Systematic Assessment of Patient Reported Outcomes in the OCOM Acupuncture and Herbal Clinic

A proposal submitted to the
OCOM Institutional Review Board

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Abstract

Approval is sought from the OCOM IRB for modifications to the current OCOM Acupuncture and Herbal Clinic informed consent and patient health history forms. These forms are completed by all incoming (new) patients treated in the main OCOM clinic and its directly-overseen satellite clinic at Hollywood Square. Patients also complete a 5th treatment follow-up form. The proposed time-frame for implementation of the revised forms is mid-September 2009, which coincides with the start of the clinical experience for a new incoming intern group. Derived from pre-existing instruments (with some new additions), the forms have been reviewed and revised over the past six months via an iterative process overseen by the OCOM Clinic Research Committee (CRC). Where feasible, the CRC process has incorporated input and suggestions from OCOM faculty, clinic administrators, and clinic reception staff. In addition to the form revisions, IBR approval is sought for a proposal to integrate the data collected from the forms into current OCOM patient medical record databases. The overall goals of this project are: 1) to enhance the validity and reliability of OCOM's patient outcomes data, encouraging improvements in the quality of care current patients receive; and 2) to develop a systematic infrastructure of data collection that will facilitate a wide range of future patient reported outcomes -based research investigations at OCOM.

Description of Current Forms and Procedures

At present, the OCOM informed consent and patient health history forms are completed by all new patients entering the main OCOM clinic. Identical forms are used at the satellite internship clinic at Hollywood Square in Northeast Portland. Forms are completed at intake (first treatment) and, in the case of the follow up form, by ongoing (current) patients prior to the start of the 5th treatment. The revised forms will be administered in the same way as current forms. They have been designed to be as patient-centered as possible, including the use of large fonts and simplified language.

As is true now, patients will be given the forms prior to intake by front desk staff (or at the start of the 5th treatment by their practitioner). Patients will be asked to review and complete the forms themselves prior to treatment, but assistance will be available from practitioners as necessary. Practitioners will always go over the patient's responses in detail (both initial forms and follow-up) in the treatment room. Practitioners will be available to assist patients as necessary if questions or difficulties arise.

Subsequently, the data from the forms will be entered by clinic data entry staff via standardized data entry procedures into OCOM patient medical record databases. The paper forms themselves will be retained in the patient file as part of the permanent medical record.

Although no specific research project is associated with these proposed form revisions, implementation of the forms will create a rich infrastructure for the collection of systematic prospective patient reported outcomes data. These data may potentially serve as a resource in the future for interested researchers, including OCOM students and faculty members. Individual IRB approval would be required for future research projects of this sort. The current proposal seeks only to obtain IBR approval for the proposed content of the instruments themselves, plus the associated data management infrastructure.

Informed Consent

The proposed informed consent form is included as Appendix A. While some wording has been retained, this represents a significant revision of the previous OCOM informed consent form. Analyses of the original form's language and grammar indicated that it was written at a relatively high level (above 12th grade according to Flesch-Kincaid reading scores). Research suggests that an average US adult reads at a 7th grade level. The wording in medical informed consent forms is often several grades higher

than this (Paasche-Orlow et al., 2003). To address this problem, the wording in the proposed OCOM form has been revised for simplicity. Its readability statistics suggest that it is now at between 8th and 9th grade reading level -- representing a significant improvement over the prior version. A larger font has also been used to optimize visual readability.

"New Patient" and "5th Treatment Follow Up" Forms

The proposed "New Patient" and "5th Treatment Follow Up" forms are included in this proposal as Appendix B and Appendix C. The "New Patient" form is designed to integrate several distinct and separately administered form elements currently in use in the OCOM clinic. These include: 1) the "Patient Health History" form; 2) the "Your Current Health Status - Initial" form; and 3) the "Current Conditions Checklist" form. The 5th Treatment Follow Up" form is an adaptation of the "Your Current Health Status - 5th Treatment: Follow Up" form, also currently in use at OCOM.

Patient Health History Form: Versions of the current "Patient Health History" form have been in use at OCOM for a number of years as a routinely administered element of all new patient intakes. No specific IRB approval has ever been sought for use of these forms in the past, because their use has in the past never been prospectively connected with research-related activities -- although interns, supervisors and faculty members have routinely used the information obtained in the form for diagnostic and treatment planning purposes. Significantly, most of the clinically relevant data in this form (e.g., information on patient red flags) has not been entered into the clinic medical record database system.

Your Current Health Status - Initial: The currently used "Your Current Health Status - Initial" form is an OCOM-specific version of the MYMOP, a well-validated patient-centered outcomes assessment instrument. (See http://sites.pcmd.ac.uk/mymop and Patterson, 1996, for details.) The form has been in use at OCOM for two years; IRB

approval for its use was first obtained in 2007. To date, data from this instrument has been collected on more than 2,000 different patients. The actual content of this portion of the new instrument remains unchanged relative to the one for which OCOM IRB approval was previously obtained. The form itself is now integrated as a single page into the larger revised instrument (specifically, as p. 4 of the "New Patient" form).

Current Conditions Checklist: The currently used "Current Conditions Checklist" was developed after much discussion and many iterative revisions in 2006-2007 by the OCOM Clinic Research Committee; IRB approval for its use in the clinic was first obtained in 2007. Over the past six months, the content of this form has been significantly simplified relative to its previously approved iteration. As with the MYMOP, it is now integrated as a single page into the larger instrument (specifically as p. 5 of the "New Patient" form).

