



R&D for Emerging Infectious Diseases

How new tools can transform the fight



In a world experiencing increasing human mobility and ecological change, emerging infectious diseases (EIDs) pose a growing threat to health security. As we saw with COVID-19, an outbreak in one corner of the world can quickly become a global pandemic with devastating human and economic costs. New vaccines, treatments, diagnostics, and other tools are urgently needed to outsmart epidemics. However, research and development (R&D) for EIDs is particularly challenging.

The market potential for tools against EIDs is too uncertain to drive commercial investment, and testing these products is especially difficult. Strong government support and smart collaboration between nations are vital to overcome these barriers and develop the tools needed to prevent, detect, and respond to these threats.

\$12.5 trillion
global economic cost of COVID-19

11,000+ lives
lost from 2014-16 West Africa Ebola outbreak

3X projected increase
in annual probability of extreme epidemics in coming decades

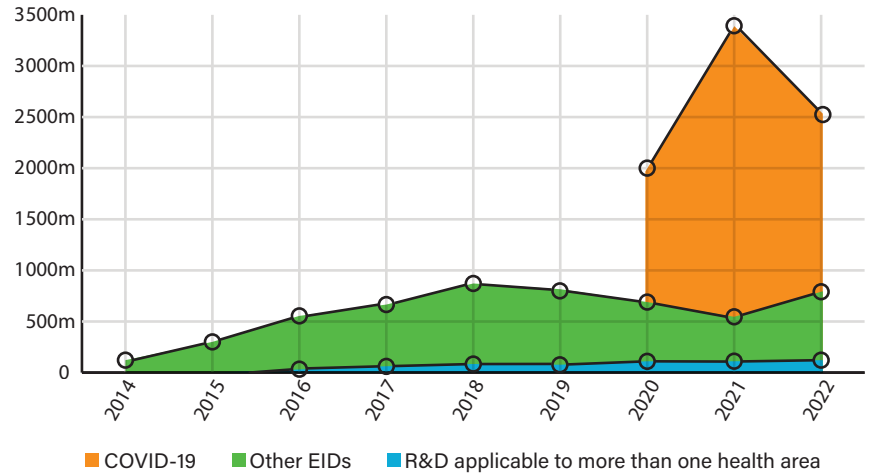
Key missing tools We are without essential tools to combat many EIDs considered most likely to cause the next epidemic:

	Vaccines	Treatments	Diagnostics
COVID-19	Several vaccines are approved but will require routine updates for variants.	Oral and intravenous treatments are approved, but continued innovation is needed to optimize treatment and address variants.	Several rapid, point-of-care (POC) tests and laboratory-based tests are available, but continued validation is needed for new variants.
Crimean-Congo Haemorrhagic fever (CCHF)	No FDA-approved vaccine is available. A Bulgarian-licensed vaccine exists, but its efficacy is unclear.	No specific licensed treatment is available. An existing antiviral has been used during outbreaks, but its efficacy remains unclear.	Commercial tests are available but require sophisticated laboratory infrastructure. Rapid POC tests are needed.
Ebola Sudan	No licensed vaccine.	No specific licensed treatment.	Confirmatory tests are available but require sophisticated laboratory infrastructure. Rapid POC tests are needed.
Ebola Zaire	Two vaccines are approved by stringent regulators.	Two licensed treatments are FDA-approved and in use globally.	Several rapid POC tests and laboratory-based tests are in use globally, including FDA-approved and -authorized options.
Lassa fever	No licensed vaccine.	No specific licensed treatment. The IV-administered antiviral ribavirin is effective if used early, but more robust research is needed, as are oral antivirals.	Confirmatory tests are available but require sophisticated laboratory infrastructure, and validation is needed for different lineages. Rapid POC tests are needed.
Marburg	No licensed vaccine.	No specific licensed treatment.	Commercial tests are available but require sophisticated laboratory infrastructure. Rapid POC tests are needed.
Middle East respiratory syndrome (MERS)	No licensed vaccine.	No specific licensed treatment.	Commercial tests are available, including FDA-authorized options, but they require sophisticated laboratory infrastructure. Rapid POC tests are needed.
Mpox	Three vaccines are approved by stringent regulators, two of which are FDA-approved.	No specific licensed treatment. An FDA-approved smallpox drug that has been used on a compassionate use basis was found ineffective.	Commercial tests are available, including FDA-authorized options, but they require sophisticated laboratory infrastructure or specialized testing systems. Further validation is needed for different clades, as are additional rapid POC tests.
Nipah	No licensed vaccine.	No specific licensed treatment.	Commercial tests are available but require sophisticated laboratory infrastructure. Rapid POC tests are needed.
Rift Valley fever (RVF)	No licensed human vaccine.	No specific licensed treatment.	Commercial tests are available but require sophisticated laboratory infrastructure. Rapid POC tests are needed.
Severe Acute Respiratory Syndrome (SARS)	No licensed vaccine.	No specific licensed treatment.	Confirmatory tests are available but require sophisticated laboratory infrastructure. Rapid POC tests are needed.
Zika	No licensed vaccine.	No specific licensed treatment.	Rapid POC tests and laboratory-based tests are available , including FDA-approved or -authorized options.
Pandemic influenza	No licensed universal vaccine. Existing flu vaccines may offer some cross protection.	Existing antivirals may be effective. Additional broad-spectrum antivirals are needed.	Confirmatory tests are available but not all commercially. Rapid POC tests will be needed.

