ORIGINAL ARTICLE

The Utility of Claims Data for Infection Surveillance following Anterior Cruciate Ligament Reconstruction

Michael V. Murphy, BA;[1] Dongyi (Tony) Du, MD, PhD;[2] Wei Hua, MD, PhD;[2] Karoll J. Cortez, MD, MHS;[3] Melissa G. Butler, PharmD, MPH, PhD;[4] Robert L. Davis, MD, MPH;[4] Thomas DeCoster, MD;[5] Laura Johnson, MD;[6] Lingling Li, PhD;[1] Cynthia Nakasato, MD;[7] James D. Nordin, MD, MPH;[8] Mayur Ramesh, MD;[6] Michael Schum, PhD;[9] Ann Von Worley, RN, BSHS;[9] Craig Zinderman, MD, MPH;[2] Richard Platt, MD, MSc;[1] Michael Klompas, MD, MPH[1]

OBJECTIVE. To explore the feasibility of identifying anterior cruciate ligament (ACL) allograft implantations and infections using claims.

DESIGN. Retrospective cohort study.

METHODS. We identified ACL reconstructions using procedure codes at 6 health plans from 2000 to 2008. We then identified potential infections using claims-based indicators of infection, including diagnoses, procedures, antibiotic dispensings, specialty consultations, emergency department visits, and hospitalizations. Patients' medical records were reviewed to determine graft type, validate infection status, and calculate sensitivity and positive predictive value (PPV) for indicators of ACL allografts and infections.

RESULTS. A total of 11,778 patients with codes for ACL reconstruction were identified. After chart review, PPV for ACL reconstruction was 96% (95% confidence interval [CI], 94%–97%). Of the confirmed ACL reconstructions, 39% (95% CI, 35%–42%) used allograft tissues. The deep infection rate after ACL reconstruction was 1.0% (95% CI, 0.7%–1.4%). The odds ratio of infection for allografts versus autografts was 0.41 (95% CI, 0.19–0.78). Sensitivity of individual claims-based indicators for deep infection after ACL reconstruction ranged from 0% to 75% and PPV from 0% to 100%. Claims-based infection indicators could be combined to enhance sensitivity or PPV but not both.

CONCLUSIONS. While claims data accurately identify ACL reconstructions, they poorly distinguish between allografts and autografts and identify infections with variable accuracy. Claims data could be useful to monitor infection trends after ACL reconstruction, with different algorithms optimized for different surveillance goals.

Infect Control Hosp Epidemiol 2014;35(6):652-659

Twenty percent of the 100,000 anterior cruciate ligament (ACL) surgeries performed each year in the United States use allograft tissue recovered from deceased human donors.[1-5] The risk of transmitting infections via allograft tissues is thought to be extremely low, but product recalls and case reports serve as reminders that allograft tissues do confer some risk of infection.[6-17] Determining the extent of the infection risk is challenging because there is no centralized process in the United States to identify and track all infections following allograft tissue implantations. The Food and Drug Administration requires manufacturers to report serious infections following tissue implantation; however, manufacturers depend on clinicians to voluntarily report this information.[18] The true number of infections may be underestimated by passive reporting and confounded by misattribution of infections with common organisms to surgical procedures rather than to allograft tissues.

Automated surveillance systems could complement passive reporting by monitoring infections after tissue implantations and detecting unusual increases that might signal problems with allograft tissues, prompting more directed investigation. Insurance claims are a promising source for automated postoperative infection surveillance since they include diagnosis, procedure, and prescription data for all encounters and settings, regardless of timing or location. Insurance claims analyses can substantially increase surgical site infection case detection

Affiliations: 1. Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, Massachusetts; 2. Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville, Maryland; 3. Office of Cellular, Tissue, and Gene Therapies, Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville, Maryland; 4. Center for Health Research–Southeast, Kaiser Permanente Georgia, Atlanta, Georgia; 5. Department of Orthopaedics and Rehabilitation, University of New Mexico School of Medicine, Albuquerque, New Mexico; 6. Center for Health Services Research, Henry Ford Health System, Detroit, Michigan; 7. Center for Health Research, Kaiser Permanente Hawaii, Honolulu, Hawaii; 8. HealthPartners Institute for Education and Research, Minneapolis, Minnesota; 9. Health Services Research Division, LCF Research, Albuquerque, New Mexico.

Received October 18, 2013; accepted January 20, 2014; electronically published April 22, 2014.

 0899-823X/2014/3506-0004$15.00. DOI: 10.1086/676430

compared with traditional hospital-based surveillance.[19-26] Routine analysis of large claims-based data sets—such as those maintained by Medicare, Medicaid, Veterans Affairs, health maintenance organizations, and commercial insurers—could provide a window into infection rates in allograft versus autograft tissues.

