



Inflammatory Bowel Disease National Action Plan

Literature Review 2018

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Introduction

IBD is a chronic disease that requires complex, long-term care. The trajectory of IBD usually involves periods of remission, flares and relapses. Diagnosed at any age but most frequently between 15 and 30 years of age, it usually has a life long impact.

The recently published Australian IBD Standards (2016) specify the expectations for the quality of care for IBD and provide the benchmark for the IBD Audit (2016) of IBD services in Australia.

The national IBD Audit highlights many deficiencies in IBD care services across Australia. The fundamental importance of the multi-disciplinary, long-term approach to IBD management is widely recognised, yet the Audit identified the widespread lack of access to this standard. This has spurred the impetus to better organise and resource IBD services within the Australian healthcare system.

This literature review was conducted by Crohn's & Colitis Australia. It provides a comprehensive summary of the international literature on the ten priority areas for the Inflammatory Bowel Disease (IBD) National Action Plan for the period 2008 - 2018.

It is our hope that the outcome of this literature review will assist in the provision of high quality of care for patients in Australia and reduce the burden on our hospital system.

Acknowledgments

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Literature Search

An electronic literature search was performed for each focus area, using PubMed, Google Scholar and Cochrane Reviews to collect peer-reviewed scholarly literature representing the latest original research in the field and grey literature published by organisations and government agencies in the gastrointestinal field published from 2008 - 2018. The titles and abstracts of electronically identified articles were reviewed. Articles deemed potentially relevant were retrieved for further scrutiny and read in full. The reference lists of relevant articles were used to identify other potentially relevant articles.

1. Increased access to specialist IBD nurses

Executive summary

- Specialist IBD nurses perform a critical role in high quality IBD patient care and improved patient outcomes.
- Specialist IBD nurses provide benefits to their patients, healthcare providers and the Australian healthcare system.
- High quality Australian and international research has demonstrated the economic and clinical benefits of IBD nursing in hospitals, resulting in the reduction of emergency department presentation, reduction in the number of hospital stays, reduction in outpatient attendance and an improvement in patient quality of life measurements and overall patient satisfaction.
- Barriers to accessing specialised IBD nursing in Australia include lack of senior management support, unclear role description, insufficient resources (time and budget), lack of knowledge or expertise and inadequate facilities.

Importance of access to specialist IBD nurses

There is growing worldwide recognition that achieving high quality of care of chronic disease requires a multidisciplinary approach. The model of introducing extended specialised nursing roles to enhance patient care has been previously validated in other diseases.

IBD is a chronic disease of episodic nature, making it difficult to tailor care to patients' needs when their doctor only sees them periodically. IBD patients are recognised to have complex, chronic disease trajectories that are best managed by a dedicated, multidisciplinary IBD service.¹

The role of the specialised IBD nurse is critical for providing high quality patient care. IBD nurses enhance patients' access to timely specialist advice and facilitate coordinated, integrated and multidisciplinary care providing patient-centred benefit.

Given the high volume of outpatient and inpatient health services required by

IBD patients throughout their lifetime, evaluation of access to specialised IBD nursing is important for an economic calculation as well as achieving a high quality of care for the estimated 85,000 Australians with this illness, predicted to increase to almost 100,000 in 2022.²

Development of specialist IBD nursing

Specialist IBD nursing began informally in the 1990s when a number of nurses began incorporating care provision for IBD patients into their professional roles in the UK and is now well established in some of these countries, such as England and Wales. IBD nursing has progressed rapidly in the UK in the past fifteen years and its beneficial role is accepted amongst gastroenterologists, IBD patients and health service providers.

The number, type and roles of specialist nurses dedicated to the care and management of IBD patients is increasing. In addition to direct nursing and surgical care for IBD patients, specialist IBD nurses perform many important functions for improving IBD-patients' quality of life, by providing the first point of contact for patients, providing social support, providing education, administering biologic therapies, managing IBD-related incontinence, advocating for patients, managing fistulae care, supporting diet and nutrition, managing faecal incontinence, managing sexuality concerns and anxiety, managing fatigue, managing pain, providing specific paediatric and adolescent carer, providing psychological support (including telephone support), staffing IBD helplines, monitoring blood tests, performing clinical trial nursing and teaching self-injections.^{3, 4, 5, 6, 7}

Specialist IBD nursing intervention outcomes

The Nurses-European Crohn's & Colitis Organisation (N-ECCO) Consensus statements defined the basic and advanced nursing care required to address patients' needs, stating that: "The Advanced IBD Nurse provides a pivotal and important role in the care of the IBD patient, which benefits the patient, the multidisciplinary team, and the healthcare provider [EL 5]" N-ECCO Statement 4A.⁵

Following the UK publication of 'Quality Care: service standards for the healthcare of people with IBD' in 2009, the Australian IBD Standards were developed and Australian IBD Audit was conducted as part of the IBD Quality of Care Program, which is providing evidence-based guidelines for the improvement of IBD health care.^{1, 8, 9} Recommendation 3 of the Australian IBD standards 2016 states that "IBD nurse roles should be incorporated into all IBD services in line with the proven benefit and standards."⁹

Intervention by IBD nurses results in hospital admission avoidance, emergency

department avoidance, outpatient clinic avoidance and patient quality of life improvement. These outcomes are largely as a result of the following: ¹⁰

- Timely and responsive access allows earlier intervention and prevention of disease deterioration and subsequent hospitalisation.
- Additional education and support improves patient adherence and outcomes.
- Improved safety and monitoring of medications, and resulting treatment efficacy.
- Better quality care resulting from the more perceived 'equal' relationship of patient to nurse as opposed to patient to doctor.

These benefits are particularly relevant given the limited access to IBD specialist doctors in Australia as challenged by limited staff, long waitlists, geographical distance and the increasing complexity of IBD management in light of biological therapies. ¹⁰

Access to specialist IBD nursing in Australia

In Australia, the role of IBD nurse is a newer concept with slower role development than in the UK, with 28 FTE specialist IBD nurses identified in PWC report and 27 FTE nationally in IBD Audit report. ^{8,9}

The data gathered from the Australian IBD Audit 2016 revealed much variability in patient care between IBD sites.⁹ The Audit revealed significant benefits in patient outcomes in sites with at least a Partial IBD Service (which included an IBD nurse) compared to those without, the most important benefit being shown to be a 15% reduction in the rate of emergency admissions. ⁹

Data also revealed that only 39% of sites that participated in the audit employed a FTE IBD nurse. ⁹ The figures for an IBD nurse were 14% for low activity sites and 65% for high activity sites respectively. ⁹ Fewer than one in five patients saw an IBD nurse during their hospital admission: 16% (Crohn's disease) and 18% (ulcerative colitis). Of the participating sites, 88% had a stoma nurse and an IBD Helpline was only available at half the sites (51%).⁹ Further, IBD nurses were not available at all specialist paediatric sites; in fact only one third had ongoing funded positions. ⁹

Evidence base for access to specialist IBD nursing

Despite the recognition that IBD nurses are of critical importance for the delivery of a high standard of care, there is growing, but limited published evidence to demonstrate this.^{1, 11} Multiple studies conducted in Australia and internationally, have demonstrated the economic, clinical and patient benefits of IBD nursing in

hospitals, and have shown emergency department avoidance, a reduction in the number of hospital stays, outpatient attendance and an improvement in quality of life measurements and overall patient satisfaction.^{11, 12, 13, 14, 15, 16, 17, 18, 19}

Although a 2009 Cochrane review of the literature found limited published evidence in the literature for improved outcomes from specialist IBD nurse intervention for patients, the study noted that this conclusion was based on a single study only with questionable methodological quality.⁴

There is data to support the decreased disease burden and economic benefit from proactive management of IBD with a gastroenterologist plus specialist IBD nurse. Evidence from the UK IBD National Audits 2006 and 2008 demonstrated that IBD nurses, as part of a multidisciplinary team, help reduce hospital admissions, increase the proportion of people with IBD to self-manage and are pivotal in offering greater patient choice of care.¹

Several Australian studies have also provided supportive evidence that the availability of a specialised IBD nurse and accessible phone line result in the reduction of emergency admissions and IBD-related healthcare costs. These studies have demonstrated consistent positive outcomes, which suggests the benefits are true, large, many and can be replicated across other institutions.^{13, 14, 15, 16, 18}

Sack et al. (2012) demonstrated the effects of the role of the specialist IBD nurse in Australia, and its superiority compared to the standard one-patient-one-doctor model of care in two audits conducted 2 years apart (n = 612 and n = 570).¹⁸ The data showed that this model of care reduced the burden of disease, as assessed by the need for inpatient care in IBD patients and the economic cost in caring for them, with a direct cost saving to the hospital of ~US\$238,407 (~AUD\$327,678) when just considering the patients contacting the hospital in a five-month period of the study, which was easily offset by the cost of employing the IBD nurses several fold.¹⁸

Leach et al. (2014) similarly assessed the effects of an IBD nurse on patient outcomes in an established IBD centre at an Australian tertiary hospital (n = 566).¹⁶ The study showed that the effect of IBD nursing was significant, even in a specialised service, in terms of hospital admissions, clinic utilisation and emergency department presentations. IBD nurse intervention led to avoidance of 27 hospital admissions (representing a saving of 171 occupied bed days), 32 emergency department presentations and 163 outpatient reviews, resulting in a direct saving to the hospital of AUD \$136,535 after deducting the additional nursing salary and on-costs.¹⁶

A third unpublished Australian study ("CHEAP") measured the effects of implementing a nurse-led patient advice line and virtual clinic in an Australian tertiary IBD clinic in 2015 (n = x).¹⁹ Though not yet published, early data analysis

has shown that this care model improves IBD patients' access to services and overall care, and reduces healthcare costs of a projected annual net cost savings of AUD \$111,061.¹⁹

Each of these studies highlights the importance of a proactive multi-disciplinary approach in optimising the care of IBD patients. IBD nursing provides accessible, timely and flexible advice through a "virtual clinic" conducted through phone and email contact, effectively triaging patients with a flare up to phone management with rapid clinic review if required, or to streamlined admission; thus benefitting patients, doctor and the broader Australian healthcare system.^{16, 18}

Other research has also demonstrated that there is much scope for the use of e-therapy/telemedicine, which can potentially reduce queues, improve access to healthcare and be cost-effective.⁷ This mode of care is increasingly becoming popular in gastroenterology, with emerging evidence showing that it can improve quality of life, treatment adherence and knowledge about the disease, and reduce healthcare costs in IBD; although more studies are needed to confirm these preliminary observations.⁷

The National IBD Audit 2016 data also provided evidence of improved patient experience at sites with a Partial IBD Service or access to IBD nurses.⁹ The Audit showed that important patient information was more commonly provided in sites with an IBD nurse than in those without, with:⁹

- Routine provision of educational material to newly diagnosed people (96% with IBD nurse; 64% without IBD nurse).
- Offer of a patient education session to newly diagnosed people (85% with IBD nurse; 5% without IBD nurse).
- Provision of written information about who to contact in the event of a relapse (100% with IBD nurse; 44% without IBD nurse).
- Availability of information about IBD in pregnancy and its effects on fertility (77% with IBD nurse; 46% without IBD nurse).

Barriers to accessing specialised IBD nursing in Australia

There are limited published studies on the barriers to IBD nursing in Australia. Mikocka-Walus et al. (2014) conducted one of the few studies to explore models of care in IBD using an online mixed-methods survey with health professionals caring for IBD patients in Australia, the UK, the Netherlands, the USA, New Zealand, Canada, Italy, Switzerland, France and Ireland (n = 135).⁷ Reid et al. (2009) studied differences between UK and Australian IBD nurses in a small, pilot study (n= 12 Australia; n = 19 UK), however it provides insight into IBD nursing in Australia and barriers to service delivery.³ Study participants were

members of IBD interest groups and provided a convenient sample. Results therefore belong to a selective group and may not apply to the rest of the target population.

i. Insufficient time and budget resources

Time was shown to be an important barrier to service delivery for Australian IBD nurses. Reid et al. (2009) found that Australian nurses more frequently cited 'insufficient time' than their United Kingdom counterparts (75% versus 50%, $p = 0.19$).³ Nurses employed specifically as 'IBD nurses' were found to be likely to feel more enthusiastic and were more inclined to provide IBD services.

Reid et al. (2009) found Australian nurses cited a 'lack of funds and budget allocation' than their United Kingdom counterparts (83% versus 42%, $p = 0.03$).³ In this study, more UK participants were 'IBD specialist nurses' and more Australian participants were 'clinical trial coordinators', which may suggest the lack of dedicated funding source in Australia. The higher proportion of clinical trial coordinators in Australia correlated to the higher percentage working in tertiary referral centres. Nursing involvement with IBD patients may be more prevalent in tertiary sectors in Australia. The opportunity for additional support for IBD patients was gained through funding from conducting clinical trials. A clear funding source and a dedicated job description may be related to more IBD service provision.

ii. Lack of senior management support

Reid et al. (2009) found that Australian nurses had less perceived 'nursing management support' from senior nursing managers and senior medical staff than their United Kingdom counterparts (50% versus 16%, $p = 0.05$, statistically significant) and 'lack of medical support' (25% versus 0%, $p = 0.05$, statistically significant).³

iii. Unclear role description

Reid et al. (2009) suggests that Australian nurses may be under-utilised in terms of their skills and experience as compared with their counterparts in the UK where nurses are an integral part of a multi-professional team especially in chronic disease management.³

The study found that UK nurses were more likely to be 'IBD specialist nurses' and Australian nurses 'clinical trial research nurses'. The study also found that more United Kingdom nurses provided dedicated services for IBD patients (47% versus 8%, $p = 0.05$), with Australian nurses providing services for a wider range of conditions.³ The study also found that Australian nurses did not provide IBD services because they were 'not part of [their] job description' (58% versus 11%, $p = 0.01$).³

The study also found that the most popular IBD services that Australian nurses

wished to offer were operating telephone support line (50%); paediatric transition care (50%); cigarette smoking cessation support (50%); and nurse clinics (45%).³ Importantly, two of these services (operating telephone support line and nurse clinics) were already being provided by all of the UK IBD nurses in the study.³

In the study by Mikocka-Walus et al. (2014), respondents were asked to discuss the role of nurses and their services as part of the survey. According to the authors, the “most important” finding of the study was the view that an optimal IBD service should be fully integrated and involve significant roles of IBD nurses “performing ‘the nursing job’ rather than dealing with a huge workload of administrative tasks”.⁷

iv. Lack of knowledge or expertise

Reid et al. (2009) found that nurses cited ‘lack of knowledge or expertise’ equally by nurses in both countries (33% of Australian and 26% of UK nurses, $p = 0.80$).³

It is likely that a perceived lack of knowledge or expertise was due to the lack of IBD-specific academic background and educational programs. The study identified the level of academic achievements and IBD-specific training received by participants, which may explain the lack of knowledge. The study showed that 33% Australian nurses achieved a hospital certificate, 8% achieved a Bachelor degree, 42% achieved a Masters degree, 8% achieved a post-graduate diploma and 8% had an IBD-specific qualification.³ The study showed that 11% UK nurses achieved a hospital certificate, 26% achieved a Bachelor degree, 26% achieved a Masters degree, 42% achieved a post-graduate diploma and 8% had an IBD-specific qualification.³

Of the study participants, the majority (75% of the Australian cohort and 79% of the UK cohort) had 4 or more years of IBD experience.³ It is likely that those without more than 4 years of IBD-specific experience felt a lack of expertise.

v. Inadequate facilities

Reid et al. (2009) found that nurses cited ‘inadequate facilities’ equally by nurses in both countries (33% of Australian and 26% of UK nurses, $p = 0.80$).³ The study did not delve further into a description or explanation for the ‘inadequate facilities’. It is possible that this is partly explained by the workplace characteristics as the majority of nurses worked in a public facility that was underfunded serving its urban population (92% Australian and 84% UK).³

The following table lists the search term/s, database and number of results used in this section (**Table 1**).

