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REVIEW ARTICLE

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Navigating the 340B Program: Impacts on Cancer Care and Patient Access

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ABSTRACT

The 340B Drug Pricing Program was launched in the United States to provide medicines and treatments at an affordable price to vulnerable populations such as low-income, uninsured, or patients from rural areas. In the context of cancer treatment, the implementation of the 340B program was expected to expand the horizons to rural areas and allow patients to opt for specialty treatments. However, several studies have shown mixed results about the impact of the 340B program in oncology therapy, like increased accessibility of oncology therapying rural areas or no significant increase in the use of targeted therapies.

This review aims to understand the evolutionary landscape of the 340B Drug Pricing Program over several decades by analyzing the data from studies regarding the benefits of this program in different healthcare entities with a main focus on cancer care.

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Introduction

The 340B Drug Pricing Program, a Federal program in the United States initially introduced in 1992 was created under the Veterans HealthCare Act of 1992. The hospitals eligible under the 340B Pricing Program are eligible to receive discounts on their outpatient drugs [1]. The eligible hospitals can purchase drugs from manufacturers at a discounted rate. These discounted drugs can be provided to outpatients irrespective of their payment ability or insurance coverage status. Therefore, the major beneficiaries include the drug administration and low-income patients. Refer to the schematic presentation of the 340B program (Figure 1) [2,3].

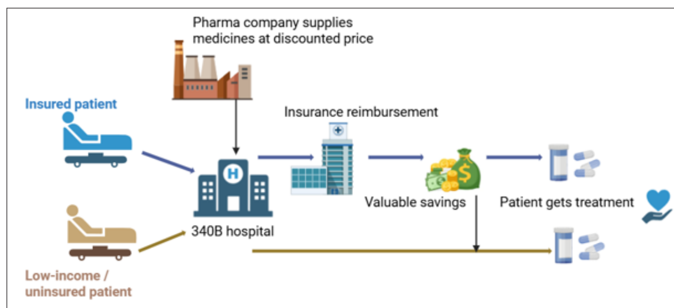

Figure 1: Schematic Representation of How the 340B Drug Pricing Program Works (Created using www.biorender.com)

The 340B Drug Pricing Program was introduced with the hope by the Federal Government to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services [1]." After its implementation, the program has seen an evolutionary change in its strategies and ways of implementation. Although the date of its introduction is as early as 1992, very few hospitals initially benefitted from it. The main reason was the non-eligibility of hospitals to enlist under this program. As years passed it underwent changes and became inclusive to benefit more hospitals, pediatric care hospitals, and cancer centers and also expanded its horizons in the rural areas so that more underprivileged Americans could get better healthcare [2].

While the 340B Drug Pricing Program includes several categories of drugs, the inclusion of high-cost oncology drugs has been highly appreciated in the health sector, especially in rural settings. In certain rural and remote areas access to oncology drugs and cancer care faces several delays resulting in a greater mortality rate at these centres. This program enables not-for-profit and public hospitals to purchase oncology drugs at discounted prices. This facilitates the accessibility to cancer care by low-income rural patients. According to published literature in the year 2019, the out-of-pocket cancer care costs for patients in the US were estimated to be approximately $16.2 billion [4]. Under the 340B Drug Pricing Program more cancer care hospitals can be directed to offer specific safety net opportunities by making the cancer treatment drugs available at low cost and help people shed off the financial burden [5,6].

The 340B Drug Pricing Program is thus a significant program for organizations that are dedicated to offering treatment and services to large-scale populations. This population mostly constitutes vulnerable groups such as low-income, uninsured, and belonging to rural segments which makes accessibility to the treatment difficult. The 340B hospitals can use their program savings well. Although there have been concerns about the proper implementation of the 340B drug Pricing program in hospitals, several discussions are ongoing to avoid any cause of abuse of this program so that millions of Americans can benefit and get access to good medical care.

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Making affordable medicine available to all Americans is the goal of this program [7]. The hospitals enlisted under the 340B Drug Pricing program can make more money through this program that needs to be invested correctly so that more people can be covered under this program and more treatment services can be given at affordable rates. Increased transparency and regulated policies regarding the implementation of this program will help in making it successful [8]. This review attempts to understand the evolutionary landscape of the 340B Drug Pricing Program over several decades. It studies the several benefits of this program in different healthcare entities mainly in cancer care. It also focuses on the accessibility of patients to cancer treatment in an affordable way by using this program.

