

# Frontline Gastroenterology

## Development and test-retest reliability of a new, self-report questionnaire assessing healthcare use and personal costs in people with Inflammatory Bowel Disease: the Inflammatory Bowel Disease Resource Use Questionnaire (IBD-RUQ)

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4 1 **Authors' Contribution:** CR, JS, CN, AH and BM designed the study; CN and BM  
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6 2 supervised the study; CR and JS implemented the study; CR and VSG performed the  
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8 3 statistical analyses. All authors had full access to all the data in the study, contributed  
9  
10 4 to analysis, interpretation, drafting of the manuscript, critical revision, and final  
11  
12 5 manuscript approval.

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## 16 Introduction

17 Inflammatory Bowel Disease (IBD), including Crohn's disease (CD) and ulcerative  
18 colitis (UC), is a chronic gastrointestinal tract condition of unknown aetiology. The  
19 prevalence of IBD is rising, due to the increasing population in cities and changes in  
20 diet and lifestyle<sup>1,2</sup>. IBD management is complex and costly, with frequent  
21 hospitalisations, investigations, operations, use of expensive medicines, out-of-pocket  
22 costs and time-off work<sup>3,4</sup>. Hence, the rising prevalence of IBD and high IBD-related  
23 costs can pose a significant financial burden to patients, health care systems and  
24 society.

25 Advances in medication and diagnostic tools have increased costs of IBD  
26 management, as reported in two large cohort studies in Germany<sup>5</sup> and the  
27 Netherlands<sup>6</sup>. They also raised the importance of accurate measurement of healthcare  
28 and other resource utilisation as part of economic evaluations to inform resource  
29 allocation decisions. The most used method of obtaining data on resource use and  
30 costs in clinical research is through self-report questionnaires such as the widely used  
31 Client Service Receipt Inventory<sup>7</sup>. However, such generic questionnaires do not  
32 include particular categories such as travel expenses for health appointments and cost  
33 for purchases of medication, products, supplements and services specifically related  
34 to people with IBD;

35  
36 This study details the development of the self-reported IBD Resource Use  
37 Questionnaire (IBD-RUQ) to measure healthcare resource use and costs among IBD  
38 patients from the perspectives of health services, patients and society. It reports IBD-  
39 RUQ's face and content validity, and test-retest reliability. The study is part of the  
40 broader IBD-BOOST (<https://ibdboost.net>) research programme, focusing on the

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3 41 development and evaluation of management interventions to improve the well-being  
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5 42 of people with IBD by relieving the most common and troublesome chronic symptoms  
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7 43 of fatigue, pain and urgency and enhancing quality of life.  
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## 45 **Materials and Methods**

### 46 **Development phase**

47 *The initial set of resource items:* The questions and resource use categories were  
48 initially informed from a questionnaire developed for an earlier project on faecal  
49 incontinence in IBD<sup>8</sup>. These questions captured key health care resource utilisation  
50 (i.e., contacts with health professionals, tests and investigations, hospital admissions  
51 and medications). Further questions about investigations, medication names and  
52 dosages (as recommended by the UK MHRA and European EMA government  
53 agencies), and out-of-pocket expenses were suggested by the investigators based on  
54 their clinical and research experience on IBD patients.

55 *Scoping review of existing resource use questions used in IBD:* Following the initial  
56 selection of resource use items, we identified additional categories associated with  
57 IBD by conducting a scoping review of relevant questionnaires. The search was  
58 undertaken in PubMed restricted to the English language. We used a combination of  
59 search terms such as “inflammatory bowel disease”, “Crohn’s disease”, “ulcerative  
60 colitis”, “resource use questionnaire”, “patient-reported outcome”, and “resource use”.  
61 We excluded IBD clinical-related measures and those developed specifically for  
62 children. We shortlisted and reviewed the studies collecting information about  
63 resources used by IBD patients.

64 *Selection of items:* A multi-disciplinary team developed the questionnaire’s first draft.  
65 Next, volunteers from Crohn’s and Colitis UK patient charity  
66 ([www.crohnsandcolitis.org.uk](http://www.crohnsandcolitis.org.uk)) and people with IBD who had previously consented to  
67 be contacted were invited to contribute to the questionnaire’s development. They  
68 provided comments on the draft questionnaire, particularly on the items associated

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3 69 with personal expenses. This consultation resulted in a wide range of items comprising  
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5 70 direct (e.g., visits to an IBD nurse), non-National Health Service (NHS) (e.g., transport  
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7 71 to hospital appointments) and indirect (e.g., sick leave days from work) costs. The  
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10 72 process of generating the final six core categories and resource use items included in  
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12 73 the pilot version of the questionnaire is presented in **Figure 1**.

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15 74 *Face and content validity:* The IBD-RUQ was piloted among 30 volunteers with IBD  
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17 75 within the patient and public involvement group to test face and content validity. They  
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19 76 anonymously filled in the draft version of the questionnaire and provided verbal and  
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21 77 written feedback. Most questionnaires were completed online, and few were  
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23 78 completed on paper during a face-to-face patient and public involvement event. The  
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25 79 questionnaire's content was tested for questions' clarity and the items' completeness  
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27 80 and refined based on the feedback received. For example, we ensured using lay  
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29 81 language instead of clinical terms. We also included additional items (e.g., over-the-  
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31 82 counter medications). In another round of testing, the revised version of the  
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33 83 questionnaire was given to a convenience sample of 12 people waiting for  
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35 84 consultations in an IBD clinic. No further issues or new suggestions emerged. The  
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37 85 final IBD-RUQ is presented in **Appendix 1**.

#### 38 39 40 41 42 43 86 **Test-retest IBD-RUQ reliability study: patient recruitment and testing phase**

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46 87 To minimise any overlap between volunteers who provided feedback during the  
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48 88 questionnaire's development and those participating in the survey, respondents were  
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50 89 recruited using a different patient pool. Between March and April 2019, 103 people  
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52 90 with IBD from the IBD-BOOST programme's<sup>9</sup> database, were invited by email to  
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54 91 participate. Another 55 people with IBD were verbally invited during an IBD patient  
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56 92 conference.

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3 93 The study's inclusion criteria were: aged 18 years or older, being diagnosed with IBD,  
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5 94 residing in the UK, and providing written informed consent. The survey's invitation  
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7 95 contained a link to the online information package describing the study's purpose, a  
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9 96 brief screening page to check the eligibility versus the inclusion criteria, a consent  
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11 97 form, and the questionnaire. Participants filled out the online questionnaire via the  
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13 98 Survey Monkey platform (<https://www.surveymonkey.co.uk>) twice, with at least two  
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15 99 weeks between the measurement occasions. To achieve an intraclass correlation  
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17 100 coefficient (ICC) of 0.8 with a 95 % confidence interval  $\pm 0.1$  for the two repeated  
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19 101 measures, we aimed to recruit at least 50 participants<sup>10</sup>. The retest invitation was sent  
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21 102 out to participants who had completed the initial test survey with an enclosed £5 gift  
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23 103 voucher to increase the likelihood of their response<sup>11</sup>. One reminder e-mail was sent  
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25 104 if the retest was not completed within a week of an invitation.

### 105 **Sources of unit costs**

106 We calculated the total costs per participant using individual-level resource use data.  
107 The unit costs for each category were obtained from official sources (**Appendix 2**).  
108 Productivity loss was estimated by multiplying the self-reported number of days off-  
109 work by the daily wage. A working week was assumed to have five working days. All  
110 unit costs are reported in British pound sterling (£) at 2019-20 prices, adjusted for  
111 inflation where necessary using the Hospital and Community Health Services Pay and  
112 Prices Index<sup>12</sup>, with total costs per participant annualised.

### 113 **Statistical analysis**

114 Differences between test and retest values were examined using descriptive statistics.  
115 To test the reliability of multiple items scores from the same participant between the  
116 2-week time gap, we calculated the ICCs using a two-way mixed-effect model with  
117 interaction for the absolute agreement. The reliability was categorised into "poor"



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3 118 (ICC<0.5), “moderate” (ICC 0.5-0.75), “good” (ICC 0.76-0.9), and “excellent”  
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5 119 (ICC>0.9)<sup>13</sup>. Missing values for quantities/frequency of individual resource items use  
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7 120 for those who reported item use were imputed using mean imputation at individual-  
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9 121 item level . The resource use was assumed to be zero, should both values for resource  
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11 122 use and quantity were left unfilled or an answer for medication use was “unsure” and  
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13 123 the corresponding frequency unfilled. All analyses were performed using Stata 16.1  
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17 124 (StataCorp, College Station, Texas, USA).

### 125 **Ethical considerations**

126 This study was approved by King’s College London, UK ethics committee (MRA-  
127 18/19-8956). Participation in the survey was voluntary, and all participants provided  
128 informed consent. The data were anonymised before the analyses, and participants  
129 were assured of anonymity.

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## 131 **Results**

### 132 **Development phase**

133 *Scoping review:* A PubMed search identified 436 studies, of which 16 reported direct  
134 or indirect healthcare resource utilisation in people with IBD. Resource utilisation was  
135 assessed using web-based or written patient self-report questionnaires<sup>14-19</sup>, an  
136 electronic database<sup>3,4,20,21</sup>, patients' records<sup>22,23</sup>, or a combination of questionnaires  
137 and patients' records<sup>24-26</sup>. To measure the participants' productivity loss due to IBD,  
138 we adapted the question on productivity from the Work Productivity and Activity  
139 Impairment Questionnaire (General Health version 2.0)<sup>27</sup> to IBD.

140 *IBD-RUQ:* The final IBD-RUQ includes 102 items in six categories, with a recall period  
141 of three months. It is well known that longer recall-periods are subject to errors of  
142 omissions and underreporting while a shorter recall period can result in missing out  
143 on rare but expensive events<sup>28</sup>. We opted for a three-month recall period as likely  
144 optimal in the context of a chronic condition such as the IBD<sup>29</sup>. Service use questions  
145 have two response options (Yes/No), and quantitative questions (e.g., "number of  
146 visits") are numeric but not capped. The medication section also includes the  
147 additional response option "Unsure".

148 *Participants' characteristics:* Of 158 participants invited to participate in the survey, 55  
149 (34.8%) completed the test questionnaire. Of them, 48 (87.3%) also completed the  
150 retest and were included in the analyses. 65% were female, the mean age of 56  
151 (Standard Deviation (SD) 16) years, 46% were retired, and 60% reported having  
152 Crohn's disease. All other participants' characteristics can be found in **Table 1**. The  
153 seven participants who did not complete the retest survey were mostly male (71%),

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3 154 their mean age was 55 (SD 12) years, 43% were employed, and 57% reported having  
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5 155 UC (**Appendix 3**).

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8 156 *Acceptability and missingness*: At test, the level of data missingness was less than 5%  
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10 157 across most individual numeric variables, with few exceptions (**Appendix 4**). There  
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13 158 were no missing data for the number of hospitalisations and days off-work due to IBD.

### 159 **Validation phase**

160 *Reliability*: Test-retest reliability of self-reported quantities of service use is shown in  
161 **Table 2**. The number of hospital admissions and working days off-work due to IBD  
162 reported by the participants had excellent reliability (ICC=1.00 and ICC=0.96,  
163 respectively). Good to excellent reliability was estimated for the number of outpatients  
164 visits to most secondary care specialists (ICC=0.85-1.00). However, there was poor  
165 to moderate reliability for the number of primary care visits (ICC=0.40-0.55). Intake  
166 quantities for most medication groups had good to excellent reliability (ICC=0.77-  
167 1.00), while diagnostics, except for magnetic resonance imaging scans (ICC=0.37),  
168 demonstrated moderate to good reliability (ICC=0.65-0.85). When aggregated, the  
169 diagnostics category had the highest reliability (ICC=0.86), and primary care visits  
170 category had the lowest reliability (ICC=0.58).

