A United Kingdom inflammatory bowel disease database: Making the effort worthwhile☆

K.D. Bardhan a,⁎, N. Simmonds b, C. Royston c, A. Dhar d, C.M. Edwards e on behalf of the Rotherham IBD Database Users Group

a The Rotherham NHS Foundation Trust, Moorgate Road, ROTHERHAM, South Yorkshire, S60 2UD, United Kingdom
b Luton & Dunstable Hospital NHS Foundation Trust, United Kingdom
c The Rotherham NHS Foundation Trust, United Kingdom
d County Durham & Darlington NHS Foundation Trust, United Kingdom
e South Devon Healthcare NHS Foundation Trust, United Kingdom

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KEYWORDS
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Ulcerative colitis;
Crohn’s disease
Epidemiology;
Database;
Health informatics

Abstract

Background: Inflammatory bowel disease (IBD), a paradigm of chronic illness, requires for its safe clinical management ready access to complete information, not always possible using paper records. Aim: To develop an IBD database (DB) for both individual patient management and collating information across centres.

Methods: Access® based, with a minimum dataset.

Results: Prospectively collected data for 11,432 patients from 21 centres.

Profile Diagnosis: Ulcerative colitis (UC) 56%, Crohn’s disease (CD) 40%, indeterminate colitis 4%. M:F ratio: UC 1.08:1, CD 0.72:1. Median age at diagnosis: UC 39, CD 30 years. Operated: UC 16%, CD 47%. Thiopurine use: UC 16%, CD 29%. IBD related mortality: 0.74%.

Discussion: A snapshot of this large IBD cohort shows the disease profile across the UK is similar to other large series. Unexpected gaps, sometimes large emerged (e.g. data on smoking and immunosuppression) highlighting the need for clear definition, consistency and completeness of data collection. Clinical management is made easier by the ‘at a glance’ summary, automated clinic letters, and facility for monitoring and audit, but the time required limited its ‘real-time’ use.

Conclusion: Our experience shows it is possible to collect data from centres across the country which truly reflects clinical practice. We have learned as much from the process itself as from the data, principally, information needs to be well defined, validated at entry, and updated at every visit, a time consuming sequence which we had underestimated. Our lessons learned may help inform the development of a national database, and support national IBD standards and audit.

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⁎ Corresponding author. Tel.: +44 1 709 304570.

E-mail addresses: bardhan.sec@rothgen.nhs.uk (K.D. Bardhan), nicola.simmonds@ldh.nhs.uk (N. Simmonds), christine.royston@rothgen.nhs.uk (C. Royston), anjan.dhar@cddft.nhs.uk (A. Dhar), cathrynedwards@doctors.org.uk (C.M. Edwards).

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1. Introduction

The ready availability of reliable information is one of the key factors in the management of patients with chronic disease of which inflammatory bowel disease (IBD) is a paradigm. The IBD standards published recently emphasize the role of information technology (IT) systems to support patient care and to optimize clinical management through data collection and audit (http://www.ibdstandards.org.uk/). This view is also endorsed by the Health Informatics Review which highlights the need for responsive, pragmatic and timely IT solutions with a focus on clinically important measurable data (“clinical metrics”).

At present there is no national IBD database and the electronic patient record is still in evolution. Several clinicians have developed and used their own databases to facilitate IBD patient care locally. Such systems are useful and reduce errors, and can offer an instrument for local audit and research. Linking across multiple centres would provide a larger picture of the disease and its management.

We have used the Rotherham–Ferring system in many centres across the United Kingdom (UK) and report our experience encompassing the disease profile, logistical problems, lessons learned, and the benefits perceived.

2. Aim

The principal objectives of the IBD database were to provide:

- An ‘at-a-glance summary’ of the key aspects of an individual patient’s illness for use during clinic consultation.
- The capacity to generate automated clinic letters and patient summaries.
- Individual centre data for cohort analysis and for audit.
- To provide a snap shot of IBD in large patient numbers across multiple centres in the UK.

3. Methods

3.1. Data collection and survey period

The minimum data criteria for inclusion in the survey were date of birth, sex, diagnosis and its date; the survey is based on the 21 centres which fulfilled this.

