The Laryngoscope

The Effect of Deep Venous Thrombosis on Short-Term Outcomes and Cost of Care After Head and Neck Cancer Surgery

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Objectives/Hypothesis: The Centers for Medicare and Medicaid Services has targeted deep venous thrombosis (DVT) and pulmonary embolus (PE) as preventable "never events" and has discontinued reimbursement for these conditions following selected orthopedic procedures. We sought to determine the relationship between DVT/PE and in-hospital mortality, postoperative complications, length of stay, and costs in head and neck cancer (HNCA) surgery.

Study Design: Retrospective cross-sectional study.

Methods: Discharge data from the Nationwide Inpatient Sample for 93,663 patients who underwent an ablative procedure for a malignant oral cavity, laryngeal, hypopharyngeal, or oropharyngeal neoplasm in 2003 to 2008 were analyzed using cross-tabulations and multivariate regression modeling.

Results: DVT/PE was diagnosed in 1,860 cases (2%) and was significantly associated with major surgical procedures (odds ratio [OR], 1.4; $P = .048$) and advanced comorbidity (OR, 1.7; $P = .034$). After controlling for all other variables, no association was found between a diagnosis of DVT/PE and obesity, weight loss, age, chronic cardiac disease, paralysis, and smoking in this HNCA surgical population. DVT/PE was associated with increased risk of in-hospital mortality (OR, 3.1; $P = .001$), postoperative surgical complications (OR, 2.1; $P < .001$), acute medical complications (OR, 1.9; $P < .001$), and was associated with significantly increased length of hospitalization and hospital-related costs.

Conclusions: DVT/PE is uncommon in HNCA patients but is associated with increased mortality, postoperative complications, length of hospitalization, and hospital-related costs. The lack of correlation with known modifiable variables suggests that despite advances in targeted prophylaxis, patients with advanced disease and comorbidity remain at increased risk. Caution must be used in the institution of reforms that threaten to inadequately reimburse the provision of care in vulnerable populations.

Key Words: Deep venous thrombosis, pulmonary embolus, head and neck neoplasms, complications, surgery, Nationwide Inpatient Sample, guidelines.

Level of Evidence: 2c.

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INTRODUCTION

Deep venous thrombosis (DVT) is common in hospitalized patients, and pulmonary embolism (PE) accounts for 10% of in-hospital deaths annually, making DVT the most common cause of preventable hospital mortality.[1] On October 1, 2008, the Centers for Medicare and Medicaid Services (CMS) began withholding reimbursement payments for 10 hospital-acquired conditions, which CMS deemed to be reasonably preventable through the use of evidence-based guidelines. These conditions are colloquially referred to as never events. The goal of CMS in exempting hospital acquired conditions from reimbursement is to improve the quality of medical care delivery while containing costs. One of the 10 non-reimbursable hospital acquired conditions (NRHAC) is the development of DVT after complete knee or hip arthroplasty.[2] Although the current CMS regulations focus only on a small subset of all surgical patients, serious questions remain whether it is truly possible to prevent all DVTs in this patient population. Additionally, there is broader concern that CMS will expand the definition of never events to include all postoperative patients.

Most head and neck cancer (HNCA) patients have multiple risk factors for DVT including a diagnosis of cancer, smoking, age >60, pulmonary disease, and decreased mobility, and are at increased risk for DVT and PE after undergoing surgery.[1] Appropriate utilization of guideline-directed DVT prophylaxis with low molecular weight heparin has been shown to decrease the incidence of clinically apparent DVT by 71% and clinically apparent PE by 75% in general surgery patients.[3] Despite compliance with these measures, DVT and PE remain a complication of critical illness as a result of nonmodifiable underlying medical conditions, which have a major influence on the epidemiologic characteristics of DVT/PE.[4] We sought to determine the effect of DVT and PE on in-hospital mortality,

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postoperative complications, length of stay, and costs in patients undergoing HNCA surgery using a national hospital discharge database. This information is essential to understanding the true risk of DVT and PE in HNCA patients and can help inform whether it is appropriate to classify DVT/PE as an NRHAC in this patient population.