Table 1

Search term/s	Database	Results
'IBD nurse'	PubMed	58
'IBD nurse' and 'Australia'	PubMed	4
'IBD nurse'	Cochrane	3
'IBD nurse' and 'Australia'	Google Scholar	2,280

2. IBD helplines responsiveness to patients and GPs

Executive summary

- Telephone helplines have been shown to be useful, cost-effective and accepted by the majority of patients in the management of many chronic diseases, however data for IBD telephone lines is limited.
- Studies have shown that IBD patients require constant clinical attention as well as non-clinical bureaucratic and logistical information, both of which can be provided in real-time with an IBD helpline.
- The IBD helpline allows a timely, responsive disease management approach and enables earlier intervention and avoidance of hospital admission. However, there is little evidence to evaluate its effect on disease outcomes.
- There is good evidence to show that IBD helplines provide additional clinical gain, care, and support and are safe and highly regarded by patients.
- There is good evidence to show that IBD helplines benefit IBD doctors and the Australian healthcare system.

Patients with complex, chronic diseases often require assistance beyond their scheduled episodic doctor appointments. The provision of good quality care in chronic diseases requires a model that offers greater access to information and education, thereby enabling self-management and patient empowerment.²⁰

This is especially true for IBD. Given its unpredictability and the speed at which the disease can deteriorate, IBD patients may need to contact their specialists to solve their daily clinical issues. It has been hypothesized that IBD service delivery can be made more efficient and demand directed through services such as dedicated IBD helplines to facilitate responsive communication between patients and doctors.

“Most IBD patients not only require constant clinical attention and reassurance, but also bureaucratic and logistical information. Therefore, the use of a simple

tool [IBD call centre], able to enhance both medical practice and patients' care, seems to be a necessity for the patient, but also for the doctor and the IBD Unit." ²¹

The function of IBD helplines

The availability of medically trained IBD specialists is limited and costly. The IBD service based on a supervising gastroenterologist-lead shared care model with specialist IBD nurse input has been shown to be economically and clinically superior to the standard one-patient-one-doctor model in Australian and international studies. These studies highlight the value of a proactive multi-disciplinary approach in optimising care of IBD patients by providing accessible, timely and flexible advice through a "virtual clinic" using phone and email contact.

Nurse-led IBD patient helplines and virtual clinic are increasingly being recognised as an integral part of the IBD service, ^{7, 19} enabling a patient-focused model of care as an adjunct to traditional face-to-face consultation. ¹⁶ This is also particularly useful for patients with geographic isolation.

The N-ECCO consensus statements on European nursing in CD and UC describe the way in which the advanced IBD nurse can perform an independent review and management of IBD patients. N-ECCO Statement 3L: "The Advanced IBD Nurse can conduct patient reviews face to face, via telephone consultation or by electronic means [EL4]. ⁵ This is consistent with the Australian IBD Standards 2016, which state that: "All IBD services should implement responsive telephone and email helplines." ⁸

The availability of nurse led IBD helpline allows a timely, responsive approach to IBD care and enables earlier intervention for problems and avoidance of hospital admission. ¹⁰ It provides clinical guidance, information, care, support, allows additional interventions to supplement the routine outpatient service and triages patients for hospital admission including: ^{18, 21}

- Monitoring of protocols for blood tests and drug therapies, thus ensuring compliance, adherence, early detection of adverse drug reactions and non-response.
- Concerns with treatment plans (withdrawal medications, and/or missed doses of medication).
- Requests for medical appointments.
- Scheduled phone follow-up for any patient with symptoms at routine clinic visits and post hospital discharge to ensure resolution, thereby preventing disease deterioration between doctor appointments.

- Active nurse management of clinic appointments according to changing patient status (no longer clerically scheduled).
- Providing a single contact point for patient queries, phone & email provided.
- Patient education and information provided for new patients and all those with treatment changes (e.g. newsletter, encouragement to join support groups such as Crohn's & Colitis Australia).

Evidence base for IBD helplines outcomes

Telephone helplines have been shown to be useful, cost-effective and accepted by the majority of patients in the management of chronic diseases (e.g. colorectal cancer, pediatrics, rheumatology, psychiatry), however data in inflammatory bowel disease (IBD) is scarcer.^{18, 21}

There is good evidence from Australian and international studies to show the clinical and economic benefit of a formal IBD service, including an IBD helpline staffed by an IBD nurse. Results have demonstrated the utility and or superiority of this model of care compared to the standard one-patient-one-doctor.^{13,14,15,16,18,19, 22} There is also good evidence to show that the use of helplines is safe and cost-effective; and patients report high levels of patient satisfaction.^{22, 23} Research has also demonstrated that telemedicine can reduce queues, treatment adherence and knowledge about the disease through improved access to healthcare.⁷

However, few studies have studied the effects of an IBD helpline in isolation. Moreover, only a few publications have described the advice line service and evaluated its efficiency, with many results presented as conference posters.²³ There is emerging evidence showing that it can improve quality of life; although more studies are needed to confirm these preliminary observations.⁷

A study of the effectiveness of IBD helplines was conducted in 2016 by Imperatore et.al (2016) using a 2-year prospective observational study after the introduction of an IBD telephone helpline in Italy between 2012 and 2015.²¹ The results demonstrated the potential practical benefit of such a helpline for both patients and physicians.

The helpline served a large volume of patients, fielding 11,080 incoming calls and managed an equally significant number of requests (11,972) from 1867 patients with a daily average of about 20 ± 5 calls.²¹ Results showed that 63% of patients phoned the helpline monthly to request a medical consultation, a percentage that testifies the importance of a telephone service for IBD subjects and others affected by chronic diseases.²¹ In addition, authors noted that the concurrent increased number of visits (>200 visits in two years) and suggested

that it was better managed thanks to the IBD service, which “doubtlessly contributed to optimize daily clinical practice”.²¹

A study by Ramos-Rivers et al. conducted a similar prospective observational study in America over 2 years at a tertiary care IBD clinic, with 2475 patients in 2009 and 3118 in 2010.²⁴ The study showed the importance of telephone communication as validated by the sheer volume of calls and the predictive ability of costly hospital-based care.²⁴

Knowles and Mikocka-Walus conducted a 2014 systematic literature review of internet-based eHealth interventions involving gastroenterological cohorts. The eHealth disease management was shown to generally improve quality of life, medication adherence, knowledge about the disease, and reduce healthcare costs in IBD, although the studies were associated with various methodological problems, and thus, this observation should be confirmed in well designed interventional studies.²⁵ This review contained a single IBD cohort study, which did not isolate the effect of helplines from general eHealth interventions. The IBD study had a small sample size, non-randomized allocation to conditions, therapy was conducted by combination of clinical psychologist or graduate clinical psychology students, and the study was limited to adolescent female sample, therefore no power-analysis was reported.

Jackson et al. (2016) conducted another literature review on the use of eHealth technologies in IBD management, of which a telemedicine is a subset.²⁶ Authors report that disease outcomes have not been formally evaluated in telemedicine interventions. Bager et al. (2017) conducted a broad systematic literature search to identify relevant studies addressing the effect of IBD phone lines.²³ The review included 10 studies with moderate-to-high quality made up of three randomised controlled trials, two economic evaluations, two cross-sectional studies, one quality improvement study, one prospective population-based study and one qualitative interview study. Authors concluded that although phone lines were shown to be safe, cost-effective and welcomed by patients, the level of evidence of the effect of advice lines in IBD was low.²³

Australian IBD helplines

The Australian IBD Standards 2016 were informed by the IBD Audit data and the recommendations are supported by audit outcome measures.

Recommendation 4 states “all IBD services should implement responsive telephone and email helplines.”⁸ Yet the Audit demonstrated that:⁹

- An IBD Helpline was only available at half of the sites in the Audit (51%).
- Only 16% of Australian IBD services offered an annual review via a telephone clinic.

This is supported by international data gathered by Mikocka et al. (2012) from Australia, the UK, the Netherlands, the USA, New Zealand, Canada, Italy, Switzerland, France and Ireland reported that only 22% of patients had access to electronic or telemedicine.⁷

Evidence- based outcomes of IBD helpline

i. Patient support and satisfaction

A significant benefit of the IBD helpline is its accessibility and real-time responsiveness. There is good evidence from Australian and international studies to show a high level of patient satisfaction in IBD care involving telephone disease management.^{17, 18, 21, 26, 27} Satisfaction with the self-management model of care has been shown to be very high. Some studies have reported figures as high as 95% of respondents more satisfied with the care provided after the activation of the contact centre²¹ and 90% of patients shown to be satisfied with before and after implementation of a patient helpline.¹⁷

Imperatore et al. (2016) reported that the service facilitated communication with doctors (98%) and allowed for a faster appointment management (97%).²¹ The authors noted that the IBD helpline provided patients with “a reassuring instrument, a tool to feel closer to the doctor and find a quick answer to his or her problems”.²¹

Moreover data from this study confirmed the psychological need for specialist responsiveness in IBD patients. An analysis of the distribution of the calls for a follow-up visit showed a trend of higher call activity in January (18%) and September (15%) and analysis of the distribution of calls during the week showed a peak on Monday (30%).²¹ Authors noted that these results signify that patients used the service more frequently after a period of interrupted contact and reassurance (after winter and summer vacation and after weekend centre closure) when outpatient activity is discontinued.²¹

ii. Early intervention and reduced hospital admissions

There is good evidence from Australian and international studies to show a reduction in hospital admissions and length of stays resulting from a formal IBD service, including an IBD helpline. IBD helplines have been shown to effectively triage patients with a flare up from phone management to a rapid clinic review if required or to streamlined admission, benefitting patients, doctor and the broader Australian healthcare system. Hospital admissions for IBD frequently result from unplanned attendances to hospital emergency departments.

Data from the Australian IBD Audit showed that even a modestly resourced Partial IBD Service (IBD nurse, helpline and medical lead) resulted in significantly lower rates of admission via the emergency department.⁹ The most important

benefit demonstrated was a 15% reduction in the rate of emergency admissions.⁹ Other Australian studies provide supportive evidence that the presence of a helpline and specialised IBD nurse are major drivers of a reduction in emergency admissions and IBD-related healthcare costs.^{14, 15,16,18,} Sack et al. (2012) showed that the IBD service model including a specialised IBD nurse and an IBD helpline reduced the burden of disease in two large cohorts, as assessed by the need for inpatient care in IBD patients and the economic cost in caring for them.¹⁸

Leach et al. (2014) similarly assessed the effects of an IBD nurse and virtual clinic on patient outcomes in an established IBD centre at an Australian tertiary hospital (n = 566).¹⁶ The study showed that the effect of IBD nursing was significant, even in a specialised service, in terms of hospital admissions, clinic utilisation and emergency department presentations. IBD nurse intervention led to avoidance of 27 hospital admissions (representing a saving of 171 occupied bed days), 32 Emergency Department presentations and 163 outpatient reviews, resulting in significant cost savings.¹⁶

A third Australian study (CHEAP) measured the effects of implementing a nurse-led patient advice line and virtual clinic in an Australian tertiary IBD clinic in 2015.¹⁹ Though not yet published, early data analysis has shown that this care model improves IBD patients' access to services and overall care, and reduces healthcare costs. Over 4 months, 111 calls were received through the helpline, resulting in 34 avoided GP consultations, 70 avoided IBD outpatient consultations; 6 avoided emergency department presentations; and 1 avoided hospital admission.¹⁹

Several international studies have confirmed these results. Nightingdale et al. (2000) showed that the addition of an IBD nurse and telephone line resulted in a reduction in hospital visits by 38% and a reduction in the length of hospital stay by 19%, representing a significant cost effectiveness.¹² Imperatore et al. (2016) noted a significant reduction of hospitalizations following the introduction of an IBD call centre (from 14 to 9%), despite an increase of patients served by the clinic (from 1650 to 1962).²¹ Kemp et al. (2017) conducted an audit following helpline introduction in the UK and demonstrated reduced in-patient hospital stays and cost effectiveness. Though unpublished, results presented in a poster show a 6-month period in 2016, 876 calls were received, resulting in 76 emergency department visits avoided, and thereby saving 380 days of hospital beds.²⁸

Importantly, the systematic study of helpline calls were also shown to be a predictor of adverse outcomes. The risk of hospitalisation was shown to exponentially increase with the number of phone calls, such as imminent emergency department admission and/or hospitalisation by both Imperatore et al. (2016) and Ramos-Rivers et al. (2014).^{21, 24} This further validates the utility of

the IBD helpline. Based on the findings of this study, IBD providers should be able to use this predictive capacity to identify patients who require more resources when they call the office frequently. In addition, providers should be able to red flag patients who call the office frequently, especially those patients who cluster a large number of telephone calls within 30 days as patients more likely to have poor clinical outcomes and increased use of health care resources.²⁹

iii. Reduced burden for doctors: managing non-clinical information

An interesting finding from several studies is IBD patients' needs for non-clinical information for the management of their IBD. These inquiries were easily handled by telephone operators and solved in real-time. IBD helplines consistently and rapidly met patients' needs for non-clinical information, preventing additional unnecessary work for GPs, specialists and emergency department staff and/or distraction from their clinical activities.

Imperatore et al. (2016) found that 37% of IBD helpline-users in an Italian IBD centre called for non-medical reasons, and, in particular, 20% required an outpatient appointment and 17% called for logistic information, such as laboratory tests' appointments, and payment methods.²¹ In addition, of the non-medical requests (37% of total calls), the study found that 63% of patients called for logistic information (e.g. ticket costs, information about their visit or procedure).²¹ This means that about a third of patients, in absence of the call center service, would overcrowd GPs and or hospital emergency departments for non-medical requests.

Ramos-Rivers et al. (2014), who conducted similar research in America, found that greater than 10% of telephone communication handled by nursing staff involved insurance authorisation and healthcare form completion alone.²⁴

Importantly, these studies suggest that the handling of non-clinical information by an administrative team would allow specialists and nurses to provide dedicated clinical care and be more cost effective for the centre.

The following table lists the search term/s, database and number of results used in this section (**Table 2**).

