Asthma in Families Facing Out-of-pocket Requirements With Deductibles

Protocol

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RESEARCH STRATEGY

A. BACKGROUND

Asthma is a major cause of preventable disease burden (*PCORI Methodology Standard RQ-3*). More than 25 million people in the U.S. have asthma, including 8% of adults and 9% of children, with significant racial and income disparities in prevalence.[1-3] Morbidity from asthma is substantial, causing 10.5 million healthcare visits, 479,000 hospitalizations, and 3,100 deaths in 2009.[1] Low income and racial/ethnic minority patients are more likely to experience adverse outcomes, leading to four times as many hospitalizations and five times as many deaths in blacks than whites, and this gap has been increasing.[4-7] Guidelines recommend controller medications such as inhaled corticosteroids (ICS), leukotriene antagonists (LTA), or combination ICS and long-acting β_2-agonists (LABA) that are proven to improve asthma control and quality of life, prevent exacerbations, and reduce need for oral corticosteroids, emergency department (ED) visits, hospitalizations, and deaths due to asthma.[8-18] However, many patients do not use daily controller medications, with 14-20% of individuals not filling prescribed controller medications once.[19] Poor adherence to asthma controller medications increases the risk for adverse clinical outcomes.[16-18] Increased levels of cost-sharing for asthma medications that lead to reduced adherence have also been associated with adverse downstream outcomes such as increased rates of asthma exacerbations, oral steroid bursts, and asthma-related ED visits and hospitalizations.[20-22]

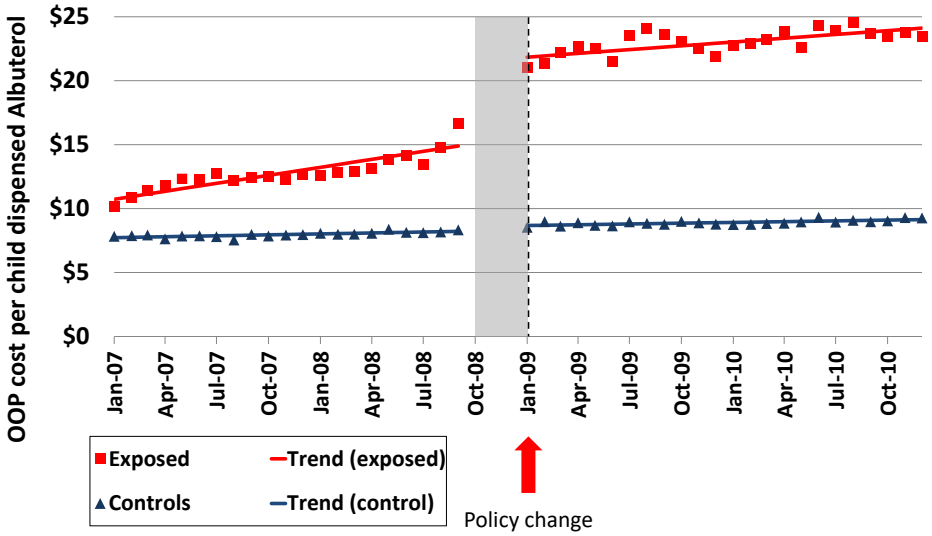
Patients are increasingly faced with high levels of cost-sharing through high-deductible health plans (HDHPs). Compared with traditional plans, HDHPs have lower premiums but subject most services to annual deductibles of at least $1000. HDHP membership more than quadrupled from 2006 to 2015 and 46% of workers now have HDHPs.[23] HDHPs with associated Health Savings Accounts (HSAs) enable enrollees to use pre-tax dollars to pay for medical care. To qualify to include an HSA, HDHPs must have federally-regulated minimum annual deductibles (individual/family: $1300/$2600), and must include all care under the deductible except for select preventive services.[24] As of early 2013, over 15 million people had HSA-HDHPs, with rates of uptake increasing rapidly, especially among large employers.[25, 26] HDHPs are also increasingly prevalent among enrollees in the ACA's health insurance exchanges.[27]

Patients experience substantial barriers to accessing needed medications for chronic conditions such as asthma due to cost-sharing. Numerous studies suggest that high cost-sharing is associated with lower use of both non-essential and essential health care, including medications for chronic diseases.[28-33] Among adults reporting difficulty paying medical bills, more than half said they had had difficulty paying for prescription drugs.[34] Studies in adults have shown that increased cost-sharing is associated with decreased use of important asthma medications.[20, 35, 36] The few studies in pediatric populations have also shown reduction in use of asthma medications with increased cost-sharing.[21, 37, 38] Evidence is limited on the impact of cost-sharing on rescue medications for asthma. Two studies have found that higher out-of-pocket (OOP) costs for bronchodilators were associated with decreased use for adults and children;[37, 39] our recent work found that higher copayments did not lead to decreased albuterol use for children relative to those without a copayment change, but did result in higher OOP costs (Figure 1).[40]

Families are increasingly concerned about OOP costs that can strain family budgets and lead to intra-familial trade-offs. OOP costs from one family member can lead to delayed/forgone care for other family members,[41] and high family OOP expenditures have been associated with lower rates of initiation of expensive medications.[42] Some data suggest that parents prioritize their children's health care over their own when faced with financial pressures.[43, 44] Our research found that both adults and children are at increased risk for delayed/forgone care due to cost when faced with high deductibles, and that the risk is greater for healthy adults in families with chronically ill children, and for healthy children in families with chronically ill adults.[45] In another study, we found that having a greater number of children in the family increased risk of financial burden among health insurance exchange plan enrollees, the majority of whom had HDHPs.[46]

HDHP enrollees are at risk for cost-related underuse of medications, especially in HSA-HDHPs. Our research team was among the first to conduct studies of modern HDHPs,[47-58] including more recent studies using the large, national dataset that we propose to use for the current project.[59] We found that a switch to a HDHP was associated with fewer ED visits[53] and hospitalizations, especially for low socioeconomic status (SES) enrollees;[51] no change in rates of well-child visits and screenings for breast, cervical, and colorectal cancer, all of which were exempt from the deductible;[48, 54] and pronounced reductions in colonoscopy among low SES members.[57, 58] Other early studies of HDHPs without HSAs demonstrated decreased utilization of both appropriate and inappropriate services,[60-62] including prescription drugs.[63-67] HDHP plans are also associated with greater patient out-of-pocket spending for care for families with chronic conditions.[68] Patients with asthma are at particular risk from deductible costs, as controller and rescue medications are expensive branded drugs, costing $140-$307 a month for some inhaled steroids and $30-60 for CFC-free albuterol inhalers[69-71] without available lower-cost generic substitutes. HSA-HDHPs have been associated with decreased adherence for medications for asthma[72, 73] and other chronic conditions.[72-75] In survey studies, we found that families in HDHPs were more likely than those in traditional plans to report health care-related financial burden and delayed/forgone care due to cost for both adults and children.[45, 46, 68, 76] In our qualitative studies, families reported challenges understanding and using HDHPs.[77, 78]

Figure 1. Impact on OOP costs from a co-pay increase for albuterol inhalers



Exposed group had increased co-pays after a policy change mandating branded CFC-free albuterol inhalers. Control group maintained prior generic co-pay levels.

Cost-sharing required by HSA-HDHPs has the potential to exacerbate disparities in access to medications for patients with asthma. Some studies suggest that the impact of increased cost-sharing is greater for low-income populations,[79] who are more likely to experience delayed/forgone care due to cost in HDHPs.[76] Low-income, Hispanic, and African-American populations are more likely to report cost-related underuse of mediations and other health care,[45, 80-82] and increases in copayments for chronic medications have a greater negative impact on adherence for low-income patients.[83] However, one of our studies found that both lower and higher-income populations experience reductions in utilization in HDHPs.[45]

Increasing adoption of Preventive Drug Lists (PDLs) has the potential to preserve use of important asthma medications by patients in HSA-HDHPs. Insurance plans increasingly seek to develop value-based health insurance designs (VBID) that include low or no cost-sharing for high-value services.[84-87] In 2008, 19% of large employers used VBID strategies for medications in their health insurance offerings.[88] The strategy of exempting medications from the deductible as part of a PDL is becoming increasingly popular among employers and health plans.[89] PDLs are lists of medications for primary and secondary prevention (including asthma controllers and rescue medications) that are exempt from the deductible and available at reduced or no cost.[90, 91] Evidence is mixed about the impact of reducing or eliminating copayments for medications. Some studies of diabetes and cardiovascular medications demonstrated modest improvements in adherence and reductions in OOP costs,[88, 92-97] no change in adverse outcomes,[96] and attenuation of racial/ethnic disparities.[98] In HDHPs without HSAs, when medications have been excluded from the deductible and copayments applied instead, we found that prescription drug use for patients with asthma was preserved.[56] We have also found this pattern in our ongoing national study of diabetes and HDHPs (1U58DP02719). However, in other studies, exempting medications from the deductible or eliminating copayments did not improve or

preserve utilization of medications,[99] including asthma medications. [85, 100] PDLs are a unique, readily adoptable VBID feature available with HSA-HDHPs with the potential to be substantially more powerful than previously studied VBID programs in traditional plans or HDHPs without HSAs because of the greater potential OOP cost differential for enrollees in HSA-HDHPs plans. However, we lack evidence about the impact of PDLs in HSA-HDHPs.

Addressing gaps in evidence (RQ-1) on strategies to support patients in HDHPs is a priority area for PCORI.[101] Most studies of HSA-HDHPs or VBID have looked at medications globally or for conditions that are largely asymptomatic, such as hypertension.[88, 92-97, 99, 102-104] Only a few such studies focus on medications for symptomatic conditions like asthma;[56, 72, 73, 85, 100] of these, none assess downstream effects on asthma-related clinical outcomes or disparities. Many studies of cost-sharing effects on asthma medications, especially those focusing on pediatric populations, have relied on weaker observational designs.[20, 35, 37, 39] Use of populations with a choice of health plan types and a lack of matched comparison groups create limitations due to selection bias in some of these studies.[20, 21, 35, 37, 39, 73, 100, 105] For some HSA-HDHP or VBID studies that include asthma medications, generalizability has been limited by inclusion of populations that come from a single employer[73, 74, 85, 100] or only include adults.[35, 73, 74, 85, 100, 106] The few studies on HSA-HDHPs or VBID that include dependents have not explicitly evaluated the impact on children or considered intra-familial effects.[65, 75, 102, 103, 107] Findings of no or only modest changes in asthma medication use in some studies of cost-sharing, HDHPs without HSAs, or VBID may reflect relatively small copayment changes, [39, 40, 75, 85, 100] and may underestimate experiences with HSA-HDHPs and PDLs in which cost differentials are much greater.

B. SIGNIFICANCE

The proposed project will improve the quality of evidence about HDHPs by being one of the first studies to examine the effect of free preventive drugs in HSA-HDHPs on asthma medication use and adverse asthma outcomes. PDLs are especially relevant to asthma patients, given their frequent need for medications that can have short and long-term impact on symptoms and morbidity. Our focus on asthma is unique among studies of chronic conditions in HSA-HDHPs and PDLs because asthma affects both adults and children, requires both preventive and symptomatic medications, and does not have available generic lower-cost alternatives in key medication classes.

As one of the first studies to explore adult-child differences and intra-familial tradeoffs that occur with increased financial pressures in HSA-HDHPs, this project will provide data on outcomes that affect parents and caregivers in families with one or more members with asthma. Most HDHP and VBID research has focused on individual adults. However, many people obtain insurance as a family, and over 60% of HDHP enrollees are in family plans.[56] Health care decisions involve trade-offs to balance family health care needs and costs against a family budget. Some studies of HDHPs have included data on dependents,[65, 75, 102, 103, 107] but these have not addressed child-specific adherence or outcomes. We lack data to know if worrisome findings from adult-focused studies apply to the same extent in children.

Findings from the proposed research will have immediate practical uses for patients, families, clinicians, employers, health insurers, and policy makers who are keen to find strategies to obtain insurance coverage with lower premiums while avoiding cost barriers to needed asthma care (*RQ-3*). [108] [109] This project will provide crucial, patient- and family-centered evidence about health insurance strategies that are already being delivered in real-life settings. Opportunities are readily available to implement policy changes stemming from our findings. Given that HSA-HDHPs are standardized to meet federal policies for HSAs, and that PDLs covering a set of common, important medications have been already implemented by some insurers nationally,[51, 89-91] our findings can easily be generalized and translated into practice in other settings. If HSA-HDHPs with PDLs promote asthma medication adherence and better health outcomes, employers and health insurers could quickly shift to such designs. Findings can inform the health insurance choices of families with asthma as they seek affordable coverage that does not create cost barriers to obtaining needed care.[109]

This research focuses on outcomes that are increasingly of concern to patients with asthma, their families, and other stakeholders, namely cost barriers to obtaining needed asthma care (RQ-6). Patients with asthma desire relevant information about the potential health and financial consequences of the multiple, complex insurance benefits options before them. Forward-looking employers, health insurers, and policy makers who wish to minimize unintended consequences of HSA-HDHPs are considering nuanced VBID strategies like PDLs to improve outcomes among patients with chronic conditions. Our research will evaluate these two "natural experiments" – employer-mandated switches to HSA-HDHPs and addition of PDLs that exempt key asthma medications from cost sharing – which increasing numbers of patients are facing. Letters of support from the Asthma and Allergy Foundation of America (AAFA), the Northeast

Business Group on Health (NEBGH), and America's Health Insurance Plans (AHIP) demonstrate the relevance of our proposed research to patients and stakeholders.

C. APPROACH

Specific Aims

Asthma is one of the most common serious chronic diseases of adults and children in the United States, affecting 18.7 million adults and 6.8 million children. Despite guidelines and evidence of their effectiveness in preventing adverse outcomes such as sick days, ED visits, and hospitalizations, adherence to recommended asthma controller medications is low. Cost is an important barrier to non-adherence to asthma medications. Employers are increasingly adopting HDHPs particularly those that qualify for HSAs, which subject most medications to deductibles rather than copayments as in traditional coverage. HSA-HDHPs can thus lead to forgone care due to cost, including clinically appropriate services such as asthma medications. As a response, value-based insurance designs have been proposed to promote high-value care by reducing or eliminating cost-sharing for these services. One common example is a PDL that can accompany HSA-HDHPs, which exempts certain chronic medications from the deductible to promote adherence. PDL's have become increasingly prevalent in HSA-HDHPs offered by employers, and many PDLs include asthma controller and rescue medications. Evidence suggests only a small adherence benefit when VBID reduces out-of-pocket (OOP) costs for already low-cost preventive medications in traditional plans without high deductibles. However, under HSA-HDHPs, where OOP costs are higher and the potential reduction by a PDL much more meaningful, we lack evidence on the response to PDL cost-sharing reductions among asthma patients. With the increasing prevalence of HSA-HDHPs, PDLs have the potential to improve controller medication adherence for both adults and children, which could improve asthma outcomes and reduce downstream costs. Lower asthma cost burden could mitigate cost-related trade-offs for families in HSA-HDHPs who must balance health care and other costs within a family budget.