MATERIALS AND METHODS

A cross-sectional analysis of patients with a diagnosis of oral cavity, laryngeal, hypopharyngeal, or oropharyngeal squamous cell carcinoma was performed using discharge data from the Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality. The NIS is the largest all-payer inpatient care database in the United States, containing data from approximately 8 million hospital stays each year from a stratified sample of 20% of nonfederal US hospitals from participating states.[5] The NIS database provides information regarding the index hospital admission and includes patient demographic data, primary and secondary diagnoses, primary and secondary procedures, hospital characteristics, and inpatient and discharge mortality rates. The International Classification of Disease, 9th Revision (ICD-9) codes were used to identify adult patients (≥18 years of age) who underwent an ablative procedure for a malignant oral cavity, laryngeal, hypopharyngeal, or oropharyngeal neoplasm for the years 2003 through 2008 (Supplementary Table I). Oropharyngeal cancer patients undergoing biopsy were included if neck dissection was the index admission procedure and no other ablative procedure was recorded. Reconstructive procedures were obtained from codes for pedicled or free flap reconstruction (Supplementary Table I).

Comorbidity was graded using the Romano adaptation of the Charlson comorbidity index,[6–8] excluding ICD-9 codes for the index cancer diagnosis from the solid tumor category. Cancer staging information is not available in the NIS, and as a result ICD-9 codes for metastases were excluded as these have not been shown to be a reliable surrogate for disease stage.[9] Prior irradiation was obtained from codes for previous exposure to therapeutic or other ionizing radiation. Codes for specific comorbid illnesses were used to create categories for acute medical and surgical complications, with additional categories created for conditions predisposing to the development of DVT/PE including paralysis, tobacco use, obesity, weight loss, chronic pulmonary disease using codes for chronic pulmonary disease and pulmonary circulation disorders, and cardiac disease using codes for congestive heart failure, valvular disease, hypertension, and peripheral vascular disease (Supplementary Table II). Acute medical complications were derived from codes for acute cardiac events, acute pulmonary edema or failure, acute renal failure, acute hepatic failure, acute cerebrovascular events, sepsis, pneumonia, and urinary tract infection assigned at the time of hospital discharge, and surgical complications were derived from codes for complications directly resulting from surgical procedures assigned at the time of hospital discharge.

In-hospital death, complications, length of hospitalization, and costs were examined as dependent variables. Independent variables included were age, sex, race, payer source (commercial or health maintenance organization, Medicare, Medicaid, self-pay, or other), procedure, comorbidity, nature of admission (emergent/urgent or other), predisposing chronic comorbid conditions, deep venous thrombosis, and pulmonary embolus. Procedures were categorized by severity as minor (excision/destruction of lesion, tonsillectomy, and partial glossectomy, with or without neck dissection, and neck dissection alone when performed as the index admission procedure) and major (partial or total laryngectomy, esophagectomy, total glossectomy, pharyngectomy, mandibulectomy, and maxillectomy, with or without neck dissection). American Joint Commission on Cancer tumor stage, tumor grade, histological subtype, and outcome after discharge were not available from the NIS database.

Hospital-related charges for each index admission were converted to the organizational cost of providing care using cost-to-charge ratios for individual hospitals. Cost-to-charge ratios were calculated using information from the detailed reports by hospitals to the CMS, providing an estimate of the all-payer inpatient cost-to-charge ratio by hospital.[10] This ratio was multiplied by each patient's charge to obtain the cost per admission.[11] All costs were adjusted for inflation based on US Bureau of Labor Statistics indices, with results converted to 2011 US$.[12] To obtain national cost estimates, all discharges were reweighted to account for cases where cost estimates were missing.[10]

Data were analyzed using Stata 10 (StataCorp, College Station, TX). Associations between variables were analyzed using cross-tabulations, multivariate logistic regression, and multinomial logistic regression modeling. Data were weighted, and modified hospital and discharge weights to correct for changes in sampling over time were applied. Variance estimation was performed using procedures for survey data analysis with replacement. Strata with one sampling unit were centered at the population mean. Variables with missing data for more than 10% of the population were coded with a dummy variable to represent the missing data in regression analysis. The primary clinical end points were evaluated using multiple logistic regression analysis. Generalized linear regression modeling with a log link was used to analyze costs and length of stay because these variables were not normally distributed. This protocol was reviewed and approved by the Johns Hopkins Medical Institutions Institutional Review Board.