Table 2

Search term/s	Database	Results
'IBD' and 'helpline'	PubMed	4
'IBD' and 'helpline'	Google scholar	224
'IBD' and 'helpline'	Cochrane	2

3. Increased administrative resources to support case-workers in IBD clinics

Executive summary

- Administrative duties are required as part of IBD patient care and this has been consistently documented in various studies across multiple countries.
- The administrative burden of IBD nursing competes for more productive health care provision services, and with additional administrative support, more time could be spent on patient care, research and teaching.
- Administrative support should be factored into each specialist IBD nursing role as a key component to support the multidisciplinary team in delivering quality patient care.
- Allocating this administrative work to more suitable staff would result in a significant cost reduction and improved quality of service.

It is widely accepted that high quality IBD patient care requires a multidisciplinary team within a specialised IBD clinic. Administrative duties are required as part of IBD patient care, for instance for facilitating prescriptions and certificates, and there is general consensus that additional administrative support for IBD caseworkers is desirable. However, this literature review has not identified published evidence to compare the existing level of administrative support with the optimal level of administrative resources required to support caseworkers in IBD clinics.

Evidence base for the administrative workload in IBD clinics

The level of administrative duties performed to support patients in IBD clinics has been measured in various high quality studies conducted in Australia and internationally. These studies have consistently described the many important functions performed by nurses and differentiated between nursing and administrative roles.

However a clear description of exactly what 'administrative duties' consist of

has not been identified by this literature review; this may possibly account for the variable rates of so called 'administrative duties' performed by IBD nurses as measured in these studies.

Each study has described the administrative burden in IBD care, which competes for more productive health care provision services, and with additional administrative support, more time could be spent on patient care, research and teaching.

Mikocka-Walus et al. (2014) conducted one of the few studies to explore models of care in IBD using an online mixed-methods survey that was conducted with health professionals caring for IBD patients in Australia, the UK, the Netherlands, the USA, New Zealand, Canada, Italy, Switzerland, France and Ireland (n = 135).⁷ Study participants were members of IBD interest groups and provided a convenient sample. Results therefore belong to a selective group and may not apply to the rest of the target population.

According to the authors, the "most important" finding of the study was the view that an optimal IBD service should be fully integrated and involve a significant role of the IBD nurse "performing 'the nursing job' rather than dealing with a huge workload of administrative tasks".⁷ Data gleaned from this study showed that on average the respondents spent 16% on administration, versus 62% of their time in clinical care, 16% on research and 9% on teaching.⁷

There is widespread growing recognition that administrative support (in the form of a clerical worker to perform administrative tasks) should be factored into any business case for a specialist nursing role as it would be for any medical service, to achieve improved patient outcomes.^{2, 30} Allocating administrative work to more suitable staff would result in a significant cost reduction and improved quality of service.²

International studies suggest that the handling of non-clinical information by an administrative team is warranted and would allow specialists and nurses to provide dedicated clinical care and be more cost effective for the centre.

i. American-specific evidence

As discussed in the previous chapter, an American study Ramos-Rivers et al. (2014) found that greater than 10% of telephone communication handled by nursing staff involved insurance authorisation and healthcare form completion alone.²⁴

ii. Australian-specific evidence

Following the UK Audit, the Australian IBD Audit 2016 similarly showed that just 6/67 (19%) participating sites had FTE administrator attached to the IBD team.⁹ This is relevant, since time was shown to be an important barrier to service delivery for Australian IBD nurses. Reid et al. (2009) found that Australian nurses

more frequently cited 'insufficient time' than their United Kingdom counterparts (75% versus 50%, $p = 0.19$).³

iii. Belgian-specific evidence

A Belgian study by Coenen et al. (2017) examined the role of the specialist IBD nurse as part of IBD management and measured its effect on quality of care over a 12-month period ($n = 1313$).¹¹ Data from the study showed that 108/1420 (7.61%) IBD nursing interventions performed were for administrative support.¹¹

iv. Chilean-specific evidence

An unpublished Chilean study by Simian et al. (2017) presented as a poster showed the results of an observational descriptive study to measure the impact of adding an IBD nurse to a cohort of tertiary centre patients over 5 years from 2012 - 2017 ($n = 1173$).³¹ The study identified 23% of patient contact to be administrative work and concluded "administrative personnel are necessary in order to enable the IBD nurse to more direct patient care."³¹

v. Italian-specific evidence

As discussed in the previous chapter, Imperatore et al. (2016) found that 37% of IBD helpline-users in an Italian IBD centre called for non-medical reasons, and, in particular, 20% required an outpatient appointment and 17% called for logistic information, such as laboratory tests' appointments, and payment methods.²¹ In addition, of the non-medical requests (37% of total calls), the study found that 63% of patients called for logistic information (e.g. ticket costs, information about their visit or procedure).²¹

vi. UK-specific evidence

The Royal College of Nursing Inflammatory Bowel Disease Nursing Audit (2012) was conducted in the UK to gather data on the roles, responsibilities and activity of nurses with specialist/advanced roles. The first IBD Nursing Audit took place in 2011 with successive national audits of general IBD care across all acute NHS trusts within the UK ($n = 240$).³⁰ Among the key findings identified by the Audit were:³⁰

- Two thirds of specialist IBD nurse services are suspended or partially suspended when the IBD nurse specialist is away, validating the vital role they perform. The Audit concludes that this "presents a risk to patient care and a source of stress on the IBD nurse specialist and other members of the multidisciplinary team" and should be addressed accordingly.
- Limited administrative support, with respondents averaging 2.5 hours of non-clinical work per day and 40% of respondents having no administrative support at all. 16% of specialist IBD nurses were shown to have to type their own clinic letters, one third to have to arrange their

own outpatient appointments and just under half (40.7%) of specialist IBD nurse services were found to have no administrative support.

- Specialist IBD nurses spent an average of 37 minutes per day (8.13% of their time each day) on non-clinical administration and an average of 72 minutes per day (15.82% of their time each day) on clinical administration, totaling an average of 109 minutes (23.95% of their time each day) on administration. This equates to an average of 545 minutes per week, or almost 10 hours, over a full workday.
- Specialist IBD nurses spent an average of 33 minutes of their day doing work beyond their contracted hours.

The Royal College of Nursing identified a number of responsibilities to address, including the need for a review of administrative support for specialist IBD nurses to ensure that proper administrative support is incorporated into IBD services so that a higher proportion of specialist nurse time can be dedicated to performing clinical activity rather than administration.³⁰

Similar levels of healthcare administrative workload has been identified by other studies, such as by Leary et al. (2010), which showed that 21% of specialist nurse time was distracted by undertaking unnecessary administration (such typing letters, data entry etc.)³² This study extrapolated that if the specialist nursing time could be freed up from administrative workload with clerical support, an extra 6.25 hours per week on an FTE basis would be available for nursing duties.

³²

The following table lists the search term/s, database and number of results used in this section (**Table 3**).

Table 3

Search term/s	Database	Results
'IBD' and 'administrative support'	PubMed	72
'IBD' and 'administrative resources'	PubMed	6
'IBD' and 'administrative support'	Cochrane Library	1
'IBD' and 'administrative support'	Google Scholar	6,140

4. Greater access to multidisciplinary allied health care teams in hospital, including increasing the number of MBS funded visits for allied health (primary care) and improved credentialing and education across all areas of allied health

Executive summary

- Allied healthcare professional support is instrumental in high-quality IBD patient care.
- There is currently a lack of evidence to define the optimal level of allied health provision within dedicated IBD units, such as the size and composition of the multidisciplinary team, and the required supporting resources (physical resources, training, documentation, administration).
- At present, multidisciplinary IBD patient care in Australia is variable and insufficient, and psychological and nutritional specialties are two notable examples.
- Improved education and credentialing for allied healthcare and increased funding for allied health care have been suggested, however there is no research to support these.

Allied healthcare in IBD

The multifaceted, chronic and complex nature of IBD, and its resulting impact on patient quality of life, means that IBD is best managed with a multidisciplinary approach. It is well recognised that allied healthcare professional support is instrumental in high-quality IBD patient care.^{7, 20, 33} Multidisciplinary IBD units can offer greater expertise and experience for patients, especially those with complex needs.³⁴

Allied health specialties involved in the care for IBD include dietitians, psychologists and pharmacists. Unfortunately, there is little information available on Australian allied health services and nursing for primary health care services funded by state governments.³⁵

Evidence base for allied healthcare in IBD

Although some integrated models of care for IBD with integrated IBD-specific allied healthcare have been suggested, there are few published studies examining models of care in IBD.³⁶ Two studies by Sack et al. (2012) and Phan et al. (2012), which have been detailed in this review in previous chapters, have shown that an integrated model of IBD care with good access to allied health improves clinical and psychosocial patient outcomes and is cost-effective.^{14, 18, 36, 36}

However, there is currently a lack of evidence to define the optimal level of allied health provision within dedicated IBD units, such as the size and composition of the multidisciplinary team, and the required supporting resources (physical resources, training, documentation, administration).

Mikocka et al. (2014) conducted one of few studies that explored models of care in IBD (n = 135).³⁶ The study involved a survey of international gastrointestinal physicians (50%) and other health care professionals providing IBD care in Europe, Australia and North America (50%). The results of the survey showed the shared view that the ideal IBD service should be fully integrated multidisciplinary clinic and involve significant, routine, clinical roles for IBD nurses, psychologists and dietitians; and these services be easily accessible and funded publicly.³⁶ It is important to note the limitations of this study, including the study design, which was based on self-reporting. In addition, healthcare professionals, not patients, were surveyed.

Louis et al. (2015) similarly conducted a survey of international IBD expert physicians (n = 238) to determine the optimal IBD unit organisation.³⁴ The study found that:³⁴

- The multidisciplinary team should include an IBD-specialist nurse, nutritionist, stoma specialist, radiologist, endoscopist, pathologist, psychologist and social worker (79% of experts agreed).
- The unit should coordinate care with additional allied health providers: primary care practitioner, a paediatric transition team, obstetrics/gynaecology specialist, rheumatologist and dermatologist (80% of experts agreed).
- All staff involved should have IBD experience so that the collaboration is effective and efficient.

It should be noted that the study consulted physicians and not allied health professionals, who may have a different opinion. Physician recommendations

were obtained from systematic searches of published evidence and structured requests for expert opinions.

Morar et al. (2017) similarly conducted a prospective, multicentre survey-based study of IBD specialists from 12 institutions across the UK (n = 24).³³ Results showed a consensus of opinions that the ideal IBD service should involve colorectal surgeons, radiologists, gastroenterologists, IBD nurse specialists, dieticians, histopathologists and the unit coordinator as core members; with collaborations as required with paediatricians, research fellows, junior doctors, pharmacists, dermatologists and rheumatologists.³³ Again, the study surveyed healthcare professionals and not patients, whose opinion could potentially be useful and or different.

Greater access to allied healthcare in IBD

Australian IBD Standards 2016 state that IBD care, like other complex, chronic diseases, requires increasingly complex multi-disciplinary health care systems with timely and reliable communication, and collaboration between specialists, generalists and primary health care physicians.⁶

A recent report into the Australian primary care landscape by the Grattan Institute outlines the major issues of care delivery: variable access, poor service integration for complex conditions, and inadequate risk-factor prevention; and goes on to explain that these are exacerbated by data and information gaps, weak systems management and the absence of national institutions to guide the development of primary care.³⁵ The report calls for:³⁵

- Increased access to primary care services, including the reduction of out-of-pocket costs, capacity constraints and geographic distribution of services.
- Improved quality of care, patient support and the efficiency of services for Australians with complex and chronic conditions.

The recent Australian IBD Audit has filled the data and information gap in the landscape of IBD and this data will be supplemented by this review, which is outlining the evidence base to guide the development of better primary care.⁹

Mikocka et al. (2014) concluded that the obstacles to establishing better services according to study respondents were not only financial but also administrative and political, “with current governing systems in hospitals in many countries poorly suited to supporting integrated models of care and with inadequate referral mechanisms for psychological and nutritional care.”

³⁶ Similarly, Louis et al. (2015) states that it is not always possible to have all

these personnel in one unit, due to resourcing and financial constraints and also notes that optimising the setup of IBD units will require “progressive leadership”.³⁴

Australian data

The Australian IBD Standards 2016 are consistent with the UK National Institute for Health and Clinical Excellence (NICE) quality statement, which were originally established in 1999 as the National Institute for Clinical Excellence, a special health authority to reduce variation in the availability and quality of National Health Service (NHS) treatments and care. The Australian IBD standards, in line with the UK NICE Standards, recommend a defined IBD team with named personnel to provide patient care.^{6, 55}

According to these Standards, which are based on the need for cross-coverage and a defined population of 250,000, the IBD team should have a minimum of 2 FTE consultant gastroenterologists, 2 FTE consultant colorectal surgeons, 1.5 FTE clinical nurse specialists with competencies in IBD, 1.5 FTE clinical nurse specialist with competencies in stoma care and ileoanal pouch surgery, 0.5 FTE dietician, and 0.5 FTE administrative support. Additionally, the team is recommended to have a named histopathologist, a radiologist, a pharmacist, a paediatrician, a psychologist, a rheumatologist, an ophthalmologist, a dermatologist, an obstetrician and a nutritionist, each with IBD-specific knowledge.⁶

At present, multidisciplinary IBD patient care in Australia is variable and insufficient.⁹ The Australian IBD Audit 2016 identified that only one site (of the 71 sites surveyed) had a full IBD team as defined in the Interim Australian IBD Standards 2015; 24% had a Partial IBD Service as described above, and 39%, an IBD nurse.⁹ Psychological and nutritional screening and support are two important allied health specialties required for high quality IBD care.

i. Evidence base for psychological access and support

In Australia, psychologists are currently involved in IBD research and practice but not routinely in patient care. Though GPs are able to refer patients for funded psychological support, their experience of IBD management is usually minimal due to low exposure. Most GPs providing primary care for IBD patients have very limited IBD exposure and experience, averaging 2-10 patients in their caseload.⁵⁹

It is known that IBD patients commonly experience anxiety and depression and that these comorbidities have a negative impact on patient clinical outcomes. Yet, access to psychologists is limited and the provision of psychological support to IBD patients is very low. Data from the Australian IBD

Audit revealed that 4% of sites had psychologist support in their IBD service.⁹ This is despite the fact that psychological conditions were the most frequently occurring comorbidity (25%).⁹ The Audit revealed that:

- Less than 5% of patients had a mental health clinician in their IBD service even though psychological condition was the most common comorbidity (30% Crohn's disease; 25% ulcerative colitis).
- Less than a quarter (21%) of patients with a comorbid psychological condition received psychological support during their hospital admission.
- When mental health care was delivered, it was often done so by a social worker and not a psychologist or psychiatrist, who would be better placed to do so.⁹

ii. Evidence base for nutritional access and support

Malnutrition is known to be a common IBD complication and is implicated in poor patient outcomes, particularly for those who undergo surgery.⁹ Several groups have recommended the need for nutritional support for assessment and management in IBD.

