What is the impact of the 340B program on drug access, healthcare quality, and finances among low-income and/or uninsured patients?

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Abstract:

The 340B Program is a pharmaceutical subsidization program enacted in 1992 aimed towards allowing safety-net hospitals and clinics to better stretch their limited resources to serve uninsured and/or low-income patients. With its rapid growth, the 340B program has faced scrutiny in regards to its levels of efficacy and integrity. This report aims to analyze academic literature related to instances of 340B enactment across the United States and evaluate the extent to which it has accomplished its original objectives in three main areas: drug access, financial effects, and healthcare quality. We conducted a comprehensive literature review utilizing Google Scholar primarily to explore these three aspects in the context of the 340B Program.

In regards to the results, they suggest that while the program has succeeded in reducing drug costs and improving healthcare outcomes in some instances, there are significant concerns regarding its misuse. Certain hospitals have been found to utilize the program to bolster their own profits rather than to improve the quality of care for vulnerable populations. The program has allowed some hospitals to sustain critical services and enhance patient care, yet evidence also shows that it has led to increased drug spending and reinvestment into hospitals in more affluent areas. Similarly, the impact on healthcare quality is varied, with some studies showing improvements in services provided by 340B hospitals, while others indicate no significant difference in care quality compared to non-340B hospitals. These findings highlight both the benefits and shortcomings of the 340B program, raising important questions about its current level of integrity in implementation and the need for potential reforms to ensure participating entities are truly utilizing the program for its original intentions.

Introduction:

The 340B Drug Pricing Program, established under the Public Health Service Act, is effectively a pharmaceutical subsidization program enacted in 1992 that allows qualifying hospitals and clinics to maximize limited federal resources and reduce the cost of pharmaceuticals to their patients (340B Health). This program essentially requires pharmaceutical manufacturers to provide outpatient prescription drugs to qualifying hospitals that treat low-income and uninsured patients at discounts of 25 percent to 50 percent off the list price (AHA, 2023). There has been a rapid growth in 340B affiliated hospitals and facilities since the enactment of the Affordable Care Act (ACA) in 2010. This growth can partially be attributed to the expansion of organizations eligible for the 340B program under the ACA (The Commonwealth Fund). With rapid growth, however, the 340B program has faced controversy and scrutiny in regards to its levels of efficacy and its financial trade-offs faced by hospitals and pharmaceutical producers.

Background:

In 1992, Section 340B of the Public Health Service Act was enacted by Congress to provide relief from high drug costs to safety-net healthcare providers, who provide needed healthcare services to uninsured, low-income, and other vulnerable patients (340B Health). The 340B program requires pharmaceutical manufacturers to enter pharmaceutical pricing agreements (PPAs). Under these PPAs, manufacturers agree to provide discounts on covered outpatient drugs to “covered entities”, specified healthcare providers that serve some of America’s most vulnerable patients in terms of insurance and income (340B Health). The purpose of 340B overall is to allow these covered entities to stretch their resources as effectively as possible to best serve their vulnerable populations (340B Health).

This research paper’s focus is to evaluate the 340B program’s extent to which it has fulfilled its original objectives of improving drug/healthcare access, healthcare quality, and finances for vulnerable patient populations and safety-net healthcare providers.

Methods:

We searched the literature using Google Scholar and related search terms pertaining to the subtopics, which John Anagnost (JA) and Aneesh Gangireddy (AG) decided to further research. The subtopics were chosen by deciding key areas where 340B’s scope of effectiveness could be analyzed with multiple perspectives using scholarly research. These subtopics included 340B’s impact on healthcare/drug quality, healthcare/drug access, and patient, hospital, and pharmacy finances. Despite our grouping into these subtopics, we realized much of our examined studies’ breadth spanned across more than just one of these subtopics. Our utilized search terms include “340b effectiveness”, “340b hospitals”, “340b drugs”, “340b healthcare quality”, “340b drug access”, “340b cost”, and “340b savings”. We formulated these

search terms by deciding on keywords that would be most effective for finding research in each of our decided subtopics, which were chosen based on our original research area and interest.

As for our inclusion criteria of our research paper, we ensured each source clearly pertained to one of our three subtopics, had concrete data to substantiate either side of the argument, and put results in the context of 340B as a federal program rather than interpreting results in regards to a specific application of 340B (i.e. at just one specific hospital).. As well, we ensured the sources analyzed 340B-participating hospitals, pharmacies, etc. rather than 340B-eligible hospitals, pharmacies, etc. Once the source initially met our inclusion criteria, we read over the source and ensured their methods and analysis were reasonable (i.e. adequate sample sizes, randomization, proper analysis using statistical significance, etc. although this was not a sole factor for us to discard such sources). If the methods and analysis were determined to be unreasonable, we discarded the source from our paper. After these criteria were met, we input these sources into an Excel spreadsheet (Supplement 1), where we summarized the sources results, study type, analytical model, authors, and year and categorized each source depending on their respective subtopics.