RESULTS

There were 93,663 cases in 2003 to 2008 (Table I). Because only 11 cases coded with PE were also coded as having a DVT, DVT and PE were combined for analysis. The majority of patients did not have a DVT/PE; 1,860 cases (2%) were diagnosed with DVT/PE, 946 cases (1%) were coded as DVT, and 925 cases (1%) were coded as PE. The majority of all patients were male, white, and under 65 years of age. The mean age was 62.0 years (range, 18–104 years) and did differ significantly between groups based on DVT/PE status, with patients 65 years of age and older more likely to be diagnosed with DVT or PE. Patients who developed a DVT/PE were more likely to have advanced comorbidity, chronic cardiac or pulmonary disease, weight loss, more likely to undergo major surgical procedures, and more likely to require medical care at another facility or at home after discharge. No association was found between a diagnosis of DVT/PE and smoking, obesity, or paralysis.

Multiple logistic regression analysis of variables known at the time of admission that were significantly associated with the risk of developing DVT/PE showed that a major procedure (odds ratio [OR], 1.36; 95% confidence interval [CI], 1.00–1.84; $P = .048$) and a comorbidity score of three or more (OR, 1.74; 95% CI, 1.90–2.14; $P = .034$) were the only variables significantly associated with DVT/PE, after controlling for all other

TABLE I.
Demographic Characteristics.

	All Patients (93,663), %	No DVT/PE (91,803), %	DVT/PE (1,860), %	*P* Value
Primary site				.0363
Oral cavity	39.0	39.0	31.9	
Larynx	26.5	26.5	30.8	
Hypopharynx	3.5	3.4	4.3	
Oropharynx	31.0	31.0	33.0	
Age group				<.0001
≤40 years	4.0	4.0	2.9	
40–64 years	53.9	54.1	41.8	
65–80 years	34.0	33.8	46.4	
>80 years	8.2	8.2	8.9	
Race				.6254
White	61.3	61.3	63.4	
Black	6.4	6.4	7.5	
Hispanic	4.4	4.5	3.8	
Asian or Pacific Islander	1.6	1.6	0.6	
Native American	0.3	0.3	0.3	
Other	1.9	1.9	2.0	
Unknown	24.1	24.2	22.4	
Sex				.4181
Male	69.6	69.7	67.5	
Female	30.4	30.3	32.5	
Payor				.0001
Private	40.2	40.4	29.5	
Medicare	42.4	42.2	55.1	
Medicaid	10.3	10.3	11.4	
Self-pay	3.7	3.7	1.0	
No charge	0.5	0.5	0.3	
Other	2.8	2.8	2.8	
Nature of admission				.0223
Elective	84.3	84.4	79.5	
Emergency/urgent	15.7	15.6	20.5	
Comorbidity				<.0001
0	61.7	61.9	50.6	
1	26.2	26.1	29.2	
2	8.5	8.4	13.2	
≥3	3.7	3.6	7.0	
Procedure severity				.0033
Minor	48.7	48.9	40.2	
Major	51.3	51.1	59.8	
Flap	9.8	9.7	13.0	.0342
Comorbid illness				
Cardiac disease	45.6	45.4	52.7	.0077
Pulmonary disease	22.1	21.9	30.7	.0001
Obesity	0.5	0.5	0.6	.7425
Tobacco use	19.1	19.3	13.7	.0066
Weight loss	6.1	6.0	9.1	.0129
Paralysis	0.6	0.6	0.8	.6095

(*Continued*)

TABLE I.
(*Continued*).

	All Patients (93,663), %	No DVT/PE (91,803), %	DVT/PE (1,860), %	*P* Value
Acute comorbidity				
Acute cardiac event	9.8	9.5	21.1	<.0001
Acute pulmonary edema/failure	3.8	3.7	6.8	.0017
Acute cerebrovascular event	0.4	0.4	0	.2315
Acute renal failure	1.2	1.1	4.1	<.0001
Acute hepatic failure	0.0	0.0	0.3	.0025
Pneumonia	6.4	6.3	13.1	<.0001
Sepsis	0.9	1.9	2.7	.0003
Urinary tract infection	1.8	1.8	2.6	.3113
Surgical complications	10.8	10.6	32.6	<.0001
Disposition				<.0001
Routine	58.3	58.7	39.4	
Short-term hospital stay	0.8	0.7	1.7	
Other facility	10.4	10.2	19.6	
Home health care	29.5	29.3	35.8	
AMA	0.1	0.1	0	
Died in hospital	0.9	0.9	3.5	

