Introduction

Human mycoses are infections of the skin or underlying tissues caused by fungi. These can be superficial, as in the case of athlete’s foot, or progressive deep-seated infections, such as invasive aspergillosis, leading to disseminated infections with high levels of morbidity and mortality if not accurately diagnosed and treated. The frequency of human mycoses caused by environmental fungi (those whose usual habitat is the natural environment) has increased dramatically over the past two decades. This increase is directly related to the expanding patient populations at risk of developing invasive fungal infections (IFI), which include the elderly, premature babies, solid-organ and haemopoietic stem cell recipients, individuals with advanced AIDS, neutropaenia, chronic granulomatous disease, and those receiving immunosuppressive drugs or aggressive anticancer therapies. In addition to the well-known opportunistic pathogen Aspergillus fumigatus, other species of filamentous fungi (moulds) have emerged as serious pathogens of humans over recent years, including the zygomycetes and ascomycete fungi, including members of the Pseudallescheria complex (Scedosporium apiospermum, Scedosporium aurantiacum and Pseudallescheria boydii), Scedosporium prolificans and the Fusarium solani species complex (Figure 1).

The saprotrophic lifestyles of these fungi enable them to utilize a wide range of substrates in the natural environment, and they are common microbial components of soil, compost, sewage, decaying plant material, polluted water and eutrophic habitats. As soil saprotrophs, they play an important role in carbon and nitrogen recycling in terrestrial environments. The ability of Aspergillus fumigatus to grow at temperatures exceeding 37ºC means that it is a major microbial component of the high-temperature phase during composting, although there is no evidence to suggest that the increase in disease caused by this organism is related to composting activity. A number of studies have shown that indoor hospital air is a frequent source of infective Aspergillus spores, particularly during indoor renovation and demolition and building at nearby sites, and measures to reduce inoculum load in the hospital environment can diminish the incidence of disease caused by this pathogen.

Fusarium spp. are ubiquitous soil saprotrophic fungi and are an important group of plant pathogens. Most localized and disseminated infections in humans are caused by the F. solani species complex, followed by members of the Fusarium oxysporum complex (FOC). Strains of a clonal FOC lineage recovered from patients were conclusively shown to genetically match those from the hospital water systems of three U.S. hospitals, providing support for the hypothesis that hospitals may serve as a reservoir for nosocomial fusarial infections. While potted plants in hospitals have been identified as reservoirs of Aspergillus, Fusarium and Scedosporium spp., the natural ecological niches of Pseudallescheria and Scedosporium spp. have yet to be defined. Nevertheless, recent studies have reported a possible association between human activities and prevalence in soil.

Environmental fungi as a cause of human mycoses

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Figure 1: Gross morphology of human pathogenic fungi grown in axenic culture on malt extract agar. Clinical isolate of Aspergillus fumigatus (strain AF293)(A), environmental isolate of Rhizopus oryzae (strain CBS112.07)(B), and clinical isolate of Fusarium solani (strain CBS24.34)(C). Bar = 1.5cm.
A study performed in Austria and The Netherlands found that *Pseudallescheria* and *Scedosporium* spp. were most abundant at industrial sites, followed by urban playgrounds and agricultural areas, but were absent in nature reserves. Abundance was correlated with increasing nitrogen concentrations and decreasing pH, with a pH range of 6.1–7.5. A study conducted in Sydney, Australia, indicated that a species-specific association might exist within areas of high human activity, hinting of a possible link between the environment and the emergence of infections caused by these fungi. Thornton found that *P. boydii* was present at high densities in estuarine sediments, along with *S. apiospermum* and *S. prolificans*. The presence of these fungi in an area of low human impact may be due to the large populations of migratory waterfowl and wading birds that frequent the mudflats at low tide and contribute to the high nitrogen concentrations of the sediments in the form of guano, which is known to attract human pathogenic fungi, most notably *Histoplasma capsulatum*, but also *P. boydii*. Zygomycetes are ubiquitous soil saprotrophs, common contaminants on rotting fruits and vegetables and are important post-harvest pathogens. While *Rhizopus oryzae* is the most important cause of human zygomycete infections, it is used in the production of Tempeh, a traditional Indonesian food made from fermented soybeans.

