Keith Bodger, MBChB(Honours), MD, FRCP, UK

- Consultant Gastroenterologist, Liverpool, UK
- Senior Lecturer, University of Liverpool, UK

GaBI Scientific Meetings

ROUNDTABLE ON REGISTRIES
Practical Considerations for Registries – making them work

26 January 2017, Pullman London St Pancras, London, UK

Linkage of registry and routine administrative datasets for pharmacoeconomic research

Keith Bodger, MBChB(Honours), MD, FRCP, UK

26 January 2017

GaBi
GENERICS AND BIOSIMILARS INITIATIVE
Building trust in cost-effective treatments

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Bringing medicines to life

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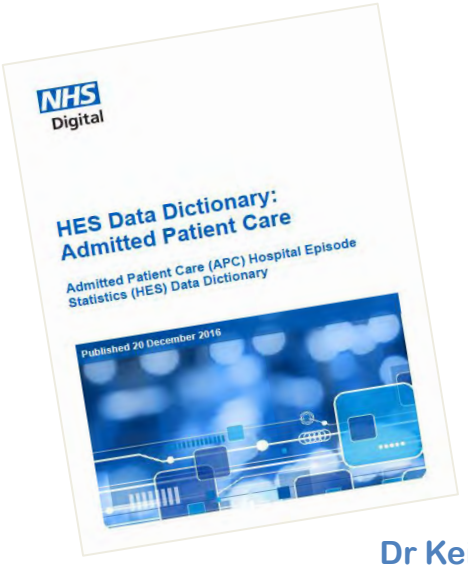
Evaluating the cost-effectiveness of high cost biological therapies for chronic diseases has been limited by a lack of long term data on real-world costs and outcomes. Models have often relied on simplistic assumptions, sparse empirical data or expert opinion when simulating downstream events beyond the timescale of clinical trials. Using the example of inflammatory bowel disease, this presentation will describe the potential for combining selected data items collected within a chronic disease register with information extracted from routine hospital administrative data to generate real-world data to inform pharmacoeconomic research.

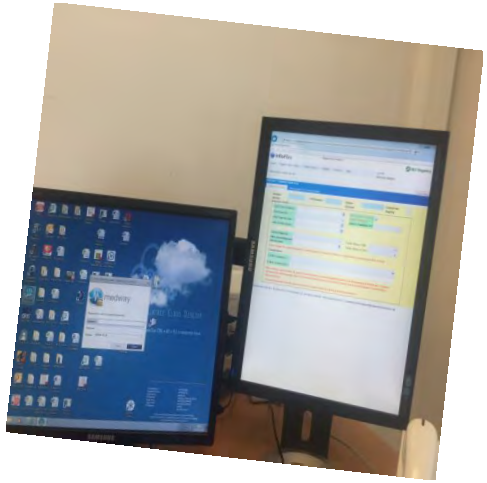
GaBI Scientific Meetings

ROUNDTABLE ON REGISTRIES
Practical Considerations for Registries – making them work

26 January 2017, Pullman London St Pancras, London, UK

Linkage of Registry and Routine Administrative Datasets for Pharmacoeconomic Research





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Overview

- Real-world data
- The UK IBD Registry
- Routine Administrative Data
- Linkage for Pharmacoeconomic Research

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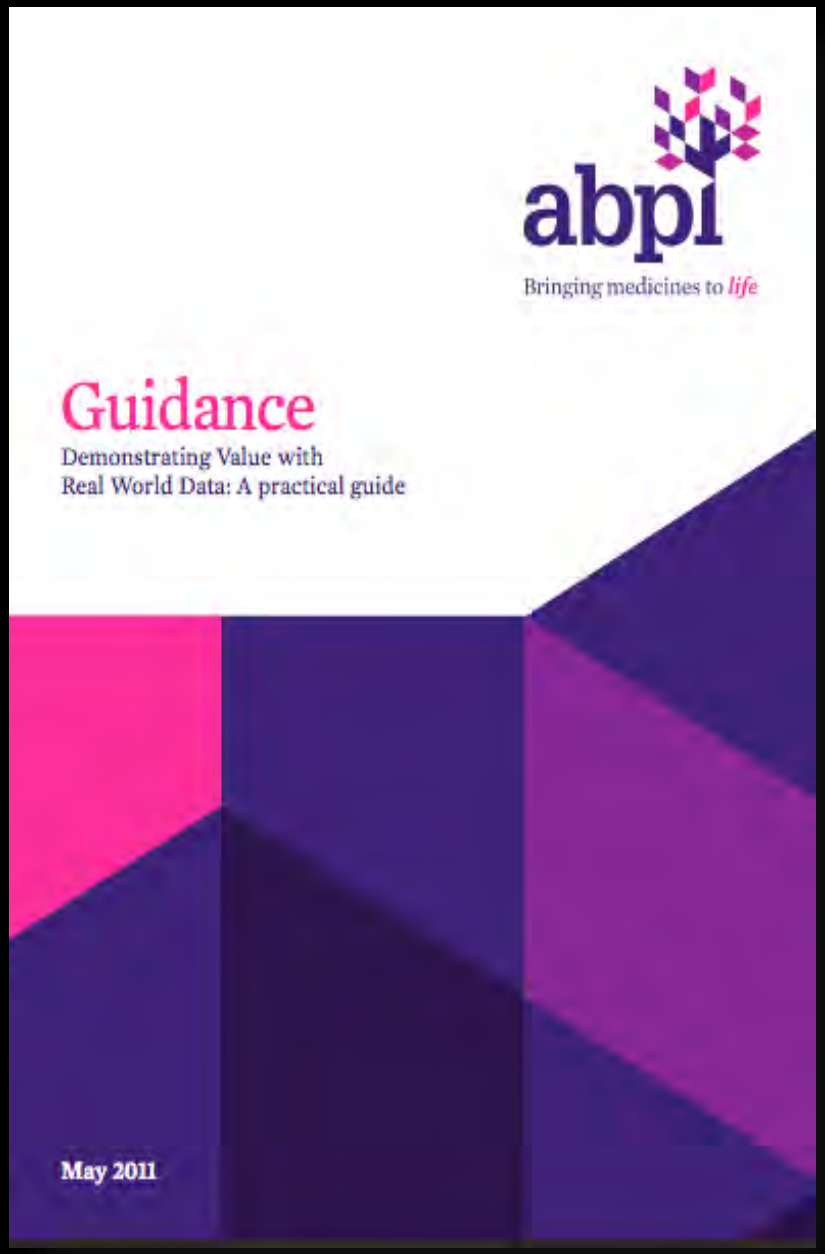
"RCTs, long regarded as the 'gold standard' … have been put on an undeserved pedestal. Their appearance at the top of 'hierarchies' of evidence is inappropriate. They should be replaced by a diversity of approaches that involve analysing the totality of the evidence-base"

Sir Michael Rawlins

"Observational studies are also useful and, with care in the interpretation of results, can provide an important source of evidence about both the benefits and harms of therapeutic interventions"



Real world data

It is increasingly recognized that conclusions drawn from classical clinical trials are not always a useful aid for decision-making - assessing the value of a drug or technology requires an understanding of its impact on current management in a practical, real-life setting.

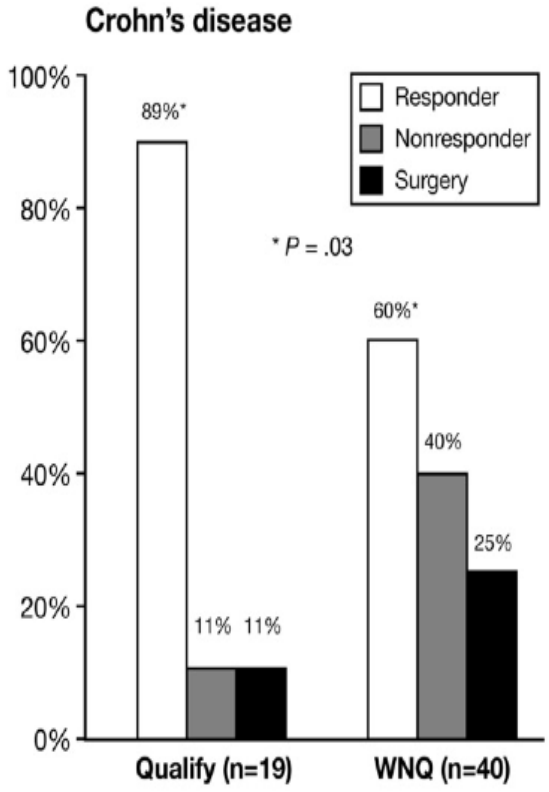
CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 2012;10:1002–1007

Patients Enrolled in Randomized Controlled Trials Do Not Represent the Inflammatory Bowel Disease Patient Population

CHRISTINA HA,* THOMAS A. ULLMAN,‡ COREY A. SIEGEL,§ and ASHER KORNBLUTH‡

*Division of Gastroenterology, The Johns Hopkins School of Medicine, Baltimore, Maryland; ‡Dr. Henry D. Janowitz Division of Gastroenterology, Mount Sinai School of Medicine, New York, New York; and §Division of Gastroenterology, Dartmouth-Hitchcock Medical Center, Hanover, New Hampshire

BACKGROUND & AIMS: Multiple randomized controlled trials (RCTs) have been conducted to determine therapeutic efficacy of the biological agents for the inflammatory bowel diseases (IBD). However, the external validity of findings from RCTs might be compromised by their stringent selection criteria. We investigated the proportion of patients encountered during routine clinical practice who would qualify for enrollment into a pivotal RCT of biological agents for IBD. **METHODS:** We performed a retrospective cohort study of adult patients with moderate-severe IBD who presented to a tertiary referral center. Inclusion and exclusion criteria were extracted from published RCTs of biologics approved by the Food and Drug Administration and applied to the study population. **RESULTS:** Only 31.1% of 206 patients with IBD (34% with Crohn's disease [CD], 26% with ulcerative colitis) would have been eligible to participate in any of the selected RCTs. Patients would have been excluded because they had stricturing or penetrating CD, took high doses of steroids, had comorbidities or prior exposure to biologics, or received topical therapies. Of the trial-ineligible patients with ulcerative colitis, 23.3% had colectomies, and 31.7% received infliximab, with a 63.2% response rate. Approximately half (49.4%) of the 82 trial-ineligible patients with CD received biological therapies, with lower response rates (60%) than trial-eligible patients (89%; $P = .03$). **CONCLUSIONS: Most patients with moderate–severe IBD evaluated in an outpatient practice would not qualify for enrollment in a pivotal RCT of biological reagents; this finding raises important questions about their therapeutic efficacy beyond the clinical trial populations. Additional evaluation of the transparency of RCT design and selection criteria is needed to determine whether trial results can be generalized to the population.**



Direct Medical Costs

Relative costs of care episodes

IBD Nurse (telephone)

£30[a]

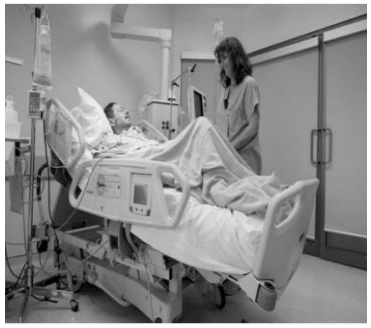
€40

Consultant (specialist) clinic

£133[b]

€179

Elective colectomy



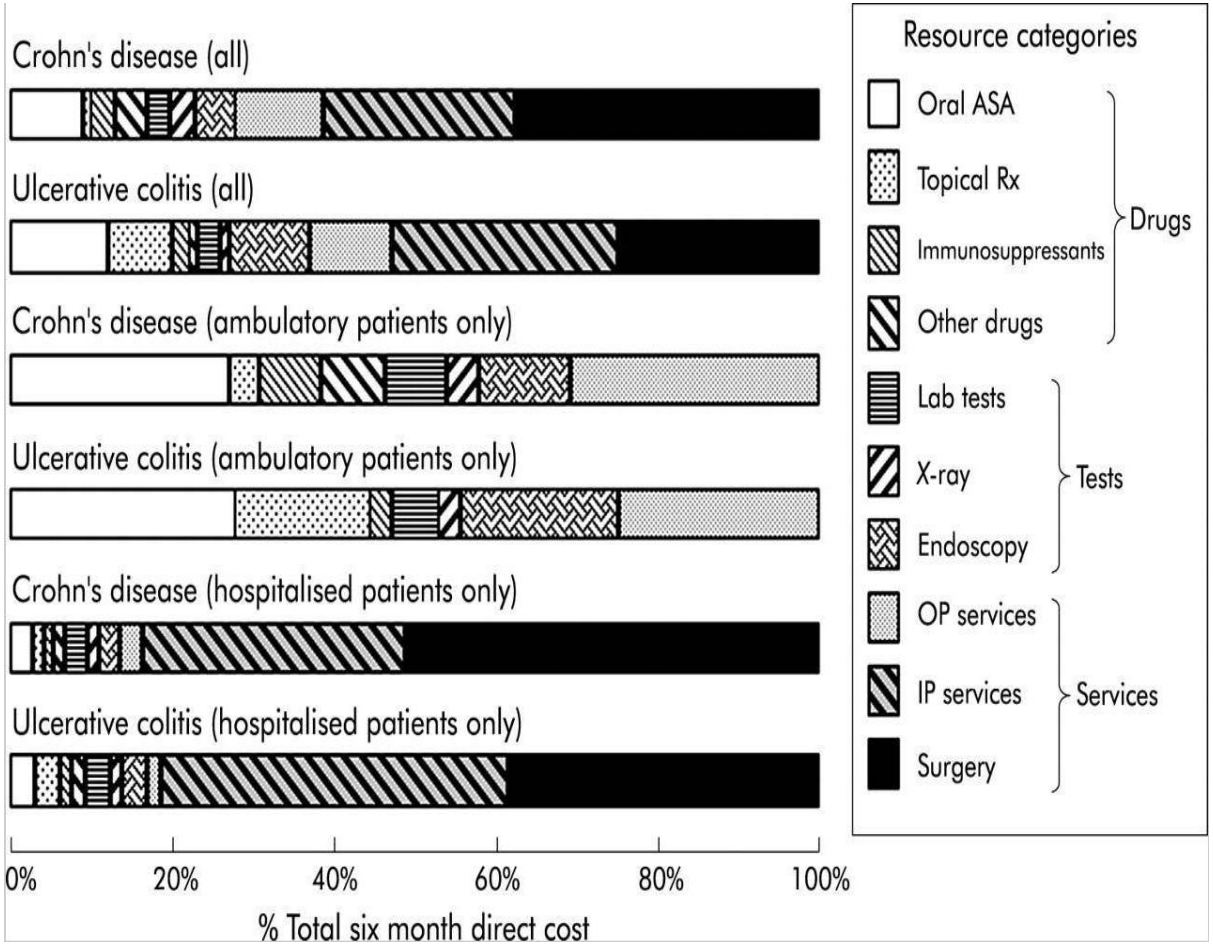
£8,793[c]

