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Toward Standard Setting for Patient-Reported Outcomes in the NHS Homeopathic Hospitals

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Introduction

Each of the United Kingdom's five National Health Service (NHS) homeopathic hospitals has reported clinical outcomes data from a wide range of medical complaints.^{1, 2, 3, 4} *[add ref for GHH data]* In each unit, positive outcome has been reported by about 70% of follow-up patients overall, indicating the need for research initiatives to establish the positive effects of the homeopathic intervention in particular diagnoses.^{5, 6} From the perspective of quality assurance, on the other hand, these outcomes studies have each been carried out without an explicit aim of knowing and sustaining the optimum clinical outcomes that can reasonably be expected in patients with given medical complaints. Moreover, the earlier studies have each used different methods and outcome scoring techniques, without an overarching objective to unify approaches to clinical data collection across all hospitals.

This work represents the beginning of a programme of quality assurance and development across all five homeopathic hospitals. It has the medium-term aim of setting standards for homeopathic practice outcomes in patients with medical complaints commonly treated in the outpatient setting of each unit. Here we report our findings from an initial pilot data collection study within this quality development process. It represents the first collaborative effort by the five individual units.

Aims

1. To pilot the collection of clinical data in the homeopathic hospital outpatient setting, using ORIDL (Outcome Related to Impact on Daily Living) as outcome measure; to record patient-assessed change (in Main Complaint, MC, and/or in Well-being, WB) since the first homeopathic appointment.
2. By obtaining a 4-week cross section of clinical data at all five homeopathic hospitals in the UK, to catalogue a representative range of medical complaints that doctors treat using homeopathy in hospital outpatients, and thus identify the complaints most frequently treated at a national level.
3. To present a cross section of patient-reported outcome scores by visit number for each of the most frequently treated medical complaints.
4. To begin to explore methods of standards setting for homeopathic practice outcome in each of the most frequently treated medical complaints in outpatients treated at the homeopathic hospitals.

Methods

The study design and methods were agreed by all the authors, many of whom are members of the Faculty of Homeopathy's Clinical Audit Sub-Committee. A total of 50 medical practitioners contributed to the data collection – see *Acknowledgements*.

An *Access* database (or *Excel* spreadsheet – see below) enabled the recording of all consecutive homeopathy appointments, under the following headings:

- Date of first homeopathic appointment for current medical complaint (day, month, year)
- Appointment number (1[=first appointment] to 6; >6 [non-specified])
- Age of patient
- Sex of patient
- Main Complaint being treated using a 'drop-down' menu^h of 263 Complaints (using ICD-10 nomenclature)ⁱ
- Whether other main medical complaint/s (Yes/No)^j
- Patient-assessed change in the Main Complaint (MC) at follow-up (FU), using ORIDL
- Patient-assessed change in overall Well-being (WB) at FU, using ORIDL
- Whether also receiving other Complementary or Alternative Medicine (CAM) therapy for this complaint at this hospital (Yes/No).

Data were collected at Homeopathy clinics only i.e. not Acupuncture, Autogenic Training, etc. Lifestyle, dietary (including vitamin supplements) or other "homeopathic" advice was not categorised as "other CAM therapy", but regarded as part of normal homeopathic therapy. "Main complaint" was the doctor's opinion as to the nature of the principal health concern at the time of initial referral (e.g. from the GP letter or his/her own notes).

^h The *Excel* version contained a "pick-list" of the same medical complaints, whose entries could be copied and pasted into an Appointments page.

ⁱ If a patient presented with a complaint that was not in the drop-down menu, the new term was typed into the free-text field (or directly into the column "Main Complaint" in *Excel*).

^j Patients with complex individual predicaments, or who had more than one nameable main complaint, were recorded under a single "Main Complaint", together with an entry "Yes" in the field labelled "Whether other main complaint/s".

The outcome measure used to assess change was ORIDL. The ORIDL instrument (formerly referred to as the Glasgow Homoeopathic Hospital Outcome Score, GHHOS) has been developed to measure a patient's views of the outcome of their care by asking about change, and relating this to impact on daily living. In a preliminary validation of ORIDL there was significant agreement between patient outcomes assessed by the ORIDL and the EQOL transition scale, the MYMOP, and the PEI-outcome instrument, suggesting that the ORIDL may be a valid and sensitive tool for measuring change in relation to impact on life.⁷ Detailed instructions on use of ORIDL were provided to each participating doctor in each hospital. These instructions are shown in **Appendix A**. Doctors recorded data during the patient appointment. All patient data were anonymous at source; individual doctor identity was not recorded. In each hospital, all data files were collected together to create a single hospital record (in *Excel* format). The file was then sent by e-mail to the study co-ordinator (RTM) and thence to the data analyst (ESB).