**Pathology of invasive fungal infections**

*Aspergillus* and *Fusarium* spp. and members of the *Pseudallescheria* complex are agents of ‘hyalohyphomycosis’, a term used to describe infections caused by hyaline, septated, fungi in infected tissues. *Aspergillus fumigatus*, second only to *Candida* as the cause of nosocomial fungal infections, is a pulmonary pathogen causing allergic bronchopulmonary aspergillosis (a hypersensitivity reaction occurring in asthma and cystic fibrosis (CF) patients) or aspergilloma (fungus ball) in pre-existing lung cavities. However, the fungus can also invade the lung tissue, resulting in a disease known as invasive pulmonary aspergillosis. This disease is now a major direct or contributory cause of death in patients with haematologic malignancies and in haemopoietic stem cell and solid-organ transplant recipients. *Fusarium* spp. have long been associated with infections of the skin, nail and cornea, but are now becoming increasingly recognized as a cause of invasive fungal infection (fusariosis) in neutropaenic patients and in those undergoing transplantation. Indeed, some hospitals have reported *Fusarium* to be second only to *Aspergillus* as the cause of life-threatening filamentous fungal infections in their transplant patients.

*Pseudallescheria boydii* is the causative agent of white grain mycetoma in immunocompetent humans, and is the most prevalent species after *A. fumigatus* in the lungs of CF patients, where it causes allergic bronchopulmonary disease and chronic lung lesions simulating aspergillosis. Near-drowning incidents and recent natural disasters, such as the Indonesian tsunami in 2004, have shown *P. boydii* and the related species *Scedosporium apiospermum* and *Scedosporium aurantium* to be the causes of fatal nervous system infections and pneumonia in immunocompetent victims who have aspirated polluted water. Its significance as a potential pathogen of disaster evacuees has led to its recent inclusion in the Centers for Disease Control and Prevention list of infectious agents in persons with altered mental statuses, central nervous system syndromes or respiratory illness. *Pseudallescheria boydii* and the related species *Scedosporium prolificans* have also recently emerged as significant invasive pathogens, particularly of immunocompromised patients, and now account for ~25% of non-Aspergillus infections in organ transplant patients. The zygomycetes are predominantly asceptate fungi, and while a number of species are capable of causing infectious diseases in humans (*Rhizopus, Rhizomucor, Absidia* and *Cunninghamella* spp.), *Rhizopus oryzae (arrhizus)* is the most important agent of zygomycosis in patients that have serious underlying conditions, such as diabetes mellitus, malnutrition, advanced AIDS, intravenous drug abuse, severe burns, or other major trauma. Invasive fungal infections caused by *Aspergillus* spp., zygomycetes and *P. boydii* have also recently been reported as a devastating complication of commercial renal transplantation.

**Diagnosis of invasive fungal infections**

Opportunistic mycoses represent formidable diagnostic challenges. It is imperative that diagnosis is made without delay, since prognosis worsens significantly in the absence of accurate identification and timely intervention with antifungal agents. There is no ‘gold standard’ for diagnosis of invasive fungal infections, and so diagnosis currently relies on a combination of data from clinical and radiological sources and from mycology and histopathology where feasible. Unequivocal proof of an IFI requires that data from histopathology, cytology, direct microscopy, and detection of antigen and cell wall constituents conforms to the European Organization for Research and Treatment of Cancer/Invasive Fungal Infections Cooperative Group and the National Institute of Allergy and Infectious Diseases Mycoses Study Group (EORTC/MSG) consensus defining “proven”, “probable”, and “possible” invasive fungal infections. Currently, no nucleic acid-based tests have been developed and externally validated for IFIs, and so, positive polymerase chain reaction (PCR) for blood, tissue or bronchoalveolar lavage (BAL) fluid for a specific fungus is not considered microbiological evidence of invasive fungal disease.

