Health Insurance, Access to Prescription Medicines and Health Outcomes in Children: A Review

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SUMMARY

Ensuring optimal access to medications has received increasing attention as health care systems struggle with increasing costs. Although this has been studied extensively in adults, there has been little investigation in pediatric populations, which have different health care needs. A literature review was conducted to examine the evidence regarding the relationship between insurance-mediated access to prescription medicines and outcomes in children. Twelve studies were classified according to i) uninsured versus insured, ii) type of insurance provider and iii), impact of family income. The studies demonstrated that insurance coverage and low cost-sharing are both essential to facilitate access to medications. Increased access was consistently observed for insured compared to uninsured children. Access to prescription drugs frequently differed by type of health provider organization. Adequate family income was an important determinant of access to and receipt of prescriptions. Moreover, income-indexed insurance coverage may increase unmet need. Compared to the literature on access to prescription medicines and health outcomes in adults, there have been few studies in children. Further research relating pharmaceutical policies to pediatric health outcomes is needed to strengthen the quality of policy decision-making regarding access to prescription medicines for children.

Keywords

health insurance; medication benefits; children; drug utilization; access; Health Maintenance Organization

INTRODUCTION

In most jurisdictions, private or public health insurance is necessary to facilitate access to health care services and resources, including prescription medications. The optimal organization of insurance benefits, the appropriate amount of cost-sharing and the criteria for eligibility are elements of ongoing debate among payers and constituents as health care systems reform themselves in response to increasing economic pressures. The debate would be informed by research that explores how policies that govern access to health insurance

benefits affect the use of health care resources. One area of health insurance benefits that has been the focus of much discussion is coverage for prescription medications. While most developed countries include a mix of privately and publicly administered health care systems, the provision of pharmaceutical benefits often demonstrates a high degree of variability across states and provinces within a single country. Pharmaceutical benefits are scrutinized to a greater degree than other types of health care benefits perhaps due to the transparency in drug costs and the relative ease in controlling formularies and drug plan budgets. Although the impact of pharmaceutical policy on health care resource use has been covered extensively for adult populations [1–4], there has been little research done on pediatric populations, which have different health care needs and disease characteristics than adults. Children represent a vulnerable population for whom adequate access to health care resources is essential to promote health and proper development and to prevent onset of disease that may reduce health status and quality of life throughout the child's life. To be truly effective, future health care reforms and changes to policies governing access to medication benefits must consider the health impact on children.

An international review of the literature was conducted to examine the evidence regarding the relationship between insurance-mediated access to prescription medicines (i.e. pharmaceutical benefits) and use of medications in children.

METHODS

A multi-step literature search for relevant articles was conducted on PubMed and Medline search engines. The first step retrieved articles with subject headings and keywords that included “insurance, pharmaceutical services”, “insurance, benefits”, “cost-sharing”, “pharmaceutical policy” and “health plans”. All of the resulting citations were combined. The second step retrieved all citations for “pediatrics” and “child”. The third step retrieved citations that included “medications”, “health services or primary health care”, “health services utilization”, “family health”, “drug utilization” and “prescriptions, drug”. The three sets of publications were then combined using a Boolean “and” so that each resulting paper included a term from each of the three sets. The final list of 174 citations papers was reviewed to remove references related to drug trials, compliance studies, drug utilization reviews and other un-related publications. Papers related to vaccines were not included. The electronic database searches were supplemented by hand searching of the reference lists of readily available studies, by searching for the names of key investigators and by searching the World Wide Web for relevant policy papers. Only articles available in English were included. All searches were conducted back to January 1996. Papers published before this date would have less significance for current pharmaceutical policy discussions. As it was expected that most studies would have an observational design, no exclusions based on study design were applied. The resulting studies were reviewed for relevance and summarized in tables. A content analysis of the included studies was then conducted to organize the papers according to salient themes.

RESULTS

In total, twelve studies and two review articles were found. Three principal themes emerged that described how medication access was analysed, namely by:

- Uninsured versus insured
- Type of insurance provider, plan or cost-sharing mechanism
- Impact of family income

These three themes flow logically and create a framework for understanding the research in the context of the various impacts of pharmaceutical policies on child health, rather than focusing on specific diseases or diagnoses. Some of the papers could be classified into more than one theme. The theme most closely related to the study's objective was used for classification. To a great extent, the papers within these themes represent the special needs and unique medication use patterns of children, such as the emphasis on access to medications for asthma. As these medications can be costly and children often require multiple prescriptions for extended periods, ensuring optimal policies that facilitate access by all income categories is important. For many studies, the main objective was not to analyze the relationship between children's access to drugs and medication use. Information on this relationship was deduced from one of several outcomes measured in the body of the study. Those few studies that primarily analyzed this relationship were two studies by Kozyrskyj et al. [5, 6], one study Adams et al. [7] one study by Hong & Shepherd [8] and one study by Finkelstein et al. [9]. The studies and their findings are described in detail below according to theme.

Uninsured versus Insured

The studies by Lave et al. (1998) and by Newacheck et al. (1998) analyzed access to prescription medicines by insurance status [10, 11]. In both of these studies, summarized in Table 1, access to prescription medication was one outcome that was part of an overall assessment of access to healthcare, and was not the main research question.

