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Insurance Status, Comorbidity Diagnosis, and Hepatitis C Diagnosis Among Antibody-Positive Patients: A Retrospective Cohort Study

Sara H. Goodman^{1,2} , Matthew Zahn³, Bernadette Boden-Albala², and Cynthia M. Lakon²

Abstract

Background: In California, laboratories report all hepatitis C (HCV)-positive antibody tests to the state; however, that does not accurately reflect active infection among those patients without a viral load test confirming a patient's HCV diagnosis. These public health surveillance disease incident records do not include patient details such as comorbidities or insurance status found in electronic medical records (EMRs).

Objective: This research seeks to understand how insurance type, insurance status, patient comorbidities, and other sociodemographic factors related to HCV diagnosis as defined by a positive viral load test among HCV antibody-positive persons from January 1, 2010 to March 1, 2020.

Methods: HCV antibody-positive individuals reported to the California Reportable Disease Information Exchange (CalREDIE), with a medical record number associated with the University of California, Irvine Medical Center, and an unrestricted EMR (n = 521) were extracted using manual chart review.

Main Outcomes and measures: HCV diagnosis as indicated in a patient's EMR in the problem list or disease registry.

Results: Less than a quarter of patients in this sample were diagnosed as having HCV in their EMR, with 0.4% of those diagnosed (5/116) patients with indicated HCV treatment in the medication field of their charts. After adjusting for multiple comorbidities, a multinomial logistic regression found that the relative risk ratios (RRRs) of HCV diagnosis found that patients with insurance were more likely to be diagnosed compared to those without insurance. When comparing uninsured patients to those with government insurance at the $P < .05$ level (RRR = 10.61 (95% confidence interval (CI): 4.14-27.22)) and those uninsured to private insurance (RRR = 6.79 (95% CI: 2.31-19.92)).

Conclusions: These low frequencies of HCV diagnosis among the study population, particularly among the uninsured, indicate a need for increased viral load testing and linkage to care. Reflex testing on existing samples and improving HCV screening and diagnosis can help increase linkage to care and work towards eliminating this disease.

Keywords

hepatitis C, public health, public health surveillance, epidemiology, health systems research, electronic medical records

Introduction

In 2020, The Centers for Disease Control and Prevention reported that the hepatitis C virus (HCV) had an incidence rate of 40.7 chronic HCV cases per 100,000 people, with HCV-associated deaths increasing from 2019 to 2020 by 4% (the mortality rate increased 3.33 to 3.45 deaths per 100,000).¹ Chronic HCV incidence rates have steadily increased in the United States since 2013.² In response to rising HCV incidence rates, the United States Preventive

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Services Task Force updated its screening guidelines in March 2020 to test everyone ages 18 to 79 regardless of risk factors.³ HCV screening is essential as untreated HCV can lead to chronic liver disease, including liver fibrosis, liver cancer, and mortality in patients without treatment.^{2,4-6} HCV is generally transmitted by infected blood exposures, sexual fluids, or from mother to child.⁴ Increased prevalent cases of HCV among particular risk groups include: individuals over 65, veterans, people who inject drugs, and people living with HIV.^{2,4,7-9}

One of the challenges with evaluating patients for HCV is the initial diagnosis and linkage to care and treatment.¹⁰ The recommended HCV diagnosis procedure is a 2-step procedure as indicated by the American Association for the Study of Liver Diseases.¹¹ Diagnosis begins with an HCV antibody enzyme-linked immune absorbed assay test and is followed by a subsequent PCR RNA viral load test.^{12,13} Antibody testing alone cannot determine a current HCV infection which must be confirmed using a PCR RNA viral load test. In some care facilities, laboratories perform “reflex” testing on the initial sample to detect viral load levels.^{14,15} A study using public health surveillance records in 2013 in New York City noted that one-third of HCV antibody-positive patients did not receive PCR RNA testing and were thus undiagnosed.¹⁶ Only HCV-positive patients evaluated with a viral load test are eligible for treatment; therefore, those not tested do not receive adequate care and may spread the disease to others.

