

The Impact of Requiring Patient Authorization for Use of Data in Medical Records Research

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BACKGROUND. In 1996, the Minnesota legislature passed a medical data privacy act requiring patient authorization for the use of medical records in research. Other state legislatures and Congress are considering similar legislation. The impact of this statute on a researcher's ability to obtain complete and representative data is unknown.

METHODS. This was a cross-sectional study of all patients visiting the outpatient clinic, emergency department, or hospital of the Olmsted Medical Center (OMC), for an appointment or admission during January 1997 or February 1997. Patients were asked to give consent for the use of their medical records for research. Our objective was to gather information on the number and characteristics of patients who refused authorization.

RESULTS. Of the 15,997 patients: 90.6% granted authorization; 3.6 refused authorization; 4.5% were undecided; and 1.3% were not asked for authorization. Refusal rates were highest among patients visiting the center for mental health concerns, trauma, or eye care, and among women aged 39 years or older. Undecided rates were highest in women presenting for pregnancy care.

CONCLUSIONS. Refusal rates were low for this community practice. However, higher refusal rates in some subgroups, such as older women or patients with mental health concerns, may increase the chance of selection bias in studies involving these patients.

KEY WORDS. Bias (epidemiology); epidemiology; informed consent; medical records. (*J Fam Pract* 1998; 47:361-365)

The debate surrounding the appropriate and ethical use of individual medical records has crescendoed.¹⁻¹⁵ Like many medical dilemmas, this one requires a balance between individual rights and societal benefit. Individual rights advocates argue that medical record studies are not intended to benefit any one person, but they may put an individual at risk.¹⁶⁻²³ But even those people most concerned about the individual's right to privacy acknowledge the societal benefits that medical research has to offer.¹⁶ To provide those benefits, the information used must be complete and unbiased. Complete access to existing data can help to ensure unbiased research results.¹

In 1996, Minnesota translated this debate into a statute that went into effect on January 1, 1997 (Minnesota Statute 144.335: "Patient Consent to Release of Records," available by visiting the *Journal's* Web site at www.jfp.denver.co.us). This law requires each patient to sign a general authorization form (not informed consent) to release records for medical or scientific research.

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The research community has speculated about the impact of the Minnesota statute and similar statutes on medical records research, but no data have been published.²⁴ Our study presents the rate of authorization refusal for a primary care multispecialty medical group and characterizes some of the differences between the people who refuse authorization and those who grant it.

METHODS

The Olmsted Medical Center (OMC) is a 75-clinician primary care multispecialty medical group in southeastern Minnesota, consisting of a large ambulatory care office in Rochester, Minnesota, and 12 branch offices in small communities throughout seven counties. The medical center includes a 65-bed acute care community hospital with an active obstetrical service, an outpatient surgery suite, an emergency department, and a full-time research department. For the past 35 years, the OMC has contributed data on all patient encounters to the Rochester Epidemiology Project, a population-based diagnostic index^{25,26} housed in the Mayo Clinic and supported by funding from the National Institutes of Health.

SAMPLE

The study sample consisted of all new and established patients seen at the OMC for their first 1997 visit, during January or February, including scheduled office visits, emergency department visits, and admissions to the hospital and the outpatient surgery center. Since each ambu-

latory office keeps its own records, separate from those at the hospital, authorization is required at every site.

STUDY DESIGN

Each patient was asked by a department receptionist or hospital registration clerk to read and sign a general authorization form as a part of the normal registration procedure.* Patients who asked for additional information were given brochures. The authorization form was mailed to those patients who were unable to complete it during their emergency department visit or hospital stay. If a patient died before becoming stable enough to grant or refuse authorization, the next of kin was asked to sign the form. A parent or guardian was asked to sign the authorization form for children aged 16 years or younger and for adults legally unable to grant authorization.

The patient's authorization decision (granted, refused, or undecided) was entered into the electronic registration database of the clinic or hospital and was electronically linked to patient demographic data and the patient's stated reason for the first 1997 appointment. Patients who had a service or billing code but no corresponding authorization code were identified as not having been asked about authorization.

ANALYSES

Simple descriptive statistics were used to estimate the proportion of patients granting authorization, refusing authorization, and remaining undecided (or not asked). The characteristics of patients refusing or granting authorization, and those either not asked or undecided, were assessed separately. Mantel-Haenszel tests were used to compare the proportions of patients granting authorization, refusing authorization, and undecided or not asked, across subgroups stratified by age, sex, and reason for appointment. Additional analyses were done to compare the two main groups, those patients granting and refusing authorization. Multivariate logistic regression analysis was used to describe the relationship between patients' characteristics and the decision to refuse authorization, after taking other characteristics into account.