€11,828

Source: **NHS National Schedule of Reference Costs 2013/14:** a. Non face-to-face attendance (Currency code: WF02C); b. Gastroenterology OP attendance (Cost code: 301); c. Colorectal surgery, Very complex large intestine procedures with CC Score 0-2 (HRG: WA12D)

Direct Medical Costs

Inpatient costs are predominant cost driver (pre-biologics era)



Source: Bassi *et al.* **Cost-of-illness of inflammatory bowel disease in the UK: A single centre retrospective study.** *Gut* 2004;53(10):1471-8

Direct Medical Costs

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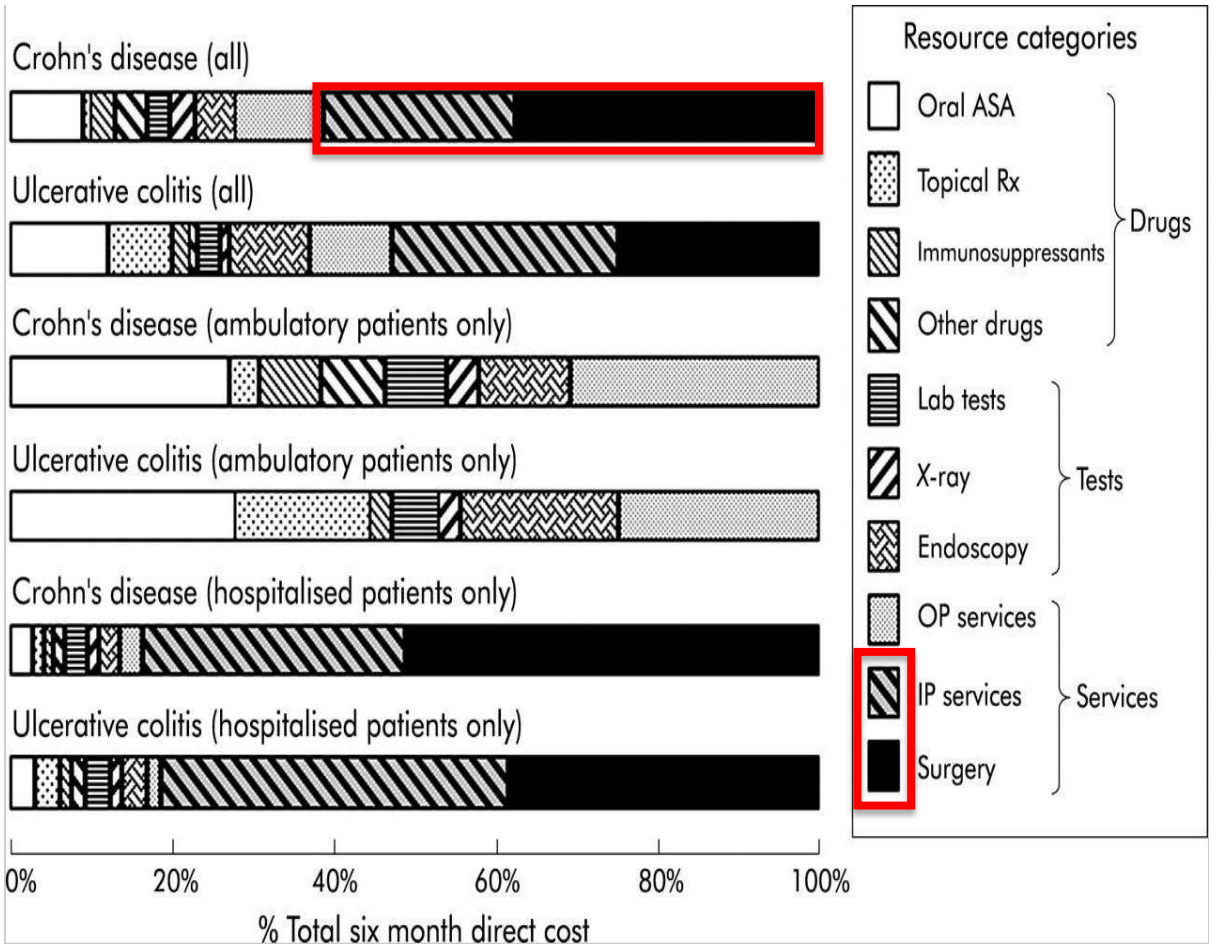


Source: Bassi *et al.* **Cost-of-illness of inflammatory bowel disease in the UK: A single centre retrospective study.** *Gut* 2004;53(10):1471-8

Direct Medical Costs

Relative costs of drugs

Oral treatment		
Sulphasalazine	500 mg q.d.s	6.97
	1 g q.d.s	13.94
Mesalazine (Asacol)	400 mg t.d.s	27.09
	800 mg t.d.s	54.19
Mesalazine (Ipocol)	400 mg t.d.s	24.64
	800 mg t.d.s	49.28
Mesalazine (Mesren MR)	400 mg t.d.s	18.49
	800 mg t.d.s	37.87
Mesalazine (Pentasa)	1.5 g o.d	21.40
	4 g o.d	57.08
Mesalazine (Pentasa sachet)	1 g b.d	33.62
	1 g q.d.s	67.24
Mesalazine (Salofalk)	250 mg t.d.s	14.65
	500 mg t.d.s	29.23
Balsalazide	2.25 g t.d.s	75.60
Olsalazine	500 mg b.d	20.57
Prednisolone 5mg	40 mg o.d	2.73
Budesonide	3mg t.d.s	64.43
Infliximab	5 mg/kg (3 vials)	1258.86
Azathioprine	100 mg(1–2 mg/kg)	4.47

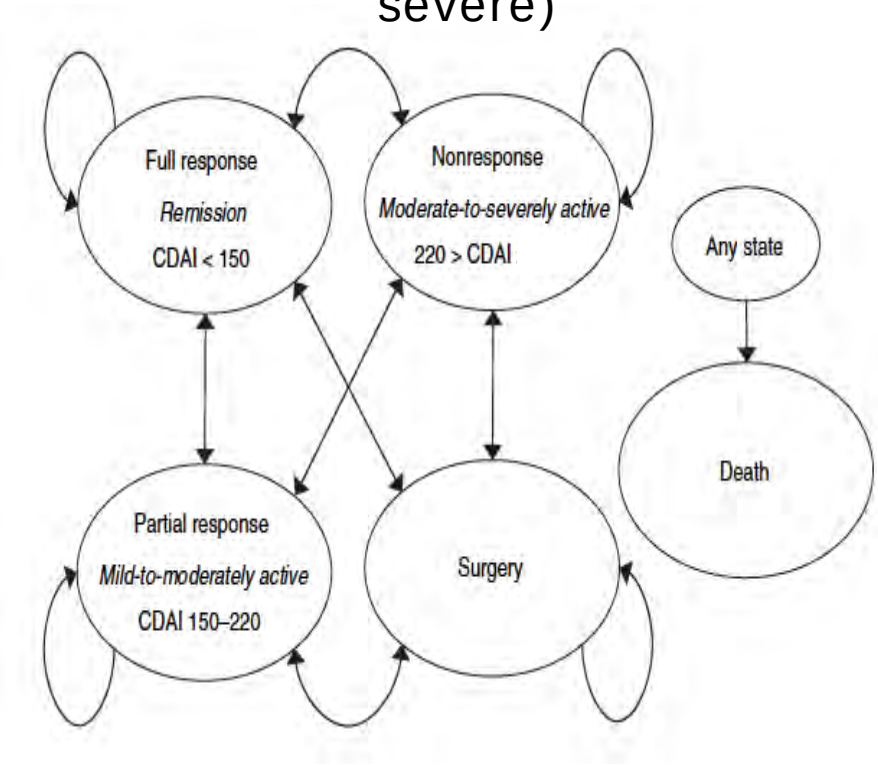
} **280-fold**

Source: Luces & Bodger. **Economic Burden of inflammatory bowel disease: a UK perspective**. Exp Rev Pharmacoeconomics Outcomes Res 2006;6(4):471-482

Cost-Effectiveness Analysis

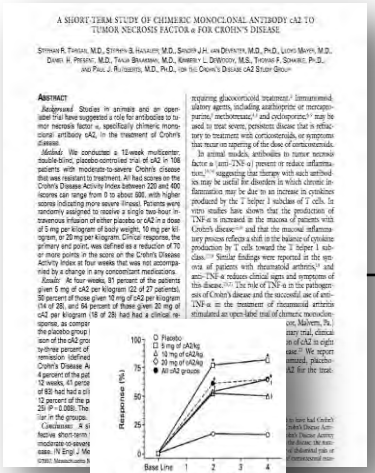
Lack of real world data on key events and costs

Crohn's disease (moderate-to-severe)



Source: Bodger *et al*. **Cost-effectiveness of biological therapy for Crohn's disease: Markov cohort analyses incorporating United Kingdom patient-level cost data**. *Aliment Pharmacol Ther* 2009;30:265-74

Randomized Controlled Trials



A SHORT-TERM STUDY OF CHIMERIC MONOCLONAL ANTIBODY cA2 TO TUMOR NECROSIS FACTOR α FOR CROHN'S DISEASE

ABSTRACT

Background. Studies in animals and an open-label trial have suggested a role for antibodies to tumor necrosis factor α, specifically chimeric monoclonal antibody cA2, in the treatment of Crohn's disease.

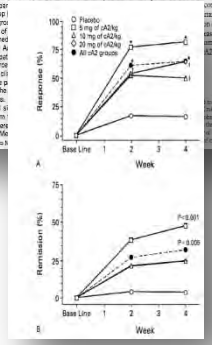
Methods. We conducted a 12-week multicenter, double-blind, placebo-controlled trial of cA2 in 108 patients with moderate-to-severe Crohn's disease that was resistant to treatment. All had scores on the Crohn's Disease Activity Index between 220 and 400 (scores can range from 0 to about 800, with higher scores indicating more severe illness). Patients were randomly assigned to receive a single two-hour intravenous infusion of either placebo or cA2 in a dose of 5 mg per kilogram of body weight, 10 mg per kilogram, or 20 mg per kilogram. Clinical response, the primary end point, was defined as a reduction of 70 or more points in the score on the Crohn's Disease Activity Index at four weeks that was not accompanied by a change in any concomitant medications.

Results. At four weeks, 81 percent of the patients given 5 mg of cA2 per kilogram (22 of 27 patients), 39 percent of those given 10 mg of cA2 per kilogram (14 of 36), and 64 percent of those given 20 mg of cA2 per kilogram (18 of 28) had had a clinical response, as compared with 17 percent of the patients given placebo (5 of 29; P = 0.001 for the comparison of the cA2 groups with the placebo group). Twenty-three percent of patients given 5 mg of cA2 per kilogram had had a clinical remission (defined as a score on the Crohn's Disease Activity Index of less than 150), as compared with 4 percent of the patients given placebo (P = 0.03). At 12 weeks, 41 percent of those given 5 mg of cA2 per kilogram (11 of 27) had had a clinical remission, as compared with 6 percent of those given placebo (2 of 29; P = 0.008). The incidence of adverse events was similar in the groups.

Conclusions. A single infusion of cA2 is effective in short-term treatment of moderate-to-severe Crohn's disease. (N Engl J Med 1994;331:1137-41.)

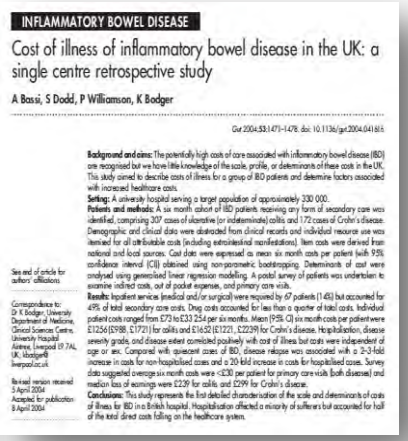
requiring glucocorticoid treatment,[1] immunomodulatory agents, including azathioprine or mercaptopurine,[2] methotrexate,[3] and cyclosporine,[4] may be used to treat severe, persistent disease that is refractory to treatment with corticosteroids, or symptoms that recur on tapering of the dose of corticosteroids.

