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Review

BSE and variant CJD: Emerging science, public pressure and the vagaries of policy-making☆

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ABSTRACT

Classical bovine spongiform encephalopathy (BSE) was first recognized in 1987 in the United Kingdom and ultimately spread to cattle across Europe and to the Middle East, North America and Japan through the movement of infected animals and contaminated meat and bone meal. The human expression of BSE, variant Creutzfeldt–Jakob Disease (vCJD), likewise was first identified in the UK and now has been observed in many countries due to human exposure to BSE contaminated products or to vCJD contaminated human tissues through transplantation and injection. BSE provides an example of an emerging infectious disease that demonstrates the challenges of policy-making in the face of rapidly changing science and public outrage pushing for action. Lessons learned through the BSE epidemic include: (1) beware of facts as new science continues to emerge; (2) complex issues rarely have simple solutions; (3) evaluate epidemics from a macro-epidemiologic perspective to understand their complexity and devise effective risk management strategies; (4) options always exist for prevention/control; (5) risk communications play a vital role before and during an emerging disease epidemic; and (6) risk management progress involves both science and politics. Adoption of One Health approaches involving systems thinking and shared leadership hold the most promise for effectively managing complex emergency global health issues like BSE.

1. Introduction

In 1989 the Chief Veterinary Officer of the USA asked me to organize a country-level risk assessment for Bovine Spongiform Encephalopathy (BSE), a new and emerging disease described 2 years earlier in the United Kingdom (Wells et al., 1987; Wilesmith et al., 1988). Thus began my more than 20 years of active involvement with BSE as an epidemiologist, risk analyst, government policy-maker, consultant, expert witness, educator and communicator. Twenty years working at the interface of science, politics and beliefs provided me insights into the dynamics of policy-making where the science is continually changing and public pressure is pushing for government action. Six 'lessons learned' from BSE will be illustrated: beware of 'facts'; complex issues rarely have simple solutions; evaluate epidemics from a macro-epidemiologic perspective; options always exist for prevention/control; risk communications play a vital role; and risk management progress involves both science and politics. These lessons learned illustrate some of the many challenges faced in responding to emerging infectious diseases of global concern.

2. Beware of 'facts'

Bovine Spongiform Encephalopathy (BSE) is now recognized as a neuro-degenerative disease of cattle that also can affect a number of other ruminants, primates and

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humans. BSE is classified as one of a family of diseases of humans and other animals called transmissible spongiform encephalopathies. Our knowledge of BSE continues to evolve, hence the 'facts' of the disease change. Change is the norm for science; the scientific method is an ongoing process of data collection and testing of hypotheses. Counter intuitively, the scientific method does not prove facts; facts simply represent the prevailing hypotheses that have not been refuted. However, the scientific method of conjecture and refutation can be difficult to explain to non-scientists so that changes in the facts appear to undermine credibility in media communications and policy-making where well-intentioned spokespersons want to demonstrate certainty and convey that the situation is under control. Thus, scientific facts can be represented as dogmas when in fact they simply represent the best available hypothesis.

The history of BSE demonstrates evolving science, where dogma was later disproven or revised as more evidence emerged on causation, host specificity and distribution. In 1987 when BSE was first recognized as similar histopathologically to scrapie in sheep, a 'slow virus' was the prevailing hypothesis regarding the etiologic agent of scrapie. Stanley Pruisner's prion hypothesis (1982) was met initially by skepticism and ridicule – "proteins can't cause infectious diseases". Accumulated evidence from epidemiology and bench science ultimately corroborated the prion hypothesis, although this too may change in the future as more evidence is collected. Other examples of the evolving science refuting earlier facts include host specificity ("BSE is a cattle disease that does not affect humans"), transmission dynamics ("the minimum infective dose is X") and the distribution of the disease ("Country X has no BSE" and "We won't get BSE here. . ."). In each case, the prevailing scientific facts were rejected and replaced by a new working hypothesis as a result of more complete understanding of the disease and its dynamics.

Current scientific knowledge is critically important for optimal prevention and control of emerging diseases. However, policy decisions cannot wait until all the relevant scientific questions are answered. The science of emerging diseases evolves rapidly, so much so that the rate of scientific discovery usually outpaces legislative and regulatory processes, resulting in situations where laws and regulations are based on outdated scientific knowledge. Caution must be exercised in creating prescriptive legislation and regulations, those that explicitly define the requirements and methods needed for compliance, even when the evidence appears indisputable. Descriptive policy instruments work better in the face of rapidly changing science. Descriptive policy instruments define the overall policy objectives and outline how scientific evidence will inform the policy implementation. Consequently, they provide flexibility to adapt as new evidence and understanding emerge. For example, specifying by regulation the exact diagnostic test, how samples are to be collected and the number of samples for a surveillance program fails to account for the continual progress being made in diagnostic tools and surveillance strategies. Describing the level of certainty needed by the surveillance system allows the utilization of new testing methods and surveillance designs as they become available. In the case of BSE, requiring that the surveillance system meet or exceed the international standards developed by World Organization for Animal Health allows the surveillance design and test methods to evolve as the global standards are updated.

3. Complex issues rarely have simple solutions

While the disease BSE can be described fairly simply, control of the global BSE and related vCJD epidemic was complex. The etiologic agent of BSE may be described simply as prion particles but the determinants of the global BSE epidemic are numerous and include genetic improvement of cattle and the search for high quality protein sources, feed formulation and industry consolidation, and international trade of cattle and feed ingredients.

The early epidemiologic investigations led by Wilesmith (1988) pointed to rendered animal protein product meal and bone meal as the primary transmission vehicle for BSE. Exquisite exposure experiments concluded that most BSE infectivity was concentrated in the cattle brain and spinal cord with lesser amounts in distal ileum and nerve bundles such as the spinal ganglia (Wells et al., 1998). Hence the simplest risk management strategy for cattle feed appeared to be prohibition of the use of cattle brain, spinal cord, spinal ganglia and distal ileum as raw material for rendering. While this was scientifically sound as a prevention strategy, it proved to be impractical. Complete removal of these specified risk materials from dead cattle is nearly impossible under commercial conditions. Further, no quick and reliable test was available to assure that the finished meat and bone meal (MBM) was free of these specified risk materials. Completely preventing cattle exposure to contaminated meat and bone meal has proven to be difficult once BSE is widespread in the population. Ultimately, prohibition of all mammalian meat and bone meal in ruminant feeds was implemented in the most affected countries until additional controls could be put in place such as segregating rendering facilities by raw material type so that only rendering facilities handling no ruminant raw materials could provide MBM for cattle feed use.

Trade of infected cattle or contaminated MBM represents the largest risk for international spread of BSE. Early in the development of the global BSE epidemic many countries focused their attention on restricting imports of British cattle and MBM. Unfortunately, these simple control approaches provided false assurance to many countries. Restricting imports was complicated by three factors: (1) the lack of identification systems so that imported animals or MBM could be tracked, (2) transshipment of cattle and MBM through third countries, e.g., imports which entered from an intermediate country that had received them from the UK, and (3) the lack of test methods to assure the absence of ruminant-derived MBM from imported feedstuffs.

Simple solutions are appealing because they can be explained easily and make intuitive sense. In practice, however, simple solutions rarely work effectively for complex problems. Often the purported simple solutions simply make the situation worse by creating a false sense of security.