Methods of data analysis

The raw data from each hospital were reformatted into a standardised *Excel* spreadsheet, which allowed ease of use for filtering and locating any incomplete or erroneous data entries. Each column of data was filtered for missing values, which were addressed either by correction or exclusion. Terminology for non-listed medical complaints was reconciled using ICD-10 coding nomenclature. Through this procedure, 23 extra options were added to the original list, bringing the final number of listed complaints to 286. All eczemas (allergic contact [9.2% of eczema patients], atopic [45.4%], seborrhoeic [3.7%], unspecified [41.7%]), except varicose eczema (4 cases), were reconciled under the single heading “eczema”.

The spreadsheet was then consolidated into a master file containing all data from all hospitals, and arranged into a number of different pivot table layouts for the various analytical approaches. The extra columns “Frequency” and “WB + MC Scores” were added to facilitate the pivot table analysis. Data from the patient sample were presented as national and single hospital statistics. In addition, the most frequently reported medical complaints and their treatment outcomes were each tabulated or graphed by number of FU visit. For this purpose, the two ORIDL scores per patient were averaged (range, -4 to +4, increments of 0.5); we have termed this aggregate the ORIDL Profile Score (OPS). Sub-set analysis was carried out on patients who had other main medical complaints (co-morbidity) or who were also being treated for their main complaint with other CAM therapy in the [same](#) hospital.

After the study was completed, practitioners were sent a brief questionnaire, designed to gauge their personal experience of using the database or spreadsheet and their opinions of the value they attributed to the data the study produced.

Results

Data collection took place during the four 5-day periods from 5th to 30th March 2007; no individual patient was expected to receive more than a single appointment within that time. The *Access* database was used at three of the hospitals, and the *Excel* version at the other two. Electronic format was used in all hospitals except one, where some practitioners used a hard-copy version of the spreadsheet, necessitating manual data transcription into *Excel*. There was a low incidence of essential missing data. Only two records were excluded altogether: one was due to missing “Complaint” data; the other was a second appointment for a single patient during the 4-week period of data collection (outside the scope of the study). There were 53 missing or invalid dates recorded, of which 22 were corrected and 31 were stated as “missing data”. These were only excluded when they were essential to a particular analysis (such as “average time to appointment”). There was one missing value in each of “Gender”, “ORIDL-WB” and “Whether other main medical complaint”, which were excluded and flagged in any analysis involving them specifically.

Patient demographics and medical complaints treated

There were 1797 patient visits overall, 195 being first appointments and 1602 FUs. The totals per hospital are shown in **Table 1**, which also shows the distributions of patient visits for up to or greater than the sixth appointment. Size of clinical service and the proportion of patients who attended more than 6 visits varied considerably between units. The precise number of visits greater than 6 was not recorded. Overall, 45% of patients had attended more than 6 homeopathic appointments, the highest frequency of appointments being patients on their second visit (**Figure 1** [*redo as relative frequency*]). The relationship between visit number and time since first homeopathic appointment per hospital is shown in **Table 2**, where inter-hospital differences in timing of FU appointments are evident, especially for appointments after number 3. Patient age profile overall showed a bimodal distribution, with a main peak at 49 years and a secondary peak at 6 years (**Figure 2**). Male: female ratio was 1: 3.5.

A wide range of complaints was reported: 235 in total over all the hospitals. The top 35 complaints (all those seen in 10 or more patients) are listed in **Table 3**: the most frequently treated were (1) eczema, (2)

chronic fatigue, (3) osteoarthritis, (4) menopausal disorder, and (5) depression. Overall, 47.8% of patients reported important co-morbidity; 13.2% of patients were receiving another CAM therapy at the hospital for their main medical complaint. The proportion of patients with important co-morbidity was higher in those seen after visit 6 (56.9%) compared with those seen before visit 6 (41.9%; $P=000$). The complaints that were most frequently treated also varied with appointment number: after visit 6, the highest frequency was chronic fatigue, followed by...

Homeopathic practice outcomes

There was close correspondence overall between ORIDL-MC and ORIDL-WB scores. ORIDL-MC and ORIDL-WB were strongly correlated over their entire range ($r_s = 0.71$).

Table 4 gives mean (s.d.) values of OPS by visit number for all FU patients taken together, as well as for each of the 10 most frequently treated medical complaints. It is clear that, in general, patients seen at later appointments reported ever more positive outcomes than those at earlier FU visits; those who had been seen more than 6 times had mean OPS=1.98, slightly higher than the mean OPS at appointments 4, 5 and 6. The apparent magnitude and degree of change of patient-reported improvement differed considerably among the top 10 complaints: patients with eczema typically reported greater degree of improvement, and at earlier appointments, compared with CFS patients, for example. Equivalent complaint-specific information per hospital was also derived (*data not shown*) and communicated directly to each.

Participating doctors' views

Completed questionnaires were received from 19 practitioners. All but one found the database/spreadsheet easy to use and the instructions helpful; only one participant had not used such software previously. A number of constructive suggestions were offered for improvement in the next phase of the study. More than half the practitioners formally used the ORIDL question sequence, and all but two felt it was straightforward to score a patient's stated outcome. All participants found it worth having recorded data in this way. All but three derived useful factual information about their own hospital's practice data and two of those practitioners had not seen their hospital's data report at that time. The following are examples of quotes from participating clinicians:

The database was easy to use, except the entry of first appointment dates.