Identification of fungi in histological sections is problematic because of similarities in hyphal morphologies and while identification may be possible from direct observation of spores or spore-bearing structures, definitive identification requires isolation of the etiological agent in pure culture. Once in culture, fungi can be identified by microscopy, but fastidious organisms, such as the zygomycete *Saksenaea vaniformis*, require specialist procedures to stimulate sporulation. This delays identification, and so, rapid and specific diagnostic assays using PCR and monoclonal antibodies (MAbs) have been developed that allow identification of infectious agents in culture and in experimentally infected tissues. Culture-based approaches rely on the availability of biopsy samples, but these cannot always be obtained from sick patients. Furthermore, the samples may not yield viable propagules for culture.
An important feature in the pathogenesis of *Aspergillus* and *Fusarium* spp. and zygomycetes infections is angioinvasion\(^{5,9,11}\), a trait that presents an opportunity to isolate infective propagules from blood directly (only possible in the case of *Fusarium* spp. and *Scedosporium* spp. whose adventitious sporulation results in haematogenous dissemination) or to track the fungi immunologically using tests that detect characteristic antigenic signatures created by their secreted (glyco)proteins. This has led to the development of diagnostic tests that detect circulating antigens in body fluids, such as serum, plasma, bronchoalveolar lavage (BAL), cerebrospinal fluid, or urine. Detection of one such signature molecule, galactomannan (and associated galactomannanprotein molecules), forms the basis of the Platelia galactomannan enzyme immunoassay (GM EIA), an assay that has found widespread use in invasive aspergillosis diagnosis\(^{32}\). No such diagnostic tests are available for *Fusarium* spp. or zygomycetes. However, a pan-fungal assay (Fungitell test) that detects the fungal cell wall component (1→3)-β-D-glucan, has proved useful in the detection of IFIs caused by a number of opportunistic fungal pathogens\(^{22,32}\), despite its inability to detect zygomycetes that lack the component in their cell walls\(^{22}\).

The current lack of standardized PCR assays, absence of validated nucleic acid-based tests in EORTC/MSG diagnostic criteria, and issues surrounding the accuracy of GM and (1→3)-β-D-glucan tests\(^{22,23,24}\) has led to the recent development of next-generation MAb-based assays, which detect surrogate markers of infection\(^{32,36}\). In the case of *Aspergillus* infections, an *Aspergillus*-specific MAb, JFS, has been used to develop an immunochromatographic lateral-flow device (LFD) for the rapid serodiagnosis of IA\(^{35}\). The LFD (Figure 2) exploits lateral-flow technology used, most famously, for the home pregnancy tests first introduced by Unipath in 1988. Monoclonal antibody JFS is immobilized to a capture zone on a porous nitrocellulose membrane.

![Control Line](image1)

**Figure 2:** Examples of results from negative (A), weakly positive (B), moderately positive (C), and strongly positive (D) lateral-flow device assays using bronchoalveolar lavage (BAL) fluids from a guinea pig model of invasive pulmonary aspergillosis\(^{35}\). In the absence of the *Aspergillus* antigen, no complex is formed in the zone containing solid-phase JFS monoclonal antibody, and a single internal control line is observed (A).

This photomicrograph depicts the appearance of a conidiophore of the fungus *Aspergillus flavus*.

The same MAb conjugated to colloidal gold particles serves as the detection reagent. One hundred microliters of serum or BAL is added to a release pad containing the antibody-gold conjugate, which binds the target antigen and then passes along the porous membrane and binds to JFS immobilized in the capture zone. Anti-mouse immunoglobulin immobilized to the membrane in a separate zone served as an internal control. Test results are available within 10–15 min. after loading the sample. Bound antigen-antibody-gold complex is observed as a red line with an intensity proportional to the antigen concentration, and test results are classified as negative (single internal control line only), weakly positive, moderately positive or strongly positive\(^{35}\). Current tests for GM and fungal (1→3)-β-D-glucan are confined to laboratories equipped for these tests or require samples to be sent to reference laboratories. The simplicity of the LFD means that it can be used as a point-of-care (POC) diagnostic test.

A major advantage of the LFD is its ability to detect activity, since MAb JFS binds to an extracellular glycoprotein antigen that is secreted during active growth of the fungus only\(^{25}\). It does not detect quiescent or moribund spores. This is an important consideration when using fluids such as BAL for diagnosing invasive infections, since fungal spores are a common component of inhaled air. A diagnostic test should be able to discriminate between the normal fungal composition of the healthy lung and that of the immunocompromised patient where the spores have evaded destruction and removal by cells of the innate immune systems and have initiated the infective growth phase. The utility of the device in diagnosing invasive pulmonary aspergillosis has been demonstrated using an animal model of infection\(^{35}\). Compared to serum tests using Platelia GM and Fungitell (1→3)-β-D-glucan assays, the LFD exhibited improved sensitivity and specificity. Similar results have also been found with BAL samples. Further testing of the device is currently underway using human BAL and serum samples.

