

Health Informatics

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TO THE EDITOR: Coiera accurately described some lessons from the United Kingdom's experience with health information technology¹ that should be noted by potential "fast followers", such as Australia's National E-Health Transition Authority (<http://www.nehta.gov.au>).

The debate about the merits of the "opt-in" versus the "opt-out" approach highlights a need for further discussion about the optimum consent model to achieve the aims of a shared electronic health record (EHR), combining patient-controlled health records with a tool for clinical decision making, and research and planning.²

Informed consent and ethical approval are vital for publication of evaluation findings. The 2007 *National statement on ethical conduct in human research*³ recognises that consent processes do vary, depending on the context and type of research.

Opt-in is an active process and is believed to build consumer confidence and reinforce a strong privacy message.² Opt-out is more passive, assuming that most people are willing to share their health information for clinical and/or research purposes.

Our own experience with opt-in is that less than 0.4% of patients approached decline to participate in data extraction projects.⁴ With opt-out, there is little evidence to show that it is in any way harmful for initial patient contact. On the other hand, opt-in has been associated with a poor response rate and a biased study population in medical record research,⁵ in research in screening clinics,⁶ and in a pilot study of patients with angina.⁷ Because recruiting unbiased patient samples with high response rates is essential for scientific rigour, opt-out should be the default recruitment strategy for studies with a low risk for participants.

The most appropriate consent model for all situations, in an ethical and secure electronic environment, is one that allows patients and providers to make their own decisions about giving expressed or implied consent within an opt-in or opt-out approach. The participants in the process must be sure that consent has in fact been granted. The health record (paper or electronic) must demonstrate that the consent

process has taken place and document the outcome.

We have developed software to enable use of this flexible consent protocol, permitting context-sensitive and ethical access to personal health information if patients, clinicians and researchers have given their consent.

The literature and our experience suggest that this flexible approach, based on the choices of patients and providers, should lead to good participation rates and allow the objectives of a shared EHR to be achieved in a cost-efficient manner.

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Should clinical software be regulated?

Ian D Williams

TO THE EDITOR: The editorial by Coiera and Westbrook¹ and indeed the letter by Fox² tended to use the term "clinical software" in a broad sense.

In Australia, doctors who use clinical applications are in fact using electronic medical records. The major functionality provided is one of information storage, with the ability to produce a range of documents that were previously handwritten. To accept that the currently available applications offer decision support is a very generous, and possibly naïve, interpretation.

The common example of decision-support tools used in Australia is the humble prescription writer. Current vendors offer a variety of prescription writers and, as Coiera and Westbrook¹ assert, they check for drug-drug interactions and dosage errors and provide various alerts.

Coiera and Westbrook go on to question whether appropriate testing is being performed on the large number of applications available. At first glance this question may seem to be somewhat invalid, as most of the software packages in Australia use either the AZDex (a proprietary internal drug database used by Medical Director) or MIMS (a pharmaceutical database of products currently available in Australia by CMPMedica Australia) drug databases. These two highly regarded sources of drug information provide the developer with an easy-to-implement set of tools that effectively ensures "quality" information is provided to the doctor preparing the prescription.

The problem is that, although we have quality databases, there is little or no compliance testing to ensure that the applications that use them are developed to an equally high standard. For example, there is no mechanism to inform end-users which parts of the database have been used, and there is no testing to ensure the end-user is presented with accurate information.

While many Australian doctors have moved to computerised clinical records, their ability to use these data for improving clinical care is being curtailed by a lack of standards and coding of conditions. Computers are not efficient in dealing with the free text that is traditionally used in clinical notes, and even data such as drug prescrip-

tions are difficult to analyse because of the lack of a standard method of drug naming or coding.

I look to a future when true clinical support tools are available. To this end, the development, coordination, and facilitation of a series of standards by the National E-Health Transition Authority should be supported.

Competing interests: I am Chairman of Stat Health Systems, which is Australia's newest medical software developer. The company is currently writing an application, but there have been no sales at present. I have received no money from the company.

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2 Fox KL. Should clinical software be regulated? [letter] *Med J Aust* 2006; 185: 527. □

Enrico W Coiera

IN REPLY: At the heart of much debate on patient consent for access to electronic data are two conflicting desires — many consumers wish to minimise access to their record, and many clinicians have genuine concerns that such restriction may lead to patient harm. In some cases, privacy is paramount (eg, psychiatric or sexual health history). In others, such as emergency presentations, patient wellbeing may override such concerns. This has led many to conclude that there is no “one size fits all” model for e-consent.¹

The current debate between the boundary cases of “opt-in” and “opt-out” is misleading because many specialist services of necessity will have local consent processes, crafted to meet the need of their patients and their clinicians. Yet, many health information technology initiatives do not seem prepared to consider this complexity, and opt-in or opt-out are all that is on offer. Liaw and Boyle's concerns about dropout rates under an opt-in system affecting secondary use of patient data for research purposes are no doubt real, but it is hard to draw too strong a comparison between patient recruitment for research and patient permission to store data for their own care.

Williams correctly points out in his letter that decision support remains a small component of the software to support clinical practice that most Australian general practitioners now use. However, anyone using a

prescription program that suggests doses, checks interactions, or generates alerts is using decision support. We can say so confidently because research repeatedly shows that such functions change clinical decisions. Indeed, something as simple as accessing research articles and guidelines using the Internet is a form of decision support, because it changes clinical decisions significantly, and sometimes negatively.² Consequently, it is perhaps naïve to await “true” decision support using artificial intelligence before we worry about how software affects clinical behaviour. If the intervention was a drug and serious patient harm resulted from infrequent side effects, everyone would quickly agree some controls might be needed. Somehow, we still don't seem to get as excited about the harm that may come from using bread-and-butter clinical software, but we should.

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1 Coiera E, Clarke R. e-Consent: the design and implementation of consumer consent mechanisms in an electronic environment. *J Am Med Inform Assoc* 2004; 11: 129-140.

2 Westbrook J, Coiera E, Gosling AS. Do online information retrieval systems help experienced clinicians answer clinical questions? *J Am Med Inform Assoc* 2005; 12: 315-321. □