

Qualitative study on the price of drugs for multiple sclerosis

Gaming the system

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Abstract

Objective

To describe pricing decisions, justifications, and attitudes among current and former biotech industry executives for companies that manufacture multiple sclerosis disease-modifying therapies.

Methods

Four leaders in biotech who have been directly involved in multiple sclerosis disease-modifying therapy pricing or marketing volunteered to participate in 30-minute semistructured interviews conducted via telephone. An expert in qualitative methods moderated and analyzed the interviews alongside the principal investigator. Brief, preinterview online surveys were also administered to provide additional context and insight for discussion. Interviews were audio-recorded and professionally transcribed.

Results

Participants consistently stated that initial price decisions were dictated by the price of existing competitors in the market. Revenue maximization and corporate growth were drivers of price escalations in the absence of continued market penetration. Lower revenue predictions outside the United States also informed pricing strategies. The growing complexity and clout of drug distribution and supply channels were also cited as contributing factors. Although decisions to raise prices were motivated by the need to attract investment for future innovation, recouping drug-specific research and development costs as a justification was not strongly endorsed as having a significant influence on pricing decisions.

Conclusions

Contrary to prevailing narratives that underscore drug development costs, findings from our interviews suggest that the existing price ecosystem, overall corporate growth, international pricing disparities, and supply chain-related distortions may play a more central role in drug pricing decision.

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Glossary

DMT = disease-modifying therapy; MS = multiple sclerosis; PBM = pharmacy benefit manager; PPT = participant.

The high cost of prescription drugs is a major public policy concern. The escalation in drug pricing has been particularly rapid for medications to treat multiple sclerosis (MS).¹ List prices for MS disease-modifying therapies (DMTs) more than doubled between 2010 and 2017, and the average annual wholesale acquisition cost for most DMTs now exceeds \$80,000 a year.²

Escalating drug prices negatively affect patient care in a multitude of ways such as higher cost-sharing amounts, reduced coverage or increased utilization management, and higher insurance costs (e.g., premiums).³ For Medicare beneficiaries with MS who commonly face 25% to 30% coinsurance amounts in their Part D plans, out-of-pocket costs for their DMTs can exceed \$6,000 for the year.⁴ In addition, patients often face other barriers to access such as a prior authorization requirement or step therapy approval.^{5–7}

The fundamental factors driving the high cost of prescriptions are complex, lack transparency, and are widely debated. Manufacturers argue that high and rising prices are necessary to incentivize high risk and expensive drug development.⁸ Pharmaceutical companies necessitate financial returns on their substantial research and development outlays; however, there is disagreement about the magnitude of resources required to develop and commercialize a drug.^{9,10} Despite the debate around the cause of high drug prices, the consequence is clear. Patients consistently report that prescription drug prices should be a top public policy concern.¹¹

The objective of this study was to describe reasoning, rationale, and attitudes about drug pricing strategies for MS DMTs among executives at biotech firms that manufacture MS-related therapies.

Methods

To solicit information on MS DMT pricing determinants and marketing factors, we conducted structured interviews using a 2-pronged qualitative approach: online survey and semi-structured interviews. Participants were recruited purposively through targeted invitations sent via e-mail from the project investigators (D.B., D.H.). Recruitment criteria mandated that participants have substantial career experience serving in leadership positions within the biotech industry and direct experience working with MS DMTs, preferably in pricing or marketing. Four individuals met the inclusion criteria and agreed to participate in the study with the expectations that they would remain anonymous.

Brief, preinterview surveys (doi:10.5061/dryad.vn5js14) were created and distributed to participants to gather initial feedback on the extent to which they felt specific factors influenced the determination of initial prices for MS DMTs or other pharmaceuticals or biologics, as well as the timing and magnitude of changes in prices for MS DMTs or other pharmaceuticals or biologics. The list of factors in the survey included the following: product features (e.g., ingredient costs, manufacturing costs, anticipated market exclusivity duration), firm features (e.g., other products in the market within/outside therapeutic area), market features (e.g., commercial vs public sales, anticipated competition), and other factors (e.g., input from stakeholders, political considerations). Participants' survey data were used both to develop tailored prompts within the structured interview guide for the moderator to use during their interviews and to supplement the interpretation of interview feedback during qualitative analysis.