As part of routine clinical care information is entered into the hospital case notes at every patient contact. This information was extracted for the database. Centres joined at different times and within each centre the clinical information for individual patients was entered into the database at varying times. It is this point of data entry which divided the individual patients information into retrospective, which therefore is historical and obtained by trawling the case notes, and prospective.

Data were censored on 31 October 2006 and the subsequent period was devoted to checking for completeness and accuracy.

3.2. Database

The system is based on Microsoft Office Access® software; the information gathered is entered into predetermined fields. Lessons learned from the first version were used to develop ‘Version 2’ currently in use at the participating centres. The database is on a CD ROM and is available free of charge from Ferring Pharmaceuticals whose staff provide the initial training at individual centres. Gastroenterologists, specialist nurses or research colleagues entered the data.

3.3. Dataset

The IBD Database ‘Core User Group’ agreed the definitions and selected the following items to comprise the minimum dataset:

- Date of birth
- Gender
- Smoking history
- Family history
- Principal diagnosis
- Date of diagnosis
- Extent of disease
- Current and past therapies
- Surgery
- Date and cause of death

Not all centres had collected the minimum dataset on every patient by the end of the survey period hence some analyses were restricted to centres with complete data.

3.4. Principal diagnosis

The diagnoses of ulcerative colitis (UC), Crohn’s disease (CD) and indeterminate colitis i.e. colonic disease not yet classified as UC or CD, were those made by clinicians in individual centres and based on accepted criteria namely, a combination of endoscopy and histology, radiology and/or surgery.

3.5. Extent of disease

The extent refers to the maximum disease encountered during the course of the illness. It was generally interpreted as a combination of macroscopic appearance and histology and divided into the following broad categories:

<table>
<thead>
<tr>
<th>Ulcerative and indeterminate colitis</th>
<th>CD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal</td>
<td>Colonic</td>
</tr>
<tr>
<td>Left-sided</td>
<td>Terminal ileum</td>
</tr>
<tr>
<td>Extensive</td>
<td>Confined to the colon</td>
</tr>
<tr>
<td></td>
<td>No disease clearly defined outside the terminal ileum</td>
</tr>
<tr>
<td></td>
<td>Involving colon and terminal ileum</td>
</tr>
<tr>
<td>Small bowel</td>
<td>One or more sites proximal to terminal ileum</td>
</tr>
<tr>
<td>Small and large bowel</td>
<td>One or more sites proximal to terminal ileum+colonic disease</td>
</tr>
<tr>
<td>Perianal +/− other site</td>
<td>Perianal with or without any other site</td>
</tr>
<tr>
<td>Other</td>
<td>Any not defined above e.g. duodenal, oral, and oesophageal disease</td>
</tr>
</tbody>
</table>

Some centres kept additional data dividing the distal category into proctitis or recto-sigmoid disease, and extensive colitis into pan colitis or disease to the hepatic flexure.
Classification was based on consensus clinical descriptors which could be mapped to international classifications if required (the Montreal classification was published after the User Group’s inception). Recording of disease behaviour patterns in CD was left to individual clinician choice.

3.6. Smoking

Smoking status was recorded as smoker, non-smoker or ex-smoker. A time point for this data was not specified; the last available entry was taken as definitive. Patient records where the smoking status was not recorded were excluded for this specific analysis.

3.7. Current and past therapies

Treatment with 5-aminosalicylic acid (5-ASAs), steroids, immunosuppressive drugs and biologicals was recorded but in this, our first survey, analysis was restricted to the latter two. The results refer to current treatment i.e. at the closing date and are limited to centres with a substantial number of patients included in the database and with data at least 80% complete regarding thiopurine and biologicals use.

3.8. Surgery

Surgical procedures defined by specific name or by description were re-categorised in to one of the following broad groups:

- UC: Colectomy with ileostomy.
- UC: Colectomy with restorative ileo-anal pouch
- CD: Resection surgery (RS) including subtotal colectomy, segmental colectomy, small bowel resection or strictureplasty.
- CD: Examination under anaesthetic (EUA) including surgical toileting of the perineal area, seton suture insertion, perianal abscess drainage (PA).
- CD: Other. All other procedures e.g. percutaneous drainage of abdominal collection.

