

**NUFFIELD
COUNCIL^{ON}
BIOETHICS**

BRIEFING NOTE

Zika: ethical considerations

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Nuffield Council on Bioethics

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This note draws on a number of Nuffield Council reports concerning public health ethics,¹ research in developing countries,² solidarity,³ the sharing of biological and health data,⁴ and the regulation of emerging biotechnologies,⁵ in order to highlight key ethical considerations relevant to the current Zika epidemic.

Background

Zika

Zika is a viral infection transmitted by aedes mosquitoes, outbreaks of which have been recorded in Africa, the Americas, Asia and the Pacific. Currently there is also a small number of known cases of sexual transmission and transmission via blood transfusion, and increasing evidence of transmission from mother to foetus via the placenta.⁶ Symptoms are generally mild. However, in recent large outbreaks, reports have emerged of neurological and auto-immune complications of the disease, and recently Brazilian national health authorities have observed a twentyfold annual increase in babies born with microcephaly in the northeast of Brazil, alongside an increase in Zika infections in the general public. An increased frequency of Guillain-Barré syndrome (GBS) has also been reported. There is currently no treatment or vaccine available, and the best known forms of prevention are protection against mosquito bites, and mosquito control.⁷

World Health Organization (WHO) response

Though the causal link between Zika in the mother and microcephaly in the child has not yet been proven,⁸ a WHO Emergency Committee has declared that the virus and its potential association with recent clusters of microcephaly and neurological disorders constitutes a 'Public Health Emergency of International Concern'.⁹ The WHO Emergency Committee has recommended a number of measures, including standardised and enhanced surveillance for microcephaly and GBS; and intensified research and data sharing to help determine whether there is a causative link between the Zika and microcephaly and neurologic disorders and other factors or co-factors. Further measures have been recommended to address Zika transmission, including enhanced surveillance in affected areas, better communication and information to promote vector (mosquito) control and reduce the risk of exposure to the virus, particularly among pregnant women and women of childbearing age, and counselling for pregnant women who have been exposed to the virus.¹⁰

General ethical considerations

The role of the state with respect to public health measures: a 'stewardship' approach

- Liberal states have a duty to look after important needs of people both individually and collectively. This includes providing conditions that enable people to live healthy lives; ensuring that people have appropriate access to medical services; reducing unfair health inequalities; and taking action to protect and promote population health and respond to public health threats such as outbreaks of infectious disease.

- At the same time, public health programmes should seek to minimise interventions that are introduced without individual consent, or without procedural justice arrangements (such as democratic decision-making); or that are perceived as unduly intrusive or in conflict with important personal values.

Justifying interventions and proportionality

- An ‘intervention ladder’ of possible policy actions provides a framework for thinking about the acceptability and justification for different public health policies.¹¹ The ‘rungs’ of the ladder start with ‘do nothing or simply monitor the situation’, and then move through providing information, enabling or guiding choice, restricting choice, and ultimately eliminating choice altogether. In the context of infectious disease control, the rungs would include:

- providing reliable information about the risks and what people can do to protect themselves
- enabling choice by ensuring people have access to preventative measures (such as bednets and repellent) and appropriate health services
- restricting choice by requiring spraying of aircraft
- eliminating choice in the compulsory collection of data, through compulsory access to private property for mosquito control, or the release of GM mosquitoes

- Choice of policy should be *proportionate*: the least intrusive measure that will achieve the desired aim should be preferred. The more intrusive the approach, the greater the justification required. Doing nothing is also an active policy choice.

Eliminate choice / compulsory intervention
Restrict choice
Guide choice, for example through incentives or disincentives
Enable choice
Provide information
Do nothing or simply monitor the situation

The importance of good evidence

- A key issue in determining whether some degree of intrusion on the part of the state can be justified will be the quality of the relevant evidence: both as to the cause and severity of the public health threat, and the effectiveness of the proposed intervention. The more intrusive the proposed policy, the greater the need for robust evidence that what is being proposed is likely to achieve its desired aim.
- The nature and extent of the risk involved will also be critical in determining what public health interventions are appropriate. Policy-makers need to take account not only of the scientific assessment of the risks posed by a particular public health threat, but also of people's perceptions of those risks, which will influence public acceptability of proposed interventions. The media, campaigning groups, and other stakeholders all have a role to play with respect to the fair and accurate presentation of evidence for or against particular health risks.

- Information shared through social media is likely to be increasingly influential in shaping public attitudes both to the risk posed by a public health threat, and the acceptability of possible interventions. Consistent public health messages, based on the best available evidence, and regular media briefings from trusted sources, will be important in counterbalancing inaccurate information and hype that are also likely to circulate on social media.

Public ethics and promoting public trust

- In times of urgency, such as may arise in the emergence of an epidemic of serious infectious disease, states and international organisations may need to make decisions in the absence of high quality evidence (recognising that 'doing nothing' is also a policy action that needs to be justified). In such cases the way in which decisions about public health policies are taken, and the extent to which relevant communities are engaged in 'public decision-making' become particularly important.
- Decisions about potentially intrusive public health measures are most likely to gain public acceptance where they are made in an open and inclusive manner; where there are clear lines of accountability; where reasoning is clear and explicit; where uncertainties are frankly acknowledged; where alternative approaches are recognised and debated; and where there is a commitment to ongoing research to improve the evidence base and reduce uncertainty.
- Early public engagement, allowing for consideration of the interests of all potentially concerned to be recognised, can play an important part in building such public trust. Social media has a potentially powerful role to play in enabling diverse public voices to be heard, and in creating a sense of solidarity between people who would not otherwise have come into contact.