**Treatment of invasive fungal infections**

Early detection of invasive fungal infections is vital for timely intervention with antifungal drugs. Correct identification of the infectious agent is of paramount importance, since the filamentous fungi most commonly encountered as invasive pathogens (*Aspergillus* spp., *Pseudallescheria/Scedosporium* spp., *Fusarium* spp. and zygomycetes) display inherent tolerance to a number of the antifungal drugs used in the clinical setting. Furthermore, they exhibit different patterns of susceptibility to the main classes of drugs, the polyenes (amphotericin B formulations), triazoles (fluconazole, itraconazole, voriconazole, posaconazole) and echinocandins (caspofungin, micafungin, anidulafungin), commonly used in the clinical setting\(^{22}\). Because of the difficulties encountered in the identification of the infectious agents, many patients ‘at-risk’ for IFIs are treated presumptively, without definitive microbiological evidence of infection, with accompanying toxic side effects.
Aspergillus fumigatis, the main cause of invasive aspergillosis (IA), is susceptible to varying degrees to all five classes of drugs. The drugs with the strongest activity against the fungus are the polyenes and the triazoles (with the exception of fluconazole, which shows no activity). The echinocandins show only modest activity against Aspergillus spp. and show no activity against the other filamentous pathogens. It is therefore more commonly used to treat disseminated candidiasis caused by Candida yeasts. Aspergillus terreus also causes IA (albeit less frequently than A. fumigatus), but is insensitive to the polyenes. Consequently, amphotericin B would be ineffective in controlling IA caused by this fungus. Unlike the polyenes, all species of Aspergillus are susceptible to voriconazole as are Fusarium spp. Voriconazole is superior to amphotericin B deoxycholate and is therefore the preferred choice for treatment of IA, but its use is problematic because of drug interactions and erratic pharmacokinetics.

Voriconazole shows no activity against the zygomycetes and only modest activity against fungi within the Pseudallescheria complex. Posaconazole shows broad spectrum activity against Aspergillus and Fusarium spp. and the zygomycetes, with mixed results against Scedosporium species38. Compared to voriconazole, fewer side effects and drug interactions are associated with posaconazole, and it is used prophylactically, to treat fungal infections in neutropenic patients with leukaemia39, for bone marrow transplant (BMT) recipients with graft-versus-host-disease40, and as second-line therapy for patients with leukaemia39, for bone marrow transplant (BMT) recipients with graft-versus-host-disease40, and as second-line therapy for patients with leukaemia39.

Effects and drug interactions are associated with posaconazole, and in controlling IA caused by this fungus. Unlike the polyenes, all species of Aspergillus are susceptible to voriconazole as are Fusarium spp. Voriconazole is superior to amphotericin B deoxycholate and is therefore the preferred choice for treatment of IA, but its use is problematic because of drug interactions and erratic pharmacokinetics.

The differences in the responses of environmental fungi to antifungal therapy decreases sensitivity of the Platelia and Fungitell tests. For example, a growing body of evidence suggests that diagnostic tests that rely on the detection of conserved cell wall components, such as the Fungitell (1→3)-β-D-glucan assay, are unable to provide the level of specificity required for accurate identification of individual species, but are useful as negative predictors of infections caused by fungi other than the zygomycetes, which lack (1→3)-β-D-glucan in their cell walls. Concerns surrounding the specificities and sensitivities of the Platelia and Fungitell tests have led to the development of nucleic acid-based assays, but lack of standardized polymerase chain reaction protocols has resulted in their exclusion as accepted diagnostic criteria for identification of IFIs by the EORTC/MSG consensus group. There is therefore a pressing need for the development of species-specific assays that conform to EORTC/MSG diagnostic criteria that permit accurate discrimination of fungal pathogens without the need for prior culture and which facilitate the effective management and treatment of life-threatening infectious diseases. The generation of genus- and species-specific monoclonal antibodies15,16 and their use in POC diagnostic tests, such as LFDs17, will provide rapid and user-friendly adjuncts to more time consuming laboratory-based technologies.