Diagnosis is critical for HCV because, unlike other types of hepatitis, HCV is treatable and curable. Approved by the Food and Drug Administration in 2014, direct-acting antiviral medications (DAAs) are highly effective (estimated at 95%) in curing the disease.^{11,17-27} DAAs vastly improved upon previous interferon-based medications, which had many side effects, did not lead to sustained virologic response (SVR, an undetectable viral load), and were taken longer than 8 to 12 weeks.^{11,17-27} One of the most significant barriers to using DAAs is their cost which can be up to \$100,000 USD per treatment course.²⁸⁻³⁰ DAAs have patient and physician barriers which may exacerbate existing social inequalities because uninsured patients cannot afford these medications and remain untreated.³¹⁻³⁹

Initial diagnosis and treatment evaluation for HCV is complex, and patients falling out of care may not receive or may interrupt treatment. HCV diagnosis is not captured by public health surveillance through the California Reportable Disease Information Exchange (CalREDIE) system or reflects diagnosis from a licensed medical professional.⁴⁰ Actively infected individuals are those with a PCR RNA test, which may underestimate the actual number of HCV infections in the county. As part of the California Health Code Title 17,⁴⁰ laboratories must report all HCV antibody-positive and PCR RNA results to the state. However, in many cases only HCV antibody-positives tests are reported to the state, even without follow-up RNA tests. These electronic laboratory morbidity reports are sent to the state health department and managed using CalREDIE.⁴⁰ Part of these CalREDIE public health

surveillance records contain a medical record number associated with a hospital system, with that hospital’s lab listed as the submitter. The patients in this study received care from the University of California, Irvine Medical Center (UCIMC), a large teaching hospital in Orange County (OC), California. Electronic medical records (EMR) have additional data that the morbidity surveillance data do not capture, including insurance status, insurance type, comorbidities, and medications the patient is taking or prescribed.^{41,42} Given the incomplete nature of surveillance data and the lack of follow-up viral load testing among HCV antibody-positive patients, this research seeks to understand how insurance type, insurance status, comorbidities, and other sociodemographic factors related to hepatitis C diagnosis, defined by a positive viral load test among HCV antibody-positive individuals in a large teaching hospital in OC, California.

Methods

Data Selection Criteria

This sample came from the CalREDIE database of “probable,” “suspect,” and “confirmed” HCV antibody-positive cases assigned to OC, California, and had a medical record number associated with the UCIMC. An existing data-sharing agreement between the OC Health Department and UCIMC provided access to these EMRs. Between January 2010 and March 2020, 743 individual disease incident surveillance records in CalREDIE originated from UCIMC.

Inclusion and exclusion criteria for this study included records found in CalREDIE and had a UCIMC medical record number associated with the patient. Exclusion criteria included restricted records or duplicates. Thirty-three EMRs had a “break the glass warning” by UCIMC, which indicated these records were unobtainable or restricted from view. Four EMRs were duplicates, and 183 CalREDIE disease incident records did not have a UCIMC EMR associated with the patient.

Sample Size information: A final sample size of $n = 521/743$ original HCV antibody-positive disease incident records were downloaded and analyzed in November 2020.

Data Extraction Procedures

Of the 743 HCV antibody-positive disease incident records, 521 EMRs were compiled and extracted from the UCIMC EPIC medical record system using manual chart review, compiled into a database, and analyzed by the first author.

Measures

The dependent variable in this analysis was HCV diagnosis, as noted in an HCV antibody-positive patient’s EMR. These patients had to have a viral load test to confirm their status. We defined a patient’s HCV diagnosis using 2 criteria: (1) if hepatitis C was present in the problem list portion of the

Table 1. Demographic Characteristics of HCV Antibody-Positive Patients at UCIMC From January 1, 2010, to March 1, 2020.