To evaluate the utility of claims data for infection surveillance after ACL reconstruction, we conducted a study to assess their accuracy to (1) detect ACL reconstruction surgeries, (2) distinguish between allograft and autograft tissue implants, and (3) detect infections following ACL reconstructions. We also explored the utility of combining different kinds of claims data to enhance their sensitivity and positive predictive value (PPV) for infections following ACL reconstructions.

METHODS

Setting and Population

We used claims data from 6 US health plans that participate in the HMO Research Network: Harvard Pilgrim Health Care, HealthPartners Institute for Education and Research, Henry Ford Health System, LCF Research, Kaiser Permanente Georgia, and Kaiser Permanente Hawaii. The claims include data on enrollment, procedures, diagnoses, outpatient pharmacy dispensings, inpatient encounters, and outpatient encounters. Institutional review boards at each site approved the study.

Identifying ACL Reconstructions

We used *Current Procedural Terminology* (CPT) code 29888 (arthroscopically aided ACL repair) and *International Classification of Diseases, Ninth Revision* (ICD-9) procedure code 81.45 (other repair of the cruciate ligaments) to identify all patients undergoing ACL reconstruction surgeries in participating health plans between January 1, 2000, and December 31, 2008. There is no procedure code specific for allograft placement, so we investigated whether the presence or absence of concurrent procedure codes for graft recovery might be used to identify surgeries involving implantation of autograft tissue.

Identifying Possible Infections

Potential infections were identified on the basis of suggestive diagnosis codes, procedure codes, antibiotic dispensings, infectious disease consults, hospitalizations, or emergency department visits within 1–90 days following the index surgery. We excluded potential infection indicators if they were present in the patients' claims records in the year prior to the initial surgery. Antibiotic dispensing indicators were limited to antibiotics started at least 3 days following surgery and continued for at least 7 days to minimize false positive signals from antibiotics prescribed for perioperative prophylaxis. Diagnoses and antibiotics were classified by presumptive organism type (bacteria, virus, fungus, parasite). Infection management procedures and microbiology lab tests were classified as generic or allograft specific as well as by presumptive organism type (see code lists and classifications, available online).

Medical Record Review

We requested medical records for a sample of the 11,778 patients with codes for ACL reconstruction to confirm whether the patient had an ACL reconstruction, to determine whether allograft or autograft tissue was implanted, and to assess postoperative infections. A hierarchical stratified sampling strategy was used to sample records of patients judged

TABLE 1. Sampling Strategy for Medical Record Review

	Patients identified, *N*	Records sampled, *N* (%)
Infection indicators employed for sampling strategy		
Diagnosis, procedure, or infectious disease consult (with or without microbiology test and/or high-probability antibiotic)[a]	842	519 (62)
Microbiology test and high-probability antibiotic[a] (no diagnosis, procedure, or consult)	81	58 (72)
High-probability antibiotic[a] alone	463	332 (72)
Microbiology test alone	393	176 (45)
None	9,999	959 (9.6)
All infection indicators		
Diagnosis (any)	467	280 (60)
High-probability diagnosis	366	258 (70)
Procedure	443	268 (61)
Microbiology test	548	287 (52)
Antibiotics (any)	1,695	710 (42)
High-probability antibiotic[a]	691	479 (69)
Infectious disease consult	41	32 (78)
Emergency department visit	890	280 (31)
Hospitalization	1,142	314 (28)

[a] Started at least 3 days after surgery and continued for at least 7 days.

https://doi.org/10.1086/676430 Published online by Cambridge University Press

TABLE 2. Sensitivity and Positive Predictive Value (PPV) of Procedure Codes

Code	Identified	Reviewed[a]	Reconstruction (%)	Sensitivity (95% CI)	PPV (95% CI)
ACL reconstruction					
CPT 29888 or ICD-9 81.45	11,778	1,744	1,676 (96)	NA	96 (94–97)
CPT 29888 (with or without ICD-9 81.45)	11,060	1,606	1,550 (97)	94 (94–94)	96 (94–98)
ICD-9 81.45 (with or without CPT 29888)	4,145	628	605 (96)	35 (34–35)	97 (95–98)
CPT 29888 and ICD-9 81.45	3,427	490	479 (98)	28 (28–29)	97 (95–99)
ACL reconstruction with allograft					
CPT 29888 or ICD-9 81.45	11,778	1,670	529 (32)	NA	37 (33–41)
CPT 29888 (with or without ICD-9 81.45)	11,060	1,540	490 (32)	95 (94–97)	38 (34–42)
ICD-9 81.45 (with or without CPT 29888)	4,145	602	215 (36)	34 (30–38)	37 (31–42)
CPT 29888 and ICD-9 81.45	3,427	472	176 (37)	29 (26–33)	39 (33–44)

NOTE. Data are no. of patients, unless otherwise indicated. ACL, anterior cruciate ligament; CI, confidence interval; CPT, *Current Procedural Terminology*; ICD-9, *International Classification of Diseases, Ninth Revision*; NA, not applicable.

