HIP AND KNEE

OSTEOARTHRITIS

CLINICAL GUIDELINE

(Final draft)

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A INTRODUCTION

Chronic diseases are a major public health burden on Australian society. An increasing proportion of the population has a risk factor/s for, or at least one, chronic disease leading to significantly increasing public health costs. Health service policy and delivery must address not only acute conditions but also effectively respond to the wide range of health and public services required by people with chronic illness [1, 2]. Strong primary health care policy is an important foundation for a successful national health delivery system and long term management of public health, and is linked to practical outcomes including lower mortality, decreased hospitalisation and improved health outcomes [1]. National strategic health policy has recently given increased recognition to the importance of chronic disease management, with Federal endorsement of a number of initiatives for the prevention or delay in onset; early detection; and evidence-based management of chronic disease, including arthritis [1, 3].

Chronic musculoskeletal conditions including arthritis account for over 4% of the national disease burden in terms of disability-adjusted life years. Over 6 million Australians (almost one-third of the population) are estimated to have a chronic musculoskeletal disease and it is the main cause of long term pain and physical disability. As such, Federal health policy has identified arthritis as a national health priority area and adopted a number of initiatives aimed at decreasing the burden of chronic disease and disability; raising awareness of preventative disease factors; providing access to evidence-based knowledge and improving the overall management of arthritis within the community [4].

General practice has an important role within the Australian health care system in the prevention, early detection and management of chronic disease. The nature of general practice provides opportunity for early screening for chronic disease and address of preventable risk factors. Musculoskeletal conditions, particularly osteoarthritis was one of the most commonly managed diseases by Australian general practitioners in 2003-2004, accounting for 17% of consultations. To manage chronic illness effectively requires well coordinated, patient-centred care that is continuous, comprehensive, and consistent. General practitioners (GPs) are well placed to provide care, coordination and a monitoring role for the multi-disciplinary management of chronic disease [1, 2, 4]. The GP undertakes this role in consultation with other medical specialists as required. The role general practitioners play in chronic disease management (CDM) through multi-disciplinary care coordination and long term care planning is recognised within the national Medicare rebate framework. Patients with arthritis are eligible for broader funding arrangements under CDM items for GP Management Plans and associated reviews [2].

As part of the Federal Government's Better Arthritis and Osteoporosis Care (BAOC) 2006-07 Budget initiative [5], these arthritis guidelines have been developed to inform evidence-based primary care of chronic disease in general practice. Three guidelines focusing on osteoarthritis, rheumatoid arthritis and juvenile idiopathic arthritis have been developed. Each guideline includes recommendations and algorithms to assist general practitioners managing patients with chronic musculoskeletal disease in early detection of disease; addressing reversible risk factors; long term care planning and management; and co-ordination of multi-disciplinary care needs. These evidence-based clinical guidelines for the management of osteoarthritis, rheumatoid arthritis and juvenile idiopathic arthritis in general practice have been developed by medical experts and endorsement by the NHMRC will be sought.

1. Commonly used abbreviations

AE: Adverse event/s
CI: Confidence interval
COX-2 inhibitors: cyclo-oxygenase- 2 selective inhibitors
DBRCT: Double blind randomised controlled trial
ES:Effect size: 0.2= small effect, 0.5=moderate effect, 0.8=large effect
MA: Meta-analysis
MACTAR: McMaster Toronto arthritis patient preference questionnaire
MSK: Musculoskeletal

NNH: Number needed to harm
NSAIDs: Non steroidal anti-inflammatory drugs
NNT: Number needed to treat
OA: Osteoarthritis
OARSI: Osteoarthritis Research Society International
OMERACT: Outcome measures in rheumatoid arthritis clinical trials
PEMF: Pulsed electro-magnetic field
ROM: Range of movement/motion
RPD: Relative percentage difference
SMD: Standardised mean difference
SMEP: Self management education program
SR: Systematic review
VAS: Visual analogue scale
WOMAC: Western Ontario McMaster
WMD: Weighted mean difference

B BACKGROUND

1 Osteoarthritis

Osteoarthritis is the most common form of chronic arthritis, with radiological evidence of osteoarthritis in more than 50% of people over the age of 65 years [6] and approximately 10% of men and 18% of women suffering symptomatic osteoarthritis [7].

Osteoarthritis is characterised by joint pain and mobility impairment associated with the gradual wearing of cartilage. There is currently no cure for osteoarthritis. Treatment is aimed primarily at symptom relief, improving joint mobility and function and optimising consumer quality of life [8]. The treatment of osteoarthritis hip and/or knee (and other sites) includes use of non-pharmacological as well as pharmacological interventions. Joint replacement surgery is a cost effective intervention for people with severe OA unresponsive to conservative therapy [8, 9].

2 The need for a guideline

In Australia, the condition is self reported by more than 1.4 million people, 7.3% of the population [4] and is the tenth most commonly managed problem in general practice [10]. This number is set to rise as the elderly population grows.

Osteoarthritis exerts a significant burden on the individual and community through reduction in quality of life, diminished employment capacity and increase in health care costs. For further details refer to the *Evidence to Support the National Plan for Osteoarthritis, Rheumatoid Arthritis and Osteoporosis: Opportunities to Improve Health-Related Quality of Life and Reduce the Burden of Disease and Disability (2004)* [11].

In 2002, all Australian Health Ministers designated arthritis and musculoskeletal conditions as Australia's seventh National Health Priority Area. In response, a National Action Plan was developed in 2004 by the National Arthritis and Musculoskeletal Conditions Advisory Group (NAMSCAG) [11]. The aim of this document was to provide a blueprint for national initiatives to improve the health-related quality of life of people living with osteoarthritis, rheumatoid arthritis and osteoporosis, reduce the cost and prevalence of those conditions, and reduce the impact on individuals, their carers and communities within Australia. The National Action Plan was developed to complement both the National Chronic Disease Strategy (which is broader) and the National Service Improvement Framework for Osteoarthritis, Rheumatoid Arthritis and Osteoporosis, and other national and state/territory structures.

3 Aim of the guideline

This guideline seek to achieve some of the aims of the National Action Plan and National Service Improvement Framework by providing recommendations for effective non surgical management of consumers diagnosed with osteoarthritis of the hip and/or knee within the primary care setting.

The guideline seeks to assist primary health care professionals to:

- Optimise health related quality of life
- Optimise self management
- Prevent repeated acute episodes
- Prevent or delay complications associated with osteoarthritis
- Prevent progression to established disease.

4 Scope and target population

The guideline is intended primarily for use in primary care settings by GPs and their patients. It is intended that through use of the guideline any health care professionals that a patient chooses to consult regarding OA are aware of the evidence regarding effective management.

The guideline is intended to refer to all adult patients diagnosed with symptomatic osteoarthritis of the hip and/ or knee up until referral for joint replacement. Many of the recommendations may be considered for management of OA in other sites where, to date, there is limited evidence available to guide management. Health care professionals managing patients waiting for joint replacement surgery should refer to care guidelines for the multidisciplinary management of joint replacement waiting list patients.

The guideline has been developed for use in primary care settings in metropolitan, regional, rural and remote areas of Australia. The guideline are also applicable to other settings in which consumers with OA may be treated such as specialist rheumatologist and orthopaedic practices.

5 Methods

The full process used to develop the guidelines is outlined in the *Process Report* (Appendix B).

This guideline is based on an evidence-based literature review to NHMRC requirements. The RACGP OA Working Group who has overseen the development of the guideline and supporting documents comprised of rheumatologists, GPs, consumer representatives, arthritis organisation representatives and an NHMRC advisor. The group defined the scope of the guideline (refer to The Process Model below), the target population, and formulated the operational definitions of diagnosis and management that defined the literature review and the development of the final guideline.

The evidence for the OA guideline is based on:

1. a review of the literature from June 2005 to March 2007;
2. an Australian national guideline for OA [12] which was assessed using the AGREE instrument [13] and identified from 13 OA guidelines as being the most appropriate, recently published, high quality guideline;
3. a review of pertinent studies reported in the national guideline for OA [12] in areas where no additional evidence had been published from June 2005 to March 2007; and
4. the RACGP OA Working Group's expert opinion (when no evidence was sourced in the literature).

Literature review

The literature review comprised a systematic search of Medline, Embase, CINAHL and the Cochrane library for English language publications. Further selection of literature was based on reading the title and/or the abstract. Reference lists in review articles and trials were also retrieved.

In addition, for interventions not represented in the initial search pertinent studies reported in the national guideline for OA [12] were included in the review. Further gray literature was also identified through personal contact with the authors. Included literature was limited to randomised controlled trials (RCTs) or systematic reviews (SRs). The evidence obtained was graded according to the 'NHMRC additional levels of evidence and grades for recommendations for developers of guidelines' [14].

The detailed literature review report for this guideline can be accessed at website TBA.

Grading of recommendations

Each recommendation statement is supported by a grading reflecting the strength of the recommendation. This guideline uses the recommendation gradings in Table 1 based on NHMRC levels of evidence [14] to identify the evidence for the overall recommendations. The gradings thus reflect implementability in terms of

trust or confidence practitioners can use in a clinical situation. The full grading system is outlined in *Evidence tables for osteoarthritis recommendations* (Appendix D).

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Table 1

Recommendation Gradings

A – Excellent evidence - body of evidence can be trusted to guide practice
B – Good evidence - body of evidence can be trusted to guide practice in most situations
C – Some evidence - body of evidence provides some support for recommendation(s) but care should be taken in its application
D – Weak evidence - body of evidence is weak and recommendation must be applied with caution

Table 2 shows the body of evidence assessment matrix, listing the components to be considered when judging the body of evidence, together with the range of grades [14]. The overall grade of recommendation used in this study is based on a summation of the grading of individual components of the body of evidence assessment.

Table 2

Component	**A**	**B**	**C**	**D**
	Excellent	**Good**	**Satisfactory**	**Poor**
Volume of evidence	At least 1 good quality SR that has at least 2 good quality RCTs	At least 2 good quality RCTs or a moderate quality SR that has at least 2 moderate -good quality RCTs	At least 2 moderate quality RCTs	Less than 2 moderate quality RCTs
Consistency	All studies consistent	Most studies consistent and inconsistencies may be explained	Some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical Impact	Very large	Substantial	Moderate	Slight or restricted
Generalis - ability	Population/s studied in body of evidence are the same as the target population for the guideline	Population/s studied in the body of evidence are similar to the target population for the guideline	Population/s studied in the body of evidence different to the target population for the guideline but it is clinically sensible to apply this evidence to the target population (eg results in adults that are clinically sensible to apply to children)	Population/s studied in the body of evidence different to the target population for the guideline and hard to judge whether it is sensible to generalise to the target population
Applicability	Directly applicable to Australian health care context	Applicable to Australian health care context with few caveats	Probably applicable to Australian health care context with some caveats	Not applicable to Australian health care context

6 The guideline

The OA guideline has been designed to provide clear information to assist clinical decision-making and support optimal patient care. It is based on the best evidence available up to July 2007. Where appropriate, the evidence has been interpreted with regard to the Australian context in which the guideline will be implemented.

The guideline consists of:

Algorithms (flow charts)

The three algorithms summarise the main recommendations of the guideline and provide an accessible desk-top reference. The algorithms are detailed flowcharts for the diagnosis and the management of OA.

Recommendations

The 34 recommendations contained in the guideline are limited to consumers/patients over the age of 18 years presenting with arthritic symptoms of the hip or knee, as well as those diagnosed as having hip/knee OA. The recommendations have been developed on the basis of the research questions and the results of the literature search.

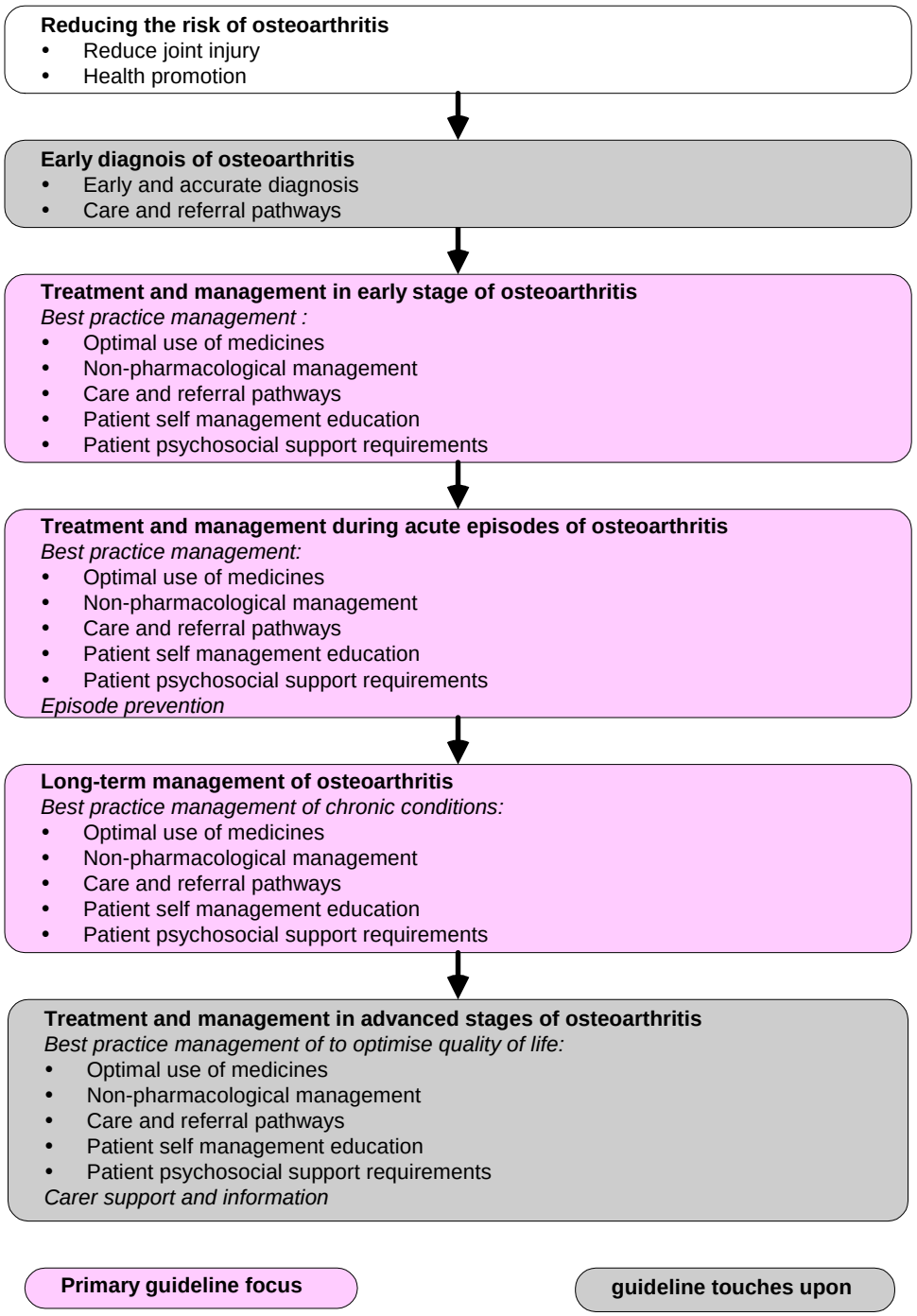
Each recommendation has been graded (from A to D) according to the NHMRC additional levels of evidence and grades [14]. The grade reflects the degree of 'trust' that the clinician can place on the clinical application of the recommendation. Each recommendation is supported by a summary of the evidence. The OA Working Group supports all 34 recommendations. The full grading and evidence base for each recommendation are presented in the document *Evidence tables for hip and knee osteoarthritis recommendations* that can be accessed at website TBA.