### 171 **IBD-related costs**

172 The mean annual IBD-related costs of study participants are presented in **Table 3** and  
173 their distribution in **Figure 2**. Extrapolating the 3-month costs from our study to yearly  
174 costs yielded mean annual costs of £5,926 (Standard Error (SE) £738) and £5,491  
175 (SE £818) per participant at test and retest, respectively, with a mean difference of  
176 £435 (SE £513). Healthcare costs accounted for the most significant part of IBD-  
177 related costs, with over 84% of all incurred costs at both test (£5,066 (SE £681)) and

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3 178 retest (£4,622 (SE £734)) with a mean difference of £444 (SE £490). Productivity loss  
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5 179 due to IBD accounted for about 9%-10% of the overall costs both at test (£531 (SE  
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7 180 £256)) and retest (£558 (SE £263)), with a mean difference of £28 (SE £78).  
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9 181 Participants' out-of-pocket expenses accounted for about 5%-6% at both test (£329  
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11 182 (SE £52)) and retest (£311 (SE £60)), with a mean difference of £19 (SE £40). The  
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13 183 overall mean annual IBD-related costs across test and retest were £5,708 (SE £1102).  
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15 184 The mean annual IBD-related costs of study participants were also stratified by IBD  
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17 185 diagnosis (**Appendix 5**).  
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## 187 Discussion

188 To the best of our knowledge, this is the first study to develop a comprehensive self-  
189 report resource use questionnaire designed for patients with IBD in the UK.

190 IBD-RUQ is unique as it provides a single, IBD-specific, all-inclusive self-reported  
191 instrument to measure IBD-related resources and costs. IBD-RUQ complements  
192 previous instruments and studies in IBD that focused on work productivity and activity  
193 impairment<sup>30</sup>, health-related quality of life<sup>31-33</sup>, and quality of care<sup>34</sup>. Previous costing  
194 and cost-effectiveness studies of IBD in the UK have used medical records<sup>22</sup>, non-  
195 published patients' questionnaires and medical notes<sup>35</sup>, patient diaries and hospital  
196 records<sup>36</sup> to quantify healthcare resource use. None of those existing tools included  
197 all categories of costs related to healthcare resource use, employment loss, and  
198 personal expenses.

199 Test-retest analyses also showed that IBD-RUQ is a reliable and valid instrument that  
200 can be used to measure service use and costs of adults living with IBD. Most sections  
201 of the IBD-RUQ achieved moderate to excellent test-retest reliability. In particular,  
202 outpatient hospital appointments and diagnostics sections showed good reliability.  
203 Visits to primary care services showed moderate overall reliability, with visits to a  
204 general practitioner or a nurse having poor reliability. We speculate this could be due  
205 to captured genuine service use differences in the two-week gap between test and  
206 retest. The suboptimal reliability of magnetic resonance imaging scan use could be  
207 due to either to confusion with the computer tomography use among participants or  
208 the possibility of the magnetic resonance imaging scan being performed in the time  
209 gap between the two assessments for assessing the participants' disease activity or  
210 intestinal inflammation.

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3 211 Medication use demonstrated overall good reliability, which was expected, given that  
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5 212 people with IBD regularly take medications to avoid disease relapses. Changes in  
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7 213 healthcare use, are also possible within the two weeks between test and retest  
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9 214 completion, which explains why reliability ranged from moderate to excellent per  
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11 215 medication group and type. Specifically, the substantial use of corticosteroids among  
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13 216 our participants, possibly, indicates that the majority of participants were experiencing  
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15 217 flare-ups at the time of the study. This may have also resulted in higher average cost  
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17 218 for medication and overall IBD costs in our study. The focus in the present study has  
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19 219 been on the reliability of the IBD-RUQ and, therefore, disease activity was not  
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21 220 recorded as it was not essential. In applications of the IBD-RUQ, researchers should,  
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23 221 however consider using disease activity validated scales for CD<sup>37</sup> and UC<sup>38</sup> in  
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25 222 conjunction with IBD-RUQ to enable interpretation of the reported resource use and  
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27 223 costs. Hospitalisations and time-off work reporting had excellent and good reliability,  
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29 224 respectively, supporting the hypothesis that more significant disease episodes (such  
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31 225 as hospital admissions) are likely to be remembered.

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33 226 Our results also suggested that older patients with IBD incur lower costs than younger  
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35 227 patients. We estimated that participants of 55 years of age or less, on average,  
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37 228 incurred 20% higher IBD-related total costs primarily due to costs associated with time  
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39 229 taken off-work due to IBD symptoms. People with IBD in employment accrued 8%  
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41 230 higher costs than those not in employment. Future studies could consider recording  
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43 231 actual work-related income and measuring workplace presenteeism to precisely  
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45 232 assess productivity loss due to IBD.

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47 233 At the time of our study, most likely, participants were at the mild end of IBD spectrum  
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49 234 as they reported high aminosalicylates use and fewer hospitalisations. Therefore, it is  
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51 235 reasonable to assume that patients with more severe IBD were less likely to participate  
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3 236 in the survey. Higher hospitalisation rates, and increased medication use and doses  
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5 237 would result in higher healthcare costs. As reported, the mean total annual health care  
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7 238 expenditure for patients with CD was lower than those with UC. This difference was  
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10 239 driven by higher aminosalicylates use, which is the first treatment option for UC and a  
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12 240 less often option in CD. In line with previous studies, CD patients in the study reported  
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14 241 higher use of outpatient appointments, diagnostics and incurred higher out-of-pocket  
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16 242 expenses<sup>6,18</sup>.

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19 243 Our study has a number of limitations. First, although in this study, the reliability, and  
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21 244 content and face validity of IBD-RUQ have been established, bias in self-reported  
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23 245 questionnaires may influence the validity of our results. To address this, our next step  
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25 246 is to assess the questionnaire's validity by comparing the self-reported hospital care  
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27 247 use with hospital administrative data in a sub-sample of NHS IBD outpatients. Second,  
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29 248 we did not record the completion time of IBD-RUQ and recognise that it may require  
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31 249 considerable time. Future studies using the IBD-RUQ could measure its completion  
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33 250 time to inform implementation plans. Also we did not include in the medication section  
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35 251 of IBD-RUQ, the widely used, in people with IBD, generic mesalamine and opioids.  
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37 252 We advise future users to modify IBD-RUQ to also include these drugs in the  
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39 253 medication section. Third, our test-retest sample was small, and while useful to study  
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41 254 questionnaire reliability and its costing, the results may not generalise well. Fourth, the  
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43 255 study was limited to people living in the UK and to the circumstances at time of  
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45 256 questionnaire development. Nevertheless, all items of healthcare resource use,  
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47 257 employment and personal expenses included in this tool should generalise well to the  
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49 258 IBD population internationally. Hence, we encourage users to adjust the specification  
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51 259 of healthcare items to local settings and clinical guidelines.  
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260 Lastly, as this study was carried out before COVID-19 pandemic (March and April  
261 2019), telephone and video consultations were not included. Future versions and  
262 applications of the IBD-RUQ, should include telephone, video and face-to-face  
263 consultation services separately to allow the accurate calculation of their costs.

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3 264 **Conclusion**  
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6 265 IBD-RUQ is a reliable and valid self-reported measure of resource utilisation and costs  
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8 266 in adults with IBD. It can be used to estimate healthcare use, productivity losses and  
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10 267 patient-related costs in people living with IBD. It is available for use in clinical trials and  
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12 268 other research studies to assess the costs of IBD and cost-effectiveness of IBD  
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14 269 interventions. We invite our colleagues to utilise it.  
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25 273 facilitated finding volunteers.  
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**Table 1: Participants characteristics at test and retest**

	<b>Test questionnaire</b>	<b>Retest questionnaire</b>
	<b>(n=55)</b>	<b>(n=48)</b>
<b>Age (years), mean (SD)</b>	55.8 (15.9)	55.9 (16.5)
<b>Sex, women (%)</b>	33 (60.0)	31 (64.6)
<b>Self-reported diagnosis, n (%)</b>		
Crohn's disease or Crohn's colitis	31 (56.4)	29 (60.4)
Ulcerative colitis	22 (40.0)	18 (37.5)
IBD Unclassified	2 (3.6)	1 (2.1)
<b>Employment status, n (%)*</b>		
Employed (inc. zero-hour contract or self-employed)	21 (38.2)	18 (37.5)
Retired	23 (41.8)	22 (45.8)
Student	3 (5.5)	3 (6.3)
Other †	5 (9.1)	4 (8.3)

Notes:

\* There are three missing observations at test and one at retest in the employment status category;

† Including unemployed and homemaker

**Table 2: Test-retest reliability of IBD-RUQ in adult people with IBD**

Type of resource use in the last <b>THREE MONTHS</b>	Test (n=48)	Retest (n=48)	Test-Retest (n=48)
	Mean (SD)	Mean (SD)	ICC (95% CI)
<b>Outpatient Visits/Contacts (Primary Care)</b>			
General Practitioner	0.7 (1.1)	0.6 (1.1)	0.40 <sup>†</sup> (0.13-0.62)
General Practice Nurse	0.7 (1.6)	0.3 (0.7)	0.47 <sup>†</sup> (0.22-0.66)
Pharmacist	1.5 (2.1)	1.1 (1.6)	0.55 <sup>‡</sup> (0.48-0.84)
<b>Total</b>	<b>2.9 (3.7)</b>	<b>2.0 (2.4)</b>	<b>0.58<sup>‡</sup> (0.35-0.74)</b>
<b>Outpatient Visits/Contacts (Secondary Care)</b>			
Gastroenterologist	0.5 (0.5)	0.4 (0.6)	0.62 <sup>‡</sup> (0.41-0.77)
Colorectal Surgeon	0.1 (0.5)	0.1 (0.4)	0.71 <sup>‡</sup> (0.54-0.83)
Rheumatologist	0.1 (0.3)	0.1 (0.2)	0.85 <sup>§</sup> (0.76-0.92)
Dietician	0.1 (0.3)	0.1 (0.3)	1.00 <sup>  </sup> (1.00-1.00)
Psychologist	0.1 (0.4)	0.1 (0.7)	0.88 <sup>§</sup> (0.80-0.93)
Accident & emergency staff	0.3 (0.8)	0.2 (0.8)	0.74 <sup>‡</sup> (0.58-0.84)
IBD nurse	0.7 (1.3)	0.7 (1.4)	0.84 <sup>§</sup> (0.73-0.91)
Advice Line	0.5 (1.2)	0.6 (1.5)	0.88 <sup>§</sup> (0.79-0.93)
<b>Total</b>	<b>2.3 (2.5)</b>	<b>2.3 (3.1)</b>	<b>0.84<sup>§</sup> (0.73-0.91)</b>
<b>Diagnostic procedures and tests</b>			
Computerised tomography scan	0.1 (0.3)	0.1 (0.3)	0.73 <sup>‡</sup> (0.56-0.84)
Magnetic resonance imaging scan	0.1 (0.2)	0.1 (0.2)	0.37 <sup>†</sup> (0.10-0.59)
Colonoscopy	0.1 (0.2)	0.1 (0.2)	0.65 <sup>‡</sup> (0.45-0.79)
Upper gastrointestinal endoscopy	0.1 (0.1)	0.1 (0.2)	0.66 <sup>‡</sup> (0.47-0.79)
Ultrasound	0.1 (0.2)	0.1 (0.3)	0.74 <sup>‡</sup> (0.58-0.85)

