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Perspective

Predictive Models and Clinical Decision Making

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The rise of the Electronic Medical Record (EMR) has precipitated an avalanche of electronic data, often in discrete data fields that can be manipulated to construct clinically meaningful tools to aid in patient care. Among these are mathematical models designed to identify individuals at high (or higher) risk of specific outcomes and who might benefit from specific interventions. The proliferation of the software necessary to construct these models has led to an almost endless supply of predictive models, risk scores and population management tools. While the number of models produced has exploded in recent years, the number that are routinely used in clinical practice remains relatively small by contrast [1]. Furthermore, the impact of the use of these models on the overall health of the populations in which they are administered remains dubious [2]. The lack of clinical utility of mathematical modeling is likely the result of the inability of model builders to identify ahead of time the specific utility to which the model might be applied and the mechanism with which it might be used in a clinical setting. Understanding these barriers and how to overcome them early in the model building process plays an important role in determining how a model will be used and whether it will meaningfully change the health of a population.

Currently, dozens of predictive models have been created to understand and facilitate better patient care in virtually every corner of the medical world. Models as disparate as those predicting suicide risk to heart failure decompensation are offered as meaningful tools to improving patient care and outcomes [3,4]. Many models are built as part of an academic exercise, or after a clinical trial. As a result, models are seldom created with a specific plan for implementation, either by individual practitioners or population managers. As a result, many (probably most) are never used in clinical settings. The reasons for the lack of implementation are numerous and probably vary widely. But these challenges can be generalized and challenges faced by models/model builders when it comes to creating clinically relevant models. This paper explores a few of those challenges.

The Patient vs. the Population

Mathematical models can be applied along the entire spectrum of patient care, from individual interactions to systematic population management interventions. While it is possible to find the utility of a specific model in both instances, there are characteristics that make any given model more applicable to population management *vs.* individual patient care. Elements that are necessary for a model to be used by a clinician/patient in an exam room may make render it useless when applied in a manner applied by population managers to direct certain kinds of care to specific groups. This is not to say that some models may have the elements necessary for application in both individual patient care and population management settings, but these are less common than those that clearly have better application in one venue *vs.* the other.

One of the distinct differences between individual patient care population management is level of outcome differentiation required to influence decision making. A population manager might use a small difference in risk within a large population to decide which patients will benefit from an intervention. The same level of risk might be considered insignificant by a physician and/or patient when deciding whether or not to undergo a procedure or start a medication.

Models that tend to have the greatest utility in individual patient management generally allow discrimination between possible courses of action with a large enough difference in predictable risk to influence decision making (Figure 1). In contrast, population based modeling may not need much discrimination between levels of risk within a population, as long as a cut point can be applied. A population manager can decide (based on a number of different factors-guidelines, available resources, etc.,) where to draw the lines of differentiation between action and inaction. A five percent difference in risk may be insignificant to an individual, but may be very important when applied to a large enough population [5].

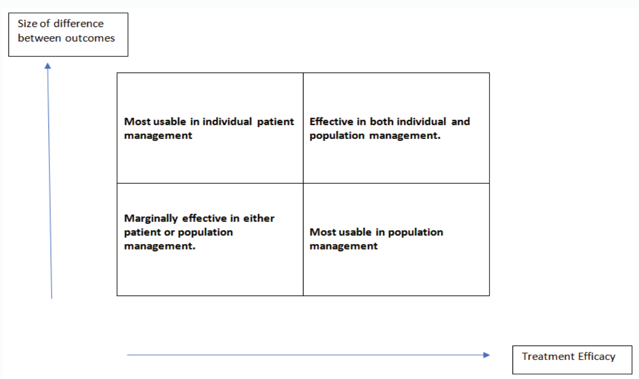

Figure 1: Models that tend to have the greatest utility in individual patient management generally allow discrimination between possible courses of action with a large enough difference in predictable risk to influence decision making.

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The Clarity of Purpose

Explanatory models are used to explain the relationship between multiple variables and a given outcome, based on assumed causal relationship. In contrast, predictive models may not require any clear causal relationship between a series of variables and an outcome, but can be useful tools to measure risks [6]. Many models are both predictive and explanatory, though often their ability to predict may be limited by only using variables that are assumed to be part of the causal chain. A purely predictive model might use variables that, at least on the surface, have no apparent causal relationship to a given outcome. One might not be able to discern the relationship between (let's say) eye color and development of heart failure, but if eye color improves a model predicting heart failure, it might be included in a predictive model. In contrast if the model is explanatory, eye color might be excluded as it has not apparent physiological relationship with heart failure.

Another way to consider the difference between explanatory (or descriptive) models and predictive models is the negative empiricism associated with predictive models-either they predict an outcome, or they do not. Whether a predictive model works can be observed and its ability to predict measured. Explanatory models may not do as good a job differentiating groups based on outcomes, but that is rather beside the point. If an explanatory model offers some insight into potential causality it has likely accomplished its purpose.

