Outcomes from homeopathic prescribing in medical practice: A prospective, research-targeted, pilot study

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Background and aims: A base for targeted research and development in homeopathy can be founded on systematic collection and analysis of relevant clinical data obtained by doctors in routine practice. With these longer-term aims in mind, we conducted a pilot data collection study, in which 14 homeopathic physicians collected clinical and outcomes data over a 6-month period in their practice setting.

Methods: A specifically designed Excel spreadsheet enabled recording of consecutive clinical appointments under the following main headings: date, patient identity (anonymised), age and gender, medical condition/complaint treated, whether chronic or acute, new or follow-up case, patient-assessed outcome (7-point Likert scale: −3 to +3) compared with first appointment, homeopathic medicine/s prescribed, whether any other medication/s being taken for the condition. Spreadsheets were submitted monthly via email to the project co-ordinator for data synthesis and analysis.

Results: Practitioners typically submitted data regularly and punctually, and most data cells were completed as required, enabling substantial data analysis. The mean age of patients was 41.5 years. A total of 1783 individual patient conditions were treated overall. Outcome from two or more homeopathic appointments per patient condition was obtained in 961 cases (75.9% positive, 4.6% negative, 14.7% no change; 4.8% outcome not recorded). Strongly positive outcomes (scores of +2 or +3) were achieved most notably in the frequently treated conditions of anxiety, depression, and irritable bowel syndrome.

Conclusions: This multi-practitioner pilot study has indicated that systematic recording of clinical data in homeopathy is both feasible and capable of informing future research. A refined version of the spreadsheet can be employed in larger-scale research-targeted clinical data collection in the medical practice setting—particularly in primary care. Homeopathy (2006) 95, 199–205.

Keywords: systematic data collection; homeopathic doctors; clinical outcomes; research targeting

Introduction

The published, peer-reviewed, research evidence base in homeopathy is slim (little more than 100 randomised controlled trials, RCTs) but gaining weight. Much of this existing body of research has investigated specific medical conditions for which evidence of the efficacy of homeopathy (individualised or non-individualised) has been sought. Future clinical research in homeopathy would benefit from being more firmly grounded in normal homeopathic practice, focusing on conditions/symptoms where there is particularly promising case-based evidence of its effectiveness. It is therefore important that clinical outcomes in the ‘real world’
of homeopathic practice are characterised by conducting suitable systematic observational studies. They are strongly advocated in the recent literature.1–4

Multi-practitioner clinical data collection in the medical profession would make a significant contribution toward meeting that principle. As stated by van Haselen and Fisher in 1994, ‘before carrying out trials of efficacy, we should critically scrutinise prescribing to analyse which prescribing features are associated with a favourable response to particular medicines and which are not’.5 Practice audit or other systematic clinical data collection in homeopathy has been reported, for example in hospital outpatient departments,6–8 in community clinics,9,10 and in the medical practice setting in the UK11–14 and elsewhere in Europe.15–17 However, the aim of these studies has not principally been one of research targeting.

The current pilot study was designed to lay the foundation for a larger-scale clinical data collection project in the Faculty of Homeopathy. The objectives of such an initiative have been defined as follows:

1. Using a spreadsheet ‘tool’, to gain insight into the complaints that doctors treat using homeopathy in the medical practice setting.

2. For follow-up (FU) cases, to determine patient-assessed change in severity of the treated medical condition/complaint (comparing the last with the first homeopathic consultation), and thus identify any specific patterns of disease, clinical responses and/or homeopathic medicines that may help to target future research projects in homeopathy.

3. For FU cases, to note any change in patients’ use of conventional medication for their medical condition/complaint since the start of homeopathic consultations.

The primary aims of this pilot study were thus:

1. To test the use of a specially designed spreadsheet, and to find how consistently practitioners complete and then return spreadsheet data to a co-ordinating centre over a 6-month period.

2. To inform our approach to a larger-scale clinical data collection project—in particular, to ascertain whether practitioners are completing the spreadsheet properly and then return spreadsheet data to a co-ordinating centre over a 6-month period.

Secondary aims were: (1) to begin the process of engaging Faculty medical practitioners in clinical data collection/research; (2) to explore whether data of this kind might be useful for practitioners in their own practice setting and/or for the research dissertation required for Specialist Registration of the Faculty of Homeopathy.