I think we need to include other conventional interventions since last visit.

Not all of the patients understood the outcome questions. Older patients had difficulties understanding, which created time pressures. It usually was easy to score, but not always.

Discussion

A database/spreadsheet for the collection of demographic and clinical outcomes data in the homeopathic hospital outpatient setting was successfully piloted, using ORIDL to record patient-assessed change in MC and WB since the first homeopathic appointment. The ORIDL Profile Score (OPS) provides a useful index of change, [reflecting strongly correlated MC and WB scores across all medical complaints](#). Information has been obtained on patient demographics and on the most frequently treated complaints. The findings illustrate the range and complexity of chronic disease managed within the homeopathic hospitals. The most frequently treated conditions reflect previously published data, with eczema and asthma in the top eight along with arthritides, menopausal symptoms, chronic fatigue and breast cancer. Research suggests that patients seek out CAM approaches for a number of reasons, including a fear of drug side effects and the desire to be more independent in their healthcare. Patients are often appreciative of their conventional care but also aware of its limitations.^{8,9} [Indeed, the medical complaints treated in the homeopathic hospitals often reflect areas of clinical practice where available conventional treatments are not fully effective – termed “effectiveness gaps”.](#)¹⁰

[The pace and duration of patient care varied considerably between hospitals. This was reflected particularly in the differing proportions of patients who received more than 6 appointments. For example, one unit, which introduced a 5-appointment package of care in 2001, saw proportionately far fewer patients after visit 6 than any other hospital. It is also clear that the scope and complexity of medical complaints changed with longer packages of care. In the short-term future, each hospital will need to carry out its own additional local audit and introduce a package of care that has more equivalence at a national level. Importantly, this pilot has informed the process by which such local audit may proceed through the adoption of identical aims and methods.](#)

The average ORIDL Profile Score of +1.81 or more that was achieved in patients who were attending at least their fourth homeopathic appointment indicates that a meaningful improvement in health (OPS \geq +2)⁷ was gained in many cases [\[?need to specify precise number/proportion in Results?\]](#). The large s.d. values around this average indicate considerable variability of individual response to treatment. The magnitude and degree of change was clearly dependent on the main presenting complaint, with chronic

fatigue patients showing less change over the period of care than eczema patients, for example. It is information of this kind that will be used in our medium-term aim of setting standards for clinical outcomes associated with homeopathic treatment in patients with given medical complaints. There is clearly a need to track individual patients over time, and this will be a key feature of the ongoing development programme. This process will also necessarily take into account severity of presenting symptoms and the presence of any important co-morbidity. Again, a unified approach will be taken to clinical data collection across all hospitals at that stage. The ultimate objective of the initiative – to establish national benchmarks for homeopathic practice outcomes in the hospital outpatient setting – will then be enabled. Benchmarking is “a process of comparing, sharing and developing practice in order to achieve and sustain best practice”.^{11, 12, 13}

This 4-week national cross section of homeopathic outcomes data supports previous reports that referral to homeopathic hospital outpatients is often associated with valuable improvement in patients’ health, and for a wide variety and complexity of medical complaints. Although these data are suggestive that patients staying within the system gain improvements both in presenting complaint and wellbeing, we cannot conclude that these are **due to homeopathy specifically**. **By definition, a study of this nature involves no reference group of patients to serve as controls**. Moreover, we are unable to take into account other factors, such as improvement of symptoms that may have happened spontaneously over time (as in menopausal disorder), or where conventional treatments might have had an important impact during the package of care (as in asthma, for example). In addition, it should be noted that these data only reflect changes in the patient sample that stayed in the system. Those patients who did not attend (DNA) may have improved to their satisfaction or found homeopathy unhelpful. **In subsequent studies, full account will be taken of DNA patients, together with those who use other CAM and/or conventional medicines**. Our pilot findings are thus informing the next stage of data collection, aiming to set and sustain the highest appropriate standards of clinical outcomes that can be expected from homeopathic treatment patients with given medical complaints.

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Appendix A

Outcome Related to Impact on Daily Living (ORIDL)

Ask every follow-up patient:

1. Compared to how you were before your initial appointment, what has been the overall effect of your treatment at this hospital on your Main Complaint (the one you came to get treated)?

If the patient says “none”, “the same” or is unsure, record 0.

If the patient says “better” or “worse”, record their perceived degree of improvement or deterioration based on the numerical scale below.

2. Compared to how you were before your initial appointment, what has been the overall effect of your treatment at this hospital on your general Well-being?

If the patient says “none”, “no change” or is unsure, record 0.

If the patient says “better” or “worse”, record their perceived degree of improvement or deterioration based on the numerical scale below.

+4	Cured / Back to normal
+3	Major Improvement
+2	Moderate improvement, affecting daily living
+1	Slight improvement, no effect on daily living
0	No change / Unsure
-1	Slight deterioration, no effect on daily living
-2	Moderate deterioration, affecting daily living
-3	Major deterioration
-4	Disastrous deterioration

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