Ethical considerations in the context of the current Zika virus

Surveillance and data sharing

- The WHO has highlighted the importance of standardised and enhanced surveillance, with respect both to Zika infections, and to possible links between the virus, microcephaly and GBS. Such surveillance will play a critical role in improving the evidence base, and informing future decisions with respect both to proportionate public health interventions, and to the development where necessary of appropriate health services.
- Data for this kind of surveillance are usually collected anonymously, or can subsequently be de-identified. However, it is increasingly the case that de-identification of patient information cannot guarantee permanent anonymity. Seeking individual consent for the collection and use of such information could, on the other hand, undermine the purpose of the surveillance (refusal of consent leading to inadequate data coverage), and would also be administratively challenging.
- Collection and use of information in these circumstances without the need for individual consent can be justified ethically on the grounds of the public interest, if carried out in an appropriate manner. This would include adequate measures being

taken to respect the private interests at stake, and trustworthy governance systems put in place.¹²

- Outbreaks of infectious disease are highly likely to cross national boundaries, and states have a duty to cooperate with others that are, or may be, affected by an outbreak, particularly with respect to sharing information. International organisations have an important role to play in facilitating such cooperation, for example through supporting surveillance capacity in poorer countries, and ensuring the establishment of a secure bioresource that will enable researchers worldwide to access the virus and contribute to research on prevention and treatment.

Public engagement and communication

- States should ensure that their populations have access to clear up-to-date information with respect to: what is known about the incidence and prevalence of Zika in their area; the potential link with microcephaly and GBS (acknowledging current uncertainties in the evidence); actions that individuals, particularly women who are or may become pregnant, can take to protect themselves against infection; and the public health interventions that are potentially available. Early public engagement with respect to choice of possible public health interventions, particularly where these may be perceived as intrusive, will be important in developing policies that are publicly acceptable, and in avoiding the loss of public trust.
- Pregnant women who have been infected with Zika should have equitable access to counselling and support.

Research into vaccines and treatments

- The recent epidemic of the Ebola virus disease highlighted the critical importance of sensitivity to local conditions on the part of international researchers, and the creation of trusting relationships with local communities. Appropriate study design needs to take into account both the necessary scientific rigour and an understanding of what is locally acceptable, particularly in the absence of any effective standard treatments and widespread anxiety about the consequences of infection.
- Considerable work has been done on the scope for flexible, adaptive study designs in circumstances where individually randomised controlled trials with a control comparator may not be acceptable to the local community.¹³ Early discussion and collaboration with local research ethics committees will maximise the possibility of speedy consideration of innovative trial designs. Where necessary, local research ethics committees should be able to call on international support. This might include local committees commissioning preparatory work from other countries or requesting advice or personnel to enhance local capacity.

Approaches to mosquito control: traditional measures

- Existing measures for eliminating the mosquitoes responsible for transmitting Zika include spraying with insecticides, and eliminating breeding sites through removing or covering standing water. Such measures may be highly intrusive, for example through requiring access to private property to identify and deal with breeding sites in buckets

or water butts. However, as in the case of data collection for surveillance purposes, it will be difficult to rely on individual consent from those concerned, either because the intervention by its nature is communal (such as spraying public areas), or because the risks of inadequate elimination of mosquitoes and/or breeding sites (if access to private property is refused) affect the security of others.

- Key factors in determining the ethical acceptability of such interventions will thus be the strength of evidence as to their effectiveness; public attitudes to the necessity of implementing them (drawing, for example, on public engagement exploring these and any potential alternative interventions), and the extent to which it is possible to minimise intrusion.
- The particular challenges of removing mosquito breeding sites in areas lacking a public water supply (where households have to make their own arrangements to store water) highlight the critical role that has been played by the provision of public health infrastructures such as piped water and drainage.
- The requirement that any response to public health threats be proportionate applies equally to action taken internationally. It is important that inappropriate travel restrictions are not imposed and that stigma against people from affected countries is challenged.¹⁴

Approaches to mosquito control: use of genetically modified (GM) insects

- There is considerable current interest in the scope for GM insects as a means of controlling mosquitoes and hence disease. British biotechnology company Oxitec has approval from Brazil's National Biosafety Committee (CTNBio) for releases of "self-limiting mosquitoes whose offspring will not survive" throughout the country, and began releasing modified aedes mosquitoes in Piracicaba's CECAP/Eldorado district in April 2015. In January 2016, Oxitec confirmed an expansion of their project and initiation of a new "mosquito production facility".¹⁵
- It is critically important that innovations such as the development of GM mosquitoes, that are likely to generate substantial public interest, should be considered alongside other possible research pathways, including alternative ways of responding to Zika, and in accordance with broader social values. Public and community engagement provide an important way of exploring and evaluating these values and their implications for acceptable means of response.

Maintaining a proportionate response

- Policy-makers have a duty to ensure that the surveillance and protection methods they recommend or implement are proportionate. International organisations and states should ensure that they keep policies under regular review, in the light of emerging evidence both as to their effectiveness and to the degree of intrusiveness experienced by those whom they affect.

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- 12 See the 'ethical principles for data initiatives' set out in Nuffield Council on Bioethics (2015) *The collection, linking and use of data in biomedical research and health care: ethical issues*.
- 13 WHO (2014) *Ethical issues related to study design for trials on therapeutics for Ebola Virus Disease*, <http://www.who.int/csr/resources/publications/ebola/ethical-evd-therapeutics/en/>.
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