Stool test (e.g. faecal calprotectin test)	0.4 (0.6)	0.4 (0.6)	0.85 <sup>§</sup> (0.75-0.91)
Blood test	1.7 (1.8)	1.5 (1.6)	0.78 <sup>§</sup> (0.64-0.87)
<b>Total</b>	<b>2.3 (2.2)</b>	<b>2.2 (2.1)</b>	<b>0.86<sup>§</sup> (0.76-0.92)</b>
<b>Medication type (number of tablets/suppositories/injections)</b>			
Aminosalicylates – tablet	146.4 (177.4)	131.3 (159.7)	0.77 <sup>§</sup> (0.62-0.86)
Aminosalicylates – suppository/foam	17.5 (48.9)	14.0 (36.1)	0.84 <sup>§</sup> (0.73-0.91)
Immunosuppressants – tablet	36.8 (75.3)	35.0 (71.1)	0.93 <sup>  </sup> (0.88-0.96)
Steroids - tablet	56.0 (158.9)	38.5 (152.0)	0.70 <sup>‡</sup> (0.53-0.82)
Steroids – injection/infusion	0.1 (0.2)	3.5 (24.2)	0.65 <sup>‡</sup> (0.44-0.73)
Supplements – tablet	60.1 (110.6)	37.6 (79.7)	0.81 <sup>§</sup> (0.67-0.90)
Biologics - injection/suppository	0.7 (1.7)	0.7 (1.7)	1.00 <sup>  </sup> (1.00-1.00)
<b>Total</b>	<b>317.5 (304.2)</b>	<b>260.6 (295.2)</b>	<b>0.77<sup>§</sup> (0.62-0.87)</b>
<b>Hospitalisations</b>	<b>0.1 (0.2)</b>	<b>0.1 (0.2)</b>	1.00 <sup>  </sup> (1.00-1.00)
<b>Employment</b>			
Time off work (days) due to IBD	1.1 (3.5)	1.1 (3.6)	0.96 <sup>  </sup> (0.92-0.98)

Notes: \*Where a resource use item was missing, this was imputed using the mean for the same resource use item for other users in the same category at the same assessment point; \*\*Reliability classification of the ICC estimate (based on the 95% confident interval): values less than 0.5: poor (†); between 0.50-0.75: moderate (‡); between 0.76-0.90: good (§), greater than 0.90: excellent (||).



**Table 3: Mean annual health care, productivity loss and out-of-pocket costs (UK£)**

Resource Use category	Test (n=48)	Retest (n=48)	Cost difference (Test-Retest, no adjustment)	Mean cost (Test, Retest)
	Mean (SE)	Mean (SE)	Mean difference (SE*)	Mean (SE)
<b>Outpatient Visits/Contacts (Primary Care)</b>				
General Practitioner	125.0 (27.4)	104.5 (27.7)	20.5 (30.2)	114.7 (39.0)
General Practice Nurse	35.2 (11.7)	16.7 (5.0)	18.5 (9.1*)	25.9 (12.7)
Pharmacist	103.7 (21.1)	75.6 (16.1)	28.1 (17.7)	89.6 (26.5)
<b>Total</b>	<b>263.9 (46.9)</b>	<b>196.7 (36.8)</b>	<b>67.1 (39.2)</b>	<b>230.3 (59.6)</b>
<b>Outpatient Visits/Contacts (Secondary Care)</b>				
Gastroenterologist	275.6 (47.2)	240.0 (56.2)	35.6 (45.5)	257.8 (77.7)
Colorectal Surgeon	75.8 (37.9)	54.2 (31.9)	21.7 (26.6)	65.0 (49.5)
Rheumatologist	46.8 (34.5)	31.2 (21.8)	15.6 (15.6)	39.0 (40.9)
Dietician	26.3 (12.7)	26.3 (12.7)	0.0 (0.0)	26.3 (18.0)
Psychologist	16.5 (16.5)	27.5 (27.5)	-11.0 (11.0)	22.0 (32.1)
Accident & Emergency staff	79.1 (32.2)	65.7 (33.6)	13.4 (23.9)	72.4 (46.5)
IBD nurse	189.8 (49.2)	197.4 (54.3)	-7.6 (29.8)	193.6 (73.2)
Advice Line	51.3 (19.4)	67.4 (24.6)	-16.1 (11.0)	14.8 (22.3)
<b>Total</b>	<b>761.3 (103.7)</b>	<b>709.7 (128.5)</b>	<b>51.6 (81.7)</b>	<b>735.5 (132.0)</b>



<b>Diagnostic procedures and tests</b>				
Computerised tomography scan	75.0 (36.3)	18.8 (9.1)	56.3 (30.3)	46.9 (37.4)
Magnetic resonance imaging scan	58.5 (40.9)	87.8 (49.6)	-29.3 (51.0)	73.1 (64.3)
Colonoscopy	285.3 (161.1)	285.3 (161.1)	0.0 (135.9)	285.3 (227.9)
Upper gastrointestinal endoscopy	132.8 (132.8)	265.5 (185.7)	-132.8 (132.8)	199.1 (228.3)
Ultrasound	38.5 (21.7)	38.5 (28.5)	0.0 (18.3)	38.5 (35.8)
Stool test (i.e. faecal calprotectin test)	42.9 (9.8)	45.5 (10.6)	-2.7 (5.6)	44.2 (14.5)
Blood test	74.8 (11.4)	65.5 (10.1)	9.3 (7.2)	70.1 (15.2)
<b>Total</b>	<b>707.6 (215.5)</b>	<b>806.7 (259.3)</b>	<b>-99.1 (202.2)</b>	<b>757.2 (337.2)</b>
<b>Medication</b>				
Aminosalicylates	1083.5 (216.8)	924.6 (184.6)	158.9 (137.9)	1004.0 (284.7)
Immunosuppressants	7.2 (2.2)	62.9 (38.3)	-55.7 (38.5)	35.1 (38.4)
Steroids	622.6 (278.5)	49.0 (24.1)	573.6 (273.9*)	335.8 (279.5)
Dietary supplements	13.9 (3.6)	10.5 (2.7)	3.5 (2.2)	12.2 (4.5)
Biologics	1511.8 (555.7)	1767.7 (598.3)	-256.0 (256.3)	1639.8 (816.6)
<b>Total</b>	<b>3239.0 (633.3)</b>	<b>2814.7 (652.8)</b>	<b>424.3 (432.0)</b>	<b>3026.9 (909.5)</b>
<b>Hospitalisations</b>				
Hospital admissions due to IBD	93.8 (65.6)	93.8 (65.6)	0.0 (0.0)	93.8 (92.8)
<b>Total healthcare costs</b>	<b>5065.6 (680.5)</b>	<b>4621.7 (733.6)</b>	<b>444.0 (489.5)</b>	<b>4843.7 (1000.6)</b>

<b>Productivity loss due to IBD</b>				
Productivity loss cost due to IBD**	530.9 (255.5)	558.4 (263.2)	-27.5 (77.8)	544.6 (366.7)
<b>Patient out-of-pocket expenses</b>				
Symptom management	55.1 (15.9)	73.0 (23.7)	-17.9 (111.5)	64.0 (28.6)
Products, complementary & alternative Therapies	181.8 (41.5)	133.5 (33.2)	48.3 (24.9)	157.6 (53.2)
Health appointment related travel	92.4 (19.0)	104.0 (30.9)	-11.7 (17.3)	98.2 (36.3)
<b>Total patient-related costs</b>	<b>329.2 (52.2)</b>	<b>310.5 (60.4)</b>	<b>18.7 (39.9)</b>	<b>319.9 (79.8)</b>
<b>Overall costs</b>	<b>5925.7 (738.3)</b>	<b>5490.6 (817.9)</b>	<b>435.1 (512.8)</b>	<b>5708.2 (1101.9)</b>

Notes:

\* P-value <0.05 (using paired t-test)

\*\* Incurred by 9 and 7 participants in employment in the test and the re-test measurement occasions, respectively. An overview of the content included in each (sub)category can be found in Appendix 1.

**AUTHORS' REPLY:**

We thank the reviewers and editor for their time in reviewing the manuscript and for their helpful comments. Please see below our responses to individual points.

**Reviewer: 1**

Comments to the Author

The paper is well written. There are a few questions arising from this paper:

1) What is the justification for having a disease specific questionnaire, when generic tools would cover all the relevant categories. Does a complete list of all possible drug brands aid or deter patients in completing a full list? With changes in drug formulations and brands this will need constant updating

**AUTHORS' REPLY:**

We have noted: "The most used method of obtaining data on resource use and costs in clinical research is through self-report questionnaires such as the widely used Client Service Receipt Inventory (*Beecham, J. and Knapp, M., 2015. Client Service Receipt Inventory*) aiming at specific resource use categories). However, such generic questionnaires do not include particular categories such as travel expenses for healthcare appointments and cost for purchases of medication, products, supplements and services specifically related to people with IBD." (lines 29-34)

As Resource Use Questionnaires are designed to capture information regarding all key resource use and/or costs, we included a comprehensive list of medications for IBD currently prescribed in the UK. Also, the electronic version of the questionnaire uses skipping patterns when certain types of medications are not used (e.g. biologics) so participants only answer the sections relevant to them.

The addition of "In the past three months, have you been prescribed any other medication?" question in the revised version of IBD-RUQ will allow participants to list any other medications (e.g. newly approved ones) and periodic updating will be beneficial.

2) How was the period of 3 months decided upon? What evidence is there that longer periods increase risk of omission?

**AUTHORS' REPLY:**

It is well known that longer recall-periods are subject to errors of omissions and underreporting while a shorter recall period can result in missing out on rare but expensive events (*Janssen LM, Drost RM, Paulus AT, et al. Aspects and Challenges of Resource Use Measurement in Health Economics: Towards a Comprehensive Measurement Framework. PharmacoEconomics. 2021;39(9):983-993*). We opted for a three-month recall period as likely optimal in the context of a chronic condition such as the IBD (*Icks A, Dittrich A, Brüne M, et al. Agreement found between self-reported and health insurance data on physician visits comparing different recall lengths. Journal of clinical epidemiology. 2017;82:167-172*). (lines 143-146)

3) Questions re contact with doctors do not specify whether a clinic appointment face to face, or telephone/online appointment, or a brief phone call for admin purposes etc. Costs must differ greatly

**AUTHORS' REPLY:**

We agree with the reviewer and have noted in discussion that applications of IBD-RUQ should allow telephone, video and face-to-face consultation services will be listed separately to also allow the accurate calculation of their costs. (lines 261-263)

1  
2  
3  
4 4) Many drugs have a tick box for 1, but then have 'other' category with no box. Patients may assume  
5 that the 'correct' dose is 1 tablet, when often it is a much larger dose.

6 **AUTHORS' REPLY:**

7 We have included medication dosage as recommended by the UK (MHRA) and European  
8 (EMA) government agencies. However, participants are still able to indicate if they are taking  
9 different dosages from those listed by specifying the exact dose (free text) next to the "other"  
10 option.  
11

12  
13 5) There are exhaustive lists of brands for many drugs but not for calcium and vitamin D. Only Adcal  
14 D. Why??

15 **AUTHORS' REPLY:**

16 Adcal D3 is the most prescribed brand for calcium and vitamin D. Other brands such as  
17 Accrete are usually prescribed to other type of population (osteoporosis). We note that a  
18 further section where participants can add any other drugs (not currently listed) should be  
19 considered in IBD-RUQ application.  
20

21  
22 6) Ostomy supplies - costs vary widely and exact device and frequency of change would help to clarify  
23 costs

24 **AUTHORS' REPLY:**

25 An assumption that a (drainable – most common) stoma bag is replaced three times a week  
26 can be made. The cost for a stoma will be derived as the average price of stoma bags used  
27 in the NHS.

