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SPEAKER SERIES

PROs in IMIDs

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October 2017

About the Speakers

Dr. Jakob Begun

After obtaining his BSc, Dr. Jakob Begun completed his MPhil in Biochemistry at Cambridge University, and his MD and PhD in genetics at Harvard Medical School. He completed his clinical training at Harvard University and his advanced training in IBD (inflammatory bowel disease) at Massachusetts General Hospital (MGH). He returned to Australia in 2014 to pursue his interest in clinical and translational IBD research. He is the IBD clinical lead at the Mater Hospital and Queen Elizabeth II Hospital in Brisbane. He is the IBD Group leader and a Senior Research Fellow at the Mater Research Institute – University of Queensland and is a Senior Lecturer at the UQ School of Medicine. He runs a basic and translational laboratory at the Translational Research Institute investigating the interaction between the innate immune functions of the gut and the microbial community with a focus on therapeutic interventions. He also performs clinical research examining the natural history of IBD, endoscopic assessment and interventions in the setting of IBD, and investigating barriers of care for adolescents and young adults with IBD at the Mater Young Adult Health Centre.

Dr. Andrew McCombie

Dr Andrew McCombie oversees the studies involving IBDsmart with Associate Professor Michael Schultz. Outside of IBDsmart, Andrew is involved in questionnaire validation, translating medical information into patient language and quality of life research in bowel cancer. His PhD was in the "Pyschological Aspects of Inflammatory Bowel Disease." He was a board member of Crohn's and Colitis New Zealand in the past and is a Postdoctoral Fellow at the University of Otago.

Abbreviations used in this review:
CD = Crohn's disease
CDAI = Crohn's Disease Activity Index
CRP = C-reactive protein
IBD = inflammatory bowel disease
IMID = immune-mediated inflammatory disease
PRO/PROM = patient-reported outcome (measurement)
RA = rheumatoid arthritis
RCT = randomised controlled trial
UC = ulcerative colitis

About this review

This publication summarises the presentations focussing on PROs (patient-reported outcomes) that were part of the IMID (immune-mediated inflammatory disease) meeting held in Auckland on Sept 29–30. IMID, which was sponsored by AbbVie NZ, was an educational meeting developed by a steering committee for enhancing medical knowledge and scientific exchange. Dr. Jakob Begun spoke on translating PROs into trials and clinical practice, and Dr. Andrew McCombie talked about their role in eHealth solutions. We hope you find the information in the publication helpful. Please also keep an eye on your inbox for publications summarising other presentations from this meeting.

IMID was an educational meeting developed by a steering committee for enhancing medical knowledge and scientific exchange. The IMID meeting was sponsored by AbbVie NZ, and this meeting write up has been commissioned and sponsored by AbbVie Ltd, Wellington. The content of the presentations is entirely independent and based on published studies and the speakers' opinions, and the views expressed are not necessarily those of AbbVie Ltd. Please consult the full datasheet for any of the medications mentioned in this article at www.medsafe.govt.nz before prescribing. Treatment decisions based on these data are the full responsibility of the prescribing physician. NZ-IMM-0065. December 2017.