Variable	N	Percent
10-year age categories		
20-29	52	9.98
30-39	92	17.66
40-49	64	12.28
50-59	120	23.03
60-69	124	23.80
70-79	49	9.40
80+	20	3.84
Age categories (binary)		
65 and younger	401	76.97
Over 65	120	23.03
Health insurance (smaller categories)		
Uninsured	155	29.75
Medicaid only	188	36.08
Medicare only/VA/TRICARE only	20	3.84
Medicare and Medicaid	88	16.89
Private insurance	42	8.06
Medicaid and private	19	3.65
other	9	1.73
Health insurance (larger categories)		
Uninsured	155	29.75
Government insurance	296	56.81
Private insurance/other	70	13.44
Gender		
Female	183	35.10
Male	328	62.96
Transgender/genderqueer	10	1.92
Mortality		
Alive	483	92.71
Deceased	38	7.29
Hepatitis C diagnosis in the chart?		
No	405	77.74
Yes	116	22.26
Smoking status		
Nonsmoker	146	28.02
Current smoker	123	23.61
Former smoker	99	19.00
Never assessed	153	29.37
Prescribed hepatitis C treatment		
No	516	99.04
Yes	5	0.96
Potential ER Visit due to missing chart data and no insurance		
No	462	88.68
Yes	59	11.32
Heart disease		
No	468	89.83
Yes	53	10.17
Hypertension		
No	381	73.13
Yes	140	26.87
Cirrhosis		
No	457	87.72

(continued)

Table 1. (continued)

Variable	N	Percent
Yes	64	12.28
Diabetes		
No	434	83.30
Yes	87	16.70
Stroke		
No	495	95.01
Yes	26	4.99

EMR or (2) part of the “HCV registry” in the registry field of the EMR system snapshot.

Independent variables in this analysis included patient age, gender, and insurance status. Gender was coded into 3 categories, (1) male, (2) female, and (3) genderqueer/transgender. Three categories of insurance status were created for analysis and to avoid small cell sizes to maintain the power of the regression. The categories were (1) uninsured, (2) government (eg, Medicare, Medicaid, or TRICARE (Veterans Administration or military insurance)), and (3) private insurance. HCV treatment as a binary variable was coded yes (when the medications list included HCV medications). We categorized patients as having ever emergency room visits where insurance and existing medical conditions were not recorded in the EMR, implying a short hospital stay. Those without any insurance listed were coded as uninsured. Comorbidities were found using manual chart review and copied into a text field and then manually coded by searching for the words “cancer,” “stroke,” “hypertension,” “hyperlipidemia,” “cirrhosis,” “diabetes,” and “obesity” using indicator or “dummy variables.” Statistical analysis of these data included the following: frequencies, multivariable logistic regression, multinomial logistic regression, and additional *post hoc* analyses such as chi-square tests to verify the utility of nested models as needed. The data were analyzed using Stata version 17 (StataCorp, College Station, TX).

Ethical Considerations

The Institutional Review Boards (IRB) of the University of California, Irvine (protocol HS # 2019-548) and the OC Health Care Agency (Research Project 2020-03) approved this research as exempt from IRB review. Participant consent was not obtained as this was a secondary data analysis on de-identified, routinely collected public health surveillance data, which fell under the existing data-sharing agreement with UCIMC, for chart review regarding enhanced public health surveillance by the OC Health Care Agency.

Results

Demographic Characteristics

A list of demographic characteristics is in Table 1. As of March 2020, 92.71% of patients were still alive when in November 2020 we pulled the EMRs. Approximately 77% of the sample

were younger than 65, with 23% over 65. In this sample, 29.75% were uninsured, 56.81% had a form of government insurance (Medicare, Medicaid, or TRICARE¹), and only 13.44% had private insurance only or “other” coverage. In this sample, most patients had only Medicaid insurance coverage (36.08%). Nearly 30% of the patient EMRs did not have any insurance noted on their chart. Another 16.89% of patients were dually enrolled in Medicare and Medicaid, and 8% were on private insurance exclusively. The sample was 63% male and 35% female, with approximately 2% identifying as transgender or genderqueer. Only 116 of 521 patients (22.26%) were diagnosed with HCV in their charts based on a positive viral load test.

Multinomial Regression Results

There were several multinomial logistic regressions conducted with these data. The first is with demographic and insurance status, and the second combined the previous regression adjusting for comorbidities indicated in a patient’s chart. In a multinomial logistic regression with HCV diagnosis as the dependent variable (Table 2), our independent variables included: patients over 65, gender, and insurance status. In this model, patients with any form of health insurance were significantly more likely to be diagnosed with HCV. When compared to uninsured patients, those with government insurance had higher relative risk ratio (RRR) of HCV diagnosis (RRR = 13.45, 95% confidence interval (CI): 5.32-34.00). For private insurance, the RRR was again higher for HCV diagnosis when compared to the uninsured (RRR = 8.49, 2.96-24.39). Those over 65 compared to those under 65 were not statistically different in likelihood of HCV diagnosis at the $P < .05$ level. Gender was not statistically significant in this regression.