The Journey of 340B Drug Pricing Program so Far

Being introduced in 1992, the 340B has been benefitting several patients. In the year 2003, the eligibility of hospitals was extended for acute care hospitals and the expansion paved the way for many hospitals to benefit from this Federal program in healthcare. Further in 2010, the program was extended to several other categories of hospitals, and in 2012 around 42% of general acute care hospitals participated in the program. In 2016, approximately 1.9 billion US dollars were saved on drug costs through this program, and a major fraction of it was attributed to cancer treatment services because the cost of chemotherapeutic drugs is substantially higher than the other drugs' costs [2].

Expanding their horizons by including several other beneficiaries in this program, in 2017, around 25% of US pharmacies also enlisted under this program [9]. In the first two decades, the program grew leaps and bounds, with 591 hospitals in the year 2005 to 1673 in 2011; while in 2017, the figure of participating hospitals reached 2437 [8]. In the year 2021, reports suggest an expenditure of nearly $44 billion on the 340B drugs.

According to a recently published analysis by Levengood et al, there is evidence that the Non-Profit and Disproportionate Share Holders are utilizing this program in a margin-motivated way [10]. Hence, going forward it is necessary to assess and scrutinize the heterogenicity of public health hospitals and compare them with the private entities to understand the successful working of this program in the current times.

While the program is dedicated to serving the underserved and underprivileged patient population, its main mechanism of working includes providing uncompensated care by using charity care to non-insured or underinsured patients [11]. Hence participation of more hospitals in the program can ensure an increase in the hospital provision for uncompensated care. However, how the revenue flows and is utilized needs constant appraisal and scrutiny.

The participation of the Pharmacies as contract pharmacies to dispense the 340B drugs to patients has also seen significant growth in the last 15 years [3].

Making the 340B Drug Pricing Program more Accessible

There is no doubt that the 340B Drug Pricing Program has completely revolutionized the picture of healthcare in the US, especially for the uninsured and low-income patient population [12]. People suffering from rare and complex conditions, chronic ailments, and cancer patients require a constant supply of specialty medication. The treatment is high-cost and the out-of-pocket expenditure is extremely high. In such instances, the 340B Drug Pricing Program offers medication at a discounted rate to those who otherwise would not be able to get the necessary treatment.

The inclusivity and expansion of the program has been consistent. The hospital-covered entities include the Disproportionate Share of Hospitals, Pediatric Hospitals, Critical Access Hospitals, Freestanding cancer care hospitals, and Sole community hospitals. Several health clinics under the Federal Grant also come under the 340B Drug Pricing Program. This list is quite long and it includes Health clinics and their look-alikes that are federally qualified, Family planning centers, Black Lung Clinics, and several HIV/AIDS intervention clinics that receive clinical grants and the State AIDS drug purchasing assistance programs. The other subcategories under this program include the Native Hawaiian health centers, Urban Indian organizations, and Ryan White program grantees. Moreover, the clinics receiving funds to treat sexually transmitted diseases and tuberculosis and the Comprehensive Hemophilia Diagnostic Centres have also been under the 340B Drug Pricing Program. The rural referral centers also benefit from it.

Another important aspect is the Contract Pharmacy Ownership under the 340B Drug Pricing Program [8]. An interesting point to note here is that its eligible covered entities distribute drugs to the patients under discounted rates, which ultimately rely on the retail pharmacies to get the drugs at discounted prices. This broadens the horizon for the pharmacies to work as contract pharmacies under this program. A survey that gathered data from the year 2009 to 2022 about the participation of contract pharmacies in the program suggested that there has been a significant growth in the participation of contract pharmacies from 1% in 2009 rising to over 40% in 2022.

Despite the efforts put in by the healthcare systems to make the 340B Drug Pricing Program available to more and more patients with financial, there have been concerns regarding how the revenue is being used and how the accessibility of patients to 340B drugs be increased [12]. With hospitals making revenue from the sale of 340B drugs and treatment options to the poor and eligible patients, there is still a gap according to some recent findings by Faraj K et al, in patients undergoing treatment for prostate cancer. According to this study, the best option suggested for making the program more accessible is to provide drug discounts to those patients who cannot afford the treatment but need it and do not qualify for payment assistance.

