

A PATIENT SURVEY ASSESSING THE AWARENESS AND ACCEPTABILITY OF THE EMERGENCY CARE SUMMARY AND ITS CONSENT MODEL

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Abstract

Background

The Emergency Care Summary (ECS) was introduced in 2006 to allow aspects of the general practitioner (GP; family doctor, equivalent to primary care physician) medical record to be viewed in hospitals and out-of-hours centers in Scotland. Records were automatically uploaded unless patients actively opted out. This study investigated patient awareness and acceptance of this process.

Methods

This was a questionnaire survey of patients in a GP surgery (office) in Paisley, Scotland.

Results

Survey results indicated that 42 percent of patients were aware of the ECS, and 16 percent said that they recognized the leaflet posted to households. Of those who recognized the leaflet, 92 percent said they were happy for their record to be part of the system, while the others did not realize their record was to be included. Having read the leaflet, 97 percent said that they were happy for their record to be included in the ECS.

Conclusions

This study shows that most patients were not aware of the Emergency Care Summary or did not remember seeing the leaflet posted to households. Having read the leaflet, the vast majority of patients were happy for their records to be included in the system. The low awareness of the ECS calls into question the validity of an implied consent model using an information leaflet distributed by post.

Key words: Emergency Care Summary, consent, Summary Care Record, confidentiality, electronic care summary, implied consent, informed consent

Introduction

Programs to introduce electronic medical records that allow sharing of health information between

sites are underway in a range of developed countries including Australia, Canada, Denmark, England, Finland, France, New Zealand, and the United States. The Emergency Care Summary (ECS) has been introduced in Scotland to store health records in a manner that gives health professionals working out of hours, or in secondary care (hospitals), access to general practitioner (GP; equivalent to primary care physician) electronic records. The information uploaded from GP records is the patient's name, date of birth, name of GP surgery (office), CHI number (a unique patient identifier in Scotland), prescribed medication, and drug reactions or allergies. All patients have their information uploaded to a central database twice daily unless they have actively opted out of the system. Health professionals who wish to access information in the ECS are expected to gain patient consent at the time of contact (except if the patient is unconscious).

The ECS was introduced on an "opt-out" basis such that patient records would be included in the system unless the patient informed the practice that he or she did not want to have the data uploaded. An explanatory patient leaflet was posted to all households about the ECS, and information leaflets and posters were given to GP surgeries, GP out-of-hours centers, and accident and emergency departments (a copy of the leaflet can be obtained at <http://www.hris.org.uk/index.aspx?o=1608>). In addition, there was media coverage at the time of the change. The ECS leaflet that was posted to all households was produced by the Scottish Executive (now Scottish Government) after drafting by Health Rights Information Scotland (a project based at the Scottish Consumer Council), based on recommendations in a 2005 report.¹

In winter 2006, one of the authors asked 50 consecutive patients and all members of the practice team if they recognized the ECS leaflet. Only the practice manager remembered having seen the leaflet. This is similar to the reported low awareness of the Summary Care Record (SCR) system in England (the SCR is the English version of the ECS and is similar in most ways).² Opt-out consent systems can only work when patients have been given sufficient information to make an informed choice.³ The public was informed about the ECS using a mass postal delivery of an information leaflet alongside other unsolicited advertising leaflets.

The most consistently expressed concern about the ECS is its security.⁴ Patients appear to accept that their GP has a computerized record and that it is secure and confidential, but they are increasingly unhappy about the security of centrally held records. The concerns are that the data may be used inappropriately by the government or may be illegally accessed. The risk of illegal access increases with the amount of data stored in a single repository (the honeypot effect). Despite this, the number of people who actually withdraw their consent for their data to be uploaded when such systems are instituted has been shown to be low, and public concern seems to be muted.⁵ There is also anxiety that the information provided to patients by the government has been biased and has thus led to fewer patients' opting out. When patients are informed about the ECS in a

different way, the opt-out rate is higher.⁶

No studies to date have looked at patients' awareness or acceptance of the ECS system in Scotland. This study was designed to investigate what proportion of patients remembered seeing the ECS leaflet, what proportion were aware of the ECS, and what their views on its acceptability were after they had read the leaflet.

Methods

The study was carried out with patients registered with a GP surgery in Paisley, Scotland. At the time of the study, the practice had 5,972 patients whose demographic and socioeconomic characteristics are shown in [Table 1](#) and [Table 2](#). Based on an assumption of a 30 percent response rate and a desire to be able to give results within 5 percent of their true value ($p = .05$), 1,210 patients were selected by random number generation from a sample frame of all registered patients aged 18 years or over. Patients were not asked for any demographic details in the questionnaire, and no record was kept of which individual patients were sent questionnaires; thus, patients could be reassured that their GP would not know if they had or had not participated in the research.

Between February and May 2008, all patients in the sample were sent an explanatory letter on practice-headed notepaper, a consent form, a questionnaire, a sealed envelope containing the ECS information leaflet, and a postage-paid return envelope. Patients were instructed to open the envelope containing the information leaflet after question 4 and to read the leaflet before completing the questionnaire. Expert advice was received on the design and content of the questionnaire before it was distributed. The responses were collated in a Microsoft Excel spreadsheet and analyzed using a Minitab statistical package to calculate tests of one proportion.

Results

Of the 1,210 questionnaires sent to patients, 5 were returned as "not known at this address," 3 were returned by nursing homes with a note saying that the patient was unable to consent, and one patient returned the questionnaire with informed dissent. A total of 283 responses with completed consent forms were received, giving a response rate of 23 percent. The results of the questionnaire are shown in [Table 3](#).

