

Ethics in epidemics, emergencies and disasters: Research, surveillance and patient care

Training manual



World Health
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Ethics in epidemics, emergencies
and disasters:
research, surveillance and patient care
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The document contains educational material; it is not intended to provide normative guidance and should not be misconstrued as doing so. It is expected that it will be revised in the light of lessons learnt in the fight against Ebola virus disease and other emergencies. For any comments to improve the document in future iterations, please contact: ct_ethics@who.int

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Cover photo: Camp residents line up to be relocated. United Nations mission in Haiti (MINUSTAH) peacekeepers and members of International Organization of Migration (IOM) helped relocate 1800 persons from a camp for people displaced in the January earthquake to a more secure location ahead of the arrival of tropical storm Tomas.

Photo: UN/MINUSTAH/Logan Abassi

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Introduction

Epidemics, emergencies and disasters raise many ethical issues for the people involved, who include responders, public health specialists and policy-makers. This training manual provides material on ethical issues in research, surveillance and patient care in these difficult contexts, as well as related issues to reduce risks before, during and after events.

The idea for this manual can be traced back to a WHO technical consultation on *Research ethics in international epidemic response* (World Health Organization, 2010). In the resulting report, the experts took positions on three main issues. First, they asserted that “the principles and values embodied in international and national ethics guidelines, as well as human rights instruments, must be upheld” (p. 7) in the conduct of research in epidemic response. Secondly, they expressed reluctance to ground the need for ethical oversight on the classical distinction between health practice and research (i.e. the primary intent of the activity), recognizing that such a distinction easily becomes blurred during emergencies. Thirdly, the experts considered a number of adaptations of ethical oversight and processes, focusing on the deliberations of research ethics committees. Other issues were more directly related to surveillance and patient care during emergencies. The technical consultation reaffirmed the importance of addressing the conflicts among various ethical considerations during research, surveillance and patient care in emergencies, including access to standards of care, confidentiality, the duty to care, fairness, informed consent, liberty, moral relativism and privacy.

In the face of recent pandemic threats (severe acute respiratory syndrome (SARS), avian influenza A H5N1, pandemic influenza A H1N1 and the 2014 Ebola virus disease outbreak) and other emergencies and disasters in general, debate has arisen about the ethical basis of research, surveillance and patient care in such situations. Scholarship on the ethics of emergencies with public health consequences draws on various areas, including clinical practice and research. Since 2000, ethical principles specifically for public health have been formulated within similar but distinct frameworks (Kass, 2001; Childress et al., 2002; ten Have et al., 2010; Petrini, 2010).

The International Health Regulations (IHR) is a legally-binding agreement for the coordination of the management of events that may constitute a public health emergency of international concern, and will improve the capacity of all countries to detect, assess, notify and respond to public health threats. But on many other normative aspects of research, surveillance and patient care in emergencies, consensus has not yet been achieved. The aim of this training manual is to give participants a certain proficiency in ethical reasoning and awareness of the main ethical dilemmas that can arise in emergencies. The editors and contributors followed the advice of the WHO technical consultation: not to preclude the development of training resources such as this because of the lack of international consensus on several issues.

A number of considerations had to be kept in mind during preparation of the manual; understanding these might help readers to navigate the document.

Definitions of emergency usually convey the need for immediate, non-routine, coordinated action. A disaster is defined by the United Nations Office for Disaster Risk Reduction as a “serious disruption of the functioning of a community or a society involving widespread human, material, economic or environmental losses and impacts, which exceeds the ability of the affected community or society to cope using its own resources”. While quantitative measures, such as thresholds of casualties or daily mortality rates, may also apply, for the purpose of this manual (and for framing ethical issues), it may be useful to consider that definitions of emergencies and disasters make reference to the capacity of the affected community or the resources available to the health community to cope with the situation. In this manual, we use the terms “emergencies” and “disasters” to cover a broad range of events that may have public health consequences on varying scales, as well as other social, economic and environmental effects, and in which the systems and the availability of resources are often tested.

It is important to keep in mind that emergencies and disasters are the result of interactions between hazards and community elements, including people's health, with differing vulnerability and capacity to cope with situations. The vulnerability, capacity and overall resilience of countries and their systems, communities and sub-populations define how well they will manage risks and determine the scale of an emergency. Emergencies and disasters can be due to natural hazards (including epidemics, hydro-meteorological and geological hazards) and human-induced hazards (including technological hazards, conflicts, food insecurity and social unrest). The requirements of the community for patient care and for research and surveillance vary case by case and are influenced by how risks are managed before, during and after events and by the type and magnitude of the consequences of emergencies when they occur.

How to use this manual

The training manual has two parts. Part 1 covers ethical issues in research and surveillance, such as conflicts that might arise between the common good and individual autonomy, ethics oversight and publication ethics. Part 2 covers patient care, including triage, standards of care and the professional duties of health care workers in emergencies.

The teaching resources are modular, comprising seven core competences and 26 learning objectives, each with a dedicated module. The modules are based on various types of instruction and activities (e.g. case study, lecture, group discussion, role play, video) to meet the learning objective. Slide sets were prepared for the lectures under each learning objective and summary slide sets for each core competence. At the end of the manual, you will find a compilation of all of the case studies used throughout the manual. They are available at this website: <http://www.who.int/ethics/topics/outbreaks-emergencies/en/>

In general, the division by learning objectives should allow course facilitators to select the appropriate modules for the level of proficiency, the available time and the training needs of their participants. Facilitators should not feel that they must follow the order in which the modules are presented in this manual. For example, the material under core competence 7 could be a good starting point for audiences comprising mainly health care professionals. Targeted users who might benefit from the material in this manual include field epidemiologists, first responders, public health practitioners, researchers and policy-makers.

Although ideally facilitators would be trained in ethics, non-experts could also use this material to facilitate discussions and learning. In such cases, the further reading sections will offer helpful assistance.



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Overview: Ethics in epidemics, emergencies and disasters



Session timeline (90 min)

0–30 min (30 min)	31–45 min (15 min)	41–80 min (40 min)	81–90 min (10 min)
Plenary presentation	Open discussion	Group activity	Summary and conclusion
		Group work Presentation	



Instruction strategy

For facilitators: This session provides an overview of the material in the manual; only some aspects are covered and only superficially. In training sessions for which time is limited, only the plenary part of the session can be given, which will take approximately 45 min. When more time is available, the group activity can be added, bringing the session to approximately 90 min.

1. The facilitator introduces the module and gives a plenary presentation on ethics and public health emergencies, using the slides provided.

For facilitators: Make sure to familiarize yourself with the content of the entire training manual before teaching this session. The explanation of each concept presented in the slides is provided in the corresponding module.

2. The facilitator opens the floor for questions from participants.

For facilitators: If the participants have no questions, you can ask volunteers to describe an emergency situation in which they might have to collect data. Ask them to describe some of the issues they find difficult, and invite feedback from the rest of the group. Alternatively, ask participants the questions proposed in the “Instruction strategy” sections of the subsequent learning objectives.

3. The facilitator separates the participants into two groups and gives each group one of the case studies (30 min).
 - One group is asked to draft guidelines for prioritizing access to intravenous fluid sets, taking into consideration the ethical issues discussed in the overview.
 - The other group is asked to outline the study design for addressing the ethical issues raised in the overview.
4. The facilitator invites a rapporteur from each group to explain the consensus reached by the group regarding the ethical issues raised by the case study.
5. The facilitator opens the floor for discussion and then concludes the session.



Case study¹

Group 1: Allocation of intravenous fluids during an outbreak of viral haemorrhagic fever

A deadly form of viral haemorrhagic fever has struck your community. The signs and symptoms of the disease include high fever and increased susceptibility to bleeding. Manifestations in confirmed cases include low blood pressure (hypotension), shock, vomiting and diarrhoea.

The capacity for laboratory diagnosis in your community is limited. The cause of the illness of some of the patients admitted to your health care centre is, however, obvious: they have advanced symptoms, such as excessive bleeding, high fever and shock. The diagnosis for other patients is less certain, as suspicion is based mainly on contact history and more general symptoms. In view of the extent of the on-going outbreak, your health care centre is overwhelmed with work.

Supportive care for patients is very limited, due to lack of resources. Although intravenous fluid therapy is known to be useful in viral haemorrhagic fever to ensure adequate hydration while the immune system combats the virus, your health care centre has insufficient intravenous sets to meet the growing demand, including for patients with other diseases. In addition to supportive care and intravenous fluid therapy, you learn that the Ministry of Health has managed to secure access to a very limited amount of treatment with an experimental medication. The quantities of this experimental treatment are so limited that you expect that only about 2% of the patients at your health care centre could be given it, should you decide to do so.

As nurses trained in epidemiology and ethics, you have been asked to prepare for a meeting on setting guidelines for care during the outbreak. You must consider how you will prioritize access to intravenous fluids and decide whether you will offer the unapproved treatment. If you do, you must decide how to allocate the limited stocks. One of your concerns is to ensure that the allocation of resources demonstrates a high level of ethical consideration.

Prepare a statement explaining your preliminary basis for allocating resources. Make sure that you justify your responses in the language of ethics.

For facilitators: If the group appears to bog down during the activity, you could ask them to reflect on some of the following questions:

- Who would you like to see sitting at the decision-making table with you, and how should decisions be taken?
- Will you provide the experimental treatment?
 - If so, will patients who receive the treatment also be eligible for intravenous fluids?
 - If so, how will you determine which patients of those receiving the treatment will also receive intravenous fluids?

¹ These case studies were developed by Renaud Boulanger and Selena Knight.

- Will you take into consideration the demographic characteristics of the patients (e.g. age, health care professional) in allocating treatment?
 - If so, will the demographic characteristics used be different for access to intravenous fluids and to the treatment (if you grant access)?
- Will you use the concept of “need” in allocating resources? If so,
 - Will you allow for consideration of how sick the patient is?
 - Will you allow for consideration of how likely the patient is to survive?
 - Will you allow for consideration of evolving needs? If so, how will this be done?
 - In the case of intravenous fluids, will you allow for consideration of whether the patient was already receiving care before implementation of the allocation policy?
- What obligations does the health care centre have to patients who are not given intravenous fluids and/or the experimental treatment?
- Will you allow patients who are not given access to treatment (e.g. an experimental drug) to challenge the decision?
 - If so, what process will be established for reviewing challenges?
- Should the allocation policy be communicated to patients, families and the broader community?
 - If so, how?
- Other considerations

Group 2: Conducting a clinical trial during an outbreak of haemorrhagic fever

A deadly form of viral haemorrhagic fever has struck your community. The signs and symptoms of the disease include high fever and greater susceptibility to bleeding. Manifestations in confirmed cases include low blood pressure (hypotension), shock, vomiting and diarrhoea.

The laboratory diagnostic capacity in your community is limited. The cause of the illness of some of the patients admitted to your health care centre is, however, obvious: they have advanced symptoms, such as excessive bleeding, high fever and shock. The diagnosis for other patients is less certain, as suspicion is based mainly on contact history and more general symptoms. In view of the extent of the on-going outbreak, your health care centre is overwhelmed with work.

A few private firms and public organizations have rapidly come together to propose a clinical trial of an antiviral drug that has been under development for a few years. Laboratory studies have shown good activity of the drug against the virus that is affecting your community, but, while the safety and efficacy of

the drug has been demonstrated in animals, no studies have yet been performed in humans. The proposal is to test the drug immediately for efficacy in humans.

Your health care centre is approached by the consortium and asked to act as a centre for a clinical trial of the experimental drug. They have requested your input as a potential co-investigator on the issues that should be discussed in the study protocol. Your understanding is that, although the number of doses currently available is very limited, manufacturing capacity could be rapidly scaled-up.

For facilitators: If the group appears to bog down during the activity, you might ask them to reflect on some of the following questions:

- What additional information might you want about the drug or research before your discussions?
 - What research designs would you consider? What methodological issues might you take into account?
 - Who will benefit from this study, and what benefits will they receive? Who may be harmed by this research and how?
 - How might you consider recruiting patients into the trial?
 - What other information should be given to the participants when seeking their informed consent?
 - What contextual factors might affect the ability of patients to provide informed consent? What provisions and adaptations might have to be considered to account for those factors?
 - How should the contextual factors be taken into consideration to ensure that the research is carried out efficiently?
 - How might the trial affect patients who do not participate, either through choice or because they are ineligible? How might any detrimental impacts be minimized?
 - What impact should the study be permitted to have on the role and duties of the health care personnel working at your centre? Should the impact be communicated to patients and the community and, if so, how?
 - How will challenges that arise from the dual role of health care personnel and researcher be dealt with?
 - How will the findings be disseminated?
 - What are the consortium's responsibilities towards trial participants and your community at the end of the trial?
 - How should you communicate with the community about the study?
-

Research and surveillance

**Core competence 1:
Ability to analyse the boundaries
between public health
practice, including surveillance,
and research and their ethical
implications in emergencies**



Core competence 1: Ability to analyse the boundaries between public health practice, including surveillance, and research and their ethical implications in public health emergencies

The criterion still predominantly used to determine whether ethics oversight of public health activities is needed is a distinction between the definitions of public health practice and research. The use of this criterion requires clarity about the scope of activity of each of these enterprises. Such considerations are addressed under learning objectives 1.1 and 1.2. Although experts are gradually moving towards a risk-based approach to ethics oversight and away from an approach that is based on a more arbitrary distinction between practice and research, mainstream normative instruments are still based on this traditional distinction. In learning objective 1.3, the core issues addressed by these mainstream instruments are clarified, while learning objective 1.4 highlights some of the shortcomings and controversies of the mainstream instruments before pointing to a risk-based alternative.



Learning objectives

- 1.1 Distinguish between public health surveillance and public health research.
 - 1.2 Identify the scope of activities that could qualify as “research” during emergency response and would normally require research ethics review.
 - 1.3 Demonstrate understanding of the ethical principles and requirements addressed in current normative instruments relative to research and surveillance in emergencies
 - 1.4 Identify the shortcomings of current normative instruments for use in emergency situations, and evaluate alternatives.
-

Learning objective 1.1: Distinguish between public health surveillance and public health research.

Michael J. Selgelid



Session timeline (60 min)

0–15 min (15 min)	16–20 min (5 min)	21–40 min (20 min)	41–55 min (15 min)	56–60 min (5 min)
Introduction	Reading	Team preparation	Team presentations and discussion	Summary and conclusion



Instruction strategy

1. The facilitator begins the session by presenting a general overview of the issue, using the slides provided as a guide.

For facilitators: Include a brief group discussion of the questions raised on the slides. See: <http://www.who.int/ethics/topics/outbreaks-emergencies/en/>.

2. The facilitator distributes scenarios (see Case studies, below) and gives participants 5 min to read them.
3. The facilitator forms the group into three teams and assigns a scenario to each.
4. The facilitator gives the teams 10–15 min to discuss their assigned scenario.
5. When the group reconvenes, the facilitator asks each team to appoint a rapporteur to:
 - summarize the team's response to each question and
 - explain the role, if any, of the distinction between research and surveillance in the team's deliberations.

For facilitators: Throughout the discussion, take notes on a flip chart of areas of consensus and of disagreement.

6. The facilitator returns to the last slide of the set and prompts further group discussion in light of the scenario discussions.
7. The facilitator summarizes the session and opens the floor for final comments.



A. Background

Since 1920, public health has been defined as “the science and art of preventing disease, prolonging life, and promoting health through the organized efforts and informed choices of society, organizations, public and private, communities, and individuals” (Winslow, 1920). Of the various public health activities (which include educational programmes and policies and the administration and regulation of health systems and services), surveillance, often referred to as the “eyes of public health” (Fairchild et al., 2007), is widely considered to be a crucial part of public health practice. Surveillance provides information about disease incidence and prevalence, the distribution of disease, outbreaks of disease and changes in disease burden over time. It thereby sheds light on the status of emerging or existing health problems and informs decision-making on appropriate control measures. It is thus an especially important public health activity (Selgelid, 2014).

Surveillance is related to research in various ways: both can involve studies or investigations, both sometimes involve the same activities (e.g. medical record review, data mining) and both often involve human subjects. As distinguishing public health practice from research may thus be especially difficult in the case of surveillance, this module focuses on the distinction between research and surveillance in particular.²

The United States (US) Centers for Disease Control and Prevention (CDC) (2010) defines public health surveillance as “a series of ongoing systematic activities, including collection, analysis, and interpretation of health-related data essential to planning, implementing, and evaluating public health practice closely integrated to the dissemination of data to those who need to know and linked to prevention and control”. Despite similarities between research and surveillance, the ethical requirements of surveillance are generally considered to be different from those that govern human research. Informed consent, for example, is a basic tenet of research ethics but is often considered unnecessary in the context of public health surveillance.³

Research ethics—the study of the ethical issues associated with biomedical research—is one the best-developed areas of bioethics. An enormous amount has been written about the ethical conduct of research involving human subjects, and well-established principles, guidelines and oversight mechanisms (e.g. research ethics committees) now govern it. Conversely, standard, general, international guidelines and oversight mechanisms for the ethical conduct of surveillance are lacking (Selgelid, 2014).

As the ethical regulation of research and surveillance differ significantly, questions about the technical and moral differences between research and surveillance are crucial. Such questions are explored in this module.

2 Similar issues may arise in the context of quality assurance, health systems research, implementation research and operational research; this point could be raised during the discussion.

3 See learning objective 3.2. It has even been claimed that informed consent is at odds with the goals of surveillance (Verity, Nicoll, 2002). If informed consent were required before identifiable reporting could be conducted, for example, it might be difficult (or impossible) to accurately estimate the incidence and/or prevalence of diseases. This, in turn, could lead to inadequate implementation of control measures, ultimately jeopardizing population health.



B. Topics⁴

How should research and surveillance be distinguished?

The relation between research and surveillance is complicated: the same kinds of activities—for example, data mining and medical record review—are sometimes considered to be research and sometimes to be surveillance. Furthermore, according to the CDC (2010), some surveillance systems constitute research.

This raises the question of the technical distinction between research and surveillance and public health practice more generally. This is not merely an academic question; it is an especially important question for those who conduct both research and surveillance, because a method is required to distinguish one from the other in order to ensure adherence to research ethics regulations.

The CDC (2010) distinguishes research from non-research in public health on the basis of the primary *intent* or *purpose* of the activity in question. While the distinguishing feature of research, according to the CDC, is the “purpose... to generate or contribute to generalizable knowledge”, the distinguishing feature of (relevant) non-research activities is the “purpose... to prevent or control disease or injury and improve health.”⁵ This formulation raises practical questions about how (primary) intentions can and should be determined and verified in practice and what should count as generalizable knowledge.⁶ The CDC distinction also raises the question of why the generalizability of knowledge should be considered ethically crucial. In other words, why should the pursuit of generalizable knowledge require adherence to special ethical principles (Rubel, 2012)? Another difficulty with the CDC distinction is that the aim of much prototypical research (i.e. clinical experimentation) is to generate generalizable knowledge *precisely in order to reduce disease and improve health* (Selgelid, 2014). Reduction of disease and improvement of health thus appear to be the primary intentions of research in such cases. This leads to the paradoxical conclusion that much prototypical research should in fact be considered surveillance, i.e. public health practice that is non-research. A better method for distinguishing research from practice might thus be needed, but it is not obvious what that method should be.⁷

What, if any, are the morally relevant differences between research and surveillance?

Even if a compelling distinction could be made between research and public health surveillance (and public health practice more generally), a second, more troubling question is: What, if any, are the morally relevant differences between the two, such that the ethical requirements for surveillance should be different from (or weaker than) those that apply to research? The ethical requirements for surveillance and research are currently very different in practice (e.g. in the case of informed consent); but why should this be the case?

4 This section is based on Selgelid (2014).

5 We focus here on the distinction between surveillance and research proposed by the CDC, because (despite the concerns raised below) it is especially well developed and influential.

6 Generalizability of knowledge might be a matter of *degree* rather than “either-or”.

7 One possibility might be a distinction based on the activities involved rather than intentions or purposes, but this might likewise lead to paradoxical conclusions. Another possibility might be to give up the idea of drawing a sharp boundary between research and surveillance (and thus public health practice) by recognizing a possible continuous spectrum between the two; i.e., rather than asking whether an activity is research or surveillance, we might consider *the degree to which* it is one or the other, which might depend on the degree to which the aims include producing generalizable knowledge and/or reducing disease and improving health. These and other possible methods of distinguishing research from surveillance could be raised in discussion.

As suggested above, both clinical research and public health surveillance generally involve studies or investigations for generating information that will be used to improve health. The morally relevant difference between the two kinds of activity is therefore not obvious (World Health Organization, 2010). It could be argued that the morally relevant factors for an activity, whether research or surveillance (as part of public health practice), are the extent to which subjects' interests and/or rights are threatened and the magnitude of the public health benefit expected to result from the activity (Selgelid, 2014). If like cases should be treated alike, then any two activities that are exactly the same in these two respects should arguably be subjected to the same constraints, regardless of whether one is research and the other is surveillance (or "practice") (Selgelid, 2014).



C. Case studies⁸

Outbreak of Ebola haemorrhagic fever in central Africa

Scenario 1

You are a clinician assigned to the care of patients in the isolation ward of a general hospital, in a country in which where an outbreak of Ebola haemorrhagic fever is under way. Some cases are obvious (bleeding, terminal stage), while others are unclear and suspicion is based largely on contact history. You are overwhelmed with work.

Questions for discussion

1. An epidemiologist asks you to take one blood sample from each patient, for diagnostic purposes. How would you react (and how is the research–practice distinction relevant to your decision)?
2. The same epidemiologist indicates that optimal calibration of the newest diagnostic test requires taking daily blood samples from all patients until their discharge. How would you react (and how is the research–practice distinction relevant to your decision)?
3. The same epidemiologist indicates that optimal calibration of the newest diagnostic test requires taking daily saliva swabs from all patients until their discharge. How would you react (and how is the research–practice distinction relevant to your decision)?
4. A renowned scientist (also a member of the outbreak response team) claims that development of potentially useful immunotherapeutic agents requires taking bone-marrow aspirates from all convalescing patients. How would you react (and how is the research–practice distinction relevant to your decision)?

Scenario 2

A researcher tries to convince you that the outbreak presented in scenario 1 is a unique opportunity for testing recombinant anticoagulant protein C as a potentially life-saving intervention. There is no established national research ethics committee. Obtaining informed consent is highly problematic: many patients are

⁸ These case studies were provided by Philippe Calain.

disoriented and/or speak only a local language, and you find it very difficult to communicate through heavy protective equipment.

Question for discussion: How would you proceed (and how is the research–practice distinction relevant to your decision)?

Scenario 3

You are a clinician assigned to the care of patients in the isolation ward of a general hospital, in a country in which an outbreak of Ebola haemorrhagic fever is under way. You consider that information on the mechanism of the disease is desperately needed in order to manage cases better and to lower the mortality rate. There is no laboratory on site. You thus feel compelled to perform a number of limited autopsies; however, rumours are circulating in the community about the motivations of rescue teams. Seeking consent from relatives might lead to misperceptions, which could put international teams at risk.

Question for discussion: How would you proceed (and how is the research–practice distinction relevant to your decision)?



D. Summary

Public health surveillance is widely considered to be a fundamental part of public health practice. Although surveillance (and thus public health practice) is often similar to research in terms of both means and goals, most jurisdictions continue to treat these two kinds of activity very differently with regard to ethical requirements. For example, while informed consent is a basic tenet of research ethics, it is often considered unnecessary in the context of public health surveillance. Although guidelines for research ethics are well established, standard general guidelines for public health surveillance ethics are lacking. The development of such guidelines will require further thought about the technical distinction between research and surveillance (and public health practice more generally) and the morally relevant differences, if any, between the two. In the meantime, when in doubt, project managers and researchers should seek the advice of ethics committees on how to proceed.



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Learning objective 1.2: Identify the scope of activities that could qualify as “research” during emergency response and would normally require research ethics review.

Renaud F. Boulanger and Matthew R. Hunt



Session timeline (85 min)

0–30 min (30 min)	31–50 min (20 min)	51–75 min (25 min)	76–90 min (15 min)
Introduction and small slide presentation	Team preparation	Team presentations and discussion	Summary and conclusion



Instruction strategy

- The facilitator introduces the module and provides a brief background on research ethics committees, using the slides. See: <http://www.who.int/ethics/topics/outbreaks-emergencies/en/>.
- The facilitator distributes a copy of “Research ethics must still apply in disaster zones” (Sumathipala, 2008) to all participants.
- For the small group exercise, the facilitator follows the following steps:
 - Divide the participants into teams of three or four.
 - Distribute to each team a paper on which is written either a type of research or a type of public health practice (e.g. surveillance, quality improvement, programme evaluation). Ask the teams not to reveal the type of activity they have been assigned to the other teams.
 - Present the emergency scenario on which the exercise will be based (see slides).
 - Ask each team to design a project of the type of activity they have been assigned and to outline:
 - the issue or problem,
 - the population and sampling and
 - the methods used to collect data.
 - Choose a representative of each team to present to the larger group the activity they have planned, without stating whether it is a research or a public health project.
 - Facilitate discussion in the larger group about:
 - whether the planned activity is research or public health practice;
 - why this type of data collection might be needed during an emergency;
 - whether the planned activity would normally require research ethics review; and
 - the main ethical issues that might be raised by the project.
- The facilitator opens the floor for discussion and final remarks.



A. Background

An important implication of the distinction between public health practice and research is that the latter is generally subject to independent ethics review (see Core competence 2 on the standards and expectations of ethics review). Since issuance of the Nuremberg Code in 1947, hundreds of documents have been prepared to guide the ethical conduct of research with humans (Office for Human Research Protections, 2012), including the well-known *Declaration of Helsinki* and the *International ethical guidelines for biomedical research involving human subjects* (see learning objective 1.3). These documents, which were prepared by various government bodies, professional organizations and agencies working at local, national or international level, generally concur that an independent body should review a research protocol before its implementation, to ensure that it meets ethical standards (World Health Organization, 2011). Such bodies, known as a research ethics committee (also called institutional review boards), usually comprise individuals with scientific expertise, individuals with legal and ethical expertise and lay people whose primary background is not in research with human participants, to increase the social accountability of the research enterprise. The role of the committee is to review all research with human participants and, in some cases, with human biological materials. The criteria for determining whether activities qualify as research do not usually change when they are being carried out during an emergency. (See learning objective 1.1 for a definition of research and the distinction from public health practice.)

As discussed under Core competence 2, specific categories of research may be subject to expedited review or be exempted from ethics review altogether. The level of review required is proportionate to the risks associated with the research; that is, the riskier the research, the greater the degree of scrutiny it will receive. Studies that involve more than minimal risk typically require full review by a research ethics committee, and international and national guidelines require that strict conditions be met for research to be exempted from ethics review. The level of review required will also be considered according to the vulnerability of the research participants. Procedures for ethics review may, however, be adjusted to facilitate the process during emergencies, in order to ensure timely research while maintaining the diligence of the review (Canadian Institutes of Health Research et al., 2010).



B. Topics

Research topics

Some priorities for research in the context of disasters and epidemics, particularly in low-resource settings, include health service management, mental health, nutrition, communicable diseases and information management (World Health Organization, 1997). Other topics of interest to public health researchers include the impact or effectiveness of aid measures, assessments of needs and health, the usefulness of new research instruments and scales and macro-analysis of the impacts of emergencies on governance structures and finance systems (Hunt et al., 2012).

Many designs can be used to study each of these potential areas, from intervention studies, such as clinical trials, to observational studies or naturalistic observations. The methods include a variety of both quantitative (e.g. surveys) and qualitative approaches (e.g. ethnographic studies).

Types of research

- Basic science research: research that is laboratory-based, such as testing of human biological materials. An example might be investigation of a genetic variant that confers vulnerability to an agent that is causing an epidemic (Chan et al., 2007).
- Clinical research: research in which participants (individuals or groups) are prospectively assigned to a health intervention, from drugs and biological products to devices and preventive programmes. An example of clinical research would be a clinical trial of therapy for disaster survivors (National Institutes of Health, 2013).
- Health services and health systems research: research concerned mainly with the administrative and social aspects of health and health care, including financial aspects. An example of a health services research project would be an investigation of the impact of dealing with an epidemic on hospital performance (Chu et al., 2008).
- Population-based research: research on individuals in a wider context, which includes epidemiological and cohort studies and investigations of the impact of social determinants of health. An example of population-based research would be a study of the health outcomes of children who lived through a disaster (Zheng et al., 2012).
- Policy and advocacy research: research on how evidence can best be transformed into practice and used to improve public health. A question for this type of research might be: “Can social media be used to improve disaster preparedness?” (Merchant et al., 2011).

Studies of each type could be conducted in the context of managing the risk of emergencies; however, some study types might be less pertinent during the response to emergencies. For instance, it is unlikely that it would be feasible or appropriate to conduct a randomized controlled trial of an investigational product during an emergency. A number of study designs and methods for collecting data can be used for each of these types of research. For example, interviews could be useful for eliciting data for clinical research, health services research, population-based research or policy research. The research question rather than the type of research generally guides the choice of design and data collection method.



C. Summary

The scope of activities that can qualify as “research” is broad. Research must be distinguished from public health practice because most institutions require that research undergo independent ethics review. Currently, commentators tend to agree that the purpose (generating new knowledge) and the conditions (exposure to an intervention or increased risk) define research (Cash et al., 2009). The same criteria apply during epidemics or disasters, although the ethics review process might be different. The types of research activities that require ethics review during an epidemic or a disaster response might be limited more by the circumstances of the event than by rules about the types of research that can be conducted in those settings.



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Learning objective 1.3: Demonstrate understanding of the ethical principles and requirements addressed in current normative instruments relative to research and surveillance in emergencies.

Ghaiath Hussein



Session timeline (90 min)

0–15 min (15 min)	16–35 min (20 min)	36–50 min (15 min)	51–80 min (30 min)	81–90 min (10 min)
Introduction	Reading	Group discussion	Slide presentation on ethics guidelines	Discussion and conclusion



Instruction strategy

1. The facilitator introduces the learning objective (15 min).

For facilitators: Ask the participants if they had ever had to use a “research ethics guideline” in their practice or if they have heard of such documents. Then, ask them whether they know about experiments or other research projects in which participants were mistreated. Encourage them to discuss local examples.

2. The facilitator separates the group into two. The first is given a copy of “What makes clinical research ethical?” (Emanuel et al., 2000) and the second a copy of “What makes clinical research in developing countries ethical? The benchmarks of ethical research” (Emanuel et al., 2004).
3. The facilitator gives each group 20 min to read the article and to identify the main ethical issues or principles discussed and examples of application of those principles to their current practice (20 min).
4. The facilitator asks each group to discuss their answers (15 min).

For facilitators: “Fair subject selection” would correspond to an ethical principle of justice.

5. The facilitator outlines the main ethical issues covered by mainstream research ethics instruments (30 min).
6. The facilitator opens the floor for discussion and final remarks (10 min).



A. Background

Research, especially that which involves humans, raises a number of ethical issues, such as the protection of participants, respect for their right to be well informed about the research in which they are being invited to participate and assurance that their participation is voluntary. Other ethical considerations include the integrity of research, such as conflict of interests, and ethical issues related to the publication of research findings.

The field of research ethics has evolved over more than a century (Resnik, 2012). A key historical turning-point for research ethics was the Nuremberg trials, which led to the creation of the Nuremberg Code in 1947. The Code has played an important role in subsequent development of a series of documents that clarify the ethical standards that a research project must meet to be deemed acceptable. These documents are known as “research ethics guidelines”, which are designed as a source of ethical guidance for researchers and for committees that review research. These committees are known as “research ethics committees” in many parts of the world (Kent, 1997), “research ethics boards” in Canada (Turbes et al., 2002) and “institutional review boards” in the USA. These committees are usually formed of members with various professional and academic backgrounds and expertise and of lay members who represent the general community. Their main task is to review the study protocols submitted to them to assess whether they meet the ethical standards of research (see learning objective 2.1).

Different committees use different regulatory documents (e.g. guidelines, legislations and laws) to make their assessments. Notably, different countries have different regulations to regulate research within their territories. Thus, the legal status of the committees and whether the guidance they provide is legally binding differs among countries.

Some of the main research ethics instruments are described below. A detailed list of relevant regulatory documents is maintained by the US Department of Health and Human Services (2012). The brief introduction below gives the main guidelines and the issues that they address. Table 1 summarizes some of the “cross-cutting” issues listed in most guidelines and examples of the relevance of those principles to emergencies. These ethical standards are generally expected to be respected by all researchers, including those working during emergencies; however, it is becoming widely recognized that their application should perhaps reflect the context in which they are to be applied (see learning objective 2.3).

During emergencies, research can help public health practitioners to assess both the impact of the emergency and what is required to mitigate its impact. In addition, research can help public health practitioners to plan better for future interventions. Nevertheless, there are methodological and other differences between research and public health activities, including those conducted during emergencies. Some commentators and guidelines argue that ethics committees should use such differences to determine whether to review a proposed activity. It is not the purpose of this module to defend or argue against this proposition. Its focus is on the ethical requirements for research conducted on humans in the context of emergencies. These requirements are arguably applicable to other activities with the same main feature of research, such as collection of human data or of biological samples. Research on human subjects during emergencies, regardless of the definition of research, must meet the ethical standards for the conduct of research under other circumstances.

Table 1. Core ethical principles and issues covered by the main guidelines and examples of their application in emergencies

Ethical principle or issue	Definition ¹	Examples in emergencies	Examples of guidelines that address the ethical principle or issue
Respect for people's autonomy	The duty to respect people's ability to make decisions on issues related to their health and their body, if they are competent to make such decisions; and the duty to protect individuals with impaired or diminished autonomy	Obtaining informed consent from people affected by an emergency before their identifiable personal information or biological samples are collected and processed for research purposes	CIOMS, General principles Tri-Council Policy Statement, article 1.1 Belmont Report, Basic ethical principles
Informed consent	A process whereby potential research participants decide whether they want to participate in the proposed study after receiving information about it. The requirements for consent considered to be valid vary by guideline and regulation. In general, they agree that decisions must be made free from coercion, by a competent person who can understand the information given and appreciate the associated risks. The information given to the participant should be in a language and format suitable to the participant's ability to comprehend it.		CIOMS, General principles, guidelines 4–6 Declaration of Helsinki, privacy and confidentiality, articles 25–32 Tri-Council Policy Statement, Chapter 3, The consent process
Beneficence	The moral duty to pursue actions that promote the well-being of others and the ethical obligation to maximize benefit and to minimize harm	To benefit from and have access to a vaccine in a pandemic	CIOMS, General principles Belmont Report, Basic ethical principles
Non-maleficence	The moral duty not to cause harm to others through interventions	Vaccine trials should involve the fewest human subjects and the fewest tests on those subjects that will ensure scientifically valid data.	CIOMS, General principles Declaration of Helsinki, Risks, burdens and benefits (articles 16–18)
Justice	Primarily distributive justice, which requires equitable distribution of benefits and burdens, i.e. distribution such that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it	Collecting samples from citizens of a developing country affected by a pandemic in order to develop a vaccine rapidly and ensure that the vaccine is made fairly available locally	CIOMS, General principles, guidelines 10 and 12 Declaration of Helsinki, Risks, burdens and benefits, articles 16–18 Tri-Council Policy Statement, article 1.1 and Chapter 4, Fairness and equity in research participation

¹ These definitions are not universal. The author tried to capture the main, or the common, features of each concept. Different guidelines may have different definitions for each of these principles. Moreover, the literature on research ethics has different approaches and definitions. One comprehensive, simple-to-use resource that provides more information on these concepts is the *Stanford Encyclopedia of Philosophy* (Zalta, 2014).

Vulnerability	A status in which some people may struggle to protect their interests or be at greater risk of being exploited. This situation is usually linked to specific physical, financial, educational or social circumstances. Groups considered as vulnerable vary by guideline, but children, mentally and/or physically disabled individuals, prisoners, refugees, terminally ill patients and women are often cited as the prime vulnerable groups.	Targeting women and children for surveillance during emergencies without epidemiological or methodological justification	CIOMS, General principles, guidelines 13–16 Declaration of Helsinki, Vulnerable groups and individuals, articles 19 and 20 Common rule, subparts B, C and D Tri-Council Policy Statement, Chapter 9, Research involving the First Nations, Inuit and Métis peoples of Canada
Privacy	The right or expectation not to be interfered with or to be free from surveillance or, more generally, a moral right to be left alone. In practical terms, privacy is for instance concerned with the setting in which a person's health-related information is acquired.	Taking precautions to interview victims of an emergency in private places (i.e. where those not related to the study cannot see or hear them)	Tri-Council Policy Statement, Chapter 5, Privacy and confidentiality Declaration of Helsinki, Privacy and confidentiality, article 24
Confidentiality	The principle that ensures that identifiable information is kept out of reach of others. All identifiable information about individuals, whether recorded (written, computerized, visual, audio) or simply held in the memory of health professionals, is subject to the duty of confidentiality.	Ensuring that identifiable data from surveillance activities are secured and not accessible by irrelevant persons (e.g. locked in filing cabinets or in encrypted files)	CIOMS, Guideline 18, Safeguarding confidentiality Tri-Council Policy Statement, Chapter 5, Privacy and confidentiality



B. Topics

Benchmarks in the history of research ethics are described below.

Before the Nuremberg trials

Attempts to change the way in which research on humans is conducted have deep historical roots. In modern history, Edward Jenner, considered to be a pioneer of vaccination, became in 1798 one of the first researchers to require that “any subject is able to agree to take part without being forced or deceived” (Davies, 2007) p. 175). A century later, Walter Reed was the first researcher to give participants a written document that outlined the risks associated with participation in his experiments on yellow fever. Reed’s document is now widely considered to be the first “informed consent” form (Levine, 1996; Bazin, 2001).

The Nuremberg trials and the Nuremberg Code (1947)

At the end of the Second World War, judges from the Allied forces held a trial of Nazi doctors accused of war crimes because of the research they had conducted on prisoners held in concentration camps (Shuster, 1997). The chief prosecutor from the USA at this tribunal, Telford Taylor, and three physicians (Leo Alexander, Werner Leibbrand and Andrew Ivy) identified 10 features that they judged necessary to make research on humans ethical. Those principles have since been referred to as the “Nuremberg Code” (Anon., 1949).

Since 1947, research ethics guidelines and regulations have been continuously devised and updated, especially in countries in Europe and North America but also elsewhere. Guidelines are generally issued by national organizations (e.g. the Canadian Institutes of Health Research), international professional bodies (e.g. the World Medical Association), United Nations agencies (e.g. WHO, the United Nations Educational, Scientific and Cultural Organization (UNESCO)) or jointly by an international nongovernmental organization and a United Nations agency (e.g. the Council for International Organizations of Medical Sciences, CIOMS).

World Medical Association Declaration of Helsinki (1964)

The Declaration of Helsinki was adopted in June 1964 in Helsinki, Finland, by the World Medical Association (1964). Although it is one of the main documents that builds on the 10 points formalized in the Nuremberg Code, it covers a wider spectrum of ethical issues and takes more nuanced stands on certain issues. For example, it tends to make the language used to describe the importance of obtaining informed consent less absolute. One of the defining characteristics of the Declaration of Helsinki is that, in contrast to the Nuremberg Code, it is updated regularly. The latest update was issued in 2013. This update requires compensation and treatment for research-related injuries (paragraph 15) and emphasizes the dissemination of research results, including “negative” results, to increase the value of medical research (paragraphs 23, 35 and 36) (Millum et al., 2013).

The Belmont Report (1979)

The Belmont Report was written by the National Commission for the Protection of Human Services of Biomedical and Behavioral Research (1979) in the USA, following disclosure of what has become one of the most widely discussed examples of a study in which research subjects were mistreated: “the Tuskegee study of untreated syphilis in the negro male”. In the research programme, which lasted for almost 40 years

(1932–1972), the progression of syphilis in 400 impoverished African–American men was compared with data for 200 uninfected individuals. Even after an effective treatment became available, it was withheld from the participants to allow the researcher to observe the natural history of progression of the disease (Brandt, 1978).

The National Commission released a report entitled “Ethical principles and guidelines for the protection of human subjects of research” in 1979. It set out three main ethical principles considered to be *sine qua non* conditions for the use of human subjects in research: respect for persons, beneficence and justice. For the Commission, *respect for persons* refers to acknowledgment and protection of the ability of competent individuals to make decisions about their participation in research. In other words, researchers should not be deceitful. In addition, people with limited decision-making competence must be protected. *Beneficence* refers to the moral duty to “do good” by maximizing benefits and minimizing risks to research subjects. The principle of *justice* has been the subject of much debate. In the context of the Belmont Report, it refers to fair distribution of the risk associated with research and an assurance that the benefits of the research will be fairly distributed.

Protection of Human Subjects (1991)

This code, referred to as the “common rule”, regulates all research supported by US federal funding in the USA and elsewhere; it was enacted into law in 1981 (Department of Health and Human Services, 1991) and revised most recently in 1995. In 2011, the Office of the Secretary of the Department of Health and Human Services, in coordination with the Office of Science and Technology Policy issued an “advance notice of proposed rulemaking” requesting comments on how current regulations for protecting human subjects who participate in research might be modernized and revised to be more effective (Department of Health and Human Services, Office of Science and Technology Policy, 2011).

The common rule addresses the following aspects of research involving human subjects:

- the membership, functions, operations and registration of institutional review boards;
- research ethics review;
- criteria for approval of research;
- general requirements and documentation for informed consent and
- specific protection for pregnant women, human fetuses, neonates, prisoners and children.

In the advance notice, modifications to seven aspects of the current regulations were proposed, including recalibrating the level of review by institutional review boards to more accurately reflect the degree of risk posed by research; providing more specificity about how consent forms should be written and requiring written consent for use of all biological specimens in research; protection standards for studies involving identifiable or potentially identifiable data; standards for studies involving identifiable or potentially identifiable data and a systematic approach to the collection and analysis of data on unanticipated problems and adverse events (Henry, 2013).

Council for International Organizations of Medical Science (CIOMS) guidelines (2002)

CIOMS, under the umbrella of WHO and UNESCO, issued the *International ethical guidelines for biomedical research involving human subjects* in 1982. The guidelines were revised in 1993 and again in 2002. The latest revisions include defining national policies on the ethics of biomedical research, applying ethical standards in local circumstances and establishing or redefining adequate mechanisms for ethical review of

research involving human subjects (Council for International Organizations of Medical Sciences, 2002). The main topics covered in the CIOMS guidelines are:

- the ethical justification and scientific validity of biomedical research involving human subjects (including the choice of controls in clinical trials);
- ethical review committees and capacity-building;
- ethical review of externally sponsored research;
- issues of individual informed consent (e.g. essential information for prospective research subjects and obligations of sponsors and investigators);
- inducement of individuals to participate in research;
- benefits and risks of study participation;
- the limitations to be placed on risk when research involves individuals who are not capable of giving informed consent;
- research in populations and communities with limited resources;
- equitable distribution of burdens and benefits in the selection of groups of subjects in research;
- research involving vulnerable persons;
- women as research subjects;
- safeguarding confidentiality;
- the right of injured subjects to treatment and compensation and
- the obligation to provide health care services.

Tri-Council policy statement (1998)

The Tri-Council Policy Statement is the Canadian equivalent of the common rule, except that it is not enacted in law (Canadian Institutes of Health Research et al., 1998, 2005). It was originally adopted by three large Canadian research bodies: the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada. The 2010 version addresses the following aspects of research involving human participants:

- the consent process;
- fairness and equity in research participation;
- privacy and confidentiality;
- governance of research ethics review;
- conflicts of interest;
- multi-jurisdictional research;
- research involving the First Nations, Inuit and Métis peoples of Canada;
- qualitative research;
- clinical trials;
- human biological materials and
- human genetic research.

Other guidelines

Other ethical guidelines with particular relevance to research in developing countries include the *Guidelines for good clinical practice for trials on pharmaceutical products* (World Health Organization, 1995), the Oviedo Convention (Council of Europe, 1997) and *Ethical considerations in HIV preventive vaccine research* (Guenter et al., 2000) of the Joint United Nations Programme on HIV/AIDS (UNAIDS).



C. Summary

Research and surveillance are integral, crucial parts of public health interventions during emergencies. Research and similar activities that involve the collection of personal human data or biological samples have given rise to much ethical concern about the rights of the participants in this type of activity. The concern has been addressed in numerous national and international guidelines, some of which are regularly updated. The research ethics guidance documents most frequently mentioned are the Nuremberg Code, the Declaration of Helsinki, the Belmont Report, the CIOMS guidelines, the common rule and the Tri-Council Policy Statement (Canada).

Although they have varying areas of emphasis, research ethics instruments tend to agree on some core issues, including the ethical principles of respect for autonomy, informed consent, non-maleficence, justice, vulnerability, privacy, confidentiality and the requirement for research ethics review.

There is also disagreement and controversy about the guidance on some topics related to research, such as the use of placebos and the involvement of certain vulnerable groups like women, children and prisoners. Specifically in the context of emergencies, there is lack of agreement about which public health interventions during emergencies should be considered research that requires ethical approval before being undertaken. The legal considerations for the formation of ethical committees and the development of ethical guidelines differ widely.



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Learning objective 1.4: Identify the shortcomings of current normative instruments for use in emergency situations, and evaluate alternatives.

Ghaiath Hussein



Session timeline (120 min)

0–5 min (5 min)	6–10 min (5 min)	11–30 min (20 min)	31–40 min (10 min)	41–55 min (15 min)	56–70 min (15 min)	71–85 min (15 min)	86–110 min (25 min)	111– 120 min (10 min)
Review of learning objective 1.3	Probing questions	Reading and case study and discussion	Reporting back	Slide presentation	Reading	Group discussion	Writing	Summary and conclusion



Instruction strategy

1. The facilitator reviews the main guidelines and core principles of research ethics studied in learning objective 1.3 (5 min).
2. The facilitator asks the trainees probing questions (5 min), such as:
 - What do they think about e.g. the number, frequency and updates of guidelines.
 - Do the guidelines appear to be applicable to emergencies?
3. The facilitator separates the group before distributing the case study.
4. The facilitator allows 20 min for the groups to read and discuss the following issues:
 - Using one of the research ethics guidelines or regulations that were introduced in learning objective 1.3, discuss three of the main ethical issues that you identified in the case study, and discuss whether you found your research ethics instrument helpful in deciding whether to approve this study.
 - If you found gaps or shortcomings in your research ethics instrument, describe them, and discuss with your colleagues at least one way of overcoming each of them.

For facilitators: This study has many ethical and political aspects for consideration, and these may arise from the trainee discussions. The facilitator should focus on the ethical issues, such as:

- the vulnerability of children during an epidemic;
- obtaining consent from participants with whom the (international) researcher cannot communicate directly;
- privacy and confidentiality, especially if the data collectors are members of the community from which they are collecting the information;
- conflicts of interests for providers when they also become researchers and for donors of medications who are also their manufacturers, and

- the roles that the researchers and the ethics review committees should have taken before and during the trial.
5. The facilitator reconvenes the participants and asks each group to share comments on their case study (10 min).
 6. The facilitator introduces the material of this learning objective (15 min).
 7. The facilitator distributes pp. 13 and 14 of the WHO report on research ethics in international epidemic response (World Health Organization, 2009a) and allows 15 min for reading.
 8. The facilitator invites the participants to share comments on the text (15 min).
 9. The facilitator asks participants to draft a “framework” of ethical standards for conducting research during emergencies that would be particularly relevant to their institution (25 min).
 10. The facilitator opens the floor for discussion and final remarks (10 min).



A. Background

As noted in learning objective 1.3, there has been a gradual increase in the number of research ethics guidelines and regulations. To different extents, these guidelines and regulations cover and emphasize major ethical issues, such as obtaining informed consent, assessment of risk–benefit ratios, privacy and confidentiality. Additional issues discussed in some of the guidance documents that were not covered in learning objective 1.3 are community participation, conflicts of interest, publication ethics and research integrity. Many of the guidelines were prepared in response to a notorious research practice that became publicly known. For example, the Nuremberg Code followed the infamous trials of Nazis who conducted research on prisoners in concentration camps, and the Belmont Report followed the Tuskegee syphilis study. Most of the mainstream or international guidelines were prepared in developed countries in Europe and North America and achieved legal status by the inclusion of their main principles in the laws of those countries.