28 ([http://www.drugtariff.nhsbsa.nhs.uk/#/00465833DB\\_1/DB00465168/COLOSTOMY%20BAGS](http://www.drugtariff.nhsbsa.nhs.uk/#/00465833DB_1/DB00465168/COLOSTOMY%20BAGS))  
29

30  
31 7) There is no opportunity to specify prescribed dietary supplements

32 **AUTHORS' REPLY:**

33 Dietary supplements (except of vitamin and minerals listed in the questionnaire) are not  
34 prescribed on the NHS. "Dietary supplements" to be deleted from "prescribed medication"  
35 section in the next version of IBD-RUQ.  
36

37  
38 8) For inpatient stays - is it sufficiently clear that only the days in hospital during the previous three  
39 months should be included.

40 **AUTHORS' REPLY:**

41 Question about inpatient stays includes in bold the recall period: "**In the last three (3) months,**  
42 have you been admitted into hospital for one or more nights".  
43

44  
45 9) It is not possible for patients to specify if they took a drug for only part of the three months. This  
46 would be common (eg prednisolone) and in that case the dose would vary week on week

47 **AUTHORS' REPLY:**

48 Yes, participants can record by adding a free text if the dose did vary week on week by  
49 selecting the "other" option on the "Number of times and frequency of dosage intake in the last  
50 3 months" medication section.  
51

52  
53 10) Are medical costs incurred for non-IBD illnesses included or excluded.

54 **AUTHORS' REPLY:**

55 Only IBD-related costs (medical costs incurred for non-IBD illnesses are excluded) are  
56 included as noted in RUQ questions' wording.  
57  
58  
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1  
2  
3 11) External validation of data available through NHS records -eg hospital stays, clinic appointments,  
4 and drug prescribing should be used for external validation

5 **AUTHORS' REPLY:**

6 We agree with the reviewer and have noted "although in this study, the reliability, and content  
7 and face validity of IBD-RUQ have been established, bias in self-reported questionnaires may  
8 influence the validity of our results. To address this, our next step is to assess the  
9 questionnaire's validity by comparing the self-reported hospital care use with hospital  
10 administrative data in a sub-sample of NHS IBD outpatients." (lines 243-247)

11  
12  
13 **Reviewer: 2**

14  
15 **Comments to the Author**

16 This is a worthy attempt at addressing IBD resource utilisation and in that sense addresses an  
17 important unmet need.

18 Please clarify the following:

19  
20  
21 1. Please add a few lines on the IBD-Boost programme which is not known to the generalist readership.  
22 This will enable readers to contextualise the cohort invited to participate.

23 **AUTHORS' REPLY:**

24 Done. We have noted that "The study is part of the broader IBD-BOOST (<https://ibdboost.net>)  
25 research programme, focusing on the development and evaluation of management  
26 interventions to improve the well-being of people with IBD by relieving the most common and  
27 troublesome chronic symptoms of fatigue, pain and urgency and enhancing quality of life."  
28 (lines 39-43)

29  
30 2. Was disease activity consciously not recorded using any tool? I notice you do allude to this in the  
31 discussion and appropriately recognise that this is a limitation. Whilst this in itself is not a flaw, please  
32 explain if this was an omission or simply because of the study design

33 **AUTHORS' REPLY:**

34 The focus of this RUQ test-retest reliability study was on IBD-RUQ itself with very limited  
35 patient characterisation. However, researchers should consider adding more detailed patient  
36 characterisation in conjunction with IBD-RUQ to facilitate interpretation of the reported  
37 resource use and costs.

38  
39  
40 3. In your discussion you state that MRI scans are infrequently used and that there could be confusion  
41 with CT scans. Is it correct that MRI scans are infrequently used? The use of intestinal U/S is not yet  
42 cemented in UK practice, so how do you reconcile with this? It is possible that your patients had fewer  
43 scans during the period tested or may have had their scheduled appointment during this period etc  
44 but please clarify this comment.

45 **AUTHORS' REPLY:**

46 We have added that: "The suboptimal reliability of magnetic resonance imaging scan use  
47 could be due to either to confusion with the computer tomography use among participants or  
48 the possibility of the magnetic resonance imaging scan being performed in the time gap  
49 between the two assessments for assessing the participants' disease activity or intestinal  
50 inflammation". (lines 206-210)

51  
52  
53 4. Also, is it really true that patients in remission consistently take their medication even when in  
54 remission?

55 **AUTHORS' REPLY:**

56 Particular medications for IBD (such as aminosalicylates, immunomodulators and biologics)  
57 are used regularly by people with IBD to maintain remission and, therefore, expected to be  
58 accurately reported.

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7 5. Or that flare up symptoms are "rare" in IBD?

8 **AUTHORS' REPLY:**

9 We have rephrased this statement: "The substantial use of corticosteroids among our  
10 participants, possibly, indicates that the majority of participants were experiencing flare-ups at  
11 the time of the study." (lines 215-217)

12  
13 6. You state that participants were more likely to be at the mild end of the IBD spectrum as they  
14 reported higher use of aminosalicylates and fewer hospitalisations. How do you assume that patients  
15 with more severe IBD were less likely to participate in the survey? Indeed, did you record this activity  
16 to be able to substantiate this comment? Or would you suggest that the questionnaire may not be  
17 applicable in the moderate to more severe disease spectrum?

18 **AUTHORS' REPLY:**

19 In this study the focus is on IBD-RUQ test-retest reliability of self-reported resource use rather  
20 than substantive costs valuation. We have noted that: "In applications of the IBD-RUQ,  
21 researchers should, however consider using disease activity validated scales for CD and UC  
22 in conjunction with IBD-RUQ to enable interpretation of the reported resource use and costs."  
23 (lines 220-223)

24  
25  
26 7. There did appear to be a substantial use of corticosteroids among your participants. Please  
27 comment and explain how that might relate to disease activity and resource utilisation?

28 **AUTHORS' REPLY:**

29 We have noted that: "The substantial use of corticosteroids among our participants, possibly,  
30 indicates that the majority of participants were experiencing flare-ups at the time of the study.  
31 This may have also resulted in higher average cost for medication and overall IBD costs in  
32 our study." (lines 215-218)

33  
34 However, we would refrain from detailed interpretation of findings in view of limited study size  
35 and patient characteristics.

36  
37  
38 8. Strikingly it is unclear whether there are differences between people with Crohn's disease and  
39 ulcerative colitis. Additionally, what are the differences in 5ASA use among people with Crohn's  
40 disease and ulcerative colitis? That could have a bearing on your observations.

41 **AUTHORS' REPLY:**

42 We have noted that: "the mean total annual health care expenditure for patients with CD was  
43 lower than those with UC. This difference was driven by higher aminosalicylates use, which is  
44 the first treatment option for UC and a less often option in CD." (lines 238-240)

45  
46 However, due to the small size of our study and the disproportionate representation of IBDs  
47 (CD=29 and UC=18) we have to be careful when making direct comparisons between  
48 participants with CD and UC. Larger cross-sectional studies are required to enable us drawing  
49 safe conclusions between different types of IBD.

50  
51  
52 9. Did you not enquire regarding the use of generic mesalamine?

53 **AUTHORS' REPLY:**

54 Mesalamine was not included in the questionnaire as a generic (not aware of its availability at  
55 the time of designing the questionnaire) but as a brand-name drug of Asacol, Pentasa,  
56 Mezavant, Salofalk and Octasa. This has been acknowledged in limitations: "Also we did not  
57 include in the medication section of IBD-RUQ the widely used, in people with IBD, generic  
58 mesalamine and opioids. We advise future users to modify IBD-RUQ to also include these  
59 drugs in the medication section." (lines 250-253)



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6 10. Was there no enquiry regarding opioid use?

7 **AUTHORS' REPLY:**

8 This is an omission on our part as opioids could be prescribed to IBD patients with chronic  
9 abdominal pain. This has been acknowledged in limitations: "Also we did not include in the  
10 medication section of IBD-RUQ the widely used, in people with IBD, generic mesalamine and  
11 opioids. We advise future users to modify IBD-RUQ to also include these drugs in the  
12 medication section." (lines 250-253)

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16 11. You include subscription to a gym as an out-of-pocket expense. Is it ever likely that it will not be  
17 an out-of-pocket expense or does it not in fact align with healthy living? I am unable to understand  
18 how this question fits into the framework of IBD resource utilisation.

19 **AUTHORS' REPLY:**

20 Physical activity is used to help reduce stress in people with inactive or mild IBD. Exercise  
21 may have beneficial effects on both the disease course and the quality of life of patients with  
22 IBDs (Engels, M., Cross, R.K. and Long, M.D., 2018. *Exercise in patients with inflammatory  
23 bowel diseases: current perspectives. Clinical and Experimental Gastroenterology, 11, p.1.*)

24  
25  
26 12. The study may provide an excellent opportunity for further iterations or validation in various  
27 cohorts. In your discussion please explain next steps and opportunities with further research and also  
28 how you see this integrate into clinical practice or service evaluation.

29 **AUTHORS' REPLY:**

30 We have noted that: "although in this study, the reliability and content and face validity of IBD-  
31 RUQ have been established, bias in self-reported questionnaires may influence the validity of  
32 our results. To address this, our next step is to assess the questionnaire's validity by  
33 comparing self-reported and hospital administrative data in a sub-sample of NHS IBD  
34 outpatients." (lines 243-247)

35  
36  
37 Thank you for taking the time to consider this and congratulations on a novel and interesting study.

38  
39 Editor(s)' Comments to Author

40  
41 Please include a section - what is known, what this study adds, implications for practice - please see  
42 instructions for authors

43  
44  
45 **AUTHORS' REPLY:**

46 Done.  
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6 • **What is already known on this topic**

7 Self-report resource use questionnaires are lacking in IBD and, therefore, particular  
8 resources often used by this patient population such as IBD medication, products,  
9 supplements and services remain unidentified.

