Innovative Data-Driven Strategies for Infectious Diseases: Opportunities, Challenges, and the Path Forward

MEETING REPORT

National Institute of Allergy and Infectious Diseases
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Executive Summary

On September 24-25, 2018, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, convened a workshop to discuss opportunities to incorporate data-driven strategies in efforts to diagnose, treat, and prevent infectious diseases. Combating infectious diseases, such as influenza, tuberculosis (TB), malaria, and HIV/AIDS remains a global public health challenge, and the development of new drugs and vaccines is still a lengthy and costly process. The volume and variety of biomedical research data have been growing exponentially for many years and are expected to continue to double every three years. As the data—generated through new research, clinical studies, observational and epidemiological studies, as well as mobile devices—increase in size, complexity, and diversity, so do the challenges of managing and analyzing that data for maximum value. Traditional data management and data analytic approaches need to be augmented with new technologies that quickly and effectively deliver useful insights. The rising popularity of artificial intelligence (AI) and machine learning (ML) technologies for biomedical research and medical applications is evident in the growing amount of research conducted in this area, the number of products that are obtaining Food and Drug Administration approvals, and the entrepreneurial investment in this space over the past few years. Innovative, next-generation, data-driven approaches combining emerging AI technologies, fields such as natural language processing, and advanced predictive analytics have the potential to revolutionize scientific research.

The NIAID workshop brought together researchers from academia, pharmaceutical companies, and technology firms to identify critical issues and challenges, and define strategic directions and priorities for data science to advance research on infectious diseases. The workshop participants developed recommendations and identified five priority areas to move this field forward.

- Identify critical needs to drive data-intensive infectious disease research and practice
- Support interdisciplinary team science in infectious disease research
- Expand shared open-access datasets and establish standards for data integration
- Advance data-driven analytical solutions for knowledge discovery
- Foster a data science workforce

Meeting Summary

Welcome

Emily Erbelding, MD, MPH, director of NIAID's Division of Microbiology and Infectious Diseases, welcomed the participants and described the numerous NIAID-funded research programs that generate data and support the development of new tools and techniques. Meeting Co-Chair Rick Stevens, professor at the University of Chicago, said a revolution in data-driven methods has sparked huge investments around the world. Clearly, extensive amounts of data are being captured, but it is time to explore how data-driven methods can translate that information to new discoveries. Most experimental biomedical research is not yet driven by predictive modeling, but the field of physics uses it extensively. The emerging capacity on the computational side can be leveraged to drive discovery and development of interventions faster. Meeting Co-Chair Vincent B. Young, MD, PhD, professor at the University of Michigan, added that infectious disease clinicians tend to take a reductionist approach to research. Clinicians often take lessons learned from the relatively small sample of patients with whom they have direct experience and translate that into their practice. The opportunity to learn from data sets of thousands or even millions of cases could transform infectious disease research and practice.

Keynote Address

The meeting kicked off with a keynote speech from Tom Rush, PhD, of GlaxoSmithKline (GSK) about the Accelerating Therapeutics for Opportunities in Medicine (ATOM) consortium, a public–private partnership to accelerate the discovery and development of therapeutic candidates for oncology. The ATOM consortium develops, tests, and validates a multi-disciplinary approach to drug discovery that integrates modern science, technology and engineering, supercomputing simulations, data science, and AI, and shortens the process of discovering promising compounds for new drugs.

Scientific Sessions

Each session included presentations followed by discussion.

Session 1: Data-Driven Discovery and Clinical Research: Challenges and Strategies, focused on challenges that investigators are facing in infectious disease research and practice. Speakers presented data-driven approaches that have demonstrated success, and barriers that limit the sharing, integrating, and reuse of data for maximum value.

Session 2: Landscape of Modeling, Scalable Analytics, and AI Methods for Biomedical Research, outlined the state of the art of emerging technologies in exascale computing and deep learning that enable data intensive research. Speakers presented examples that harness the power of big data and leverage advanced computational learning systems to drive systems immunology research and accelerate translational discoveries.

Panel Discussions and Recommendations

Participants engaged in discussions to develop recommendations to advance the use of data-driven approaches in infectious disease research.