New Form Elements: Several new elements are proposed for the revised "New Patient" instrument. None of these have previously been reviewed or approved by the OCOM IRB. Each of the proposed new elements has been identified for inclusion by the OCOM Clinic Research Committee (CRC). Specifically, the CRC identified several forms from the federally-sponsored "PROMIS" project form library (Patient-Reported Outcomes Measurement Information System). See http://www.nihpromis.org; see also Ader (2007) and Callahan et al. (2008) for more information about the PROMIS project itself.

The proposed new elements include: 1) the "PROMIS Global Items Form"; 2) the "PROMIS Pain Impact - Short Form"; and 3) the "PROMIS Physical Functioning - Short Form". These PROMIS forms are each incorporated as single page questionnaires into the proposed "New Patient" instrument as pages 3, 6, and 7 respectively.

All PROMIS content has been tested by NIH-sponsored researchers on many thousands of subjects, and has been comprehensively evaluated for reliability and validity (Callahan et al., 2008). PROMIS forms were designed to be simple to complete

and consist for the most part of checkbox-based Likert scale responses. They are available at no cost for research purposes from NIH without licensing restrictions.

5th Treatment Follow Up: The proposed "5th Treatment Follow Up" instrument is a slightly modified version of the currently approved "Your Current Health Status - Follow Up: 5th Treatment" form, which is based on the MYMOP follow up form (Patterson, 1996). To this pre-existing instrument will be added the three PROMIS forms described earlier in the "New Patient" instrument. The addition of these PROMIS elements will significantly expand the range and usefulness of the patient reported outcomes data collected in the OCOM clinic. The follow up form also now includes a page for general feedback from patients.

Estimates of Time Burden for Patients

Consent: The proposed revisions to the informed consent form comprise two pages rather than a single page. However, because of its simplified language and larger font, it may be more straightforward for patients to read. Nevertheless, because of its increased length overall we estimate a slightly longer duration to complete this form for patients than for the previous iteration.

New Patient: Based on pilot testing the forms, our preliminary estimates suggest that, despite its length, the proposed "New Patient" form will take most patients about 15 minutes to complete. This compares favorably with estimates of the duration required to complete the current new patient forms.

Follow Up: We estimate that the "5th Treatment Follow-Up" form should take no more than 10 minutes to complete.

Population & Expected Sample Size

All new OCOM clinic patients who are competent to sign informed consent forms will be expected to complete the forms as part of the standard intake process, and also at 5th treatment. Because the outcomes data is valid only for self-report, children or other patients who are not cognitively intact or who are not otherwise able to sign informed consent or complete self-report questionnaires will not be required to complete the forms.

Once in place, we envisage that use of the the instruments and related (password-protected) data entry infrastructure will facilitate rapid accumulation of substantial volumes of secure data. OCOM typically treats more than 3,500 different patients over the course of a year, about 50% of whom (approximately 1,750) are new patients (meaning that no current medical record exists for them in the OCOM system at the time of their intake).

In total during an annual cycle, more than 25,000 distinct treatment encounters occur at the OCOM clinic; most of the 3,500 different patients are, of course, seen multiple times over their course of treatment.

Thus, over the course of a year we estimate approximately 1,750 new patients will complete the "Informed Consent" and "New Patient" forms; and that approximately 500 of these will return five or more times, and will thus complete the "5th Treatment Follow Up" form.

Subject Research Participation Agreement

OCOM administers a teaching clinic that treats patients at very low cost. New patients are all aware of this. But OCOM also conducts research, and new patients may not initially be aware of these aspects of the college's activities. Both of these activities

(clinical patient care and research) are, however, central to the college's mission. The clinical enterprise meshes particularly well with the college's research goals, in that it can serve to provide a structured source for rich research-relevant data.

The informed consent form completed by all new patients now mentions explicitly that OCOM conducts patient care related research activities in the clinic. It also explains that anonymized patient data may be used for research purposes. It indicates how patient data may be used, while assuring appropriate levels of patient confidentiality. It also provides patients with a mechanism to permit them to request in the future that their data not be used for research purposes, should they choose not to participate.

As is true currently, only authorized employees of the college will be able to access patient electronic medical record data. All systems are password protected and secure. HIPAA guidelines for protecting patient privacy are used at all times. Patients receive a copy (to keep) of OCOM's statement of Patient Privacy Practices at intake.

Overall Goals of the Proposed Changes

The principal goal of the proposed changes in the instruments and outcomes data infrastructure is to improve the quality of patient care in the OCOM clinic -- a central element of the OCOM mission statement. This goal will be accomplished by improving the validity and reliability of the patient-reported outcomes data collected. Validated outcomes data can serve as a vital source of input for effective clinical decision making, because data of this sort helps to validate (or, alternatively, raise questions about) prior diagnostic and treatment decisions. It also provides an evidence-based rationale for future treatment planning.

A second important goal of the proposed changes is to facilitate the creation of a flexible and powerful infrastructure for the collection and storage of of patient reported

outcomes datasets. It is envisaged that this data source will provide a key research resource in the future for interested students, faculty, and other researchers.

Risks and Benefits

Risks: No risks to patients are anticipated from this project.

Benefits: Likely benefits to patients take several forms: 1) at the aggregate level, more reliable assessment of treatment outcomes, which will lead to; 2) better diagnostic decision making on the part of practitioners; 3) an improved "outcomes feedback loop" that will enable better treatment planning; and 4) improved long term care, and hopefully improved long term outcomes.

Prior Scientific Review

This proposal has been previously reviewed and approved by the OCOM Clinic Research Committee (CRC).

References

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