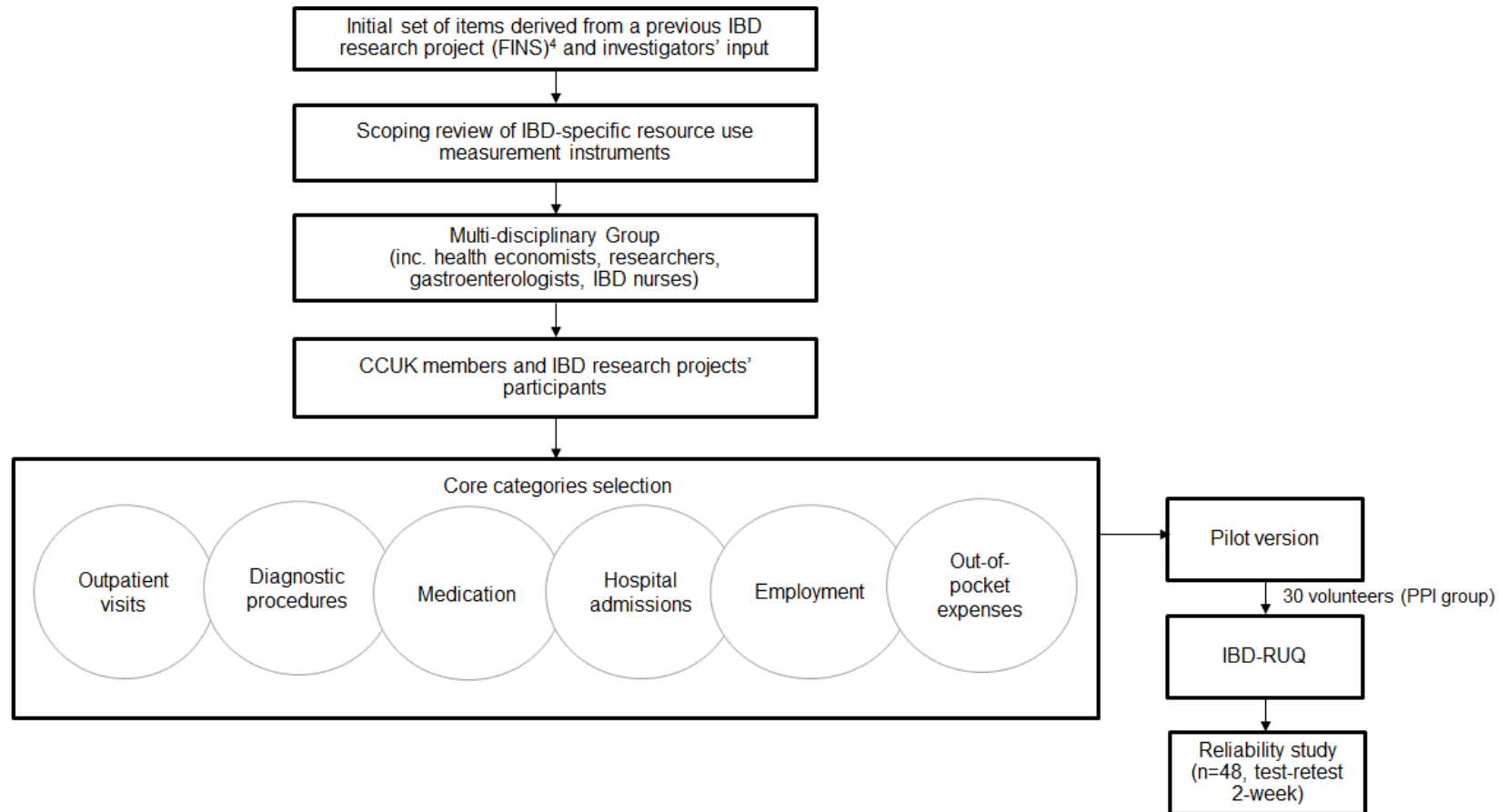
10  
11 • **What this study adds**

12 We present the first IBD-Resource Use Questionnaire (IBD-RUQ) to reliably measure  
13 resources and costs of patients with IBD from the perspectives of health services,  
14 patients and the society.

15  
16 • **How this study might affect research, practice or policy**

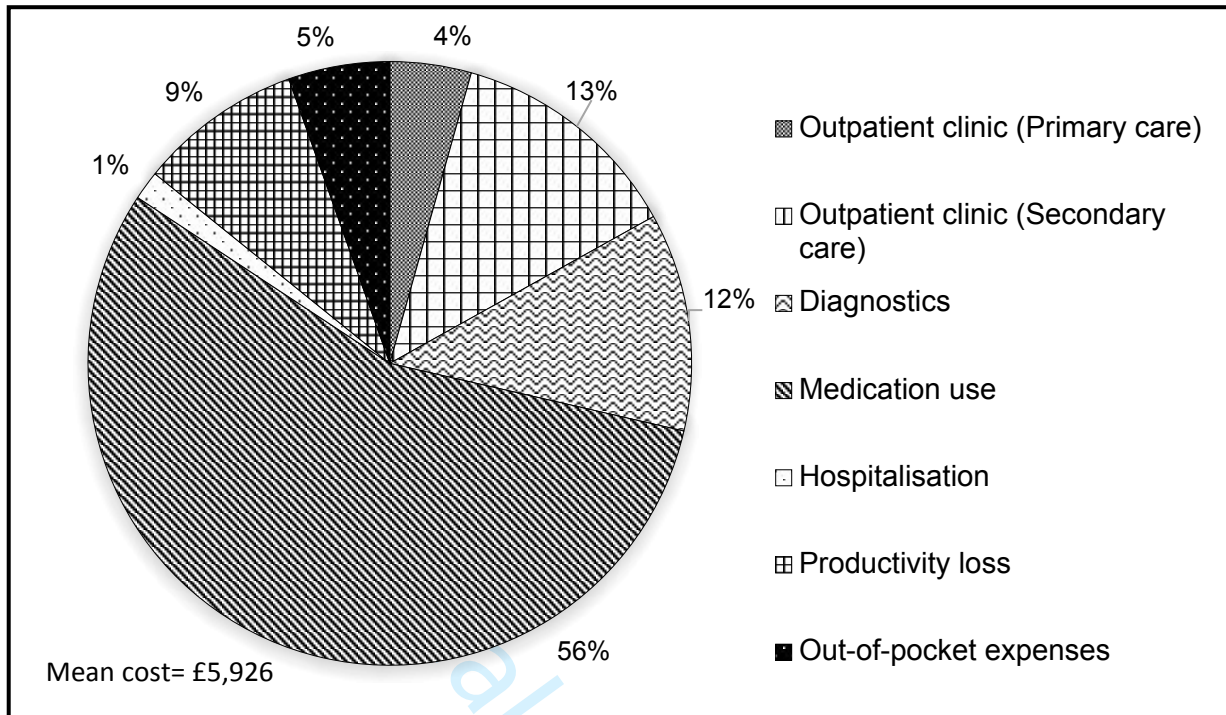
17 The IBD-RUQ can be used in research studies to capture resource utilisation and assess  
18 IBD-related costs.  
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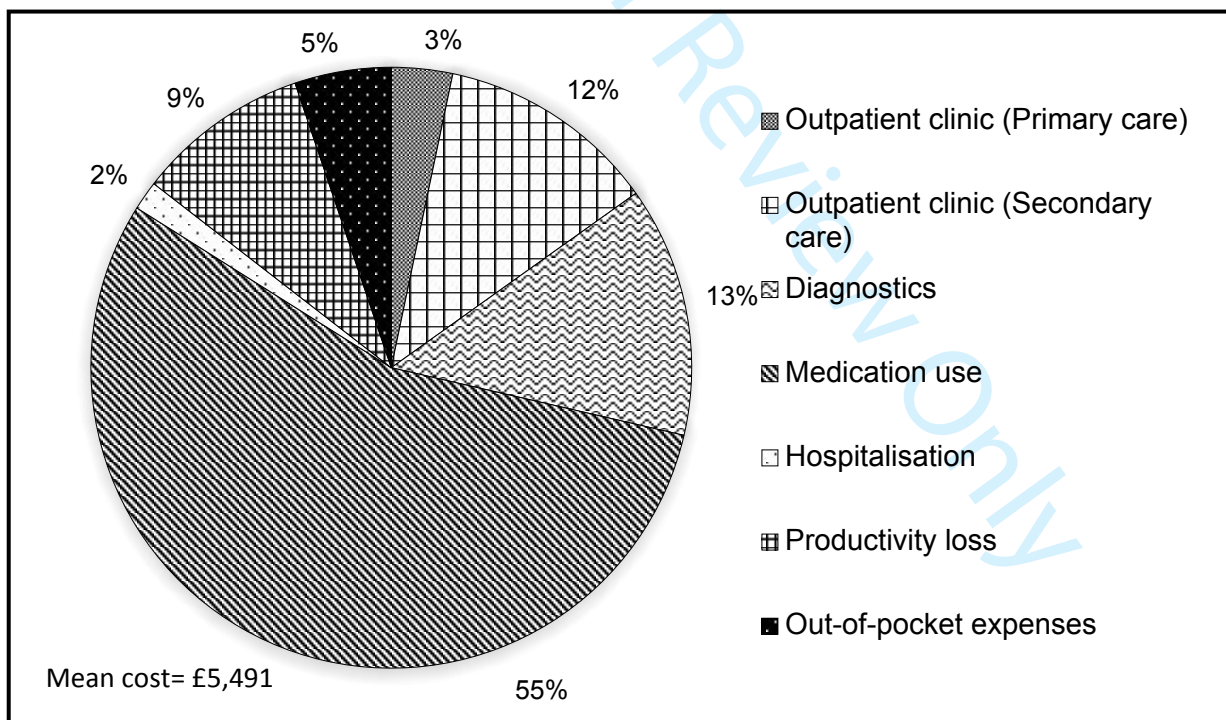
**Abbreviations:**

IBD: Inflammatory Bowel Disease; FINS: Faecal incontinence Intervention Study; CCUK: Crohn's and Colitis UK; PPI: Patient and Public Involvement; IBD-RUQ: Inflammatory Bowel Disease Resource Use Questionnaire

a) Distribution of IBD costs at Test



b) Distribution of IBD costs at Retest



## Appendix 1: The IBD-Resource Use Questionnaire

# The IBD Resource Use Questionnaire

## RESOURCE USE

### 1 OUTPATIENT VISITS

In the last **three (3) months**, have you been seen by or contacted any of the following health professionals for your inflammatory bowel disease? Please tick YES or NO to each of the following

	Yes	No	If yes, number of visits or contacts in the last 3 months
<b>Specialist doctor (Consultant or team):</b>			
Gastroenterologist			
Colorectal surgeon			
Rheumatologist			
Other specialist doctor (please specify below):			

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Other health professional:	Yes	No	If yes, number of visits or contacts in the last 3 months
	IBD nurse (by phone or in person)		
IBD advice line / helpline (by phone or by email)			
Stoma nurse			
Accident and Emergency (A&E) staff			
General Practitioner (GP)			
General Practice nurse			
Dietician			
Psychologist			
Pharmacist (by phone or in person)			
Other (please specify below):			

## 2. DIAGNOSTIC PROCEDURES

In the last **three (3) months**, have you had any of the following diagnostic tests or procedures for your inflammatory bowel disease? Please tick yes or no for each.

Test	If yes, number of tests in the <b>last 3 months</b>		
	Yes	No	
CT-Scan			
MRI-scan			
Colonoscopy			
Upper GI Endoscopy			
Ultrasound			
Stool tests (e.g. faecal calprotectin test)			
Blood test			
Any other test (please specify):			

<b>3. MEDICATIONS</b>		
<b>Medication name</b>		<b>Number of times and frequency of dosage intake <u>in the last 3 months</u></b>
<b>METHOD OF ADMINISTRATION:</b>		
<b>BY MOUTH</b>		
<b>STEROIDS</b>		
<i>Budenofalk</i> ( <i>budesonide</i> ) tablets 3mg	Yes/No/Unsure	once (1) daily <input type="checkbox"/> twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<i>Clipper</i> ( <i>beclometasone</i> <i>dipropionate</i> ) tablets 5mg	Yes/No/Unsure	once (1) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>

<p><i>Cortiment</i> (<i>budesonide</i>) tablets 9mg</p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p><i>Entocort</i> (<i>budesonide</i>) tablets 3mg</p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p><i>Medrone</i> tablets 2mg</p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p><i>Medrone</i> Tablets 4mg</p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>

<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16</p> <p><i>Medrone</i> <i>tablets 16mg</i></p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p>17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37</p> <p><i>Plenadren</i> <i>(hydrocortisone)</i> <i>tablets 5mg</i></p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>eight (8) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p>38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60</p> <p><i>Plenadren</i> <i>(hydrocortisone)</i> <i>tablets 20mg</i></p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>eight (8) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>



<p><i>Prednisolone</i> <i>tablets 5mg</i></p>	<p><i>Yes/No/Unsure</i></p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p><b>AMINOSALICYLATES (5-ASAs)</b></p>		
<p><i>Asacol</i> <i>(mesalamine)</i> <i>tablets 400mg</i></p>	<p><i>Yes/No/Unsure</i></p>	<p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p><i>Asacol</i> <i>(mesalamine)</i> <i>tablets 800mg</i></p>	<p><i>Yes/No/Unsure</i></p>	<p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p><i>Colazide</i> <i>(balsalazide disodium)</i> <i>tablets 750mg</i></p>	<p><i>Yes/No/Unsure</i></p>	<p>four (4) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>eight (8) daily <input type="checkbox"/></p> <p>nine (9) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p><i>Mezavant</i></p>	<p><i>Yes/No/Unsure</i></p>	<p>twice (2) daily <input type="checkbox"/></p>