[a] For ACL reconstruction, medical records with sufficient information to confirm or refute ACL reconstruction. For ACL reconstruction with allograft tissue, medical records with sufficient information to confirm allograft or autograft tissue implanted or confirmed non-ACL reconstruction.

a priori to have a higher probability of infection (Table 1). Successive sampling strata were nonoverlapping and excluded all patients identified by higher probability strata. We selected 2,044 medical records for review (17% of the 11,778 patients with ACL reconstruction codes), including 1,085 records with infection indicators and 959 records without any infection indicators (to facilitate calculating sensitivities).

Medical records at each site were reviewed by trained nurse abstractors using a standardized abstraction form. An infectious disease physician adjudicated unclear cases. Postoperative infections were assessed using the Centers for Disease Control and Prevention's National Healthcare Safety Network definitions for surgical site infections.[27] For surgeries using an autograft, only infections of the implant site were included. Antibiotics used to treat wound redness or erythema were considered presumptive evidence for superficial infection. We limited the postoperative risk window for deep and organ/space infections (ie, involving tissues deeper than the skin) to 6 months rather than 1 year since prior studies have shown that almost all infections occur within 180 days of surgery.[3,4,28]

Statistical Analyses

We calculated the sensitivity and PPV of each potential claims-based infection indicator. We used inverse probability weighting to correct for differences in the percentage of patients sampled in each stratum. Specifically, for each combination of site and sampling strata, we calculated the number of patients identified via claims and the number of medical records reviewed. We then projected the total number of infections in the strata as patients identified × (true infections/records reviewed). For each infection indicator, we summed the number of patient records identified across all strata and summed the estimated number of true infections across all strata. We estimated sensitivity by dividing the estimated number of infections among patients with the infection indicator by the estimated total number of infections in the entire study population. We estimated PPV by dividing the estimated number of true infections by the number of patient records identified for each infection indicator.

We estimated the number of ACL reconstructions within each stratum as estimated grafts = patients identified × (confirmed grafts/records reviewed). The number of infections for each graft type (allograft or autograft) was estimated within each stratum as estimated infections = estimated grafts × (infections with graft type/records reviewed with graft type). We then summed across all strata and divided the estimated infections by the estimated grafts to obtain graft-specific infection rates.

For all estimations described in this section, we generated 95% confidence intervals (CIs) for infection rates and the odds ratio of infection by graft type using Monte Carlo simulations. Specifically, we simulated the number of infections for each stratum using multinomial distributions and probabilities estimated from the observed data. We repeated this process 100,000 times and derived 95% CIs from the resulting 2.5 and 97.5 percentiles. All analyses were performed using SAS (ver. 9.3; SAS Institute).

Developing Optimized Infection-Finding Algorithms

After assessing individual infection indicators, we combined infection indicators to maximize sensitivity and PPV for deep and organ/space infections (deep infections). We focused on deep infections as a combined outcome since diagnoses of superficial infection can be highly subjective and deep infections may provide more objective and quantifiable findings.[29,30]

To optimize PPV, we combined candidate criteria using "and" statements; to maximize sensitivity, we combined multiple high PPV criteria using "or" statements. We used the data from 4 study sites (hereafter derivation sites) to derive combination algorithms and then validated them using data from the remaining 2 sites (hereafter validation sites). We calculated 95% CIs for these algorithms using the Monte Carlo simulations described above with 50,000 replications.

https://doi.org/10.1086/676430 Published online by Cambridge University Press

TABLE 3. Sensitivity and Positive Predictive Value (PPV) of Potential Infection Indicators for Deep Infections

	Patients identified	Records reviewed	*N* (%)	Sensitivity (95% CI)	PPV (95% CI)
Any infection indicator	3,570	910	61 (6.7)	93 (90–98)	3.4 (2.4–4.7)
Infection diagnosis					
Any	467	215	57 (27)	68 (56–84)	22 (17–28)
Unspecified	356	195	56 (29)	63 (51–79)	24 (18–30)
Bacteria	81	55	45 (82)	43 (32–59)	74 (61–90)
Fungus	14	10	2 (20)	1.5 (0.0–3.0)	18 (0.0–27)
Micro test					
Any	548	216	33 (15)	51 (37–73)	12 (6.9–16)
Unspecified	332	140	29 (21)	51 (24–64)	21 (8.9–23)
Bacteria	284	108	22 (20)	35 (23–51)	17 (8.1–22)
Fungus	62	25	0 (0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)
Infection management procedure					
Any	443	222	47 (21)	75 (65–88)	23 (15–32)
Allograft specific	313	159	38 (24)	62 (51–76)	26 (18–36)
Antibiotic					
Any	1,695	518	51 (9.8)	63 (47–82)	5.0 (3.5–7.0)
Bacteria	1,623	504	51 (10)	63 (47–82)	5.3 (3.7–7.3)
Fungus	54	18	2 (11)	1.5 (0.0–2.2)	9.1 (0.0–9.1)
High-probability antibiotic[a]					
Any	691	347	45 (13)	59 (36–89)	12 (6.7–16)
Bacteria	677	341	44 (13)	59 (35–89)	12 (6.7–17)
Fungus	17	9	2 (22)	1.5 (0.0–2.2)	20 (0.0–20)
Infectious disease consult	41	31	18 (58)	14 (9.2–21)	52 (37–63)
Emergency department visit	890	212	25 (12)	35 (24–47)	5.2 (3.6–6.7)
Hospitalization	1,142	257	44 (17)	50 (36–66)	6.0 (4.4–7.7)