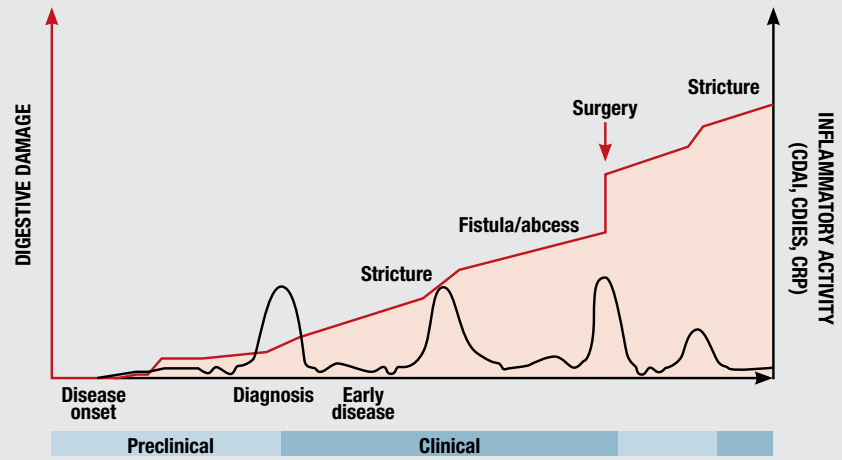
PATIENT-REPORTED OUTCOMES: TRANSLATION TO TRIALS AND CLINICAL PRACTICE

Dr. Jakob Begun

Dr Begun started his presentation noting that patient outcomes are a critical goal of treatment in IBD to improve patients' lives. In general goals of therapy of any chronic illness include hard outcomes (e.g. mortality) and softer outcomes (e.g. preventing disability). Additional outcomes include PROs, which are closely related to PROMs (patient-reported outcome measurements) obtained using validated tools, clinician reported outcome measures, and clinical disease activity assessments, which take into account both PROs and clinician-reported outcomes.

Dr Begun commented that in daily practice, clinicians incorporate clinical signs and symptoms of disease activity (PROs) and objective measurements from laboratory tests such as blood and faecal markers of inflammation. Although endoscopic assessment remains the gold standard of disease assessment, this is a more invasive and resource intensive test, although there are imaging modalities (such as intestinal ultrasound) that can be a useful noninvasive alternative. Histopathological assessments can also be important for diagnosis and prognosis. In the context of the evolution of CD (Crohn's disease) where there are preclinical, clinical and remission phases (Figure 1),[1] clinical activity and indices are useful, but in the preclinical and possible remission phases, where symptoms are absent, there is the potential for missing subclinical inflammation leading to the accumulation of bowel damage.

Figure 1. Progression of digestive damage and inflammatory activity in a theoretical patient with CD (adapted from Pariente B *et al.* Inflamm Bowel Dis 2011;17:1415–22)



Indices for IBD

There are multiple clinical indices that are used in IBD. In CD, these include the CDAI (Crohn's Disease Activity Index) and the HBI (Harvey Bradshaw Index), both of which are used extensively in clinical trials and clinical research. In UC (ulcerative colitis), the two most commonly used indices are the partial Mayo score and the SCCAI (Simple Clinical Colitis Activity Index). While these are mostly research tools, the CDAI and the two UC indices are also used to determine patient eligibility for biological treatment in New Zealand and Australia. These indices are derived from patient symptoms as well as physician assessments, and the CDAI includes laboratory data. In contrast, PROMs are standardised, validated questionnaires intended for completion by patients, without physician input, in order to measure their perceptions of their own functional status and wellbeing.

CDAI: an imperfect instrument

Development of the CDAI, which has been in use for several decades, was based on clinician-generated weighting of signs and symptoms (see Table 1). It is a ~600-point scale, in which changes of 70–100 points are considered meaningful. CDAI scores of <150 are considered disease in remission, scores of 200–445 are considered moderate disease activity, and scores of >450 indicate severe disease.

Table 1. Variables of CDAI[2]

Variable	Multiplier
Number of liquid or soft stools	×2
Abdominal pain (0=none, 1=mild, 2=moderate, 3=severe)	×5
General wellbeing (0=well, 1=slightly under par, 2=poor, 3=very poor, 4=terrible)	×7
Number of listed complications: IBD associated complications (arthritis, eye complications, skin lesions, perianal disease, other fistula, fever [>37.8°C])	×20
Use of antidiarrhoeal medications (0=no, 1=yes)	×30
Abdominal mass (0=no, 2=questionable, 5=definite)	×10
Haematocrit (males: 47%; females 42%)	×6
Bodyweight (1– [ideal/observed]) × 100	×1

Dr Begun commented that some of the more subjective measures in CDAI (e.g. general wellbeing, pain) tend to be weighted more heavily than more objective measures. He also noted that some patients with functional gastrointestinal disease (e.g. irritable bowel syndrome with diarrhoea) can have high CDAI scores without active inflammation. Furthermore, in a 1990 study, no correlation was found between CDAI score and disease severity on endoscopy according to validated CDEIS (Crohn's Disease Endoscopic Index of Severity) scores (R=0.13 [p value not significant]).[3]

Indices for UC

The SCCAI used in NZ for assessing disease activity in UC includes a number of objective components, such as average number of daytime bowel movements, average number of nocturnal bowel movements, rectal bleeding and extra-intestinal manifestations of IBD, but also more subjective measures such as urgency of defaecation and general wellbeing. More widely used for UC is the Mayo score, which includes objective measures including the number of bowel movements above baseline and degree of rectal bleeding, but equally weighted is the PGA (Physicians' Global Assessment) score. The partial Mayo score includes these three measures, whereas the full Mayo score also includes endoscopic severity. Each component is scored on a 0- to 3-point scale. Although there is some variability in the definitions of disease severity according to partial Mayo score, a score of <2 is often used to define remission, whereas partial or full Mayo scores of ≥6 typically denote moderate-to-severe disease.[4–6]