Acknowledgement
The author thanks Nathan Wiederhold and co-workers for supply of the guinea pig BAL fluids used in Figure 2.

References


Compliance with hygiene management systems in highly regulated environments

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Introduction

To most microbiologists working in the food and medical professions, discussions around the topic of "cultures" will bring to mind laboratory benches, agar plates or test tubes containing broth. Increasingly for both groups of microbiologists, this is likely to change. Although this article is primarily written about the food industry and food safety, similarities and differences with the healthcare profession and infection prevention will be explored. Food microbiologists talk about foodborne disease, with environmental contamination recognized as an increasingly important risk factor. Medical microbiologists are concerned about healthcare-associated infections (HCAIs), although some are less sure about the role of the environment in cross infection.

The names of the pathogens associated with causing foodborne disease and HCAIs in some cases are different, but increasingly may be the same. Norovirus is known to be food transmitted and also to cause outbreaks in healthcare establishments, with 2009 showing a particularly high prevalence. Clostridium difficile, historically thought of as an HCAI, is now thought to also cause cases lacking the normal risk factors in the community, with food, especially meat, a vehicle for its transmission. Similarly, other pathogens more traditionally linked with healthcare infections, including MRSA and ESBL-producing E. coli, are becoming more common in the general community and have been detected in food-producing animals, and subsequently, foods. This has led to questions concerning the significance and role of food in their transmission.

In an attempt to minimize infection risks, both the food and healthcare industries have established and documented safety management systems, and as such, both are considered as highly regulated environments. However, having systems is the first stage in the prevention of both HCAIs and foodborne disease, but human compliance with documented systems is recognized as a major problem/barrier.

Burden of disease

In its 126th meeting, held in Jan 2010, WHO reiterated that food safety continues to be a growing public health problem. Whether the problem is growing as opposed to better reported is the subject of debate and involves careful interpretation of data. Certainly in the UK, although stabilizing over the past 10 years at between 60,000-70,000 cases per year, the trend over the past 30 years has been for a significant increase in reported cases. The real figure is likely to be much higher with, depending on the pathogen, only the minority of cases reported.

The main issue however is not whether cases are increasing but that the present burden of disease is too high. The costs associated with illness fall on government, industry and consumers, themselves. Costs to industry result from recalls, food wastage, loss of business, fines and compensation, loss of brand value and even closure. Recalls of food products in the USA, e.g. in meat products, often result in significant wastage. A good example of adverse financial consequences affecting brand value is the Snow Brand milk outbreak in Japan, in 2000. The company’s market share fell from 45% to less than 10% and was associated with considerable brand damage. Consumers however may pay the ultimate price with a higher risk of mortality associated with some pathogens, e.g. Shiga toxin-producing Escherichia coli or Listeria.

In a similar way, concerns over HCAIs have increased in prominence over the past 10 years, with outbreaks of nosocomial infections being front page news and a political issue at election times. This is sometimes linked to the evolution of antibiotic resistant strains or the recognition that organisms previously not thought to be a problem could cause infection. Statistics over the precise level of HCAIs are also subject to uncertainty and variability, although following the application of political will in the form of new legislation, recent publications suggest that after years of increase, levels of MRSA bacteraemia and Clostridium difficile are at their lowest for 5 years. However, these are only two of the organisms which are causing problems. Once again, the real question, especially given the evolution and increasing antibiotic resistance of nosocomial pathogens, is whether present levels are acceptable, and if not, how can they be further reduced?

Management systems and HACCP

It has been said with respect to foodborne illness, and the same could be applied to HCAIs, that despite much research and money being spent on addressing the problem, present levels are unacceptable. Part of the reason for this may be microbiological, with the continued "emergence" of new pathogens. However, in finding a solution, just to treat the problem as a microbial one may itself be a contributory factor. It is increasingly recognized that failure to prevent both types of illnesses may involve a large human element. One study suggested that 97% of foodborne illness outbreaks involved human error. Management in both food and healthcare therefore have a responsibility to educate and train their workforce. Training can fill a knowledge gap, enabling people to act hygienically when they are motivated to do so, but there is good evidence to show that food handlers and healthcare professionals often do not implement known hygiene practices. Central to compliance is the nature and efficacy of the management systems in place. Over the past 40 years, there has been a paradigm shift in the way that food safety has been managed (Figure 1).