In animal models, antibodies to tumor necrosis factor α (anti-TNF-α) prevent or reduce inflammation,[5,6] suggesting that therapy with such antibodies may be useful for disorders in which chronic inflammation may be due to an increase in cytokines produced by the T helper 1 subclass of T cells. In vitro studies have shown that the production of TNF-α is increased in the mucosa of patients with Crohn's disease[7,8] and that the mucosal inflammatory process reflects a shift in the balance of cytokine production by T cells toward the T helper 1 subclass.[7,8] Similar findings were reported in the synovia of patients with rheumatoid arthritis,[9] and anti-TNF-α reduces clinical signs and symptoms of this disease.[10,11] The role of TNF-α in the pathogenesis of Crohn's disease and the successful use of anti-TNF-α in the treatment of rheumatoid arthritis stimulated an open-label trial of chimeric monoclonal anti-TNF-α antibody cA2 in eight patients with severe, refractory Crohn's disease.[12] We report here the results of a multicenter, randomized, placebo-controlled, double-blind trial of cA2 for the treatment of moderate-to-severe Crohn's disease.



Efficacy

"Real world" Observational data



INFLAMMATORY BOWEL DISEASE

Cost of illness of inflammatory bowel disease in the UK: a single centre retrospective study

A Bassi, S Dodd, P Williamson, K Bodger

Gut 2004;53:1471–1478. doi: 10.1136/gut.2004.041616

Background and aims: The potentially high costs of care associated with inflammatory bowel disease (IBD) are recognised but we have little knowledge of the scale, profile, or determinants of these costs in the UK. This study aimed to describe costs of illness for a group of IBD patients and determine factors associated with increased healthcare costs.

Setting: A university hospital serving a target population of approximately 330 000.

Patients and methods: A six month cohort of IBD patients receiving any form of secondary care was identified, comprising 307 cases of ulcerative (or indeterminate) colitis and 172 cases of Crohn's disease. Demographic and clinical data were abstracted from clinical records and individual resource use was itemised for all attributable costs (including extraintestinal manifestations). Item costs were derived from national and local sources. Cost data were expressed as mean six month costs per patient (with 95% confidence interval (CI)) obtained using non-parametric bootstrapping. Determinants of cost were analysed using generalised linear regression modelling. A postal survey of patients was undertaken to examine indirect costs, out of pocket expenses, and primary care visits.

Results: Inpatient services (medical and/or surgical) were required by 67 patients (14%) but accounted for 49% of total secondary care costs. Drug costs accounted for less than a quarter of total costs. Individual patient costs ranged from £73 to £33 254 per six months. Mean (95% CI) six month costs per patient were £1256 (£988, £1721) for colitis and £1632 (£1221, £2239) for Crohn's disease. Hospitalisation, disease severity grade, and disease extent correlated positively with cost of illness but costs were independent of age or sex. Compared with quiescent cases of IBD, disease relapse was associated with a 2–3-fold increase in costs for non-hospitalised cases and a 20-fold increase in costs for hospitalised cases. Survey data suggested average six month costs were <£230 per patient for primary care visits (both diseases) and median loss of earnings were £239 for colitis and £299 for Crohn's disease.

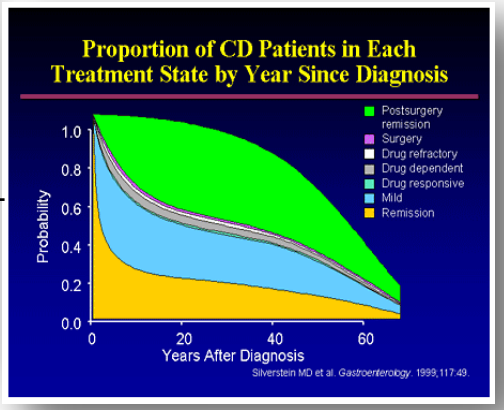
Conclusions: This study represents the first detailed characterisation of the scale and determinants of costs of illness for IBD in a British hospital. Hospitalisation affected a minority of sufferers but accounted for half of the total direct costs falling on the healthcare system.

See end of article for authors' affiliations

Correspondence to: Dr K Bodger, University Department of Medicine, Clinical Sciences Centre, University Hospital Aintree, Liverpool L9 7AL, UK; kbodger@liverpool.ac.uk

Revised version received 3 April 2004
Accepted for publication 9 April 2004

Cost inputs



Use of tumour necrosis factor alpha (TNF α) inhibitors adalimumab and infliximab for Crohn's disease

Report commissioned by: NHS R&D HTA Programme

On behalf of: The National Institute for Health and Clinical Excellence

Produced by: West Midlands Health Technology Assessment Collaboration
Department of Public Health & Epidemiology
University of Birmingham
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Date completed: July 2008

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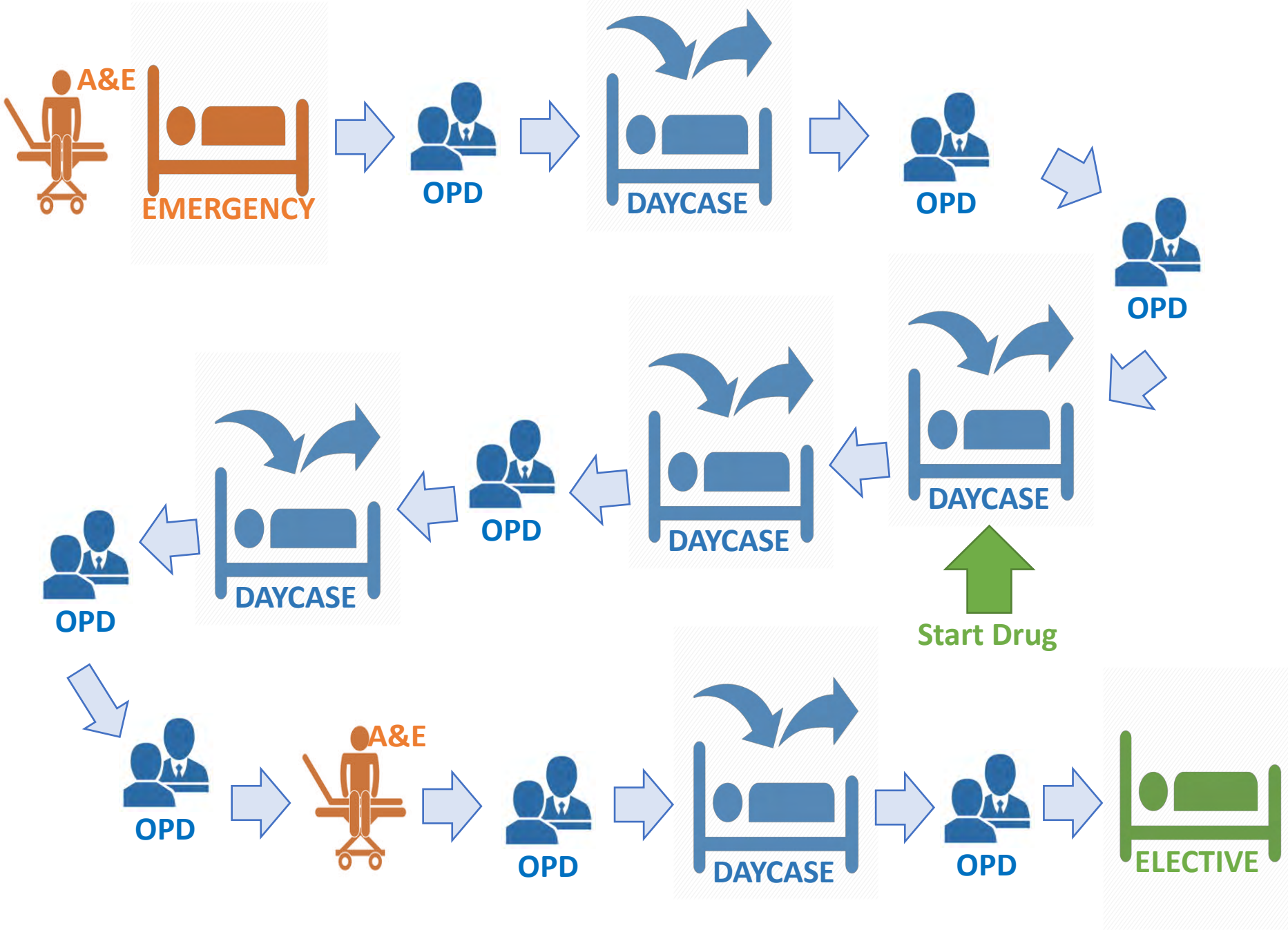
Declared competing interests of the authors:
None

Effectiveness of standard care


A&E
EMERGENCY
OPD
DAYCASE
OPD
OPD
DAYCASE
DAYCASE
OPD
DAYCASE
OPD
Start Drug
OPD
A&E
OPD
OPD
DAYCASE
OPD
ELECTIVE

What do we need?

- Common set of data items and standards for an IBD Electronic Health Record
- IT systems to support electronic data capture
- Local support for point-of-care data collection
- IG and permissions for secondary uses of data
- Analytics (data → information → knowledge)
- Clinical and patient engagement

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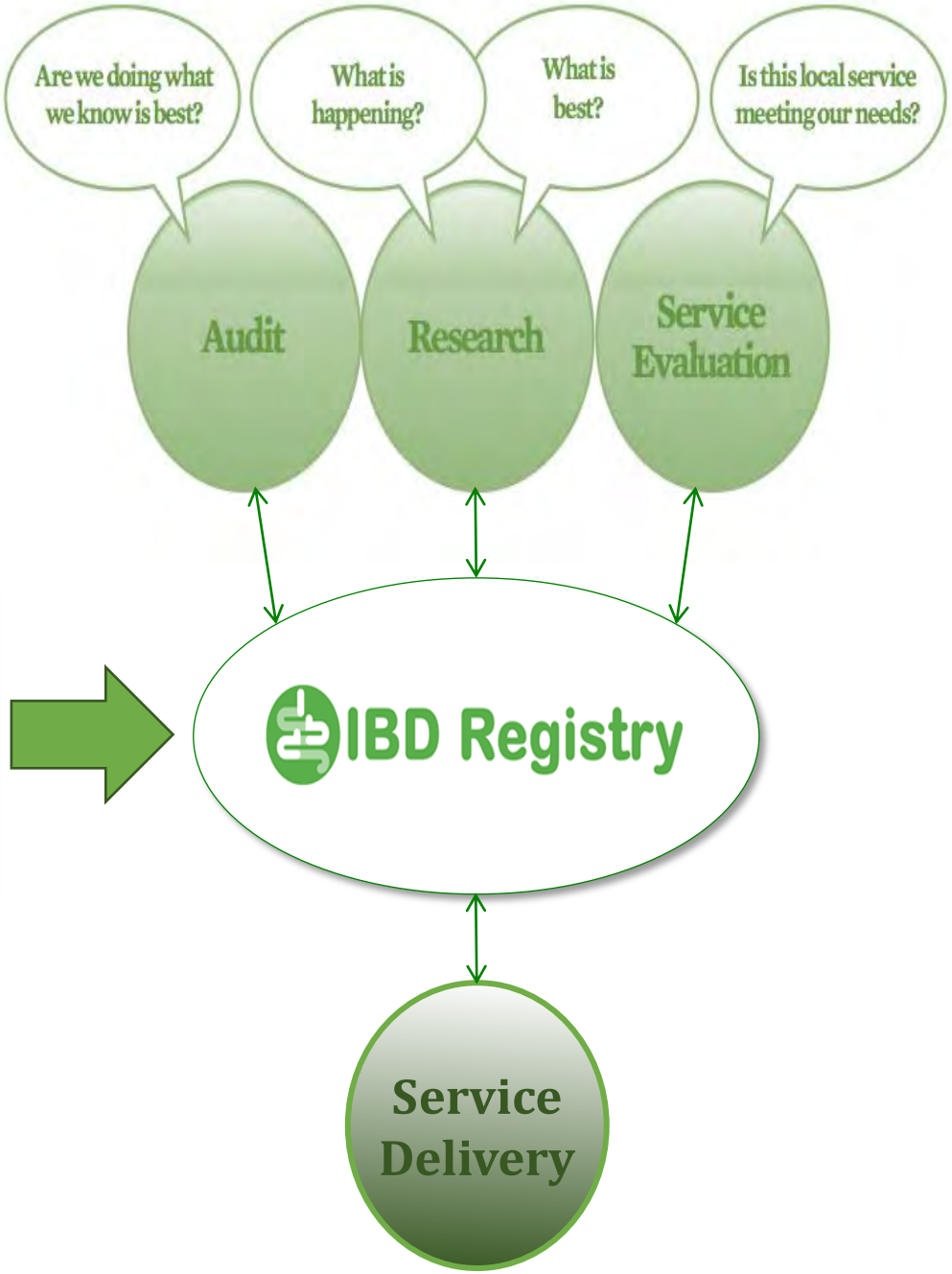


Overview

- Real-world data
- The UK IBD Registry
- Routine Administrative Data
- Linkage for Pharmacoeconomic Research

PMS

Patient Management System (InfoFlex)

Web Portal

Web-based Tool

Existing

Local System

IBD Audit

Royal College of Physicians

RCP Biologics Audit

IBD Registry

NHS Digital

UK IBD Registry

The national IBD audit is changing and the IBD Registry is now the vehicle for the biologics audit and quality improvement programme. Teams can participate using a choice of data entry systems including existing local systems.