Lave et al. (1998) [10] examined the effect of providing insurance to previously uninsured children residing in Pennsylvania on access to care, including the reduction of unmet need and delays in acquiring medications. This study reported that unmet need and delays for prescription medicines decreased from 8% before enrollment to 1% 12 months after enrollment for children who were uninsured for less than 6 months prior to enrollment in the program. For children who were uninsured for more than 6 months prior to enrollment, unmet need and delays for prescriptions decreased from 15% before enrollment to 0.3% 12 months after enrollment. Enrollment in insurance programs increased access to care for all children. The number of children using healthcare services, rather than the intensity of use, increased. This study relied on a before/after design with the data reported by primary caregivers. The long recall interval of 6 months may have introduced some bias in reporting of pre-insurance health care use by new enrollees. Although the researchers included a comparison group, they were merely a second cohort of new enrollees rather than a continuously enrolled group that might control for the effect of secular trends. There may

have been volunteer bias among the respondents and the cohort was predominantly low income, thereby limiting generalizability.

Newacheck et al. (1998) [11] examined the effect of insurance coverage on children's access to primary care, including medications, using 1993–1994 U.S. National Health Interview Survey (NHIS) data. The NHIS is a periodic cross-sectional survey of the civilian, non-institutionalized U.S. population. This study showed that insurance increased access to care for children and the ability to access medicines was significantly greater among those children with insurance coverage. The inability to get medications was 7% among uninsured and 2% among insured. The adjusted odds ratio for inability to get needed medications was 3.4 for uninsured children compared to insured children.

This study examined a wide number of indicators and access to medicines was grouped with access to mental health care and eyeglasses. As access to prescriptions usually represents a need of greater acuity than eyeglasses and would be more common than the need for mental health services, it would have been of interest to study this indicator alone. The cross-sectional nature of the analysis does not permit one to conclude that insurance *caused* an improvement in access, only that an *association* between insurance and the ability to gain access to care existed. The use of NHIS data did allow for control of many potential confounders, including age, sex, race, income, family composition and size, region, perceived health status and disability.

Type of Insurance Provider, Plan or Cost-Sharing Mechanism

Five studies examined the relationship between insurance plan characteristics and utilization of prescription medications among plan enrollees. These are summarized in Table 2.

Kozyrskyj et al. (2001) compared the level of medicine access (receipt of prescriptions) before and after a policy change to Pharmacare, the publicly administered provincial drug benefits program in Manitoba, Canada [5]. The policy change was from a fixed deductible (Cdn \$237 per family) and fixed co-payment system (40% of drug costs above Cdn \$237, per family) to an income-based deductible (2% of income for annual family incomes less than Cdn \$15,000 and 3% for those above Cdn \$15,000). The experimental group included those children that met the case definition of asthma and who were enrolled in the Pharmacare provincial drug benefit program one year before and two years after the policy change, i.e. from 1995 to 1998. The control group involved children meeting the case definition for asthma who were enrolled in drug programs other than Pharmacare. There was no change in the drug cost-sharing policy in the control group. The control group received prescriptions at no charge, through the income assistance and Treaty First Nations prescription programs.

As family income could influence the number of prescriptions for asthma, the children in the experimental group were divided into high and low income groups, based on the average income in their neighborhoods. The control group was by definition, low income. In addition to income, asthma severity may be a predictor of prescription medication use. Thus all children were classified as having mild-moderate or severe asthma based on their overall prescription medication profile and on their history of hospitalization for asthma. The

outcomes measured were the effect of the program change on the likelihood of receiving a prescription for an inhaled corticosteroid (asthma controller), and on the mean number of inhaled corticosteroids doses dispensed. Outcomes were measured one year before and two years after the policy change.

In all the groups (high income Pharmacare, low income Pharmacare, and non-Pharmacare), decreases were observed in the proportions of children who received prescriptions for inhaled corticosteroids over the study period with peaks of prescription use observed in May, September and December. In the second year after the policy change, the likelihood of receiving a prescription for an inhaled corticosteroid decreased significantly (odds ratio 0.68) for all children with mild to moderate asthma in the experimental group. A less pronounced reduction (odds ratio 0.87) was observed in the control group. For children with severe asthma, the likelihood of receiving a prescription for an inhaled corticosteroid decreased significantly (odds ratio 0.82) only for high income children in the experimental group. The results demonstrated that higher income children covered by the new income-indexed deductible program had a significantly decreased likelihood of receiving a prescription (after the policy change) compared to children covered by an unchanged insurance system.

The mean number of inhaled corticosteroid doses that were dispensed decreased from 184 doses per year to 131 doses per year two years after the policy change among mild to moderate asthmatic children in the experimental group. In mild to moderate asthmatics in the control group, the mean number of doses fell from 151 to 134 doses per year. The decrease was statistically significant only for the experimental group. The reduction in doses dispensed in children with severe asthma was not significant for the experimental or control groups.

As the new policy linked the deductible to income levels, the higher income group faced higher out-of-pocket expenditures and appeared to be respond with a greater relative reduction in medication use. It should be noted however that high income children had higher baseline levels of prescriptions for inhaled corticosteroids. Given the higher baseline rate of usage and the higher out-of-pocket expenditures, the higher income group demonstrated a greater elasticity of demand, i.e. sensitivity to price change, compared to low income groups.

