# Questioning why health care IT manufacturers aren't liable for product-related medical errors

March 25 2009

Even when their products are implicated in harm to patients, manufacturers of healthcare information technology (HIT) currently enjoy wide contractual and legal protection that renders them virtually "liability-free," writes Ross Koppel, Ph.D., of the University of Pennsylvania School of Medicine, in the March 25th issue of the *Journal of the American Medical Association*.

The current system needs to be changed so that all liability does not rest entirely with physicians, nurses, hospitals, and clinics, even when these users of faulty HIT scrupulously follow vendor instructions, according to Dr. Koppel's piece, co-authored with David Kreda, a software designer.

The HIT industry avoids liability by relying on a legal doctrine known as "learned intermediaries" that holds physicians, nurses, pharmacists, and healthcare technicians responsible for HIT errors because are presumed to be able to identify—and correct— medical mistakes generated by software faults.

"HIT vendors claim that, because they cannot practice medicine, clinicians should be accountable for identifying errors resulting from faulty software or hardware," said Koppel. "But errors or lack of clarity in HIT software can create serious, even deadly, risks to patients that clinicians cannot foresee."

In one example, a trauma team did manage to catch an error in a piece of faulty vendor software that miscalculated intracranial pressures. Had they not, patients would have been severely threatened and the hospital would have been responsible for the resulting harm. "From an equity standpoint," says Dr. Ross Koppel, "This is unacceptable."

Other examples of internal software mistakes include confusing kilograms and pounds used to derive medication doses based on a patient's weight, and software that erroneously removes warnings about fatal drug allergies. In both cases "learned intermediary" clauses hold that clinicians are responsible for noticing the mistake before prescribing.

Equally unfortunate and unacceptable according to Koppel are the provisions in most HIT contracts that prohibit healthcare organizations from openly disclosing any problems caused by vendor software, even to the other HIT licensees using the same products, e.g., clinicians and hospitals. Such stipulations defeat patient safety efforts and are contrary to the principles of evidence-based medicine, says Koppel.

The authors also identify circumstances where HIT vendors should not be held accountable for patient safety failures arising from their products' misbehavior, e.g., user misuse and medical circumstances not knowable in advance. "Legal and contractual changes must not reduce incentives to vendor innovation," said Koppel. "We must achieve a better balance among patient safety concerns, fairness to clinicians, vendor responsiveness, and vendor marketing." The authors suggest moving the HIT industry toward this balance may require several changes to the status quo, including:

Dr. Koppel's research on HIT came to national attention in 2005 with a *JAMA* article on medication errors associated with computerized physician order entry (CPOE) systems. More recently, his work on

errors in bar-coded medication administration and on the interactions between HIT and the organizations implementing it has received international focus. Dr. Koppel has also published widely on the many benefits of HIT.

Source: University of Pennsylvania School of Medicine (news : web)