DVT = deep venous thrombosis; PE = pulmonary embolus; AMA = against medical advice.

variables. Multiple logistic regression analysis of independent variables associated with the risk of in-hospital death and postoperative complications are shown in Table II. After controlling for the effects of all variables, the only statistically and independently significant factors associated with the risk of in-hospital death were urgent or emergent admission, age >80 years, major surgical procedures, pedicled or free flap reconstruction, Medicare or Medicaid status, advanced comorbidity, and DVT/PE. Postoperative surgical complications and acute medical complications were both significantly associated with pedicled or free flap reconstruction and major surgical procedures, weight loss, Medicaid payor status, and DVT/PE. Acute medical complications were in addition significantly associated with age ≥65 years, Medicare or self-pay payor status, urgent or emergent admission, underlying cardiac disease, and comorbidity.

Multivariate generalized linear regression analyses of independent variables predictive of length of hospital stay and hospital-related costs are shown in Table III, with mean values representing the change in the value of the intercept mean. After controlling for all other variables; urgent or emergent admission; Medicare, Medicaid, and self-pay payor status; comorbidity; major surgical procedures; pedicled or free flap reconstruction; paralysis; chronic pulmonary disease; and weight loss were significantly associated with greater length of hospitalization, whereas urgent or emergent admission; Medicare, Medicaid, or self-pay payor status;

TABLE II.
Multivariate Logistic Regression Analysis of Variables Associated With High-Volume Care and Risk of In-Hospital Death and Postoperative Complications.

Variable	Odds Ratio	95% CI	*P* Value
In-hospital death			
Urgent/emergent admission	1.86	1.24–2.79	.003
Age >80 years	2.11	1.27–3.50	.004
Medicare	2.60	1.42–4.78	.002
Medicaid	2.47	1.32–4.63	.005
Comorbidity score 1	2.01	1.23–3.29	.005
Comorbidity score 2	5.30	2.95–9.52	<.001
Comorbidity score ≥3	6.20	3.16–12.16	<.001
Pedicled or free flap reconstruction	2.44	1.52–3.92	<.001
Major procedure	2.17	1.39–3.40	.001
DVT/PE	3.08	1.56–6.12	.001
Postoperative surgical complications			
Medicaid	1.25	1.04–1.49	.016
Pedicled or free flap reconstruction	1.85	1.57–2.18	<.001
Major procedure	2.49	2.19–2.83	<.001
Weight loss	1.97	1.62–2.38	<.001
DVT/PE	2.14	1.66–2.75	<.001
Acute medical complications			
Urgent/emergent admission	1.56	1.33–1.81	<.001
Age 65–80 years	2.07	1.44–2.98	<.001
Age >80 years	3.41	2.29–5.09	<.001
Pedicled or free flap reconstruction	1.41	1.19–1.66	<.001
Major procedure	1.59	1.43–1.76	<.001
Medicare	1.39	1.20–1.59	<.001
Medicaid	1.58	1.35–1.85	<.001
Self-pay	1.27	1.02–1.58	.032
Cardiac disease	1.44	1.30–1.59	<.001
Weight loss	2.74	2.29–3.29	<.001
Comorbidity score 1	2.25	2.02–2.51	<.001
Comorbidity score 2	4.65	4.02–5.39	<.001
Comorbidity score ≥3	7.35	5.97–9.04	<.001
DVT/PE	1.94	1.49–2.52	<.001

CI = confidence interval; DVT = deep venous thrombosis; PE = pulmonary embolus.

comorbidity; major surgical procedures; pedicled or free flap reconstruction; chronic pulmonary disease; and weight loss were significantly associated with increased hospital costs. DVT/PE was associated with significantly increased hospital-related costs.

