Balancing the goals of improving health care quality with out-ofpocket costs in breast cancer patients

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High deductible health plans (HDHPs) use high costsharing requirements as a mechanism to incorporate patients into the efficiency equation. It is theorized that when patients have "skin in the game," or are more directly responsible for the costs of the healthcare services they receive, they make more optimal and costconscious utilization decisions by seeking out high-value services (1). Even in the contemporary efficiency-driven context of the healthcare system, intensified by reforms of the Patient Protection and Affordable Care Act (ACA), the proliferation of HDHPs has been profound. Ten years ago, approximately 20% of non-elderly adults with private health insurance were enrolled in HDHPs (2); since that time, the percentage has more than doubled to 43.2% (3).

A growing body of evidence suggests that HDHPs are associated with lower healthcare costs in the short term due to a reduction in the use of healthcare services (4). However, HDHPs may also reduce the utilization of appropriate services, including preventive care (4-6), which may lead to greater costs in the long term. In the context of breast cancer diagnosis and treatment, a key concern surrounding HDHPs is that they may delay cancer-related care due to high out-of-pocket costs (7,8). However, little is known about the magnitude of harm caused by this delay.

In a recent article by Wharam *et al.* (9), the authors quantified the delay in the receipt of key breast cancer diagnostic and treatment services in women enrolled in HDHPs versus their counterparts enrolled in low deductible health plans. To measure delay in receipt of these key services, the authors examined times to first diagnostic breast imaging, breast biopsy, incident early-stage breast cancer diagnosis, and breast cancer chemotherapy. In their study, HDHPs were defined as plans having deductibles of at least \$1,000, while low deductible health plans were defined as those having deductibles up to \$500. Using a de-identified database of member utilization data from a national health plan, the authors identified generally healthy women between the ages of 25-64 years without evidence of breast cancer at inclusion. Additionally, the women were employed for at least 1 year before and after an employermandated switch from a low deductible health plan to an HDHP ("HDHP group") or an employer-mandated continuation of a low deductible health plan ("control group"). In the HDHP and control groups, there were 270,000 and 2.4 million women, respectively. Both groups were followed from 2003 to 2012.

Using Cox models, the authors found that women in the HDHP group experienced delays in all of the four study measures. Compared to the low deductible health plan control group, HDHP participants experienced a 1.2-month delay in first diagnostic breast imaging, a 2.1-month delay in breast biopsy, a 5.8-month delay in incident early-stage breast cancer diagnosis, and a 7.4-month delay in chemotherapy initiation. Significant delays persisted after adjusting for age, morbidity score, poverty level, US region, index date, and employer size. Researchers accounted for

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differences in covariate balance at baseline between the HDHP and control groups using a matching and weighting approach.

This is an innovative study, and the findings strongly suggest that HDHPs might have a negative impact on the receipt of key breast cancer services. As an explanation for their results, the authors provide an additional analysis demonstrating that the higher deductibles of HDHPs translate to larger total out-of-pocket medical spending among HDHP members. The larger out-of-pocket burden of HDHPs may cause women to delay seeking care even when they are symptomatic (increasing the time to first diagnostic breast imaging) or may cause women to hesitate in their progression along the diagnosis-treatment spectrum (ultimately increasing the time to definitive treatment).

There are several minor limitations to the Wharam et al. study. First, as with any observational study, the assignment of exposures (in this case, HDHP group versus the control group) to subjects is not actively randomized, which can lead to confounding. In order to address this confounding, the authors included neighborhood-level covariates (income, education, and ethnicity) and individual-level covariates (comorbidity score, region of residence, and employer size). Residual confounding likely remains because neighborhood-level ethnicity was operationalized using a combination of geocoding and surname analysis, potentially favoring paternal lineage; additionally, the analysis did not take into account the effects of being a minority relative to one's neighborhood. Given that racial and ethnic disparities in breast cancer are well documented (10), the mischaracterization of ethnicity has the potential to impact study results.

A second limitation of the Wharam *et al.* study, as acknowledged by the authors, is that the study is underpowered to determine the association between HDHPs and care delays within specific subgroups. Of particular interest are low-income or racial/ethnic subgroups, which represent some of the highest-risk populations in terms of cancer outcomes (11). Thus, additional studies are needed to both clarify the current impact of HDHPs on these groups and to understand how the rise of HDHPs might intensify socio-economic or racial/ethnic disparities.

A third limitation of the Wharam *et al.* study relates to the follow-up period spanning from 2003 to 2012. This includes only a brief period during which the ACA was fully implemented. At a system level, the ACA has encouraged payment and service delivery reforms (12), leading to the wider implementation of patient-centered medical homes, accountable care organizations, and bundled payments. These system-level reforms have the potential to bring higher-value services to patients. Utilization patterns among HDHP members may adapt in response to these higher-value services. Thus, it is unclear how the Wharam *et al.* study generalizes in this new milieu.

The minor limitations of the study are outweighed by its numerous strengths. For example, the decision to examine the exposure of HDHPs versus low deductible health plans (control) is an evolution from many traditional studies of insurance status and cancer outcomes. These studies often account for insurance status in a dichotomous fashion (for example, "insured" versus "uninsured"). A dichotomous insurance status indicator dismisses the heterogeneity in insured and uninsured individuals. Furthermore, within insured individuals, there is large variation in benefit structures. In this case, the study exposure acknowledges the differences in benefit structure between participants in HDHPs versus low deductible health plans. Both types of insurance plans cover breast cancer screening and recommended preventive services at no out-of-pocket cost. However, additional costs may accumulate more rapidly in HDHP participants since these plans generally have higher cost-sharing requirements for diagnostic testing (following abnormal screenings) and for oncologic care. Put simply, screening itself is only the first step in a cascade of events enabling early diagnosis and treatment of subclinical disease-a cascade whose completion may result in substantial cost to subjects with high deductibles. These costs may have the effect of delaying time to definitive treatment and may cause considerable financial toxicity.

Another strength of the study lies in the four outcome measures (times to first diagnostic breast imaging, breast biopsy, incident early-stage breast cancer diagnosis, and breast cancer chemotherapy). These outcomes span the continuum from breast cancer diagnostic workup to treatment and represent important performance measures in breast cancer management (13). Since the Wharam *et al.* study does not examine the impact of HDHPs on breast cancer survival, a logical next step for future studies is to establish the association of HDHPs with breast cancer survival. We advocate the use of the cancer diagnosistreatment spectrum framework to enable a clearer understanding of the relative contributions of each point on the spectrum to survival. Identifying potentially actionable

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points of failure at each phase can ultimately improve survival.

The study by Wharam *et al.* will have enduring significance as the American health care system continues to evolve in the coming years. By all indications, the growth of HDHPs in the private insurance market (employer-based insurance and insurance purchased individually through the ACA's Health Insurance Exchanges) will figure prominently into that evolution. The authors' findings strongly suggest that HDHPs have a negative impact on the timely receipt of key breast cancer services. Given the greater abundance of registry data available in cancer relative to other chronic diseases, the lessons learned from this study may have value in enhancing our general understanding of the relationship between out-of-pocket spending and chronic disease outcomes. Understanding this relationship could inform policy and practice in a time of rapid health system change.

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