Results:

Drug Access

We collected data on three studies (Bazargan-Hejazi et al. 2014, Levinson 2018, and Rana et al. 2021) related to our first hypothesis: “340B has improved drug access among uninsured and low-income patients”. In general, these studies examined the relationship between drug access and patients served in 340B hospitals, though the methods and research design varied.

Bazargan-Hejazi et al. (2014) collected data from two community based Federally Qualified Health Centers. This type of health center employs healthcare providers who serve primarily medically underserved populations. The researchers used a specific subgroup of data of patients who met the criteria for 340B and Patient Assistance Programs (PAPs) - programs set up voluntarily by drug companies to provide free or low cost medications to patients unable to afford them - eligibility for their analysis to attain data specifically on the effectiveness of 340B and PAPs. Through this analysis, this study found that pharmacies associated with safety net hospitals were able to significantly lower medication costs to uninsured patients. It was also found that such profound savings led to greater adherence to prescribed therapy and better overall healthcare outcomes for these patients. Although PAPs were shown to be more effective at inducing drug savings for uninsured patients, 340B was also proved to be significantly effective at inducing pharmaceutical savings, improving drug access to underserved populations, and allowing for better overall healthcare outcomes.

Another study that provided valuable insight on the efficacy of 340B in regards to medication/drug access was “A comparison of medication access services at 340B and non-340B hospitals” by Rana et al (2021). This study specifically aimed to evaluate medication access services, types of services that remove barriers to care and ensure patients receive necessary medication, at 340B and non-340B hospitals. This study collected data via a questionnaire sent out to a randomly selected sample of 500 general acute care hospitals. The researchers found that 340B hospitals offer a higher amount of medication access services on average in comparison to non-340B hospitals. In addition to this, it was also found that a much higher proportion of 340B hospitals provide drug/alcohol and HIV/AIDS outpatient treatment

services than non-340B hospitals. These services help hospitals go beyond what they are federally required to provide under 340B and allow hospitals to provide more support for other critical issues medically underserved communities suffer from. Their ability to do so is expanded by savings from the 340B program, allowing them to allocate funding towards such initiatives.

Levinson (2018) examined factors affecting the efficacy of the 340B program. This study uses federal data pertaining to the 340B program in order to evaluate its effectiveness at improving healthcare access for the medically underserved. They found that access to needed medical/dental care and prescriptions worsened overall as 340B covered entity sites and pharmacies became increasingly prevalent from 2009/2010 to 2015. Moreover, the study suggests that 340B status hospitals are utilizing their status to improve profits rather than reducing healthcare inequality among uninsured and impoverished patients. There are three main routes 340B hospitals take to leverage 340B's financial incentives: acquisitions, contract pharmacies, and over-prescription of outpatient drugs. In regards to acquisitions, it is stated many 340B status hospitals acquire private oncology clinics in order to leverage benefits under the 340B program and make additional profits via discounted chemotherapy and other medication. It is claimed that oftentimes multiple locations of a hospital reap the benefits of 340B due to a single eligible site that treats a high number of eligible patients. With the profits reaped from these discounted outpatient drugs, the study claims hospitals often develop the facilities of other locations in more affluent areas rather than using the profits to develop the facilities of the original location serving more low-income and/or uninsured patients. It is claimed that hospitals also utilize the opening of contract pharmacies in order to profit additionally from drug and treatment discounts, as well as prescribing more drugs and more expensive drugs. This is exemplified by the higher per beneficiary Medicare Part B drug spending at 340B hospitals compared to non-340B hospitals. The study also raises concerns in regards to 340B hospitals' violations of rules such as diverting drugs, transferring 340B drugs to ineligible patients, and double discounting, which refers to utilizing both 340B and Medicaid Drug Rebate Program discounts.

Financial Effects

In regards to the financial effects of 340B, we collected data from four different studies (Schur et al. 2007, Chang et al. 2023, Jones et al. 2019, and Conti 2014). These studies were related to our second hypothesis: "340B allows for more affordable healthcare and medications for hospitals and patients". In general, these studies examined the finances of 340B participating entities in relation to their 340B status and the extent to which 340B has had an impact on the cost of healthcare and medications to patients.

