

Osteopathic Development Group PROM Database Development Project Project Initiation Document

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1 Introduction

1.1 Purpose of this document

The purpose of this document is to define the scope and approach for the Osteopathic Development Group (ODG) project for the development of an evidence base for osteopathy comprising a Patient Reported Outcomes Measure (PROM) database for osteopaths and an online platform for reporting patient incidences.

2 Project definitions

2.1 PROMS project

The PROMS project relates to one significant aspect of a larger PhD programme of study being undertaken by Carol Fawkes at Barts and The London School of Medicine and Dentistry. The PhD is being supervised by Dr Dawn Carnes and Dr Robert Froud. The wider remit of the PhD project will aim to:

- Recommend a series of outcome measure appropriate for routine data capture following osteopathic treatment following evaluation based on their clinimetric (statistical reliability and validity) properties and relevant coverage properties
- Develop a data capture facility to allow osteopaths to submit data concerning their patients including, for example, their symptoms/symptom areas, the treatment delivered, use of other resources (medication and imaging), and the number of treatments provided;
- Pilot the recommended outcome measures within the electronic data capture facility, which will be developed by a third-party (CLINVIVO; *vide infra*)
- Develop a facility to allow osteopaths to receive summaries of analysed data concerning their patients.

A series of preliminary projects are on-going currently to try to identify the most suitable outcome measures for use in the patients' data collection facility.

2.2 Patient incident reporting project

The patient incident reporting platform is part of two IT projects to design and develop patient incident reporting for osteopathic practitioners and for osteopathic patients. This project is being managed by NCOR and Queen Mary University of London.

These projects will run concurrently.

2.3 Background

The osteopathic profession has continued to evolve and mature since the introduction of statutory regulation in 1998.² One key aspect of this developmental process is the need to maintain high professional standards through the evaluation of care provision including the evaluation of risk. The introduction of clinical governance for all healthcare professions in 1998 has provided a range of requirements that must be met by healthcare professionals in the 21st Century.³ Implicit among these requirements is the need to measure and evaluate

performance, risks and care delivery through a variety of media. Diagnosis, evaluation of therapy, and prediction of future course are regarded as important objectives of measurement in clinical practice (Guyatt et al, 1992). It is thought that the introduction of Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs), and their use as part of routine clinical care will facilitate the evaluation of therapy and the process of care.⁴

A wide range of outcome measures (OMs) are in use currently in all areas of clinical practice, and within these there is a range of standards in terms of the developmental and testing processes applied.⁵ The most recent innovation for clinicians managing patients with musculoskeletal symptoms is the development of a pan-professional musculoskeletal outcome measure (M-PROM) which is currently being pilot tested for validity.⁶ Prior to this outcome measure becoming available, a range of commonly used and accepted measures are employed in primary and secondary care settings to measure patients' progress during and after care provision.

2.4 Aims

To develop the evidence base for osteopathy by systematically collecting Patient Reported Outcome Measures and Patient Reported Experience Measures (known as PROMs/PREMs) and creating a vehicle for anonymous reporting of adverse events. These data will support the promotion of osteopathic healthcare and integration into wider public health provision.

2.5 Objectives

1. To pilot and implement validated Patient Reported Outcome Measures (PROMs) into osteopathic practice
2. Establish an online patient incident reporting system that captures information anonymously and can be used for learning purposes

We have commissioned Clinvivo a specialist phone app development company to develop a facility meeting the following specification:

1. To provide a user-friendly service for routinely collecting patient reported outcome data using validated instruments. This will be achieved using:
 - i. a mobile phone and tablet app which will work on all leading market brands and browsers
 - ii. the Internet (online)
2. To provide a facility to remind patients to complete follow up data at *a priori* specified time points
3. Secure storage of these data
4. Managing data back to NCOR at regular agreed intervals (*e.g.* monthly)
5. Pilot the data collection facility for a three-month period starting Feb 2014 to April 2014.

2.6 Critical Success Factors for PROMS and patient incident reporting systems

A range of different factors will potentially affect the success of the project. These include:

- Capital investment to commission Clinvivo to build and manage the platforms and the mobile application (APP)
- Clinician engagement to use the database

- Clinician engagement to encourage their patients to complete the different outcome measures identified as being suitable for inclusion in the Clinvivo facility
- Patient participation to an extent that they regard as being acceptable and not burdensome
- Educational issues – ensuring the participating osteopaths and/or their support staff feel suitably confident when using
- Guaranteeing confidentiality of information for both patients and practitioners

2.7 System scope – the patient interface

Patients will be able to enrol, and register their practitioner's identifier (ID) on a front page and input data on a separate form. The following criteria should be satisfied:

- i. The mobile app will be compatible with all major market shareholder operating platforms. At the time of writing, this includes iOS, Android, Windows Phone, and Blackberry branded smart phones and tablets. Backward compatibility will be observed in order to maximise market share as a function of the application's performance. The online version will be compatible with all major browsers, including Chrome, Firefox, Internet Explorer, Safari, and Opera and have a similar appearance and functionality to the mobile app, allowing seamless cross-use by osteopathic patients.
- ii. Datapoints/fields: The data collection tools should be simple, feasible, and acceptable to complete in terms of length (patient focus group data will help to determine this). It will contain some basic demographic data, *e.g.* age, gender ethnicity, clinic treated in/or osteopath providing treatment (anonymised/pseudo-anonymised), description of complaint, patient related outcome measures.

Once developed, data collection must be possible both via the internet (online) and email prompts, and app alerts (*e.g.* vibration and/or pop-up boxes) following first registration for follow up data will be sent at set time-points.

The service has a potential for high use and demand. Based on the 4678 osteopaths currently registered, carrying out more than seven million consultations in the United Kingdom (UK) each year.^{13,14} This work is consistent with efforts being made within publicly-funded healthcare systems as attempts are made to meet the requirements of Clinical Commissioning Groups who will be commissioning various services including the management of musculoskeletal care.

2.8 Constraints

- A programme of preliminary work in the form of a systematic review and focus groups will inform the content of the systems. The system fundamentals can be constructed while this work is on-going.
- Parallel activities are planned to make best use of the available time, and they have been carefully considered to ensure the different aspects of the problem dovetail together.

2.9 Risks

- Project not being completed on time and within the specified budget.
 - The project will be run according to a series of identified project milestones. A series of financial milestones will be contingent on the project milestones being met.

- Failure to recruit enough osteopaths and engage them in the process
 - A rolling series of articles and/or talks to groups of osteopaths will be delivered to inform the profession about the project, its intended purpose, and its application to benefit individual practices and practitioners. Social media and any other form of innovative communication process will be used to make the project as transparent to osteopaths and patients as possible.
- Failure to recruit sufficient numbers of patients
 - A project website will be constructed to allow updated information to be added so that patients can learn more about the project.

We will run focus groups with patients and osteopaths to identify opportunities and barriers for dissemination and use of these new technologies. A communication and implementation strategy to launch these projects will be designed in consultation with the ODG board.

3 Project methodology

- i) Scoping of current PROMs and patient incident learning platforms used in musculoskeletal health care.
- ii) A systematic review to assess the quality of current commonly used PROMs in use from the perspective of their development, validity, and reliability testing, and their responsiveness to clinical change.
- iii) Conduct focus groups with patients to identify what is practical and feasible in terms of the use and completion of PROMs and incident reporting, and what type of analysed data they would like to be able to see.
- iv) Conduct focus groups with osteopaths to identify any barriers or fears they may have about PROM use, the type of support they feel they need, and the volume of data to be collected and its most helpful presentation format.
- v) Develop PROM data collection facility with IT specialists
- vi) Process evaluation of PROM data collection facility using survey and qualitative data

4 Business case

4.1 Rationale and strategic fit

- The necessity to collect practice-based data which can then be analysed and produced in a usable format for a practice
- The requirements of insurers to look at the numbers of treatments, and the effectiveness of treatments as assessed by the change in a number of robustly developed and tested patient reported outcome measures (PROMs)
- The use of the facility by osteopaths who wish to collect data as part of the newly-introduced Any Qualified Provider (AQP) system. The ability to collect data from patients independently ensures the data is more robust and less likely to be prone to a series of recognised biases
- Osteopaths will be able to evaluate their own practice profile by using this system, identify areas where outcomes could be improved, and identify areas for continuing professional development

4.2 Timescale and costs

Agree specifications	July, 2013
Prototype app produced and tested for usability, navigation and design Prototype online system for incident reporting	By December, 2013
'Live' testing i.e. sent to osteopaths; osteopaths' patients inputs data, data appears in database	By February, 2014
'Live' testing i.e. sent to patient; patient inputs data, and data appears in database followed up longitudinally	By March, 2014
Initial pilot test on 20 -30 patients (recruited by NCOR)	By April 2014
Make any necessary refinements based on feedback from pilot	By May 2014
Final version ready for on-going use Online incident websites operational App operational Database functional Downloads delivered in acceptable format Aim achieved	By June 2014
Agreement in place for on-going implementation and use	By June 2014
On-going data capture and return of data to NCOR	By June 2015
Conclusion of initial project period	By June 2016

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