<p>(mesalamine) tablets 1200mg</p>		<p>three (3) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p>Octasa (mesalamine) tablets 400mg</p>	<p>Yes/No/Unsure</p>	<p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>five (5) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>eight (8) daily <input type="checkbox"/></p> <p>ten (10) daily <input type="checkbox"/></p> <p>twelve (12) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>

<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30</p> <p><i>Octasa</i> <i>(mesalamine)</i> <i>tablets 800mg</i></p>	<p>Yes/No/Unsure</p>	<p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>five (5) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>eight (8) daily <input type="checkbox"/></p> <p>ten (10) daily <input type="checkbox"/></p> <p>twelve (12) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p>31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48</p> <p><i>Pentasa</i> <i>(mesalamine)</i> <i>tablets 1gr</i></p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>eight (8) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p>49 50 51 52 53 54 55 56 57 58 59 60</p> <p><i>Pentasa</i> <i>(mesalamine)</i> <i>tablets 1gr</i></p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p>

		eight (8) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<p><i>Salazopyrin</i> (<i>sulfasalazine</i>) tablets 500mg</p>	<p>Yes/No/Unsure</p>	twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> four (4) daily <input type="checkbox"/> eight (8) daily <input type="checkbox"/> twelve (12) daily <input type="checkbox"/> sixteen (16) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<p><i>Salofalk</i> (<i>mesalamine</i>) tablets 250mg</p>	<p>Yes/No/Unsure</p>	once (1) daily <input type="checkbox"/> twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> four (4) daily <input type="checkbox"/> five (5) daily <input type="checkbox"/> six (6) daily <input type="checkbox"/> nine (9) daily <input type="checkbox"/> twelve (12) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>

<p>1 2 3 4 5 6 7 8 9 10 11 <i>Salofalk</i> 12 <i>(mesalamine)</i> 13 14 <i>tablets 500mg</i></p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/> twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> four (4) daily <input type="checkbox"/> five (5) daily <input type="checkbox"/> six (6) daily <input type="checkbox"/> nine (9) daily <input type="checkbox"/> twelve (12) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/></p>
<p>26 27 28 29 30 31 32 33 <i>Salofalk</i> 34 <i>(mesalamine)</i> 35 36 <i>tablets 1000mg</i></p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/> twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> four (4) daily <input type="checkbox"/> five (5) daily <input type="checkbox"/> six (6) daily <input type="checkbox"/> nine (9) daily <input type="checkbox"/> twelve (12) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/></p>
<p>51 <i>Salofalk</i> 52 <i>(mesalamine)</i> 53 54 <i>granules 500mg</i></p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/> twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> four (4) daily <input type="checkbox"/></p>

		<p>five (5) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>nine (9) daily <input type="checkbox"/></p> <p>twelve (12) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p><i>Salofalk</i> (mesalamine) granules 1000mg</p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>five (5) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>nine (9) daily <input type="checkbox"/></p> <p>twelve (12) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p><i>Salofalk</i> (mesalamine) granules 1,5gr</p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>five (5) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>nine (9) daily <input type="checkbox"/></p> <p>twelve (12) daily <input type="checkbox"/></p> <p>other (please specify):</p>

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<i>Salofalk</i> <i>(mesalamine)</i> <i>granules 3gr</i>	<i>Yes/No/Unsure</i>	once (1) daily <input type="checkbox"/> twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> four (4) daily <input type="checkbox"/> five (5) daily <input type="checkbox"/> six (6) daily <input type="checkbox"/> nine (9) daily <input type="checkbox"/> twelve (12) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<b>IMMUNOSUPPRESSANTS</b>		
<i>Azathioprine</i> tablets 25mg	<i>Yes/No/Unsure</i>	once (1) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<i>Azathioprine</i> tablets 50 mg	<i>Yes/No/Unsure</i>	once (1) daily <input type="checkbox"/> other (please specify):

		don't know <input type="checkbox"/>
<i>Mercaptopurine (6-MP)</i> tablets 50mg	<i>Yes/No/Unsure</i>	once (1) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<i>Methotrexate</i> tablets 2,5mg	<i>Yes/No/Unsure</i>	once (1) weekly <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<i>Methotrexate</i> tablets 7,5mg	<i>Yes/No/Unsure</i>	once (1) weekly <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<i>Methotrexate</i> tablets 10mg	<i>Yes/No/Unsure</i>	once (1) weekly <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<i>Methotrexate</i> tablets 12,5mg	<i>Yes/No/Unsure</i>	once (1) weekly <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>



1 2 3 4 5 6 7 8 9 10 11 12 13	<i>Methotrexate</i> tablets 15mg	<i>Yes/No/Unsure</i>	once (1) weekly <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
14 15 16 17 18 19 20 21 22 23	<i>Methotrexate</i> tablets 17,5mg	<i>Yes/No/Unsure</i>	once (1) weekly <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
24 25 26 27 28 29 30 31 32 33	<i>Methotrexate</i> tablets 20mg	<i>Yes/No/Unsure</i>	once (1) weekly <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
34 35 36 37 38 39 40 41 42 43	<i>Methotrexate</i> tablets 22,5mg	<i>Yes/No/Unsure</i>	once (1) weekly <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
44 45 46 47 48 49 50 51 52 53 54	<i>Methotrexate</i> tablets 25mg	<i>Yes/No/Unsure</i>	once (1) weekly <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>

<p><i>Methotrexate</i> tablets 27,5mg</p>	<p><i>Yes/No/Unsure</i></p>	<p>once (1) weekly <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p><i>Methotrexate</i> tablets 30mg</p>	<p><i>Yes/No/Unsure</i></p>	<p>once (1) weekly <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p><b>VITAMINS &amp; MINERAL SUPPLEMENTS (REMINDER: <u>BY PRESCRIPTION ONLY</u>)</b></p>		
<p>Adcal D3 (calcium carbonate) <i>chewable tablets 1500 mg</i></p>	<p><i>Yes/No/Unsure</i></p>	<p>once (1) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p>Folate (folic acid) <i>tablets 5 mg</i></p>	<p><i>Yes/No/Unsure</i></p>	<p>once (1) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p>Forceval (multivitamins)</p>	<p><i>Yes/No/Unsure</i></p>	<p>capsules per day 1 / 2 / 3 / 4</p> <p>don't know <input type="checkbox"/></p>
<p><i>Iron tablets</i></p>	<p><i>Yes/No/Unsure</i></p>	<p>once (1) daily <input type="checkbox"/></p> <p>other (please specify):</p>

		don't know <input type="checkbox"/>
<b>METHOD OF ADMINISTRATION:</b>		
<b>BY INJECTION / INFUSION</b>		
<b>STEROIDS</b>		
<i>Hydrocortisone</i>	<i>Yes/No/Unsure</i>	once (1) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<i>Methylprednisolone</i>	<i>Yes/No/Unsure</i>	once (1) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<b>IMMUNOSUPPRESSANTS</b>		
<i>Azathioprine</i> injection 50mg	<i>Yes/No/Unsure</i>	once (1) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<b>ANTI-TNF INHIBITORS / BIOLOGIC MEDICATION</b>		
<i>Entyvio</i> ( <i>vedolizumab</i> ) infusion 300mg	<i>Yes/No/Unsure</i>	once (1) every 4 weeks <input type="checkbox"/> once (1) every 8 weeks <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<i>Humira</i> ( <i>adalimumab</i> )	<i>Yes/No/Unsure</i>	once (1) every week <input type="checkbox"/>

injection 20mg		once (1) every two weeks <input type="checkbox"/> twice (2) every two weeks <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
Humira (adalimumab) injection 40mg	Yes/No/Unsure	once (1) every week <input type="checkbox"/> once (1) every two weeks <input type="checkbox"/> twice (2) every two weeks <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
Infliximab infusion 100mg	Yes/No/Unsure	once (1) every 6-8 weeks <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
Simponi (golimumab) injection 50mg	Yes/No/Unsure	once (1) every 4 weeks <input type="checkbox"/> twice (2) every 4 weeks <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
Simponi (golimumab) injection 100mg	Yes/No/Unsure	once (1) every 4 weeks <input type="checkbox"/> twice (2) every 4 weeks <input type="checkbox"/> other (please specify):

		don't know <input type="checkbox"/>
Stelara (ustekinumab) infusion 130mg	Yes/No/Unsure	once (1) every 8 weeks <input type="checkbox"/> once (1) every 12 weeks <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
Stelara (ustekinumab) injection 45mg	Yes/No/Unsure	once (1) every 8 weeks <input type="checkbox"/> once (1) every 12 weeks <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
Stelara (ustekinumab) injection 90mg	Yes/No/Unsure	once (1) every 8 weeks <input type="checkbox"/> once (1) every 12 weeks <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<b>VITAMINS</b>		
B12 injection	Yes/No/Unsure	once (1) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
Iron infusion	Yes/No/Unsure	once (1) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>

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METHOD OF ADMINISTRATION: <b>BY RECTAL SUPPOSITORY / FOAM / LIQUID</b>		
<b>STEROIDS</b>		
Budenofalk ( <i>budesonide</i> )	Yes/No/Unsure	once (1) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
Colifoam ( <i>hydrocortisone</i> )	Yes/No/Unsure	once (1) daily for 2 weeks <input type="checkbox"/> once (1) daily for 3 weeks <input type="checkbox"/> twice (2) daily for 2 weeks <input type="checkbox"/> twice (2) daily for 3 weeks <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
Predfoam ( <i>prednisolone</i> )	Yes/No/Unsure	once (1) daily for 2 weeks <input type="checkbox"/> once (1) daily for 3 weeks <input type="checkbox"/> once (1) daily for 4 weeks <input type="checkbox"/>

		other (please specify): don't know <input type="checkbox"/>
<b>AMINOSALICYLATES (5-ASAs)</b>		
<i>Asacol (mesalamine) suppositories 500mg</i>	<i>Yes/No/Unsure</i>	twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> six (6) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<i>Asacol (mesalamine) suppositories 500mg</i>	<i>Yes/No/Unsure</i>	twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> six (6) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>
<i>Pentasa (mesalamine) enema 1gr</i>	<i>Yes/No/Unsure</i>	once (1) daily <input type="checkbox"/> twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> four (4) daily <input type="checkbox"/> six (6) daily <input type="checkbox"/> eight (8) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/>

<p>1 2 3 4 5 6 7 8 <i>Pentasa</i> 9 10 <i>(mesalamine)</i> 11 12 <i>enema 1gr</i></p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/> twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> four (4) daily <input type="checkbox"/> six (6) daily <input type="checkbox"/> eight (8) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/></p>
<p>22 23 24 25 26 27 <i>Salazopyrin</i> 28 29 <i>(sulfasalazine)</i> 30 31 <i>suppositories 0,5gr</i></p>	<p>Yes/No/Unsure</p>	<p>twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> four (4) daily <input type="checkbox"/> eight (8) daily <input type="checkbox"/> twelve (12) daily <input type="checkbox"/> sixteen (16) daily <input type="checkbox"/> other (please specify): don't know <input type="checkbox"/></p>
<p>40 41 42 43 44 45 <i>Salofalk</i> 46 47 <i>(mesalamine)</i> 48 49 <i>suppositories 500mg</i></p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/> twice (2) daily <input type="checkbox"/> three (3) daily <input type="checkbox"/> four (4) daily <input type="checkbox"/> five (5) daily <input type="checkbox"/> six (6) daily <input type="checkbox"/> nine (9) daily <input type="checkbox"/> twelve (12) daily <input type="checkbox"/> other (please specify):</p>



		don't know <input type="checkbox"/>
<p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p>26</p> <p>27</p> <p>28</p>	<p>Salofalk (mesalamine) suppositories 1gr</p> <p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>five (5) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>nine (9) daily <input type="checkbox"/></p> <p>twelve (12) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p>29</p> <p>30</p> <p>31</p> <p>32</p> <p>33</p> <p>34</p> <p>35</p> <p>36</p> <p>37</p> <p>38</p> <p>39</p> <p>40</p> <p>41</p> <p>42</p> <p>43</p> <p>44</p> <p>45</p> <p>46</p> <p>47</p> <p>48</p> <p>49</p> <p>50</p> <p>51</p> <p>52</p> <p>53</p> <p>54</p> <p>55</p> <p>56</p> <p>57</p> <p>58</p> <p>59</p> <p>60</p>	<p>Salofalk (mesalamine) rectal foam 1gr</p> <p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>five (5) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>nine (9) daily <input type="checkbox"/></p> <p>twelve (12) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>