Additional multinomial logistic regressions controlled for the following comorbidities (Table 3): any type of cancer, liver cancer stroke, cirrhosis, diabetes, compared to those

without these comorbidities. Insurance was still a statistically significant covariate in this regression model. When compared to those uninsured: those with government insurance were more likely to be diagnosed (RRR = 10.61, (4.14-27.22) and those with private insurance were more likely to be diagnosed (RRR = 6.79 (2.31-19.92) all other factors equal. When adjusting for selected comorbidities, cirrhosis was the only significant covariate. Patients with a diagnosis of cirrhosis in their chart compared to no cirrhosis had an RRR of 3.68 (2.01-6.74) with all other factors equal. Hyperlipidemia and hypertension were not statistically significant when adjusting for age group, gender, insurance any type of cancer, liver cancer stroke, cirrhosis, diabetes, and thus were not included in the regression.

As the majority of this sample was under 65, and to adjust for potential confounding by age-related insurance status such as Medicare, we conducted stratified multiple logistic regressions by age group, separating those over 65 and 65 and younger, and found no significant differences between the age groups even though the sample skewed younger. The results among the older age group were not statistically significant due to small cell sizes.

Table 2. Multinomial Logistic Regression of Hepatitis C Diagnosis in EMR Among HCV Antibody-Positive Patients at UCIMC on Explanatory Variables.

Variable	Relative risk ratio (RRR) (95% CI)
Age group (binary)	
Younger than 65	Reference
Over 65	1.46 (0.90-2.36)
Health insurance	
Uninsured	Reference
Government insurance	13.45 (5.32-34.00)
Private insurance/other	8.49 (2.96-24.39)
Gender	
Female	Reference
Male	1.14 (0.72-1.80)
Transgender/Genderqueer	0.00 (0.00-0.00)
Constant	0.03 (0.01-0.08)
Observations	521

Table 3. Multinomial Logistic Regression on Hepatitis C Diagnosis in Chart on Explanatory Variables and Comorbidities Coded as Binary.

Age group	RRR (95% CI)
Over 65	
No	Reference
Yes	1.15 (0.68-1.95)
Gender	
Female	Reference
Male	1.17 (0.73-1.89)
Transgender/Genderqueer	0.00 (0.00-0.00)
Health insurance	
Uninsured	Reference
Government insurance	10.61 (4.14-27.22)
Private insurance/other	6.79 (2.31-19.92)
Comorbidities	
Any cancer	
No	Reference
Yes	1.29 (0.69-2.41)
Stroke	
No	Reference
Yes	0.77 (0.30-2.01)
Cirrhosis	
No	Reference
Yes	3.68 (2.01-6.74)
Diabetes	
No	Reference
Yes	1.22 (0.69-2.15)
Liver cancer	
No	Reference
Yes	0.83 (0.28-2.46)
Constant	0.03 (0.01-0.07)
Observations	521

Discussion

After adjusting for comorbidities, patients with government insurance had the highest RRR of HCV diagnosis based on viral load testing compared to those uninsured. This study illustrates an important gap in HCV diagnosis and linkage to care. At the time of writing, there is a dearth of literature looking at insurance status and HCV diagnosis, making study comparisons challenging. Therefore, we compared this study with studies examining other HCV outcomes such as treatment initiation. One study looking at insurance status and treatment initiation found a⁴³ statistically significant difference between DAA treatment denial and insurance status in Maryland, Delaware, New Jersey, and Pennsylvania. In over 2321 patients with nearly half on commercial insurance, 43.2% of patients covered by Medicaid were denied DAA access, compared to patients with Medicare (5%) or private insurance 10.2%.⁴³ Another study⁴⁴ found that among individuals coinfecting with HIV/HCV, compared to public insurance, those with private insurance were 2.70 times more likely to receive DAA therapy.⁴⁴ Again, both of these studies looked at only those who received DAA therapy, not HCV diagnosis.