Conti (2014) used a cross-sectional observational study design to investigate geographic placement of 340B hospitals and type of patient served. The main objective of Conti's study was to investigate the use of safety net hospitals' profits from their 340B discounted drugs. The study utilized nationally representative data on 340B participants and socioeconomic characteristics of hospitals in order to track trends regarding the types of patients served by 340B hospitals in various timeframes. The study ultimately found that 340B disproportionate share hospitals (DSHs) served poorer and more uninsured communities than the average US community. It was also found that 340B DSH hospitals registered after 2004 have tended to be in higher-income communities in comparison to hospitals that joined the 340B program earlier. Additionally, the study found that the affiliated clinics of these DSH hospitals served higher income and lower poverty communities in comparison to their parent hospitals. The study suggests these 340B

participating hospitals are utilizing profits from 340B discounts to open new clinics and hospitals in more affluent areas to further gain monetarily. This suggestion directly contrasts with some of 340B's original objectives, including bolstering healthcare facilities and resources for uninsured and/or low-income communities.

Schur et al. (2007) used a cross-sectional observation study design and administered a survey to a sample of 150 pharmacy directors of rural hospitals participating in 340B. The study aimed to ultimately investigate the extent to which 340B can improve the finances and resources of these already underserved and under resourced rural hospitals. The data found from the rural 340B-participating hospitals was then compared to non-participating rural hospitals. The researchers found that higher annual revenue in 340B eligible rural hospitals correlated with a higher proportion of those hospitals participating in 340B. As stated in the study, among 340B eligible rural hospitals with annual revenue over $100 million, 61% participated in 340B. As well, the study found 340B participation allowed rural hospitals to save substantially on outpatient drugs: mean savings reported by respondents were $19,700 per month. These cost savings were used by these safety-net hospitals to offset losses from providing pharmacy and/or other services, improving the range of services and medications provided, and directly reducing medication costs to patients.

Chang et al. (2023) utilized a longitudinal observational study to measure the association between 340B participation and spending on outpatient oncological drugs. OptumLabs Data Warehouse data between 2007 and 2019 was utilized and restricted to include 5 specific outpatient biologic oncology drugs. The study ultimately found that drug spending (of included drugs) in oncology patient treatment episodes increased on average following the start of 340B program participation. Specifically, drug spending in oncology patient treatment episodes of 340B participating hospitals increased $4,074.69 in the first year of 340B participation relative to non-participating hospitals. This spending was also found to increase even further in the first three years of participation.

Jones et al. (2019) utilized a pooled cross-sectional study design and conducted a budgetary impact analysis on a safety-net medical center in Boston, Massachusetts. The goal of the researchers was to investigate the financial impact of 340B participance on a hepatitis C virus (HCV) treatment program from the perspective of the participating hospital. The study included 302 HCV-infected patients referred to the medical center's HCV treatment program from 2015-2016. The hospital received a net revenue of $930 per patient referred to the HCV treatment program with 340B, but the hospital would lose $370 per patient referred in the absence of 340B. The hospital utilized this additional revenue to support case management services for HCV-infected patients and improve the overall quality of their patient care. It was also noted that without 340B, the HCV treatment program might have been unable to support crucial ancillary services to HCV patients such as case management and pharmacy services. Without these ancillary services, it was claimed patient adherence to the program could decline substantially.

Healthcare Quality

Related to 340B's impact on healthcare quality, we collected data from five different studies (Desai et al. 2018, Smith et al. 2023, Owsley et al. 2024, Tripp et al. 2023, and Malouin et al. 2018). These studies were related to our third hypothesis: "340B has improved healthcare and drug access among uninsured and low-income patients". Overall, these studies were focused on the quality and breadth of healthcare and medications provided to low-income and

uninsured 340B patients. These studies mainly intended to evaluate the extent to which 340B has made progress towards expanding the quality and range of healthcare available to low-income and uninsured patients.

Desai et al. (2018) used an observational longitudinal study type and a regression-discontinuity design to analyze the effects of the 340B program on 340B-participating hospitals, which were classified using the eligible disproportionate share hospital percentage threshold (11.75%). The main aspects of healthcare observed included hospital-physician consolidation and the outpatient administration of parenteral drugs, drugs given by routes other than digestion (i.e. injections, etc.). The study's main findings are that 340B eligible hospitals have responded to program incentives by prescribing more parenteral outpatient drugs and employing additional hematology and oncology physicians. There was also no evidence that the additional monetary resources attained by these hospitals by administering discounted drugs was utilized to invest in safety-net hospitals or improve care for vulnerable patients.This directly contradicts one of the main goals of 340B.