Analysis was restricted to the 3 centres with complete data.

3.9. Mortality

Only validated data was accepted; this included a thorough review of patient records past and current and verification against death certificate where necessary. Data is presented for South Devon and Rotherham only. Mortality is arbitrarily divided into those where death was "directly related" to the IBD as opposed to death from all others causes. "Direct relation" we defined as when death is clearly, immediately and unarguably connected to the disease, e.g. following emergency colectomy for toxic megacolon. Examples of death from "all other causes" are where the connection is tenuous, e.g. colonic cancer on a background of distal UC, or remote, e.g. from myocardial infarct in an elderly person with stable IBD.

3.10. Data protection

All data submitted as part of the research project was initially collected as part of the clinical care by the individual clinicians. All patient identification was removed and anonymised data used for analysis; therefore, explicit patient consent was not required.

4. Result

4.1. Patient numbers (Table 1)

21 centres, serving populations ranging from 90,000 to 680,000, contributed between 49 and 1233 patients to the database (total=11,432 patients) for analysis. Table 1 shows details of the individual centres, the approximate population served, the number of hospital beds and the number of patients submitted. Data from one Trust (South Devon) has been additionally validated by auditing of Primary Care Read codes showing that the secondary/primary care split of IBD patients is 77% vs. 23% (C Edwards. Personal communication).

For the two pilot Trusts, South Devon and Rotherham, estimated crude prevalence rates per 100,000 population were 233 and 154 for UC and 185 and 137 for CD, respectively. Annual incidence for the calendar year 2006 was 13.1 and 6.8 for UC and 5.5 and 5.2 for CD, respectively.

4.2. Diagnosis; demography

Amongst our 11,432 patients UC was a little more common than CD and on average UC patients were about almost a decade older. Indeterminate disease was uncommon (Table 2).

4.3. Extent of disease

One third of patients (34%) had extensive UC compared with 44% with distal disease only. CD was confined to the colon in 38% and to the terminal ileum in a further 24%; another 22% had ileo-colonic disease (Table 3).

4.4. Smoking

Smoking habits were recorded in only 5237/11,432 patients (46%). The biggest difference seen was in the proportion who smoked: UC 11% and indeterminate colitis 18% compared with 33% in CD. There was a less marked difference in ex-smokers: UC 20%, CD 15%.

4.5. Immunosuppression

Data are presented for 4 centres (n=3143) with >80% complete data as described in Methods. Thiopurines were in current use in 13% of UC and 27% of CD patients (19% for IBD
as a whole). Their use varied widely in UC ranging from <8% to ∼18%, but for CD was similar across centres (∼27%) (Table 4).

4.6. Surgery

Data are presented based on 3 centres with complete information. Almost 16% of UC patients underwent colectomy, the majority of them with ileostomy and the remainder with a pouch construction (Table 5, Fig. 1).

Operation rates were much higher in CD; 568 (47%) of patients underwent 1097 procedures. Further analyses showed 346 (61%) were operated upon once only, 114 (20%) twice and 108 (19%) 3 times or more.

4.7. Mortality

Data are presented for the 2 pilot centres. In South Devon, 42/1233 (3.4%) patients died, 6 (0.5%) from IBD related causes: UC 1/24, CD 5/14, indeterminate colitis 0/4. Correspondingly, in Rotherham, 73/778 (9.4%) died, 9 (1.2%) deaths were IBD related: UC 3/37, CD 5/32 and indeterminate colitis 1/4.
5. Discussion

Our study has proven instructive for three reasons. It has given us a profile of over 11,000 IBD patients across twenty-one centres in the United Kingdom, has afforded the participants the opportunity to examine their own practice in depth, and has identified practical problems others too may encounter in a national effort.

