

Consumer Cost Sharing and Use of Biopharmaceuticals for Rheumatoid Arthritis

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James C. Robinson, PhD, MPH

Objectives: To evaluate the effect of consumer cost sharing on use of physician-administered and patient self-administered specialty drugs for rheumatoid arthritis.

Design: Multivariate statistical analysis of probability and use of physician-administered specialty drugs, patient self-injected specialty drugs, non-biologic disease-modifying anti-rheumatic drugs, and symptom relief drugs. Analyses were conducted for patients enrolling in preferred provider organization (PPO) plans and health maintenance organization (HMO) plans with different cost-sharing requirements, adjusted for patient demographics, health status, and geographical location.

Setting: Professional, facility, and pharmaceutical claims for beneficiaries of CalPERS, the public employee insurance purchasing alliance in California, for 2008-2009. Consumer cost-sharing requirements were obtained for each type of drug and service for each type of insurance plan.

Results: PPO insurance enrollees face substantially higher cost sharing for physician-administered specialty drugs, compared with HMO enrollees in CalPERS. PPO patients with rheumatoid arthritis are only half as likely as HMO enrollees to choose a physician-administered specialty drug (4.2% vs 9.3%) ($P \leq .05$), and use 25% less of the drugs if they use any (\$10,356 vs \$13,678) ($P < .05$). They are 30% more likely to use a self-administered specialty drug than are HMO enrollees (29.3% vs 22.1%) ($P \leq .05$), and use 35% more of the drugs if any (\$16,015 vs \$12,378) ($P \leq .05$).

Conclusions: Consumer cost sharing reduces the use of physician-administered specialty drugs for rheumatoid arthritis. The higher use of patient self-administered specialty drugs suggests that the disincentives for use of physician-administered drugs were offset by an increased incentive to use self-administered drugs.

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Pharmaceutical innovation in recent years has come largely from biopharmaceuticals and other specialty drugs that need novel methods of handling, storage, transportation, and use.¹⁻⁴ Many are administered to the patient by a physician in the office, in a community-based infusion center, or in a hospital ambulatory care center. Some new specialty drugs also can be administered by the patient, often through self-injection. Physicians and patients with immunity disorders, cancer, and other complex conditions now often experiment with modes of administration to find the drug that best treats the patient's symptoms and underlying disease.

The choice between office infusion and self-injection for biopharmaceuticals is based in part on clinical factors, as some patients respond better to one drug than to another despite the similarity in their reported effects and US Food and Drug Administration labeling.⁵ Convenience to the patient also plays an important role, with some patients preferring to avoid the time and cost of an office visit while others appreciate the single point of access, administration, and monitoring of side effects at the office.^{6,7} Economic factors also may influence drug choices, to the extent the patient's insurance coverage differentially requires cost sharing depending on the mode of administration.⁸⁻¹⁰

The literature on the effects of consumer cost sharing on patient use and adherence to prescription drugs has been the subject of 3 extensive reviews.¹¹⁻¹³ All report that patients facing high deductibles, coinsurance, coverage limits, and cost sharing through tiered drug formularies are less likely to use prescribed drugs. Where outcomes data are available, the studies find worse reported outcomes among patients facing higher levels of cost sharing. However, only 1 of the published studies considers the impact of cost sharing on the use of physician office-administered specialty drugs and patient self-injected specialty drugs, given the difficulty in obtaining data on specialty drug use

and linking it to data on insurance benefit design and cost sharing. In that study,¹⁴ Karaca-Mandic and colleagues report that benefit generosity affected the likelihood that rheumatoid arthritis patients initiate and continue with specialty drug therapy. The authors did not find an impact of consumer cost sharing for physician-administered (medical benefit) as distinct from patient self-administered (pharmacy benefit) specialty drugs.

This study evaluated the association between consumer cost sharing on the one hand and the choice between physician-administered and patient self-administered biopharmaceuticals for rheumatoid arthritis on the other. We analyze cost-sharing requirements for patients under both the medical benefit (covering physician-administered drugs) and the pharmacy benefit (covering self-administered drugs). In addition to examining patterns of use and expenditure for biopharmaceuticals, it examined use and cost of symptom-relief medications and non-biologic disease-modifying anti-rheumatic drugs (DMARDs).

