface area affected; inhalational injury
- C. Cardiac arrest with any of the following: unwitnessed cardiac arrest; witnessed arrest not responding to defibrillation or pacing; recurrent cardiac arrest
- D. Advanced untreatable neuromuscular disease

**Step 4: calculate Sequential Organ Failure Assessment (SOFA) score\***

Variable	Score				
	0	1	2	3	4
Respiratory: PaO <sub>2</sub> /FiO <sub>2</sub>	> 400	≤ 400	≤ 300	≤ 200	≤ 100
Haematological: platelet count, × 10 <sup>6</sup> /L	> 150	≤ 150	≤ 100	≤ 50	≤ 20
Hepatic: bilirubin level, mg/dL (μmol/L)	< 1.2 (< 20)	1.2–1.9 (20–32)	2.0–5.9 (33–100)	6.0–11.9 (101–203)	> 12 (> 203)
Cardiovascular: hypotension <sup>†</sup>	None	Mean arterial blood pressure < 70 mmHg	Dopamine ≤ 5	Dopamine > 5; epinephrine ≤ 0.1; norepinephrine ≤ 0.1	Dopamine > 15; epinephrine > 0.1; norepinephrine > 0.1
Neurological: Glasgow Coma Scale	15	13–14	10–12	6–9	< 6
Renal: creatinine level, mg/dL (μmol/L)	< 1.2 (< 106)	1.2–1.9 (106–168)	2.0–3.4 (169–300)	3.5–4.9 (301–433)	> 5 (> 434)

\* Adapted with kind permission from Springer Science and Business Media: Vincent et al.<sup>5</sup> † Doses of dopamine, epinephrine and norepinephrine in μg/kg/min.

**Step 5: exclusion criteria 3**

Exclude the patient if they have the following result from Step 4:

- A. SOFA score ≤ 8
- B. SOFA score ≥ 14

**Step 6: calculate number of organ systems failing‡**

Determine the number of following laboratory or clinical criteria for organ failure that the patient has present:

- A. Pulmonary: acute respiratory distress syndrome; ventilatory failure; refractive hypoxia
- B. Cardiovascular: left ventricular failure; hypotension; new ischaemia
- C. Renal: hyperkalaemia; oliguria despite fluid resuscitation; increasing creatinine
- D. Hepatic: transaminase levels more than twice the normal upper limit; increased bilirubin or ammonia levels
- E. Neurological: altered mental status not related to fluid volume status; metabolic or hypoxic source; stroke
- F. Haematological: clinical or laboratory evidence of disseminated intravascular coagulation
- G. Cirrhosis with ascites, history of variceal bleeding, fixed coagulopathy, or encephalopathy
- H. Irreversible neurological impairment that makes the patient dependent for personal care (eg, severe stroke, congenital syndrome, persistent vegetative state)

**Step 7: exclusion criterion 4**

Exclude the patient if they have three or more criteria from Step 6 present

**Additional discharge criteria****Step 8: discharge criterion 1**

Between Day 2 (48 hours) and Day 6 (144 hours) after admission, discharge the patient if they are no longer receiving invasive mechanical ventilation

**Step 9: discharge criterion 2**

On Day 7 (168 hours) after admission, discharge the patient from the ICU

For patients excluded or discharged, continue non-ICU level care and provide palliative care if indicated

‡ Adapted with kind permission from NSW Health — Policy Directive PD2010\_028,<sup>2</sup> and John Wiley and Sons: Hick and O’Laughlin.<sup>4</sup>