

BURDEN OF OSTEOARTHRITIS



- Osteoarthritis (OA) is the most common form of arthritis, affecting 1 in 8 Canadians.
- Almost everyone over 65 years of age has OA in at least one joint (1)

OA, which is an incurable disease (2), can result in disability and the need for joint replacement surgery (3,4). It affects the three major components (bone, synovium, and cartilage) of diarthrodial joints (5).

UNMET NEED AND CURRENT STANDARD OF OA DIAGNOSIS

- While knee OA is relatively easy to diagnose as a condition, it is difficult for a physician to objectively identify the biomechanical markers that are known predictors of OA progression.
- Current diagnostic modalities such as X-ray and MRI are standard OA assessment tools that are utilized while the patient is static ("remaining still during X-ray/MRI"), thus making it impossible to identify biomechanical markers and misalignment that can only be accurately detected when a patient is in motion ("walking").

BACKGROUND

Figure 1: The KneeKG System



THE KNEE KINESIOGRAPHY (KneeKG) SYSTEM

- The KneeKG system, developed by Emovi, Inc., is an FDA 510(k) cleared medical device that specifically and accurately identifies biomechanical markers while the patient is both weight bearing and in motion, which serve as predictors of OA disease progression (6).
- The KneeKG measures and analyzes the 3D position of the knee by placing markers on a brace specifically designed to limit the skin movement artifacts. This allows to assess the bone movement underneath, thereby providing precise information on dynamic misalignments.
- The test using the KneeKG system is referred to as 'Knee Kinesiography'. It provides a real-time objective assessment of biomechanical markers by quantifying knee biomechanics (kinematics) during gait and produces immediate 'Knee Kinesiography' reporting.
- A knee kinesiography with KneeKG takes 15 to 20 minutes and is performed by a health care professional. The generated summary report allows for personalized mechanical interventions specifically addressing the identified deficits (such as the varus misalignment, varus thrust, and others) that can lead to progression of knee OA.
- A three-arm cluster randomized clinical trial reported significant improvements in clinical symptoms, pain, and function during daily activities in the Knee Injury and Osteoarthritis Outcome Score (KOOS) in both groups which benefited from a KneeKG test (all p<0.05) (7).

OBJECTIVE

The present study aimed to introduce a conceptual framework for assessing the economic value of the KneeKG in the management of knee OA in a primary care setting.

METHODS

MODEL STRUCTURE

- A conceptual framework was designed based on the diagnostic pathway and available clinical trial data.

CLINICAL VALIDATION OF THE MODEL

- The expert panel consisted of Health Technology Assessment specialists and clinicians to guide key decisions in model design using a practical framework for the clinical validation of HE models (KOLVF) that previously was described (8).

COMPARATORS

- Three global care strategies (current medical management [CMM], CMM + KneeKG, and CMM + KneeKG + EBBM (Education about Evidence-Based Biomechanical Interventions) were compared, as was done in the clinical trial.

INPUTS (EPIDEMIOLOGY AND COSTS)

- Findings from the clinical trial and a targeted literature review were used to inform the KneeKG model framework conceptualization.