Resources

Useful references and supporting documentation are provided in this guideline. Appendix C contains additional resources including an OA management plan template, as well as contact details for organisations providing services and support to people with OA. *The RACGP OA Working Group recommend consulting the Therapeutic Guidelines (www.tg.com.au) and the National Prescribing Service (www.nps.org.au) for detailed prescribing information.*

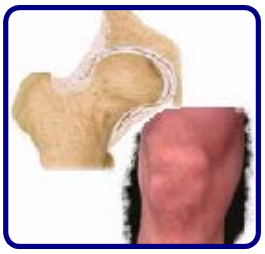
7 Process model for the OA guideline

The guideline focus is on hip and knee osteoarthritis. Although many of the recommendations are relevant to osteoarthritis in other sites, research relating to other forms of osteoarthritis was not included in the literature review. The following osteoarthritis process model identifies the stages in chronic disease management and the focus of these osteoarthritis guidelines.



C ALGORITHMS

1 Hip/knee osteoarthritis diagnosis and assessment algorithm



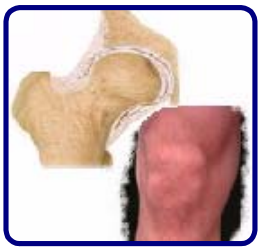
Hip/Knee Osteoarthritis
Diagnosis and Assessment Algorithm

Target Population: Adults aged over 18 years with signs/symptoms of hip/knee OA

Prompts for Decision & Assessment	Key Stages in OA Diagnosis and Assessment	Documentation and Actions
• Clinical History • Weight-bearing radiographs **Exclude:** • Trauma • Soft tissue conditions • Referred pain syndromes • Septic/crystal arthritis • Haemarthrosis	**Confirm OA Diagnosis**	• Date of weight bearing Xray • Basis for diagnosis of OA • Basis for differential diagnosis
Condition Assessment • Pain, swelling • Function, impairment • Emotional disability • Other Disability **Comorbidities** • Nutritional assessment (BMI, girth) **Falls Risk Assessment** **NSAID risk** • Age, Hypertension, Upper GIT events, cardiovascular, renal or liver disease **Medication risk** • Polypharmacy • Aspirin allergy • Diuretics, ACEI • Anticoagulants **Knowledge, Expectations & goals**	**Perform Comprehensive Assessment**	• Document baseline/ current OA status • Document BP, renal function if using or considering NSAID/ Cox-2 • Use information to assess need for medication review (HMR, RMMR), CDM items • Use information to develop goal setting care plan

Care Planning and Management

2 Hip/knee osteoarthritis care planning and management algorithm



Hip/Knee Osteoarthritis
Care Planning and Management Algorithm

Evidence Based Interventions
[Grade A, B, C recommendations]

Key Stages in OA Care Planning

Documentation and Actions

Prescription

Non-pharmacological Therapy

- Weight loss [**Grade B**, pg 19]
- Land based exercise [**Grade B**, pg 20]
- Aquatic exercise [**Grade C**, pg 20]
- Multimodal physical therapy [**Grade C**, pg 22]
- Tai Chi [**Grade C**, pg 23]
- Self management education programs (SMEP) [**Grade C**, pg 24]
- Thermotherapy [**Grade C**, pg 25]
- TENS [**Grade C**, pg 26]
- Acupuncture [**Grade C**, pg 27]

Pharmacological Therapy

Short term (up to 4 weeks)

- Simple Analgesia (paracetamol) [**Grade A**, pg 33]
- Oral NSAID/Cox-2 (with caution) [**Grade B**, pg 33]
- Intra-articular corticosteroid [**Grade B**, pg 36]
- Topical NSAIDs [**Grade C**, pg 37]

Longer term treatment

- Simple Analgesia (paracetamol) [**Grade A**, pg 32]
- Weak and strong opioids (with caution) [**Grade A**, pg 35]
- Viscosupplementation (5-13 weeks for OA knee) [**Grade C**, pg 39]

- **Develop goal setting care plan based on:**
  - identified need,
  - evidence for effectiveness
  - patient preferences
- **Optimise conservative therapy**
- **Optimise quality of life**
- **Minimise risk of adverse events**
- **Monitor & Review**

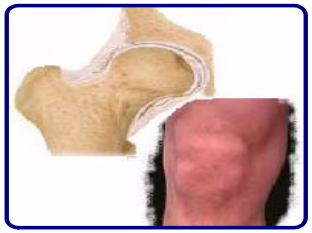
- GP management plan
- Document plan for BP/ Renal function monitoring if using NSAID/Cox-2
- Refer for allied health / health care provider assessment
- Refer to rheumatologist for intra-articular injection/ pain management input as required
- Medicare CDM items used
- **Document healthcare prescription**

- Joint replacement surgey (JRS) guidelines
- Hip and knee questionnaire (MAPT)
- JRS referral template

severe OA and fails to respond to conservative therapy

- complete JRS referral for orthopedic assessment
- patient completes hip and knee questionnaire (MAPT) **see www.XXXXX**

3 Hip/knee osteoarthritis management flowchart



Hip/Knee Osteoarthritis Management Flow Chart

Assess non-pharmacological interventions for all patients according to individual need at all stages of OA

Optimise Weight
[Grade B]
- Optimal weight BMI 18.5 to 25
- Combination of two or more interventions: nutritional education, cognitive behaviour therapy, low energy diet, exercise regime.
- Dietician referral

Allied Health Interventions
- Land based exercise program **[Grade B]**
- Aquatic therapy **[Grade B]**
- Tai Chi (esp if at risk/fear of fall) **[Grade C]**
- Thermotherapy **[Grade C]**
- Multi-modal physical therapy **[Grade C]**
- TENS **[Grade C]**
- Acupuncture **[Grade C]**
- Patellar taping **[Grade D]**
- Massage therapy **[Grade D]**

Education/Self Management Support
- Self management and education programs (SMEP) **[Grade C]**

Monitoring Strategies
- Telephone Support **[Grade C]**

Assess need and risk for additional pharmacological interventions
Provide pharmacological interventions in accordance with good practice principles
Refer to pharmacist for medication review as required (HMR, RMMR)
refer to www.health.gov.au do search on 'medication good practice principles'

Mild-moderate persistent symptoms

Simple Analgesia [Grade A]
- Regular paracetamol (maximum 4g/day)

and/or:
Topical therapies
- Trial short term (4 weeks)
- NSAIDs **[Grade A]**
- capsaicin **[Grade D]**

if symptoms persist:
Oral NSAID[Grade A]
- Check risk http://www.nps.org.au
- Monitor blood pressure, renal function
- Trial short term (4 weeks)

Moderate-severe persistent symptoms in those whom mild-moderate strategies have not been successful

Check use of simple analgesia [Grade A]
- Adequate dose
- Regular dose - paracetamol (maximum 4g/day)

and consider:
Oral NSAID [Grade A]
- Check risk http://www.nps.org.au
- Monitor blood pressure, renal function
- Trial short term (4 weeks)

then consider:
Viscosupplementation (eg Hyaluronate) **[Grade C]**
Opioid therapy [Grade A]
- Consider for severe symptoms where surgery is contraindicated or patient is on surgical waiting list and surgery cannot be expediated

Management of an acute flare of symptoms

Simple Analgesia [Grade A]
- Regular paracetamol (maximum 4g/day)

and/or:
Topical therapies
- Trial short term (4 weeks)
- NSAIDs **[Grade A]**
- capsaicin **[Grade D]**

and/or:
Oral NSAID [Grade A]
- Check risk http://www.nps.org.au
- Monitor blood pressure, renal function
- Trial short term (2-4 weeks)

and/or:
Intraarticular corticosteroid injection [Grade B]

Assess readiness for surgery for progressive OA where symptoms are not adequately controlled with conservative therapy
refer to joint replacement surgery guidelines see www.XXXXXX

D SUMMARY OF RECOMMENDATIONS

General recommendations

RECOMMENDATION 1 – GP EDUCATION (Grade D)
Health care professionals should have appropriate knowledge and skills to support assessment and management of exercise and nutrition lifestyle behaviour change.

RECOMMENDATION 2 - PERFORMING INTRA-ARTICULAR INJECTIONS (Grade D)
GPs who choose to perform intra-articular knee joint aspiration and injection should be appropriately trained. Intra-articular injection of the hip should be performed using appropriate imaging assistance.

RECOMMENDATION 3 - MULTIDISCIPLINARY CARE (Grade D)
Health care professionals should assess individual patient need for multidisciplinary care intervention for management of OA hip and/or knee.

RECOMMENDATION 4 - COMPREHENSIVE PATIENT ASSESSMENT (Grade D)
Health care professionals should perform a comprehensive assessment to confirm the diagnosis, assess health and medication risks, and to inform management for people with OA hip and/or knee.

Non-pharmacological interventions

RECOMMENDATION 5 - WEIGHT REDUCTION (Grade B)
There is good evidence to support GPs recommending weight reduction for obese patients with OA knee.

RECOMMENDATION 6 – LAND BASED EXERCISE (Grade B)
There is good evidence to support GPs recommending land-based exercise for people with OA hip and knee.

RECOMMENDATION 7 - AQUATIC THERAPY (Grade C)
There is some evidence to support GPs recommending aquatic therapy for treatment of OA hip and knee.

RECOMMENDATION 8 - MULTI-MODAL PHYSICAL THERAPY (Grade C)
There is some evidence to support GPs recommending multi-modal physical therapy (up to 3 months) for treatment of OA of the knee or hip.

RECOMMENDATION 9 – TAI CHI (Grade C)
There is some evidence to support GPs recommending Tai Chi for treatment of OA knee.

RECOMMENDATION 10 – SELF MANAGEMENT EDUCATION PROGRAMS (Grade C)
There is some evidence to support GPs recommending self management and education programs for treatment of OA hip and knee.

RECOMMENDATION 11 – THERMOTHERAPY (Grade C)
There is some evidence to support GPs recommending cold therapy.

RECOMMENDATION 12 – TENS (Grade C)
There is some evidence to support GPs recommending use of TENS for at least 4 weeks for treatment of knee OA.

RECOMMENDATION 13 – ACUPUNCTURE (Grade C)
There is some evidence to support GPs recommending acupuncture for treatment of OA knee.

RECOMMENDATION 14 - PATELLAR TAPING (Grade D)
There is weak evidence to support GPs recommending patellar taping for treatment of OA of the knee.

RECOMMENDATION 15 - MASSAGE THERAPY (Grade D)
There is weak evidence to support GPs recommending massage therapy for treatment of OA of the knee or hip.

RECOMMENDATION 16 - TELEPHONE SUPPORT (Grade D)
There is weak evidence to support GPs recommending telephone treatment counselling support from a trained health or non-medical person.

RECOMMENDATION 17 - MAGNETIC BRACELETS (Grade D)
There is weak evidence to support GPs recommending magnetic bracelets for treatment of OA hip or knee.

RECOMMENDATION 18 – LEECH THERAPY (Grade D)
There is weak evidence to support GPs recommending leech therapy for treatment of OA of the knee or hip.

Pharmacological interventions

RECOMMENDATION 19 - PARACETAMOL (Grade A)
There is excellent evidence to support GPs prescribing paracetamol in regular divided doses to a maximum of 4 g per day as first line pharmacological therapy for treating persistent pain in people with osteoarthritis of the hip or knee.
Note: The most recent research on paracetamol suggests it is efficacious in the management of pain related to knee and hip OA. Although not as effective as NSAIDs, the lower risk of adverse events, particularly of the gastro-intestinal system, makes paracetamol a first-line medication consideration.

RECOMMENDATION 20 – ORAL NSAIDS (Grade B)
There is good evidence to support GPs prescribing NSAIDs or cox-2 NSAIDs for reducing pain in the short term treatment of OA hip or knee where simple analgesia and non pharmacological measures are ineffective. The potential small benefits of NSAIDs need to be measured in relation to potential harms.
Note: GPs should apply caution when using traditional NSAIDs and cox-2 NSAIDs in view of the known side effects, especially in those at risk such as the elderly, and those on concomitant medication. Careful monitoring of blood pressure and renal function is indicated for older people and others at risk when using these agents. For patients with high NSAID risk for whom NSAIDs are considered a necessary part of treatment, GPs should prescribe a traditional NSAID plus PPI or a cox-2 inhibitor.

RECOMMENDATION 21 – WEAK AND STRONG OPIOIDS (Grade A)
There is good evidence that GPs consider prescribing weak or strong opioids with caution for treating at least moderate or severe pain in people with osteoarthritis of the hip or knee who have not responded to, or are unable to tolerate, other analgesic medications or NSAIDS and in whom joint replacement surgery is contraindicated or delayed.
Note: GPs should commence opioids at a low starting dose with slow titration of dose, particularly in people at increase risk of adverse effects, such as the elderly, and closely monitor patients for adverse events.

RECOMMENDATION 22 – INTRA-ARTICULAR CORTICOSTEROID INJECTION (Grade B)
There is good evidence to support GPs prescribing intra-articular corticosteroid injections for short term treatment of OA knee and hip.

RECOMMENDATION 23 – TOPICAL NSAIDS (Grade C)
There is some evidence to support GPs recommending short term treatment of OA knee with topical NSAIDs.

RECOMMENDATION 24 – TOPICAL CAPSAICIN (Grade C)
There is weak evidence to support GPs recommending topical capsaicin for short term treatment of osteoarthritis of the hip and knee.

RECOMMENDATION 25 – VISCOSUPPLEMENTATION FOR KNEE OA (Grade C)
There is some evidence to suggest hyaluronic acid is of some benefit for OA knee.

RECOMMENDATION 26 - GLUCOSAMINE (Grade C)
The role of glucosamine products, including types and dose, remains uncertain. GPs may inform patients about the availability and safety of these agents.

Interventions not supported by current evidence

RECOMMENDATION 27 - BRACES AND ORTHOSES (Grade B)
There is good evidence to suggest that knee brace, neoprene sleeve or lateral wedged insole are of little or no benefit for treatment of OA knee. GPs could inform patients about lack of evidence of benefit.

RECOMMENDATION 28 - ELECTROMAGNETIC FIELDS (Grade B)
There is good evidence to suggest that electromagnetic field or electric stimulation interventions are of no benefit in the treatment of OA knee. GPs could inform patients about lack of evidence of benefit.

RECOMMENDATION 29 - VISCOSUPPLEMENTATION FOR HIP OA (Grade C)
There is some evidence to suggest hyaluronic acid is of no benefit for OA hip. GPs could inform patients with OA hip about the lack of evidence of benefit.

RECOMMENDATION 30 – CHONDROITIN SULFATE (Grade C)
There is some evidence to suggest that chondroitin sulphate is of no benefit in treating OA knee. GPs could inform patients about the lack of evidence of benefit.

RECOMMENDATION 31 - HERBAL AND NUTRITIONAL THERAPIES (Grade C)
There is some evidence to suggest that nutritional and herbal therapies are of limited or no benefit in treating OA hip or knee. GPs could inform patients about the lack of evidence of benefit, or limited evidence for benefit.

RECOMMENDATION 32 - THERAPEUTIC ULTRASOUND (Grade C)
There is some evidence to suggest that therapeutic ultrasound is of no benefit in treating knee or hip OA. GPs could inform patients about lack of evidence of benefit.

RECOMMENDATION 33 – LASER THERAPY (Grade D)
There is weak evidence to suggest that low level laser therapy is of no benefit in treating knee OA. GPs could inform patients about lack of evidence of benefit.

RECOMMENDATION 34 – SOCIAL SUPPORT (Grade D)
There is weak evidence to suggest cognitive behavioural therapy is of limited or no benefit in treating OA. GPs could inform patients about lack of evidence of benefit.

E HIP AND KNEE OA RECOMMENDATIONS

The recommendations are intended for adult patients diagnosed with symptomatic osteoarthritis of the hip and/ or knee up until referral for joint replacement. **Many of the recommendations may be considered for management of OA in other sites where, to date, there is limited evidence available to guide management.** Full evidence statements and grading for each recommendation are outlined in the *Evidence tables for osteoarthritis recommendations* (Appendix D).

1 General recommendations

1.1 GP education

RECOMMENDATION 1 (Grade D)

Health care professionals should have appropriate knowledge and skills to support assessment and management of exercise and nutrition lifestyle behaviour change.

The importance of lifestyle modification, particularly weight loss and undertaking appropriate exercise, has been well-recognised in both the prevention and management of osteoarthritis [11, 15]. Health professionals require access to current education on lifestyle modification including risk modification, smoking cessation, joint protection and evidence-based management strategies for OA to ensure patients receive the most recent health advice [16].