The Australian IBD Audit 2016 recommended that all hospitals caring for people with IBD should encourage access to dietitians with specialised IBD knowledge and that nutritional screening should be part of the assessment of all people with IBD.⁹ The evidenced-based consensus statements on acute severe ulcerative colitis, developed by a multidisciplinary Australian group similarly call for multidisciplinary care, comprising a gastroenterologist, colorectal surgeon, gastroenterology nurse, dietitian, pharmacist, and stomal therapist on a specialised gastrointestinal ward.³⁷

Data from the Australian IBD Audit revealed that there were low rates of nutritional screening and assessment and dietetic intervention pre and post-operatively. The Audit revealed that:⁹

- The use of dietary therapy was rarely reported among patients at admission (1%).
- Less than half (44% Crohn's disease; 42% ulcerative colitis) saw a dietitian during hospital admission;
- Less than half (40% Crohn's disease; 38% ulcerative colitis) had a nutritional risk screen during their hospital admission;

- A dietician followed up 56% (Crohn's disease) and 44% (ulcerative colitis) of patients for whom nutritional supplementation was recommended.

Malnutrition is particularly critical in paediatric IBD patients as poor nutrition can hamper growth and development. The Australian IBD Audit 2016 showed that nutritional screening was less common for paediatric admissions (19% Crohn's disease admissions; 13% ulcerative colitis admissions).⁹

In the paediatric IBD cohort, apart from the use of IBD medications similar to those used to treat adult IBD patients, a strong emphasis is now placed on exclusive enteral nutritional therapy where possible.¹⁰

iii. Evidence base for pharmacist involvement

The role of a clinical pharmacist in the inflammatory bowel disease (IBD) clinic is an emerging role within Australia. Studies have demonstrated the effectiveness of pharmacist interventions to improve patient education to increase adherence to IBD maintenance medication. Ashok et al. (2017) conducted a prospective, interventional follow up study in an Indian cohort (n= 110).³⁸ Tiao et al. (2017) conducted a multicenter prospective longitudinal parallel interventional study (n = 100).³⁹

Unpublished data from Rentsch et al. (2015) analysed the effect of introducing of a pharmacist into an Australian IBD clinic to establish a thiopurine monitoring program, based on a successful UK model.⁴⁰ Pharmacists were able to prescribe, escalate and modify treatment in line with established protocols and in consultation with the medical team. Results showed that pharmacists were able to direct the thiopurine-monitoring program by providing specialised medication education, dose adjustment and assessment of drug intolerance and adherence as required.

Improving access to allied health in IBD

Given the evidence of the lack of access, it is clear that there is a pressing need to address these barriers and provide greater access to these allied health services in IBD. Improved education and credentialing for allied healthcare and increased funding for allied health care have been suggested, however there is no research to support these.

i. Improved education and credentialing for allied healthcare

It has been proposed that allied health models of care provide opportunities for extended scope of practice. This can be achieved by progressing better education, training and resources for allied health professionals. No studies were found in the literature on this subject.

Credentialing formally recognises the advanced knowledge and skills of nurses within the specialty of gastroenterology and is a useful benchmarking tool for both advanced practice nurses and employers. ⁴¹ Increasing the IBD-training of nurses can provide IBD patients with improved access to specialist care. There are several existing care models of integrated IBD-care at selected clinics worldwide, as outlined by Mikocka et al. (2012) and each of these includes access to allied health professionals, with significant roles for IBD-nurses and other IBD- specific providers as funding permits. ⁷

ii. Increased funding for allied health

The Australian IBD Audit 2016 makes the recommendation that “hospitals should be funded, and should make funding internally available, to provide the resources required to deliver IBD services according to the Australian IBD Standards 2016.” ⁹

Increasing IBD patient access to allied health professionals will require secure, long-term financial backing. ⁷ The Grattan Institute report calls for reforming the current fee-for-service funding and developing new funding, payment and organisational arrangements for integrated care for chronic diseases. ³⁵

Future studies will need to establish the feasibility and costs of increasing access to allied health services for IBD patients, and to identify other benefits for outcomes for patient care and the health system. ⁷

Though costly to implement, increasing the number of Medicare funded visits for allied healthcare providers has been suggested, especially through enhanced care plans. No studies were found in the literature on this subject.

The following table lists the search term/s, database and number of results used in this section (**Table 4**).

Table 4

Search term/s	Database	Results
'IBD' and 'IBD multidisciplinary allied health care hospital	PubMed	0
'IBD' and 'IBD multidisciplinary allied''	PubMed	0
'IBD multidisciplinary hospital'	PubMed	108
'credentialing allied health' and 'IBD'	PubMed	0
'MBS allied health' 'IBD'	PubMed	0
'Greater access to allied' and 'IBD'	Google Scholar	1,800
'credentialing allied health' and 'IBD'	Google Scholar	62
'MBS allied health' and 'IBD'	Google Scholar	23

5. Funding of therapeutic drug monitoring including faecal calprotectin testing

Executive summary

- Recent advancements in IBD treatments include biologic and molecular therapies.
- Though research has shown the clinical and economic utility of faecal calprotectin testing in diagnosis and treatment of IBD, it was recently rejected for proposed Medicare funding in August 2018.
- Therapeutic drug monitoring is increasingly being used to assist in guiding dosing in Australia for anti-TNF and thiopurine therapies with limited evidence for cost-effectiveness to date.
- For further economic analyses, several variables need to be determined, including the prevalence of IBD in the presenting population and the sensitivities, specificities and the costs of each test.

In the past few decades, the advancements in understanding the pathophysiology of IBD have been translated into newer, more effective therapies, biologic and molecular therapies. These technological advancements have dramatically improved IBD treatment and management; they have decreased the occurrence of flares, led to remission in more patients, and improved patients' quality of life.⁴²

The use of inflammatory biomarkers (e.g. faecal calprotectin) and therapeutic drug monitoring (e.g. for thiopurines and biologics) are two examples of such advances. IBD diagnosis and subsequent disease treatment is based on a clinical assessment involving physical examination, patient history, testing (blood and stool) and endoscopy, biopsies and imaging studies.¹⁰ Testing of biomarkers aids in disease diagnosis, assessment and management. The debate for funding therapeutic drug monitoring, including faecal calprotectin testing, requires an analysis of economic benefit in conjunction with clinical effectiveness.

Diagnosis of IBD

There is no single test that confirms IBD.¹⁰ Many intestinal disorders have similar symptoms. The requirement for multiple tests on multiple occasions to identify IBD can delay its diagnosis, particularly where disease is mild.¹⁰

Irritable bowel disease (IBS) and IBD have many symptoms and clinical signs in common and is the most likely differential diagnosis that requires exclusion when considering IBD in the primary care setting. IBS is approximately 50 times more common than IBD in the Australian population (affecting 10-15% of the population compared to a 0.3% prevalence for IBD).¹⁰

Distinguishing between IBS and IBD is critical, as there are great differences between the diseases and in their ensuing management.⁴³ Faecal calprotectin, a protein released by the white blood cells (neutrophils) of inflamed bowel in IBD is a sensitive marker of intestinal inflammation. IBS does not produce the inflammation that characterises IBD.

In recent years, faecal calprotectin testing has been shown to be an accurate discriminator between IBD and IBS, and can preclude more invasive and expensive tests such as colonoscopy and endoscopy, especially where there are no alarm symptoms, and in younger, low risk patients.¹⁰ Research has shown that at a cut-off concentration of 50 mg/g, the negative predictive value of faecal calprotectin for inflammatory bowel disease can be as high as 98%.⁴⁴

Faecal calprotectin testing offers a simple, non-invasive, and relatively cheap screening test that can predict inflammation and act as a proxy for IBD with high accuracy and precision. It is stable in faeces and can be measured by laboratory tests, and more recently by “point of care tests”. Additionally, these qualities potentially allow for stool sample collection at home and potential delays in transport to the laboratory. Faecal calprotectin is the most widely used neutrophil derived protein biomarker in Australia and worldwide.¹⁰

Several studies have analysed the clinical and economic effects of using faecal calprotectin testing in primary and specialist practice. Economic effects are determined by assuming several variables, including the prevalence of IBD in the presenting population and the sensitivities, specificities and the costs of the tests. Economic analyses also need to include the additional costs of incorrect treatment among identified false negatives.

Evidence base for faecal calprotectin testing

In the primary care setting where the prevalence of IBD is low (absolutely or compared with IBS), the emphasis is on “ruling out” or lowering the probability of the IBD diagnosis to provide reassurance or to adopt a “watchful waiting” strategy for the GP. In these instances, tests with a low negative likelihood ratio are preferred and guidance for GPs to prevent inappropriate use is important to maintain its utility.⁴⁵

The emphasis in tertiary care is usually on “ruling in” or increasing the probability

of IBD to establish a firm diagnosis; and start appropriate treatment. ⁴⁵ In this case, faecal calprotectin can guide the need for more expensive, time consuming, and invasive procedures. Therefore a diagnostic test with a high positive likelihood ratio is preferred. ⁴⁵

In a specialist care setting, faecal calprotectin levels can contribute important information and guide patient management and has also been shown to be effective in: ¹⁰

- Monitoring IBD patients on therapy by determining whether there is current disease activity, risk of relapse and response to current treatment type; and
- Monitoring IBD course as a surrogate, non-invasive marker of mucosal healing, or for post-operative recurrence where colonoscopy is not practical (due to access, cost or patient reluctance/ refusal).

However GESA guidelines state that faecal calprotectin alone should not replace clinical assessment of patients with IBD, but should be integrated into the assessment tools used by gastroenterologists. ¹⁰

Research has shown that faecal calprotectin testing is clinically effective for identifying gut inflammation and thereby differentiating between IBS and IBD cases in the primary care setting. A 2010 meta-analysis of faecal calprotectin testing studies published up to 2009, mostly predating the time period of literature included in this literature review, included 6 studies in adults and 7 in children and teenagers that were selected for their methodological robustness. ⁴⁵ The study concluded faecal calprotectin to be a useful screening tool for identifying those patients who are most likely to need endoscopy for IBD.

A later systematic literature review and meta-analysis assessed the clinical and economic value of faecal calprotectin testing for distinguishing between IBS and IBD analysed data from twenty-eight studies published up to 2013 (7 for adult cohorts and 8 for paediatric cohorts). ⁴³ The inclusion criteria restricted studies to those which contained data prior to IBD confirmation by direct endoscopic evaluation. It found that faecal calprotectin testing in primary care could reduce the need for referral and invasive and expensive colonoscopies, although noted that there are trade-offs between sensitivity and specificity, with some false positives (IBS with positive calprotectin) if a low calprotectin cut off was used. ⁴³

Of the three studies included in the review, the economic benefit from introducing faecal calprotectin testing varied according to the assumed variables in the model, but each showed a cost effectiveness. Authors mentioned that a reduction in colonoscopy for distinguishing between IBD and functional conditions would help reduce waiting list pressures for colonoscopy for other indications, such as colorectal cancer screening. ⁴³

A subsequent study by Yang et al. (2014) evaluated the cost-effectiveness of using faecal calprotectin testing to identify adults and children who require endoscopic confirmation of IBD.⁴⁶ The study aimed to provide quantitative parameters to guide health policy recommendations on the optimal use of faecal calprotectin testing. The study showed that in adults, faecal calprotectin screening saved \$417/patient but delayed diagnosis for 2.2/32 patients with IBD, among 100 screened patients. In children, faecal calprotectin screening saved \$300/patient but delayed diagnosis for 4.8/61 patients with IBD, among 100 screened patients. Authors noted that the major contributor to the cost-effectiveness shown in the study was the significant specificity differences in testing cut-offs for adults and children.⁴⁶

Medical Services Advisory Committee economic analysis

In August 2018, the Medical Services Advisory Committee (MSAC), an independent non-statutory committee that appraises new medical services proposed for public funding, rejected the appeal for Medicare funding of faecal calprotectin testing for the following:^{47, 48}

- Differential diagnosis of IBS from IBD in the adult population.
- Differential diagnosis of IBD from non-IBD in the paediatric population; and
- Monitoring disease activity in patients with known IBD.

The application proposed two Medicare items for differential diagnosis between IBD and functional bowel disease, and two MBS items for monitoring IBD activity, allowing for laboratory-based testing (Category 6 – Pathology) and POCT (Category 2 – Diagnostic).

Economic modeling predicted that introducing faecal calprotectin testing would cost \$17.8 million in 2017-18 and be partly offset by savings of \$9.2 million due to a decrease in demand for other procedures. The overall economic impact on Medicare would be an increase in spending of \$8.6 million in 2017-18. The proposed fee for faecal calprotectin testing was \$80, for which the MSAC considered that the proposed fee for FC testing (\$80) required justification, with an estimated total cost of \$102 million for differential diagnosis and monitoring.⁴⁷

Although MSAC acknowledged that there was a clinical need for a diagnostic testing to differentiate IBD from IBS and avoid more invasive and expensive investigations such as colonoscopies, the committee ruled that the submission lacked evidence for cost-effectiveness in low prevalence settings.⁴⁷

MSAC noted that all of the included studies were undertaken in secondary settings among selected populations with a high prevalence of IBD (ranging

from 20% to 69% in studies of adults and 36% to 80% in studies of children). It concluded that this performance could not be extrapolated to the primary care setting of the MBS where the expected proportion of false positive test results would be greater due to lower disease prevalence and that none of the included studies evaluated test performance in a general practitioner setting.⁴⁷

The committee also recommended that GESA and the RACGP be approached regarding the development of guidelines for faecal calprotectin testing.

Therapeutic drug monitoring

The advancements in understanding the pathophysiology of IBD have been translated into newer, more effective therapies, biologic and molecular therapies. Biological drugs (biologics) are large proteins, often monoclonal antibodies, which bind to a target molecule. Anti-tumour necrosis factor (TNF) agents, including infliximab and adalimumab, were the first biological agents effective in inducing and maintaining IBD remission.⁴⁹ Subsequently, other biologics have been developed.

Biologics have revolutionised IBD treatment in recent years, however this has come with increased pharmaceutical costs on the Australian healthcare system. In the USA, the top six biologic agents account for 43% of the outpatient Medicare drug budget.¹⁰ Biologic drug treatment is expensive and typically required for the patient's lifetime. In addition, there are limited biological drug choices for IBD treatment.⁴⁹ Furthermore, the goals of IBD therapy have evolved from symptom control to include mucosal healing (assessed either endoscopically or non-invasively with faecal calprotectin and/or intestinal ultrasound) and as result there are greater opportunities to maximise outcomes, optimise drug classes and minimise adverse outcomes and/or treatment failures.¹⁰ Therefore, biologics need to be used in a high quality, cost effective manner.¹⁰

Primary non-responsiveness and secondary loss-of-response are common in IBD patients, with resulting adverse outcomes.⁴⁹ Inappropriate use of biological agents to treat IBD leads to increased healthcare cost burden, toxicity risk and delay rescue strategies. Therapeutic drug monitoring can guide therapeutic decisions at the diagnosis and during the course of the disease.

Therapeutic drug monitoring is increasingly being used to assist in guiding dosing in Australia and worldwide for anti-TNF and thiopurine therapy in particular, to guide switching or dose changes and allow these decisions to be made in a timely manner, thus optimising IBD treatment and maximising the benefits from these drugs.¹⁰ This strategy is especially appropriate in IBD, a life-long disease affecting a young demographic with a limited choice of approved biological agents for treatment.

Thiopurine metabolite testing

Thiopurines are established and effective IBD therapies. Drug toxicity and lack of efficacy are significant problems with the use of these therapies, and as a result, thiopurine metabolite testing is important in guiding treatment.