Mucosal inflammation versus symptoms

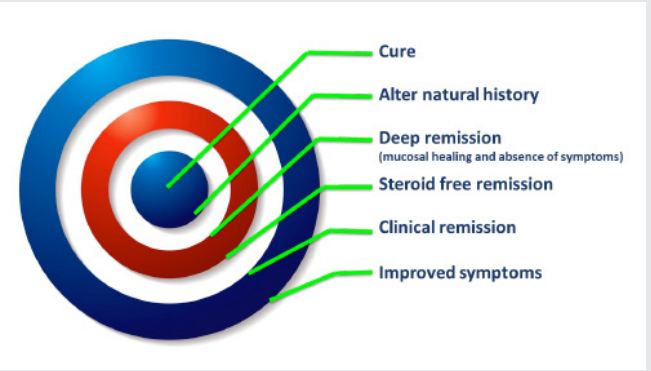
The importance of subclinical inflammation can be demonstrated by a study that followed 351 patients with CD in clinical remission, including 69 with an elevated CRP (C-reactive protein) level.[7] Patients with an elevated CRP level were significantly more likely to require disease-related hospitalisation over the subsequent 24 months (adjusted hazard ratio 2.12 [95% CI 1.13, 3.98]). Dr Begun commented that these asymptomatic patients with an elevated CRP level could represent around one-quarter of patients with CD in clinical remission, therefore objective assessment of inflammation is critical.

Similar findings have been reported for patients with IBD in clinical remission according to endoscopic findings. In patients with CD in clinical remission, those without mucosal healing at 1 year were more likely to require surgery over the subsequent 5 years (3 vs. 13 patients with mucosal healing [p=0.02]).[8] Similarly, for UC in remission after treatment with infliximab, more patients with endoscopic Mayo subscores of 2 or 3 needed to undergo colectomy over 54 weeks than those with endoscopy subscores of 0 or 1 (24 vs. 14 patients p=0.004).[9]

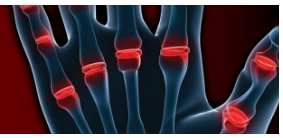
Goals of IBD treatment

Due to the association of poor outcomes with subclinical inflammation, a treat-to-target approach is becoming increasingly popular in the IBD field. Dr Begun commented that there is some debate on exactly what the target outcomes should be, but there is concensus that mucosal healing represents an important goal of therapy. With the advent of the newer more potent treatments, we can target goals beyond mucosal healing, including biochemical normalisation and radiological and histological healing (Figure 2), but data are lacking on the effects of more aggressive treatment. What we can achieve in IBD treatment determines what is acceptable; however, we also need to consider healthcare resources and costs in order to know where to 'draw the line'.

Figure 2. Goals of care in IBD



STRIDE (Selecting Targets of Remission in Inflammatory Bowel Disease) is an initiative of the IOIBD (International Organization for the Study of Inflammatory Bowel Disease) that, by consensus, sought to establish goals of therapy for IBD.[10] The consensus was that the importance of both PROs and endoscopic outcomes be acknowledged for IBD treatment targets, and including some biochemical markers, for which the data aren't as robust, as adjunctive measures (see box on next page). However, these treatment targets have the potential to create a disconnect between the physician and patient. For example, a patient may feel that if PROs are met, they may wish to decrease their medications, but the physician may wish to increase medications if mucosal healing has not been achieved on endoscopy.