It is concerning that after the change in pharmaceutical access policy that introduced income-indexed co-payments, children with severe asthma were less likely to receive prescriptions for inhaled corticosteroids. Among those who received these prescriptions, there was a reduction of more than 15% in the mean number of annual doses per child. The study did not address the issue of appropriate level of care. That is, the observed reduction in doses was not studied for clinical importance. As this was a large population-based study, there was ample statistical power and the findings are unambiguous and highly significant. A limitation of working with large administrative claims databases is the inability to collect additional study information. Despite this, the authors were able to control for the major confounders of income and asthma severity by linkage of medications claims data to census data and to health services use claims files.

The study by Adams et al. (2001) looked at asthma medication usage patterns by age, sex, and health care organization. The 13,352 children in this study were enrolled in one of 4 U.S. managed care organizations (MCO's) that participated in the PAC-PORT II study, which was a multi-center pediatric asthma trial of strategies to improve pediatric asthma health outcomes [7]. The data reported came from 4 types of care delivery systems as follows:

1. Staff model, closed panel
2. Group Model
3. Network-model
4. Staff model component of a mixed model (reference group)

Ninety per cent of subjects had prepaid drug coverage with a \$5–10 co-payment per prescription. Only subjects who were continuously enrolled in the MCO for the 12-month observation period and who had prepaid drug coverage were included. The outcome measure was the frequency of controller therapy dispensing, including inhaled corticosteroids, cromolyn sodium, or nedocromil. Beta-agonist (reliever) dispensing was used as a surrogate for disease severity as the need for beta-agonists is a recognized marker of asthma control [12]. Children were classified according to four severity categories. Children were also classified according to four age groups and by sex.

The study revealed that there might be differences in access to drugs between the four types of MCO's. Compared to MCO 4, children from MCO 1 and from MCO 2 were more likely to receive one or more inhaled corticosteroid prescriptions (Odds ratio 1.2). In contrast children from MCO 3 were less likely to receive an inhaled corticosteroid (Odds ratio 0.8). The pattern was reversed for the probability of receiving 5 or more inhaled corticosteroid prescriptions. MCO 1 children were significantly less likely, and MCO 3 children more likely, to be dispensed five or more controllers in comparison to MCO 4. Underuse of controllers was evident in all of the MCO's.

While this study drew upon a large pediatric population enrolled in diverse health management systems, the authors did not speculate on reasons for observed differences between MCO's. The study did not investigate the differences in access to needed prescriptions, such as level of cost-sharing. Because the study was cross-sectional, only associations between MCO type and medication use could be deduced. The administrative data did not include information on important confounders, including asthma severity, race, smoking and socioeconomic status.

In contrast to the Adams study, the two studies by Finkelstein et al. [9, 13] reported no differences in access among enrollees of different U.S. Health Management Organization (HMO) types. One study by Finkelstein et al. (2002) studied the predictors of asthma medication underuse among low income children insured by Medicaid and enrolled in one of five different HMO's¹ [9]. In a cross-sectional telephone survey of 1,648 parents of children with asthma, controller (inhaled corticosteroid) medication use was determined by asking parents to list controller medications they had at home, and how often their child had used each of them in the past 2 weeks. Parents self-reported demographic characteristics

including sex, race, income, education and processes of care, including visits to primary care physicians and specialists, and receipt of a written asthma action plan. Parents reported on their children's health status by reporting symptom frequency, the Physical Function Score of the American Academy of Pediatrics and the Child Health Status Assessment for Asthma. Patients who were symptomatic more than 5 days per week were classified as having persistent asthma. Patients who were symptomatic less than 5 days per week were categorized as having intermittent asthma. Underuse of controller medications was defined as less than daily use. In the intermittent asthma category, 92% of the children did not use controller medications at all and the remaining 8% underused them. In the persistent asthma category, 49% did not use controller medications at all and 24% underused them. Only 27% used controller medications daily. Multiple logistic regression indicated that underuse was associated with the following factors: Black or Latino race, high school education or less, not having a primary care physician, not having seen a specialist, not having received a written action plan and not having a follow-up visit scheduled. Measures of the child's health status and the type of managed care plan were not associated with underuse.

This study demonstrated that inadequate use of controller medications was present regardless of the type of managed care plan. As the study enrolled only Medicaid children, i.e. low income, it did not examine financial barriers to access, such as socioeconomic status or medication cost-sharing. The authors conceded that a major limitation was the cross-sectional nature of the design and the reliance on parent reports. This design precludes the establishment of a cause and effect relationship between demographic factors and controller underuse or between process of care issues and underuse.

The second study by Finkelstein et al. (2000) was a comparison of Medicaid and commercially-insured children within the same HMO² [13]. The subjects enrolled were children with at least one physician encounter with a diagnosis of asthma during the study period (1991–1996). No co-payments were required of Medicaid recipients for medications, and there were no formulary restrictions. Medicaid and non-Medicaid patients were compared for prescribing and for dispensing of both beta-agonists (reliever) and inhaled corticosteroids and cromolyn sodium (controller) medications. The number of refills authorized on each prescription and the ratio of refills to new prescriptions were compared for Medicaid and non-Medicaid patients.