RESULTS

A summary of the available characteristics of the 15,997 people who presented to OMC is provided in Table 1. Approximately 2% of the patients (n = 315) presented to multiple sites during the study and were counted when they made their first visit to each site.

Refused authorization was uncommon; 576 patients (3.6%) refused authorization, 14,493 (90.6%) granted authorization, 720 (4.5%) were undecided, and 208

(1.3%) were not asked. The proportion of patients who explicitly refused authorization, however, was not uniform across groups stratified by age, sex, site, and reason for visit (Table 2). The proportion of patients who refused authorization was highest among those presenting to the main Rochester office (4.6%) and lowest among those presenting to the branch offices (1.7%). Women were slightly more likely to refuse authorization than men (3.9% vs 3.3%, *P* = .03). When stratified by reason for visit, the greatest proportion of patients refusing authorization was found among those seen for mental health reasons (8.5%), eye care (5.1%), trauma (4.5%), and gynecology (4.0%).

Similarly, the proportion of patients who were undecided or not asked also varied across strata; the pattern, how-

TABLE 1

Demographics of All Patients Visiting the Olmsted Medical Center During the Study Period (N = 15,997)

Characteristic	No. (%)
Sex*	
Female	9491 (59)
Male	6490 (41)
Age, years*	
≤16	4384 (27)
17 to 40	5892 (37)
41 to 64	4059 (26)
≥65	1662 (10)
Site of visit*	
Main office	7817 (49)
Branch	4231 (26)
Emergency department	2290 (14)
Hospitalized	581 (4)
Outpatient surgery	304 (2)
Laboratory only and other	774 (5)
Reason for visit*†	
Infectious disease/acute illness	4188 (26)
Signs and symptoms	1200 (8)
Trauma	1192 (8)
Musculoskeletal	1102 (7)
Pregnancy	993 (6)
Dermatology	954 (6)
Gynecology	929 (6)
Mental health	670 (4)
Eye problems	624 (4)
General medical exams	553 (4)
Cardiovascular	542 (3)
Well-baby care	493 (3)
Ear/nose/throat	399 (2)
Endocrine	388 (2)
Gastrointestinal	378 (2)

*May not total 15,997 because some subjects had missing data elements.

†Top 15 reasons listed.

TABLE 2

Authorization Rates for All Patients Visiting Olmsted Medical Center During the Study Period (N=15,997)

Characteristics	Authorization No. (%)	Refusal No. (%)	Undecided/Not Asked No. (%)
Site of visit*			
Branch offices	4125 (97.5)	70 (1.7)	36 (.9)
Main office	7338 (93.9)	357 (4.6)	122 (1.8)
Outpatient surgery	248 (84.9)	7 (2.3)	39 (12.9)
Emergency department	1830 (79.9)	3.9 (3.9)	370 (16.1)
Laboratory only	515 (77.3)	41 (6.2)	110 (16.3)
Hospital admission	392 (67.5)	15 (2.6)	174 (29.9)
Sex/Age*			
Men, age (years)			
≤16	2047 (92.2)	73 (3.3)	100 (4.5)
17 to 40	1664 (89.1)	73 (3.9)	130 (7.0)
41 to 64	1545 (90.5)	55 (3.2)	107 (6.3)
≥65	629 (90.4)	12 (1.7)	55 (7.9)
Women, age (years)			
≤16	1969 (91.2)	66 (3.1)	124 (5.7)
17 to 40	3653 (90.9)	141 (3.5)	225 (5.6)
41 to 64	2110 (89.9)	120 (5.1)	117 (5.0)
≥65	854 (88.4)	40 (4.1)	72 (7.5)
Reason for visit*†			
Well-child care	470 (95.3)	14 (2.8)	9 (1.9)
Dermatology	902 (94.5)	31 (3.2)	21 (2.2)
Urology	282 (94.0)	4 (1.3)	14 (4.7)
Gynecology	865 (93.1)	37 (4.0)	27 (2.9)
Eye care	581 (93.1)	32 (5.1)	11 (1.8)
Infectious disease/acute illness	3895 (93.0)	146 (3.5)	147 (3.5)
General medical exam	498 (90.0)	22 (4.0)	33 (6.0)
Musculoskeletal	974 (88.4)	30 (2.7)	98 (8.9)
Mental health	589 (87.9)	57 (8.5)	24 (3.6)
Trauma	1027 (86.1)	54 (4.5)	111 (9.3)
Pregnancy	811 (81.7)	30 (3.0)	152 (15.3)

* $P = .001$ for differences among all categories of patient characteristics.