NOTE. Data are no. of patients, unless otherwise indicated. CI, confidence interval.
[a] Started at least 3 days after surgery and continued for at least 7 days.

RESULTS

We identified 11,778 patients with a procedure code for ACL reconstruction, requested 2,044 medical records, and received 1,752 for review. On review, 1,744 medical records had sufficient information to confirm or refute ACL reconstruction, and 1,676 were confirmed to be ACL reconstructions (PPV, 96% [95% CI, 94%–97%]). Sensitivity and PPV of the most common procedure code, CPT 29888, was 94% (95% CI, 94%–94%) and 96% (95% CI, 94%–98%) respectively (Table 2). Only a small fraction of autograft surgeries had concurrent procedure codes for graft recovery (4%); hence, the absence of these codes did not enhance sensitivity or PPV for use of an allograft.

On the basis of medical record review of the 1,676 confirmed ACL reconstructions, 529 used allografts, 1,073 used autografts, and 74 were indeterminate. The PPV of CPT 29888 or ICD-9 81.45 for identifying ACL reconstruction using allograft tissue was 37% (95% CI, 33%–41%). Sensitivity and PPV of CPT 29888 for ACL reconstruction using allograft tissue was 95% (95% CI, 94%–97%) and 38% (95% CI, 34%–42%) respectively (Table 2). After correcting for sampling weights, we project that 39% (95% CI, 35%–42%) of ACL reconstructions used an allograft.

On review of 1,471 medical records where ACL reconstruction was confirmed and with data on graft type and infection status, we found 55 deep infections. After correcting for sampling weights, we projected 118 deep infections after ACL reconstruction among the entire population for a net deep infection rate of 1.0% (95% CI, 0.7%–1.4%) in the 6 months following surgery. Of these, 25 were projected to be in allograft tissue recipients (net allograft infection rate, 0.5% [95% CI, 0.3%–0.8%]) and 93 in autograft recipients (net autograft infection rate, 1.3% [95% CI, 0.8%–1.9%]). The difference between these 2 rates was significant (odds ratio for allograft vs autograft infection, 0.41 [95% CI, 0.19–0.78]).

The sensitivity and PPVs for potential claims-based infection indicators are presented in Table 3. Of the 11,778 patients with procedure codes for ACL reconstruction, 3,570 (30%) had 1 or more potential infection indicators. Overall, the presence of any infection indicator detected 93% of cases, but only 3.4% of patients identified had confirmed deep infections. There was a trade-off between sensitivity and PPV. The most sensitive individual indicators were infection management procedures (75% [95% CI, 65%–88%]), infection diagnosis codes (68% [95% CI, 56%–84%]), antibiotic dispensings (63% [95% CI, 47%–82%]), and microbiology tests

https://doi.org/10.1086/676430 Published online by Cambridge University Press

TABLE 4. Combination Algorithms with the Highest Sensitivity for Deep Infections

	Derivation sites		Validation sites	
	Sensitivity (95% CI)	PPV (95% CI)	Sensitivity (95% CI)	PPV (95% CI)
Diagnosis, bacteria or infection management procedure or ID consult	84 (72–98)	26 (19–33)	78 (66–100)	19 (6.0–36)
Diagnosis, bacteria or ([infection management procedure or ID consult] and [hospitalization or antibiotic sustained[a] or micro test, unspecified])	66 (55–82)	44 (34–54)	69 (46–100)	41 (14–75)
Diagnosis, bacteria or (micro test and bacterial antibiotic) or (infection management procedure and bacterial antibiotic) or ID consult	69 (56–84)	25 (20–30)	59 (42–100)	17 (6.7–29)
Infection management procedure and diagnosis	51 (41–65)	65 (52–75)	53 (32–100)	52 (20–83)
Antibiotic, sustained[a] and diagnosis	49 (39–63)	42 (34–49)	52 (20–100)	41 (16–66)
Diagnosis, bacteria or (micro test and bacterial antibiotic)	58 (47–73)	26 (21–31)	51 (33–100)	19 (7.9–32)
Infection management procedure and micro test, unspecified	32 (23–43)	51 (36–66)	51 (0–85)	94 (0–100)
Antibiotic, sustained[a] and high-risk diagnosis	48 (38–62)	45 (36–52)	50 (20–100)	41 (17–66)
Infection management procedure and diagnosis, unspecified	50 (40–64)	72 (58–83)	48 (30–100)	50 (19–82)
Antibiotic, sustained[a] and diagnosis, unspecified	46 (37–60)	46 (38–54)	47 (18–100)	40 (16–64)

