



## POST-INTENSIVE CARE SYNDROME FOLLOWING CARDIOTHORACIC CRITICAL CARE: FEASIBILITY OF A COMPLEX INTERVENTION

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**Objectives:** To describe the long-term outcomes of cardiac intensive care unit patients and their primary caregivers, and to explore the feasibility of implementing a complex intervention, designed to support problems associated with post-intensive care syndrome and post-intensive care syndrome–family, in the year following discharge from the cardiac intensive care unit.

**Design:** A complex multidisciplinary rehabilitation programme, delivered as a quality improvement initiative, in a single centre in the West of Scotland. Outcomes were measured using surveys of health related quality of life, self efficacy, anxiety, depression, pain, caregiver strain, and insomnia.

**Participants:** Patients and their caregivers were invited to participate 12 weeks after hospital discharge. Twenty-seven patients and 23 caregivers attended the programme.

**Results:** Over 90% of patients had problems in at least one quality of life domain at baseline, 41% of patients had symptoms of anxiety and 22% had symptoms of depression. During the baseline visit, caregiver strain was present in 20% of caregivers, 57% had symptoms of anxiety, and 35% had symptoms of depression. Improvements in outcomes were seen in both patients and caregivers at 1-year follow-up. The programme was implemented, and iterative learning obtained about the content and the operationalization of the service, in order to understand feasibility.

**Conclusion:** This small-scale quality improvement project has demonstrated that this complex multidisciplinary rehabilitation programme is feasible and has positive implications for patients following discharge from the cardiac intensive care unit, and their caregivers.

**Key words:** rehabilitation; post-intensive care syndrome; cardiac; quality improvement.

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### LAY ABSTRACT

Patients, and relatives (or caregivers) of patients, treated in specialist intensive care units often only have access to limited recovery programmes focussing on a single disease. For patients treated in general intensive care units a recovery programme called InS:PIRE has been developed. The programme runs over multiple weeks, combining healthcare teams with social and financial help, and involves community organizations. It also brings groups of patients and relatives together so that they can help each other (known as peer support). This study describes the process of adapting the InS:PIRE programme for those treated in a specialist heart and lung centre. The problems these patients and relatives experience in the year after their illness is described, demonstrating that these issues are similar to those experienced after general intensive care. The results show that this model of recovery is possible in this setting and appears to be valued by the participating patients and relatives.

Most patients now survive major cardiac surgery, and survival after cardiac arrest is also increasing (1). The American Heart Association has highlighted that such survivorship can be associated with long-lasting emotional, cognitive, physical, and social problems (2).

Post-intensive care syndrome (PICS) and post-intensive care syndrome–family (PICS-F) are well recognized following general intensive care unit (ICU) care (3). PICS appears to encompass the same spectrum of problems (social, physical, cognitive, and emotional), with similar timelines for partial or complete recovery to those in patients after cardiac events (2, 3). These parallel recovery trajectories are also comparable for family members (4). One of the few documented differences in recovery trajectories, however, may be a more stark dichotomization in the cardiac population. Some patients follow a clear linear improvement over the first year, while others plateau or see a reduction in quality of life (5, 6).

The aims of this study are to describe the long-term outcomes of cardiac intensive care unit (CICU) patients and their primary caregivers; and to explore the

feasibility of implementing a complex intervention, designed to support problems associated with PICS and PICS-F, in the year following discharge from the CICU.

## MATERIALS AND METHODS

### Design and setting

The initiative was undertaken in a single CICU in Scotland. The Golden Jubilee National Hospital (GJNH), in Clydebank, is the major centre for national heart and lung services in Scotland, with over 2,000 annual admissions to the CICU per year. The primary patient group admitted to the GJNH are post-operative cardiac surgical patients. However, the CICU also admits patients from the regional revascularization service and the National Heart Failure Service. The multi-disciplinary team (MDT) delivering the initiative worked with a national collaborative to adapt a pre-existing intervention for PICS, with input from previous CICU patients and caregivers. These steps ensured that the intervention implemented was responsive to the challenges of this population.