An important point to ponder over is the equality in accessing the program is compromised especially when it comes to specialty medicines such as those in Oncology [13]. The impact of the program thus is overshadowed by the disparity that arises mainly due to the type of hospitals that are eligible under this program. It has been observed that large hospitals handle the higher volume of patients and purchase drugs in higher volumes and thus negotiate for better prices thereby providing better care to patients. Unlike these, the smaller clinics or the rural healthcare clinics have a lesser volume of patients and scanty resources that keep them away from the impact of the 340B Drug Pricing Program. To make the program accessible to patients requiring

specialty medicine such as patients needing Cancer treatment and some other diseases and those residing in rural areas, there is a need for equal distribution of resources and medicines so that every needy patient will have access to the drugs irrespective of where they reside.

Oncology and 340B Drug Pricing Program

Cancer happens to be the major cause of mortality in the US with the figures touching around 2,510,597 of new cancer cases in the US in the year 2024 [14]. Furthermore, the mortality rates also have jumped to 640,038 in the US. By the year 2040 this trend is set to increase at an alarming level as suggested in a review by Rahib L et al [15]. The cancer treatment comes with a heavy price to pay both mentally, physically, and economically [16]. As mentioned earlier, in the year 2019, cancer patients paid around $16.2 billion in out-of-pocket cancer care costs and lost around $5 billion in time costs. From the cancer diagnosis to treatment, a substantial amount of money is lost raising the economic burden of the cancer patients.

As healthcare providers and healthcare systems aim to provide effective and quality treatment to oncology patients, they have several healthcare schemes to choose from [5]. The availability of a Program such as the 340B drug pricing program enhances the access of cancer patients to specialty drugs for treatment. The 340B drug pricing program provides incentives to hospitals and physicians to provide cancer treatment at reasonable rates to people who are underprivileged and cannot afford cancer treatment [17]. Figure 2 depicts the benefits of the 340B program extended to oncology treatment [7].

Figure 2: Benefits Expected from 340B drug Pricing Program in the Field of Oncology Treatment. (Created using www.biorender.com)

The Transactions of 340B Drug Pricing Program in Oncology

Let us try to understand how the program works on several levels in the Oncology section to make it most effective for the patients. The very foundation of the program is to use the drugs purchased under the 340B Program exclusively for the patients eligible to receive the treatment under the 340B Drug Pricing Program. The eligible patient must fulfill the requirements of the Health Resources and Services Administration (HRSA), the division of the US Department of Health and Human Services that manages the 340B program. Several business models may operate for the successful expansion of services of the program. The existing hospital working under the program can open its work in a new location or purchase an outpatient department of a hospital in a new location. Physicians getting affiliated with 340B Program hospitals is also an option if all the criteria are met. Additionally, a hospital working under the 340B program may also affiliate with a non-eligible hospital to establish an oncology clinic that qualifies for 340B program discounts.

While all the above attempts are made to make quality treatment available to cancer patients, it is necessary to abide by all the rules and regulations and maintain documentation as there have been concerns raised about the revenue flow in the 340B Drug Pricing Programs and audits are necessary to closely examine the working [17].

The Impact of the 340B Drug Pricing Program on Cancer Care

The impact of the 340B Drug Pricing Program is noteworthy in the Department of Oncology especially because drug therapies play a vital role in the treatment of cancer. The hospitals under 340B provide low-mark prices for cancer patients in comparison to the rest of the hospitals in America [18]. In the year 2010, the Affordable Care Act included the freestanding cancer hospitals and critical access hospitals in the 340B Program irrespective of their DSH status [19]. One such cohort study that closely evaluated the association of the 340B Program on spending in Oncology, concluded that after the inclusion rules changed in 2010, there has been significant spending on oncology drugs by the hospitals under the 340B program. Another study, compared the impact of the program on the cancer care site of drug administration to the cancer care spending in Medicare [20]. The study revealed that with the new 340B hospitals in the market, the probability of a patient receiving cancer drugs in a hospital setting increased by 7.8% versus receiving it in the physician's office. Moreover, the per-patient spending on other cancer care also increased drastically.