Evidence statement

It is the opinion of the Working Group that promotion of preventative and therapeutic lifestyle strategies by GPs is important in the management of OA hip and knee. A full review of the literature relevant to this consensus recommendation was not undertaken.

Management of chronic disease requires both preventative and therapeutic lifestyle strategies. Education and behavioural modification can reduce the risk of developing osteoarthritis and prevent further joint injury in at risk populations. The role of the GP in chronic disease management increasingly incorporates self-management support, including emphasis on patient self-education, self-care and counselling in behavioural change. To undertake the important role of providing patients with self-care skills and knowledge the GP needs a current awareness of health promotion and disease prevention issues [11, 17-19] .

A large multi-centre study investigated the effectiveness of a training program for GPs that focused on non-pharmacological and lifestyle pain management interventions and appropriate analgesic prescription for patients with in OA. Patients of GPs who received this training intervention were found to have improved pain relief (316 +/- 290 mm/day vs 265 +/- 243 mm; $p < 0.0001$); greater improvement in Lequesne and WOMAC scores ($p < 0.0001$); and better overall perception of treatment ($p = 0.002$) than patients of GPs who received a placebo training unit [20].

In a Canadian study including 650 family GPs, the researchers used an audit of medication prescriptions to evaluate the effectiveness of a medical education program consisting of case study workshops run by a trained facilitator aimed at increasing the knowledge and skills of GPs in managing chronic MSK disorders. The study found that education on non-pharmacological intervention, including lifestyle change, contributed to improved management of chronic MSK disease by GPs, including a reduction in NSAID use [21].

In a prospective French study adherence by 1030 randomly selected GPs to EULAR recommendations on management of knee OA was investigated. The researchers established that adherence to both pharmacological and non-pharmacological / lifestyle recommendations was positively influenced by participation of the GP in ongoing education on current OA management strategies (OR 0.76 (0.59 to 0.98) [22].

1.2 Performing intra-articular injections

RECOMMENDATION 2 (Grade D)

GPs who choose to perform intra-articular knee joint aspiration and injection should be appropriately trained. Intra-articular injection of the hip should be performed using appropriate imaging assistance.

Evidence statement

It is the opinion of the Working Group that safe performance of intra-articular injection is an imperative. A full review of the literature relevant to this consensus recommendation was not undertaken.

Clinicians should be appropriately trained and experienced in the safe performance of intra-articular (IA) injection procedures.[23]. Adverse reactions of IA injection (e.g. injury, infection, bruising) are minimised and clinical efficacy is increased by accuracy of needle placement and adherence to an appropriate sterile technique during the injection procedure [24, 25].

One Irish survey of GPs' experiences and attitudes found that the main perceived barrier to performing IA injections for GPs was lack of ability to maintain appropriate clinical skills. GPs who had access to postgraduate training and the ability to maintain injection skills were more confident in performing IA injection and more likely to perform the procedure [26]. An Australian study into the effectiveness of continuing medical education on patient clinical outcomes found statistically significant improvements in pain and physical function in those receiving intraarticular injection from a GP who had recently acquired the necessary joint injection skills [27].

Depth of the joint as well as the close proximity of sensitive structures such as the femoral artery and nerves complicates intra-articular injection of the hip joint. One study reported that specialist rheumatologists were only 53% accurate in the placement of IA hip injections administered blindly [24]. To increase the precision of medication administration to the joint, and reduce the risk of adverse events, hip IA injection should always be performed under X-ray screening or ultrasound guidance [23-25, 28].

1.3 Multidisciplinary care

RECOMMENDATION 3 (Grade D)

Health care professionals should assess individual patient need for multidisciplinary care intervention for management of OA hip and/or knee.

Management of OA requires a multidisciplinary approach with regular communication between health practitioners (eg. GP, rheumatologist, physiotherapist etc) to facilitate holistic management for the patient. GPs should refer patients to appropriate health practitioners for input in the patient's management plan. Referral to a rheumatologist should be considered for elderly patients, patients with significant co-morbidity, those with extensive disease or when the diagnosis is uncertain [16, 29, 30].

Evidence statement

It is the opinion of the Working Group that multi-disciplinary care is important in the management of OA hip and knee. A full review of the literature relevant to this consensus recommendation was not undertaken.

National strategic health policy has given increased recognition to the importance of chronic disease management, with a number of recent Federal initiatives for the prevention or delay in onset; early detection; and evidence-based management of chronic disease, including osteoarthritis. The role of multi-disciplinary input in the management of chronic disease is highlighted throughout chronic disease management policy, with focus on improving capacity, effectiveness and efficiency of multi-disciplinary collaboration [1-3, 31].

There is support throughout this guideline and other primary osteoarthritis guidelines of the importance multi-disciplinary collaboration in the ongoing management of patients with hip or knee OA, particularly for patients accessing the broad range of non-pharmacological interventions used in OA treatment. Weight loss, a variety of exercise interventions and multi-modal therapies as well as numerous other non-pharmacological interventions are regularly provided by multi-disciplinary health care providers including physiotherapists, occupational therapists, massage and manual therapists, personal trainers, dieticians, nurses and others. In addition, various health professionals (general practitioner, rheumatologist, orthopaedic surgeon, other specialists, pharmacist etc) may have involvement in the patient's pharmacological regime. Multi-disciplinary collaboration and communication is essential to promote continuous, co-ordinated, patient-centred care [9, 12, 32-34].

A wide range of interventions implemented by multi-disciplinary health care providers were reviewed for these recommendations. In the vast majority of trials the intervention of interest was implemented by a health care provider with specific training and qualifications. Seeking health advice and management from an appropriately trained health care provider is considered to be a component of effective and safe therapy [35].

1.4 Comprehensive patient assessment

RECOMMENDATION 4 (Grade D)

Health care professionals should perform a comprehensive assessment to confirm the diagnosis, assess health and medication risks, and to inform management for people with OA hip and/or knee.

Confirm OA diagnosis

Diagnosis of osteoarthritis is usually made based on a detailed patient history and clinical presentation. Presenting signs and symptoms suggestive of osteoarthritis include symmetrical joint symptoms, usually in one or two joints; pain and stiffness; decreased joint mobility; joint swelling; crepitus, and increased age [11, 16, 30, 36-39].

If the patient has a recent history of infection or fever, is less than 40 years old, or presents with abnormal routine blood tests, other forms of arthritis (eg. rheumatoid, septic) should be considered. Laboratory tests (eg. ESR, rheumatoid factor (RF) and synovial fluid analysis may be used to rule out alternative diagnoses [30, 36, 38, 39].

Radiographs (particularly weight bearing X-rays) may be used to confirm diagnosis and exclude alternative diagnoses (eg. trauma) however often findings are non-specific. Radiographic findings indicative of OA include narrowing of the cartilage space, marginal osteophyte formation, subchondral sclerosis, and breaking of the tibial spines, however these may not be observed in early disease. In addition, some patients may show radiographic changes of osteoarthritis without significant symptoms, therefore X-ray should be used in conjunction with clinical presentation to make a diagnosis [11, 36-39].

Perform comprehensive assessment

Comprehensive assessment of the patient with knee/hip OA should include:

1. Joint signs and symptoms [16, 30, 36-38, 40]:

- joint pain, often after weight-bearing activity
- joint stiffness, particularly after periods of inactive eg morning
- joint inflammation

- decrease in joint mobility and/or function
- crepitus (a crinkly, crackling or grating feeling in the joint)
- joint tenderness upon palpation

2. Co-morbidities:

- nutritional assessment: Overweight and obesity are risk factors for development of osteoarthritis and may contribute to disease progression. Patients with OA should be screened for the need to lose weight, as this is one of the most significant modifiable risk-factors [11, 16].
- other co-morbidities: numerous other diseases may impact on the management of OA. Co-morbidities such as cognitive impairment; cardio-vascular disease; peptic ulcer disease; renal disease; diabetes, asthma, allergies and liver disease may influence the patient's ability to self-manage their OA, the appropriateness of specific non-pharmacological interventions, and implications for pharmacological therapy [16, 40].

3. Psychosocial assessment:
   Patients with chronic diseases such as osteoarthritis have a higher rate of depression and anxiety than the general population. Chronic pain is related to feelings of helplessness, anxiety and self-image. Understanding of the disease process and management; ability to manage self care and make health care decisions; and ability to cope with the often debilitating effects of osteoarthritis are influenced by the patient's psychosocial state. Osteoarthritis may also have a significant impact on the patient's social well being and participation in leisure, relationships and community and these factors should be considered in holistic patient assessment [11, 40].

4. Falls risk assessment:
   Pain and decline in function from knee/hip OA may impact upon mobility and contribute to risk of falls. Assessment for a history of falls is recommended. A falls risk assessment should be considered for patients with a history of falls. In high risk settings such as residential care regular assessment is recommended [16].

5. Medication and NSAIDs risk:
   Assess for presence of risk factors for OA medications (particularly NSAIDs) including age, hypertension, upper gastro-intestinal events, cardiovascular, renal or liver disease. Consider aspirin allergy and polypharmacy, for example concurrent use of diuretics, ACEI and/or anticoagulants [16]. Health professionals should refer to the most recent version of Therapeutic Guidelines or National Pharmaceutical Services website for full details of medication risks. (see Appendix C *Osteoarthritis resources*).

<u>Development of care plan</u>

Development of the OA management plan should be based on individual needs established during patient assessment, evidence of effectiveness of specific interventions and the patient's personal preferences. Aims of management plans should focus on optimising the patient's quality of life (eg decreasing pain, improving function), providing the patient with appropriate knowledge and skills to manage chronic disease and minimising risk of adverse events [30]. An OA management plan template is included in the *Osteoarthritis Resources* (Appendix C).

2 Non-pharmacological interventions

Non-pharmacological interventions are the mainstay management strategies for knee and hip osteoarthritis. Non-pharmacological interventions, which often involve the clinical input of the multi-disciplinary health care team, include patient education, aerobic and resistive exercises, lifestyle changes and weight loss, and various physical therapies. These interventions generally have low-no side effects and are used in conjunction with a pharmacological regime to decrease pain and promote functioning and quality of life.

2.1 Weight reduction

RECOMMENDATION 5 (Grade B)

There is good evidence to support GPs recommending weight reduction for obese patients with OA knee.

Obesity is a risk factor for developing osteoarthritis, particularly for women. Overweight people are at higher risk of their osteoarthritis being symptomatic and progressing, thought to be related to the increased load placed on weight-bearing joints and increased stress on cartilage [11, 38, 41, 42]. Body mass index (BMI) (kg/m^2) is suggested as the most appropriate determinate of healthy weight range. An acceptable weight range is considered to be a BMI 18.5 to 25. BMI of 25-29 is considered overweight and BMI over 30 is obese [4].

Weight loss and strategies to avoid gaining weight are suggested as primary preventative strategies for osteoarthritis of the knee and hip [38]. For patients with osteoarthritis who are overweight or obese, weight loss is related to an improvement in symptoms of pain and disability, and weight control programs are appropriate [11, 29, 41, 42].

An excellent volume of evidence that was of satisfactory consistency provided support for the recommendation that obese patients with OA knee undertake weight reduction programs.

Evidence statement

There is evidence from a recent good quality SR including 4 RCTs and 454 participants, to support the benefit of weight reduction (6.1 kg, 95% CI 4.7 to 7.6) in reducing pain (effect size 0.2) and physical disability (effect size 0.23) in obese people with OA of the knee. A significant benefit was noted with more than 5% weight reduction or at a weight reduction rate of at least 0.24% per week [43].

2.2 Exercise

RECOMMENDATION 6 (Grade B)

There is good evidence to support GPs recommending land-based exercise for people with OA hip and knee.

RECOMMENDATION 7 (Grade C)

There is some evidence to support GPs recommending aquatic therapy for treatment of OA hip and knee.

<u>Caution note:</u> Consideration should be given to co-morbidities, particularly cardio-vascular disease, in prescribing exercise programs for patients with OA. Exercise is generally contra-indicated for patients with uncontrolled arrhythmias; third degree heart block; recent changes on ECG; unstable angina; acute myocardial infarction and acute congestive heart failure. Exercise should be prescribed with caution and supervision for patients with cardiomyopathy, valvular heart disease, uncontrolled metabolic disease or poorly controlled blood pressure [41]. Before undertaking a physical exercise program the patient should receive a comprehensive assessment by an appropriately-qualified health care provider. This assessment should include clinical evaluation of the patient's osteoarthritis as well as identification of other health conditions that may be exacerbated by exercise. Exercise programs should be individualised to the patient's specific needs, abilities and preferences and implemented by an appropriately trained health care provider [9, 41, 42].

Exercise is an important component of management of osteoarthritis as both a preventative strategy and to treat symptoms of OA. Increasing physical activity improves general physical health, reduces the risk of other chronic disease development (e.g. coronary artery disease, diabetes), facilitates weight control and may have psychological and social benefits that improve the patient's overall quality of life [38, 41, 42].

Particularly in knee osteoarthritis, weakness of the quadriceps muscles contributes to functional disability caused by joint instability, thus appropriate exercise also has a role in reducing signs and symptoms of OA [41]. Physical exercise of a light-to-moderate intensity increases muscle strength as well as range-of-motion, aerobic capacity, and endurance that contributes to improved physical functioning and pain reduction. A range of both supervised and home-based exercise programs are available for patients with osteoarthritis, including quadriceps muscle strengthening; resistance training; aerobic exercise; and flexibility exercises. Various programs offer different benefits and no specific type of exercise regime has been shown to be superior [9, 30, 38, 41, 42].

Aquatic exercise programs, performed in either group or individual settings, provide the same general benefits as land-based exercise programs with reduced stress to the joints due to buoyancy. This form of exercise may be better tolerated than land-based exercise for some patients with hip and knee OA (e.g. obese patients with excess joint stress). Patients do not need the ability to swim to undertake aquatic exercise, however level of comfort in the water and personal preferences are primary considerations in selecting this form of therapy [9, 29, 38].

A large volume of evidence that was of good consistency provided support for the recommendation that GPs recommend exercise for patients with OA knee and hip.

<u>Evidence statement: land based exercise</u>

One good quality SR including 13 RCTs with 2304 participants with OA knee, reported benefit for aerobic walking in reducing pain (ES 0.52) and self reported disability (ES 0.46), and for quadriceps strengthening exercise in reducing pain (ES 0.39) and self reported disability (ES 0.46) compared to education and lifestyle advice, telephone support, no intervention and sham intervention. There was variation in program content and duration (8 weeks-2 years) of program. Adverse events were not reported [44].

One moderate quality SR including 16 RCT and 2 quasi-controlled trials with 2154 participants with OA knee, reported modest benefit for exercise in improving perceived physical health (ES 0.29) and overall impacts (a composite measure) (ES 0.20) compared to no treatment, standard care, attention, sham electrical stimulation. There was heterogeneity in study design, definition of exercise program, intensity of exercise program and methods of impact assessment. Adverse events were not reported [45].

A moderate quality systematic review including 17 RCT (OA knee) and 2RCT (OA hip) with 2562 participants reported small benefits of land-based exercise (simple to complex programs including aerobic walking, resistance, stretching, strengthening, and manual therapy) for treatment of OA hip or knee delivered either individually or in groups, compared to controls (including no treatment, waiting list, education, telephone support). The benefits varied with SMD 0.39, 95% CI 0.3 to 0.47 for self reported pain, and SMD 0.31, 95% CI 0.23 to 0.39 for self reported physical function. The benefit was similar for both individual and group exercise classes. Adverse events were not reported [46].

A good quality SR including 1 low-moderate quality small RCT with only 39 participants with OA knee, reported no difference in pain, functional state, gait and aerobic capacity between low intensity and high intensity exercise for OA knee over a short term (10 weeks) follow up period. It is doubtful with a sample size of 39 there was adequate power to detect a difference if one truly existed. Adverse events were not reported [47].