Confidential semistructured interviews were conducted individually, via telephone, by an expert trained in qualitative methods (L.A.) and the principal investigator (D.H.). The principal investigator is a pharmacist and experienced researcher in drug pricing; the moderator (L.A.) had no background in pharmacy or drug pricing and was able to recognize and address any biases that arose in the discussion. Participants had no knowledge about responses from the other participants. All interviews were audio-recorded. The interview guide consisted of 9 questions designed to solicit feedback on the participants' experiences with MS DMT pricing in general, determinants of initial pricing decisions, distinctions between MS DMTs and other products, strategies used to manage public perceptions, and factors informing the timing and magnitude of price changes. Interviews were ≈30 minutes in length (range 22–46 minutes) and were professionally transcribed and deidentified.

Qualitative analysis of interview data was performed with NVivo 11 (QSR International, Cambridge, MA) using a deductive approach, due to the small sample size and participants' varying experience and occupational status. Participants' responses were grouped first by question-specific codes to compare feedback on each item across the sample (e.g., initial price factors, timing and magnitude of price changes, etc.). Then, after listening to interview recordings together, we established additional codes through an iterative process to capture unanticipated themes that emerged across items and participants (e.g., affect, corporate growth, justification of pricing, United States vs international). Outputs were analyzed by the principal investigator and qualitative research expert. Because of the small sample size and varied backgrounds of the participants, saturation in any 1 theme was not achieved. Thus,

results are reported using a descriptive approach, acknowledging diverging and similar perspectives across themes.

Standard protocol approvals, registrations, and patient consents

The Oregon Health & Science University Institutional Review Board reviewed and approved the study protocol and all related interview and participant consent materials. This was a low-risk study, and verbal consent was obtained from all study participants.

Data availability

The source data for this qualitative study are interview transcripts, which cannot be publicly released due to concerns about maintaining participant confidentiality.

Results

Participant description

The 4 participants had extensive and varied experience within the biotech and pharmaceutical industry. They reported roles in multiple companies over their careers, with collective experience pertaining to companies with products in the MS therapeutic area at 4 major multinational pharmaceutical firms. All 4 participants were based in the United States, but their positions within these firms varied. Participant (PPT) 1 was a clinician who had also worked in MS clinical research divisions for >30 years combined. PPT2 held leadership positions in various segments of marketing and brand development for a firm with an MS therapy for 19 years. PPT3 had >40 years of combined experience in the pharmaceutical and biotech industries, including acting as chief operating officer for several firms, and was currently retired. PPT4 held leadership roles for ≈35 years with a variety of companies, including 5 years as chief commercial officer with a firm with an MS therapy. In total, these individuals provided a diversity of perspectives about pricing strategies with nearly 30 years of combined experience within biotech companies producing MS drugs. None of the participants were currently working for a company manufacturing an MS therapy.

Preinterview survey

The survey tool and results are summarized in the e-supplement available from Dryad (doi:10.5061/dryad.vn5js14). Items reported having the highest weight in either initial price determination or subsequent price increases included other products on the market, perceived value, clinical attributes, existing competition, pricing structure of competition, and trends in pricing. Items ranking lowest included international pricing, political considerations, input from stakeholders in the supply chain, and research and development pipeline within the therapeutic area.

Initial pricing strategy

Although not all subjects were actively part of ultimate price setting decision, all participants expressed a general understanding of how prices were determined. Participants agreed that initial pricing decisions were driven largely by

prices of competitors in that therapeutic area, and in some cases, the initial prices of the products were intentionally matched to those of similar products offered by competitors.

PPT3

Well it was pretty simple, actually, because the other guys had been out there at that point for, I don't know, a couple of years... and we priced it on a per annual patient year basis the same as the product that was already on the market.

PPT1

We're not going to be able to exceed that new guy; we'd better not be so far out of line with our comparable.

PPT4

In the MS world in XXXX [year suppressed], we priced XXXX [product suppressed] similarly to XXXX [product suppressed], which was already in the market. That made it much easier for the supply chain to manage the price, since XXXX [product suppressed] had a "buy x, get y free" kind of thing over the course of the year. We just put their total x-unit price and divided it by 12 and that was the price for XXXX [product suppressed] for years, per month therapy.