While both groups had equal rates of beta-agonist prescriptions and dispensing, Medicaid patients were less likely to purchase controller medications (i.e. have them dispensed), despite a similar rate of prescription for controller medications as the non-Medicaid group. When the authors investigated whether refills could explain the difference in dispensing (as some prescriptions were for multiple refills), they observed that the refill rate had no effect on the results. After adjusting for dispensing at multiple pharmacies, the dispensing rate difference between Medicaid and non-Medicaid patients persisted. This was a large,

¹The large, non-profit health care plans that participated in the studies were the Harvard Vanguard Medical Associates in Massachusetts, Kaiser Permanente in Northern California, Group Health Cooperative in Washington State, Partnership Health plan of California, and Neighborhood Health Plan in Massachusetts. The first three are group-model HMO's, and the last two are mixed-model HMO's.

²11 staff-model pediatric departments of Harvard Pilgrim Health Care, now Harvard Vanguard Medical Associates), in New England.

population-based retrospective cohort study. By restricting the analysis to a single HMO, the researchers were able to control for different provider types. The analysis also controlled for the child's age, sex and race. Limitations of working with administrative data were evident. Although race was included as a co-variate, it was missing for 40% of the sample. The researchers could not control for income or asthma severity, both potential confounders. Other factors, including exposure to second-hand smoke and indoor allergens, may also explain the observed differences between the two populations.

On the premise that states may be reluctant to enroll children with special health care needs into managed care plans because the co-payments that exist in such plans may deter access to care, Mitchell and Gaskin (2004) compared unmet need for various categories of care, including prescription medications, between capitated managed care enrollees and fee-for-serve users in the U.S. [14]. A survey of a random sample of parents of children with special needs revealed that while unmet need was low (less than 5%) in both groups, the unmet need for prescription medications for children was almost twice as high in the fee-for-service group compared to the managed care group (3.8% vs. 2.0%, $P<0.07$). More fee-for-service parents reported difficulty getting prescriptions filled (13.3% vs. 9.9%, p not significant). Although access to prescription medications was not significantly different between the groups, the authors commented that the fee-for-service group reported greater process-related barriers to access, including waiting times and regular management by a primary care physician. These effects may explain significant differences observed with respect to the need for other types of health care resources. While this study enrolled a random sample for interview, there was no systematic comparison of demographic and socio-economic characteristics between the groups and the data were based on self-report.

The last retrieved study that examined the impact of insurance plan characteristics was by Hong and Shepherd (1996) [8]. The objectives of this study were to determine the mean level of cost sharing per prescription, and to examine the effects of cost-sharing on prescription drug use among ambulatory children. Ten categories of commonly prescribed medications were included. The authors conducted a study comparing pediatric drug use among ambulatory children enrolled in five different drug benefit plans in the U.S. from 1992 to 1993. The source of the data was third party administrative records of enrollees.

Two of the drug plans were administered by a pharmacy benefit manager and the prescriptions could only be filled at participating pharmacies. All five plans differed in their level of cost-sharing between generics and brand name drugs. All plans were under preferred provider organizations for general insurance. Plans A and B, both in New Mexico, had co-payment schedules of \$2 per generic prescription and \$8 per branded prescription. Plan C, in Mississippi, had co-payments of \$4 per generic and 100% for branded pharmaceuticals. Plans D and E, both in Arkansas, had co-payment schedules of \$3 and \$4 per generic, respectively, and \$10 or 20%, whichever was greater, for branded prescriptions.

The mean prescription price was \$16.38, with 11.7 days of therapy duration. Higher levels of cost-sharing per prescription were associated with higher prevalence of prescription medication use, with higher frequency of prescriptions per child and with higher total annual expenditure rates for medications. Cost-sharing was on average, 37% of total medication

expenditures in all children. While the relationship between cost-sharing level and generic drug use rate was inconsistent, cost-sharing uniformly increased as the difference between brand and generic drug prices increased. The plan with the highest percentage co-payment per prescription had the highest rate of generic drug use.

This study suffered from many of the same limitations discussed above. The use of third party insurer administrative data did not allow for analysis of potential confounding factors. Also, an increase in cost-sharing created an incentive for parents to purchase prescriptions outside of the plan, resulting in under-reporting of the number of prescriptions filled and expenditures.

Impact of Family Income

Socioeconomic status is well known to influence use of health services and health status in children [15–17]. Low-income or socially deprived adults and children have reduced use of primary and preventive health care services and asthma medications and increased emergency services and admissions compared to higher income groups. Low income groups are particularly susceptible to financial barriers in the form of cost-sharing. When charged with co-payments or subjected to other forms of medication cost sharing, low-income adults and children reduce their use of primary and preventive health services and/or prescription drugs to a greater extent than higher income groups facing the same absolute co-payment [1, 18]. The three studies that examined the impact of income as a primary objective are summarized in Table 3.