†A representative sample of visit type with highest and lowest refusal rates.

ever, was different. Nearly 30% of the patients admitted to the hospital and 16% of the patients seen in the emergency department were not asked or were undecided, compared with only 1.8% of those seen in the main office and .9% of those seen in the branch offices. The percentage of patients who were undecided or not asked was greatest in those patients seen for pregnancy-related visits (15.3%), trauma (9.3%), and musculoskeletal conditions (8.9%).

When analysis was restricted to those patients providing explicit refusal or authorization, the overall trends in refusal were confirmed. Compared with patients seen in the branch offices, patients seen in the main office were almost three times more likely to explicitly refuse authorization (odds ratio [OR] = 2.8; 95% confidence interval [CI], 2.2 - 3.7). Likewise, the odds of refusal were elevated among patients in the emergency department, admitted to the hospital, and seen for laboratory or x-ray tests. Compared by age and sex, women aged 41 to 64 years were more likely to explicitly refuse authorization (OR = 1.6; CI, 1.2 - 2.1), compared with the reference group, boys 16 years or younger (selected as the reference group because it had one of the lowest refusal rates in a group with a sufficient N). When stratified by reason for visit, the odds of refusal were greater in those seen for mental health reasons (OR = 12.6; CI, 1.7 - 92.1), trauma (OR = 7.7; CI, 1.1 - 56.4), and eye care (OR = 7.5; CI, 1.0 - 55.7). In a multivariate model that considered all the covariates of age, sex, and reason for visit simultaneously, there was very little change in the estimates of association.

DISCUSSION

In this community-based primary care practice, only 3.6% of the patients refused to allow their medical records to be used in research. The resulting 96% authorization rate is adequate for most research- or population-based assessments.²⁷⁻³²

However, the proportion of medical records unavailable for research because of patient refusal was higher in two subgroups: hospitalized women older than 65 (8%) and patients presenting for mental health issues (8.5%). The lower authorization rates for these groups raise concerns about the representativeness of study samples involving these subjects. Among patients presenting for mental health concerns, for example, 8% of

women and 18% of men refused authorization, which could lead to sex bias in the results of mental health studies based on these records.

The Minnesota general authorization law may affect research and practice in ways other than those seen within this single practice. For example, the Rochester Epidemiology Project, a unique resource, and the basis for more than 1000 studies of primary and tertiary care in a well-defined, population-based cohort, combines data from multiple practices within a single community.^{25,26} Many patients within the community receive care from multiple sources, making it necessary to request authorization from the same person at each site visited. Multiple requests may result in patient frustration and refusal. Within our own practice, almost 1% of patients who granted permission at the first site they visited in 1997 later refused permission at another site. The problem may be compounded when patients are referred to a clinic for tertiary care and are again asked to sign a general authorization form.

Ambulatory care research networks, which combine information across many physician practices, are an important source of information regarding rural primary care practice, and may be especially at risk.³³ The need to obtain general authorization from each patient at each site adds an extra burden to each practice. The cost and time required to obtain authorization, which is not required for treatment, may be more of a burden than some small primary care practices are willing to bear. This could adversely affect the ability to recruit practices into research networks.

The results from our study may not be generalizable to all medical care facilities. The trend to decreased authorization in large, more specialized segments of our practice suggests that our general authorization rate may be higher than it would be in large tertiary care centers. The average educational level and yearly income of Olmsted County residents are higher than the state and national average.²⁶ This may increase the individual's understanding of the process and the potential benefits of medical record research, although we were unable to study this association.

CONCLUSIONS

In our study, we were able to identify some basic characteristics of those refusing general authorization, such as age, sex, site, and reason for the current visit. However, under Minnesota's new data privacy law, it is not possible to review the medical records of those patients refusing authorization. Thus, it would not be possible to predict the bias that may occur in the sample, or the direction or magnitude of that bias for results obtained using the restricted records for medical records research.³⁴⁻⁵⁰ The internal and external validity of any records-based study is put at risk by the introduction of this undefined and undefinable authorization bias.^{34,40,45,48,49} Study conclusions from such

biased studies could harm patients and incorrectly inform public policy.^{29,30,32,45,49}

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