Intensive Care Syndrome: Promoting Independence and Return to Employment (InS:PIRE), is a 5-week multidisciplinary peer support rehabilitation programme for ICU survivors and their caregivers. Previous research has described InS:PIRE and the initial evaluation of the programme (7, 8). Briefly, InS:PIRE is run on a cohort basis, providing patients and caregivers access to individual sessions with medical and nursing staff, a pharmacist, and physiotherapist, alongside sessions with psychology. Community organizations provide welfare and benefit support; this involves financial, housing, welfare benefit, and social advice. Peer support is encouraged, using shared waiting areas, group sessions, and the involvement of patient and caregiver volunteers further along the recovery trajectory. Peer support has been implemented in a variety of centres internationally to support recovery from

critical illness, reduce social isolation, and improve mental health and wellbeing (9). The aim of the programme is to ameliorate the signs and symptoms associated with PICS and PICS-F.

To understand the feasibility of undertaking a complex intervention post-hospital discharge, the MDT implemented 5 pre-planned cohorts of the InS:PIRE program over 20 months. One year follow-up was completed in September 2019. The programme was delivered as a quality improvement (QI) initiative, with a learning session at the end of each cohort. This session formed the function of the plan, study, and act stages of a formal QI project, although staff did not use these terms. At this session, facilitated by a QI coach, staff discussed potential improvements to the programme, based on user feedback and staff experience. The research and development department within the GJNH reviewed the proposal for the project. As this was the implementation of a new service, which was piloted as part of a QI process, ethics approval was waived. However, overall governance, including patient attendance and safety approvals were managed by the research and development department of the GJNH.

This innovation differed distinctly from traditional cardiac rehabilitation services; it did not provide a prescribed programme or service, but, instead, patients were able to access services as needed. Furthermore, the InS:PIRE programme provided social, emotional, and physical rehabilitation services for any presenting complaint, from both the patient and caregiver (see Table S1<sup>1</sup>). Of note, patients could attend both cardiac rehabilitation and the InS:PIRE programme.

### Patients

Patients were invited to participate in InS:PIRE 12 weeks after hospital discharge (baseline appointment). Further follow-up was in-person at 3 and 12 months after initial attendance. Inclusion criteria for the initiative were: patients who were ventilated

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**Table I.** Summary of outcome measures utilized

| Tool utilized                                | Description  | Ranges   | Use in this innovation                             |
|--|--|--|--|
| EQ-5D 5L (EuroQol: Quality of Life Group)    | Measurement of HRQoL comprising 2 sections: a 5-question descriptive component exploring health domains (each scored 1–5) and a visual analogue scale describing quality of life on the day of questionnaire completion. Descriptive component can be converted to a 5-digit sequence and then used to determine a Health Utility Score (HUS). | In EQ-5D evaluations, a HUS of one equates to the best health state possible, 0 with death, and a negative HUS equates to a state worse than death. Based on previous literature, the minimally important clinical difference (MCID) for the HUS for critical care and the UK time-trade-off “tariff,” is approximately 0.08 (26–27).  | Patient Only<br>Baseline, 3 and 12 months          |
| Hospital Anxiety and Depression Scale (HADS) | The HADS questionnaire contains 14 statements relating to mood, with 7 questions relating to depression and 7 to anxiety.  | Scale Interpretation (scored separately for anxiety and depression):<br>0–7: Normal<br>8–10: Mild<br>11–14: Moderate<br>15–21: Severe  | Patient and caregiver<br>Baseline, 3 and 12 months |
| Carer Strain Index (CSI)                     | The CSI, which measures strain related to care provision from the caregiver perspective. There are elements related to emotional adjustment, social issues, and physical and financial strain.   | Each question is given one point. A score of 7 or greater is the generally accepted cut-off point for a high level of stress   | Caregiver Only<br>Baseline, 3 and 12 months        |
| Insomnia Severity Index (ISI)                | The ISI is a 7-question tool, which has been validated as a screening tool for clinical insomnia.  | Participants are asked to rank the severity of their sleep problems on a scale of 0 to 4 and to answer 4 other questions regarding satisfaction with their sleeping patterns. The end result is a score of between 0 and 28. Guidelines for the interpretation of the ISI suggest that a score of 0–7 represents no clinically significant insomnia, 8–14 subclinical insomnia, 15–21 moderate clinical insomnia, and 22–28 severe clinical insomnia | Caregiver Only<br>Baseline, 3 and 12 months        |
| Brief Pain Inventory (BPI)                   | On the BPI, patients record the severity of their pain over the previous 24 h as worst, least, mean and current pain, on a 0–10-point numerical rating scale (where 0=no pain and 10=worst pain imaginable).   | Developers of the tool recommend that all 4 items be used in a mean score (14). The optimal cut-off points for pain severity using the BPI are as follows: 0 = no pain, 1–3 = mild pain, 4–6 = moderate pain, and 7–10 = severe pain.  | Patient Only<br>Baseline, 3 and 12 months          |

EQ-5D-5L: EuroQol 5-dimension 5-level instrument; HRQoL: health-related quality of life.

for longer than 48 h with a prolonged and/or complicated critical care stay. Exclusion criteria were: patients on an end of life care pathway, and patients with significant, ongoing, brain injuries.