Other studies examined HCV screening (initial HCV testing) by insurance status. A study by Kasting et al.⁴⁵ found that compared to those without a Medicare supplement, patients with the supplement had the highest odds of HCV screening. Specifically, patients with Medicaid, Medicare, military, and other types of public or government provided insurance were less likely to be screened compared to private insurance for average-risk baby boomers between 2015 and 2017.

Other studies^{33–39} examined access to DAA treatment among different sociodemographic populations of HCV-positive patients along with insurance status. These studies indicated significant disparities in access to DAA treatment for HCV, particularly with lower treatment uptake among those with Medicaid/state insurance, individuals under age 45, and Hispanic/Latino individuals compared to other racial/ethnic groups.^{33–39} Another study looking at the uptake of DAAs in 4 metropolitan areas visits found similar results with Medicaid-enrolled patients compared to privately insured patients.^{33,35}

Only 5 patients in this sample of 521 (less than 1%) had a record of receiving any DAA treatment in this sample. All 5 patients were treated with the medication Mavryet, one of the newer, less expensive approved DAAs, in 2017.⁴⁶

Approximately 30% of this sample (n = 155) had no health insurance noted in their chart, a significant barrier to HCV diagnosis and treatment.^{47–49} Javanbakht et al⁴⁷ found that prior insurance authorization regardless of provider for HCV treatment is one of the most significant barriers to initiating HCV treatment, especially for shorter 8-week course treatments.⁴⁷ A review by Shehata et al³¹ found similar results that similar barriers to treatment emerged among HCV providers treating these patients. These barriers included the cost of testing, lack of health insurance, stigma, and discrimination, lack of knowledge, and low perceived risk of HCV infection.³¹ Their systematic review

examined studies in the United States, United Kingdom, Canada, and other smaller countries.

Limitations

This study has several limitations in the data collection and analysis. These UCIMC medical records are only a small subsample of the over 33,000 cases of antibody-positive HCV reported to OC from 2010 to 2020. These comprise a small sample size overall and may not be adequately powered to draw these conclusions. These data may not be generalizable to other settings and counties in the United States or California. UCIMC is a large public teaching and research hospital with over 786,000 outpatient visits and over 51,800 emergency department visits in 2018.⁵⁰ The size and scope of this hospital make it unique compared to other smaller, private healthcare settings in OC, such as private practices.

There may be selection bias in patients going to UCIMC as opposed to other care facilities, and patients may have had their viral load test performed elsewhere, which we could not track through this dataset. Unfortunately, this EMR does not explain any treatment performed outside of UCIMC. Ideally, EMRs should distinguish if a treatment or testing event has been reported in other states, especially if a patient moved. This sample covers only those with healthcare encounters at UCIMC, and does not capture a patient's diagnosis or treatment at another healthcare facility. UCIMC patients may be fundamentally sicker than other HCV antibody-positive patients because of UCIMC's status as a research hospital and academic nature and its status as a National Cancer Institute Designated Comprehensive Cancer Center, introducing some bias.^{51,52} We cannot definitively classify emergency room visits in this sample. These potential emergency room visits resulted in incomplete chart data, which may underestimate the patient's total number of comorbidities or severity of those diseases. Only EPIC's "chart snapshots" portions could be downloaded, leaving the viral load testing and HCV diagnosis dates unclear. In addition, we cannot establish temporality as to which comorbidity or HCV diagnosis came first in a patient's medical history. Finally, only 1.5% of the sample (n = 8) had race/ethnicity data entered in their chart, which did not allow for multiple imputation. Information on income and education level was not provided or captured in these EMRs for this analysis.

Conclusions

This study highlights disparities in insurance status and HCV diagnosis elucidating gaps in the HCV linkage to care using routinely collected EMR and public health surveillance data. This study offers opportunities to improve diagnosis, treatment, and linkage to care in a large research hospital setting among uninsured patients. The lack of diagnosis and treatment among this antibody-positive population helps elucidate gaps in care and areas for improvement, especially among those without insurance.