Methods

Recruitment took place following announcement at the Faculty of Homeopathy’s Members’ Committee and at the British Homeopathic Congress in 2004. Fourteen doctors contributed to the study: 10 NHS GPs, two private practitioners, two both NHS and private practice (12 based in England, two in Scotland). Twelve were qualified MFHom, two LFHom. All 14 were given the opportunity to comment on a draft of the spreadsheet (Microsoft Excel), designed by the authors and approved by the Homeopathic Research Committee of the British Homeopathic Association.

The spreadsheet allowed the recording of consecutive appointments, row by row, under the following column headings:

- Appointment date (day, month).
- Unique (anonymised) patient identity/number.
- Age of patient.
- Gender of patient.
- The condition/complaint treated. A separate page comprised a ‘pick-list’ containing 118 medical terms in 11 categories—see below. The list was not designed to limit prescribing, but to ensure consistency of nomenclature by using the ‘copy/paste’ function in Excel. Practitioners were invited to add terms to the pick-list as required. The pick-list was based on that used in an earlier study of homeopathy, and proven to be user-friendly in the context of NHS general practice in the UK.14
- System-based category of condition/complaint—CNS and Psychiatry (CNS), Cardiovascular (CV), Dermatology (DERM), Endocrine (ENDO), Ear, Nose and Throat (ENT), Eye (EYE), Gastrointestinal (GI), Musculo-skeletal (MSK), Respiratory (RESP), Obstetrics and Gynaecology (OG), or Urogenital (URO).
- Whether the condition/complaint is ‘chronic’ or ‘acute’. In the context of a 6-month study (see below), this was defined as symptoms greater than or less than 4 weeks’ duration.
- Whether, in relation to the previous 12 months, this is a new or a FU appointment for the same complaint.
- Patient-assessed change in the treated complaint at the current FU compared with the initial homeopathic consultation, using 7-point scale (‘no change’ or ‘unsure’ [0] / ‘mild’ [±1] / ‘moderate’ [±2] / ‘major’ [±3]).
- Homeopathic medicine/s prescribed, using a ‘pick-list’ containing 132 remedies (including the option ‘none’). Again, this was not designed to limit prescribing options, but to ensure consistency of nomenclature using ‘copy/paste’ in Excel. Practitioners were invited to add to the pick-list as required. This pick-list was also based on that used in an earlier study.14
- Homeopathic medicine/s prescribed at previous appointment.
- Any other (conventional) medication/s being taken for the condition/complaint.
- Any plausible alternative explanation for clinical outcome to date.
Notes/comments, especially those that qualify or amplify other data for the same appointment. State ‘phone’ if FU information obtained by that means.

Detailed instructions on using the spreadsheet format, and how to ask patients questions about their clinical outcome, were provided on separate pages of the file. The following standard question sequence was recommended: ‘Are your symptoms better, worse or exactly the same?’ If the patient says he/she is better, then ask: ‘Has there been what you would call a mild, moderate or major improvement?’ Responses scored as follows: mild improvement = +1; moderate improvement = +2; major improvement = +3. If the patient says he/she is worse, then ask: ‘Has there been what you would call a mild, moderate or major deterioration?’ Responses were scored: mild deterioration = −1; moderate deterioration = −2; major deterioration = −3. Record ‘no change’ or ‘unsure’ as 0.

Additional, personalised, ‘bolt-on’ columns were allowed as desired per practitioner (eg for noting potency or prescribing strategy). Such data were not forwarded to the central co-ordinator for analysis.

The duration of the study was 6 months: 1 January–30 June 2005. Practitioners were expected to send data to one of us (RTM, the project co-ordinator), via email attachment, on a monthly basis (on the last day of each month); this allowed the co-ordinator to oversee data generally, to point out obvious errors to practitioners, and generally to maintain contact with those collecting the original data.

End-of-study data analysis was by practice (with individual feedback to each practitioner) as well as overall (reported in this paper). Two–three weeks after the final despatch of their practice data, practitioners were sent a brief questionnaire, designed to gauge their experience of using the spreadsheet and their opinions of the value they attributed to the data it produced. The Chair of the South Bedfordshire Research Ethics Committee (REC) advised that the study did not require REC approval.