PPT2

I mean, I will tell you, I have sat through hours of my life of countless meetings debating pricing, but really what it came down to was, "what is everyone else pricing; what do we think we can get for it," relative to the features, benefits, those conjoint points that we think that we can drive in terms of utility. So historically, the fact that a new therapy would come on the market and be darn close to the therapies that are already there should have surprised no one.

In addition to setting launch prices close to the existing norm, 1 participant's response suggested that undercutting existing products might send an implicit message of clinical inferiority.

PPT1

We can't come in at less. That would mean we're less effective, we think less of our product, so we have to go more.

Thus, initial pricing decisions seem to be driven by the desire to align economically with other therapies, to telegraph clinical superiority, yet not price so high as to draw unwanted scrutiny. In addition, 1 participant (PPT4) stated that, "Distribution channels have become much more complex over the last 20 years, and are taking a much higher percentage of the total list prices, and so that has become a bigger piece of considering what initial price, pricing is." This suggests that the balance of profit-seeking across pharmaceutical corporations, wholesalers, and retailers may also drive initial pricing decisions of MS drug manufacturers.

Ongoing pricing strategy

The basic pricing strategy revealed an objective to conform to existing patterns, with a premium added for real or perceived product-specific benefits. However, a variety of factors were

identified that guided the overall industry trend over time. First, price increases were often taken to maximize revenue and less explicitly tied to other considerations such as recouping research costs or the costs of manufacturing.

PPT1

I would say the rationales for the price increases are purely what can maximize profit. There's no other rationale for it, because costs have not gone up by 10% or 15%; you know, the costs have probably gone down.

PPT2

Companies have been able to raise prices because nobody has pushed back or told them that they're not able to. There has been, back to your first of those 2 questions, the public perception, has been that it is kind of villainized the pharmaceutical industry to a certain degree. But, you know, not villainized to the point that people are taking fewer drugs.

PPT4

The worldwide capacity for the protein manufacturing was highly stretched. Cost of goods became a real consideration. It's far less of one today.

Justification for price decisions

When probed about the reasons that underlie price escalations, participants offered decision-making factors spanning 5 subthemes: promote innovation, international vs domestic markets, general corporate growth, drug distribution channels, and market dynamics.

Promote innovation

One participant (PPT4) reaffirmed that the US model of drug development, buttressed by exclusivity designations and patent protections, guarantees that companies have only a limited period both to recoup the costs of development and to incentivize investments for continued commercialization.

PPT4

We generally resort to the nature of the patent system, which provides an incentive for innovators that they harvest through increased prices after they get a drug approved. Then when the patents expire, those drugs become very inexpensive, and that seems to be a fair societal tradeoff to encourage the advances that come with innovation.

How this social contract applies in the evolving biologic environment is less clear. PPT2 indicated that biosimilars have yet to realize the same economic role of small-molecule generic drugs.

PPT2

There hasn't been the impact of biosimilars in anti-TNF [tumor necrosis factor] or in MS or in cancer or in diabetes at this point. In theory bring it down prices by about 30% to 50%, which is what all the biosimilar manufacturers are saying, but we just haven't seen that yet because it hasn't been available.

Finally, the issue of orphan drug pricing was raised by 1 participant (PPT3), who shared that the difficulties developing orphan drugs (e.g., developing, managing multiple clinical trials, filing for approval) and the need to optimize return on investment for shareholders necessitate uniquely high price points.

PPT3

The amounts of money that are involved in trying to solve these problems are staggering. Absolutely staggering. And the system works because you can make money at it. Period. No ifs, ands, or buts.

Corporate growth

As expected, corporate growth was a frequently cited explanation for continued price increases. From the financial perspective, pharmaceutical and biotech firms are similar to other publicly owned companies with shareholders who demand positive returns on their investment. Although most companies publicly acknowledge their unique societal position developing products aimed at improving human health and reducing suffering, shareholder obligations and fiscal growth strongly affect pricing decisions.

PPT4

You have to demonstrate better than average returns for your shareholders or they're going to go elsewhere, as high tech companies become Wall Street darlings and generate incredible revenue growth at far less risk than pharmaceutical or biotech.

It was also noted that corporate growth, for any particular product, is achieved principally through either increased product sales and market penetration or price increases.