A moderate quality RCT that included 109 participants over 55 years with hip OA assessed the effectiveness of a exercise program with routine treatment. The study reported a small positive clinical effect measured by Harris hip scale (HHS) pain (ES 0.38) HHS total score (ES 0.34), timed 'up and go' test (ES 0.35), and walking test (0.22) [48].

Evidence statement: aquatic therapy

There is evidence from a good quality single blinded RCT with 312 participants with OA hip or knee reported benefit for aquatic therapy in reducing WOMAC pain scores (ES 0.44, CI 0.03, 0.85) and improving WOMAC physical function (ES 0.76, CI 0.33, 1.17) at a 12 week assessment compared to usual care. A small benefit was also reported at 12 months (ES 0.25, CI 0.02, 0.47) however the effect was not significant at 18 months [49].

Evidence is also provided by a moderate quality single blinded RCT with 71 participants with OA hip or knee for the benefit of a 6 week course of twice weekly aquatic physical therapy. Improvements in primary outcome measure of VAS pain on movement (ES 0.24) and secondary outcomes including WOMAC pain (ES 0.28), stiffness (ES 0.24), function (ES 0.08) and physical function (75% versus 17%) were achieved at the 6 week assessment compared to a waiting control group. The benefits were sustained at twelve weeks although control data was not available at this timepoint. The NNT for both pain and for physical function improvement was 2. Minor adverse events were reported that did not affect participation [50].

A further RCT moderate quality RCT included 152 participants with OA hip or knee and compared 12 weeks aquatic therapy to two control groups, Tai Chi and waiting list control. Benefits were reported for aquatic therapy and tai chi in improving WOMAC function scores (aquatic therapy SRM 0.62; 95% CI 0.49 to 0.75; Tai Chi SRM 0.63; 95% CI 0.5 to 0.76) at the 12 week assessment. Aquatic therapy, but not Tai Chi reduced WOMAC pain scores (SRM 0.43, CI 0.3, 0.56). Of those assessed as OMERACT responders at 12 weeks, 66% aquatic therapy and 58% Tai Chi responders demonstrated sustained response at 24 weeks. The 11 reported adverse events did not relate to the interventions [51].

2.3 Multi-modal physical therapy

RECOMMENDATION 8 (Grade C)

There is some evidence to support GPs recommending multi-modal physical therapy (up to 3 months) for treatment of OA of the knee or hip.

Caution note: Multi-modal physical therapy is generally well tolerated, with no adverse effects reported in the reviewed studies [52-55]. Multi-modal physical therapy regimes often include non-pharmacological interventions discussed throughout this guideline . Caution notes for each specific intervention that have been included with the other relevant recommendations should be considered.

Multi-modal physical therapy involves various different therapeutic strategies aimed at relieving pain and stiffness and improving joint mobility and overall function. Therapies include range of motion exercise, soft tissue mobilisation, and muscle strengthening and stretching [29, 30, 55]. Multi-modal therapy generally consists of manual therapy consisting of muscle stretching and passive range-of-movement exercise as an adjunct to an active exercise component of treatment [52]. Studies suggest that patients with osteoarthritis receive moderate short-term (up to 8 weeks) clinical impact measured on WOMAC global and pain scores from multi-modal physical therapy [52-55].

A satisfactory volume of evidence that was of good consistency provided support for the recommendation that GPs recommend multi-modal physical therapy for patients with OA knee.

Evidence Statement

A moderate quality RCT involving 134 participants with OA knee provided evidence that participants in a clinically-based physical therapy (CPT) program that included supervised exercise and individualised manual therapy (no placebo group) achieved greater benefit at 8 weeks measured by global WOMAC score ($p<0.001$) compared to participants in a home-based exercise (HE) program. Average 6-minute walk distances improved by approximately 10% (95% CI 30 to 48 metres) in both groups. At one-year follow-up both groups improved over baseline measurements, with no difference between groups for rate of knee surgery (CPT 11% vs HE: 10%) or rate of steroid injection (CPT: 3% vs HE: 2%). CPT participants were less likely to be taking medications for OA knee (48% vs. 68%; $p = 0.03$) [53] .

Evidence from a moderate quality RCT involving 109 participants with OA hip showed participants in a manual physiotherapy program focusing on specific manipulations and mobilisation of the hip had greater benefit at 5 weeks in general improvement measured on a Likert scale (odds ratio 1.92; 95% CI 1.30 to 2.60), VAS pain at rest and on walking (both effect size 0.5, $p<0.005$), stiffness and range of motion measures ($p<0.05$), hip function (Harris hip score effect size 0.9, $p<0.05$), walking speed (effect size 0.3, $p<0.05$) and SF-36 role physical function subscale (effect size 0.4, $p<0.05$) than those in an exercise program that focused on active exercises to improve muscle function and joint motion. This study was under-powered due to a high drop out rate (more than 20% drop-out from the intervention group). Adverse effects not reported [55].

Evidence from a moderate quality RCT involving 325 adults aged over 55 years with knee pain reported short-term benefit (not sustained beyond 3 months) for community physiotherapy compared to a group receiving a pharmacy review and a control group (advice leaflet and follow-up telephone call) for pain (adjusted change score 1.19; 95% CI 0.3 to 2.1; $p=0.008$); and function (adjusted change score 3.65; 95% CI 1.0 to 6.3; $p=0.008$) scores measured on WOMAC. These differences were not sustained at 6 or 12-month follow-up. Caution is required in interpreting these results in view of the lack of blinding and broad inclusion diagnosis of knee pain [54].

Evidence from one low quality RCT involving 83 participants with OA knee found statistical improvements from baseline in 6-minute walk distance (12.3% vs 13.1%, $p<0.05$) and WOMAC total scores (51.8% vs 55.8%, $p<0.05$) at 4 and 8 weeks for participants in a manual physical therapy and exercise (MPT) group (n= 42) compared to a placebo group who received ultrasound therapy only (n= 41). At one year follow up the rate of knee surgery was 5% in the MPT group and 20% in the control group. In this study the control group did not receive any supervised exercise program and it is unclear what effect was due to manual physical therapy compared to the exercise component of the intervention. Adverse event were not addressed [52].

2.4 Tai chi

RECOMMENDATION 9 (Grade C)

There is some evidence to support GPs recommending Tai Chi for treatment of OA knee.

Caution note: Patients who are aged over 40, overweight, suffering from a chronic illness or have not participated in recent regular exercise should be reviewed by the GP before commencing a new exercise program. Programs for pregnant women should be modified by an appropriately qualified health care provider [56, 57].

Tai chi is a Chinese exercise that involves slow, fluid movements designed to improve cardiac and respiratory fitness; flexibility; balance and muscle strength. Traditional Tai Chi may also improve psychological well-being and relaxation. Tai Chi is considered a safe form of exercise for most people, with minor adverse events (e.g. muscle soreness and foot/ankle pain) reported by some participants [56-58].

A small volume of evidence that was of satisfactory consistency provided support for the recommendation that GPs recommend Tai Chi for patients with OA knee.

Evidence statement

A moderate quality RCT included 152 participants with OA hip or knee and compared 12 weeks aquatic therapy to two control groups, Tai Chi and waiting list control. Benefits were reported for aquatic therapy and tai chi in improving WOMAC function scores (aquatic therapy SRM 0.62; 95% CI 0.49 to 0.75; Tai Chi SRM 0.63; 95% CI 0.5 to 0.76) at the 12 week assessment. Aquatic therapy, but not Tai Chi reduced WOMAC pain scores (SRM 0.43, CI 0.3 to 0.56). Of those assessed as OMERACT responders at 12 weeks, 66% aquatic therapy and 58% Tai Chi responders demonstrated sustained response at 24 weeks. The 11 reported adverse events did not relate to the interventions [51].

One low quality small RCT including 41 participants with OA knee provided evidence for a small benefit of Tai Chi (TC: 6 weeks group then 6-7 weeks home based program) in reducing pain and physical function compared to an attention control group (AC: 6week course of lectures). There was benefit for TC over the AC group at 6 and 9 weeks for mean maximum pain when measured using a VAS but not at other time points to 12 weeks. The overall WOMAC score was only different between the two groups when measured at 9 weeks post intervention. The absolute size of the benefit was reported only in graphic format [58].

2.5 Self management education programs

RECOMMENDATION 10 (Grade C)

There is some evidence to support GPs recommending self management and education programs for treatment of OA hip and knee.

Self management education programs (SMEPs) are interventions designed to educate the patient on self care activities that promote health and management of chronic diseases such as osteoarthritis. SMEPs aims to provide patients with knowledge of their disease, motivation and practical skills to relieve pain and reduce the impact of functional deficits on the patient's life. By combining patient education with behavioural modification and empowerment techniques, SMEPs also aim to increase patient adherence to treatment, promote decision-making related to disease management and manage psychosocial impacts of disease such as anxiety, low self-image and/or confidence, depression and helplessness [11, 59-62]. For some patients, participation in SMEPs has been associated with positive outcomes such as decreased pain and improved quality of life [38, 42, 45, 61, 62].

Effectiveness of SMEPs is likely to be influenced by the content of the program (eg. relevance of information to patient, level to which information is aimed), delivery of the program (eg. format, speed) and patient characteristics (eg. readiness for education) [42]. There is insufficient research on these factors to recommend specific SMEPs. In reviewed studies, one program included education, demonstration and participation in a group setting [61] and another used lecture-style delivery [45]. Content of programs included joint preservation and protection; evaluating and controlling pain; treatments recommended for OA; aids and devices; exercise; and diet management including low fat food, setting goals and counselling [45, 61].

A good volume of evidence that was of good consistency provided support for the recommendation that GPs recommend SMEPs for patients with OA .

Evidence statement

There is evidence from one moderate quality SR of 16 RCTs [45] and 2 moderate quality RCTs [61, 63]. There is variation in content and definition of the SMEP interventions, which makes comparisons of the results of different studies difficult. In addition studies commonly use outcomes of pain and physical function which may not be the primary focus of the intervention. There is evidence of a small positive benefit of SMEP on psychological outcomes after participating in a program [45, 63].

There was evidence of benefit of SMEP in conjunction with an exercise component on psychological outcomes (SR Mean ES 0.19). There was some evidence that SMEPs without an exercise component have no effect on physical function [45].

The research methods (particularly the outcomes measured) may not have been able to answer the question of interest. There is currently a lack of evidence pertaining to other patient health outcomes, such as ability to self manage.

2.6 Thermotherapy

RECOMMENDATION 11 (Grade C)

There is some evidence to support GPs recommending cold therapy.

Caution note: Thermotherapy is generally well tolerated, with few adverse effects reported in the literature [64, 65]. Hot and cold packs should not be placed directly against the skin due to the risk of burn or frostbite. Thermotherapy is contraindicated for patients with reduced sensation, impaired communication and/or cognition or thermo-regulatory impairments. Avoid heat therapy when a malignancy or acute injury (eg. open wounds, areas of recent bleeding, acute dermatitis, psoriasis, infection) is present. Patients with a history of peripheral vascular disease, diabetes, cardiovascular disease and hypertension or who are pregnant should use thermotherapy with caution [66].

Thermotherapy involves the application of heat or cold (eg. heat or ice pack, ice massage) to treat symptoms of osteoarthritis [42, 65]. Cold has an effect by reducing swelling and inflammation, numbing pain and blocking nerves impulses and muscle spasms to the joint [60, 67]. Treatment appears to be most effective in an acute flare of osteoarthritis when minor joint inflammation is present and is administered through the application of an ice pack wrapped in a towel for 20 minutes, 5 days a week for 2 weeks [65, 68].

There was no research using sound methods available on use of heat therapy in managing osteoarthritis, however some patients may prefer it to cold treatments. Application of heat to the joint may reduce pain and stiffness through promotion of relaxation, joint flexibility and blood flow to the joint, although these effects may contribute to inflammation and oedema [65, 68]. Mild-moderate heat is applied using moist towels or heat packs wrapped in a towel for 15-20 minutes [29, 67].

A good volume of evidence that was of poor consistency provided support for the recommendation that GPs recommend cold thermotherapy for patients with OA knee. No evidence was available on the use of heat therapy in managing osteoarthritis.

Evidence statement
A moderate quality SR including 3 RCTs, studying different types of thermotherapy and including a total of 179 patients, reported conflicting results for treatment OA knee. One RCT reported that ice massage had a beneficial effect on ROM, function and knee strength but not on pain when used for 20 minutes 5 days per week for 2 weeks. Another trial reported that cold packs decreased swelling but hot packs had no similar beneficial effects. A further trial reported that ice packs did not affect pain significantly. No adverse effects were reported in included trials [65].

2.7 TENS

RECOMMENDATION 12 (Grade C)

There is some evidence to support GPs recommending use of TENS for at least 4 weeks for treatment of knee OA.

Caution note: Manufacturers of TENS devices warn that they may interfere with pacemakers, other medical devices (e.g. cochlear implants) or epileptic conditions. Because TENS may interfere with blood pressure the electrodes should not be placed over the carotid sinus. It is recommended that electrodes not be placed on areas with reduced sensitivity or over broken skin. The safety of TENS during pregnancy has not been established [69, 70].

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive therapy with no known side effects. TENS is administered through the stimulation of cutaneous nerve fibres by a device worn and operated by the patient [60, 67, 71]. It is theorised that TENS provides pain relief by inhibiting the transmission of painful stimuli to the spinal cord and brain pain receptors. The type of device, wave form produced by the device (eg. amplitude, rate and width of pulse) and the location in which stimulators are placed all influence the quality of TENS administered to the patient and are generally adjusted by the clinician depending on the patient's response. Various TENS regimes are used in clinical practice: high frequency (>50Hz), low frequency (<10Hz) and burst frequency or hyper-stimulation (high frequency bursts of stimulation using various pulse widths) [67, 71].

A good volume of evidence that was of satisfactory consistency provided support for the recommendation that GPs recommend TENS for patients with OA .

Evidence Statement
A moderate quality Cochrane SR of 7 moderate quality RCT involving 294 participants with OA knee reported benefit for TENS (high frequency and strong burst mode) compared to placebo (WMD -0.448 VAS) for pain relief and knee stiffness (WMD -5.972) when TENS was applied for more than 4 weeks duration [71].

A low quality RCT including 60 participants with OA knee reported no difference over a six month followup between use of intra-articular injection of Hylan (3 injections given once weekly over 3 weeks) in reducing pain and stiffness and improving function and Lesquesne index compared to TENS (applied 5 times per week for 20 minutes at 150hz for 3 weeks). There was no placebo group. Effect sizes were not stated and adverse events were not reported [72].

A second low quality RCT including 51 participants with OA knee provided evidence that TENS or interferential current (IFC) treatments given twice weekly at standard doses for 20 mins and in association with 20 minutes exercises had no benefit over a 20 minute exercise program (isometric quadriceps exercises, aerobic and resistance training) alone. All groups showed improvement in WOMAC score over time. There was no placebo group [73].

2.8 Acupuncture

RECOMMENDATION 13 (Grade C)

There is some evidence to support GPs recommending acupuncture for treatment of OA knee.

Acupuncture is a therapy administered through the insertion of sterile needles into specifically identified acupuncture points. After insertion needles are manually manipulated. The therapy is theorised to have an effect on pain through the triggering of endogenous opioid pathways [67]. Acupuncture has few reported serious side effects when administered by an appropriately trained health care provider [15].

A good volume of evidence that was inconsistent in its findings provided support for the recommendation that GPs recommend acupuncture for patients with OA knee.

Evidence statement

There is evidence from a moderate quality SR of acupuncture used for chronic knee pain including osteoarthritis, including 13 RCT, 8 of which were included in a meta-analysis with 2362 participants, for a small benefit for acupuncture in reducing pain and improving function compared to sham acupuncture for treatment of OA knee (when used for at least 6 treatments given at least once weekly with at least 4 points per painful knee needled for 20 minutes for up to 12 weeks). The overall effect size for use of acupuncture in chronic knee pain was 0.4 (CI 0.1, 0.6). Caution needs to be applied as the SR provided an overall validity score but did not clearly indicate which studies had adequate randomisation, randomisation allocation or blinding. There was considerable heterogeneity between studies. Adverse events were not reported [74].

