

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?
-



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?
-

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
-

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?
-



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.
-



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?
-

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?
-

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?
-



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?
-



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?
-



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?
-