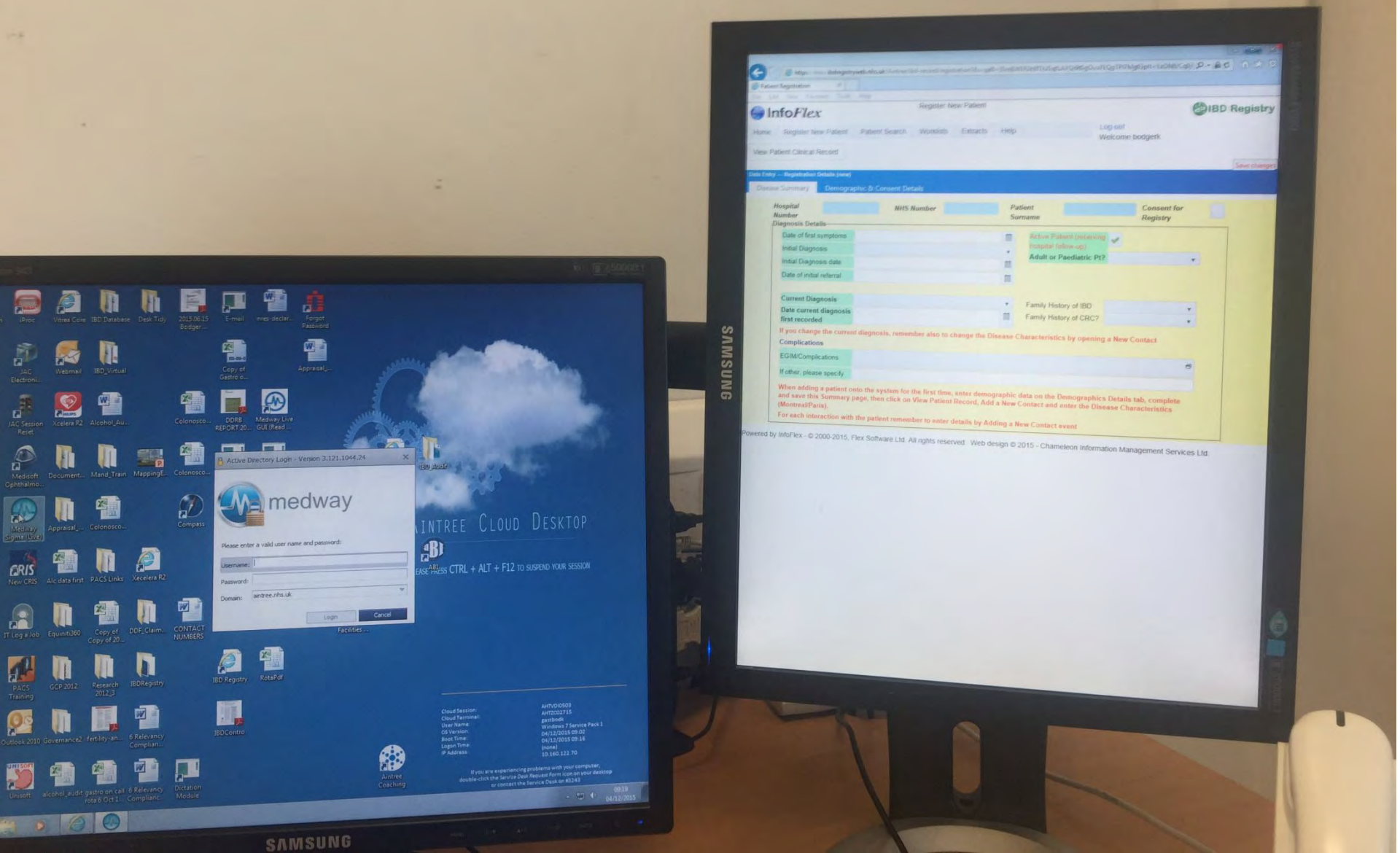
Being part of the IBD Registry will give teams:

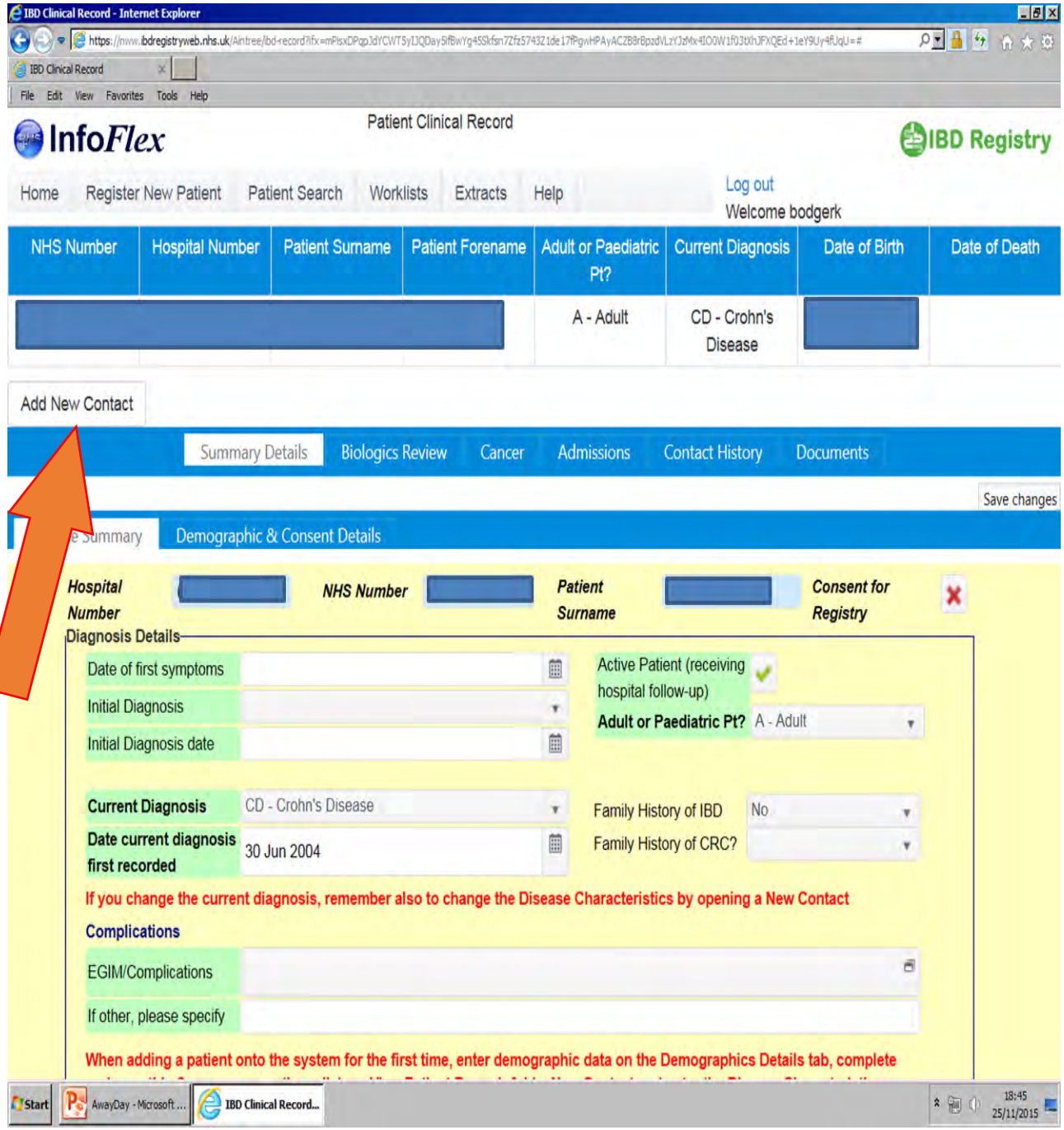
- Local data to manage their biologics patients and IBD service more effectively
- The chance to be part of a national audit of the safety and appropriate use of biologics and biosimilars

In time the Registry will become a unique resource for real-world clinical effectiveness and health economic studies in IBD care. The goals for 2016/17 are:

- Transfer data collection to the IBD Registry from the RCP biological therapy audit web tool, which will be closing
- Develop a near-complete UK Register of IBD patients on biologics by the end of 2017

We approach the end of the year with **60 sites actively participating** in the IBD Registry, and **over 21,000 patient records** submitted. 80 sites in total have a 'live' system for data capture, and 21 additional sites are in the process of setting up so we expect patient numbers to increase steadily. If you have not yet registered to participate in the IBD Registry, would like help uploading your data, or have any other registry related queries please contact support@ibdregistry.org.uk


InfoFlex
IBD Registry
Register New Patient
Home
Register New Patient
Patient Search
Worklists
Extracts
Help
Log off
Welcome bodgerk
View Patient Clinical Record
Disease Summary
Demographic & Consent Details
Hospital Number
NHS Number
Patient Surname
Consent for Registry
Diagnosis Details
Date of first symptoms
Initial Diagnosis
Initial Diagnosis date
Date of initial referral
Active Patient (receiving hospital follow-up)
Adult or Paediatric Pt?
Current Diagnosis
Date current diagnosis first recorded
Family History of IBD
Family History of CRC?
If you change the current diagnosis, remember also to change the Disease Characteristics by opening a New Contact
Complications
EGIM/Complications
If other, please specify
When adding a patient onto the system for the first time, enter demographic data on the Demographics Details tab, complete and save this Summary page, then click on View Patient Record, Add a New Contact and enter the Disease Characteristics (Montreal/Paris).
For each interaction with the patient remember to enter details by Adding a New Contact event
Powered by InfoFlex - © 2000-2015, Flex Software Ltd. All rights reserved. Web design © 2015 - Chameleon Information Management Services Ltd.
Active Directory Login - Version 3.121.1044.24
medway
Please enter a valid user name and password:
Username:
Password:
Domain:
aintree.nhs.uk
Login
Cancel
AINTREE CLOUD DESKTOP
PLEASE PRESS CTRL + ALT + F12 TO SUSPEND YOUR SESSION
SAMSUNG
SAMSUNG


IBD Clinical Record - Internet Explorer
https://www.ibdregistryweb.nhs.uk/Aintree/ibd-record?ifx=mPlsxDPqpJdYCWT5yIJQDay5fBwYg45Skfsn7Zfz57432Ide17fPgwHPAyACZB8rBpzdVLzYJzMx4IO0W1f03tXhJFXQEd+1eY9Uy4fUqU=#
IBD Clinical Record
File Edit View Favorites Tools Help
InfoFlex
Patient Clinical Record
IBD Registry
Home
Register New Patient
Patient Search
Worklists
Extracts
Help
Log out
Welcome bodgerk
NHS Number
Hospital Number
Patient Surname
Patient Forename
Adult or Paediatric Pt?
Current Diagnosis
Date of Birth
Date of Death
A - Adult
CD - Crohn's Disease
Add New Contact
Summary Details
Biologics Review
Cancer
Admissions
Contact History
Documents
Save changes
Summary
Demographic & Consent Details
Hospital Number
NHS Number
Patient Surname
Consent for Registry
Diagnosis Details
Date of first symptoms
Initial Diagnosis
Initial Diagnosis date
Active Patient (receiving hospital follow-up)
Adult or Paediatric Pt?
A - Adult
Current Diagnosis
CD - Crohn's Disease
Date current diagnosis first recorded
30 Jun 2004
Family History of IBD
No
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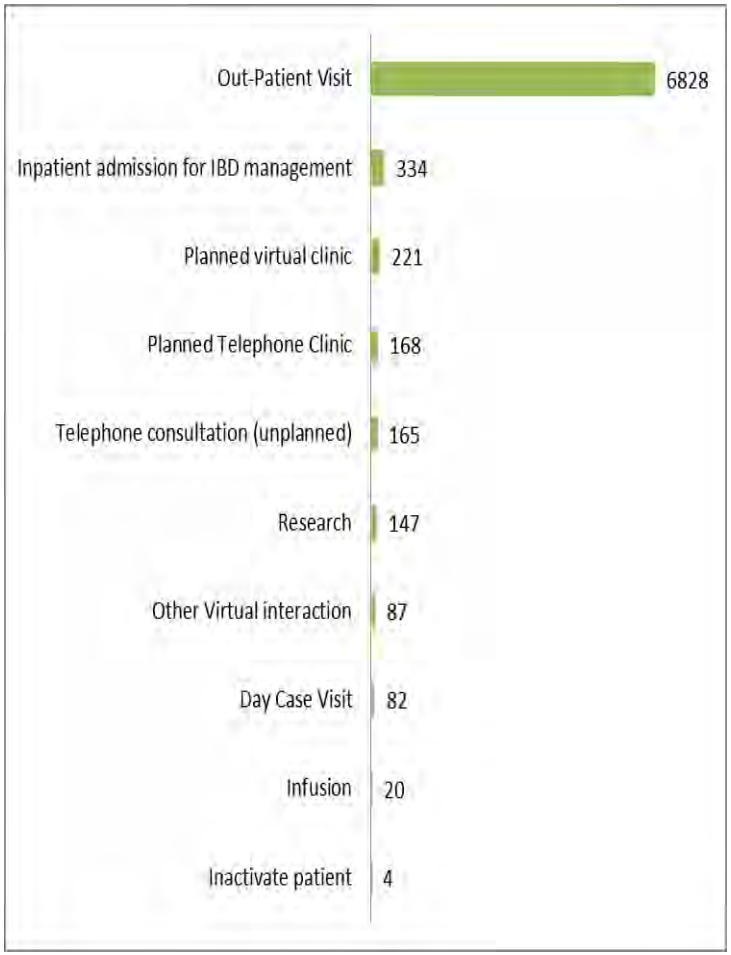
If you change the current diagnosis, remember also to change the Disease Characteristics by opening a New Contact
Complications
EGIM/Complications
If other, please specify
When adding a patient onto the system for the first time, enter demographic data on the Demographics Details tab, complete
Start
AwayDay - Microsoft ...
IBD Clinical Record...
18:45
25/11/2015