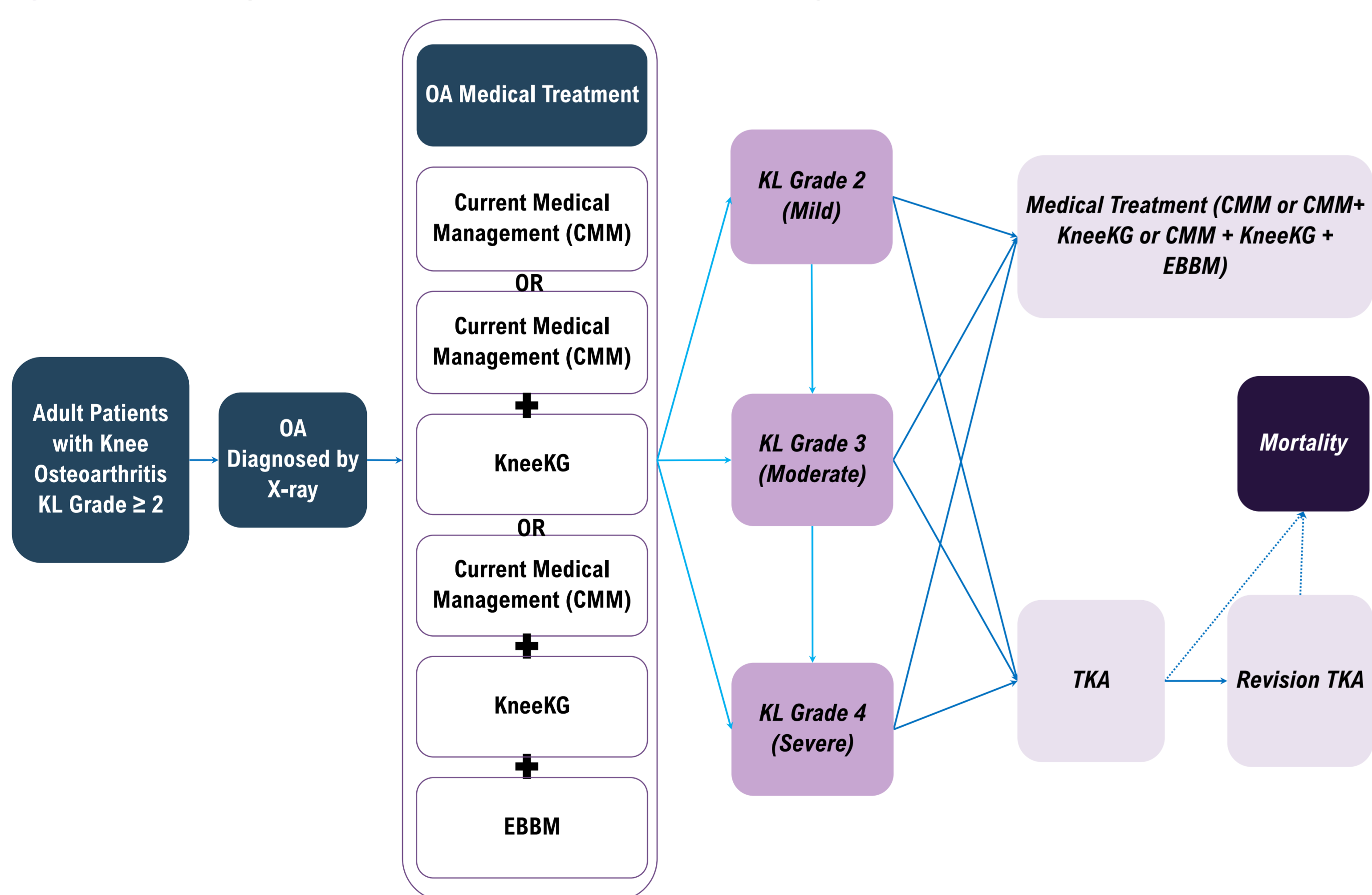
DIAGNOSTIC PATHWAY

- Diagnostic pathway was assumed to start with current medical management (CMM) or CMM + KneeKG, or CMM + KneeKG + EBBM
- Patients were subsequently grouped into one of three categories by the Kellgren and Lawrence (KL) grading system: KL grade 2 (mild), KL grade 3 (moderate), or KL grade 4 (severe).
- The main treatment was considered as medical and surgical treatments:
 - Medical treatments: pain killers (NSAIDs) and corticosteroids
 - Surgical treatments: total knee arthroplasty and revision of total knee arthroplasty.