PPT3

We had focused on market growth, not price increases, as drivers of revenue growth and margin—not necessarily margin expansion, but at least profit expansion—many of the early years of DMTs being available. But once the market growth started slowing, then they looked for growth in other areas.

PPT4

Our response was to try and improve our returns to shareholders, do that by finding new and exciting drugs that make a real difference in various diseases, or do it with the existing portfolio by increasing prices in the US and increasing penetration. And penetration is usually not a problem, until you're left with only price as the lever that you can use to drive shareholder return.

PPT2

The way that they're able to maintain a relative stable revenue for xxx over a period of years, or for any therapies, is you take commensurate price increases so that it overcomes the loss of prescriptions that you're seeing over a period of time.

In addition, PPT2 noted that “historically a lot of the therapies in MS have been the lifeblood of their companies,” and

erosion of growth for 1 product would have more pronounced effects for these companies relative to other more diversified firms.

United States vs international markets

Several participants noted the uniqueness of the US health care system and its capacity to absorb continual price increases. Conversely, in Europe, the next largest market, the highest price a company can achieve is typically observed at launch. After that, prices decrease over time.

PPT2

A lot of pharmaceutical companies that have sort of modeled their financial outcomes primarily on the US definitely first and Europe second always assumed that in the US health care system this is a system that is entirely elastic; in other words you can price a therapy at whatever you feel that you can get reimbursed at.

PPT4

When you're making these decisions, you're looking at the whole world. And it is only in the United States, really, that you can take price increases. You can't do it in the rest of the world. In the rest of the world, prices decline with duration in the marketplace.

Although the price escalations in the United States do not perfectly correlate with declines elsewhere, PPT4 suggested the US market makes up for potential losses in other markets. Specifically, PPT4 suggested, "The rest of the developed world is subsidized by the US consumer." PPT4 further elaborated that in other non-US markets, single payers dictate the price received for a given number of patients because of real or perceived fixed resources.

PPT4

That's what drives how they put prices is what kind of revenue they can allocate to health care in these systems. So as demand increased, you get approval in France, let's say \$10,000 a year for a 1,000 patients. If there are 15,000 patients in France running treatment 3 years later, the government wouldn't allow you to have the same price unless you generated additional data.

Drug distribution channel

Three participants acknowledged the increasing complexity of pharmaceutical supply chain contracting and its influence on pricing. Specifically, participants felt that the influence of multiple profit-seeking entities throughout the drug supply chain led, in part, to inflated prices and price increases. PPT3 stated, "Hospital pharmacies weren't then what they are now; hospital groups weren't then what they are now. The whole landscape of influences on pricing has changed." PPT2 noted how payers have increasingly approached the MS therapeutic category using traditional pharmaceutical benefit management techniques, including strategic rebating to maintain a preferred status on formularies. They also suggested that financial gain may motivate certain aspects of formulary management.

PPT2

"It hasn't been until the past 3 to 5 years that a lot of the major payers started managing this therapeutic area as a category...as more products have come into the market, and people have really jockeyed using a traditional pharmaceutical blocking tactics, blocking various products out of formularies based on rebating strategies."

PPT2 also acknowledged that profit-seeking supply chain intermediaries may also be playing a role.

PPT2

"I'm not a huge fan of the payer world; they're just a necessary evil. They play games and they make an awful amount of money as well. I talked about the fact that pharmaceutical products are 9% to 11% of the health care spent; the payers are making a bunch of money off of gaming the system, too. I understand what they're trying to do by paring this back, but they're paring this back and padding their pockets at the very same time."

Changing market dynamics

Finally, participants acknowledged that MS pricing dynamics are changing due to evolution and maturation of the market, as well as increasingly negative public perceptions. PPT2 indicated that the historical lack of generics in the category has affected the trajectory of price growth. Furthermore, the approval of ocrelizumab (Ocrevus, Roche, Basel, Switzerland)—offered at a list price substantially lower than other DMTs—is likely to disrupt pricing dynamics in the United States. Consistent with this, both PPT1 and PPT4 suggested that pricing in the MS market is likely to moderate in the near future. However, it still is uncertain whether these changes will actually lead to downward pricing trends.