5.1. The profile of IBD

5.1.1. Incidence

As most previous reports of IBD epidemiology in the UK come from major tertiary centres, one might expect a degree of referral bias. Our report is of patients seen predominantly in non-university centres (i.e. District General Hospitals) in England and Northern Ireland and based mostly on outpatient assessments; yet the disease profile is similar, not only to reports from the major UK centres but also to those from tertiary centres overseas. The annual incidence (per 100,000 population) of UC and CD cited in the literature ranges from 8.8 to 13.4 and 5.6 to 8.6 respectively,11–13 and is comparable to the calculated crude incidence for Rotherham and South Devon, the two pilot centres (10.4 to 13.1 for UC and 3.6 to 5.5 for CD). These figures, particularly from South Devon are higher than the estimates cited in the British Society of Gastroenterology Strategy Document and by the National Association for Colitis and Crohn’s Disease and would, if replicated, have implications for the National Service Strategy.14,15

5.1.2. Age

The median age at diagnosis for UC and CD was 39 and 30 years respectively. This younger age at diagnosis of CD is similar to observations made by others.16,17

5.1.3. Extent of disease

One third (34%) of our UC patients had extensive disease (i.e. beyond the splenic flexure) compared with 27% in the recent Danish study. There were differences in the extent of distal disease but details are clouded by the difference in definitions used. Thus 31% in the Denmark series had rectal disease only whereas in our study rectal disease is grouped with sigmoid involvement as “distal disease”, 44%.17

The colon was the sole site of CD in 38% of our patients, somewhat higher than the 27% reported from the USA three decades ago18 but mirrored by the recent studies from Denmark and Wales, UK.19 The latter, a time-trend series, also shows a corresponding fall in the proportion with ileal disease matching our snapshot of 24%. The decline in ileal but rise in colonic disease may represent a changing natural history.

These observations raise the issue of how disease is staged and defined for the purpose of national data collection. Factors affecting the description and definition of disease may vary according to imaging method, the histological definition, its extent, and inter-observer variation. Despite these potential confounding factors, the broad pattern of disease we observed was consistent with that noted in current literature. This has practical relevance as genetic and molecular methods are increasingly used to study IBD for which a necessary pre-requisite is accurate phenotyping.

5.1.4. Smoking

Smoking was not consistently recorded by all centres, having been noted in only 5237 of the 11,432 patients (46%) which compares poorly with the 85% noted in the National Audit20 (see below). This is a surprising omission for smoking is a known environmental risk factor associated with CD relapse.21 However, more information (up to 86% complete) was noted in those centres where the database is being used regularly as a clinical management tool. The data available are

### Table 4

<table>
<thead>
<tr>
<th>Trust</th>
<th>Ulcerative colitis n (%)</th>
<th>Crohn’s disease n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%) on thiopurines</td>
<td>n (%) on infliximab</td>
</tr>
<tr>
<td></td>
<td>Ulcerative colitis/indeterminate</td>
<td>Crohn’s disease</td>
</tr>
<tr>
<td>South Devon</td>
<td>87/724 (12.0)</td>
<td>139/509 (27.3)</td>
</tr>
<tr>
<td>Rotherham</td>
<td>73/435 (16.8)</td>
<td>95/343 (27.7)</td>
</tr>
<tr>
<td>Heart of England</td>
<td>29/375 (7.7)</td>
<td>53/208 (25.5)</td>
</tr>
<tr>
<td>Co. Durham &amp; Darlington</td>
<td>66/378 (17.5)</td>
<td>46/171 (26.9)</td>
</tr>
</tbody>
</table>

5.2. Number of patients operated upon. This includes patients operated upon at any time and irrespective of type of operation.