The authority, clarity and relevance of research ethics guidelines and regulations have been critiqued. For example, the relevance of the guidance documents to non-physician practitioners and their adequacy for research in low-resource settings has been questioned (Henderson, 2007; Alahmad et al., 2012; Millum et al., 2013). A particular concern is that, generally speaking, most research ethics guidelines were written for clinical research, which is usually undertaken in a stable context in which adequate resources are available. In contrast, emergencies are by their nature disruptive and often hit most strongly in places with limited resources. This creates a state of urgency that can make it nearly impossible to abide to the letter of mainstream research ethics guidelines.

That said, states of urgency should be assessed in the overall context and not be taken as an excuse to bypass or ignore the main ethical principles of research. A useful example is the recent report of an advisory panel to WHO on *Ethical considerations for use of unregistered interventions for Ebola viral disease*. The panel concluded that “it would be acceptable on both ethical and evidential grounds to use as potential treatments or for prevention unregistered interventions”, although its members acknowledged that “this is a departure from the well-established, historically evolved system of regulation and governance of therapies

and interventions.” [World Health Organization, 2014]. The precondition for doing so was that other ethical principles, such as transparency about the effects of the interventions, fair distribution, solidarity, informed consent, freedom of choice, confidentiality and involvement of the community are respected.

During most emergencies, research is crucial to providing efficient humanitarian aid; however, the overall structures of the health care system and of research governance can be expected to be affected negatively and be unable to function properly. As a result, it may be impossible to conduct research in the “normal” frame of reference. This module covers some of the shortcomings of many mainstream research ethics guidelines for addressing the issue of research during emergencies. The emphasis is on uniquely complex issues, such as the effect of the emergency on the perception of ethical questions, the patient–provider relationship, the integrity of studies and ethical review. Steps are proposed that could be taken by stakeholders to adapt and evaluate the appropriateness of mainstream guidelines in the context of emergencies.



B. Topics

Altered perceptions of ethical issues

Emergencies often offer an interesting opportunity for conducting time- and location-constrained research that involves people who are directly or at risk of being affected. Such research may involve the collection of personally identifiable information or biological samples, which raises concern about confidentiality.

An example of changing perceptions of ethical issues in emergencies is the issue of risks and benefits. Many research ethics guidelines emphasize the importance of the principles of beneficence and non-maleficence (see learning objective 1.3) and generally agree that risks to research subjects are justified only if the expected benefits reasonably outweigh those risks. For example, the Canadian Tri-Council Policy Statement recognizes this constraint and proposed a proportionate approach to research ethics review, in which the level of review is determined by the level of foreseeable risks to participants (Canadian Institutes of Health Research et al., 2010).

The perceptions of risk for harm may differ in an emergency. The desire to survive may make some people desperate for any kind of perceived help, regardless of the potential trade-offs, and individuals may accept higher levels of risk than they would have accepted under non-emergency circumstances. A similar shift in perception might occur in the shaping of policies, for instance setting vaccination policies during influenza pandemics that are based on sub-optimal evidence (Jefferson, 2006). Similarly, individuals who are infected or at risk of being infected could foreseeably be amenable to participating in a phase-III clinical trial during a pandemic of a highly lethal infection, even if the safety and efficacy of the treatment under study has not yet been well established. For example, Chor and colleagues (2009) showed that the intention to accept pre-pandemic vaccines among a sample of 2255 health care workers in Hong Kong hospitals increased from 28.4% in the case of H5N1, characterized by a phase-3 alert by WHO, to 47.9% in the case of H1N1, with a phase-5 alert. A recent advisory panel to WHO concluded that it is “an ethical imperative to offer the available experimental interventions [...] to patients and people at high risk of developing the disease”, although it also acknowledged that this measure is a “departure from the well-established, historically evolved system of regulation and governance of therapies and interventions” (World Health Organization, 2014)

Although mainstream international guidelines are unanimous that obtaining consent is mandatory for involving competent persons in a trial, and some specify vulnerable groups whose consent may require special procedures, they tend not directly to address the issue of transient circumstances and factors, such as pandemics, that might affect people's ability to adhere to their usual preference towards participation in research. Similarly, the common rule emphasizes that "an investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate" (Department of Health and Human Services, 1991).

Roles and relationships

Many research ethics instruments provide some guidance on the relationship between researchers and research subjects. For example, the Declaration of Helsinki states that more caution should be taken by the researcher when "the potential subject is in a dependent relationship with the physician [researcher]" (paragraph 27).

These examples show that most research ethics instruments provide guidance in "doctor-patient" types of relationships, in which it is assumed that a treating doctor is the researcher and that the research subject is a patient. Yet, in emergencies, not all those who are affected are patients and not all researchers are physicians. For instance, some affected people may have lost access to safe homes, health care or other basic needs. Others may be affected indirectly, such as family members of people who are directly affected. Throughout emergencies, various methods may be used to collect data, not all of which can be expected to be predominantly clinical or always undertaken by clinicians.

The people who undertake research during an emergency are not necessarily government public health authorities but may be, for example, volunteers working in local, national or international nongovernmental organizations. Often, providers work within different sets of professional standards and regulations, depending on the institutions to which they belong. In some cases, it is not clear to what extent they are bound by mainstream research ethics guidelines, given that their organizations are not necessarily accountable to the structures that enforce abidance to the guidance (e.g. university institutions).

Nevertheless, most international research ethics guidelines emphasize that research must be undertaken and supervised by qualified researchers. For example, the Declaration of Helsinki clearly states in its guiding principles that "research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional" (World Medical Association, 2008). Similarly, the CIOMS considered that "research with human subjects should be carried out only by, or strictly supervised by, suitably qualified and experienced investigators" (Council for International Organizations of Medical Sciences, 2002).

In an emergency, however, there might be lack of agreement or consistency in defining what is research and therefore who is a researcher. This ambiguity might make it harder to determine, for example, whether a volunteer working for a nongovernmental organization who collects data on people affected by an emergency is a researcher, whose qualifications as a researcher should be guaranteed as per the guidelines.

Research integrity and conflicts of interest

Maintaining the integrity of research is crucial for both the maintenance of public trust and providing adequate evidence for good policy-making. One of the main threats to the integrity of research is the existence of conflicts of interest (see learning objective 7.3). A frequently cited concern is the impact that the relations of researchers with pharmaceutical companies might have on the outcome of their research (Thompson 1993; Emanuel et al. 2000; Bekelman et al., 2003). Therefore, research ethics guidelines, as well as editorial publication policies, tend to emphasize the importance of disclosing such relationships in detail. For example, the guidelines of the International Committee of Medical Journal Editors (2013) state that researchers are “responsible for disclosing all financial and personal relationships that might bias their work”. Moreover, almost all the mainstream guidelines contain a section on conflicts of interests; for example, see chapter 7 of the TriCouncil policy statement (Canadian Institutes of Health Research et al., 2010); guidelines 2 (Ethical review committees), 3 (Ethical review of externally sponsored research) and 20 (Strengthening capacity for ethical and scientific review and biomedical research) of the CIOMS (Council for International Organizations of Medical Sciences, 2002) and articles 22, 26 and 36 of the Declaration of Helsinki (World Medical Association, 2008).

The issue of conflicts of interest and integrity came under public scrutiny during recent emergencies. There were numerous debates, for example, during and after the 2009 H1N1 “swine” flu pandemic about the efficacy of the vaccine that was being manufactured by a handful of the largest pharmaceutical companies (Henderson 2007; Cohen & Carter, 2010; Alahmad et al., 2012). An independent investigation by the *British Medical Journal* and the Bureau of Investigative Journalism suggested that there was evidence that raises troubling questions about how the conflicts of interest of experts were managed (Cohen & Carter, 2010). The debates were often emotionally intertwined with debates about the distribution of the limited numbers of doses of vaccine to those who needed it, both across and within countries (Kotalik, 2005; Longini & Halloran, 2005).

Although research ethics instruments address the issue of conflict of interest in a number of ways, they do not specifically address it in settings where compelling factors exert strong pressure to ensure that the results of research (e.g. pharmaceutical products) become available as rapidly as possible. Partly because of this, it has been suggested that priority should be given to the principles of accountability, integrity and transparency during emergency research (World Health Organization, 2009a). These principles might indeed be important for mitigating the risk of individuals being tempted to abuse the “emergency” label to give priority to their personal or institutional interests.

Alternative models and guidelines

“Normal” research ethics review tends to take a long time—sometimes months (Hyder et al., 2004; Hunter, 2007; World Health Organization, 2009). During an emergency, when timely generation of information is crucial for proper planning and efficient interventions, such delays can be counterproductive. In general, mainstream research ethics guidelines do not provide alternative models of ethics review that would be more suitable for the circumstances associated with emergencies.

The four shortcomings of mainstream research ethics guidelines described above are among the most important. Identification of such shortcomings by communities of practice has led to a number of attempts to provide guidance specifically tailored to research in emergencies. So far, these have focused mainly on influenza pandemics: the CDC *Ethical guidelines in pandemic influenza* (Kinlaw et al., 2009), the WHO *Ethical considerations in developing a public health response to pandemic influenza* [World Health Organization,

2007) and the WHO guidance document on *Pandemic influenza preparedness and response* (World Health Organization, 2009b) are some of the best known.

Alternatives specifically for research undertaken during emergencies have also been proposed. One was the report of the WHO technical consultation on *Research ethics in international epidemic response* (World Health Organization, 2009b), which suggested considerations that are not widely addressed in mainstream research ethics guidance:

- lessening the burden on the research oversight system by distinguishing crucial tasks from non-crucial ones during public health emergencies (Non-crucial tasks that do not qualify for exempted or expedited review could be reserved for review after the emergency.);
- proportional review, i.e. pairing the level of scrutiny of suggested research projects with their level of risk;
- fast-track reviews (although not to the point of ignoring or narrowing the ethical principles to be met);
- creation of a pre-emergency repository of (parts of) study protocols;
- establishment of a wiki-like platform to store “best practices” in emergency research design and
- “rolling” or contemporaneous review of protocols, in which parts of protocols are approved while other elements are modified in real time as the projects are launched and remain conditional to supervision and periodic re-approval by a research ethics committee.



C. Case study

Trovan trial in Nigeria

Stephens J (2000). Where profits and lives hang in balance, Washington Post, 17 December 2000 (http://www.washingtonpost.com/wp-dyn/content/article/2008/10/01/AR2008100100973_pf.html).

See also http://www.pfizer.com/files/news/trovan_fact_sheet_final.pdf.



D. Summary

Most of the internationally used research ethics guidelines provide guidance based on a clinical model of research conducted under normal conditions. The context of emergencies is significantly different from the more stable conditions under which standard research is conducted. Hence, the mainstream frames of reference may not offer useful guidance for the conduct of ethical research during emergencies. Specific shortcomings were explored in this learning objective; they include the fact that current mainstream research ethics guidelines:

- address mainly the ethical issues that could be encountered in a clinical research setting, where the researcher is usually the health care provider;
-

- propose an ethics review model that requires resources and time that may not be available during emergencies, especially in less-developed countries, and
- do not address the additional factors that could influence “freedom from coercion and undue influences” of research participants in an emergency, whose vulnerability may change from that before the emergency.

Public health practitioners must be aware of the shortcomings of mainstream research ethics instruments and should become involved in efforts to provide operational alternatives. This could comprise re-orientation or local adaptation of guidelines and not necessarily a completely new model of guidance. The complexity of emergencies creates situations in which timely production of information is required. This should not, however, be used as an excuse for undertaking research that does not meet the ethical standards for respect of the rights of participants and their communities.



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Core competence 2: Ability to define adequate processes for ethics review in public health interventions, surveillance and research in emergencies

Source: WHO



Source: WHO

Core competence 2: Ability to define adequate processes for ethics review in public health interventions, surveillance and research in emergencies

When ethics oversight is deemed necessary for public health activities, it is important that such oversight be of high quality. The standard procedures that should be followed in the case of research are described in learning objective 2.1. Learning objective 2.2 describes the circumstances in which public health surveillance activities should also be reviewed by an ethics committee. Learning objective 2.3 describes alternatives to standard procedures of ethics review that might be particularly useful during emergencies.



Learning objectives

- 2.1 Describe “standard” procedures that should govern an ethics review of research activities, including public health research.
 - 2.2 Identify circumstances in which public health surveillance activities should possibly undergo formal ethics review.
 - 2.3 Describe possible variations to standard procedures of ethics review that are applicable to research in emergencies.
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Learning objective 2.1: Describe “standard” procedures that should govern an ethics review of research activities, including public health research.

Kenneth W. Goodman and Sergio Litewka



Session timeline (90 min)

0–20 min (20 min)	21–45 min (25 min)	46–70 min (25 min)	71–85 min (15 min)	86–90 min (5 min)
Introduction	Debate	Case study and discussion	Discussion	Summary and conclusion



Instruction strategy

1. The facilitator introduces the module and provides background information on “standard” procedures for ethics review.
2. The facilitator identifies key (conceptual) differences between biomedical research and public health research.
3. The facilitator divides the group and asks them to come up with arguments in favour or against the question “Are there circumstances in which the review standards of research ethics committees could be altered?”

For facilitators: See *Challenges raised specifically by the review of research for emergencies*, below, for an example.

4. The facilitator presents the case study, asking participants to answer the following questions:
 - Identification of applicable cases is often the first step in a research project. What might be the research question here?
 - If this is a research study, what questions would you pose as a research ethics committee member?

For facilitators: In this case, the CDC determined that this study represented surveillance and intervention, not research; therefore, research ethics committee approval was not required. Others might dispute that conclusion. The case is presented to illustrate the difficulty in deciding whether ethics review is required for studies that fall between research and surveillance.

5. The facilitator forms three groups and gives each 8 min to take a position on one of three questions:
 - Why do we go to so much trouble to oversee the ethics of research? Does it not add unnecessary costs to research?
 - Service on a research ethics committee is time-consuming. Is it worth it, and why?

- Should research ethics committee approval be unanimous, or are dissenting votes on individual protocols acceptable?
6. The facilitator asks each group to appoint a rapporteur to summarize the team's discussion.
 7. The facilitator concludes the session and opens the floor for discussion.



A. Background

The objective of health research is to produce generalizable knowledge to improve health and/or increase scientific knowledge. As explored in learning objective 1.1, it is, however, sometimes difficult to separate public health research from public health practice (e.g. population surveillance, disease control and prevention, programme development and evaluation) in emergencies (World Health Organization, 2010). There are clearly significant areas of overlap between the two activities.

Although the objective of health research is “to do good”, it can also potentially inflict harm on participants, including exploitation. The role of research ethics is generally seen to be to ensure that participants are treated with dignity and respect while they contribute to the social good. Learning objective 1.3 also shows, however, that the field of research ethics is evolving rapidly. A number of constituents continue to make important contributions; for example, the Nuffield Council on Bioethics has played a strong role in framing the obligations of researchers working in low- and middle-income countries by emphasizing their duty to alleviate suffering, to show respect for persons, to be sensitive to cultural differences and to refrain from exploiting vulnerable people when conducting research in these countries (Nuffield Council on Bioethics, 2002, 2005). The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979) proposed that the protocols of research projects ensure minimal risks to participants, fair selection of subjects, on the basis of scientific criteria rather than cost or convenience, and respect for informed consent. These principles are now commonly accepted.

It is now broadly agreed internationally that there are good reasons to review the ethical aspects of research involving humans before it is implemented. The justifications for independent prospective ethics review of each research project range from the requirement to respect human rights (against potentially conflicting interests inherent in research) to the requirement to establish the trustworthiness of the research enterprise (Edwards, 2009). The purpose of ethics review is thus not (contrary to what is sometimes implied) to impede research, slow it down or frustrate those conducting it.

In most jurisdictions, dedicated committees review the ethics of research. These committees are often multidisciplinary, depending on the nature of the research being reviewed. Importantly, “community members” or people unaffiliated with the institution conducting the research are often included to ensure the independence of the committee's decisions and to “democratize” science (Klitzman, 2012).

Many of the rules and standards for the review of research involving human subjects were written after disclosure of research activities that had resulted in exploitation, unnecessary harm or violation of the rights of people (see learning objective 1.3). Other rules and standards have evolved as scholars have considered the proper relations between scientists and the people they study.

Now, researchers who wish to conduct studies with human subjects are often required to submit a detailed description of the project—the “research protocol”—to the research ethics committee before they recruit anyone. Their application must state how ethical issues will be addressed throughout the research project. Research ethics committees then review the application, paying particular attention to the issues discussed in the next section, and then approve it, ask for revisions before approving it or reject it. In some countries, ethics review is a condition for funding.



B. Topics

Areas covered by standard ethics review

A review of the ethical aspects of a project, including during an emergency, should cover 11 important areas: the applicability of the research to the situation in question and the social need and anticipated utility; informed consent and voluntariness of participation; the role of community consultation and participation; exploitation; dignity, privacy and confidentiality; risk minimization; professional competence; public interest and distributive justice; dissemination of results; international collaborative research; and institutional responsibilities and arrangements (Sumathipala et al., 2010). In other words, research ethics committees might ask questions about topics such as:

- the balance of therapeutic and non-therapeutic risks and potential benefits;
- the adequacy of the proposed informed consent process, including:
 - the sufficiency of the information provided, such that prospective participants can decide whether to participate;
 - protection from undue influence, pressure or even force (i.e. voluntariness); and
 - mechanisms to ensure the individual’s capacity to understand and appreciate the information and make a free choice;
- confidentiality and how the disclosure of information will be handled and by whom;
- protection of vulnerable populations;
- the evidence base that justifies conducting research and efforts undertaken to prevent duplication of research;
- equitable distribution of the burdens and benefits of participation, including measures:
 - to ensure that the knowledge will be returned to the community;
 - measures put in place by and resources available to the research team to ensure that they will not constitute a drain on local resources; and
 - to limit the likelihood that the research activities will hamper needs assessment, health care provision, relief distribution or even search and rescue.

Several resources are available to guide decision-making by research ethics committees.

Ethics review of public health research

As discussed in learning objective 1.3, most normative instruments governing research were initially developed specifically with a clinical or biomedical model in mind. Many of these standards are also applicable to public health research and to epidemiological research, although some aspects might change.

- Concern about direct harm to individual participants might be supplemented by concern for harm to entire groups (although, as noted in learning objective 4.1, individual harm is also possible in research for emergencies).
- The requirement for individual informed consent to participate in the project may be waived (see learning objective 4.3).
- The ability to withdraw from studies may be limited.
- The use of aggregate data might diminish concern about the identifiability of individual data but raises the question of “group privacy” or cultural or community rights.

Because of these different concerns, research ethics committees assigned to the review of public health research require that members be familiar with the methods and ethical issues of epidemiology and public health. In addition, whereas a biomedical research ethics committee might include only one community member, a research ethics committee focused on public health research might include several.

Challenges raised specifically by research in emergencies

Research design

Research on emergencies raises important empirical and ethical issues. For instance, a randomized controlled trial would be unsuitable both ethically and logistically for studying how best to respond to the needs of people immediately after a tsunami or at the beginning of a pandemic influenza crisis. Instead, a study of the use of social media during or after such an emergency could be conducted to determine the kinds of resources most needed in hospitals and to identify communities in greatest need of vaccine.

Expertise

Suppose a research ethics committee receives the protocol of a study to monitor social media before, during and after an emergency (Petrini, 2013; Stephens et al., 2013). If all the members of the committee are clinicians with no public health experience, the committee might lack the necessary expertise to review the protocol. When expertise cannot be found among the members of the committee, the help of external specialists should be sought.

Representation from the community

Research ethics committees should include community representatives. In an emergency with grave public health consequences, however, sustaining such representation may be difficult. The “representativeness” of community representatives should also be kept in mind, as some emergencies may affect subpopulations that are not normally well represented on the committee.

Altered standards

Clinical practice is usually guided by “standards of care”. In situations of lack of resources or rationing in an emergency, however, the standard of care may be altered (see learning objective 7.1). For example, a shortage of ventilators or hospital beds during a public health crisis might make it impossible to provide the usual level of care.

The case might be made on utilitarian grounds that research ethics committees should be permitted to consider and approve research according to standards different from those used for studies conducted in non-emergency settings (Limkakeng et al., 2013; Sims et al., 2013). The issue of consent is likely to be raised in particular. For example, the protocol of a study to monitor social media traffic during and after an emergency could be granted a waiver of consent:

- As the investigators do not know in advance who will be using social media, they cannot obtain their consent beforehand.
- Once a crisis begins, there is no time to obtain consent from social media users.
- The very idea of interrupting emergency communication in order to study it is ethically questionable, so consent itself is problematic in the circumstances.

When the standard procedures that should govern ethics review of research activities, including public health research, cannot be followed, an ethics committee might impose alternative requirements. In the case of the social media study discussed above, the committee could request that the community be notified in advance that their use of social media might be monitored. In general, it might be easier to study a community with altered standards of ethics review and approval once a rapport and trust have been established.



C. Case study

“In March 2003, during the worldwide SARS outbreak, the CDC engaged in a series of [...] efforts to systematically identify potential SARS cases and those within contact of these persons. As part of these activities, CDC focused efforts on potential cases of SARS spread through casual contact among airline travelers. CDC asked state and local public health agencies to assist in following up with potential contacts. In particular, during this critical time, if CDC became aware of a person known or suspected to be infected with SARS who had recently flown into or within the USA, it would identify the flight, contact the airline for the flight manifest, and then ask state or local public health agencies to help locate persons who had flown with the individual, and thus may have been exposed to SARS. Sometimes, obtaining flight manifests and locating named individuals would result in a 3–4 weeks administrative delay between the time CDC suspected a potential exposure and when an investigation could be conducted. Nevertheless, CDC requested that state or local agents supervise physicians to draw blood samples and obtain medical histories of healthy, unaffected air travelers who were on the plane with a known or apparent SARS case. When administrative delays mounted, the time period for performing these blood tests on asymptomatic individuals would have surpassed their likely incubation period for SARS, revealing only that they may have been exposed. Thus, the tests would not directly benefit asymptomatic individuals who were not ‘cases’ because they were not ill.”

Source: Hodge and Gostin (2004), pp. 34–35.



D. Summary

Ethics review is now widely seen as an important component of research on human subjects. This module provides an overview of the core elements of ethics review, describing the areas or topics frequently addressed by ethics committees and noting the roles of such values as privacy, informed consent, concern for vulnerable populations and equity in the distribution of burdens and benefits. The session also itemizes some of the challenges that arise in emergencies; the case study of the outbreak of a deadly new virus stimulated discussion of the challenges posed by such public health threats for ethics review.



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Learning objective 2.2: Identify circumstances in which public health surveillance activities should possibly undergo formal ethics review.

Kenneth W. Goodman



Session timeline: 75 min

0–25 min (25 min)	26–30 min (5 min)	31–45 min (15 min)	46–65 min (20 min)	65–75 min (10 min)
Introduction	Reading	Case study and discussion	Debate	Summary and conclusion



Instruction strategy

1. The facilitator introduces the module.
2. The facilitator splits the group into two and asks participants to explore why surveillance might sometimes have to be reviewed by research ethics committees.

For facilitators: Emphasize differences between laws and regulations and ethics by explaining that morality sometimes permits or requires actions regarded as illegal and that, conversely, what is legal might sometimes be immoral. Does the law sometimes require too much or too little research oversight?

3. The facilitator presents the case study to participants and asks them to answer the following questions:
 - Why can't such a study be conducted without formal review? Consider your answer in terms of both informed consent and confidentiality.
 - The institution determined that the activity constituted research (see suggestion) and, *for that reason*, required review. Did the institution make the right decision for the right reason?

For facilitators: In this case, the leadership of the institution decided that this project constituted research “because the information produced by the study is intended to contribute to generalizable knowledge, human research subjects are involved, and personally identifiable health data are being collected.” This could be contested.

- The intent of the project could be described as an assessment of the value of such testing to hospital screening protocols, rather than research per se. Are there epidemiological or public health practice alternatives that could have achieved the same goal without meeting the institution's rationale for classifying the activity as research?
- If so, would formal ethics review still be useful? Why? What questions would you ask as a research ethics committee member?

4. The facilitator divides the group into three and gives each 8 min to address one of three questions:
 - Which kinds of surveillance should undergo formal ethics review?
 - Which kinds of surveillance do not require such review?
 - Why not require research ethics committees to review all surveillance studies, in addition to research studies?
5. The facilitator asks each group to appoint a rapporteur to summarize the team's discussion.
6. The facilitator concludes the session and opens the floor for discussion.



A. Background

The questions of how and by what criteria public health practice, including surveillance, can be distinguished from research remain among the most elusive ones in bioethics. Mechanisms developed over nearly a century to protect human subjects in research contexts have co-evolved with increasingly powerful tools to conduct public health surveillance. There is no credible disagreement that we must both monitor the public's health and simultaneously protect people from research abuse. The challenge in certain kinds of inquiry is in doing both at the same time. Customarily, research requires formal ethics review, but surveillance does not.

One of the differences between research and surveillance is that research usually involves some kind of intervention: a drug (or placebo) is administered or withheld, a device is tested or a treatment is explored. In other words, participants are exposed to quantifiable risk. It has been suggested that "The distinction between research and practice in public health does not correlate with the extent to which an activity either carries risks for individuals and communities [...]" (World Health Organization, 2010). Nevertheless, the presence or absence of risk and its magnitude are among the criteria for determining the requirement for and scope of ethics review.

Much surveillance is based on the collection of data and/or information. Indeed, in many kinds of widely accepted, ethically uncontroversial surveillance, the people being studied do not know that their information is being collected. This being the case, what criteria should be in place to identify circumstances under which surveillance activities should undergo formal ethics review?

For facilitators: Recall that learning objectives 1.1 and 1.2 address the question "What is surveillance?" and ask the participants to "Identify differences among public health research, practice and surveillance."



B. Topics

Ethical foundations for formal ethics oversight of public health surveillance

The sciences of epidemiology and public health originated in the recognition that patterns of data in population health can be used to prevent the spread of contagion. That is, aggregated data about many individuals can be used to educate, shape policy and improve collective health. In some cases, special new

surveillance initiatives are conducted only temporarily. Several considerations enter into deciding whether to acquire such data:

- Civil society assumes a level of mutual responsibility for individuals' health.
- Citizens therefore have some obligation to allow use of their health information—especially if it is appropriately safeguarded and managed—to protect and improve the health of others (Goodman & Meslin, 2014).
- While this can raise conflicts between autonomy or self-determination on the one hand and the common good on the other, it is widely agreed that collective, simultaneous surrender of some autonomy can be a moral obligation (Lee et al., 2012). In other words, surveillance can be understood to be to public health what traffic signals are to transport or taxes to civic infrastructure.
- Because the information collected during surveillance can be intensely personal and quite delicate, very large databases are increasingly required to store and analyse information, and, as public trust in a surveillance enterprise is essential to its success, suitable steps must be taken to ensure the appropriate use of surveillance data by appropriate users.

Underlying these considerations is the value of public trust and reliance on recruitment process and the cooperation of the community to protect it. When residents or citizens of a region or jurisdiction understand and appreciate the benefits to be gained from public health services, there is a foundation for trust in those who provide the services. Generally, populations in at least some regions of the world not only trust public health authorities but both assume that those authorities are already using their stored information and welcome such use (Meslin & Goodman, 2010). This trust can, however, be damaged or diminished. For instance, early in the HIV crisis of the 1980s and 1990s, data on seroconversion were used in some jurisdictions to isolate people with HIV infection; such use of information for discriminatory purpose undermined trust in surveillance institutions.

The main reason for advocating for formal ethics review of surveillance may be to foster that trust. If the review can be accomplished without impeding surveillance, it can in principle help reassure populations that the people collecting and analysing data are acting in a transparent, inclusive way.

Reasons for formal ethics review of surveillance

There are good reasons for decoupling research with review and surveillance with no review. If that is the case, what kinds or scope of surveillance should be reviewed? One way to begin answering this question is to itemize some of the issues customarily raised in research ethics review.

- *Valid consent*

Seen as a cornerstone of ethical interventional research, the requirement to receive permission from informed, competent, freely acting participants is generally unchallenged. While consent is not always essential for surveillance (see learning objective 3.2)—and sometimes impossible for large-scale efforts—*informed or valid consent can be a useful way to engage with and demonstrate respect for participants in specific kinds of surveillance activity.*

- *Privacy and confidentiality*

If identifiable data are to be collected, it is important that adequate provisions be in place to protect the data from inappropriate use or disclosure. In addition, racial, ethnic, religious and other subpopulations

have stakes in the use of information that reflects on the group as a whole, as even de-identified data can in aggregate cause prejudice to subpopulations (see learning objective 3.1). In either case, formal research ethics review can identify challenges, recommend and/or require best practices or otherwise support or help refine measures to protect privacy.

- *Vulnerable populations*

There is broad agreement that certain populations, including children, pregnant women, people with disabilities, prisoners, soldiers and ethnic minorities, pose special challenges to research review. When such populations are targeted in surveillance studies, an argument can be made that research ethics committees should be consulted to ensure that the rights of these groups are protected and that they are not exposed to greater-than-usual social risks. As above, just as trust is essential in public health research, these issues can establish a warrant for formal ethics review of a surveillance study.

While formal ethics reviews of surveillance can be justified on the grounds discussed above, it is important that the reviews be balanced against the benefits derived from the proposed surveillance. If formal review is overused, or required too broadly, it may discourage surveillance in the first place. There are various ways of regulating professional public health practice, and not all require case-by-case prospective review by committee. For instance, general data protection laws and common law redress for battery or breaches of confidentiality might be regarded as sufficient in some cases (Edwards, 2009). The term “formal ethics review” does not necessarily entail a requirement that all participants provide informed consent, and at least some reviews might be expedited.



C. Case study

Protein-calorie malnutrition increases morbidity and mortality, slows wound-healing and impairs the immune response. These effects can increase the incidence and duration of hospitalization, readmission and disease-related complications. The laboratory test used most frequently to detect protein-calorie malnutrition is the serum level of albumin. The usefulness of albumin is, however, limited by its long half-life (changes cannot be detected quickly) and the effects of inflammation and chronic disease (e.g. kidney and liver disease) on albumin levels. Other, more sensitive laboratory tests include determination of serum pre-albumin, retinol-binding protein and C-reactive protein. Use of these tests allows quicker assessment of a patient's condition.

Scientists proposed a project to determine the value added to hospital screening protocols and to patient monitoring by testing for these proteins. All non-maternity, non-palliative, non-parenteral nutrition inpatients at a certain nutrition risk would be eligible and asked to accept the intervention. Patients who refused would be asked to explain their decision, and their responses would be recorded anonymously and used to devise strategies to increase patient participation in similar activities in the future. Enrolled patients would receive the current standard of nutritional care at the hospital. If enrolled patients required parenteral nutrition or transition to palliative care, they would receive it but would not be withdrawn from the project.

All patients would initially be tested for protein levels with each of the four tests (albumin, pre-albumin, retinol-binding protein and C-reactive protein) and given a bedside nutritional assessment and a treatment plan. They would be scheduled for follow-up testing three times a week during their admission. The patients would be divided into two groups. The control group would receive standard care with additional laboratory

testing for the proposed markers, but the results would not be shared with the patients or their caregivers; in the intervention group, the results of testing would be shared with the patients and their caregivers. The clinical outcomes (including length of stay in the hospital, days spent on a ventilator, infection rate) of the two groups would be compared to determine whether knowing laboratory results affects clinical outcomes. The data collected would include patients' protein results, cost, demographic information, risk factors and functionality.

Source: adapted from Hodge & Gostin, 2004.



D. Summary

International and national rules for formal review of the ethics of biomedical research were established in response to grievous abuses of people during research (see learning objective 1.3). The processes and systems for research ethics committees are well established (see learning objective 2.1). Until now, only *research* has been considered in these processes and committees, which left unanswered the question of whether public health surveillance activities should also, at least occasionally, be subject to formal ethics review. The reasons for foregoing such review include the fact that the risks associated with surveillance are generally quite minimal and are often already regulated by professional bodies and case law. In addition, the process adds to the duties of ethics review committees, some of which are already heavily burdened, and might discourage certain kinds of surveillance that are important for public health. Conversely, the reasons for considering formal ethics reviews include the recognition that participants might nevertheless be exposed to social risks that are not otherwise regulated, that such review can serve to build trust between public health organizations and the communities they serve and that formal ethics reviews can provide useful guidance for the people conducting surveillance. Overall then, traditional definitions of “research” are in some cases inadequate to guide a decision of whether to require formal ethics review, giving weight to calls to move towards risk-based approaches instead (World Health Organization, 2009).



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Further reading

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Learning objective 2.3: Describe possible variations to standard procedures of ethics review that are applicable to research in emergencies.

Athula Sumathipala



Session timeline (75 min)

0–5 min (5 min)	6–15 min (10 min)	16–30 min (15 min)	31–40 min (10 min)	41–65 min (25 min)	66–75 min (10 min)
Introduction	Small group discussion	Group discussion	Slide presentation	Case study and discussion	Summary and conclusion



Instruction strategy

1. The facilitator introduces the module and briefly reminds participants of the standard procedures for ethics review (see learning objective 2.1) (5 min).
2. The facilitator asks participants to reflect on the following question in groups of three (10 min): What deviations from standard review of research on human subjects—if any—could be acceptable for research during emergencies?
3. The facilitator asks each group to appoint a rapporteur to summarize the team's discussion (15 min).

For facilitators: Ask groups that will present later to add only items that have not already been mentioned by other groups.

4. The facilitator uses the slides to present some of the variations to standard procedures of ethics review that have been discussed in the literature (10 min).
5. The facilitator reconvenes the participants and presents the two case studies.
6. The facilitator asks each of the three groups to answer the following questions for one of the two case studies:
 - Would you categorize this project as research or surveillance?
 - Does the project require specific ethics review?
 - If so, do you think that any variations to the standard procedures would be appropriate?
 - Should the ethics committee insist on a full information leaflet and a consent form, as expected in routine research?
 - Is there a case for expedited review?
7. The facilitator asks each group to appoint a rapporteur to summarize the team's discussion (10 min).

For facilitators: Ask groups that will present later to add only items that have not already been mentioned by other groups.

8. The facilitator concludes the session and opens the floor for discussion.



A. Background

Although global thinking about research ethics review has changed quite radically over the past half century, it is possible to identify a lasting primary motive for research ethics review: to find the “least harmful” ways to conduct research. Understanding this motivation is crucial to the ability to innovate when it becomes apparent that research ethics processes are not adapted to the circumstances. As new types of research questions and challenges emerge, it is indeed reasonable to expect that the conventions for ethics review will also evolve.

Of particular relevance to this module is the inclusion in current oversight infrastructures of novel ways for reviewing research conducted during complex emergencies. There is wide agreement that research should be done in emergencies and that it may in fact be unethical *not* to conduct research in such situations, particularly in view of the “10/90” divide in research (Sumathipala et al., 2010). Of course, this “need of the hour” should not perpetuate the historical injustice of exploitation of resource-poor settings for easy, cheap research (Sumathipala & Fernando, 2014). But, as it becomes more widely accepted that research is essential for evidence-based management of emergencies, research ethics committees may increasingly be faced with requests to provide oversight. Given that this is a relatively new area, existing guidelines and norms pertaining to research on human participants may not be sufficient to address all the situations that can be expected to arise in emergencies.

It might be thought initially that greater scrutiny is necessary in emergency research to ensure that general ethical principles are adhered to and that participants are protected. At the same time, the circumstances may be such that research ethics committees find it difficult to become more involved. Hence, certain variations to standard procedures of ethics review might have to be made for research in emergencies. This module covers some alternatives that have been proposed in the literature, and participants are invited to reflect on other possible mechanisms.



B. Topics

Possible variations to standard procedures

Most ethical issues in research conducted in emergency situations are not unique to emergencies (World Health Organization, 2010). Therefore, one could argue that the issues are already adequately addressed in non-specific national and international guidelines governing research on human subjects and that the procedures for ethics oversight should therefore be the same.

The likelihood of enhanced vulnerability during emergencies has often been emphasized (Sumathipala et al., 2010), but this premise has been challenged (O’Mathúna, 2012). For example, attendees at a conference bringing together professionals from diverse backgrounds and family members of victims of the attacks in

Oklahoma and at the World Trade Center in New York took the position that survivors are not necessarily vulnerable (Kilpatrick, 2004). In complex disasters such as the 2004 Indian Ocean tsunami and the 2013 Pakistan earthquake, however, unlike in circumscribed man-made disasters such as the Oklahoma bombings and the World Trade Center attacks, all existing infrastructure collapsed in the worst-affected areas.

The notion that disaster survivors are not always vulnerable is not shared by all ethicists in the developing world and was challenged by the Working Group on Disaster Research and Ethics (Sumathipala et al., 2010). One concern of the Working Group is that the global divide and disparities that already exist within societies are exaggerated further in disasters, especially in developing countries. Hence, the Group took the position that disasters, by their very nature, make individuals and social groups vulnerable, particularly in disadvantaged communities. Thus, any research involving human participants during public health emergencies and disasters should require robust, continuous ethical review, with greater vigilance and more safeguards than for research conducted in non-emergency situations (Sumathipala et al., 2010).

The challenges are to ensure that participants are treated with dignity and respect while they contribute to the social good and to find the “least harmful” way of doing research during an emergency (Sumathipala & Fernando, 2014). Possible variations proposed to standard procedures of ethics review to achieve these dual objectives include expedited review, weighing the proportionality of risks and benefits, special scrutiny, combining speed and flexibility with intense scrutiny, preparation of generic anticipatory protocols, especially for predictable, repetitive emergencies, and proactive ethics review.

- *Expedited review*

Expedited or delegated review is usually applied to studies with minimal risk and no novel or worrisome ethical issues (Tansey et al., 2010; World Health Organization, 2010). Although the word “expedite” implies the removal of restrictions or impediments, expedited review (Tansey et al., 2010) should not be misinterpreted as relaxing the usual procedures for a full review by a research ethics board. Although it may be necessary in exceptional situations, it should be conducted with extreme caution (Sumathipala et al., 2010; Tansey et al., 2010). Hence, expedited review should not be construed as a way to bypass normal review simply for convenience; instead, the qualifier “expedited” simply suggests that the time taken for the review should be shortened.

- *Generic protocols*

Generic protocols can be developed well in advance of emergencies, particularly when they are predictable or recurrent (Sumathipala et al., 2010; Tansey et al., 2010). Once a generic protocol has been developed, it can be adapted to specific settings. This approach might facilitate prompt implementation of research and time-sensitive review once a disaster strikes.

- *Pre-approved protocols*

Generic proposals could also be reviewed beforehand, allowing rapid adaptation for specific emergencies, and expedited re-review. Final ethics review and approval may therefore be done before initiation of research for emergencies of a periodic or recurrent nature. The research should be started only after consultation with the affected community (Sumathipala et al., 2010; O’Mathúna, 2012).

- *Review waiver*

Review waiving has been proposed for routine programme implementation, needs assessments and analysis of routinely collected data a posteriori (with proviso) during complex emergencies (Schopper, 2011). Waiving review for needs assessments can, however, compromise coordination, as occurred after the 2004 Indian Ocean tsunami, when multiple needs assessments were conducted without tangible outcomes, increasing the frustration of survivors (Siriwardhana et al., 2012).

An argument for waiving review of some public health research projects might be that there is no foreseeable risk of harm or discomfort to participants beyond what can be expected in daily activities. "Risks in daily activities" might, of course, take on new meaning in an emergency. Therefore, the suggestion that ethics approval might not be necessary in public health research projects remains extremely controversial. Review waiving should be the exception rather than the norm during emergency research.

Angell (1997) poignantly expressed the reason why continued oversight is necessary:

"One reason ethical codes are unequivocal about investigator's primary obligation to care for the human subjects of their research is the strong temptation to subordinate the subjects' welfare to the objectives of the study. That is particularly likely when the research question is extremely important and the answer would probably improve the care of future patients substantially. In those circumstances it is sometimes argued explicitly that obtaining a rapid, unambiguous answer to the research question is the primary ethical obligation. With the most altruistic of motives, then, researchers may find themselves slipping across a line that prohibits treating human subjects as means to an end. When that line is crossed, there is very little left to protect patients from a callous disregard of their welfare for the sake of research goals."

Frameworks for departure from normal review process

It has been suggested that it may be morally permissible (or even required) for research ethics committees to approve a project on the basis of pragmatic or operational standards that are different from those for studies conducted in non-emergency settings (Edwards, 2013; Limkakeng et al., 2013; Sims et al., 2013). Frameworks for departures from normal research ethics review have been proposed (Council for International Organizations of Medical Sciences, 2009; Canadian Institutes of Health Research et al., 2010; Sumathipala et al., 2010; Tansey et al., 2010; Schopper, 2011). For example, Tansey et al. (2010) proposed that "a framework for emergency ethics reviews explicitly combines increased diligence (similar to that of special scrutiny with enhanced procedural flexibility (consistent with expedited review) in a manner that is proportionate to the perceived risks and specific circumstances associated with the research protocol". Many of the frameworks are, however, generic. Apart from the guidelines proposed by the Working Group on Disaster Research and Ethics (Sumathipala et al., 2010) and the Research for Health in Humanitarian Crises initiative (Curry et al., 2014), few resources are available to guide the process explicitly.

Concern about departures from the normal review process

The danger of departures from normal review processes is that they could undermine the 11 important areas of research ethics review listed in learning objective 2.1. One concern is that variations in the review of protocols could result in neglecting issues of exploitation. Emergencies make certain individuals vulnerable and exacerbate the existing vulnerability of social groups such as children, women and impoverished communities and individuals (Sumathipala et al., 2010). Emergencies may also deepen existing disparities

both within societies and at global level. Variations of standard procedures of ethics review must stay true to the goal of minimizing exploitation.

Variations of standard review might increase the risk for therapeutic misconception (see learning objective 8.2). When research is combined with humanitarian aid or clinical care, it may not be clear whether the endeavour is part of routine care or part of research. This can be particularly confusing when the information provided to potential participants is inadequate (e.g. no explicit mention of research, too much emphasis on the therapeutic intent of the project). Even variations of standard procedures of ethics review must ensure that informed consent procedures reduce the likelihood that participants will mistake research for therapeutic services.



C. Case study

Case discussion 1:

To facilitate therapeutic access to a new vaccine for people at risk of infection with a new deadly pathogen, it is proposed that a small sub-committee review an application to evaluate the effects of the new vaccine in humans within a week and that they submit their comments to the chair, who will collate them and notify the researcher of the committee's decision.

The committee is asked to approve use of a new vaccine in people who are at immediate risk before studies in experimental animals have been completed. The vaccine would be made available in one community at a time, so that comparisons can be made with a control group consisting of people waiting for the drug. As more vaccine is manufactured, more communities would be recruited into the study.

Consent to recruit communities will not be sought, and the new vaccine will be dispensed at retail outlets for convenience and increased uptake. Leaflets accompanying the new vaccine will provide the information on which members of the community can decide to take it. In addition, a public health campaign would be conducted through text messaging to raise awareness of the new vaccine.

The researcher proposes to inform the ethics committee periodically of any revisions to the information leaflet as more information becomes available on the effects of the vaccine. The data will be evaluated continuously and analysed periodically so that the study can be stopped quickly if harmful effects become apparent.

Source: Edwards (2013)

Case discussion 2:

The risk of bioterrorism is a constant source of concern. Early detection of a pathogen released to the public could in principle save many lives, and authorities are keen to detect a bioterrorism attack as soon as possible. They set in place a system in which public health authorities collect data on sales of over-the-counter drugs, logs from emergency departments and data on absenteeism from large community employers. By collecting and analysing such data, the authorities can determine the symptoms caused by the toxic agent and the location of its release and make credible inferences about the scale of the attack. They will then be able to deploy appropriate containment units and marshal resources to respond to the attack.

The data entering public health offices are identifiable, that is, each pharmacy purchase, emergency department admission and absentee report is associated with an individual, in some cases with data including their address, credit card number and employer. The authorities argue that, if they were required to obtain consent, safeguard privacy and protect vulnerable populations, they would be unable to act and would lose the opportunity to save many lives, at least in principle.

Source: A composite case, but see Missouri Department of Health (2009).



D. Summary

This module covers possible variations of standard procedures of ethics review that may apply to research in emergencies. Advance preparation of generic proposals for predictable, recurring public health emergencies and obtaining pre-approval are discussed as strategies in conducting research after emergencies. Expedited review and review waiving are discussed as possible options to facilitate public health research by preventing delays. The aim of expedited review, however, is to expedite review and not to relax the usual procedures. Review waiving remains extremely controversial and should be the exception rather than the norm.



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Core competence 3: Ability to identify conflict between the common good and individual autonomy in surveillance during emergency response



Local health staff work with experts from Médecins Sans Frontières to disinfect the house of a patient who died of Ebola. Democratic Republic of the Congo, 2007.
Source: WHO/Christopher Black

Core competence 3: Ability to identify conflict between the common good and individual autonomy in surveillance during emergency response

Even though public health practice, including surveillance, is meant to improve the common good or the aggregate public welfare, it can harm individuals and communities. Public health practitioners should be aware of the exact nature of the harms and benefits that might accrue to individuals and communities in the course of public health activities (learning objective 3.1). Given the threat of harm, some circumstances warrant that informed consent be sought, as suggested in learning objective 3.2. Public health practitioners should also be aware of the measures they should take to protect both privacy and confidentiality during emergency response (learning objective 3.3). Measures are also particularly important to protect the confidential nature of biological materials; such measures are discussed in learning objective 3.4. Learning objective 3.5 provides a description of the circumstances under which the common good might take precedence over the autonomy of individual community members.



Learning objectives

- 3.1 Identify possible harm and benefit to individuals and communities resulting from public health practice and surveillance.
 - 3.2 Assess the factors to be considered in determining when public health surveillance requires explicit informed consent from individuals or communities.
 - 3.3 Evaluate the measures required to protect privacy and confidentiality in an emergency.
 - 3.4 Describe specific measures required to protect and collect data and biological materials during public health surveillance.
 - 3.5 Describe circumstances in which the common good might overrule individual autonomy during public health surveillance.
-

Learning objective 3.1: Identify possible harm and benefit to individuals and communities resulting from public health practice and surveillance.

Dónal O'Mathúna



Session timeline (105 min)

0–5 min (5 min)	6–25 min (20 min)	26–30 min (5 min)	31–35 min (5 min)	36–50 min (15 min)	51–60 min (10 min)	61–70 min (10 min)	71–100 min (30 min)	101–105 min (5 min)
Writing and discussion	Introduction	Writing	Reading	Group discussion	Class discussion	Slide presentation	Case study and discussion	Summary and conclusion



Instruction strategy

1. The facilitator asks participants to write a brief answer to the following question and share their answer with the group: Under what, if any, circumstances would quarantining people be ethically justified? Explain your rationale.
2. The facilitator introduces the module and briefly describes the harms and benefits that might result from public health practice and surveillance.

For facilitators: Discuss the notion of psychosocial harm and the potential conflict between public good and individual rights. Psychosocial harm and benefit extend beyond physical and biological effects to include emotional, mental, social, cultural and spiritual impacts (Williamson & Robinson, 2006).

3. The facilitator gives the participants 5 min to write a brief response to the following situation: An earthquake has devastated an urban region. Give examples of the types of public health interventions that you think would be justified at each of the rungs of the Nuffield intervention ladder (Nuffield Council on Bioethics, 2007, and see slides).
4. The facilitator distributes a copy of "Fear of a swine flu epidemic in 1976 offers some lessons and concerns today" (Pollack, 2009) and gives participants 5 min to read it.
5. The facilitator asks participants to discuss in groups of three or four how they would ethically balance the harms and benefits of a new influenza vaccine like that discussed in the article.
6. The facilitator asks each group to appoint a rapporteur to summarize their discussions for the rest of the group.

For facilitators: Ask groups that will present later to add only items that have not already been mentioned by other groups.