NOTE. Data are sorted by sensitivity in the validation sites. CI, confidence interval; ID, infectious disease; PPV, positive predictive value.
[a] ≥7 days to first new prescription flag and ≥7 days supplied.

(51% [95% CI, 37%–73%]); all had PPVs below 30%. Conversely, potential infection indicators with the highest PPV were bacterial diagnosis codes (74% [95% CI, 61%–90%]) and infectious disease consultation (52% [95% CI, 37%–63%]); both had sensitivities below 50%.

We experimented with combining potential infection indicators to maximize sensitivity and PPV. We were able to develop combination algorithms that improved sensitivity (Table 4) or PPV (Table 5) but not both. The most sensitive combination algorithm (bacterial diagnosis code or infection management procedure or infectious disease consult) detected 84% (95% CI, 72%–98%) of deep infections in the derivation sites but with a PPV of only 26% (95% CI, 19%–33%). On validation in 2 independent sites, sensitivity was 78% (95% CI, 66%–100%), and PPV was 19% (6.0%–36%). The algorithm for infection management procedure and microbiology test, unspecified organism had the highest PPV in the validation sites, 94% (95% CI, 0%–100%) with sensitivity of 51% (95% CI, 0%–85%), but had a PPV of only 51% (95% CI, 36%–66%) with sensitivity of 32% (95% CI, 23%–43%) in the derivation sites.

DISCUSSION

Our study provides an estimate of allograft tissue use in ACL reconstruction and infection rates by graft type and illustrates the potential benefits and limitations of using claims data for active surveillance for allograft tissue infections. This is the largest multicenter study of infections following ACL surgery to date and likely the first study to use insurance claims data as a primary means to investigate infections after ACL reconstruction. Claims data can accurately identify ACL reconstruction surgery, but medical records must be reviewed to determine whether allograft or autograft tissue was implanted. Individual indicators found in claims data (eg, diagnosis or procedure codes, antibiotic dispensings) can identify deep infections after ACL reconstruction, but with many false positives. Combining different indicators can optimize either sensitivity or PPV for infections but not both.

Our estimated rate of deep infections (1.0%) is consistent with previously reported rates ranging from 0.14% to 1.7%.[3,28,31-40] As in previous studies,[3,28,37] we did not find an elevated rate of infections in allograft tissue recipients, suggesting that the risk of infection transmission from allograft tissues is small. Decreased surgical time, less extensive tissue dissection, and less graft preparation are possible explanations for decreased infection risk among allograft recipients, although clinical and procedural factors influencing surgeons' graft choices may confound this association.[3,28]

Our findings are also consistent with previous reports on the utility of claims data for surgical site infection surveillance. Two studies that explored multiple algorithms found similar trade-offs between sensitivity and PPV. One used data from a commercial health plan to identify all nonobstetric procedures from 1 hospital. Their initial algorithm resulted in 92% sensitivity and 21% PPV for any infection. Modifying the algorithm increased PPV to 48% but dropped sensitivity to 74%.[19] Another study used data from 2 commercial health plans to identify breast surgeries and data from 1 health plan to identify cesarean sections.[20] Their least restrictive algorithm had 18% PPV for any infection after breast surgery (sensitivity not reported). A more restrictive algorithm increased PPV to 50% but found only 26% of infections identified by the least restrictive algorithm. For cesarean sections, the least restrictive algorithm had 32% PPV for any infection (sensitivity not reported). The more restrictive algorithm increased PPV to 44% but found only 37% of infections identified by the least restrictive algorithm.

