

Ethics of Epidemiological Modeling

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Preamble

Research- fundamental to advancement of knowledge in any field

Ideal research- need based research, doing justice to research, abiding research protocols, no harm to anyone or society and benefit all

Too hard principles - doing the right research in the right way and in the right spirit

Going wrong- pitfalls can have serious implications on lives of people, societies,

unintentional infection to participants

Ethics- regulations to safeguard from harming participants

WHO and ICMR Guidelines

WHO bioethics guidelines is not a set of rules but a framework which are internationally accepted and relevant to local culture. It covers the following broad aspects of ethics:

- 1.) Individual autonomy (the ability to make decisions for oneself);
- 2.) Beneficence (the obligation to “do good” for others);
- 3.) Non-maleficence (the obligation to avoid causing harm to others);
- 4.) Justice (distributing benefits and burdens fairly).

A Policy Statement on “Ethical Considerations involved in Research on Human Subjects” was released by ICMR first in 1980 then introduce ‘Ethical Guidelines for Biomedical Research on Human Subjects’ in 2000 and further revised in 2006. It elaborates the WHO guidelines under 12 guiding principles.

Epidemiological Models in Public Health

Statistical models used clinical and laboratory data, risk and socioeconomic factors to comprehend the complexities of health outcomes including pandemic situations

Two most common purposes of statistical modelling are explanation and prediction

Explanatory models for health are intended to inform and direct actions needed to mitigate risk factors

If the results from epidemiological models indicates that the likelihood of child has congenital heart disease at birth is 5 times in older anemic women, triple among women smokers and double among malnourish women then the public health intervention is to reduce such risk factors in the population

Epidemiological Models in Public Health-Contd.

Predictive models are used to inform physicians about patients health status and prognosis so as to enable to take preventive and curative actions

Model based prediction can also facilitate in identification of sub-populations at risk of disease in order to focus actions for reducing or eliminating risk factors

A predictive model, as its name suggests, aims to make an accurate prediction with the greatest possible accuracy

But the problem is that variables considered in the models can't be measured precisely and not all confounders can be control

Cause of Death-Physician Assignment Vs Machine Coded

Verbal autopsy (VA) is about post-mortem survey collecting past medical and treatment history with other details leading to death of individuals

Trained physicians used the information from the post-mortem retrospective survey to assigned cause of death (COD)

COD pattern emerging from VA are used for disease control prioritization

The main issue of VA is the settlement of differences in COD assigned from the set of information in the survey data by different physicians

The other issue is the time gap between data collection and COD assignment by physicians

Cause of Death-Physician Assignment Vs Machine Coded-Contd.

In recent time various computer algorithm have been proposed for assignment of COD

It aims to standardized the assignment of COD

The current leading computational VA techniques include, InterVA-48
Tariff⁷, InSilicoVA⁹, King-Lu¹¹, and Naïve Bayes Classifier (NBC)¹²

All these computer algorithms adopt some statistical methods to integrate and synthesize data from post-mortem survey which ranges from physician weighting of COD and risk factors, rank and sum up to assigned COD, computation of uncertainty for individual level COD and population level distribution of COD using hierarchical Bayesian framework

Artificial Intelligence in Health Research

Artificial intelligence for simple understanding can be considered as an extended computer assisted system for mimicking functions of human intelligence with computer [Simple example-Spam filter in email]

Can reduce misclassification of disease and wrong diagnosis

AI can predict and diagnose disease at a faster rate than physicians [AI using algorithms and deep learning diagnosed breast cancer at a much faster rate than 10 physicians]

Use of AI in healthcare facilitates predict, comprehend, learn and act

The COVID19 Pandemic

In March 2020 WHO declared COVID19 as pandemic, devastating and unpredictable, unstoppable spread have put lives of millions at risks all over the globe

WHO called for immediate research actions by immediately assessing available data to learn what standard of care approaches are the most effective and taking up trials for effective vaccine

Epidemiological modeling since the outbreak of the pandemic are used for estimating and predicting the scale and time course of epidemics, for evaluating the effectiveness of public health interventions, and informing public health policies

The challenges to epidemiological modelling of COVID19 are no precedent and availability of limited data especially in the initial stage

Modelling the COVID19 Pandemic

Epidemiological modelling of COVID19 adopts one or the other of the following statistical models:

Polynomial regression model

Generalized logistic growth model

Susceptible-Infectious-Recovered (SIR) model

Reservoir-people (RP) diffusion network modelling for simulation

Quadratic regression model

Optimization techniques

MCMC models

Ethics in Epidemiological Modeling

The advantage of using statistical models in describing, explaining and predicting disease outbreak comes with potential for misuse

The misuse of statistical models in epidemiological modeling largely comes from not appreciating the fact that there is no simple answer to complex phenomena, such as, the COVID19

An epidemiological model misclassifying vulnerable subpopulation shall deprived from preventive and curative attentions

Failing to control potential confounder may result can make a significant risk factor insignificant

Underestimation and overestimation shall not only lead to unjudicial utilization of resources but shall also make gap in public health preparedness

Ethics in Epidemiological Modelling-Contd.

With limited data in the initial phase of the outbreak of COVID19 and no comprehensive knowledge there are no certainty of appropriate statistical models

Using statistical models for real time analysis is always a challenge

Automation of measurement and data collection procedure coupled with fast speed computational provisions is a boon to data scientists and epidemiologists but at the same time also raise ethical concern

For instance MCMC is based on generations of pseudo data imitating the limited available data by re-sampling and jackknife methods

It might reduce cost and time but violates the principles of equity and inclusion

Ethics in Epidemiological Modelling-Contd.

Statistics and data science which at the center of epidemiological modelling look largely from technological advancement if it were a question of reaching a new status

Overlooks the balancing act of benefits overriding harm

A large number of epidemiological models uses data collected for some other purposes which might have followed the simple ethics of consent

May lead to intentional manipulative practice to earn a living

This leads to not only misuse data but privacy breach

Best Practice Guidance for AI

Use of AI in epidemiological modelling needs to address questions concerning transparency, reproducibility, ethics, and effectiveness

Best practice recommendations for design, conduct, analysis, reporting, impact assessment, and clinical implementation are not adequate to address these questions in the case of use AI in health research

Some but not exhaustive ethical issues of use of AI

Briefing of benefit of algorithm to patients

Validation of the tools capture real time constraints

Statistical methods incorporate trade-offs of benefits and competing risks

Availability of codes and algorithms to others for replication and generalization

Cost effectiveness to build and sustain

Initiating Debate

Should IRB encompass tools for modeling?

Should there be separate stricter data collection ethics?

Should there be a body at the national level for clearance and certification of tools for analysis and modelling?

Thank You