Kozyrskyj et al. (2001) conducted a study on the relationship between socioeconomic status and likelihood of children to receive prescriptions for inhaled corticosteroids using the population-based administrative claims databases for the province of Manitoba, Canada [6]. A cohort of children who had not received an inhaled corticosteroid prescription 6 months prior to the study was nested within a population of asthmatic children who were regularly receiving asthma prescription drugs. The nested population was evaluated for receipt of new prescriptions for inhaled corticosteroids, including beclomethasone, budesonide, fluticasone, flunisolide and triamcinolone from 1995 to 1998 and for the factors associated with the probability of receiving the prescription.

The subjects were classified as 1) those enrolled in the provincial drug insurance program, Pharmacare, and living in low income neighbourhoods, 2) those enrolled in Pharmacare but living in a higher income neighborhood and 3) those enrolled in the provincial income assistance or Federal Treaty First Nations prescription programs. The latter was by definition low income and received prescription coverage at no charge, whereas Pharmacare beneficiaries paid an income-indexed deductible.

The children were also classified according to asthma severity using prescription and hospitalization history. New inhaled corticosteroid prescriptions were significantly more likely to be received by children with more severe asthma, asthma specialist care, previous healthcare visits or hospitalizations for asthma, and frequent respiratory tract infections. In comparison with higher income Pharmacare children, low income Pharmacare children had a lower likelihood of receiving an inhaled corticosteroid prescription (odds ratio 0.88). The

authors also found that low income children consisting of Native Canadians and welfare recipients had a significantly lower likelihood of receiving a new prescription for an inhaled corticosteroid despite facing no co-payment. This may indicate that these groups' less frequent use of the health care system may result in fewer opportunities for close asthma management and new prescriptions. Despite access to drug insurance, deductible levels in some low income families may require considerable out-of-pocket payment for expensive drugs. Although this study was limited by the use of administrative data, the authors controlled for asthma severity and used a long (three-year) period of follow-up.

Studies by Feinberg et al. (2002) [19], Guendelman & Pearl (2001) [20] and Davidoff (2004) [21] measured unmet need for prescription medications as a function of access to insurance and family income level. In two of the studies [19, 20], unmet need decreased significantly after enrollment in an insurance program. In all three studies, access to pharmaceuticals was one of many outcome measures and was not the main objective of the study.

The 2002 study by Feinberg et al. [19] examined the relationship between family income and the impact of expansion to include higher income children in the Massachusetts Children's Medical Security Plan. Parents of 996 children enrolled in the state-sponsored health insurance program³ were surveyed about the need for services and the unmet need or delay for health services, including prescription medications. The children were grouped by income category: low-income (below 133% of the U.S. federal poverty limit), medium-income (between 134% and 200% of the federal poverty limit) and high-income (above 200% of the federal poverty limit). Income and unmet need were measured before and after enrollment in the program. Prescription drug utilization was one of five indicators that were used to determine unmet need.

The results of this study showed that prescription drugs was the health service needed most frequently, reported by 64%, 73% and 70% of low, medium and high income respondents, respectively. The need for prescription medications was significantly greater for kids who had been uninsured for longer than 6 months before enrollment in the program. During the first 6 months of enrollment, the need for prescription drugs did not change appreciably in any of the three income groups. This reported need increased to 79%, 90% and 94% after one year in the low, medium and high income respondents, respectively. Differences between income groups were statistically significant after 12 months of enrollment ($P<0.05$). Unmet need for prescription drugs was low, 4% overall before enrollment and it decreased to 3% after enrollment. Ninety-eight percent of parents cited cost as a reason for difficulty in obtaining needed health care. Income was not a significant predictor of unmet need or delayed care among children enrolled in the program. The before-after design of this study is an important limitation. Self-report of 'before' behaviour is a poor substitute for a parallel control group of uninsured children, as other factors related to the health care climate may have explained the observed differences, rather than the introduction of insurance. The study may also suffer from volunteer bias.

³Massachusetts Children's Medical Security Plan, with benefits provided on a sliding-fee basis, and limited prescription drug coverage up to \$100 a year.

Guendelman & Pearl (2001) compared access to and utilization of care by children of working poor families, defined as less than 200% of the U.S. federal poverty level, to children of non-working poor and children of moderate to affluent families, defined as 200% or more of the U.S. federal poverty level [20]. The study assessed the influence of the State Children's Health Insurance Program (SCHIP) in making insurance more available to the working poor. Data were obtained from the 1997 U.S. NHIS. The measures of the study were financial access (current coverage and disruptions to insurance coverage), structural access (presence of a regular source of care, delayed or missed care, unmet health needs) and utilization (visits, number of visits, emergency visits, hospital admissions, all stratified by perceived health status).

Compared with children of non-working poor parents and moderate to affluent parents, more working poor children were uninsured (22% versus 12% and 5%, respectively; $P<0.01$) and experienced disruptions in insurance coverage ($P<0.01$). After adjusting for other covariates, disparities in insurance coverage and continuity persisted, as did delays in care and unmet care needs. These delays were far higher for the working poor. One of the access variables measured was unmet need for prescriptions. The working poor children had an unmet need for prescription drugs of 4.2%, which although low, was significantly greater than the moderate to affluent children (0.9%), $P<0.05$. The unmet need for prescriptions of working poor children did not differ significantly from non-working poor children (3.7%). The children of the working poor had a higher likelihood of not obtaining a needed prescription compared to moderate to affluent children (odds ratio 2.1). Compared to working poor children who sought care in public clinics or hospitals, those who sought care in the private sector were less likely to forgo prescription medication ($P<0.02$).