DATA AND METHODS

Data on Patients, Drugs, and Drug Expenditures

Comprehensive 2008-2009 medical insurance claims were obtained for employees, dependents, and retirees from the California Public Employees Retirement System (CalPERS), a multi-employer alliance that purchases health insurance coverage for the state of California and other public entities such as cities and school districts.

CalPERS professional, facility, and pharmaceutical claims were merged to create a file for each individual patient. The analysis was limited to individuals aged 18 to 64 years (as Medicare claims data were not available). Rheumatoid arthritis (RA) status was identified for an enrollee based on having experienced an episode of treatment for the condition, with episodes calculated from pharmacy, professional, and facility claims using the Thomson Reuters MedStat episode grouper.¹⁵ The episode grouper is based on claims data for 43 million covered lives and uses expert opinion and the medical literature to develop criteria for selecting which of the claims filed on behalf of any 1 patient are associated with which underlying disease. Enrollees are identified as having particular underlying diseases based on the claims filed on their behalf by the treating physicians. Thomson Medstat is the manager of the CalPERS data warehouse.

Claims data were combined with demographic data from CalPERS on the individual's age, gender, subscriber status (employee, dependent, retiree), and zip code of residence. Zip codes were used to assign individual members to 1 of 21 hospital referral regions, as defined by the Dartmouth Atlas as corresponding to local hospital markets.¹⁶ Since CalPERS was unable to provide information directly on each enrollee's household income, we assigned to each patient the median household income in his or her zip code of residence, using data from the 2000 Census of Population.

Rheumatoid arthritis severity and presence of comorbidities were included using measures developed by Thomson Medstat. Thomson Medstat analyzed CalPERS claims to identify which patients had juvenile onset (as distinct from adult onset) RA and which had RA complications as defined by the presence of conduction disorder, pericarditis, cardiomyopathy, Felty's syndrome, amyloidosis, anemia, pneumoconiosis, interstitial fibrosis, respiratory failure, uveitis, and/or vasculitides.

Comorbidities were identified in terms of whether the individual's claims included *ICD-9* diagnosis codes for any of 12 broad categories of health conditions, including infectious and parasitic disease; neoplasms; endocrine, nutritional, metabolic, and immunity disorders; diseases of the blood and blood-forming organs; mental disorders; diseases of the circulatory system; diseases of the respiratory system; diseases of the digestive system; diseases of the genitourinary system; diseases of the skin and subcutaneous tissue; and diseases of the musculoskeletal and connective tissue.

Expenditures were measured in terms of the total payment (allowed charge) for drugs used for the treatment of rheumatoid arthritis. The patient's portion of the total drug payment (copayment and coinsurance requirements) is included as part of the allowed charge and measure of expenditure used in the study. Based on enrollment information, approximately 7% of enrollees in each of the 2 study years were enrolled for less than the full 12 months.

We annualized their expenditure data by multiplying actual expenditures by the inverse of the fraction of the year for which they were enrolled. We also analyzed the data excluding these individuals.

Drugs were classified as to whether they were for relief of arthritic symptoms, DMARDs, or specialty drugs.¹⁷ Specialty drugs for this patient population include Orenzia (abatacept), Rituxan (rituximab), Cimzia (certolizumab), Enbrel (etanercept), Humira (adalimumab), Kineret (anakinra), Remicade (infliximab), and Simponi (golimumab). DMARDs include methotrexate, leflunomide, sulphasalazine, gold sodium thiomalate, auranofin, antimalarials (hydroxychloroquine, chloroquine phosphate, chloroquine sulphate), minocycline, penicillamine, cyclophosphamide, cyclosporine, azathioprine, misoprostol, methylprednisolone, and aurothioglucose.¹⁷ Symptom relief drugs include analgesics, non-steroidal antiinflammatory drugs, and corticosteroids.

Patient self-administered drugs were obtained from the CalPERS pharmaceutical claims data. Drugs administered by physicians in an office setting were obtained from the professional and facility claims data. Four expenditure measures were calculated: annual expenditures on physician-administered specialty drugs, patient self-administered specialty drugs, DMARDs, and symptom relief drugs.