IBD Registry

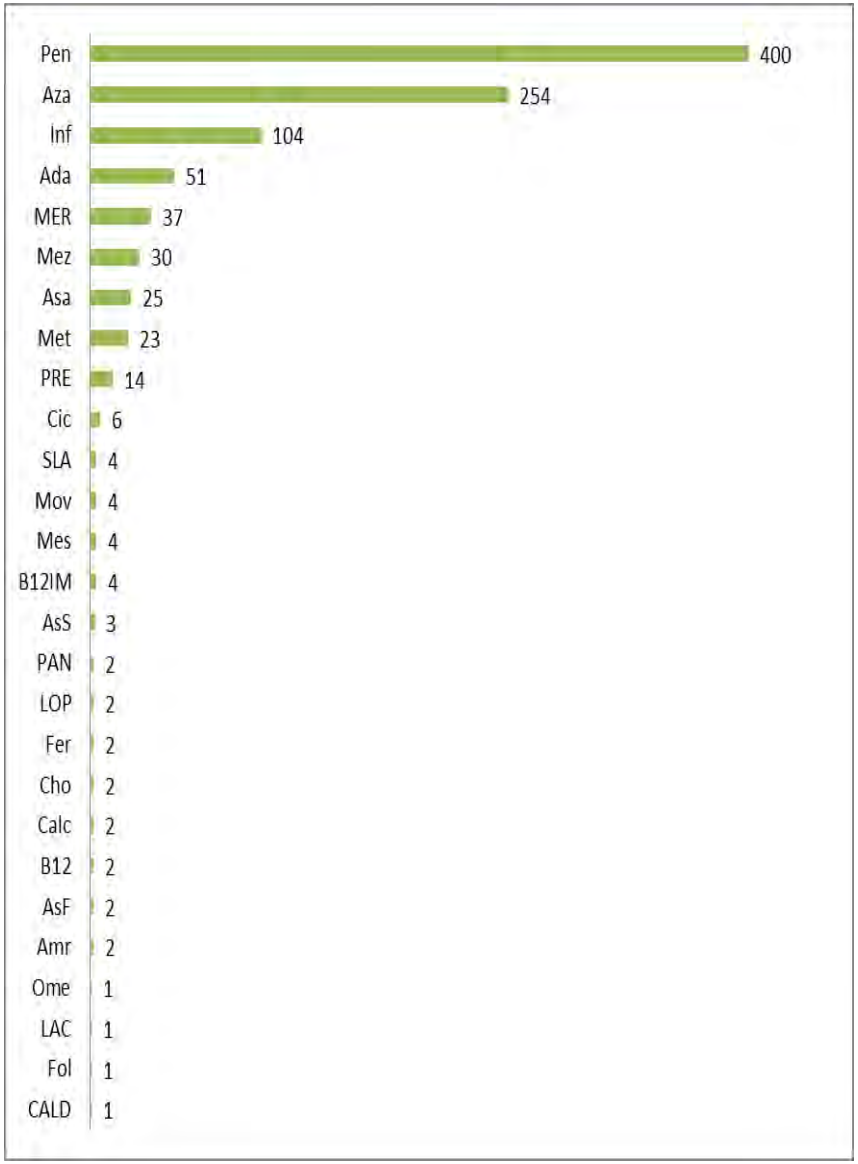
NHS Number
Date of birth
Gender
Postcode
GP Practice code
Date of death
IBD involvement in death
Date of Current Diagnosis
Current diagnosis
Date of onset of symptoms
Earliest Diagnosis
Date of Earliest Diagnosis
Local unit code
IBD Audit code
Date consent last recorded
Informed consent for registry
Informed consent for linkage
Informed consent for research
Consent to be contacted for future research
Date of contact
Contact type
Adult or paediatric service patient
Postcode at time of contact
AgeOfOnsetAdult(Montreal)
Extent of UC Adult (Montreal)
Behaviour Crohns Adult (Montreal)
LocationCrohnsAdult (Montreal)
Disease Proximal to terminal Ileum (Montreal L4)
AgeOfOnsetPaediatric(Paris)
Extent of UC Paediatric(Paris)
Behaviour Crohns Paediatric(Paris)
LocationCDPaediatric(Paris)
Disease Proximal to terminal Ileum (Paris L4a L4b)
Perianal Crohn's Disease
HBI Total Score
Modified UCDAI
weightedPCDAI
PUCDAI
SCCAI
Smoking status
Local unit code
IBD Audit code
Date of hospital admission for IBD management
Type of admission
Reason for admission
Date of discharge
Local unit code
IBD Audit code
Date of surgery
Hospital where surgery took place

Hospital where surgery took place
Main Surgical Procedure
Other Surgical Procedure
Surgery performed laparoscopically
Local unit code
IBD Audit code
Date of diagnosis of cancer
Site of cancer
Local unit code
IBD Audit code
Date of measurement
Height (m)
Weight (kg)
Local unit code
IBD Audit code
Date Occupation Status Recorded
Primary Occupation Status
Year Type
Relevant Year
Days lost - number
Days lost - range
Local unit code
IBD Audit code
Date of Control PROM
Question1a
Question1b
Question2
Question3a
Question3b
Question3c
Question3d
Question3e
Question 3f
Question4a
Question4b
Question4c
Question4d
Question5Vas
IBDCTRL-8SCORE
Local unit code
IBD Audit code
Drug Code
Drug Start Date
Drug End Date
Dose
Unit
Frequency
Route of Administration
Biologics Drug End Reason
Local unit code
IBD Audit code
IBD Biologics Audit site code

IBD Registry Contacts



IBD Registry
Medication



Selected centres

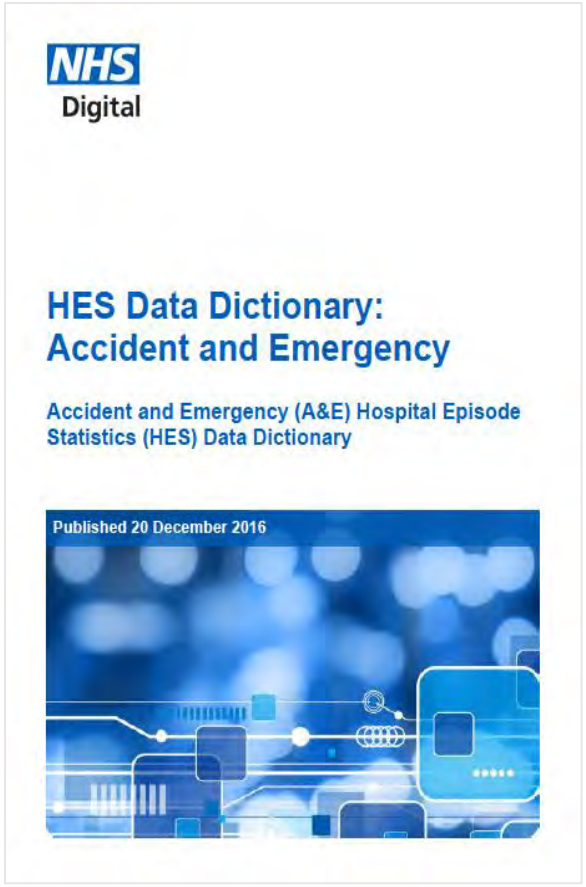
Missing cases

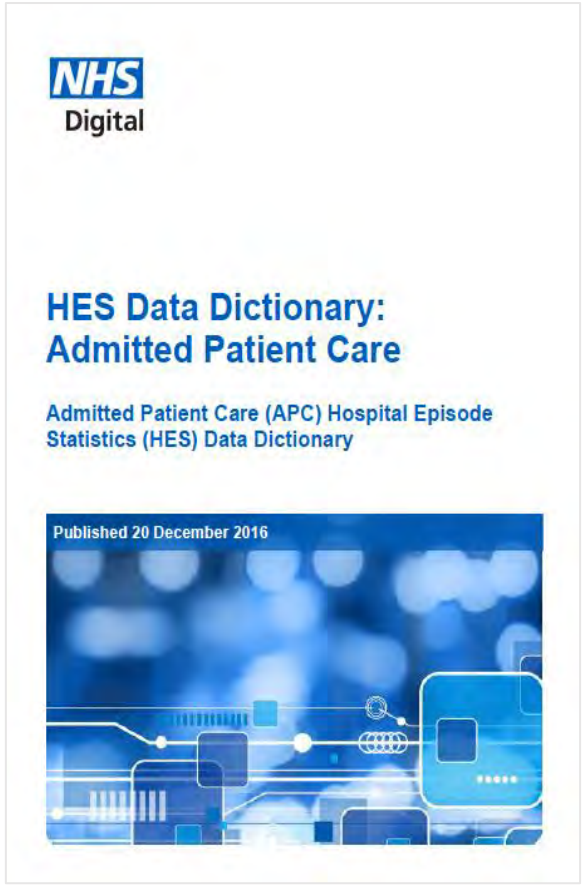
Missing data

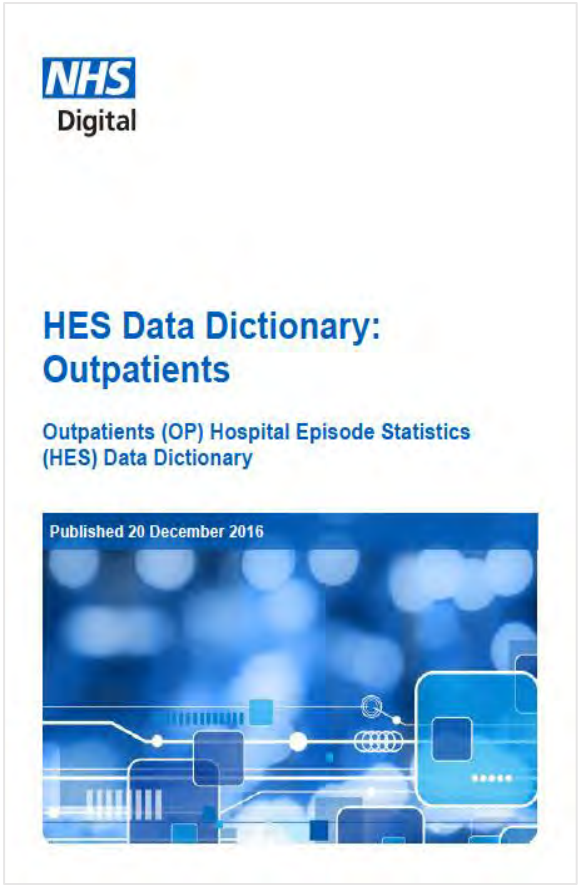
Overview

- Real-world data
- The UK IBD Registry
- Routine Administrative Data
- Linkage for Pharmacoeconomic Research

Hospital Episode Statistics







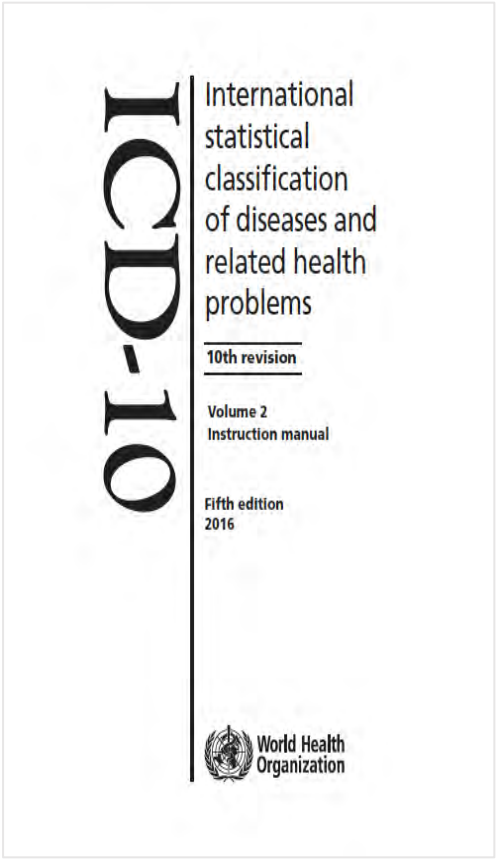
Admitted Patient Care: Diagnoses

NHS Digital

HES Data Dictionary

Admitted Patient Care (APC) Data Set

Diagnosis - 4 characters (DIAG_4_NN)	
Field	DIAG_4_NN
Field Name	Diagnosis - 4 characters
NHS Field Name	N/A
Category	Clinical
Length and format	4an
Availability	1989-90 onwards
Description	This provides the first four characters of diagnosis codes.
Value	4an = A valid ICD-9 or ICD-10 diagnosis code Null = Not applicable R69X = Not known, invalid or null
Cleaning Rule	None



Note: No ‘date of diagnosis’

Admitted Patient Care: Procedures

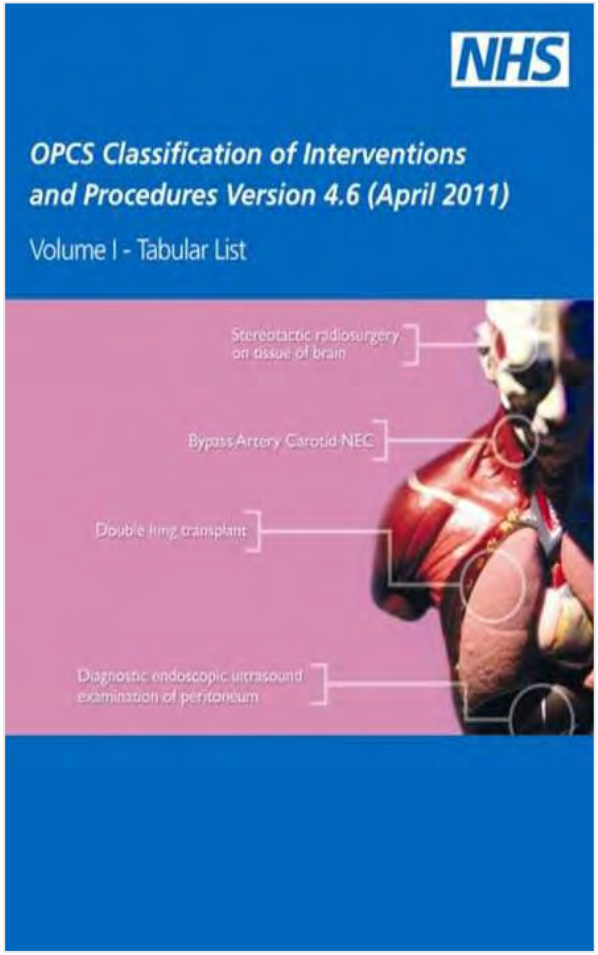
NHS Digital

HES Data Dictionary

Admitted Patient Care (APC) Data Set

Operative procedure (OPERTN_NN)