This study concluded that children of working poor have more problems accessing healthcare overall (not exclusively prescription medications) compared to children of non-working poor who benefit from social assistance and other government 'safety nets' or compared to moderate to affluent children, as they tend to lack healthcare insurance or continuity in insurance coverage. These data were cross-sectional and thus a causality relationship between health insurance coverage and access or unmet need cannot be inferred. The data were self-reported with lengthy 12-month recall intervals.

Since the advent of the State Child Health Insurance Program in the U.S., there has been increasing interest in examining the adequacy of insurance coverage for low income children. Davidoff (2004) examined the extent of insurance coverage and unmet need for prescriptions and other health care resources in children with special health care needs, stratified by level of income [21]. While fewer children with special health care needs were uninsured compared to other children, these families faced formidable cost-sharing that reached 7% of income for privately insured families. Among special needs children, 7.4% of low income vs. 2.0% of high income had an unmet need for prescriptions ($P<0.05$). Among non-special needs children, 2.9% of low income vs. 0.8% of high income children had an unmet need for prescriptions ($P<0.05$). This study suffered from many of the same limitations associated with administrative databases and cross-sectional analyses discussed above. While the analysis did control for important demographic and socio-economic

variables, the ability to measure insurance adequacy with NHIS data was limited and the special needs pediatric population was highly heterogeneous.

DISCUSSION

The studies included in this review reinforce the concept that insurance coverage and low levels of cost-sharing are both essential to facilitate access to needed medications in children. Studies that compared insured and uninsured pediatric populations directly showed increased access to healthcare services and medications for insured children [10, 11]. Access to prescription drugs frequently differed by type of health insurance provider and by the type of cost-sharing arrangement. Deductibles, co-payments and co-insurance influence prescription purchasing behaviour in different ways and the interactions between them are complex. These disparate effects, along with the effects of different health insurance provider types need to be investigated further to understand fully how to promote optimal access while maintaining acceptable levels of expenditures for the health plan.

The studies that investigated the effect of family income on access to pharmaceuticals showed that household income is an important determinant in the likelihood of access to and receipt of prescriptions [6, 19–21]. Income-based insurance coverage may increase unmet need, especially for higher-income families, who face the highest user fees, and in the working poor, for whom even low co-payments may constitute a barrier to access.

None of the studies addressed medication compliance. The findings of the studies that used secondary claims databases drew their conclusions based on prescription dispensations rather than consumption. Surveys of parental respondents often focused on their perceptions of unmet need. While some studies examined the appropriateness of care, e.g. the use of inhaled corticosteroids in asthma, they rarely assessed the clinical relevance of the observed levels of medication use or clinical outcomes. Further research is required to elucidate the impact of insurance type, of cost-sharing and of socioeconomic factors directly on child health status.

EXPERT OPINION

Due to the scarcity of the literature on this topic, all relevant studies were included regardless of study quality. Many of the studies reviewed suffered from methodological limitations. Most were conducted using secondary data sources, such as administrative databases that were not primarily designed for research. These databases typically lack information on important co-variables that might influence the outcomes measured. In contrast, those studies that used the NHIS database had a rich source of information on numerous important co-variables related to medical history, health status and sociodemographic characteristics. However, the reliability, validity and completeness of the data in both the claims databases and the NHIS databases must be assured.

All of the studies that utilized NHIS data and some of the secondary database studies and surveys were cross-sectional in design. While this analytic approach is useful for initial identification of associations for hypothesis generation, the relationship between health insurance characteristics and access to medicines in children requires the more rigorous

approach offered by a longitudinal analysis. Only with a repeated measures design offered in a cohort study can causality be ascertained. Some of the studies were designed as before/after surveys to observe the impact of the introduction of health insurance or a change in insurance policies. Unfortunately many of these studies lacked a control group and thus could not distinguish observed effects from those due to other health care system changes that might have been occurring concomitantly. Before/after studies can also be biased if they focus on the *immediately* 'before' period and the *immediately* 'after' period, which may not be truly representative of normal baseline behaviour or post-policy change behaviour. Those surveys that rely on parental recall over intervals of several months are prone to this form of bias.

Most of the studies cited in this review discussed specific sources of bias that affected their results. In his study of access to asthma medicines, Adams [7] discussed the importance of measuring and controlling for asthma severity, which obviously would have an impact on the unmet need, access to and actual utilization of prescription medicines. In her analyses of claims data, Kozyrskyj et al. derived a method to control for severity using history of hospitalization and medication use profiles [5, 6]. Children with changes in asthma severity over time were excluded from the analysis so that any observed changes in prescriptions received over time could be directly attributed to the drug policy change. Other potential confounders cited in the studies reviewed were race, length of observation period (if short, may be skewed towards higher disease severity or acuity) and other barriers which may affect access to medicines, such as lack of childcare, transportation, and the burden of office waits.