Data on Insurance and Consumer Cost Sharing. CalPERS members are offered a choice among 3 principal forms of health insurance coverage. Individuals may select Kaiser Permanente, a large group model health maintenance organization (HMO); Blue Shield of California, which manages medical groups and Independent Practice Associations for the CalPERS network model HMO; or Anthem Blue Cross, which contracts with physician practices for the CalPERS preferred provider organization (PPO) product. This study is limited to CalPERS members selecting either Blue Shield HMO or Anthem PPO, since the Kaiser Permanente system does not generate claims data comparable to those generated by the other plans.

CalPERS has standardized some elements of the insurance benefit package and consumer cost-sharing requirements for PPO and HMO plans, while leaving others distinct. Costsharing requirements differ between the PPO and HMO for the medical benefit, which covers professional and facility claims plus claims for physician-administered drugs.

PPO members face a \$500 annual deductible (individuals) and \$1000 deductible (family) under the medical benefit. PPO patients must pay 20% of the cost of office-administered specialty products such as biologics and allergy treatments. Physician office visits for PPO patients require a \$20 copayment if done in-network and 40% coinsurance if done out of network. HMO patients must pay \$15 for a physician visit but pay nothing for physician-administered products. HMO member cost sharing is limited to a maximum of \$1500 per year (\$3000 for families). PPO members face a higher costsharing maximum (\$2000-3000 for individuals, \$4000-\$6000 for families).

Cost-sharing requirements under the pharmacy benefit, which covers patient self-administered drugs obtained from a retail pharmacy, mail order pharmacy, or specialty pharmacy, have been standardized by CalPERS and are similar, though not identical, for the PPO and HMO plans. All patients must pay \$5 for generic drugs, \$10 for preferred brand drugs, and \$45 for non-preferred brand drugs for the first month's supply. PPO patients must pay \$10, \$25, and \$75 for these drugs after the first month's supply. Self-administered drug cost-sharing payments accrue to the patient's pharmacy benefit maximum while physician-administered drug cost-sharing payments accrue to the patient's medical benefit maximum. Pharmacy benefit cost sharing for both PPO and HMO enrollees is capped at \$1000 per year.

Expenditure differences for self-administered drugs reflect differences between PPO and HMO patients in the volume of use rather than in drug prices, because self-administered drugs are purchased for both PPO and HMO enrollees by the CalPERS-contracted pharmacy benefit management firm. However, expenditure differences for physician-administered drugs may reflect price as well as volume differences if the Anthem PPO and Blue Shield HMO reimburse physician practices at different rates for the same physician-infused specialty drugs. Provider payment rates are confidential, but the CalPERS staff expressed confidence that prices for physician-administered drugs were similar across the PPO and HMO plans.

In summary, the PPO and HMO enrollees face costsharing requirements that differ in several dimensions, most importantly with respect to physician-administered specialty drugs. In the statistical analysis, we use plan type (PPO

vs HMO) as an indicator of the mix of cost-sharing requirements facing each patient, with PPO enrollment requiring substantially more cost sharing than HMO enrollment for physician-administered drugs but similar cost-sharing requirements for self-administered drugs. We expect to observe that the higher cost-sharing requirement for physician-administered drugs but similar cost-sharing requirement for self-administered drugs will induce PPO enrollees to use less of the first category and more of the second category of drugs compared with HMO enrollees.

Statistical Analysis. We calculated mean expenditures on each category of drug (physician-administered specialty drugs, patient self-administered specialty drugs, non-biologic DMARDs, symptom relief drugs) and compared differences for PPO and HMO enrollees. It is possible that PPO and HMO enrollees differ in drug expenditures due to variance in demographic, health status, or geographic characteristics. We therefore computed adjusted mean expenditures after taking into account patient-specific characteristics.

While many RA patients use symptom-relief drugs and DMARDs, most do not use specialty drugs in any given year. We therefore employed a 2-part model to examine the association between type of insurance coverage and the probability of use of each type of specialty drug (office-administered and self-administered), adjusting for demographic characteristics, disease severity, comorbidities, and geographic location.

This statistical approach first analyzes the decision to use a physician-administered or patient self-administered specialty drug (eg, to have zero or positive expenditures on each of these classes of drugs). The model then analyzes expenditures during the year for patients who use any of each type of specialty drug (eg, have nonzero expenditures). The model is implemented through a probit equation (whether the patient uses any drug or not), and a generalized least-squares regression equation (annual expenditures, for patients with nonzero expenditures).