In this project, we intend to evaluate the impact of two important developments in the health insurance landscape, HSA-HDHPs and PDLs, on medication use, clinical outcomes, and patient experiences for adults and children with asthma. We will take advantage of a rolling cohort of over 621,000 adults and 310,000 children with asthma who receive employer-sponsored coverage from a large national insurer between 2004 and 2017. We will employ a rigorous quasi-experimental interrupted time-series (ITS) and difference-in-differences (DiD) designs to examine the effect of being switched by an employer from HSA-HDHPs without PDLs to HSA-HDHPs with PDLs compared to controls who remain in HDHPs without PDLs. We will compare changes in medication use and patient-centered clinical outcomes (asthma-related ED visits and hospitalizations) for adults and children and within families. Qualitative interviews with patients with asthma in HDHPs will provide more in-depth patient-reported data on health care decision making and experiences in these plans, which will inform quantitative analyses. The overarching goal of this research is to provide needed evidence – including data gathered directly from patients – on whether pairing PDLs with HSA-HDHPs can mitigate cost barriers and improve patient-centered outcomes for adults and children with asthma. Our Specific Aims are:

1. To understand health care decision making and experiences of families with asthma under HSA-HDHPs and PDLs
2. To examine the impact of HSA-HDHPs with and without PDLs on use of asthma controller and rescue medications, and on adverse clinical outcomes (asthma-related ED visits and hospitalizations), overall and for vulnerable subgroups (low-income and racial/ethnic minority patients)
3. To examine the extent to which the response to HSA-HDHPs and PDLs is affected by the presence of other family members with asthma or other chronic conditions
4. To examine the impact of HSA-HDHPs with and without PDLs on out-of-pocket (OOP) costs for patients and families with asthma

With input from patients with asthma and other stakeholder partners, the proposed project will focus on patient-centered outcomes related to asthma care in new insurance designs. This research will meet a pressing need to understand the impact of a readily adoptable health insurance innovation that has major potential to improve asthma medication adherence and outcomes. Findings will advance the goal of developing and implementing insurance designs to promote access to high-value health care services and improve clinical outcomes while avoiding burdensome costs for families.

Overview of Study Protocol (RQ-2)

This project will employ both qualitative and quantitative methods, based on theoretical models adopted from Levy and Meltzer's model of the effect of health insurance on health outcomes,[110] and known causal pathways linking asthma controller medication adherence to reductions in short-term complications.[8-12]

In Aim 1, we will conduct in-depth qualitative interviews with approximately 60 commercially-insured patients with asthma or parents of children with asthma who have HDHPs with and without PDLs, or traditional plans. These telephone interviews will explore how patients and their families understand and navigate their HDHP and make health care decisions and trade-offs when faced with out-of-pocket costs. Insights gained from these interviews will shape and inform the quantitative analyses in Aims 2-4.

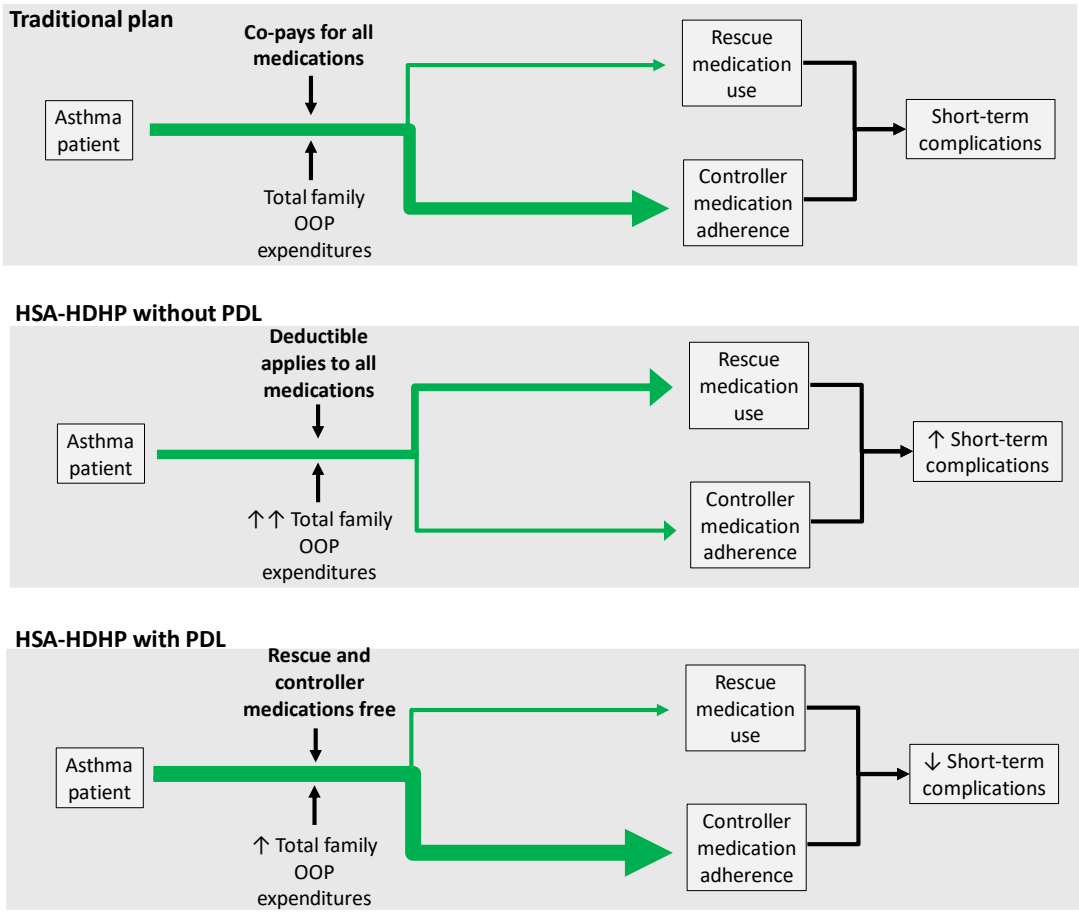
In Aims 2-4, we will maximize internal validity, reduce selection bias, and address causal inference standards by employing cutting-edge study designs and analytic methods that we have used in our prior work (CI-1,4): (1) ITS with comparison series design, the most rigorous quasi-experimental design for causal inference;[111] (2) a population whose employers offer only a single health plan type, minimizing self-selection bias; (3) matching groups on the functional form of the baseline trend, recently shown to approximate estimates from RCTs;[112] and (4) a rigorous and validated two-level propensity score matching approach that matches on both individual and employer baseline characteristics and includes family-level characteristics.[113] We will follow individuals and families with asthma for 1 year before and up to 3 years after an index date when they are required to switch to HSA-HDHPs with or without PDLs, or to remain in HSA-HDHPs without PDLs or remain in traditional plans. We will identify two primary intervention groups of interest: 1) patients with asthma switched by employers from traditional plans to HSA-HDHPs *without* PDLs; and 2) patients switched from HSA-HDHPs without PDLs to HSA-HDHPs *with* PDLs. Patients in each group will be propensity-matched to patients with asthma who remain by employer choice in the same plan.

Conceptual Model Underlying Study Hypotheses

The theoretical underpinnings of our study derive from Levy and Meltzer's conceptual model of the effect of health insurance on health outcomes,[110] and known causal pathways linking asthma controller medication adherence to short-term complications.[8-12] In our model (Figure 2), level of medication cost-sharing for patients with asthma is determined by plan type, as follows: 1) HSA-HDHPs without PDLs - full cost-sharing for controller and rescue medications; 2) HSA-HDHPs with PDLs - no cost-sharing for controller and rescue medications; and 3) traditional plans - three-tiered copayments for controller and rescue medications.

We hypothesize that higher cost-sharing in HSA-HDHPs without PDLs leads to decreased adherence to controller medications and decreased rescue medication use (offset by increased need for rescue medications due to suboptimal controller adherence). Reductions in controller medication use can increase asthma exacerbations and short-term complications such as ED visits and hospitalizations. Because a patient's OOP costs contribute to total family OOP cost burden, which can strain family budgets and lead patients to avoid or defer care and further decrease medication use, OOP costs are an additional outcome of interest. We hypothesize that lower cost-sharing due to PDLs, on the other hand, should lead to increased controller medication adherence, less need for rescue medications, fewer asthma complications, and lower OOP costs and family cost burden.

Figure 2. Conceptual model illustrating the impact of HSA-HDHPs with and without PDLs relative to traditional plans. Green arrows represent patterns of medication use, with wider arrows representing greater use.



Sources of Data (IR-1)

The project's four-year duration will enable us collect data from qualitative interviews on patient-reported experiences (Aim 1) that will inform quantitative analyses (Aims 2-4) and will allow us to accrue an adequate sample size of patients who experience the "intervention" of switching to an HSA-HDHP with or without a PDL and have one to two years of follow up.

Aim 1. We will collect patient-reported data through in-depth qualitative interviews with patients with asthma or parents of children with asthma who are enrolled in HDHPs (with and without PDLs) or traditional plans. Interviews will be conducted by phone using an interview guide with open-ended questions designed to take approximately 45 minutes. Interviews will be audiotaped and transcribed. There will be two sources of data:

1) Interviews of health plan members in non-group and employer-sponsored plans, including those identified from national employer accounts from Harvard Pilgrim Health Care (HPHC) which has a partnership with the large national health insurer whose data will be used in Aims 2-4. HPHC is a large non-profit health plan based in New England which partners with the national health plan to provide services to members living outside New England.

2) Interviews of subjects recruited through the AAFA, a national non-profit organization founded in 1979 to control and prevent asthma and allergic conditions through patient education, public awareness, and support for research (see Section F.1).

Aims 2-4 will use 14 years (2004-2017) of enrollment and benefits data, insurance claims, standardized cost data, geocoded census data, and credit report SES variables from a large U.S. commercial health plan obtained through Optum. We will have detailed benefit information for ~80% of employer groups obtaining coverage from the health plan. For employers with missing deductible levels, we have developed an imputation algorithm that has 97.0% sensitivity and 96.2% specificity (MD-2). The health plan links insurance claims to de-identified credit report data, including novel indicators of individual-level SES (household income and net worth) and imputed information on ethnicity based on member surname (MD-2, see 'Methods to monitor and address missing data', below). Data from this insurer have been used in published health services research studies[72, 114, 115] and the study team has experience examining a range of health care outcomes using these data. [59, 116-121] The research team's extensive experience using these data will enable us to efficiently create analytic cohorts and study variables, building upon previously developed methods. We will leverage existing health plan data from 2004-2014 that the study team has used in other projects, and add data through 2017 in December 2017 (see Optum letters).

Description of Comparators (RQ-5)

This project will assess the impact of the "intervention" of being switched to an HSA-HDHP with a PDL, relative to a control group that was not switched and remained in an HSA-HDHP, and of being switched to an HSA-HDHP without a PDL relative to a control group that was not switched and remained in a traditional plan. Comparator groups include:

HSA-HDHP with PDL: enrollment in an HSA-qualified HDHP with a PDL that exempts asthma controller and rescue medications from the deductible, after being switched by an employer from an HSA-HDHP without PDL or from a traditional plan. There is limited data on the effectiveness of HSA-HDHPs with PDLs on asthma outcomes, despite an estimated prevalence of 19% among HSA-HDHP enrollees based on the national health plan to be studied. Other VBID programs have shown modest increases in adherence to chronic medications.[88, 92-97]

HSA-HDHP without PDL: enrollment in an HSA-qualified HDHP without a PDL, after being switched by an employer from a traditional plan. Those who enroll in HSA-HDHPs without PDLs and do not switch will also be used as a control group for those who switch from HSA-HDHPs without PDLs to HSA-HDHPs with PDLs. Evidence in adult populations suggest a reduction in adherence to asthma medications for those enrolling in HSA-HDHPs without PDLs.[72, 73] In 2015, the prevalence of HSA-HDHPS among covered workers was 15%.[23]

Traditional plan: enrollment in a plan with no or a low (<$500) deductible through an employer who offers only one plan. Fifty-four percent of covered workers have traditional plans, with a baseline proportion of days covered (PDC) for asthma medications of 46%.[74]

Study Population (PC-2) (See section D below for further detail)

The **Aim 1** study population will consist of adults with asthma and parents of children with asthma. Eligible participants will be those who are currently enrolled in employer-sponsored and non-group health insurance plans (high-deductible plans with and without a PDL, or traditional plans). Participants will be drawn from two different populations. First, we will recruit members of a health plan in order to ensure representation of patients through their membership in HSA-HDHPs with and without PDLs. Second, we will recruit additional patients with asthma and their caregivers through AAFA in order to ensure representation of patients who have other health insurance carriers.

The health plan population will be identified through enrollment and claims data from HPHC among non-group plans and large national employer accounts. HPHC offers HSA-HDHPs with the same standardized, federally mandated benefits as the national health plan used in Aims 2-4, as well as a PDL containing similar medications, including asthma controller and rescue medications. Eligible patients will include adults aged 18-64 with a diagnosis of asthma and/or a child with asthma. Using methods from our previous asthma studies,[19, 40, 122] an asthma diagnosis will be defined as having at least one inpatient, ED, or outpatient claim in the prior year with a diagnosis of asthma based on the following International Classification of Diseases, 9th edition (ICD-9) codes (up through 2015): 493.XX and ICD-10 codes (2015 and after): J45.2x, J45.3x, J45.4x, J45.5x, J45.90x, J45.990, J45.991, J45.998. We will select patients who have been enrolled in an employer-sponsored or non-group market HSA-HDHP with or without a PDL, or a traditional plan without a high deductible, for the prior year. We will identify other family members with asthma sharing the same insurance plan. Among those eligible in each sub-group outlined in Table 1 below, we will randomly select up to 140 from each cell to send a recruitment mailing/email, for a total of up to 660 patients or parents invited to participate.

