Do-it-yourself biology: an open innovation movement or a threat?

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BACKGROUND INFORMATION

The word “hacker”, coined in 1963 by The Tech (MIT student newspaper), became a commonly used term and pop culture phenomena. It was only a matter of time when this computer science sensation expanded to other data manipulation fields. Surprisingly, back in 1963, no one would think that hacking culture would expand to biology however, DNA is an information vector and can be hacked or altered in order to achieve new properties.[1,2]

In 2005, Rob Carlson wrote in Wired that "the era of garage biology is upon us. Want to participate? Take a moment to buy yourself a lab on eBay."[3] He then set up a garage lab the same year, working on a project he had previously worked on at the Molecular Sciences Institute in Berkeley, California.[4] In 2010, Genspace opened the first community biology lab, followed by BioCurious.[5] Many other labs and organizations followed, including but not limited to Counter Culture Labs in Oakland, Baltimore Underground Science Space in Baltimore, among many others.

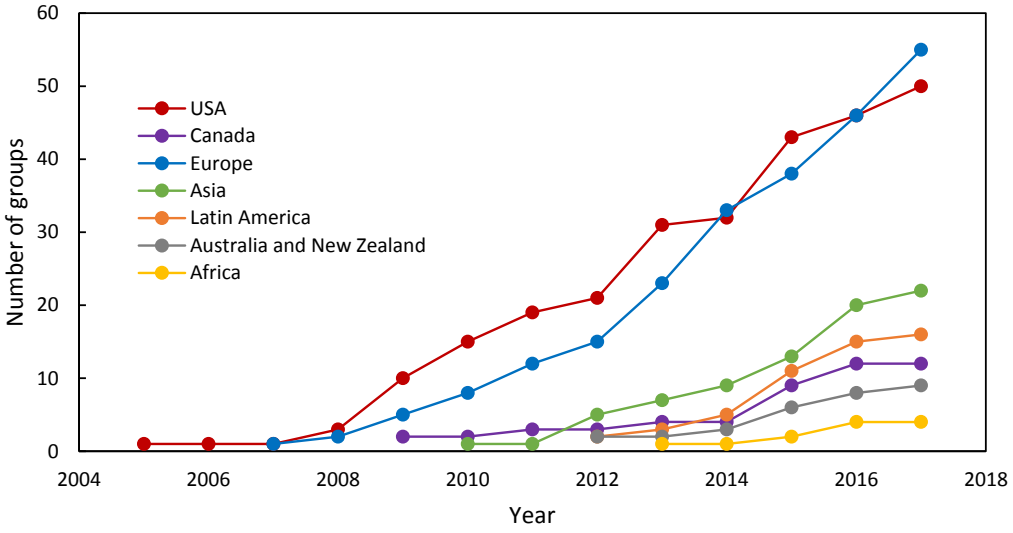

Figure 1 Number of active do-it-yourself biology groups by country/continent. Reproduced from Brookings Institution.[6]

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[1] Wu, F. and You, L. Hacking DNA copy number for circuit engineering. *Nature Genetics* 49, 1164–1165 (**2017**)
[2] Regalado, A. One man’s quest to hack his own genes. *MIT Technology Review* (**2017**), https://www.technologyreview.com/s/603217/one-mans-quest-to-hack-his-own-genes/
[3] Carlson, R. Splice it yourself. *Wired* (**2005**), https://www.wired.com/2005/05/splice-it-yourself/
[4] Ledford, H. Garage: life hackers. *Nature* 467 (7316): 650–2 (**2010**)
[5] Ochoa Cruz, E.A., de la Barrera Benavidez, O.J., Giménez, M., Chavez, M. and Van Sluys, M.A. The biohacking landscape in Latin America. *BioCoder* (**2016**)
[6] Kolodziejczyk, B. Do-it-yourself biology shows safety risks of an open innovation movement. Brookings Institution (2017), https://www.brookings.edu/blog/techtank/2017/10/09/do-it-yourself-biology-shows-safety-risks-of-an-open-innovation-movement/