Field	OPERTN_NN
Field Name	Operative procedure
NHS Field Name	PRIMARY PROCEDURE (OPCS) PROCEDURE (OPCS)
Category	Clinical
Length and format	4an
Availability	1989-90 onwards
Description	There are twenty-four fields (twelve before April 2007), oper_01 to oper_24, which contain information about a patient's operations. The field oper_01 contains the main (ie most resource intensive) procedure. The other fields contain secondary procedures. The codes are defined in the Tabular List of the Classification of Surgical Operations and Procedures. The current version is OPCS4. Procedure codes start with a letter and are followed by two or three digits. The third digit identifies variations on a main procedure code containing two digits. The third digit is preceded by a full stop in OPCS4, but this is not stored in the field. A single operation may contain more than one procedure.
Value	4an = Procedure code - = No operation performed & = Not known X998 = Outpatient procedure carried out but no appropriate OPCS-4 code available X999 = No outpatient procedure carried out X997 = Not known
Cleaning Rule	Rule # 450, 540, 550, 560, 610 and 620



Note: No prescription data

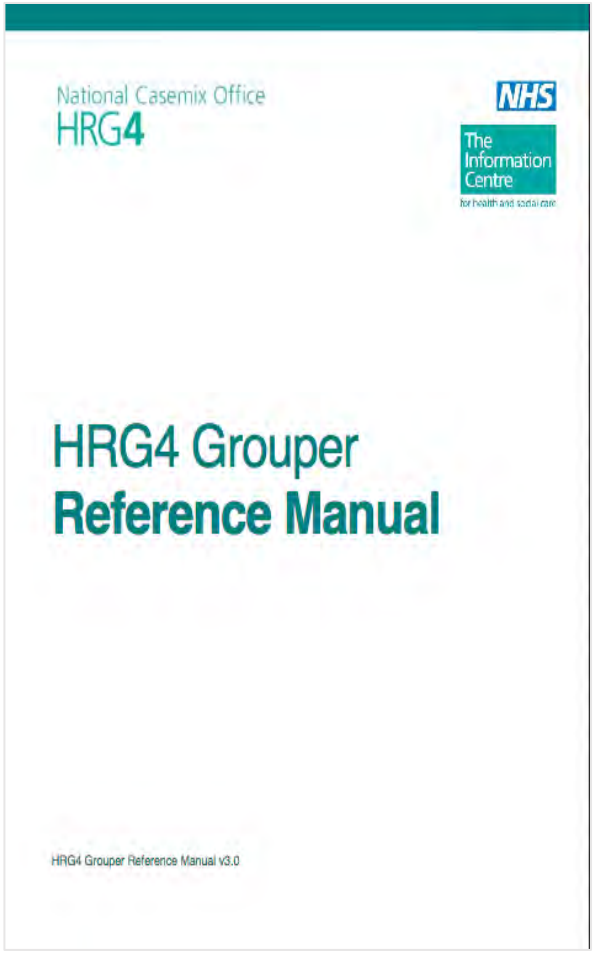
Admitted Patient Care: HRG's

NHS Digital

HES Data Dictionary

Admitted Patient Care (APC) Data Set

Healthcare resource group: version 3.1 (HRG_N.N)	
Field	HRG_N.N
Field Name	Healthcare resource group: version 3.1
NHS Field Name	N/A
Category	Healthcare resource groups (HRG) data
Length and format	ann
Availability	2001-02 to 2008-09
Description	This derived field contains healthcare resource group (HRG) values. HES adds the two most recent versions of HRG codes to records. For example, a record for 2004-05 will have codes for HRG version 3.1 and HRG version 3.5.
Value	3.1 = Applied HRG code from 1989-90 to 2005-06 inclusive 3.5 = Applied HRG code from 2003-04 onwards 4.0 = Applied HRG code from 2006-07 onwards Null = Not applicable
Cleaning Rule	None



Admitted Patient Care: ADMIMETH

NHS Digital

HES Data Dictionary

Admitted Patient Care (APC) Data Set

Method of admission (ADMIMETH)

Field	ADMIMETH
Field Name	Method of admission
NHS Field Name	ADMISSION METHOD (HOSPITAL PROVIDER SPELL) (V6-1) ADMISSION METHOD CODE (HOSPITAL PROVIDER SPELL) (V6-2)
Category	Admissions; Period of Care
Length and format	2n
Availability	1989-90 onwards
Description	This field contains a code which identifies how the patient was admitted to hospital. Admimeth is recorded on the first and also all subsequent episodes within the spell (ie where the spell is made up of more than one episode).

