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Review

Bridging the gap between evidence and policy for infectious diseases: How models can aid public health decision-making

Gwenan M. Knight [a,b,1,*], Nila J. Dharan [c,1], Gregory J. Fox [d], Natalie Stennis [e], Alice Zwerling [f], Renuka Khurana [g], David W. Dowdy [f]

[a] National Institute for Health Research Health Protection Research Unit in Healthcare Associated Infection and Antimicrobial Resistance, Imperial College London, 8th floor Commonwealth Building, Hammersmith Hospital Campus, Du Cane Road, London, W12 0HS, UK
[b] TB Modelling Group, TB Centre, Centre for Mathematical Modelling, Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London, UK
[c] New Jersey Medical School – Rutgers, the State University of New Jersey, Newark, New Jersey, USA
[d] Respiratory Epidemiology Clinical Research Unit, McGill University, Montreal, Quebec, Canada
[e] New York City Department of Health and Mental Hygiene, Bureau of Tuberculosis Control, New York, New York, USA
[f] Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA
[g] Maricopa County Department of Public Health, Clinical Services, Phoenix, Arizona, USA

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SUMMARY

The dominant approach to decision-making in public health policy for infectious diseases relies heavily on expert opinion, which often applies empirical evidence to policy questions in a manner that is neither systematic nor transparent. Although systematic reviews are frequently commissioned to inform specific components of policy (such as efficacy), the same process is rarely applied to the full decision-making process. Mathematical models provide a mechanism through which empirical evidence can be methodically and transparently integrated to address such questions. However, such models are often considered difficult to interpret. In addition, models provide estimates that need to be iteratively re-evaluated as new data or considerations arise. Using the case study of a novel diagnostic for tuberculosis, a framework for improved collaboration between public health decision-makers and mathematical modellers that could lead to more transparent and evidence-driven policy decisions for infectious diseases in the future is proposed. The framework proposes that policymakers should establish long-term collaborations with modellers to address key questions, and that modellers should strive to provide clear explanations of the uncertainty of model structure and outputs. Doing so will improve the applicability of models and clarify their limitations when used to inform real-world public health policy decisions.

1. Introduction

Public health policy decisions must balance a range of scientific, budgetary, social, and political considerations. Ideally, each of these elements should be considered in a transparent fashion before reaching a decision or implementing a specific policy. While socio-political considerations will always be somewhat subjective, scientific evidence can – in theory – be used to evaluate the potential epidemiological or economic impact of alternative decisions. For example, in the setting of a high-profile outbreak, the probability of making political gains or alleviating public fears is not objectively quantifiable (despite their importance to the decision-making process), but scientific outcomes, such as potential trajectories of the outbreak under different policy decisions, can be estimated quantitatively with appropriate tools using the best available data as inputs, such as the known incubation period.

In the realm of infectious diseases, the tools for integrating and translating scientific data into policy-relevant outcomes are often classified in the domain of 'mathematical models',[1,2] which are defined here as quantitative frameworks for the analysis of dependent happenings (events where the number affected at one time depends on the number already affected[3]). For example,

* Corresponding author. Tel.: +44 (0)208 383 2730.
E-mail address: g.knight@imperial.ac.uk (G.M. Knight).
[1] Gwenan M. Knight and Nila J. Dharan contributed equally to this work.

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systems of diagnosis and treatment are represented in mathematical terms such as the rate of movement from an infectious to a treated state. These models have the ability to translate existing scientific evidence into projected outcomes at the population level for both endemic diseases like tuberculosis (TB) and epidemic situations such as the Ebola virus disease (EVD) outbreak in West Africa in 2014–2015,[4,5] in a way that is transparent and verifiable or refutable by external observers. These estimates can also help with clinical decision-making at the individual level, to improve patient outcomes.

Unfortunately for most public health decisions regarding the control of infectious diseases, such models are seldom constructed – and when they are, they often have limited impact upon the decision-making process. This is likely due to several factors, including perceptions that models are too complex to understand or too dependent on assumptions, coupled with a history of insufficient communication between public health practitioners with specific policy questions and modellers with the quantitative tools to address them.

Here, the potential role of mathematical modelling in decision-making for health policy in the realm of infectious diseases is explored, and key reasons why mathematical models have historically not fulfilled this potential are evaluated. To do this, the current status of modelling in public health decision-making is first outlined and a case study modelling question described. Details of how to construct a relevant model and how to link it to policy are then given, and some of the potential limitations and challenges of using modelling described. Finally, a framework by which improved collaborations between public health stakeholders and modellers may broadly benefit public health is proposed.

