Quality counts: how to best capture patient experience in IBD

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Ferring Pharmaceuticals have reviewed these slides for technical content

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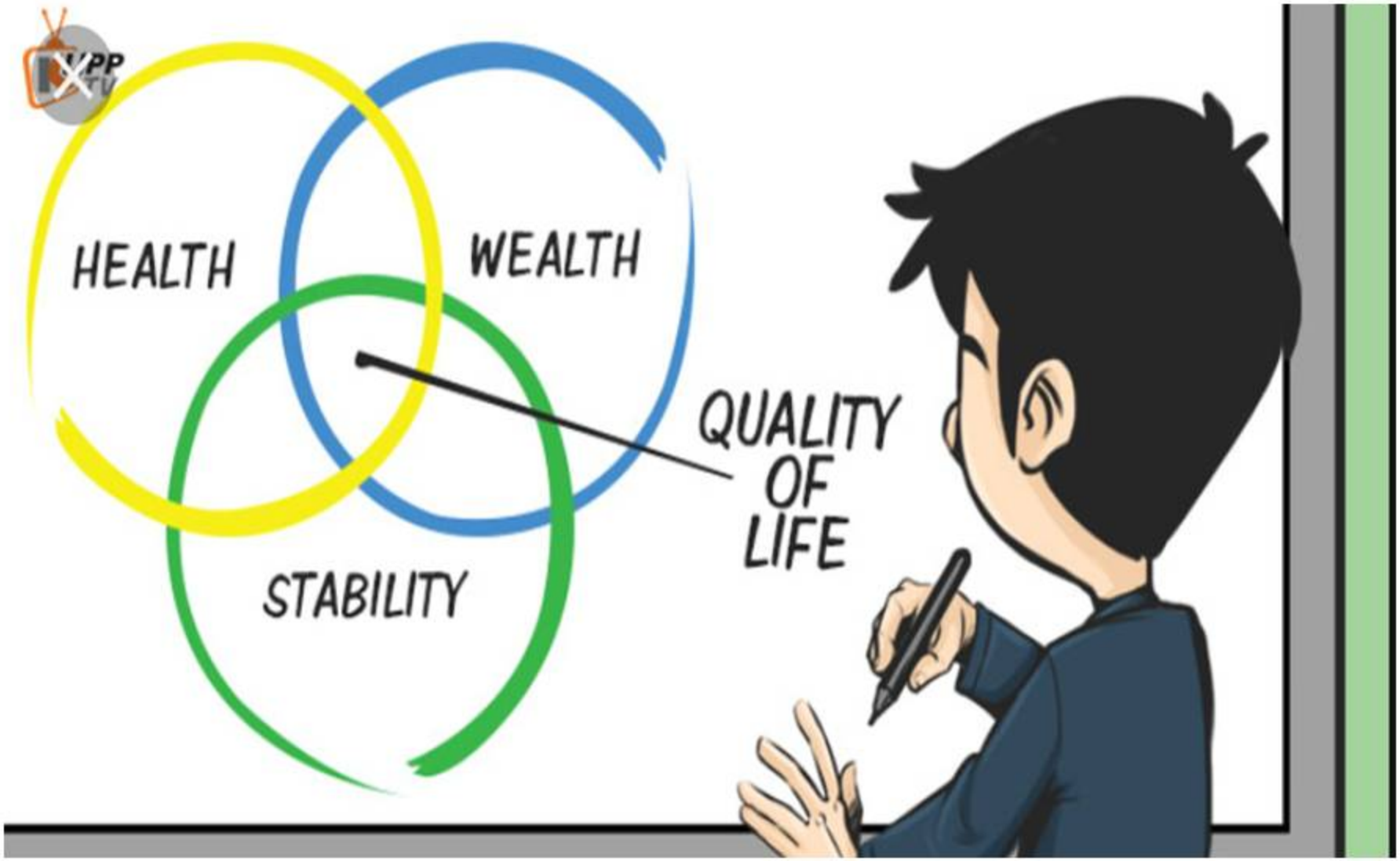
Disclosures

