GLOBAL BIOSECURITY

Oladimeji O, Kennedy S, Oladimegi O. Dual Use Research of Concern: Perspective of Clinicians from a Training Viewpoint. Global Biosecurity, 2019; 1(1).

PERSPECTIVES FROM THE FIELD

Dual Use Research of Concern: Perspective of Clinicians from a Training Viewpoint

Oluwatoyin Oladimeji[1], Sean Kennedy[2], Olawale Oladimeji[3]

[1]Wesley Guild Hospital, Obafemi Awolowo University Teaching Hospitals Complex, Nigeria
[2]School of Women's & Children's Health, UNSW Sydney, Australia
[3]Obafemi Awolowo University Teaching Hospitals Complex, Nigeria

Abstract

The field of Dual use research of concern (DURC) has been rapidly expanding in the last decade. Though this has led to unprecedented breakthroughs in Life sciences and Technology, it is also associated with significant risks. These risks are enormous, transcend local and national boundaries and have the potential of catastrophic effects. Some of these include the release of highly infectious pathogens capable of sparking unnatural outbreaks, with resultant widespread illness and deaths. Yet Clinicians who are significant first responders involved in the management of cases in outbreaks, often lack relevant training on DURC and its associated risks. We propose that the World Health Organization (WHO) should develop global guidelines on the integration of relevant DURC training into undergraduate and postgraduate medical curricula. In addition, country-level national policy should be developed by each member country in line with their specific context.

Introduction

Now more than ever in history, the immense growth in biological sciences and technology has led to a phenomenal increase in the creation and modification of infectious pathogens using genetic engineering (1). The research underpinning these scientific and technological advances is broadly referred to as Dual Use Research of Concern (DURC). DURC is research conducted with the intent of good but has the potential of causing harm. DURC includes research using technologies such as synthetic biology, clustered regularly interspaced short palindromic repeats (CRISPR) and gene editing (1-3). Despite the rapid expansion in DURC, relevant training on DURC and its associated risks have not up till now generally been included in undergraduate and postgraduate medical training curricula (4). We outline the global challenge of DURC from the perspectives of two clinicians and a health policy analyst with training from a developing (Nigeria) and a developed country (Australia). We then recommend the need for global guidelines and country-level national policy on inclusion of DURC training in undergraduate and postgraduate medical curricula.

The global challenge of DURC

Research classified as DURC has enormous benefits with respect to understanding mutations that lead to transmissibility, antimicrobial resistance, prevention of genetic disorders, and drug and vaccine development. However, it is also associated with a significant risk of intentional or accidental release of novel infectious agents, with far-reaching global consequences (1-5). With rapid international travel and trade, a single released infectious pathogen could, within a short period, spark unnatural pandemics with profound negative effects (illnesses and deaths) on individuals both within the country of release and in distant countries (1, 6). DURC thus has a potential for extensive catastrophic health, economic and social outcomes, which transcend local and national boundaries (1, 5). Hence, there is the need for a highly coordinated, dynamic and robust program that adequately engages all important stakeholders (clinicians included) that are directly or indirectly affected by or involved with DURC, as well as those charged with the responsibility of biosecurity.

The perspective of clinicians on DURC training as first responders

Despite being frontline responders in managing cases directly affected in outbreaks (natural or unnatural), few clinicians have training in DURC, its risks, or identification of red flags which may suggest a DURC associated outbreak. Examples of such past outbreaks which were not recognized by treating clinicians or public health authorities were the Rajneesh salmonella attack and Operation Seaspray (7, 8). In the former, salmonella culture was added by members of the Rajneesh sect into salad bar constituents in eight restaurants in the Oregon county, United States of America (USA)(7). This resulted in 751 morbidities including 45 admissions. Similarly, Operation Seaspray was a secret experiment by the USA Navy in which Serratia marcescens was sprayed over San Francisco Bay region in California (8). This

also resulted in 11 admitted cases of urinary tract infection, including one mortality. Despite these cases having some unusual features, neither managing clinicians nor public health experts considered those outbreaks as DURC related. Adequate training is crucial, not only to ensure optimal patient management but also to promptly alert public health experts, who are charged with the responsibility of conducting comprehensive outbreak investigations (9, 10).

From our experience, undergraduate medical and residency training in Nigeria (a developing country) and Australia (a developed nation) conspicuously lacks training in DURC, its associated risks and peculiar challenges in recognition and management of cases in unnatural outbreaks. Indeed, a recent report from global experts in the field of bio-safety revealed that post-doctoral, graduate and undergraduate training of professionals in life sciences, including medicine, are devoid of discussions or courses about DURC, except in specific cases where a trainee is working directly with a select agent (4). Similarly, a recent survey in the United States of America among Administrators and Trainers in life sciences revealed about 59% of them had no knowledge of DURC, only 19% of them could define DURC, and about 22% of them were unsure of what DURC meant (11).

With endorsement of open publishing of DURC related research methods by the United States National Science Advisory Board for Bio-defense in 2012 (12), and the numerous 'Do-it-Yourself' laboratories constantly springing up in different parts of the world (4), DURC related threats appear to be inevitable. Hence, all relevant stakeholders should be adequately prepared to effectively tackle these threats whenever they occur. Physicians as first responders are stakeholders with obvious knowledge gaps in recognizing and tackling threats related to DURC and its outcomes.

A recent, highly publicized example of DURC highlights the current lack of adequate controls. A Chinese scientist (He Jiankui) purportedly altered the CCR5 gene to activate HIV resistance in a set of twin girls (13). This was reportedly achieved using CRISPR, a tool that can be used by scientists to excise, embed and change specific pieces of Deoxyribonucleic acid (DNA). He Jiankui's 'experiment' may have unknown and unquantifiable risks attached to it. Dr. Burgio Gaeten, a genetic researcher, describes these risks as "off-target effects" that could turn-off genes that maintain good health, including those that suppress cancerous growths (13).