DISCUSSION

In our study population DVT/PE occurred in 2% of patients and was an independent predictor of mortality, acute medical and surgical complications, length of hospitalization, and costs in patients undergoing surgery for HNCA. Advanced comorbidity and major surgical procedures were associated with an increased risk of DVT/PE. Because these variables are prevalent in the HNCA population, HNCA patients represent a unique group at increased risk for DVT/PE in whom prevention may not always be possible. Although data on DVT prophylaxis were not available for this patient cohort, our observed incidence of postoperative DVT/PE in this study is similar to a recent, small, single-institution study of venous thromboembolism in head and neck cancer patients[13] and is higher than that observed in two older large cohorts of head and neck surgery patients.[14,15] Our incidence is also comparable to the 1.6% incidence DVT found in a recent study of 2,189 general surgery patients who received guideline-directed DVT prophylaxis postoperatively.[16] These data suggest that the goal of eliminating DVT may be unobtainable despite compliance with preventive measures known to reduce the incidence of DVT.

Current thromboprophylaxis guidelines for patients who undergo major surgical procedures recommend the use of intermittent pneumatic compression combined with low–molecular-weight heparin, low-dose unfractionated heparin, or fondaparinux. A survey-based study from 1997 found a low rate of compliance with venous thromboembolism prophylaxis among otolaryngologists[17]; however, intensive efforts over the last decade to increase awareness of the risk of postoperative venous thromboembolism as well as the development and institution of prophylaxis guidelines have increased the rate of compliance with guideline-directed prophylaxis among head and neck cancer surgeons, which is currently the standard of care for hospitalized HNCA patients. Head and neck surgical patients have a low incidence of DVT/PE, compared to rates of 40% to 80% for orthopedic and general surgery patients, with an increased risk in patients undergoing major procedures for HNCA.[14,15] HNCA patients have an increased incidence of several known risk factors for DVT/PE including smoking, age >60 years, chronic pulmonary disease, and an underlying cancer diagnosis. The risk of DVT/PE in this group is further increased by major surgery and preoperative chemotherapy or radiation therapy.[1] The use of prophylaxis has been shown to reduce the incidence of DVT/PE in the orthopedic and general surgical population by over 70%, but the risk remains elevated in severely ill patients.[4,16] We found that advanced comorbidity and major surgical procedures were associated with an increased risk of DVT/PE, which are nonmodifiable risk factors that are common in HNCA surgical patients, and patients who develop a DVT/PE have longer hospital stays and higher costs of care.

There is concern among physicians in many specialties that CMS will broaden the definitions of NRHSCs to include additional patient groups. In response to the definition of post-total joint replacement DVT/PE as a NRHAC, orthopedic surgeons have studied the incidence of DVT/PE in their patient populations with the use of guideline-directed thromboprophylaxis. A recent meta-analysis by Januel and colleagues, which included 44,844 joint replacement patients, found a rate of DVT/PE of 1% patients who underwent knee arthroplasty and of 0.5% in patients who underwent hip arthroplasty despite adherence to published venous thromboembolism prophylaxis guidelines.[4] These data suggest that the goal of eliminating DVT/PE is unobtainable and calls

TABLE III.
Generalized Linear Regression Analysis of Length of Stay and Hospital Costs.

Variable	Estimate	95% CI	*P* Value	Mean
Length of stay (d)				
Intercept	1.3609	1.2838–1.4379	<.001	7.4
Urgent/emergent admission	0.2810	0.2285–0.3335	<.001	2.1
Medicare	0.1250	0.0715–0.1785	<.001	0.9
Medicaid	0.3171	0.2552–0.3790	<.001	2.4
Self-pay	0.1734	0.0936–0.2532	<.001	1.3
Comorbidity score 1	0.1107	0.0701–0.1514	<.001	0.8
Comorbidity score 2	0.2374	0.1783–0.2965	<.001	1.8
Comorbidity score ≥3	0.3639	0.2637–0.4640	<.001	2.7
Pedicled or free flap reconstruction	0.2561	0.1947–0.3175	<.001	1.9
Major procedure	0.6712	0.6349–0.7074	<.001	5.0
Paralysis	0.2454	0.0476–0.4432	.015	1.8
Chronic pulmonary disease	0.0873	0.0411–0.1336	<.001	0.7
Weight loss	0.4944	0.4142–0.5746	<.001	3.7
DVT/PE	0.4324	0.3307–0.5341	<.001	3.2
Hospital costs (2011 US$)				
Intercept	9.5602	9.4694–9.6509	<.001	$22,122
Urgent/emergent admission	0.1326	0.0522–0.2130	.001	$2,934
Medicare	0.0744	0.0124–0.1364	.019	$1,646
Medicaid	0.2394	0.1801–0.2988	<.001	$5,297
Self-pay	0.1089	0.0307–0.1870	.006	$2,409
Comorbidity score 1	0.0823	0.0372–0.1275	<.001	$1,822
Comorbidity score 2	0.2308	0.1689–0.2927	<.001	$5,107
Comorbidity score ≥3	0.2452	0.2469–0.4435	<.001	$7,637
Pedicled or free flap reconstruction	0.3115	0.2489–0.3742	<.001	$6,892
Major procedure	0.6640	0.6281–0.7000	<.001	$14,690
Chronic pulmonary disease	0.0565	0.0050–0.1081	.032	$1,251
Weight loss	0.4579	0.3712–0.5447	<.001	$10,131
DVT/PE	0.4662	0.3634–0.5689	<.001	$10,313