- Dr Alissa Walsh has received research/educational grants and/or speaker/consultation fees from Abbvie, Falk, Ferring, GSK, Hospira, Janssen, Pfizer, Takeda



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Quality of Life

- The goal of therapy for IBD is to achieve and maintain disease control and thereby optimise QoL
- The routine use of patient-reported outcome measures (PROMs) in clinical practice is increasingly advocated as a means of supporting patient-centred care, informing decisions and driving service quality.
- Value-driven care relies on reporting and systematic tracking of patient-centred outcomes, allowing providers to compare meaningful outcomes for patients

Kim et al, JCC 2018, 408-18, Porter et al, NEJM 2010;363: 2477-81

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What are PROMs

- PROMs are standardised, validated questionnaires intended for completion by patients in order to measure their perceptions of their own functional status and well-being
- PROMs have begun to find a role in national audits and registers and there is rapidly growing interest in their potential to inform individual care.
- The US Food and Drugs Administration has advocated routine inclusion of PROs as co-primary endpoints in clinical trials.

Dawson, et al. Br Med J 2010;340:186, Department of Health. Outcomes Framework 2012/13

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Where are we now?

- Last decade – wealth of work
- Only a limited number in clinical trials
- NONE have established a significant place in routine practice
  1. Administrative burden
  2. Lengthy multidomain questionnaires
  3. Even shortened forms are not used widely

What is needed?

- Acceptable to both patients and healthcare teams
- Demonstrates added value
- Requires simple interpretation
- Needs to combine user-friendliness
- Properties that will help tp support decisions for individual patients (relevance)

Table 3. Domain coverage and psychometric properties of IBD-specific PROMs.

	Domain coverage by IBD-specific PROMs								
Outcome domains*	IBDQ	SIBDQ	IBDQ-9	UK-IBDQ	CUCQ-32	CUCQ-8	IBD-control	RFIPC	IBD-DI
Overall change in symptom status	Partially	No	Partially	No	No	No	Yes	No	No
Abdominal pain / discomfort	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Bowel habit	Yes	No	Yes	Yes	Yes	No	Indirectly	No	Yes
Rectal bleeding	Yes	No	No	Yes	Yes	No	Indirectly	No	Yes
Tenesmus	Yes	Yes	No	Yes	Yes	No	Indirectly	No	No
Night-time bowel movement / leakage	Indirectly	No	No	No	Yes	Yes	Yes	No	Indirectly
Faecal incontinence	Yes	No	No	Yes	Yes	No	Indirectly	Yes	No
Perianal fistula / discharge / pain	No	No	No	No	No	No	Indirectly	No	No
Unintentional weight change	Yes	Yes	No	No	No	No	No	No	No
Health-related QoL	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Fatigue and energy	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Emotional health	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Limitations to usual ADL	No	No	No	Yes	Yes	No	Indirectly	No	Yes
Work/education productivity	Yes	No	No	Yes	Yes	No	Yes	Partially	Yes
	Psychometric properties by IBD-specific PROMs								
Psychometric properties	IBDQ	SIBDQ	IBDQ-9	UK-IBDQ	CUCQ-32	CUCQ-8	IBD control	RFIPC	IBD-DI
Test–retest reliability [= reproducibility]	High	High	High	High	High	High	High	High	Med
Reliability – internal consistency	Med	Med	Med	Med	High	High	High	High	High
Content validity	High	High	High	High	High	High	High	High	High
Construct validity	Med	Med	Med	Med	High	High	High	High	High
Responsiveness [ability to detect change]	Med	Low	Low	Med	Unknown	Unknown	High	Low	Unknown

*Outcomes preliminarily selected by Working Group for inclusion within the Symptoms, Function, and Quality of Life domain.

Which one to choose?

- Speaking the same language is important

- Comprehensive, available for free, practical, validated

Let's focus on IBD Control

Table 3. Domain coverage and psychometric properties of IBD-specific PROMs.