In many cases the explanatory/predictive model difference is important only as an abstraction. In many (most) cases models attempt to be both. It is important for model builders to decide what the goal is behind the model. If the goal is prediction, those variables best suited to predict and outcome should be included, if not, and if they don't have a discernable relationship to the outcome, they should be abandoned.

Is this better than my Doctor?

Clinicians make many decisions on a daily basis relying only on experience and intuition. Ideally, a mathematical model will inform the clinician and patient as they make a decision, and be weighted appropriately in decision making based on the precision and accuracy of the model. In reality, models are often used to validate intuitive judgement and seldom, if ever, replace them. This is unfortunate given the accuracy of models relative to clinician judgement. For example, meta-analysis in the area of mental health, support the idea that "mechanical" prediction is generally better than intuition [7]. Similarly, studies of clinician intuition *vs.* mathematical prediction in assessing risks associated with acute coronary syndrome found much the same result, suggesting that clinician intuition was less accurate and resulted in an abandonment of well-established treatment guidelines [8,9].

So, if mathematical prediction is more accurate that clinical intuition, why isn't it more frequently applied? It has been noted that the automated systems on commercial airplanes provider greater safety and are less prone to error than human pilots, yet it seems unlikely that anyone in the public would conceive completely abandoning control of an aircraft to a computer [10]. Similarly, few patients are likely to abandon long held acceptance of physician advice, regardless of its veracity. Like airline pilots, physicians might be better off relying more on computer driven decisions, though there may be an obvious bias against it.

We were going to do that anyway......

In many instances a clinical decision isn't really a decision. The action taken by the clinician and/or patient would be made regardless of the addition of more information. In fact, most clinical decisions are unambiguous enough not to require prediction models at all. For example, there is little question that nearly all patients with hypertension and diabetes should be treated with angiotensin converting enzyme inhibitors, as the risk of adverse effects are low and the benefits are great. Conversely, many conditions have treatments that are of little (or even no) benefit to the patient and knowing whether or not a disease is present or if it will progress.

In deciding what models to build, model builders must consider potential treatments and therapeutic options if they hope to build a meaningful model. Some might argue that the prediction of a given outcome is itself a therapeutic outcome, and in some cases, it may be. Regardless, it is incumbent to decide what role a mathematical model will play in clinical decision making before building the model.

Generalizability, Validation and Overfitting

In large integrated medical systems, model building and use may become a significant differentiating factor in providing high quality affordable care. Systems that are large enough have enough electronic data to build and use models internally, making the concept of external validation somewhat meaningless. Still, for most model builders the idea of building a model as generalizable as possible is highly attractive. Generalizability necessitates validation across as many populations as possible, often with some element of recalibration [11].

In many cases the systemic application of mathematical models has been achieved with the widespread use of electronic medical records. While EMRs have definite advantages in terms of allowing centralized standardized changes in care decision making, many parts of the EMR lack discrete data fields for clinical information necessary to the use of a model. Additionally, there is often variation in data that is entered into EMRs, even when the data appears in discrete data fields. For example, different clinics may use different protocols and different sphygmomanometers to measure blood pressure, a seemingly standardized measurement.

Overfitting is a common problem for model builders. Simply put, overfitting means the model is designed in a manner that reflects not patterns in the underlying data, but also any error (systematic or random). Resulting r-squared values can be misleading and the application of the model will only accentuate the underlying errors. External (and in some cases internal) validation can help identify instances when overfitting has occurred [12].

Conscientious Modeling

Predictive model builders have an obligation to clearly articulate the potential risks inherent within their models prior to allowing them to be clinically applied. Clinicians using predictive models in their practice are similarly obligated to understand as much as they can about the potential pitfalls and inaccuracies associated with a given model. Knowing whether and how it has been validated, what exactly it measures and how it is intended to be applied should be considered an important part of utilizing these new tools in clinical practice. Much like understanding the potential adverse effects of a new medication, the clinician is obligated to know where the model might provide inaccurate assessments of risk. Before using a model five questions should be understood by the user: 1) What is the model actually measuring? 2) How significant and accurate are the model's assessment of risk? 3) Among what patients or population was the model intended to be used? 4) How was the model validated? 5) Is the application of the model going to actually alter a clinical decision? When these questions can be asked and answered a model should be pursued (Table 1).

Table 1: Five questions to ask before building a clinically meaningful model.

1	What is the model measuring?
2	How significant and accurate are the model's assessment of risk?
3	Among what patients or population was the model intended to be used?
4	How was the model validated?
5	Is the application of the model going to alter a clinical decision?

Great advances in electronic medical data and tools to use those data have led to numerous new tools that might benefit patients and physicians. Learning how to properly create and use these tools is a necessity if they are to be routinely applied to clinical practice.

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