Figure 1:
Managing Food Safety: Food Safety Equations

| 2008 | PRPs + HACCP = SF |
| PRPs = Prerequisite Programs, HACCP = Hazard Analysis |
| SF = Safe Food |

| 2010 | PRPs + HACCP + FSC = SF |
| PRPs = Prerequisite Programs, HACCP = Hazard Analysis, FSC = Food Safety Culture, SF = Safe Food |

A reliance on end-product testing coupled with GMP and a traditional floors, walls and ceilings inspection has given way to a preventative risk-based approach based on a Hazard-Analysis Critical Control Points approach (HACCP). However, HACCP does not work in a vacuum and must have the foundations laid for food safety management in the form of properly implemented prerequisite programmes (PRPs).
Food handler behaviour, training and culture

It was hoped in the food industry that, with a HACCP-based management approach, there would be a major reduction in foodborne disease. There is some evidence to show that food handling practices may be better in those businesses that use HACCP, but given the uncertainty and variability in the number of reported cases of food poisoning, it is impossible to show whether the introduction of HACCP has had any effect on its incidence. While having good management systems is a start, crucial to the operational food safety practices used in a business is its food safety culture (Figure 2).

It is relatively easy to devise safety management systems but much more difficult to ensure they are complied with. There is evidence, certainly from the food industry, that food handlers do not handle food hygienically, that human errors are responsible for a significant number of cases of foodborne disease and that often food handlers do not implement known food safety practices.

Many managers blame the individual for being unhygienic or assume training will solve the problem. Training either food handlers or staff working in healthcare in hygiene principles and more specific practices helps—but is not a panacea. Knowledge helps people to be hygienic when they are motivated to do so. Noncompliance with systems may be partly due to specific factors relating to the individual, but it is known that a person’s behaviour is related to the environment or social context in which they work, and a major component may be due to the prevailing food safety culture within a business. The creation and maintenance of this is directly related to senior management and its hygiene leadership.

Although one textbook and three peer-reviewed papers have been published, with a conference dedicated to creating the right food safety culture planned for 2011, the subject is still in its infancy compared to other disciplines, such as health and safety culture. Repeatedly reported as a risk factor in major accident inquiries, it is starting to be reported as a contributory factor in food poisoning outbreaks. For this reason, as far as the food industry is concerned, it has been viewed as an “emerging risk factor”.

In healthcare, arguably lagging behind the food industry in the use of risk-based management systems, the importance of infection prevention culture is more widely accepted. It has also been recognized as a contributory factor in outbreaks of HCAIs, and advice on how hospitals/trusts can improve their organizational infection prevention culture is available.

HACCP differs from PRPs in a number of ways:

**Table 1:**

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<td>Indirectly with food safety</td>
<td>Directly with food safety</td>
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<tr>
<td>General</td>
<td>Product: Process specific</td>
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<tr>
<td>Failure less likely to result in illness</td>
<td>Failure results in much higher probability of illness</td>
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It is now a legal requirement in the EU for all food businesses, with the exception of primary production, to have a documented food safety management system based upon HACCP principles. These must be tailored to meet the needs of the individual business. The Codex Alimentarius Committee has laid down guidelines, based on 7 principles (Table 1) and 12 logic steps, on how HACCP is to be undertaken. It has also been realized that a different approach may be needed for food service and retailing, and various approaches based upon HACCP principles have been developed. Use of HACCP has also been advocated within healthcare, with classical HACCP applicable to sterilization of endoscopy units, and HACCP-based approaches for use with individual patient related procedures. To date, HACCP, although a generic risk-based management approach, has not had anywhere near the same impact in the food industry, although the use of care bundles does use some HACCP-type principles.

