Results: The subjects in the study were divided into 3 diagnostic groups: 1. OA (subjects with knee OA and chronic knee pain, n = 502), 2. Pain (subjects with chronic knee pain, but no knee OA, n=496), 3. Controls (subjects with neither chronic knee pain nor knee OA, n=421). The overall F-test and all pairwise differences between the 3 diagnostic groups were statistically significant (p<0.001) with all HRQL instruments and subscales were ranked regarding their ability to discriminate the diagnostic groups (see Table 1). For a hypothetical repeat study with the 3 diagnostic groups, the approximate number of subjects per group needed with the HRQL instruments are given in Table 2.

Conclusion: As judged from the present study, QoL(KOOS), Pain(KOOS), and Symptoms(KOOS) are the most powerful discriminators between the different diagnostic groups, and EQ-5D single index is the least powerful one. The results indicate that only 50-70 subjects are needed in a hypothetical repeat study when using KOOS and WOMAC discriminators as compared to 1,000 subjects for EQ-5D single index.

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ENHANCING THE PROCESS OF A CLINICAL TRIAL IN OSTEOARTHRITIS WITH EMBEDDED QUALITATIVE APPROACHES

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Purpose: The value of qualitative research methods in the design and conduct of clinical trials is increasingly recognised. In this study we describe qualitative approaches embedded within a randomised controlled trial of anaesthesia regimens for patients with osteoarthritis receiving lower limb joint replacement (the ’APEX’ trial). We explore the role that such methods have to play in improving design and conduct of trials.

Methods: Patients with osteoarthritis and receiving total knee or hip joint replacement are eligible to take part in the APEX trial. This aims to include 600 participants recruited at a single site within the UK’s NHS system. The trial design was informed by existing literature and our research to date on patients’ experience of osteoarthritis and outcomes after joint replacement surgery. Within the APEX trial qualitative approaches are used to assess the acceptability of participation to patients and to advise on enhancement of the recruitment process.

To examine the recruitment process we used a peer-listening approach. Research nurses audio-recorded recruitment interviews with potential trial participants. The audio-recordings were listened to by other members of the research nurse team. The nurses evaluated the recruitment interviews using a data extraction form and meetings to compare findings. In addition, qualitative interviews were conducted by an experienced researcher with a sub-sample of participating patients three weeks after their surgery. These in-depth interviews addressed trial participation, expectations and experiences of surgery, and pain management.

Results: Process analysis of the inclusion of a peer-listening approach and qualitative research within the APEX trial shows that research nurses prefer to conduct their own peer-review of recruitment interviews rather than relying on external observers to do so. The process of peer-review improves consistency in recruitment and provides a structured forum through which to discuss how best to confirm equipoise, ensure informed consent and maximise participation in a trial. Qualitative interviews with patients who participated in the APEX trial provide evidence about the clarity of trial information packs, the acceptability of altered modes of anaesthesia during joint replacement surgery as well as significant detail and depth about pain and the hospital management of joint replacement surgery.

Conclusions: Research into the process of clinical trials in osteoarthritis and other areas has begun to highlight the importance of qualitative research within the trial design stages. This study highlights the value of nurse-led ‘peer’ observation of recruitment interviews using audio-recording techniques as well as the value of ongoing inclusion of qualitative interviews with trial participants. Further research will explore the impact of these methods on patient acceptability of trials in treatment of osteoarthritis and ultimately potential improvements in levels of recruitment and retention within research studies.

REACHING THOSE MOST IN NEED: A SCOPING REVIEW OF INTERVENTIONS TO IMPROVE HEALTH CARE QUALITY FOR DISADVANTAGED POPULATIONS WITH OSTEOARTHRITIS

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Purpose: To conduct a systematic review to identify and describe the scope and nature of the research evidence on the effectiveness of interventions to improve health care quality or reduce disparities in care of disadvantaged populations with osteoarthritis (OA).

Methods: We searched electronic databases from 1950 through February 2010 and the grey literature for relevant articles in any language using any study design. Studies with interventions designed explicitly to improve health care quality or reduce disparities in care for disadvantaged adult populations with OA were eligible. Those that evaluated the effectiveness of the intervention were included. Disadvantaged populations were identified using the PROGRESS-Plus framework. Reviewers abstracted data from studies to determine study and participant characteristics, details on the intervention, results and quality.

Results: Of 4,701 citations identified through the search process, 10 studies met the inclusion criteria. Most studies were community-based (n=8) and targeted race/ethnicity/culture (n=6). All 10 studies evaluated interventions aimed at people with OA; 2 hospital-based studies also targeted the health care system by providing individualized assessment or reinforcement using follow-up telephone calls not previously provided by health care providers.