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Responsiveness [ability to detect change]	Med	Low	Low	Med	Unknown	Unknown	High	Low	Unknown

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Kim et al, JCC 2018, 408-18

The IBD-Control Questionnaire

Inflammatory bowel disease

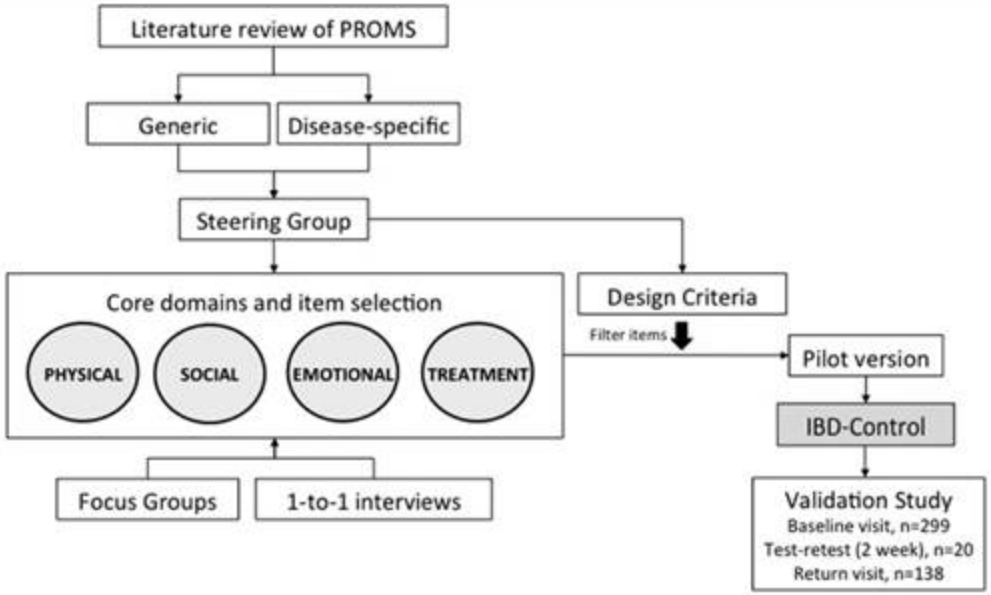
OPEN ACCESS

GUT

ORIGINAL ARTICLE

Development and validation of a rapid, generic measure of disease control from the patient's perspective: the IBD-Control questionnaire

Keith Bodger,[1,2] Clare Ormerod,[1,2] Daniela Shackcloth,[2] Melanie Harrison,[2] on behalf of the IBD Control Collaborative



How might it impact on clinical practice in the foreseeable future?

- In routine practice, IBD-Control has potential to provide patients and healthcare teams with a practical means of capturing simple but reliable outcome data in a standardised and easily interpretable form.
- The strong measurement properties suggest potential for use in clinical studies, particularly in long-term or large-scale trials, surveys or registries where its minimal user and administrator burden will favour serial capture of PROM data in routine settings.

Source: Bodger *et al*, Gut 2014;63:1092-1102

IBD Control-8 Score

1 Do you believe that:

	Yes	No	Not sure
a. Your IBD has been well controlled in the past *two weeks* ?	☐	☐	☐
b. Your *current treatment* is useful in controlling your IBD?	☐	☐	☐

(If you are not taking any treatment, please tick this box ☐)

3 In the past 2 weeks, did you:

	Yes	No	Not sure
a. Miss any planned activities because of IBD? (e.g. attending school/college, going to work or a social event)	☐	☐	☐
b. Wake up at night because of symptoms of IBD?	☐	☐	☐
c. Suffer from significant pain or discomfort?	☐	☐	☐
d. Often feel lacking in energy (fatigued) (by 'often' we mean more than half of the the time)	☐	☐	☐
e. Feel anxious or depressed because of your IBD?	☐	☐	☐
f. Think you needed a change to your treatment?	☐	☐	☐

- Responses to eight questions, each item allocated a score of zero, one or two
- Range: **0-16** (Zero = worst possible control; 16 = best possible control)