Methods of spreadsheet analysis

Upon receipt of practitioners’ final spreadsheets at the end of the project, the original data were re-checked and scrutinised for obvious missing data and typographical errors. These were flagged up, and rectified where possible. A particular note was made of whether the condition/symptom treated and the homeopathic medicine prescribed seemed to have been copy/pasted from the pick-lists provided—absence of capital letters, for example, made it certain that copy/pasting had not been used. Appointments data from all 14 practitioners were combined together into a master spreadsheet. Pivot-table analysis (one each for conditions and homeopathic medicines) allowed a count of the total number of pick-list items and their transfer to the appointments page by copy/paste. Near-duplicate descriptions of what were clearly identical conditions or medicines were reconciled into single unique terms. Any conditions not on the pick-list were ascribed category headings. Two new categories were added as a result of this approach: ‘Miscellaneous’ (‘MISC’); ‘Poly-symptomatic’ (‘POLY’).

A new master copy of the complete appointments page was then created, into which were added columns to indicate: (1) the appointment number per patient per condition/symptom (when this could be determined); and (2) whether or not an appointment was the final one for a given condition/symptom in a given patient during the 6 months of the study. These procedures enabled pivot-table analysis based on final appointments only—ie on the number of individual patient conditions treated, irrespective of whether they were treated by the practitioner once, twice or more often (The term ‘individual patient condition’ is used because a given patient could present with different conditions on a different—or even the same—occasion. Also, if a patient presented at one appointment with more than one condition—each of which was treated separately with homeopathy—the practitioner reported each on a different row of the spreadsheet. This approach was adopted because a key purpose of the study was to catalogue the frequency and success rate of treating named conditions, even if a given individual patient exhibited more than one).

The following three principal pivot-table analyses were then carried out: (1) ‘final’ outcome score by medical category and condition; (2) ‘final’ outcome score by medical category and homeopathic medicine used at previous appointment; (3) ‘final’ outcome score by medical category.

Results

Use of the spreadsheet

Doctors submitted data reliably to the project co-ordinator: each sent an updated spreadsheet for every consecutive month, and most were punctual in their communication (5 days early to 22 days late; average 4 days late per month). All doctors returned data for the entire 6-month study period, except for two practitioners, who changed practices during the project and so discontinued data collection after 4 or 5 months.

Technical difficulties, such as failure of email or of attaching a file, occurred rarely and were always rectified. Misunderstandings over the detailed use of the spreadsheet occurred infrequently, and most appointments appeared to be recorded meaningfully. The most common difficulty was in cases where a patient presented with two discrete medical conditions that were treated separately with two different homeopathic medicines: it took a month or so of taking part in the project before all practitioners adopted the recommended use of two separate rows to describe two independent medical complaints of this
kind. These early errors were rectified prior to analysis. There were occasional problems in representing the homeopathic treatment style within the spreadsheet format. For example, the constitutional approach to treating a patient with several medical complaints or deep emotional issues meant that limiting the recording to just one named condition did not provide a full picture of the case. In the small number of patients where the diagnosis changed during the course of treatment, there was little opportunity to make this obvious without recourse to extended notes and comments.

The total number of appointments per participating doctor for the 6-month period varied from 42 to 548 (mean, 178). The large majority of data cells were completed as required, though 4.8% of those specified for homeopathic medicine had missing information. 5.0% of medical category cells had missing information, which were rectified before final analysis. Entries for 'homeopathic medicine prescribed at previous appointment' had 9.7% missing data; these were rectified, where possible, before final analysis. The greatest amount of missing data occurred in the first month or two, while participants became familiar with the spreadsheet. The presence of other (conventional) medication(s) taken for the condition/complaint (including 'none') was noted on just 13.7% of appointments. A plausible alternative (non-homeopathic) explanation for any clinical change was noted on 3.7% of occasions only. The Notes/Comments column was used in 20.8% of appointments; some participants made ready use of this column for additional notes, while others used it sparingly.