### Table 5

<table>
<thead>
<tr>
<th>Trust</th>
<th>Ulcerative colitis n (%)</th>
<th>Crohn’s disease n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Colectomy + ileostomy</td>
<td>Colectomy + pouch</td>
</tr>
<tr>
<td></td>
<td>Resection/strictureplasty</td>
<td>EUA/PA</td>
</tr>
<tr>
<td></td>
<td>Total a</td>
<td></td>
</tr>
<tr>
<td>South Devon</td>
<td>76/642 (11.8)</td>
<td>209/509 (41.1)</td>
</tr>
<tr>
<td></td>
<td>42/642 (6.5)</td>
<td>255/509 (50.1)</td>
</tr>
<tr>
<td>Rotherham</td>
<td>38/386 (9.8)</td>
<td>136/343 (39.7)</td>
</tr>
<tr>
<td></td>
<td>7/386 (1.8)</td>
<td>159/343 (46.4)</td>
</tr>
<tr>
<td>United Bristol</td>
<td>30/278 (10.8)</td>
<td>128/346 (37.0)</td>
</tr>
<tr>
<td></td>
<td>10/278 (3.6)</td>
<td>154/346 (44.5)</td>
</tr>
</tbody>
</table>

a Some Crohn’s patients had EUA/PA and resection/strictureplasty.
unsurprising, showing that three times as many CD patients smoked compared with UC (33% vs. 11%). This emphasises the need to extend service provision for smoking cessation particularly to the Crohn’s population and for keeping complete and accurate records of this important environmental risk in IBD.

5.1.5. Immunosuppression

The considerable variability in the use of immunosuppression across centres is one of the key findings of our snapshot, suggesting that practice countrywide may be highly variable and not in keeping with nationally perceived standards of care. This variability was also noted in the National Audit, a retrospective survey carried out in 2006 of 5681 in-patients across 185 UK centres, a sample of IBD patients admitted during the previous 2 years.

Our overall use of immunosuppressants was less than that in Oxford (19% vs. 28%) as reported in their 30 year review,22 particularly so in UC (13% vs. 26%) where there was much variability across our centres. Similar rates were seen in CD (27% vs. 32% respectively). These differences are unlikely to be explained by incomplete data collection for even in centres where the data is complete the use in UC is lower (South Devon 12%, Rotherham 17%). One interpretation is that in hospitals outside major teaching centres, changes in therapy take longer to implement and are dependent on clinician experience.

Only few patients were currently receiving infliximab at the time of enquiry (CD around 3% and only 0.1% in UC), although its use, and that of other monoclonals is likely to have increased subsequently in all centres. We suggest the use of this important new treatment be an important part of future national data collection.

5.1.6. Surgery

About 16% of UC patients underwent colectomy, less than one third with construction of an ileo-anal pouch, even during the last ten full years of the survey (1996 to 2005). In contrast almost three times as many (47%) with CD were operated upon. Some underwent a series of operations which accords with international experience,23,24 and emphasises the distinct natural history of a subset with progressive disease.

5.1.7. Mortality

The overall mortality in the two centres (South Devon and Rotherham) differed (3.4% vs. 9.4% respectively), a difference in part because of the longer period of data collection at the latter site. Only a minority of the deaths in both centres were related to IBD itself i.e. co-morbidity was the principal cause.

5.2. Lessons learned from data collection

The collection of descriptive data even against pre-defined criteria has taken much longer than planned. Unexpected gaps were found which made comparison of detail across centres difficult; information therefore had to be regrouped into broad categories, a time consuming process.

Survey of our participating investigators showed that whilst appreciating its strength, realising the full potential of the database was proving difficult for practical and logistical reasons. A major problem was that its use was “too time consuming”, and lack of refresher training and standardisation was a hindrance. As a result few used the system in the clinic in ‘real-time’, or used it for regular audits or to produce letters. There was general agreement easy linking with hospital patient information and results systems coupled with ready access to the database from the clinic might increase its use. On the positive side, those who did use the database as a record commented it was very useful when patients phoned the help line or when case notes were missing.

5.3. Suggestions

We have learned that ease of use, relevance, and easily demonstrable benefits to users encourage continued entry of good quality data. Our experience prompts us to make the following suggestions which may be helpful for the development of any future IBD database and may also have relevance for other chronic disease management systems or electronic patient records.