Smith et al. (2023) utilized an observational longitudinal study type to analyze the effect of 340B on healthcare quality for low-income patients. The study sourced data from Agency for Health Care Research and Quality's Healthcare Cost and Utilization Project State Inpatient Data, Hospital Cost Reporting Information System Data, Office of Pharmacy Affairs Information System Data, and American Hospital Association Annual Survey. The researchers extracted and analyzed healthcare quality measures, 340B eligibility, and 340B participation from general acute care hospitals in 15 states between 2008 and 2014. The healthcare quality measures used included all-cause mortality, 30 day readmissions, and other condition-specific measures. The study found that 340B participation does not improve general quality of inpatient care for Medicaid and uninsured patients. Almost all of the measures directly support that there was no substantial difference in healthcare quality between all patients and Medicaid and uninsured patients regardless of 340B participation. The two measures of acute myocardial infarction mortality and postoperative sepsis were the exceptions. However, improvements within these measures were mainly concentrated among privately insured and Medicare patients and were not statistically significant for Medicaid and uninsured patients.

Owsley et al. (2024) also used a longitudinal observational study to evaluate the services provided by 340B-participating hospitals compared to non-participating hospitals. The study analyzed data from never participating and newly participating 340B hospitals in the US from 2010 to 2019. The study comprised a total of 2152 hospitals, of which 1074 were newly participating and 1078 were not participating. The researchers found participating hospitals were more likely to be critical access and teaching hospitals, have higher Medicaid shares, be located in Medicaid expansion states, and be located in rural areas. It was found that a significant increase in unprofitable services was associated with 340B participation at public hospitals. Other needed services such as substance use and psychiatric services also observed marginal increases. On the other hand, there was no significant association between 340B and service offerings among nonprofit hospitals. These findings suggest that 340B allows certain public hospitals to sustain and further develop crucial unprofitable services for their vulnerable, safety-net patients.

The study conducted by Tripp et al. (2023) included an observational cross-sectional design to evaluate the extent to which 340B has addressed disparities in drug treatment and adverse outcomes of Medicare patients with moderate to severe chronic asthma. The study utilized Medicare Fee-For-Service claims data from 2017 to 2019 to conduct a cross-sectional

study that analyzed risk-adjusted drug claim, treatment measures, and adverse outcomes data among Medicare beneficiaries treated at both 340B and non-340B hospital systems. The results of the study indicated that there were no statistically significant differences between the quality of drug treatments or adverse health effects at 340B and non-340B hospitals. The study hypothesized the disparities regarding quality of drug treatments and adverse health effects for Medicare beneficiaries with asthma would be lower at these 340B hospitals due to drug discounts. However, this hypothesis was largely contradicted by the results of the study.

Malouin et al. (2018) provides another perspective on the efficacy of 340B in regards to healthcare quality. This study utilized an observational cross-sectional design to observe the impact of the 340B pharmacy program on patients served by hemophilia treatment centers (HTCs) across the United States. The study collected data via a questionnaire distributed to these HTCs. The questionnaire included questions on the demographics of the HTC and the types of services provided by the HTC. Some of these types of services included comprehensive clinic visit services, in-person outpatient follow-up services, etc. The study found that HTCs rely extensively on 340B income to support crucial services such as special healthcare for children, telephone triage, medical care coordination, and salaries for social workers, nurses, and physical therapists. The 340B income helps them maintain services needed by patients with blood disorders such as hemophilia. As well, it was found HTCs are able to establish outreach clinics to provide their services to medically underserved, rural areas. HTCs were also found to be able to support community outreach programs through home and school visits and peer camps. HTCs noted that many of these services would not have adequate funding without supplementary 340B income.

Limitations:

There are several different limitations regarding our study. Firstly, we mainly only utilized Google Scholar to find sources to incorporate in our research. This could have possibly limited the breadth of our research and the extent to which we captured all relevant studies. In regards to our screening process of studies, however,we could have been more systematic and predefined with our approach by setting down specific guidelines before engaging in our research. Rather than doing this, we used more of a quasi-structured method of looking over abstracts of studies and using our general judgment along with a few requirements to make a decision regarding its inclusion.

Beyond just our inclusion criteria, our methods of analysis were largely uniform. We mainly used qualitative analysis by examining the outcomes in each individual study rather than taking a more quantitative approach and using meta-analysis. A more quantitative approach was generally unrealistic due to a lack of overlap of the outcomes of each study. Despite this, we could’ve used quantitative analysis on the studies that did happen to have overlap with one another.