Source: Bodger *et al*, Gut 2014;63:1092-1102

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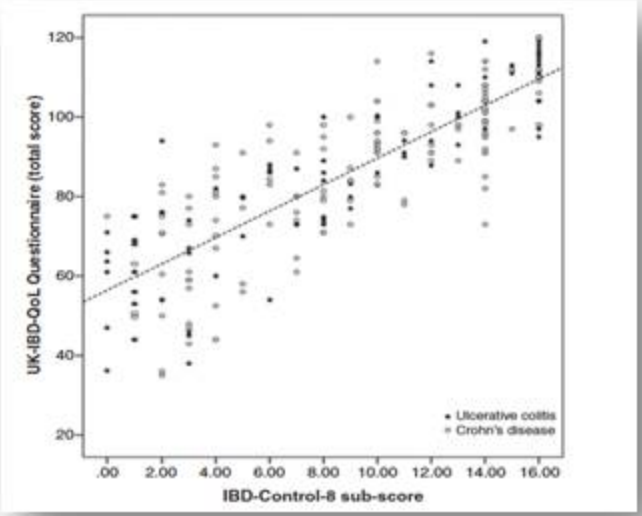
Why choose IBD Control?

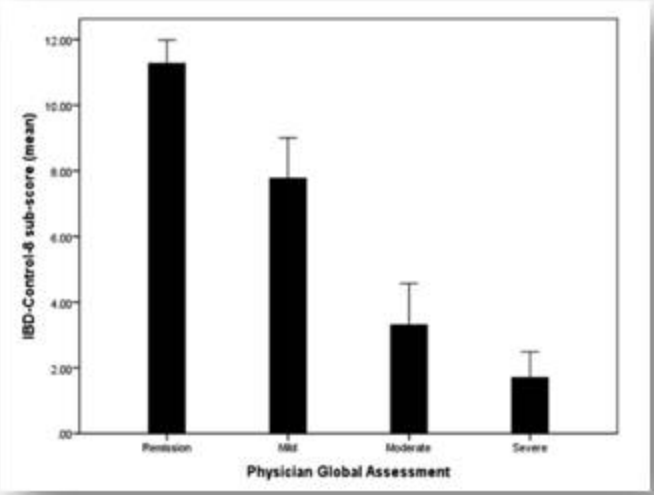
- 100% (20/20) agreement for adoption of this index by the ICHOM IBD working group
- Free
- Captures disease control from patient's perspective
- Generic language
- Measures themes which all patients with IBD can identify
- Less than 1 minute: Practical and feasible
- Adopted by the UK IBD Registry
- Translated into other languages

IBD-Control-8 Score

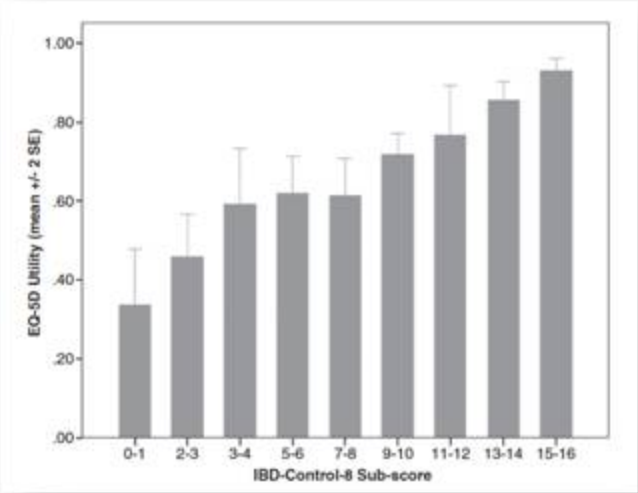
IBD-Q (32 item)