7. The facilitator presents the case study and asks the group to discuss the following questions:
 - What are the potential harms and benefits of the public health surveillance activity proposed by Dr Chingana?
 - Dr Chingana may argue that he is simply collecting data and cannot be responsible for how his findings are used to incite stigmatization or stereotyping. Do you agree or disagree with this view? What reasons can you give to support your view?
 - Let us assume that Dr Chingana proposes to carry out this survey without obtaining informed consent. He would ask the questions during his background interview with patients. He claims that this is necessary to ensure that all patients answer the questions and do so completely honestly. Would you approve this approach? Why or why not?
8. The facilitator concludes the session and opens the floor for discussion.



A. Background

As discussed in learning objective 1.1, the aim of public health activities (including surveillance) is to benefit people by preventing disease or injury or by identifying unusual public health events in order to minimize harm (Lee et al., 2012). As in clinical medicine, the nature of the benefits of public health practice and surveillance (psychological, social or physical) varies, but they are well established (Bernstein & Sweeney, 2012) and include more efficient use of health resources and better health for individuals and communities. Public health practice and surveillance can sometimes lead to harm, however, which, like benefits, varies in nature and is attributable to different aspects of public health activities (Lee et al., 2012). Harm may for example be related to violation of autonomy, such as when the collection of biological samples is mandatory.

While parallels can be drawn between the benefits provided by clinical care and by public health, important differences emerge. Ethical dilemmas in clinical medicine tend to focus on balancing harm and benefits for patients at the individual level. The same person usually experiences both potential harm and potential benefits. As a result, the person would seem to be in the best position to judge which interventions to undergo and which to refuse. The ethical principle of autonomy, which states that individuals should be allowed to determine the course of their lives and what happens to them, supports this approach (see learning objectives 3.2 and 3.5). Conversely, in the case of public health practice and surveillance, benefits and harm can accrue to different entities; for example, benefits for the community (the “public good”) accrue at the expense of respect for individual rights. Take the issue of quarantine. Even if public health practice generally seeks to uphold the principle of autonomy, it is sometimes impossible to do so to the extent that can be expected in clinical care. During an outbreak of an infectious disease, it may seem prudent to quarantine some people to prevent spread of the contagion. In an ideal situation, exposed individuals would voluntarily enter quarantine; but, if they refuse, should they be quarantined against their will? How will this be enforced practically and by whom? At what point will this be done, and for how long? Who will make these decisions?

These questions raise two issues: balancing harm and benefits that accrue to different entities (addressed in learning objective 3.5) and deciding who should balance the potential risks and benefits. When public health programmes are voluntary, people weigh the benefits and risks themselves and make informed decisions, as they would about other health care interventions. In order to maximize the benefit to the community of some public health interventions, however, a large proportion of the population must accept the intervention.

Mandatory programmes are particularly challenging when trust in public health authorities has broken down, as exemplified during the 2014 Ebola outbreak. This highlights the importance of ethical practice as a means of building trust.

For example, some favour mandatory vaccination programmes, in which people are required to receive vaccinations or to have their children vaccinated. Others disagree, noting that voluntary approaches may increase public acceptance of vaccination and that complete coverage is not necessary for herd immunity. Ethical, scientific and political issues are involved in deciding if and when mandatory programmes are justified. The public health benefits of such programmes may be clear, but the intrinsic harm of violating people's autonomy must be carefully considered (Field & Caplan, 2008; see learning objective 3.2).

Weighing risks against benefits is ideologically-laden: different political and ethical theories may lead not only to different conceptualizations of what constitutes a benefit and what constitutes harm but also to the attribution of different weights to each. The main ethical theories that might guide decision-making in health are explored in learning objective 4.2.

The following section includes a non-exhaustive list of potential physical and psychosocial harm and benefits that might accrue as a result of public health practice and public health surveillance.



B. Topics

Potential benefits of public health practice and surveillance

- *Better health for individuals*

Individuals who respond positively to public health programmes will probably benefit by better health. For example, they may adopt a healthier lifestyle. Similarly, vaccination programmes tend to benefit the vast majority of individual recipients by protecting them from illness.

- *Better health for communities*

By carefully monitoring public health, communities can be protected from emerging health concerns. An unusual increase in the incidence of a particular illness may be followed by a more rapid response, which in turn might limit the impact of the threat. In addition, large-scale vaccination programmes can provide health benefits to the whole community through "herd immunity" (Field & Caplan, 2008).

- *More efficient use of health resources*

Surveillance may also indicate that greater attention or public awareness is required on a particular issue and thus facilitate the preparation of relevant programmes and policies. In other words, public health surveillance may identify areas that are not being addressed adequately and facilitate reallocation of resources towards those areas. If this means that public resources benefit more members of the public, the benefit of promoting greater social justice is added. For instance, the needs of marginalized and vulnerable groups such as the elderly, disabled people and minorities may thereby be provided for more justly.

- *More scientific opportunities*

Publicly led health interventions and surveillance may reveal the cause of an emergency sooner, which, in the case of contagious illnesses, will be prevented from spreading further. This, in turn, might contribute to the preparation of effective responses, including the manufacture of new vaccines or drugs. In addition, public health activities might open the door to international collaboration, such as initiatives to build public health capacity in regions in which it was limited.

Potential harm of public health practice and surveillance

- *Adverse effects*

Public health interventions are not free of risk, and the adverse effects can be serious. For example, in 1976, a vaccine against “swine flu” was linked to an increased risk for contracting Guillain-Barré syndrome (Pollack, 2009). Apart from the suffering caused, the feared epidemic of swine flu did not materialize, indicating that there was arguably no benefit from the vaccination campaign.

- *Loss of privacy and/or confidentiality*

No data retention procedure is fully secure, so that the private information of individuals collected in the course of public health practice may be leaked—either intentionally or not. Leaks may directly or indirectly affect people who have relationships with affected individuals, such as their families and those caring for them. For example, as genetic material is shared through ancestry, a leak of genetic data could reveal risk factors that family members might share, which could lead to further harm, such as stigmatization.

- *Stigmatization*

Individuals may be stigmatized if it becomes known that they have an illness of public health concern. Stigmatization may result from scientifically valid concerns or from unrealistic ones. For instance, much of the stigmatization of HIV/AIDS patients and people exposed to Ebola virus is derived from false beliefs about transmission.

Whole communities can be stigmatized if public health activities reveal that they have a higher prevalence of a condition that can be traced to practices that society generally disapproves of. This could also happen to religious or cultural groups if they are identified as being significantly different in some way. A particular problem arises if one group is blamed by another for “causing” a public health problem.

- *Rights violation*

Emergencies can create a climate in which human rights are more readily overlooked or even violated in the interest of the so-called common good. Coercive actions may be publicly justified by overestimating their benefits and underestimating the negative impact of the resulting loss of public trust. For example, although collecting biological specimens from everyone in a camp for displaced persons may result in the best epidemiological information, doing so without consent increases the risks for other harm. Particular attention must be paid to ensure that such data collection does not violate individual rights.

Violation of rights is sometimes commonly agreed upon. For instance, personal autonomy may be sacrificed for the public good, but very careful ethical justification is required before such violation is condoned. Loss of liberty, as during quarantine or in compulsory vaccination, is particularly challenging ethically. The Siracusa Principles (United Nations Commission on Human Rights, 1984) are a set of guidelines for limiting human rights in the name of public health, including in emergencies.

- *Wasteful use of limited resources*

Data from public health practice and surveillance can sometimes accumulate without being put to beneficial use. While this can occur for unexpected reasons, the fact that resources are limited means that their waste is harmful to public infrastructures. Poorly planned data collection and analysis can be similarly wasteful.

Minimizing harm

A number of strategies have been proposed to minimize harm from surveillance (Lee et al., 2012). These include collecting the minimum amount of the simplest data to meet the surveillance goals; engaging early with individuals, families or communities, especially when sensitive data are to be collected or vulnerable populations are included; using rigorous data protection procedures; acting on new evidence as quickly as possible; and promoting transparency, inclusiveness and openness. Similar strategies should be envisaged when conducting other public health activities.



C. Case study

The records of the sexually transmitted infections clinic at the largest general hospital in a southern African country indicate that there are twice as many cases in the segment of the population that self-ascribes itself as “coloured” as in the segment that self-ascribes itself as “black”. The numbers of cases of almost all the other conditions seen in the hospital’s outpatient department in each racial and ethnic group are proportional to the percentage of that group in the general population. Even after control for socioeconomic status, the distinction in the distribution of sexually transmitted infection remains.

Before the country’s independence, Government officials assigned individuals to one of four racial categories—black, white, coloured and Asian—on the basis of factors such as physical appearance, descent, language and behaviour. Since independence, an individual’s membership in one of these racial groups, or in a new alternative, “other”, is self-ascribed. Authorities may investigate an individual’s self-categorization if they suspect him or her of self-identifying to a racial group in order to accrue a particular benefit.

Dr Chingana, the Director of the sexually transmitted infections clinic, believes that the disproportionately higher number of cases in people who identify themselves as “coloured” than in those who self-identify as “black” reflects differences in their biological susceptibility to these diseases. He is, however, unsure of the underlying mechanism. In order to bolster the evidence for his hypothesis, Dr Chingana designs a survey to link symptoms of sexually transmitted infections with a variety of risk factors, including race⁹ and ethnicity¹⁰. He presents his protocol to his institution’s research ethics committee for approval.

⁹ As used here, “race” refers to a group of people connected by common descent or origin.

¹⁰ “Ethnicity” here refers to the culture and/or collective identity shared by a group of people of common descent or origin.

Ms Johnson, a community representative on the committee who self-identifies as coloured, objects to the targeting of race in the survey. She argues that the coloured population is already stigmatized by stereotypes that portray them as promiscuous and lax in using health services. She contends that if higher rates of sexually transmitted infections are found in the coloured population these deeply held prejudices will be reinforced. Further, she is sceptical of the notion that being coloured increases one's risk for contracting a sexually transmitted infection and asks for further explanation. Do the bacteria behave differently in coloured people? Is their anatomy different? She wants the race and ethnicity question removed from the questionnaire.

Dr Chingana argues that this question is critical to the study. Moreover, the findings might lead to further research that could result in programmes for control of these diseases and especially in reducing the high rate of infection among coloured people.

Source: Cash et al. (2009)



D. Summary

The physical harm posed by public health practice and surveillance must be taken into account and balanced against potential benefits. Such balancing raises some of the core challenges of public health ethics: in contrast with standard clinical care, individual good must sometimes be weighed against the public good in public health practice. Even when these practices are scientifically valid and pose limited apparent physical harm, they may go against the cultural, moral or religious beliefs of individuals and communities. Harm can occur in a wide range of psychosocial areas and is not necessarily only physical (Williamson & Robinson 2006).

The psychosocial benefits and harm of public health practice and surveillance may be even more challenging to deal with than the physical ones, as they are not amenable to quantitative assessment. Their evaluation is nonetheless very important. Before harm and benefits can be balanced, they must first be identified; however, the relative weight given to each harm and benefit depends on the context and on moral and cultural beliefs. For example, closing schools during a pandemic might appear to some communities a reasonable way to protect children from spreading an illness; in other communities, however, schools may be the safest, most nurturing settings for children, and, without access to them, children may be put at risk of more serious harm (Faden, 2007). These conflicting perspectives indicate the importance of involving communities that are affected by emergencies in making decisions about potential harm and benefits.



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Learning objective 3.2: Assess the factors to be considered in determining when public health surveillance requires explicit informed consent from individuals or communities.

Carl Coleman



Session timeline (60 min)

0–15 min (15 min)	16–20 min (5 min)	21–35 min (15 min)	36–56 min (20 min)	56–60 min (5 min)
Introduction	Reading	Team preparation	Team presentations and discussion	Summary and conclusion



Instruction strategy

1. The facilitator presents a general overview of the issue, using the slides (15 min).
2. The facilitator distributes the case study and gives participants 5 min to read it (5 min).
3. The facilitator divides the group into teams of three or four, asks each team to appoint a rapporteur and gives them 10–15 min to discuss the following questions (15 min):
 - Is the activity described surveillance, research or both?

For facilitators: According to some guidelines, the distinction between surveillance and research depends on the primary intent of the activity (see learning objective 1.1). In this situation, however, appropriate application of this distinction is unclear. On the one hand, the long-term goal is not to produce generalizable knowledge but rather to benefit the local population by generating international support for improved treatment of multi-drug-resistant tuberculosis (MDR-TB). On the other hand, the individuals who will participate in the survey are unlikely to benefit directly, as access to treatment for MDR-TB is currently limited. The discussion should address the difficulty of applying the “primary intent” standard in this context and whether the standard is useful for determining the nature of the ethical issues or the appropriate process for ethical review.

- What are the risks to the patients whose blood is taken for the survey?

For facilitators: The primary risk is that patients will be identified as having MDR-TB, which may lead to stigmatization and discrimination against both the patients and their household members. Whether this is a concern depends on whether patients could be identified solely from the date and place of samples collection. This would depend on the size of the clinics and the number of patients.

- Should patients be asked to provide informed consent to the survey? If so, what information should be disclosed as part of the consent process?

For facilitators: Some people would argue that explicit consent is not necessary because no identifying information is being collected. Others would say that asking for consent is appropriate because the activity exposes individuals to increased risks and is not necessary for their clinical care. If consent is sought, the information to be disclosed would include the purpose of testing, the risk that patients' identities could be discovered, the fact that the test results will not be reported to the patients and the fact that access to treatment for MDR-TB is currently limited.

- Should patients have the right to refuse to participate in the survey?

For facilitators: Some would argue that, even if obtaining explicit consent is not considered necessary, tests should not be performed on anyone who objects. This argument might be grounded on appeals to patients' rights as autonomous individuals or on concern that forced testing could reduce patients' trust in the health care system, thereby impeding public health. Others would argue that allowing individuals to refuse would undermine the public health value of the survey (It may be useful to distinguish between "opt in" and "opt out" methods and explore when the latter suffice.).

- Should community consultation be instituted before the survey is initiated? If so, why? Who should be consulted, what should they be asked, and how should the information obtained be used?

For facilitators: Community consultation is an important means of showing respect for the community and preserving patients' trust in the health care system. It may also increase community members' willingness to participate in the survey. Consultation should be conducted with community leaders, local public health officials and representative people likely to be included in the survey. They should be given understandable information about the purposes, methods, risks and benefits of the proposed survey and asked to give their perspectives. If concern is voiced, those responsible for designing the survey should either redesign it to address the concern or explain why they are unable to do so.

4. Once the group has reconvened, the facilitator asks one of the rapporteurs to summarize his or her team's response to the first question. The other rapporteurs are then asked to contribute any additional points raised by their teams; other participants may also contribute to the discussion. Once discussion of the first question is completed, the same process is repeated for the remaining questions, a different rapporteur taking the lead for each question (20 min).

For facilitators: During the discussion, take notes on a flip chart, focusing on areas of consensus and areas of disagreement.

5. The facilitator reviews the areas of consensus and disagreement on the flip chart and asks for further comments (5 min).
6. The facilitator concludes the session and opens the floor for discussion.



A. Background

Informed consent is the process by which individuals make an explicit choice about whether to accept a particular intervention, after having been fully informed about the risks, potential benefits and available alternatives. Informed consent is widely recognized as a fundamental ethical and legal requirement in medical treatment and research. It is central to all the major international guidelines on research ethics—the Nuremberg Code (Nuremberg Military Tribunals, 1949), the Declaration of Helsinki (World Medical Association, 2013) and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council of International Organizations of Medical Sciences, 2002)—and is also reflected in national legislation and judicial decisions in many countries. While informed consent is often obtained by asking individuals to sign a written form, oral informed consent is considered sufficient in many circumstances. Use of written consent forms may, however, sometimes be required legally.

Several justifications for the principle of informed consent have been published. Capron (1974) argued that obtaining informed consent can promote individual autonomy, protect the individual's status as a human being, avoid fraud or duress, encourage doctors to consider their decisions carefully, foster rational decision-making and involve the public in medicine. While informed consent is usually an ethical and legal prerequisite for both medical treatment and research, it can exceptionally be waived or modified. For example, a doctor generally does not have to ask for consent to perform routine blood tests as part of a medical examination (Coleman et al., 2012). Research ethics committees may waive the requirement of obtaining consent if the risks to participants are minimal and requiring individual informed consent would be logistically burdensome, such as in large-scale studies involving a review of medical records (Department of Health and Human Services, 2009). Similarly, CIOMS (2009) considers it acceptable to waive consent for epidemiological studies if the risks are minimal, the data are “anonymized” or the studies are “carried out under legislative or regulatory authority for public health, such as disease surveillance.”

Whether consent is obtained orally or in writing, the fact that an individual has provided consent does not in itself demonstrate that the consent is ethically or legally acceptable. As explained in the Nuremberg Code, genuine informed consent requires that the individual have “sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision” (Nuremberg Military Tribunals, 1949). Ensuring this level of understanding can be challenging when individuals are not generally familiar with medical concepts. Language and cultural barriers can further complicate the process, particularly in settings where individuals are not accustomed to making important decisions on their own (Mystakidou et al., 2009) or where they perceive (correctly or incorrectly) that they would be subject to negative repercussions if they did not agree to a project that has the support of powerful public health officials or community leaders.

Unlike in the areas of medical treatment and research, informed consent is often not obtained as part of routine public health practice, including surveillance (Gostin, 2008). For example, public health officials may routinely collect personal health information from doctors or hospitals without asking the individuals concerned if they are willing to have their information collected. In some situations, public health officials may even order individuals to submit to interventions that they actively oppose. For example, individuals with tuberculosis (TB) may be confined against their wishes if they are infectious and are unwilling or unable to take precautions to prevent transmission. According to the principles of international human rights, however, non-consensual interventions should be used only as a last resort, never if they constitute cruel, inhuman or degrading treatment and only if the individual is provided with safeguards of due process (Coleman et al., 2012).



B. Topics

As noted above, while informed consent is a central requirement in medical treatment and research, it has often played a much lesser role in public health surveillance. The rationales for this distinction include the fact that surveillance is usually conducted by government officials pursuant to legal obligations; that individuals often do not have the right to refuse to participate in surveillance, so that asking for consent may be seen as unnecessary or misleading; and that the risks associated with surveillance are often thought to be insignificant. Yet, the line between surveillance and medical research is often difficult to draw (see learning objective 1.1). Moreover, even when an activity is properly characterized as surveillance, the ethical issues at stake may be indistinguishable from those involved in research. For these reasons, some commentators have argued that public health authorities engaged in surveillance activities should pay greater attention to the role of informed consent.

Risks to individuals and communities associated with surveillance

The fact that an activity is characterized as surveillance rather than research does not necessarily mean that the individuals involved will not face any risks (see learning objective 3.1). In some cases, surveillance can result in the disclosure of identifiable information about individuals that could be stigmatizing or lead to discrimination or harassment. Examples include surveillance activities with identification of individuals with HIV infection, MDR-TB or other stigmatizing conditions or individuals who engage in illegal activities such as drug use or prostitution. Information generated through surveillance can also stigmatize entire communities, such as when a particular ethnic group is identified as having a higher prevalence of an undesirable genetic mutation or when individuals in a particular geographical area are identified as being more likely to be infected with a dangerous new virus (see learning objective 3.3).

The role of informed consent in surveillance

Even if informed consent is not legally required in surveillance activities, providing information to individuals and asking for their agreement to participate can be important means of demonstrating respect, promoting trust and generating individual and community support for the activity (Parmet, 2005). Most individuals, if given full information and an opportunity to ask questions, will be willing to participate in legitimate public health surveillance; if more than a very small number of people refuse to participate, the activity may be poorly designed or lack community support.

The role of community consultation

If obtaining individual informed consent to surveillance is determined to be inappropriate or unfeasible, it may still be appropriate to consult community leaders before initiating the activity. Community consultation is particularly appropriate when the primary risks of the activity extend to communities as a whole rather than to individual members, as in the example of the risk of associating a particular ethnic group with an undesirable genetic mutation. Moreover, in some contexts, consulting with community leaders may be necessary to show respect for local norms.

One challenge of community consultation is determining who to consult—that is, identifying the individuals or institutions that can legitimately speak on behalf of the community. A “community” is not necessarily a singular entity, and outsiders may not be able to identify whether a leader or leadership group represents

the entire community or just a part of it. It is therefore essential to work with cross-cultural advisors to ensure that health professionals do not wrongly consider a particular leader as representative of a “community.”

It is also important to consider in advance what will be done with the information that is received during community consultation. If communities are to have a genuine role in surveillance activities, their input must be sought early enough that they can influence the design of the intervention. Public health officials who seek community input on surveillance should be prepared for the possibility that the community will oppose the proposed activity, in which case they should be prepared to revise their plans.



C. Case study

The Republic of Coconut Paradise is a low-income island nation that has had high rates of TB. In the past few years, the rate of MDR-TB has been increasing dramatically. MDR-TB is highly contagious and often fatal; individuals who are thought to be infected are often shunned from their communities, and the household members of people with MDR-TB also face stigmatization. While there are some treatments for MDR-TB, they are not accessible to most people on the island. Most patients who are infected eventually die of the condition.

Public health officials concerned about the spread of MDR-TB have proposed to conduct tests on patients at the national TB centre to determine how many are infected with a drug-resistant strain. They consider that, by determining the actual rate of MDR-TB in the country, they will be in a better position to negotiate with international donors for assistance in obtaining treatment and improving local treatment facilities.

The officials propose to conduct the assessment by approaching a randomly selected sample of TB patients (one out of every 10 patients who attends the main site of the national clinic over a period of 2 months). Clinic staff will be instructed to take blood samples from these patients and to send them to the national reference laboratory, which will conduct testing to determine whether the patient is resistant to standard TB drugs. The samples will be identified only by the date on which they were collected; no patient names will be recorded. The results of the assessment will be reported in aggregate form. Because samples will not be identified by name, it will not be possible to report individual test results back to patients.



D. Summary

Informed consent is a process by which individuals make an explicit choice about whether to accept a particular intervention, having been fully informed about the risks, potential benefits and available alternatives. Unlike in medical treatment and research, informed consent is often not obtained as part of public health practice, including surveillance. Yet, the fact that an activity is characterized as surveillance does not necessarily mean that the individuals involved will not face any risks. In some cases, surveillance can result in the disclosure of individually identifiable information that could be stigmatizing or lead to discrimination or harassment. Even if informed consent is not legally required in surveillance activities, providing information to individuals and asking for their agreement to participate can be important means of demonstrating respect, promoting trust and generating individual and community support for the activity. If obtaining individual informed consent to surveillance is determined to be inappropriate or unfeasible, it may still be appropriate to consult community leaders before initiating the activity. Community consultation

is particularly appropriate in situations in which the primary risks of the activity extend to communities as a whole rather than to individual members.



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Learning objective 3.3: Evaluate the measures required to protect privacy and confidentiality in an emergency.

Ghaiath Hussein



Session timeline (90 min)

0–5 min (5 min)	6–15 min (10 min)	16–20 min (5 min)	21–45 min (25 min)	46–60 min (15 min)	61–85 min (25 min)	86–90 min (5 min)
Introduction	Discussion	Reading	Team preparation	Group discussion	Team presentations and discussion	Summary and conclusion



Instruction strategy

1. The facilitator briefly describes the learning objective (5 min).
2. The facilitator probes the understanding of the trainees of the concepts of privacy and confidentiality and asks them to share any professional or personal experience (10 min).
3. The facilitator separates the group into three, distributes the case and asks the following questions:
 - Do you think that the team should comply with the requests of the village leader? Justify your choice on the basis of ethical principles.

For facilitators: Trainees may find various reasons for sharing or not sharing the information with the village leader. The important point is that no one should be interviewed unless he or she freely accepts to do so. In addition, the only people allowed to look at the collected data should be those explicitly authorized to do so for the purpose for which data were collected.

- Describe how privacy and confidentiality would be breached if the team did comply with the leader's requests.
- Suggest two or three practical steps that should have been taken by the nongovernmental organization and the survey team before, during and after the survey to protect the privacy of the survey participants and the confidentiality of the collected data.

For facilitators: Some protective measures might include:

- Contacting the community leaders before the survey to clarify the purpose, emphasizing the concept of random selection; this might reassure the village leader of the fairness of the process.
- Explaining that collecting data from that sample of villagers does not mean that only they will receive aid; this might convince the village leader that he did not have to undergo screening.

- Avoiding the collection of identifiable information such as the names and addresses of participants. Giving participants a code or unique identification number would make it more difficult for people who are not part of the research team to understand the data.
 - Transporting filled questionnaires in locked boxes, to which data collection teams do not have the key. Doing so might disarm the situation by making it impossible for the data collection team to comply with the village leader's request.
4. The facilitator allows time for reading and discussion (30 min).
 5. The facilitator asks each small group to present its responses (15 min).
 6. The facilitator presents the learning objective material and concludes the session by opening the floor for final remarks (25 min).
 7. The facilitator concludes the session and opens the floor for discussion (5 min).



A. Background

Emergencies often provide an opportunity for conducting activities that involve the collection of personal data and/or biological samples from people who are directly or indirectly affected. Such activities, including surveillance, allow public health practitioners to identify public health threats early, which can improve the management and outcomes of a crisis. The benefits of data collection during emergencies can therefore extend to an entire community. These benefits are not without costs. Collection of personal data about an individual's health status or condition might pose a threat to that individual, particularly with regard to stigmatized conditions, such as TB, HIV/AIDS, hepatitis and sexually transmitted infections.

This module explores two ethical issues (first introduced in learning objective 1.3) related to activities that involve the collection of personal data and/or biological samples during emergencies: privacy and confidentiality.



B. Topics

Defining privacy and confidentiality

Privacy is the right or expectation not to be interfered with, to be free from surveillance or, more generally, to be left alone. It also refers to the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Boruch and Cecil (1979), defined privacy as "persons and to their interest in controlling the access of others to themselves." (Boruch and Cecil, 1979) This right to privacy, following Beauchamp and Childress (1994), gives the person the right to authorize or refuse access to one's life (Beauchamp and Childress, 1994).

Confidentiality pertains to the professional duty to keep the information that an individual has disclosed in a relationship of trust in the course of care or research out of reach of others without authorization from the person disclosing it. The duty of confidentiality includes all identifiable health related personal information

that is collected by the health professional from the patient, whether written, computerized, visual, audio or simply memorized by the health professional.

In normal clinical practice, personal information can be expected to be confined to a secure location (e.g. a hospital), with access limited to a small group of individuals (e.g. health care personnel). In the context of emergencies, factors that threaten privacy and confidentiality might come to the forefront. First, the setting in which data are collected tends to be less well controlled. Secondly, the collected data tend to be shared more broadly, for instance when a local health authority is mandated to send non-aggregated data to the national health authority. Thirdly, data recording may be more improvised during emergencies, making it less secure; for example, use of paper-based questionnaires might increase the risk for loss. Lastly, and perhaps most importantly, adequate means of keeping identifiable information safe from prying eyes might demand more resources than can be mustered. Locked file cabinets, for instance, might be difficult to find under some circumstances. Moreover, the security of digitally collected or stored data is becoming more difficult to sustain even in normal conditions. With the increasing use of electronic devices to collect, store and share data, it is reasonable to expect that more and more of the data collected during emergencies will be stored digitally. The safety of data is further threatened by logistical difficulties; for instance, electricity may not be available or stable, so data may be lost. Moreover, sharing data on “data clouds” and in e-mails may expose them to risks of hacking or leaking.

Justifying the moral duty to respect privacy and ensure confidentiality

Many ethical principles can be called upon to justify the duty to respect privacy and enforce confidentiality. Four are relevant here: beneficence, non-maleficence, respect for autonomy and trustworthiness.

- *Beneficence and non-maleficence*

Although beneficence and non-maleficence are two distinct medical ethical principles, looking at them jointly in this context can be fruitful. As discussed in learning objective 1.3, beneficence refers to the duty to “do good”, while non-maleficence in its simplest form refers to the duty not to harm others. To the extent that they apply at all to public health, these two principles together suggest that public health authorities should ensure that interventions are as beneficial and as least burdensome as possible to the community they are to serve. Fundamentally, the principles also suggest that sharing an individual's personal health information is ethically wrong if it is reasonable to suspect that its disclosure would have a negative outcome, such as stigmatization or distress.

- *Respect for autonomy*

Although most people agree that overriding an individual's will can be justified in some circumstance, the justification is limited. John Stuart Mill stated that “the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant” (Mill, 1859, p. 18). In conjunction with the principle of “least intrusion”, which holds that “the full force of state authority and power should be reserved for exceptional circumstances and that more coercive methods should be employed only when less coercive methods have failed” (Upshur, 2002, p. 102), Mill's statement makes a strong case for the protection of privacy. Hence, public health surveillance and associated activities undertaken during emergencies should seek to respect the ability of the individuals being investigated to decide for themselves.

- *Trustworthiness*

Trust is essential for the efficient functioning of health care systems and public health interventions. People who accept to seek medical advice and to collaborate with public health authorities do so because they have a certain level of trust in health care institutions. In addition, trust can be considered part of the continuum of health care providers' duty to respect the autonomy of the people they serve. The served population should be given the chance to enjoy their right to know and then to decide which data that they share with public health workers will be further shared with other parties. Should it become understood that people should not share medical information for fear that this information would not be treated in ways that ensure its confidentiality, people might be hesitant to collaborate with public health authorities. This could have implications for public health. For example, community members might seek healing alternatives that are not based on scientific evidence or from unregistered practitioners who are not inclined to provide information to national registries. Apart from these direct threats to the well-being of the people making such choices, threats to public health policy-making can also be expected. Decisions made on the basis of poor or inaccurate estimates could be devastating in the long-term.

To be worthy of trust, those conducting surveillance and data collection during emergencies should fulfil their assigned responsibility and not let down expectations. This speaks directly to the importance of protecting privacy and ensuring confidentiality to the extent possible when requested by users and participants.

Measures to respect privacy and confidentiality

The measures used to protect privacy should depend on circumstances. Certainly, data should be collected in isolation from surroundings, possibly apart from family members. Some of the main measures to be used by practitioners and their institutions are described in Box 1.

Box 1. Measures to respect privacy and confidentiality

- Avoid collecting unnecessary identifiable information. For example, do not collect full names and addresses unless necessary.
- Use coding to refer to respondents. For example, refer to respondents with an alphanumerical code so that only those who have the key to the code can link identities and data. This key should be stored in a secure place, separate from the associated data. Consent forms can be stored separately from the data collected in a separate, secure location.
- Limit access to data on the basis of a clear understanding of the roles and information required to complete an assignment. For example, people who can help a patient without knowing his or her identifiable details and people who cannot directly help (e.g. health care professionals who are not looking after the patient) should not be allowed access to such information.
- Do not discuss an individual's personal data with unauthorized personnel. For example, in some settings, any health care personnel who "wear a white coat" are often given unlimited access to medical information; this practice undermines the notions of privacy and confidentiality. Assign "record-keepers" who have a list of "who needs to know what"; staff identification tags should be requested before information is shared.

- Be explicit about the circumstances in which identifiers might have to be disclosed (e.g. a court order).
- Set policies to regulate access to medical information and the management of any breach of confidentiality. For example, formulate a policy with a clear description of: when it is permissible to disclose identifiable information; which identifiable information can be disclosed; by whom; to whom and how to manage any breach of confidentiality.
- Do not collect information that is not related to the public health activity. The collection of irrelevant information wastes resources (e.g. practitioners' and participants' time) and adds a burden with regard to the protection of confidentiality and privacy. For example, if marital status is of no relevance to the purpose for which data are collected, do not ask about it.
- Do not inappropriately access records or facilitate access.
- Lock doors of offices.
- Establish the identity of visitors (unknown individuals) near record storage sites.
- Advise senior personnel if anything suspicious or worrying is noted.
- Whenever possible, separate clinical details from demographic data.

Hand-written records

- Hold in secure storage.
- Track if moved or transferred, for instance by adding a note of their current location in the filing system.
- Return records to the filing system as soon as possible after use.
- Store and close the filing system when not in use so that the contents are not easily accessed by others.
- Be clear who is responsible for locking the file cabinet (or equivalent).

Electronic records

- Always correctly log out of applications and computers when you have completed your work.
 - Do not leave a terminal unattended and logged in.
 - Do not share passwords or electronic cards with others.
 - Regularly change all your passwords.
 - Always clear the screen of confidential information when others are present.
 - Seek to encrypt data when feasible.
 - Do not share personal information by e-mail if the communication is not encrypted.
 - If data are collected on transportable devices, make sure that these are also password-protected.
-



C. Case study

An emergency is occurring in a remote region of a country. This region is home to an indigenous tribe that has had disputes with neighbouring tribes about the use of water sources, on which their cattle are heavily dependent. As part of its relief intervention, an international nongovernmental organization decides to conduct a survey to assess the impact of the emergency in various villages to better target resource deployment. To do so, the organization recruits some of the more educated members of the local community and trains them to interview respondents and fill in the survey questionnaires.

The recently trained survey teams start collecting data from randomly selected villages in the affected region. As one of the teams is collecting data from an affected village, the members are stopped by the village leader because one of them is not from the same tribe. The leader accuses the individual of being biased and of collecting data that will help his or her tribe obtain additional aid from the nongovernmental organization. The leader asks the team to show him the filled questionnaires so that he can check the identity of the people who contributed to the survey to ensure that they are the neediest families in the village. He also asks the team to allow his assistant to attend all interviews with selected households. If the team does not comply with his requests, he threatens to stop the team from collecting data in the village.



D. Summary

Public health activities undertaken during emergencies, including those that involve the collection of personal data and/or biological samples, should be guided by ethical standards that are relevant to the context of the emergency and that can reasonably be respected by the responders. Two main ethical standards are the duty to respect privacy and the duty to ensure the confidentiality of data collected during the emergency. The urgency of the situation should not override the affected people's claim to privacy and confidentiality. In order to meet expectations, measures must be taken during emergencies to protect the process of data collection and the data collected. Ideally, the importance of privacy and confidentiality should be reflected in the operating procedures of the institutions conducting surveillance and data collection during emergencies.



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Learning objective 3.4: Describe specific measures required to protect and collect data and biological materials during public health surveillance.

Carl Coleman



Session timeline (60 min)

0–15 min (15 min)	16–20 min (5 min)	21–35 min (15 min)	36–55 min (20 min)	56–60 min (5 min)
Introduction	Reading	Team preparation	Team presentations and discussion	Summary and conclusion



Instruction strategy

1. The facilitator presents a general overview of the issue, using the slides as a guide (15 min).
2. The facilitator distributes the case study and gives participants time to read it (5 min).
3. The facilitator divides the group into teams of three to four, asks each team to appoint a rapporteur and gives them 10–15 min to discuss the following questions (15 min):
 - What should the household residents be told before they are asked to give blood or participate in the survey?

For facilitators: Important information includes why the blood and information are being collected; what will be done with the sample when the analysis is completed (including the fact that positive samples will be shared with a vaccine producer in Europe); the fact that no names will be collected, but the date, time and location of sample collection will be recorded; and the fact that no information will be reported back to participants, even if the test results are positive.

- Would it be possible to identify individuals who test positive for the virus? If so, what risks does this entail?

For facilitators: Because the date, time and location of the collection will be recorded, and participants will be asked to describe their daily behaviour, it might be possible to identify the source of a sample, even without names. This would be true in particular in a small community. If the information is not kept confidential and identities are known, individuals who test positive might be stigmatized and discriminated against.

- Describe the safeguards that should be established to protect the privacy of the source of the biological materials.

For facilitators: It is important to determine whether it is really necessary to collect all the information requested at the level of detail the investigators propose. Geographical information should be recorded

at the broadest level possible (for example, by neighbourhood instead of street), if doing so would not compromise public health goals. In addition, the data should be protected in locked filing cabinets and password-protected computer files, and the number of people who have access should be limited.

- Should the test results be reported to the people who provided the samples?

For facilitators: Doing this would require collecting identifying information, thereby increasing concern about confidentiality. Participants may, however, assume that if they receive no further information they have nothing to worry about, thereby creating a false sense of security. If results are not to be reported back, it is important to ensure that individuals know this and that they know what other steps they can take to protect their health.

- What conditions should be placed on use of the samples by the European vaccine producer?

For facilitators: A material transfer agreement should be drawn up that clearly specifies the vaccine manufacturer's obligations to the community from which the samples were collected. Ideally, the manufacturer should commit itself to making the vaccine available at an affordable price for the community.

- Should this project undergo ethical review and/or community consultation? If so, who should be involved in these processes?

For facilitators: Ethics review and community consultation are always desirable in large-scale collections of biological specimens. The process should include recognized community leaders, local public health officials and a representative sample of ordinary citizens.

4. Once the group has reconvened, the facilitator asks one of the rapporteurs to summarize his or her team's response to the first question. The other rapporteurs are then asked to contribute any additional points raised by their teams; other participants may also contribute to the discussion. Once the discussion of the first question is completed, the same process is repeated for the remaining questions, a different rapporteur taking the lead for each question (20 min).

For facilitators: During the discussion, take notes on a flip chart, particularly on areas of consensus and of disagreement.

5. The facilitator reviews the areas of consensus and disagreement on the flip chart and asks the participants for further comments (5 min).
6. The facilitator concludes the session and opens the floor for discussion.



A. Background

Biological specimens, such as blood samples, may be taken for a variety of activities in emergencies, including determining who has been exposed to a novel virus or chemical agent, identifying the prevalence of drug-resistant bacteria in a population or developing new vaccines or other interventions. Specimens may be analysed on site or sent to a laboratory in another region or country. After they are analysed, they may either be discarded or stored for future use.

The collection and analysis of biological specimens raises several ethical issues. First, the collection process itself may be perceived as intrusive or uncomfortable, particularly in light of individual and cultural attitudes about blood and other biological materials. Secondly, there is a real risk for stigmatization or discrimination if undesirable health information, such as the presence of a disease or of a genetic mutation associated with susceptibility to a disease, is found when the samples are analysed. The risk extends beyond the individuals from whom the samples were obtained to their broader community. For example, if an infection is found to be disproportionately prevalent in samples taken from a particular community, *all* the members of that community may face stigmatization and discrimination, including individuals who are not actually infected. Ensuring that samples cannot be linked to specific individuals can minimize individual risk but does not change the potential community concerns.

An additional ethical risk in the collection of biological specimens is the possibility of exploitation. Exploitation can occur if the specimens are used to develop interventions that will not be accessible to the individuals or communities from which the specimens were obtained (see learning objective 7.2), such as if they are used to develop a vaccine that is marketed at too high a price to be affordable by the local population. Concern about exploitation also arises when products derived from the specimens give profits to researchers and corporations without ensuring that the community from which the specimens were obtained can share the benefits.

These concerns explain Indonesia's decision, in 2007, to stop sending samples of the avian flu virus collected in the country to WHO. Indonesia expressed concern that the virus samples would be used to create vaccines and treatments that would be too expensive for the country to afford and that the profits would go to pharmaceutical companies. In 2011, WHO Member States agreed to a new virus-sharing framework that includes mechanisms to ensure equitable access to affordable vaccines (see learning objective 7.2).



B. Topics

Ethical issues in the collection and use of biological specimens should initially be addressed by a prospective review of the activity by an independent ethics committee, as discussed in the modules associated with Core competence 2. The ethics committee can determine whether it will be necessary to obtain informed consent and, if consent is deemed to be necessary, how the consent process should be designed. It can also consider mechanisms for limiting the collection, use and disclosure of individually identifiable information and strategies for ensuring equitable benefit-sharing with the individuals and communities from which the biological specimens were drawn.

Informed consent to the collection of biological specimens

An initial question in determining whether informed consent is necessary is deciding whether the activity can be characterized as research. This issue is further discussed in learning objective 1.2. As noted in learning objective 3.2, informed consent may be appropriate even if the activity does not technically fall within the definition of research. Useful questions for determining whether informed consent will be necessary for the collection of biological specimens are: Will individually identifiable information be collected with the specimens? Could disclosure of information related to the specimens lead to stigmatization or discrimination against either the individual or the community? Will public health goals be compromised if individuals are given the opportunity to refuse collection and analysis of their specimens (National Bioethics Advisory Commission, 1999).

If informed consent is deemed to be necessary, individuals should be given understandable information about the purpose for which the sample is being collected and what will be done with the sample once the analysis is completed. It should be made clear during the consent process whether individually identifiable information is to be collected. The person who provides the information should know who will have access to the information and what measures to protect confidentiality are in place. In addition, individuals should know whether they will receive the results of any testing performed on the sample. This is particularly important if the tests might reveal information that is directly relevant to the health of the individual and family members. Other information that should be provided includes how long the sample will be stored and whether the sample will be made available for other purposes, including research or product development (College of American Pathologists, 2012).

Defining the concept of “individually identifiable” information

The fact that the names of the individuals who provide specimens are not recorded does not necessarily mean that their identities will be protected. Depending on the context, it may be possible to identify individuals from the general location in which the samples were collected, the facility admission and discharge dates and the grouping of samples according to families or other social networks, such as place of work. When samples are taken from very small groups or communities, it may not be possible to guarantee anonymity after storage. For example, if there has been an isolated outbreak of a novel disease in a small group of people, other community members may already know who those people are. If biological specimens are taken from this group, it may not be possible to ensure that their identities remain hidden.

Use of stored specimens for additional purposes

In some cases, public health officials may seek to use biological specimens collected for one purpose for an unrelated project. For example, they may seek to use blood collected as part of patients' clinical care to determine how many people in a community have been exposed to a virus or a chemical agent. Testing existing clinical samples is likely to be quicker and more cost-effective than collecting new samples solely for the purpose of public health testing. Yet, the use of existing samples may not be consistent with the purposes for which the samples were initially obtained.

In assessing the appropriateness of using samples initially collected for one purpose for an unrelated project, an important factor is whether the new use is consistent with the original consent of the sources. If the new use goes beyond the purposes for which the samples were initially collected, it may be appropriate to go back to the sources to authorize the new use. If seeking authorization is impracticable, another option would be to provide general notice of the new use to the community from which the samples were drawn, with information about how individuals who object to the new use can make their objections known. If the new use goes beyond the original consent, an additional safeguard would be to remove any identifying information associated with the samples, which would minimize the possibility that the sample sources will be subjected to stigmatization or discrimination on the basis of the new test results.

Equitable distribution of benefits

Individuals and communities that provide biological specimens for use in public health activities have the right to expect that they will reap the benefits of those activities (see learning objective 7.2). Thus, the results of analyses of the specimens should be shared with local public health officials so that they can use them to design appropriate interventions. Any products or techniques developed as a result of the availability of the specimens, such as a vaccine or diagnostic method, should be offered to the local population at prices they

can afford (National Bioethics Advisory Commission, 2001). If ownership of specimens will be transferred to a data repository, a material transfer agreement outlining the conditions of any future use of the specimens should be drawn up, ideally with community consultation. A sample material transfer agreement is available from the National Cancer Institute (2010).



C. Case study

During the past few weeks, isolated cases of a new, highly deadly strain of influenza virus have been reported in remote villages in the Republic of Coconut Paradise. In response, the Government of the country has contacted your organization, an international medical relief agency, for assistance in collecting biological specimens from village inhabitants. The specimens will be used to characterize the strain, assess its prevalence and modes of transmission and begin the work necessary to develop a vaccine.

The Government proposes door-to-door visits in the villages in which cases have been reported to request household residents to contribute a blood sample and answer some short questions on their current health status and behaviour (for example, where they get their food and water, where they work or go to school, whether they have recently attended large public gatherings). The answers to the questions will be kept with the specimens and identified by the date, time and general location of collection, but no names will be recorded.

Samples will be tested at a central Government laboratory, and the results will be correlated with the information obtained from the questionnaire. No information will be reported back to the individuals who provided the samples. Samples that test positive for the virus will be shipped to a commercial vaccine producer in Europe.



D. Summary

Biological specimens, such as blood samples, may be taken for a variety of emergency public health activities, including determining who has been exposed to an agent, identifying the prevalence of a drug-resistant bacterium in a particular population or developing new vaccines. The collection and analysis of biological specimens raises several ethical issues. First, the collection process itself may be perceived as intrusive or uncomfortable, particularly in light of individual and cultural attitudes about blood and other biological materials. Secondly, there is a real risk of stigmatization or discrimination if undesirable health information, such as the presence of a disease or of a genetic mutation associated with susceptibility to a disease, is discovered when the samples are analysed. The risk extends to the individuals' broader communities. Thirdly, there is a risk of exploitation if the specimens are used to develop interventions that will not be accessible to the individuals or communities from which they were obtained, or when products derived from the specimens provide profits to researchers and corporations but not to the source community. These issues should be addressed by prospective review of the activity by an independent ethics committee, which can determine the necessity of obtaining informed consent, mechanisms for limiting the collection, use and disclosure of individually identifiable information and strategies for ensuring equitable benefit-sharing.



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Further reading

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Learning objective 3.5: Describe circumstances in which the common good might overrule individual autonomy during public health surveillance.

Michael J. Selgelid



Session timeline (60 min)

0–15 min (15 min)	16–20 min (5 min)	21–35 min (15 min)	36–55 min (20 min)	56–60 min (5 min)
Introduction	Reading	Team preparation	Team presentations and discussion	Summary and conclusion



Instruction strategy

1. The facilitator presents a general overview of the issue, using the attached slides as a guide.
2. The facilitator distributes the case study and the accompanying questions and gives participants 5 min to read it.
3. The facilitator then divides the group into teams of three or four participants, asks each team to appoint a rapporteur and gives teams 10–15 min to discuss each question.
4. After the group reconvenes, the facilitator asks one of the rapporteurs to summarize his or her team's response to the first question.
5. The facilitator asks the other rapporteurs to contribute any additional points raised by their teams, before asking other participants if they wish to contribute to the discussion.
6. Once discussion of the first question is completed, the facilitator repeats the process for the remaining questions.

For facilitators: Choose a different lead rapporteur each time. Throughout the discussion, take notes on a flip chart, particularly on areas of consensus and areas of disagreement, and draw links between responses to different questions.

7. The facilitator reviews the areas of consensus and disagreement on the flip chart and asks the participants for further comments.
8. The facilitator summarizes the session and opens the floor for comments.



A. Background

Depending on the disease, the public health measures required to protect the greater good of society (e.g. by epidemic disease prevention) may include surveillance, notification of third parties (including public health authorities), mandatory testing and/or treatment and isolation and/or quarantine. Each of these measures could interfere with basic human rights and liberties. For instance, surveillance and notification interfere with privacy, mandatory testing or treatment conflicts with the right to informed consent, and isolation and quarantine conflict with the right to freedom of movement (Selgelid, 2005). All these measures ultimately involve infringement of autonomy.

There are numerous reasons why autonomy is ethically important. First (given knowledge of self, including one's own primary values and goals), individuals are specially placed to determine what is in their own best interests. Respecting autonomy usually promotes the well-being of individuals and thereby the greater good of society (in terms of aggregate well-being) (Mill, 1859). Autonomy is not only instrumental in the promotion of well-being but is arguably itself a component of well-being (with other things like happiness and desire satisfaction) (Brock, 1998). Respecting autonomy is also often considered essential to respect for persons, e.g. because (sane or rational) individuals should be considered sovereign over themselves. It is partly for this reason that paternalism, i.e. forcing people to do things for their own benefit, is usually considered ethically problematic.

Nonetheless interference with individuals' autonomy might sometimes be necessary to protect others or for the greater good of society. What should be done in such cases? For the reasons given above, it is widely acknowledged that individuals have a right to autonomy, and a right is, by definition, something that should *usually* be respected or protected even when the overall consequences brought about by its violation would be positive for society as a whole (Dworkin, 1978).

The right to autonomy is not, however, usually considered to be absolute. If the threat of an emergency to public health is great enough, rights (including the right to autonomy) may be outweighed by other considerations. A balance must be struck, or trade-offs made, between the aim to protect or respect individual autonomy and the aim to promote the greater good of society in cases of conflict. This raises the question of what would be a principled way of striking such a balance or making such trade-offs (Selgelid, 2007).



B. Topics

How great would a threat to society have to be to justify violations of autonomy?

In different scenarios, it may be more or less important to interfere with individuals' autonomy in order to protect the greater good of society in terms of public health. In other words, the stakes may vary with the circumstances. In cases such as foot fungus and the common cold, for example, public health policy does not usually resort to public health measures that infringe liberty in order to prevent individuals from infecting others. In epidemics—such as SARS, H1N1 influenza and Ebola virus disease—however, coercive isolation and quarantine measures have often been implemented.