Other studies have shown similar potential and limitations of claims data for infection surveillance. One used ICD-9 diagnosis codes from inpatient and outpatient Medicare

https://doi.org/10.1086/676430 Published online by Cambridge University Press

TABLE 5. Combination Algorithms with the Highest Positive Predictive Value (PPV) for Deep Infections

	Derivation sites		Validation sites	
	Sensitivity (95% CI)	PPV (95% CI)	Sensitivity (95% CI)	PPV (95% CI)
Infection management procedure and micro test, unspecified	32 (23–43)	51 (36–66)	51 (0–85)	94 (0–100)
Infection management procedure and micro test, bacteria	26 (18–35)	60 (41–77)	29 (0–72)	67 (0–100)
Infection management procedure and micro test	37 (28–49)	54 (39–67)	41 (0–96)	65 (0–100)
Infection management procedure and diagnosis, bacteria	38 (30–50)	88 (74–97)	29 (12–69)	61 (24–95)
Diagnosis, bacteria or ([ID consult] and [hospitalization or infection management procedure or micro test, unspecified])	47 (37–61)	80 (68–89)	37 (18–96)	54 (28–91)
Infection management procedure and diagnosis	51 (41–65)	65 (52–75)	53 (32–100)	52 (20–83)
Diagnosis, bacteria or (infection management procedure and antibiotic, sustained[a] and hospitalization)	50 (39–65)	86 (74–94)	39 (19–98)	51 (25–89)
Infection management procedure and diagnosis, unspecified	50 (40–64)	72 (58–83)	48 (30–100)	50 (19–82)
ID consult and diagnosis	17 (12–22)	78 (58–89)	8.3 (3.7–34)	50 (50–50)
Infection management procedure and hospitalization	46 (36–59)	57 (43–69)	34 (12–80)	49 (15–80)

NOTE. Data are sorted by PPV in the validation sites. CI, confidence interval; ID, infectious disease.

[a] ≥7 days to first new prescription flag and ≥7 days supplied.

claims to identify infections after a variety of surgeries at more than 200 hospitals and found 48% sensitivity for deep infections with 24% PPV.[21] Another study using Medicare claims identified coronary artery bypass grafting patients and used diagnosis and procedure codes to identify infections.[22] Using data from 671 hospitals and reviewing medical records from 20% of hospitals, their algorithm had 21% PPV for deep infections (sensitivity not reported).

Our results need to be interpreted within the context of the study's limitations. We were unable to retrieve all requested medical records, and some records had incomplete information. We compared patients with retrievable and nonretrievable medical records on age, sex, year of surgery, and presence of infection indicators. Among all these parameters, only antibiotic dispensings were more common among patients whose infection status could not be confirmed (41% vs 33%; $P = .002$). However, there was no difference in the frequency of antibiotic dispensings in patients with allografts versus autografts; hence, this factor is unlikely to have led to differential misclassification of infections. Another potential limitation is our decision to search for infections in the medical record up to 6 months after surgery rather than 1 year, per National Healthcare Safety Network criteria. However, on the basis of prior studies, we expect to identify almost all infections in this time frame.[3,4,28] In our study, 98% of confirmed deep infections occurred with 90 days. Finally, we note potential sources of error in claims data, including failure to capture some important transactions (eg, use of low-cost generic antibiotics rather than claiming the cost from insurance) or loss of follow-up due to loss of insurance or change in insurance carrier.

Our results show that while routine analysis of claims data is an imperfect strategy to monitor for infections after allograft tissue implantation, it could be a reasonable approach if algorithms are optimized to enhance sensitivity or predictive value, depending on the surveillance goal. A high-sensitivity algorithm could serve as a screening tool to identify cases with a high likelihood of infection for targeted medical record reviews. Conversely, high PPV algorithms could be used to monitor for unusual changes in infection rates, which, if detected, might prompt further investigation. Even algorithms with low to moderate PPV can make medical record review much more efficient. We estimate that with blind sampling, one would need to review 100 records to identify 1 deep infection. Using our highest-sensitivity algorithm, which had a PPV of 23% across all sites, one need review only an average of 4 or 5 medical records to find 1 case.

Coupling these algorithms with cluster detection statistics may further increase capacity to detect unusual changes from baseline infection frequency, prompting more directed investigation. More broadly, the utility and efficiency of claims data for allograft tissue safety surveillance could be enhanced by adding dedicated diagnosis and/or procedure codes for allografts versus autografts to the coding lexicon. ICD-10 procedure codes do not include such codes, possibly a missed opportunity. Finally, combining claims data with electronic health record data—such as microbiology culture results and natural language parsing of clinicians' notes—may be a further means to refine surveillance.

ACKNOWLEDGMENTS

We thank the project managers, programmers, and medical record reviewers at each site. We also thank Yury Vilk for developing the data extraction program and Victoria J. Morrison for leading record reviews and training abstractors at each site. The views expressed in this article are those of the authors and are not intended to convey official Food and Drug Administration policy or guidance.

Financial support. This study was supported through funding from con-

tracts HHSF223200810026I/TO6 and HHSF22301005T from the Food and Drug Administration.

Potential conflicts of interest. All authors report no conflicts of interest relevant to this article. All authors submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest, and the conflicts that the editors consider relevant to this article are disclosed here.