Studies have shown that up to 50% of patients do not respond to standard weight-based thiopurine dosing.^{10, 50} As well as identifying non-responding patients, thiopurine monitoring can detect non-adherence, a particular problem in adolescent patients.⁵⁰ However, at present, uniform thresholds for clinically relevant antibody titres are lacking, and the evidence to clarify optimal management or cost effectiveness is lacking.⁵¹

Anti-TNF testing

Therapeutic drug monitoring for tumor necrosis factor antagonists, (anti-TNF) agents involves measurement of drug levels and anti-drug antibodies and can be reactive (performed in patients failing treatment in order to guide decision-making) or proactive (performed in responding patients to optimise therapy and potentially prevent future flare and loss-of-response.)⁴⁹

A committee of twenty five Australian and international experts conducted a systematic literature search and composed an evidence-based consensus statements for therapeutic drug monitoring -guided anti-TNF therapy, especially in situations of treatment failure.⁴⁹ Following a systematic literature review, and an assessment of the level of evidence and grade of recommendation according to the Australian National Health and Medical Research Council (NHMRC) guidelines, statements with 80% agreement without reservation or with minor reservation were accepted as consensus.

The committee recommended that therapeutic drug monitoring of anti-TNF agents is 'an important component of personalised IBD therapy' and should be used upon treatment failure, following successful treatment induction, and when contemplating a drug holiday. The consensus statements noted that there is inconsistent evidence for proactive therapeutic drug monitoring, and recommended that it be used for patients in stable remission only if results are expected to impact clinical management.

The committee noted the limitations of evidence around the required therapeutic range, lack of longitudinal intervention studies on therapeutic drug monitoring of biological agents in different disease phenotypes, and sparse data on biological agents beside infliximab and adalimumab. With emerging evidence, particularly regarding TDM of other biological agents, these guidelines would need to be revised.⁴⁹

In Australia, there is no access to dose intensification of biologics via the PBS and extra doses are either funded by health providers, self-funding patients or via application for compassionate access doses from pharmaceutical companies.¹⁰ There is emerging evidence that there is potential for the costs of therapeutic drug monitoring guided dose increases to be offset by dose decreases in some patients. This is likely to become standard practice in time.¹⁰

A randomised controlled study, the Trough Concentration Adapted Infliximab Treatment (TAXIT) study (n = 263) demonstrated such cost savings using therapeutic drug monitoring.⁵² The TAXIT study compared the efficacy and cost-effectiveness of concentration-based dosing to clinically based dosing of infliximab in a cohort of IBD responder patients treated with infliximab maintenance therapy. Results showed that targeting concentrations to a set point (7 mg/mL) allowed a safe reduction of the dose, resulting in substantial drug cost savings.⁵² Unfortunately, the evidence from the TAXIT study was considered very low quality.⁵¹

The following table lists the search term/s, database and number of results used in this section (**Table 5**).

Table 5

Search term/s	Database	Results
'IBD' and 'funding for faecal calprotectin'	PubMed	3
'IBD' and 'funding for faecal calprotectin'	Google Scholar	6,220
'IBD' and 'funding for faecal calprotectin'	Cochrane Reviews	8
'IBD' and 'funding for therapeutic drug monitoring'	PubMed	14
'IBD' and 'funding for therapeutic drug monitoring'	Google Scholar	17,900
'IBD' and 'funding for therapeutic drug monitoring'	Cochrane Reviews	31

6. Establish clearer GP referral guidelines and protocols

Executive summary

- Specialist gastroenterologist care is essential in IBD, however the role of the GP collaboration in IBD management is also very important.
- Data suggests that primary care physician's IBD knowledge and comfort in IBD management is suboptimal.
- There is limited but emerging evidence to identify the barriers to clear and effective GP referral pathways. These include: difficulty in disease diagnosis, lack of clear treatment guidelines and action plans, limited GP adherence to guidelines and poor referral quality.
- It is important to give GPs the tools to provide better IBD care given that primary care can provide a more economically efficient service with rapid access, an ability to address other healthcare issues during standard review and is typically geographically closer location to patients than specialists.

Clinicians who care for IBD patients recognise that this population requires specialised and personalised care.⁵³ Rates of new cases of IBD are increasing world-wide, and concurrent technological and pharmaceutical advancements are being made, resulting in more medical and surgical treatment options. These factors, as well as high patient healthcare costs, all add up to more and better patient care being required.⁵⁴

This requires increasingly complex health care systems. Australian IBD Standards 2016 state that IBD care, like other complex, chronic diseases, requires increasingly complex multi-disciplinary health care systems with timely and reliable communication, and collaboration between specialists, generalists and primary health care physicians.^{8, 7}

Multidisciplinary care is widely accepted as best practice in IBD care. However, to date, this approach for IBD care has remained challenging, with evidence showing that Australia patients often experience variable and insufficient patient care.⁹ The Australian IBD Audit 2016 identified that only one site had a full IBD team as defined in the Interim Australian IBD Standards 2015; 24% had a

Partial IBD Service as described above, and 39%, an IBD nurse.⁹

Australian IBD primary care landscape

In Australia, primary care is not only the foundation of healthcare in our community, but also the pathway to specialist services.³⁵ Specialist gastroenterologist care is essential in IBD,¹⁰ however much IBD care could and probably should be delivered in primary care with continued collaboration between all stakeholders.⁵⁴ Gastroenterologist consultation requires referral from a GP and healthcare professionals based in secondary or tertiary centres in metropolitan and regional cities provide the majority of IBD care.⁸

Given that a chronic care model achieves better outcomes for patients, GPs are ideally placed to monitor the treatment plan once it is in place as they are often the first point of care for disease management.¹⁰ There is huge scope for GPs to address health issues in IBD care including:

- Monitoring/treating IBD related complications.
- Medication compliance.
- Iron and other nutritional deficiencies.
- Preventative medicine, osteoporosis checks, pap smears, vaccinations, quitting smoking, skin checks (e.g. associated non-melanoma skin cancer risk with thiopurine use).
- Addressing psychological health.
- Sexual and reproductive health.
- Prompt recognition of IBD relapse and/or acute severe ulcerative colitis.
- Management of non-IBD disease.

The Australian IBD Standards 2016 describe effective hub-and-spoke structures to enable rapid, preferably local, access to specialised services, though they may be geographically separated from the local care. This can be achieved through protocol-based shared care by GPs.⁸ Smaller and regional centres may not have these services, thus communication and referral pathways are particularly important and should be established with appropriate centres.⁸

Recommendation 6 of the IBD Standards 2016 states that hospitals with low IBD admission rates should “review their systems to ensure that people presenting with IBD receive the breadth and quality of services described in the Australian IBD Standards 2016 on site or via clear referral and support pathways.”

The implementation of shared care is critical for patient care. Arrangements for shared care and the circumstances in which the patient should be referred for hospital care, must be defined between the IBD team and the GP; explained to

the patient, supplemented with written information, using clear and appropriate language. ⁸

GP specialist referral

The Australian IBD Standards 2016 are consistent with the UK National Institute for Health and Clinical Excellence (NICE) quality statement, which were originally established in 1999 as the National Institute for Clinical Excellence, a special health authority to reduce variation in the availability and quality of National Health Service (NHS) treatments and care. One of the four NICE quality statements states that: “People with suspected IBD have a specialist assessment within 4 weeks of referral.” ⁵⁵

The Australian IBD Standards 2016 states that to enable high quality patient care, rapid access to specialist advice is required when needed. “Protocols and pathways need to be agreed locally to ensure prompt referral and investigation of patients who are suspected of having IBD”. ⁸ Standard A4 of the Australian IBD Standards 2016 states that

- GPs should be prepared to periodically review their diagnosis in patients with unresponsive, atypical or troublesome abdominal symptoms.
- A communication pathway must be agreed for referral of possible IBD patients for rapid assessment. Such patients should be contacted within two weeks of referral and seen within four weeks, or more rapidly if clinically necessary (in line with NICE).
- Newly diagnosed patients for whom surgery is not an immediate consideration should be assessed by a medical gastroenterology team.
- Management of all new diagnoses should adhere to contemporary clinical guidelines and should be reviewed by the multidisciplinary team.

Yet, access to specialists is often limited and long specialist waiting lists are frustrating. ¹⁰ The Australian IBD Audit data revealed that 86% of participating sites saw urgent referrals within 4 weeks (94% vs 86% for those with and without a Partial IBD Service). ⁹ Urgent referral pathways between general practitioners (GPs) and outpatient clinics were less common, only occurring around half of the time (52%). ⁹ It is well known that failure to access rapid specialist assessment and treatment of acutely unwell patients can result in adverse outcomes. ⁹

Barriers for GP referral best practice

i. Difficulty in IBD diagnosis

Identifying IBD in undiagnosed patients presenting to GPs describing new bowel symptoms can be difficult to diagnose.⁵⁶ There is no single definitive test that can reliably diagnose all cases of IBD, therefore many people require a number of tests, which may delay diagnosis, particularly where disease is mild.⁵⁶

In suspected IBD, tests are aimed at differentiating IBD from infectious gastroenteritis, IBS and coeliac disease; such investigations also help in defining disease activity and severity, to determine the need for urgent referral.¹⁰

Mowat et al. (2016) describes the issue of the absence of any reliable predictor of pathology, resulting in patients having to be referred to secondary care for investigation, the vast majority of which undergo invasive investigations yet the yield of pathology is low.⁵⁶ New means of assessing patients in primary care would help GPs determine which patients need rapid investigation and, in turn, ease pressure on secondary care services.

ii. Lack of clear GP guidelines

Treatment guidelines and clinical pathways have been constructed by several groups, including the Gastroenterological Society of Australia (GESA)¹⁰ and the European Crohn's and Colitis Organisation (ECCO)^{57, 58} however these guidelines are detailed and complex and are intended to support specialists.⁵⁴ Whilst existing guidelines are helpful for GPs, they are therefore not designed for the primary care setting,⁵⁴ and this is exacerbated by the fact that most GPs providing primary care for IBD patients have very few patients, averaging between 2 and 10 in their caseload.⁵⁹ This is problematic, as the proportion of patients with IBD-related healthcare issues cared for in the primary care setting appears to be widespread, and will likely become more so as the disease incidence increases.⁵⁴ Good primary care is particularly important for patients with mild disease.

The Australian IBD Standards 2016 state that "the development of GP guidelines will assist the identification and referral of symptomatic patients in whom IBD is suspected", that period review by GPs should occur in patients with unresponsive, atypical or troublesome abdominal symptoms, and that all referring GPs should receive regular written information about each patient's progress and changes in management.⁸

Yet, data suggest that general practitioner's IBD knowledge and comfort in IBD management is suboptimal, and expecting them to adopt detailed guidelines that are specialist-aimed, such as the ECCO ones, is unrealistic.^{54,59} A study by Tan et al. (2011) of 1800 South Australian GPs found that 37% were generally 'uncomfortable' with IBD management of their patients. Participating GPs

reported being quite uncomfortable with newer IBD therapies, immunomodulators or biological; only 9% and 5% respectively reported some positive level of comfort in their use.⁵⁹

Bennet et al. (2014) conducted a systematic literature review to investigate what IBD assessment and management tools are published for non-gastroenterologists in readily searchable published medical literature, and found almost none.⁵⁴ This greatly contrasted to the situation for other chronic disorders such as asthma and diabetes, also with high prevalence rates, where such tools were readily found and action plans are also easily discovered. There is also good evidence for the usefulness of these tools in other chronic diseases.⁵⁴

This study showed that there are little non-expert management tools or guidelines that exist for IBD and scant data has been published regarding the usefulness of such tools including IBD action plans and associated supportive literature. Bennett concluded that primary care physicians are already managing a substantial proportion of the IBD caseload, (although only a few patients each), without tools to help them.⁵⁴

Given that primary care can provide a more economically efficient service and typically closer location to patients than specialists, with reduced fees and an ability to address other healthcare issues during standard review, it is important to give GPs the tools to provide better IBD care. Authors hypothesised that if GPs were supported by clinical tools, including clear referral guidelines, better IBD management would likely be possible, resulting in better patient outcomes and reduced healthcare costs.⁵⁴

iii. GP adherence to guidelines

It has previously been reported that there are a variety of barriers that prevent GP adherence to guidelines, which include lack of awareness, a lack of familiarity, the inertia of previous practice, and external barriers.⁶⁰ Though not IBD specific, and published in 1999, it is possible that these factors may be relevant in IBD management today, in light of data from Tan et al. (2011) as described above.⁶⁰

Jackson et al. (2017) conducted a study to investigate clinicians' adherence to international ECCO IBD guidelines for therapeutic treatment and chronic disease management of IBD care.⁶¹ Retrospective data was collected from patients attending a tertiary Australian hospital IBD clinic over a 12-month period (n = 288) between 2014 and 2015. Results showed a gap between adherence to international guidelines and clinical practice. Overall adherence to disease management guidelines only occurred in 204/288 (71%) of patient encounters.

This study demonstrated that despite the availability of guidelines, there is a

widespread variation in clinical practice and a lack of adherence to clinical guidelines for IBD which is likely to impact on the delivery of quality care for patients with IBD, especially in 5-ASA drug treatment, psychological care and preventative care. Results showed that assessment of psychological wellbeing, a quality indicator, was undertaken in only 16/288 (6%) of patients. The under-delivery of preventative has potentially serious health outcomes. A minority of patients received adequate bone health reviews, vaccinations, skin cancer surveillance and pap smears whilst on thiopurines. Only a quarter of IBD patients in our cohort who had previously used corticosteroids underwent a bone health review.⁶¹ Low skin cancer surveillance was also demonstrated, despite the increased risk among thiopurine-treated patients with IBD, especially in high-incidence countries such as Australia.⁶¹

Authors noted that external clinical evidence does not replace individual clinical expertise that forms the 'art of medicine' and contributes to clinical decision-making but conclude that standardising practice using evidence-based clinical pathways may be a strategy towards improving the quality of IBD outpatient management.⁶¹

iv. Poor referral quality

An effective referral pathway relies on good and agreed communication for referral of possible IBD patients for rapid assessment. Such patients should be contacted within 2 weeks of referral and seen within 4 weeks, or more rapidly if clinically necessary.⁸ Urgent referral to a gastroenterologist and possible hospitalisation can be made without laboratory testing and should not be delayed while waiting for test results.¹⁰

To receive timely care, referrals must include a high quantity/quality of information. Canada, like Australia, requires GP referral to an IBD specialist. Data from the study of the 1800 South Australian GPs found that 12% sometimes referred to a specialist; 34% often referred to a specialist; and 55% always referred to a specialist.⁵⁹

Mathias et al. are conducting an ongoing retrospective cohort study of patients referred for appointments in the Nova Scotia, Canada, IBD program between August 2016 – 2017.⁶² Emerging data (as yet unpublished research) of 150 reviewed to date have shown that the majority of referrals are low quality and have longer average wait times. Of the 150 referrals, 9 were high quality referrals (6.0%), 32 moderate (21.0%) and 109 low quality referrals (72.7%). The majority of referrals were from family doctors (49.3%) with 81.1% of those being low quality.