STRIDE consensus treatment targets for CD[10]

- Clinical/PRO remission
  - Resolution of abdominal pain and altered bowel habit
  - Assessed at a minimum of 3 months during active disease (at least 6–12 monthly once in remission)

and

- Endoscopic remission
  - Resolution of ulceration at ileocolonoscopy
  - Assessed at 6- to 9-month intervals during the active phase

Adjunctive measures of disease activity that may be useful in the management of selected patients but are not a target

- CRP level
- faecal calprotectin level

STRIDE consensus treatment targets for UC[10]

- Clinical/PRO remission
  - Resolution of rectal bleeding and diarrhoea
  - Assessed at a minimum of 3 months during active disease (at least 6–12 monthly once in remission)

and

- Endoscopic remission
  - Resolution of friability and ulceration at flexible sigmoidoscopy or colonoscopy
  - Assessed at 3- to 6-month intervals during the active phase

Adjunctive measures of disease activity that may be useful in the management of selected patients but are not a target

- CRP level
- Faecal calprotectin level
- Histology

PROMs in clinical trials

There has also been considerable interaction with clinical trialists to determine PROMs generated from qualitative patient interviews that are reliable and responsive for clinical trials and are also acceptable to both the FDA and EMA (European Medicines Agency). A two-item PROM, abdominal pain and stool frequency, was identified as most important for patients with CD, and has been validated in two clinical trials.[11,12] For patients with UC, another two-item PROM, rectal bleeding and stool frequency from the Mayo clinical score, was identified as important, and has been assessed in *post hoc* analyses of clinical trial data.[13]

In future clinical trials, PROMS will be combined with objective inflammatory measures, including endoscopy and biochemical measures. Endoscopy data will be centrally read; endoscopic scores are still evolving. Standard disease instruments such as the CDAI and Mayo scores will likely still be used, but mainly for historical comparison purposes. It is also not clear how regulatory agencies will view outcomes like 'steroid-free clinical remission' and 'durable clinical remission', which will be reported as secondary endpoints only.

TAKE-HOME MESSAGES

- Established clinical IBD indices don't adequately consider patient's perspective.
- Lack of symptoms does not equate to mucosal healing.
- PROs are here to stay.
- Will be integrated into other tools and measures.

REFERENCES

1. Pariente B *et al.* Development of the Crohn's disease digestive damage score, the Lémann score. Inflamm Bowel Dis 2011;17(6):1415–22 [Full text]
2. Best WR *et al.* Development of a Crohn's Disease Activity Index: National Cooperative Crohn's Disease Study. Gastroenterology 1976;70(3):439–44 [Abstract]
3. Modigliani R *et al.*, and the Groupe d'Etude Therapeutique des Affections Inflammatoires Digestives Clinical, biological, and endoscopic picture of attacks of Crohn's disease. Evolution on prednisolone. Gastroenterology 1990;98(4):811–8 [Abstract]
4. Lewis JD *et al.* Use of the non-invasive components of the Mayo score to assess clinical response in ulcerative colitis. Inflamm Bowel Dis 2008;14(12):1660–6 [Full text]
5. Sandborn WJ *et al.* Adalimumab induces and maintains clinical remission in patients with moderate-to-severe ulcerative colitis. Gastroenterology 2012;142(2):257–65 [Full text]
6. Australian Government Department of Health: The Pharmaceutical Benefits Scheme. Drug Utilisation Sub-Committee (DUSC). Analysis of medicines used to treat ulcerative colitis. June 2017. Downloaded (pdf 496KB) on Jan 19, 2018 from http://www.pbs.gov.au/industry/listing/participants/public-release-docs/2017-06-meeting/ulcerative-colitis-dusc-prd-2017-06.pdf
7. Click B *et al.* Silent Crohn's disease: asymptomatic patients with elevated C-reactive protein are at risk for subsequent hospitalization. Inflamm Bowel Dis 2015;21(10):2254–61 [Full text]
8. Frøslie KF *et al.* Mucosal healing in inflammatory bowel disease: results from a Norwegian population-based cohort. Gastroenterology 2007;133(2):412–22 [Full text]
9. Colombel JF *et al.* Early mucosal healing with infliximab is associated with improved long-term clinical outcomes in ulcerative colitis. Gastroenterology 2011;141(4):1194–201 [Full text]
10. Peyrin-Biroulet L *et al.* Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE): determining therapeutic goals for treat-to-target. Am J Gastroenterol 2015;110(9):1324–38 [Abstract]
11. Gasink C *et al.* Evaluation of an interim Crohn's disease outcome measure (PRO-2) based on two patient-reported components (stool frequency, abdominal pain) of the Crohn's Disease Activity Index (CDAI) in the ustekinumab CERTIFI study. ECCO Congress 2015; P164 [Abstract]
12. Khanna R *et al.* A retrospective analysis: the development of patient reported outcome measures for the assessment of Crohn's disease activity. Aliment Pharmacol Ther 2015;41(1):77–86 [Full text]
13. Jairath V *et al.* Development of interim patient-reported outcome measures for the assessment of ulcerative colitis disease activity in clinical trials, Aliment Pharmacol Ther 2015;42(10):1200–10 [Full text]