A further moderate quality SR included 18 RCTs, of which 14 were knee OA RCTs and 12 of these were included in the review by White (2006). Meta-analysis data from 3 trials (2 knee, 1 hip) found small benefits in pain reduction (SMD 0.24, CI0.01-0.47) for manual acupuncture compared to sham acupuncture for treatment of OA hip and knee. When two of the knee trials were analysed alone the heterogeneity of studies for electro-magnetic acupuncture precluded meta-analysis [75].

One recent and large good quality RCT included 3,633 participants with OA hip or knee, of whom 357 were randomised to receive acupuncture (non standardised intervention for up to 3 months duration), 355 randomised to a control (delayed treatment) group and 2,921 were included in a preference-based non-randomised intervention group. Neither patients nor doctors were blinded to randomisation status. The study reported significant benefits (based on WOMAC scores) for the acupuncture group at 3 months. The proportion of responders (defined as 50% reduction in WOMAC score) was 34.5% in the intervention group compared to 6.5% in the control group. Caution is required in interpreting these results in view of the lack of blinding and questionable appropriateness of the control group. Adverse effects were reported in 5.2% (N=184), including minor local bleeding (66%), and pain at the needle site (5%). No life threatening side effects were seen [76].

There is additional evidence from a recent moderate quality RCT with 52 participants with OA knee that 904-nm low level laser acupuncture provided 20 min per day for 5 days per week (total 10 sessions) in association with an exercise program provides no additional benefit to sham laser acupuncture other than for knee circumference measurement when assessed at 2 and 12 weeks. No information was provided regarding the inter- or intra-rata reliability of this measurement. Both laser and sham laser acupuncture were associated with improvements in pain on walking (VAS scale) and 50 foot walking time over a twelve week period. There were no local nor systemic adverse events [77].

One further moderate quality placebo (streitberger needle) controlled RCT provided evidence for benefit in reducing VAS pain for true acupuncture when used once weekly for 12 sessions in conjunction with diclofenac 50 mg three times daily compared to placebo [78].

2.9 Patellar taping

RECOMMENDATION 14 (Grade D)

There is weak evidence to support GPs recommending patellar taping for treatment of OA of the knee.

Patellar taping has been used as a strategy to reduce pain in knee OA by stabilising the knee joint, and altering the distribution of stress and joint pressure, thereby reducing strain on inflamed joint tissue. Patellar taping is generally used as a short term, intermittent treatment, particularly when the patient is performing activities that aggravate their condition [79-81]. Effectiveness of patellar taping appears to be related to the strapping technique used and the length of time taping remains in place. Although some patients may experience topical irritation from tape application, no significant adverse effects have been reported [79-82].

A poor volume of evidence that was of satisfactory consistency provided support for the recommendation that GPs recommend patellar taping for patients with knee OA .

Evidence statement

A moderate quality RCT involving 87 participants with OA knee showed those treated with therapeutic medial patellar taping had significant improvement on 10cm VAS for pain on movement (ES=1.19) and during worst activity (ES=1.00) after 3 weeks of taping (reapplied weekly) compared to neutral taping or no tape. This effect was sustained at 6 weeks. Compared to no taping, there was a RR of 7.0 (95% CI 2.34 to 20.92) of participants in the therapeutic taping group reporting improvement in pain status following 3 weeks of treatment (neutral taping group RR=4.67; 95% CI 1.50 to 14.53). Therapeutic taping was associated with improvements in WOMAC pain (ES=0.82) and WOMAC function (ES=0.83) at 3 weeks but not at 6 weeks. Outcome measures were subjective and participants were not blinded. 28% of participants in the therapeutic taping group experienced minor skin irritations [80].

There is one small low quality RCT involving 18 participants with painful OA knee randomly assigned to two different knee taping techniques - therapeutic tape and neutral tape – or no taping. The study reported benefits for participants in the therapeutic taping group of reduced pain during gait ($p<0.017$), stair climbing ($p<0.017$), step test ($p<0.017$) but not in walking speed or 'timed up and go' compared to the neutral taping intervention and un-taped conditions. No adverse symptoms were observed during the study period. There was poor allocation concealment methods and blinding of the assessors and results may relate to placebo effect. Long-term benefits and cost of these interventions is unclear [81].

A low quality RCT involving 14 participants with painful OA knee assessed three types of patellar taping (medial, lateral and neutral) for 4 days each in a randomised regime order. The study reported reduced pain for days 2-4 for participants when using the medial taping technique ($p<0.05$) compared to the neutral and lateral taping. No benefits were reported for lateral taping over neutral taping. No functional outcome measures were used and participants were not blinded. No adverse symptoms were observed during the study period [83].

2.10 Massage therapy

RECOMMENDATION 15 (Grade D)

There is weak evidence to support GPs recommending massage therapy for treatment of OA of the knee or hip.

<u>Caution note:</u> Massage therapy is generally a safe intervention. Patients may experience minor discomfort. A small number of serious adverse events have been reported, however the risk is low if the therapy is performed by a trained practitioner [84].

Massage is the use of manual techniques such as stroking, friction and compression to apply traction and pressure to the soft tissues, including skin and underlying muscle tissue. The therapy aims to relieve pain and promote function through reduction of muscle tension and spasm, increase in circulation of blood and lymph, and promotion of mental relaxation. Massage may also contribute to positive outcomes for to the patient through the therapeutic benefit of touch [60, 67, 84, 85]. A wide variation of massage types are available including conventional muscular massage (Swedish massage), deep tissue massage, and Shiatsu, however there is limited research on their use in osteoarthritis and no research comparing the effective various massage forms [85].

There was only one low quality study on massage therapy, hence the recommendation that there is weak evidence to support massage therapy in the treatment of OA of the knee or hip.

<u>Evidence statement</u>
There is one low quality RCT involving 68 participants aged over 35 years with radiographically confirmed and symptomatic OA knee that reported a reduction in mean WOMAC scores for global pain, stiffness, and physical function domains (all $p<0.001$); VAS pain score ($p<0.001$), range of motion using goniometric assessment ($p=0.03$), and time to walk 50 ft ($p<0.01$) for participants receiving standard Swedish massage for 8 weeks compared to controls. At 8 weeks the effect size for change on WOMAC scores ranged from 0.64 to 0.86 but beneficial effects were no longer statistically significant at 16 weeks. One participant reported adverse events of increased discomfort. There was poor allocation concealment method, lack of blinding of outcome assessors and the study was underpowered due to the small sample size and the high number of dropouts (56% in the treatment group and 47% in the control group) [86].

2.11 Telephone support

<u>RECOMMENDATION 16</u> (Grade D)

There is weak evidence to support GPs recommending telephone treatment counselling support from a trained health or non-medical person.

Telephone support has been proposed in the ongoing management of chronic diseases as a cost-effective intervention that may be associated with positive clinical outcomes through increasing patient contact with health care providers [38, 60].

There was only one low quality study on telephone support for patients with OA, hence the recommendation that there is weak evidence to support telephone support in the management of OA of the knee or hip.

<u>Evidence statement</u>
A low quality RCT including 405 participants with rheumatoid arthritis or osteoarthritis hip or knee, randomised to telephone treatment counselling (n=135), telephone symptom monitoring (n=135) and usual care (n=135) reported benefit for telephone treatment counselling over other groups for total health status measured by the Arthritis Impact Measurement Scale-2 (AIMS) (ES 0.3, CI 0.09-0.56). There were differences between arthritis groups with OA patients demonstrating improvements in physical function and pain but minimal improvement in psychological effects. The mean number of medical visits reduced in the OA group. There is no cost effectiveness data.[87]

2.12 Magnetic bracelets

RECOMMENDATION 17 (Grade D)

There is weak evidence to support GPs recommending magnetic bracelets for treatment of OA hip or knee.

Caution note: Manufacturers of magnetic bracelets warn that magnetic devices may interfere with pacemakers and other medical devices. Because magnet therapy may increase the blood flow in areas where magnets are placed, it is recommended that they not be placed near transdermal medication delivery patches (e.g. nicotine) [88].

A variety of static magnetic devices are used for therapeutic purposes including bracelets, shoe inserts and pillows [89]. Static magnets have an unchanging magnetic field that has a unidirectional configuration and are available in different intensities, measured in gauss (G) [90, 91]. Magnets are either worn directly over the affected area for a specified period each day, or on the wrist to provide an effect on the entire body [91].

There are a variety of theories on how magnetic therapy may have an effect on pain however research on magnetic therapy is hindered by the difficulty in adequately blinding participants to the presence of magnetic fields [89, 90]. One theory suggests that magnets may increase blood flow through the skin and muscles; whilst others focus on biological changes related to polarisation [90].

Only one study provided evidence on the effectiveness of magnetic bracelets in treating OA.

Evidence statement

One moderate quality RCT including 194 participants aged 45-80 years with OA hip or knee, reported that pain measured on the WOMAC scale from hip and knee OA decreased by a small amount (mean difference between standard strength and placebo for WOMAC pain scale was -1.3 points) when wearing standard strength static bipolar magnetic bracelets compared to weak magnetic or non-magnetic 'dummy' magnets for 12 weeks. The mean difference between standard and weak magnet groups was not significant. The effect of the standard strength group may have been related to a placebo effect as there is likely to have been unblinding of participants (54% standard magnet and 47% placebo group correctly identified which group they were in [92].

2.13 Leech therapy

RECOMMENDATION 18 (Grade D)

There is weak evidence to support GPs recommending leech therapy for treatment of OA of the knee or hip.

Caution note: Although no adverse events were reported in a study of OA patients [93] undertaking leech therapy, previous research in other populations has reported a risk of severe progressive cellulitis from application of leeches [94].

Leech therapy is an alternative treatment proposed for the treatment of OA. Proponents of leech therapy suggest that leech saliva has analgesic effects, however early research in the field failed to demonstrate either the ability of leech salivary secretions to reach the joint or the analgesic properties of leech saliva content [94].

There was only one moderate quality study on leech therapy, hence the recommendation that there is weak evidence to support leech therapy in the treatment of OA of the knee or hip.

Evidence statement
Evidence from one moderate quality RCT including 51 participants with OA of the knee receiving a single treatment of 4-6 locally applied medicinal leeches reported benefit for pain at 7 days compared to diclofenac topical gel treatment for 28 days (WOMAC pain subscale 23.9; group difference (95% CI 32.8 to 15.1). Differences in pain scores were no longer significant after day 7; however, differences in function, stiffness, total symptoms and quality of life remained significant in favour of leech therapy at 4 weeks [93].

3 Pharmacological interventions

The main goals of pharmacological interventions for osteoarthritis relieving pain and reducing inflammation. Treatment aims to improve functioning and quality of life whilst minimising the risk of side effects [95, 96]. *The RACGP OA Working Group recommend consulting the Therapeutic Guidelines (www.tg.com.au) and the National Prescribing Service (www.nps.org.au) for detailed prescribing information.*

3.1 Paracetamol

RECOMMENDATION 19 (Grade A)
There is excellent evidence to support GPs prescribing paracetamol in regular divided doses to a maximum of 4 g per day as first line pharmacological therapy for treating persistent pain in people with osteoarthritis of the hip or knee.

Note: The most recent research on paracetamol suggests it is efficacious in the management of pain related to knee and hip OA. Although not as effective as NSAIDs, the lower risk of adverse events, particularly of the gastro-intestinal system, makes paracetamol a first-line medication consideration.

Caution note: Many common over-the-counter preparations (such as cold and flu tablets) contain paracetamol. Patients should be warned of the risk of over-dose when combining medications. Hepatotoxicity is a potential severe side effect, particularly in patients with pre-existing liver disease, chronic alcohol use or higher than recommended doses, and paracetamol should be used cautiously in patients at risk [95-97]. Paracetamol is also known to prolong the half-life of warfarin, therefore patients taking these medications concurrently should have regular international normalised ratio (INR) monitoring [96]. Health practitioners are advised to review the most recent Therapeutic Guidelines for prescribing details and full review of adverse events.

Paracetamol is the oral analgesic of choice management of osteoarthritis. Because it reduces pain and fever but has minimal effect on inflammation it is used more often in mild – moderate OA. Paracetamol is generally well-tolerated with few side effects when used at the recommended dose of up to 4g/day (usually taken as 2 500mg tablets up to 4 times daily) for up to 12 months. Effectiveness of paracetamol is related to adequate dosage and patients should be encouraged to take medication regularly according to the directions to reduce pain episodes [15, 30, 95-97].

An excellent volume of evidence that was of excellent consistency provided support for the recommendation that GPs prescribe paracetamol as a first-line pharmacological treatment for patients with OA .

Evidence statement

A good quality SR including 15 RCTs with 5986 participants with OA hip or knee provided evidence for effectiveness of paracetamol for between 7 days and 12 months, when provided in regular divided doses to a maximum dose of 4g per day, in treating pain (SMD -0.13, CI -0.22, -0.04) of people with OA hip and knee compared to placebo. The NNT was 4-16. Paracetamol was found to be as safe as placebo. In comparator controlled RCTs (n=10), paracetamol was less effective than NSAIDs (WOMAC total SMD -0.46 CI -0.73, -0.19), but there was a higher risk of gastrointestinal adverse events (RR 1.47, CI 1.08-2.0) amongst patients using traditional NSAIDs [98].

A moderate quality RCT including 581 participants with mild-moderate OA hip or knee provided evidence of benefit of paracetamol (4g/day) and naproxen (750mg/day) compared to placebo in reducing WOMAC pain for 6-12 months, but no difference in effectiveness between the two active agents [99]. A low quality RCT with a small number of participants (n=20) with OA knee reported similar effectiveness of paracetamol (mean improvement 40.7 mm) and rofecoxib (42.5mm) compared to placebo for VAS pain and for WOMAC function for 3 months [100].

3.2 Oral NSAIDs

RECOMMENDATION 20 (Grade B)

There is good evidence to support GPs prescribing NSAIDs or cox-2 NSAIDs for reducing pain in the short term treatment of OA hip or knee where simple analgesia and non pharmacological measures are ineffective. The potential small benefits of NSAIDs need to be measured in relation to potential harms.

Note: GPs should apply caution when using traditional NSAIDs and cox-2 NSAIDs in view of the known side effects, especially in those at risk such as the elderly, and those on concomitant medication. Careful monitoring of blood pressure and renal function is indicated for older people and others at risk when using these agents. For patients with high NSAID risk for whom NSAIDs are considered a necessary part of treatment, GPs should prescribe a traditional NSAID plus PPI or a cox-2 inhibitor.

Caution note: Traditional NSAIDs and cox-2 NSAIDs should be used with caution in elderly patients and those with renal disease, cardiovascular disease and/or aspirin-induced asthma. Traditional NSAIDs have a significant risk of GIT events (eg. perforation, ulceration and bleeding). Cox-2 NSAIDs have a lower risk of GIT adverse events, but are associated with an increased risk of myocardial infarction, stroke, heart failure, and hypertension. There is a higher risk of adverse events for patients with concomitant use of diuretics, ACE inhibitors, angiotensin II receptor blockers, cyclosporin, warfarin, oral corticosteroids or aspirin [15, 95-97, 101, 102]. Health practitioners are advised to review the most recent Therapeutic Guidelines for prescribing details and full review of adverse events.

NSAIDs are recommended for treatment of acute pain due to their anti-inflammatory and antinociceptive effects. When inflammation of a joint is present and paracetamol is not sufficient for pain relief, an appropriate traditional NSAID or cox-2 NSAID may be added to the patient's pharmacological regime [15, 30, 96]. Due to the range of adverse events related to these medications, particularly in elderly patients, the lowest dose should be prescribed for the shortest duration. Using paracetamol in conjunction with a NSAID may achieve effective pain management with a lower NSAID dose, as may the use of an intermittent dose taken before aggravating activities rather than a continuous dose [30, 95, 97, 101, 102].

An excellent volume of evidence that was of good consistency provided support for the recommendation that GPs prescribe NSAIDs for the pharmacological treatment for patients with OA.