The AAFA population will be recruited through postings to AAFA's Asthma Online Community, Educational Support Group, email listserv, Facebook page, newsletters, flyers, and/or other communication channels. These posts will include a description of preliminary eligibility criteria (i.e. have a diagnosis of asthma or are parents of children with asthma who currently have an employer-sponsored or non-group commercial plan).

Both the HPHC recruitment mailing/email and AAFA recruitment messaging will invite potential participants to complete a pre-screening questionnaire to confirm eligibility, either by phone or online via REDCap, a secure web application for data capture. The questionnaire will assess insurance plan type, asthma diagnoses in the family, as well as other sociodemographic characteristics. The study team will schedule interviews with eligible participants, selecting participants to ensure diversity of socioeconomic status, race/ethnicity, geographic location and asthma severity. Interviews will be conducted to reach the target distribution of sub-groups outlined in Table 1 below with equal numbers of each sub-group coming from HPHC and AAFA, or until thematic saturation is reached. If the team is particularly interested in one category, we may oversample from that sub-category. The totals below are approximate. We will offer a gift card incentive of $50 for completed interviews.

Table 1: Targeted study sample for interviews		**HDHP**		
	Traditional plan	**With PDL**	**Without PDL**	**Total**
Adult with asthma	6	6	6	18
Parent of child with asthma	6	6	6	18
Adult with asthma who also has a child with asthma	6	6	6	18
Total	18	18	18	54

For **Aims 2-4**, the study population will be drawn from 14 years of data from a large U.S. commercial health plan with membership in all 50 states and annual enrollment of ~30 million members. The eligible population will consist of adults aged 18-64 years and children aged 4-17 years with asthma in a baseline year while insured in a traditional plan; all subjects must have continuous insurance coverage with pharmacy benefits for at least 24 consecutive months. Study subjects must have spent a year in a traditional health plan with no or low deductibles prior to the switch to an HSA-HDHP without a PDL, or have spent a year in an HSA-HDHP without a PDL before switching to an HSA-HDHP with PDL, and then remain enrolled for at least one-year post-switch. Control group members spend a year in a traditional plan or a HSA-HDHP without PDL then remain that plan for at least another 12 months. As study groups for secondary analyses, we will also identify enrollees switching from traditional plans to HSA-HDHPs with PDLs for comparison with those remaining in traditional plans. We will also identify enrollees with other plans types, not just HSA-HDHPs, which appear to have PDLs in that they have lower cost-sharing for asthma medications compared to other non-preventive medications. Based on preliminary findings from qualitative interviews as part of Aim 1 of the project, we have learned the cost of asthma medications is a problem not only for enrollees in HSA-HDHPs but in other types of HDHPs and in traditional plans with low deductibles as well, so we will also identify enrollees who are switched from having no PDL to having a PDL. Each of these groups will be matched with controls who start in the same type of plan and remain in that type of plan without gaining a PDL.

Thus, to be included in the study, all subjects will have at least 12 months in both the Pre and Post periods. We selected a follow-up period of up to three years because we hypothesized that patients in HSA-HDHPs with PDLs might experience benefits that take longer than one year to manifest. A primary purpose of the pre period is to ensure precise matching between groups on both the level and trend in key baseline characteristics (e.g., employer characteristics, demographics, utilization patterns, etc.). Our difference-in-difference analyses will include annual-to-annual comparisons (baseline to follow-up year 1, baseline to follow-up year 2, etc.). This will allow intuitive comparisons such as "relative to controls, adherence among HSA-HDHP members with PDLs increased by 4% in follow-up year 1 compared to baseline, but by follow-up year 2, adherence had increased by 11% compared to baseline." We have used this approach in a variety of studies[49, 57, 58, 123] and find that it translates well to clinical and policy audiences. For analyses of outcomes in the second and third year post-switch, we will only include study group patients and their matched controls who have had that length of follow up. We will compare and report differences in baseline characteristics for the subgroups of study cohort members that remain enrolled for each additional year.

We will exclude those over age 64 who are eligible for Medicare. We will identify members with asthma during a 12-24-month period prior to the index date using the same claims-based algorithm used to identify HPHC members with asthma for the Aim 1 interviews, with the inclusion of ICD-9 codes 493.XX to identify a diagnosis of asthma through October 2015. This broad definition will include patients with *intermittent asthma* as well as those with *persistent asthma*, for whom controller medications are recommended. Subgroup analyses will focus on the subset of patients who meet the HEDIS definition of persistent asthma (≥ 1 ED or inpatient visit with asthma as the principal diagnosis, ≥4 outpatient visits with any asthma diagnosis, or ≥4 asthma drug dispensing events in the baseline year).

Eligible employers are those that offer only one plan type in a given benefit year: 1) traditional HMO/PPO/POS plans (deductibles <$1000, copayments of <$50 for most services, tiered copayments for medicines); 2) HSA-HDHPs without PDLs; or 3) HSA-HDHPs with PDLs. We will select "full-replacement" employers that replace a traditional plan with an HSA-HDHP without PDL, or replace an HSA-HDHP without PDL with an HSA-HDHP with PDL, for all employees at a given point in time; matched comparison employers will include those that keep all employees in their prior plan. Including only full-replacement employers is a key strategy used in multiple previous studies to reduce member self-selection bias.[47-59, 124] The index dates for HSA-HDHP enrollees will be the dates of the employer-mandated plan switch. Matched controls will have contemporaneous enrollment in traditional plans also mandated by their employers; index dates will be assigned to be the same as matched intervention enrollees. We will also include matched controls who remain in HSA-HDHPs without PDLs. To reduce bias due to dropout, we will censor both HDHP and control patients together when either one drops out, and weight the remaining population to retain its baseline demographic and clinical profile.[125] We estimate that there will be 621,481 adults and 310,741 children with asthma from 2004-2017 who will meet our inclusion criteria: 18,000 asthma patients in HSA-HDHPs without PDLs, 4,222 in HSA-HDHPs with PDLs, and 910,000 in traditional plans.

Outcomes

Aim 1 qualitative interviews will assess patient and family experiences across a number of domains related to asthma health care decision making and outcomes in HDHPs (*RQ-6, PC-3*). These domains have been selected based on patient concerns and interests expressed in our prior surveys, qualitative interviews, and focus groups with HDHP members and asthma patients;[45, 68, 77, 126] suggestions from AAFA co-investigator Meryl Bloomrosen; and postings from readers of Dr. Wu's asthma blog (url: http://asth.ma) (RQ-6).[127] Domains and interview questions will be refined based on input from the project's Stakeholder Advisory Board and Patient and Family Research Council. Given the limitations of claims data for understanding the perceptions and experiences of patients, these patient-reported qualitative outcomes will provide complementary, in-depth insight into decision making about health and financial outcomes that matter most to patients. See Appendix for the draft interview guide. Area to be explored will include:

1. Understanding and perceptions of insurance benefits (understanding cost-sharing requirements, especially for asthma medications, awareness of having a PDL, perceptions about PDL usefulness for asthma medications)
2. Impact of cost barriers on health care use for asthma, especially medications (decision making around delaying or forgoing care due to cost and for which types of services, patient-defined adverse consequences related to asthma care and disease burden)
3. Financial burden of asthma care (OOP cost burden from asthma care, other unmet medical or non-medical needs due to paying for asthma care, other patient-defined adverse consequences, strategies to reduce OOP barriers for asthma care, experiences discussing cost barriers with providers)
4. Intra-familial trade-offs (impact on asthma care needs, other family members' medical and non-medical needs)

Interviews will also explore non-financial barriers to adherence faced by families with asthma, such as low parental expectations for symptom control, concern about side effects, competing household priorities, and lack of routines for medication administration.[128] We will also explore the relative importance of financial vs. non-financial barriers to adherence to asthma medications.

The primary study outcomes for **Aims 2-4** are the claims-based measures of asthma medication use, outcomes, and OOP costs listed below, measured at the individual level. Our project focuses on these patient-centered, clinically-relevant outcomes (RQ-6), and will not focus on total costs to employers and the health care system.

1. Adherence to controller medications (Aims 2-3): We will assess adherence to guideline-recommended asthma controller medications, including ICS, LTA, or ICS-LABA, which have been shown to reduce asthma morbidity and adverse outcomes.[8] These medications are subject to the deductible in HSA-HDHPs without PDLs, free in HSA-

HDHPs with PDLs, and subject to copayments in traditional plans. We will measure: 1) PDC, the proportion of days that members have their medication available per month. Proportion of days covered is calculated based on the days' supply in each pharmacy fill, spread over the days following the fill. Previous studies have used proportion of days covered as a valid measure of adherence that is associated with better clinical outcomes (IR-4).[19, 129] 2) medication discontinuation, defined as experiencing a gap of more than 60 days in availability of a controller medication following a period of at least 180 days of continuous treatment (i.e. with no gap in availability greater than 60 days). Claims-based measures such as these have been shown to be valid measures of adherence (IR-4).[130]

Because PDLs are not standardized nationally, there is some variation among health plans in the specific types of drugs included. From a review of several other insurers' and employers' PDLs, those that include asthma medications cover both controllers and beta agonists/rescue medications.[90, 131-133] However, some of these PDLs include a few less commonly used inhaled corticosteroids which are not included in the PDL that we propose to study. To address this variation, in addition to measuring adherence to asthma controller medications generally, we will also measure adherence to the specific controller medications included in the PDL and adherence to the sub-set of controller medications that are not included in the PDL (Aerospan, Arnuity ellipta, Asmanex HFA, Aerobid, Azmacort).

2. Use of asthma rescue medications (Aims 2-3): We will assess use of albuterol and levalbuterol inhalers, the primary asthma rescue medications prescribed to patients, which are subject to the deductible in HSA-HDHPs without PDLs, free in HDHPs with PDLs, and subject to copayments in traditional plans. All albuterol and levalbuterol inhalers are brand-name drugs containing 200 puffs each. We will exclude nebulized versions as these are predominantly used by younger children and do not come in standardized doses. As in our prior study,[40] we will measure the standardized number of inhalers dispensed per month based on National Drug Code (NDC) in pharmacy claims. Given the inter-relationship between rescue and controller medication use, we will also measure the ratio of controller medications to total asthma medications, a metric for which higher values are associated with better asthma control and lower rates of asthma-related ED visits.[134, 135]
3. Use of spacers and nebulizer machines (Aims 2-4): Based on input from patients and stakeholders, and with additional input from questions from added questions in the qualitative interview guide in response, we will assess changes in the number of spacers and nebulizer machines received by study patients, based on claims data. We will measure changes in receipt of spacers and nebulizer machines after a switch to an HSA-HDHP vs. remaining in a traditional plan to see if changes in the cost-sharing for these devices leads to a decrease in receipt and an increase in OOP costs to families.
4. Asthma-related ED visits and hospitalizations (Aims 2-3): As a measure of potentially avoidable short-term complications, we will measure asthma-related ED visits and hospitalizations that have a primary ICD-10 diagnosis code for asthma.
5. OOP health care costs (Aim 4): We will calculate consumer price index (CPI)-adjusted OOP costs for asthma medications and other health services, summing deductible, co-pay, and coinsurance amounts, aggregated into annual measures. Financial burden due to OOP costs will be defined as annual family OOP costs as a percent of family income, with cutpoints of >5% and >10% to indicate financially burdensome OOP costs.[136-139]

Predictors and Covariates

Table 2 shows the main predictors and covariates we will use in the proposed study for propensity matching to create study cohorts (CI-1, 4-5), predicting or adjusting outcomes, or stratifying analyses. Our primary predictor variables include study period and insurance type. Study period indicates the one-year period before or up to three years after the index date. Insurance type includes: 1) HSA-HDHP without PDL; 2), HSA-HDHP with PDL; and 3) traditional plan.

Table 2: Predictors and covariates

Covariate	Use*	Notes
Study period	P	Pre (1 yr pre), Follow-up (up to 3 yrs post)
Insurance type	P	HSA-HDHP without PDL, HSA-HDHP with PDL, traditional plan
Income	P, M, S	Subscriber income in dollars and as a % of Federal Poverty Level (FPL) (<250%, 250-399%, >400%)
Lives in neighborhood with:		
Low education	P,M	≥25% with less than high school education
High poverty	P,M	≥10% living below poverty level
Low SES	P,M	Either low education or high poverty
Race/ethnicity	P,M,S	Hispanic; Asian; Black; White; Other
Persistent asthma	P,S	Based on HEDIS definition
Severe asthma	P,S	On oral steroids or omalizumab
ACG Score	P,M,S	For patient and mean for family; >2 signifies high morbidity
Other chronic conditions	P,M,S	For patient, other family members, from AHRQ Chronic Condition Indicator list
Region of residence	M	State classified into 9 geographic regions
Sex	P,M	
Age on index date	M	For patient; mean for adults and children in family
Adult vs. child	P, S	Age 18-64 vs. age 4-17
Family coverage	M	In a family vs. individual plan
Family size	M	Number sharing same insurance account
Family members with asthma	P	Other adults, other children
Number of medications	P,M	For baseline year, controller, rescue, other (on and off PDL); for patient, other family members
Outpatient visits	M	For baseline year: for patient and mean for family
Hospitalization	M	For baseline year: ≥1 admission, mean per family
Total expenditures	M	For baseline year: for patient and mean for family
Employer size	M	2–50; 51–250; 251–999; ≥1000 employees
Employer health care expenditures	M	Per capita, for baseline year

* P=predictors; M=used in propensity matching; S=used to stratify analyses

Other co-variates include asthma severity in the baseline period using the HEDIS definition for persistent asthma (see above under Study Population), and using chronic oral corticosteroid therapy (180+ days in the prior year) or any use of omalizumab in the baseline year to define severe asthma. To estimate co-morbidity, we will use the well-established Johns Hopkins Adjusted Clinical Groups (ACG) scores[140, 141] which use ICD-10 codes in the baseline period to calculate a standardized morbidity score in a specified time period. We will measure the presence of other chronic conditions from claims data in the baseline year using the Johns Hopkins ACG system. We will also measure whether enrollees have COPD as a co-morbidity, as there can be overlap with COPD and asthma, and use of similar medications.

A unique innovation of our study is the availability of data linkages (IR-2) with consumer data from a major credit reporting company linked to insurance claims from our data vendor, Optum. Consumer data elements include total household income, net worth, and race/ethnicity. We will combine self-reported race/ethnicity data from credit card and loan applications with data from Optum on surname analysis for identifying Hispanic or Asian ethnic groups and geocoding to derive race/ethnicity from census data.[143] We will also use census-based indicators for neighborhood education and poverty levels.[144-147] Other variables used to propensity-match cohorts and adjust for confounding will include sex and age; state/region of residence; individual versus family plan; baseline number of outpatient visits, presence of an inpatient hospitalization, and total expenditures; employer size (number of employees); and average employer baseline expenditures per capita (CI-1, 4-5).