Hong and Shepherd stated that drug use data used in their study, which was derived from third-party administrative records, may have suffered from under-reporting, especially if the enrollees purchased drugs outside of the insurance plan [8]. This would occur if the out-of-pocket cost was close to the actual cost of the drug. Adams also mentioned that children may have received medicines from non-pharmacy sources, such as samples and family members, which would impact on the reported results [7].

It is important to consider these methodological limitations and potential sources of bias when reading and interpreting results and when carrying out future research that examines the relationship between health insurance, access to medications and health outcomes in children.

FIVE-YEAR VIEW

Studies of the effects of health insurance on health resource utilization are not new. The 1980s RAND Health Insurance study was the first to demonstrate that the elasticity of demand for medical care is not zero, i.e. patients will reduce consumption when faced with cost-sharing [22]. Subsequent RAND studies in children demonstrated that the presence of cost-sharing in plans for low income children resulted in only a 56% likelihood of receiving highly effective outpatient care compared to 85% of low income children in plans with no cost-sharing [23]. Unfortunately the RAND studies, like many of the studies discussed above, did not focus on the special problem of access to prescription medicines. Compared

to the literature on access to prescription medicines and health outcomes in adults, studies in children are rare. The initial investigations described in this review reinforce the early RAND findings regarding the detrimental effects of the lack of health insurance and the presence of cost-sharing, particularly in low income populations. Despite the negative effects of cost-sharing, it is likely that some form of it will remain in a health care climate increasingly characterized by economic constraints. Given the reality of medication cost-sharing, in effect a user fee, what's needed now are high quality prospective controlled evaluations of specific provider types and cost-sharing arrangements to determine the optimal strategy for delivering care while removing financial barriers to access. Only evaluations of specific types of programs will be informative for policy decision-making. Moreover, there must be greater development of outcome measurement. Overall rates of prescribing under different insurance and cost-sharing scenarios may be of relative interest when comparing sub-groups, but say little regarding whether appropriate care is being delivered. Studies that focus on specific classes of drugs known to be under-prescribed, such as inhaled corticosteroids for asthma, are more informative, but must also be interpreted in the context of what constitutes an adequate level of use. The few studies available on the effect of health insurance on asthma medication use in children are noteworthy. These need to be supplemented by studies that examine rates of use of other commonly used pediatric treatments, such as antibiotics and medications for attention deficit hyperactivity disorder, growth deficiencies and other conditions. Few of the studies in this review examined age effects and the particular challenges associated with access to medications in adolescents. Future research must consider that older children face unique challenges related to access that are compounded by school and peer pressures. Ensuring adequate access to mental health treatments is also critical for older children.

Research examining the relationship between access to health insurance such as pharmaceutical benefits and health outcomes in children must be intensified if progress is to be made in setting good health policy. The SCHIP program came about as policy makers realized that American children were underserved and thus created a means to expand health care coverage to children throughout the U.S. This program has been successful in expanding access to care, including prescription medications [24], and has spurred important child-centred research efforts in this field. Findings from these investigations will help to keep the needs of children visible as a prominent health policy issue.

Acknowledgments

This research was funded by an operating grant from the Canadian Institutes of Health Research (Grant #37919). Ms. Ariely is presently employed at Novartis Pharma AG, however, Novartis was not a study sponsor. Dr. Ungar is supported by a Canadian Institutes of Health Research New Investigator Career award.

This research was funded by an operating grant from the Canadian Institutes of Health Research (Grant #37919). Dr. Ungar is supported by a Canadian Institutes of Health Research New Investigator Career award. We thank Magdalena Krtstevska for her technical assistance.

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KEY ISSUES

- Lack of access to health insurance, particularly pharmaceutical benefits, remains a problem in pediatric populations. All studies that have compared insured to uninsured populations have demonstrated improved health outcomes in the insured children.
- Cost-sharing, mediated through deductibles and co-payments, creates a financial barrier to access to needed medications. Different types of cost-sharing arrangements exert different effects and these must be studied separately to ensure that pharmaceutical policies maximize access to needed treatments.
- Children from low income families are most susceptible to financial barriers. Even in the absence of cost-sharing, low income children display worse health outcomes compared to higher income children with cost-sharing. Thus policies must be designed to facilitate access of low income children to needed prescription medications.
- Research to date has been inadequate. The few studies that have been done suffer from many methodological limitations, including cross-sectional design, non-specific populations, lack of control groups, response bias and poorly developed outcome measures.
- Although several studies have been completed in asthma, additional studies are needed that examine access to treatments for infectious disease, attention deficit hyperactivity disorder, cystic fibrosis, growth deficiencies and mental health conditions.
- Factors influencing access to prescription medicines in adolescents may differ from those observed for younger children and must be investigated.
- Health policy research in pediatrics must become a greater funding priority to ensure that the health needs of children are met.

