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### CIS: A Longstanding Debate

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The debate about the role and reliability of clinical information systems (CIS) goes back several years.

As far back as 1994, a British Medical Journal editorial entitled 'Are clinical information systems safe?' portrayed a series of high-profile failures (which entailed physical harm to patients), and raised some disturbing questions. These included the lack of safety critical certification as well as issues of liability on the part of device manufacturers.

The Journal also observed that "Computer consultants should recognise that lack of input from clinicians in the development of information systems in the past may have increased the dangers of failure." It concluded that the ensuring of "reasonable safety for clinical information systems is, then, essentially a problem for clinicians."

Such a debate continues today. However, both its contours and content have become far more complicated. In its editorial, the Journal noted that the speed and complexity of information systems "makes it impossible for humans to verify that the results are correct" or allow clinicians to be firmly 'in the loop' of control. That was almost a generation ago.

Today's CIS systems are much faster and complex. The challenges are therefore also greater. And yet, much more is also expected from them.

An Institute of Medicine report, 'Crossing the Quality Chasm: A New Health System for the 21st Century', recently identified the design of more sophisticated clinical information systems as essential for the highest-quality, lowest-cost patient care.

When the British Medical Journal published its editorial, formalised IT design techniques were still in their infancy. Indeed, the editorial emphasised that design was less important (and possibly more cumbersome and impractical) than prototyping and field testing, which would then be formally incorporated into an acceptable certification process.

In the late 1990s, the design of CIS systems acquired an artisanal nature – especially due to the growth in platform and functionality convergence, and a rise in object-oriented/componentised architecture. One of the visions of this era was to generate a multitude of clinical information applications from a common foundation, with new systems built out of generic software adapted for different specialties, with a certain inbuilt element of connectivity. These were, of course, the years when the Internet was just taking off.

Today, CIS design – like that of other healthcare IT systems – is being driven by a new generation of design tools and formal models. These include Platform-Based Design (PBD), with system specifications mapped to Service-Oriented Architecture (SOA) platforms by means of Internet-era languages such as XACML. Alongside, the design of new CIS systems also typically take close account of human-computer interfaces (HCI), healthcare decision support and clinical guidelines, system integration and change management policies, the implications of e-health and distributed IT technologies.

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