These results were significant because patients with low quality referrals had a mean wait time of 48.0 days until triage and a mean wait time of 29.9 weeks to be seen by a gastroenterologist, whereas patients with moderate-high quality

referrals had a mean wait time of 16.6 days for triage and a mean of 16.7 weeks to be seen by a gastroenterologist. Given the unpredictable nature of IBD and potential to rapidly deteriorate, these differences in wait times are significant. Prolonged wait time is concerning given its documented impact on patient satisfaction, quality of life and administrative resources.⁶² In mild disease, the delay is usually not overly harmful, however more severe cases usually present more obviously and delays should be minimal.¹⁰

Further analysis will focus on whether there are significant differences in patient outcomes between the qualities of referrals, and identifying the factors that inform referral quality. Authors suggest that higher levels of referrer education, as well as patient awareness and advocacy are needed.

The following table lists the search term/s, database and number of results used in this section (**Table 6**).

Table 6

Search term/s	Database	Results
'IBD' and 'GP referral	PubMed	5
'IBD' and 'GP referral guideline	PubMed	8
'IBD' and 'administrative support'	Cochrane	1
'IBD' and 'GP referral guideline	Google scholar	1,810

7. Improved consumer knowledge

Executive summary

- It is assumed that patients who are well informed about their IBD and its treatment are more likely to achieve a better quality of life.
- This is particularly important as IBD patients self-manage.
- Several published IBD patient education interventions have consistently demonstrated improved consumer knowledge, but no change in quality of life indicators or significant improvements in psychosocial outcomes, however many of these studies have had significant methodological issues.
- It has been argued that a stronger focus on improving self-management knowledge might be more effective than purely educational programs.

Consumer knowledge is important in any complex, chronic disease when patient involvement is important. Limited health literacy is a barrier to optimum medical care and can lead to poor adherence and increased complications and health care costs. Disease-specific knowledge can positively influence the acceptance of a disease, increase treatment compliance and improve quality of life.

It is assumed that providing patients with health education about their condition, both how to cope with it and how to manage it, will lead to changes in health behaviours that will in turn improve health (and other) outcomes. Educational interventions in other chronic diseases have successfully been shown to improve consumer knowledge, psychosocial parameters, medication adherence and quality of life, ⁶³ for example improved quality of life (reduced hospitalizations and a reduction in missed school/ work days) (asthma). ⁶⁴

Like most chronic diseases, IBD patients perform self-management- they undertake most of their care themselves, away from healthcare settings. ⁶⁵ For this reason, disease-specific knowledge is critical.

It is assumed that patients who are well informed about their IBD and its treatment have a greater chance of achieving a better quality of life, as such knowledge allows them to adapt to the physical, social and psychological effects of their illness. In theory, better-educated patients should be more likely to manage their disease appropriately, for example by attending colonoscopies or adhering to medication protocols.

There is a wealth of available information for consumers from patient groups, such as Crohn's & Colitis Australia, books and the Internet. However, it is well known that IBD patients have knowledge deficits and desire more information about IBD. ⁶³ Little literature exists regarding what patients with IBD understand of their illness. ⁶⁶ Moreover, relative to chronic diseases such as asthma, diabetes, and heart disease, there is less literature on the self-management of IBD. ⁶⁵

It is therefore necessary to assess and target patient's knowledge gaps in order to develop educational interventions, and evaluate the impact of these interventions in quality of life and other outcomes on IBD patients.

Australian IBD patient education guidelines

The Australian IBD Standards highlight the importance of patient education and support and include the recommendation for patient education. IBD Standard 2016, Standard D: Patient education and support states: "IBD care should empower patients to understand their condition and its management in order to achieve the best possible quality of life." ⁸

Standard D1: Provision on information:

- Patients should be offered relevant information about their care and treatment options at all stages of their illness, delivered by an identified member of the IBD care team.
- Information should be appropriate to the age, understanding and communication needs of patients and their carers.
- Clear, written information about IBD should be provided in outpatient clinics, wards, endoscopy and day-care areas.
- Information should be available in languages other than English if required, and in a variety of formats including written, audiovisual and web-based, when appropriate.
- Informed consent should be obtained by a member of the team and written in clear, simple language. A member of the team should ensure patient understanding before signing.
- Patients being considered for surgery, especially pouch surgery or ileostomy, should be offered written, audiovisual or web-based information. Whenever possible, they should have an opportunity to talk with those who have had pouch surgery or a permanent ileostomy. They should also be provided with information about their postoperative care before discharge.
- Information should be provided to all inpatients about their follow-up

care before discharge from the ward.

Standard D2: Education for patients

Nominated members of the IBD service should provide educational opportunities for patients and their families including disease education, local healthcare system mechanisms, treatment options, information about nutrition, information about medicines and self-management strategies.

Australian IBD patient education provision data

According to the Australian IBD Audit, the provision of information material was variable across sites. Patient education sessions for newly diagnosed patients were available at 85% of sites with an IBD nurse and 5% at sites without.⁹

Patient education was provided across the following areas: IBD pregnancy and fertility information (77% with an IBD nurse; 46% without an IBD nurse), information material for newly diagnosed patients (96% with an IBD nurse; 64% without an IBD nurse) and information material on IBD treatments (96% with an IBD nurse; 51% without an IBD nurse).⁹

Evidence base for the IBD education and self management interventions

Several studies have been conducted to identify the effectiveness of IBD education and self-management programs. Knowledge about the effectiveness of patient education in IBD is limited, and inconsistent study methodologies make it difficult to compare data sets or draw conclusions.⁶⁷ This is largely due to heterogeneity of definitions of patient education and outcomes measures. Furthermore, understanding the characteristics of such interventions that lead to improved patient outcomes is not yet clear.

Thus far, IBD patient education interventions have consistently demonstrated improved patient knowledge, but failed to demonstrate positive effects on psychosocial outcomes.^{63, 68}

Barlow et al. (2010) examined the IBD self-management and educational intervention studies published from 1986 to 2007, which predates the time period of published research included in this literature review.⁶⁵ The authors noted that the patient education and self-management programs were heterogeneous in intervention and outcomes.

Authors also noted the methodological issues to be considered. Of the twenty-three studies included in the analysis, thirteen of these (57%) were randomised controlled trials; nine studies included sample sizes of greater than 100 participants; and six studies carried out power calculations to determine sample size.⁶⁵ Results showed that self-management interventions increased the

behaviours associated with managing the condition (e.g. following dietary advice and medication regimes) as well as improving clinical outcomes, symptoms, physical functioning, and emotional well being. The studies that measured disease-related knowledge consistently found that the provision of information increased knowledge.

However, in line with other research into chronic disease, education cannot be assumed to lead to improvements in health outcomes, and there is a need to establish the role of education in IBD. ⁶⁵ Barlow et al. (2010) concluded that there was “no clear evidence base on what patient self-management behaviours are effective for individuals with IBD” and noted that programs with a stronger focus on self-management skills might be more promising than purely educational programs. ⁶⁵

A Cochrane review by Timmer et al. (2011) assessed educational interventions in IBD and demonstrated that a very small effect on quality of life that was not statistically significant. ⁶⁹ The review assessed studies published from 1989 to 2010. Overall, twenty-one studies were included in the review, however authors noted that all studies were of low methodological quality. ⁶⁹ Non-randomised trials were included in the study and not all studies provided sufficient data for the different study questions. Ten of the studies were identified as being primarily educational, aiming to improve self-management by enhancing knowledge about the disease. Authors noted that most of the included educational programs had a strong or sole focus on providing medical information rather than psychological self-management skills, which may be more relevant. ⁶⁹

Timmer et al. (2011) noted that the two included paediatric studies demonstrated a significant positive short-term effect of psychotherapy in the adolescent subgroup. ⁶⁹ Authors concluded that conclusive results for the wider cohort could not be made due to the heterogeneity of trials and difficulties in retrieving exact data on relevant outcomes. Both reviews by Barlow et al. (2010) and Timmer et al. (2011) were unable to conduct data synthesis due to clinical heterogeneity of patients, interventions and settings. ^{65, 69}

Promising effects of six self-management IBD interventions conducted between 2001 and 2014 are summarised in a recent systematic review by Conley et al. (2016). ⁷⁰ All six studies were randomised controlled trials and the pooled total involved 1,815 participants. Three interventions revealed positive effects of self-management on either disease-specific or generic health related quality of life. Again, authors noted that generalized conclusions about symptoms could not be drawn due to the heterogeneity of the symptoms measured. ⁷⁰ Authors also noted that the term symptom was used interchangeably with both disease activity and generic health related quality of life, but that these should each be defined and ‘conceptually distinct’. ⁷⁰

Berding et al. (2016) conducted a prospective, randomized, waitlist-controlled

trial of a manualised education intervention program for IBD patients addressing medical and psychological issues in a German outpatient cohort (n = 181).⁶⁷ Though the study found significant large positive effects on knowledge, self-management skills and coping with IBD, no effects on health related quality of life or symptoms of anxiety or depression were observed.⁶⁷

Reusch et al. (2016) developed a group-based psychoeducational program that combined provision of both medical information and psychological self-management skills, delivered in an interactive manner, and evaluated it in a large, prospective, cluster-randomized trial in a German cohort (n = 540).⁶⁸ Results did not demonstrate the superior effectiveness of the program as compared to a control group. However, the study showed significant positive effects in both the intervention and control group, which authors suggested may have resulted from both groups receiving some psychosocial treatment as part of the usual rehabilitation program.⁶⁸

Quality of life sub-outcomes

Increasing consumer knowledge ultimately aims to improve patient health related quality of life. Most studies have measured this outcome accordingly. However, quality of life is an umbrella term for multiple sub-outcomes, and in IBD, psychological and nutritional outcomes are particularly relevant. Each of these is clinically relevant and a full literature review could, and should be conducted on each topic. A brief summary of the importance of the very important psychological, nutritional and medication adherence outcomes is given below.

i. Psychological outcomes

The presence of psychological comorbidities, specifically anxiety and depression, is well documented in IBD. The risk for anxiety and depression is consistent throughout IBD course and is independent of disease activity. Psychological comorbidities are known to affect patients' psychological wellbeing and contribute to reduced quality of life, poorer adherence to therapy, earlier relapse and more need for inpatient care.⁹

Yet mental health is often unaddressed in current models of care. Identifying patients who are at risk for psychological comorbidities may lead to early intervention and improve patient outcomes. Understanding available psychological treatments and establishing referral resources is an important part of the evolution of IBD patient care.

Data from the Australian IBD Audit showed that less than 5% of IBD sites had a mental health clinician in their IBD service, even though a psychological condition was the most frequently occurring comorbidity (25%); and mental

health care was often delivered by a social worker rather than a psychologist or psychiatrist.⁹

Thus far, education interventions have consistently demonstrated improved patient knowledge, but failed to demonstrate positive effects on psychosocial outcomes and quality of life.^{63, 68, 69}

ii. Nutritional outcomes

Malnutrition and nutritional deficiency is common in IBD. Identifying patients who are malnourished or at risk for malnutrition may lead to early intervention and improve patient outcomes. To date, little is known about the role of nutritional assessment and management in IBD care. However it is well known that nutritional intervention improves patients' quality of life and nutrition is an important component of IBD care.

Anaemia, which can be caused by iron deficiency, blood loss, inadequate nutrient intake or absorption and chronic inflammation, is a common IBD complication. Other potential nutritional deficits in IBD include albumin, B12, folate, zinc, magnesium and selenium.¹⁰ Malnutrition, nutrient deficiencies and dehydration are particularly relevant in severe disease, and dietitian involvement to manage these is vital.³⁷

A recent study conducted in a US cohort of patients (n = 567) reported that just 27% of participants rated their knowledge of nutrition in IBD as "very good."⁷¹ More than half of patients (59%) felt that nutrition was "very important" as an IBD management strategy, however only 36% of patients reported routinely talking with any healthcare provider about nutrition.⁷¹ Almost one-third of patients felt that their providers did not have time during their appointment to discuss nutrition and over 1 in 5 patients thought that their doctor had insufficient knowledge on their nutrition.⁷¹ Results also identified a lack of adequate IBD nutritional resources and significant gaps in knowledge in IBD nutrition (among both patients and doctors).⁷¹

This study showed that targeted educational initiatives, improved access to nutritional experts and the development of a standardised process for the nutritional screening for patients are warranted.

In response to the study, Crohn's and Colitis Foundation America (CCFA) launched a Healthy Nourishment in IBD Program within the framework of CCFA's innovative IBD Qorus™ (a quality of care initiative).⁷² CCFA is developing a Nutritional Care Pathway to provide educational tools for patients (and doctors and dietitians) to prevent and treat malnutrition and its related complications, and develop a set of validated tools to identify and assess patients for malnourishment.

iii. Medication adherence

Medication adherence is particularly important in complex, chronic disease. IBD patients require long-term medication usage to maintain remission. As summarized by Tiao et al. (2017), medication nonadherence is common in IBD patients (up to 45%) and is associated with disease deterioration, poorer clinical outcomes, increased healthcare usage and economic costs.⁷³

Medication nonadherence can be intentional or unintentional. Intentional nonadherence, the deliberate decision to stop maintenance medication is known to be driven by the patient's perception of the necessity of medications and/or concerns about their side effects. Modification of attitudes towards IBD medication adherence however, has not been tested and to date, interventions to improve patient education to increase adherence to IBD maintenance medication have not resulted in a successful and easily implementable solution.⁷³

The IBD Pharmacist Adherence Counselling (IPAC) intervention involved a single-personalized counseling session with nonadherent IBD patients conducted by a clinical IBD pharmacist. Tiao et al. (2017) conducted a multicenter prospective longitudinal parallel interventional study (n = 100).⁷³ The educational intervention focused on IBD medications to identify barriers and to develop strategies to address unintentional and intentional nonadherence. Results showed that 36% of baseline adherers suffered disease relapse as evidenced by the need for medical or surgical treatment escalation over a 24 month period compared to 28% of baseline nonadherers receiving IPAC intervention.⁷³ This was the first study of its kind to demonstrate that intentional nonadherence could be successfully addressed and was sustained for 24 months post intervention. As the intervention involved personalised counseling at baseline, it also demonstrated economic feasibility.⁷³

A recent study by Broekman et al. (2018) confirmed previous findings of nonadherence and showed that IBD patients who perceived a low necessity or high concerns for their IBD treatment using thiopurine were more likely to discontinue treatment prematurely (n = 576).⁷⁴ Authors suggested that targeting these patients with extra attention and information might prevent premature discontinuation.

Both Tiao et al. (2017) and Broekman et al. (2018) noted that there are significant discrepancies between self-reported adherence and objective assays and that evaluation of treatment adherence is a challenge for research.^{73, 74} Authors noted that this is particularly important since nonadherence to thiopurines might "seduce the attending physician to an unjustified switch to expensive biologic drugs" in an effort to control disease, thereby increasing costs on the healthcare system.⁷⁴

Necessary components to increase consumer knowledge

Prior to understanding ways to increase disease-specific knowledge, it is relevant to understand the literacy level and knowledge gap of each patient. Appropriate targeting of interventions is important, as well as the selection of outcomes to measure the objectives of the intervention. ⁶⁵

Innovative education programs that are flexible and accessible to those with IBD need to be developed. Further, programs should include a component of ongoing education. ⁶⁶ Technology such as the Internet, smartphone and computer-based education may provide an effective means of facilitating ongoing education and overcoming the known barriers to access (time, geographic isolation, illness and transportation).