Using methods from our prior family-level studies,[50, 68] we will aggregate individual member data to create family-level co-variates that will be applied to each subject and used for individual-level propensity matching and analyses. Patients with individual coverage will be considered a family of one. Family-level variables include: number of family members; mean age of children in the family; mean age of adults; baseline mean family ACG score; number of family members with asthma; and number of asthma and other medications used by the family, and number of ED visits and hospitalizations in the baseline year.

Our study population includes health plan members working for employers that either switched to an HSA-HDHP without PDL or HSA-HDHP with PDL, or remained in a traditional plan or an HSA-HDHP without PDL, respectively, for all employees. While this minimizes member-level selection, employer-level selection could still bias results. We will therefore use a validated and rigorous employer- and individual-level propensity score classification/matching approach (CI-1, 4-5)[148-151] that is superior to a single-level matching technique.[113] For employer-level propensity matching, potential predictors of an employer HSA-HDHP switch in our propensity score models will include employer size

category; baseline level and trend of total per capita health care expenditure quintile; baseline level and trend of outpatient, ED, and hospital visits quintile; median employee age; median employee ACG score; and percentage of employees who are women, in family plans, and living in lower SES neighborhoods (Table 2). We will perform this employer-level match separately for each intervention group of interest (HSA-HDHPs with and without PDLs) in order to generate each comparison with the control group remaining in traditional plans or HSA-HDHPs without PDLs. Intervention and control groups will be matched based on their baseline characteristics when both were in the same type of plan. We will set $p<0.05$ as a cutoff for including predictors and use backwards selection to choose a parsimonious model, testing for significant effects on remaining predictors when one is eliminated. Following methods in our ongoing work, we will stratify employers based on resulting propensity scores into quartiles. We will then perform individual-level propensity matching within each quartile (below) to develop a multiple control groups for each intervention group.

Within employer propensity quartiles, we will create closely matched control groups using individual-level propensity score matching (CI-1, 4-5),[148] with family-level covariates included in the matching. Using individual and family-level covariates from the baseline period, we will match four contemporaneous control group patients to each intervention group patient within a standard propensity score caliper (0.2 of the standard deviation of the logit of the pooled baseline propensity score).[152] Use of a comparison group matched at both employer- and individual-level will generate study cohorts with nearly identical employer/member demographics and baseline health care trends, offering a further degree of control for any potential changes that may influence specific study outcomes.[57, 111, 153-156]

Methods to monitor and address missing data (MD- 1-3, 5)

We have identified the following 5 variables as exhibiting data missingness (MD-1) in our dataset for this study:

- Variable 1: Geocoded poverty level
- Variable 2: Geocoded education level
- Variable 3: Member-level income level
- Variable 4: Member-level net worth
- Variable 5: Member-level deductible Level

Missing poverty, education, income, and net worth data: We will use 3 methods to accommodate missingness (MD- 2-3): (a) multiple imputation, (b) modeling missingness as a member-level characteristic, and (c) excluding members with missing data. If findings differ, we will present results using all 3 methods in manuscripts or attached appendices. We will use SAS procedures PROC MI and PROC MIANALYZE to impute the missing individual level covariates and conduct the statistical analyses under the assumption of missing at random. The SAS procedure PROC MI will impute the missing variables (including individual net worth, income level, poverty level and education level) using other available variables such as age, gender, census block level income, poverty, education etc. Then we will use PROC MIANALYZE to analyze the imputed data. We will also explore certain Bayesian imputation techniques to handle missing data in case missing is not at random and compare the results. If the degree of missingness for member-level credit report data is found to be too great, we will still be able to use geocoded poverty and education census block-level data, for which missingness has been less than 1% in the study team's prior work using this data source.

Missing Deductible Level Data: Through our data vendor, Optum, we will have detailed benefit information for ~80% of employer groups obtaining coverage from the health plan. For smaller employers (with approximately 100 or fewer employees), we will use a benefits type variable that is not missing for smaller employers. For larger employers with missing deductible levels, we will take advantage of the fact that health insurance claims data are the most accurate source for assessing out-of-pocket obligations among patients who utilize health services. Our claims data contain an in-network/out-of-network deductible payment field. For patients who use expensive or frequent services, the sum of their yearly deductible payments will add up to clearly identifiable exact amounts such as $500.00, $1000.00, $2000.00, etc. When several members have these same amounts, it provides strong evidence that the employer offered such an annual deductible level. It will also be possible to detect employers that offer choices of deductible levels when multiple employees have deductibles at two or more levels, such as 20 employees with an annual amount of $1000.00 and 12 employees with $500.00. For employers with at least 10 workers, we therefore will sum each employee's in-network deductible payments and number of claims over the enrollment year and plan to assess other key characteristics such as percentage with Health Savings Accounts. On a randomly selected half of the employer data set that contains our calculated employer characteristics (such as the percentage of patients with deductible levels between $1000-$2500) as

well as actual deductible amounts, we will use a logistic model that predicts the 5-level outcome of deductible <=$250/$250-$499/$500-$999/$1000-$2499/>$2500 based on multiple aggregate employer characteristics such as the first and second most common whole number deductible value, the percentage with Health Savings Accounts, the median deductible payment, the percentage of employees using services, the employer size, the percentage of employees with deductible levels between $100-$250/$250-$500/ $500-$1000/ $1000-$2500/ >$2500, etc. This predictive model will output the probability that employers had deductibles in the 5 categories (summing to 1) and we will assign the employer to the level that has the highest probability. If we detect employers that have 10 or more employees with whole number deductible levels both above and below $500 (e.g. $250.00 and $1500.00), we will assign the employers' category as "choice." If 100% of employees have Health Savings Accounts, we will also overwrite any previous assignment to classify the employer as a high-deductible employer. We will test the predictive model on the other half of the sample for which we have actual deductible levels. We have previously used a similar algorithm and, at employers with 75-100 workers, we found sensitivity and a specificity of over 96% (MD-5).

Analysis plan (IR-3; HT-2)

Aim 1: to understand health care decision making and experiences of families with asthma under HSA-HDHPs and PDLs.

We will analyze qualitative data in iterative cycles of content analysis in the manner described by Patton. In the first, inductive phase of analysis, two coders will independently read initial transcripts multiple times in their entirety, and then analyze them through a process of open coding aimed at identifying broad topics of discussion. Through discussion with the larger study team, coders will identify codes of interest, and will structure subsequent interviews to explore these topics in greater depth. Over time, coders will refine codes and organize them into a codebook. When interviews begin to yield little new information (i.e., saturation), we will systematically apply codes to all transcripts using NVIVO.

In the second, deductive phase of analysis, we will consider data code-by-code to identify areas of convergence and divergence by insurance type (e.g., perceptions of medication affordability between participations with high-deductible versus traditional health plans). We will also consider data across codes by our three participant categories (i.e., patient, parent, patient and parent). We will describe emergent codes thematically, selecting representative quotations to illustrate key themes. We will then re-read transcripts to test identified themes to check for “dissenting views,” or exceptions to overall themes, that might require additional analysis or discussion. To conduct “member checking,” we will present our themes to AAFA partners, using facilitated discussion to elicit and incorporate their views in our analysis.

Findings will inform quantitative analyses for Aims 2-4. Outcomes of interest identified in the interviews will be added to Aim 2-4 where possible with claims data. Findings related to intrafamilial trade-offs will be used to refine analyses for Aim 3, and findings related to financial burden will be used to refine analyses for Aim 4.

Aim 2: to examine the impact of HSA-HDHPs with and without PDLs on use of asthma controller and rescue medications, and on adverse clinical outcomes (asthma-related emergency department (ED) visits and hospitalizations), overall and for vulnerable subgroups (low-income and racial/ethnic minority patients).

> *Hypothesis (see Figure 2): Enrollees with asthma in HSA-HDHPs without PDLs will have worse adherence to controller medications, greater need for rescue medications, and higher rates of asthma-related ED visits and hospitalizations, with widening of income and racial/ethnic disparities; the addition of a PDL will improve use of controllers and rescue medications, reduce ED and hospitalization rates, and lessen disparities.*

Analyses will compare changes in outcomes from baseline to up to three years of follow-up among 1) asthma patients switched to HSA-HDHPs without PDLs from traditional plans vs. matched patients whose employers remain in traditional plans; and 2) patients switched to HSA-HDHPs with PDLs from traditional plans vs. matched controls remaining in HSA-HDHPs without PDLs. Sensitivity analyses will compare patients switched to HSA-HDHPs with PDLs from traditional plans vs. those who remain in traditional plans to examine the combined impact of both increasing the deductible and gaining a PDL. We will use separate regression models to compare year-to-year changes for each intervention group relative to its matched control group, rather than including all patients in a single model with multiple interaction terms. For secondary analyses of enrollees in the larger set of plan types that include PDLs, we will compare enrollees who are switched from plans with no PDL to plans with a PDL vs. those who remain in plans without a PDL. These analyses will match and adjust for different baseline plan types and deductible levels.

We will begin by performing descriptive analysis using the full dataset of all enrollees with asthma and their family members to examine predictors and trends over time concerning insurance coverage type, asthma care utilization, and costs for asthma care. Then among the targeted study groups, we will compare baseline characteristics between study groups using chi-square, t-tests, and Poisson or quantile regression.[157] We will next display each outcome as a monthly time series of rates or counts, comparing trends over time in the groups of interest. We will use both ITS and DiD frameworks for analyses. Presuming our matching approach will generate similar baseline trends in the intervention and control groups, we will use ITS to display results and DiD to convey effect estimates in a more intuitive manner than ITS estimates. Controlling for potential confounders, we will use generalized linear models (GLMs) to model the independent effect of switching to each of the two types of HSA-HDHPs (with or without PDLs) on the likelihood of each outcome, assessed by interacting insurance type and study period variables in models. Data from the same patients in successive years are correlated, as are data from individuals from the same family. Extended GLMs - generalized estimating equations (GEE) and generalized linear mixed models (GLMM) - are appropriate methods to adjust for this correlation[158, 159] and to examine changes in outcomes between baseline and follow-up.

Asthma controller medications are intended to be taken regularly, so we will examine controller medication adherence using ITS. We will test the statistical significance of level or trend changes following insurance plan type switch using GLM models, adjusting for seasonality and first-order autocorrelation between sequential monthly measurements using the empirical sandwich estimator. Our analytic model will compare the odds ratio of having the primary therapy in the category available each day before and after the coverage switch. Our key independent variables will be: month, period (before or after the benefit switch), and month after the plan switch, adjusting for the same covariates as above. In addition to modeling changes in adherence to controller medications generally, we will address the variation across health plans in the types of controller medications included in PDLs by conducting sub-analyses to examine changes in adherence to the specific controller medications that are included in the PDL and those that are <u>not</u> included in the PDL (Aerospan, Arnuity ellipta, Asmanex HFA, Aerobid, Azmacort). For patients using medications that are not included in the PDL, we will examine the degree to which patients change to medications that are included on the PDL.

For analyses of rescue medication use, we will focus on albuterol and levalbuterol inhaler users. We will limit the time period of interest to 2009-2017, as albuterol inhalers, the primary asthma rescue medication, became available only as higher-priced branded CFC-free medications as of 2009 due to the FDA ban on generic CFC-containing inhalers. The standardized number of rescue inhalers dispensed will be modeled as count data in difference-in-differences models. ITS models will be used to model changes in level and trend of monthly rates of rescue inhalers dispensed, as in our previous study.[40] Because use of controller medications can affect need for rescue medications, we will add controller medication adherence as a co-variate; sub-analyses will stratify by controller medication use in the baseline period. We will also model the ratio of controller medications to total asthma medications. For analyses of asthma-related ED visits and hospitalizations, outcomes can be binary, counts, or continuous. We will use logistic GEE models to estimate the effect of switching to each type of HSA-HDHP on binary outcomes such as any asthma-related hospitalization. We will use negative binomial regression to model the effect for count outcomes such as ED visits. We will select the conditional mean and variance functions based on the actual data, using a log link with a Gamma error distribution.[160, 161] To inform final model specification, we will employ specification tests including the Pregibon Link test for non-linearity[162] and a modified Park test to select the conditional variance function.[161]

In all statistical models, we will include key individual-level predictors from Table 2 to adjust for potential confounding. To determine the impact of HSA-HDHP with and without PDLs on vulnerable populations (RQ-4) and <u>test for heterogeneity of treatment effects among vulnerable populations (HT-1-4)</u>, we will first perform stratified analyses, comparing outcomes between intervention and control subgroups defined by the binary measures of the risk factors of interest (low income, minority race/ethnicity, moderate-severe asthma, presence of other chronic conditions (including co-morbid diagnosis of COPD; we will also conduct analyses limited to ages 4-50 to remove the effect of COPD co-morbid diagnoses), high ACG morbidity). We hypothesize that these vulnerable subgroups will have worse adherence, more frequent adverse clinical outcomes, and higher OOP costs. We will use three-way interaction terms (insurance type * study period * subgroup) to test for statistical differences between subgroups in the impact of the change to an HSA-HDHP with PDL vs. remaining in a traditional plan. Heterogeneity of treatment effect analyses for these key variables will be reported along with overall findings from the combined population. Given that we will be conducting sub-group analyses to test for heterogeneity of treatment effect based on race/ethnicity and income using three-way interaction terms, we elected to separate the analyses of heterogeneity of treatment effect by age group into Aim 3 (described below), rather than add a fourth interaction term to the analyses in Aim 2. In Aim 2 analyses, we will include

both adults and children together, with age included as a co-variate. Given that health plan cost-sharing policies in HSA-HDHPs and PDLs usually apply across enrollees regardless of age, and given that health plans, employers, policy makers, and families must make decisions about HSA-HDHPs and PDLs for both adults and children together, we felt it was important to evaluate the impact at the overall population level.

Aim 3: to examine the extent to which the response to HSA-HDHPs and PDLs is affected by the presence of other family members with asthma or other chronic conditions.