Address correspondence to Michael V. Murphy, BA, Harvard Pilgrim Health Care Institute, 133 Brookline Avenue, 6th Floor, Boston, MA 02215 (michael_murphy@harvardpilgrim.org).

Presented in part: 17th Annual HMO Research Network Conference; Boston, Massachuestts; March 23–25, 2011; 18th Annual HMO Research Network Conference; Seattle, Washington; April 29–May 2, 2012.

REFERENCES

1. Greenberg DD, Robertson M, Vallurupalli S, White RA, Allen WC. Allograft compared with autograft infection rates in primary anterior cruciate ligament reconstruction. *J Bone Joint Surg Am* 2010;92(14):2402–2408.
2. Lyman S, Koulouvaris P, Sherman S, Do H, Mandl LA, Marx RG. Epidemiology of anterior cruciate ligament reconstruction: trends, readmissions, and subsequent knee surgery. *J Bone Joint Surg Am* 2009;91(10):2321–2328.
3. Katz LM, Battaglia TC, Patino P, Reichmann W, Hunter DJ, Richmond JC. A retrospective comparison of the incidence of bacterial infection following anterior cruciate ligament reconstruction with autograft versus allograft. *Arthroscopy* 2008; 24(12):1330–1335.
4. Crawford C, Kainer M, Jernigan D, et al. Investigation of postoperative allograft-associated infections in patients who underwent musculoskeletal allograft implantation. *Clin Infect Dis* 2005;41(2):195–200.
5. Cohen SB, Sekiya JK. Allograft safety in anterior cruciate ligament reconstruction. *Clin Sports Med* 2007;26(4):597–605.
6. Mallick TK, Mosquera A, Zinderman CE, Martin LS, Wise RP. Reported infections after human tissue transplantation before and after new food and drug administration (FDA) regulations, United States, 2001 through June, 2010. *Cell Tissue Bank* 2012; 13(2):259–267.
7. Cartwright EJ, Prabhu RM, Zinderman CE, et al. Transmission of *Elizabethkingia meningoseptica* (formerly *Chryseobacterium meningosepticum*) to tissue-allograft recipients: a report of two cases. *J Bone Joint Surg Am* 2010;92(6):1501–1506.
8. Mei-Dan O, Mann G, Steinbacher G, Ballester SJ, Cugat RB, Alvarez PD. Septic arthritis with *Staphylococcus lugdunensis* following arthroscopic ACL revision with BPTB allograft. *Knee Surg Sports Traumatol Arthrosc* 2008;16(1):15–18.
9. Mroz TE, Joyce MJ, Steinmetz MP, Lieberman IH, Wang JC. Musculoskeletal allograft risks and recalls in the United States. *J Am Acad Orthop Surg* 2008;16(10):559–565.
10. Lee EH, Ferguson D, Jernigan D, et al. Invasive group-A streptococcal infection in an allograft recipient. A case report. *J Bone Joint Surg Am* 2007;89(9):2044–2047.
11. Wang S, Zinderman C, Wise R, Braun M. Infections and human tissue transplants: review of FDA MedWatch reports 2001–2004. *Cell Tissue Bank* 2007;8(3):211–219.
12. Brief report: investigation into recalled human tissue for transplantation—United States, 2005–2006. *MMWR Morb Mortal Wkly Rep* 2006;55(20):564–566.
13. Kainer MA, Linden JV, Whaley DN, et al. Clostridium infections associated with musculoskeletal-tissue allografts. *N Engl J Med.* Jun 17 2004;350(25):2564–2571.
14. Barbour SA, King W. The safe and effective use of allograft tissue—an update. *Am J Sports Med* 2003;31(5):791–797.
15. Centers for Disease Control and Prevention. Hepatitis C virus transmission from an antibody-negative organ and tissue donor—United States, 2000–2002. *MMWR Morb Mortal Wkly Rep* 2003;52(13):273–276.
16. Centers for Disease Control and Prevention. Update: allograft-associated bacterial infections—United States, 2002. *MMWR Morb Mortal Wkly Rep* 2002;51(10):207–210.
17. Centers for Disease Control and Prevention. Septic arthritis following anterior cruciate ligament reconstruction using tendon allografts—Florida and Louisiana, 2000. *MMWR Morb Mortal Wkly Rep.* 2001;50(48):1081–1083.
18. Food and Drug Administration (FDA) . *Guidance for Industry: MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).* Silver Spring, MD: FDA, 2005. http://www.fda.gov/biologicsbloodvaccines /guidancecomplianceregulatorinformation/guidances/tissue /ucm074000.htm. Accessed October 19, 2011.
19. Sands K, Vineyard G, Livingston J, Christiansen C, Platt R. Efficient identification of postdischarge surgical site infections: use of automated pharmacy dispensing information, administrative data, and medical record information. *J Infect Dis* 1999; 179(2):434–441.
20. Miner AL, Sands KE, Yokoe DS, et al. Enhanced identification of postoperative infections among outpatients. *Emerg Infect Dis* 2004;10(11):1931–1937.
21. Lawson EH, Louie R, Zingmond DS, et al. A comparison of clinical registry versus administrative claims data for reporting of 30-day surgical complications. *Ann Surg* 2012;256(6):973–981.
22. Huang SS, Placzek H, Livingston J, et al. Use of Medicare claims to rank hospitals by surgical site infection risk following coronary artery bypass graft surgery. *Infect Control Hosp Epidemiol* 2011;32(8):775–783.
23. Sands KE, Yokoe DS, Hooper DC, et al. Detection of postoperative surgical-site infections: comparison of health plan–based surveillance with hospital-based programs. *Infect Control Hosp Epidemiol* 2003;24(10):741–743.
24. Calderwood MS, Ma A, Khan YM, et al. Use of Medicare diagnosis and procedure codes to improve detection of surgical site infections following hip arthroplasty, knee arthroplasty, and vascular surgery. *Infect Control Hosp Epidemiol* 2012;33(1):40–49.
25. Olsen MA, Fraser VJ. Use of diagnosis codes and/or wound culture results for surveillance of surgical site infection after mastectomy and breast reconstruction. *Infect Control Hosp Epidemiol* 2010;31(5):544–547.
26. Platt R, Kleinman K, Thompson K, et al. Using automated health plan data to assess infection risk from coronary artery bypass surgery. *Emerg Infect Dis* 2002;8(12):1433–1441.
27. Horan TC, Andrus M, Dudeck MA. CDC/NHSN surveillance definition of health care–associated infection and criteria for