Identify critical needs to drive data-intensive infectious disease research and practice

Data-driven approaches can improve infectious disease research in many areas, including the enhanced innovation and accelerated development of interventions, more efficient clinical and field studies, and increased patient-centric diagnostics and treatments. Cancer research has embraced data-driven approaches faster than other fields. Researchers have had success using ML for cancer detection and diagnosis, particularly for medical imaging. A research group from Stanford University was able to identify melanomas with performance comparable to trained pathologists using deep learning applied to a training set of 129,450 pathology images[1]. Researchers are successfully applying ML to other disease areas. A team of Google investigators applied deep learning to more than 128,000 images of patients with diabetic retinopathy and compared them to controls[2]. Their algorithms were able to identify diabetic retinopathy with similar performance to ophthalmologists with an AUC of 0.99. Using ML, massive medical imaging data sets can be processed. Combined with recent advances in computer vision, machine accuracy will soon exceed that of humans. In addition, ML has proven successful in developing tools for predicting major histocompatibility complex binding because of large amounts of publicly available data and increased computing performance.

Examples of data-driven challenges in infectious disease research were discussed. Development of vaccines involves perturbation of two interacting complex systems, pathogen and host. In GSK's vaccine pipeline from preclinical to post-implementation, a data team is dedicated to predictive analytics, applying ML for antigen discovery and adjuvant mode of action, and estimating field effectiveness. Learning from bioinformatic predictions and experimental data generated in the past 20 years, researchers can start with thousands of potential proteins, compare them with a large slate of biologically relevant features, and develop a small subset for testing. This ML pipeline outperforms the existing computational methods. A key driver for performance is the quality of the training datasets, and negative controls are as important as positive controls.

ML can also help reduce the timeline from recognition of a new seasonal influenza strain to development of a vaccine. Large data sets are needed to bridge the gap that would help vaccine developers predict antigenicity. In addition, the effectiveness of seasonal influenza vaccines varies from year to year, and more data may help reveal the reason why. ML could augment the current vaccine strain selection process to improve accuracy. Predictions from computational models may also help identify new antigens to improve vaccine efficacy.

The NIAID-funded International Centers of Excellence for Malaria Research consortium applies a multidisciplinary, integrated approach using laboratory, molecular and genomic methods to study the complex interactions between the human host, mosquito vector and the *Plasmodium*

[1] https://www.ncbi.nlm.nih.gov/pubmed/28117445
[2] https://www.ncbi.nlm.nih.gov/pubmed/27898976

parasites that cause malaria. These studies collect data from diverse sources, including remote sensors, genetic sequencing, social media, supply chain, people and vectors, and environmental databases. Using new technology, researchers analyze huge amounts of data and apply them to nowcasting (predicting the immediate future) using an interactive approach. For example, by using satellite images of the target, researchers can pinpoint hotspots and use supervised ML to identify where mosquitoes may be headed and build a potential malaria map.

Recommendations

- Apply data-driven strategies to accelerate development of novel and improved diagnostics, therapeutics, and vaccines.
    - AI, big data, and high-performance computing can accelerate the discovery, development, and delivery of innovative diagnostics and therapeutics.
    - Advanced learning analytics can be used to predict optimal vaccine targets for rational and timely design of effective vaccines.
    - Existing and new data on immune responses can be applied in the development of personalized vaccines, customized to individual history, genetics, and exposure.
- Use data-driven strategies for analyses of risk prediction and patient outcome.
    - Patterns can be discovered in vast and complex datasets from disparate sources, such as electronic health records (EHRs), clinical trial data, and 'omics research, to identify signatures that reliably predict patient outcomes.
    - Learning from diverse datasets integrating patient-driven biology with real-world data from sources such as EHRs, digital health devices, and social media networks can delineate immunologic profiles and deliver deeper medical insights for developing personalized treatment plans.
    - Optimizing antibiotic therapy through integration of data, including pathogen genomics, host pharmacogenomics, and microbiome composition to allow selection of effective therapies to treat multidrug-resistant infections and stop the spread of resistant microbes while minimizing collateral damage to gut commensals.
- Integrate new modeling strategies in epidemic and pandemic preparedness efforts.
    - Holistic modeling of disease dynamics using real world evidence such as data from surveillance, mobile devices and social media, and variables from the complex multi-scale interplay between host-pathogen and host-host interactions across the globe can help answer epidemiologic questions such as where a virus emerged and how it is transmitted, assess infectious disease impact for faster decision-making, and enable rapid public health and research responses.
- Encourage implementation science for preventing and eliminating infectious diseases
    - Integrating research findings with parameters from diverse sources including economic analyses, supply chain, sociopolitical factors, ecological and demographic conditions, and other evidence-based practices can improve efforts to develop and implement effective interventions in routine health services.