> *Hypothesis: Adults with asthma will disproportionately experience negative effects of HSA-HDHPs on adherence and outcomes relative to children with asthma (HT-2), as will patients who have other family members with asthma or other chronic conditions; differences will be mitigated by the addition of a PDL.*

Aim 3 will focus on intra-familial trade-offs in response to cost-sharing changes in HSA-HDHPs and PDLs, and on adult-child differences in response to HSA-HDHPs and PDLs. Analyses will use the same population, outcomes, study group comparisons, and modeling strategies as Aims 1 and 2 except that we will perform stratified analyses, comparing outcomes between intervention and control groups stratified by adult/child status (RQ-4). To statistically test for heterogeneity of treatment effect for adults vs. children (HT-1-3), we will use three-way interaction terms (insurance type * study period * adult/child) to test for statistical differences between adults and children in the impact of the change to an HSA-HDHP with PDL vs. remaining in an HSA-HDHP without PDL, and the change to an HSA-HDHP without PDL vs. remaining in a traditional plan. Analyses will be done at the individual level, but will include family-level variables listed in Table 2 as predictors of interest. Separately for adults and children, we will test the extent to which having another family member with asthma, another chronic condition, or high baseline family ACG morbidity modifies the impact of HDHPs and PDLs on study outcomes for an individual asthma patient. The primary predictor of interest will be the interaction between the family-level variable, study period, and study group.

We will conduct secondary analyses on the subset of families in the study population that have both an adult and child with asthma insured in the same family plan, and will assess whether adults and children within the same family are differentially impacted by HDHPs and PDLs by comparing outcomes between intervention and control groups in separate strata for adults and children (HT- 1-2, IR-5).

Aim 4: to examine the impact of HSA-HDHPs with and without PDLs on out-of-pocket (OOP) costs for patients with asthma.

> *Hypothesis: Enrollees with asthma in HSA-HDHPs without PDLs will have higher OOP costs and increased financial burden as measured by the percent of income spent on OOP costs; the addition of a PDL will diminish these adverse outcomes.*

Analyses will be similar to those of Aim 2, but for OOP cost outcomes. Our primary analyses of changes in OOP costs will use a DiD analytic framework. We will follow the same approaches as used in analyzing ED visits and hospitalizations, employing two-part models/zero-inflated negative binomial models to account for zero costs. We will use GEE or GLMM models to examine changes in outcomes between baseline and follow-up to model the independent effect of switching to each of the two types of HSA-HDHPs (with or without PDLs) on the likelihood of having financial burden (OOP cost greater than 5% of income).

Hypothesized Effect Size for Intervention on Main Patient-Centered Outcome

Based on prior studies of chronic medications, we hypothesize that we will find a decrease of 5-9% in the PDC for controller medications after switching to HSA-HDHPs without PDLs relative to traditional plans,[74] and an increase in the number of fills of 1-4% for those who switch to HSA-HDHPs with PDLs relative to HSA-HDHPs without PDLs.[100]

Sample Size and Power

Aim 1: We will conduct qualitative interviews with approximately 60 patients or parents or patients.

Aims 2-4: We estimate that there are 1,695 patients with asthma eligible for our study in 2004 in our dataset (12% of HSA-HDHP members), increasing to 2,449 by 2011 (17% of HSA-HDHP members). Projecting current trends, we expect a total of 22,500 HSA-HDHP members with asthma by 2017. Preliminary numbers suggest a third of the cohort will be children under age 18. Based on detailed estimates from our health insurance partners, ~19% of HSA-HDHP members have a PDL. We will have an abundant number of traditional plan members, more than seven times the number in HSA-

HDHPs. Table 3 displays power calculations for pairs of regression models we plan to run for three primary outcomes: controller medication adherence (PDC) (Aims 2-3), and adverse clinical outcomes (rate of asthma-related ED visits or hospitalizations) (Aims 2-3), and OOP costs (Aim 4), both overall and for stratified analyses by adult/child (power calculations for children are displayed, as they are the smaller group). Power calculations, which assume 80% power and 0.05 alpha level, were performed using PASS software.[163]

Table 3: Power calculations

Contrast of Interest		Least detectable absolute difference	
Intervention Group	**Control**	**Overall**	**Children**
Controller medication adherence (PDC)*			
HSA-HDHP with PDL (n=4,222)	HSA-HDHP without PDL (n=16,888)	2.0%	3.5%
HSA-HDHP without PDL (n=18,000)	Traditional plan (n=72,000)	1.0%	1.7%
Asthma related ED visits or hospitalizations**			
HSA-HDHP with PDL (n=4,222)	HSA-HDHP without PDL (n=16,888)	1.2%	2.0%
HSA-HDHP without PDL (n=18,000)	Traditional plan (n=72,000)	0.6%	1.0%
OOP costs***			
HSA-HDHP with PDL (n=4,222)	HSA-HDHP without PDL (n=16,888)	$47	$80
HSA-HDHP without PDL (n=18,000)	Traditional plan (n=72,000)	$23	$40

*Baseline rate estimated at 46% [74] ** Baseline rate estimated at 8.4 per 100 patients with asthma[164] ***Baseline OOP costs estimated at $740 based on data from current studies in the same data set.

Generalizability and Limitations

This study has several limitations. We include in our sample only members offered no choice in health plan selection (exogenous insurance choice). By doing so, we limit generalizability but minimize individual-level selection bias, the major threat to internal validity. Employer selection is still possible, but we minimize this via the two-stage propensity score matching approach. Propensity score matching cannot control for selection on unobserved characteristics, but our planned approach of matching on the baseline trend of outcomes of interest approximates the estimates of randomized controlled trials.[112] Dropout is a problem in longitudinal studies in insured populations. In our analyses, we will track and document drop out from disenrollment and changing plans, and will compare baseline pre-index characteristics of members who have one, two or three years of follow up. Furthermore, we will censor propensity-matched members of our study and comparison groups together if one drops out, and adjust analyses by weighting the members present during a given period of interest based on the baseline distributions of their demographic and health characteristics. If drop out in the third year of follow-up ends up being substantial in the proposed study population, we will limit the follow-up period to 2 years.

There are multiple factors that affect adherence to asthma medications and asthma outcomes in addition to insurance type and cost barriers. We are able to measure many of these factors using claims (e.g. baseline disease severity, age, gender, income, race/ethnicity) but not others (e.g. attitudes, provider factors, competing demands). Claims data also do not allow measurement of important asthma outcomes such as symptom days, missed school/work days, or lung function. The Aim 1 qualitative study will be able to contribute these additional dimensions of non-financial barriers to adherence and asthma outcomes, however. Despite its limitations, claims data permit population-level measurement of important and commonly used downstream indicators of asthma complications such as asthma-related ED visits and hospitalizations which we have experience measuring in our prior asthma studies.[19, 40, 122, 128, 165, 166] The use of geocoding and surname analysis limits our ability to determine member race/ethnicity at the individual level, but provide excellent population-level estimates when used together.[143, 167-172] We will assess the degree of missingness for these fields in our study, but do not anticipate that it will be problematic given that annual missingness of geocoded SES variables in the study team's prior work using this data source has been less than 1% (MD-1).

Sharing of asthma medications within a family may affect the accuracy of measurement of an individual's medication use based on claims data. However, only 16% of children share or borrow asthma medications, usually bronchodilators.[173] Unlike other studies of cost-sharing and medication use in the literature, our study can capture this effect by measuring family-level medication use and OOP costs. Utilization of medications and other health services in HSA-HDHPs may be affected by the amount of funds in a member's HSA, which can be used to pay deductible costs. Data on HSA balances is not available for all members, however.

Because our interest is assessing clinically relevant effects of an economic intervention, the proposed project does not examine the impact of HSA-HDHPs and PDLs on total costs to employers or the health care system. The impact of HDHPs with PDLs on total costs is important to the decision making of employers and payers, and while beyond the scope of this project, our findings will inform future studies to address this topic using datasets with premium and full cost data.

Prior studies on inhaled asthma rescue medications have found that utilization of these medications is relatively inelastic to price changes,[39, 174] raising the possibility of a "no effect" study. In our study that showed no significant impact on inhaler use from an increase in co-payment,[174] we did not include HDHPs, so the cost increase was not large. In the study by Jena et al, which found a modest decrease in inhaler use with increased out-of-pocket costs, the increases in cost-sharing took the form of both co-payments and deductibles. It is possible that the larger cost-sharing changes associated with HSA-HDHPs and PDLs (ranging from $0 in PDLs to $140-$307 for some inhaled steroids and $30-60 for albuterol inhalers[69-71]) could have a larger impact on medication use. Studying the impact of HSA-HDHPs and PDLs with respect to asthma rescue inhalers will still be important even if our study finds no effect on inhaler utilization, as there are likely to be significant changes in out-of-pocket costs for rescue inhaler medications even if use is unchanged.[39, 174] The cost of asthma medications can cause financial burden for families (e.g. having to borrow money or cut back on other necessities),[126] so studying the impact of HSA-HDHPs and PDLs on out-of-pocket costs for asthma rescue inhalers is important even if the utilization analyses produce a "no effect" study.

D. PATIENT POPULATION (see Section C - Study Population above for further details)

For this study of patients with asthma, we expect the patient populations will be similar to that of commercially-insured populations with asthma nationally in which asthma is more prevalent among African-Americans and among women overall (although more prevalent among boys for children) (Table 4).[1, 3]

The **Aim 1** population will consist of adult patients with asthma or parents of children with asthma identified through HPHC and through AAFA. We will reach out to up to 660 HPHC members divided equally among those with HSA-HDHPs with and without PDLs or with traditional plans, and stratified to equally represent adults with asthma, parents of children with asthma, and adults with asthma who also have a child with asthma. Potential participants will include adults aged 18-64; those 65 and over will not be included because they are eligible for Medicare, which may cover the costs of some health care services. These patients will represent a range of geographic locations, both genders, different race/ethnicities and levels of socioeconomic status, and asthma severity. To ensure adequate representation of patients with lower incomes and lower educational attainment, we propose to oversample HPHC members who live in low socioeconomic status zip codes where more than 20% of households are below the poverty level or where more than 25% of adults did not complete high school,[175] such that approximately one quarter to one third of the sample live in low socioeconomic status zip codes. A pre-screening questionnaire will be used to confirm eligibility and to ensure equitable distribution of subgroup membership prior to scheduling interviews. We will conduct interviews with approximately 27 eligible HPHC members (approximately 6 from each subgroup).

Table 4: Estimated Final Racial/Ethnic and Gender Enrollment Table (for interview population for Aim 1 plus claims-based population for Aims 2-4)

Race	Male (N)	Female (N)	Total (N)
American Indian/Alaska Native	--	--	--
Asian	1,745	1,675	3,420
Black/African American	4,537	7,522	12,059
Hawaiian/Pacific Islander	--	--	--
White	40,138	50,032	90,170
Multirace	2,443	3,072	5,515
Ethnicity	**Male (N)**	**Female (N)**	**Total (N)**
Hispanic (Latino/Latina)	5,235	6,457	11,692

Non-Hispanic	43,628	55,844	99,472

We will also recruit commercially-insured patients with asthma and parents of children with asthma through AAFA. Through pre-screening of interested patients who respond to AAFA's recruitment outreach, we will select approximately 27 patients or parents to represent the same subgroups based on insurance plan type and which family member has asthma. Our goal is to include interviews with patients representing a range of incomes and educational levels, as well as those with varying levels of asthma severity, control, and engagement with their illness. In addition to recruiting participants from AAFA's Asthma Online Community, email listserv, Facebook page, and newsletters, AAFA will be able to conduct outreach beyond its currently engaged community members to attract interview participants via intermediaries such as AAFA's Chapters and Educational Support Groups, the school community and school nurses, and faith based and local community organizations with whom AAFA has established partnerships from current and prior projects (e.g. a project with CDC focusing on the safety-net adult asthma population which involved community and faith-based entities and Federally Qualified Health Centers). Through our prescreening questionnaire of interested patients, we will be able to further ensure that patients selected for interviews are representative of the asthma population. If after completing interviews with HPHC members, we find that particular sub-groups are not well represented, we will use information from the pre-screening questionnaire to identify and include patients with these characteristics (RQ-3-4). Pre-screening will allow us to ensure participation of patients with a range of asthma severity in order to explore how differences in severity affect health care decision making and impact of OOP costs. Children will not themselves be research participants, although their experiences will be reflected through the participation of their parents.

We will overcome barriers to enrollment by providing patient participants with a $50 gift card to thank them for their time in completing the 45-minute interview. Working with AAFA will also help us overcome barriers to enrollment, as AAFA has trust and experience with outreach among this patient population. Patients recruited through HPHC and AAFA will be prescreened by online questionnaire or by study staff with experience interviewing patients for qualitative studies.

Through our strategy of recruiting patients through a health plan and AAFA, we expect that patient participants will reflect a range of plan types, geography, asthma severity, and socioeconomic status. The inclusion of the health plan population enables us to guarantee that the study population includes patients who have an HSA-HDHP with a PDL, since patients from the AAFA population may not know if their plan includes a PDL. The standardization of HSA-HDHPs and the similarity of HPHC's PDL to other insurers' PDLs (including the one to be studied in Aims 2-4) will enhance generalizability. In inclusion of the AAFA population will ensure a more diverse population across the country with commercial insurance from other carriers. Most patients are likely to know if they have a high-deductible plan, although they may not be aware if their plan is an HSA-HDHP or if it includes a PDL. Nonetheless, they will still be able to provide relevant data on their experiences in a plan with a high-deductible and cost-sharing for asthma medications.

The patient population for **Aims 2-4** will consist of patients with asthma enrolled in a large U.S. commercial health plan from 2004-2017. We will capitalize on one of the largest and most geographically diverse observational datasets of commercially-insured asthma patients, including adults and children from all 50 states over 14 years. The size and geographic reach of this health plan will allow our study to be representative of a wide range of sociodemographic groups, geographic locations, and delivery systems. Our study will analyze retrospective de-identified data routinely collected by the health plan, and the study team will not contact or recruit patients for these Aims. We will systematically identify eligible patients using claims-based algorithms that have been used in multiple studies to identify patients with asthma.[19, 40, 122] The characteristics and numbers of patients whose claims data will be analyzed are described above in Tables 2 and 3.

Our study will specifically examine potential disparities for low-income and racial/ethnic minority populations in response to high levels of cost sharing in high deductible plans, based on prior evidence that these groups may be adversely affected (RQ-3).[51, 57, 98] We will identify patient subgroups based on income and race/ethnicity using our dataset's credit report information and imputed information on ethnicity based on member surname and neighborhood SES data. We will use claims-based measures employed in other studies to identify patient subgroups based on asthma severity, other chronic conditions, and morbidity who may be likely to be adversely affected by high cost-sharing(RQ-3).[19, 40, 50, 54, 176, 177]

E. RESEARCH TEAM AND ENVIRONMENT

The proposed project will be conducted primarily at the Department of Population Medicine (DPM), which resides within the Harvard Pilgrim Health Care Institute (HPHCI), and is a department of Harvard Medical School.