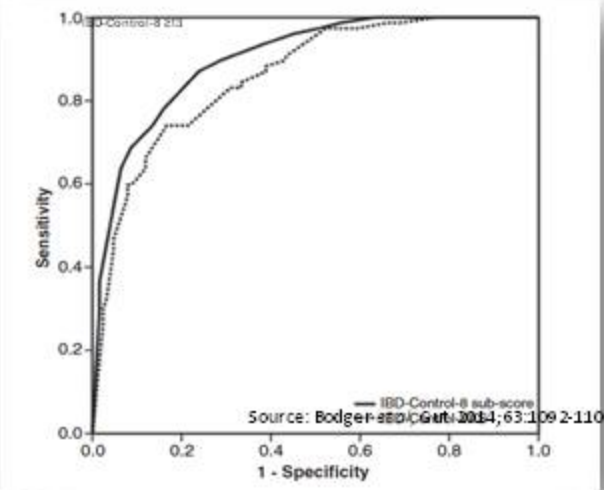
Physician Global Assessment



EQ-5D (Utility)



ROC for 'quiescent disease'

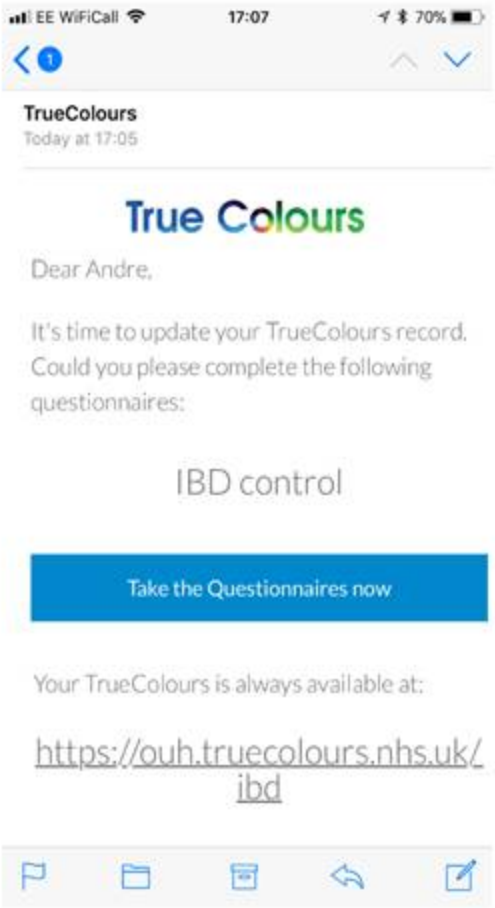


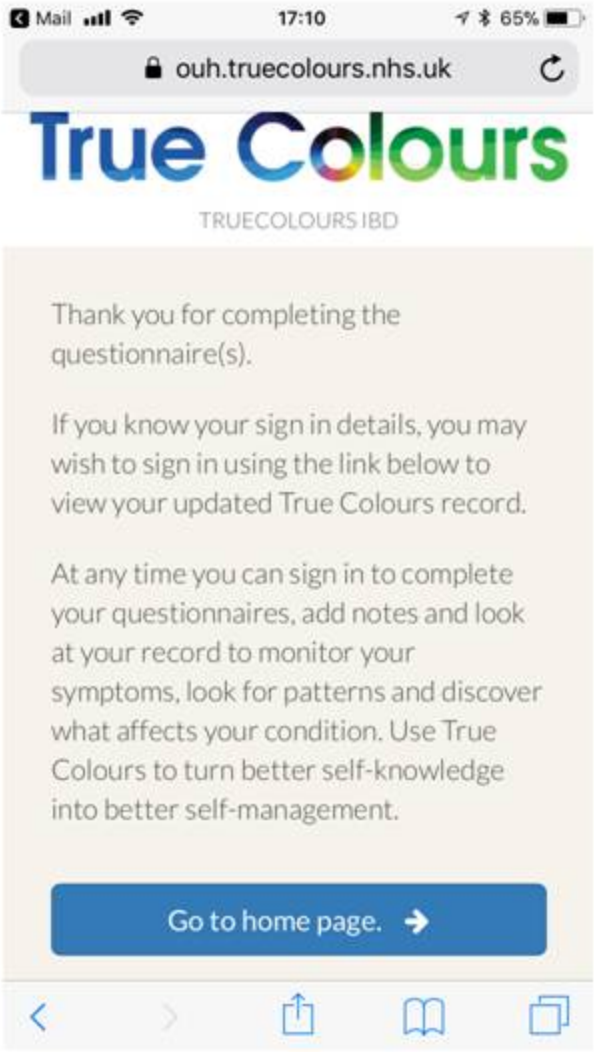
Source: Bodger et al, Gut 2014;63:1092-1102

Why not do the IBDQ?