PATIENT-REPORTED OUTCOMES: EHEALTH SOLUTIONS IN THE DIGITAL AGE

Dr. Andrew McCombie

This presentation on electronic PROs described available apps for IBDs (including IMDsmaart) and RA (rheumatoid arthritis, including RAConcect), and the common challenges faced with their development; their application in dermatology was also discussed. Electronic PROs were defined as electronic collection of *"any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else"* – US FDA (pdf; 295KB).[1] IBD and RA share some commonalities: they are both chronic diseases, they both relapse and remit, it can be difficult to estimate when a patient's next appointment will be needed, and PROs, or indices that can be adapted into PROs, are available for both.

Apps for IBD

Systematic review

Dr McCombie presented the findings of a systematic review he and his colleagues conducted in 2016 on available apps for monitoring IBD symptoms.[2] They identified apps available on the Google Play and iTunes stores using the search terms 'Crohn's disease', 'ulcerative colitis' and 'inflammatory bowel disease'. There were several inclusion and exclusion criteria, the most important of which were inclusion of symptom monitoring elements (minimum requirement of bowel motion frequency and pain) and a mechanism by which the patient and healthcare professional could communicate electronically.

Results

A total of 233 apps were identified (202 and 49 in the Google Play and iTunes stores, respectively) using the search terms described.[2] Once duplicates were removed and the inclusion and exclusion criteria applied, 17 remained for review. All 17 recorded PROs, but only one (Gut Check™) used a validated index (CDAI and Mayo score), none incorporated objective measures (e.g. blood or stool test results) and none had been tested in trials for feasibility, usability or enhanced patient-doctor communication.

Conclusion of systematic review of apps for IBD[2]

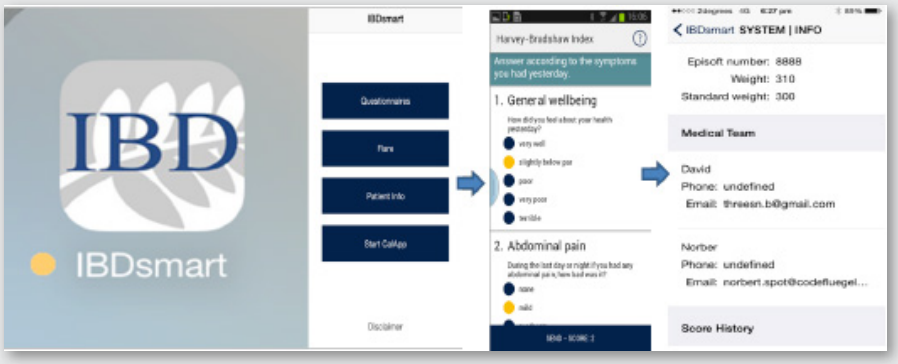
- Smartphone apps for monitoring IBD do not use validated clinical indices.
- More research is required to determine if smartphone apps can replace face-to-face outpatient appointments, enhance quality of life, reduce flares and improve other outcomes.

A similar systematic review done the same year, but with slightly different inclusion/exclusion criteria, reached the similar conclusions that apps for patients to monitor their IBD lack professional involvement, do not adhere to international guidelines and lack validation from clinical studies.[3] These authors also highlighted that the safety and quality of IBD apps is jeopardised as a result of these limitations, rendering them unsuitable as potential medical tools from a clinician's perspective. Dr McCombie added that he believed many apps have been developed without adequate medical input, and often by patients.

IBDsmart

IBDsmart (Gut Health Network) is an app for iPhones and Android smartphones that has been developed to collect PROs (e.g. SCCAI [Simple Clinical Colitis Activity Index]) based on data entered by the patient into their smartphone.[4] Dr McCombie provided a demonstration of how the app works (Figure 3).

Figure 3. IBDsmart home page, login screen, and data entry forms.