No studies targeted health care providers. Nine of 10 studies evaluated arthritis self-management interventions and 6 described cultural tailoring of the intervention. Arthritis self-management interventions improved the health care quality of disadvantaged populations by improving participant arthritis self-efficacy, health behavior, and health status. Only one study measured the impact of an intervention in reducing disparities in care by comparing the difference in effect between the disadvantaged populations and the relevant PROGRESS-Plus comparator group.

Conclusions: There are few studies evaluating the effectiveness of interventions to improve health care quality in disadvantaged populations with OA, and a lack of studies evaluating interventions targeting health care providers. Further research is needed to evaluate interventions aimed at health care providers and the health care system, as well as other patient-level interventions. Promising interventions at the provider-level, such as cultural competence training and shared decision-making skills, are worthy of future evaluation. Gap intervention research is important to evaluate whether an intervention is effective in reducing documented health care inequities.

GENERIC AND DISEASE-SPECIFIC HEALTH-RELATED QUALITY OF LIFE - A SWEDISH POPULATION-BASED STUDY ON CHRONIC KNEE PAIN AND KNEE OSTEOARTHRITIS

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Purpose: To estimate generic and disease-specific health-related quality of life (HRQL) in subjects with knee osteoarthritis in Sweden assessed by the EuroQol-5D (EQ-5D) index, Knee Injury and Osteoarthritis Outcome Score (KOOS), and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC, version 3.0).

Methods: A self-reported questionnaire about knee pain was sent to 10,000
subjects (responders 7,736) from the population-based Malmö Diet and Cancer cohort. A random sample of 1,300 subjects with chronic knee pain (duration of at least one month in the last year), and a control group of 650 subjects, were invited to a clinical examination including x-ray of both knees (998 + 487 subjects underwent examination and x-ray). Subjects who fulfilled ACR criteria and/or had radiographic knee OA (ROA) were considered to have knee OA. The EQ-5D index states were converted into a single index value according to the UK TTO value set. A normalized score was calculated for each KOOS and WOMAC subscale, and for the WOMAC total score. Data were analysed using analysis of variance with age, sex, and BMI as covariates.

**Results:** Approximately 20% (1,605/7,736) of the subjects had chronic knee pain. Of those that participated in the examination and x-ray, 50% (502/998) had knee OA. Subjects with knee OA were to a larger extent women (63% vs. 57%, p<0.05), had higher mean age, and BMI than controls (mean age: 70.2 vs. 69.2 years, p<0.05; BMI: 29.0 vs. 26.3 kg/m², p<0.01). Subjects with knee OA reported significantly worse scores compared to those without knee OA in all HRQL instruments. Subjects fulfilling ACR criteria reported significantly worse scores than those with ROA only, according to all HRQL instruments. Subjects of age ≥ 75 reported significantly worse scores than subjects of age <65 in all KOOS subscales but Symptoms, in EQ-5D index, in all WOMAC subscales but Stiffness, and in the WOMAC total score. Subjects with BMI >30 kg/m² reported significantly worse scores than subjects with BMI <25 in all HRQL instruments. Females reported significantly worse scores than males in all HRQL instruments and subscales, except KOOS Qol. and EQ-5D index.

**Conclusions:** In this population-based study, those fulfilling ACR criteria were associated with significantly worse generic and disease-specific quality of life compared to those having ROA only. In general, being a woman, being old, or having high BMI was associated with worse outcome.

### 372 MANAGEMENT OF KNEE OSTEOARTHRITIS: IMPACT ON PAIN ON A DAILY BASIS

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**Purpose:** Knee osteoarthritis is a real public health problem. According to data from the Framingham study, its prevalence is estimated to be 6.1% of adults over the age of 30. This prevalence increases with age, to more than 40% after the age of 75. Knee osteoarthritis is generally not life-threatening, but it does significantly affect the daily lives of patients who have it and incurs very high costs for the community.

**Methods:** Pragmatic, longitudinal and prospective follow-up carried out by rheumatologists in the context of their daily professional activities; the objective is to observe, under actual conditions of use, the effect obtained, in the context of management of knee osteoarthritis, combining a prescription of Avian ACS (Structum® - 1 g/day) between 2 courses of treatment of 3 injections of hyaluronic acid (Structovial®) spaced out by a maximum of 12 months.

**Results:** 200 patients are treated with Structovial® and Structum®, and the gender ratio favours women (64% versus 36%). The average age is 65.30 years (±7.10); men are not statistically younger than women. While height and weight are different for men and women, the Body Mass Index calculation does not differ by gender: 28.80±5.95 for the women versus 20.15±1.43 for the men (p<0.35). 50% percent of the patients are treated for their left knee and 50% are treated for their right knee.