<p>1 2 3 4 5 6 7 8 9 10 11 <i>Salofalk</i> 12 <i>(mesalamine)</i> 13 14 15 16 <i>enema 2gr</i> 17 18 19 20 21 22 23 24 25</p>	<p>Yes/No/Unsure</p>	<p>once (1) daily <input type="checkbox"/></p> <p>twice (2) daily <input type="checkbox"/></p> <p>three (3) daily <input type="checkbox"/></p> <p>four (4) daily <input type="checkbox"/></p> <p>five (5) daily <input type="checkbox"/></p> <p>six (6) daily <input type="checkbox"/></p> <p>nine (9) daily <input type="checkbox"/></p> <p>twelve (12) daily <input type="checkbox"/></p> <p>other (please specify):</p> <p>don't know <input type="checkbox"/></p>
<p>26 27 <b>OSTOMY SUPPLIES</b> 28</p>		
<p>29 30 Do you use stoma 31 bags? 32 33 34</p>	<p>YES</p>	<p>NO</p>

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11 **4. HOSPITALISATIONS**  
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15  
16 In the **last three (3) months**, have you been admitted into hospital for one or more nights  
17 because of your inflammatory bowel disease? Please tick Yes or No  
18  
19

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21  
22 No (Please go to Question 1.5)  
23  
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25  
26 Yes  
27  
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29  
30 If yes, please give number of times: times  
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39 **If ticked “Yes”, please give details for the five most recent admissions.**  
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48 **1<sup>st</sup> hospital admission:**  
49

50 When were you admitted in hospital and for how long?  
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52 Date of admission: D D M M M Y Y Y Y  
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56 Number of nights in hospital  
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Did you spend time in the intensive care unit? Yes No

If yes, please specify days spent in intensive care: days

Did you have an operation? Yes No, If no, please go to next admission

If you had an operation: Type of IBD surgery (during this hospital admission)

Yes, surgery in the small bowel (either laparoscopically or with open surgery)

Yes, surgery in the large bowel (colon)

Yes, surgery resulting in either temporary or permanent stoma formation

Yes, surgery for a fistula or abscess

Yes, other, please state name of operation below

No, I didn't receive surgery

*Note: Hospital admission section is replicated for total number of admissions reported*

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## 5. IMPACT OF IBD ON YOUR EMPLOYMENT

Which of the following best describes your current employment status?

Please tick ONE box only

Employed (including zero-hour contract or self-employed)

If yes, please give average number of hours of work per week (e.g. 37.5) :

– – Hours

Retired

Student

Unemployed

Other (please specify below)

In the **last three (3) months**, have you had any days (including half days) off work due to your inflammatory bowel disease? Please tick ONE box only

Yes

No

N/A

If yes, please give the number of days including half days (please specify):

. Days

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8 Have you had to **stop working / retire early** because of your IBD?

9  
10 Yes

No

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13  
14 If yes, in what year did you stop working / retire early:

15  
16  
17 (Year)

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36 **6. OUT-OF-POCKET EXPENSES**

37  
38 In the **last three (3) months**, have you purchased (without prescription) any form of  
39 medication, products, supplements or complementary and alternative medicines and  
40  
41  
42  
43 services **related specifically to your inflammatory bowel disease?**

44  
45 Please tick yes or no for each

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54 **Symptom Management:**

Yes

No

If yes,  
please give  
APPROX cost (£)

55  
56  
57 Anti-diarrhoeal medication (e.g. Imodium)

£

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4 Pain killers (e.g. paracetamol) £

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6  
7 Iron Supplements £

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10 Vitamin supplements (e.g. Multivitamins, £  
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12 Calcium, Vitamin D, Folic Acid)

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14  
15 Rehydration solutions (e.g. Dioralyte or £  
16  
17 Electrolade)

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19  
20 Meal replacements (e.g. Complan, Ensure) £

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22  
23 Lifestyle (e.g. subscription to gym) £

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32 If yes,

33 please give

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36 **Products:** Yes No APPROX cost (£)

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38  
39 Pads and/or pants for faecal incontinence £

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41  
42 Wet wipes £

43  
44  
45 Air fresheners £

46  
47  
48 Creams (e.g. Sudocream, Zinc & castor oil) £

49  
50  
51 Bed protection (e.g. mattress protector) £

In the **last three (3) months**, have you purchased (without prescription) any form of complementary and alternative medicines and services **related specifically to your inflammatory bowel disease?** *Please tick yes or no for each*

**Complementary & Alternative**

If yes,

**Therapies: do you use these to help**

please give

**with symptoms of IBD?**

Yes

No

APPROX cost (£)

Herbal Supplements

£

Probiotics

£

Prebiotics

£

Fish oil

£

Acupuncture / Massage / Relaxation

£

(private/out-of-pocket costs)

Psychological Therapy

£

(e.g. Cognitive Behavioural Therapy)

Cannabidiol (CBD) Oil/Spray

£

Other (e.g. specialised diet, devices,

£

home alterations)





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**Other** (e.g. childminder/ carer's costs while attending appointments for your inflammatory bowel disease):

Yes	No
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If yes please specify:

Please give total costs:

Final: For Review Only

**Appendix 2: Unit costs of health and social care resource items used to calculate costs**

<b>Resource item</b>	<b>Unit costs*</b>	<b>Source of cost data</b>	<b>Basis of estimate</b>
<b>Outpatient services</b>			
GP (at surgery/practice)	£45.00	PSSRU 2018 <sup>1</sup>	weighted average of all outpatient adult attendances
Practice Nurse (surgery)	£13.00	PSSRU 2018	weighted average of all outpatient adult attendances
Pharmacist	£17.00	Csikar JI et al, 2016 <sup>2</sup>	20 min appt
IBD Nurse	£67.00	PSSRU 2018	page 18; based on NHS reference costs 2011/2012
IBD Advice line	£28.00	PSSRU 2018	page 130; telephone triage (nurse-led)
Gastroenterologist	£150.00	2019-20 National Tariffs <sup>3</sup>	weighted average of all outpatient adult attendances
Colorectal Surgeon	£130.00	2019-20 National Tariffs	weighted average of all outpatient adult attendances
Rheumatologist	£187.00	2019-20 National Tariffs	weighted average of all outpatient adult attendances
Dietician	£79.00	PSSRU 2018	page 18; based on NHS reference costs 2011/2012
Psychologist	£66.00	PSSRU 2018	hourly unit cost for a clinical psychologist (UK NHS Agenda for Change band 8a)

<b>Diagnostic procedures and tests</b>			
CT scan	£225.00	NHS Ref Costs 2017/18 <sup>4**</sup>	weighted average of all adult attendances
MRI scan	£351.00	NHS Ref Costs 2017/18	weighted average of all adult attendances
Colonoscopy	£1141.00	NHS Ref Costs 2017/18	weighted average of all adult attendances
Upper GI Endoscopy	£1593.00	NHS Ref Costs 2017/18	weighted average of all adult attendances
Ultrasound	£154.00	NHS Ref Costs 2017/18	weighted average of all adult attendances
Stool test (i.e. faecal calprotectin test)	£30.00	NICE <sup>5</sup>	Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel
Blood test/phlebotomy	£11.00	Akhtar W et al, 2014 <sup>6</sup>	includes FBC,LFT,U&E,CRP
<b>Inpatient services</b>			
IBD admission (per night)	£563.00	NHS Ref Costs 2017/18	weighted average of IBD overnight admission without interventions
<b>Medications &amp; Dietary supplements</b>			
Adcal D3	£2.72	BNF <sup>7</sup>	48 tablets per pack
Asacol 400mg	£27.45	BNF	84 tablets per pack
Asacol 800mg	£54.90	BNF	84 tablets per pack
Azathioprine 25mg	£1.71	BNF	28 tablets per pack
Azathioprine 50mg	£2.47	BNF	56 tablets per pack
B12 injection	£14.50	BNF	5 infusions per pack

Budenofalk 2mg	£57.11	BNF	14 enemas per pack
Budenofalk 3mg	£75.05	BNF	100 tablets per pack
Clipper 5mg	£56.56	BNF	30 tablets per pack
Colazide 750mg	£30.42	BNF	130 tablets per pack
Colifoam rectal 100	£9.33	BNF	14 doses per pack
Cortiment 9mg	£75.00	BNF	30 tablets per pack
Entocort 3mg	£84.15	BNF	100 tablets per pack
Entyvio	£2,050.00	BNF	1 infusions per pack
Folate	£3.52	BNF	90 tablets per pack
Humira 20	£352.14	BNF	2 infusions per pack
Humira 40	£704.28	BNF	2 infusions per pack
Hydrocortisone	£10.60	BNF	5 infusions per pack
Infliximab	£377.66	BNF	1 infusion per pack
Iron	£1.29	BNF	28 tablets per pack
Iron infusion	£39.85	BNF	5 vials per pack
Mercaptopurine 50	£49.15	BNF	25 tablets per pack
Mezavant 1200mg	£42.95	BNF	60 tablets per pack
Octasa 400 tablets	£16.58	BNF	90 tablets per pack
Pentasa 1g	£42.95	BNF	60 tablets per pack
Pentasa 1G enema	£17.73	BNF	7 enemas per pack
Pentasa 1G suppository	£40.01	BNF	28 tablets per pack
Pentasa 500mg tablets	£30.74	BNF	100 tablets per pack
Predfoam	£187.00	BNF	14 metered applications per pack
Prednisolone 5mg	£1.80	BNF	28 tablets per pack
Salazopyrin 500mg tablets	£6.65	BNF	112 tablets per pack
Salofalk 1,5g granules	£48.85	BNF	60 granules per pack

Salofalk 1g granules	£28.74	BNF	50 granules per pack
Salofalk 1g suppository	£29.62	BNF	30 suppositories per pack
Salofalk 1gr rectal	£30.17	BNF	14 doses per pack
Salofalk 1000gr	£28.74	BNF	50 granules per pack
Salofalk 250gr	£16.19	BNF	100 tablets per pack
Salofalk 2gr enema	£29.92	BNF	7 enemas per pack
Simponi 100	£1,525.94	BNF	1 infusion per pack
Stelara 90	£2,147.00	BNF	1 infusion per pack
<b>Salaries</b>			
18-21 (age)	£249.00	ONS <sup>7</sup>	Weekly pay – Gross (£)
22-29 (age)	£476.00	ONS	Weekly pay – Gross (£)
30-39 (age)	£613.00	ONS	Weekly pay – Gross (£)
40-49 (age)	£669.00	ONS	Weekly pay – Gross (£)
50-59 (age)	£624.00	ONS	Weekly pay – Gross (£)
60+ (age)	£471.50	ONS	Weekly pay – Gross (£)