PPT1

[Ocrevus] is at least the first inkling of reversing the trend to ever-increasing prices, because you could argue that Ocrevus is pretty unique in a way. I mean, first drug for primary progressive, first B-cell therapy in relapsing, has tremendous patient efficacy, and safety is pretty okay relative to these highly effective therapies. So, they could certainly have continued the previous trend of premium pricing, but they've reversed this for whatever reason. It's at least a glimmer of hope.

PPT2

Pricing constraints are coming to MS. The hall pass that MS therapies have received for years and years is soon to be expiring, right, and I can talk about category and segment management and where I believe the payers are going to do this, and I've spoken directly with them on this and they've told me that it's coming, and you're already seeing it happen.

PPT4

It'll be interesting to see how the market evolves over time, but my suspicion [is] you'll see prices moderate as people fight for share instead of margin growth.

Discussion

The issue of escalating drug prices has been heavily debated in the media and medical literature. There is growing recognition that the issue of rising drug prices is complex and multifactorial. Yet, the specific rationale for ever-escalating launch prices and yearly (or twice yearly) price increase in excess of 15% for many drugs, including MS DMTs, has lacked transparency. To the best of our knowledge, this is the first study to consult with executives involved in pricing decisions to explore these phenomena.

Although our investigation was limited in sample and scope, several important themes emerged. First, our participants affirmed that initial price setting is based primarily on pricing structures in the existing market. In prior work, we documented a pattern that newly approved DMTs generally entered the market with prices close to prices of other products.¹ The major exceptions to this were for DMTs that represented important therapeutic advances such as with the approval of the first oral DMT fingolimod, which was priced 25% above the other interferons and glatiramer acetate on launch. In addition to MS DMTs, this pattern of price setting has been noted with biologics for rheumatologic conditions,¹² oncology medications,¹³ and insulin products.¹⁴ The pattern of price escalation observed for these and other classes of drugs for which branded products predominate reflects a fundamental disconnect with the normal economic forces that inform pricing for other consumer goods. One participant indicated that a launch price premium (rather than a discount) such as that observed when Tysabri (first high-potency infusion) or Gilenya (first oral DMT) entered the market may implicitly telegraph some purported advantage of the new product over other drugs in classes. Given the widespread scrutiny that drug prices are now under, this strategy may be changing as companies are increasingly lauded for bringing products to market with price points below expectations.^{15,16} For instance, despite clinical efficacy data suggesting a meaningful therapeutic advantage over several other DMTs, the launch price for Ocrevus was $\approx 30\%$ less than the launch prices of other products in the category.¹⁵

A second theme was that the ongoing pricing strategies used were primarily to support yearly corporate growth numbers, which initially could be achieved through market penetration, as was the case for MS in the late 1990s and early 2000s. However, after market saturation, the simplest way to continue revenue growth has been through annual price increases. In the MS market, pricing of interferon beta-1a (Avonex), interferon beta-1b (Betaseron), and glatiramer acetate (Copaxone) was generally flat from the mid-1990s to the early 2000s. However, for much of the last 15 years, price increases for most DMTs (including the interferons and glatiramer acetate) were often $\geq 15\%/y$.²

Third, in contrast to other developed countries, the US market is unique in its capacity to absorb price increases. One

participant's assertion is supported by documents produced through congressional inquiry involving the development and price strategies for Harvoni and Sovaldi, hepatitis C drugs, that explicitly note that drug price reductions internationally occur on a parallel path with price escalations in the United States.¹² The pharmaceutical industry commonly justifies the need for high US-based drug prices as a necessity both to recoup research and development costs and to incentivize high-risk future innovation.¹⁷ These facts implicitly support the notion that US revenues subsidize global research and development investment to compensate for reduced revenues in other countries where pharmaceutical markets are more constrained. The extent to which this directly affects drug pricing in the United States is uncertain. A recent analysis of pricing and revenue for 15 top drug manufacturers found that revenue derived solely from the drug price premium paid in the United States relative to other developed countries was sufficient to cover 163% of global research and development expenditures for these companies.⁸ This suggests that US-based prices could be lowered substantially and still cover global research and development expenditures. In October 2018, the Trump administration proposed a new drug reimbursement model for Medicare Part B, the program that pays for drugs that are injected or infused in physician offices or outpatient centers, whereby prices would be tied to prices paid by other industrialized countries.¹⁸ Currently, Part B drug prices are based on average sales price (plus 6%), which reflects a weighted average for all manufacturer sales of that product. Under the new proposal, Part B drugs would be reimbursed according to a pricing index derived from a sample of foreign countries with similar developed economies. However, it is unclear how this might affect the MS market because there are only 3 approved DMTs reimbursed through Part B (ocrelizumab, alemtuzumab, and natalizumab). Regardless, funding research and development investments did not seem to be a predominate response from our participants.