It is known that educational tools improve patients' understanding of IBD, but the real question is how to translate increased knowledge into improved disease outcomes and quality of life. ⁶⁶

Comparison with asthma patient knowledge and self-management, a similarly complex, chronic illness, is informative. Research has shown that asthma self-management results in clinically important improvements in asthma health outcomes, where the interventions involve a written action plan, self-monitoring and regular medical review. ⁶⁴ These interventions result in improved quality of life. Less intensive interventions, particularly those without a written action plan were shown to be less efficacious. Hopefully these clues will inform future research for IBD self-management and improve patients' quality of life.

The following table lists the search term/s, database and number of results used in this section (**Table 7**).

Table 7

Search term/s	Database	Results
'IBD' and 'consumer knowledge'	PubMed	1
'IBD' and 'patient knowledge'	PubMed	541
'IBD' and 'consumer knowledge'	Cochrane Trials	1
'IBD' and 'patient knowledge'	PubMed	541
'IBD' and 'patient knowledge'	Cochrane Trials	53
'IBD' and 'patient knowledge'	Cochrane Review	3

8. Support for practice management software (IBD specific auditable clinical management software)

Executive summary

- The Australian IBD Standards 2016 highlight the importance of accessible and accurate patient data and good information technology systems.
- For high quality care, IBD patients require an electronic health record to provide specialists with rapid access to accurate medical records and for regularly ongoing monitoring and the provision of surveillance tests, medication and other information.
- The Australia and New Zealand Inflammatory Bowel Disease Consortium (ANZIBDC) has recently developed “Crohn’s Colitis Care” (CCCare), an integrated, national, cloud-based, evidence-based, IBD-specific clinical management system capturing real-time clinical data in routine care in Australia (and New Zealand).
- Early usability and feasibility results (unpublished as of September 2018) show that it is usable, secure and ready for clinical rollout later in the year.

The chronic nature of IBD means that long-term management is of utmost importance. Management can vary depending on the state of the disease. When patients are symptomatic, specialists require rapid access to accurate patient data, and regular monitoring is important to optimise therapy and ensure adequate response. When patients are asymptomatic, less regular monitoring is needed to ensure sustained remission and control of inflammation beyond symptoms.

Australian evidence base

The Australian IBD Standards 2016 highlight the importance of accessible and accurate data, information technology and audit. Australian IBD Standards 2016, Standard E1 - Register of patients under the care of the IBD service states that: “IBD services should implement an electronic clinical management system that records patients’ disease histories and treatments.”⁸

This is important for many reasons, including: ⁸

- For responsive, safer patient care, greater patient understanding of their condition to enable efficient, cost-effective high quality, patient-centred care.
- To demonstrate patient outcomes and hospital services to assist hospital management of IBD patients.
- To facilitate continuous, high- quality prospective audit of all aspects of clinical care focused on patient outcomes.
- To be a resource from which to conduct research.

The Australian IBD Audit data showed that 82% of sites with a Partial IBD Service had a searchable database of IBD patients, and 25% of sites without an IBD service had a searchable database of IBD patients. ⁹ Only sites with a searchable database are equipped to undertake regular and reliable self-audit and practice review. ⁹

Evidence base need for IBD clinical management software

The recent Australian IBD Audit highlighted several key issues including inadequate and inconsistent care, poor documentation and high healthcare utilisation and costs. ⁹ For high quality care, IBD patients require rapid access to specialist treatment, which requires rapid access to accurate medical records. Patients also require an electronic health record to regularly monitor and provide surveillance for tests, medication and other information.

Electronic health records, rather than site-based records, are particularly important for the IBD patient cohort as there is a large demographic of young people, who are often mobile. Currently there is no IBD-specific multisite management tool to support safe, consistent, evidence-based IBD care in Australia and New Zealand. There is clear need for an integrated, national, evidence-based, IBD-specific clinical management system capturing real-time clinical data in routine care in Australia (and New Zealand).

To address this, the Australia and New Zealand Inflammatory Bowel Disease Consortium (ANZIBDC) has recently developed a comprehensive cloud based IBD clinical care management system entitled “Crohn’s Colitis Care” (CCCare). ^{75, 76, 77} The ANZIBDC is made up of 14 centres across Australia and New Zealand, providing care for ~20,000 IBD patients.

i. CCCare development

Clinical guidelines, standards of care and usual practice across the 14 sites informed CCCare development. The software captures symptoms, imaging, endoscopy, blood results, medications in standardised fields along with clinic

letters and other correspondence in a single IBD-specific medical record.

Safety monitoring, disease management plans, patient reminders, patient portal and summary reports are also available. De-identified longitudinal data is stored separately in a clinical quality registry.

CCCare consists of:

- Clinical module- to support routine patient care.
- Research module- to provide structured, longitudinal real-time data for further analysis.
- Patient portal- to capture patients reported outcomes.

ii. Beta testing results

CCCare was tested for feasibility and usability in two large ANZIBDC sites, the Royal Adelaide and Royal Brisbane Hospitals. Results from 13 users [clinicians (n=3), nurses, administrative staff and patients] showed a mean SUS (usability) score of 75 (50 – 95). SUS broadly classifies usability of a system from poor (< 70) to superior (> 90). The “Usability” and “Learnability” sub-scores were 77 and 68 respectively. ^{75, 76}

All user groups rated the software as user-friendly and intuitive qualitatively. Patients anticipated better communication with clinical team and improved ability to track their own disease, which is important in self-management.

Clinicians identified structured recording of adherence, the standard management plan to support best practice and centralised data repository as positive features. Penetration test was also shown to be successful (and highly secure) demonstrating that CCCare is suitable for deployment in routine clinical care. ^{75, 76}

iii. Roll out to clinical practice

Roll out of CCCare to other ANZ public hospitals and private practices is anticipated in mid to late 2018, where it will be integrated with other hospital platforms.

The following table lists the search term/s, database and number of results used in this section (**Table 8**).

Table 8

Search term/s	Database	Results
'IBD' and 'practice management software'	PubMed	3
'IBD' and 'software' and 'monitoring'	PubMed	8
'IBD' and 'practice management software'	Cochrane	5
'IBD' and 'software' and 'monitoring'	Cochrane	2

9. Increased investing in clinical trials and audit of paediatrics

Executive summary

- There are at least 5,000 Australian children with IBD, with few choices of medications with a sound evidence base for effectiveness, safety and dosage.
- Many published papers have called for performing timely, well designed and ethical clinical trials in paediatric IBD as a priority, as too many medications are prescribed as 'off label' in children, largely driven by challenges to paediatric drug trials and the delay to pediatric drug approval.
- Funding is one of the challenges to conducting urgently needed paediatric IBD clinical trials.
- It is hoped that further investment to repeat the Australian IBD Audit will monitor and enable improvements in the quality of paediatric care provision in IBD, as has occurred in the UK.

Today, pediatric-onset IBD presents at an earlier age and increasing prevalence. Epidemiological studies around the world, including Australia, have shown an exponential increase in the reported incidence of IBD in children and adolescents over the last 2-3 decades.¹⁰ There are at least 5,000 Australian children with IBD.¹⁰

The major goals of treating children with IBD are to:¹⁰

- Control debilitating symptoms.
- Enable maximum linear growth and maintain normal pubertal progression.
- Achieve maximal bone accrual and preserve bone density.
- Minimise interruption of schooling and education.
- Maintain age-appropriate peer relationships.

Paediatric-onset IBD is more typically severe IBD phenotype, with additional issues of growth failure, delayed puberty and consequences of a chronic disease commencing at a vulnerable period of psychosocial development.⁷⁸ Due to its age of onset and the chronic disease course, medical treatment remains the cornerstone of treatment, with most patients requiring lifelong therapy. The ultimate treatment goal in paediatric IBD is moving beyond

symptom- control towards mucosal healing.

The management of paediatric IBD has evolved significantly over recent years with evidence-based guidelines in place to provide guidance in clinical practice.⁷⁹ The optimal paediatric IBD care is undertaken by a paediatric gastroenterologist in conjunction with multidisciplinary team care, including specialist nursing and dietetic support.⁹

Funding for paediatric clinical trials

Although paediatric-onset IBD is becoming more common, there is a lag before pediatric trials are started for established adult-IBD therapies, and even longer before such therapies to receive approval for pediatric usage.⁸⁰ On average, it takes nine years from the time of a product's approval for use in adults until the label includes pediatric data.⁸¹

Very few randomised clinical trials have been performed in paediatric IBD cohorts, unlike adult cohorts. As a result, few medications have a registered paediatric indication. Moreover, a significant proportion of children with IBD do not respond to currently available treatment.⁷⁹

Paediatric pharmacometric approaches are increasingly applied to drugs already in use for the adults IBD population, but are used prior to paediatric trials having shown safety and efficacy. During this time such drugs are used unlicensed and off-label in paediatric IBD patients due to the lack of information on age-appropriate dosing, efficacy and safety.

Medications used to treat pediatric gastrointestinal conditions are frequently prescribed off-label.⁸¹ Unfortunately, especially given that paediatric patients are vulnerable, some long-established and well accepted off-label uses have been shown to be either ineffective or harmful when prospectively evaluated in paediatric randomized controlled trials, such as proton pump inhibitors.⁸¹ Similarly, monoclonal antibodies are used in Crohn's disease based on demonstrated efficacy in induction and maintenance of remission; however, the long-term safety profile is less well established.⁸²

Moreover, evidence supporting the longer-term safety of off-label drugs can remain lacking despite widespread use, which is particularly important in paediatric populations typically requiring life-long treatment.⁸¹

Off-label prescribing is not illegal in Australia, nor is it regulated by the Therapeutic Goods Administration.⁸² Many published papers have called for performing timely, well designed and ethical clinical trials in pediatric IBD as a priority. An outline of the issues at the heart of off-label medication use in pediatric gastroenterology was published as part of the 30th anniversary issue of the Journal of Pediatric Gastroenterology and Nutrition in 2012. Paediatric

professionals from Australia, Asia, Europe, and the United States called for approved products to treat paediatric IBD patients, among other gastrointestinal conditions.⁸²

Authors called for evidence based research prescribing for paediatrics and noted the “landmark legislative and regulatory reforms” in the United States and Europe in recent years that have resulted in more pediatric medicines research and improvements in licensing of some medications.⁸² The adoption of such initiatives for paediatric studies in the US and then in Europe has significantly changed the worldwide legislative frameworks.⁸³ Such reforms have indicated that it is possible to stimulate development of paediatric medicine research.⁸³

However, in Australia, despite many paediatric initiatives instigated through professional and government advisory bodies, formal legislative and regulatory reforms addressing paediatric medicines are still lacking.⁸⁴

Yamashiro et al. (2012) described the strategies suggested to provide an evidence base for paediatric off-label drugs, including better paediatric medicines research, drug regulatory reforms and substantial commitment of public funding and dedicated infrastructure.⁸²

The UK IBD Audit (2014) called for IBD services to continue to enroll eligible patients to relevant clinical trials and a coordinated national clinical trial network for paediatric IBD to increase patient recruitment further.⁸⁵ The Audit showed a rise in the number of services participating in paediatric research since the previous audit round, with 67% (116/173) of services reporting that they have enrolled patients into an IBD trial in the previous 2 years, compared with 35% (71/201) who were active in research.⁸⁵

The need for increased funding to achieve increased research is well known, however there is limited discussion of the appropriate funding levels in the literature. Paediatric drug development has largely relied on the pharmaceutical company's product strategy, and generally paediatric strategies are often driven by the incentives relating to adult markets rather than the needs of children. It is also important to include paediatric-specific needs into the drug development strategies.⁸⁰

Turner et al. (2014) describes the market forces that have not been a sufficient incentive for adequate research and development of paediatric medicines and drug development has changed following recent legal and regulatory framework changes in the EU and US as regulators, industry and investigators have developed a system that guides research.⁸³ A positive economic return from these US incentives for paediatric drug development has even been described.⁸³

Barriers to paediatric clinical trials

There are several hurdles to performing clinical trials in paediatric IBD-cohorts in addition to funding.

i. Study design

There is no consensus on the optimal outcome measures for clinical trials in paediatric IBD cohorts.⁸⁰ Invasive procedures, such as endoscopy pose significant barriers to the conduct of pediatric trials.

Clinical outcome measures should be predictive of pre- defined goals important to patients including long-term wellbeing, quality of life and prevention of damage, tolerance and safety issues.⁸⁰ There is no gold standard for IBD 'disease activity' therefore assessment is based on symptoms, signs, radiographic appearance, presence and severity of inflammation and biomarkers. Another important consideration in the study design is who should score the outcome measures in IBD, patients themselves or their specialists.⁸⁰

The Paediatric European Crohn's and Colitis Organisation committee established an international expert panel to determine the best primary and secondary outcome measures in paediatric IBD studies to inform the optimal design of clinical trials for emerging and existing IBD therapies.⁸⁰

The correct use of placebo is another controversial issue in the design of paediatric IBD studies. The position paper from ESPGHAN, ECCO, the global PIBDnet, and the Canadian Pediatric IBD network emphasizes that it is important to perform pediatric trials, but that the correct usage of placebo is essential. For example, placebo should only be used in pediatric IBD cohorts when true equipoise exists against the active treatment or when it is an add-on treatment to an effective treatment and after a long period of deep remission.⁸⁶

It has been suggested that small underpowered comparative trials in children should be acceptable to confirm the prior findings in adult trials, providing that adult efficacy data already exists and pharmacokinetic and pharmacodynamic findings are similar to adults.⁸⁷ The fact that paediatric trials may be confirmatory to similar larger adult trials should assist in mitigating the challenge of recruitment in children.⁸⁸ However, it is not possible to predict growth and bone- related issues from adult studies.⁸⁰ Thus, each proposed trial requires individual consideration of its study design.

ii. Recruitment

The design of paediatric clinical trials must address the barriers to the recruitment of children.⁸⁸ Fewer children than adults are generally available for study recruitment, as the paediatric IBD cohort is small compared with the adult

population. Moreover there are several age-specific considerations that must be considered in the design of pediatric trials.

Parents concerned about potential side effects of therapy and the additional invasive tests are more reluctant to have their children engaged in intervention trials than are adult patients and their clinicians may have same concerns about their participation in trials.⁸⁰

Funding for audit of paediatrics

There is good evidence that clinical audit, with responsive intervention and reassessment, can improve the quality of care provision in chronic diseases, such as IBD.⁸⁹ The UK IBD Audits have provided evidence of service improvements in many areas since the initial benchmarking audit.⁸⁹

It is hoped that the 2016 Australian IBD Audit, which provided benchmarking for equivalent Australian IBD services will prove to do the same, as there were no published standards or guidelines to provide a point of reference for audit of IBD services until the publication of the IBD Standards concurrently with the aforementioned IBD Audit in 2006.⁹

The Australian IBD Audit objectives were to identify the factors of a service that result in high quality care and those that contribute to variation in care. The Audit identified five sites that were designated as specialist paediatric hospitals with the remainder being general hospitals that may or may not treat paediatric patients.