Questionnaire button

Every 3 months, the app notifies the patient to complete a questionnaire specific to their IBD; i.e. HBI (Harvey-Bradshaw Index) for CD or SCCAI for UC. As some aspects of the questionnaires are usually addressed by physicians, the app includes support to help, including images (e.g. to illustrate what eye, mouth and skin problems look like) and some instructional videos (e.g. how to assess for abdominal mass). Once completed, the patient is advised that their activity index result has been sent to their IBD care team, and if the patient does not hear back within 3 working days and remain concerned, they are advised to make direct contact with their IBD health provider; Dr McCombie stated that 99% of results are received by the IBD team.

Flare button

If a patient believes they are experiencing a disease flare, they can use this button. The patient completes the appropriate questionnaire (as previously described), and the email sent to the IBD team also notes that the patient has reported a flare (rather than a routine score), thereby raising its level of importance.

Patient info button

At the time of reporting, the patient information included a list of the score history, but further development is planned to include a graph.

IBDsmart studies

IBDsmart has been evaluated in a pilot study and an ongoing RCT (see below). There is also a study on IBDsmart REMIND, which is investigating sending push notifications to remind patients to do a CDAI assessment on their smartphone (for anti-TNF [tumour necrosis factor] therapy renewal) and also let them know when their blood tests are due. A trial is also planned to investigate using IBDsmart indices sent before appointments to augment teleconsulting.

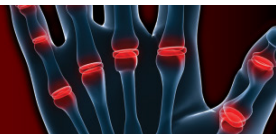
Original pilot study

The IBDsmart pilot study recruited 35 adults with IBD who were already accustomed to completing questionnaires on their health and wellbeing.[5] The participants completed a questionnaire (see text box) on the usability and acceptance of IBDsmart using a 7-point scoring system of agreement (1 = strongly disagree, 7 = strongly agree). For questions 1–6, which generally focus on usability, ≥74% of participants expressed agreement. Agreement was lower than average for the issues of tracking disease severity and IBDsmart replacing specialist visits.

Questionnaire for IBDsmart pilot study

Q1: Overall, I am satisfied with how easy it is to use this system.
Q2: I could effectively complete the tasks (reporting, entering my data) using this system.
Q3: I was able to complete the tasks (reporting) quickly using this system.
Q4: I was able to efficiently complete the tasks (reporting) using this system.
Q5: I felt comfortable using this system.
Q6: It was easy to learn to use this system.
Q7: I would like to see a tracking of my disease severity scores to see if I have improved or not.
Q8: Could IBDsmart replace a visit to the specialist?

Dr McCombie commented that improvements were made to IBDsmart based on the findings of this pilot study, including the addition of the help function and integration with IBDoc®. He also mentioned that future versions may provide data in a format that can be integrated directly into health system databases.



IBDoc®

IBDoc® is another smartphone app that can generate a faecal calprotectin level, an objective IBD biomarker, based on an image taken by the smartphone's camera of a faecal sample obtained using an accompanying kit. For ease of use and understanding, different colours (red, yellow and green) are used on the smartphone screen to denote high, moderate and normal results, respectively, for faecal calprotectin levels (Figure 4). Faecal calprotectin is used to differentiate IBD from irritable bowel syndrome, is a measure of bowel inflammation and may help predict IBD relapse.[6–8] Dr McCombie commented that trial doctors have provided generally favourable responses regarding faecal calprotectin levels recorded by this app.

Figure 4. Screen example of IBDoc® app.

IBDsmart RCT

The RCT to evaluate IBDsmart recruited participants from the Waitemata, Hutt Valley, Canterbury and Southern DHBs, and was ongoing at the time of reporting; the trial is registered at ANZCTR (ACTRN12617000389303p). The participants were randomised to use smartphone apps (IBDsmart and IBDoc®) every 3 months or attend face-to-face clinic visits over a 12-month period. The primary outcomes are acceptability and noninferiority of IBDsmart versus face-to-face visits, and the secondary outcome is adherence.

Adherence data presented at the meeting suggest better adherence with IBDsmart than with IBDoc® (Figure 5), which Dr McCombie believes is due to IBDsmart being quicker to complete (~1 min) and the requirement for stool analysis with IBDoc®.[9] Preliminary responses to acceptability questionnaires completed by participants (n=31) indicated that:

- 77.4% of participants felt comfortable using IBDsmart for reporting IBD symptoms instead of doing so at face-to-face outpatient appointments,
- 83.9% indicated they would continue to use IBDsmart in the future,
- 90.3% would recommend the use of IBDsmart to other patients with IBD, and
- 48.4% claimed that IBDsmart helped them better manage their disease.