Policy recommendation

Responding to the accessibility and ease of DURC is a global challenge. In our opinion, the World Health Organization (WHO) should develop guidelines on how DURC can be integrated into the medical curricula of physicians in member countries, which each country should adapt to fit their setting (14). Additionally, country-level policy development is critical because of the diversity and complexity associated with DURC in each country. The policy approach for each individual nation should be country specific, with each country developing policies grounded in the WHO framework that can be implemented within her context (14). Also, we propose that a combination of top-down and bottom-up approaches involving physicians, public health experts, federal ministry of education, federal ministry of health, research and ethics committees, security and intelligence agencies and other relevant stakeholders, would be most appropriate to utilize in the development of curricula and policies.

The learning outcomes and content of DURC related medical curricula should clearly respond to differences in knowledge needs of undergraduate and postgraduate trainees. While for undergraduates, a foundational course to prepare them for DURC related challenges is required (15), postgraduate courses should be more in-depth with focus on heightened index of suspicion with unusual clinical patterns, DURC related ethics, research methodology and emergency response, among others. In addition, the importance of interoperability and collaboration with all other first responders and important stakeholders should be incorporated into the post-graduate medical curricula (6, 16).

Conclusion

DURC is a rising global challenge, yet there is lack of educational curricula, knowledge and skills about DURC among clinicians who are important first responders. Clinicians should thus be adequately equipped with knowledge and skills to effectively manage DURC related medical threats. Country-level policies on integrating DURC training into the curricula of undergraduate and postgraduate medical trainee is therefore of paramount importance. Such training should also be considered for undergraduate and postgraduate science curricula and research degrees.

References

1. MacIntyre CR. Re-thinking the ethics of dual-use research of concern on transmissible pathogens. Environment Systems and Decisions. 2015;35(1):129-32. DOI: https://doi.org/10.1007/s10669-015-9534-9
2. MacIntyre CR. Biopreparedness in the Age of Genetically Engineered Pathogens and Open Access Science: An Urgent Need for a Paradigm Shift. Military medicine. 2015;180(9):943-9. DOI: https://doi.org/10.7205/MILMED-D-14-00482
3. Getz LJ, Dellaire G. Angels and Devils: Dilemmas in Dual-Use Biotechnology. Trends in Biotechnology. 2018;36(12):1202-5. DOI: https://doi.org/10.1016/j.tibtech.2018.07.016

4. National Academies of Sciences E, Medicine, Policy, Global A, Committee on Science T, Law, et al. Dual Use Research of Concern in the Life Sciences: Current Issues and Controversies. Washington (DC): National Academies Press (US)
5. Connor S. First Human Embryos Edited in U.S.: MIT Technology Review; 2017 [Available from: https://www.technologyreview.com/s/608350/first-human-embryos-edited-in-us/.]
6. Lipsitch M, DA R. New game, new rules: Limiting the risks of Biological Engineering: Foreign Affairs; 2015 [Available from: https://www.foreignaffairs.com/articles/2015-08-31/new-game-new-rules.]
7. Torok TJ, Tauxe RV, Wise RP, Livengood JR, Sokolow R, Mauvais S, et al. A large community outbreak of salmonellosis caused by intentional contamination of restaurant salad bars. Jama. 1997;278(5):389-95. DOI: https://doi.org/10.1001/jama.1997.03550050051033
8. Loria K. 'One of the largest human experiments in history' was conducted on unsuspecting residents of San Francisco: Business Insider; 2015 [Available from: https://www.businessinsider.com/the-military-tested-bacterial-weapons-in-san-francisco-2015-7?IR=T].
9. New South Wales Government Department of Health. Disease Notification 2018 [Available from: https://www.health.nsw.gov.au/infectious/pages/notification.aspx].
10. US Centers for Disease Control and Prevention. Steps in an outbreak investigation 2011 [Available from: https://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson6/section2.html.]
11. Mann T, Oates K. An Analysis of Education on Dual Use Research of Concern. Annual International Conference on Advances in Biotechnology2015. DOI: https://doi.org/10.5176/2251-2489_BioTech15.14
12. National Institute of Health. Statement on NSABB's March 30, 2012 Recommendations to NIH on H5N1 Research 2012 [Available from: https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nsabbs-march-30-2012-recommendations-nih-h5n1-research].
13. Smith B, N M. Gene editing babies was irresponsible, risky and unnecessary, say experts. Why?: ABC Science; 2018 [Available from: https://www.abc.net.au/news/science/2018-12-01/crispr-gene-editing-twins-controversy-legal-ethical-china/10567542].
14. World Health Organization. WHO handbook on guideline development 2012 [Available from: apps.who.int/iris/bitstream/10665/75146/1/9789241548441_eng.pdf].
15. World Health Organization. Report of informal consultation forum on Dual Use Research of Concern 2013 [Available from: www.who.int/csr/durc/durc_feb2013_full_mtg_report.pdf].
16. Salloch S. The dual use of research ethics committees: why professional self-governance falls short in preserving biosecurity. BMC medical ethics. 2018;19(1):53. DOI: https://doi.org/10.1186/s12910-018-0295-0

How to cite this article: Oladimeji O, Kennedy S, Oladimegi O. Dual Use Research of Concern: Perspective of Clinicians from a Training Viewpoint. *Global Biosecurity*, 2019; 1(1).

Published: February 2019

Global Biosecurity is a peer-reviewed open access journal published by University of New South Wales.