### Outcomes and analysis

Data were collected to understand the long-term outcomes of patients and their caregivers. The tools utilized were reviewed by patient groups involved in the initial set-up of InS:PIRE, ensuring the outcomes evaluated were important to service users. These tools, with a brief description of their content and scoring matrix, are shown in Table I. Medication management and medication-related problems (MRPs) were examined throughout the intervention. This process was undertaken by a senior ICU pharmacist; each medicine management intervention delivered to correct any MRP was independently reviewed by 2 external clinicians and categorized using the scoring scheme shown in Table SII<sup>1</sup>. All data analysis for this project was undertaken using Microsoft Excel.

## RESULTS

### Baseline characteristics and attendance

During the study period InS:PIRE was delivered in 5 cohorts, 113 patients were invited to attend the clinic, 27 (24%) patients and 23 caregivers attended. Only one patient did not complete the programme (due to a hospital readmission unrelated to InS:PIRE attendance) thus the completion rate was 96%. Of the patients who attended, 18 were male (67%) and the median age was 66 years (interquartile range (IQR) 61–75 years). Planned admissions represented 56% of those attending. Further details of admission characteristics are shown in Table II. Of the caregivers, 17 (74%) were spouses, 3 (13%) were children, and 3 (13%) had other relationships. Median

**Table II.** Characteristics of patients and caregivers

| Patient and caregiver characteristics                     | Patients <i>n</i> = 27 |
|---|------------------------|
| Number of cohorts   | 5                      |
| <i>Patient details</i>                                    |                        |
| Male, <i>n</i> (%)  | 18 (67)                |
| Median age, years (IQR)                                   | 66 (61–75)             |
| Median APACHE II score (IQR)                              | 17 (14–18.5)           |
| ICU length of stay, days (IQR)                            | 13 (9–21)              |
| Days ventilated, median (IQR)                             | 6 (4.5–10)             |
| Elective or scheduled admissions, <i>n</i> (%)            | 15 (56)                |
| Diagnosis or operation on admission                       |                        |
| Coronary artery bypass grafting (CABG) only, <i>n</i> (%) | 7 (26)                 |
| Valve replacement surgery only, <i>n</i> (%)              | 5 (19)                 |
| CABG and valve replacement, <i>n</i> (%)                  | 5 (19)                 |
| Out of hospital cardiac arrest, <i>n</i> (%)              | 4 (15)                 |
| Aortic dissection, <i>n</i> (%)                           | 3 (11)                 |
| Thoracic surgical procedure, <i>n</i> (%)                 | 2 (7)                  |
| Cardiogenic shock, <i>n</i> (%)                           | 1 (4)                  |
| Caregivers attended                                       | 23                     |
| Caregivers' relationship to patient                       |                        |
| Spouse, <i>n</i> (%)                                      | 18 (78)                |
| Child, <i>n</i> (%)                                       | 2 (9)                  |
| Sibling, <i>n</i> (%)                                     | 1 (4)                  |
| Parent, <i>n</i> (%)                                      | 2 (9)                  |

IQR: interquartile range; APACHE II: Acute Physiology And Chronic Health Evaluation Two.

time to first clinic attendance was 20 weeks (IQR 14–25 weeks) post-CICU discharge.

### Feasibility, quality improvement, and learning

Important developments and the key iterative changes planned and completed during the learning sessions are summarized in Table III. The high rates of programme completion were indicative of high patient tolerability, and this was confirmed by the informal feedback discussed during the programme and disseminated between staff during the learning sessions. Similarly, no patient or caregiver was observed or reported to come to any harm, or develop problems caused by the intervention.

The primary issue was the uptake rate. Initial 14% uptake rates were improved to between 25% and 30% following some changes in procedure. The first change was to utilize phone calls to invite patients to participate in InS:PIRE, rather than simply sending letters. This also allowed the team to give more details on the purpose of InS:PIRE and what to expect from the clinic. The geographical spread of this national service also contributed to reduced attendance. In order to improve both attendance and patient and caregiver support, the MDT changed the timetable to a 3-week programme, delivered over 5 calendar weeks, with phone call appointments on weeks of non-attendance. The in-person sessions were each longer, thus increasing the time spent in clinic resulting in increased attendance from patients with the furthest to travel. Another and more profound benefit from the longer sessions was the more intense interaction resulting in improved peer support.