Emergency Admission

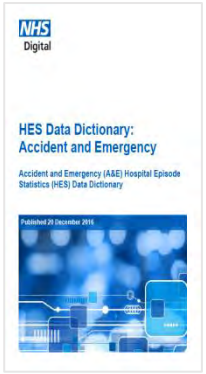
EMERGENCY

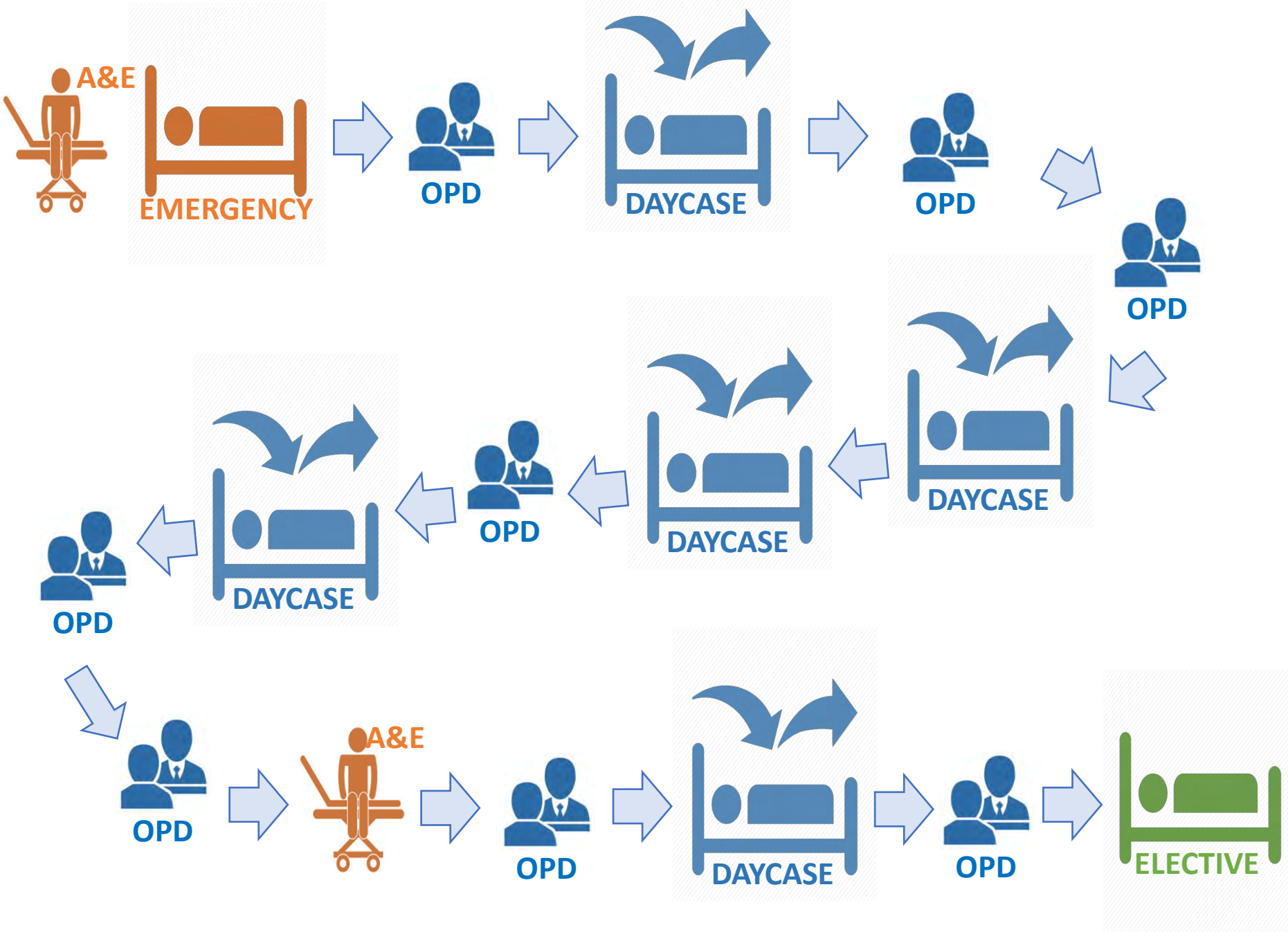
Elective Admission

ELECTIVE

DAYCASE

Secondary Care Events

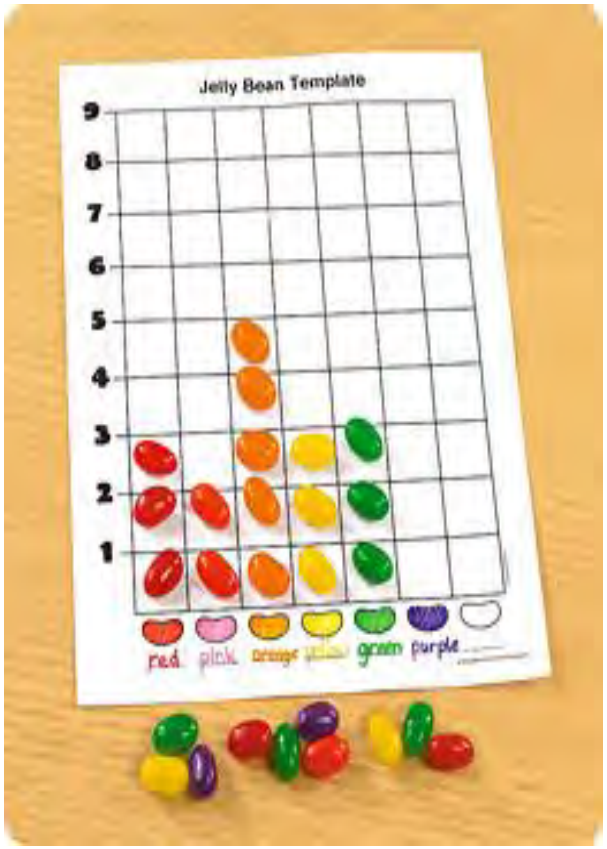


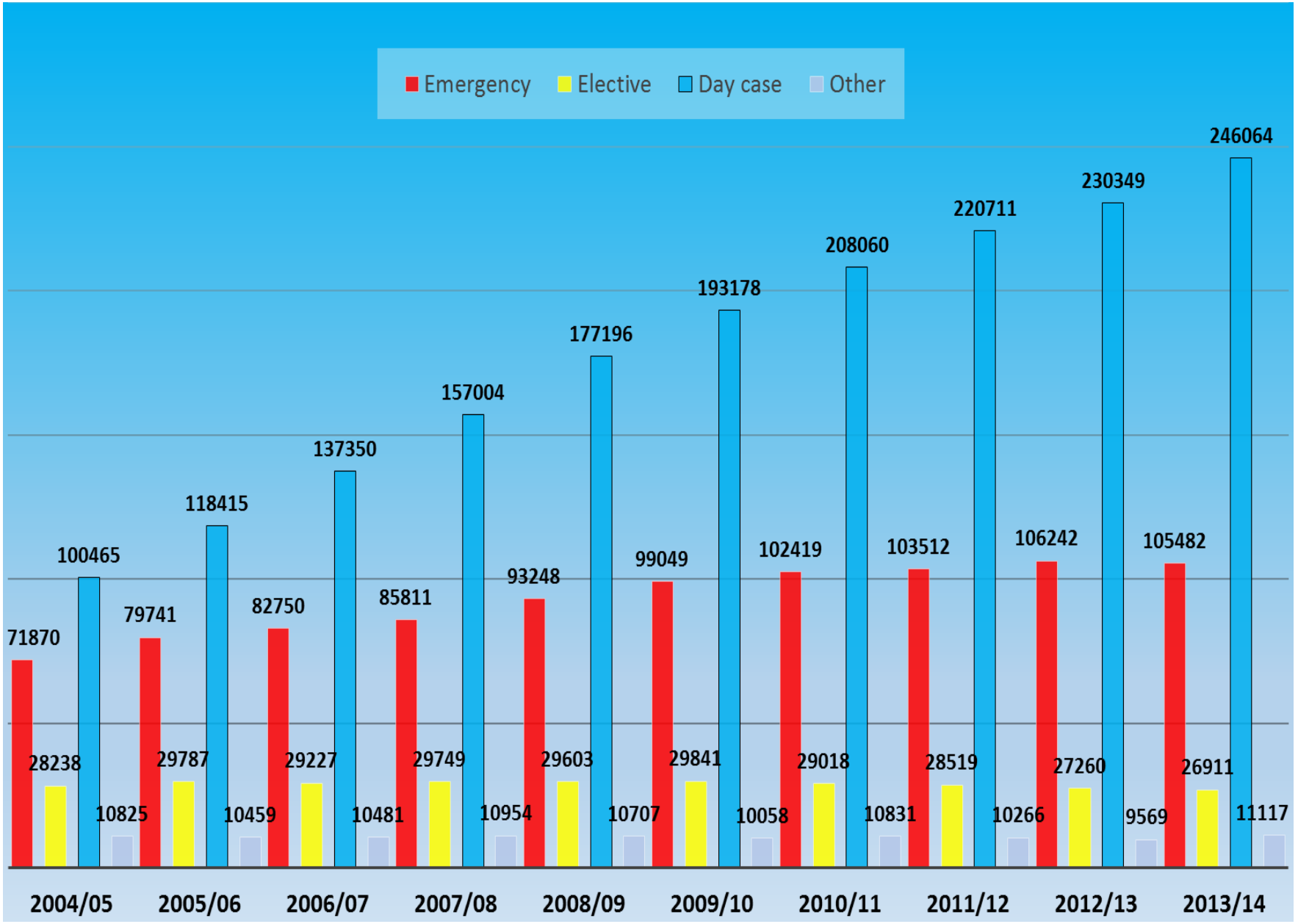

A&E
EMERGENCY
OPD
DAYCASE
OPD
OPD
DAYCASE
DAYCASE
OPD
DAYCASE
OPD
OPD
A&E
OPD
DAYCASE
OPD
ELECTIVE

Clinically Led Analytics

Data

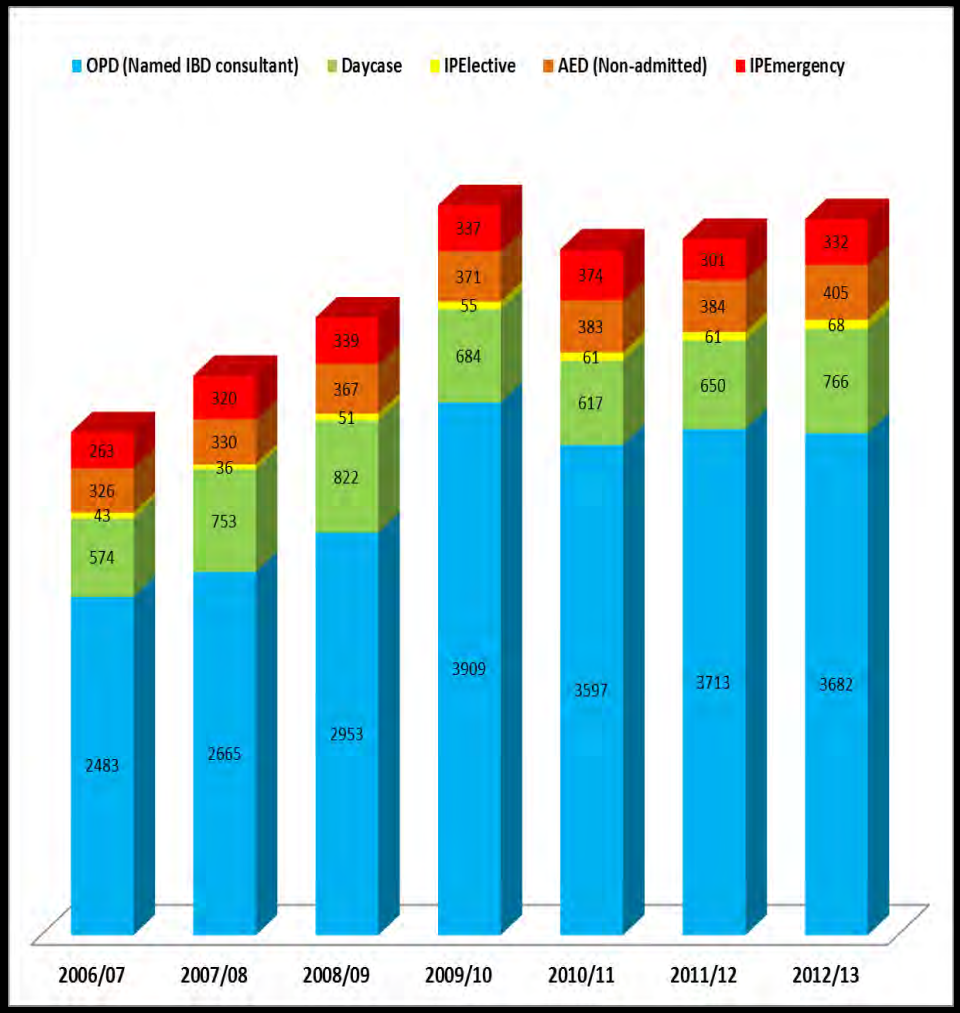
Information



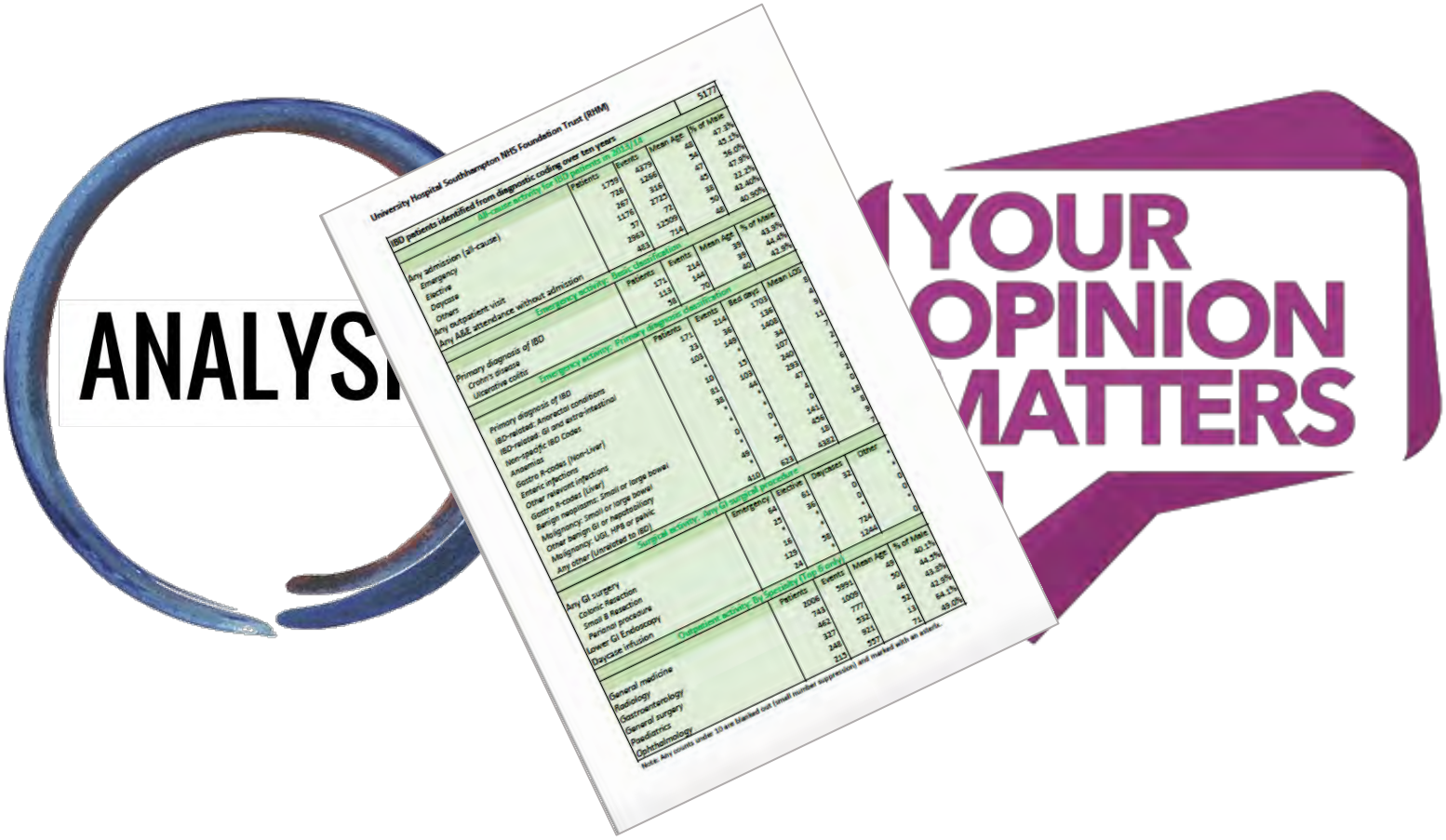


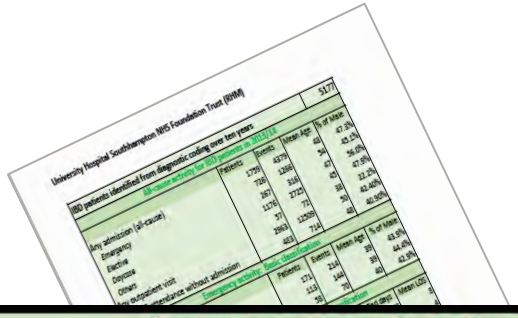
Ten years trends in hospital activities relating to the IBD patient population in England (derived from Hospital Episode Statistics)

Hospital Activities (Site Level Data)



Front line feedback

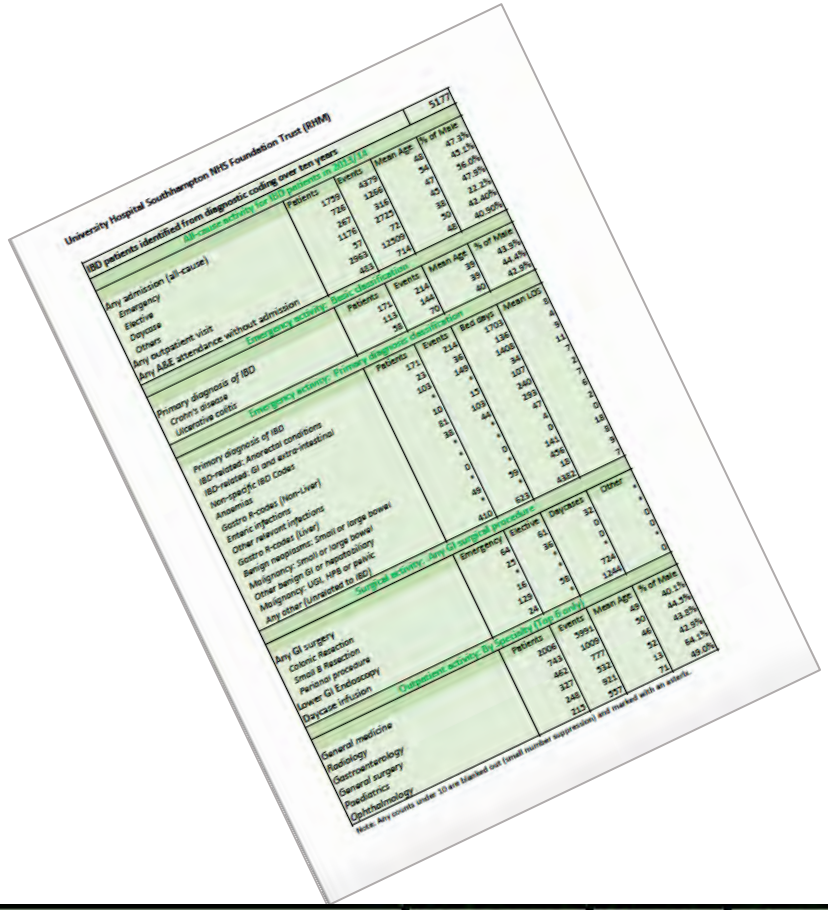




Emergency activity: Basic classification				
	Patients	Events	Mean Age	% of Male
Primary diagnosis of IBD	171	214	39	43.9%
Crohn's disease	113	144	39	44.4%
Ulcerative colitis	58	70	40	42.9%

Emergency activity: Primary diagnosis classification				
	Patients	Events	Bed days	Mean LOS
Primary diagnosis of IBD	171	214	1703	8
IBD-related: Anorectal conditions	23	36	136	4
IBD-related: GI and extra-intestinal	103	149	1408	9
Non-specific IBD Codes	*	*	34	11
Anaemias	10	15	107	7
Gastro R-codes (Non-Liver)	81	103	240	2
Enteric infections	38	44	293	7
Other relevant infections	*	*	47	6
Gastro R-codes (Liver)	*	*	4	2
Benign neoplasms: Small or large bowel	0	0	0	0
Malignancy: Small or large bowel	*	*	141	18
Other benign GI or hepatobiliary	49	59	456	8
Malignancy: UGI, HPB or pelvic	*	*	18	9
Any other (Unrelated to IBD)	410	623	4382	7

Relevant emergency admissions "missed" by focusing on primary diagnosis alone



University Hospital Southampton NHS Foundation Trust (RHM)

IBD patients identified from diagnostic coding over ten years: 5177

All-cause activity for IBD patients in 2013/14

	Patients	Events	Mean Age	% of Male
Any admission (all-cause)	1755	4379	46	47.3%
Emergency	738	1366	54	45.1%
Elective	267	316	47	36.0%
Daycase	1176	2725	45	47.9%
Others	57	72	38	22.2%
Any outpatient visit	2563	12509	50	42.4%
Any A&E attendance without admission	483	714	48	40.56%

Emergency activity: Basic classification

	Patients	Events	Mean Age	% of Male
Primary diagnosis of IBD	171	214	39	43.9%
Crohn's disease	113	144	39	44.4%
Ulcerative colitis	58	70	40	42.9%

Emergency activity: Primary diagnosis classification

	Patients	Events	Bed days	Mean LOS
Primary diagnosis of IBD	171	214	1705	8
IBD-related: Anorectal conditions	23	36	136	6
IBD-related: GI and extra-intestinal	169	148	1408	9
Non-specific IBD Codes	*	*	94	11
Anaemias	19	13	127	7
Gastro A-codes (Non-Liver)	61	109	240	2
Enteric infections	38	44	292	7
Other relevant infections	*	*	47	8
Gastro A-codes (Liver)	*	0	4	2
Benign neoplasms: Small or large bowel	0	*	0	0
Malignancy: Small or large bowel	*	39	141	18
Malignancy: GI or hepatobiliary	0	*	456	9
Other benign GI or hepatobiliary	*	0	58	9
Malignancy: UGI, HPB or pelvic	0	*	4382	7
Any other (unrelated to IBD)	46	619		

Surgical activity: Any GI surgical procedure

	Emergency	Elective	Daycases	Other
Any GI surgery	64	61	32	*
Colonic Resection	25	36	0	*
Small B Resection	*	*	0	0
Perianal procedure	16	*	*	0
Lower GI Endoscopy	129	58	724	*
Daycase infusion	24	*	1244	0

Outpatient activity: By Specialty (Top 5 only)

	Patients	Events	Mean Age	% of Male
General medicine	2009	3954	40	40.1%
Radiology	763	1069	50	44.3%
Gastroenterology	462	777	46	43.8%
General surgery	337	532	52	42.9%
Paediatrics	248	921	13	64.1%
Ophthalmology	215	557	71	49.0%

Note: Any counts under 10 are blanked out (small number suppression) and marked with an asterix.