Do-it-yourself (DIY) biology is now a rapidly evolving and emerging social biotechnology movement, in which individuals, community groups, and small organizations study biology and life science using the same or similar methods as traditional research institutions.[2,3] DIY biology may be done as a hobby, as a not-for-profit endeavour, an open-science innovation, or for-profit business. In recent years, maker spaces and community do-it-yourself biology laboratories have been sprouting up across the globe, to harness an interest in learning and working in non-academic settings.[7] Data published by Brookings Institution shows that in 2017 there were at least 168 do-it-yourself biology groups around the world, including 55 across Europe, 50 in the US, and 22 groups in Asia and these has been significant growth in the last six years (Figure 1).[6]

Currently, DIY biology is primarily undertaken by individuals with extensive research training from academia or biotech and pharmaceutical corporations, who then mentor and supervise novice do-it-yourself biologists with little or no formal training.[2,3,7] According to a report by the Woodrow Wilson International Center for Scholars in Washington, DC, 36% of do-it-yourself biologists are under 35 years of age, while 78% are below the age of 45.[8] The community has coined the terms, biohacking, wetware hacking, and biopunk to describe their movement and emphasizes links to hacker culture and ethic. These terms, just like their archetypal conventional hacker counterpart, emphasize the intellectual challenge of creatively overcoming limitations of biological systems to achieve novel and clever outcomes. Additionally, the mentor/mentee relationship creates a novel educational experience at the forefront of genetic science and synthetic biology, creating important opportunities for students and inspiring students to pursue science as a career.

However, there are substantial concerns with this growing movement. One recent example, in 2016, an iGEM (International Genetically Engineered Machine, a student DIY competition) team attempted to build a gene drive system but failed.[9] Environmental release of gene drives altered organisms is potentially a scary scenario as these modified organisms can change the genetics of an entire population. After this "accident", the iGEM team updated their safety policies to include gene drives and a strict '*do not release policy*'.[9] If a group of students is able to attempt building a gene drive system, using "garage" lab and equipment, it is only a matter of time when it will be possible for large-scale participation and given the power of genetic and synthetic biology experiments, there are serious public health and safety concerns.

Safety concerns

While do-it-yourself biology groups and their supporters argue that their experiments are safe, ethical and don't pose a threat to health or environment, governmental agencies and scientists are worried that emerging synthetic biology technologies can cause damage.[10] Todd Kuiken in his commentary for Nature argues that "the citizen-science community has a responsible, proactive attitude that is well suited to gene-editing."[11] However, recent accidents tend to disfavour the do-it-yourself community.

In January 2017, the German government (Federal Office for Consumer Protection and Food Safety), concerned by the growing open science movement and availability of so-called DIY biology kits,

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[7] Mullin, E. Obama advisers urge action against CRISPR bioterror threat. *MIT Technology Review* (**2016**)
[8] Grushkin, D., Kuiken, T. and Millet, P. Seven Myths and Realities about Do-It-Yourself Biology. Woodrow Wilson International Center for Scholars (**2013**)
[9] Braverman, I. Gene editing, law, and the environment: life beyond the human. Routledge (**2017**)
[10] Oye, K.A., Esvelt, K., Appleton, E., Catteruccia, F., Church, G., Kuiken, T., Bar-Yam Lightfoot, S., McNamara, J., Smidler, A. and Collins, J.P. Regulating gene drives. *Science* 1254287 (**2014**)
[11] Kuiken, T. Governance: learn from DIY biologists. *Nature* 531(7593):167-8 (**2016**)

issued a statement banning practicing of genetic engineering outside of designated labs. Any science enthusiast doing genetic engineering outside of a licensed facility can be fined of up to 50,000 Euros or sentenced up to three years in prison.[12] The statement was a surprise to the do-it-yourself biology community, although it is only a reminder. These regulations were introduced back in 1990 when German Genetic Engineering Act (Gentechnikgesetz) was issued.[13] Only two months later, in March 2017, the German authorities reported the contamination of a 'do-it-yourself' bacterial gene engineering CRISPR kit produced in the US. The kit was contaminated with pathogenic multidrug-resistant bacteria. According to the producer the kit was safe for home use and contained a harmless, non-hazardous and nonpathogenic strain of *E. coli*.[14]

In February 2018, Aaron Traywick injected himself in the thigh with an experimental herpes treatment created by his startup, Ascendance Biomedical. The whole occurrence took place on stage in front of the audience at a biohacking conference held in Austin, Texas and was broadcasted on Facebook Live. Traywick later confessed that he did it as a political statement.[15]