The strengths of this analysis include the completeness of individual data, including comorbidities and insurance status/type, that is not routinely collected by CalREDIE as part of public health surveillance, creating a more robust dataset. We can see the comorbidities of each patient, insurance provider, and type. Previous analysis on HCV in OC used the surveillance data from CalREDIE, which had limited information contained in the disease incident records at the patient level.⁵³ Surveillance data is limited and does not include comorbidities or insurance status. EMRs indicate what types of medications the patient is taking. In general, sicker patients with comorbidities who seek care more regularly are more likely to be diagnosed.

The public health impacts are the overall lack of diagnosis in this sample. This lack of diagnosis implies that undetected, asymptomatic individuals may seek care in hospitals but do not receive HCV treatment. Patients may fall out of HCV care because those who are HCV antibody-positive patients must return for additional visits to receive care and testing. These findings have important health policy and practice implications for HCV diagnosis in a large academic research hospital. A third of the sample's visits had no evidence of health insurance, lowering their diagnosis odds. The gap must be bridged for those without health insurance to get diagnosed with HCV and treated to avoid liver cancer and liver-related mortality.

This sample has additional information on comorbidities that may aid county health departments, and hospitals in improving diagnosis rates and treatment. These can be done by running routine reports on existing hospital data and EMR systems. These reports would help identify HCV antibody-positive individuals and flag their EMRs to receive a follow-up test. Another strategy to increase HCV diagnosis in a hospital system includes routine reflex testing of existing HCV antibody-positive samples to help evaluate people for and initiate HCV treatment. In addition, positive serology of patients who have been treated for HCV but have SVR should be considered in EMRs to help identify this problem in HCV cases with severe liver damage requiring a liver transplant. These institutional changes in EMRs can help improve outcomes and save lives. Future research should examine larger individual data samples across different health settings. There should also be a qualitative component, including focus groups and key informant interviews with HCV-positive patients and their providers, to examine barriers to diagnosis and treatment at an individual level. To work towards HCV elimination, we must combat HCV diagnosis and treatment challenges and bridge the gap for uninsured patients to receive care.

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Author Contributions

Conceptualization: S.G.; methodology: C.L. and B.B.A.; software: S.G.; validation, formal analysis: S.G.; investigation: S.G.; resources: M.Z.; data curation: S.G.; writing—original draft preparation: S.G.; writing—review and editing: C.L., B.B.A., S.G.; visualization: S.G.; supervision: M.Z., C.L., B.B.A.; project administration: S.G.; funding acquisition: S.G. All authors have read and agreed to the published version of the manuscript.

Data Availability Statement

The data supporting this study's findings are available with restrictions from the California Department of Public Health CalREDIE data warehouse and the EPIC Electronic Medical Record system at the University of California, Irvine Medical Center. These data were used under data-sharing agreements for the current study and are not publicly available. Data are, however, available from the authors upon reasonable request and with permission of the University of California, Irvine Medical Center, and the California Department of Public Health (CDPH). UCIMC can be reached by phone at 714-456-3333 (Orange) / 949-824-3434 (Irvine). CDPH can be reached by phone or email: Point of contact: +1 866-866-1428 or CalREDIEHelp@cdph.ca.gov.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Boards of the University of California, Irvine protocol H.S. # 2019-548 and the Orange County Health Care Agency (Research Project 2020-03).

Informed Consent Statement

No consent was obtained as this is routinely collected public health data. As part of routine infectious disease surveillance under California State Health Code Title 17 a §2500, §2593, §2641.5-2643.20, and §2800-2812 Reportable Diseases and Conditions. This data is collected regularly and may be used for enhanced surveillance. SG's role as an intern epidemiologist at the Orange County Health Care Agency, the director of the communicable disease control branch, M.Z. (a co-author on this paper), through the California Department of Public Health granted permission for S.G. to use this anonymized data for analysis as part of her doctoral dissertation. In addition, the Orange County Health Care Agency has a data-sharing agreement with the University of California, Irvine Medical Center, for chart review as it pertains to enhanced public health surveillance.

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Note

1. N.B this sample does not contain Veterans Health Administration data, only individuals who had TRICARE indicated on their chart as insurance provider who had a care encounter at UCIMC.

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