Support interdisciplinary team science in infectious disease research

Collaboration across infectious disease research has been a challenge as experimental scientists and data scientists have different priorities and approaches. Data-driven team science requires integration of diverse expertise and collaborative efforts with shared goals, but incentives are not aligned with team science and data sharing. In an effective multidisciplinary team, individual researchers appreciate the limits of each other's perspectives, acknowledge a shared desire to create new approaches to overcome those limits, and demonstrate a willingness to learn about new ideas. The field of physics has been very successful in promoting team science. More support for team science in infectious disease research could create bridges between the data generators and the data users. Team science sparks innovations that may not be identified inside the boundaries of individual disciplines.

One example of successful team science comes from a hospital-based research group that added an ML specialist to its team. The ML specialist drew on findings that a particular strain of *Clostridium difficile* was associated with severe disease; from there, the team worked backwards to identify individuals at risk of acquiring the infection in hospitals. Using copious data from EHRs—regardless of whether specific data points seemed germane to clinicians—the team created a successful model for predicting an individual's risk of becoming infected with *C. difficile*.[3]

Recommendations

- Support team science that enables integration of diverse expertise to pursue systems thinking and collaborative innovations to address complex, high priority scientific challenges such as antimicrobial resistance (AMR), TB, and HIV/AIDS.
- Support high-risk research to develop pioneering approaches using engineering and computer science focused on difficult problems in infectious disease research.

Expand shared open-access datasets and establish standards for data integration

Data availability is critical for developing advanced analytical and computational approaches, including ML and AI. The depth, quality, and accuracy of training datasets and resources significantly affect the performance of advanced analytic algorithms. Availability and incorporation of negative control data are equally important for successful ML. However, huge challenges persist in harmonizing and sharing of data, ensuring quality and availability of data, and inferring causation from the data. In order to advance data-driven strategies, high quality data are needed that 1) represent a large and diverse pool of study subjects; 2) meet a number of quality criteria; and 3) can be gathered and maintained at low cost. Ideally, databases should be able to be integrated to allow for scaling data sets that can be used in different domains. Existing NIAID bioinformatics infrastructures need to be optimized to eliminate barriers to sharing, integrating, and reusing data.

Data-driven solutions require machine-digestible knowledge representation. The wealth of medical, research and patient data in a wide variety of unstructured formats is often inaccessible or spread across different platforms. Many sources of metadata are not standardized, or metadata

[3] https://www.ncbi.nlm.nih.gov/pubmed/29576042

are missing, so most ML projects rely on single-source datasets or require extensive manual curation. Efforts to create community standards for knowledge representation are largely volunteer with little dedicated funding. Standards and governance are needed to improve data integration. Interoperability is difficult because researchers have little incentive to create and publish new standards for harmonizing existing and new data sets. The goal of a universal language to represent biomedical data might be in reach but adopting it may be painful unless incentives are provided to the scientific community.

Recommendations

- Utilize new technologies and best practices to support innovative data collection methods that lower the barriers for researchers to collect, integrate, and share data.
- Provide incentives for researchers to harmonize data and metadata, and promote transparent and reproducible research
- Establish environments that provide mechanisms of aggregating and harmonizing independent data sets and make high quality data available more quickly and in more useful formats for access by scientists and machines.

Advance data-driven analytical solutions for knowledge discovery

New and advanced analytical tools and solutions are needed to analyze data and identify novel insights. Algorithms powered by emerging technology, such as AI, address many of the weaknesses of existing data analytics tools to meet today's big data challenges. ML brings the capability to search vast data sets quickly and to continually learn from discoveries. ML can handle enormous numbers of predictors and combine them in nonlinear and highly interactive ways. This capacity allows the use of new kinds of data which previously would have been impossible to analyze given their sheer volume or complexity.

The use of ML algorithms in addressing antimicrobial resistance (AMR) has made promising progress. ML-based algorithms[4] [5] using clinical and genomic data to predict antimicrobial susceptibility phenotypes demonstrated very good accuracies. Such algorithms could be applied to develop rapid diagnostics that complement traditional culture techniques and antimicrobial susceptibility testing that can take several days to weeks to produce results for clinical decisions. Efforts are underway to make these algorithms accessible as web-based services through which researchers can upload their own data to make predictions. ML has also been explored to improve treatment of multidrug resistant infections, including ML-aided drug design using ligand and receptor-based methods to screen candidate compounds.