1. The research team has the capability to accomplish the goals of the proposed research. Our multidisciplinary study team has a strong track record that brings together expertise in health services research, health policy, asthma care, and health economics; experience studying asthma, HDHPs, medication adherence, health care decision making, and financial burden for adults, children, and families; capability conducting patient surveys, qualitative research, and rigorous claims-based analyses; a successful history of collaboration between study team members and with health plans including HPHC and the large national insurer whose claims data will be studied; partnership with Meryl Bloomrosen and AAFA; and the input of a Stakeholder Advisory Board and Patient and Family Research Council (described below in Section F.2).

Alison Galbraith, MD, MPH, Principal Investigator, is a health services researcher and general pediatrician who has conducted formative studies of the impact of new health insurance designs such as HDHPs and VBID-like policies on health care decision making, health care utilization, health outcomes, and financial burden; she has conducted some of the first family-level studies of health insurance and cost-sharing.[45, 46, 50, 54, 68, 76-78] Her research on asthma includes studies of asthma care quality, disparities, and cost barriers using claims-based and survey methods.[40, 126, 128, 166, 178] J.Franklin Wharam, MB, BCh, BAO, MPH, Co-Investigator, is a general internist and leading national expert in the effects of HDHPs on appropriate care for patients with cancer, diabetes, and mental illness, including studies of VBID-like arrangements.[47-49, 51-53, 55-58] He leads five large grants examining HDHPs using the same large national health plan population and rigorous methods as in the proposed project. Dennis Ross-Degnan, ScD, Co-Investigator, is a health services researcher and methodologist who is known for his pioneering longitudinal evaluation methods and his studies of the impact of health insurance benefit design changes on use of medications and other health care services.[153-156, 179-186] Ann Chen Wu, MD, MPH, Co-Investigator, is a general pediatrician and asthma health services researcher who has conducted claims and survey-based studies of asthma medication use, outcomes, and disparities. Through her leadership of multiple studies in the Population-based Effectiveness in Asthma and Lung Disease (PEAL) network of multiple health plans, she has experience developing and using claims-based methods to identify members with asthma, assess asthma severity, and measure adherence.[19, 122, 165] She also writes an award-winning asthma blog (url: http://asth.ma) designed for communicating with patients with asthma and parents of children with asthma. Melissa Gilkey, PhD, Co-Investigator, is a behavioral scientist specializing in health communication who has expertise in qualitative methods, health communication theory, medical decision making, and patient engagement.[187-189] Fang Zhang, PhD, Biostatistician and Co-Investigator, has expertise in designing observational research methods to study the impact of HDHPs and other insurance policies.[49, 51, 52, 56-59, 155, 183] Anna Sinaiko, PhD, Co-Investigator, is a health economist with expertise in health insurance, evaluation of consumer response to health insurance benefit design, and claims-based analyses.[46, 78, 190-196] Meredith Rosenthal, PhD, Co-Investigator, is a health economist with expertise in evaluating the impact of market-based health policy reforms to alter consumer behavior.[45, 54, 68, 88, 192, 194, 195, 197-202] Meryl Bloomrosen, MBA, MBI, Co-Investigator, is Senior VP for Policy, Advocacy and Research at AAFA and has experience engaging patients in the research process.[203] She is a PCORI Ambassador and leads a PCORI Engagement award entitled, "Training Patients with Asthma to Understand and Participate in Patient-Centered Outcomes Research."

2. The project's research environment is well-suited for conducting the proposed study. DPM's unique position within a health plan has fostered the study team's experience engaging health plan members and health plan representatives in research. DPM has assembled an extensive collection of data from a large U.S. commercial health plan through Optum, and has built the infrastructure, analytic capacity, and familiarity with the data to facilitate high quality, efficient research. The HPHC environment enables the research team to identify and recruit interview participants from across the country whose benefits allow them to access services through HPHC's partnership with the large national insurer whose claims data will be used in Aims 2-4. Our partnership with the Harvard School of Public Health brings added expertise in health economics which has been instrumental in prior collaborations. We worked with AAFA to develop this proposal as AAFA is an important advocate for patients with asthma and has experience as a PCORI engagement site developing innovative new methods of training patients to serve as research advisors. AAFA is an optimal site for implementing the project's engagement plan and for recruiting patients and parent participants.

F. ENGAGEMENT PLAN

1. Planning the Study

Input from patients, families, and health plan stakeholders has informed the planning of the proposed project. The design of the project and the issues to be addressed have been informed by the study team's existing relationships with health plan partners, including HPHC and the large national insurer whose population will be used in Aims 2-4. These colleagues have identified questions that enrollees and employers have raised regarding HDHPs, PDLs, and strategies to promote adherence to important medications while reducing costs. Input on the salience of the topic to patients and suggestions about problem areas to examine in the proposal, such as the high costs of albuterol inhalers, were obtained through a solicitation for input about cost-related issues in HDHPs through Dr. Wu's blog (http://asth.ma).[127]

The research team has been fortunate to have the opportunity to partner with AAFA in the planning of the proposed project. AAFA is a national organization that advocates on behalf of patients with asthma through patient education, public awareness, and support for research. AAFA's work as a PCORI engagement awardee on training asthma patients in research has informed the planning of the project's engagement strategy. Both the engagement plan and research strategy reflect the contributions of Meryl Bloomrosen, Senior Vice President of Policy, Advocacy and Research at AAFA, who is a member of the study team and a co-investigator. Ms. Bloomrosen has been part of discussions about the design of the project and has provided input about the proposal to make it relevant to asthma patients and their families. She has suggested useful strategies to strengthen our recruiting strategy for patient participants and advisors using AAFA's multimodal methods of outreach to asthma patients. Her prior experience with recruiting and involving patient and family advisors in AAFA's Patient and Family Advisory Council has led us to use this approach for our Patient and Family Research Council.

The plan for patient engagement was also informed by our recent research with HPHC members about their perceptions related to serving as research advisors. In this focus group study, preliminary findings show that health plan members are interested in serving as research advisors, especially if they have a health condition that makes the topic salient. Members expressed the need to have clearly defined and respected roles, to receive education about the research process and the study, and to have the opportunity to contribute in ways that fit with their interests, skills, and time constraints. In particular, our plan to create a Patient and Family Research Council was based on our finding that some people did not feel that they could make a long-term commitment to a multi-year study but would like opportunities to participate in research with short-term or one-time contributions based on their unique background, skills, and interests, as exemplified by the quotes below:

> "I think people would tend to play to their strengths and also work within whatever parameters they have around time that's available."
>
> "So if I would like to participate but I can't come here on a weeknight, I can edit a manuscript. So okay, over e-mail I can do that in my time when it's convenient for me and that way still participate. So I think it's definitely important to give different levels of participation or engagement for individuals."

2. Conducting the Study

A key foundation of our patient and stakeholder engagement strategy is our partnership with AAFA. Ms. Bloomrosen, who helped develop this proposal, will serve as a co-investigator on the project for all four years. She will attend monthly study team meetings in person or by phone, and will contribute her experiences working with asthma patients and caregivers, asthma clinicians, researchers, and policy makers to address the medical and educational needs of patients with asthma. Her input will allow us to refine the engagement plan post-award to incorporate the learning and experience from AAFA's ongoing PCORI engagement award in which they will develop trainings for asthma patients as research partners. AAFA will conduct and videotape patient trainings in 2017 at several regional AAFA sites around the country. Patients or parents trained in these sessions who have HDHPs will be invited by AAFA to participate in our project as advisors, either on our Stakeholder Advisory Board or on our Patient and Family Research Council (described below). Ms. Bloomrosen and AAFA staff will review the Aim 1 interview guide to ensure that it is understandable and covers relevant aspects of asthma care and patient experiences.

Conduct of this research will be informed at all stages by input from patients with asthma, their parents, and other stakeholders through the project's Stakeholder Advisory Board (*PC-1, 2, 4*). The Board will include: 1) an adult patient with asthma; 2) a parent of a child with asthma; 3) a representative of AHIP, the health insurance industry trade association; 4) a clinician-researcher who studies and treats patients with asthma; 5) a pediatrician who studies health policy and intergenerational family services; and 6) a representative from the NEBGH, an organization serving large

employers. We will use AAFA's existing Asthma Online Community, Educational Support Group, email listserv, Facebook page, and print and email newsletters to recruit the patient and parent members of the Board at the start of the project. All Board members will be given a descriptive summary of the project before the Board meets, and patient/parent members will be offered the opportunity to view AAFA's online research training video. The Board will meet with the study team three times a year to provide guidance on research questions of interest, target populations, recruitment strategies and domains to explore in Aim 1 interviews, outcomes and other measures, interpretation of results, presentations, and writing of manuscripts. The Board will help interpret the qualitative findings from Aim 1 and use them to refine the target outcomes and analyses for the quantitative work in Aim 2-4, and will help interpret the quantitative findings from Aims 2-4. The Board will assist the study team develop and implement dissemination strategies, especially to their respective stakeholder groups.

We will work with AAFA to create a Patient and Family Research Council. The Council will be modeled on the virtual Patient and Family Advisory Councils that AAFA has successfully created for other projects. The Council will be a rotating cohort of up to 50 patients and parents who will be available for requests for specific feedback or tasks during the project. During recruitment of patient/parent advisors at the start of the project, we will offer the opportunity to participate in the Council to those interested in being involved with less of a time commitment. Potential Council members will be asked about their background (e.g. type of insurance plan, asthma severity, state of residence), skills and interests (e.g. Would they be interested in doing cognitive testing of the interview guide? Do they like numbers and would like to review data tables?), and their preferred amount of time and setting for participation (e.g. daytime or evening meetings, conference calls, email only). Upon joining the Council, members will be given a descriptive summary of the project and will be invited to obtain training through AAFA's online video sessions. Based on their reported background and preferences, we will target outreach to Council members as appropriate study activities arise. Tasks would include reviewing and providing input on interview recruitment materials, interview questions, preliminary findings, dissemination materials, claims-based outcomes, and research questions for future research. Members can choose to cycle off the Council, and new patients/parents will be recruited by AAFA.

We are privileged to have the opportunity to work with AAFA, the Stakeholder Advisory Board, and the Patient and Family Advisory Council. We are committed to transparency, honesty, and trust in these collaborations, and strive to foster collaborative, mutually beneficial reciprocal relationships. We recognize that open communication is crucial to bringing out the unique contributions of all partners and fostering a spirit of collaboration and trust necessary to achieve our shared goals of improving asthma care and outcomes and reducing cost burden. Major study decisions will be discussed at Stakeholder Advisory Board meetings, and Board members will be apprised of any key decisions made outside of the Board meetings. The contributions of the Board and Council will be acknowledged in all project manuscripts and reports, and those interested in playing a more substantial role in the conduct of the study and manuscript writing will be offered the opportunity for co-authorship.

We intend for the Stakeholder Advisory Board and Patient and Family Research Council to serve as forums for co-learning for all partners. Study investigators will learn about the perspective of the patient and stakeholder communities represented on the Board and Council, while the Board and Council members will have the opportunity to learn about the research topic and general research processes through participation in AAFA's web-based research training. Additionally, we will convene the Council annually for a webinar in which the research team will provide background information about study topics (e.g. use of asthma medications, barrier to adherence, health insurance design) and methods, and summarize study findings to date, while Council members can share their experiences, feedback, and questions. We also hope that bringing stakeholder representatives together on the Advisory Board will facilitate co-learning and relationship building between Board members who share interests but may not have had the opportunity to work together before.

In establishing a partnership with the Stakeholder Advisory Board and Patient and Family Research Council, the research team will strive to balance the desire to involve them in key aspects of the project with the desire to be respectful of their jobs, families, and other commitments and to adequately compensate them for their efforts. Board members will be given a $500 stipend per year to compensate them for attending the three Board meetings each year, pre-meeting review of materials. The Patient and Family Research Council provides opportunities for patients/parents to be involved in the research process with a flexible, smaller time commitment as determined by their own needs and interests. Patients/parents who join the Council will be eligible for a biannual drawing for a $200 gift card for as long as they remain on the Council, and will be given a $25 gift card for each completed activity.

3. Disseminating the Study Results (PC-4) (See also the section below on Dissemination and Implementation Potential)

AAFA and our patient and stakeholder partners will play a central role in the dissemination of study results, and will help us determine which findings will be of greatest interest to patients with asthma and their families, and which channels will be most effective in reaching patients living with asthma. AAFA will use its wide range of existing outreach channels (Asthma Online Community, Educational Support Group, email listserv, Facebook and Twitter, print and e-newsletters) to provide multi-pronged opportunities to disseminate results to patients in understandable, meaningful ways. Additionally, AAFA's Medical Scientific Council will be involved as a resource for dissemination of findings to the clinical and scientific community. The project's Stakeholder Advisory Board will also be involved in planning dissemination strategies. The Board's inclusion of representative from diverse stakeholder groups will enable us to develop strategies that will effectively reach a wide range of stakeholders and enable findings to be framed to be most relevant to each group's interests. The Patient and Family Research Council will review and provide input on dissemination materials and ensure that findings are communicated in understandable, salient ways.

DISSEMINATION AND IMPLEMENTATION POTENTIAL

A. Describe the potential for disseminating and implementing the results of this research in other settings (PC-4).

We will disseminate the results of the project to a broad range of patients, families, providers, health plans, policy makers, employers, and researchers who share an interest in improving health care for patients with asthma and reducing cost barriers. Our partnership with AAFA, our Stakeholder Advisory Board, and Patient and Family Research Council will help us prioritize findings that are important to them and others like them, and design effective, understandable, multi-pronged dissemination strategies to reach out to their constituencies. See Section F.3 above for details about patient and stakeholder engagement in dissemination efforts.

Summaries of study findings will be disseminated to patients and families through existing AAFA channels such as their Asthma Online Community, Educational Support Group, email listserv, Facebook page, and in notices in AAFA's existing print and e-newsletters. Ms. Bloomrosen and AAFA staff, patient and family members of the Stakeholder Advisory Board, and Patient and Family Research Council will review materials to make sure the information is understandable to lay audiences.