CI = confidence interval; DVT = deep venous thrombosis; PE = pulmonary embolus.

into question the decision to classify a medical condition as a NRHAC if it is not entirely preventable with guideline-directed prophylaxis. Financial penalties that link reimbursement to outcomes risk limiting access to care for high-risk populations, who pose a financial risk under this reimbursement system. A more equitable solution would be to tie reimbursement to the use of appropriate prophylaxis rather than outcome. This would achieve the goal of improving quality of care by encouraging the use of guideline-directed prophylaxis, while not penalizing providers who treat patients that develop a complication despite the appropriate use of evidence-based prophylaxis guidelines.

There are several limitations to the use of hospital discharge data that may influence our findings. The NIS database provides no follow-up data beyond the index admission, is limited to a 30-day postoperative window, and contains no information on stage, grade, or subtype of the disease or survival. Although extent of surgery may be a surrogate for stage of disease, the effect of tumor stage and size on outcomes cannot be accurately determined. The ability to adequately control for case-mix is limited when discharge diagnoses from administrative databases are used. Postoperative complications may not be apparent at the time of discharge, and as a result the incidence of complications may be underreported. Similarly, the true incidence of DVT and/or PE is likely underestimated because of undercoding of this complication, which may not be recognized and coded by administrative personnel. Although patients with a body mass index (BMI) <19 were included in the definition of weight loss, a low BMI may not always indicate malnutrition, and patients with a normal BMI may be malnourished. The extent of weight loss as a percentage of body weight, which has been used to classify severity of malnutrition, cannot be determined from this database. Codes for overweight and obese did not appear in this database before 2005 and only just approached 0.5% of cases in 2008, suggesting that obesity is undercoded. The use of DVT prophylaxis administered in the perioperative period cannot be identified in hospital discharge data, which are limited to diagnosis and procedural codes that do not cover prophylaxis. Another potential limitation is that the cost analysis was based on hospital-related charges, adjusted for institutional expense-to-revenue ratios, and did not include physician-related costs, as these data are not contained in the NIS database.

Nevertheless, these data demonstrate a significant association between DVT/PE and mortality, postoperative surgical complications, acute medical complications, length of hospitalization, and costs in HNCA surgical patients after controlling for all other patient variables, and demonstrate that comorbidity and advanced-stage disease requiring major surgery are associated with an increased risk of postoperative DVT/PE in this population. Because DVT/PE cannot be prevented in all patients despite adherence to currently available medical prophylaxis guidelines, it is inappropriate to classify postoperative DVT/PE as an NRHAC. Efforts to reduce the incidence of DVT/PE through financial incentives that reward guideline adherence, rather than financial penalties for the occurrence of DVT/PE as an outcome, are a more appropriate means of reducing costs, morbidity, and mortality in high-risk vulnerable populations.

CONCLUSION

DVT/PE is uncommon in HNCA patients but is associated with increased mortality, postoperative complications, length of hospitalization, and hospital-related costs. The lack of correlation with known modifiable variables suggests that despite advances in the use of targeted prophylaxis, the subset of patients with advanced disease and comorbidity remain at increased risk. Caution must be used in the institution of reforms that threaten to inadequately reimburse the provision of care to vulnerable populations.

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