Evidence statement

NSAID efficacy
There is evidence from a good quality SR and meta-analysis of 23 trials with 10,845 participants with OA knee pain to support a small benefit (10.1mm VAS scale) for oral NSAIDs, including cyclo-oxygenase agents, in reducing the intensity of pain at between 2-13 weeks follow up. On average people with OA knee who were on NSAIDs were 15.6% better off than placebo. This benefit may not be of clinical importance as the minimally important clinical difference for OA knee has been estimated to be a change from baseline of at least 17-22%. In addition benefit was not seen at longer time periods (1-4years). Harms were not reported [103].

One good quality RCT including 13,274 participants with OA hip, knee or hand reported evidence to support equivalent efficacy of celecoxib 200mg or 400mg per day in divided doses compared to diclofenac 50 mg twice daily or naproxen 500 mg twice daily over a duration of 12 weeks. There were fewer ulcer complications in the celecoxib group (0.8/100 patient years traditional NSAID, 0.1/100patient years Celecoxib OR 7.02 (CI 1.46-33.8), and no difference in the number of cardiovascular thromboembolic events. However, the number of such events was low and the study was not powered to detect such differences. Patients requiring daily use of anti-ulcer medications were excluded from the trial. No cost-effectiveness data was provided [104].

A low quality placebo controlled RCT including 511 participants with OA hip or knee reported differential benefit of treating knee or hip OA with improvement in WOMAC pain (ES knee 0.8, ES hip 0.5), stiffness (ES knee 0.8, hip 0.55) and physical function (ES knee 0.78, hip 0.51) compared to placebo when measured at 6 weeks. The paper did not report adverse events [105].

NSAID safety
There is evidence that use of oral NSAIDS is associated with a number of side effects [106], including gastrointestinal adverse effects (risk of perforation or bleeding 1/50-100 patient years [107]), increase in blood pressure, aggravation of cardiac failure, renal failure and drug interactions, and that this risk is increased by older age, concomitant medication use and duration of use. However there are no head to head trials or cost-effectiveness analyses of cox-2 medications versus traditional NSAIDs used in conjunction with effective anti-ulcer preparations such as misoprostol, H2 receptor antagonists or proton pump inhibitors or antacids.

A low quality SR reported the risk of athero-thrombosis associated with traditional and cox-2 NSAIDs. There is evidence to support a moderately increased risk (1.86; CI 1.33-2.59) of myocardial infarction with cox-2 NSAIDs (0.6%/year) compared to placebo (0.3%/year). There is evidence to support equal risk (1.16; CI 0.97-1.38) among cox-2 (1.0%/year) and traditional NSAIDs (0.9%/year) for serious vascular events with some heterogeneity between naproxen (0.92) and ibuprofen (1.51) and diclofenac (1.63) [108].

A moderate quality RCT involving 34,701 participants (pooled data from three studies) aged over 50 years reported on cardiac thrombotic events in participants taking NSAIDs, the majority of whom (24,913) had OA hip, knee, hand or spine. When treated for an average period of 18 months, there was similar cardiac thrombotic event rates for etoricoxib (1.24/100 patient years) prescribed at doses of 60-90mg/day and diclofenac (1.3/100 patient years) prescribed in a divided daily dose of 150mg/day, resulting in a hazard ratio of 0.95 (CI 0.81-1.11). The rates of upper GIT perforation, bleeding, obstruction , ulcer were lower with etoricoxib compared to diclofenac (0.67 v 0.97/100 patient years). There was no placebo group. Participants were able to use prophylactic low dose aspirin and proton pump inhibitors (PPIs) or misoprostol was recommended for patients at high risk of upper GIT clinical events. Subgroup analyses of these patients in relation to outcomes was not provided [109].

Evidence from a moderate quality RCT involving 287 participants with arthritis and a history of ulcer bleeding after using NSAIDs but at a stage when their ulcers had healed (negative for Helicobacter pylori) showed that combination treatment of 75 mg diclofenac twice daily plus 20 mg of omeprazole daily (n=143) had a reduced risk of recurrent ulcer compared to celecoxib 200 mg twice daily plus a daily placebo (n=144) for six months. Probability of recurrent bleeding during the six month period was 4.9% (95% CI 3.1 to 6.7) for celecoxib compared to 6.4% (95% CI 4.3 to 8.4) for diclofenac plus omeprazole (difference, -1.5%; 95% CI -6.8 to 3.8). Renal adverse events, including hypertension, peripheral oedema, and renal failure occurred in 24.3% of participants in the celecoxib group and 30.8% of those receiving diclofenac plus omeprazole. A number of GI events were questionably excluded as adverse event cases, there was no placebo group and participants with active ulcers were excluded, which may have contributed to the favourable results [110].

Evidence from a moderate quality RCT involving 273 arthritis participants who had a history of previous, now-healed gastric ulcer as a result of taking non-selective NSAIDs (negative for Helicobacter pylori) showed that combination treatment with 400mg daily celecoxib and 20 mg esomeprazole twice daily (n=137) was more effective than 400mg daily celecoxib and placebo (n=136) for 12 months for prevention of recurrent ulcer bleeding. 13-month cumulative

incidence of recurrent ulcer bleeding was 0% in the combined-treatment group and 12 (8.9%) in the controls (95% CI difference: 4.1 to 13.7; p=0.0004). Discontinuation of treatment and the incidence of adverse events were similar in the two treatment groups [111].

A low quality SR including 114 double-blind RCTs involving 116,094 participants with different co-morbidity status, (OA being most common) provided evidence on the safety of oral NSAIDs. Analysis of 127 trials (40 rofecoxib, 37 celecoxib, 29 valedecoxib/parecoxib, 15 etericoxib and 6 lumiracoxib) found that celecoxib was associated with lower risk of both renal dysfunction (RR 0.61, 95% CI 0.40 to 0.94) and hypertension (RR 0.83, 95% CI 0.71 to 0.97) compared to rofecoxib . No significant increased risk was established for valedecoxib/parecoxib, etericoxib or lumiracoxib [112].

Note: Rofecoxib and lumiracoxib have been withdrawn from use.

3.3 Weak and strong opioids

RECOMMENDATION 21 (Grade A)

There is good evidence that GPs consider prescribing weak or strong opioids with caution for treating at least moderate or severe pain in people with osteoarthritis of the hip or knee who have not responded to, or are unable to tolerate, other analgesic medications or NSAIDS and in whom joint replacement surgery is contraindicated or delayed.

Note: GPs should commence opioids at a low starting dose with slow titration of dose, particularly in people at increase risk of adverse effects, such as the elderly, and closely monitor patients for adverse events.

Caution note: In an acute overdose opioids may cause respiratory depression. Adverse events including dry mouth, nausea, vomiting, dizziness, somnolence and constipation are commonly reported by patients and regularly lead to patients ceasing opioid therapy. A small risk of addiction suggests stronger opioids should be used with caution in patients with a history of drug/alcohol abuse; psychiatric problems; psychosis or suicidal tendency. Patients should be warned against driving under the influence of opioids. Patients may experience withdrawal effects (eg insomnia, muscle contractions) that may be reduced through dose tapering [15, 96, 113-115]. Health practitioners are advised to review the most recent Therapeutic Guidelines for prescribing details and full review of adverse events.

Opioids have a modest effect in managing moderate-severe OA pain in patients for whom paracetamol is ineffective and who do not respond to, or have contra-indications for, NSAIDs. However, most of the research on opioid use has been in short-term trials and long term efficacy has not been shown. Because of the high rate of adverse effects that impact upon the patient's quality of life, the modest benefit to be gained from opioid therapy should be considered carefully [15, 96, 114, 115].

The use of weak opioids (eg codeine) should also be considered cautiously as these preparations are less effective than strong opioids with the same adverse effects. Consider referring patients who require opioid therapy for review by a pain specialist/clinic. [97]

An excellent volume of evidence that was of excellent consistency provided support for the recommendation that GPs consider weak or strong opioids for management of moderate-severe OA pain for some patients.

Evidence statement

There is evidence from a moderate quality meta-analysis of weak (codeine, propoxyphene, tramadol) and strong (oxycodone, oxymorphone, fentanyl, morphine sulphate) opioids used for a duration of up to 13 weeks for benefit in reducing pain intensity and improving physical function when used in treating osteoarthritis of the hip and knee compared to placebo. There was a high proportion of patients reporting adverse effects including nausea (30%), constipation (23%), dizziness (20%), somnolence (18%) and vomiting (13%) resulting in discontinuation of therapy in 25% patients taking strong opioids and 19% taking weak opioids compared to placebo (7%) [116].

The findings from the meta-analysis [116] support previous evidence from systematic reviews on Tramadol [117], oxymorphone [118] and fentanyl [119].

There is evidence of a small benefit, of tramadol for between 7 days – 3 months duration, when provided in divided doses of up to 400 mg per day, in treating persistent moderate to severe pain of people with OA hip and knee. The NNT for benefit was 6 [117].

The use of tramadol in mild to moderate pain is limited by drug interactions and CNS adverse effects. Tramadol was associated with a greater risk of adverse events compared to placebo (NNH for minor adverse events was 5, for major adverse events was 8) [117]. Note: Tramadol had greater risk of adverse events than diclofenac or dextropropoxyphene but a lower risk compared to pentazocine. There is potential multiple drug interactions. In particular, the combination of Tramadol with other serotonergic drugs must be avoided due to the risk of serotonin syndrome (refer to NPS *Analgesic Choices in Persistent Pain* [101]) The most commonly reported adverse events were nausea, vomiting, dizziness, constipation, somnolence, tiredness and headache.

There is evidence of a small benefit, of oxymorphone (an opioid analgesic medication) when used for at least 2 weeks duration, when provided in doses of 20-50 mg twice daily, in treating persistent pain of at least moderate intensity of people with OA hip and knee, who have had suboptimal response to simple analgesia. There was a high withdrawal rate due to adverse events [118].

There is evidence of a moderate benefit for the knee and small benefit for the hip, of transdermal fentanyl (an opioid analgesic medication) used for 5 weeks duration, when provided in doses of 1-4 patches (25mcg) every 72 hours, in treating persistent pain of at least moderate intensity of people with OA hip and knee who were awaiting joint replacement surgery, who have had suboptimal response to simple analgesia. Use of transdermal fentanyl was associated with a higher rate of adverse events and withdrawal symptoms compared to placebo [119].

3.4 Intra-articular corticosteroid injection

RECOMMENDATION 22 (Grade B)

There is good evidence to support GPs prescribing intra-articular corticosteroid injections for short term treatment of OA knee and hip.

Caution note: Rarely, complications including fluid retention, hyperglycaemia (particularly in diabetic patients) and hypertension may occur due to absorption of IA corticosteroid into the body [25, 95]. Health practitioners are advised to review the most recent Therapeutic Guidelines for prescribing details and full review of adverse events. The procedure of intra-articular (IA) injection carries some risks, including allergic reaction to the medication and/or dressing, post-injection swelling due to increased fluid within the joint, haematoma and (rarely) infection. Practitioners administering intra-articular medication should be appropriately trained (see recommendation 2) [25, 95].

Intra-articular corticosteroid injection is indicated for short term symptom management when the patient has an acutely painful, swollen joint. Generally synovial fluid is aspirated from the joint to reduce swelling prior to the administration of the corticosteroid directly into the joint cavity. The procedure allows for a greater concentration of medication at the site of action, with a lower risk of systemic side effects [25, 30, 95, 96].

Due to possible cartilage damage from repeated intra-articular injections the number of corticosteroid injections is generally limited to 3 times a year for large weight-bearing joints and 4 times per year for smaller joints. Intra-articular injections to the same joint are usually administered at no shorter than 3-monthly intervals [25, 38, 95].

An excellent volume of evidence that was of good consistency provided support for the recommendation that GPs recommend intra-articular corticosteroids for short-term symptom management in patients with knee OA .

Evidence statement

One good quality systematic review of 28 RCT with 1973 participants with OA knee provided evidence for short term (1-34 weeks) benefit for pain reduction and patient global assessment but not physical function of intra-articular corticosteroid preparations. The NNT to improve pain and patient global assessment was 3-4. Nine trials compared corticosteroid injection with hyaluronan and hylan derivatives. HA products demonstrated a similar but slower onset but were more durable with clinical benefit being detected at 5-13 weeks post injection. There is limited data comparing different corticosteroid preparations. The authors were unable to recommend one preparation over another. There were no major adverse effects reported. Compared to placebo there was no greater number of participants reporting post-injection flare [25].

One moderate quality RCT of 101 participants with OA hip provided evidence for short term (28 days) benefit on pain on walking (ES 0.6) for a single intra-articular injection of 1ml methylprednisolone and 2 placebo injections compared to 3 placebo injections and also to three injections of 2 ml hyaluronan (hyalgan). There were no serious adverse events [120].

3.5 Topical NSAIDs

RECOMMENDATION 23 (Grade C)

There is some evidence to support GPs recommending short term treatment of OA knee with topical NSAIDs.

Caution note: Some patients report local adverse effects including skin dryness, pruritus and/or rash. Patients should be advised to follow the manufacturer's directions when using over-the-counter topical preparations. Systemic side effects of NSAIDs such as gastrointestinal effects may be experienced, however the risk is significantly lower than for oral NSAIDs [15, 96, 121-123].

Topical NSAIDs have an analgesic and anti-inflammatory effect related to suppression of local prostaglandin synthesis [96]. Topical NSAIDs are applied to the skin over the affected joint and absorbed into the tissue, producing an increased concentration of the drug at the local site whilst minimising systemic drug levels. The benefit is a reduced risk of side effects and medication interactions compared to oral NSAIDs [95, 121].

A satisfactory volume of evidence that was of satisfactory consistency provided support for the recommendation that GPs recommend short-term use of topical NSAIDs for patients with knee OA .

Evidence statement
There is evidence from one low quality meta-analysis, including 4 RCTs (no quality assessment provided) with 811 participants with OA knee, treated for 4-12 weeks, of a very small benefit (effect size -0.28, CI -0.42—0.14) for topical NSAIDs (diclofenac and eltenac) in reducing pain associated with OA knee compared to placebo or vehicle. Adverse effects reported included self limited local skin reactions (dryness, rash, pruritus) [123].

There is evidence from a good quality RCT with 238 participants with OA knee that diclofenac gel applied 4 times/day for up to one minute each time for 3 weeks compared to placebo was no different at 1 week but provided a small benefit with reduced pain on movement (reduced VAS score 4 mm), and reduced total WOMAC score (6 mm) during the second week, and that this response was sustained in week 3. Four patients reported local skin reactions [122].

3.6 Topical capsaicin

RECOMMENDATION 24 (Grade D)

There is weak evidence to support GPs recommending topical capsaicin for short term treatment of osteoarthritis of the hip and knee.

Caution note: Local adverse reactions such as stinging, burning and erythema are commonly reported by patients using capsaicin cream. These effects are reported to diminish with repeated use. Patients may apply capsaicin cream with a glove to prevent inadvertent spread to eyes and other mucous membranes [15, 38, 96, 121, 124]. Patients should be advised to follow the manufacturer's directions when using over-the-counter topical preparations.

Capsaicin cream is a topical preparation derived from chillies that is available over-the-counter in various concentrations [38, 96, 121, 125]. Capsaicin cream causes a reduction in sensation through its effect in depleting a chemical (substance P neuropeptide) associated with sensory nerve transmissions [96, 125]. There was only one low quality study on topical capsaicin, hence the recommendation that there is weak evidence to support its use in the treatment of OA of the knee or hip.

Evidence statement
A low quality placebo-controlled RCT with 200 participants with OA hip (n=33), knee (n=66), shoulder and hand reported statistically significant reduction in VAS measured pain for 0.025% Capsaicin cream used in combination with 1.33% GTN cream when applied 4 times daily over the affected joint for 6 weeks, however no effect size is reported. There was no difference in improvement in pain reported for use of Capsaicin or GTN when used alone in comparison to placebo [126].

Participants using capsaicin and/or GTN creams were reported to be more likely to prefer therapy continuation than those using placebo, however non completers were not included in the analysis. This study included small numbers of participants with OA hip (n= 33) and OA knee (n=66) in each group and was probably underpowered to analyse differences between 4 groups [126].