Recognizing the potential of AI and ML and implementing these emerging technologies in biomedical research will require some safeguards. For example, there is a lack of basic understanding about performing and evaluating ML predictions, which can lead to overfitting. ML does not necessarily have a process for recognizing and managing outliers. Most importantly, a problem analyzed through ML may not fully represent the problem as a whole. The field must recognize that ML is not a panacea. Investigators should understand what ML can

[4] https://www.ncbi.nlm.nih.gov/pubmed/?term=PMID%3A+30333126

[5] https://www.ncbi.nlm.nih.gov/pubmed/27297683

do and its limits. To gain buy-in from the community, new tools should demonstrate qualitatively different results, not just slight improvements.

Recommendations

- Develop novel methods for efficient and automatic data (e.g., EHRs) quality assessment, cleaning, and integration to improve metadata and data for translating findings into comparable computations.
- Support new and improved data-driven and ML-based analytic solutions and tools to prioritize hypothesis design to drive discovery, and to inform evidence-based learning and decision-making.
- Provide access to, and improve utility of, analytical tools.

Foster a data science workforce

Increasing the number of people trained in data science in infectious disease research will help advance the use of data-driven strategies. Biomedical researchers need help using the knowledge base and new data approaches, as well as an increased understanding of how to refine the data and the models. In some cases, building predictive models can be easy, but the challenge is interpreting the results, and understanding how the model fits with prior knowledge and how to communicate the model and integrate it into clinical research. In vaccine research, for example, there has been some success using high-dimensional ML tools, but there are few highly trained quantitative scientists who understand the methods and can apply them in context.

Clinicians need help understanding how to implement models in real-time practice, whether data are accessible to feed the model, whether the model works in their population, and how to incorporate more data streams. ML is often "fuzzy"—that is, it is not entirely clear how the model interprets the data; clinicians may accept that the model identifies associations, but they usually want to know "why" that leads to a finding. The next generation of researchers and clinicians needs to understand how to interpret results of ML and how to refine models through iterative learning to improve predictions for better clinical decisions.

Recommendations

- Establish a community of data science researchers with quantitative skills to succeed in a collaborative and multidisciplinary team environment.
- Develop research leaders with expertise in big data and ML.
- Support the training of the next generation of biomedical scientists and clinicians to tackle data-driven challenges.
- Support the development of curricula with a focus on data science and its applications in biomedical research and medical practice.

APPENDIX 1: WORKSHOP AGENDA

Innovative Data Driven Strategies for Infectious Diseases Opportunities, Challenges, and the Path Forward

Hosted by: National Institute of Allergy and Infectious Diseases, NIH

September 24-25, 2018

BACKGROUND

The development of drugs and effective vaccines is still very lengthy, costly, and risky. As a result, the treatment and prevention of infectious diseases such as influenza, tuberculosis, malaria, and HIV/AIDS remain to be global challenges. This expensive and lengthy process of discovering and developing interventions is ripe for a creative disruption. The volume and diversity of biomedical research and health care data is growing at an unprecedented rate and emerging technologies are enabling data intense research environments. The last decade has seen major advances in the production and collection of data, as well the ability to better analyze and understand data and extract knowledge. Data is also changing the research landscape and opening the door for major advances in understanding, detection, diagnosis, and treatment of diseases. Data driven strategies have been used to successfully demonstrate accelerated research, ranging from drug discovery, vaccine design, disease surveillance, and precision medicine as identifying predictive signatures for enhancing and guiding clinical decisions and for predicting risk, severity, and progression of diseases, especially in cancer. Technology innovations such as high-performance computing and artificial intelligence have powered self-driving cars, super-human image recognition, and medical image processing for diagnosis. These technologies are revolutionizing scientific fields and advancing the future development of targeted therapeutic interventions and predictive signatures, drawing from heretofore unapproachable banks of data.

GOAL

This workshop is to discuss critical issues and grand challenges, thereby defining strategic directions and priorities for data science to drive the investigation of infectious diseases. The workshop will bring together researchers from academia, industry, non-profit organizations, and government agencies to discuss next-generation of data-driven strategies that maximize the value of data to generate new knowledge and deeper insights. The focus will be on identifying advanced and integrated analytics and machine learning-based approaches that harness the predictive power of emerging technologies to accelerate discovery science and drive innovation for developing therapeutic interventions for personalized healthcare and precision medicine for infectious diseases.

OVERARCHING QUESTIONS

- What developments can we expect to see in applying emerging technologies such as machine learning and AI in biomedical research in general in the next 5 years?
- How to accelerate the use of AI and machine learning to advance data-driven strategies for drug discovery, diagnostics development, and therapeutic interventions?
- What are strategies to increase engagement of clinicians, health care workers, computational scientists, discovery scientists, engineers, statisticians to enable better utilizing and translating both new

platforms, computational tools and knowledge for developing and improving therapeutic interventions and predictive capabilities?
- What short and longer-term investments should be made to advance the agenda of data-driven modeling and prediction for discovery science, vaccine development, and therapeutics?