Previous research has found that locating a physical space to host rehabilitation programmes can be a challenge; the current innovation was no different (13). However, having the clinic on-site appeared beneficial for several reasons, including: the ability to quickly access other clinicians to enquire about ongoing care (especially in relation to ongoing medicine management); access to patient records; access to ongoing care if needed; and access to the ICU to allow participants to visit, if they requested. Facilitating visits to the ICU appeared to be beneficial for patients, caregivers, and staff alike, and it offered staff the opportunity to understand the recovery trajectory more fully.

The psychology input also evolved. Initially, psychology was delivered as one session with patients and caregivers together. This quickly changed to separate sessions, in order to facilitate more open discussion with each group about their psychological and emotional challenges during and after critical illness. Specifically, caregivers could be more open about lived experiences, and both groups benefited from greater patient independence, as some caregivers had not left the patient's side since they were discharged from hospital. This was

**Table III.** Intensive Care Syndrome: Promoting Independence and Return to Employment (InS:PIRE) development and patient attendance through the 5 cohorts

| Cohort details (n=number of patients) Feedback and development notes   |  |
|--|--|
| <p><i>First cohort</i><br/>28 invited<br/>4 attended: 14% of invited patients<br/>4 completed programme: 100% of those attending</p>     | <ul style="list-style-type: none"> <li>• Programme first established, time from hospital discharge to follow-up was generally long.</li> <li>• Five-week programme, reflecting InS:PIRE at other sites at the time.</li> <li>• Follow-up timescale too long for many patients. Those approached more than one year after CICU did not see the relevance of the programme or wish to attend.</li> <li>• Reliance on letter invitations resulted in very low uptake rates. Collation of contemporary patient phone numbers was inadequate and this required attention.</li> <li>• Patient feedback from those completing the programme was positive and patients appreciated the input.</li> <li>• Physical and emotional issues encountered from those attending the programme were significant, signalling an ongoing need.</li> </ul>   |
| <p><i>Second cohort</i><br/>19 invited<br/>7 attended: 37% of invited patients<br/>6 completed programme: 85% of those attending</p>     | <ul style="list-style-type: none"> <li>• During planning, had further discussions with other hospitals running InS:PIRE after general ICU.</li> <li>• InS:PIRE team was expanded to include 2 nurses rather than 1. Extra resource allowed more time to be allocated to patient calls, including education about what the programme offers. This was especially important as PICS after CICU is a relatively novel concept.</li> <li>• Greater involvement from caregiver/relative encouraged in this cohort and discussed in more detail during phone calls.</li> <li>• Uptake improved with this strategy, alongside targeting a shorter time from discharge to InS:PIRE attendance.</li> <li>• Informal patient feedback was positive. Similar range of critical illness related problems as those seen in the first cohort. The team felt that those attending had demonstrated a real need.</li> </ul>  |
| <p><i>Third cohort</i><br/>22 invited<br/>5 attended: 22.7% of invited patients<br/>5 completed programme: 100% of those attending</p>   | <ul style="list-style-type: none"> <li>• Trial of a younger cohort planned for this stage, as this group may have a different spectrum of problems.</li> <li>• Age target was under 55 years; initial proposed cut-off of 40 years was too restrictive and cohort would have been very small.</li> <li>• Timing of programme even more important for this group. Patients had often returned to work if invited &gt;6 months after CICU.</li> <li>• Overall, group did not interact with each other as well. Programme would need more adaptation for this model to continue. Pool of patients meeting criteria was too restrictive and resulted in patients attending 6 months after discharge from CICU.</li> </ul>  |
| <p><i>Fourth cohort</i><br/>20 invited<br/>7 attended: 30% of invited patients<br/>7 completed programme: 100% of those attending</p>    | <ul style="list-style-type: none"> <li>• New model introduced, clinic times changed from 3–4 h, “half day” sessions, to 5–6 h “full day” sessions. Lunch provided, improving patient and caregiver interaction and peer support. Patients only attended in-person for 3 sessions (weeks 1, 3, and 5) and had nurse-led phone call appointments on weeks 2 and 4. This 3:2 split was tolerated well, especially for those who had longer travel times.</li> <li>• Cohort worked very well. Staff and patients felt lunch was an “ice-breaker” and facilitated better patient and caregiver peer support.</li> <li>• Staff felt that this model should continue and the range of problems facing these patients were, again, significant.</li> </ul>   |
| <p><i>Fifth cohort</i><br/>24 invited<br/>6 attended: 25% of invited patients<br/>6 completed the programme: 100% of those attending</p> | <ul style="list-style-type: none"> <li>• Model of care consolidated during this cohort.</li> <li>• Continued the 3:2 split, with lunch, and cohort ran well.</li> <li>• Staff more efficient at reviewing patients and anticipating problems.</li> <li>• Third-sector and community groups more embedded in clinic overall.</li> <li>• Informal positive feedback from patients and caregivers continued.</li> <li>• Feedback from staff and patients/caregivers encouraged continuation of this model.</li> </ul>   |
| <p><i>All cohorts</i></p>  | <p><i>Learning across all cohorts:</i></p> <ul style="list-style-type: none"> <li>• Many patients attended who did not think that they had problems or needed to attend. The majority of these patients, when asked directly at follow-up, felt that they had benefited from the clinic.</li> <li>• Longer sessions every second week, with lunch provided, was the best model.</li> <li>• The complex transitions for some patients from CICU to general ICU or hospital, especially those with long CICU/ICU lengths of stay, meant aspects of routine follow-up could be missed. InS:PIRE helped to correct this.</li> <li>• This CICU could identify approximately 20–25 patients per quarter meeting the inclusion criteria. Future work may involve extending the criteria to those with shorter ventilation times, but long treatment times in high-dependency or coronary care areas.</li> <li>• Aiming for patients to attend within 16 weeks of hospital discharge may be the most effective strategy. Those &lt;4 weeks from hospital discharge were not included, and it is unclear whether this group would benefit from InS:PIRE.</li> </ul> |