Twenty-seven gastroenterologists with patients in the smartphone app group and 21 with patients in the face-to-face group had also completed usability questionnaires at the time of reporting. Preliminary results from these questionnaires were reported at the meeting (Table 2).

Figure 5. IBDsmart and IBDoc® adherence: RCT results[9]

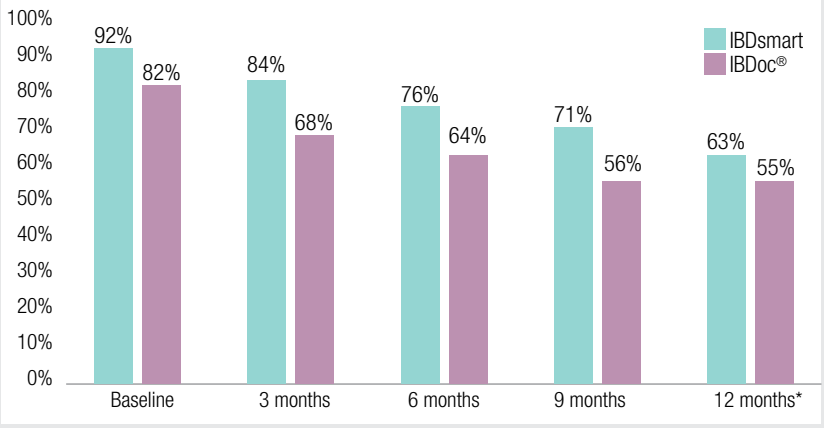


Table 2. Usability questionnaire responses (%) from gastroenterologists regarding patient smartphone app use versus face-to-face visits

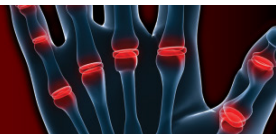
Smartphone app group (n=27)		Usual treatment group (n=21)	
Did you feel comfortable using IBDsmart/ IBDoc® for this patient?		**Did you feel comfortable communicating face-to-face with your patient?**	
Very	63.0%	Very	100%
Somewhat	25.9%	Somewhat	0%
Not really	7.41%	Not really	0%
Not at all	3.7%	Not at all	0%
Did IBDsmart/IBDoc® give you enough information about the patient's disease activity?		**Did face-to-face appointments give you enough information about the patient's disease activity?**	
Very	51.9%	Very	95.2%
Somewhat	18.5%	Somewhat	4.8%
Not really	25.9%	Not really	0%
Not at all	3.7%	Not at all	0%
Was there anything you were not able to communicate with the patient because you were seeing them via IBDsmart/IBDoc® and not face-to-face?		**Was there anything you were not able to communicate with the patient because you were seeing them face-to-face and not via IBDsmart/IBDoc®?**	
No	3.3%	No	85.7%
Yes	66.7%	Yes	14.3%

Apps for RA

Systematic review

The NZ Google Play and iTunes stores were searched for the terms 'arthritis', 'rheumatoid', 'RA', 'rheumatoid arthritis' and 'rheumatic' to identify English language smartphone-based apps capable of running on Android or iOS operating systems that were useful for patients with RA or to assist clinical care of such patients.[10] Apps were excluded if they targeted other conditions, were intended for information, education or reference purposes only, included only treatment algorithms or were explicitly only for clinician use. Of 721 and 216 search results on the Google Play and ITunes stores, respectively, 11 and 16 apps met the criteria.

Based on their results, the authors commented that there was a lack of high-quality apps for longitudinal assessment of RA disease activity.[10] They identified two categories of apps: i) simple calculators primarily for rheumatologists; and ii) data tracking tools for people with RA. However, many of the data tracking tools did not use validated instruments or composite disease activity measures. The authors concluded that a need exists for appropriate, high-quality apps for the comanagement of RA by patients and their rheumatologists.



RAconnect

RAconnect, which was developed by the same company that developed IBDsmart, is an app for a patient with RA to enter their disease activity information and send to their rheumatologist and/or specialist nurse. It was designed for patients with RA who want to be involved in their disease management, as well as their rheumatology healthcare team, to facilitate patient-centred care, provide real-time monitoring of their disease, enable a rapid response when required and reduce outpatient appointments when no change to management is required. RAconnect was undergoing further evaluation at the time of reporting, and it is hoped that it will be available for use in clinics in the second half of 2018.

