

# Patient reported outcome measures (PROMS) – 30-day mortality and adverse events post colonoscopy: A prospective observational study from a metropolitan Australian hospital

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## Introduction

Colonoscopy has an excellent internationally proven and accepted safety profile, with large scale studies demonstrating very low rates of post-procedural mortality and severe complications. Little information exists about patient reported outcome measures (PROMs) in Australia. PROMs have been demonstrated to be an advanced measure of quality incorporating patient/user feedback. We performed a patient reported outcome measure quality assurance study of our metropolitan hospital colonoscopy service to identify and assess the incidence of adverse events and mortality occurring at or within 30 days of colonoscopy.

## Design

Prospective, single-centre study with PROMs from all patients having inpatient and outpatient colonoscopy procedures from January 2018 to June 2018.

## Setting

Tertiary/quaternary metropolitan hospital (regional centre for congenital heart diseases, cystic fibrosis, complex cardiology, cardiothoracic surgery, and heart and lung transplantation services).

## Methods

Patients were provided with a feedback form to record any adverse events that occur at or within 30 days post colonoscopy and were required to return the form to the hospital. If not received after two attempts, patient clinical databases were interrogated to examine for unexpected hospital admissions, pathology or additional procedures undertaken in the 30-day period post colonoscopy. The primary endpoints were mortality that occur  $\leq 30$  days of colonoscopy, and adverse events which were categorised into minor (defined as not requiring medical attention), moderate (defined as requiring attention from the general practitioner) and severe (defined as requiring either an emergency department presentation or hospital admission).

## Results

1,416 of 2,237 patients (63%) responded with the feedback form on adverse events; the patient mean age was 59 years (standard deviation  $\pm 15$  years) and 51.7% of them were males.

The primary outcome of 30-day mortality in the outpatient cohort was 0%. However, three unrelated deaths were recorded in the non-responding cohort (3/821 or 0.37%). These inpatients were found to have had significant comorbidities and died 9–18 days after their procedure from unrelated causes including chronic lung allograft rejection in one patient, critical lower limb ischaemia in the second patient, and ventilator associated pneumonia post coronary artery bypass and valve replacement in the third patient.

The rates of minor, moderate and severe adverse events were 4.07%, 1.70%, and 1.48%, respectively, (incidence rates of 40.68, 16.99, and 14.75 per 1,000 exams, respectively; Table 1). Of the patients with severe adverse events, only one patient suffered a perforation post outpatient colonoscopy for bowel cancer screening which improved with medical management (incidence 0.45/1000 exams).

**Table 1. Outcome measures (n=2,237)**

	Rate (%)	Incidence per 1,000 exams (95% confidence interval)
Replied to questionnaire	1,416 (63.30)	
<b>Adverse events</b>		
Nil	1,254 (56.06)	
Minor	91 (4.07)	40.68 (33.25–49.68)
Moderate	38 (1.70)	16.99 (12.40–23.23)
Severe	33 (1.48)	14.75 (10.52–20.64)
Perforation	1 (0.04)	0.45 (0.08–2.53)
<b>Mortality</b>		
Deaths $\leq 30$ days	3 (0.13)	1.34 (0.46–3.94)

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## Conclusions

The results of our single centre quality assurance PROMs study in colonoscopy is consistent with international standards with regards to published and accepted outcome measures for complications post outpatient and inpatient colonoscopy. We identified three deaths that took place in the inpatient cohort, occurring in patients with significant comorbidities, independent assessment confirms

that the colonoscopy did not contribute to mortality. This is the first Australian PROMs study in colonoscopy and reaffirms a favourable safety profile of colonoscopy in our institution. ■

## Conflicts of interest

None declared.