**Figure 2:**

Operational Performance:
What happens

Hygiene Management  
Hygiene Culture

**PRPs versus HACCP**

- Indirectly with food safety
- General
- Failure less likely to result in illness

**PRP and the general food environment**

- Design (layout), siting, construction of premises
- Siting construction of machinery
- Pest control
- Cleaning/sanitation
- Raw materials (including selection/purchasing)
- Traceability & recall
- Personal hygiene (including facilities)
- Training
- Transport and storage
- Glass policy

**Food handler behaviour, training and culture**

It was hoped in the food industry that, with a HACCP-based management approach, there would be a major reduction in foodborne disease. There is some evidence to show that food handling practices may be better in those businesses that use HACCP, but given the uncertainty and variability in the number of reported cases of food poisoning, it is impossible to show whether the introduction of HACCP has had any effect on its incidence. While having good management systems is a start, crucial to the operational food safety practices used in a business is its food safety culture (Figure 2).

**Table 1:**

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<th>HACCP: 7 Codex Principles</th>
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What is organizational culture?

Although work on organizational culture has advanced over the last 20 years and a range of definitions proposed, the concept is still not universally accepted. One definition of food safety culture suggested for the food industry is: “The aggregation of the prevailing, relatively constant, learned, shared attitudes, beliefs and values contributing to the hygiene behaviours used within a particular handling environment.” This definition suggests that cultures are relatively stable over time and are learned by new members of staff. The hygiene practices used are linked to the common shared attitudes, beliefs and values with respect to hygienic behaviour. Examples of the financial costs of failing to achieve the right culture can be found in both food and healthcare, although if preliminary reports are proved to be correct, the recent oil spillage may be one of the most expensive examples. It has been alleged that the prevailing culture within BP was one of tacit disregard of safety problems, showed a pattern of neglect and was skewed towards silencing whistleblowers. Safety inspections were said to have been cut short or delayed in order to reduce inspection costs.

Similarly, hygiene culture will often have to compete with other “business” cultures or priorities, and there is evidence from within healthcare and the food industry that financial imperatives or the need to achieve other targets are a threat to hygienic behaviour. In the report of the South Wales E. coli O157 inquiry, it was stated that, “The culture that existed was one of little regard for the importance of food safety but where making and saving money was the priority. Similarly, in the inquiry into the Clostridium difficile outbreak at Stoke Mandeville hospital in 2006, the culture was criticized and the NHS chiefs were said to “be driven by targets (cutting waiting times, local finance etc) rather than patient safety” and staff “were too rushed to take basic precautions, such as washing hands and cleaning the ward properly“. It is possible, even likely, that different staff levels within an organization will have their own hygiene cultures, and this is likely to be particularly true in large or multisite operations.

All businesses or hospital organizations will have a hygiene culture, and this may be positive or negative towards hygienic behaviour. Negative cultures may just ignore the subject or even actively support or encourage noncompliance or poor hygiene performance.

Many studies have tried to examine what contributes to a positive compliance culture and numerous reviews have identified component factors. While these often use different terminology, they are usually based on similar underlying principles or components. In turn, this has led to discussions concerning the importance of, and mechanisms for, assessing the hygiene culture within a business.

Conclusions

The levels of foodborne disease and HCAIs remain at an unacceptable level, with significant cost implications for countries, businesses and individuals. Compensation claims can be substantial. It cannot be denied that there is a microbiological problem, but levels will not decrease until there is full recognition that there is also a major human problem. Responsibility may not just lie with individuals; managers in addition to the development of management systems must also show hygiene leadership and create the right hygiene culture, and as such, the 2008 model for producing safe foods needs to be amended (Figure 3). A lot has been spoken about food safety management but little about food safety leadership. In the financial and other service sectors “Directors of Compliance” have been appointed. These are usually more concerned about compliance with complex external requirements or legislation rather than implementation of internal systems and tend to take a more mechanistic “systems” approach to compliance rather than one based on culture. In the food industry, much of their work may be taken on by quality assurance staff; however, director-of-compliance roles have been established in some care-home and related businesses. What is likely to be more important than how it is achieved will be whether systems are compiled with, and in the future, investigations of foodborne illness or of HCAI outbreaks may not just involve examination of microbial cultures but also the culture of compliance.

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Published as a service to Microbiology.

Our thanks go to the Culture editorial board: Professor Grahame W Gould, Dr David Petts, Mr David E Post, Dr Peter Stephens

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