Table 1

Studies comparing Uninsured to Insured

Author	Year	N	Study Design	Outcomes Measured	Main Findings
Lave	1998	1,031	Before and after telephone survey of children covered under one MCO and who paid a minimal co-payment for prescription drugs.	Unmet medical needs or delayed care in newly enrolled children.	Access to healthcare services improved after enrollment in the insurance program. Unmet/delayed need for prescriptions decreased from 8% before enrollment to 1.1% after enrollment for those who were uninsured for less than 6 months prior to enrollment. Unmet/delayed need for prescriptions decreased from 15% before enrollment to 0.3% after enrollment for those who were uninsured for more than 6 months.
Newacheck	1998	43,091	Cross-sectional retrospective analysis of 1993-94 National Health Interview Survey data comparing insured to uninsured.	Unmet needs for prescription medications and other health care resources.	Inability to get medications, eyeglasses, or mental health care was 7% among uninsured and 2% among insured. Overall unmet need was 2.6%. Adjusted odds ratio for inability to get needed medications, mental health care, or eyeglasses was 3.4 for, uninsured children compared to insured children.

Table 2

Studies of Type of Insurance Provider, Plan or Cost-Sharing Mechanism

Author	Year	N	Study Design	Outcomes Measured	Main findings
Kozyrskyj	2001	10,703	Population-based before/after analysis of change in provincial drug benefit policy from fixed deductible and co-payment system to income-based deductible using administrative claims data	Likelihood of receipt of prescriptions and mean annual doses of inhaled corticosteroids	After policy change, children with severe asthma covered by the policy were less likely to receive prescriptions for inhaled corticosteroids. Among those who received prescriptions, there was a reduction of more than 15% in the mean number of annual doses. There was no change in prescriptions for inhaled corticosteroids in the control group.
Adams	2001	13,352	1-year cross-sectional study using automated database comparing 4 MCO types representing 3 different regions.	Frequency of controller therapy dispensing	There were differences in use of inhaled corticosteroids by children enrolled in different kinds of MCO's.
Finkelstein	2002	1648	Cross-sectional telephone survey of parents of children insured by Medicaid and enrolled in 1 of 5 MCO's.	Rate of underuse of asthma medication	Controllers were not used by 92% of intermittent asthmatics. Only 27% of those with persistent asthma used controllers, and 73% of these were under users. Of the under users, 49% were non users. Self-reported family income was not associated with differential underuse of asthma controller medications.
Finkelstein	2000	12,935	Retrospective cohort study comparing pediatric asthma patients in same HMO under either Medicaid or commercial payer (staff model HMO).	Rates of reliever and controller therapy prescribing and dispensing	Equal dispensing for beta-agonists for both groups. Equally likely to have controller medicines prescribed but Medicaid patients less likely to have them dispensed.
Mitchell	2004	1,088	Cross-sectional random telephone survey of parents of children with special health care needs in managed care vs. fee-for-service.	Rate of unmet need for prescription medicines	2% of parents in managed care reported unmet need for prescription medications for their children compared to 3.8% of parents in a fee-for-service system. Greater impediments to access were reported in the fee-for-service system.
Hong	1996	3144	Comparison of pediatric drug use and relationship to cost sharing among children enrolled in 5 different drug benefit plans from 1992–1993.	Relationship of co-payment to use of drugs (branded and generic).	The higher the out-of-pocket expense, the higher the use of generic drugs, and the lower the prescription expenditure.

Table 3

Studies of Impact of Family Income

Author	Year	N	Study Design	Outcomes Measured	Main Findings
Kozyrskyj	2001	12,481	Population-based cohort study of relationship between socioeconomic status/type of insurance and receipt of preventative pharmacotherapy.	Likelihood ratio of new inhaled corticosteroid prescription, adjusted for asthma severity and asthma specialist use for 3 groups: high-income with cost-sharing, low income with cost-sharing and low income with no cost-sharing.	Compared to higher-income children with cost-sharing, low-income children with cost-sharing and low income children with no cost-sharing were less likely to receive prescriptions for inhaled corticosteroids (odd ratios of 0.88 and 0.82, respectively).
Feinberg	2002	996	Before and after survey of healthcare needs for enrollees of state-funded insurance, stratified by income level (low, medium, high).	Need and unmet/delayed need for health care services, including pharmaceutical prescriptions.	Before insurance, the need for prescription drugs was the most needed service, reported by 70%. Unmet need for prescription drugs was low and decreased from 4% before insurance to 3% after insurance. Significantly more high income respondents reported a need for prescription drugs (94%) compared to low income respondents (79%). Ninety-eight per cent of parents quoted cost as the most important barrier to access to care.
Gunendelman	2001	13,785	Cross-sectional retrospective analysis of 1997 National Health Interview Survey data.	Prevalence and continuity of insurance coverage, delayed or missed care, unmet need for prescriptions.	Children in working poor families have greater unmet needs for prescriptions (4.2%) than children of nonworking poor (3.7%) and moderate to affluent (0.9%) families. Compared to higher income families, children of the working poor had a higher likelihood of an unmet need for a prescription (odd ratio 2.1).
Davidoff	2004	2,879 special needs children +21,909 non-special needs children	Cross-sectional retrospective pooled analysis of 2000 and 2001 National Health Interview Survey data.	Level and adequacy of insurance coverage, unmet need for prescription medications comparing special needs to non-special needs children	Special needs children had higher rates of insurance coverage. Among special needs children, 7.4% of low income vs. 2.0% of high income had an unmet need for prescriptions. Among non-special needs children, 2.9% of low income vs. 0.8% of high income had an unmet need for prescriptions.