specific types of infections in the acute care setting. *Am J Infect Control* 2008;36(5):309–332.
28. Barker JU, Drakos MC, Maak TG, Warren RF, Williams RJ 3rd, Allen AA. Effect of graft selection on the incidence of postoperative infection in anterior cruciate ligament reconstruction. *Am J Sports Med* 2010;38(2):281–286.
29. Anderson DJ, Chen LF, Sexton DJ, Kaye KS. Complex surgical site infections and the devilish details of risk adjustment: important implications for public reporting. *Infect Control Hosp Epidemiol* 2008;29(10):941–946.
30. Ming DY, Chen LF, Miller BA, Anderson DJ. The impact of depth of infection and postdischarge surveillance on rate of surgical-site infections in a network of community hospitals. *Infect Control Hosp Epidemiol* 2012;33(3):276–282.
31. Wang C, Ao Y, Wang J, Hu Y, Cui G, Yu J. Septic arthritis after arthroscopic anterior cruciate ligament reconstruction: a retrospective analysis of incidence, presentation, treatment, and cause. *Arthroscopy* 2009;25(3):243–249.
32. Van Tongel A, Stuyck J, Bellemans J, Vandenneucker H. Septic arthritis after arthroscopic anterior cruciate ligament reconstruction: a retrospective analysis of incidence, management and outcome. *Am J Sports Med* 2007;35(7):1059–1063.
33. Binnet MS, Basarir K. Risk and outcome of infection after different arthroscopic anterior cruciate ligament reconstruction techniques. *Arthroscopy* 2007;23(8):862–868.
34. Judd D, Bottoni C, Kim D, Burke M, Hooker S. Infections following arthroscopic anterior cruciate ligament reconstruction. *Arthroscopy* 2006;22(4):375–384.
35. Burks RT, Friederichs MG, Fink B, Luker MG, West HS, Greis PE. Treatment of postoperative anterior cruciate ligament infections with graft removal and early reimplantation. *Am J Sports Med* 2003;31(3):414–418.
36. Schollin-Borg M, Michaelsson K, Rahme H. Presentation, outcome, and cause of septic arthritis after anterior cruciate ligament reconstruction: a case control study. *Arthroscopy* 2003; 19(9):941–947.
37. Indelli PF, Dillingham M, Fanton G, Schurman DJ. Septic arthritis in postoperative anterior cruciate ligament reconstruction. *Clin Orthop Relat Res* 2002(398):182–188.
38. Viola R, Marzano N, Vianello R. An unusual epidemic of *Staphylococcus*-negative infections involving anterior cruciate ligament reconstruction with salvage of the graft and function. *Arthroscopy* 2000;16(2):173–177.
39. McAllister DR, Parker RD, Cooper AE, Recht MP, Abate J. Outcomes of postoperative septic arthritis after anterior cruciate ligament reconstruction. *Am J Sports Med* 1999;27(5):562–570.
40. Williams RJ 3rd, Laurencin CT, Warren RF, Speciale AC, Brause BD, O'Brien S. Septic arthritis after arthroscopic anterior cruciate ligament reconstruction. Diagnosis and management. *Am J Sports Med* 1997;25(2):261–267.