Few studies are also directed toward specific types of cancer such as Prostate cancer [21]. The retrospective study was carried out on patients diagnosed with advanced prostate cancer between 2012 and 2019. The patients were prescribed oral targeted drugs for prostate cancer. The sample size included 20% of fee-for-service Medicare beneficiaries. The result of the study showed that even with the 340B penetration, the men with advanced prostate cancer were unlikely to use targeted therapy. In this study, the 340B Program did not bridge the gap that could bring more patients under the targeted therapy. Several drugs have been approved as 340B drugs under pediatric oncology and have been purchased by pediatric oncology hospitals at discounted rates [22,23]. A study on newly approved pediatric oncology drugs showed that the hospitals eligible under the program can gain steep prices for the sale of these drugs from commercial insurers. According to the findings of a study published by Danea Horn in 2024, the physicians treating breast cancer patients under the 340B Drug Pricing Program increase the intensity of per-patient prescribing and also increase the patient share receiving prescription treatments [24]. Moreover, it also points to increased prescriptions of drugs that treat the side effects and other symptoms. However, there is no change in the patient survival rate according to the findings.

Accessibility to Cancer Management Services

The incidence of cancer and mortality due to it is increasing at an exponential speed in the USA [25]. It has been observed that there exist disparities in rural and urban cancer mortalities and one of the responsible factors for this is the limited accessibility to effective cancer treatment in rural areas [26]. Cancer patients in the rural part of the USA do not get timely cancer treatment and often face delays resulting in poor patient compliance to the treatment. Additionally, the high costs of anticancer drugs and radiotherapy are the barriers to accessing cancer treatment in rural populations [4,27].

For the last several years, the 340B Program has been supporting rural service providers to support low-income patients and improve healthcare services in rural areas [9]. A study demonstrated that because of the 340B program in rural hospitals, the type and volume of care saved almost ten thousand US dollars per month in prescription purchases [28]. There was also a several-fold increase in pharmacy savings per month depending upon whether chemotherapy was available on an outpatient basis or not [29]. A recent study conducted in 2023 by Owsley and Bradley analyzed the data from the survey of the American Hospital Association and established a strong correlation between medical expansion, the 340B program, and the capacity of rural hospitals to deliver effective oncology services to patients. The authors used the data from 2011-2020 to establish the relationship between rural hospitals not having oncology services in 2011 and new enrolments till 2020 for adding oncology services [30]. There was a significant 8.3% increase in new additions of oncology treatments proving the successful expansion of the program. These new additions of oncology treatment hospitals were in countries with low rates of uninsurance. Overall this analysis concluded that oncology treatment accessibility has increased in rural areas. Another retrospective time-series analytical study used the data from surveys of the American Hospital Association from 2008 to 2017. The researchers compared prospective payment systems in rural, urban, and critical access hospitals [31]. In 2008, critical access hospitals were less likely to provide chemotherapy as well as radiotherapy compared to other rural and urban hospitals. This study found that there was no significant difference between rural and critical access hospitals regarding the availability of radiation therapy. Concerning prospective payment services, critical care hospitals offered fewer oncology treatment services and also there was a decline in services. However critical access hospitals were more likely to provide chemotherapy services than rural hospitals. The mixed findings in different studies might be due to the lack of transparency in the spending of funds saved through the 340B program by participating hospitals [31].

A study analyzed the change in preference for prostate therapy as an impact of the 340 program [9]. Prostate cancer, a leading cause of cancer-related death in men is often diagnosed in advanced form socio-economically disadvantaged men [22,23]. Although oral drugs are more convenient and safer, they are expensive. A retrospective cohort study used the data of 8 years from 2012 involving 3337 men suffering from advanced prostate cancer. The 340B program did not influence patients to opt for specialty treatment, but those who started treatment showed more adherence to the therapy [32]. Therefore, the authors reported that there is no association between the implementation of the 340B program and the use of targeted therapies.

According to a recent report, pediatric hospitals in the 340B Drug Pricing Program can buy oncology drugs at a discount and charge insurers higher prices, but the extent of these markups is unclear [22]. The prices of oncology drugs vary widely between the pediatric hospitals [24].

Conclusion

In cancer care, the 340B program was aimed to improve access to affordable medications for cancer patients. Although it has successfully provided discounted medications to low-income and patients from rural areas, the overall results about the effectiveness of the pricing program are mixed. Increased transparency and more regulated policies are essential for the overall success of the 340B program. S can be effectively addressed by ensuring that the savings generated are effectively reinvested into patient care and improving access to more advanced and targeted therapies. Implementing better reporting mechanisms, enhancing accountability, and fostering collaboration between healthcare providers, policymakers, and the pharmaceutical industry can help in achieving the program's goals more effectively. With such improvements, the 340B program can better serve its mission of providing affordable medications and improving healthcare outcomes for vulnerable populations. Additional research needs to be conducted to identify gaps in the program and develop strategies to optimize its implementation.

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