How serious, then, must a disease or the harm resulting from transmission be to justify violation of autonomy? To answer this question appropriately, it should first be noted that public health measures may

involve different degrees of autonomy violation. Quarantine for 1 day, for example, is less intrusive than quarantine for 1 week. The ultimate question is thus how great the risk (or expected public health benefit) must be *to justify an autonomy violation of a given magnitude*.

For facilitators: Raise this question during discussion of the case studies.

Should freedom to do immoral things be respected?

During (severe) epidemics, there may be calls for voluntary quarantine. If an individual has been exposed to the disease in question—and there is a reasonable scientific probability that he or she has been infected and thus may become sick or contagious, posing risks to others—it might be argued that the individual in question has a moral duty to voluntarily submit him- or herself to quarantine.

Such a duty is arguably entailed by the duty to do no harm, which implies an obligation to avoid infecting others (Harris & Holm, 1995). If an individual is unwilling to do what he or she has a moral obligation to do in circumstances such as these, should interference with his or her autonomy (in order to protect others or public health more generally) be considered less problematic than would otherwise be the case? Freedom is generally considered to be morally important, but should freedom to do immoral things be protected (Dworkin, 1978)?

For facilitators: Raise this question during discussion of the case studies.

Beneficial coercion

Paternalism, defined as coercing individuals for their own benefit, is usually considered to be morally problematic in health ethics. In the case of public health, however, the coercive measures that might be required to benefit others or society more generally might also benefit those individuals who are coerced (although their own benefit is not the main motivation for the coercion in question). In an emergency involving an epidemic disease, for example, there might be calls for mandatory treatment or vaccination. If there is good reason to believe that undergoing treatment or vaccination in such a scenario would benefit not only the individuals who are treated or vaccinated but also public health more generally, should there be less reluctance to make treatment or vaccination mandatory than would otherwise be the case?

For facilitators: Raise this question during discussion of the case studies.



C. Case study

John Jones was recently diagnosed with MDR-TB. He was prescribed second-line medication¹¹ (on an outpatient basis) and advised to follow standard infection control measures. Further studies of his lung isolates revealed that the strain of *Mycobacterium tuberculosis* with which he is infected is possibly (and even probably) a rare, newly emerged strain of extensively drug-resistant TB that is especially virulent and contagious. The public health authorities therefore decided that John Jones should be isolated for further analysis, observation and treatment. When they tried to contact him, however, they were unable to do so. From their previous interactions with him, they had reason to believe that he was afraid of the possibility of

¹¹ “First-line” TB drugs are those used to treat ordinary strains of *M. tuberculosis*. “Second-line” drugs are used to treat drug-resistant strains.

isolation (He repeatedly said “I don’t want to be locked up... please don’t lock me up!”) and that he thus might have gone into hiding. When it was impossible to locate him after 1 week, it was proposed that his name and photograph be sent to major media outlets (e.g. newspapers and television news providers) and that a public warning be issued, with instructions to notify the authorities if he is seen anywhere.

Questions for discussion

- Should John Jones’s name and photograph be made public?
- How else might this case be managed?
- Some might argue that John Jones’ actions are immoral and that it is thus less problematic to infringe upon his privacy or autonomy. If he actually has gone into hiding, would that be immoral? Is the morality of his action relevant to the question of whether his privacy or autonomy could permissibly be infringed under the circumstances?
- Suppose that, before a decision is made to publish his picture, further analysis reveals that other people infected with the same strain usually infected an average of one other person each month. Would this make publishing his photo more or less justifiable? What if other people with the same strain usually infected only one person every 2 months, or every 6 months, or every 12 months? What would the average rate of infection of others have to be in order for it to be permissible to publish his photograph? Or would it never be permissible to publish his photograph regardless of how high the infection rate was?
- If John Jones is eventually located, for how long (if at all) would it be ethically permissible to forcibly isolate him?



D. Summary

Public health measures to promote and protect the greater good of society sometimes involve interference with individual rights and liberties, and with autonomy in particular. Although autonomy is ethically important, the right to autonomy is not absolute. The protection of autonomy must be balanced against other legitimate societal values, such as public health. Coercive measures that violate autonomy are arguably most justifiable when the public health stakes are high (i.e. when coercion is required to prevent the greatest harm), individuals are coerced into doing what they have a moral duty to do, and coercion benefits those who are coerced as well as society as a whole. Plans for coercive measures should ensure safe, habitable, and humane conditions of confinement, including the provision of basic necessities.



References

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Core competence 4: Ability to identify conflict between the common good and individual autonomy in research and clinical trials during emergency response

Haiti Earthquake January 12, 2010.
Hospital Universite d'Etat D'Haiti.
Source: WHO/AMRO/Victor Ariscain



Core competence 4: Ability to identify conflict between the common good and individual autonomy in research and clinical trials during emergency response

Research is poised to become an integral part of the response to emergencies with public health consequences. Like other public health activities, however, public health research might lead to harm, in addition to the expected benefit to individuals and communities. This issue is reviewed in learning objective 4.1. To assess potential harms and benefits from the perspective of ethics, it is important to have a good grasp of moral theories and frameworks. These are briefly introduced in learning objective 4.2. In learning objective 4.3, the issue of consent and the circumstances under which it could be deemed unnecessary for proceeding with research receive attention. Working with traditional communities or in low-resource settings can make it difficult for researchers to fulfil their duty of seeking genuine consent to research participation. The processes necessary to improve informed consent during emergencies in such contexts are discussed in learning objective 4.4.



Learning objectives

- 4.1 Identify potential harm and benefit to individuals and communities resulting from conducting research in emergencies.
 - 4.2 Discuss moral theories, and identify frameworks applicable to research in emergencies.
 - 4.3 Explain the current norms under which a waiver of consent could be deemed acceptable for research in critical care settings, and assess when they could be applicable to research in emergencies.
 - 4.4 Explain the processes required to improve informed consent to research in emergencies, with particular consideration of traditional communities and low-resource settings.
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Learning objective 4.1: Identify potential harm and benefit to individuals and communities resulting from conducting research in emergencies.

Lisa Schwartz



Session timeline (60 min)

1–15 min (15 min)	16–25 min (10 min)	26–35 min (10 min)	36–50 min (15 min)	51–60 min (10 min)
Introduction	Slide presentation and class discussion	Small group discussion	Case study and discussion	Summary and conclusion



Instruction strategy

1. The facilitator divides the group into teams of three or four participants.
2. The facilitator asks half of the small groups to discuss the potential harm to individuals and to communities that can result from conducting research during emergencies. The facilitator asks the other half of small groups to discuss the potential benefits to individuals and communities that may be derived from the conduct of research during emergencies.

For facilitators: Potential benefits and harms are discussed in section B.

3. The facilitator asks each group to appoint a rapporteur to summarize the group's ideas.

For facilitators: Ask groups that will present later to add only items that have not already been mentioned by other groups. If the facilitator considers it relevant, one of two YouTube videos could be shown:

- The influenza pandemic of 1918 (<http://www.youtube.com/watch?v=rbYwNOcKqqc>) (2 min 37 s)
- Pandemic 1918 (by high-school students) (<http://www.youtube.com/watch?v=5ftqWGaFVXg>) (3 min 10 s)

4. The facilitator briefly describes the relevant ethical concepts and principles before engaging the group in a discussion of the following questions:

- Do you think the list discussed is complete? Should some principles or concepts be removed?
- What should happen if two or more of these principles or concepts conflict?

For facilitators: While there is no definite way of choosing with certainty, the conflict of principles should open debate about why each is important and relevant and which can be compromised or take precedence over the other. The losses and gains of doing so should also be discussed. You may not settle the matter during the workshop; the debate is a key part of learning. The intention is not to achieve perfect harmony:

there are times when one principle takes precedence over the other. The aim is not to make all the pieces fit but to understand the premises used to justify support for one principle over another.

5. The facilitator divides the group into three and asks each to discuss the different values involved in one of the three following quotations:
 - “Public health activities [must] of necessity be directed at enhancing the health of whole populations. This goal may conflict with the desire to always place the rights and needs of individuals above those of society.” (Benatar, 2006)
 - “...ethics of the next century will increasingly recognize that some patient benefits must be sacrificed to fulfill duties to others—either the duty to serve the interests of others or other duties such as keeping promises, telling the truth, and, particularly, promoting justice.” (Veatch, 2000)
 - “No physician is justified in placing science or the public welfare first and his obligation to the individual, who is his patient or subject, second. No doctor, however great his capacity or original his ideas, has the right to choose martyrs for science or for the general good.” (Pappworth, 1967)
6. The facilitator asks each group to appoint a rapporteur to summarize the group’s reflections.
7. The facilitator asks the rest of the participants whether anything was missing from each rapporteur’s presentation.
8. The facilitator introduces the two case studies.
9. The facilitator divides the group in eight and asks each group to discuss one of the following questions from the perspective of *one* of the two case studies:
 - Which principles were adhered to (or breached) in this case? Which were prioritized? Which were compromised?
 - What benefits could be anticipated by researchers during this emergency? Which individuals were likely to benefit most?
 - What risks were involved in this research? Who bore the greatest burden of risk?
 - How could the burden of risks have been minimized (or better managed)?

For facilitators: Ask groups that finish early to work on the rest of the questions from the perspective of their case study.

10. The facilitator asks each group to appoint a rapporteur to summarize the group’s discussion.
 11. The facilitator asks the rest of the participants if anything was missing from each of the rapporteur’s presentations.
 12. The facilitator concludes the session and opens the floor for discussion.
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A. Background

Fair, informed implementation of interventions during emergencies requires that as much evidence about them be gathered either during or after the event. There are clear examples of public health emergencies in which research contributed to improving the outcome. One is the SARS outbreak, during which identification of the virus by research slowed its progression to pandemic proportions (Naylor et al., 2003). Other examples indicate, however, that risk and harm are also associated with research in public health emergencies. In some studies, the harm has included permanent disability and death (Nyika, undated). Such threats of harm introduce important ethical considerations, which are intrinsic to all steps of research, from setting the research agenda (including allocation of funds and prioritization of projects) to execution of the study. Ethical considerations include “What scientific standards, if any, are we willing to compromise in order to respond quickly to an emergency?”, “Who will bear the greatest risks associated with the use of unapproved treatments?”, “Which project has the greatest potential for positive results for people at risk in an emergency?” and “How do we decide who will receive first access to a newly developed, scarce treatment?”

Concern about barriers to valid consent by potential participants is also a significant consideration, especially for participants in traditional communities or low-resource settings (see learning objective 4.4), where differences in literacy, issues of women signing forms, the symbolism of signing a form in some societies, and contextual coercion might have an impact (National Collaborating Centre for Aboriginal Health, 2012).

Among the ethical considerations listed above, the issue of just distribution of the benefits and burdens of research is at the heart of research ethics and is arguably in the foreground in emergencies, when people may become more vulnerable and balances of power shift (O’Mathúna, 2010). The double question of whose interests will be served and who will bear the greatest burden of sacrifice is even more acute when resources are stretched, as is often the case in emergencies. A fundamental ethical consideration is setting a research agenda during an emergency and deciding who will take part in the discussions. How will the resources available for research be distributed? How can we ensure that the outcomes of research will serve the public interest? How can wider public interests be balanced with the interests of marginalized and vulnerable populations? How can we be sure that exploitative interests do not dominate? The last question is most important when research carries high risks for participants or requires public funding.

These ethical considerations are commonly discussed in ethics education, which often focuses on *problems* related to research. It is also important to remember the important benefits of public health research and the moral obligation to perform research that can generate such benefits. Therefore, the identification not only of potential harm but also of potential benefits of research in emergencies is essential.



B. Topics

Below is a non-exhaustive list of potential physical and psychosocial harm and benefits that might accrue to individuals and communities as a result of research in public health emergencies. The potential harm and benefits of public health surveillance are discussed in learning objective 3.1, some of which could also apply to research.

Potential benefits to individuals and communities of emergency research

- *Rapid access*

Access to new and experimental drugs or facilitated off-label use of approved drugs can speed up treatment. This may be especially important when the prognosis is dire, as in SARS or Ebola virus disease. As robust scientific evaluation remains important, rapid access may depend on imaginative study design by researchers and regulators. Natural experiments and a lower threshold of evidence have been suggested as possible solutions, but additional innovative, reliable research designs should continue to be sought (Edwards, 2013).

- *Better understanding of the condition*

Research—whether epidemiological, laboratory-based or clinical—can further understanding of a condition, including its causes, transmission and best treatment. Use of this knowledge can help in containing the disease, improve medical outcomes and advance the development of new treatment.

Potential harms to individuals and communities of emergency research

- *Adverse effects*

Emergency research still entails risks, and the adverse effects can be serious. The case study discussed in this module illustrates how research in an emergency can result in serious adverse events. Care must be taken that research interventions are safe and not initiated too quickly, ignoring potentially significant risks in order to “get it out there”.

- *Inefficiency*

In emergencies, human and logistic resources tend to be scarce. If the resources for care are reallocated to research, some patients may not receive the care they otherwise expected.

Opportunities may be missed when the priorities for a research agenda are set under severe time constraints. Prioritization of projects and funding can affect the achievable public or individual benefit. Suboptimal allocation of resources can cause harm indirectly. For instance, the typically larger studies required to observe small effects not only cause delays but also tend to monopolize patients who cannot then be enrolled in studies of other promising interventions. The entire process of research can thus be slowed down. Arguably, in such cases, the “greater good” of obtaining robust research results for clinically relevant outcomes is aligned with individual interest in obtaining effective interventions faster. For this reason, some have argued in favour of smaller trials focusing on observation of large effects (Horrobin, 2003).

- *Violation of rights*

Should the benefits anticipated by research be given more significance than individual interests, even if individual liberty is overridden? This may be justifiable when the utilitarian benefits of “the greatest good for the greatest number” are favoured. With this justification, it may be ethical in some cases to favour the greater good over individual good. It is widely agreed that such balancing should be done transparently and with a degree of reciprocity for those whose rights are compromised or violated intentionally or unintentionally.

- *Unnecessary exposure to risk*

Care must be taken to ensure that participation does not unnecessarily put individuals at risk. In the design of trials, research methods can be calibrated to detect larger or smaller effects. Typically, research designs for smaller effects require larger samples and more time and include a stronger requirement for a control group. If a study is poorly designed, more participants might have to be exposed to the intervention in order to detect an effect.

Ethical concepts and principles for the conduct of research in emergencies

Ethical principles can assist decision-makers by helping to ensure that they consider relevant values and commitments. For example, they can be used to assess whether the balance of expected harm and benefit is correct. In other words, ethical concepts can be used to answer the question “How can we balance the justification that a research project will be for the ‘greater good’ with the duties of researchers (who may also be health professionals) to attend to the interests of research participants?” The literature indicates an emerging consensus on a set of concepts and principles for the ethics of public health research in emergencies.

For facilitators: The list below is drawn from a variety of sources and may be incomplete. If you have the time, you could review the list with the participants and discuss the adequacy of the principles, individually and as a whole.

- *Autonomy:* respect for individuals and their liberties expressed through, for example, informed consent and protection of confidentiality
- *Beneficence:* commitment to the welfare of research participants
- *Concern for welfare:* protection of the interests of patients, participants and populations (Canadian Institutes of Health Research, 2010, Chapter 1, section B).
- *Equity:* fair access to health-related resources, such as treatment
- *Efficiency:* use of resources in such a way that the desired outcomes are maximized and waste is minimized
- *Fair process:* means of reaching a decision that is inclusive, accountable and informed (Daniels & Sabin, 1997)
- *Global justice:* notions of fair and responsible practices among communities
- *Reciprocity:* relation of corresponding mutual action (World Health Organization, 2007)
- *Responsibility:* willingness to be held accountable for the consequences of one’s actions
- *Social justice:* notions of fair and responsible practices within communities and institutions
- *Solidarity:* mutual global fellowship that transcends divisive categories of “us” and “them” (Baylis et al., 2008)
- *Transparency:* provision of honest, accessible information about reasons and decisions



C. Case study

1. Trovan trial in Nigeria

Stephens J (2000). Where profits and lives hang in balance, Washington Post, 17 December 2000 (http://www.washingtonpost.com/wp-dyn/content/article/2008/10/01/AR2008100100973_pf.html).

See also http://www.pfizer.com/files/news/trovan_fact_sheet_final.pdf.

2. SARS in Toronto

Box 3. SARS outbreak in Canada (Naylor et al., 2003, Chapter 2)

“In February 2003 a 65-year-old doctor who had treated atypical pneumonia patients in Guangdong [China] travelled to Hong Kong to attend his nephew’s wedding. By the time he checked into the Metropole Hotel, he was feeling unwell. The doctor infected at least 12 other guests and visitors from several countries, including a 78-year-old woman from Canada, Mrs. K S-C.

“Mrs. K returned to Toronto on February 23, 2003 after a 10-day trip to Hong Kong [...] Two days after arriving in Toronto, Mrs. K developed a high fever, and by the time she visited her family doctor on February 28, she was also complaining of muscle aches and a dry cough. Mrs. K’s condition continued to deteriorate, and she died at home on March 5, 2003. Family members did not want an autopsy and the coroner thought it unnecessary. On the death certificate, the coroner listed heart attack as the cause of death.”

Shortly after her death, Mrs K’s son became ill with similar symptoms and died soon after. The virus quickly spread to people in emergency waiting rooms, hospital visitors and, of course, hospital staff who would later comprise 40% of all patients infected with SARS.

SARS had an enormous impact on the entire civic structure of Toronto. People missed work, as they were asked to self-quarantine and self-monitor, health workers were apprehensive about the risks to which they were exposed, and an entire school was closed because a single student was found to be infected with the SARS virus. Hospitals were put on hold until infection control could be established.

“Several interviewees noted the massive number of cancelled services, and suggested that the collateral casualties from the suspension of health care activities may never be fully measured. Other harms were more subtle, including hardship caused by restrictions on visits between families and patients hospitalized with conditions other than SARS.”

Possibly the greatest controversy during the outbreak in Toronto was about surveillance and research. There was concern about the lack of collection of data and access to data about SARS cases. Data were not readily transferred, partly because clinicians were not clear about the application of provincial privacy legislation to personal health information. There was wide uncertainty about the authority for overriding these laws for the purposes of public health surveillance, let alone research.

The nature and extent of the crisis meant that most qualified practitioners were too busy treating patients to give any time to research. Protocols that might have addressed epidemiological, clinical and biological questions still required funding support and research ethics board approval. “Canadian researchers were hamstrung by patient care and scientific advisory responsibilities, a lack of data, infighting about data access, limited research funds, and the need to obtain ethics approvals at multiple institutions.”

Canadian researchers did publish a few papers during the outbreak. Nevertheless, “on July 26, 2003, a major paper with multinational authorship was published in *The Lancet*, providing data in support of the proposition that the new SARS-associated coronavirus had met the criteria to be designated the causative agent of the new disease. Patient data were included from six countries: Hong Kong, Singapore, Vietnam, Germany, France, and the United Kingdom. No Canadians appeared among the 22 authors, and no Canadian patients were included in the study sample.”



D. Summary

Conducting research during emergencies can have genuine social benefits, including better evidence to inform treatment. As discussed in this module, such research also has potential individual benefits, including better access. Proponents must nevertheless keep in mind the risks and harm to both individuals and communities that can result from emergency research. The case studies show that the harm includes breaches of privacy and liberty and risks associated with speedy, unsafe experimental interventions.

The principles and ethical concepts discussed in this module provide material for ethical deliberation on research during emergencies. When applied to the two cases, it is clear, however, that, while useful, they must also be negotiated, as moral challenges arise when some principles cannot be prioritized without compromising others. In general, justifications for research and public health interventions grounded in arguments of the “greater good” are controversial if weighed against individual or social harm. While we are all interdependent members of communities, injustice results in all societies due to social determinants of health that leave some members vulnerable and marginalized. Public health research that relies on the justification of “greater good” must make explicit who will bear the sacrifices—i.e. who will become more vulnerable— and how the risks can be minimized. As will become clear in subsequent modules, informed consent is an important component of increased protection in research in emergencies.



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Learning objective 4.2: Discuss moral theories, and identify frameworks applicable to research in emergencies.

Michael J. Selgelid



Session timeline (60 min)

0–15 min (15 min)	16–25 min (10 min)	26–55 min (30 min)	56–60 min (5 min)
Slide presentation of slides 2–5 and discussion	Slide presentation of slides 6–7	Slide presentation of slide 8 and discussion	Summary and conclusion



Instruction strategy

For facilitators: This session should be run as an interactive, discussion-oriented seminar with the slides provided.

1. The facilitator describes the major ethical frameworks (slides 2–5) and elicits participants' opinions on their applicability to research in emergencies.

For facilitators: In the discussion, draw feedback from participants on the merits, limitations and potential flaws of the frameworks, and draw out relations among the theories.

2. The facilitator explains the motivation for a pluralistic approach (slides 6–7).

For facilitators: Familiarize yourself with Selgelid (2009).

3. The facilitator shows slide 8, spends 4–5 min describing each principle and moderates a brief discussion on what each principle calls for and why it might be justified.

For facilitators: For each principle, cover the following topics:

- its ethical justification,
- its perceived legitimacy and
- the practicality and implications of applying the principle in the context of research during emergencies.

Add any refinements or modifications suggested by participants.

4. The facilitator summarizes the session and opens the floor for comments.



A. Background

Different ethical theories emphasize different values. According to *utilitarianism*, the right action or policy is that which is expected to maximize utility, i.e. the amount of happiness or well-being enjoyed by members of society. According to *egalitarianism*, human equality is especially important, and the aim of policies should be to redress social inequalities. Rawls (1999), for example, argues that justice requires policies that maximally improve the situation of the worst-off groups in society. According to *libertarianism*, individual liberty is especially important and should not be interfered with in order to promote equality or overall utility. According to *rights-based theories*, human rights (as enshrined by international instruments such as *The Universal Declaration of Human Rights*) should be respected and promoted.

While the values of utility, equality, liberty and human rights emphasized by these theoretical approaches are each important, they can sometimes conflict. As a result, different ethical theories sometimes provide conflicting guidance about the course of action or policy to be pursued. In some cases, the policy required to maximize utility may require compromising liberty, equality or human rights. Consider, for example, the collection of blood or information without people's consent when it can provide a large amount of data that may benefit many people. In other cases, the policy that maximally protects liberty may require compromises of utility or equality. We do not usually isolate people infected with the common cold, for example, even though the population may thus have higher incidence.

The four theoretical frameworks described above prioritize certain values, but, from the perspective of common sense or policy-making, none of these values should always overrule all the others, regardless of the degree to which they are undermined. When minor infringements of liberty are necessary to prevent large losses of utility, the infringement might be justified. The use of coercive social distancing measures such as quarantine, for example, might be justified in the context of an epidemic if it is necessary to avoid a disaster (see learning objective 3.5). We should not, however, interfere with individual rights and liberties on any and every occasion when this would provide benefits (however small) for society as a whole.

Existing frameworks of public health ethics (Kass, 2001; Upshur, 2002; Gostin, 2006; Selgelid, 2009) provide guidance on the conditions under which use of liberty-infringing measures may be justified to protect the greater good of society in an epidemic or other emergency. While such frameworks were developed to guide public health practice, many of the principles they advocate may be applicable to the conduct of research in emergencies as well.



B. Topics

Ethical principles

- *Evidence*

The evidence principle is based on the idea that we should not impose a liberty-restricting measure (such as quarantine) unless there is good reason to believe that the measure will effectively protect public health.

For facilitators: Draw attention to the fact that questions might be raised about how much evidence would be needed and what should be done in cases where evidence is inevitably limited (e.g. a novel epidemic disease about which relatively little is known).

Ask participants how this principle might apply to research during emergencies. For example, in the context of research, application of this principle might require that proposals to test new liberty-restricting interventions be justified by theory (based on empirical knowledge).

- *Least restrictive alternative*

This principle is based on the idea that liberty should not be infringed to a greater extent than that necessary to achieve the public health goal in question.

For facilitators: Draw attention to the fact that questions might be raised when the effectiveness of various alternatives is not clear or when a more restrictive measure might be more effective than a less restrictive measure. What should be done, for example, if mandatory quarantine and voluntary quarantine are both expected to have a public health benefit, but mandatory quarantine is expected to have the greater benefit?

Ask participants how this principle might apply to research during emergencies. For instance, when conducting research during an emergency, the principle of the least restrictive alternative might mandate that investigations not infringe upon the privacy of participants unnecessarily.

- *Proportionality*

The proportionality principle holds that there must be a balance between the extent of infringement of liberty and the strength of the requirement that justifies the infringement. Among other things, this implies that avoiding moderate adverse consequences may justify a small infringement of liberty but not a large one. Extreme liberty-infringing methods such as isolation and quarantine should not be used unless the consequences would otherwise be severe.

For facilitators: Draw attention to the fact that questions might be raised about how large the expected public health benefits must be to justify infringement of liberty of a given magnitude.

Ask participants how this principle might apply to research during emergencies. The idea might be that we should not resort to liberty-infringing research on any and every occasion in which we are faced with an emergency. If the research in question involves major infringement of privacy, for example, the stakes would have to be high.

- *Equity*

The equity principle holds that liberty-infringing interventions should be used in an equitable—e.g. non-discriminatory—manner and that the threshold for imposing such measures should be highest (with regard to the evidence required or the utility threatened) when the people being considered for confinement are members of the worst-off groups of society. Thus, vulnerable groups in society warrant special protection.

For facilitators: Ask participants to reflect on the legitimacy of greater reluctance to infringe upon the liberty of the poor and disempowered than of those who are relatively well off in order to protect public health, other things (e.g. expected public health benefits) being equal.

Ask participants how this principle might apply to research during emergencies. When used in conducting research during an emergency, the equity principle reflects the customary attention to vulnerability and the just distribution of harm and benefit.

- *Least harmful alternative*

This principle holds that infringements of liberty imposed for public health purposes should be minimally burdensome. For example, confined individuals should receive basic necessities (such as food and health care), be made as comfortable as possible and not suffer the harm of discrimination or stigmatization.

For facilitators: Draw attention to the fact that it is not clear to what lengths society should go to respect this principle, especially when this might prove particularly difficult, such as when a whole region might be quarantined.

Raise questions about how this principle might apply to research during an emergency. For instance, the time-limited nature of public health research during emergencies should not be used to justify exposing participants to unnecessary risks.

- *Compensation*

The principle of compensation is based on the idea of reciprocity: that society should give something back to those it has taken from. People whose liberty is infringed are arguably harmed because their autonomy is compromised, and they may also suffer financial loss if they are unable to work while quarantined or are required to cull their livestock. If society as a whole benefits from the liberty infringement, compensation should be given to those who suffer the burdens that make the social benefit possible.

For facilitators: Draw attention to the fact that establishing the appropriate level of compensation will be an important difficulty in trying to apply this principle. Ask participants how research during emergencies may lead to harm that warrants compensation.

- *Due (legal) process*

It has been argued (Gostin, 2006) that restricting liberty for public health protection should involve due (legal) process, including the right to appeal in the case of confinement. Ideally, legal and regulatory questions should be solved during preparedness planning. The principle of due process is to prevent abuse of power and unwarranted infringements of liberty.

For facilitators: Draw attention to the fact that legitimate processes might be difficult to establish in severe emergencies, as decisions might have to be made quickly and appeals might not be feasible.

Ask participants how this principle might apply to research during emergencies. One example would be the requirement to obtain informed consent whenever possible (see learning objective 4.3), for example before people are subjected to investigational interventions. Similarly, population-level research may require governmental approval.

- *Democracy and transparency*

As there are numerous ways to make trade-offs between the values that conflict in public health contexts, this principle holds that policy-making should involve democratic processes, so that decisions are aligned with the values held by citizens, or, at the very least, that those decisions be made in a transparent manner such that the explicit rationale behind them is made public. Democracy and transparency are both essential for the promotion of trust in public health. Trust, in turn, is widely acknowledged as essential for the success of public health systems.

For facilitators: Ask participants to reflect on the requirements entailed by the principles of democracy and transparency and on the feasibility of meeting those requirements in the context of research conducted during emergencies. Consider the question of whether the ethical acceptability of placebo controlled trials of experimental interventions against Ebola virus disease depends on whether such trials would be acceptable to the communities in which they are conducted.



D. Summary

The four main moral theories discussed above—utilitarianism, egalitarianism, libertarianism and rights-based approaches—prioritize different values. Public health ethics frameworks have been based largely on principles applicable to the conditions in which constraints on individual rights and liberties might be justified. While such principles were developed for public health ethics in general, they might be applicable to research in emergencies. Nevertheless, questions about their adequacy and legitimacy and how they might be implemented warrant further reflection.



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Learning objective 4.3: Explain the current norms under which a waiver of consent could be deemed acceptable for research in critical care settings, and assess when they could be applicable to research in emergencies.

Lisa Schwartz



Session timeline (75 min)

0–10 min (10 min)	11–25 min (15 min)	26–40 min (15 min)	41–60 min (20 min)	61–75 min (15 min)
Small group discussion	Group discussion	Slide presentation	Case study and discussion	Summary and conclusion



Instruction strategy

1. The facilitator divides the group into teams of three or four participants.
2. The facilitator asks half the small groups to find arguments to justify the assertion “Research should never be permitted to proceed without informed consent” and the other half of small groups to find arguments backing the opposite, that “Public health research yields better results when it can proceed without consent.” (10 min)
3. The facilitator asks each group to appoint a rapporteur to summarize their discussions (15 min).

For facilitators: Ask groups presenting later to add only items that have not already been mentioned by other groups.

4. Using the arguments suggested by the small group, the facilitator moderates a discussion on the theme “Under what conditions could a study without informed consent be permissible?”
5. The facilitator briefly describes the norms under which a waiver of consent is currently deemed acceptable (10 min).
6. The facilitator presents the case studies from learning objective 4.1 and asks participants the following questions related to consent:
 - Do the circumstances described satisfy the conditions of minimal risk required for waiver of consent?
 - How was consent managed in the research on Trovan? And in the case of SARS research?
 - Did the processes described mirror the ethical obligations for “minimal risk” studies?
 - Should consent be required for all public health interventions?

For facilitators: The Trovan case raises many ethical issues. It has been claimed that the researchers could have given the parents more information about the study, the trial drug and alternative treatment options, and they could have been offered support for making a decision for their children. This would represent proxy consent by a substitute decision-maker, who was under a great deal of stress and may have had barriers to adequate understanding. Nevertheless, parents are usually recognized as decision-makers for their children. In addition, although consent might have been difficult to obtain, it would not have been impossible. Therefore, this case does not meet acceptable criteria for a waiver of consent.

The SARS case was also very complicated, but one issue is obvious: the lack of clarity about access to personal health records prevented adequate surveillance and research. This regulatory gap created an ethical conflict for the people responsible for patient health records. In this case, a research ethics board would probably have approved a waiver of consent, because the studies met the Tri-Council criteria for minimal risk (see below). The research was very likely to have great benefit, and the people involved would have recognized that there was less risk of harm and more potential for good if their personal information contributed to controlling SARS.

7. The facilitator summarizes the session and opens the floor for comments.



A. Background

For research during emergencies to be permissible, participants must be recruited fairly and their interests protected. All the statements on ethics in human research emphasize the protection of participants and cite informed consent as one of the means of achieving this. But what happens when research believed to have strong potential to produce benefits cannot proceed if individual consent is required because, for example, it would be too difficult to obtain, or the intervention requires a complete data set?

In critical care, there is a long-standing practice of not seeking consent in certain circumstances, a practice that is often protected by law. Circumstances in which a patient may not be asked for consent usually involve emergency interventions for unconscious patients. When the legal framework permits treatment without consent, it is because the treatment is considered to be both in the best interests of the patient and what an ordinary person would wish; it usually consists of the best available treatment or measures based on the best available evidence.

Some legal frameworks also allow waiver of the consent requirement for research interventions under certain conditions. Usually, this waiver is limited to studies with minimal risk, but it may also be granted for studies designed to back evidence-based practice in emergency situations. The accepted norm in these cases is that, if the research cannot be done any other way, it may be possible to waive the consent requirement (see box below).



B. Topics

What types of research might require a waiver of consent?

Examples of research that requires waiver of consent include retrospective data collection and observational epidemiological research based on the fullest possible data set from large populations. Examples in critical care include studies in which the intervention is urgent and there is no time to seek consent without endangering the patient or when the patient is unconscious and no substitute decision-maker is available. Such studies could be conducted at the scene of an accident or another trauma-inducing event.

When is a waiver of consent requirements permissible?

National legislation should be considered, and several codes of research ethics include guidance on waiving individual informed consent. In general, these statements require that researchers demonstrate that the study is likely to confer benefits and that obtaining consent was impracticable in the proposed context. The Canadian Tri-Council Policy Statement (Canadian Institutes of Health Research et al., 2010) provides such an example of criteria for minimal-risk research. An excerpt from the section entitled “Departures from general principles of consent” is given in Box 4.

Box 4. Alteration of consent in minimal risk research (Canadian Institutes of Health Research et al., 2010)

“**Article 3.7.** The Research Ethics Board (REB) may approve research without requiring that the researcher obtain the participant’s consent [...] where the REB is satisfied, and documents, that all of the following apply:

“(a) the research involves no more than minimal risk to the participants;

“(b) the lack of the participant’s consent is unlikely to adversely affect the welfare of the participant;

“(c) it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;

“(d) whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information [...], at which point they will have the opportunity to refuse [...]; and

“(e) the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.”

When are these criteria relevant to emergencies?

Although these criteria would ideally be relevant in the context of emergencies, research interventions in these circumstances may not meet the usual ideas of minimal risk. In such cases, permission to waive the consent requirement could be sought on the grounds that conditions (c) and (d) above still apply. Such justification would rely on the assumption that risk should be assessed in relation to context: a risky

experimental intervention may pose no greater risk to an individual in need of emergency treatment than the already accepted standard of treatment for that condition.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (Institute of Dental and Craniofacial Research, 2013).

The same criteria are relevant during emergencies. If the relative risk is assessed to be acceptable, *and* the research is judged to be of sufficient value to the affected community, *and* it cannot be done in any other way, *and* consent will be sought for continuation of the study if and when possible, a waiver of consent may be granted. All of these conditions may be fulfilled during an emergency; however, in order to minimize conflicts of interest, the decision to waive the consent requirement should be made by an ethics review board that is independent of the proposed research.



C. Summary

Individual consent cannot always be obtained, particularly in research during emergencies. In some cases, strict adherence to this requirement would interfere with potentially beneficial research. Nevertheless, informed consent is the best way of respecting autonomy and safeguarding the interests of participants. For this reason, consent from individual participants should be regarded as the standard of practice. Any exception must be fully justified, and it must be demonstrated to meet the strict criteria for a waiver of consent. In such cases, a research ethics committee qualified to review the study may approve a waiver of consent.



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Learning objective 4.4: Explain the processes required to improve informed consent to research in emergencies, with particular consideration of traditional communities and low-resource settings.

Caroline Clarinval



Session timeline (90 min)

0–15 min (15 min)	16–25 min (10 min)	26–45 min (20 min)	46–65 min (20 min)	66–85 min (20 min)	86–90 min (5 min)
Introduction	Slide presentation	Reading	Group work	Discussion	Summary and conclusion



Instruction strategy

1. The facilitator introduces the learning objective (15 min).
2. The facilitator presents the slides (10 min). See: <http://www.who.int/ethics/topics/outbreaks-emergencies/en/>

For facilitators: The main issues to be covered are the relations between informed consent and recruitment, poverty, impairment due to the emergency situation, education and culture in the context of emergencies.

3. The facilitator hands out the Trovan case study and three additional news items covering it and asks participants to read them (20 min).
4. The facilitator separates the group into three and asks each to explore one of the following questions (20 min):
 - In general, what is the ethical challenge of conducting research in traditional communities or low-resource settings?

For facilitators: The requirement to obtain informed consent remains unquestionable. Owing to barriers of language, culture and others, however, it might be difficult to obtain. Participants in any setting may not understand the nature of the information relevant to research, but this is particularly relevant in settings where many prospective participants are likely to lack formal education. Other means, such as obtaining community permission, might be explored. Other possible ethical issues include the risks of restricting the autonomy of the participants and of discrimination among and within communities. Populations in low-resource settings may be at particular risk for being coerced and exploited by researchers. The layers of vulnerability of both groups are likely to increase, especially in emergencies.

- How (if so) could the sponsor have avoided the wrong-doing and the resulting scandal?

For facilitators: In this case, the researchers did not disclose all the necessary information, and the research participants were unable to provide informed consent. Principles such as autonomy, beneficence and justice were challenged, and the population was exploited because of their particular vulnerability, with high mortality and morbidity rates and an overstretched local health care system. Moreover, the researchers abused their authority and the trust the local populations had put in them. The sponsor could have avoided the scandal by adhering to best practices for obtaining the informed consent of vulnerable populations, including ensuring full disclosure, i.e. providing all the relevant information necessary for the study participants to make an informed choice. The sponsor could have discussed the issues at stake with the local community in order to obtain community permission (Diallo et al., 2005). The sponsor should have taken all relevant measures to ensure the protection of these vulnerable research participants.

5. The facilitator invites each group to present its conclusions, with all participants contributing to the discussion (20 min).
6. The facilitator concludes the session and opens the floor for comments (5 min).



A. Background

Obtaining truly informed consent for research, even in non-emergency situations in high-resource settings, is difficult; it is all the more challenging in low-resource settings and in traditional communities. The main difficulties are language, research literacy, lack of empowerment and poverty (Ekunwe & Kessel, 1984; Benatar, 2002). Yet another layer of complexity is added in emergencies. This learning objective addresses the processes required to deal with these various layers. The module complements previous ones on challenges to assumptions about autonomy in emergency settings (learning objective 3.5). The case discussed in this learning objective and other trials in deprived populations illustrate how the difficulty of obtaining informed consent can place traditional communities and people in low-resource settings at risk for harm. Bhutta (2004) and Marshall (2006) point out that the existing guidelines for obtaining informed consent do not provide sufficient guidance for obtaining consent from vulnerable populations in emergency situations. Traditional communities and people in low-resource settings are therefore likely to meet another layer of vulnerability (Luna, 2009) in an emergency.

Various external factors are taken into consideration in a “decision” to participate in research. Factors that might affect voluntariness and autonomy (Molyneux et al., 2005; Ganguli Mitra, 2012) include:

- therapeutic misconceptions (see learning objective 7.2),
- monetary incentives,
- the availability of medicines,
- quests for relations of trust with the community,
- concern about power differentials and
- concern about exchange and fairness.

Thus, many “cultural” responses to research, apparently derived from “traditional” beliefs or deficit of education, are in fact meaningful responses to poverty and political or economic instability. In other words,

needs beyond accessing health care, such as adequate shelter, sufficient food and safe drinking-water, can exacerbate an individual's vulnerability.

Populations living in resource-poor settings may face additional challenges. In certain circumstances, although they may be fully informed and able to consent, they might do so because they face difficult circumstances. Vulnerability is therefore not solely a matter of informed consent or harm. People may make certain choices when they are fully aware of the potential risks, and researchers should not assume that informed choices protect them: vulnerable populations may be exposed to "an identifiably increased likelihood of incurring additional or greater wrong" (Hurst, 2008). Unless people are granted access to universal health care and other social safety nets, they may be more likely to agree to participate in research, at the risk of being exploited, that is, to contribute to research without benefitting from it (Ganguli Mitra, 2012). Researchers engaging in studies in low-resource settings should consider the various reasons that drive people to take part in research studies.

The aims of the case study and the questions proposed are designed to raise questions about assumptions and to invite participants to discuss the issues pertaining to the possible risks for causing harm, such as power and economic inequalities, in research in the context of emergencies.



B. Topics

Although standard procedures for obtaining informed consent are well established (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; Council for International Organizations of Medical Sciences, 2002), applying them in the case of participants in traditional communities and populations in low-resource settings in the context of an emergency can be particularly challenging. In addition to the factors discussed above, other realities may jeopardize truly informed consent. For example, differences in skills, knowledge and status between the local population and an expatriate or national research team may be strong barriers, and traditional communities are at particular risk for being treated condescendingly by foreigners (Beauchamp et al., 2014). As a result, they may be less likely to be given the necessary information in a way that facilitates understanding of the issues at stake. Moreover, literacy may vary in low-resource settings, raising concern about signed consent forms as a protective measure. Researchers must remain alert to possible additional layers of vulnerability and use precautionary measures to avoid exposing affected populations and individuals to additional harm.

What processes are required for obtaining informed consent from traditional communities in an emergency?

Community consultation might be particularly appropriate when the main risk associated with a study applies to communities as a whole rather than to individual members. In traditional communities, the informed consent process mandated by international research ethics guidelines may be foreign to local traditions. Although the guidelines require that all community members be able to participate, regardless of their socioeconomic background (Vreeman et al., 2012), and that therefore both research participants and community representatives should be asked to provide consent, community representatives are likely to take decisions according to local tradition and to exclude certain individuals. Researchers might therefore have to take additional precautions to protect vulnerable groups from unnecessary harm (Molyneux et al., 2005).

If communities are to have a genuine role in research, their input must be sought early enough that they could influence the design of the project. The community might disagree with all or some aspects of the

proposal, in which case revisions should be considered. This issue has been addressed in tools such as the “good participatory blueprint for stakeholder engagement” (AVAC, 2014).

In general, it is essential to consult community leaders, as it shows respect for local norms. When they are the main point of entry, preliminary meetings should be held to discuss the aims of the research, the methods and the expectations in an appropriate manner. In both consultations and meetings with community leaders, researchers must ensure that community consent does not supersede individual consent (Dresden et al., 2003). Even in emergencies, community consent should not usually be considered a waiver for obtaining individual consent to participate in research.

Researchers working with traditional communities must talk with them in order to understand their needs and expectations. Researchers should remain alert to differences in perceptions between the participants and the researchers and promote trust and respect. Researchers should avoid treating traditional communities condescendingly in their approach to informed consent by:

- investigating cultural sensitivities before starting the study;
- being attentive to the needs of the population and reconsidering the investigation if the context does not permit it to be carried out;
- involving local staff and interpreters to ensure community and individual consultation;
- strengthening community engagement as part of the research and involving communities in both writing protocols and the actual conduct of the research (Vreeman et al., 2012);
- ensuring that individuals are not singled out and coerced to take part in the study without fully understanding the implications;
- carefully considering the cultural norms of ethnic or social groups when designing approaches to informed consent;
- respecting the decision of an individual by accepting refusal to consent;
- avoiding any kind of psychological or economic pressure on individuals and the community; and
- considering community structures in making decisions (Vreeman et al., 2012).

What processes are required for obtaining informed consent in low-resource settings in an emergency?

Many of the issues mentioned above also apply to populations living in low-resource settings, who might refuse to take part in research or lack the appropriate information necessary to give informed consent. Moreover, certain individuals in a community may be more vulnerable than others and be excluded from giving informed consent.

Populations living in low-resource settings may also be at particular risk of coercion and exploitation because of their limited ability to generate income. In particular, during an emergency, health systems may be overstretched and unable to meet the participants' health care needs. Researchers and aid agencies should therefore collaborate to ensure that:

- the basic needs for survival are met throughout the research project for all individuals, irrespective of their participation;
 - the population has access to basic health care; and
 - the research team does not drain any health care resources for their study and thereby deprive the local population of such care.
-

Once these issues have been addressed, the “host” population has a real choice about whether to take part in the research—an essential condition for informed consent to be valid.

Even research that has potential benefits cannot be carried out if there is risk of exploiting the participants. According to the principle of reciprocity, the researchers and the companies and organizations that directly benefit from the study have an obligation to find means to support the participants who contributed to the study or to strengthen the local health system (Ganguli Mitra, 2012).



C. Case study

Trovan trial in Nigeria

Stephens J (2000). Where profits and lives hang in balance, Washington Post, 17 December 2000 (http://www.washingtonpost.com/wp-dyn/content/article/2008/10/01/AR2008100100973_pf.html).

See also http://www.pfizer.com/files/news/trovan_fact_sheet_final.pdf.



D. Summary

During research projects, traditional communities and populations living in low-resource settings are confronted with different cultures and sometimes an imbalance of skills and knowledge. These may result in condescending treatment by researchers. Poverty, political instability and lack of access to universal health care might encourage people in such communities to participate in research even at the risk of being exploited. In emergencies, their needs may go beyond health care, further exacerbating their vulnerability.

Researchers must balance the potential benefits for future patients and populations against protecting the interests of the people involved in the study (Ganguli Mitra, 2012). Researchers must bear in mind that it might be morally unacceptable to engage in research at times of crisis; thus, the interests of the community and the need for research must be weighed carefully (Dawson & Kass, 2005). Researchers have the responsibility to inflict no further harm on traditional communities and populations living in low-resource settings and to share any benefits. This responsibility is all the greater in crises.

In summary, preliminary meetings should be held with community representatives to explain the risks and benefits of the research. Researchers must attempt to obtain individual consent, and they must ensure that community consent does not supersede individual consent. In certain circumstances, consent may be obtained before an emergency. To mitigate the risks for coercion and exploitation, researchers working in low-resource settings could liaise with other agencies in the field to ensure that the basic needs of the population are met.



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Core competence 5: Ability to explain how publication ethics are related to public health surveillance or research in emergencies



Core competence 5: Ability to explain how publication ethics are related to public health surveillance or research in emergencies

When new knowledge is generated to protect the public during an emergency, there is a moral obligation to share and publicize the relevant findings in due time. Such scientific knowledge can be obtained during routine surveillance. Therefore, data collection might have been initiated without proper ethics oversight. In such cases, it is important that the conditions under which the collected data can be disseminated as scientific knowledge be clear (learning objective 5.1).

Furthermore, it is crucial that public health practitioners have a solid grasp of the implications of the various publication biases, an issue discussed in learning objective 5.2. Ultimately, the obligations tied to the ownership of data must be clear, as such ownership can have dramatic consequences for the quality of scientific evidence or the amount of financial resources spent on a technical intervention of disputable value. This topic is covered in learning objective 5.3.



Learning objectives

- 5.1 Explain the conditions in which data gathered during public health surveillance or routine clinical management can be published as scientific knowledge.
 - 5.2 Explain what is meant by “publication bias” and how it might affect the response to emergencies.
 - 5.3 Explain the ethical obligations of researchers, public health practitioners and publishers regarding ownership of scientific data.
-

Learning objective 5.1: Explain the conditions in which data gathered during public health surveillance or routine clinical management can be published as scientific knowledge.

Philippe Calain



Session timeline (75 min)

0–15 min (15 min)	16–35 min (20 min)	36–40 min (5 min)	41–60 min (20 min)	61–75 min (15 min)
Introduction	Reading	Role play and presentation	Group discussion	Summary and conclusion



Instruction strategy

1. The facilitator introduces the module and lists the conditions in which data could be ethically disseminated as scientific knowledge.
2. The facilitator distributes the paper by Balasegaram et al. (2006) and asks participants to read it, particularly the first two pages.

For facilitators: Explain to the participants that they should disregard the fact that the paper is published and should imagine that it is an advanced draft submitted to a journal. They should consider whether it should be approved for publication.

3. The facilitator takes the role of a technical officer requesting ethics approval before submission of the paper to a peer-reviewed journal.

For facilitators: To play the role of a technical officer, use the arguments proposed by Gollogly (2006) and any others considered relevant.

4. The facilitator divides the participants into groups of four or five and asks them to discuss the technical officer's request and to decide if post-hoc clearance for publication should be granted.
5. The facilitator asks each group to appoint a rapporteur to summarize their discussions.

For facilitators: Ask groups that will present later to add only items that have not already been mentioned by other groups. The issues that should be discussed include the fact that the patients were not informed that they were part of a trial; there was no prior ethics review; and how to address the conflict between respect for persons and social benefits in approving dissemination of the research.

6. The facilitator summarizes the activity and opens the floor for discussion.



A. Background

When new information is generated that could benefit individuals and the public in an emergency, there is an overwhelming moral obligation to share and publicize the information as quickly as possible (Langat et al., 2011). As such scientific information can be generated during routine clinical or surveillance activities, collection of data might have been initiated without ethics oversight or without individual consent (see learning objective 3.2).