A total of 2488 appointments in which homeopathy was used was recorded. One thousand eight hundred and six (72.6%) were for conditions present in the pick-list. Of those 1806 appointments, it was estimated that copy/pasting took place in 81.7% of occasions. Participating doctors treated 416 different medical conditions in total; 105 of these appeared in the original pick-list. Of the total 2488 appointments, 1988 (79.9%) resulted in prescriptions of homeopathic medicine(s) from the pick-list. Of those 1806 appointments, it was estimated that copy/pasting took place in 81.7% of occasions. The remaining appointments had no entries in this column. Of the 1988 appointments where a listed remedy was used, copy/pasting occurred in an estimated 80.7% of occasions. Two hundred and eighty-two different homeopathic medicines (or combinations of medicines) were reported in total; 106 of these appeared in the original pick-list; 92 single homeopathic medicines and 84 combinations were not in the pick-list.

### Analysis of clinical data

#### Patient demographics

The 2488 homeopathy appointments represented data from 1783 individual patient conditions. Of these 222 were recorded in patients who had also been recorded for another treated condition—there were actually 1561 individual patients in the study overall: 1110 (71.1%) were female, 450 (28.8%) male; one patient’s gender was not recorded. The age profile was: 0–9 years, 227 patients; 10–19, 133; 20–29, 126; 30–39, 213; 40–49, 224; 50–59, 218; 60–69, 188; 70–79, 142; 80–89, 72; 90–95, 5; unknown, 13. The mean of the 1548 known ages was 41.5 years. 23.3% of the patients of known age were children or adolescents (aged 19 years or less).

Analysis of the data from the 1783 conditions treated shows the most frequently treated were depression, anxiety, cough, menopausal flushing, chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME), catarrh, and osteoarthritis. A fuller list is given in Table 1.

Additional analysis of the data from the 1783 patient conditions shows the homeopathic medicines most frequently used at the penultimate appointment were as follows: Nat mur, 77; Sulphur, 38; none, 30; Sepia, 29; Pulsatilla, 27; Phosphorus, 25; Nat phos, 23; Rhus tox, 23; Arsen alb, 22; Lycopodium, 22; Staphysagria, 22; Ignatia, 19; Bryonia, 18. Although individualised prescribing was the general rule, there were several instances of matching between a specific medical condition and a particular homeopathic medicine. The following medicine-condition pairings were most apparent: Rhus tox for osteoarthritis (23 of 41 osteoarthritis patients at last appointment where the medicine was noted); Ignatia for grief (20 of 27); Sulphur for eczema (atopic, non-atopic and unspecified; 19 of 53); Arnica for bruise (18 of 19); Coffea for anxiety (16 of 81); Pulsatilla for upper respiratory tract infections (URTI; 15 of 36).

### Table 1 Most frequently treated medical conditions/complaints

<table>
<thead>
<tr>
<th>Rank</th>
<th>Condition/complaint</th>
<th>Total no. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Depression</td>
<td>88</td>
</tr>
<tr>
<td>2</td>
<td>Anxiety</td>
<td>83</td>
</tr>
<tr>
<td>3</td>
<td>Cough</td>
<td>69</td>
</tr>
<tr>
<td>4</td>
<td>Menopausal flushing</td>
<td>62</td>
</tr>
<tr>
<td>5</td>
<td>CFS/ME</td>
<td>45</td>
</tr>
<tr>
<td>6</td>
<td>Catarrh</td>
<td>43</td>
</tr>
<tr>
<td>6</td>
<td>Osteoarthritis</td>
<td>43</td>
</tr>
<tr>
<td>8</td>
<td>IBS</td>
<td>38</td>
</tr>
<tr>
<td>9</td>
<td>URTI</td>
<td>36</td>
</tr>
<tr>
<td>10</td>
<td>Hayfever</td>
<td>31</td>
</tr>
<tr>
<td>11</td>
<td>Grief</td>
<td>27</td>
</tr>
<tr>
<td>12</td>
<td>Colic</td>
<td>25</td>
</tr>
<tr>
<td>12</td>
<td>Headache</td>
<td>25</td>
</tr>
<tr>
<td>14</td>
<td>Eczema—non-atopic</td>
<td>24</td>
</tr>
<tr>
<td>15</td>
<td>PMS</td>
<td>23</td>
</tr>
<tr>
<td>15</td>
<td>Tired all the time</td>
<td>23</td>
</tr>
<tr>
<td>17</td>
<td>Cramp</td>
<td>22</td>
</tr>
<tr>
<td>17</td>
<td>Insomnia</td>
<td>22</td>
</tr>
<tr>
<td>19</td>
<td>Back pain</td>
<td>21</td>
</tr>
<tr>
<td>19</td>
<td>Otitis media</td>
<td>21</td>
</tr>
<tr>
<td>21</td>
<td>Cystitis</td>
<td>20</td>
</tr>
<tr>
<td>21</td>
<td>Eczema—unspecified</td>
<td>20</td>
</tr>
<tr>
<td>21</td>
<td>Sinusitis</td>
<td>20</td>
</tr>
<tr>
<td>21</td>
<td>Sprain</td>
<td>20</td>
</tr>
</tbody>
</table>