We use 2 years of data (2008 and 2009) because RA is a chronic condition subject to periodic flare-ups in symptoms and hence in patient requests for treatment. The same patient may have large drug-related expenditures in one year but low expenditures in the next. Including 2 years of data on most patients (this is an unbalanced panel) allows the analysis to better pick up the association between cost sharing and drug use, since it smooths out some of the fluctuations in disease severity. In order to account for the presence of some patients in both years' data, standard errors in the statistical analyses incorporate clustering at the patient level.¹⁸ In order to check on the impact of combining 2 years' data (and thereby counting the same individual twice), we also conducted analyses for each of the 2 years separately. A total of 3445 CalPERS enrollees with rheumatoid arthritis appear in the data: 2687 appear in both 2008 and 2009, 69 are present only in 2008, and 111 are present only in 2009. The analytic data set was constructed as a 2-year panel creating a total analytic sample of 5554.

We use the output of the 2-part statistical model to calculate adjusted mean expenditures for PPO and HMO patients, controlling for demographic, health, and geographic variables. We present adjusted mean expenditures for the full sample of PPO and HMO patients, the probability of use of physician-administered and patient self-administered drugs for each group, and mean expenditures for those who have used each type of drug. These adjusted figures can be interpreted as the expenditures and probabilities of use that would be observed if PPO and HMO enrollees had the same demographic, health, and geographic characteristics.

RESULTS

Table 1 presents descriptive statistics on CalPERS members suffering from rheumatoid arthritis, both for the full sample and for those selecting the PPO and HMO plans, respectively. The majority (78%) of patients are women, consistent with the higher RA disease prevalence among women in the general population.^{19,20} Small minorities of CalPERS enrollees have juvenile onset RA (1.5%) or RA with complications (3.5%).

Total drug expenditures for treatment of rheumatoid arthritis average \$4975 per year and are 12% higher for PPO enrollees (\$5572) than for HMO enrollees (\$4449). Total drug expenditures are categorized into physician-administered specialty drugs, patient self-administered specialty drugs, DMARDs, and symptom relief drugs for the treatment of RA. Three-fourths of expenditures are incurred for patient self-administered specialty drugs, with most of the remainder incurred for physician-administered drugs. Use of non-biologic DMARDs and symptom-relief drugs is quite common but is inexpensive relative to the use of specialty drugs.

The choice between physician-administered and self-administered drugs is made quite differently by PPO and HMO enrollees. While 85% of specialty drug use by PPO enrollees is for self-administered drugs (\$4730 per patient per year) and only 9% is for physician-administered drugs (\$498), 64% of drug use by HMO enrollees is for self-administered specialty drugs (\$2828) and 32% is for physician-administered drugs (\$1428). These figures refer to expenditures averaged across the entire PPO and HMO enrollee populations with rheumatoid arthritis, not merely across those enrollees who use these drugs in the given year.

As indicated in the second section of Table 1, the percent using self-administered specialty drugs (26.0%) is much higher than the percent using physician office-administered drugs (7.8%). However, the ratio of self-to-office administered drugs is much greater for PPO enrollees (30.0% to 4.5%) than for HMO enrollees (22.9% to 10.7%). Annual expenditures are much higher for patients using self-administered drugs (\$3720) than for patients using office-administered drugs (\$991).

Table 2 presents multivariate regression parameters for the association between type of insurance coverage (PPO vs HMO), on the one hand, and use of and annual expenditure on specialty drugs, on the other, after adjusting for patient characteristics, health status, and geographic location. The first and third columns of the table present the marginal effect of the covariates on the probability of use, derived from maximum likelihood probit estimates. Adjusting for patient characteristics, PPO enrollees are 5.5 percentage points ($P \leq .01$) less likely to use physician-administered specialty drugs and 7.1 percentage points ($P < .01$) more likely to use patient self-administered specialty drugs than are HMO enrollees. These differences are to be evaluated against the baseline use rates of 7.8% for physician-administered and 26.0% for patient self-administered specialty drugs in the CalPERS population suffering from rheumatoid arthritis.