2. Current role and potential opportunities for modelling in public health decision-making

The use of structured frameworks for applying evidence to public health decision-making is well established.[6] For example, the World Health Organization (WHO) advocates the use of the GRADE process,[7] which is a framework that connects a public health question to an evidence-based analysis and recommendation.[8] The United States Preventive Services Task Force (USPSTF) similarly uses decision-making algorithms to assess the level and quality of evidence to support the introduction of specific interventions.[9] However, these frameworks for using scientific evidence to support policy decisions often lack quantitative assessments of how different decisions will impact health at a population level.

This is especially true in the realm of infectious diseases, where the dynamics of transmission may cause great disparity between the individual-level benefit or harm of an intervention (for example, side effects of a vaccine for a rare disease such as polio that may outweigh an individual's risk of contracting the disease) and its population-level impact (for example, maintaining elimination of polio through herd immunity). As a result, in settings where population-level benefits are unproven, interventions with strong scientific evidence for individual effectiveness may be recommended over those with a potentially dramatic impact for populations. This decision-making process, if uninformed by insight at the population or system level (as provided by models), may perversely result in outcomes that are good for certain people, but bad for the population as a whole.

Models can address this knowledge gap by estimating the effects of interventions when the collection of population-level empirical evidence (e.g., from cluster-randomized trials) is infeasible, unethical, or untimely. For example, mathematical models suggested that universal voluntary HIV testing and immediate antiretroviral therapy (ART) might dramatically reduce future HIV transmission,[10–12] even though the individual-level effectiveness of ART at higher CD4+ T-cell counts is small,[13] and reduced transmission at the population level is difficult to prove empirically. By projecting population-level effects of potential interventions, the models informed not only key policy decisions but also the design of future clinical trials.[14]

Despite the potential impact that model outputs can have on public policy decisions, the use of models by public health decision-makers has traditionally been limited.[2] Many public health and policy decisions must be reached rapidly, in too short a time for new models to be developed, parameterized, and calibrated. Modellers must therefore achieve a balance between anticipating future policy questions (in which case models may ultimately not speak to the specific policy question at hand) and responding to existing questions (in which case models may be constructed too late to inform policy decisions). In addition, as mentioned above, complex models that are poorly presented are unlikely to be used by time-pressured policymakers. Furthermore, it remains unclear in most settings how to weigh evidence from models against other epidemiological and clinical data. As described below, all models must make certain assumptions and manage attendant uncertainty. These aspects of models are often not well-understood by public health stakeholders, and as a result, model outputs may be seen as difficult to interpret and untrustworthy. A framework by which modellers and decision-makers can work together to more appropriately incorporate evidence from infectious disease models into public health decisions, without over- or underemphasizing the importance of those models, is proposed here.

3. Modelling infectious diseases for policy: the example of a rapid TB diagnostic

To demonstrate the utility and process by which mathematical models can inform infectious disease policy, the case study of a new molecular diagnostic test for TB is used: the Xpert MTB/RIF test (Xpert).[15] Xpert provides a comparatively rapid, point-of-treatment diagnosis in under two hours, if placed in settings where individuals present for initial TB diagnosis and/or follow-up evaluation. Xpert is also substantially more sensitive than the most widely used diagnostic test for TB worldwide (sputum smear microscopy). However, at over 10 times the cost of sputum smear microscopy (which costs less than $2 fully-loaded per test, compared to about $20 for Xpert), scale-up of Xpert has the potential to dramatically increase the cost of TB control in high-burden settings.

The key policy-related questions around the use of Xpert are the following: Do the clear individual-level benefits of improved diagnosis translate into population-level effects on transmission, and if so, would scale-up of Xpert have sufficient impact to justify the added cost (i.e., would Xpert be cost-effective)? These questions can be, and have been, addressed effectively using mathematical modelling.

In the case of Xpert, an initial modelling study projected the impact on TB-associated morbidity and mortality, and cost-effectiveness, in five countries of southern Africa.[16] This study adopted a regional approach, which allowed the authors to use a single model framework (due to similar epidemics across the five countries) and existing data (which are reported on the national level). A global model would likely have required more model complexity, whereas a sub-national model might have been limited by available data or generalizability. The authors aimed primarily to publish their results in the scientific literature, although the model has subsequently been used in country-level discussions and extended to other regions. The model predicted a