AGENDA: Monday, September 24, 2018

7:30am – 8:30am **Arrival and Registration**

8:30am – 8:45am **Welcome from NIAID**
Emily Erbelding, MD, MPH | Director, DMID/NIAID

8:45am – 9:00am **Welcome from Co-Chairs**
Rick Stevens, PhD | University of Chicago
Vincent B. Young, MD, PhD | University of Michigan

9:00am – 9:40am **KEYNOTE:**
ATOM: A Public-Private Partnership to Accelerate the Discovery and Development of Therapeutic Candidates for Oncology
Tom Rush, PhD | GlaxoSmithKline

SESSION 1: Data Driven Discovery and Clinical Research: Challenges & Strategies (9:00am-12:40pm)

Session Chair: Vincent B. Young

9:40am – 10:00am **Data and the Systems Biology of *Clostridium difficile* Infection**
Vincent B. Young, MD, PhD | University of Michigan

10:00am – 10:20am **Data Collection Strategies to Drive Human Infectious Disease Research: Improving Quality, Dimensionality, and Long-Term Impact**
Martin S. Zand, MD, PhD I University of Rochester Medical Center

10:20am – 10:40am **BREAK**

10:40am – 11:00am **Opportunities and Challenges Using Data from Large Observational HIV Cohorts**
Bryan Shepherd, PhD | Vanderbilt University

11:00am – 11:20am **Data Driven Discoveries: from receptor:ligand interactions to identifying disease relevant cell types**
Bjoern Peters, PhD | La Jolla Institute for Allergy and Immunology

11:20am – 11:40am **Data Science for Malaria**
Malla Rao, PhD | NIAID

11:40am – 12:00pm **Data Science for Vaccines R&D**
Duccio Medini, PhD | GlaxoSmithKline

12:00pm – 12:40pm **DISCUSSION**

12:40pm – 1:40pm **LUNCH** (*5601 Fishers Lane Café, on your own)*

SESSION 2: Landscape of Modeling, Scalable Analytics, and AI Methods for Biomedical Research (2:00pm-5:30m)

Session Chair: Rick Stevens

1:40pm – 2:00pm **Progress and Opportunities in Machine Learning for Infectious Disease and Cancer**
Rick Stevens, PhD | University of Chicago

2:00pm – 2:20pm **Systems Immunology of the Human Host: Fishing Using Machine Learning**
John Tsang, PhD | NIAID

2:20pm – 2:40am **Promises and Challenges of Genome Analytics for Viruses**
Sergei Pond, PhD | Temple University

2:40pm – 3:00pm **Data Needs in the Selection and Development of Influenza Vaccine Antigens**
Mario Barro, PhD | Sanofi Pasteur

3:00pm – 3:20pm **BREAK**

3:20pm – 3:40pm **The Future Impact of Sequencing Everyone**
Michael McManus, PhD | Intel

3:40pm – 4:00pm **Hardware + Architecture = Faster Training**
Rob Schreiber, PhD | Cerebras

4:00pm -- 4:20pm **Accelerating Bio Discovery with Machine Learning**
Lucy Colwell, PhD | Google

4:20pm – 5:30pm **DISCUSSION**

5:30pm **ADJOURN DAY 1**

6:45pm – Evening
INFORMAL GROUP DINNER – Reflection on Opportunities and Approaches,
Synthesizing Input
Matchbox Pizza, Congressional Plaza, 1699 Rockville Pike, Rockville, MD 20852

AGENDA: Tuesday, September 25, 2018

SESSION 3: Panel Discussions (9:00am-12:00pm)

Session Chairs: Rick Stevens and Vincent B. Young

9:00am – 12:00pm Panel Discussion

Trends for AI, Machine Learning, and Prediction
What is the 5-10 year landscape going to look like?

Strategies for Acceleration
What can we do faster, better, more cheaply?

New Models for Engagement and Cross-disciplinary Collaboration
How to structure the attack that sweeps in more diverse and deep collaborations?

Investments that would make a difference
What are the highest priority challenges that need to be overcome with programs and projects?

12:00pm – 12:15pm Closing Remarks

Rick Stevens and Vincent B. Young

12:15pm ADJOURN

APPENDIX 2: PARTICIPANT LIST and ORGANIZING COMMITTEE

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