Common challenges for developing IBD and RA apps

Dr McCombie commented that while many apps already exist for IBD and RA, most are unsuitable for physicians and patients to use together to manage the patient's disease. He also raised the issue of whether measures used by the app have been validated for self-reporting, and noted the complexities of app development in terms of achieving agreement on what the physicians and researchers want, all in the framework of what the software developer can produce within the allocated budget.

It should also be remembered that an app needs to be produced twice if it is to be available on both the Android and iOS platforms. However, Dr McCombie pointed out that it is best to not make early versions of the apps available on these stores until they have undergone adequate pilot testing, as apps in these stores that aren't fully ready are likely to get bad reviews.

Dr McCombie also noted that some doctors and patients may be apprehensive about technological tools for managing diseases; for example, many patients like to see their doctor regularly. The ownership of data obtained from the apps can also be an issue. Bugs and adherence are also factors Dr McCombie identified that can cause problems. Another important consideration he raised is whether use of the app does actually save time; e.g. is the time needed to process the incoming information from the app less than the time saved by not seeing the patient?

Dermatology

Dr McCombie only briefly spoke on dermatology apps. A 2013 systematic review of eight 'teledermatology' apps concluded that the quality of images used by apps had improved due to improvements in phone cameras, with sensitivity of 98%.[11] It was also noted that >75% of teledermatology patients lived in geographically isolated regions and at or below 200% of the federal poverty level. The authors also noted that the cost effectiveness of telemedicine is likely to continue to increase as smartphones become more affordable.

TAKE-HOME MESSAGES FOR APP DEVELOPMENT

- Inspect the market first.
  - Does a validated symptom monitor already exist?
- Development is intensive.
- Apps need to be validated in a clinical setting.
- Will be integrated into other tools and measures.

REFERENCES

1. U.S. Food & Drug Administration. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims. CDER, 2009 Downloaded on Oct 26, 2017 from https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282
2. McCombie A *et al.* Systematic review of IBD smartphone apps for symptom monitoring and communication with healthcare professionals. Journal of mHealth 2016;3(3):36–41. Issue downloaded (pdf; 4.5MB) on Oct 26, 2017 from http://docs.wixstatic.com/ugd/85fd63_aff479fc6c9e40f39cb3da8f3feb9532.pdf
3. Con D & De Cruz P. Mobile phone apps for inflammatory bowel disease self-management: a systematic assessment of content and tools. JMIR mHealth uHealth 2016;4(1):e13 [Full text]
4. Gut Health Network. IBDsmart. Accessed on Nov 2, 2017 at https://www.guthealthnetwork.com/tools-and-links/ibdsmart/
5. Regenbrecht H *et al.* Field test of a questionnaire-based mobile health reporting system. Proceedings of the 26th Australian Computer-Human Interaction Conference on Designing Futures: the Future of Design; Sydney, New South Wales, Australia. ACM 2014;2686670:384–7 [Abstract]
6. Waugh N *et al.* Faecal calprotectin testing for differentiating amongst inflammatory and non inflammatory bowel diseases: systematic review and economic evaluation. Health Technol Assess 2013;17(55):xv–xix,1–211 [Full text]
7. Bunn SK *et al.* Fecal calprotectin: validation as a noninvasive measure of bowel inflammation in childhood inflammatory bowel disease. J Pediatr Gastroenterol Nutr 2001;33(1):14–22 [Full text]
8. Mao R *et al.* Fecal calprotectin in predicting relapse of inflammatory bowel diseases: a meta-analysis of prospective studies. Inflamm Bowel Dis 2012;18(10):1894–9 [Abstract]
9. McCombie A et al. Adherence and usability of the smartphone apps IBDsmart and IBDoc®. New Zealand Society of Gastroenterology/NZNO Gastroenterology Nurses College. Annual Scientific Meeting 2017. Nov 22–24, 2017. Auckland NZ. Poster 42. Downloaded (pdf; 2.0MB) on Nov 27, 2017 from http://gastro2017.co.nz/wp-content/uploads/2016/03/Poster-Presentations.pdf
10. Grainger R *et al.* Apps for people with rheumatoid arthritis to monitor their disease activity: a review of apps for best practice and quality. JMIR Mhealth Uhealth 2017;5(2):e7 [Full text]
11. Brewer AC *et al.* Mobile applications in dermatology. JAMA Dermatol 2013;149(11):1300–4 [Full text]