Chapter VIII

Clinical Safety and Quality Management in Health IT

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Abstract

This chapter describes the principle risks that are associated with the supply of healthcare information systems, services, and technologies and the emerging best clinical safety and quality management practices that are being adopted by both users and suppliers in order to mitigate or remove these risks. It states that there are two principle sources of risk: one derived from the potential harm that could be caused to patients and users in a care environment and the other derived from possible failures to achieve the specifications and service levels demanded by a buyer. It argues that for a health IT supplier, implementing industry best practices in an effective way not only provides a high level of protection from both sources of risk but has in any event now become a minimum expectation on the part of users such as the NHS Connecting for Health programme. The chapter concludes that although quality, safety and performance standards in health IT still lag behind other, more established sectors of healthcare innovation—such as pharmaceuticals and medical devices—new standards for clinical safety and quality management are rapidly emerging, introducing a new dimension into informatics standardisation and substantially but necessarily raising the barriers to entry into the health IT market place.

Risks and Liabilities

Sources of Risk in Health IT

There are four basic sources of risk to which a provider of information systems, services, or technologies for use in health or social care can be exposed:

- Hardware defects
- Software defects which affect an automated physical process
- Software defects which affect the advice given to a user
- Organisational and human failures

This classification is complicated by the fact that hardware, software, organisations, and people all interact and it may require a detailed analysis to discover the precise cause or causes of an adverse incident. This is especially the case in health and social care, where a typical care pathway may carry a patient and their information through several different care environments and perhaps through different settings within those environments, where they will come into contact with a diverse range of technologies, equipment, drugs, skills, and expertise. Given the complex interactions that are taking place it is inevitable that sometimes things will go wrong.

Within the immediate care environment, risk management and patient safety are crucial components of the overall quality management system known as "clinical governance." But they are no less important outside of that environment. Every supplier of products and services, which are used in a health or social care setting must recognise that these products and services are being used in a safety-critical environment and must, as is discussed in depth in this chapter, conform to the best quality, safety and risk assurance and management practices that are presently available.

Indeed, when supplying such products and serviced there are two principle sources of risk. One is the external source associated with clinical safety and previously described, which derives from the potential harm that could be caused to patients and users of a product or service in a care environment. The other, however, is an internal and subtly different risk: that of failing to achieve the specifications and service levels defined in a contract to supply these products and services, which will lead to the payment of financial penalties to a client. For a supplier of healthcare IT products, systems and services, implementing industry best practices in an effective way can provide a high level of protection from both sources of risk.