Documentation was considered to be substandard across sites. The Audit demonstrated that fundamental aspects of patient history, examination and the results of important tests were not recorded in many cases. For example, disease severity was formally scored (using the paediatric Crohn's disease activity index [PCDAI]) for only 6% of paediatric patients.⁹

The Audit identified variable levels of staff providing IBD care. IBD nurses were not available at all specialist paediatric sites and only one third had ongoing funded positions.⁹ Nutritional screening was less common for paediatric admissions (19% Crohn's disease admissions; 13% ulcerative colitis admissions).⁹

All the participating paediatric specialist hospitals had a paediatric gastroenterologist and paediatric anaesthetist, while only half had a paediatric colorectal surgeon, even though paediatric surgery rates were similar to those for adults.

The Audit recommended ongoing funding to facilitate repeated audits to measure change and identify new or ongoing variation in IBD care. Ultimately, responsiveness to gaps in paediatric IBD care to enable the completion of the quality of care cycle.

The following table lists the search term/s, database and number of results used in this section (**Table 9**).

Table 9

Search term/s	Database	Results
'IBD' and 'paediatric clinical trials'	PubMed	71
'IBD' and 'paediatric audit'	PubMed	9
'IBD' and 'paediatric investing'	PubMed	1
'IBD' and 'paediatric clinical trials'	Google Scholar	12,200
'IBD' and 'audit of paediatrics'	Google Scholar	2,040
'IBD' and 'paediatric investing'	Google Scholar	12,200
'IBD' and 'paediatric clinical trials'	Cochrane	4
'IBD' and 'paediatric audit'	Cochrane	1
'IBD' and 'paediatric investing'	Cochrane	0

10. Explore the effectiveness of medical home funds bundling

Executive summary

- Patient- centered medical homes (PCHMs) are intended to centralise primary care needs among a population of patients while decreasing costs and improving the quality of care, and have been used in primary practice.
- Specialised PCMHs are emerging, including 2 IBD PCMHs that have been established in the US.
- Though slightly different, the two models show the necessary factors: a team- based approach, a close and integrated payer– provider relationship, and the placement of the patient at the center of the health care universe.
- There is early but promising evidence of successes of the 2 IBD PCMHs.
- To date, results have shown reduced healthcare utilization (significantly reduced emergency room visits and hospitalizations) and improved patient outcomes resulting from the IBD PCMH model, although only one study has been published thus far.

To address increasing costs of healthcare utilisation and inadequate and variable patient care in IBD, clinicians, governments and patient advocate organisations are searching for new models of patient care.^{2,9} Despite differences in care delivery and financial infrastructure, rising health expenditures are putting healthcare systems under increasing pressure and this seems to be a universal ‘unsolvable’ problem worldwide.⁹⁰

IBD ranks among the most costly of chronic diseases, and physicians nowadays are increasingly engaged in health economics discussions.⁹⁰ In the last 20 years, the number of available treatments for IBD patients has expanded dramatically, and so too has the complexity of their disease management. The increasing global IBD incidence and complexity of care, often required for a patient’s lifetime, coupled with new and expensive IBD therapies have resulted

in a marked increase in the cost of IBD care.⁹¹

Average IBD-related healthcare costs in the USA are estimated to be between \$5000 and \$19,000 per person per year.⁹⁰ In Australia in 2012 alone, hospital costs attributable to IBD were estimated to be around \$100 million and productivity losses (including loss of earnings, absenteeism and premature death) of more than \$361 million.²

There is widespread agreement that there is an urgent need to improve the consistency and quality of care for IBD patients at the same time as reducing healthcare costs. The concept of a specialised IBD patient-centred medical home (PCMH) has been put forward to achieve these goals. At the time of writing, data is limited, with only 2 such centres established. A good evidence-based is essential to designing and implementing the IBD- PCMH and is sorely needed to forge the path ahead for Australian IBD patients and the healthcare system.

The PCMH model

“We cannot bring the cost of care under control and have any meaningful effect on the management of chronic disease unless we bring the patient into the solution as a member of the health care team.” Konsinski et al. (2017).⁹²

The concept of the “medical home” originated from the American Academy of Pediatrics in 1967, as a central source for all the medical information about a child, especially those with special needs.⁹² Since then, the medical home has developed into a model of team-care for a population of patients.

Primary care medical home models have emerged in the US over the last decade as the prominent component of the health care reform bill, the Affordable Care Act. Proponents maintain that the medical home model holds promise as a way to improve health by transforming how primary care is organised and delivered.⁹³

As part of its 2013–14 Budget submission, the RACGP agreed with this sentiment and called for the federal government to fund and implement key elements of the medical home, stating that “synonymous with comprehensive, integrated, quality care and access, the medical home encapsulates the very definition of general practice in Australia. The concept of continuous care supports the critical and core role of the GP as the coordinator of patient care.”⁹⁴

Now referred to as the patient-centred medical home (PCMH), this model uses a patient-centered approach and an accessible multidisciplinary team of integrated providers that is leveraged through a payer–provider partnership to decrease healthcare costs and improve quality of care.⁵³

The PCMH is not limited to a single place or location.⁹⁵ Rather, it is a team of

caregivers that serves as the patient's main point of contact and coordinates the patient's acute, chronic, and preventative care.⁵³ The PCMH model is supported by robust health information technology (IT), provider payment reform focused on patient outcomes and health system efficiencies, and team-based education and training of the healthcare professionals. This model provides a better patient experience by enhancing access to care, improving patient safety, eliminating unnecessary treatments, and focusing on preventive care.⁵³

Starting in late 2017, the Australian Government has now established more than 170 Health Care Homes around Australia providing primary care medical homes to patients with chronic and complex conditions.⁹⁶ Health Care Home-enrolled patients have multiple chronic conditions and access Medicare Benefits Schedule (MBS)-funded allied health services under a GP Management Plan and Team Care Arrangement, a Health Assessment for Aboriginal and Torres Strait Islander People or a GP Mental Health Treatment Plan.⁹⁶ This model is expecting approximately 65,000 patients to enrol by the end of 2018 with around 55 patients are expected to enroll per full-time GP. The data that is generated from these Health Care Homes will no doubt be interesting and relevant to IBD patients.

The IBD PCMH

Though PCMHs have been developed in the primary care domain, they have yet to be fully tested in specialty care.⁵³ To date, the role of specialists within the PCMH is less well defined. Specialty PCMHs have only recently begun to emerge for specific disease care, such as IBD, and involve:⁹⁷

- A principal provider who is a specialist (in the case of IBD, a gastroenterologist).
- Collaboration with a payer or insurance company around the cost of the patient.
- A team of providers under the direction of the principal care provider who manages the whole patient in addition to providing direct IBD care.
- Incorporation of health information technology (e.g., remote monitoring and telemedicine to keep the patient at home or in school without having to make multiple trips to the doctor).

The IBD PCMH involves a gastroenterologist as the principle physician and coordinates the patient's full multidisciplinary care. This includes behavioral health experts, social workers, nurse practitioners, and dietitians, via office visits, telephone calls, and telemedicine.

Two IBD PCMHs have been set up in the USA to better manage chronic IBD

care. Though slightly different, each model shows the necessary elements: close collaborations with payers/ insurance plans, a sufficiently large patient population, a specialist, and accessible multidisciplinary care.⁹⁸

The IBD PCMH payment structure

In the IBD PCMH, population-based medicine is practiced in conjunction with a multidisciplinary team-based approach. Health care professionals and providers work together to provide value to a population of patients rather than focusing on one patient at a time.⁹²

Under the current 'fee-for-service' payment structures, specialists are incentivised to often deliver more care than is necessary, and necessary preventive care is under-delivered.⁹⁰ Patients are usually unaware since there is little reporting on quality and health outcomes by individual physicians or hospitals.⁹⁰

In contrast, this model focuses on preventative medicine and gives the patient one single comprehensive place to turn, thereby preventing costly and unnecessary medications, unplanned hospital visits or admissions. It is expected this will result in a more appropriate use of medications and thereby lead to a medical cost offset with improved IBD outcomes, a reduction in health care utilisation and optimised work and life productivity.⁹⁷

Clinicians who care for IBD patients recognise that this population requires specialised and personalised care, especially the subset of IBD patients who are heavy users of healthcare services and are therefore very expensive to treat.⁵³ Identifying the "cost drivers" is required to build in the required healthcare professionals and infrastructure necessary for creation of the IBD-SMH to decrease unplanned care and utilisation.⁵³

This is evidenced by some early successes of the PCMH that have come out of integrated delivery systems that have an economic incentive to invest in improvements in patient care to help avoid costly hospital stays.⁵³ For instance, the Royal Adelaide Hospital in Australia introduced an IBD chronic care model in 2008 that included specialised IBD nurse case managers, follow-up phone calls, and standardised protocols for blood test monitoring, and resulted in a decrease in IBD-related hospitalisations, as has previously described in this review.¹⁸ Data and IT systems to identify the most expensive subgroups of patients can inform how best to care for them, and in the process reduce their cost of healthcare.

As the IBD PCMH is new, the optimal payment model has yet to be determined, to incentivise the provider to use proven and effective therapy for patients who need it most. It is hoped that moving from fee-for-service to the PCMH fee-for-value reimbursement will result in declines in the cost of care with a concurrent

improvement in the quality of care provided.⁹² Although bundled payments have been implemented to reduce costs, to date, no good evidence exists thus far on how specialists can take risks for the populations they serve.⁹⁷

Evidence base for the IBD-PCMH

To date, there is promising, but limited data on these IBD PCMHs, consisting of one published paper and a few abstracts. There will likely be differences in application of this model to the Australian environment.

At present, there are two “early adopters” of the IBD PCMH, the University of Pittsburgh Medical Center (UPMC) and the Illinois Gastroenterology Group (IGG).⁹²

i. The “UPMC Total Care-IBD”

In 2015, University of Pittsburgh Medical Center (UPMC) gastroenterologists and the UPMC Health Plan established an IBD specialty medical home to provide high-quality, comprehensive, cost-effective, patient-centered health care for all health plan-insured IBD patients, with a specific focus on the high-utilisation (high cost) patients.⁵³

The goal of the UPMC Total Care-IBD was to take a multidisciplinary and personalised approach to care by putting the patient in the centre of the “medical universe” with a team of specialists revolving around the needs of each patient.⁹⁵

There were 6,319 IBD patients (including all insurance plans) at the time of the centre’s establishment, with nearly one third of patients accounting for approximately 80% of the total cost of IBD care. Data demonstrated that 14% of UPMC’s patients with IBD accounted for 46% of total expenditures, of which the 3 greatest expenditures derived from the costs of pharmacy, injectable drugs, and surgery.⁵³

The use of health IT and data analysis, integral to the PCMH model, identified gaps in patients needs and allowed UPMC to address them accordingly. The UPMC Total-Care IBD created specific programs to meet the identified needs of its patients (mental illness, pain, and poor social support). Data showed consistent unplanned care due chronic pain and psychosocial factors.

Addressing this gap in psychosocial care, the UPMC developed the “BESST CARE” program. Patients were assessed for unmet psychosocial issues (mental illness, chronic pain, lack of social support, non-adherence to medical care, fatigue, and sleep disturbance) and given access to psychiatrists, psychologists, and social workers around the clock to help reduce stress and improve disease self-management and coping skills.

The early successes of reduced healthcare utilisation and improved patient outcomes resulting from the UPMC model have been promising, although only

one study has been very recently published at the time of writing this review by Regueiro et al. (2018).⁹⁸

Early results in the first year of the study showed a significant reduction in disease activity, unplanned care and hospitalisations, and an increase in patient quality of life after one year of enrollment. A significant decrease in emergency department utilisation and hospitalizations was even demonstrated after only 3 months of enrollment.⁹⁸

Of the 322 patients enrolled, results showed 47.3% reduced emergency room visits and 35.9% reduced hospitalizations, significantly improved quality of life as measured by the Short-Form Inflammatory Bowel Disease Questionnaire from 50 to 51.8 and 99% patient satisfaction for physician communication.⁹⁸ Results also showed moderate, but significant, improvement in secondary outcomes of depression and anxiety scores after enrollment in the medical home.⁹⁸

According to the study's authors, the reduction in unplanned care and quality of life improvement was due to identification of the determinants that drove health utilisation, care plans that used the multidisciplinary team, and the partnership between the provider group and health plan around the collective care of a population of patients.⁹⁸ The study showed that patient stratification by biological, social, and behavioral risk factors for high health care utilisation, through the use of data and health IT, allowed individualised care plans and resource allotment to improve their care.⁹⁸ Unfortunately this study did not include data on the cost of care, however authors noted that this would be evaluated in future.

ii. Illinois Gastroenterology Group

In 2012, the Illinois Gastroenterology Group (IGG) developed Project Sonar, incorporating an IBD population health management/monitoring tool across multiple states with one insurance company.⁹⁹ Project Sonar utilises nurse care managers and physician medical directors in a team approach to coordinate care for patients with IBD, along with clinical decision support and patient engagement.

Project Sonar is a community-based registry and disease management program developed to improve clinical and economic outcomes in IBD. This cloud-based program integrates monthly patient-reported symptoms and health-related quality of life information with clinical data, which are combined with payer provided-claims data to provide comprehensive, real-time information to physicians and patients on current symptoms and health status, as well as composite 'Sonar' scores.⁹⁹

The success of a Project Sonar pilot in 2013 led to a partnership between IGG and a major payer to launch a PCMH in 2014. Results of the pilot showed a reduced hospitalisation rate for enrolled patients from 17% to 5% at the end of

the first year.⁹⁹ Data from the first year of the PCMH alone showed 57.14% decline in inpatient costs driven by an equivalent decline in admissions/complications.⁹⁹

Although presented as an abstract only, Project Sonar demonstrated value-based improvement in care for n = 152 Crohn's disease patients in a community-based setting between 2014 and 2015.¹⁰⁰ Results showed over a 50% reduction in hospital admissions and emergency room visits resulting in total payments for patients declining by 11.03%. As yet, results are unpublished.¹⁰⁰

Under the PCMH model, IGG receives a supplemental per-member per-month care management payment for each enrolled patient and a shared savings opportunity at the end of each study period. Data from the above study showed a net 9.87% savings, which, based upon the US \$11,000 annual cost per patient, amounts to a savings in payments of over US \$1,000 per patient per year.¹⁰⁰

iii. UCLA

In 2012, the Division of Digestive Disease at UCLA introduced a comprehensive, integrated, and holistic approach to value-based care in the chronic disease management of IBD. Kosinski et al. (2017) includes this as an IBD PCMH, however other authors such as Regueiro et al. (2017) classify it as a variant model and not a PCMH.^{92, 97}

The following table lists the search term/s, database and number of results used in this section (**Table 10**).

Table 10

Search term/s	Database	Results
'IBD' and 'funds bundling'	PubMed	0
'IBD' and 'medical home'	PubMed	50
'IBD' and 'funds bundling'	Cochrane	0
'IBD' and 'medical home'	Cochrane	1
'IBD' and 'funds bundling'	Google Scholar	886
'IBD' and 'medical home'	Google Scholar	21,100

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