Notes: \*Unit costs at 2019/20 prices/costs; \*\*Costs adjusted to 2019/20 prices using the Hospital and Community Health Services Pay and Prices Index (Accessed 07/02/2021)

#### References:

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**Appendix 3: Participants characteristics who only completed the test questionnaire**

	(n=7)
<b>Age (years), mean (SD)</b>	54.9 (12.1)
<b>Sex, women (%)</b>	2 (28.6)
<b>Self-reported diagnosis, n(%)</b>	
Crohn's disease or Crohn's colitis	2 (28.6)
Ulcerative colitis	4 (57.1)
IBD Unclassified	1 (14.3)
<b>Employment status, n(%)*</b>	
Employed (inc. zero-hour contract or self-employed)	3 (42.9)
Retired	1 (14.3)
Other †	1 (14.3)

Notes:

\* There are two missing observations in the employment status category;

† Including unemployed and homemaker

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3 **Appendix 4: Missing data at test and retest**  
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Type of resource use (in the last three months)	Test n=48		Retest n=48	
	Users/Non-users	Missing quantity of use (% of users)	Users/Non-users	Missing quantity of use (%)
<b>Outpatient visits/contacts (Primary or Community care)</b>				
General Practitioner (GP)	20/28	2 (4.2)	15/33	1 (2.1)
General Practice Nurse	13/35	1 (2.1)	11/37	1 (2.1)
Pharmacist	23/25	1 (2.1)	20/28	2 (4.2)
<b>Outpatient visits/contacts (Secondary care)</b>				
Gastroenterologist	21/27	1 (2.1)	16/32	1 (2.1)
Colorectal Surgeon	5/43	0 (0.0)	3/45	0 (0.0)
Rheumatologist	2/46	0 (0.0)	2/46	0 (0.0)
Dietician	4/44	0 (0.0)	4/44	0 (0.0)
Psychologist	1/47	0 (0.0)	1/47	0 (0.0)
A&E staff	8/40	0 (0.0)	6/42	1 (2.1)
IBD nurse	17/31	0 (0.0)	15/33	1 (2.1)
Advice Line	9/39	0 (0.0)	10/38	1 (2.1)
<b>Diagnostic procedures and tests</b>				
Computerised Tomography (CT) scan	4/44	0 (0.0)	4/44	1 (2.1)
Magnetic Resonance Imaging (MRI) scan	2/46	0 (0.0)	3/45	0 (0.0)
Colonoscopy	3/45	0 (0.0)	3/45	1 (2.1)
Upper gastrointestinal (GI) endoscopy	1/47	0 (0.0)	2/46	0 (0.0)



Ultrasound	3/45	1 (2.1)	2/46	0 (0.0)
Stool test (i.e. faecal calprotectin test)	15/33	1 (2.1)	15/33	1 (2.1)
Blood test	38/10	4 (8.3)	34/14	4 (8.3)
<b>Medication type (number of tablets/injections)</b>				
Aminosalicylates – tablet	23/25	4 (8.3)	24/24	3 (6.3)
Aminosalicylates – suppository/foam	7/41	1 (2.1)	7/41	0 (0.0)
Immunosuppressants – tablet	12/36	0 (0.0)	17/31	0 (0.0)
Steroids - tablet	8/40	2 (4.2)	3/45	0 (0.0)
Steroids – injection/suppository	1/47	0 (0.0)	1/47	0 (0.0)
Dietary supplements – tablets	20/28	9 (18.8)	17/31	7 (14.5)
Biologics - injection/infusion	9/38	0 (0.0)	10/38	0 (0.0)
<b>Hospitalisations</b>				
Number of hospital admissions due to IBD	2/46	0 (0.0)	2/46	0 (0.0)
<b>Employment</b>				
Time off work (days) due to IBD	9/39	0 (0.0)	7/41	0 (0.0)

**Appendix 5: Mean annual health care, productivity loss and out-of-pocket costs [UK£], by IBD diagnosis, age and employment status at enrolment**

Resource Use Category	By IBD diagnosis		By age		By employment status	
	Crohn's disease (n=29)	Ulcerative Colitis (n=18)	Age ≤ 55 (n=22)	Age > 55 (n=26)	Employed (n=18)	Other (n=29)
<b>Outpatient Visits/Contacts (Primary Care) (SE)</b>						
General Practitioner (GP)	152.7 (32.6)	60.0 (27.2)	153.5 (39.9)	81.9 (24.9)	137.6 (39.4)	101.4 (29.6)
General Practice Nurse	25.9 (9.0)	27.4 (15.1)	22.9 (12.2)	28.5 (10.1)	15.0 (8.5)	32.7 (11.7)
Pharmacist	90.1 (22.6)	93.8 (25.1)	111.8 (25.0)	70.9 (21.8)	100.7 (30.1)	84.6 (20.3)
<b>Total</b>	<b>268.7 (55.4)</b>	<b>181.3 (41.0)</b>	<b>288.2 (59.7)</b>	<b>181.3 (45.7)</b>	<b>253.4 (64.9)</b>	<b>218.7 (47.5)</b>
<b>Outpatient Visits/Contacts (Secondary Care) (SE)</b>						
Gastroenterologist	312.9 (67.7)	166.7 (55.4)	262.5 (72.7)	253.8 (61.6)	254.2 (82.3)	269.0 (58.3)
Colorectal Surgeon	98.6 (52.3)	0.0 (0.0)	23.6 (16.3)	100.0 (57.8)	28.9 (19.8)	89.7 (52.1)
Rheumatologist	64.5 (45.7)	0.0 (0.0)	85.0 (59.9)	0.0 (0.0)	103.9 (72.9)	0.0 (0.0)

Dietician	43.6 (20.6)	0.0 (0.0)	28.7 (19.8)	24.3 (16.8)	35.1 (24.1)	21.8 (15.1)
Psychologist	36.4 (36.4)	0.0 (0.0)	48.0 (48.0)	0.0 (0.0)	58.7 (58.7)	0.0 (0.0)
A&E staff	109.8 (48.8)	16.2 (16.2)	71.8 (28.0)	73.0 (52.0)	79.5 (33.3)	70.5 (46.7)
IBD nurse	168.0 (68.9)	238.2 (73.1)	215.4 (77.0)	175.2 (65.5)	226.0 (92.3)	180.2 (59.6)
Advice Line	18.3 (7.9)	10.1 (6.6)	27.3 (11.0)	4.3 (2.2)	22.5 (10.5)	10.6 (6.0)
<b>Total</b>	<b>906.9 (158.0)</b>	<b>461.6 (121.5)</b>	<b>844.1 (164.7)</b>	<b>643.6 (146.7)</b>	<b>876.1 (187.6)</b>	<b>673.6 (136.9)</b>
<b>Diagnostic procedures and tests (SE)</b>						
Computerised Tomography (CT) scan	73.7 (35.0)	6.3 (6.3)	25.6 (25.6)	64.9 (33.7)	31.3 (31.3)	58.2 (30.4)
Magnetic Resonance Imaging (MRI) scan	72.6 (40.4)	78.0 (78.0)	127.6 (75.0)	27.0 (27.0)	39.0 (39.0)	96.8 (57.5)
Colonoscopy	314.8 (186.9)	0.0 (0.0)	103.7 (103.7)	438.8 (253.8)	0.0 (0.0)	472.1 (237.0)
Upper gastrointestinal (GI) endoscopy	329.6 (242.1)	0.0 (0.0)	434.5 (317.6)	0.0 (0.0)	531.0 (286.4)	0.0 (0.0)
Ultrasound	63.7 (38.6)	0.0 (0.0)	0.0 (0.0)	71.1 (42.9)	0.0 (0.0)	53.1 (37.7)
Stool test (i.e. faecal calprotectin test)	56.6 (14.1)	26.7 (12.1)	44.6 (17.1)	43.8 (11.3)	47.9 (17.5)	43.4 (12.2)

Blood test	74.9 (12.7)	65.1 (18.0)	78.4 (16.9)	63.1 (12.3)	76.3 (16.7)	67.1 (13.5)
<b>Total</b>	<b>985.9 (314.7)</b>	<b>176.1 (90.3)</b>	<b>814.4 (349.5)</b>	<b>708.7 (273.4)</b>	<b>725.4 (396.5)</b>	<b>790.8 (264.5)</b>
<b>Medication (SE)</b>						
Aminosalicylates	469.9 (126.7)	1915.2 (377.7)	831.1 (270.5)	1150.5 (265.2)	810.7 (314.2)	1158.8 (243.5)
Immunosuppressants	29.2 (22.6)	46.5 (36.4)	39.4 (29.8)	31.4 (25.3)	44.7 (36.4)	30.3 (22.7)
Steroids	125.0 (82.6)	693.9 (345.8)	184.4 (154.7)	463.8 (228.2)	38.4 (38.4)	531.9 (229.0)
Dietary supplements	16.9 (4.5)	5.3 (2.2)	6.4 (2.4)	17.1 (4.9)	8.0 (2.9)	15.0 (4.5)
Biologics	1608.7 (654.8)	1780.9 (1090.6)	1839.7 (781.9)	1470.6 (814.3)	1532.8 (697.1)	1762.7 (832.8)
<b>Total</b>	<b>2249.6 (639.0)</b>	<b>4441.9 (1191.1)</b>	<b>2900.9 (767.6)</b>	<b>3133.4 (924.0)</b>	<b>2434.6 (714.1)</b>	<b>3498.6 (894.7)</b>
<b>Hospitalisations (SE)</b>						
Hospital admissions due to IBD	<b>155.3 (107.8)</b>	<b>0.0 (0.0)</b>	<b>0.0 (0.0)</b>	<b>173.2 (120.0)</b>	<b>0.0 (0.0)</b>	<b>155.3 (107.8)</b>
<b>Total NHS costs</b>	<b>4566.4 (773.4)</b>	<b>5260.7 (1282.1)</b>	<b>4847.6 (858.4)</b>	<b>4840.3 (1003.0)</b>	<b>4289.5 (822.7)</b>	<b>5337.0 (964.8)</b>
<b>Productivity loss due to IBD</b>						
Productivity loss cost due to IBD*	<b>637.2 (366.8)</b>	<b>425.7 (353.7)</b>	<b>1188.3 (533.5)</b>	<b>0.0 (0.0)</b>	<b>1452.3 (638.1)</b>	<b>0.0 (0.0)</b>

<b>Patient out-of-pocket expenses (SE)</b>						
Symptom management	70.6 (28.4)	57.1 (19.2)	90.5 (37.0)	41.6 (13.3)	93.2 (44.8)	48.1 (12.8)
Products, complementary & alternative Therapies	149.0 (33.3)	180.2 (78.8)	145.0 (34.1)	168.3 (59.4)	135.9 (38.1)	176.6 (53.8)
Health appointment related travel	127.9 (38.1)	54.3 (15.1)	142.1 (49.5)	61.1 (12.6)	129.6 (56.7)	82.1 (19.1)
<b>Total patient-related costs</b>	<b>347.5 (69.8)</b>	<b>291.5 (85.0)</b>	<b>377.6 (81.6)</b>	<b>271.0 (68.8)</b>	<b>358.7 (98.7)</b>	<b>306.8 (62.5)</b>
<b>Overall costs</b>	<b>5551.2 (866.0)</b>	<b>5978.0 (1412.0)</b>	<b>6413.5 (1027.1)</b>	<b>5111.3 (1047.8)</b>	<b>6100.6 (1104.0)</b>	<b>5643.8 (1003.9)</b>

Notes: SE, standard error

\* Incurred by 9 and 7 participants in employment in the test and the re-test measurement occasions, respectively. An overview of the content included in each (sub)category can be found in Appendix 1.