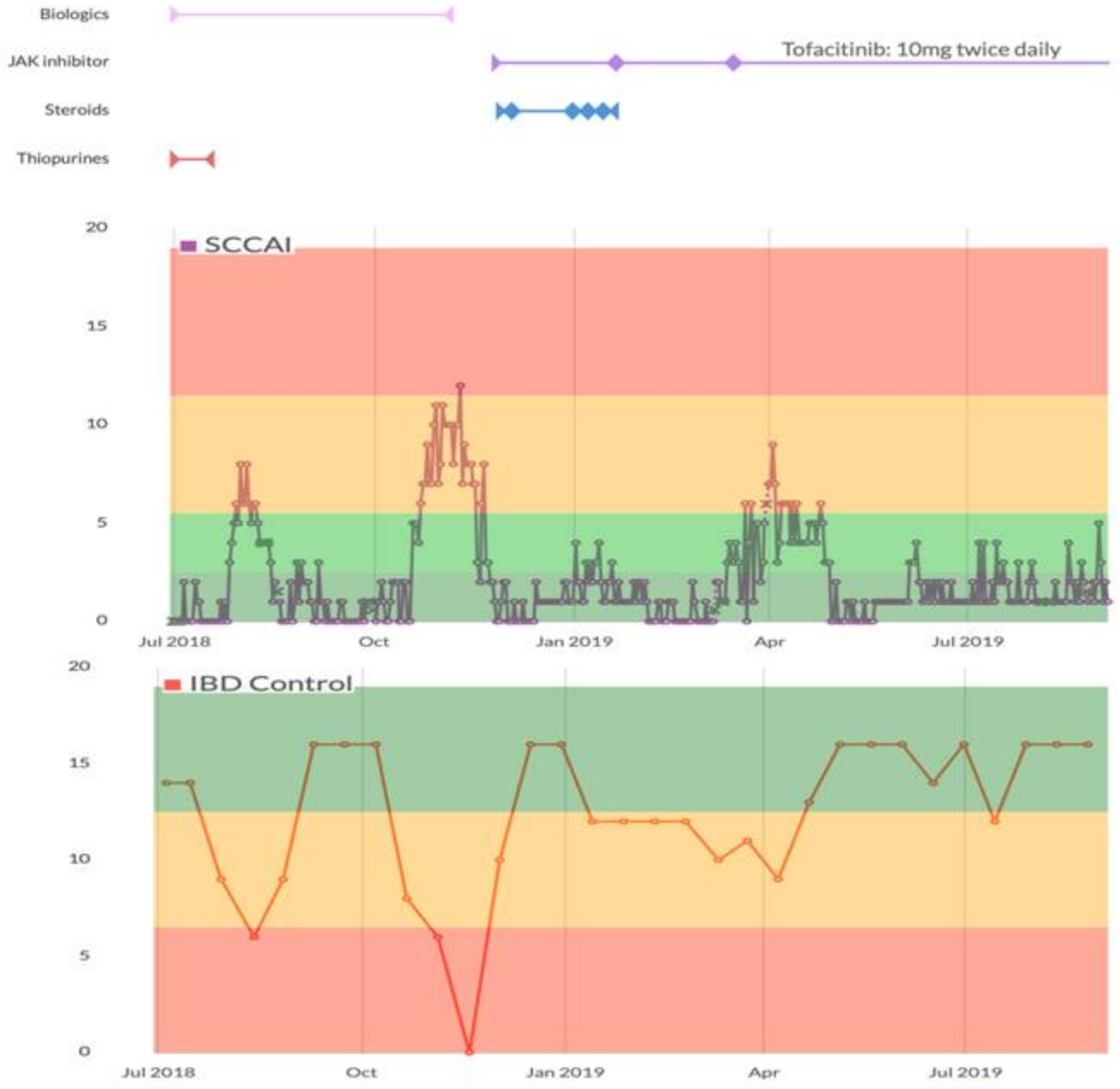
- IBDQ is the best established…..however, has failed to embed itself in clinical practice
  - Length
  - Need for a licence

So how do we do it?