Fourth, participants noted that the drug distribution channel is consuming a greater proportion of pharmaceutical spending. Over the last few years, growing attention has been directed at how the drug supply chain (e.g., pharmacy benefit managers [PBMs], wholesalers, and pharmacies) affects rising drug prices and pharmaceutical expenditures. Recent studies suggest that 40% of drug spending is consumed by supply chain entities, a number substantially higher than administrative costs for health care expenditures in total (8%–14%).^{19–21} In particular, PBMs, who negotiate with manufacturers on behalf of health plans for drug formulary placement and rebates, are often economically incented by high list prices and large rebates. The PBM market is highly concentrated, with 3 firms (Express Scripts, CVS Health, Optum) controlling two-thirds of the market.²² The implications of this are that PBMs may have considerable market power to promote high list price and larger rebate favorable contracts when negotiating with pharmaceutical companies. While PBMs argue that large rebates are important for stabilizing premiums for payers (plans or consumers) because

they are confidential, it is challenging to know how much of these savings are ultimately passed onto consumers. Moreover, even if large rebates mitigate the effect of rising list prices, patients are typically exposed to undiscounted list prices before meeting their deductible or if they have a co-insurance type of cost sharing.²³ For Medicare beneficiaries without low-income subsidies, annual out-of-pocket costs for MS DMTs average \$6,900 and are among the most costly for patients by drug class.^{4,24} In January 2019, the Trump administration proposed fundamental changes to safe-harbor provisions that protect rebates paid by manufacturers to PBMs from antikickback laws.²⁵ In addition, a new safe-harbor provision was added that allows patients to receive discounts directly from manufacturers. If enacted, this proposal, in theory, may reduce the perverse incentives that drive list price escalation and facilitate prescription drug discounts directly to patients.

The primary limitation of this study was that we used a small sample of executives who represented 4 companies with an MS therapy. All participants were identified by the senior author (D.B.) on the basis of his knowledge of their professional background; therefore, they represent a self-selected convenience sample and may not reflect experiences of executives in other companies. However, the limited number of individuals available and willing to speak with us is emblematic of the opaqueness of the pharmaceutical industry. It is interesting to note that the number of individuals in our sample is only moderately lower than the number of executives testifying to the US Senate Committee on Finance.²⁶ Comments from our interviews provide a distinct, and rarely represented, lens on the issue of drug pricing. While participants reviewed this manuscript to ensure that their comments were not taken out of context and that their identity was not revealed, they may not necessarily endorse conclusions drawn in this discussion. Finally, the drug pricing debate has been recently redirected toward market distortions and inefficiencies caused by the drug supply chain (e.g., PBMs).^{25,27} While this was noted by one of our participants, our analysis would have benefited from inclusion of a participant involved directly with supply chain contracting.

In this qualitative study, 4 former executives within biotech and pharmaceutical companies involved in the production and marketing of MS drugs discussed a number of issues that are currently debated by elected officials and policy makers. Major themes included maintaining incentives for research and development, international pricing disparities, and supply chain-related economic effects. Contrary to the contention by the Pharmaceutical Research and Manufacturers of America that prices need to be sufficiently high to recover research and development costs, our participants did not uniformly cite this as the primary factor involved in initial price setting and subsequent price increases. The existing empirical data and responses from our participants (interview and survey data) suggest that initial prices and subsequent changes are driven by prices of other products in the market. If

anything, companies may have applied a price premium to indicate product superiority. It was also clear that aggressive pricing strategies were the main levers to generate revenue critical to support annual growth. Although our study is not a comprehensive assessment of the problem, it provides a contextual backdrop that complements the ongoing conversation about the costs of prescription drugs in the United States and potential policy solutions.

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Lindsey Alley, MS	HealthInsight Oregon, Portland	Author	Interviewed participants, analysis and interpretation of data, qualitative data analysis, revised the manuscript for intellectual content
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