This session deals with ethical clearance for the publication of data obtained retrospectively and compiled and analysed as part of programme monitoring, public health surveillance or “operational research”. Originally, the data may—rightly or wrongly—have been collected without ethical oversight or individual consent, as is likely to occur in an emergency (Calain et al., 2009). With an example of operational research conducted during a humanitarian project, the module introduces notions of an ethical calculation in which the importance of publishing data of public health importance might outweigh the absence of prior consent or ethical review.

International codes of conduct for medical journal editors (International Committee of Medical Journal Editors, 2009; Committee on Publication Ethics, 2011) refer to the Declaration of Helsinki and cite the protection of individuals as a prerequisite for medical publication. The 2013 version of the Declaration of Helsinki itself (World Medical Association, 2013, paragraph 36) states that:

Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

In this module, participants will critically examine the necessary conditions for publication of data generated during public surveillance or clinical management.



B. Topics

The criteria for publication clearance of routinely collected data listed below are based on the work and experience of the author (see also Schopper et al., 2009).

Type of activity

When determining whether data obtained as part of an informal research project should be disseminated, the type of activity that resulted in data collection should be determined, as some types (such as in operational research) may allow departures from standard ethics review. Activities such as operational research may, however, be difficult to define. For example, Balasegaram et al. (2006) considered research conducted

during humanitarian operations as operational research, while others consider operational research to be one of various types of research to improve health systems (Remme et al., 2010).

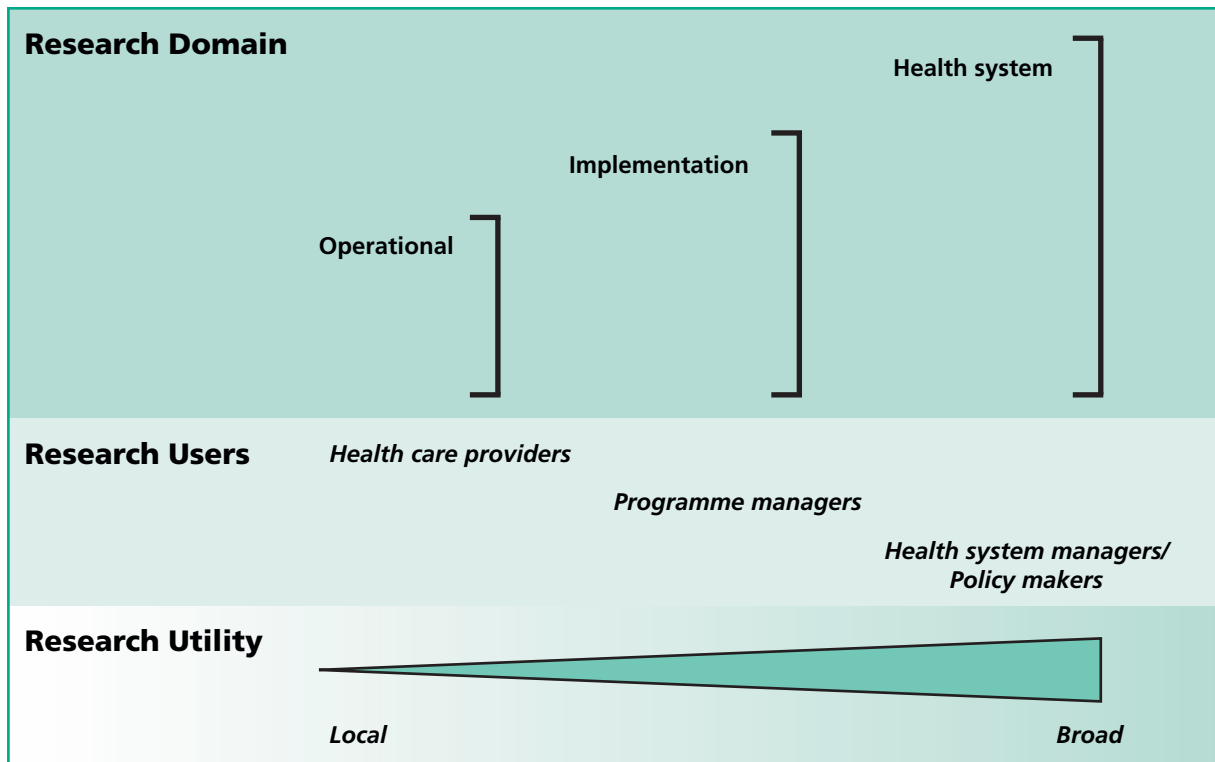


Figure 1. Research to improve health systems (Remme et al., 2010)

Relevance of data

The relevance of the collected data must be assessed. Data from routine clinical monitoring are often the easiest and the first to be collected in an emergency. The decision to disseminate such data should take into account whether the potential benefits gained from publication outweigh the fact that consent was not sought before collection of the data. This would be particularly important if work will continue in the settings in which the data were collected or if stakeholders might use the data to implement and advocate for a modification of treatment protocols, for instance.

Scientific validity

Data collected during public health surveillance or routine clinical management might be less rigorous than data collected in formal research projects the protocols of which have been reviewed for scientific validity. When the scientific merits of data collection activities are debatable, it is particularly important that any limitations are explicitly acknowledged.

Confidentiality

Learning objective 3.3 covers the issue of confidentiality during emergencies. As defined there, confidentiality is the principle for ensuring that identifiable information is kept out of the reach of others. In a publication

based on public health surveillance or clinical management, all identifying information about individuals is subject to the duty of confidentiality and should therefore be left out.

Risk minimization

The confidentiality criterion helps to ensure that the risks to participants and communities resulting from dissemination of the data are minimal. As discussed in learning objective 3.1, however, communities, groups or individuals may be stigmatized if public health activities reveal a higher prevalence of a condition linked to practices that are frowned upon. For this reason, extra effort might have to be made to minimize the risks to which publication of data exposes individuals. Even when the risks are expected to be minimal, they must be explicitly acknowledged by researchers in their publication.

Permission and partnerships

Before submission or dissemination, the relevant national and local health authorities must be informed and agree to release of the data if they were directly involved in its collection. Similarly, pre-publication partnerships with local stakeholders should be pursued when reasonably feasible. For instance, engagement with a body representing the community and, if possible, authorship by a local authority or partner should be sought.

Availability and accessibility

The outcomes of data analysis should be made available to patients and communities in appropriate, accessible forms, when reasonably feasible.

If ethics approval was not obtained to conduct the activity that led to collection of the data being considered for publication, post-hoc ethics approval cannot be granted. By making a decision to publish, the investigators and publishers take moral responsibility regarding all the issues listed above.



C. Summary

As discussed by Gollogly (2006), there are “grey areas” with regard to the circumstances in which data collected as a result of public health surveillance or routine clinical management should be disseminated as scientific information. One issue explored in this module is the likelihood that proper informed consent was not obtained from patients who become participants (see also learning objective 3.2). Another, related area of concern is the lack of a-priori ethical approval. When investigators and publishers debate whether data should be published, they should balance the harm that might result from publication against the expected benefits (Public Health Ontario, 2011). One way of doing so is to use the list of criteria presented here. Additional ethical considerations related to publication ethics will be raised in learning objectives 5.2 and 5.3.



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Learning objective 5.2: Explain what is meant by “publication bias” and how it might affect the response to emergencies.

Maxwell J. Smith



Session timeline (90 min)

0–20 min (20 min)	21–40 min (20 min)	41–55 min (15 min)	56–85 min (30 min)	86–90 (5 min)
Introduction	Reading	Video and group discussion	Case study and discussion	Summary and conclusion



Instruction strategy

1. The facilitator provides background information on publication bias and its effects on emergency preparedness and response.

For facilitators: Allow time for questions and discussion.

2. The facilitator distributes copies of the papers by Godlee and Loder (2010) and Cohen (2009) to the participants and gives them 20 min to read. If possible, the facilitator could give the articles to the participants before the session.

For facilitators: The editorial by Godlee and Loder highlights the significance of publication bias and the importance of mitigating its effects. The article by Cohen provides background for the case study to be discussed in this module.

3. The facilitator shows a video on concerns about the antiviral medication Tamiflu (Channel 4 News, 2009) (12 min).
4. The facilitator introduces the case study.
5. The facilitator divides the group into smaller ones and gives each 10 min to discuss one of the following questions:

- Could this case study indicate a publication bias? Why or why not? What kind of publication bias might exist in this case?

For facilitators: To determine the types of bias that might exist, examine the interests of all stakeholders and consider how (if at all) the study results might be affected.

- What could be done to prevent or mitigate the potential publication bias in this case?

For facilitators: Consider some of the methods identified below, under *Proposed methods for addressing publication bias*.

- How could this case affect the response to an emergency?

For facilitators: There are opportunity costs associated with funding and using public health measures, and these costs may be perceived to lack justification if the measures are ineffective.

6. If time permits, the facilitator can decide to assign some of the questions in Box 5 to participants and moderate a discussion.
7. The facilitator concludes the session and opens the floor for discussion.



A. Background

Decisions about how to prepare for and respond to emergencies are likely to be informed by evidence generated from research. This reflects the trend in public health policy and practice to make decisions that are evidence-based or evidence-informed (Banatvala & Zwi, 2000; Kohatsu et al., 2004; Bowen and Zwi, 2005). Evidence that may inform a public health decision can come in many forms, such as from a single research study, a systematic review or a meta-analysis of many studies. What is published and, therefore, what makes up the evidence base on which decisions are based has the potential for bias (Knox Clarke & Darcy, 2014).

Bias is defined as “[a]ny process at any stage of inference which tends to produce results or conclusions that differ systematically from the truth” (Sackett, 1979, p. 60). While bias can occur at any stage of research, as in sampling or measurement, the focus of this module is bias in the publication stage of research. “Publication bias” occurs when the information published is systematically unrepresentative of the existing data (Rothstein et al., 2005). This might occur when only some data or results from a single study are selected for publication, when some data from a study are suppressed or when no data from a study are published. For example, it was reported that only 21 of 73 registered randomized control trials of H1N1 influenza vaccines were published in peer-reviewed journals 2 years after the emergence of the pandemic strain (Ioannidis et al., 2011). As only a minority of trials on this topic have been reported, it is not clear whether what *has* been published accurately represents the full evidence base.

Hence, as a result of publication bias, it can be difficult to ascertain whether single studies accurately reflect the collected data or if, in the case of systematic reviews or meta-analyses, they take into consideration all existing studies. As systematic reviews and meta-analyses combine and contrast the findings of many studies in an effort to discern patterns, their validity is jeopardized by the lack of availability of studies that are not completed, not published or not reported (Rothstein et al., 2005).

Ultimately, the consequence of publication bias is distortion of the evidence base (Egger & Smith, 1995). Therefore, if decisions are based on the *available* evidence, they will ultimately be based on incomplete or inaccurate information. This raises at least two practical challenges for researchers and decision-makers: the first is how decisions should be made in the light of a potentially biased evidence base, and the second is how publication bias can be prevented or mitigated in the future.



B. Topics

Various forms of publication bias are discussed below.

“Positive results bias”

“Positive results bias” occurs when statistically significant positive results from a study are more likely to be published than results that support the null hypothesis or are inconclusive (known as “negative” results) (Hopewell et al., 2009). As this bias can involve selective reporting of results, depending on the direction and statistical significance of those results, it could be considered to fall under what is otherwise called “outcome reporting bias” (Dwan et al., 2008). Positive results bias occurs because statistically significant positive results are more likely to be submitted for publication, are more likely to be accepted by editors, journals and peer-reviewers, are more likely to be published more than once, are more likely to be cited by others and are more likely to be published quickly (Stern & Simes, 1997; Hopewell et al., 2009).

The consequence of a positive results bias could be the use of certain measures in response to an emergency (e.g. use of antiviral agents for prophylaxis or treatment) when the effectiveness of those measures has been exaggerated. Alternatively, a positive results bias could suggest that a treatment would be effective as a public health measure when there is not actually an effect or the effect is actually counterproductive to the response goal. This could result in use of scarce resources in an intervention as part of an emergency response that is of disputable value. Moreover, if statistically significant positive results are more easily and quickly published, then studies initiated during a public health emergency that produce negative or inconclusive results may not be published until after the emergency response phase, or not at all, which would in turn affect the knowledge base for future responses. Furthermore, research may continue to be funded and conducted on topics that have been thoroughly researched but for which results have simply not been published.

“Hot stuff bias” and “lack of interest” bias

A significant bias for emergencies is what has been called “hot stuff bias” (Sackett, 1979). This bias occurs when a topic is popular within the scientific community or in the broader public domain, leading to increased interest for publication on that topic. Beyond the inherent disparities that may arise between worthy research that is and is not published, this bias could lead to the publication of preliminary or even “shaky” results, because of the push to publish on the matter (Sackett, 1979). During an emergency, an effort will be made to expedite the production of research results that inform decisions about the response. Because of the importance of publishing and communicating study findings and messages quickly during this time, there is a risk that preliminary or “shaky” results will be published. Furthermore, there may be pressure to publish early positive results rather than emerging negative results. Public health and government agencies may be pushed to communicate messages to the public about emergency preparedness and response, and there is a risk that publications will be expedited for that purpose, potentially introducing publication bias.

Conversely, bias might exist as a result of *lack of interest* by those involved in the research and in publication (Sackett, 1979). For instance, researchers may lose interest in a given research question and choose to abandon publication, leaving data unpublished. As emergencies can be short, research initiated during the response phase might later be disregarded because a significant time has elapsed between initiation of the study and preparation of a manuscript for publication. Moreover, after several years of interest in a given

research topic, like pandemic planning, study investigators may lose interest in completing studies on the topic or pursuing publication of their results, and journals and editors may be less inclined to publish such studies because of “topic fatigue”.

A slightly different interpretation of what could be considered “hot stuff bias” is related to the career interests of the researcher(s). Given the pressure to publish original research and to publish in “high-impact” journals, researchers may have less incentive to make relevant, time-sensitive research results available to the broader scientific community or the public if they have a mutually exclusive career-enhancing alternative, such as publishing in a format or venue that is more prestigious for the study authors. In such cases, findings that could have an immediate positive impact on the public’s health might be (at least temporarily) suppressed. Consideration of where to publish original research may affect when and in what form it is published; journals with a rapid review process that are available through open access may be passed over if the researcher has an opportunity to publish in a journal without these qualities but with a higher “impact factor”. Evidence generated from research relevant to any facet of emergency preparedness and response can be highly time-sensitive. A greater incentive to have original research published in a high-impact journal than to make it available for broader scientific scrutiny and, ultimately, public benefit, could constitute a type of publication bias (see also learning objective 5.3).

Other forms of publication bias

“Confirmation bias” might be present when the results of research match or support the interests, expectations or hypothesis of the researcher or study sponsor (Mahoney, 1977). This bias could be particularly significant for research sponsored by entities that have some vested interest in favourable results—financial or otherwise. Commercial involvement can affect both research and activities during an emergency (Delva, 2013). In this case, confirmation bias could be related to what is often called “funding bias” or “sponsorship bias”, which is the tendency for a study to support the interests of its sponsor. Confirmation bias, which is a problem for research beyond publication, leads to bias in what is published.

Other types of bias include “language bias” (selective publication of studies in English), the “all’s well literature bias” (selective publication of papers that minimize controversies), the “one-sided reference bias” (in which authors restrict the references in their paper to those that support their view), “availability bias” (selective publication of studies that are accessible to the researcher), “familiarity bias” (selective publication of studies from the author’s own discipline) and “cost bias” (selective publication of studies in journals that are available for free or at a low cost) (Sackett, 1979; Rothstein et al., 2005). One of the challenges of addressing publication bias is identifying and accounting for these biases.

Proposed methods to address publication bias

Many proposals have been made to prevent or mitigate publication bias, some of which argue for making data (more) publicly accessible, thereby calling into question who owns the data, who should have access to them and who can make use of them.

Transparency in the publication process might counteract publication bias, as greater accountability would be required. For instance, transparency in peer-review, which might involve reporting the names of peer-reviewers and publishing their comments, might deter or at the very least better enable identification of bias associated with peer-review. In addition, making publications “open access” might facilitate the identification and retrieval by researchers, practitioners and policy-makers of important data and findings that might otherwise have been more difficult to access.

Various methods have been developed to manage publication bias in meta-analyses, such as funnel plots, and techniques have been introduced to identify unpublished studies (Hopewell et al., 2009). Clinical trial registries have been set up to help keep track of trials with human participants, regardless of their findings (Hopewell et al., 2009). While publication bias has been discussed largely in terms of clinical trials, it can occur in the reporting of any type of research, including studies with methods different from those of clinical trials, like qualitative studies. Means to prevent or mitigate publication bias must also be found in those contexts.



C. Case study

In 2003, a paper was published reporting the results of a study sponsored by F. Hoffmann-La Roche Ltd about the impact of treatment with oseltamivir (brand name, Tamiflu) on influenza-related lower respiratory tract complications and hospitalization. The paper reported that treatment of influenza with oseltamivir reduced lower respiratory tract complications, antibiotic use and hospitalizations for both at-risk and other adults (Kaiser et al., 2003).

This study involved the analysis of 10 separate phase-III randomized controlled trials sponsored by Roche, of which only two have been published in peer-reviewed journals. A subsequent report of a Cochrane review (Jefferson et al., 2009) claimed that there was insufficient evidence to determine whether oseltamivir is effective in reducing lower respiratory tract complications, antibiotic use and hospitalizations if the data from the eight unpublished studies mentioned in the initial paper were not included. Nevertheless, the evidence from the original study, along with many other relevant publications, has been used by public health decision-makers to justify recommending oseltamivir as a treatment option in combating influenza, including pandemic strains of influenza (Godlee & Clarke, 2009). This has led to stockpiling of oseltamivir for use during an influenza pandemic.

The authors of the Cochrane review concluded “[i]t is possible that there is a publication bias, especially as we know of eight trials that are unpublished and inaccessible [...] Its direction might be in favour of exaggerating the treatment effect” (Jefferson et al., 2009, p. 6).

Box 5. Questions for further discussion

1. What fundamentally drives publication? Is the motivation any different during an emergency? (Suggestion: Consider public health (and other) benefits, career interests and financial interests.)
2. How can questionable evidence of the effectiveness of a public health intervention (for example, the use of quarantine in response to an infectious disease like SARS), because of suggested publication bias, affect the justifiability of using that public health intervention? (Suggestion: See Bensimon & Upshur, 2007, for discussion on this topic).
3. Could publication bias occur in the publication of papers on the ethics of emergency preparedness and response? Might papers with conclusive answers to difficult ethical questions be published more easily or quickly? (Suggestion: Is a paper that unequivocally argues for an ethical position more likely to be published than one that carefully considers the merits of different ethical positions and does not come to a clear conclusion?)
4. If the trustworthiness of the evidence base upon which decisions are informed has been diminished by publication bias, how should decisions be made? (Suggestion: This question is meant to engage users about how decisions could or should be made in situations of uncertainty. On the one hand, decision-making bodies may be criticized if they make decisions when they know that the evidence on which they are based may be biased in a particular direction; on the other hand, they may be criticized for failing to take action on a public health issue even if their decision is based on evidence that may be biased (in other words, it's the only evidence they have, so that's the best they can do).
5. Should peer-reviewers or journal editors (or some other entity) have the opportunity to review study data? (Suggestion: This question addresses the question of whether this would reduce publication bias.)



D. Summary

The measures used to prepare for and respond to emergencies are largely informed by evidence generated from research conducted before, during and after those emergencies. For the most part, this evidence is disseminated through scholarly publication. What is published and therefore what makes up the evidence base on which decisions are informed can potentially be biased. The consequence of publication bias is distortion of the evidence base, which could result in the support and use of public health measures that have exaggerated, in-existent or even counterproductive effects for public health emergency preparedness, response and recovery.

In the midst of an emergency, publishers, public health officials and the public are eager for studies that could inform planning and response efforts. This increased interest may in turn affect the quality, nature and even the findings of studies and may affect which studies and what evidence are published. Efforts to mitigate publication bias are required for an effective, ethical response, but they will not solve the problem of bias in the current evidence base used in preparing for and responding to emergencies. Decision-making bodies pressured to make decisions in the interest of the public's health may be required to use incomplete or evidence. They may be criticized for making decisions when they know that the evidence on which they base their decisions may be biased but may also be criticized for failing to take action on a public health issue even if their decision is based on evidence that may be biased.

To mitigate publication bias, the interests of all stakeholders must be examined to identify the ways in which they impact the study effects. Further mitigation techniques include making data more accessible and finding innovative techniques for research registration and evidence synthesis. In particular, publishers, researchers and research sponsors must work together during emergencies to make the public's health a priority when disseminating data that are crucial for response and recovery.



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Learning objective 5.3: Explain the ethical obligations of researchers, public health practitioners and publishers regarding ownership of scientific data.

Maxwell J. Smith



Session timeline (120 min)

0–20 min (20 min)	21–50 min (30 min)	51–65 min (15 min)	66–110 min (45 min)	111–120 min (10 min)
Introduction	Reading	Video and group discussion	Case study and discussion	Summary and conclusion



Instruction strategy

1. The facilitator provides background information on data ownership, data-sharing and the corresponding ethical responsibilities of researchers, public health practitioners and publishers.

For facilitators: Allow time for questions and discussion.

2. The facilitator distributes copies of the papers by Langat et al. (2011) and Crowcroft et al. (2014) to the participants and gives them 30 min to read them. If possible, facilitators could give the articles to the participants before the session.

For facilitators: These articles describe the potential ethical responsibilities of researchers, public health practitioners and publishers with respect to scientific data ownership during emergencies.

3. The facilitator shows a video on concerns about the antiviral medication, Tamiflu (Channel 4 News, 2009) (12 min)
4. The facilitator introduces the case study.
5. The facilitator separates the group into two and gives each 20 min to prepare for a debate on data ownership in the context of an emergency.

For facilitators: One group should be instructed to favour stricter data ownership and control and the other to favour more open data sharing and access. Each group should be asked to come up with as many arguments to back their position as possible.

6. The facilitator invites a representative(s) chosen by each group to present their arguments.
7. The facilitator moderates a discussion about the two sets of arguments.

For facilitators: The aim of this step is to enable participants to develop preliminary thoughts about what should be included in a data-sharing policy during an emergency.

8. The facilitator asks participants the following questions about the case study:

- What is the conflict in this case? What are the central arguments for and against making the data in question available?

For facilitators: There are competing interests of data ownership and public benefit.

- What might be the effect of not having full access to all data about the effectiveness of oseltamivir, in terms of both preparing for and responding to an influenza pandemic?

For facilitators: The opportunity costs associated with funding and using public health measures may be perceived to lack justification if the measure is ineffective. Also, consider the health effects that may be found.

- To what extent should the following groups have access to all research data in this case? Should the access of any of the groups be limited? Why or why not?
 - Researchers
 - Research institutions
 - Research sponsors
 - Publishers
 - Practitioners
 - The public
- In your opinion, what responsibility does each of the following groups have with respect to data ownership and data sharing?
 - Researchers
 - Research institutions
 - Research sponsors
 - Publishers
 - Practitioners
 - The public
 - Others?
- If regulatory bodies, public health agencies and other government bodies are responsible (to any degree) for the safety and effectiveness of a measure used in response to an emergency (e.g. oseltamivir), to what extent should they be obliged to base their decisions about safety and effectiveness on *all* the data? If not all the data can be accessed, what responsibilities do these bodies have in making their decisions?

For facilitators: This question is meant to engage the participants in a discussion about how decisions could or should be made when there is uncertainty. Decision-making bodies may be criticized for making decisions without having all the evidence but may also be criticized for failing to take action on a public health issue even if their decision would have to be made in the absence of all the data.

9. If time permits, the facilitator can decide to assign some of the questions in Box 6 to participants and moderate a discussion.
10. The facilitator concludes the session and opens the floor for discussion.



A. Background

Data collected or generated from research play a key role in public health practice and policy (Kohatsu et al., 2004). The availability and accessibility of research data can therefore be important in determining whether and to what extent the data can be used by public health researchers, practitioners and decision-makers to promote and protect the public's health. As restrictive policies and practices limit access to research data and as biases may exist in research (including publication bias, see learning objective 5.2), there is significant concern about how "the truth" regarding the effectiveness of a public health measure can be determined if not all the data are available for scrutiny. As the case study discussed in this module shows, the truth about the effectiveness of Tamiflu in responding to pandemic influenza is unclear, due, at least partly, to incomplete access to relevant study data.

Making research data available during an emergency can have a significant impact on response capability (World Health Organization, 2007; Langat et al., 2011). Because of the vast scope, urgency and demand for collaboration required in responding to an emergency, researchers and the data they collect are integral to providing time-sensitive information for response or for preparing for future emergencies.

Not surprisingly then, lack of access to data can limit an effective response to an emergency. For instance, the absence of protocols for data sharing among different levels of government and general uncertainty about data ownership created systematic deficiencies in the Canadian response to SARS in 2003 (National Advisory Committee on SARS and Public Health, 2003). Similar challenges occurred during the 2009–2010 H1N1 influenza pandemic, when a lack of timely, full disclosure of research data and findings about vaccination led to confusion among the public and decision-makers (Langat et al., 2011). Questions must therefore be raised about the ethical responsibilities of researchers, public health practitioners and publishers in managing and sharing research data with the broader research community, health and government agencies and the public. While many factors are important in data ownership and data sharing in the context of emergency response (including legal agreements and considerations and technical specifications of data management systems), this module focuses on the *ethical* obligations of researchers, public health practitioners and publishers.



B. Topics

"[...] when patients' questions arise from unpublished—and inaccessible—study results, practitioners are in an impossible position. Unable to appraise the research, clinicians are left with an uncertain foundation for making decisions about patient care and, at best, can only echo what has been said publicly by others." (Stanbrook & Hébert, 2010).

Why share data?

The benefits of research depend on exactly what is done with the research data. If data are not published or their analysis is restricted, they may not produce the most benefit that they could or are meant to confer.

Seminal documents on the ethical conduct of research on human subjects require that research have social or scientific value (Emanuel et al., 2002). This requirement has been used to support arguments in favour of data sharing, as restricting access to data can be seen as antithetical to the social or scientific value of research (Vanderpool, 1996; Langat et al., 2011). For instance, limiting access to data that may be essential for the development of diagnostic tests, vaccines and other public health measures for responding to an emergency may limit progress in reducing morbidity and mortality and, ultimately, in generating something of social value (World Health Organization, 2007).

While several health agencies and institutions support data sharing (e.g. National Institutes of Health, 2003; World Health Organization, 2007), data sharing in public health remains largely aspirational (Pisani & AbouZahr, 2010). Less restrictive data-sharing practices in fields outside public health (e.g. genomics) have shown that it can reduce duplication of research, increase scientific progress and even create more career opportunities for researchers (Pisani et al., 2010). Moreover, limiting access to research data may obstruct further use, while making data available and accessible allows researchers to determine what data exist and where future research should be directed (Taylor, 2007). Thus, some have argued that, in order to have (or to promote) scientific value, data producers have an ethical responsibility to share their data (Langat et al., 2011).

Challenges and barriers to sharing data

Given the pressures to publish original research and to publish in high-impact journals, researchers may have less incentive to make available relevant, time-sensitive research data or results to the broader scientific community or the public. For instance, study data (including samples of e.g. viruses) or findings that might have an immediate, positive impact on public health may be (at least temporarily) withheld if the study authors decide to publish in the format or venue that is most prestigious for them (i.e. to promote their own *academic competitiveness*) (Chan et al., 2010). Consideration of where to publish original research may affect when and in what form it is published (see learning objective 5.2).

Dependence on publishing research in peer-reviewed journals for career advancement and funding is a disincentive to making research data available to other researchers (Pisani et al., 2010). When other researchers gain access to data, they can publish other papers on the basis of the data set, which may mean that the data producers receive no (or less) benefit.

Furthermore, research, and perhaps especially industry-sponsored pharmaceutical research, may have commodity-driven interests to maintain data secrecy (Taylor, 2007): research data may be considered the intellectual property of research sponsors, who may require permission or payment for access to or use of the data (Langat et al., 2011). These issues present challenges to developing widely acceptable policies on the ethical obligations of researchers, public health practitioners and publishers regarding scientific data.



C. Case study

In 2003, a paper was published reporting the results of a study sponsored by F. Hoffmann-La Roche Ltd about the impact of treatment with oseltamivir (brand name, Tamiflu) on influenza-related lower respiratory tract complications and hospitalization. The paper reported that treatment of influenza with oseltamivir reduced lower respiratory tract complications, antibiotic use and hospitalizations for both at-risk and other adults (Kaiser et al., 2003).

This study involved the analysis of 10 separate phase-III randomized controlled trials sponsored by Roche, of which only two have been published in peer-reviewed journals. A subsequent Cochrane review (Jefferson et al., 2009) claimed that there was insufficient evidence to determine whether oseltamivir is effective in reducing lower respiratory tract complications, antibiotic use and hospitalizations, as the data from the eight unpublished studies mentioned in the initial paper were not included. Nevertheless, the evidence from the original study, along with many other relevant publications, has been used by public health decision-makers to justify recommending oseltamivir as a treatment option in combating influenza, including pandemic strains of the virus (Godlee & Clarke, 2009). This has led to stockpiling of oseltamivir for use during an influenza pandemic.

The authors of the Cochrane review (Jefferson et al., 2009) concluded that, despite their attempt to include all data in their review, they were unable to access key data that purportedly supported the findings of the original Roche-sponsored study.

Box 6. Questions for further discussion

1. When considering whether a particular public health measure should be used to respond to an emergency, what data should be used? Should an attempt be made to include data that are unpublished or are tightly controlled by a researcher, study sponsor or research institution?

For facilitators: The aim of this question is to engage participants in discussing whether public health decisions should be made in the absence of all existing data. If an attempt *should* be made to incorporate even unpublished data, the participants should explore how this might reflect the obligation of researchers to make their data available.

2. If the mandate of research ethics boards is to weigh the benefits and risks of proposed human participation in research, can they be said to have met this obligation if data ownership and data secrecy create a barrier to public benefit?

For facilitators: This question addresses ethics approval and oversight of research and the obligations of research ethics committees. If human participants will be burdened or harmed in a study, the study may still be considered ethically justified if significant benefits may accrue as a result of the research. If the benefits are contingent on dissemination of the research results, however, some might argue that such committees have a responsibility to ensure that the data are adequately disseminated.

3. Can public health research be said to have scientific and social value if it is not accessible by the larger research community and the public?

For facilitators: Is research that is not published or otherwise disseminated a waste of resources, and thus unethical?

4. Do researchers, public health practitioners and publishers have different responsibilities for sharing different types of data (e.g. raw data versus cleaned data, qualitative observational data versus quantitative experimental data)? If so, how do these responsibilities differ? Consider the pathway(s) that different stakeholders might have to follow in order to share their data, given each stakeholder's distinct needs and constraints.

For facilitators: This question should engage participants in a discussion of the value of different kinds of research data and whether data could be transformed in order to address potential barriers to sharing.

5. Is dissemination of research data generated during emergencies to other researchers and the public a higher priority than dissemination of data generated in non-emergency scenarios?

For facilitators: Some might argue that, because of the potential severity and time-sensitive nature of emergencies, sharing data might be a higher priority for developing or implementing effective public health measures. How might such priority-setting be hindered or facilitated, given the information in learning objective 5.2 on publication bias?

6. Is there a direct conflict between the requirement to publish and sharing data?

For facilitators: Is the fact that career advancement often depends on publishing original articles in high-impact journals, which requires significant financial and human investment, a conflict or a barrier to sharing data? If so, is this an area in which changes in policy and practice could positively affect data sharing?

7. Who should be responsible for developing protocols for data sharing?

For facilitators: The responsibility could be that of study funders, sponsors, universities, individual researchers or professional organizations.



D. Summary

Decision-making bodies in public health aspire to make decisions that are informed by the best available evidence. It is not surprising, then, that lack of availability of and access to research data can significantly affect their decisions. Restrictive policies and practices to limit access to research data, for instance, raise concern about how “the truth” of the effectiveness of a public health measure can be determined if not all the data are available for scrutiny. Yet another layer of complexity is added during emergencies, when making emerging research data readily available can have a significant impact on response and recovery capacity.

If research data are unpublished or are otherwise restricted, they may not be considered in making decisions in emergency planning and response. Thus, some argue that data producers and publishers have an ethical responsibility to share any data generated from research activities in a transparent manner, in order to promote scientific value. Given the pressure to publish original research and to publish in high-impact journals

and given the commodity-driven interests of industry-sponsored pharmaceutical research, researchers and publishers may have less incentive to make time-sensitive research data or results available to the broader scientific community or the public.

This raises questions about the ethical responsibilities of researchers, research sponsors, public health practitioners and publishers in managing and sharing research data with the broader research community, health and government agencies and the public. In view of the potential severity and time-sensitive nature of emergencies, there may be an additional responsibility to share data in order to develop or implement effective, timely public health measures.



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Patient care

Core competence 6: Ability to define ethically relevant criteria for triage, resource allocation and standard of care in emergency response



Core competence 6: Ability to define ethically relevant criteria for triage, resource allocation and standard of care in emergency response

Triage and rationing are often at the centre of responses to emergencies crises. Specific criteria and general frameworks have been drawn up for these activities; they are discussed in learning objective 6.1. This discussion is followed by an exploration of three related issues of justice. First is one that can be vexing for care providers and recipients, namely the fact that standards of care can be considerably altered during different types of emergencies (learning objective 6.2). A second issue, which has raised much controversy during the past few years, is the issue of benefit-sharing with communities that are subject to public health surveillance, such as when communities send samples so that the international community can plan for the next influenza vaccine (learning objective 6.3). Thirdly, the provision of access to treatments being developed in research projects conducted during an epidemic or disaster is also subject to debate. Reflections on this issue are offered in learning objective 6.4.



Learning objectives

- 6.1 Discuss ethical frameworks and criteria for triage and rationing in emergencies.
 - 6.2 Understand how criteria for standards of care and treatment can be altered during emergencies.
 - 6.3 Identify issues of benefit-sharing with communities under public health surveillance.
 - 6.4 Identify issues of equity of access to unproven treatments during research in the course of emergency response.
-

Learning objective 6.1: Discuss ethical frameworks and criteria for triage and rationing in emergencies.

A.M. Viens



Session timeline (90 min)

0–15 min (15 min)	16–20 min (5 min)	21–35 min (15 min)	36–45 min (10 min)	46–70 min (25 min)	71–80 min (10 min)	81–90 min (10 min)
Introduction	Small groups discussion	Large group discussion	Large group discussion	Reading	Discussion	Summary and conclusion



Instruction strategy

- The facilitator introduces the module and provides background information on triage and rationing, including the criteria that could be used in emergencies.
- The facilitator separates the group and provides each small group with one (or a few) of the following questions. The groups are given 5 min for discussion before reconvening.
 - What are some of the critical resources that might have to be allocated during an emergency?
 - Who should make triage decisions during an emergency? If such decisions are made at different levels or by different categories of people, should they use the same criteria?
 - Are there some considerations (e.g. demographic) that should never be used when allocating health care resources?
 - In an emergency, the most seriously injured patients with the least probability of being saved might be left untreated because their care would require too many resources and personnel. This illustrates a conflict between the common good and the individual good of patients. What other conflicts might arise in triaging during an emergency?
 - Triage is often used to maximize the number of lives saved. But should we aim to maximize the number of lives or the number of life-years saved? What if this favours some kinds of discrimination, such as “ageism”?
 - Questions about the quality of life and years lived could also be taken into consideration in triage models. Is it appropriate to make decisions about allocation on the basis of quality of life or life-years?
 - We often seek to allocate health care resources in a fair and just way. Should our notions of fairness and justice differ during emergencies, or should the ethical principles remain the same as in normal times?
- The facilitator distributes copies of Smith & Viens (forthcoming) to all participants and asks the following questions:
 - What triage criteria do you think should be used in this case?
 - Given the triage criteria you selected, which substantive and/or procedural ethical principles would best support your decision? Support your answer with reasons or examples.

4. The facilitator distributes copies of Melnychuk & Kenny (2006) and Persad et al. (2009), and provides reading time.
5. The facilitator opens the floor for discussion.
6. The facilitator provides background information on different ethical principles and how they can be used to formulate an ethical framework for justifying decisions for triaging clinical patients during an emergency.

For facilitators: Allow time for questions and discussion to ensure that the participants understand what the ethical principles are, how they are used in choosing a process of triage and how the use of different ethical principles can result in different triage decisions.

7. The facilitator distributes pp. 3–8 and 15–16 of “Stand on guard for thee” (University of Toronto Joint Centre for Bioethics Pandemic Influenza Working Group, 2005) and gives participants time to read (15 min).
8. The facilitator asks participants to review the case study on the basis of the following questions:

For facilitators: When possible, try to guide participants to refer to the ethical principles discussed and ask them for their reasons or arguments for using the principles to justify the course of action they recommend.

- Is it more productive to start with allocation criteria or with the principle(s) underlying the criteria when setting priorities and allocating resources?
 - What if one or more ethical principles conflict? For instance, if the principle of equity requires that patients be triaged to allow equal access to a resource, and the principle of protection from harm requires that patients be triaged in order to save the most lives, how can the conflict be resolved? In which way should we eventually triage patients?
 - People may disagree about which substantive ethical principles should be used to select a process for triaging patients during emergencies. Would it be sufficient to ensure that the process of selecting the triage method was ethical? That is, could we choose to triage patients by a process that met procedural ethical principles (e.g. a process that is transparent, accountable, etc.)?
 - Should we always use the same principles to allocate resources or triage patients? Can you think of any resource or situation in which we would be justified in using different ethical principles to use a different allocation criterion or strategy?
 - To what extent do the ethical principles outlined in this objective match the principles you use in your professional practice? Are any principles missing?
9. The facilitator concludes the session and opens the floor for discussion.
-



A. Background

During emergencies, one of the main objectives of medical and public health personnel is to minimize mortality and morbidity. Because of time and resource constraints, however, their ability to do so is limited, and a way must be found to choose who should be given what treatment. Effective planning and management of resources and personnel will significantly affect the duration and severity of the emergency but also raises important ethical questions about setting priorities and allocating resources fairly.

Resources can be managed in various ways. One process is triage, which involves prioritizing the use of scarce medical resources for certain individuals when there is not enough to provide immediate treatment or diagnostic interventions for everyone. Effective triage should help determine who to treat first, and with what kind of treatment. In other words, triage involves assessing the nature and severity of the illness or injury of particular individuals to determine their health status and whether they can be saved, as well as using the information to decide on the priority and type of care to give. Triage can also be based on non-medical factors, such as socio-economic status and social utility, in deciding to whom priority should be given. Beyond decisions about care, triage can also involve decisions about priority for transport and facilities in which individuals will receive further care. Triage is used not only where the resources and/or medical personnel are insufficient to provide the necessary immediate care to everyone at the same time but also in, for example, accident and emergency departments.

A second means of effective resource management is rationing, which involves delaying or withholding immediate treatment for individuals for economic reasons. Rationing, like triage, is used not only during emergencies; for instance, most health care systems ration the number of individuals who can obtain a hip replacement each year, because there are not enough resources to treat everyone.

Triage and rationing can be used together. For example, the number of hip replacement procedures in a health care system in 1 year might be rationed to 4500. Once this limit is established, a decision must still be made about which 4500 individuals will receive a replacement. Making this decision will involve triaging everyone who is a candidate for replacement, on the basis of some set of criteria. Both processes are due to a shortfall of resources but should not be conflated as identical.

The focus of this learning objective is triage and, in particular, the criteria that can be used to overcome the scarcity of resources during an emergency. The module also includes examination of some of the ethical principles on which these criteria are based and which provide independent means to justify how victims are triaged. The combination of criteria and principles can form a decision-making framework for setting priorities and allocating scarce resources in an emergency.

Various criteria can be used to set priorities and allocate resources; for example, resources should be distributed in such a way that everyone has an equal chance of obtaining them. Even if there is agreement on the criterion to be used, more than one strategy may satisfy that criterion (e.g. a lottery system, in which a resource is randomly allocated, giving each individual a fair and equal chance for selection). The choice of both criteria and strategies for selection that would be most appropriate in a particular circumstance can be justified by ethical principles. For instance, it could be argued that use of a lottery as an allocation strategy for randomly giving each individual an equal chance of access to the resource is justified by considerations of justice and equality of opportunity.



B. Topics

Levels of triage

There are three levels of triage: primary (e.g. at the scene), secondary (e.g. in the emergency room) and tertiary (e.g. in an operating theatre). Different or more specific criteria may be used at each level, and different medical personnel might use different triage protocols, depending on their function and the level at which they intervene. For example, the criteria provided to a paramedic at the scene of an earthquake might differ from those of a physician receiving the patients at a hospital or from those of a public health executive deciding which services to prioritize in the population.

At each level, considerations such as the safety of patients and personnel, the degree of medical need, human resource constraints and treatment options vary, which in turn changes the nature of the ethical decision to be made.

Triage criteria

A variety of protocols for triaging exist, each with a specific ethical justification.

- *Save the greatest number of people*

This criterion directs us to give priority in allocation decisions to the category or categories of people that will result in the most lives saved. This usually involves allocating resources on the basis a patient's prognosis and the amount of resources and/or personnel that will be required to sustain life.

- *First come, first served*

This criterion directs us to give priority in allocation decisions to whoever accesses the resource first, independent of the severity of medical need or the needs of others. This criterion is based on the assumption that everyone has equal ability to access the relevant resource—a presumption that is questionable during an emergency.

- *Protect the most vulnerable*

This criterion directs us to give priority in allocation decisions to the most vulnerable category or categories of people in an emergency. Depending on the nature of the emergency, the most vulnerable groups could include infants, elderly people, pregnant women or people with particular medical conditions (e.g. obesity). If this criterion is chosen, we should give priority for live-saving interventions to members of vulnerable groups.

- *Equal access*

This criterion directs us to give everyone (or at least similar categories of people) equal access to the benefit(s) of a resource when it is distributed, or at least an equal chance of accessing the benefits. If this criterion is chosen, no person should be given priority over another: each person is as important as any other, and all

have an equal claim to access the resource. This differs from the “first come, first served” criterion in that its aim is to provide equal access to as many people as possible, not just those who access it first.

Another version of this criterion is that if equal access cannot be given, an equal *chance* to access the benefits should be given; for instance, through a lottery process in which people who will receive a resource are chosen randomly.

- *Priority for the most important*

This criterion directs us to allocate resources in such a way as to ensure that the individuals who are most important for society are given priority for access. The importance of individuals is usually understood in terms of who contributes most to the stability and protection of society (e.g. first responders, health care workers). If this criterion is chosen, individuals judged as having such a social function are given priority over those who do not.

Alternatives to triage

A number of non-resource-based strategies can be used to mitigate a scarcity of resources or personnel. They include discharging patients early, redirecting non-urgent patients to other care structures and cancelling elective surgery, diagnostic procedures or laboratory testing. Such strategies are not, however, ethically neutral alternatives to triage but instead themselves raise important ethical questions.

Ethical principles

Ethical principles can be categorized as either substantive or procedural. Substantive ethical principles include considerations to explain why a particular policy or course of action is ethically justified. Procedural ethical principles outline the way in which decisions or actions should be made if they are to be considered ethically justified. Both kinds of ethical principle are relevant for deciding how to triage people during an emergency. The principles discussed here are from the assigned reading (University of Toronto Joint Centre for Bioethics Pandemic Influenza Working Group, 2005, pp. 6–8):

Ten substantive ethical values

- *Individual liberty*: In an emergency, restrictions to individual liberty may be necessary to protect the public from serious harm. Restrictions to individual liberty should be proportional, necessary, relevant, be the least restrictive possible and be applied equitably.
- *Protection of the public from harm*: To protect the public from harm, health care organizations and public health authorities may be required to take actions that impinge on individual liberty. Decision-makers should weigh the imperative for compliance, provide reasons for public health measures to encourage compliance and establish mechanisms to review decisions.
- *Proportionality*: Proportionality requires that restrictions to individual liberty and measures taken to protect the public from harm should not exceed those necessary to address the actual level of risk to or critical needs of the community.
- *Privacy*: Individuals have a right to privacy in health care. In an emergency, it may be necessary to override this right in order to protect the public from serious harm.
- *Duty to provide care*: Inherent to all codes of ethics for health care professionals is the duty to provide care and to respond to suffering. Health care providers will have to weigh the demands of their professional roles against other competing obligations to their own health and to families and friends. Moreover,

health care workers will face significant challenges in resource allocation, scope of practice, professional liability and workplace conditions.

- *Reciprocity*: Reciprocity requires that society support those who face a disproportionate burden in protecting the public good and take steps to minimize the burden as much as possible. Measures to protect the public good are likely to impose a disproportionate burden on health care workers, patients and their families.
- *Equity*: All patients have an equal claim to receive the health care they need under normal conditions. During a pandemic, difficult decisions will need to be made about which health services to maintain and which to defer. Depending on the severity of the event, this could curtail not only elective surgeries but could also limit the provision of emergency or other essential services.
- *Trust*: Trust is an essential component of the relationships between clinicians and patients, staff and their organizations, the public and health care providers or organizations and among organizations within a health system. Decision-makers will be confronted with the challenge of maintaining stakeholder trust while simultaneously implementing various control measures during an evolving emergency. Trust is enhanced by upholding such process values transparently.
- *Solidarity*: As the world learned during the SARS outbreak, a pandemic outbreak of influenza will require a new vision of solidarity among nations. A pandemic can challenge conventional ideas of national sovereignty, security or territoriality. It also requires solidarity within and among health care institutions. It calls for collaborative approaches that set aside traditional values of self-interest or territoriality among health care professionals, services or institutions.
- *Stewardship*: People entrusted with governance roles should be guided by the notion of stewardship. Inherent in stewardship are the notions of trust, ethical behaviour and good decision-making. This implies that decisions regarding resources are intended to achieve the best patient health and public health outcomes in the unique circumstances of the influenza epidemic.

Five procedural values

- *Reasonable*: Decisions should be based on reasons (i.e. evidence, principles and values) that stakeholders can agree are relevant to meeting health needs in a pandemic influenza emergency. The decisions should be made by people who are credible and accountable.
- *Open and transparent*: The process by which decisions are made must be open to scrutiny, and the basis on which decisions are made should be publicly accessible.
- *Inclusive*: Decisions should be made explicitly with stakeholders' views in mind, and stakeholders should have opportunities to engage in the decision-making process.
- *Responsive*: There should be opportunities to revisit decisions as new information emerges throughout the event. There should be mechanisms to address disputes and complaints.
- *Accountable*: There should be mechanisms in place to ensure that decision-makers are answerable for their actions and inactions. Defence of actions and inactions should be grounded in the 14 other ethical values discussed.



C. Case study

Smith & Viens (forthcoming)



D. Summary

Triage is the process of using information about the nature and severity of injury to particular individuals to decide on the type and priority of care they should be granted. Decisions about allocation by triage can be guided by a number of ethical principles but should also take into consideration the amount of resources, the ease of obtaining a new supply, the demand for resources and the personnel available to distribute and/or administer the resources. These will determine the extent to which triage initiatives succeed. Although there may be strategies to decrease the need for triage, their use also raises ethical questions. Regardless of which triage protocol is chosen, it is essential that the ethical justification be explicit.



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Learning objective 6.2: Understand how criteria for standards of care and treatment can be altered during emergencies.

Philippe Calain and Renaud F. Boulanger



Session timeline (90 min)

0–10 min (10 min)	11–15 min (5 min)	16–30 min (15 min)	31–35 min (5 min)	36–75 min (40 min)	76–90 min (15 min)
Introduction	Reading	Video and group discussion (case study 1)	Reading	Write-up and group discussion (case study 2)	Summary and conclusion



Instruction strategy

For facilitators: Make sure that you are familiar with the case studies (see section C and Box 7) before beginning the session.