Age, gender, and household income are not significantly associated with use of specialty drugs. Patients with juvenile onset RA are 14.5 percentage points ($P \leq .01$) more likely to use self-administered specialty drugs than are those with adult onset RA. Patients with more severe RA are 5.1 percentage points ($P \leq .01$) more likely to use physician-administered specialty drugs than are those with less severe RA conditions. Employment status, comorbidities, and geographic location are not consistently associated with use of specialty drugs.

The second and fourth columns of Table 2 present generalized least squares parameter estimates for the association between type of insurance plan and annual patient expenditures on specialty drugs. These analyses are limited to patients incurring positive expenditures on these drugs during the year. After adjusting for patient demographic, health status, and geographic characteristics, PPO enrollees who use physician-administered specialty drugs incur annual expenditures \$3322 lower ($P \leq .01$) than do HMO enrollees who use physician-administered drugs. PPO enrollees who use self-administered drugs incur annual expenditures \$3637 higher ($P \leq .01$) than do HMO enrollees who use self-administered specialty drugs.

Table 3 presents the adjusted probabilities of use for physician-administered and patient self-administered specialty drugs, and annual expenditures on those drugs, for PPO and HMO enrollees. They are computed based on the regression parameters reported in Table 2. PPO patients are only half as likely to choose a physician-administered specialty drug as are HMO enrollees (4.2% vs 9.3%) ($P \leq .05$), and use 25% less of the drugs if they use any (\$10,356 vs \$13,678) ($P \leq .05$). They are 30% more likely to use a self-administered specialty drug than are HMO enrollees (29.3% vs 22.1%) ($P \leq .05$), and use 35% more of the drugs if they use any (\$16,015 vs \$12,378) ($P \leq .05$).

DISCUSSION

Patients suffering from rheumatoid arthritis incur high medical care expenditures, with the majority of expenditures accounted for by physician-administered and patient self-administered specialty drugs. The choice of treatment and mode of administration are based in large part on clinical evidence on effectiveness and the patient's experience. However, economic incentives stemming from the insurance benefit design and cost-sharing requirements also are strongly associated with these choices.

This study compared the use and cost of specialty drugs for rheumatoid arthritis patients enrolled in PPO and HMO insurance plans, respectively. The benefit designs and cost-sharing requirements across these 2 insurance types were standardized in part by the multi-employer purchasing alliance that provides the benefits, but also varied in meaningful ways. The principal difference was a higher overall level of cost sharing required of PPO enrollees seeking to access physician-administered drugs.

The study found that differential cost-sharing requirements were significantly associated with differences in the probability of use and expenditures on physician-administered and self-administered specialty drugs. After adjusting for patient demographic, health status, and geographic residence differences, PPO enrollees were less likely to use physician-administered specialty drugs and more likely to use patient self-administered specialty drugs than were HMO enrollees. PPO enrollees who used physician-administered drugs incurred lower annual expenditures on those drugs, indicating less frequent use and/or lower doses, than did HMO enrollees. In contrast, PPO enrollees who used self-administered drugs incurred higher annual expenditures for those drugs, indicating more frequent use and/or higher doses, compared with HMO enrollees.

The higher expenditures for HMO enrollees compared with PPO enrollees for physician-administered specialty drugs is of particular interest since the former enrollees are required to obtain a referral from their primary care physician prior to obtaining a specialty consultation. Physician-administered specialty drugs usually are obtained in specialist offices or infusion clinics, not through primary care practices. Nevertheless, utilization of physician-administered specialty drugs is significantly higher for HMO enrollees than for the PPO enrollees, who face no equivalent requirement for primary care referral and who can self-refer to specialty care. This suggests that the influence of PPO consumer cost sharing is stronger than the influence of HMO administrative controls for the type of drug and mode of drug administration.

LIMITATIONS

The findings from this study must be interpreted within the limitations of the available data. We had only partial controls on the severity of each patient's disease. Severity was measured using a set of 10 indicators for rheumatoid arthritis complications; a set of 12 indicators for presence of comorbidities; and an indicator of juvenile versus adult onset. Nevertheless, CalPERS enrollees can select between PPO and HMO coverage and it is possible that there remain unmeasured illness severity differences between them. Very few CalPERS enrollees switch between PPO and HMO coverage, and hence it is not possible to study patterns of drug use for the same individuals under different types of insurance coverage.