Research progress

- Several **COVID-19 vaccines, therapeutics, and rapid POC diagnostic tests** were developed with cross-US government support, significantly changing the course of the pandemic. Next-generation **nasal COVID-19 vaccines, combination influenza and COVID-19 vaccines, and pan-coronavirus vaccines** are now in development with US support.
- **Two licensed vaccines, two approved therapeutics, and a rapid POC test for Ebola Zaire** were developed via various partnerships with NIH, DoD, and BARDA. Since their introduction, these tools have helped bring subsequent outbreaks under control more quickly, dramatically reducing their scale and toll.
- A promising **vaccine for Marburg**—a deadly cousin of the Ebola virus—which was developed by NIH, advanced with BARDA support, and trialed at a DoD-supported overseas lab, was deployed under clinical trial protocols to respond to the 2024 outbreak in Rwanda. A **vaccine for Ebola Sudan** that is built on the same vaccine platform is also undergoing a Phase 2 trial with US support.
- Thanks to investments from BARDA, the United States was prepared with an approved **mpox vaccine** when the global epidemic hit. Researchers are now advancing an **adapted version of this vaccine for children**.
- Vaccines for several other EIDs have recently entered or advanced in clinical trials, including the first human trial of a **Nipah vaccine**, the first Phase 2 study of a **Lassa vaccine**, and a Phase 2 trial of an **mRNA-based Zika vaccine**.
- Clinical trials are underway for several **potential universal flu vaccine candidates**, including an mRNA-based candidate developed at NIH's Vaccine Research Center.
- Numerous **diagnostic tools for EIDs** beyond Ebola and COVID-19 have been advanced to market, including four tests for Zika that have full FDA approval, as well as 14 tests for Zika, 8 for mpox, and 2 for MERS that received Emergency Use Authorization.

US government investment in R&D for EIDs (in 2022) US\$ millions



US Government R&D efforts

The US government is developing tools to improve health security through a whole-of-government approach:

- **Biomedical Advanced Research and Development Authority (BARDA)** supports the advanced development of vaccines, drugs, diagnostics, and other medical countermeasures against EIDs considered a threat to national security.
- **National Institutes of Health (NIH)** conducts basic and clinical research to advance new treatments, vaccines, diagnostics, and vector control products to combat EIDs.
- **Department of Defense (DoD)** supports R&D to create vaccines, drugs, and other tools for EIDs considered a threat to US service members or to national security.
- **Centers for Disease Control and Prevention** works to develop new and improved diagnostics and surveillance tools to improve global capacity to prevent, detect, and respond to outbreaks.
- **US Agency for International Development** has supported the development of select tools to combat EIDs designed for low-resource settings and contributes to the Coalition for Epidemic Preparedness Innovations (CEPI), a global vaccine development partnership.
- **Food and Drug Administration (FDA)** administers the Tropical Disease and Material Threat Medical Countermeasures Priority Review Programs to incentivize industry investment in products for select EIDs and grants Emergency Use Authorization to permit the use of not-yet-approved products during an emergency.