5.3.1. Data

- From the outset, data fields need to be clearly defined based on National Standards, standardised, validated at
entry, and regularly reviewed to ensure continued high quality.
• Data needs to be collected prospectively and updated at every visit
• Facilities to record changes in the disease and its treatment

5.3.2. Making the database work

• Ongoing and complete data collection is achievable if each participant collects the little that is required, consistently, and at every contact.
• Intuitive "user-friendly" interface allowing data to be entered in a structured format with minimal need for free text, for example by "tick boxes" and "drop down" lists: this speeds data entry hence aids prospective data collection.
• Integrate with existing computerised patient administration and laboratory reporting systems thus avoiding duplication. An example in the UK is the HL7 system, version 3 of which has been adopted by 'Connecting for Health' for all national applications, its 'message' component lending itself for laboratory reporting.
• If more than one software solution is in use a common data format is required to facilitate multi-centre analysis

5.3.3. Working with the clinician

• "Record what the clinician does and not make the clinician record what the system says" i.e. reflect the reality of practice. Automatically capture the quality measures (identified in the National IBD audit and Standards) and produce regular reports tailored to the individual users need (which is sometimes referred to in current literature as 'dashboards').
• Facilities to support audit and quality improvement

5.4. Conclusion

By 2010 in the UK all those providing care for IBD will be expected to meet the six major benchmarks of the National IBD Clinical Quality Standards, one of which is information technology and audit. IBD is a worldwide problem so others may find our experience of interest. This project has demanded technology but even more of time, discipline and doing the 'simple' things well. The technical aspect of creating the database, however, is not an end in itself but a means towards it, namely raising our own standards of IBD care.

Acknowledgements

The authors are indebted to Bryan Archer, Independent IT Consultant who has worked on the database since its inception and has facilitated data processing for the whole group, to Tim Orchard for his helpful review of the paper, and to Ferring Pharmaceuticals for their continued commitment to the Database as part of their ongoing support to the IBD community. This work would not have been possible without the input of our colleagues throughout the country (see Appendix A) to whom we are grateful.

Appendix A

<table>
<thead>
<tr>
<th>Name of trust</th>
<th>Contributors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolton Hospitals</td>
<td>Cath Pearson</td>
</tr>
<tr>
<td>Brighton and Sussex University Hospitals</td>
<td>Lyn Dyer, Stuart Cairns</td>
</tr>
<tr>
<td>Chesterfield Royal Hospitals</td>
<td>Keith Dear, Kay Greveson</td>
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<tr>
<td>County Durham and Darlington</td>
<td>Jane Donachy</td>
</tr>
<tr>
<td>East and North Hertfordshire</td>
<td>David Rowlands, Deborah Morris</td>
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<tr>
<td>Hammersmith Hospitals</td>
<td>Marta Carpani, Lyn Evans</td>
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<td>Heart of England</td>
<td>Rex Poulson</td>
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<td>Ipswich Hospitals</td>
<td>Monica Cutmore, Yin Miao</td>
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<tr>
<td>Luton &amp; Dunstable Hospital</td>
<td>Tony Griffiths</td>
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<tr>
<td>Newry &amp; Mourne</td>
<td>Charles O'Brien</td>
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<tr>
<td>North Bristol</td>
<td>Melanie Lockett, Lyn Williams</td>
</tr>
<tr>
<td>North Hampshire Hospital</td>
<td>Jeanne Prosser</td>
</tr>
<tr>
<td>Royal Wolverhampton Hospitals</td>
<td>Brian McKaig</td>
</tr>
<tr>
<td>South Devon Healthcare</td>
<td>Hilary Durbin, Anita Coulson</td>
</tr>
<tr>
<td>Ulster Community and Hospital Trust</td>
<td>Tony Tham</td>
</tr>
<tr>
<td>United Bristol Healthcare</td>
<td>Aileen Fraser</td>
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<tr>
<td>United Lincolnshire Hospitals</td>
<td>David Allen</td>
</tr>
<tr>
<td>University Hospitals Coventry &amp; Warwickshire</td>
<td>Jayne Eden, Sonia Ford</td>
</tr>
<tr>
<td>West Dorset General Hospitals</td>
<td>Sheila Phillips</td>
</tr>
<tr>
<td>Whittington Hospital</td>
<td>Clive Onnie, Vidja Morgan</td>
</tr>
</tbody>
</table>

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