Journal of Hospital Infection 86 (2014) 90–94

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Structuring our response to hospital outbreaks under conditions of uncertainty

Michael R. Millar*

Department of Infection, Royal London Hospital, Barts and the London NHS Trust, London, UK

ARTICLE INFO

Article history:
Received 30 July 2013
Accepted 3 November 2013
Available online 1 December 2013

Keywords:
Outbreaks
Precautionary
Uncertainty

SUMMARY

Background: Sometimes decisions have to be made even when we do not have all of the information that we would like to have. It is not uncommon for infection control professionals to be faced with an outbreak of colonization or infection while there is uncertainty about the impact of the outbreak on patient outcomes. How do we decide a proportional response when we do not know the seriousness of the outbreak?

Aim: The precautionary approach has become established in the European Union (EU) as a way of structuring responses to potentially serious threats (such as novel pandemic influenza viruses) when there are substantial uncertainties about the true impact of the threat. The potential of this approach to help with structuring responses to outbreaks involving substantial uncertainties is considered in this article.

Methods: The EU approach requires that actions should be proportional, non-discriminatory, consistent, take account of costs and benefits, be subject to review, and that the responsibility for producing the scientific evidence to fill critical information gaps is assigned. The example of management of outbreaks with multidrug-resistant *Acinetobacter baumannii* is used here to illustrate how the precautionary approach might be used in infection prevention and control.

Findings and conclusion: The precautionary approach has potential to provide a structured response to outbreaks of hospital infection when there is uncertainty about the impact of the outbreak on outcomes. Most importantly there is a requirement that we specify which risks we are prioritizing for control, the information that is uncertain but critical to informing decisions, and the responsibilities for gathering that information.

Introduction

A recent report from the charity Sense about Science was entitled *Making sense of uncertainty*.[1] The main emphasis of the report was on the importance of acknowledging the inevitability of uncertainty in science. Infection control professionals are frequently confronted with having to take action without having all of the information that they would like to have. Lipsitch *et al*. capture this quandary when they state that:

> Early action is required, but decisions about action must be made when the threat is only modest — and consequently, they involve a trade-off between the comparatively small, but nearly certain, harm that an intervention may cause (such as rare adverse events from large-scale vaccination or economic and social costs from school dismissals) and the uncertain probability of much greater harm from a widespread outbreak. This combination of urgency, uncertainty, and the costs of interventions makes the effort to control infectious diseases especially difficult.[2]

* Address: Department of Infection, Level 3, Pathology and Pharmacy Building, Royal London Hospital, 80 Newark Street, Whitechapel, London E1 2ES, UK. Tel.: +44 (0) 203 2460296; fax: +44 (0) 203 2460303.
E-mail address: Michael.Millar@bartshealth.nhs.uk.

0195-6701/$ — see front matter © 2013 The Healthcare Infection Society. Published by Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.jhin.2013.11.006

There are many different types and classifications of uncertainty; for example, some distinguish aleatoric from epistemic uncertainty. Aleatoric refers to the uncertainty associated with complex systems such as predicting the evolution of the human microbiome, or the impact of CO_2 emissions on global warming – systems in which random and unpredictable effects are intrinsic to the system. Epistemic knowledge refers to that which we can come to know, for example estimates of how many people will succumb to a new strain of influenza virus. The focus of this paper is those hospital infection scenarios in which the impact (on patients, and the institution) of doing something or nothing is uncertain. There is a risk of a serious adverse outcome but that risk cannot be estimated with any degree of accuracy.

At the outset of an outbreak investigation there is often uncertainty about the clinical significance of the outbreak. *Acinetobacter baumannii* is a frequent focus for outbreak investigations.[3] The impact of multidrug-resistant (MDR) *A. baumannii* colonization and infection on outcomes for patients in intensive care units is controversial.[4–6] It is not clear that antibiotic resistance influences the risk of death associated with MDR *A. baumannii* infection.[7–9] This may be because the antibiotics that are effective *in vitro* are ineffective *in vivo*, or because the determinants of adverse outcomes are not directly related to colonization or infection with MDR *A. baumannii*. Variations in the virulence of dominant strains and the characteristics of study groups may also contribute to variations in outcome.[10–14]

The uncertainty about the impact of outbreaks of MDR *A. baumannii* on patient outcomes has probably contributed to the widely differing approaches to the management of outbreaks.[15] Uncertainty engenders anxiety and responses vary from person to person depending on experience, how the problem is framed, the perspective of decision-makers, and culture.[16] One way of structuring our response(s) to outbreaks in the presence of uncertainty is to follow the template of the European Union (EU) precautionary approach.[17]

Precautionary approach

The precautionary principle came to prominence following the Rio Declaration on environmental policy in 1992. Principle #15 states that 'Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'[18] The key message of the principle is that scientific uncertainty should not preclude preventive action when there is a threat of serious or irreversible damage if no action is taken.[19]

The precautionary principle now informs many areas of policy and practice across the world, for example in public health, in transfusion medicine, in EU food safety legislation, occupational health and in influenza pandemic preparedness.[20–26] Recent guidelines from the Chief Medical Officer in England on reducing the risks of infection associated with the preparation of infant formula also emphasize a precautionary approach.[27]

The EU approach is an attempt to give a structured approach to decision-making once it has been decided to take preventive action in the presence of uncertainty. The particular focus of the EU precautionary approach is the management of potential risks under conditions of uncertainty rather than risk assessment or risk communication. 'Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty.'[17]

A precautionary approach to hospital outbreaks

The EU precautionary approach is designed to avoid 'paralysis by analysis' when there is uncertainty about the seriousness of a threat.[17] A precautionary approach can only be invoked when there are both good reasons to believe that there is potential for serious harm and when the risks are uncertain. The precautionary approach should not be invoked when there is sufficient information to enable a full risk assessment. For many outbreaks there is sufficient information for a risk assessment: quite a lot is known about the risks of uncontrolled meticillin-resistant *Staphylococcus aureus* (MRSA) in a neonatal unit or chickenpox in an oncology unit, so it would be inappropriate to invoke the precautionary principle for these types of problem.

The EU guidelines suggest that measures based on the precautionary principle should be proportional, non-discriminatory, consistent, based on an examination of the potential benefits and costs, subject to review, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.[17] The EU approach describes a process and is not in itself a decision rule. The EU approach requires that why a particular course of action is decided upon is specified. An example of the EU approach was the decision to ban virginiamycin and bacitracin from animal feeds. The European Court of Justice (2002) concluded 'that despite uncertainty as to whether there is a link between the use of those antibiotics as additives and the development of resistance to them in humans, the ban is not a disproportionate measure by comparison with the objective pursued, namely the protection of human health.'[28] The reason for deciding on the ban is the threat to human health. The uncertainty that needs to be addressed before the decision can be reviewed or revoked is the link between the addition of antibiotics to animal feeds and antibiotic resistance in humans.

Proportionality

To gauge a proportional response it needs to be decided what and/or who is at risk, and the potential significance of the threat. Box 1 lists some considerations relevant to a proportional response.

Box 1
Proportionality: some considerations

- What are the risks, how serious and how likely?
- What are the uncertainties?
- Who or what is at risk?
- What are the available and feasible options to mitigate the risks?
- What are the risks, costs and benefits associated with these options?