1. The facilitator introduces the module by drawing a distinction between triage and resource allocation (see learning objective 6.1) and altered standards of care (10 min).
2. The facilitator distributes the first two pages of the article by Fink (2009) and asks participants to read the story individually (5 min).
3. The facilitator shows the video “Eye to Eye: Dr. Anna Pou” (CBS News, 2006) to complement the reading (4 min 30 s).
4. The facilitator asks participants to answer the following questions (10 min):
 - What was Dr Pou’s moral dilemma?
 - Who among you sympathizes with Dr Pou, and who thinks she is “guilty”? Explain your position.
 - What do you mean by “guilty” in this case? Are there differences between moral and legal responsibilities?
5. The facilitator distributes scenarios 2 and 5 from Levin et al. (2009) and invites participants to write brief individual reflections (15 min).
6. The facilitator divides the participants into groups of three or four and asks each group to designate a rapporteur.
7. The facilitator asks each group to discuss the case and determine what Dr Smith should do (i.e. perform the operation in violation of hospital rules or not) and why (10 min).
8. The facilitator asks each rapporteur to present the conclusions of the group (15 min).

For facilitators: At this point, it is not expected that a consensus will be reached.

9. The facilitator briefly explains the circumstances in which the scenarios were originally designed and tested by Levin et al. and reveals the opinion of the “stakeholders” in the survey (Box 7) (5 min).
10. The facilitator concludes the session and opens the floor for discussion (15 min).



A. Background

The concepts of triage and resource allocation were introduced in learning objective 6.1. The notions differ from the issue of altered standards of care, covered in this module. Standard of care refers to the treatment recognized by peer professional consensus as adequate for a given condition. In health care, the notion has both ethical and legal implications. Legally, care providers may be required to give the standard of care or risk being sued for malpractice. From an ethical standpoint, it might be discussed whether it is acceptable that the standard of care vary according to circumstances, such as the availability of resources and the wealth of health care systems. In an emergency, practitioners may be compelled to select patients by triage or rationing or decrease the standard of care for all in an attempt to share resources more equitably. Needless to say, this can cause controversy, liability or moral conflict. The concepts of triage and standard of care are not necessarily exclusive: triage could also be used to determine who should receive an altered standard of care, and altering the standard of care might be a means of allocating limited resources.

Compromising the gold standard of care when resources and capacities are stretched in emergencies can have serious implications for externally funded research. In an uncomfortable turn of events, when the standard of care is lowered, clinical trials may become cheaper to conduct, because, when the care offered to the control arm is simpler, external stakeholders may find it easier to mobilize the necessary resources for the trial. Obviously, research should not be conducted at the expense of the standard of care. When resources are limited such that the standard of care is lowered, it is generally agreed that it would be unethical to divert already scarce resources from human resources to supplies for research and thereby justify a further decrease in the standard of care. Furthermore, it is widely agreed that purely “opportunistic” research or research that does not directly benefit the victims of the current emergency should be avoided (Calain et al., 2009). What the standard of care should be in international medical research is a much-debated topic, particularly with regard to the choice of a control arm in comparative treatment trials (Selgelid, 2005). It is clear, however, that a decision to lower the standard of care should be free from the influence of people with competing interests in the results of the research.

The two cases discussed in this module illustrate the ethical dilemmas that clinicians might face when standards of care have to be altered because of the pressures of an emergency. In a way, the two cases present different aspects of the same moral dilemma. Left on her own, Dr Pou decided to alter the standard of care and was later sued, while Dr Smith confronted the hospital managers and refused to comply with the new standard of care imposed in the middle of a pandemic. Before turning to these cases, it might be helpful to understand some of the factors that affect the definition of standards of care.



B. Topics

Below is a non-exhaustive list of factors that might make it likely that an established standard of care would be altered in the middle of an emergency.

Logistical constraints

Logistical factors may be the most straightforward reasons for offering an individual an altered standard of care. When demand for medicines is high, manufacturing capacity may be exceeded, obviating the normally agreed standard of care. In such circumstances, an alternative may be established. Other logistical constraints with similar outcomes include difficulty in importing or exporting a product needed to provide the standard of care or lack of human resources capable of providing the full treatment, because of either lack of training or limited numbers of personnel.

Increased availability of unproven treatments

During emergencies, experimental treatments that were either not yet ready for clinical trials in humans or whose efficacy has not been definitively established might be offered to patients with otherwise limited solutions. When the standard of care has poor outcomes (e.g. lack of effective treatment), medical authorities and the public may agree to “bend” expectations of an established standard of care and instead explore alternatives that are in the pipeline. If an emergency is drawn out, the pipeline can quickly become full as more agents enter the race to find a treatment.

Variation in risk aversion

Risk aversion plays a role in defining the standard of care, as it balances maximization of benefits with minimization of harm. Under normal circumstances, a satisfactory standard of care is treatment that does not put the patient at great risk. In the context of emergencies, however, the notion of risk might shift. Individual patients and their caregivers might be more inclined to take greater risks, thereby de facto altering the (range of) standard of care.

Research with controlled arms

In many emergencies, trade-offs must be made to the standard of care so that limited human resources can cope with the caseload. In emergency research, arguments can be made for providing both the highest and minimum standards of care to participants enrolled in controlled arms. This debate has a long history in research ethics, and a number of high-profile cases have been reported in the literature and the media. Concern about use of altered standards of care in research are not fully misguided: if an experimental treatment is compared with less than the gold standard, the effectiveness of the therapy outside a crisis environment may be difficult to establish. Nevertheless, providing the minimal standard of care to the control arm may facilitate the research as it is likely to be both logistically and financially less burdensome.

Variation in coverage by the public sector

As an emergency follows its course, governments may try to contain the threat or limit the harm caused. As a result, the treatment assured by the public health sector may evolve. This may affect the potential or actual standard of care in a given context: if a government decides to fund an expensive drug that was not previously available in the country, the standard of care for the condition is bound to change.



C. Case study

Case study 1. Dr Pou and Hurricane Katrina in New Orleans, USA

The background material consists of the article by Fink (2009) and a video (CBS News, 2009).

Case Study 2. Dr Smith and influenza pandemic (Levin et al., 2009)

The context is as follows. An influenza pandemic has been under way for 6 weeks, and the health care system has been burdened beyond capacity, with every hospital bed full, every ventilator in use and all health care providers working extended shifts. To increase the number of beds to accommodate the surge of influenza patients, all scheduled operations have been postponed for the past 2 weeks. The postponed procedures include diagnostic and palliative operations for patients with pancreatic cancer, ovarian cancer and malignant brain tumours. The expected survival of many of these patients is less than 6 months, but, without an immediate operation, they will probably die within 2 weeks. As a result of the pandemic, medical resources are scarce, and the usual critical care that would follow such operations could not be provided to all those who need it. Hospitals throughout the country are independently making decisions to modify the standards of critical care in order to provide limited interventions and processes for many additional patients.

Hospital A decides to provide critical care according to the usual standards on a first-come, first-served basis. Hospital B decides to provide important critical care interventions only to those patients who are expected to survive for more than 6 months.

A surgeon, Dr Smith, deeply opposes hospital B's decision. This new rule requires that Dr Smith cancel bowel obstruction surgery scheduled for later in the week. Without surgery, his patient, a 36-year-old mother of three with ovarian cancer, will die within 2 weeks. Dr Smith is considering whether to perform the operation in violation of hospital rules, potentially risking his career. In light of this disagreement with recent hospital policies, Dr Smith is torn between his professional mission to use his skills and expertise to help the patients who need him and his obligation to observe the rules of his institution.

Box 7. Additional information for case study 2 (Levin et al., 2009)

To obtain feedback from a diverse audience, the authors recruited residents of Massachusetts to deliberate the scenarios presented and the issues raised by them. Two meetings, one for consumers and one for health care practitioners, were held in July 2006, each attended by approximately 15 residents. Each meeting lasted 4 h, during which time the consumers participated in professionally facilitated discussions of five scenarios, which are summarized in a table in the article.

Although both groups recognized that it was important that health care providers act as advocates for their patients, the providers opposed violation of hospital policy, as a surgeon's decision to violate hospital rules would implicate others. They said, however, that better systems of support to physicians were required in hospitals if the rules governing the allocation of critical care interventions were introduced, including protection against liability and mental health support.

This article illustrates that there may be no single correct course of action and that different stakeholders may have different views on the decisions to be taken.



D. Summary

Establishing a standard of care is always a challenge, even in non-emergency settings. During an emergency, however, this can be expected to be a source of particularly heated discussions. The circumstances are such that it can be difficult to define an adequate standard of care in which the dignity of patients is respected (the last value we should be willing to compromise on) while taking into consideration the finite resources. In the face of scarce resources during an emergency, practitioners might have to resort to triage or lower the standard of care.

When the standard of care is lowered, it might be inappropriate to conduct research that deflects resources from care.

Reaching consensus on acceptable alterations to a standard of care in an emergency has serious ethical implications: not only does it help protect patients, it also defines expectations about the kind of control arm that can be used in health research conducted during that period.



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Learning objective 6.3: Identify issues of benefit-sharing with communities under public health surveillance.

Dónal O'Mathúna



Session timeline (105 min)

0–20 min (20 min)	21–35 min (15 min)	36–40 min (5 min)	41–55 min (15 min)	56–65 min (10 min)	66–70 min (5 min)	71–100 min (30 min)	101–105 min (5 min)
Introduction	Individual reflection	Reading	Group discussion	Class discussion	Case presentation	Case discussion	Summary and conclusion



Instruction strategy

1. The facilitator introduces the module and provides a brief background to the concept of benefit-sharing and its historical evolution.
2. The facilitator asks the participants the following question and gives them 5 min to write a short answer:

Article 15 of the UNESCO Declaration on Bioethics and Human Rights (UNESCO, 2005) states that the benefits shared should not be such that they represent an unethical inducement. Where do you think public health surveillance should draw a line between appropriate benefits and inappropriate inducements for participation?

3. The facilitator asks each participant to share his or her thoughts with the group.
4. The facilitator distributes a copy of the article by Simm (2007) and gives participants 5 min to read it.
5. The facilitator asks participants to discuss in groups of three to four how they would apply the notions of benefit-sharing described by Simm (2007) to public health surveillance.
6. The facilitator asks the groups to summarize their discussions and present the results to the group.

For facilitators: Ask groups that will present later to add only items that have not already been mentioned by other groups.

7. The facilitator presents the case study and asks the group to discuss the following questions:
 - How could Dr Supar's position that Indonesia should withhold avian flu samples be ethically justified?
 - Using the language of ethics, how would you justify the position that a country has an obligation to participate fully in global viral surveillance, including sharing viral samples?
 - Using the language of ethics, how would you justify the position that vaccine manufacturers have an obligation to share the benefits of their products with those who contributed to their development?

8. The facilitator asks the participants the following question and gives them 5 min to write a short answer:

How do you think the last two positions above can be ethically balanced?
9. The facilitator asks each participant to share their thoughts with the group.
10. The facilitator concludes the session and opens the floor for discussion.



A. Background

The principle of benefit-sharing was developed in the 1970s in response to factors such as the common heritage of humankind, the use of genetic resources and globalization of clinical research. Although there is still much debate and controversy about the precise definition of the principle and its practical implications (Dauda & Dierickx, 2013), benefit-sharing was not a major topic in research ethics until relatively recently. Even with the recent attention, benefit-sharing is still not as prominent as many other issues in research ethics.

The notion of a common heritage has played a key role in justifying the obligation to share benefits. At the core of the concept of common heritage is the belief that certain resources are so broadly distributed that it is inappropriate for any individual, organization or state to monopolize, possess or own them. The examples commonly given include the oceans and the moon, certain biological species and the human genome. Because of this shift away from ownership, the concept of a common heritage of humankind was originally seen as a way of overcoming disparities between rich and poor countries. Gaps in the distribution of power and wealth, however, quickly led to concern that the notion of common heritage could in fact encourage exploitation and biopiracy (Dauda & Dierickx, 2013). For example, plants seen as having medicinal promise could be taken from low-income countries by developers in affluent countries; if those plants were seen as part of humanity's common heritage, the developers might see no need to obtain permission to remove them or to compensate local communities. It rapidly became clear that the idea of common heritage had to be coupled more explicitly with the obligation to share common resources equitably.

The Convention on Biological Diversity, endorsed in 1992, described the concept of benefit-sharing more clearly (United Nations Environment Programme, 1992). In the context of genetic resources (plants, microbes, animals and humans), benefit-sharing means that the people granting access to the resources are entitled to receive benefits from those using or developing them. In other words, benefit-sharing became linked to justice, in the sense that the benefits resulting from exploitation of common heritage resources should be made available to all, and particularly to less affluent groups (Schroeder, 2007). It has taken some time for the legal basis of the Convention to be clarified and strengthened. A turning point in this process was adoption of the Nagoya Protocol to the Convention in 2010, an event that brought legal certainty and transparency to benefit-sharing for genetic resources (United Nations Environment Programme, 2010). The Protocol states that benefits arising from the utilization of genetic resources should be shared in a fair and equitable way.

Benefit-sharing has also become more widely accepted in health research. The growing trend to internationalization of research has directed attention to how the benefits of health research should be shared, both with research participants and with the rest of humanity. A number of high-profile clinical trials

in the 1990s led to controversy about the ethics of affluent pharmaceutical companies conducting drug trials in low-income countries (Nuffield Council on Bioethics, 2002). One of the ethical issues raised by these trials was whether some of the benefits gained by research participation should accrue to the participants themselves (such as in the form of on-going medical care) or their communities (such as new products made available at a reduced price).

The Universal Declaration on Bioethics and Human Rights (UNESCO, 2005) significantly endorsed benefit-sharing by listing it as one of its fundamental principles of bioethics. Article 15 states that:

“Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries.” Benefits can be shared in many ways, including providing special assistance to those who participated in the research, supporting health services and building research capacity in developing countries. At the same time, the Declaration states that benefits “should not constitute improper inducements to participate in research.”

While participants are entitled to some benefit from research under the principle of benefit-sharing, the extent and nature of the benefits to be shared remains hotly debated (Nuffield Council on Bioethics, 2005).



B. Topics

Definition

The definition of benefit-sharing has been widely debated. One definition developed in the context of human genetic material (Schroeder, 2007) incorporates many of the central aspects:

“Benefit sharing is the action of giving a portion of advantages/profits derived from the use of human genetic resources to the resource providers to achieve justice in exchange, with a particular emphasis on the clear provision of benefits to those who may lack reasonable access to resulting healthcare products and services without providing unethical inducements.”

This definition highlights the way in which benefit-sharing is not so much a philosophical idea as a tool of distributive justice.

Ethical justification

Benefit-sharing can be ethically justified on a number of grounds (Simm, 2007). Each approach is influenced by the context in which it is used, and one approach may not be readily applicable to another context. This is partly why no single definition has received widespread acceptance.

In the context of plant and animal genetics, benefit-sharing was first justified on the grounds of property rights. If local knowledge held that a particular species of herb had medicinal value, and local people grew and harvested this plant, the notions of property rights would hold that those people deserved to share in any benefits derived by developing the herb into a commercial pharmaceutical product.

In the context of clinical research, ownership is not usually a relevant argument. Instead, benefit-sharing can be justified on the grounds that research participants take risks in exposing themselves to an experimental

intervention. As they are the ones taking the risks, the argument goes, they should reap some of the rewards. Thus, the most recent revision of the Declaration of Helsinki states that participants in clinical trials should be provided with beneficial interventions after the trial ends (World Medical Association, 2013).

Another justification is based on the notions of solidarity with fellow human beings and global justice, which are used to suggest that research should benefit those in greatest need, even if its costs are borne by more affluent entities.

Benefit-sharing and public health surveillance

Day-to-day application of the principle of benefit-sharing is still controversial, particularly in public health surveillance. The case study used in this module is set in the context of this evolving debate.

For over 50 years, virus samples have been collected from many countries and analysed by WHO collaborating laboratories. Since 2005, the International Health Regulations have committed WHO Member States to participate in international surveillance networks by reviewing and implementing sound surveillance strategies that contribute to global outbreak intelligence (Sedyaningsih et al., 2008). International agencies have donated funds to build up surveillance networks in lower-income countries, whereby the countries provide various biological samples (including viruses) to WHO in order to confirm diagnoses and contribute to global risk assessment.

Surveillance is viewed as central to monitoring virus evolution and developing future viral vaccines (Garrett & Fidler, 2007). On the basis of predictions about which strain is most likely to spread, the industry manufactures tailored vaccines each year. Most of the manufactured vaccine doses, however, are used by people in higher-income countries, partly because of the cost of the vaccines but also because of the amount of vaccine produced and the way in which it is distributed. With rising fear of an eventual pandemic influenza outbreak, many countries are becoming concerned about the availability of influenza vaccine for their populations. Some countries have suggested that, as they share their viral samples, they are entitled to a greater share of the vaccine produced—construed as the “benefits” of the surveillance initiative.¹²

On the other side of the debate, a vaccine manufacturing company might argue that it makes the vaccine available at the lowest cost: it cannot provide the vaccine for free, even for countries in which few individuals can afford it at the current cost. The basis of their argument is that the company is providing the most benefit it can, at a cost it can bear.

Sedyaningsih et al. (2008) summarized the impasse as follows:

“Countries that are hardest hit by a disease must also bear the burden of the cost for vaccine, therapeutics and other products, while the monetary and non-monetary benefits of these products go to the manufacturers that are mostly in the industrialised countries [...] Virus sharing is a critical part in the global effort for pandemic preparedness and global health security. Hence, the global community should continue the efforts to create a mechanism for virus access and benefit sharing that is accepted by all nations.”

¹² A somewhat analogous example that also raises ethical issues is proposed research on black African immigrants to the USA that includes the collection and storage of genetic information (Buseh et al., 2013). This could lead to information and products that could benefit humanity and future African communities, but there is concern that the benefits might not be shared with these communities.

In 2011, WHO adopted a new “pandemic influenza preparedness framework” (World Health Organization, 2011). The primary objective was to put the sharing of influenza biological materials with pandemic potential (and not simply seasonal influenza virus) on an equal footing with access to vaccines, antiviral medication and other benefit-sharing programmes.



C. Case study

Indonesia reported the largest number of human cases of influenza A (H5N1) in the world between 2005 and 2007. Of the 116 cases, 94 (81%) were fatal. Viral outbreaks in poultry were reported in 31 of Indonesia’s 33 provinces (Sedyaningsih et al., 2008), where 80% of poultry are kept in small backyards, the remainder being raised in industrial facilities. Poultry cannot be exported, under a World Trade Organization agreement, because of the presence of a highly pathogenic infection in the national flock.

In 2007, Indonesia announced that it would no longer send avian flu samples to WHO collaborating centres (Fidler, 2010). A number of countries argued that poorer nations were contributing virus for the development of pandemic vaccines without reaping any benefits, because the resulting vaccines were unavailable or unaffordable. They alleged that higher-income countries were profiting from such arrangements and using the donated virus to develop biological weapons (Holbrooke & Garrett, 2008).

Although the argument was made that the viruses belong to the common heritage of humankind and should be shared with the rest of humanity for their good, Indonesia’s then Minister of Health, Dr Siti Fadilah Supari, used the notion of “viral sovereignty” to support her argument (Holbrooke & Garrett, 2008). The Convention on Biological Diversity supports the rights of countries to ownership and patents of indigenous plants and botanicals, and Dr Supari claimed that viruses fall into this category and that the International Health Regulations (2005) require sharing only of information and facts, not biological samples. Others claim that viruses are distinct from other biological resources as they naturally spread beyond national boundaries. Furthermore, the potential risk of harm from a global pandemic overrides any notion of “viral sovereignty.”

When it was suggested that Indonesia had an obligation to the rest of humanity, Indonesian officials countered that the global community had an obligation to the people of Indonesia, as the country would probably be severely affected by any pandemic.



D. Summary

Benefit-sharing is an evolving principle in research ethics. In part because of its novelty, it remains contested and the object of conceptual analysis. Unlike earlier formulations, the principle tends now to be linked explicitly to justice and equity.

In general, benefit-sharing can be described as the return of a portion of the benefits derived from the use of resources to those who made access to the resources possible but who otherwise lack reasonable access to the products and services that result from such use. For example, traditional remedies based on natural products may lead to the development of effective, profitable pharmaceuticals. The principle of benefit-sharing suggests that those who can claim ownership of the natural products should benefit fairly from their use. In some cases, ownership could be claimed by humanity as a whole.

There remains considerable controversy, however, about precisely what benefits ought to be shared. This is particularly challenging when the resource in question is biological material used to develop vaccines—a costly endeavour. While the principle of benefit-sharing is ethically compelling, the existence of power imbalances and commercial pressures continues to make its application highly contested. Yet, as benefit-sharing becomes incorporated more explicitly and clearly into legal instruments and conventions, such as the Convention for Biological Diversity, it can be hoped that the benefits derived from use of common heritage resources will be distributed more equitably.



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Learning objective 6.4: Identify issues of equity of access to unproven treatments during research in the course of emergency response.

Philippe Calain and Renaud F. Boulanger



Session timeline (60 min)

0–15 min (15 min)	16–30 min (15 min)	31–45 min (15 min)	46–60 min (15 min)
Introduction	Reading	Debate	Summary and conclusion



Instruction strategy

1. The facilitator introduces the module material.
2. The facilitator distributes copies of the case study for participants to read.

For facilitators: The case concerns the availability of post-exposure prophylaxis during an outbreak of Ebola haemorrhagic fever in central Africa. It illustrates the conflict between generating robust data about investigational interventions and the immediate need to save lives through “compassionate” use. The case illustrates an ethical dilemma raised by the availability of an investigational intervention that could potentially increase the chances of individuals exposed to lethal agents for survival. On the one hand, well-designed trials are needed to assess both the efficacy and the safety of unproven treatments. In this case, the potential beneficiaries (especially in placebo-controlled trials) are future generations of victims, not current victims. On the other hand, the need to save lives immediately threatened by exposure to highly lethal conditions calls for less rigid trial schemes.

In 2014, the issue of development of and access to investigational treatments became the centre of much scientific and media attention as the worst outbreak of Ebola virus disease the world has ever known unravelled. In August 2014, WHO convened a panel discussion on the ethical considerations of using unregistered interventions for Ebola virus disease (World Health Organization, 2014). The consensus of the meeting was that—in the exceptional circumstances of the ongoing epidemic—it would be ethical to offer unproven interventions of unknown efficacy and with unknown adverse effects as potential treatment or for prevention.

3. The facilitator divides the group in seven and asks each to address one of the questions below.
 - On what moral grounds was the Hamburg scientist offered investigative treatment? Is this a case of compassionate use?
 - Could “humanitarian” reasons be put forward to justify the effort of shipping the post-exposure vaccine from Canada? If yes, could reciprocity be the moral criterion (“The scientist made the sacrifice of risking her life by choosing to study a highly lethal agent. In return, the community should make all efforts to save her life in case of accidental exposure.”)?

- When local health workers are exposed to needle-stick injuries in the course of an Ebola virus disease outbreak in Africa, should they be given the same opportunity of receiving a potentially life-saving treatment? Do the same moral grounds apply (e.g. “Are they any less or more worthy of reciprocity?”)?
- If the investigative treatment is made available during an outbreak, should its use be restricted to the boundaries of a defined clinical trial? Or should it be made available on compassionate grounds, as in the case of the Hamburg scientist?

For facilitators: The compassionate approach may be more appropriate when accidental exposure has been confirmed, whereas clinical trials may be appropriate if large populations are at constant risk for exposure.

- If a trial is the only acceptable solution, what design should be used? For example, consecutive series with historical comparisons or a placebo-controlled trial?
 - Ultimately, who are the main or intended beneficiaries of research on treatment for filovirus infection?
4. The facilitator asks each group to appoint a rapporteur to summarize their discussion.
 5. The facilitator concludes the session and opens the floor for discussion.



A. Background

The distribution of resources during emergency responses is a highly debated topic (see learning objective 6.1). The issue becomes even more difficult in the context of the development of novel treatments to respond to emergencies. As discussed in learning objective 6.3, the principle of benefit-sharing would require that a portion of the benefits derived from collecting data be returned to those whose data were used—for example, access to the treatment being developed. In the context of a response to an emergency that involves the development of new treatments, however, application of the benefit-sharing principle may not be straightforward, for two main reasons. First, the “benefits” sought may be associated less with the accumulation of knowledge (as might be the case with the development of less time-sensitive pharmaceuticals) than with minimizing the magnitude of the harm suffered by a population, especially when such efforts are publicly led. Secondly, the emergency nature of epidemics and disasters might be used to argue—appropriately or not—that scaling up interventions proven to be beneficial might be unrealistic if large populations are involved and production capacity is still limited.

Access to investigational treatments for rapidly lethal or disabling diseases has been an issue of contention for decades. Fights for access to antiretroviral therapy in the 1980s are a well-known example (Schuklenk, 2013). In certain fields, such as oncology, it is generally accepted that there are “seamless” trials, in which safety and efficacy are tested simultaneously (Wages & Tait, 2014). The recent debate around the Medical Innovation Bill in the United Kingdom (colloquially known as the Saatchi Bill) has also attracted interest. The Bill would change the law so that doctors could use investigational treatments to treat individual patients suffering from incurable illnesses, instead of awaiting the opportunity of participating in a formal clinical trial. But traditional debates about access to investigational treatments tend not to raise the important question of what to do when an entire population is threatened by an outbreak.

In discussing issues of equity of access to investigational treatments during research in the course of a response to an emergency, at least four types of situation can be envisioned. First, issues of equity of access can arise when a physician uses the professional privilege granted by many jurisdictions to prescribe a drug for off-label use. Under such circumstances, patients might not be considered research subjects per se, and, as a result, may not enjoy the kind of protection that individuals formally enrolled in a research project can expect, such as review of the treatment protocol by scientific and research ethics boards. The concern with regard to equitable access is that physicians act as gatekeepers, so that several individuals who might be good candidates to receive the untested therapy might not be able to access it. The second situation arises when research is in fact conducted in line with established international research ethics guidelines, but some patients are unable (or unwilling) to enrol in the study, even though they consider that they have a legitimate claim to receive the agent under investigation (Edwards, 2006). Thirdly, issues of access can be constrained by physical bottlenecks, such as limited manufacturing capacity. In this case, issues of equity may be due to allocation of finite resources (see learning objective 6.1). Finally, issues of equitable access to treatment can arise with regard to innovative treatments that are not yet broadly accessible but are already believed to be at least relatively efficacious. The case study of Ebola virus disease discussed in this module illustrates this situation.

Hence, before equity of access is evaluated, access to the investigational compound must first be secured. This module explores possible mechanisms for extending access during an emergency response, before discussing issues of equity. Calculation of an acceptable risk:benefit ratio in the case of unproved interventions to control highly lethal diseases is outside the scope of this module.



B. Topics

Avenues to increase accessibility

Decrease regulatory restrictions

Access to investigational compounds is usually granted by national regulatory agencies only after they have been demonstrated to be effective and safe. As Edwards (2006) noted, a number of motives justify this situation: “research restrictions on access are primarily geared towards protecting and benefiting future patients and avoiding opportunity costs associated with funding treatments that do not work.” Chief among these motives is consideration of the precautionary principle, which, in essence, guides decisions in circumstances in which there is a fear that severe adverse effects could occur (Gonzalvo-Cirac et al., 2013). In these circumstances, the principle suggests that introduction of a new technology should be delayed until there is more confidence in its safety (Edwards, 2013).

Some consider that “risk-averseness” is incompatible with emergency situations. Such sceptics have suggested that regulatory restrictions placed on investigational compounds could be relaxed in times of emergencies, such that access could be (at least partially) deregulated (Edwards, 2013). Critics, however, argue that such deregulation might undermine research efforts (Gonzalvo-Cirac et al., 2013), as deregulation to increase access to treatment in the short term might threaten long-term access and harm an unnecessarily large number of individuals when the treatment under investigation is ineffective or deleterious.

Use alternative research designs

Another suggested mechanism for increasing access to innovative treatments in research programmes is to use alternative or unconventional research designs. Unfortunately, finding an appropriate unconventional research design is difficult. Alternatives described as promising, such as stepped wedged cluster randomized clinical trials, in which an investigational compound would be introduced gradually to small groups of subjects (Edwards, 2013), might be difficult to use, methodologically and ethically, during a true pandemic (van der Tweel & van der Graaf, 2013). For example, if the investigational compound is in fact not superior to standard care, more individuals could ultimately be exposed to harm than might have been the case in approaches such as sequential trials (van der Tweel & van der Graaf, 2013). Depending on the circumstances of the emergency, more efficient trial designs might decrease access to investigational drugs only in the short term, i.e. until regulatory approval.

Multiply the “treatments” under investigation

Although pursuing several investigational compounds simultaneously does not address the issue of accessibility to one treatment, doing so may increase access more generally. At any given time, a number of research groups might have molecules that require testing. In large-scale epidemics, there may be opportunities to test several compounds simultaneously. Similarly, molecules with similar mechanisms of action could be tested during responses to emergencies. Given the time-limited nature of emergencies, simultaneous testing might offer the double advantage of increasing access to promising classes of molecules and choosing the best one.

Appeal to compassionate use

Another mechanism that can be used to increase access to investigational treatment is programmes of “compassionate use”, as exist under a rule of the US Food and Drug Administration. In such programmes, a patient facing a life-threatening crisis with no satisfactory therapeutic alternative may gain access to a drug through a special arrangement between the treating physician and the manufacturing entity. Although doubt has been expressed that such arrangements would increase access (Edwards, 2013), Solomon (2013) is optimistic: “It is puzzling that someone would argue that the compassionate use approach to providing access to investigational drugs in an emergency cannot be applied in a pandemic when it both can be used and has been used in a pandemic situation.”

Eliminate physical bottlenecks

Physical bottlenecks might arise from factors such as limited manufacture (lack of capacity or willingness) or a poor delivery mechanism. These can be particularly vivid issues in the context of emergency responses, as some geographical areas might be inaccessible because, for example, of quarantine measures or destruction of transport infrastructure. In the case of limited manufacture, outputs could in some cases be increased through mechanisms such as compulsory licensing. When infrastructure restricts access, reconstruction could help address the problem.

Determine minimal doses

To avoid bottlenecks such as limited manufacture, a possible avenue would be to find the minimal effective dose. Under normal circumstances, prescription patterns are optimized to minimize the treatment period, maximize full recovery and minimize side-effects. When the need is such that accessibility is threatened,

research should be conducted to identify the minimal dose required for efficacy, in order to reduce the manufacturing requirement.

Appeal to the “rule of rescue”

The rule of rescue reflects our instinct “to rescue identifiable individuals in immediate peril, regardless of cost” (Cookson et al., 2008). As a result, this rule is notorious for giving rise to conflicting considerations of cost-effectiveness at the level of health care systems and the lives of identifiable individuals in the course of care provision. Under circumstances of emergencies, the rule of rescue could potentially be appealed to, despite concern about the cost-effectiveness of treatments that have not yet been proven to be effective. It is not clear, however, that such appeals would make consensus. Cookson et al. (2008), for example, have suggested that policy-makers should not necessarily, “as a matter of public policy, exempt any one group of unidentified individuals within society from the rules of opportunity cost at the expense of all others.”

Considerations of equity

Access limited to enrolled participants

During the investigation of new treatments, access to compounds is largely restricted to individuals formally enrolled in a study, and many patients find themselves unable to access the product. If any individual who wished to do so could enrol in a study, concern about equity would not be particularly convincing; however, trials are often geographically limited and have strict inclusion and exclusion criteria. Although some of the latter are justified for the safety of participants, others are added for the convenience of data collection and/or data analysis.

Concern about equity may be particularly strong in some cases. In the cluster trials discussed above as a means of increasing access, the clusters would have to be geographically defined during an emergency. In this case, suspicion that political power would come into play in determining who would be given the investigational product would be difficult to dismiss. Thus, “Depending on how local communities are formed, providing access to promising new therapies sequentially according to geographically defined clusters may exacerbate any preexisting social inequalities.” (Edwards, 2013).

In addition, “even if a patient is eligible for a bigger-scale study, they may not be in the right place at the right time. Research is never evenly spread over the population of patients who might want to participate in it.” (Edwards, 2006).

Risk-bearing

Concern about equity is also closely related to which individuals or communities bear the risk associated with research in an emergency. If the treatment being investigated is offered only to individuals on whom data would be collected as part of the research project, it could be argued that a fair exchange would be achieved: the group exposed to the risk of the research protocol would be the one that would stand to benefit (especially if there is a particularly poor alternative standard of care). If individuals gain access to the investigational product outside research, however, they would not equitably share the burdens associated with access.

In addition, as Edwards (2013) suggests, “it is more likely that, in a pandemic, the risks of not receiving anything would be seen to be problematic especially when the effects of any inequality would be long-lasting

or when they would be impossible to address afterwards.” This issue would become particularly clear in a stepped wedged cluster trial. Individuals exposed to an emergency might consider that not receiving the treatment under investigation would expose them to a similar risk as receiving it, and that the risk would not be offset by a potential benefit (i.e. access to an investigational product).

Conflicts of interest

When resources are severely limited, the possibility of conflicts of interest during allocation is high. For example, if an epidemic is rampant, organizations with limited access to a treatment under study might prioritize their members, even if agreed-upon mechanisms for allocation do not justify doing so. This is an issue discussed in the case study of this module. The disparity can be institutionalized at higher levels, too. The outbreak of Ebola virus disease in West Africa in 2014 raised concern about the sharing of the limited doses of some of the experimental treatments (Kass, 2014).



C. Case study

Outbreaks of filovirus haemorrhagic fevers (Ebola and Marburg) have occurred in central and, since 2014, West Africa. The case:fatality ratio is within a range of 20–90%. Nosocomial transmission, disruption of the health care system and community upheaval are well-known features of these outbreaks in Africa. There is no approved therapy for use in humans. On very rare occasions, laboratory personnel working in biosafety laboratories of industrialized countries have been accidentally inoculated with filovirus. In 2009, in Germany, a scientist suffered a needle-stick injury, possibly contaminating herself with Ebola virus (Tuffs, 2009; see Box 8). Within 48 h, she received post-exposure treatment with an experimental recombinant vaccine developed in Canada—the first time that the vaccine was used in humans. According to the press (Mullin, 2009), the decision was made after consultation between experts in Canada and Germany. The vaccine had been shown in 2007 (Feldman et al., 2007) to be highly effective for post-exposure protection of experimentally infected primates. The scientist survived unharmed, although it is still not known whether the treatment was effective or whether the patient was never infected (Günther et al., 2011). The effort to give the scientist the best chance of surviving a possible infection with a very lethal agent is laudable. There is no doubt that the availability of post-exposure treatment would be highly beneficial and feasible during responses to filovirus outbreaks in Africa, especially for local health workers mobilized for emergency care of infected patients, sometimes with minimal protection. From a moral standpoint, it is legitimate to ask what effort has been made since 2007 to develop the necessary clinical monitoring protocols, to assess the effectiveness of the product and to ensure the stockpiles and regulatory and logistic procedures necessary to make the same experimental post-exposure vaccine equally available in Africa as in Germany, and with the same diligence if such an intervention proved to be effective.

Box 8. Case study: Potential infection with Ebola virus by a needle-stick injury

A scientist from the Bernard Nocht Institute for Tropical Medicine in Hamburg who was quarantined for a week because of a possible infection with the Ebola fever virus has left the isolation ward of Hamburg University Hospital. She has been transferred to a normal ward, because she had no clinical signs of infection, and neither the virus nor any antibodies against the virus were found in her blood.

This positive development may be due to the use of an experimental vaccine given to the scientist that has never previously been used in humans. The vaccine virus was found in her blood shortly after vaccination but vanished within two days, indicating that the patient's immune system had eliminated it.

“She is currently doing well,” said Stephan Günther, head of virology at the Bernhard Nocht Institute. “However, the Ebola virus can have an incubation period anywhere between four and 21 days, which means she could still fall ill.”

The dangerous virus is named after the Ebola River in the Republic of Congo, near where the first recognized outbreak occurred in 1976. Several outbreaks have since occurred, mainly in central Africa.

On 12 March the Hamburg scientist, who had been working in a high security laboratory on a project to produce antibodies against the Ebola virus, had pricked herself through three layers of safety gloves with a needle containing the virus. The particular virus type is lethal in 90% of infections.

The benign outcome may have been aided by the swift reaction of the international Ebola research community, members of which were contacted by colleagues of the Hamburg scientist. Within 48 hours the scientist was given an experimental attenuated live vaccine against the virus, which had been shown to be effective in monkeys but which had not yet been tested in humans.

The vaccine was developed by Heinz Feldman and former colleagues at the National Microbiology Laboratory of the Public Health Agency of Canada, in Winnipeg, Manitoba, along with Boston university virologist Thomas Geisbert, who tested it in macaque monkeys at the US Army Medical Research Institute of Infectious Diseases, Frederick, Maryland.

About 12 hours after vaccination the Hamburg scientist developed a fever and headaches and other clinical signs typical of a reaction to a vaccine, which have subsided since.

Source: Tuffs (2009)



D. Summary

When responses to emergencies involve the pursuit of new treatments, issues of equity of access are quick to emerge. On the one hand, formal research studies may limit access in such ways that individuals who are excluded—voluntarily or not—from the projects are left unsatisfied. On the other hand, restricted access through research projects may facilitate equitable distribution of burdens and benefits while minimizing the risk of wasted resources or unnecessary exposure. The use of alternative research designs may help to deal with the difficult issue of equity of access to investigational compounds in the course of a response to an emergency. Indeed, Solomon (2013) suggests that we must get “creative with our research designs so that both good research can be done and the practical realities that people are facing, especially the dire realities of a pandemic, can be met.” However, as Edwards (2013) states, the use of alternative research designs may involve both technical and moral constraints. For example, concern has been raised about the possibility of obtaining true informed consent when the toxicological information that would normally be available before enrolment of patients is deeply deficient. Other alternatives include deregulation and elimination of resource bottlenecks. The case study reveals the global dimension of unequal access to investigative and potentially life-saving treatment. More broadly, the case also illustrates issues of inequity of access to investigative treatments, while raising the question of who are the intended beneficiaries of research (“western” scientists versus African health workers in the case study). In other words, we must not be immune to critiques that new treatments are sometimes developed primarily for national security reasons as opposed to adherence to a notion of cosmopolitan obligation and solidarity.



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Core competence 7: Ability to discuss the professional duties of health care workers during public health surveillance or research in emergencies



Core competence 7: Ability to discuss the professional duties of health care workers during public health surveillance or research in emergencies

Emergencies are conducive to several types of moral conflict for health care workers. One classical example is the duty to care for victims of contagious diseases. When health care providers act as researchers during an emergency, additional conflicts can arise. Their allegiances to different ethics frameworks (e.g. care versus research) might lead to conflicts (learning objective 8.1). When health care providers assume at the same time the role of researchers, patients might be at risk of falling victim to the “therapeutic misconception” (learning objective 7.2). Research activities can also expose clinicians to additional conflicts of interest, which might take a unique dimension during periods of emergency (learning objective 7.3).



Learning objectives

- 7.1 Distinguish three ethics frameworks: medical care ethics, public health ethics and research ethics, and explore the ways in which the values and principles that guide these frameworks diverge or overlap.
 - 7.2 Explain what is meant by “therapeutic misconception” and how it could affect the duties of health care workers in emergencies.
 - 7.3 Explain the potential conflicts of interest of health care workers participating in emergency research activities.
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Learning objective 7.1: Distinguish three ethics frameworks: medical care ethics, public health ethics and research ethics, and explore the ways in which the values and principles that guide these frameworks diverge or overlap.

Leigh-Anne Gillespie and Lisa Schwartz



Session timeline (100 min)

0–5 min (5 min)	6–25 min (20 min)	26–45 min (20 min)	46–75 min (30 min)	76–95 min (20 min)	96–105 min (10 min)
Introduction	Template and discussion	Video and group discussion	Case study and discussion	Role-play	Summary and conclusion



Instruction strategy

1. The facilitator introduces the different aims of medical care, public health and research and discusses their respective ethics frameworks.
2. The facilitator divides the group into smaller ones, distributes a copy of the template below to each small group, and asks trainees to identify the distinctions and areas of convergence among the three ethics frameworks.

For facilitators: Once the trainees have reconvened, ask them whether they think the template shows a complete picture of the three perspectives or whether they have found gaps.

3. The facilitator shows the video “Disaster ethics: The collision between public health ethics and clinical ethics” (<https://www.youtube.com/watch?v=JYYAGJB5t4E>) and invites comments.

For facilitators: To stimulate discussion, you could ask the questions below.

- Is it possible to promote the values of clinical medical ethics in public health interventions and research projects?
- What values ought to be promoted in clinical contexts? Public health contexts? Research contexts? Can these be harmonized when more than one type of intervention is being conducted at one time?
- Which framework has moral authority to inform ethical action in contexts in which more than one framework is applied? Which one ought to prevail in emergencies, or can they be “nested” or applied to different aspects or dimensions of the issues or problems?
- What liberties, if any, will have to be infringed upon in a public health context?

4. The facilitator introduces the case study and asks the trainees the following questions.
 - What are the ethical issues raised by this scenario? Which of the different points or arguments do you think is the most convincing?
 - One participant suggested that the data should be collected now and research ethics board approval sought at a later stage. What do you think of this option?
 - Another suggestion is that incentives (e.g. cash) could be offered to people questioned during the outbreak to encourage them to keep in touch with the team until research ethics board approval can be sought. Payment would then be made after the research was completed. What ethical issues would be raised by such a case?
 - What ought to be done in this case? Give reasons for your answer.
5. The facilitator introduces the role-play activity and selects volunteers to act out the three scenarios.
6. The facilitator concludes the session and opens the floor for discussion.

Template: Areas of divergence and overlap among three distinct ethics frameworks

Responsibility, principle or practice	Medical care ethics	Public health service ethics	Research ethics
To whom duty of "care" is owed			
Aims of intervention			
Role of informed consent			
Issues of confidentiality and privacy			
Meaning of fairness and equity			



A. Background

The different models of health interventions have a common purpose: to ensure respect and to promote the health of persons and communities. Statements (and debates) on ethical practice have been issued with regard to medical care (World Medical Association, 2013a), public health (Public Health Leadership Society, 2002) and research (World Medical Association, 2013b), with common elements. (For a more detailed discussion of the normative instruments guiding research, see learning objective 1.3.) The distinct ethics frameworks reflect the specific goals of each:

- In medical care, health professionals apply existing knowledge to benefit individual patients, while taking into consideration the good of the community in the use of resources and the risks associated with communicable diseases.
- In public health activities, knowledge is applied or collected to benefit communities, even sometimes overriding the interests and liberties of individuals (an exception to the general rule of protecting people and of their rights).
- In research ethics, as the aim of research is to generate new, generalizable knowledge to promote the greater good of individuals who may not be affected by a condition or issue, the knowledge created by research is expected to be applied to clinical care and public health practice.

The principles followed in these different health activities can come into conflict in certain situations, contexts and roles.



B. Topics

Three ethics frameworks

- *Medical care ethics*

The ethics of medical care emphasize the individual, focusing on patient autonomy and the patient's best interests but including justice and duty to others in the public good. The framework is thus dominated by patient-focused values and moral issues in clinical practice. It tends to focus on the cure and treatment of health conditions.

- *Public health ethics*

The ethics of public health and medical care are both related to health and contribute to the common good; however, public health ethics includes the protection and enhancement of the health of the public and the prevention of ill health (for example, in the management of large-scale programmes and policies), which are different from the diagnosis and treatment of disease (Thomas, 2004). The public health ethics framework emphasizes the greater good of a population or a community and the pursuit of collective action; the activities are directed to improving the health of populations. As noted by Benatar (2006), this goal may be in conflict with the duty of placing the rights and needs of individuals above those of society. As, however, the public is made up of individuals, public health can result in health benefits for individuals (Williams, 2009). Moreover, if public health interventions are conceived as creating positive conditions for the realization of certain rights, some of the conflict falls away.

For facilitators: Additional resources (audio and slide presentations, texts, websites, exercises) on public health ethics can be found at Thomas (2004).

- *Research ethics*

The goal of research is to produce evidence to advance the greater good, including that of individuals not affected by a condition or issue. At the same time, "traditional research ethics points to the primary value of the human person, and focuses largely on constraining the use of individuals (whether their bodies, parts, stories, or information) as means for the pursuit of collective scientific or technological ends" (Kenny & Giacomini, 2005, p. 252).

Choosing the right framework

The context dictates which of the three frameworks should prevail. Once that is established, it should not be assumed that the ethical obligations of the other frameworks no longer apply. Instead, a unified framework should apply in various contexts, or perhaps other interventions are required to protect all affected parties. For instance, when public health interventions are applied broadly, it may be impracticable or impossible to acquire individual informed consent, and other safeguards might have to be put in place to protect

individual interests and to ensure the respect of persons and their privacy, including the liberty to refuse or withdraw consent.

An “ethical dilemma” is a situation in which the course of action is not clear, for example, because the most ethical response is not clear; it is clear but cannot be applied; a choice must be made between equally acceptable responses; or a choice must be made between equally unacceptable responses. A good example of this is the outbreak of SARS, which made research ethics committees aware of the rapid response required in emergencies (Naylor et al., 2003). For certain research interventions, they were willing to waive the requirement for informed consent, such as for collecting data on patients’ health care, because finding a treatment for a lethal virus was considered to be of greater benefit than protecting individual data. Nevertheless, patient privacy was protected in a number of ways, including limiting to a great extent who had access to the information and to what elements they had access. Therefore, overriding a given ethical framework does not necessarily mean diluting protection. In some cases, it may actually imply the creation of more stringent protection of a different sort.

The issue of multiple allegiances

When practitioners are trained or prepared to perform a role in a certain setting, the aims and ethical obligations of that role must be set out as clearly as possible to pre-empt confusion about duties and allegiances. A potential challenge to reconciling the ethics of medical care, research and public health is in answering the question “To whom is the duty of care owed?”, because many health decisions affect an individual patient, a community and, possibly, future generations.

Confusion about duty is especially likely when the aims of an intervention are layered, possibly with more than one intended goal, as might be the case when health professionals are engaged to perform research in a public health intervention. The issue of multiple allegiances has been discussed in the literature, including for professionals working in situations of disaster or armed conflict (Schwartz et al., 2012). Identification by health professionals of their primary duties can help them navigate or manage multiple allegiances.

The areas of divergence and overlap among the three ethics frameworks with regard to responsibilities, principles and practice are: to whom duty of care is owed, the aims of the intervention, the role of informed consent, issues of confidentiality and privacy and the meaning of fairness and equity.



C. Role play

For facilitators: This exercise addresses issues involved in obtaining informed consent during a TB outbreak. Ask six volunteers to act out the following situations.

1. Participant A is a clinician; participant B is a patient who presents with symptoms of TB. How does participant A obtain participant B’s informed consent for treatment?
2. Participant C is a clinician on a public health team responsible for managing a severe TB outbreak; participant D is a patient who presents with symptoms of TB. What role does informed consent play in the treatment of participant D?

3. Participant E is a clinician on a public health team who is conducting a randomized controlled trial; participant F is a patient who presents with symptoms of TB; participant A is responsible for obtaining informed consent to administer the experimental intervention instead of the classic intervention to participant F. What role does informed consent play in the treatment of participant F?



D. Summary

Practice based on the intentions and goals of each of the three frameworks discussed in this module differs significantly. Practitioners must be aware of these differences in order to intervene for participants and communities in ways that are consistent with the duties associated with their assigned role. Participants and communities should also be informed of these differences in order to minimize confusion.

While differences of focus on and the weight given to common principles can create ethical conflict, the good of individuals and the good of communities can generally be served harmoniously. The best interventions might be those designed to promote both types of well-being. At the least, researchers should mitigate the threats the interventions may pose to some stakeholders.



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Learning objective 7.2: Explain what is meant by “therapeutic misconception” and how it could affect the duties of health care workers in emergencies.

Elysee Nouvet, Lisa Schwartz and Michael Baxter



Session timeline (75 min)

0–10 min (10 min)	11–25 min (15 min)	26–45 min (20 min)	46–65 min (20 min)	66–75 min (10 min)
Introduction	Discussion	Case study and discussion	Role-play	Summary and conclusion



Instruction strategy

- The facilitator introduces “therapeutic misconception” and reviews why it may be an ethical problem.
- Having introduced the issue of risks and the three strategies to reduce them, the facilitator asks participants to reflect on the following questions:
 - Consider the three strategies discussed for improving individuals’ understanding of the differences between clinical research and medical care. Are these realistic in every setting?
 - How might language barriers, trauma and scarce resources impact the effectiveness of each of these strategies?
 - Would one or more of the three strategies be helpful in settings in which you have worked or lived? Why or why not?
- The facilitator asks participants to share their reflections with the rest of the group.
- The facilitator presents the case study and ask participants the following questions:
 - In what ways does this case create the possibility for therapeutic misconception?
 - What strategies could the physician have used to decrease the possibility of therapeutic misconception—if it is avoidable?
 - If Justin appears to be incapable of differentiating between his participation in research and his treatment, would the doctor’s most ethical course of action be to deny his patient access to the study? Why or why not?
 - Are there circumstances in which the therapeutic misconception is ethically tolerable?
- The facilitator moderates the role-play about dengue in Brazil.

