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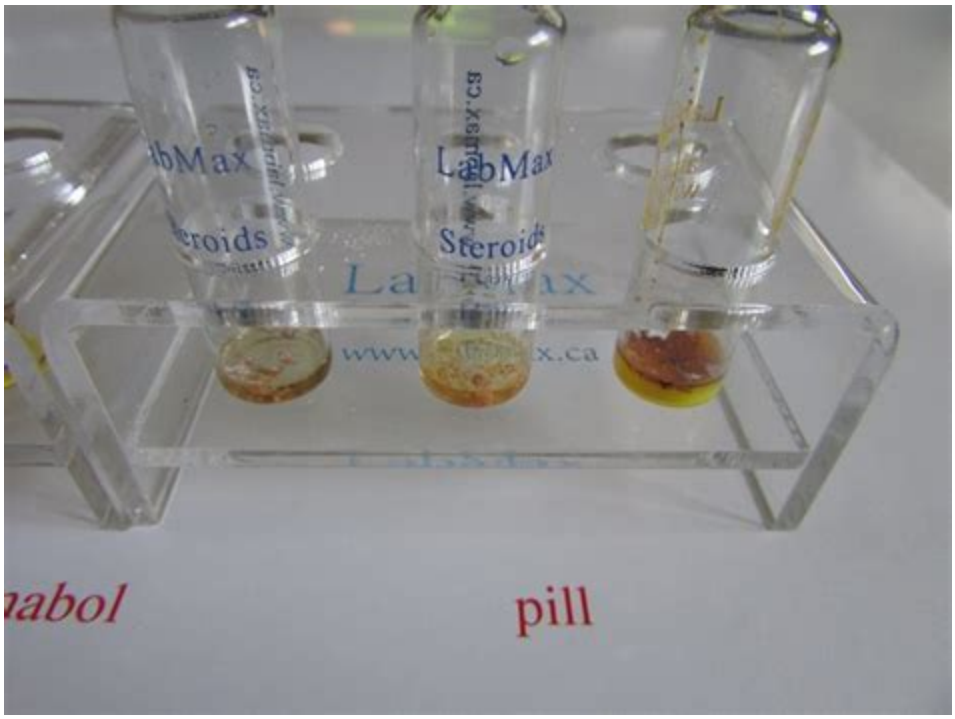

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The use of patient-specific equipoise to support shared decision-making for clinical care and enrollment into clinical trials

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Abstract

Background: To enhance enrollment into randomized clinical trials (RCTs), we proposed electronic health record-based clinical decision support for patient–clinician shared decision-making about care and RCT enrollment, based on "mathematical equipoise." *Objectives:* As an example, we created the Knee Osteoarthritis Mathematical Equipoise Tool (KOMET) to determine the presence of patient-specific equipoise between treatments for the choice between total knee replacement (TKR) and nonsurgical treatment of advanced knee osteoarthritis. *Methods:* With input from patients and clinicians about important pain and physical function treatment outcomes, we created a database from non-RCT sources of knee osteoarthritis outcomes. We then developed multivariable linear regression models that predict 1-year individual-patient knee pain and physical function outcomes for TKR and for nonsurgical treatment. These predictions allowed detecting mathematical equipoise between these two options for patients eligible for TKR. Decision support software was developed to graphically illustrate, for a given patient, the degree of overlap of pain and functional outcomes between the treatments and was pilot tested for usability, responsiveness, and as support for shared decision-making. *Results:* The KOMET predictive regression model for knee pain had four patient-specific variables, and an r^2 value of 0.32, and the model for physical functioning included six patient-specific variables, and an r^2 of 0.34. These models were incorporated into prototype KOMET decision support software and pilot tested in clinics, and were generally well received. *Conclusions:* Use of predictive models and mathematical equipoise may help discern patient-specific equipoise to support shared decision-making for selecting between alternative treatments and considering enrollment into an RCT.

Introduction

The ethical and scientific basis for randomly assigning treatments in a randomized clinical trial (RCT) is the presence of clinical equipoise, the absence of a clearly superior treatment. However, this is typically not an individual patient-centered determination, but rather based on inference from groups defined by pivotal studies' inclusion and exclusion criteria.

An alternative would be to compare patient-specific predictions of treatment outcomes, if available. If such predictions are generated by mathematical models that account for individual patient characteristics, then the potential outcomes can be compared, looking for "mathematical equipoise" [1]. Thereby, individuals could be enrolled in an RCT only when there is equipoise between treatment options based on their specific characteristics and preferences. And, if in making this determination, the treatment outcomes' predictions are importantly different, i.e., mathematical equipoise is not present, then the patient can be offered the treatment most likely to benefit this individual. The objective is to adhere to the RCT principle of equipoise, based on patient-individualized information.

If there is the capacity to identify patient-specific equipoise embedded in electronic health records (EHRs), it could serve as a practical way in routine clinical care to detect potentially eligible patients for RCT enrollment. It also could identify those *not* appropriate for random treatment assignment, for whom this decision support could enhance care by indicating the potentially superior treatment for a given patient. This could help make transparent the basis for selection for an RCT in real time and enhance fully informed consent in the midst of clinical

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