

Clinical pathology selected abstracts

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Trends in the incidence of new-onset hypertensive disorders of pregnancy in rural and urban areas

December 2023—Efforts to develop biomarkers that help predict risk factors for preeclampsia/eclampsia and to better understand the trends and implications related to new-onset hypertensive disorders in pregnancy have grown. New-onset hypertension arising during pregnancy (gestational hypertension and preeclampsia/eclampsia) is associated with coronary heart disease, heart failure, stroke, and other cardiovascular-related mortality. Hypertensive disorders of pregnancy have grown into major public health problems that contribute to maternal morbidity, mortality, and future risk of cardiovascular disease. The authors conducted a study to describe contemporary trends in new-onset hypertensive disorders of pregnancy in the United States. They conducted a serial cross-sectional analysis of 51,685,525 live births to women aged 15 to 44 years, from 2007 to 2019, using the Centers for Disease Control and Prevention's natality database. Women who had new-onset gestational hypertension and preeclampsia/eclampsia were included in the analysis. The authors calculated the age-adjusted incidence per 1,000 live births overall and by urbanization status (rural or urban). They also used joinpoint software to identify inflection points and calculate the rate of change. They employed rate ratios to compare the relative incidence of new-onset hypertensive disorders of pregnancy in rural versus urban areas. The results showed that incidences of the disorders increased in rural areas (48.6 to 83.9) and urban areas (37 to 77.2) during the study period. The authors found that the rate of annual increase in new-onset hypertensive disorders of pregnancy was more rapid after 2014, with a greater increase in urban versus rural areas. This significant increase was observed in each self-identified racial and ethnic group and U.S. region. The rate ratios in rural and urban areas decreased from 1.31 in 2007 to 1.09 in 2019. The authors concluded that even though the rural-urban gap decreased during the study period, it reflected a greater increase in rates of hypertensive disorders of pregnancy among individuals in urban areas as opposed to improvements in rural outcomes. The incidence of new-onset hypertensive disorders of pregnancy doubled from 2007 to 2019. This study highlights the need for targeted interventions to improve the health of pregnant women and their children.

Cameron NA, Everitt I, Seegmiller LE, et al. Trends in the incidence of new-onset hypertensive disorders of pregnancy among rural and urban areas in the United States, 2007 to 2019. *J Am Heart Assoc.* 2022. doi:10.1161/JAHA.121.023791

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Frequency of ordering lab-developed tests in an academic hospital system

The FDA is authorized under the Medical Device Amendments of 1976 to regulate medical devices, including in vitro diagnostics, that are introduced into interstate commerce for commercial distribution. The amendments and other federal regulations established the framework under which manufacturers of in vitro diagnostic (IVD) test kits and instruments are required to obtain FDA clearance or approval before distributing the products to diagnose human disease. A hospital laboratory may design, manufacture, and use lab-developed tests (LDTs), but it cannot distribute them to other laboratories. The Verifying Accurate Leading-edge IVCT Development (VALID) Act has been introduced in Congress and, if enacted, will provide a unified regulatory oversight system for all in vitro clinical tests, including IVDs and LDTs. However, regulation of LDTs is a source of controversy as clinical laboratories are currently exempt from having to register devices with the FDA. The authors conducted a study at their academic medical center to determine how frequently LDTs were ordered by clinicians in the inpatient and outpatient setting. They performed a retrospective analysis of 2021 test-order data from their institution, which includes a

hospital, outpatient clinics, and a cancer center. The authors analyzed assay type, assay methodology, regulatory status, test-order volume, inpatient versus outpatient setting, and provider medical specialty. The frequency distributions of the most commonly ordered LDTs were then analyzed overall and for each specialty. The authors found that of the 3,016,928 tests ordered in 2021, 2,831,489 (93.3 percent) were tests that were cleared, approved, and/or authorized by the FDA; 116,583 (3.9 percent) were LDTs; and 68,856 (2.3 percent) were standard methods. The test orders were carried out using 1,954 distinct assays. Of these, 983 (50.3 percent) were FDA assays, 880 (45 percent) were LDTs, and 91 (4.7 percent) were standard methods. Of interest, the LDTs were more commonly ordered in the outpatient versus inpatient setting and represented a higher proportion of test volume at the cancer center than the university hospital (5.6 versus 3.6 percent, respectively). Ninety percent of the LDT order volume (104,996 orders) was represented by 167 (19 percent) LDT assays. The most frequently ordered LDTs were mass spectrometry assays and tests used in the care of immunocompromised patients. The highest total number of orders were from internal/family medicine physicians, but this specialty accounted for the lowest proportion (3.2 percent) of LDT orders. The authors concluded that this study showed that LDTs made up a small percentage of the total amount of laboratory tests ordered within an academic health system and that only a small proportion of LDT assays made up the majority of the LDTs ordered. Therefore, legislative reform for LDTs could result in regulatory costs associated with low-volume, low-margin tests and make current clinical offerings unsustainable. The authors noted that those advocating regulatory reform should consider all approaches to ensuring the most appropriate and cost-effective patient care.

Rychert J, Schmidt RL, Genzen JR. Laboratory-developed tests account for a small minority of tests ordered in an academic hospital system. *Am J Clin Pathol*. 2023;160:297–302.

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