Discussion

The study was limited by the time delay (approximately 15 months) between the distribution of the information leaflet and the distribution of the questionnaire. The delay could have reduced the number of patients who remembered seeing the leaflet. However, the delay does increase the likelihood of patients' having come into contact with the out-of-hours services or the accident and

emergency department and being asked for consent to view their record. Consequently, this time delay might have increased the awareness of the Emergency Care Summary. The response rate was 23 percent, and the lack of formal piloting of the study or attempts to send further questionnaires to nonresponders limited the ability of the researchers to quantify what effect this rate had on the results. Although only 43 respondents answered question 5 positively (that they had seen the leaflet before), 53 answered question 6. Some respondents said that they had seen other information about the ECS (apart from the leaflet) that may account for some of this anomaly.

One implication of the study is that informed consent was unlikely to have been gained for the introduction of the ECS in a large proportion of the population because only 42 percent of patients were aware of the Emergency Care Summary and only 16 percent remembered seeing the information leaflet. Although ECS is an opt-out system, it has the safeguard that every person wishing to access the system has to confirm that that he or she has obtained the patient's permission to do so (unless the patient is unconscious). This is different from the SCR, where access is not dependent upon patient permission at each time of access, although it has since been announced that the SCR will change in line with the ECS model. This safeguard may be compromised because permission is usually gained at times of anxiety and ill health (e.g., when patients are in contact with NHS24 or in the accident and emergency department) or because people accessing the record might claim they have the patient's permission when in fact they do not. A breach of this safeguard may have occurred recently when a health professional with access to the ECS database allegedly reviewed a variety of high profile patients' electronic summaries without their permission.

A further implication of the study is that 3 percent of patients did not want their record to be included in the ECS or were not sure that they wanted it included. Although the proportion is small, it means that approximately 165,000 patients (95 percent confidence interval, 75,000–305,000) in Scotland would not give informed consent if it were requested using an "opt-in" model. This is significantly more than the 1,853 patients who had opted out as of September 2009, although these results have to be interpreted with caution given the low response rate and the single-practice sample frame.⁷ Greenhalgh and colleagues' evaluation of the English version of the ECS, the SCR, showed that acceptance of the electronic summary was personal, context-bound, and subject to change with time.⁸ Some critics of the introduction of the ECS have expressed concern that the contents of the leaflet were unbalanced and that this might have inflated the proportion of patients happy for their record to be included. For example, the leaflet suggests that consent to access the ECS "must" be obtained and that access can only be obtained by health professionals involved in the patient's care. No mention is made that the data may be held unsafely and that other people could access their health records inappropriately. When patients were informed about the ECS from a different perspective, there was a much higher opt-out rate.⁹ True informed consent does not depend only on patients' being informed but on their being informed in a balanced and unbiased

way.

Although the present ECS only holds small amounts of data and does not include the full medical history, some aspects of the medical history may be inferred from the drug history (for example, someone receiving Vitamin B co forte and thiamine may be assumed to have a problem with alcohol, and a patient prescribed Sildenafil may be assumed to have erectile dysfunction). Comments in a conference submission suggest that expansion of the ECS, presumably to include the whole medical record, might be desirable: "Once the system is accepted and benefits accepted, then the data set can easily be expanded. . . . There is a great deal of interest surrounding the system, and plans to expand the data set and the number of agencies accessing it will improve its usefulness."¹⁰ Expanding the data set in this way will exacerbate any issues that may arise with the security of a centrally held database and the honeypot effect that this will generate.

Conclusions

This study shows that most patients were aware of the arrangements for GPs' storing their medical records within the practice but that most patients were not aware of the Emergency Care Summary or did not remember seeing the leaflet that was posted to all households. Having read the information leaflet, the vast majority of patients were happy for their records to be included. The low awareness of the ECS calls into question the validity of an implied consent model using an information leaflet distributed by post. Although the ECS, as described by the leaflet, seems to be acceptable, this fact should not be used to justify an expansion of the data set without a better method of obtaining patient consent.

This study justifies the belief that the opt-out method of consent is inappropriate for such an important change in how electronic medical records are stored and accessed. Transfer of medical data without anonymity for other purposes requires explicit, informed consent. The model illustrated here for the ECS, in common with the SCR in England and other systems around the world, deviates from this principle. A full public debate on what level of information and consent should be required before such programs are implemented in the future is merited.

Personal medical data is valued and valuable. The medical consultation relies on patients' being able to tell their doctor important facts in a confidential setting. Fear of imparting these facts may result in poor or even dangerous medical treatment. If patients lose faith in what they can tell their doctor, clinical care and the relationship between clinicians and patients will suffer. The more information that is stored centrally, the less confidential it becomes. These data are also valuable to insurance, medical and marketing companies. Proof of medical data being traded illegally already exists.¹¹ Patients in Scotland are already having their faith in the confidentiality of the ECS challenged by an upcoming court case in which it is alleged a health professional inappropriately accessed the

ECS records of some well-known Scots.¹² Thus, despite reassurances that only health professionals may access the ECS, data confidentiality may be compromised if health professionals themselves act unprofessionally.

This study suggests that an anonymous leaflet drop with other unsolicited mail is not an effective method of informing the population of an important change in how confidential medical information is shared. An opt-in system of consent to such information sharing involving an improved mechanism for informing the public should be considered for any extension of the ECS in Scotland and for any similar plans to share electronic medical records elsewhere.

Research Governance, Ethics, Funding, and Competing Interests

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Ethics approval was granted by the Greater Glasgow and Clyde primary care, community, and mental health local research ethics committee (reference number 07/SO701/166).

Gerry McCartney and Chris Johnstone have no competing interests to declare.

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Notes

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