The previously mentioned failed attempt by a team of students at an iGEM competition was alarming to many experts. Meanwhile, the sophomore who attempted the project stated that the controversy around it has only motivated him to further pursue his gene drive DIY experiments, even despite potentially serious consequences.[16]

At the International Workshop on "assessing the security implications of genome editing technology" held last year in Hannover, Germany, experts established that "it is essential to continue educating scientists, including the DIY community, about codes of conduct", and that "there is little evidence available for defining the threat from DIY science; subsequent discussion explored how to engage better with the DIY community." On the other hand, experts stated that "the do-it-yourself (DIY) biology community is probably unlikely to do human genome editing in the near future." A summary report from this workshop was published by the InterAcademy Partnership.[17]

POLICY RECOMMENDATIONS

Governance measures

It is unlikely that strict regulations like the German Genetic Engineering Act introduced by the Federal Office for Consumer Protection and Food Safety in Germany will be effective. Governments must acknowledge the value of this open science citizen movement but at the same time they cannot

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[12] Gentechnik mit Biologiebaukästen: Einfach, aber möglicherweise strafbar. *Federal Office for Consumer Protection and Food Safety* (**2017**), https://www.bvl.bund.de/DE/06_Gentechnik/04_Fachmeldungen/2017/2017_01_25_DIY-Kits.html

[13] German Genetic Engineering Act (Gentechnikgesetz), http://web.uni-frankfurt.de/si/gentech/GenTGengl10-95c.pdf (Unauthorized English translation)

[14] European Centre for Disease Prevention and Control, Risk related to the use of 'do-it-yourself' CRISPR-associated gene engineering kit contaminated with pathogenic bacteria (**2017**), https://ecdc.europa.eu/sites/portal/files/documents/2-May-2017-RRA_CRISPR-kit-w-pathogenic-bacteria_2.pdf

[15] Mullin, E. A biotech CEO explains why he injected himself with a DIY herpes treatment on Facebook Live. *MIT Technology Review* (**2018**), https://www.technologyreview.com/s/610179/a-biotech-ceo-explains-why-he-injected-himself-with-a-diy-herpes-treatment-live-on-stage/

[16] Swetlitz, I. College students try to hack a gene drive — and set a science fair abuzz. *STAT News* (**2016**), https://www.statnews.com/2016/12/14/gene-drive-students-igem/

[17] Fears, R. Assessing the security implications of genome editing technology - report of an international workshop, Herrenhausen, Germany, 11-13 October 2017, IAP, https://www.volkswagenstiftung.de/sites/default/files/downloads/Summary_Report_Genome_Editing.pdf

underestimate the potential threats. It must be noted that self-governance is unlikely to completely work within a community formed by enthusiasts, hobbyists and biohackers and there is therefore an urgent need for adaptive policies and regulations. Specially designated government units and offices should be created and be able to respond on a timely basis to any new developments in the field. To do so, continuous engagement, and evaluation of do-it-yourself biology groups is required. Statements like the one quoted previously, regarding motivation driven by project controversy are worrying, and are most likely result of poor understanding of the potential threats and damages that release of gene drives could cause. This is evidence that ongoing engagement and education in terms of biosafety and bioethics is of high importance within the do-it-yourself community.

Safety by design

DIY research projects should ideally address potential security and safety issues at the time of project inception and be part of the experimental design. Here, DIY practitioners would identify safety issues and integrate solutions (safety by design) as part of the research project in a similar way to how government and academic agencies provide safety oversight of academic laboratories. In addition, there should be sufficient flexibility to change the course of a project if safety/security issues are identified during the course of the project. It would be wise to require involvement of experts and government agencies responsible for approving and monitoring any new community project. For that, robust, effective and clear standards, norms and expectations must be set by the community of recognized expert practitioners and it is recommended that standards and guidelines be produced and adopted. The do-it-yourself community must be aware of these standards and regulations and would be required to evaluate their projects against these criteria, before seeking formal approval from a governing body. This initial self-evaluation of the project, doesn't counter the statements mentioned in the "governance measures" section of this paper but supports adaptive and multi-level governance, at the same time putting potentially less burden on regulatory agencies. Addressing potential issues with the use of new technologies before the work begins is needed to prevent hindering innovation and discouraging potential citizen practitioners/scientists. The safety by design aspects of the project, have to be evaluated on a case-by-case basis. Some projects may require light governance and oversight, while others would need to be assessed in more detail.