Discussion:

Throughout this paper’s research, the main focus was to evaluate the level to which the 340B program has fulfilled its original intentions of improving care for low-income and/or uninsured patients in vulnerable areas. This focus was split into three main realms: financial effects, drug access, and healthcare quality. In regards to the drug access area of research,

one main takeaway is that the 340B program allows eligible hospitals to lower the cost of outpatient drugs, improve overall healthcare outcomes, and expand services to better cater towards the medically underserved communities they treat. Despite this, it was also found that certain hospitals utilized the 340B program to reap benefits financially by establishing healthcare centers in more affluent areas, overprescribing drugs, etc. This finding was especially crucial as it shed light on the reality of the downsides of a well-intentioned program like 340B and its implementation in the healthcare industry. The lack of uniformity in the studies analyzed in regards to drug access suggests the applications of the 340B program and its ethics are nuanced. Future research could further the understanding of the applications of 340B by studying the types of hospitals utilizing 340B to further their own finances and potential amendments to 340B to prevent unethical exploitation of the program.

From the financial-oriented studies on 340B, it was suggested that many 340B participating hospitals used profits reaped by the program to expand into more affluent communities. This phenomenon is seemingly more prevalent among more corporatized healthcare systems. From the examined studies, it seemed more local and specialized healthcare centers such as rural hospitals and hemophilia treatment centers were more adept at truly utilizing the benefits of 340B to further the treatment of uninsured and/or low-income patients. This trend was also seemingly present in regards to the healthcare quality of 340B hospitals. The more general, corporatized healthcare centers failed to reinvest much of their profits from 340B back into helping vulnerable patients, while more rural and/or specialized healthcare centers used such profits to expand healthcare services and quality. With these findings present, it is largely suggested that the ethics regarding the use of the 340B program vary highly depending on the hospital itself and its management. It is truly in the hands of the hospital to utilize 340B for its intended purposes or for additional profits.

Some pharmacy benefit managers (PBMs) play a substantial role in the exploitation of 340B for profit. Many 340B pharmacies actually have financial ties to these PBMs, driving profit to these PBMs rather than using these profits to benefit low-income patients. Additionally, more than 50 cents of each 1 dollar in profits contract pharmacies receive through the 340B program go to just four PBM and pharmacy companies — Walgreens, Walmart, CVS Health and Express Scripts. The average profit margin earned by covered entities and the pharmacies they contract with on commonly dispensed 340B medicines is an estimated 72% vs. a margin of 22% for non-340B medicines dispensed through independent pharmacies (Longo 2024).

Looking into the current policies regarding the 340B compliance, 340B auditing and recertification seem to be the main methods of monitoring 340B hospitals. The HRSA (Health Resources and Services Administration) can audit both covered entities and drug manufacturers to ensure they're in line with the requirements of 340B. 340B covered entities also must endure an annual recertification process in which an Authorizing Official evaluates the entity's compliance with the requirements of 340B (CompleteRx, 2024). Some of these requirements include double discounting, which occurs when a drug purchased with a 340B discount is also subject to a state Medicaid rebate, and drug diversion, which occurs when a 340B drug is provided to 340B ineligible patient or at a 340B ineligible facility (Pharmacy Times, 2016). Despite such stringent policies regarding 340B's requirements, there is limited monitoring of the 340B income reaped by participating entities. This essentially leaves the allocation of the reinvestment of 340B income entirely up to the discretion of the entity's management. Future policies should look to introduce 340B income monitoring into the current auditing and

recertification processes to ensure 340B income is reinvested into its original purpose, bolstering healthcare for uninsured and/or low-income patients.

Amidst continued litigation regarding 340B, several rulings have uncovered that the states containing 340B covered entities hold the majority of the power regarding 340B compliance rather than the federal government. Several members of the 118th Congress have expressed interest in reforming the 340B statute, however. To summarize their main suggestions, they have a couple key points to refine the 340B statute. Firstly, members of Congress have suggested possibly limiting the number of contract pharmacies a single covered entity is capable of utilizing. As well, more stringent regulations on duplicate discounting and transactions within 340B entities have been suggested. Members of Congress also expressed interest in more hands-on monitoring of 340B entities via ongoing investigations and ensuring only eligible patients receive 340B drugs. Congress is also considering new legislation such as the PROTECT 340B Act, which enacts more strict regulation of the relationships between PBMs/health insurance plans and 340B covered entities, ensuring the main objective of 340B implementation isn't additional profit (Congressional Research Service 2024).

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