	Emergency	Elective	Daycases	Other
Any GI surgery	64	61	32	*
Colonic Resection	25	36	0	*
Small B Resection	*	*	0	0
Perianal procedure	16	*	*	0
Lower GI Endoscopy	129	58	724	*
Daycase infusion	24	*	1244	0

Emergency Admissions To Your Trust

Ulcerative colitis

58

51 patients

30 28

AGE 18-87

168 days

2013/14

Crohn's disease

42

37 patients

22 20

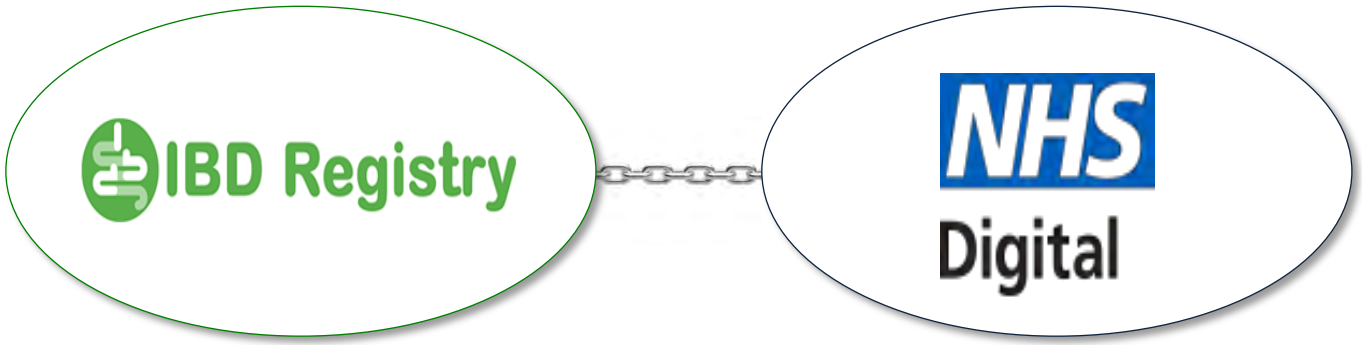
AGE 18-77

245 days

2013/14

Overview

- Real-world data
- The UK IBD Registry
- Routine Administrative Data
- Linkage for Pharmacoeconomic Research


IBD Registry
NHS
Digital

IBD Registry

NHS Digital

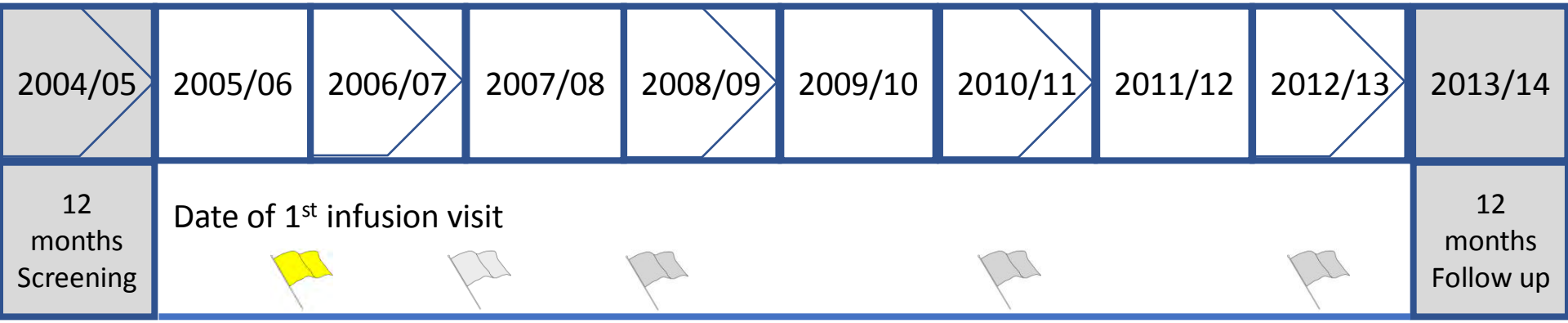
Selected Data Items

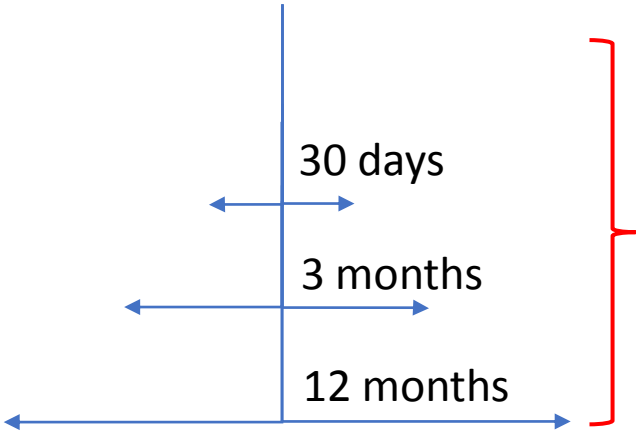
- ❑ **Current diagnosis** (UC, CD or IBD-U)
- ❑ **Date of diagnosis**
- ❑ **Drug name (anti-TNF agent)**
- ❑ **Drug start date**

Hospital Episode Statistics

- ❑ **Inpatient & Daycase Episodes**
- ❑ **Outpatient attendance**
- ❑ **Accident & Emergency attendance**

Key events before and after initiation of biological therapy for Crohn's disease

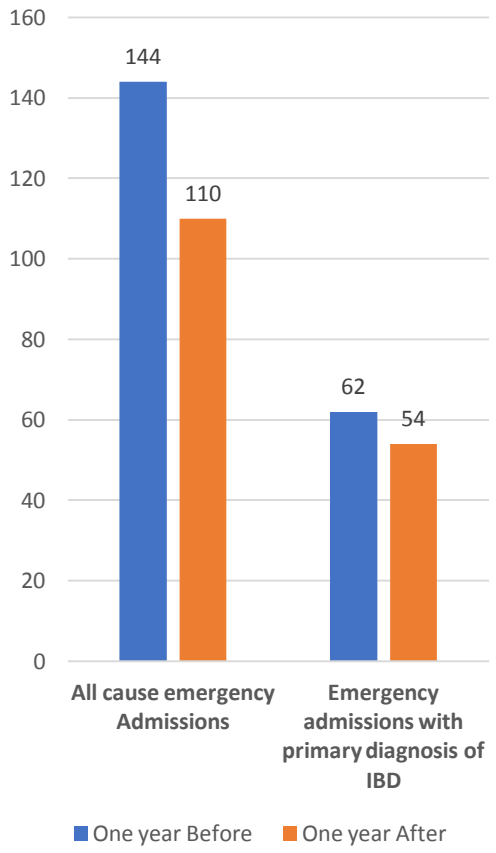




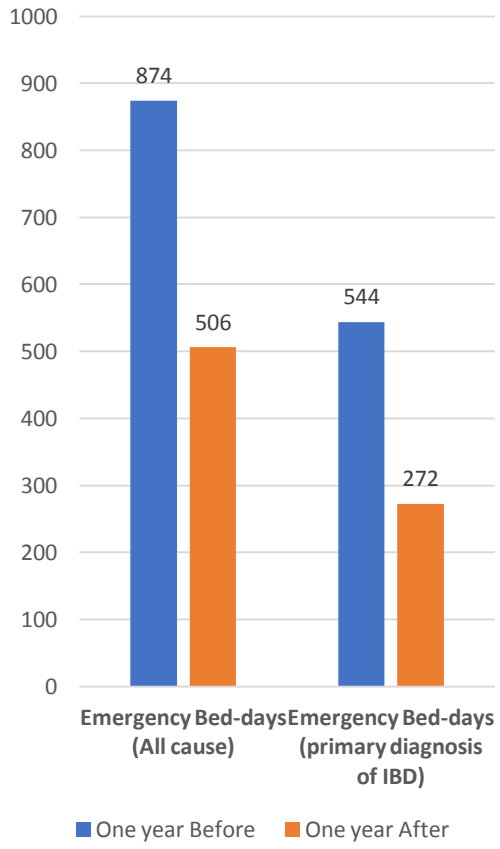
- All-cause admissions (Emergency, Elective, Day case, Other)
- Primary diagnosis and any co-morbidities
- Emergency admissions for IBD care (with or without surgery)
- Major surgical resection (e.g. Colonic, Small bowel)
- Minor surgery (Perianal procedure)
- Infusion visits
- Endoscopies
- OPD visits (e.g. by specialities, consultant)
- A&E (all-cause) attendances (Admitted/ Not admitted)
- In-hospital mortality

Key events before and after initiation of biological therapy for Crohn's disease

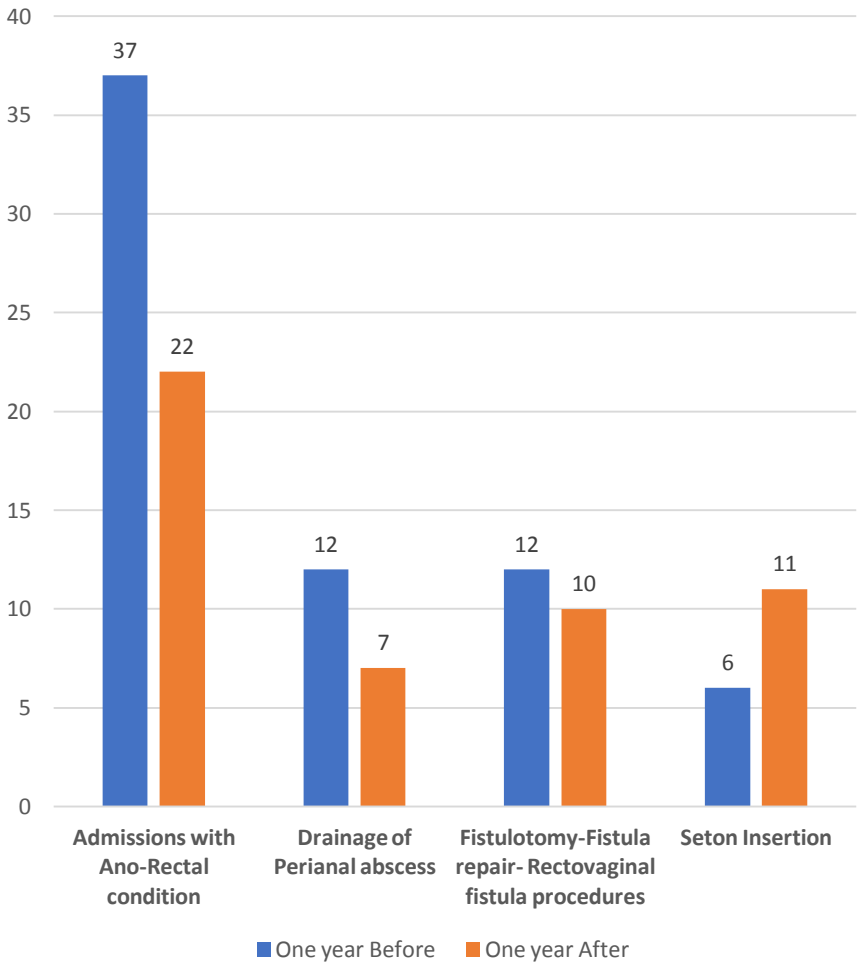
Emergency Admissions



Emergency Bed Days



Key events before and after initiation of biological therapy for Crohn's disease



Key events before and after initiation of biological therapy for Crohn's disease

'Enrichment' via extra Registry data items

- Patient clinical characteristics (sub-groups)
- Specific biologics (named agent)
- Concomitant medication (mono vs. combo)
- Biologics Audit KPI's (process measures)
- Disease activity indices (and PROMs)
- Drug stop dates
- Adverse events

Key events before and after initiation of biological therapy for Crohn's disease

Serious and/or rare events from HES

- All-cause inpatient emergency admissions
- Infections (all, or specific groupings)
- Malignancies
- Cardiovascular events (e.g. MI, Stroke)
- Venous Thromboembolism
- All-cause inpatient death

Key events before and after initiation of biological therapy for Crohn's disease

Geographical Variation

Temporal Trends

Conclusions

- Real-world data is required for health economic studies
- The UK IBD Registry is a vehicle for capturing such data
- Routine administrative data requires careful interrogation
- Linkage can support pharmacoeconomic research

Acknowledgements

- Funding from: Crohn’s & Colitis UK