A total of 416 different conditions was reported overall; the tabulation lists only those 24 comprising at least 20 cases in each.
Clinical outcomes

Two or more homeopathic appointments per patient condition were obtained for 961 individual cases—53.9% of those treated. Of these 961 FUs, there was a positive outcome in 75.9%, no change in 14.7% and deterioration in 4.6%; outcome was not recorded in 4.8% of cases. For the same 961, a score of +2 or +3 was recorded in 58.9% of cases; a score of –2 or –3 was recorded in 2.4% of patients. One hundred and forty-five FUs were for ‘acute’ conditions; 816 were ‘chronic’. These data, with further details, are illustrated in Table 2.

A summary of positive outcomes by medical category is presented in Table 3: the greatest percentage of high positive scores was in patients presenting with gastrointestinal or ENT complaints. An equivalent summary of negative outcomes by medical category is also presented in Table 3: very few patients had strongly negative outcome scores, and there was no particular medical complaint that typically seemed to respond adversely. Table 3 also contains summarised data of patients who reported little or no change. A summary of +2/+3 outcome scores by medical condition is given in Table 4. High positive scores were achieved most notably in the frequently treated conditions of anxiety, depression, and Irritable Bowel Syndrome (IBS). The success rate in treating CFS/ME appeared relatively modest.

Final outcome scores in terms of the homeopathic medicines most frequently used at the penultimate appointment were as follows (score of +2 or +3): Arsen alb, 77.3%; Lycopodium, 72.7%; Ignatia, 66.7%; Pulsatilla, 63.0%; Phosphorus, 60.0%; Rhus tox, 59.1%; Bryonia, 58.8%; Sepia, 58.6%; Staphysagria, 54.5%; Nat phos, 52.2%; Sulphur, 50.0%; Nat mur, 48.1%; none, 43.3%.

Participating doctors’ views

Completed questionnaires were received from all 14 doctors who took part. Few entered the clinical data during the homeopathic appointment itself, but all found the spreadsheet practical to use and the instructions helpful. Half had used Excel previously. A majority found it easy to copy/paste data from the pick-lists. The outcome question sequence seemed to be understood by most patients and, in general, it proved easy to score a patient’s stated outcome on the 7-point scale. A minority of doctors felt the scores had a positive bias; one felt that any bias was negative. All the doctors found it convenient to return data on a monthly basis via email. All found it a worthwhile exercise, and most derived useful factual information from the analysis of their own practice data.

In connection with the secondary aims of the study, eight of the 14 would potentially use data of this kind in a Faculty dissertation for specialist registration. All would be willing to take part in a larger-scale clinical data collection study, and most would probably take part in future controlled research work.

The following is a sample of specific comments/suggestions made by practitioners:

‘Very helpful experience. The study increased enthusiasm for homeopathy as well as increasing numbers of consultations in which it was used.’

‘It is an extra task but I feel that the time spent is a good investment.’

‘The whole process, though very useful, was time consuming and I often had to wait till the end of the clinic to add data.’

‘... a fuller range of conditions and remedies are required [in a bigger project].’

‘I think that you get woolly results by just looking at the presenting complaint. Sometimes the presenting complaint is just what brought the person to the doctor, and the real problem is not [initially] mentioned.’
‘I tried to be as balanced as I could in outcomes reporting, and that is why I used the comments section so much.’