Mail
17:10
65%
ouh.truecolours.nhs.uk
True Colours
TRUECOLOURS IBD
Thank you for completing the questionnaire(s).
If you know your sign in details, you may wish to sign in using the link below to view your updated True Colours record.
At any time you can sign in to complete your questionnaires, add notes and look at your record to monitor your symptoms, look for patterns and discover what affects your condition. Use True Colours to turn better self-knowledge into better self-management.
Go to home page.

Summary


Biologics
JAK inhibitor
Tofacitinib: 10mg twice daily
Steroids
Thiopurines
SCCAI
20
15
10
5
0
Jul 2018
Oct
Jan 2019
Apr
Jul 2019
IBD Control
20
15
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5
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Summary

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Other
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10
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0
Mar
May
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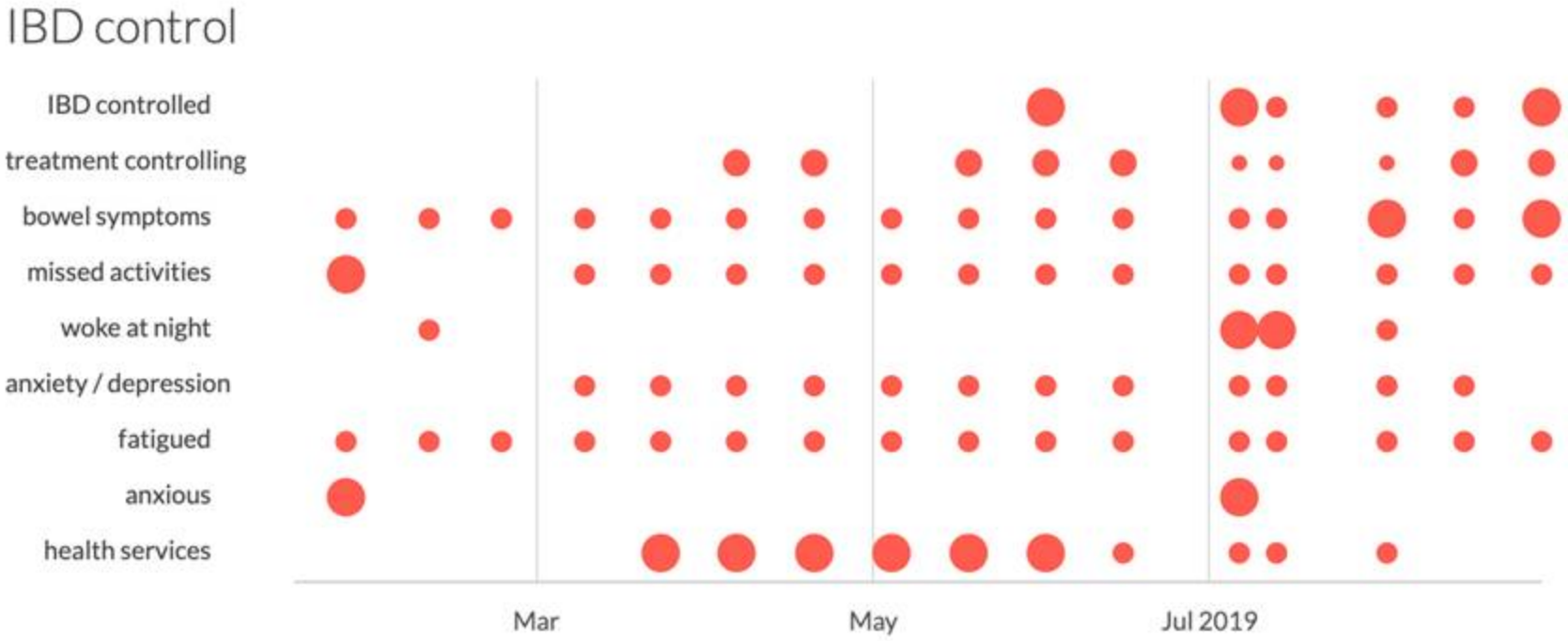
IBD Control
20
15
10
5
0
Mar
May
Jul 2019