CONCEPTUAL FRAMEWORK

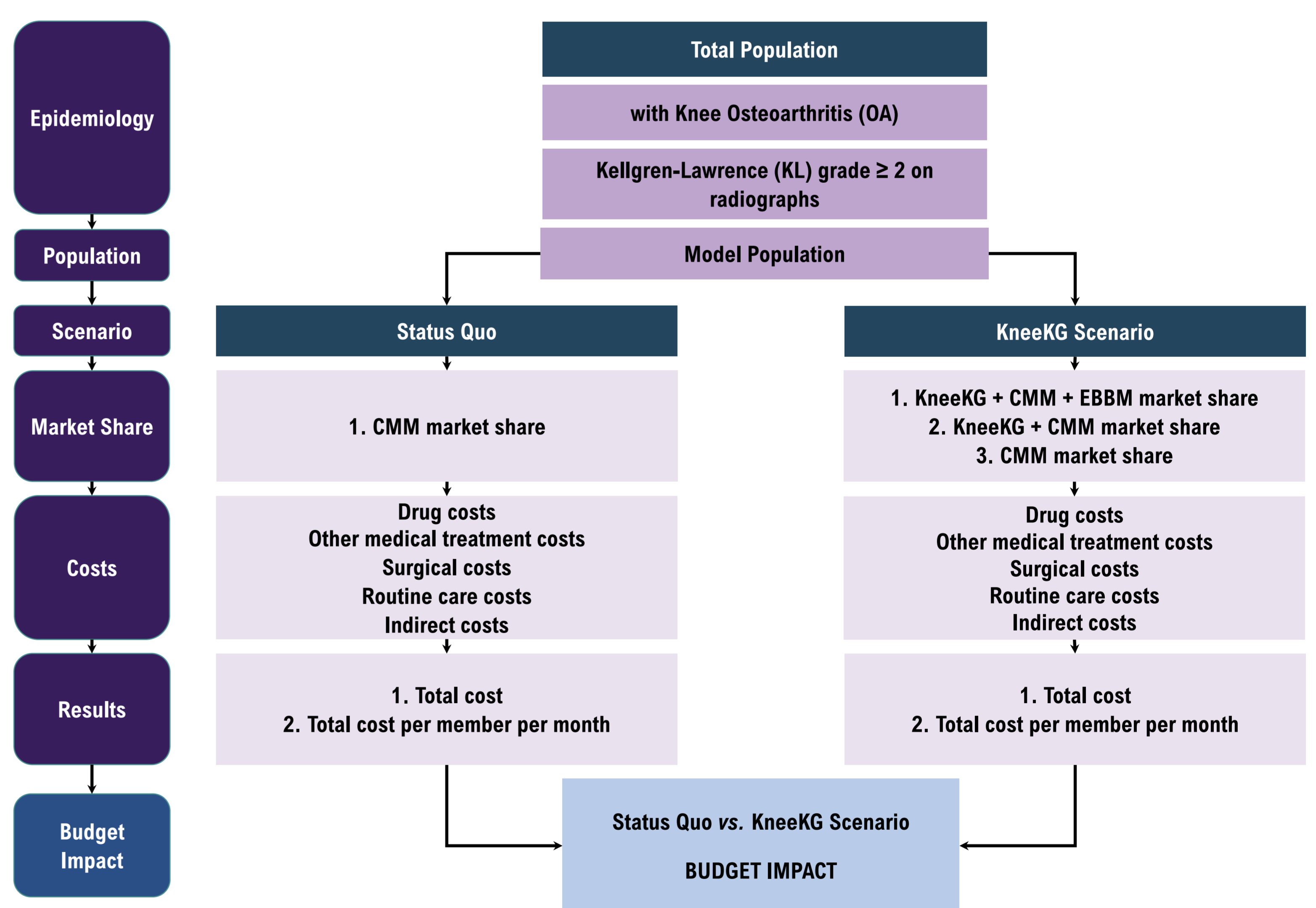
- Outcomes were defined as global care strategies adherence, and related costs.
- Costs were estimated for diagnostic tests, drugs, routine care, complications, adverse events, productivity costs, and death.
- OA severity index was used to define the health states based on the clinical validation. The severity of knee OA was defined by KL grading system where grades 2, 3, and 4 are mild, moderate, and severe OA.

Figure 2: Diagnostic and treatment pathway



EBBM: Education about Evidence-Based Biomechanical Interventions; KL: Kellgren and Lawrence grading system; OA: Osteoarthritis; TKA: Total knee arthroplasty

Figure 3: Conceptual framework



CMM Current Medical Management; EBBM Education about Evidence-Based Biomechanical Interventions

DISCUSSION

- While Knee OA is a dynamic problem, current diagnostic tests such as X-ray and MRI are static modalities, so they cannot detect misalignments when they happen in motion.
- KneeKG can accurately identify biomechanical markers while the patient is both weight bearing and in motion.
- We conducted a conceptual framework for budget impact model using the practical framework for the clinical validation of HE models (KOLVF) to effectively manage the consultation with clinicians.
- The main limitation was the lack of long-term data after the application of this new diagnostic method.

CONCLUSION

The clinical effectiveness of the KneeKG exam in the conservative management of knee OA was previously reported. Using results from a clinical trial and targeted literature review, we designed a health economic model to evaluate the economic value of KneeKG system.

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