For facilitators: The goals of this activity are to (i) increase participants’ awareness of the various social, economic and personal factors that can lead an individual to seek health care through research participation; (ii) increase participants’ confidence in responding to therapeutic misconceptions in emergency settings;

and (iii) outline the possible consequences for patients who have therapeutic misconceptions to enrol or refuse to enrol in public health research.

- Ask for two volunteers to act out a role-play between a study nurse administering a vaccine against dengue or a placebo to Brazilian children and a concerned Brazilian parent.
- Give each volunteer the information (boxes 8 and 9) for their role.

For facilitators: Neither the “nurse” nor the “parent” should see the description of the other character.

- Give the volunteers 5 min to prepare their characters

For facilitators: The volunteers may involve other session participants if they feel it appropriate.

- While the two volunteers are preparing their roles, ask the other participants to write down what they would tell parents and children, if anything, if they were the health care professional giving the vaccine.
- Begin the role-play.

For facilitators: The role-play will establish the basis of the parent’s therapeutic misconception and may or may not include a resolution.

If you feel that the role-play is losing momentum, clap your hands to stop it and begin a discussion with the whole group using the following questions as a guide:

- Would you consider this parent capable of making a decision regarding his or her child’s participation in this study?
- Are there additional strategies the research nurse could have used in response to this parent’s therapeutic misconception?
- Do you have any ethical concern about refusing to include this parent’s child in the study because of uncertainty about the parent’s decision-making capacity?
- What are the risks of administering the vaccine to the child if the parent fails to understand that this is a trial?

For example, the parents may not show up for follow-up information sessions; they may take more risks, such as allowing their child to sleep without a net, if they are confident that he or she is protected; if the child does contract dengue, the parents may not associate the symptoms with dengue if they believe that the child is protected.

6. The facilitator concludes the session and opens the floor for discussion.



A. Background

“The therapeutic misconception occurs when a research subject fails to appreciate the distinction between the imperatives of clinical research and of ordinary treatment, and therefore inaccurately attributes therapeutic intent to research procedures.” (Lidz & Appelbaum, 2002).

Medical professionals and clinical contexts are normally associated with therapeutic care. As a result, individuals approached to participate in a study that involves clinical procedures, a clinical context and/or clinicians may assume that the intervention constitutes medical care. A patient who enrolls in a clinical study to increase understanding of their condition or to develop a treatment that might work better than current options may become overly optimistic and have a distorted sense of the possible therapeutic benefits of their participation. Alternatively, when a physician has both a therapeutic and a research relationship with an individual, as is often the case in surgical research, both the physician and the patient may be unsure where individualized care ends and research begins.

Although the problem of therapeutic misconception was first formally defined for the bioethics community in 1982 (Appelbaum et al., 1982), the notion that it is ethically essential for research participants to clearly understand the difference between research and their medical care was in fact well established in post-Second World War ethical codes for medical research. Specifically, the imperative that no research on humans may be conducted without the voluntary and *informed* consent of research subjects *and* the associated promise that researchers will foster and respect their autonomy is stressed throughout the Nuremberg Code of 1947 and the Declaration of Helsinki of 1964 (see learning objective 1.3).

The notion of therapeutic misconception has attained such prominence in bioethics because it is considered that it can compromise the ethical integrity of a research project. It undermines the informed and voluntary consent of research participants, which is the cornerstone of the trust of participants and society in health research. Most health research requires the voluntary informed consent of research participants, and, when it is required, researchers have the duty, in accordance with established ethical principles of transparency and fair process, to provide honest, accessible explanations of the research goals, procedures, risks and benefits to potential participants. If participants do not understand how health research differs from routine medical care, they are unlikely to understand fully the potential consequences of participation in research and thus cannot make an informed decision to participate or refuse to participate in a study. Participants cannot be considered to be exerting agency and autonomy in decision-making if they do not understand the objectives of a study. If individuals volunteer for research because they misconceive it as therapy, they may later grow resentful or withdraw from the study when their misunderstanding dissipates. There may be a backlash against the research team and the research enterprise in general if a participant enters a study expecting therapeutic benefits that never materialize (Lidz & Appelbaum, 2002).

Health care workers must play a significant role to mitigate the risk for therapeutic misconception throughout emergencies. Some of the strategies they can adopt are explored below.



B. Topics

Why might therapeutic misconceptions be more likely during emergencies?

During or after emergencies, people may be severely vulnerable because of loss of properties and assets, insecurity, mental stress, trauma, greater exposure to risks and dependence on external assistance to survive. As a result, they may be in less of a position to fully discern the differences between research and emergency care, or they may feel too exhausted or preoccupied to consider—let alone discuss—the pros and cons of participation. The authority of health care professionals, especially physicians, is significant under normal circumstances in most cultural contexts; during an emergency, their authority may increase for a number of reasons, including acute awareness of their importance to individual and social well-being or even survival;

the strong need for and limited availability of these professionals; recognition of or respect for the unique stresses, risks and responsibilities they take on in emergencies; individual and social gratitude for their contribution to managing the emergency; and their foreign (“western”) provenance, if they are expatriate volunteers, who might be considered particularly knowledgeable by local people or treated as such according to cultural norms and welcomed and appreciated as foreign “guests”. The increased authority of health care professionals in emergencies can in turn increase the likelihood that potential research participants will harbour therapeutic misconceptions.

The authority, reputation or visible resources of an international research team or privately funded research centre may increase the likelihood of therapeutic misconceptions in low- and middle-income settings during emergencies. Even in resource-rich countries, potential participants (and even care providers) may become less able to distinguish between research and therapy in an emergency situation. During screening for radiation contamination by the Japanese Ministry of Health after the tsunami-related nuclear emergency in 2011, medical teams were sent throughout the affected areas to measure residents’ radiation levels and to answer questions (Saito & Kunimitsu, 2011). While providing biomedical treatment for contamination was not one of their goals, the teams were in a way caring for the population by measuring radiation levels. It is easy to see how, in such a context, these teams might have been (mis)perceived as engaging in therapeutic activity rather than research.

Are volunteers’ hopes of deriving therapeutic benefit from research participation grounds for their exclusion?

All humans are different, and our attitudes and mental states shift throughout the life course and depending on circumstances. Some research volunteers express more optimism than others and may communicate the hope that their participation will benefit them directly. Hope and optimism are not grounds for excluding a participant from research; however, the researcher has the responsibility to dispel unrealistic hopes of therapeutic benefit. Moreover, as noted above, it is the researcher’s duty to ensure that a decision to participate or not is as well informed and voluntary as possible. This means taking the time to ensure that volunteers understand the difference between any medical attention received as a study participant and normal medical attention, in which the therapeutic outcome is a priority. The researcher must ensure that volunteers understand the odds of deriving therapeutic benefits from the research. If volunteers express certainty that they will fare better than other research participants and if they are participating on the basis of that misconception, further clarification or exclusion are appropriate. Even in an emergency, it is the duty of the researcher to ensure that each participant understands the limited therapeutic impact, unproven effectiveness or non-therapeutic goals of the attention given. It should never be the case that the only choice is to participate in research or to have no care at all (see learning objective 4.4). People who refuse to participate should at least have access to the usual care.

Strategies for reducing the risk for therapeutic misconception in a study

- *Better information with a neutral discloser*

In this strategy, a knowledgeable individual who is “neutral” because he or she is not involved in the study and, ideally, not part of the participant’s circle of care explains to potential participants the main methodological aspects of the research project “especially methods that might conflict with the principle of personal care” (Appelbaum et al., 1987, p. 23). As Miller and Wendler (2006, p. 39) noted in a review of therapeutic misconception, “subjects exposed to this neutral and augmented disclosure had a better

understanding of important aspects of the research design, including randomization, use of placebo, and protocol-defined limitations on treatment”.

- *Community consultation*

Increasingly, health researchers recognize that collaboration with study communities is a key ethical principle of good medical research. When public health research involves working with a population or in a context that is unfamiliar to the researcher(s), community consultations are particularly important. Work with the community can help researchers ensure that their explanations of the study goals, procedures and potential risks and benefits make sense to potential participants, taking educational, cultural and linguistic differences into account. Consent forms and information sessions for the study should be tested for clarity with representatives of the community before the research begins. “Pre-testing” the informed consent process can help a research team to identify possible sources of or reasons for therapeutic misconception among participants in the particular context.

Community consultation cannot be a substitute, in any context, for individual discussion of research participation and, when appropriate, individual consent. Community consultation is necessary but not sufficient for research participants and individualized therapeutic interventions.

While time may be limited in emergencies, the risk that participants will harbour therapeutic misconceptions about a study can be reduced by holding community information sessions before the study. These can increase understanding in the community of both the proposed research, its goal and the importance and process of informed consent, thereby ensuring that potential participants do not harbour misconceptions and that they make informed, voluntary decisions. Such information sessions can also build trust between community members and the research team, making it easier for community members to raise questions or concern before deciding to participate in the study.



C. Case study

AIDS develops from infection with the HIV lentivirus. Although it was first identified clinically in the United States in 1981, tissues tested from as far back as 1959 in central Africa have been shown to carry the virus (Zhu, 1998). HIV is spread easily through fluid exchange, and exposed individuals are more vulnerable to AIDS. In the 1980s and early 1990s, AIDS was identified mainly with specific marginalized populations, such as intravenous drug users, sex workers and men who have sex with men. This is no longer the case: women and children, particularly in low- and middle-income countries, are bearing an increasing proportion of the global burden of AIDS due to social determinants of health and cultural practices.

As HIV/AIDS patients are immunocompromised, they often present with a number of opportunistic infections, or infections that would not be sufficient to cause disease in a healthy person. One such disease is pneumocystis pneumonia (PCP), an infection caused by a fungus that does not normally cause symptoms in people with functioning immune systems (Morris et al., 2004). Although HIV/AIDS is a serious public health issue, efforts to develop a vaccine have been relatively unsuccessful because of the high rate of viral replication. Therefore, despite the availability of antiretroviral treatment (ART) for managing symptoms, many patients eventually become resistant to the medication and die from AIDS-related complications.

Justin is a 38-year-old bartender who lives in downtown Los Angeles, USA. He is a long-time, chronic user of intravenous drugs. Justin has always done his best to use clean needles, but nearly 15 years ago he acquired HIV from an unsterile heroin injection. Justin's symptoms have been managed to date with various "cocktails" of ART therapy, however the HIV virus in his body has been slowly developing resistance over the years to many of the drugs used in these ART cocktails. Justin recently developed a serious flu-like illness, and during an appointment with his physician, he was diagnosed with a PCP infection. This meant that the HIV virus in his body had become resistant to the newest drug in his ART cocktail, and that the virus had decreased Justin's immune system to a dangerously low level. Unfortunately, Justin had now exhausted the last effective combination of ART therapy.

Desperate for further treatment options, Justin urges his physician to find another solution to manage his disease. Justin's physician proposes that he enrol in the hospital's phase-III clinical trial of a new antiretroviral cocktail, of which the physician is a primary investigator.



D. Role-play

Dengue is a mosquito-borne viral infection that infects 50–100 million individuals globally each year (World Health Organization, 2012). The four strains of the virus are transmitted by mosquitoes of the genus *Aedes*, which are common in tropical and subtropical climates. Dengue can be difficult to diagnose without laboratory testing for antibodies, as the symptoms (high fever, muscle pain, headaches, vomiting, sore throat) are often mistaken for other problems, such as diarrhoea, or diseases such as malaria, yellow fever, measles and influenza. Dengue haemorrhagic fever or severe dengue, its most dangerous form, can result in very high fever accompanied by respiratory distress, severe vomiting and bleeding and can lead to death.

Unusual torrential rains have been battering eastern Brazil for over 3 weeks, including many areas of high urban concentration where dengue has been hyperendemic (continuously circulating) for the past 5 years. Now, in the face of an exploding rate of hospitalization for reported dengue fever, the Brazilian Government declares a dengue epidemic and a state of emergency. It is announced that there are 90 000 cases of dengue fever and 112 confirmed deaths in the State of Rio de Janeiro alone, with 50% of deaths in children aged 5–9 years. The epidemic is expected to spread from urban centres to rural areas in the coming weeks.

A Japanese company has been working in collaboration with a Brazilian university on a vaccine against dengue for several years. The university has completed phase-I and phase-II testing when the Brazilian epidemic begins. The early testing showed that the vaccine is 90% effective, with minimal non-serious side-effects in 5% of recipients (itching, redness, soreness at the site of injection, mild nausea, headache, sleepiness). It receives approval from both the Federal research ethics committee and the municipal government to test the vaccine in a town of 150 000 inhabitants, which the epidemic is expected to hit within the month. It is decided that the vaccine will be administered to school-age children accompanied by a parent capable of providing informed consent in a double-blind trial; children who do not receive the experimental vaccine will receive a placebo. The research team will fund additional health care resources (10 nurses, 5 doctors, 12 extra beds) for the community in the next year while monitoring contamination rates.

In the role-play, a nurse who is to administer the vaccine in the trial faces a very worried parent (Mr or Mrs Briceño). In preparation for this role-play, print and cut out one copy of each of the following boxed instructions (Box 9 and Box 10).

Box 9. Information for nurse administering dengue trial vaccine

“Nurse”: use the following details to guide your role in the “Dengue in Brazil” role-play.

You are an employee of the university running this clinical trial; therefore, you are not familiar with Mr or Mrs Briceño when he or she shows up with their two children.

Your first objective is to ensure that all the parents and children you meet at the clinic understand any risks and benefits of participating in this vaccination trial. These include the possibility that the children will not receive the experimental vaccine as this is a double-blind placebo-controlled trial: half the participants will receive a placebo, and you do not know which doses are the placebos.

An equally important objective is to build and maintain trust with the members of the community. This will not only ensure wide participation in the trial but also, crucially, ensure that participation is based on clear understanding, as trust creates the conditions in which participating parents and children feel comfortable in asking questions during the trial.

No family or child is obliged to participate. Consent is oral and should be voluntary.

Box 10. Information for “Mr” or “Mrs Briceño”, a parent of the child being vaccinated

“Parent”: use the following details to guide your role in the “Dengue in Brazil” role-play.

You grew up with very poor parents on a sugar plantation in the northeast of the country. Today, you work at a factory 6 days a week and sell lottery tickets. You are a very committed parent of two children and are hopeful that they will finish school and perhaps even go to university.

You hate the rainy season. When you hear the rain pounding on your roof, you have trouble sleeping. It reminds you of when your 5-year old, Tiago, got dengue fever. He was so pale, he looked blue. Then, the blood started coming out of his nose and ears. At the hospital, they had tubes coming out of him everywhere, but Tiago died that night. Today, you are at the clinic with your 4-year-old and 8-year-old children, who are eligible for the dengue vaccine. You understand that some children will receive a placebo. You are determined to that both your children will receive the vaccine. **You are convinced that it can protect them from dengue fever and therefore from death.**



E. Summary

A therapeutic misconception occurs when a study participant fails to understand the difference between clinical research and clinical care. Therapeutic misconception raises ethical issues because it hinders voluntary informed consent and limits autonomy and agency in treatment decisions. In emergencies, study participants may be more vulnerable to therapeutic misconception than in other settings because of factors such as emotional stress, trauma, limited care options and a great need for care, compensation or hope. The risk for therapeutic misconceptions may be compounded by a scarcity of affordable, safe health care, which may lead some people to participate in clinical research as a therapeutic option. Researchers working in emergencies should exert extra caution during informed consent processes to avoid enlisting volunteers

whose decision-making capacities may be compromised by unrealistic hopes or therapeutic expectations. The researcher has the ethical duty to ensure that participants understand the known and unknown therapeutic limits as well as the non-therapeutic goals of all study-related procedures.



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Learning objective 7.3: Explain the potential conflicts of interest of health care workers participating in emergency research activities.

Marie-Josée Potvin and Bryn Williams-Jones



Session timeline (90 min)

0–15 min (15 min)	16–25 min (10 min)	26–55 min (30 min)	56–85 min (30 min)	86–90 min (5 min)
Introduction	Presentation of problem-solving tools	Case study and discussion, phase 1	Case study and discussion, phases 2 and 3	Summary and conclusion



Instruction strategy

For facilitators: This session is highly interactive; it requires that you spend time familiarizing yourself with the content and format of the session.

1. The facilitator starts the session by presenting definitions and concepts (slides 1–4).
2. The facilitator presents the problem-solving tools (slides 5–7), highlighting the main approaches to identifying, evaluating and managing conflicts of interest.
3. The facilitator summarizes the model for ethical management of conflicts of interest.
4. The facilitator presents the first part of the case study (slide 8).

For facilitators: Provide a general overview of the case, and discuss its key contextual features.

5. The facilitator moderates phase 1 of the analysis, using the “facilitators’ discussion guide”, below.
6. The facilitator progressively presents parts 2a–2c of the case study (slide 8) and moderates phases 2 and 3 of the analysis, using the “facilitators’ discussion guide”.

For facilitators: Present progressively the contextual elements of the case. Introduce various scenarios to show that it is essential to understand the social, political and cultural context. Identify contextual factors, and ask questions that will help students to identify potential conflicts of interest.

When progressing to phase 3, help participants to reflect on the lessons that can be learnt from ethical analysis of the case about how things could have been managed differently to avoid the problems identified.

7. The facilitator concludes the session and opens the floor for discussion.



A. Background

Public health research involves a wide variety of stakeholders (e.g. researchers, populations, politicians, policy-makers) with different, often conflicting and sometimes irreconcilable interests at multiple levels (e.g. intervention, research, policies). This context provides fertile ground for conflicts of interest.

In public health emergencies with a dramatic human impact and significant uncertainty, it is impracticable and unreasonable to expect researchers or health care workers to identify, analyse and manage conflicts of interest when they have other pressing responsibilities (Ezeome & Simon, 2010). In addition, when powerful stakeholders with vested commercial or political interests are involved, effective policies to prevent conflicts of interest may be difficult to both elaborate and implement (Conflicts of Interest Coalition, 2012; London et al., 2012). As there is no clear definition of “conflict of interest” explicitly related to research in emergencies and as pressure to elaborate and apply conflict of interest policies is likely to be exerted by academia and civil society, researchers working in the context of emergencies with public health consequences must familiarize themselves with the notion. Both education and strong public health research policies should be developed at all levels that both define acceptable and unacceptable behaviour and provide clear procedures and guidance. These policies should be supported by sufficient political leverage to ensure their application in research during emergencies.



B. Topics

Defining conflicts of interests

The term “conflict of interest” is often viewed as or equated with fraud or ethical misconduct (Stell, 2011). For many people, the term is necessarily pejorative (Williams-Jones, 2011). In the world of health research and professional practice, this perception is most likely due to highly publicized scandals involving poor management of financial conflicts of interest, such as in the case of industry involvement in studies of meningitis in Nigeria (Ezeome & Simon, 2010). The resulting media coverage arguably helped to undermine public confidence in the integrity of researchers, academic institutions and health professionals (Stephens, 2000; Weinfurt et al., 2006; Smith, 2011).

Unfortunately, this pejorative view helps to make the concept of conflict of interest largely unusable: if, in people’s minds, it is equated with fraud or misconduct, it follows that only “bad people” have conflicts of interest. Therefore, goes the thinking, a well-intentioned person can have no conflict of interest. The truth is, however, that conflicts of interest are frequent in research and professional practice, and there is nothing inherently blameworthy about having such a conflict. Institutional arrangements in fact sometimes make them probable, if not inevitable (MacDonald et al., 2002). If actual or apparent conflicts of interest are inappropriately managed or, worse yet, not addressed or covered up, they can seriously damage the trust of colleagues, patients and the public in professionals and their institutions. It is essential, then, to use effective, transparent strategies to identify, evaluate and manage those conflicts of interest that cannot be avoided, such as disclosure to stakeholders, excluding individuals from certain decision-making and the involvement of neutral third parties.

The definitions tend to concur that a conflict of interest is necessarily associated with a process of judgement or decision-making and that they most often arise in situations in which an individual or group has to make an objective or impartial decision. A conflict of interest may thus be internal to an individual researcher, health care worker or community leader, for example, or external and thus structurally embedded or part of collective decision-making.

If the definitions of conflict of interest are relatively simple to understand, at least conceptually, they may be difficult to apply in distinguishing what is and is not a conflict of interest. They are, for example, often confounded with conflicts of role and loyalty. Although these can indeed be conflicts of interest, they are not necessarily. In the case of a physician–researcher employed by a pharmaceutical company, the two affiliations may put the individual at risk for uncomfortable inner conflicts, especially in the context of research during an emergency. Which role should take precedence e.g. in terms of priority or time commitment? That of the physician with a duty to respond to the medical health needs of a population or that of the researcher whose responsibility should be to focus on the good conduct of the study? This conflict is an example of a conflict of loyalties and roles, which creates situations as equally problematic as a conflict of interest but that are only related to and not synonymous with it. This situation could, however, create a challenging conflict of interest if the interests or responsibilities of one professional role (e.g. a researcher focused on advancing knowledge) create bias that undermines the responsibilities of the other role (e.g. a clinician focused on advancing a patient's best interests).

In order to become more expert in recognizing and managing conflicts of interest in public health research or surveillance, researchers, health care workers and others must make an active commitment to individual reflexivity and preparation and individual and collective analysis.

One strategy for recognizing a conflict of interest is to determine the conditions or characteristics of the situation. A variety of actors or stakeholders are often implicated, and it is important to recognize who those actors are and their interests (e.g. personal and not financial, financial, institutional), in order to identify the conflicts that could arise, the risks that they create and for whom. Only then can it be possible to evaluate the severity of the risks posed by the conflict and determine the most appropriate management strategy.

Types of conflicts of interests

Financial

In the context of public health research, obvious financial conflicts of interest can occur in the relationship between clinical scientists and the private sector (Potvin, 2012). Researchers have a conflict of interest if they prioritize personal interests (e.g. money, promotion) over their professional duties, such as protecting the welfare of participants or ensuring the integrity of the scientific process. Similarly, community leaders working in collaboration with public health researchers may have financial interests that conflict with their responsibilities to either their community or the researchers.

Non-financial

Conflicts of interest are not always financial, nor are they always those of people who, at first glance, may appear to have the most power or influence. Research-related conflicts of interest may be associated with local politics and be more difficult to detect. They may also arise within the community in which research is being conducted. Some community leaders might want to benefit from a research project, for example, to enhance their reputation in the community and therefore try to please the investigators rather than provide support for the research endeavour (Cash et al., 2009).

It is important to pay attention to the risks associated with conflicts of interest for both vulnerable people and for the more powerful actors who may be involved. Some groups, such as patients and vulnerable populations, might lack the capacity to judge fully the interests of those with whom they are interacting or to resist those interests. For example, some potential research participants might have no other means of accessing necessary health care than to “consent” to a project, in which the principal investigator might have three different roles and interests: researcher, health care provider and shareholder in the company for which the drug is being tested (Cash et al., 2009).

Even people in more powerful positions, such as researchers and health care workers, may risk being involved in, or associated with, a conflict of interest. The risks are most commonly loss of trust in both the individual and the profession but also in research findings and the research establishment. Such loss of trust can endanger established working relationships (inside and outside the research team) as well as international collaboration, thus negatively affecting the safety of the patient or participant and, ultimately, public health.

Contexts in which conflicts of interests occur

Context is central to both the identification and the management of conflicts of interest. The detailed context is, however, rarely evident at first glance and even less so in an emergency. To complicate matters further, although some insight can be gained from anticipating the type of context, factors and situations often evolve and can change dramatically and rapidly. Therefore, for effective management of a conflict of interest, it is important to be prepared for multiple scenarios. Thinking proactively and being well prepared can help refine understanding and the capacity to quickly recognize and address conflicts of interest, leaving resources (time, energy) to process new insights and deal with unresolved conflicts that are more likely to have negative consequences.



C. Case study

Source: Cash et al. (2009)

Part 1

The staff-benefits group of a West African mining company asks a research team based at a European university to help determine the economic impact of the AIDS epidemic on their workforce. The group wants to convince senior management that the cost is much higher than expected. They suspect that absenteeism due to AIDS, rapid turnover of highly trained and semi-skilled staff (leading to re-training costs), treatment costs for the illness, one-time benefits and funeral costs to the families of affected workers have been underestimated.

The research centre puts together a team consisting of a physician, an economist, a public health specialist and a research associate and travels to the country for 3 weeks of intensive fieldwork and investigation. At their request, the team is given access to the records of all employees who had to leave the company because of AIDS or AIDS-related illness. Any data that could identify individual employees are removed from the records. No data on the prevalence of infection exist in the company, but sample surveys have been done in other parts of the country to examine the rates of HIV infection in similar age groups.

Part 2a

The staff-benefits group hopes that, if they demonstrate the costs of the epidemic, the company will provide more preventive programmes, such as distribution of pamphlets, lectures at the workplace and recreational activities for single men who live at the company hostels, some of whom frequent a nearby area with a high concentration of commercial sex workers. Preventive and educational services could also be provided to the families of married workers. Other interventions might include establishment of clinics to treat sexually transmitted infections more aggressively or long-term provision of family housing units. The staff-benefits group believes that a report from a well-respected university research group will be an effective way to influence company policy and promote preventive programmes.

Part 2b

The research team will be fully funded by the company, including overhead payments commensurate with university guidelines. The company has stated that it will not restrict the researchers' ability to publish the study findings, although it will require that the company and all its employees remain anonymous in any reports or publications.

As data collection nears completion and the research team prepares to return home to analyse the data and prepare the report, a senior member of a trade union requests a private meeting. He expresses concern that the company will not use the results of the study to improve public health programmes but will instead conclude that anyone who is HIV-positive will be too costly to retain and that therefore even HIV-positive individuals who are still healthy will be released on some pretext. Although the company is barred from testing new employees, it can require that employees obtain private health insurance, which often requires an HIV test. Finally, he states that the company will probably cut back its workforce (and therefore decrease its liability) by downsizing and outsourcing.

The team members request a meeting with the sponsors of the research and, without disclosing their source, express their concern that the report could be used for purposes that are contrary to their intentions. The company insists that any rumours they may have heard about misuse of the report are untrue. However, the research associate is not satisfied with the company's explanation and asserts that, unless the company provides an assurance in writing, she will immediately withdraw from the project. The company says that it cannot sign such a statement, as doing so would reflect badly on the integrity of the organization.

The research team analyses the data and presents the following conclusions to the management of the company before publication:

- The prevalence of HIV infection in the general population will probably mean an employee turnover rate of at least 10% per year for the company.
 - The health care costs for the company will increase significantly over the next 5 years and could constitute 15% of its total operational costs. By law, if an employee's illness is diagnosed while he or she is working for a company, all the health care costs related to that illness must be paid by the company, whether or not the illness is work-related.
 - To reduce costs, the company should begin a home-treatment programme for employees with AIDS.
 - Prevention programmes would almost certainly reduce the incidence of HIV infection among employees, although the cost-effectiveness of these programmes is not known.
-

Part 2c

Managers at the company are alarmed by the report and by the projected costs of caring for HIV-positive employees. The chief executive officer says that, if the company is forced to take on the health care costs of all employees who become HIV-positive during their employment, it will be unable to compete in the international market and will be forced to declare bankruptcy or relocate to a lower-cost country that does not make the same demands. In either case, everyone at the company will lose their job, leaving many households without any income.

He asks that the research team take this issue into account in writing their conclusions. In fact, he asks the team to recommend that employer-subsidized health insurance plans be allowed to cap benefits for HIV infection at far less than the cost of the treatment needed. Employees with HIV infection would then either pay for their own treatment, forgo treatment or rely on publicly provided services. Households and extended families would probably bear the brunt of the costs, as the health care facilities of government and nongovernmental organizations are already overwhelmed with HIV/AIDS patients. The chief executive officer argues that transferring the costs to the government, households and other companies is a rational response for a profit-maximizing business. Given the international reputation of the research team, he expresses confidence that a report that recommends a cap on benefit will persuade government regulators to change their policy.

Facilitators' discussion guide

Part 1

Ask participants to identify the main actors in the situation and the potential conflicts of interest that may emerge.

For facilitators: The actors may include people not explicitly identified in the case, such as politicians and company shareholders. Anticipating the existence of these actors may minimize potential conflicts of interest. Use the table below to guide the discussion on the main actors involved and their interests. Ask participants to list the obvious primary (real or potential) interests of each actor.

Encourage students to start thinking proactively by identifying possible scenarios for the case of conflict of interest with which they might be confronted. This will make them more aware from the beginning of the possible interests at stake and thus help them to identify and embody their own interests in their roles and duties as researchers or health care workers. Use the table below to guide the discussion about the actors' interests.

Identify the main actors involved	Each actor's real or potential (future) interests
Research team at a European University	Produce valid research data in public health to participate in knowledge development Population health; public good or interest University, research group and recognition or prestige of researchers University and research group financing
A staff-benefits group of a West African mining company	Workers' benefits (health, financial) Community well-being Settle old battles with the employer

West African mining company	Financial health of the business Political interests Response to shareholder pressure
Highly trained workers and semi-skilled staff	Personal benefits (good job, financial, housing conditions)
Workers' unions	Workers' interests Union's interests
Community organization	Community interests Workers' interests
Nongovernmental organization	Sustainability of operations, reputation, influence Community, global interests
Shareholders	Financial interests (profit)
Political actors (local, national, international)	Economic development Political interest (power, influence)

Ask participants to identify possible conflicts of interest and briefly discuss their associated risks, and use the table below to guide the discussion.

<p>1. The mining company may have financial and/or political interests, and our results may be seen as a means to bring them to fruition.</p> <ul style="list-style-type: none"> • Potential conflict of interest for researchers: What if the results are not in line with the mining company's agenda (valid research and integrity versus funds for the research group (a contract)? • Possible consequences: <ul style="list-style-type: none"> — High interpersonal tension — Impossibility of publishing valid research results that might help to improve workers' conditions and community well-being overall • Risk: High, because it is directly related to the researchers' primary interest.
<p>2. We may suspect that unions will eventually be involved and bring in old, enduring conflicts between the workers and the company (e.g. salary, contracts).</p> <ul style="list-style-type: none"> • Potential conflict of interest: possible pressure from the union if the results go against the interests of the workers. • Possible consequences: <ul style="list-style-type: none"> — Overstating the findings of the research in order to help the workers, considered as victims, to gain better working conditions — Alternatively, overly prudent analysis — Strong political tension in the mining company • Risk: High, because it is directly related to the researchers' primary interest, it may be seen as an intrusion into the political matters of another country.

3. We may wonder whether local political actors also have political or financial interest in the survival of the mining company; this could be an added pressure that might interfere with the research process.

- Potential conflicts of interest:
 - Pressure possibly added to those of the company in order to orient the process to their advantage
 - Subtle pressure (e.g. invitations for meals, gifts or other incentives)
- Possible consequence: Impasse in which the research group might be suspected of corrupting the results (whatever the analysis) and is mistrusted by the workers and the general population.
- Risk: High, because it is directly related to the researchers' primary interests, it may undermine population trust and jeopardize other, future research projects in the population.

4. We may wonder whether local politicians also have political or financial interests and may question our own interest in carrying out the project, beyond a simple "search for knowledge".

- Potential conflict of interest: The pressure to make "positive" findings that can be published, to maintain good research environments and to succeed with academic promotion.
- Possible consequence: Situation that makes you more tolerant to questionable practices because you do not want the project to be compromised; it will be an excellent addition to your curriculum vitae, thus enhancing your opportunities.
- Risk: High and low, because it is directly related to the researchers' primary interest, but you have control over it.

Part 2

After each addition of contextual information (parts 2a–2c), ask participants the following questions:

- How do the new contextual elements affect your analysis of part 1?
- Are there emerging conflicts of interest (actual and/or potential)?
- Can you briefly discuss the risks associated with these emerging conflicts of interest?

In conclusion, ask participants what they consider important in managing conflicts of interest on the basis of the discussion so far and the specificity of research in an emergency context. Use the following points to enrich the concluding discussion.

Messages specific to the case study

- In this situation, by taking a proactive approach, we could have reduced the chance of having to manage a delicate conflict of interest that was perhaps inevitable but probably manageable.
- We could have asked better questions (e.g. about interests, the political and institutional context) and provided solutions on which the whole group could have agreed from the start (e.g. personal and professional limits, priority given to private interest or research and the public interest).

General messages

- Be better prepared, less stressed and thus more efficient in decision-making.
- Better understand the scope of responsibility and basic ethical rules for all actors involved.
- Involve, when needed, experts (in e.g. policy, political science, anthropology) to better understand the whole context of the research project.
- Undertake a *priori* and a *posteriori* discussions with the research ethics committee on conflicts of interest, and communicate your experience to inform other groups.
- Encourage dialogue about conflicts of interest during the research project.
- Inform and educate as many people involved in the project as you can. Consider that everyone is part of the problem and of the solution.
- Communicate your experience to the team, researchers and policy-makers when possible (e.g. in research publications), and enrich this educational material by adding examples of your own and other situations of conflict of interest.



D. Summary

To become more expert at recognizing and managing conflicts of interest in public health research or surveillance contexts, researchers, health care workers and other actors will have to increase their individual reflexivity, individual and collective preparation and continuing analysis. The goal of this module, to improve the identification and management of conflicts of interest in practice, might seem idealistic, as the realities faced by researchers and health care workers already pose an overwhelming variety of challenges. Nonetheless, this module has an attainable goal, to propose a means and an opportunity to discuss a delicate matter—one that is often taboo—that can have a significant negative impact not only on research integrity but also on individuals (e.g. injustice, stress) and whole communities (e.g. resource distribution, policy-making). The context of emergency situations is highly unpredictable, making it all the more important to learn from experience. This module presents a practical, pragmatic approach for collecting, organizing and communicating information about experiences with conflicts of interest in order to prevent or manage those that can be predicted in advance and to deal with unpredicted or inevitable conflicts that arise in the context of public health practice.



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Glossary



Staff at the Medical Records Office sort through patient's at Karapitayam Hospital, Galle. The hospital was not affected by the Tsunami as it is away from the seafont and on higher ground. WHO is providing computers and training in Epi Info software so that they can enter patient data and track certain health parameters. Source: WHO/Gary Hampton

This glossary provides definitions of common concepts, principles and values in health ethics. For many of the terms, a number of definitions are available. This glossary is therefore not intended to be definitive but to aid understanding of common terminology, in particular as used in this document.

Concept, principle, or value	Definition
Accountability for reasonableness	Framework that requires that the rationale or reasons underlying health-care-limiting decisions be made publicly available. Moreover, “fair-minded” individuals – those who seek cooperation with others on mutually justifiable terms – must agree on the applicability of these reasons to health care delivery in resource-constrained settings (1).
Autonomy	Most often taken to refer to the ability of an individual to be his or her own person, to make his/her own choices on the basis of his/her own motivations, without manipulation by external forces. However, others in a more Kantian tradition see autonomy as being firmly related to accepting and acting on the basis of one’s obligations, i.e. acting morally, the precise opposite of doing what one wants (2, 3).
Beneficence	Principle requiring that governments, health care providers, and researchers do good for, provide benefit to, or make a positive contribution to the welfare of populations, patients and study participants (4).
Bioethics	The field of enquiry that examines ethical issues arising from the “creation and maintenance of the health of living things”. Bioethics is much broader than medical ethics, and includes all ethical issues in medicine, the life sciences and biomedical research (5).
Confidentiality	The obligation to keep information secret unless its disclosure has been appropriately authorized by the person concerned or, in extraordinary circumstances, by the appropriate authorities (6).
Dignity	A term used to suggest the idea of human worth or value. It is often used to link to the idea of persons as being of value. “The notion of dignity is used to mark a threshold, a kind of respect and care beneath which the treatment of any human being should never fall” (7).
Distributive justice (see also <i>Equity</i>)	A set of principles that provide “moral guidance for political processes and structures that affect the distribution of economic benefits and burdens within societies”. It is generally thought to be difficult, if not impossible, to distribute health. However, there are a number of factors that may be considered relevant to the just distribution of health (including income, wealth, utility), the number of possible persons involved (individuals or groups), and differences in how the distribution should be made (equality, maximization, etc.). Egalitarianism is one example of a distributive justice principle (8).

Egalitarianism	A belief in equality. However, egalitarians disagree about what it is that should be equal, for example whether people are entitled to equal opportunities, an equal share of resources, or whatever level of opportunities and resources are necessary to generate equal results (9).
Equity (see also <i>Distributive Justice</i>)	Equity focuses on equal outcomes and this may require an unequal distribution of some good to bring about the equal outcome. Health equity requires responding to “differences in health which are not only unnecessary and avoidable but, in addition, are considered unfair and unjust” (10).
Ethics	Branch of knowledge concerned with questions about right versus wrong conduct and what constitutes a good or bad life, as well as the justificatory basis for such questions (11).
Human rights	Fundamental freedoms and rights enshrined in a set of universal legal statements. Some of the most important characteristics of human rights are that: they are acknowledged in international declarations; states and state actors are obliged to respect them; they cannot be waived or taken away (although the enjoyment of particular human rights may be limited in exceptional circumstances); they are interdependent and inter-related; and they are universal (12).
Informed consent	Agreement to a certain course of action, such as treatment or participation in research, on the basis of complete and relevant information by a competent individual without coercion (13).
Justice	A highly contested concept that can, roughly, be thought of as giving people what they deserve (14). See also: Equity and Distributive justice.
Liberty	A highly contested and complex concept that is often presented as freedom from such things as the interference, influence, or control of others. However, other accounts of liberty focus on authenticity, self-realization, or even appropriate relations with others (15).
Non-maleficence	A principle requiring that health care providers and researchers do not inflict undue harm, either intentionally or through negligence (4).
Principle	A broad but fundamental norm which can provide justification for more specific rules or standards. For example, it is often claimed that informed consent (a standard) is necessary because of the need to respect autonomy (a principle) (16).
Privacy	Privacy seeks to protect a person from scrutiny by others. Respect for privacy implies that a person should not be expected to share personal information unless they so choose. Any violation of privacy requires ethical justification although it might be outweighed by other considerations in some cases (i.e. for the protection of the common good) (17).
Procedural justice	Discussion of the values and processes necessary to bring about a just outcome. For example, where resources are scarce and rationing is needed, a procedurally just outcome would provide clear and justifiable reasons for the decisions made (18).
Proportionality	The balancing of the positive features and benefits of a particular intervention, policy, or research study against its negative features and effects, when deciding whether or not to implement it (19).
Public good	A commodity or service that meets the following two criteria: it is practically non-excludable (i.e. no one can be excluded from consumption, irrespective of individual contributions to provision) and non-rival (i.e. consumption by some does not reduce the benefits of consumption accrued by others). For example, the eradication of smallpox counts as a public good because it meets these criteria (20).
Public health ethics	The field of enquiry that examines ethical issues and dilemmas relevant to the protection and promotion of population health and the collective actions necessary to achieve these aims (21).

Reciprocity	A principle that focuses on “providing something in return for contributions that people have made”. In some cases this can be a strict matching between an action, such as participation in research, and compensation for any harm caused. In other cases, reciprocity may be less direct and involve more general contributions for the benefit of others or society in general (22).
Social justice	A concept focused on the root causes and existence of inequalities in society and the need to explicitly address them. In some cases, this may require a redistribution of resources to compensate for existing inequalities and further actions to prevent their perpetuation (23).
Solidarity	A social relation in which a group, community, or nation stands together. It is often appealed to in discussions about justifications for the welfare state or shared risks through insurance pooling, and in thinking about how states might defend the interests of vulnerable groups within their population (23).
Utilitarianism	A set of theories centred on the principle of utility which is often taken to require that any action should maximize benefits for the greatest number of people (24).
Value	Concept that is “used to explain how and why things matter. Values are involved wherever we distinguish between things as good and bad, better or worse.” Values are central to ethical judgements. Often, the place to start in a discussion about what ought to be done is to make clear what values are most relevant and what weight should be attached to them (25).



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Annex I. List of modules and course timetables

Refugee camp, Goma
Source: WHO/Christopher Black



List of modules

Overview: Ethics of epidemics, emergencies and disasters

90 min

Core Competence 1: Ability to analyse the boundaries between public health practice (including surveillance) and research, and their ethical implications in emergencies

Learning Objective 1.1. Distinguish between public health surveillance and public health research	60 min
Learning Objective 1.2. Identify the scope of activities that could qualify as "research" during emergency response and would normally require research ethics review	90 min
Learning Objective 1.3. Demonstrate understanding of ethical principles and requirements addressed in current normative instruments relative to research and surveillance in emergencies	90 min
Learning Objective 1.4. Identify the shortcomings of current normative instruments for use in emergency situations, and evaluate alternatives	120 min

Core Competence 2: Ability to define adequate processes for ethics review in public health interventions, surveillance, and research in emergencies

Learning Objective 2.1. Describe "standard" procedures that should govern an ethics review of research activities, including public health research	90 min
Learning Objective 2.2. Identify circumstances in which public health surveillance activities should possibly undergo formal ethics review	75 min
Learning Objective 2.3. Describe possible variations to standard procedures of ethics review that are applicable to research in emergencies	75 min

Core Competence 3: Ability to identify conflict between the common good and individual autonomy in surveillance during emergency response

Learning Objective 3.1. Identify possible harm and benefit to individuals and communities resulting from public health practice and surveillance	105 min
Learning Objective 3.2. Assess the factors to be considered in determining when public health surveillance requires explicit informed consent from individuals or communities	60 min
Learning Objective 3.3. Evaluate the measures required to protect privacy and confidentiality in an emergency	90 min
Learning Objective 3.4. Describe specific measures required to protect and collect data and biological materials during public health surveillance	60 min
Learning Objective 3.5. Describe circumstances in which the common good might overrule individual autonomy during public health surveillance	60 min

Core Competence 4: Ability to identify conflict between the common good and individual autonomy in research and clinical trials during emergency response

Learning Objective 4.1. Identify potential harm and benefit to individuals and communities resulting from conducting research in emergencies	60 min
Learning Objective 4.2. Discuss moral theories, and identify frameworks applicable to research in emergencies	60 min

Learning Objective 4.3. Explain the current norms under which a waiver of consent could be deemed acceptable for research in critical care settings, and assess when they could be applicable to research in emergencies	75 min
Learning Objective 4.4. Explain the processes required to improve informed consent to research in emergencies, with particular consideration of traditional communities and low-resource settings	90 min

Core Competence 5: Ability to explain how publication ethics are related to public health surveillance or research in emergencies

Learning Objective 5.1. Explain the conditions in which data gathered during public health surveillance or routine clinical management can be published as scientific knowledge	75 min
Learning Objective 5.2. Explain what is meant by “publication bias” and how it might affect the response to emergencies	90 min
Learning Objective 5.3. Explain the ethical obligations of researchers, public health practitioners and publishers regarding ownership of scientific data	120 min

PART II. PATIENT CARE

Core Competence 6: Ability to define ethically relevant criteria for triage, resource allocation, and standard of care in emergency response

Learning Objective 6.1. Discuss ethical frameworks and criteria for triage and rationing in emergencies	90 min
Learning Objective 6.2. Understand how criteria for standards of care and treatment can be altered during emergencies	90 min
Learning Objective 6.3. Identify issues of benefit-sharing with communities under public health surveillance	105 min
Learning Objective 6.4. Identify issues of equity of access to unproven treatments during research in the course of emergency response	60 min

Core Competence 7: Ability to discuss the professional duties of health care workers during public health surveillance or research in emergencies

Learning Objective 7.1. Distinguish three ethics frameworks: medical care ethics, public health ethics and research ethics, and explore the ways in which the values and principles that guide these frameworks diverge or overlap	105 min
Learning Objective 7.2. Explain what is meant by “therapeutic misconception” and how it could affect the duties of health care workers in emergencies	75 min
Learning Objective 7.3. Explain the potential conflicts of interest of health care workers participating in emergency research activities	90 min

Course timetables

Practice-oriented two-day session

Day 1

9:00 – 9:15 Opening remarks

9:15 – 10:15 First session

Learning Objective 1.1. Distinguish between public health surveillance and public health research	60 min
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10:15 – 10:30 Break

10:30 – 12:15 Second session

Learning Objective 7.1. Distinguish three ethics frameworks: medical care ethics, public health ethics and research ethics, and explore the ways in which the values and principles that guide these frameworks diverge or overlap	105 min
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12:15 – 13:00 Lunch

13:00 – 14:30 Third session

Learning Objective 6.1. Discuss ethical frameworks and criteria for triage and rationing in emergencies	90 min
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14:30 – 14:40 Break

14:40 – 16:10 Fourth session

Learning Objective 6.2. Understand how criteria for standards of care and treatment can be altered during emergencies	90 min
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16:10 – 16:30 Break

16:30 – 18:15 Fifth session

Learning Objective 3.1. Identify possible harm and benefit to individuals and communities resulting from public health practice and surveillance	105 min
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Day 2

9:00 – 9:15 Review remarks

9:15 – 10:30 Sixth session

Learning Objective 2.2. Identify circumstances in which public health surveillance activities should possibly undergo formal ethics review	75 min
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10:30 – 10:45 Break

10:45 – 11:45 Seventh session

Learning Objective 3.2. Assess the factors to be considered in determining when public health surveillance requires explicit informed consent from individuals or communities	60 min
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11:45 – 12:30 Lunch

12:30 – 14:00 Eighth session

Learning Objective 3.3. Evaluate the measures required to protect privacy and confidentiality in an emergency	90 min
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14:00 – 14:15 Break

14:15 – 16:00 Ninth session

Learning Objective 6.3. Identify issues of benefit-sharing with communities under public health surveillance	105 min
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16:00 – 16:15 Break

16:15 – 17:15 Tenth session

Learning Objective 3.4. Describe specific measures required to protect and collect data and biological materials during public health surveillance	60 min
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17:15 – 18:30 Eleventh session

Learning Objective 5.1. Explain the conditions in which data gathered during public health surveillance or routine clinical management can be published as scientific knowledge	75 min
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Research-oriented two-day session

Day 1

9:00 – 9:15 Opening remarks

9:15 – 10:15 First session

Learning Objective 1.1. Distinguish between public health surveillance and public health research	60 min
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10:15 – 10:30 Break

10:30 – 12:15 Second session

Learning Objective 7.1. Distinguish three ethics frameworks: medical care ethics, public health ethics and research ethics, and explore the ways in which the values and principles that guide these frameworks diverge or overlap	105 min
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12:15 – 13:00 Lunch

13:00 – 14:30 Third session

Learning Objective 1.2. Identify the scope of activities that could qualify as “research” during emergency response and would normally require research ethics review	90 min
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14:30 – 14:45 Break

Learning Objective 4.1. Identify potential harm and benefit to individuals and communities resulting from conducting research in emergencies	60 min
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14:45 – 15:45 Fourth session

15:45 – 16:00 Break

16:00 – 17:30 Fifth session

Learning Objective 2.1. Identify circumstances in which public health surveillance activities should possibly undergo formal ethics review	90 min
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Day 2

9:00 – 9:15 Review remarks

9:15 – 10:45 Sixth session

Learning Objective 7.3. Explain the potential conflicts of interest of health care workers participating in emergency research activities	90 min
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10:45 – 11:00 Break

11:00 – 12:15 Seventh session

Learning Objective 7.2. Explain what is meant by “therapeutic misconception” and how it could affect the duties of health care workers in emergencies	75 min
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12:15 – 13:00 Lunch

13:00 – 14:30 Eighth session

Learning Objective 4.4. Explain the processes required to improve informed consent to research in emergencies, with particular consideration of traditional communities and low-resource settings	90 min
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14:30 – 15:00 Break

15:00 – 16:00 Ninth session

Learning Objective 6.4. Identify issues of equity of access to unproven treatments during research in the course of emergency response	60 min
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15:50 – 16:00 Break

16:00 – 18:00 Tenth session

Learning Objective 5.3. Explain the ethical obligations of researchers, public health practitioners and publishers regarding ownership of scientific data	120 min
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Annex II. Case studies



A doctor inspects patients in an MSF supported hospital in Aweil, Northern Bar El Ghazal in Southern Sudan on January 14, 2011
Source: IRIN/Siegfried Modola

Core Competence 1



Case Study 1: Outbreak of Haemorrhagic Fever (p. 12)

Used in: Overview: Ethics in emergencies

Source: *Renaud Boulanger and Selena Knight*

Group 1: Allocation of intravenous fluids during an outbreak of viral haemorrhagic fever

A deadly form of viral haemorrhagic fever has struck your community. The signs and symptoms of the disease include high fever and increased susceptibility to bleeding. Manifestations in confirmed cases include low blood pressure (hypotension), shock, vomiting and diarrhoea.