Standard of care

Further granularity of results



The whole picture

IBD Control

Inflammatory Bowel Disease Control Questionnaire

1 Do you believe that:

	Yes	No	Not sure
a. Your IBD has been well controlled in the past *two* weeks ?	☐	☐	☐
b. Your *current treatment* is useful in controlling your IBD?	☐	☐	☐

(If you are not taking any treatment, please tick this box ☐)

2 Over the past 2 weeks, have your bowel symptoms been getting worse, getting better or not changed?	Better	No change	Worse
	☐	☐	☐

3 In the past 2 weeks, did you:

	Yes	No	Not sure
a. Miss any planned activities because of IBD? (e.g. attending school/college, going to work or a social event)	☐	☐	☐
b. Wake up at night because of symptoms of IBD?	☐	☐	☐
c. Suffer from significant pain or discomfort?	☐	☐	☐
d. Often feel lacking in energy (fatigued) (by 'often' we mean more than half of the the time)	☐	☐	☐
e. Feel anxious or depressed because of your IBD?	☐	☐	☐
f. Think you needed a change to your treatment?	☐	☐	☐

4 At your next clinic visit, would you like to discuss:

	Yes	No	Not sure
a. Alternative types of drug for controlling IBD	☐	☐	☐
b. Ways to adjust your own treatment	☐	☐	☐
c. Side effects or difficulties with using your medicines	☐	☐	☐
d. New symptoms that have developed since your last visit	☐	☐	☐

5 How would you rate the OVERALL control of your IBD in the past *two weeks*?

Please draw a vertical line (|) on the scale below

Worst possible control — Best possible

Bodger *et al*, Gut 2014;63:1092-1102
Kim et al, JCC 2018, 408-18

Escalation decision predictor: symptoms & QoL

ETI Calculator

SCCAI	Points	+	IBD CONTROL	Points	=	TOTAL POINTS	Probability of Escalation
0	0		0	24		0	0.01
1	7		1	22		13	0.05
2	14		2	21		34	0.25
3	21		3	20		47	0.50
4	29		4	18		59	0.75
5	36		5	16		80	0.95
6	43		6	15		100	0.99
7	50		7	14			
8	57		8	12			
9	64		9	11			
10	71		10	9			
11	79		11	8			
12	86		12	6			
13	93		13	5			
≥14	100		14	3			
			15	2			
			16	0			

Walsh et al, 2018l

Escalation decision predictor: symptoms & QoL

ETI Calculator

SCCAI	Points	+	IBD CONTROL	Points	=	TOTAL POINTS	Probability of Escalation
0	0		0	24		0	0.01
1	7		1	22		13	0.05
2	14		2	21		34	0.25
3	21		3	20		47	0.50
4	29		4	18		59	0.75
5	36		5	16		80	0.95
6	43		6	15		100	0.99
7	50		7	14			
8	57		8	12			
9	64		9	11			
10	71		10	9			
11	79		11	8			
12	86		12	6			
13	93		13	5			
≥14	100		14	3			
			15	2			
			16	0			

The next frontier

ETI Calculator

SCCAI	Points	+	IBD CONTROL	Points	=	TOTAL POINTS	Probability of Escalation
0	0		0	24		0	0.01
12	86		12	6			
13	93		13	5			
≥14	100		14	3			
			15	2			
			16	0			

PROJECT RAINBOW

Summary

- QoL is important and useful
- Encourage use in routine practice
- If you want to collect however have not made a choice, → choose IBD Control
- Reflect on electronic capture

Thank you

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QUALITY-OF-LIFE GUARD
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