The participants using capsaicin had higher baseline discomfort scores associated with application (averaged over the first five days) than other groups however this settled with continued use. There was no reporting of other potential adverse events [126].

3.7 Viscosupplementation (hyaluronan and hylan derivatives) for knee OA

RECOMMENDATION 25 (Grade C)

There is some evidence to suggest hyaluronic acid is of some benefit for OA knee.

Caution note: Intra-articular injection carries some risks, including allergic reaction to the medication and/or dressing, post-injection swelling due to increased fluid within the joint, haematoma and (rarely) infection. Practitioners administering intra-articular medication should be appropriately trained (see recommendation 2) [25, 95].

Viscosupplementation is the procedure of administering synthetic hyaluronic acid or hylan products into the joint via intra-articular injection. Hyaluronic acid is a naturally occurring substance in the body that contributes to the elasticity and lubrication of synovial and cartilage within the joints. In patients with osteoarthritis the concentration and molecular weight of naturally produced hyaluronic acid is reduced, providing a rationale for supplementing natural hyaluronic acid by viscosupplementation. The aim of viscosupplementation is to relieve pain and improve mobility by restoring the protective functions performed by hyaluronic acid [15, 38, 95, 127, 128]. Various hyaluronic products are available, and research suggests there may be differences in efficacy between particular products. Hyaluronic acid products are produced with either low or high molecular weights, which influences the number of injections and amount of medication administered in the viscosupplementation course [95, 128, 129].

An excellent volume of evidence that was of good consistency provided support for the recommendation that viscosupplementation provides some benefit for patients with OA knee.

Evidence statement

There is evidence from one good quality systematic review of 76 RCTs of moderate quality level 3 on Jadad score (range 1-5) that found varying levels of benefit for pain, function and global assessment for between 5-13 weeks for viscosupplementation compared to placebo in treating OA knee. The SR reported viscosupplementation was equivalent to ongoing use of NSAIDs and superior to placebo. The results need to be interpreted with caution, as there was heterogeneity manifested by differences in the magnitude of clinical impact as measured by weighted mean differences of clinical effect across product class as well as studies. No major safety issues were detected. There is inadequate evidence about differences in benefit between products. There is some evidence for similar, but more sustained benefit, of hyaluronan products compared to corticosteroid injection [128].

A moderate quality RCT with 106 participants with knee OA reported reduced pain at 3 weeks with a 6 week course of weekly intra-articular injections of hyaluronic acid compared to placebo but this was not sustained at 6 weeks or 12 weeks [130].

A low quality RCT with 60 participants with OA knee reported benefits in reducing pain and improving function for intra-articular injection of Hylan (3 injections given once weekly over 3 weeks) and TENS (applied 5 times per week for 20minutes at 150hz) but no difference between the two groups. The improvements were noted up to 6 months after treatment, however effect sizes were not stated. Adverse events were not reported [72].

A low quality RCT with 157 participants with OA knee reported no difference in benefit between mean VAS improvement of high molecular weight hyaluronic acid given over 3 weeks (26 mm) and low molecular weight hyaluronic acid given over 5 weeks (27 mm). Adverse events (most common pain at the injection site) were reported in approximately 1/3 participants in both groups [129].

3.8 Glucosamine

RECOMMENDATION 26 (Grade C)

The role of glucosamine products, including types and dose, remains uncertain. GPs may inform patients about the availability and safety of these agents.

Caution note: Glucosamine products contain shellfish extracts and should be avoided by patients with shellfish allergy. Glucosamine may influence blood glucose levels. People taking glucosamine, especially those with diabetes, should be monitored for signs of glucose intolerance such as increased urination, infections and disturbed vision. There is insufficient evidence on safety in pregnancy therefore pregnant women should avoid using glucosamine [131].

Glucosamine is found naturally in articular cartilage and has a role in cartilage formation and repair. Glucosamine has been used in the management of osteoarthritis as an analgesic and for restorative properties, although no good quality research supports the role of glucosamine in cartilage repair. Research on effectiveness of glucosamine has produced varied results that may be related to length of therapy and/or severity of osteoarthritis [132, 133]. Glucosamine is available over-the-counter in Australia as glucosamine sulphate or glucosamine hydrochloride dietary supplements. The usual dosing is 1,500 mg per day in 3 divided doses. Research suggests improvement in symptoms requires at least 4 weeks of therapy and this is generally well-tolerated, with no significant adverse events reported. Gastrointestinal upsets, sleepiness, headaches and skin reactions have been reported in some people [131, 132].

A good volume of evidence was available on glucosamine use in OA, however there were significant inconsistencies in the findings.

Evidence statement

There is conflicting evidence of benefit for glucosamine sulphate and glucosamine hydrochloride in the treatment of the symptoms of OA knee. There is insufficient evidence to support benefit for preventing progression of OA knee cartilage loss.

A moderate quality SR included 20 studies. Subgroup analysis of the best designed studies (8 with adequate allocation concealment) found no benefit of glucosamine sulphate or glucosamine hydrochloride over placebo when used in variable doses between 400 -1500 mg/day for up to 6 months for treatment of OA knee. The review reported that subgroup analysis of one product, the Rotta preparation (10 studies), demonstrated small improvements in pain and function using the Lesquene index but no benefit as assessed by the WOMAC pain, stiffness or function subscales. However the 2 Rotta studies with the largest number of participants were negative and analysis of other products did not demonstrate benefit. The pooled results demonstrated a small benefit (0.61 improvement out of 10 for pain) for glucosamine which is unlikely to be of clinical importance and the results need to be interpreted with caution in view of inclusion of low quality RCT [134].

A recent good quality RCT involving 318 participants with OA knee provided some evidence for a small benefit of glucosamine sulphate (1500 mg/day) for treatment of knee OA compared to placebo or paracetamol (3g/day) when measured using the composite Lesquesne or WOMAC composite scores, but no benefit for reducing pain as measured using WOMAC pain scale. The difference of 1.2 points in Lesquesne scale between glucosamine sulphate and placebo (the overall scale being 1-24) may be of doubtful clinical significance. In addition evidence for effectiveness of chondroitin sulphate in treatment of OA knee is lacking (see below) [135].

One moderate quality large RCT compared glucosamine hydrochloride (1500 mg/day), alone or in combination with chondroitin sulphate (1200 mg/day) to placebo and celecoxib (200 mg/day). Glucosamine alone, or in combination with chondroitin sulphate was found to have no benefit over placebo in reducing pain for patients with OA knee. The response to combined therapy was higher in a subset of patients with moderate –severe OA, however these results need to be interpreted with caution as this was a post hoc subgroup analysis [136].

In all reported studies, glucosamine was safe compared to placebo [134-136].

4 Interventions not supported by current evidence

A number of interventions have been proposed in the treatment of OA for which evidence showed no benefit for patients.

4.1 Braces and orthoses

RECOMMENDATION 27 (Grade B)

There is good evidence to suggest that knee brace, neoprene sleeve or lateral wedged insole are of little or no benefit for treatment of OA knee. GPs could inform patients about lack of evidence of benefit.

Braces and orthotics are used to provide increased stability and support to weak muscles and joints and redistribute weight load to the joint. Splints are also used to rest joints. Both custom-fitted and over-the-counter products are available, including heel wedges/insoles, knee braces and splints [29, 30, 137]. Research does not support the hypothesis that braces and orthoses improve the symptoms of knee or hip osteoarthritis. There appears to be limited risk of side effects, with a small number of patients reporting increased pain in various areas (eg lower back, foot sole) [30, 137].

A good volume of evidence that was of good consistency provided support for the recommendation that there is no benefit from braces and orthotics for patients with OA .

Evidence statement

There is evidence from one good quality SR based on 3 low-moderate quality RCTs with 334 participants diagnosed with knee OA, that a lateral wedged insole did not reduce pain, stiffness nor improve function (WOMAC score) but was associated with reduced NSAID intake compared to a neutral insole. Participant compliance was marginally better with the lateral wedged insole in treatment of OA knee [137].

The same review reported one study of 119 participants that demonstrated benefit of a valgus knee brace and neoprene sleeve above no support with improvement in pain, stiffness and physical function. The brace was more effective than the sleeve. It is uncertain whether outcome assessment was blinded. The four included studies had inadequate or unreported allocation concealment and blinding and it is unlikely the findings are of clinical significance [137].

There is evidence from one low quality SR, based on one prospective 6-month multi-centred, double-blinded RCT that a neutrally wedged insole had no benefit compared with lateral wedge insoles. At 6-month follow up there were no significant differences in any clinical outcome measures. Some decrease in concomitant drug therapy in the participants with lateral wedge insoles was observed [138].

4.2 Electromagnetic fields

RECOMMENDATION 28 (Grade B)

There is good evidence to suggest that electromagnetic field or electric stimulation interventions are of no benefit in the treatment of OA knee. GPs could inform patients about lack of evidence of benefit.

Caution note: Clinical trials of PEMF therapy have reported no major adverse events. Manufacturers of PEMF devices do not recommend use of the product by people with a pacemaker or other implanted device; epilepsy; cancer; diabetes; cardiac infarction less than two months ago; congenital pathology of central nervous system or kidney disease. Use of PEMF devices is not recommended during pregnancy [139, 140].

Pulsed electromagnetic field (PEMF) therapy is a non-invasive treatment in which electromagnetic field pulses are delivered to the painful area via a specific device. The small pulses of athermal electrical fields are applied either through direct placement of electrodes on the skin over the area requiring treatment or through a non-contact technique. The therapy is used to reduce pain and inflammation [60, 141, 142], however there clinical research does not support this hypothesis.

A good volume of evidence that was of good consistency provided support for the recommendation that there is no benefit from PEMF for patients with OA.

Evidence statement
A good quality SR provides evidence from 5 moderate – good quality RCTs (276 patients) that PEMF therapy (2 studies used low frequency, 3 studies used pulsed short wave high frequency) has no effect over placebo on pain or function in knee OA for patients aged over 18 years treated for 2-6 weeks [141]. The review did not report on adverse events.

4.3 Viscosupplementation (hyaluronan and hylan derivatives) for hip OA

RECOMMENDATION 29 (Grade C)

There is some evidence to suggest hyaluronic acid is of no benefit for OA hip. GPs could inform patients with OA hip about the lack of evidence of benefit.

Caution note: Intra-articular injection carries some risks, including allergic reaction to the medication and/or dressing, post-injection swelling due to increased fluid within the joint, haematoma and (rarely) infection. Practitioners administering intra-articular medication should be appropriately trained (see recommendation 2) [25, 95].

Viscosupplementation is the procedure of administering synthetic hyaluronic acid or hylan products into the joint via intra-articular injection. Hyaluronic acid is a naturally occurring substance in the body that contributes to the elasticity and lubrication of synovial and cartilage within the joints. In patients with osteoarthritis the concentration and molecular weight of naturally produced hyaluronic acid is reduced, providing a rationale for supplementing natural hyaluronic acid by viscosupplementation. The aim of viscosupplementation is to relieve pain and improve mobility by restoring the protective functions performed by hyaluronic acid [15, 38, 95, 127, 128]. Various hyaluronic products are available, and research suggests there may be differences in efficacy between particular products. Hyaluronic acid products are produced with either low or high molecular weights, which influences the number of injections and amount of medication administered in the viscosupplementation course [95, 128, 129].

A satisfactory volume of evidence that was of good consistency provided support for the recommendation that viscosupplementation provides no benefit for patients with OA hip.

Evidence statement
There is evidence from a low quality SR of 8 studies with participants with OA hip, only two of which were RCT, that hyaluronic acid provided no benefit measured by WOMAC scores or Lesquene's index when assessed for 3 months to 1 year. No major adverse events occurred [127].

A moderate quality RCT with 101 participants with OA hip reported evidence for no benefit of three intra-articular injections of 2ml hyaluronic acid (hyalgan) on reducing pain on walking for up to 90 days compared to placebo. There were no serious adverse events [120].

4.4 Chondroitin sulfate

RECOMMENDATION 30 (Grade C)

There is some evidence to suggest that chondroitin sulphate is of no benefit in treating OA knee. GPs could inform patients about the lack of evidence of benefit.

Caution note: Chondroitin may increase the risk of bleeding and should be used cautiously in patients taking anticoagulants [131].

Chondroitin is found naturally in the body and has a role in preventing degradation of articular cartilage by body enzymes. Chondroitin sulfate supplement, generally taken in conjunction with glucosamine, may be used in the management of osteoarthritis, although its effectiveness as either an analgesic or a restorative agent is not supported by good quality research. Chondroitin sulfate supplements are available over-the-counter in Australia and have a usual dose of 1,200 mg per day in three divided doses. There have been few reported adverse effects, with minor gastrointestinal upset reported by some patients [131-133].

One low quality systematic review provided support for the recommendation that chondroitin sulphate provides no benefit for patients with OA of the knee or hip.

Evidence statement
Evidence from a recent low quality SR based on analysis of high quality RCT studies (N=3, 3846 participants) demonstrated that chondroitin sulphate (800-1200mg daily) for up to 2 years is not associated with clinical benefit in treatment of OA hip or knee [143].

4.5 Herbal and nutritional therapies

RECOMMENDATION 31 (Grade C)

There is some evidence to suggest that nutritional and herbal therapies are of limited or no benefit in treating OA hip or knee. GPs could inform patients about the lack of evidence of benefit, or limited evidence for benefit.

<u>Caution note:</u> Although generally considered to have low risk of serious side effects, herbal and nutritional supplements may have harmful effects, particularly through interaction with other medication the patient may be taking. Health professionals should ask about complementary therapies when conducting medication reviews [95, 131].

Patients often seek alternative therapies for treatment of osteoarthritis, particularly if they have had insufficient results from conventional medication. Alternative therapies used for the treatment of osteoarthritis include herbs, vitamins and/or mineral supplements, aromatherapy, naturopathic and homeopathic products. These products are widely available without prescription in Australia. [95, 132]. Research on the use of a wide range of complementary therapies in the treatment of osteoarthritis does not demonstrate any clinical benefits above placebo.

A satisfactory volume of evidence that was of good consistency provided support for the recommendation that there is limited, or no evidence, of benefits from herbal and/or nutritional therapies for patients with OA

<u>Evidence statement</u>
There is evidence from one low quality SR including 52 RCTs of variable (mostly low) quality including participants with osteoarthritis (knee hip, spine and possibly other sites*) of;
No benefit for clinically important outcomes with use of Rosa Canina, salix , vitamin E, ginger, uncaria guianensis, cetyl myristoleate.
Conflicting or very limited evidence for benefit with use of ASU, NZ mussel powder, bromelain (this agent was associated with side effects and requires further investigation of safety) , harpagophytum procumbens, flavonoids, vitamin C, duhuo jisheng wan [144].
limited evidence for benefit with use of SK1306X in treating hip or knee OA compared to placebo or diclofenac 100 mg/day. Three severe adverse events (not described) were reported in compared to 11 with use of diclofenac [144].
limited evidence for benefit with use of Methylsulfonylmethane (MSM) for treating knee OA knee [144].

There is insufficient information provided about each RCT to assess adequacy of randomisation or blinding.

** not all studies adequately described the patient populations included in the study.*

4.6 Therapeutic ultrasound

<u>RECOMMENDATION 32</u> (Grade C)

There is some evidence to suggest that therapeutic ultrasound is of no benefit in treating knee or hip OA. GPs could inform patients about lack of evidence of benefit.

<u>Caution note:</u> Therapeutic ultrasound is generally well tolerated, with few adverse effects reported in the literature [64, 145]. Therapeutic ultrasound should be avoided in patients with impaired circulation, venous thrombosis, pacemaker or other implanted electrical devices, pregnancy or malignancy [66].

Therapeutic ultrasound is a form of therapy consisting of high frequency inaudible acoustic vibrations that are either applied in a continuous or pulsed fashion to skin over the painful joint to reduce inflammation and improve flexibility through increasing collagen elasticity [67, 145]. Frequencies of ultrasound range from 0.75 and 3.0 MHz and intensity between 0.5 and 3 W/cm2, with lower frequencies having deeper penetration [67]. Pulsed ultrasound has non-thermal effects whilst continuous ultrasound has a thermal effect that contributes to therapy benefits [145].