CICU: cardiac intensive care unit; ICU: intensive care unit; PICS: post-intensive care syndrome.

replicated within the physiotherapy session; the physiotherapist could undertake a more accurate assessment of patient need and functionality when the patient had to carry out activities independently.

*Outcome measures*

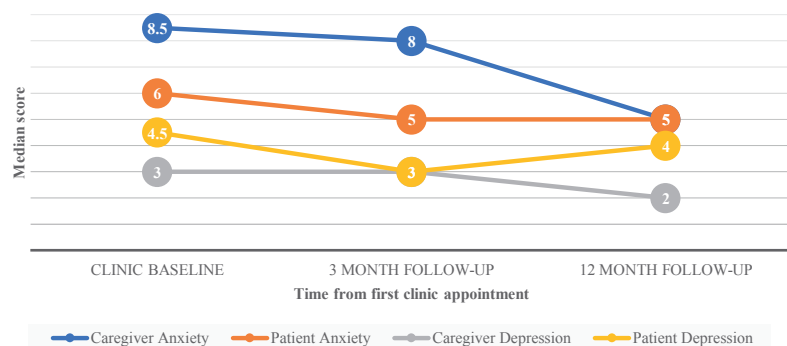
A total of 14/27 (53%) patients and 13/23 (57%) caregivers completed outcome measures at one year. Health-related quality of life, measured using the EuroQol Visual Analogue Scale (EQ-VAS), demonstrated a mean score of 70/100 (standard deviation (SD) 18) at initial InS:PIRE attendance (baseline) and increased to 78/100 (SD 16) by one year (Table IV) (10). The proportion of

**Table IV.** Breakdown of EuroQol 5 dimension 5-level questionnaire (EuroQol 5-level) version domains

| EQ-5D-5L domain                                      | Clinic baseline | 3-month review | 12-month review |
|--|-----------------|----------------|-----------------|
| <i>Percentage expressing problems in each domain</i> |                 |                |                 |
| Mobility   | 56              | 50             | 45              |
| Self-care  | 40              | 33             | 36              |
| Usual activities                                     | 80              | 61             | 55              |
| Pain or discomfort                                   | 76              | 72             | 64              |
| Anxiety or depression                                | 64              | 39             | 45              |
| Mean EQ-VAS score (range 0–100)                      | 70              | 78             | 78              |

Percentage of patients experiencing problems in each of 5 domains: mobility; self-care; usual activities; pain or discomfort; anxiety or depression. Mean EuroQol visual analogue scale (EQ-VAS) at each time-point, range 0–100. EQ-5D-5L: EuroQol 5 dimension 5 level questionnaire.