**Discussion**

These 14 Faculty of Homeopathy doctors were clearly capable of recording homeopathic cases systematically in a spreadsheet and communicating the data reliably to a co-ordinating centre. The Excel format appeared to allow most appointments to be recorded in a meaningful way. The complaints that were treated most frequently and with greatest apparent success were readily ascertained. The outcomes recorded at FU have already highlighted several named conditions (anxiety, depression and IBS, for example) that may be especially promising for homeopathy research in the medical practice setting—most notably in primary care, given the high proportion of practitioners, based in that setting, who took part. In the only two previous data collection studies in UK primary care, psychological/mental and gastrointestinal/digestive complaints were not necessarily the most often or the most successfully treated with homeopathy; neither paper provided outcomes data on specific medical conditions. The overall rate of positive outcome in 75.9% of FU patients in our study is similar to that reported in other homeopathy outcome studies in primary care and in the hospital setting. A score of +2 or +3 was recorded in 58.9% of FU patients in our study is similar to that reported in other homeopathy outcome studies in primary care and in the hospital setting. A score of +2 or +3 was sufficient for the purpose intended. For targeted research in named medical conditions, however, it is much more important to have validated outcome scales. Such research would also typically attribute a clear baseline reference assessment against which to gauge any health changes that may be due to homeopathy. Our scale assessed only changes from a recalled baseline. Controlled research would also normally specify time-points for FU assessment; in a non-controlled data collection study such as this, patients are assessed opportunistically when they return. This inevitably means that the FU intervals—even for a single named medical condition—are highly variable.

Relying on patient recall is one of the several potential sources of outcome bias in studies of this kind. Additional sources of bias (probably positive) include: (a) the ‘doctor-with-patient’ dialogue in identifying the outcome score; (b) the fact that doctors may have selected, unwittingly, some of their most promising cases for homeopathy instead of conventional treatment; (c) patients attending a homeopathic doctor may have more confidence in the therapy and empathy with its practitioners. Empathy has been shown to have a positive association with outcome (enablement) from homeopathic treatment, and targeted research would usefully address issues such as this. It is interesting that most doctors in this study did not feel that the outcomes scores had a positive bias.

Another limitation of this study is the rather brief 6-month duration of systematic recording. This means that a full course of homeopathic treatment will be registered in a limited number of cases only. This would be the situation particularly for long-term chronic cases, where the start and/or end of homeopathic treatment would lie outside the 6-month ‘window’ of recordings. Data might be distorted also by seasonal factors (the study took place mainly in winter and spring months) and by the unequal number of cases treated by each of the 14 practitioners (42–548 appointments). Because of some practitioners’ base in private practice and some in the NHS, there was a wide
range of consultation characteristics. None of these issues is of major concern in a pilot study, but they would be important considerations in designing a more definitive data collection project. Such a project would be informed importantly by the practical aspects of the current work, and would benefit from having more comprehensive lists of named medical conditions/complaints and homeopathic medicines which could be copied and pasted into the appointments file.

Practitioners completed the spreadsheet with considerable care and attention to detail. The number of data cells with missing information was encouragingly low, and precision in data entry was good overall. This was probably assisted by availability of the pick-lists and by the fact that few doctors completed the data entry during the homeopathic appointment itself. Nevertheless, a sizeable amount of work was required by the project co-ordinator during data synthesis to ensure that the maximum quantity and quality of information was analysed and reported. Also, two columns of data were poorly completed by practitioners: patients’ use of other medication was noted on only 13.7% of appointments, and alternative (non-homeopathic) explanation of outcome was noted on just 3.7% of occasions. Since absence of information cannot be interpreted in any meaningful way, the data from these columns have not been reported. In another data collection study of this type, one might wish to ensure that practitioners were obliged to enter information in all data cells (except in Notes/Comments).

Most practitioners gained useful factual information from their own practice data and were engaged by the concept of taking part in future data collection work and, in several cases, controlled research. Several practitioners also appreciated the possibility of using data of this type in research dissertations for Faculty specialist registration.

Conclusions

Clinical outcomes studies of this type and other non-randomised designs are fundamental in informing well-targeted future research in homeopathy. The current study has successfully piloted a spreadsheet that, with some revision, can be used effectively in larger-scale systematic clinical data collection in the medical practice setting—particularly in primary care.

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References