Average pain during activities of daily living was measured by means of a visual analogue scale. It is 52.02±20.53 at inclusion. At 6 months, this average pain measured under the same conditions is 33.58±25.21. A third measurement at 12 months situates it at 30.44±22.86. Pain during activities of daily living is significantly reduced between inclusion and month 6 (p<0.0001) and between inclusion and month 12 (p<0.0001). The average reduction in pain during activities of daily living measured between inclusion and 12 months is also significant (p<0.0001). Accordingly, the reduction obtained in 12 months is 41%. With regard to pain measured at rest, it was also measured at inclusion, at 6 months and at 12 months, by means of a visual analogue scale. There is a significant reduction in pain at rest between inclusion and 6 months (p<0.0052) and the reduction between inclusion and month 12 is also significant (p<0.0005). At inclusion, at 6 months and at 12 months, the average pain observed is 29.86±21.16, 20.95±23.13 and 17.33±6.97, respectively.

**Conclusions:** During a previous non-inferiority, randomised, controlled trial, Structovial® showed proof of its non-inferiority compared with a baseline high molecular weight hyaluronic acid (Synvisc®). With Structovial®, improvement is observed early (week 6); this improvement is maintained at 6 months. Moreover, overall clinical improvement is manifested in an improvement in quality of life [5].

In addition, in another study, 256 subjects with knee osteoarthritis were randomised into 2 groups: 127 randomised subjects were placed in the group treated with Avian ACS (Structum®) and 129 randomised subjects were placed in the group receiving the placebo. At inclusion, the PCS-12 index (Physical Component) was 36.43 and 36.64, respectively, for the group treated with Avian ACS (Structum®) and the group receiving the placebo. There was a statistically significant improvement in the score of the physical component for the group of patients to treat with Avian ACS (Structum®) compared with that of the placebo group (p<0.05).

Our study, which assesses the effect on pain obtained in the context of management of subjects with knee osteoarthritis, combining a prescription of Structum® (1 g/day) between 2 courses of treatment of 3 injections of Structovial®, showed a reduction in pain during activities of daily living. This reduction in pain, which is significant at 6 months, then perpetuated at 12 months, shows the relevance of the treatment protocol used by the doctors.

### 373 BURDEN OF ILLNESS IN OSTEOARTHRITIS

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**Purpose:** The objective of the study was to assess the burden of osteoarthritis (OA) across different countries.

**Methods:** A structured literature review was conducted to assess the burden of osteoarthritis worldwide using Medline (year 1995 to 2009). Keywords included (but not limited to): osteoarthritis, prevalence, burden of illness, treatment, quality of life, and cost. Search was limited to articles written in English.

**Results:** Published studies on burden of OA were found in 20 countries. Overall prevalence rates have been reported between 4% to 57% across different countries. Japan had the most published prevalence studies with rates reported as low as 4% to as high as 56%. Despite differences in prevalence, all studies consistently reported OA to be more prevalent in women than men. Although all joints in the body may be affected by OA, the knee, followed by the hip and hand, were found most common. The literature review found a lack of any true disease-modifying OA drug; consequently, treatments were targeted at the reduction of pain and inflammation and maintenance of function. The literature findings also found no major changes in recent years to the treatment and management of OA, which primarily involves pain palliation and maintenance of function. Among guidelines, there was general consensus that a combination of pharmacological and non-pharmacological modalities should be used in management of OA. Most common non-pharmacological interventions reported include exercise, weight reduction, and patient education. Across all countries, pharmacological interventions are aimed to reduce pain and mainly consist of acetaminophen (paracetamol) and NSAIDs with opioid use varying by geographical location. While NSAIDs are the most frequently used therapy worldwide, it is associated with well-documented adverse events such as GI discomfort, bleeding, ulceration, and perforation. Patients' functioning and quality of life were also reported in many studies to be negatively affected by the burden of OA pain. Other symptoms (e.g. sleep disturbance, depression, fatigue, and anxiety) were also found to be associated with OA. Furthermore, OA patients were reported to have reduced activities of daily living, social isolation, and limitations in regards to career advancement.

The economic burden of OA have been highlighted in a number of reviewed studies and have been estimated to cost the US economy nearly $128 billion per year in medical care and indirect expenses (including lost wages and productivity) with individual studies reporting an average of $18,000 per OA patient per year. Globally, OA represents a huge economic challenge. The average annual total cost that have been reported across all