We plan to disseminate study findings through presentations at research meetings and publications in peer-reviewed journals. Preliminary findings will be presented at meetings of groups such as AcademyHealth, the American Thoracic Society, the Pediatric Academic Societies, the Society for General Internal Medicine, and the Health Care Systems Research Network. We will submit manuscripts describing study findings to medical, health services research, and health policy journals such as the Journal of the American Medical Association, Health Services Research, American Journal of Respiratory and Critical Care Medicine, Journal of Allergy and Clinical Immunology in Practice, Annals of the American Thoracic Society, Health Affairs, Pediatrics, and Annals of Internal Medicine. We will develop a newsletter summarizing published results for electronic and print transmission to individuals and organizations suggested by our Stakeholder Advisory Board and Patient and Family Research Council. We will transmit published research findings to a wide range of patients, stakeholders, and the general public through traditional news media and social media, for example, through the Harvard Medical School and HPHC press offices, and through Dr. Wu's award-winning asthma blog (http://asth.ma) and her Twitter account (@Asthma3Ways) which has over 8,000 followers.

Study team members will communicate findings to providers at national meetings of groups such as the American Thoracic Society, Pediatric Academic Societies, and Society of General Internal Medicine. We will communicate findings to clinicians on AAFA's Medical Scientific Council, who can serve as conduits to the provider community and suggest other avenues to reach providers. As practicing physicians, Drs. Galbraith, Wu, Wharam, Hartert, and Rosen will be able to communicate findings to their provider communities.

Findings will be disseminated to health plan, employer, and policy communities to inform decision making about implementation of HSA-HDHPs and PDLs. We will communicate study findings to colleagues at the large national health plan involved in the study, to HPHC, and to AHIP through Board member Kevin Fahey to inform health plan efforts to improve asthma care and refine insurance plan design. We will be able to communicate results to other health plans through the annual meeting of the Health Care Systems Research Network, (formerly known as the HMO Research Network), of which HPHC is a longstanding member, so that other health plans can learn from our study. Through Board member Jeremy Nobel from NEBGH, we will disseminate findings to the community of employers who must make decisions about the insurance benefit designs they offer to their employees. Through his experience as the Director of PolicyLab at Children's Hospital of Philadelphia, Board member David Rubin will be able to advise the research team about various routes for sharing results, such as meetings with policy makers and key staff, testimony, blogs, and conferences.

Study findings have the potential to be implemented widely into existing health insurance designs. This project will provide crucial, patient-centered evidence about health insurance strategies already being delivered in real-life settings and their impact on adherence, clinical outcomes, and cost burden for asthma patients. Given the increasing use of PDLs,[89-91] our results will be applicable to other health plans, employers, and public payers who are interested in adopting effective VBID strategies.[204-206] Because federally standardized benefits policies must be met for HSA-HDHPs to qualify for HSAs, our findings are relevant to the large numbers of health plans and employers who offer HSA-HDHPs, for

whom PDLs could be readily incorporated if shown to be effective. Our project's inclusion of Mr. Fahey and Dr. Nobel on the project Stakeholder Advisory Board will enable us to report our findings to AHIP and NEBGH and assist us in developing strategies to communicate our findings to wider health plan and employer communities nationally.

B. Describe possible barriers to disseminating and implementing the results of this research in other settings.

One goal of the proposed study is to provide relevant data to stakeholders to find strategies to provide more affordable health insurance while also ensuring that asthma patients can obtain needed medications. Up until now, health plans and payers have had to decide whether to invest in strategies like PDLs with limited data on their effectiveness, so our study will allow them to know if this investment is worthwhile. Even if our study shows that HSA-HDHPs with PDLs improve adherence to asthma medications and reduce adverse clinical outcomes, employers and health plans may still choose not to adopt such strategies if total costs in such arrangements is not reduced. Further research, beyond the scope of this PCORI award, may be needed to establish whether the additional costs to payers for medications on PDLs in HSA-HDHPs can be offset by avoidance of costly adverse outcomes.

Dissemination and implementation of our findings to other health insurers may be a challenge for HDHPs that differ from those of the large health insurer studied in this project. However, given the standardization of HSA-HDHPs, with federally-regulated policies about which services are subject to the deductible, and the commonalities in the preventive medications on many large insurance carriers' PDLs,[90, 91] implementation in other health plans' HSA-HDHPs should be feasible.

Barriers to the dissemination and implementation of study findings could arise due to the complexity of health insurance benefits, and of HDHPs in particular. Health plans, employers, and public payers may decide not to adopt HSA-HDHPs with PDLs if they feel that the added complexity of a PDL would make it hard for patients to understand and use appropriately. For PDLs to be effective, patients must be aware that asthma medications are on the list and free of cost-sharing; our research will identify areas where there are information gaps and learning effects over time. Limitations in provider awareness of cost barriers for patients in HDHPs and of what medications and services will cost their patients could also pose barriers to successful implementation of HDHPs and PDLs. The Aim 1 qualitative interviews will explore knowledge barriers related to potential costs in HDHPs and PDLs on the part of both patients and providers, and how patients might discuss costs with their providers to mitigate cost issues for asthma care. These findings, together with input from the Stakeholder Advisory Board and Patient and Family Research Council, will suggest ways to address awareness issues to help successfully implement PDLs.

C. Describe how you will make study results available to study participants after you complete your analyses.

As part of the interview process in Aim 1, we will ask participants if they would like to receive follow-up information about study findings. If so, we will note their preferred contact method (postal address or email), and provide a copy of our publications when they become available and a results summary in plain language appropriate for a lay audience, which will be reviewed by AAFA and members of our Patient and Family Research Council. Because our data on health plan members participating in the quantitative studies (Aims 2-4) will come from fully de-identified existing health plan data, we have no way of contacting these participants directly. However, they may be reached through our other efforts to disseminate study results to the asthma community described above.

REPLICATION AND REPRODUCIBILITY OF RESEARCH AND DATA SHARING

A. Describe the ability to reproduce potentially important findings from this research in other data sets and populations.

Our Aim 1 in-depth interviews could readily be replicated with other patient populations who have high-deductible plans with PDLs or other strategies to prevent cost barriers to use of high-value care. Replicating our qualitative work among patients with insurance through federal and state-based health insurance exchanges would be particularly beneficial and feasible, as commercial health plans are increasingly offering HSA-HDHPs in health insurance exchanges in an effort to contain costs. Our interview instrument could also easily be adapted to conduct similar qualitative research among patients with other chronic conditions. Additionally, findings suggested from our qualitative study could be used to develop more structured surveys to test the reproducibility of our findings on a larger scale among broader populations of patients with asthma and their families in the future, through AAFA or our health plan partners.

Our claims analyses (Aims 2-4) could readily be replicated in datasets of other health plans, although not on the same scale as our proposed analyses, which will be conducted among one of the largest insurers in the U.S. Additionally, analyses using other datasets may not yield the same amount of comprehensive, detailed, and robust information for such large numbers of patients. However, there may be value in replicating our studies in future years, given that insurance designs are constantly evolving, and HDHPs and strategies to help patients cope with cost barriers may change in future years.

The implementation of the ACA and the launch of federal and state-based insurance exchanges has accelerated the growth of HDHPs, with expansion into the individual, non-group insurance market due to the ACA's coverage mandate and the lower premiums afforded by HDHPs. It will be crucially important to conduct studies examining how patients with asthma fare in HDHPs in exchanges and non-group market, especially given that exchange enrollees are more likely to come from vulnerable populations. However, while these potential studies could borrow some of the measures and design features of our proposed claims-based studies, they would not be able to offer our study's ability to mitigate selection effects by studying employers who did not offer enrollees a choice of plans.

B. Describe your data management and sharing plan, including how you will make study data sets available in a manner that is consistent with applicable privacy, confidentiality and other legal requirements, if requested.

Transcripts of Aim 1 individual patient/parent in-depth interviews and the intermediate coded material from interviews cannot be shared with requestors external to our study team. These data will be collected from patient/parent participants with the promise of confidentiality by agreement with participants as part of the informed consent process. This agreement also affirms that the study team will share data only in aggregate form. Our finalized interview instrument will be made available to other researchers upon request, and our qualitative analysis methods will be presented in a transparent manner in published papers and on-line appendices should other researchers wish to adopt them.

Unfortunately, the individual-level analytic dataset for Aims 2-4 of our proposed study cannot be made available to other researchers by our study team. The datasets used are proprietary, obtained from Optum. Other researchers may contact Optum directly and propose to purchase and analyze the same data. Our study methods will be presented in a transparent manner in published papers and on-line appendices, so that others may replicate our analyses. Our study variable dictionaries and SAS statistical programs will be made available to other researchers upon request.

C. Propose a budget to cover costs of your data-sharing plan, if requested.

Our SAS statistical programs, interview instrument, and methods summaries would be made available free of charge.

PROTECTION OF HUMAN SUBJECTS

Describe the protection of human subjects involved in your research.

PROTECTION OF HUMAN SUBJECTS

The proposed study examines insurance design features that can influence quality and cost of asthma care. The study will collect qualitative data from patients with asthma or parents of children with asthma through telephone interviews (Aim 1) and will use retrospective analysis of insurance claims and linked data to detect differences in health care utilization patterns and costs for adults and children with asthma (Aims 2-4). This constitutes human subjects research according to federal guidelines. Prior to obtaining data, we will seek Institutional Review Board approval from the Harvard Pilgrim Health Care (HPHC) Human Studies Committee.

A. Risks to Human Subjects

1. Human Subjects Involvement, Characteristics, and Design

Our aims include understanding health care decision making and experiences of families with asthma with high-deductible health plans (HDHPs) and determining the impact of HDHPs and preventive drug lists (PDLs) on controller and rescue medication adherence, emergency department visits, hospitalizations, and out-of-pocket costs, overall, for vulnerable subgroups, and within families.

Subjects for Aim 1 will include adults aged 18-64 who have asthma or have a child with asthma, and have commercial health insurance plans (high-deductible plans with and without a PDL or traditional plans). Potential subjects will be recruited through Harvard Pilgrim Health Care (HPHC) and through our partnership with AAFA. Potential subjects from HPHC will be identified from enrollment and claims data, and invited to participate through a mailing and/or email. Enrollees will be given the option to opt out of the study by calling a toll-free number, and the study team will contact by phone those who do not opt out to invite them to participate. To recruit subjects through AAFA, the AAFA team will send out a description of the study to potential subjects through its Asthma Online Community, Educational Support Group, email listserv, Facebook page, newsletters, and/or other outreach channels; patients with high-deductible plans and traditional plans will be invited to participate.

Those interested will complete a pre-screening questionnaire, either online or by phone with a member of the research team. The research team will use pre-screening information to confirm eligibility and representation of sociodemographic and clinical sub-groups, and will schedule and conduct the phone interviews. Interviews will take approximately 45 minutes and will include open-ended questions and a few demographic questions. Interviews will be audiotaped with permission of the subject, and transcribed for analysis without identifying information. Children are included in the proposed research insofar as their experiences may be reported by their parent, but children themselves will not be contacted directly in the proposed research.

Aims 2-4 will be retrospective studies using existing health plan data. Subjects will include adults aged 18-64 years and children aged 4-17 years who have employer-sponsored insurance coverage from a large national insurance carrier and have a diagnosis of asthma based on claims data. For analyses of intra-familial effects in Aim 3, we will include data for other family members sharing the subject's insurance plan in order to create family-level variables, such as the number of family members, family-level morbidity, and presence of other family members with asthma or other chronic conditions. The research will be performed at the Department of Population Medicine at the Harvard Pilgrim Health Care Institute/Harvard Medical School and the Harvard School of Public Health; datasets will remain solely at the Department of Population Medicine.

2. Sources of Materials

For Aim 1, we will use existing computerized HPHC enrollment data to identify and select subscribers and their families for the study samples. Analysts from the Research Support Data Center (RSDC) in the Department of Population Medicine at the Harvard Pilgrim Health Care Institute will access HPHC claims data for eligible patients. Data on plan

benefits policies will be provided by HPHC from existing data files, and will be linked by plan to study families. We will collect patient-reported data from eligible subjects through in-depth qualitative interviews with patients with asthma or parents of children with asthma. Interviews will be conducted by phone using an interview guide with open-ended questions designed to take approximately 45 minutes. Interviews will be audiotaped and transcribed.

For Aims 2-4, we will use existing computerized data on insurance enrollment, claims, and linked consumer credit bureau data from a large health insurance plan. These data were collected by the health plan for administrative purposes and not specifically for the proposed research project. The administrative data are anonymized, linked to credit bureau data, archived, and made available for purchase to health services researchers. The health plan will also provide linked data on members' access to a preventive drug list. All data, including credit report data on household income, net worth, and race/ethnicity, will be obtained in de-identified form from Optum. The dataset provided by Optum will not contain names, dates of birth, social security numbers, or exact addresses beyond zip code. The subjects themselves will only be identified by an encrypted study ID. Please see the section below on Protections Against Risk for further details.

3. Potential Risks

The risks to participating subjects are minimal. The greatest potential risks to subjects in our study is loss of confidentiality of their medical data or potential psychological distress to the subscribers from being interviewed. However, all potential identifying information except service dates and zip code have been removed from claims and substituted with encrypted study identifiers. Please see the section below on Protections Against Risk for further details.

B. Adequacy of Protection Against Risks

1. Recruitment and Informed Consent

For the Aim 1 qualitative interviews, study subjects will be identified from existing HPHC computerized enrollment data. We will request a waiver of consent and HIPAA authorization to obtain these initial data to establish the sampling frame. We will approach up to 660 HPHC members by mail and/or email to invite them to participate. This message will include an information sheet that describes the study and includes elements relevant to informed consent (e.g. the voluntary nature of participation, confidentiality, etc.). We will recruit patients through AAFA through postings to Asthma Online Community, Educational Support Group, email listserv, Facebook page, newsletters, flyers, and/or other communication channels; subjects recruited through AAFA who are eligible to participate will receive the information sheet following completion of the pre-screening questionnaire. Copies of the information sheet will be made available to all participants by their choice of email, mail, or as an immediate download from REDCap (if the pre-screening was completed online).

We estimate completing approximately 27 phone interviews with each group (HPHC and AAFA). Participants will be offered a $50 gift card incentive for completion of a phone interview. Interviews will be conducted by the study investigators and will be audiotaped and the tapes transcribed. We will request approval for a waiver of written consent for the interviews, and verbal consent will be obtained.

Because our Aims 2-4 studies involve retrospective analysis of insurance claims data, there will be no recruitment and we will request a waiver of consent for these studies.