We use annual expenditures (allowed charges) as our measure of volume and mix of specialty drugs, as we had no direct information on prescriptions and dosages for each of the many drug options. Expenditure data accurately reflect volume and mix differences between PPO and HMO patients for self-administered specialty drugs, since CalPERS uses the same pharmacy benefit management firm for PPO and HMO patients, and hence unit prices for drugs are the same for both. For office-administered specialty drugs, payment is made by the physician practices and it is possible that unit prices vary between PPO and HMO patients. However, these patients see the same rheumatology specialists in most cases, and hence the unit prices will be similar. The CalPERS health benefits staff strongly maintains that unit drug prices are similar for PPO and HMO patients, but this could not be verified.

The study population contained patients who were enrolled for both years, for only 1 year, and for only a part of 1 year. We annualized the expenditure data for part-year enrollees but also conducted the analyses excluding those individuals. Statistical results were the same with both approaches. To account for the fact that patients enrolled in CalPERS for both years are double-counted in the 2-year analyses, we used econometric methods to adjust the regression standard errors and conducted separate year-specific regressions. Results were similar in all cases.

This study has no data on patient outcomes and it is not possible to ascertain whether the influence reported here of cost sharing on drug choice was associated with the subsequent course of the patient's illness. As highlighted by the national debate over the need for "comparative effectiveness research," there is a paucity of published research on the comparative performance of physician-administered versus patient self-administered specialty drugs for this condition.²¹

The data used here may not be fully representative of the larger population of patients with employment-based insurance. As a public employment purchasing coalition, CalPERS offers a richer insurance benefit design with less consumer costsharing than many of the plans prevalent in the private sector. In particular, its pharmacy benefit design requires only modest dollar copayments, up to an annual maximum of \$1000, for self-administered specialty drugs, non-biologic DMARDs, and symptom-relief drugs. By way of contrast, the dominant benefit designs for these self-administered drugs in the private sector and in Medicare Part D plans impose percentage coinsurance on specialty drugs, over and above the dollar copayments required for oral medications.^{22,23}

CONCLUSION

The purpose of cost sharing is to create incentives for consumers to consider the cost as well as the clinical effectiveness of treatment alternatives. These incentives are appropriate in contexts where the consumer can understand the alternatives and is the primary decision maker, as in the choice between branded versus generic versions of commonly used oral medications. The social benefits of cost sharing must be balanced, however, against the social costs. Required out-of-pocket payments dissuade some patients from using even low-cost drugs. There is an extensive research literature on the association between consumer cost sharing and the use of common ambulatory drugs. This literature reports that even modest cost sharing reduces initiation and adherence to prescriptions for common and serious chronic illnesses.

The choice among different types of specialty drugs has longterm implications in terms of exposure to adverse side effects, irreversible disease progression, and disability due to symptom severity. The study of cost sharing and specialty drug use for rheumatoid arthritis finds a smaller effect on patient drug use than that reported in the studies of common ambulatory drugs, but the available data on specialty drug use were limited by difficulties in measuring the structure and level of each patient's cost-sharing obligations.^{24,25} Choice among specialty drugs challenges even the most sophisticated patient and may be overwhelming for those with less education and self-confidence.

Insurance principles imply that coverage should be more complete, and consumer cost sharing more limited, for treatments such as specialty drugs for rheumatoid arthritis. Insurance design should not inadvertently influence choices between physician infusion and patient self-injection for these complex treatments. Consumer cost sharing should be imposed in contexts where the social benefits of limiting use exceed the social costs, rather than in contexts where the clinical and economic effects of such limitations have not been evaluated.

Take-Away Points

- Consumer cost sharing influences the use of physician-infused and patient self-administered specialty drugs for complex diseases such as rheumatoid arthritis.
- Insurance benefit designs and cost sharing should be structured to encourage use of the most effective and cost-effective drugs, including high-cost biopharmaceuticals.
- Preferred provider organization insurance products tend to have higher coinsurance than health maintenance organization products, which is likely to influence patterns of use for office-administered drugs as well as for imaging tests and implantable devices.

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Address correspondence to: James C. Robinson, PhD, MPH, Leonard D. Professor of Health Economics and Director, Berkeley Center for Health Technology, University of California, 247 University Hall, Berkeley, CA 94720-7360. E-mail: james.robinson@berkeley.edu.

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