Low quality evidence that was of good consistency showing no effect above placebo provided support for the recommendation that there is no benefit from therapeutic ultrasound for patients with OA.

Evidence statement
There is limited evidence from a moderate quality SR of 3 studies, including 294 participants, of no benefit of therapeutic ultrasound above placebo, for treatment of OA hip and knee, when assessed immediately after therapy or after two months [145]. There were no adverse events.

4.7 Laser therapy

RECOMMENDATION 33 (Grade D)

There is weak evidence to suggest that low level laser therapy is of no benefit in treating knee OA. GPs could inform patients about lack of evidence of benefit.

Low-level laser therapy (LLLT) is a form of treatment applied using a device that generates pure light in a single wavelength that causes cellular photochemical reaction [60]. Clinical outcomes with LLLT may depend on the device, method and site of application, wavelength and treatment regime [60, 146].

There was only one low quality study on laser therapy that suggested there was no clinical benefits from LLLT for patients with OA of the knee or hip that suggested there was no clinical benefits from LLLT for patients with OA of the knee or hip, hence the recommendation that there is no evidence to support its use in the treatment of OA.

Evidence statement
There is evidence from one low quality RCT including 60 participants with OA knee treated daily for 5 days that low level laser therapy has no effect on WOMAC pain, stiffness or disability compared to placebo laser treatment when observed at week 3 and month 6 following treatment. The study reported that no side effects were observed [146].

4.8 Social support

RECOMMENDATION 34 (Grade D)

There is weak evidence to suggest cognitive behavioural therapy is of limited or no benefit in treating OA. GPs could inform patients about lack of evidence of benefit.

Cognitive behaviour modification therapy and various psychosocial therapies are proposed to assist patients in the long-term management of chronic disease. Social support interventions aim to improve the general well-being of patients through educational interventions, lifestyle modification and social support networks and are conducted in a group setting, often including the patient's family and/or other significant others [15, 147, 148]. However, research on the effectiveness of social support interventions for patients with osteoarthritis have shown no significant benefit to the patient [147].

There was only one low quality study on social support, hence the recommendation that there is no evidence to support its use in the treatment of OA

Evidence statement

There is one small, low quality RCT involving 40 participants diagnosed with OA randomly assigned to cognitive behaviour modification sessions (n=20) provided once weekly for 10 weeks or 10 weekly didactic lectures (n=20). The study reported no difference in measurement of the quality of well being (QWB) scale between the groups at 12 months followup. There was a non-significant trend towards improvement in QWB scale from baseline in the CBT group. There was no placebo group [147].

F FURTHER INFORMATION

Useful references and supporting documentation are provided in this guideline and the Appendices. A full detail of the evidence on which the guideline is based is presented in the accompanying documents *Evidence tables for osteoarthritis recommendations* and the *Osteoarthritis literature review*. Appendix C contains additional resources, as well as contact details for organisations providing services and support to people with OA.

Useful references and supporting documentation are provided in the guideline, together with contact details for organisations providing services and support to people with OA.

For those recommendations involving pharmacological treatment, the RACGP OA Working Group recommend consulting the Therapeutic Guidelines (www.tg.com.au) and the National Prescribing Service (www.nps.org.au) for detailed prescribing information including:

- indications
- drug dosage
- method and route of administration
- contraindications
- supervision and monitoring
- product characteristics.

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H APPENDICES

1 Appendix A: Membership of the Osteoarthritis Working Group

Project Officer: Emily Haesler

Member	Representation	Qualifications
Assoc Prof Caroline Brand (Chair)	Rheumatologist	MBBS, FRACP, BA, MPH
Prof Rachelle Buchbinder	Rheumatologist/ Clinical Epidemiologist	MBBS (Hons), MSc, PhD, FRACP
Dr Anita Wluka	Rheumatologist/ Epidemiologist	MBBS, FRACP, PhD, GradCertHealthEc
Dr Denise Ruth	GP	MBBS, FRACGP, MPH, FAFPHM
Dr Suzanne McKenzie	GP	MBBS, FRACGP, MmedSci(ClinEpid), GCertULT
Prof Tracey Bucknall	Academic Nurse	RN, BN, ICU Certificate, Postgrad Diploma Advanc Nurs, PhD, MRCNA
Lerma Ung	Arthritis Victoria	PhD , BS, DipAppSc(Education), MHlthSc, RN
Assoc Prof Geoff McColl	Rheumatologist	MB, BS, BMedSc, FRACP, PhD
Dr Rana Hinman	Physiotherapist	BPhysio(Hons), PhD
Prof Karen Grimmer-Somers	NHMRC Advisor	PhD, MMedSc, BPhty, LMusA, Cert HlthEc
Amy Jasper	RACGP - Education Evaluation Manager	MBA, GDip(Human Services Research), BAppSci(Advanced Nursing)
Emily Haesler	RACGP Project Officer	BN, PGradDipAdvNsg

1.1 Terms of reference of the Working Group

Aim of the Working Group

The aim of the Working Group was to undertake activities required to fulfil the aims of the project as outlined in the funding agreement, including to:

- carry out a review of literature as per the NHMRC requirements
- develop clinical practice guidelines based on the evidence obtained within the literature review.

Establishment of Working Group

In accordance with the project contract, membership of the Working Group endeavoured to include:

- three or more experts in each field - medical (including one general practitioner) and allied health
- one expert NAMSCAG member
- one consumer representative
- one departmental representative
- a consultant appointed by the NHMRC.

In addition, the following groups were represented in accordance with the project contract:

- a nominee of the Australian Rheumatology Association or the Australian and New Zealand Bone and Mineral Society
- a nominee of the Endocrine Society of Australia and of the Faculty of Rehabilitation Medicine.

2 Appendix B: Hip and knee osteoarthritis resources

Resources

- Useful publications
- Useful electronic sources
- Chronic disease management musculoskeletal flow chart
- Assessment and management of osteoarthritis flow chart
- GP management plan for osteoarthritis

Useful Publications

National Health and Medical Research Council, (NHMRC). 2005. Making decisions about tests and treatments: Principles for better communication between healthcare consumers and healthcare professionals. Canberra: NHMRC.

National Prescribing Service Limited, (NPS). 2006. *Indicators of Quality Prescribing in Australian General Practice* Sydney:National Prescribing Service Limited (NPS).

National Health and Medical Research Council, (NHMRC). 2003. *Dietary Guidelines for Australian Adults.* Canberra: NHMRC

The RACGP OA Working Group recommends consulting the Therapeutic Guidelines (www.tg.com.au) and the National Prescribing Service (www.nps.org.au) for detailed prescribing information.

Useful Electronic Sources

URL addresses were accurate at the time of publication.

Arthritis Australia	www.arthritisaustralia.com.au
Australian Rheumatology Association	www.rheumatology.org.au
Carers Australia	www.carersaustralia.com.au
National Health and Medical Research Council	www.nhmrc.gov.au
National Prescribing Service	www.nps.org.au
Therapeutic Guidelines	www.tg.com.au

NB: Refer to the Medicare Benefits Schedule items/ notes for details of fees and requirements
NB: Check that no EPC item numbers have been claimed in the last 12 months

Chronic Disease Management Musculoskeletal flow chart

Preparation of Patient Goal Setting General Practice Management Plan (GPMP) MBS # 721

Team Care Arrangements (TCA) MBS# 723

Home Medication Review (HMR) MBS # 900 **& Residential Medication Management Review (RMMR)**

Consider for HMR/RMMR if:

- Currently taking 5 or more regular medications
- Taking more than 12 doses of medication per day
- Recently (last 4 wks) admitted to medical facility/ hospital
- Significant changes to medication regimen in last 3 months
- On medication with narrow therapeutic index or requiring therapeutic monitoring
- Have symptoms suggestive of an adverse drug reaction
- Have a sub-therapeutic response to medication treatment
- Suspected non-compliance or not managing medication related therapeutic devices
- Manage own medications and/or at risk due to language difficulties, dexterity problems, impaired sight, confusion dementia or other diagnosis
- Resident in Residential Aged Care Facility (RACF)

Review of GPMP (within 3-6 months)
MBS # 725

- Review progress to date and agreed goals
- Consider involvement of community health service providers

Review of TCA
MBS # 727

On-going reviews and reassessment of patient

Role of Practice Nurse &/or Allied Health Professional
Assist with :

- Assessment of patient and documentation
- Identification of patient needs.
- Provision of self-management information and other patient education or exercise, eg BHSM or 'Active Scripts'
- Preparation of GP management plan.
- Contacting services outlined in GPMP.
- GP needs to confirm and assess with patient present
- Review and reassessment of patient.
- Referral to Community Health or Community Rehabilitation Programs
- Inform patient of any expenses likely to be incurred as a result of involving other providers (Note: patients eligible for Medicare rebates for up to 5 allied health consultations a year).
- Facilitation of communication between GP and allied heath professional to discuss their contribution to the Team Care arrangements - the treatment and services they will provide.
- Provision of copy of TCA to allied health professional, with patient's agreement.

Assessment and Management of Osteoarthritis

Has the diagnosis of osteoarthritis hip/ knee been confirmed?

Document site - confirmation of hip OA with x-ray; use of weight bearing X-ray for OA knee assessment
Document x-ray date & severity (normal, mild OA, moderate OA, severe OA)

Does the patient have co-morbidities or medication risks relevant to management of OA?

Document:
- girth circumference & BMI
- NSAID/analgesic risks - refer to:
  http://www.nps.org.au/site.php?content=/html/ppr.php&ppr=/resources/Prescribing_Practice_Reviews/ppr35
- Number of falls in previous year, Cognitive Impairment,
- psychosexual issues (includes emotional and sexual dysfunction)
- general education/medication management issues.
- Medication allergies

Consider:
- Annual Health Assessment MBS 700 (clinic) MBS 702 (home) if patient 75 years or more
- 45 year old Health Check MBS 717 if patient is between ages of 45 & 49 (inclusive) & at risk of developing chronic OA

Document the clinical status of the patient

Document: Pain, stiffness, function, disability
Consider: formal measurement tool such as the 'hip and knee questionnaire'
http://www.health.vic.gov.au/electivesurgery/pubs/owlsumrep.pdf

Has the patient previously used effective conservative therapies?

Document:
- previous treatment (see treatment flow chart)
- effectiveness
- adverse effects and barriers

Refer to joint replacement surgery flow chart for patients with severe disease

Develop a patient centred goal setting care plan with the patient and prescribe medication

Refer to :
- treatment flow chart, General Practice Management Plan (GPMP) MBS 721

Consider:
- Medication Review for patients with polypharmacy and chronic comorbidities MBS 900 or 903
- Comprehensive or Annual Health Check MBS 730

Provide patient education and information materials

Refer to:
- Educational material available at **http://RACGP website for this project**

Consider :
- Team Care Arrangements (TCA) MBS 723

Coordinate community service plan

Consider:
- Team Care Arrangements (TCA) MBS 723

Establish processes for monitoring, and for planned and urgent review

For severe OA, unresponsive to conservative therapy, consider referral for Joint replacement surgery
(See JRS Guide)

GP MANAGEMENT PLAN - MBS ITEM 721 (OSTEOARTHRITIS)

Patient's Name:

Date of Birth:

Contact Details:
[Full address]

Medicare or Private Health Insurance Details:
[Medicare number]
[Health insurance details]

Details of Patient's Usual GP:
[Doctor Name]
[Doctor full address]

Details of Patient's Carer (if applicable):

Date of last Care Plan/GP Management Plan (if done):

Other notes or comments relevant to the patient's care planning:

Date of weight bearing X-ray: [date]
X-ray site: [site]
Xray Severity [no changes, mild, moderate, severe]
Body Mass Index (BMI): [ ]
Girth circumference: [cm]

Number of falls in last 12 months: [ ]

PAST MEDICAL HISTORY

[Clinical details: History list]

FAMILY HISTORY

[Clinical details: Family History]

MEDICATIONS

[Clinical details: Medication list]

Medication self management issues Yes ☐ No ☐

ALLERGIES

Patient's Name:

GP MANAGEMENT PLAN - MBS ITEM 721 (OSTEOARTHRITIS)					
Issues	**What I need to do:**	**How important is this goal for me?** ❋❋❋ *Most important* ❋❋ *Important* ❋ *Less important*	**How will I go about reaching this goal?**	**Who will support me to reach this goal?**	**How am I going? [*Review Date*]**
1. Education/Self-Management					
	I want to learn more about my OA.		I have been given information to help me locate an arthritis self-management course in my local area.	My GP / practice nurse My partner/family Physio Arthritis foundation	
	I want to know more about how to manage my OA.		I have been given information about OA. I have been given information about how to join an arthritis support group.	GP, Library, physio,	
2. Assessed problems					
Pain	I need to know more about what I can do to manage my pain.		With my GP, I have developed a plan to help me manage my pain better.	GP, Practice nurse, Pain management expert, Psychologist, Physio, OT, Pharmacist, Rheumatologist	
Joint stiffness	I want to know more about how to manage the stiffness in my joints.		I have been given information about how to become involved in local activity programs. I have been given information about how to join an arthritis support group.	GP Physio CHC	
Weight	I need to know more about healthy eating and exercise so that I can manage my weight better.		I have been referred to a dietitian to help me work out a healthy eating plan that will suit me. I have been referred to a physiotherapist to help me work out a physical activity program that will suit me.	GP Dietitian Physiotherapist Ex physiologist	
Mood	I need to understand how my OA problem affects my mood and how to manage this.		I have been given information about how OA problems can affect my mood/emotional state. With the support of my GP and other health care professionals, I have developed a plan to help me manage my pain better. I have been referred to a physiotherapist to help me work out a physical activity program that will suit me.	GP Practice nurse Psychologist	
Impact on daily activities	I need to learn ways of making everyday activities easier for me to do.		I have been referred to an occupational therapist to help me work out ways of making everyday activities easier for me to do.	GP (referral) OT	

Patient's Name:

What are the things that concern me?	What I need to do:	How important is this goal for me? ❋❋❋ *Most important* ❋❋ *Important* ❋ *Less important*	How will I go about reaching this goal?	Who will support me to reach this goal?	How am I going? [*Review Date*]
3. Medication Management					
	I need to have a better understanding of my medications, why I am taking them & how to use them.		I have discussed the importance of taking medication and why with my GP. I have been given the address for the consumer section of the NPS website.	GP HMR Pharmacist	
	I need to understand the side effects my medications may cause. I need to understand what information I can provide that will help my GP & pharmacist choose the best medication for me.		I have discussed possible medication problems with my GP and been given written information on the medication I take. I have been given the address for the consumer section of the NPS website. My doctor has advised me on what tests and physical checks are needed to detect and prevent side effects.	GP Pharmacist HMR	
.	I need to have a better understanding of what my medicines are for (including any alternative medicines) and check that I am using them all correctly.		I have had all my medications checked by my doctor **OR** I have been referred to my pharmacist for a home medication review (HMR). My doctor has advised me on how to correctly use my medicines and what side effects I need to look out for.	GP Pharmacist (Home medication review)	
4. What do I do if my OA flares up?					
	I need to learn what to do if my OA gets bad ("flares up").		I will ➢ Try rest, local ice packs, antiinflammatory creams ➢ Increase my pain relief medicines ➢ Make sure I am taking my medication as recommended ➢ Arrange to see my GP	GP Practice nurse Physiotherapist Rheumatologist Orthopaedic surgeon	
Other					
Other					

Copy of GP Management Plan offered to patient? **Yes ☐ No ☐**

Copy / relevant parts of the GP Management Plan supplied to other providers? **Yes ☐ No ☐**

Date service was completed: _____ *[date]* **Proposed Review Date:** _____ *[recommended >3-6 months]*

My GP has explained the steps and any costs involved, and I agree to proceed with the plan.
Yes ☐ No ☐

Patient's Signature: _____ Date: _____

GP's Signature: _____ Date: _____

When will I need to see my GP again?

As required, for ongoing management of my OA & other conditions, **AND** on _____ *[Proposed review date]*

to review this plan.

NOTE: *Original template compiled by Monash Division of General Practice, March 2006*