### Median caregiver and patient anxiety and depression: Hospital Anxiety and Depression Scale scores



**Fig. 1.** Median Hospital Anxiety and Depression Scale (HADS) scores for patients and caregivers at first clinic attendance (baseline), 3 months, and 12 months after initial attendance. Numbers completing HADS surveys at each time-point are: clinic baseline, 24 patients, 20 caregivers; 3-month follow-up, 20 patients, 16 caregivers; 12-month follow-up, 17 patients, 13 caregivers.

patients with problems in at least one domain of EQ-5D-5L decreased from 92% at baseline to 73% at 1-year, while those with severe problems in any domain of the EQ-5D-5L, was 22% at baseline and 18% at one year. Defining depression and anxiety as a Hospital Anxiety and Depression Scale (HADS) >7 at baseline, 41% of patients had symptoms of anxiety, with 26% of this group having “severe” symptoms (HADS >9) (11). In this cohort 22% of patients had symptoms of depression (Fig. 1). The Brief Pain Inventory identified 14 patients (52%) with ongoing pain at baseline (12).

During the baseline InS:PIRE visit, caregiver strain, defined via the Carer Strain Index was present in 20% of caregivers, with the need to alter personal plans (35%) the most common reason for this strain (13). Eleven caregivers (48%) had symptoms of anxiety and 6 (26%) had symptoms of depression. Interestingly, caregiver anxiety exceeded that of patients at baseline, reaching similar levels at 12 months (Fig. 1). Utilizing the Insomnia Severity Index (ISI), 77% of caregivers expressed problems with sleep (14).

All 27 patients were reviewed by the pharmacist; 56% of patients had a medication-related problem. Of the 32 individual MRPs identified, 27 were deemed clinically significant ( $\geq$  grade 2, see Table S2<sup>1</sup>). Most problems were related to cardiovascular drugs (70%), of which 24% were related to antiplatelet or anticoagulation medications. When reviewing the problems, most were related to the absence of a clear management plan across transitions of care.

## DISCUSSION

This single-centre QI project found that patients and caregivers who received care in the CICU have pro-

blems consistent with those described in the post-intensive care literature. Furthermore, this study shows that the implementation of a multi-faceted programme to support these issues is feasible and safe in the clinical environment and appears to improve important outcomes for patients and caregivers.

Previous work has estimated the incidence of PICS as 56% at one year after discharge in the general ICU population (15). The current programme of work describes similar physical and emotional challenges to that population (4, 7, 15). What is particularly notable about these results is that caregivers seemed to have equally troubling issues, such as anxiety and insomnia. Given that informal support is often delivered by close family

members in the post-ICU recovery period, underpinning formal rehabilitation, more work is urgently required into how best to support caregivers both during and after the critical care stay. The core components of the programme in this context appear to be peer support, social care provision, and timely MDT follow-up to ensure patient safety and optimal recovery. Consistent with previous evidence related to PICS, access to social support was crucial, particularly in relation to welfare advice (16). This advice provided reactive, as well as preventative, care. For example, social care services offered access to fall alarms and signposted patients to community organizations, such as addiction services. In terms of transferability, these components can be offered by different services, depending on the geographical context, and in different formats, but should make up part of any service. A further mechanism by which InS:PIRE appeared to improve patient care was through taking a holistic, patient-centred approach that allowed important aspects of health and social care to be integrated with important aspects of case management. Other services and outpatient clinics, including cardiac rehabilitation, often centre on an organ or system (17). This complex intervention focuses on what makes the patient healthy in relation to physical, emotional and social health needs, rather than the delivery of specific healthcare interventions.

Although this single-centre QI project describes important learning, it has some limitations. Firstly, the study was performed in one geographical context with one specific team. As such, the intervention may not be appropriate or feasible in other contexts. Secondly, the study describes the problems of patients and caregivers, and the learning from the implementation of this QI initiative. However, the effectiveness

of this intervention was not analysed; hence, more research is required in this area. Finally, the study describes mental health outcomes for participants, but no information on pre-CICU mental health status was included; hence, the problems described may not be directly associated with recovery following critical illness.

### CONCLUSION

This evaluation has shown that emotional and physical problems are prevalent in the months following discharge from the CICU. The purpose of this evaluation was not to measure the effectiveness of the interventions; its primary goal was to understand whether this model of care could be adopted and implemented for the CICU population. This small-scale QI project has demonstrated that this programme is feasible and has positive implications for patients and caregivers.

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