The capacity for laboratory diagnosis in your community is limited. The cause of the illness of some of the patients admitted to your health care centre is, however, obvious: they have advanced symptoms, such as excessive bleeding, high fever and shock. The diagnosis for other patients is less certain, as suspicion is based mainly on contact history and more general symptoms. In view of the extent of the on-going outbreak, your health care centre is overwhelmed with work.

Supportive care for patients is very limited due to lack of resources. Although intravenous fluid therapy is known to be useful in viral haemorrhagic fever to ensure adequate hydration while the immune system combats the virus, your health care centre has insufficient intravenous sets to meet the growing demand, including for patients with other diseases. In addition to supportive care and intravenous fluid therapy, you learn that the Ministry of Health has managed to secure access to a very limited amount of treatment with an experimental medication. The quantities of this experimental treatment are so limited that you expect that only about 2% of the patients at your health care centre could be given it, should you decide to do so.

As nurses trained in epidemiology and ethics, you have been asked to prepare for a meeting on setting guidelines for care during the outbreak. You must consider how you will prioritize access to intravenous fluids and decide whether you will offer the unapproved treatment. If you do, you must decide how to allocate the limited stocks. One of your concerns is to ensure that the allocation of resources demonstrates a high level of ethical consideration.

Questions for Discussion:

1. Who would you like to see sitting at the decision-making table with you, and how should decisions be taken?
 2. Will you provide the experimental treatment?
 - a. If so, will patients who receive the treatment also be eligible for intravenous fluids?
 3. How will you determine which patients of those receiving the treatment will also receive intravenous fluids?
-

4. Will you take into consideration the demographic characteristics of the patients (e.g. age, health care professional) in allocating treatment?
 - a. If so, will the demographic characteristics used be different for access to intravenous fluids and to the treatment (if you grant access)?
5. Will you use the concept of “need” in allocating resources? If so,
 - a. Will you allow for consideration of how sick the patient is?
 - b. Will you allow for consideration of how likely the patient is to survive?
 - c. Will you allow for consideration of evolving needs? If so, how will this be done?
 - d. In the case of intravenous fluids, will you allow for consideration of whether the patient was already receiving care before implementation of the allocation policy?
6. What obligations does the health care centre have to patients who are not given intravenous fluids and/or the experimental treatment?
7. Will you allow patients who are not given access to treatment (e.g. an experimental drug) to challenge the decision?
8. If so, what process will be established for reviewing challenges?
9. Should the allocation policy be communicated to patients, families and the broader community?

Group 2: Conducting a clinical trial during an outbreak of haemorrhagic fever

A deadly form of viral haemorrhagic fever has struck your community. The signs and symptoms of the disease include high fever and greater susceptibility to bleeding. Manifestations in confirmed cases include low blood pressure (hypotension), shock, vomiting and diarrhoea.

The laboratory diagnostic capacity in your community is limited. The cause of the illness of some of the patients admitted to your health care centre is, however, obvious: they have advanced symptoms, such as excessive bleeding, high fever and shock. The diagnosis for other patients is less certain, as suspicion is based mainly on contact history and more general symptoms. In view of the extent of the on-going outbreak, your health care centre is overwhelmed with work.

A few private firms and public organizations have rapidly come together to propose a clinical trial of an antiviral drug that has been under development for a few years. Laboratory studies have shown good activity of the drug against the virus that is affecting your community, but, while the safety and efficacy of the drug has been demonstrated in animals, no studies have yet been performed in humans. The proposal is to test the drug immediately for efficacy in humans.

Your health care centre is approached by the consortium and asked to act as a centre for a clinical trial of the experimental drug. They have requested your input as a potential co-investigator on the issues that should be discussed in the study protocol. Your understanding is that, although the number of doses currently available is very limited, manufacturing capacity could be rapidly scaled-up.

Questions for Discussion:

1. What additional information might you want about the drug or research before your discussions?
 2. What research designs would you consider? What methodological issues might you take into account?
 3. Who will benefit from this study, and what benefits will they receive? Who may be harmed by this research and how?
 4. How might you consider recruiting patients into the trial?
 5. What other information should be given to the participants when seeking their informed consent?
 6. What contextual factors might affect the ability of patients to provide informed consent? What provisions and adaptations might have to be considered to account for those factors?
 7. How should the contextual factors be taken into consideration to ensure that the research is carried out efficiently?
 8. How might the trial affect patients who do not participate, either through choice or because they are ineligible? How might any detrimental impacts be minimized?
 9. What impact should the study be permitted to have on the role and duties of the health care personnel working at your centre? Should the impact be communicated to patients and the community and, if so, how?
 10. How will challenges that arise from the dual role of health care personnel and researcher be dealt with?
 11. How will the findings be disseminated?
 12. What are the consortium's responsibilities towards trial participants and your community at the end of the trial?
 13. How should you communicate with the community about the study?
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Case Study 2: Outbreak of Ebola Haemorrhagic Fever in Central Africa (p. 24)

Used in: Learning Objective 1.1. Distinguish between public health surveillance and public health research

Source: Michael J. Selgelid

Scenario 1

You are a clinician assigned to the care of patients in the isolation ward of Bundibugyo Hospital, in a country in which where an outbreak of Ebola haemorrhagic fever is under way. Some cases are obvious (bleeding, terminal stage), while others are unclear and suspicion is based largely on contact history. You are overwhelmed with work.

Questions for Discussion:

1. An epidemiologist asks you to take one blood sample from each patient, for diagnostic purposes. How would you react (and how is the research–practice distinction relevant to your decision)?
2. The same epidemiologist indicates that optimal calibration of the newest diagnostic test requires taking daily blood samples from all patients until their discharge. How would you react (and how is the research–practice distinction relevant to your decision)?
3. The same epidemiologist indicates that optimal calibration of the newest diagnostic test requires taking daily saliva swabs from all patients until their discharge. How would you react (and how is the research–practice distinction relevant to your decision)?
4. A renowned scientist (also a member of the outbreak response team) claims that development of potentially useful immunotherapeutic agents requires taking bone-marrow aspirates from all convalescing patients. How would you react (and how is the research–practice distinction relevant to your decision)?

Scenario 2

A researcher tries to convince you that the outbreak presented in scenario 1 is a unique opportunity for testing recombinant anticoagulant protein C as a potentially life-saving intervention. There is no established national research ethics committee. Obtaining informed consent is highly problematic: many patients are disoriented and/or speak only a local language, and you find it very difficult to communicate through heavy protective equipment.

Question for Discussion:

1. How would you proceed (and how is the research–practice distinction relevant to your decision)?
-

Scenario 3

You are a clinician assigned to the care of patients in the isolation ward of Bundibugyo Hospital, in a country in which an outbreak of Ebola haemorrhagic fever is under way. You consider that information on the mechanism of the disease is desperately needed in order to manage cases better and to lower the mortality rate. There is no laboratory on site. You thus feel compelled to perform a number of limited autopsies; however, rumours are circulating in the community about the motivations of rescue teams. Seeking consent from relatives might lead to misperceptions, which could put international teams at risk.

Question for Discussion:

1. How would you proceed (and how is the research–practice distinction relevant to your decision)?



Case Study 3: Meningitis in Nigeria (p. 47)

Used in:

Learning objective 1.4. Identify the shortcomings of current normative instruments for use in emergency situations, and evaluate alternatives; and

Learning objective 4.1. Identify potential harm and benefit to individuals and communities resulting from conducting research in emergencies

Trovan trial in Nigeria

Stephens J (2000). Where profits and lives hang in balance, Washington Post, 17 December 2000 (http://www.washingtonpost.com/wp-dyn/content/article/2008/10/01/AR2008100100973_pf.html).

See also:

http://www.pfizer.com/files/news/trovan_fact_sheet_final.pdf

Core Competence 2



Case Study 4: SARS Outbreak (p. 57)

Used in: Learning objective 2.1. Describe “standard” procedures that should govern an ethics review of research activities, including research

Source: *Hodge and Gostin (2004), pp. 34–35.*

Scenario

In March 2003, during the worldwide SARS outbreak, the CDC engaged in a series of [...] efforts to systematically identify potential SARS cases and those within contact of these persons. As part of these activities, CDC focused efforts on potential cases of SARS spread through casual contact among airline travelers. CDC asked state and local public health agencies to assist in following up with potential contacts. In particular, during this critical time, if CDC became aware of a person known or suspected to be infected with SARS who had recently flown into or within the USA, it would identify the flight, contact the airline for the flight manifest, and then ask state or local public health agencies to help locate persons who had flown with the individual, and thus may have been exposed to SARS. Sometimes, obtaining flight manifests and locating named individuals would result in a 3–4 weeks administrative delay between the time CDC suspected a potential exposure and when an investigation could be conducted. Nevertheless, CDC requested that state or local agents supervise physicians to draw blood samples and obtain medical histories of healthy, unaffected air travelers who were on the plane with a known or apparent SARS case. When administrative delays mounted, the time period for performing these blood tests on asymptomatic individuals would have surpassed their likely incubation period for SARS, revealing only that they may have been exposed. Thus, the tests would not directly benefit asymptomatic individuals who were not ‘cases’ because they were not ill.

Questions for Discussion:

1. Identification of applicable cases is often the first step in a research project. What might be the research question here?
 2. If this is a research study, what questions would you pose as a research ethics committee member?
 3. In this case, the CDC determined that this study represented surveillance and intervention, not research; therefore, research ethics committee approval was not required. Others might dispute that conclusion. The case is presented to illustrate the difficulty in deciding whether ethics review is required for studies that fall between research and surveillance.
 4. Form three groups and give each 8 min to take a position on one of three questions:
 - a. Why do we go to so much trouble to oversee the ethics of research? Does it not add unnecessary costs to research?
 - b. Service on a research ethics committee is time-consuming. Is it worth it, and why?
 - c. Should research ethics committee approval be unanimous, or are dissenting votes on individual protocols acceptable?
-



Case Study 5: Malnutrition (p. 63)

Used in: Learning Objective 2.2. Identify circumstances in which public health surveillance activities should possibly undergo formal ethics review

Source: Adapted from Hodge & Gostin, 2004.

Scenario:

Protein–calorie malnutrition increases morbidity and mortality, slows wound-healing and impairs the immune response. These effects can increase the incidence and duration of hospitalization, readmission and disease-related complications. The laboratory test used most frequently to detect protein–calorie malnutrition is the serum level of albumin. The usefulness of albumin is, however, limited by its long half-life (changes cannot be detected quickly) and the effects of inflammation and chronic disease (e.g. kidney and liver disease) on albumin levels. Other, more sensitive laboratory tests include determination of serum pre-albumin, retinol-binding protein and C-reactive protein. Use of these tests allows quicker assessment of a patient’s condition.

Scientists proposed a project to determine the value added to hospital screening protocols and to patient monitoring by testing for these proteins. All non-maternity, non-palliative, non-parenteral nutrition inpatients at a certain nutrition risk would be eligible and asked to accept the intervention. Patients who refused would be asked to explain their decision, and their responses would be recorded anonymously and used to devise strategies to increase patient participation in similar activities in the future. Enrolled patients would receive the current standard of nutritional care at the hospital. If enrolled patients required parenteral nutrition or transition to palliative care, they would receive it but would not be withdrawn from the project.

All patients would initially be tested for protein levels with each of the four tests (albumin, pre-albumin, retinol-binding protein and C-reactive protein) and given a bedside nutritional assessment and a treatment plan. They would be scheduled for follow-up testing three times a week during their admission. The patients would be divided into two groups. The control group would receive standard care with additional laboratory testing for the proposed markers, but the results would not be shared with the patients or their caregivers; in the intervention group, the results of testing would be shared with the patients and their caregivers. The clinical outcomes (including length of stay in the hospital, days spent on a ventilator, infection rate) of the two groups would be compared to determine whether knowing laboratory results affects clinical outcomes. The data collected would include patients’ protein results, cost, demographic information, risk factors and functionality

Questions for Discussion:

1. Why can’t such a study be conducted without formal review? Consider your answer in terms of both informed consent and confidentiality.
 2. The CDC determined that the activity constituted research (see suggestion) and, *for that reason*, required review. Did the CDC make the right decision for the right reason?
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3. In this case, the leadership of the CDC decided that this project constituted research “because the information produced by the study is intended to contribute to generalizable knowledge, human research subjects are involved, and personally identifiable health data are being collected.” This could be contested.
 - a. The intent of the project could be described as an assessment of the value of such testing to hospital screening protocols, rather than research per se. Are there epidemiological or public health practice alternatives that could have achieved the same goal without meeting the CDC’s rationale for classifying the activity as research?
 - b. If so, would formal ethics review still be useful? Why? What questions would you ask as a research ethics committee member?

 4. Divide the group into three and give each 8 min to address one of three questions:
 - a. Which kinds of surveillance should undergo formal ethics review?
 - b. Which kinds of surveillance do not require such review?
 - c. Why not require research ethics committees to review all surveillance studies, in addition to research studies?
-



Case Study 6: Approval of New Vaccine (p. 70)

Used in: Learning objective 2.3. Describe possible variations to standard procedures of ethics review that are applicable to research in emergencies

Source: Edwards, 2013.

Scenario 1:

To facilitate therapeutic access to a new vaccine of people at risk for infection with a new deadly pathogen, it is proposed that a small sub-committee review an application to evaluate the effects of the new vaccine in humans within a week and that they submit their comments to the chair, who will collate them and notify the researcher of the committee's decision.

The committee is asked to approve use of a new vaccine in people who are at immediate risk before studies in experimental animals have been completed. The vaccine would be made available in one community at a time, so that comparisons can be made with a control group consisting of people waiting for the drug. As more vaccine is manufactured, more communities would be recruited into the study.

Consent to recruit communities will not be sought, and the new vaccine will be dispensed at retail outlets for convenience and increased uptake. Leaflets accompanying the new vaccine will provide the information on which members of the community can decide to take it. In addition, a public health campaign would be conducted through text messaging to raise awareness of the new vaccine.

The researcher proposes to inform the ethics committee periodically of any revisions to the information leaflet as more information becomes available on the effects of the vaccine. The data will be evaluated continuously and analysed periodically so that the study can be stopped quickly if harmful effects become apparent.

Scenario 2:

The risk for bioterrorism is a constant source of concern. Early detection of a pathogen released to the public could in principle save many lives, and authorities are keen to detect a bioterrorism attack as soon as possible. They set in place a system in which public health authorities collect data on sales of over-the-counter drugs, logs from emergency departments and data on absenteeism from large community employers. By collecting and analysing such data, the authorities can determine the symptoms caused by the toxic agent and the location of its release and make credible inferences about the scale of the attack. They will then be able to deploy appropriate containment units and marshal resources to respond to the attack.

The data entering public health offices are identifiable, that is, each pharmacy purchase, emergency department admission and absentee report is associated with an individual, in some cases with data including their address, credit card number and employer. The authorities argue that, if they were required to obtain consent, safeguard privacy and protect vulnerable populations, they would be unable to act and would lose the opportunity to save many lives, at least in principle.

Questions for Discussion:

Divide into three groups and answer the following questions for one of the two case studies:

1. Would you categorize this project as research or surveillance?
 2. Does the project require specific ethics review?
 3. If so, do you think that any variations to the standard procedures would be appropriate?
 4. Should the ethics committee insist on a full information leaflet and a consent form, as expected in routine research? review?
 5. Is there a case for expedited
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Core Competence 3



Case Study 7: Issues Involving Race (p. 81)

Used in: Learning Objective 3.1. Identify possible harm and benefit to individuals and communities resulting from public health practice and surveillance

Source: *Cash et.al, 2009*

Scenario:

The records of the sexually transmitted infections clinic at the largest general hospital in a southern African country indicate that there are twice as many cases in the segment of the population that self-ascribes itself as “coloured” as in the segment that self-ascribes itself as “black”. The numbers of cases of almost all the other conditions seen in the hospital’s outpatient department in each racial and ethnic group are proportional to the percentage of that group in the general population. Even after control for socioeconomic status, the distinction in the distribution of sexually transmitted infection remains.

Before the country’s independence, Government officials assigned individuals to one of four racial categories—black, white, coloured and Asian—on the basis of factors such as physical appearance, descent, language and behaviour. Since independence, an individual’s membership in one of these racial groups, or in a new alternative, “other”, is self-ascribed. Authorities may investigate an individual’s self-categorization if they suspect him or her of self-identifying to a racial group in order to accrue a particular benefit.

Dr Chingana, the Director of the sexually transmitted infections clinic, believes that the disproportionately higher number of cases in people who identify themselves as “coloured” than in those who self-identify as “black” reflects differences in their biological susceptibility to these diseases. He is, however, unsure of the underlying mechanism. In order to bolster the evidence for his hypothesis, Dr Chingana designs a survey to link symptoms of sexually transmitted infections with a variety of risk factors, including race¹³ and ethnicity¹⁴. He presents his protocol to his institution’s research ethics committee for approval.

Ms Johnson, a community representative on the committee who self-identifies as coloured, objects to the targeting of race in the survey. She argues that the coloured population is already stigmatized by stereotypes that portray them as promiscuous and lax in using health services. She contends that if higher rates of sexually transmitted infections are found in the coloured population these deeply held prejudices will be reinforced. Further, she is sceptical of the notion that being coloured increases one’s risk for contracting a sexually transmitted infection and asks for further explanation. Do the bacteria behave differently in coloured people? Is their anatomy different? She wants the race and ethnicity question removed from the questionnaire.

Dr Chingana argues that this question is critical to the study. Moreover, the findings might lead to further research that could result in programmes for control of these diseases and especially in reducing the high rate of infection among coloured people.

13 As used here, “race” refers to a group of people connected by common descent or origin.

14 “Ethnicity” here refers to the culture and/or collective identity shared by a group of people of common descent or origin.

Questions for Discussion:

1. What are the potential harms and benefits of the public health surveillance activity proposed by Dr Chingana?
 2. Dr Chingana may argue that he is simply collecting data and cannot be responsible for how his findings are used to incite stigmatization or stereotyping. Do you agree or disagree with this view? What reasons can you give to support your view?
 3. Let us assume that Dr Chingana proposes to carry out this survey without obtaining informed consent. He would ask the questions during his background interview with patients. He claims that this is necessary to ensure that all patients answer the questions and do so completely honestly. Would you approve this approach? Why or why not?
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Case Study 8: MDR-TB (p. 88)

Used in: Learning objective 3.2. Assess the factors to be considered in determining when public health surveillance requires explicit informed consent from individuals or communities

Source: Carl Coleman

Scenario:

The Republic of Coconut Paradise is a low-income island nation that has had high rates of TB. In the past few years, the rate of MDR-TB has been increasing dramatically. MDR-TB is highly contagious and often fatal; individuals who are thought to be infected are often shunned from their communities, and the household members of people with MDR-TB also face stigmatization. While there are some treatments for MDR-TB, they are not accessible to most people on the island. Most patients who are infected eventually die of the condition.

Public health officials concerned about the spread of MDR-TB have proposed to conduct tests on patients at the national TB centre to determine how many are infected with a drug-resistant strain. They consider that, by determining the actual rate of MDR-TB in the country, they will be in a better position to negotiate with international donors for assistance in obtaining treatment and improving local treatment facilities.

The officials propose to conduct the assessment by approaching a randomly selected sample of TB patients (one out of every 10 patients who attends the main site of the national clinic over a period of 2 months). Clinic staff will be instructed to take blood samples from these patients and to send them to the national reference laboratory, which will conduct testing to determine whether the patient is resistant to standard TB drugs. The samples will be identified only by the date on which they were collected; no patient names will be recorded. The results of the assessment will be reported in aggregate form. Because samples will not be identified by name, it will not be possible to report individual test results back to patients.

Questions for Discussion:

1. Is the activity described surveillance, research or both?
 2. What are the risks to the patients whose blood is taken for the survey?
 3. Should patients be asked to provide informed consent to the survey? If so, what information should be disclosed as part of the consent process?
 4. Should patients have the right to refuse to participate in the survey? (It may be useful to distinguish between "opt in" and "opt out" methods and explore when the latter suffice.)
 5. Should community consultation be instituted before the survey is initiated? If so, why? Who should be consulted, what should they be asked, and how should the information obtained be used?
-



Case Study 9: Intercultural Communication (p. 96)

Used in: Learning objective 3.3. Evaluate the measures required to protect privacy and confidentiality in an emergency

Source: *Ghaiath Hussein*

Scenario:

An emergency is occurring in a remote region of a country. This region is home to an indigenous tribe that has had disputes with neighbouring tribes about the use of water sources, on which their cattle are heavily dependent. As part of its relief intervention, an international nongovernmental organization decides to conduct a survey to assess the impact of the emergency in various villages to better target resource deployment. To do so, the organization recruits some of the more educated members of the local community and trains them to interview respondents and fill in the survey questionnaires.

The recently trained survey teams start collecting data from randomly selected villages in the affected region. As one of the teams is collecting data from an affected village, the members are stopped by the village leader because one of them is not from the same tribe. The leader accuses the individual of being biased and of collecting data that will help his or her tribe obtain additional aid from the nongovernmental organization. The leader asks the team to show him the filled questionnaires so that he can check the identity of the people who contributed to the survey to ensure that they are the neediest families in the village. He also asks the team to allow his assistant to attend all interviews with selected households. If the team does not comply with his requests, he threatens to stop the team from collecting data in the village.

Questions for Discussion:

1. Do you think that the team should comply with the requests of the village leader? Justify your choice on the basis of ethical principles.
 2. Describe how privacy and confidentiality would be breached if the team did comply with the leader's requests.
 3. Suggest two or three practical steps that should have been taken by the nongovernmental organization and the survey team before, during and after the survey to protect the privacy of the survey participants and the confidentiality of the collected data.
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Case Study 10: Influenza Virus (p. 102)

Used in: Learning objective 3.4. Describe specific measures required to protect and collect data and biological materials during public health surveillance

Source: Carl Coleman

Scenario:

During the past few weeks, isolated cases of a new, highly deadly strain of influenza virus have been reported in remote villages in the Republic of Coconut Paradise. In response, the Government of the country has contacted your organization, an international medical relief agency, for assistance in collecting biological specimens from village inhabitants. The specimens will be used to characterize the strain, assess its prevalence and modes of transmission and begin the work necessary to develop a vaccine.

The Government proposes door-to-door visits in the villages in which cases have been reported to request household residents to contribute a blood sample and answer some short questions on their current health status and behaviour (for example, where they get their food and water, where they work or go to school, whether they have recently attended large public gatherings). The answers to the questions will be kept with the specimens and identified by the date, time and general location of collection, but no names will be recorded.

Samples will be tested at a central Government laboratory, and the results will be correlated with the information obtained from the questionnaire. No information will be reported back to the individuals who provided the samples. Samples that test positive for the virus will be shipped to a commercial vaccine producer in Europe.

Questions for Discussion:

1. What should the household residents be told before they are asked to give blood or participate in the survey?
 2. Would it be possible to identify individuals who test positive for the virus? If so, what risks does this entail?
 3. Describe the safeguards that should be established to protect the privacy of the source of the biological materials.
 4. Should the test results be reported to the people who provided the samples?
 5. What conditions should be placed on use of the samples by the European vaccine producer?
 6. Should this project undergo ethical review and/or community consultation? If so, who should be involved in these processes?
-



Case Study 11: MDR-TB (p. 106)

Used in: Learning objective 3.5. Describe circumstances in which the common good might overrule individual autonomy during public health surveillance

Source: Michael J. Selgelid

Scenario:

John Jones was recently diagnosed with MDR-TB. He was prescribed second-line medication (on an outpatient basis) and advised to follow standard infection control measures. Further studies of his lung isolates revealed that the strain of *Mycobacterium tuberculosis* with which he is infected is possibly (and even probably) a rare, newly emerged strain of extensively drug-resistant TB that is especially virulent and contagious. The public health authorities therefore decided that John Jones should be isolated for further analysis, observation and treatment. When they tried to contact him, however, they were unable to do so. From their previous interactions with him, they had reason to believe that he was afraid of the possibility of isolation (He repeatedly said "I don't want to be locked up... please don't lock me up!") and that he thus might have gone into hiding. When it was impossible to locate him after 1 week, it was proposed that his name and photograph be sent to major media outlets (e.g. newspapers and television news providers) and that a public warning be issued, with instructions to notify the authorities if he is seen anywhere.

Questions for discussion:

1. Should John Jones's name and photograph be made public?
 2. How else might this case be managed?
 3. Some might argue that John Jones' actions are immoral and that it is thus less problematic to infringe upon his privacy or autonomy. If he actually has gone into hiding, would that be immoral? Is the morality of his action relevant to the question of whether his privacy or autonomy could permissibly be infringed under the circumstances?
 4. Suppose that, before a decision is made to publish his picture, further analysis reveals that other people infected with the same strain usually infected an average of one other person each month. Would this make publishing his photo more or less justifiable? What if it only one person was infected every 2 months or every 6 months or in 1 year? What would the average rate of infection of others have to be in order for it to be permissible to publish his photograph?
 5. If John Jones is eventually located, for how long (if at all) would it be ethically permissible to forcibly isolate him?
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Core Competence 4



Case Study 12: SARS in Toronto (p. 116)

Used in: Learning objective 4.1. Identify potential harm and benefit to individuals and communities resulting from conducting research in emergencies

Source: Naylor et al. 2003, Chapter 2

Scenario:

“In February 2003 a 65-year-old doctor who had treated atypical pneumonia patients in Guangdong [China] travelled to Hong Kong to attend his nephew’s wedding. By the time he checked into the Metropole Hotel, he was feeling unwell. The doctor infected at least 12 other guests and visitors from several countries, including a 78-year-old woman from Canada, Mrs. K S-C.

Mrs. K returned to Toronto on February 23, 2003 after a 10-day trip to Hong Kong... Two days after arriving in Toronto, Mrs. K developed a high fever, and by the time she visited her family doctor on February 28, she was also complaining of muscle aches and a dry cough. Mrs. K’s condition continued to deteriorate, and she died at home on March 5, 2003. Family members did not want an autopsy and the coroner thought it unnecessary. On the death certificate, the coroner listed heart attack as the cause of death.”

Sadly, shortly after her death, Mrs K’s son also became ill with similar symptoms. He died soon after. The virus quickly spread to people in emergency waiting rooms, hospital visitors and of course, hospital staff who would later comprise 40% of all patients infected with SARS.

SARS had an enormous impact on the entire civic structure of Toronto. People missed work as they were asked to self-quarantine and self-monitor, health workers were apprehensive about the risks to which they were exposed, and an entire school was closed because of a single student diagnosed with the SARS virus. Hospitals were put on hold until infection control could be established.

“Several interviewees noted the massive number of cancelled services, and suggested that the collateral casualties from the suspension of health care activities may never be fully measured. Other harms were more subtle, including hardship caused by restrictions on visits between families and patients hospitalized with conditions other than SARS.”

Possibly the greatest controversies during the outbreak in Toronto were related to surveillance and research. There were concerns about lack of collection of data and access to data about SARS cases. Data was not readily transferred in part because clinicians were not clear about the application of provincial privacy legislation regarding personal health information. There was wide uncertainty about the authority of overriding these laws for the purposes of public health surveillance, let alone research.

The nature and extent of the crisis meant that most qualified practitioners were just too busy treating patients to give any time to research. Protocols that might have been able to address epidemiological, clinical and biological questions still required funding support and Research Ethics Board approval. “Canadian

researchers were hamstrung by patient care and scientific advisory responsibilities, a lack of data, infighting about data access, limited research funds, and the need to obtain ethics approvals at multiple institutions.”

Canadian researchers did publish a small number of papers during the outbreak. Nevertheless, “on July 26, 2003, a major paper with multinational authorship was published in *The Lancet*, providing data in support of the proposition that the new SARS-associated coronavirus had met the criteria to be designated the causative agent of the new disease. Patient data were included from six countries: Hong Kong, Singapore, Vietnam, Germany, France, and the United Kingdom. No Canadians appeared among the 22 authors, and no Canadian patients were included in the study sample.”

Questions for Discussion:

1. Which principles were adhered to (or breached) in this case? Which were prioritized? Which were compromised?
 2. What benefits could be anticipated by researchers during this emergency? Which individuals were likely to benefit most?
 3. What risks were involved in this research? Who bore the greatest burden of risk?
 4. How could the burden of risks have been minimized (or better managed)?
-

Core Competence 5



Case Study 13: Tamiflu (p. 151)

Used in: Learning objective 5.2. Explain what is meant by “publication bias” and how it might affect the response to emergencies

Learning objective 5.3. Explain the ethical obligations of researchers, public health practitioners and publishers regarding ownership of scientific data

Source: Jefferson et al., 2009, p. 6

Scenario:

In 2003, a paper was published reporting the results of a study sponsored by F. Hoffmann-La Roche Ltd about the impact of treatment with oseltamivir (brand name, Tamiflu) on influenza-related lower respiratory tract complications and hospitalization. The paper reported that treatment of influenza with oseltamivir reduced lower respiratory tract complications, antibiotic use and hospitalizations for both at-risk and other adults (Kaiser et al., 2003).

This study involved the analysis of 10 separate phase-III randomized controlled trials sponsored by Roche, of which only two have been published in peer-reviewed journals. A subsequent report of a Cochrane review (Jefferson et al., 2009) claimed that there was insufficient evidence to determine whether oseltamivir is effective in reducing lower respiratory tract complications, antibiotic use and hospitalizations if the data from the eight unpublished studies mentioned in the initial paper were not included. Nevertheless, the evidence from the original study, along with many other relevant publications, has been used by public health decision-makers to justify recommending oseltamivir as a treatment option in combating influenza, including pandemic strains of influenza (Godlee & Clarke, 2009). This has led to stockpiling of oseltamivir for use during an influenza pandemic.

The authors of the Cochrane review concluded “[i]t is possible that there is a publication bias, especially as we know of eight trials that are unpublished and inaccessible [...] Its direction might be in favour of exaggerating the treatment effect” (Jefferson et al., 2009, p. 6).

Questions for discussion for Learning objective 5.2.:

1. Could this case study indicate a publication bias? Why or why not? What kind of publication bias might exist in this case?
 2. What could be done to prevent or mitigate the potential publication bias in this case?
 3. How could this case affect the response to an emergency?
-

Questions for further discussion:

1. What fundamentally drives publication? Is the motivation any different during an emergency?
2. How can questionable evidence of the effectiveness of a public health intervention (for example, the use of quarantine in response to an infectious disease like SARS), because of suggested publication bias, affect the justification for using that public health intervention?
3. Could publication bias occur in the publication of papers on the ethics of emergency preparedness and response? Might papers with conclusive answers to difficult ethical questions be published more easily or quickly?
4. If the trustworthiness of the evidence base upon which decisions are informed has been diminished by publication bias, how should decisions be made?
5. Should peer-reviewers or journal editors (or some other entity) have the opportunity to review study data?

Questions for Learning objective 5.3:

1. When considering whether a particular public health measure should be used to respond to an emergency, what data should be used? Should an attempt be made to include data that are unpublished or are tightly controlled by a researcher, study sponsor or research institution?
 2. If the mandate of research ethics boards is to weigh the benefits and risks of proposed human participation in research, can they be said to have met this obligation if data ownership and data secrecy create a barrier to public benefit?
 3. Can public health research be said to have scientific and social value if it is not accessible by the larger research community and the public? (Is research that is not published or otherwise disseminated a waste of resources, and thus unethical?)
 4. Do researchers, public health practitioners and publishers have different responsibilities for sharing different types of data (e.g. raw data versus cleaned data, qualitative observational data versus quantitative experimental data)? If so, how do these responsibilities differ? Consider the pathway(s) that different stakeholders might have to follow in order to share their data, given each stakeholder's distinct needs and constraints.
 5. Is dissemination of research data generated during emergencies to other researchers and the public a higher priority than dissemination of data generated in non-emergency scenarios?
 6. Is there a direct conflict between the requirement to publish and sharing data?
 7. Who should be responsible for developing protocols for data sharing?
-

Questions for further discussion:

1. What is the conflict in this case? What are the central arguments for and against making the data in question available?
 2. What might be the effect of not having full access to all data about the effectiveness of oseltamivir, in terms of both preparing for and responding to an influenza pandemic?
 3. To what extent should the following groups have access to all research data in this case? Should the access of any of the groups be limited? Why or why not? (Researchers, research institutions, research sponsors, publishers, practitioners, the public etc.)
 4. In your opinion, what responsibility does each of the following groups have with respect to data ownership and data sharing? (Researchers, research institutions, research sponsors, publishers, practitioners, the public etc.)
 5. If regulatory bodies, public health agencies and other government bodies are responsible (to any degree) for the safety and effectiveness of a measure used in response to an emergency (e.g. oseltamivir), to what extent should they be obliged to base their decisions about safety and effectiveness on all the data? If not all the data can be accessed, what responsibilities do these bodies have in making their decisions?
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Core Competence 6



Case Study 14: Triage (p. 179)

Used in: Learning objective 6.2. Understand how criteria for standards of care and treatment can be altered during emergencies

Source: Levin et al., 2009.

Scenario:

An influenza pandemic has been under way for 6 weeks, and the health care system has been burdened beyond capacity, with every hospital bed full, every ventilator in use and all health care providers working extended shifts. To increase the number of beds to accommodate the surge of influenza patients, all scheduled operations have been postponed for the past 2 weeks. The postponed procedures include diagnostic and palliative operations for patients with pancreatic cancer, ovarian cancer and malignant brain tumours. The expected survival of many of these patients is less than 6 months, but, without an immediate operation, they will probably die within 2 weeks. As a result of the pandemic, medical resources are scarce, and the usual critical care that would follow such operations could not be provided to all those who need it. Hospitals throughout the country are independently making decisions to modify the standards of critical care in order to provide limited interventions and processes for many additional patients.

Hospital A decides to provide critical care according to the usual standards on a first-come, first-served basis. Hospital B decides to provide important critical care interventions only to those patients who are expected to survive for more than 6 months.

A surgeon, Dr Smith, deeply opposes hospital B's decision. This new rule requires that Dr Smith cancel bowel obstruction surgery scheduled for later in the week. Without surgery, his patient, a 36-year-old mother of three with ovarian cancer, will die within 2 weeks. Dr Smith is considering whether to perform the operation in violation of hospital rules, potentially risking his career. In light of this disagreement with recent hospital policies, Dr Smith is torn between his professional mission to use his skills and expertise to help the patients who need him and his obligation to observe the rules of his institution.

This article illustrates that there may be no single correct course of action and that different stakeholders may have different views on the decisions to be taken.

Question for Discussion:

The facilitator asks each group to discuss the case and determine what Dr Smith should do (i.e. perform the operation in violation of hospital rules or not) and why?



Case Study 15: Influenza and H5N1 in Indonesia (p. 186)

Used in: Learning objective 6.3. Identify issues of benefit-sharing with communities under public health surveillance

Source: Dónal O'Mathúna

Indonesia reported the largest number of human cases of influenza A (H5N1) in the world between 2005 and 2007. Of the 116 cases, 94 (81%) were fatal. Viral outbreaks in poultry were reported in 31 of Indonesia's 33 provinces (Sedyaningsih et al., 2008), where 80% of poultry are kept in small backyards, the remainder being raised in industrial facilities. Poultry cannot be exported, under a World Trade Organization agreement, because of the presence of a highly pathogenic infection in the national flock.

In 2007, Indonesia announced that it would no longer send avian flu samples to WHO collaborating centres (Fidler, 2010). A number of countries argued that poorer nations were contributing virus for the development of pandemic vaccines without reaping any benefits, because the resulting vaccines were unavailable or unaffordable. They alleged that higher-income countries were profiting from such arrangements and using the donated virus to develop biological weapons (Holbrooke & Garrett, 2008).

Although the argument was made that the viruses belong to the common heritage of humankind and should be shared with the rest of humanity for their good, Indonesia's then Minister of Health, Dr Siti Fadilah Supari, used the notion of "viral sovereignty" to support her argument (Holbrooke & Garrett, 2008). The Convention on Biological Diversity supports the rights of countries to ownership and patents of indigenous plants and botanicals, and Dr Supari claimed that viruses fall into this category and that the International Health Regulations (2005) require sharing only of information and facts, not biological samples. Others claim that viruses are distinct from other biological resources as they naturally spread beyond national boundaries. Furthermore, the potential risk of harm from a global pandemic overrides any notion of "viral sovereignty."

When it was suggested that Indonesia had an obligation to the rest of humanity, Indonesian officials countered that the global community had an obligation to the people of Indonesia, as the country would probably be severely affected by any pandemic.

Questions for Discussion:

1. How could Dr Supar's position that Indonesia should withhold avian flu samples be ethically justified?
 2. Using the language of ethics, how would you justify the position that a country has an obligation to participate fully in global viral surveillance, including sharing viral samples?
 3. Using the language of ethics, how would you justify the position that vaccine manufacturers have an obligation to share the benefits of their products with those who contributed to their development?
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Case Study 16: Post-exposure Protection for Ebola Patients (p. 194)

Used in: Learning objective 6.4. Identify issues of equity of access to unproven treatments during research in the course of emergency response

Source: Tuffs, 2009.

A scientist from the Bernard Nocht Institute for Tropical Medicine in Hamburg who was quarantined for a week because of a possible infection with the Ebola fever virus has left the isolation ward of Hamburg University Hospital. She has been transferred to a normal ward, because she had no clinical signs of infection, and neither the virus nor any antibodies against the virus were found in her blood.

This positive development may be due to the use of an experimental vaccine given to the scientist that has never previously been used in humans. The vaccine virus was found in her blood shortly after vaccination but vanished within two days, indicating that the patient's immune system had eliminated it.

"She is currently doing well," said Stephan Günther, head of virology at the Bernhard Nocht Institute. "However, the Ebola virus can have an incubation period anywhere between four and 21 days, which means she could still fall ill."

The dangerous virus is named after the Ebola River in the Republic of Congo, near where the first recognized outbreak occurred in 1976. Several outbreaks have since occurred, mainly in central Africa.

On 12 March the Hamburg scientist, who had been working in a high security laboratory on a project to produce antibodies against the Ebola virus, had pricked herself through three layers of safety gloves with a needle containing the virus. The particular virus type is lethal in 90% of infections.

The benign outcome may have been aided by the swift reaction of the international Ebola research community, members of which were contacted by colleagues of the Hamburg scientist. Within 48 hours the scientist was given an experimental attenuated live vaccine against the virus, which had been shown to be effective in monkeys but which had not yet been tested in humans.

The vaccine was developed by Heinz Feldman and former colleagues at the National Microbiology Laboratory of the Public Health Agency of Canada, in Winnipeg, Manitoba, along with Boston university virologist Thomas Geisbert, who tested it in macaque monkeys at the US Army Medical Research Institute of Infectious Diseases, Frederick, Maryland.

About 12 hours after vaccination the Hamburg scientist developed a fever and headaches and other clinical signs typical of a reaction to a vaccine, which have subsided since.

Questions for Discussion:

1. On what moral grounds was the Hamburg scientist offered investigative treatment? Is this a case of compassionate use?
 2. Could “humanitarian” reasons be put forward to justify the effort of shipping the post-exposure vaccine from Canada? If yes, could reciprocity be the moral criterion (“The scientist made the sacrifice of risking her life by choosing to study a highly lethal agent. In return, the community should make all efforts to save her life in case of accidental exposure.”)?
 3. When local health workers are exposed to needle-stick injuries in the course of an Ebola virus disease outbreak in Africa, should they be given the same opportunity of receiving a potentially life-saving treatment? Do the same moral grounds apply (e.g. “Are they any less or more worthy of reciprocity?”)?
 4. If the investigative treatment is made available during an outbreak, should its use be restricted to the boundaries of a defined clinical trial? Or should it be made available on compassionate grounds, as in the case of the Hamburg scientist?
 5. If a trial is the only acceptable solution, what design should be used? For example, consecutive series with historical comparisons or a placebo-controlled trial?
 6. Ultimately, who are the main or intended beneficiaries of research on treatment for filovirus infection?
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Case Study 17: AIDS Trial (p. 211)

Used in: Learning objective 7.2. Explain what is meant by “therapeutic misconception” and how it could affect the duties of health care workers in emergencies

Source: Elysee Nouvet, Lisa Schwartz and Michael Baxter

Scenario:

AIDS develops from infection with the HIV lentivirus. Although it was first identified clinically in the United States in 1981, tissues tested from as far back as 1959 in central Africa have been shown to carry the virus (Zhu, 1998). HIV is spread easily through fluid exchange, and exposed individuals are more vulnerable to AIDS. In the 1980s and early 1990s, AIDS was identified mainly with specific marginalized populations, such as intravenous drug users, sex workers and men who have sex with men. This is no longer the case: women and children, particularly in low- and middle-income countries, are bearing an increasing proportion of the global burden of AIDS due to social determinants of health and cultural practices.

As HIV/AIDS patients are immunocompromised, they often present with a number of opportunistic infections, or infections that would not be sufficient to cause disease in a healthy person. One such disease is pneumocystis pneumonia (PCP), an infection caused by a fungus that does not normally cause symptoms in people with functioning immune systems (Morris et al., 2004). Although HIV/AIDS is a serious public health issue, efforts to develop a vaccine have been relatively unsuccessful because of the high rate of viral replication. Therefore, despite the availability of antiretroviral treatment (ART) for managing symptoms, many patients eventually become resistant to the medication and die from AIDS-related complications.

Justin is a 38-year-old bartender who lives in downtown Los Angeles, USA. He is a long-time, chronic user of intravenous drugs. Justin has always done his best to use clean needles, but nearly 15 years ago he acquired HIV from an unsterile heroin injection. Justin’s symptoms have been managed to date with various “cocktails” of ART therapy, however the HIV virus in his body has been slowly developing resistance over the years to many of the drugs used in these ART cocktails. Justin recently developed a serious flu-like illness, and during an appointment with his physician, he was diagnosed with a PCP infection. This meant that the HIV virus in his body had become resistant to the newest drug in his ART cocktail, and that the virus had decreased Justin’s immune system to a dangerously low level. Unfortunately, Justin had now exhausted the last effective combination of ART therapy.

Desperate for further treatment options, Justin urges his physician to find another solution to manage his disease. Justin’s physician proposes that he enrol in the hospital’s phase-III clinical trial of a new antiretroviral cocktail, of which the physician is a primary investigator

Questions for Discussion:

1. In what ways does this case create the possibility for therapeutic misconception?
 2. What strategies could the physician have used to decrease the possibility of therapeutic misconception—if it is avoidable?
 3. If Justin appears to be incapable of differentiating between his participation in research and his treatment, would the doctor's most ethical course of action be to deny his patient access to the study? Why or why not?
 4. Are there circumstances in which the therapeutic misconception is ethically tolerable?
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Case Study 18: AIDS Epidemic (p. 219)

Used in: Learning objective 7.3. Explain the potential conflicts of interest of health care workers participating in emergency research activities

Source: Cash et al. (2009, pp. 168–9)

Scenario 1

The staff-benefits group of a West African mining company asks a research team based at a European university to help determine the economic impact of the AIDS epidemic on their workforce. The group wants to convince senior management that the cost is much higher than expected. They suspect that absenteeism due to AIDS, rapid turnover of highly trained and semi-skilled staff (leading to re-training costs), treatment costs for the illness, one-time benefits and funeral costs to the families of affected workers have been underestimated.

The research centre puts together a team consisting of a physician, an economist, a public health specialist and a research associate and travels to the country for 3 weeks of intensive fieldwork and investigation. At their request, the team is given access to the records of all employees who had to leave the company because of AIDS or AIDS-related illness. Any data that could identify individual employees are removed from the records. No data on the prevalence of infection exist in the company, but sample surveys have been done in other parts of the country to examine the rates of HIV infection in similar age groups.

Scenario 2.a

The staff-benefits group hopes that, if they demonstrate the costs of the epidemic, the company will provide more preventive programmes, such as distribution of pamphlets, lectures at the workplace and recreational activities for single men who live at the company hostels, some of whom frequent a nearby area with a high concentration of commercial sex workers. Preventive and educational services could also be provided to the families of married workers. Other interventions might include establishment of clinics to treat sexually transmitted infections more aggressively or long-term provision of family housing units. The staff-benefits group believes that a report from a well-respected university research group will be an effective way to influence company policy and promote preventive programmes.

Scenario 2.b

The research team will be fully funded by the company, including overhead payments commensurate with university guidelines. The company has stated that it will not restrict the researchers' ability to publish the study findings, although it will require that the company and all its employees remain anonymous in any reports or publications.

As data collection nears completion and the research team prepares to return home to analyse the data and prepare the report, a senior member of a trade union requests a private meeting. He expresses concern that the company will not use the results of the study to improve public health programmes but will instead conclude that anyone who is HIV-positive will be too costly to retain and that therefore even HIV-positive individuals who are still healthy will be released on some pretext. Although the company is barred from testing new employees, it can require that employees obtain private health insurance, which often requires

an HIV test. Finally, he states that the company will probably cut back its workforce (and therefore decrease its liability) by downsizing and outsourcing.

The team members request a meeting with the sponsors of the research and, without disclosing their source, express their concern that the report could be used for purposes that are contrary to their intentions. The company insists that any rumours they may have heard about misuse of the report are untrue. However, the research associate is not satisfied with the company's explanation and asserts that, unless the company provides an assurance in writing, she will immediately withdraw from the project. The company says that it cannot sign such a statement, as doing so would reflect badly on the integrity of the organization.

The research team analyses the data and presents the following conclusions to the management of the company before publication:

- The prevalence of HIV infection in the general population will probably mean an employee turnover rate of at least 10% per year for the company.
- The health care costs for the company will increase significantly over the next 5 years and could constitute 15% of its total operational costs. By law, if an employee's illness is diagnosed while he or she is working for a company, all the health care costs related to that illness must be paid by the company, whether or not the illness is work-related.
- To reduce costs, the company should begin a home-treatment programme for employees with AIDS.
- Prevention programmes would almost certainly reduce the incidence of HIV infection among employees, although the cost-effectiveness of these programmes is not known.

Scenario 2.c

Managers at the company are alarmed by the report and by the projected costs of caring for HIV-positive employees. The chief executive officer says that, if the company is forced to take on the health care costs of all employees who become HIV-positive during their employment, it will be unable to compete in the international market and will be forced to declare bankruptcy or relocate to a lower-cost country that does not make the same demands. In either case, everyone at the company will lose their job, leaving many households without any income.

He asks that the research team take this issue into account in writing their conclusions. In fact, he asks the team to recommend that employer-subsidized health insurance plans be allowed to cap benefits for HIV infection at far less than the cost of the treatment needed. Employees with HIV infection would then either pay for their own treatment, forgo treatment or rely on publicly provided services. Households and extended families would probably bear the brunt of the costs, as the health care facilities of government and nongovernmental organizations are already overwhelmed with HIV/AIDS patients. The chief executive officer argues that transferring the costs to the government, households and other companies is a rational response for a profit-maximizing business. Given the international reputation of the research team, he expresses confidence that a report that recommends a cap on benefit will persuade government regulators to change their policy.

Questions for Discussion:

1. After each addition of contextual information (Scenarios 2a–2c), discuss the following questions:
 - a. How do the new contextual elements affect your analysis of Scenario 1?
 - b. Are there emerging conflicts of interest (actual and/or potential)?
 - c. Can you briefly discuss the risks associated with these emerging conflicts of interest?
 2. What lessons can be learnt from ethical analysis of the case about how things could have been managed differently to avoid the problems identified?
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