2. Protections against Risk

To mitigate the potential risk of psychological distress from being interviewed, the study protocols will specify that respondents be allowed to decline any question or to end the interview at any time. The risk of loss of confidentiality will be minimized by storing computerized data in password-protected files accessible only to research staff. Interviewers will take steps to avoid the inclusion of identifiers in interview audio recordings. For transcription of audio files, we will use only vendors that have established a Business Associate Agreement with Harvard Pilgrim, detailing their compliance with HIPAA data security requirements.

Computerized claims and enrollment data will be available to study investigators only as a limited data set. All data used encrypted study identifiers and no identifying information will be included except dates of services and zip code. The subjects in the Optum dataset will only be identified by an encrypted study ID. Optum maintains a link of encrypted enrollee ID to other identifiers, but the study team will never have access to this. Through Drs. Wharam and Ross-Degnan, the Department of Population Medicine (DPM) has licensed these Optum data and has an existing Data Use

Agreement to use these data (described in the application's letter of support from Michael Sanky from Optum). Dr. Galbraith has completed Optum's required privacy and compliance training for users licensing these data. License requirements stipulate that re-identification of the data is prohibited by law. We will not attempt to link Optum data with other data sources other than through geographic linkages provided by Optum as part of the deidentified data.

To protect the privacy and confidentiality of participant data and to minimize the risk of a breach of confidentiality, we have strong confidentiality and data security measures in place for these electronic records. The Optum datasets will be stored at DPM on password-protected, virus-protected DPM hard drives subject to rigorous Harvard Pilgrim Health Care security. Data will be stored only on a secure network and not on any laptops, portable drives, or other unsecured devices. Data will remain on DPM's local servers/computers at all times, as per our data-use agreement with Optum. Investigators may access these servers/computers remotely within the United States using DPM's approved Citrix software, which is approved under the DUA that governs the dataset.

These data are only available to the study teams whose research projects are approved for their use and may be used only for the purposes of completing the approved analyses. Only investigators Dr. Galbraith, Dr. Wharam, and Dr. Zhang, programmer, data manager, and project manager will have access to the data on their computers at DPM for the proposed research. All investigators and study staff who access the data must have completed required CITI training and privacy and security training. These data will not be accessed by DPM or Harvard Pilgrim employees not directly involved in the work required to complete the project. Each member of the study team will undergo structured HIPAA training in procedures to maintain confidentiality and must sign an oath of confidentiality; breach of confidentiality is grounds for immediate termination. Study investigators outside of the DPM will not be allowed to access these data, and only summarized data will be shared outside the DPM.

3. Potential Benefits of the Proposed Research to Human Subjects and Others

The proposed research will provide no direct benefit to study subjects. The proposed research may benefit other similar populations by providing important information about health plan policies that may lead to improvements in the design of health insurance benefits. The future potential benefits on insurance plan design that might emerge from the findings of this study outweigh the minimal risk of loss of confidentiality.

4. Importance of the Knowledge to be Gained

The analyses in this study have potential benefits for individuals and families with asthma with commercial insurance. Results could help health plans and employers refine insurance benefit design to target the needs of patients with asthma while containing costs. Findings may be especially useful to vulnerable populations who may suffer worse health under insurance with high levels of cost sharing. This project will increase awareness of particular sub-groups who are at risk for adverse outcomes, and for whom strategies such as preventive drug lists may be beneficial. Risks to subjects are small and the benefits from the knowledge to be gained far outweigh these minimal risks.

INCLUSION OF WOMEN AND MINORITIES

This research focuses on adults and children enrolled in commercial health insurance plans. The proposed study will include all women and minorities who qualify for the study based on age, presence of asthma, and having commercial insurance from an employer or (in Aim 1) through the non-group market. The proposed project does not use race/ethnicity or sex/gender as part of its inclusion criteria. We expect the distribution of study subjects by sex/gender and race/ethnicity to be similar to that of commercially-insured populations with asthma nationally, in which asthma is more prevalent among certain racial and ethnic minorities and among women overall (although more prevalent among boys for children). Study aims will specifically examine potential disparities for racial/ethnic minority populations in response to high levels of cost sharing in high deductible plans, based on prior evidence that these groups may be adversely affected. We expect that we will have sufficient sample size to make comparisons based on race/ethnicity and on sex/gender. Thus, we do not propose specific outreach programs for recruiting subjects of a particular race/ethnicity or sex/gender.

INCLUSION OF CHILDREN

Subjects in the Aim 1 interviews will be adults, including parents of children with asthma, but children themselves will not be contacted directly. Children aged 4-17 years with asthma will be included as subjects in the proposed claims-based research in Aim s 2-4. Children under 4 years of age will be excluded because their diagnosis of asthma may not

be well established before that point, and because their asthma medication use may differ from that of older children and adults. We will use existing health plan data on children to measure medication use, health care utilization, and out-of-pocket costs. We will not be approaching or contacting children directly as part of the project. The research team includes two practicing pediatricians with experience working with children and conducting health services research on pediatric populations.

CONSORTIUM CONTRACTUAL ARRANGEMENTS

Describe the proposed research projects that subcontracted organizations will perform. Explain the strengths that these partners bring to the overall project.

Our proposed plan involves two subcontracted organizations, the Harvard T. H. Chan School of Public Health and the Asthma and Allergy Foundation of America.

The Harvard T. H. Chan School of Public Health (HSPH) in Boston, Massachusetts is a premier U.S. educational institution dedicated to advancing the health of populations worldwide. Our subcontract to HSPH will be for the services and effort of our co-investigators on the application, Anna Sinaiko, PhD and Meredith Rosenthal, PhD as well as a research assistant. Dr. Sinaiko is a Research Scientist in the Department of Health Policy and Management at HSPH with extensive expertise in health economics and health policy. She has conducted claims-based and qualitative studies of consumer evaluation of consumer response to health insurance coverage options and benefit design. Dr. Rosenthal is a Professor of Health Economics and Policy and Associate Dean for Diversity in the Department of Health Policy and Management at HSPH. Dr. Rosenthal has broad experience conducting research on the impact of market-based health policy reforms, and has advised both federal and state policymakers in healthcare payment policy and implementation The principal investigator on this study, Dr. Alison Galbraith, has a history of successful collaboration with Drs. Sinaiko and Rosenthal on studies of health insurance innovations such as high-deductible plans and health insurance exchanges plans and their impact on patient decision-making strategies, insurance plan selections, and spending. Drs. Sinaiko will collaborate and provide economic expertise on all aims of the project. Her work will include assisting with research strategy design, conceptualization and definition of variables, providing input on preliminary results, manuscript writing, and interpreting and inseminating results. She will lead a manuscript as part of Aim 4 on the impact of HDHPs and PDLs on out-of-pocket costs for families. Dr. Rosenthal will also provide economic expertise and guidance for all aims of the project, particularly for Aim 4. She will advise on generation of study hypotheses, the design for the empirical analyses, the interpretation and framing of findings in a policy context, and dissemination of findings. She will take a senior author role in manuscript-writing for Aim 4.

The Asthma and Allergy Foundation of America (AAFA) is a not-for-profit voluntary health organization that has been recognized nationally and internationally as the trusted source of information and education about asthma and allergies for patients, their families, and caregivers. AAFA has a national network of health professionals, certified asthma educators, and volunteers (patients, parents and family caregivers) that delivers its national and community-focused programs through five state and regional chapters, with over 45 affiliated educational support groups and 141 community awareness partners, including clinics and pharmacies, and allied health providers and faculty. AAFA's websites house hundreds of pages of evidence-based content and resources for disease prevention, management, treatment, and support; together, these websites host an average of 700,000 unique visitors each month. AAFA has received funding from multiple cooperative agreements from the Centers for Disease Control and Prevention (CDC), including a five-year comprehensive school-based initiative to educate school staff, teens, parents, and community health professionals with asthma using AAFA's Power Breathing Program and a five-year project to create easy-to-read educational lesson materials in English and Spanish for home visitors and childcare providers to educate families and their preschool-age children with asthma. AAFA has also received cooperative agreements from EPA including a six-year project to educate child care providers about asthma management and controlling indoor and outdoor environmental triggers. In addition to AAFA's federal projects, AAFA educates and informs the asthma and allergy community via print and e-newsletters, regular social media posts (Facebook and Twitter), monthly webinars, numerous public awareness campaigns, the product certification program, educational support groups, and through their extensive website content. These capabilities, resources, and relationships are unique strengths that AAFA will bring to the proposed project which will enhance the project's scientific quality, patient and stakeholder engagement, and dissemination.

Meryl Bloomrosen, MBI, MBA, Senior Vice President of Policy, Advocacy, and Research, will be a co-investigator on the project. She has over 30 years of experience in healthcare and currently oversees AAFA's research portfolio, including projects supported by the CDC, Genetic Alliance, and PCORI. As Co-Investigator, Ms. Bloomrosen will attend monthly study team meetings via conference call, and attend meetings with the project's Stakeholder Advisory Board three times

a year via. She will assist with study design, selection of target populations, and outcomes to be measured. In Aim 1 of the study, she will review and provide input on the interview guide for the qualitative interviews with patients and will recruit patient participants for interviews and for the Advisory Board and Patient and Family Research Council. Ms. Bloomrosen will also review findings from the qualitative and quantitative analyses and co-author presentations and manuscripts. Through AAFA's extensive resources and relationships with the patient, provider, research, and policy communities, MS. Bloomrosen and AAFA will be able to implement a robust dissemination strategy for project findings.

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APPENDIX (optional)

APPENDIX: DRAFT INTERVIEW GUIDE FOR AIM 1

As part of the prescreening process, we will ask subjects to have their insurance card on hand during the interview. After describing the study and obtaining verbal consent and permission to audiotape the interview, the interview will be conducted as follows:

Introduction:
In this study, we want to understand how people living with asthma obtain health care and manage their illness. We are especially interested in how health insurance affects their choices. In answering the following questions, please think of your experiences as a [patient with asthma/parent of a child with asthma] in the past year.

INTERVIEW QUESTIONS *(with bulleted questions as prompts)*

1. Tell me about [your/your child's] asthma.
    a. At what age [were you/your child] diagnosed?
    b. What medications [do you/your child] take for asthma?
    c. How often [do you/does your child] take these medications?
    d. How well do these medications work for [you/your child]? Have [you/your child] had to change medications over time, and if so, why?
    e. In the past year, have [you/your child] had to miss [work/school] because of [your/his/her] asthma?

2. I'd like to talk more about [your/your child's] asthma medications. For some people, taking these medications is challenging. What challenges have [you/your child] faced with taking asthma medications?
    a. How often [do you/ does your child] miss doses?
    b. Why [do you/does your child] miss doses?

3. Health care for asthma can be expensive, so the next questions are about cost.
    a. How affordable are [your/your child's] asthma medications?
    b. How much of the cost is covered by your insurance? How much of the cost do you pay for yourself?
    c. What challenges have you faced paying for asthma medications? Paying for other asthma care such as doctor visits or emergency room visits?
    d. How often have [you/your child] had to skip doses of asthma medication because the medication is not affordable? How did this affect [your/your child's] asthma?
    e. How much of a challenge is the cost of asthma medications compared to other challenges that [you/your child] face in taking asthma medications?
    f. Can you describe a situation when you talked with [your/your child's] doctor about the costs of asthma medications?
    g. What strategies do you use to reduce asthma costs? Have [you/your child] used medication sharing as a way to reduce asthma costs?

4. Tell me about how the affordability of asthma medications affects your family's finances as a whole.
    a. What other health-related costs affect your family?
    b. To what extent have you faced trouble paying medical bills?
    c. How have the costs of asthma medications affected your family's use of other medical care?

d. Can you think of a time when the cost of health care made it a challenge to meet the needs of more than one family member? How did you respond?
e. How have the costs of asthma medications required your family to make trade-offs with other non-medical needs?

5. There are many different types of insurance, and it would be helpful for me to know more about the kind of plan you have. Feel free to use your insurance card to help you answer.
   a. Please describe your current health insurance plan.
   b. How did you choose your current plan?
   c. Did you have other plans to choose from?
   d. How much do you have to pay out-of-pocket before your insurance covers most types of care? This is known as the deductible amount.

6. [For respondents with PDL] You have a special type of insurance that covers some important medications for free. Can you describe this benefit?
   a. Tell me about how you have used this benefit.
   - To what extent does this benefit cover [your/your child's] asthma medications?
   - When it comes to managing [your/your child's] asthma, how helpful is this benefit?
   - What other types of medications does this cover? Have you used any of these medications?
   - How does this benefit affect how you and your family use other medications?

SOCIODEMOGRAPHIC QUESTIONS

7. What is your age? _____

8. What is your child's age? _____

9. Including you, how many family members live in your household? _____

10. In what state do you live? _____

11. Are [you/your child] of Hispanic or Latino origin or descent?
    - ☐ Yes, Hispanic or Latino
    - ☐ No, not Hispanic or Latino
    - ☐ Don't know
    - ☐ Refused

12. What is [your/your child's] race? Please select 1 or more of the following races:
    - ☐ White
    - ☐ Black or African American
    - ☐ American Indian or Alaska Native
    - ☐ Asian
    - ☐ Native Hawaiian or other Pacific Islander
    - ☐ Other → _____
    - ☐ Don't Know
    - ☐ Refused

13. This study looks at the costs of health care. While we don't need to know the exact amount, we would like to know roughly your annual household income to be able to interpret your answers accurately. These data are completely confidential and will only be used to come up with averages for the purpose of this study.

    a. Could you tell me whether your total annual household income in 2016 was under $30,000 or over $30,000 before taxes?
        - □ Under $30,000 *(go to 13b)*
        - □ Over $30,000 *(go to 13c)*
        - □ Don't know *(skip to CLOSE)*
        - □ Refused *(skip to CLOSE)*

    b. Was it under $10,000, between $10,000 and $20,000, or over $20,000?
        - □ Under $10,000 *(skip to CLOSE)*
        - □ Between $10,000 and $20,000 *(skip to CLOSE)*
        - □ Over $20,000 *(skip to CLOSE)*
        - □ Don't know *(skip to CLOSE)*
        - □ Refused *(skip to CLOSE)*

    c. Was it under $40,000, between $40,000 and $50,000, between $50,000 and $80,000, or over $80,000?
        - □ Under $40,000
        - □ Between $40,000 and $50,000
        - □ Between $50,000 and $80,000
        - □ Over $80,000
        - □ Don't know
        - □ Refused

Close:

We are nearing the end of the interview. Those are all the questions I have. Do you have any comments or questions? *Pause, record comments below.*

Thank you very much for your time. Your knowledge and insights will be very helpful to this study.