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Outpatient remdesivir treatment program for hospitalized patients with coronavirus disease-2019: Patient perceptions, process and economic impact

Supavit Chesdachai [a,*,1], Christina G. Rivera [b,1], Jordan K. Rosedahl [c], Lindsey M. Philpot [c,d], Ruchita Dholakia [e], Bijan J. Borah [e], Evan W. Draper [b], Richard Arndt [f], Ravindra Ganesh [g], Jennifer J. Larsen [h], Molly J. Destro Borgen [a], Raymund R. Razonable [a,**]

[a] Division of Public Health, Infectious Diseases, and Occupational Medicine, Mayo Clinic, Rochester, MN, USA
[b] Department of Pharmacy, Mayo Clinic, Rochester, MN, USA
[c] Department of Quantitative Health Sciences, Mayo Clinic, Rochester, MN, USA
[d] Department of Community Internal Medicine, Mayo Clinic, Rochester, MN, USA
[e] Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, MN, USA
[f] Department of Pharmacy, Mayo Clinic Health System, Eau Claire, WI, USA
[g] Department of General Internal Medicine, Mayo Clinic, Rochester, MN, USA
[h] Department of Nursing, Mayo Clinic, Rochester, MN, USA

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ABSTRACT

Background: Remdesivir is FDA-approved for the treatment of hospitalized patients with severe COVID-19. Many patients improve clinically to allow for hospital dismissal before completing the 5-day course. In a prior work, patients who continued remdesivir in an outpatient setting experienced better 28-day clinical outcomes. Here, we assessed patients' perspectives and the economic impact of this outpatient practice.

Methods: Hospitalized patients who received remdesivir for COVID-19 at Mayo Clinic, Rochester, from 11/6/2020 to 11/5/2021 and were dismissed to continue remdesivir in the outpatient setting were surveyed. The cost of care was compared between those who remained hospitalized versus those who were dismissed.

Results: 93 (19.8 %) among 470 eligible patients responded to the electronic survey. Responders were older than non-responders. The majority (70.5 %) had symptoms resolved by the time of the survey. Ten (11.4 %) patients had persistent symptoms attributed to long COVID-19. The majority were satisfied with the quality of care (82.3 %) and overall experience (76.0 %) in the infusion clinic. After adjusting for gender, comorbidity score, and WHO severity scale, the predicted costs for the groups were $16,544 (inpatient) and $9,097 (outpatient) per patient (difference of $7,447; $p < .01$). An estimate of 1,077 hospital bed-days were made available to other patients as a result of this transition to outpatient.

Conclusion: An outpatient remdesivir program that allowed for early dismissal was perceived favorably by patients. The program resulted in significant cost and resource savings, the latter in terms of the availability of hospital beds for other patients needing critical services.

1. Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19), continues to cause morbidity and mortality globally.[1] Evidence-supported treatments for COVID-19 include three antiviral drugs, several anti-spike neutralizing monoclonal antibodies (although they are no longer available due to the emergence of resistant variants), and select immunomodulatory agents.[2] Remdesivir, an intravenous direct-acting nucleotide inhibitor of SARS-CoV-2 RNA-dependent RNA polymerase, was the first antiviral

* Corresponding author. 200 First St SW, Rochester, MN, 55905, USA.
** Corresponding author. 200 First St SW, Rochester, MN, 55905, USA.
E-mail addresses: chesdachai.supavit@mayo.edu (S. Chesdachai), razonable.raymund@mayo.edu (R.R. Razonable).
[1] Contributed equally.

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drug approved for clinical use, and it remains the only FDA-approved antiviral drug treatment for hospitalized patients with COVID-19.[3–5]

Remdesivir was initially demonstrated to be effective for the treatment of hospitalized patients with severe disease and, later on, among high-risk outpatients with mild to moderate COVID-19. A phase 3 trial showed that a 5-day course of remdesivir shortened recovery time among hospitalized patients with COVID-19.[4,6,7] Among non-hospitalized outpatients with conditions that predispose to severe disease progression, a 3-day course of remdesivir lowered hospitalization or death rates by 87 % compared to placebo.[8]

In our clinical practice, we have observed that many hospitalized patients improve clinically before completing the full 5-day course of intravenous remdesivir. However, there were reasonable concerns that premature dismissal from the hospital would lead to clinical worsening and re-admissions. Our institution developed hospital-based COVID-19-designated infusion therapy centers (ITCs) in November 2020 to allow for the administration of intravenous therapeutics for patients with COVID-19. This program permitted the continued administration of intravenous remdesivir and allowed for earlier dismissal of hospitalized patients who had achieved clinical improvement from severe COVID-19. In a prior work, we demonstrated that those who completed the five-day course of remdesivir had significantly lower odds of death within 28 days compared to those who did not complete the five-day treatment course.[9] Based on this study, we surmise that a 5-day course is necessary among hospitalized patients to gain the full benefits of remdesivir through a strategy that facilitates quality patient experience.

In this article, we provide a comprehensive account of our process for transitioning the administration of intravenous remdesivir to the hospital-based outpatient setting. Additionally, we present the results of a patient perception survey, shedding light on their experiences with this innovative treatment program. Furthermore, we analyze the economic implications of this strategy, unveiling its potential benefits and long-term viability.

2. Methods

2.1. Outpatient administration of intravenous remdesivir

Our outpatient remdesivir program leveraged the infrastructure that was built for the Monoclonal Antibody Treatment Program, which infused novel anti-spike monoclonal antibodies to high-risk outpatients with mild to moderate COVID-19 (the only treatment available in 2020 for mild to moderate COVID-19).[10,11] The framework of this outpatient COVID-19 infusion program has been previously described.[12]

Treating providers caring for patients with severe COVID-19 in the hospital were informed of the new infusion program to transition to the outpatient setting if patients have improved clinically, based on their assessment, and no longer require hospitalization for their acute care needs. It was important for the providers to ensure the patients were stable and had clinically improved so as not to require hospital-level care. The patients were provided detailed education about this program prior to hospital discharge, as well as the clinical signs and symptoms of disease progression.

Patients considered at high risk of disease progression were also enrolled in a remote monitoring program where they were assessed daily, including vital signs and oxygenation.[13] The daily appointment at the ITC for their remdesivir infusion also allowed for further in-person evaluation of their clinical status by the health care providers at the ITC, who were trained to respond to the needs of patients with COVID-19 and to assess signs of disease progression.[12]

2.2. Study's objectives

The primary objective of this study is to examine the potential impact of a remdesivir outpatient infusion program on patient satisfaction, with a secondary objective of assessing its impact on healthcare costs. We hypothesize that implementing early discharge and outpatient infusion programs will result in high patient satisfaction and cost savings attributed to reduced hospital stays.

2.3. Survey population

Hospitalized COVID-19 patients (≥18 years of age) who were started on remdesivir in the inpatient setting and dismissed following clinical improvement and received at least one outpatient dose of remdesivir at Mayo Clinic, Rochester, from November 6, 2020, to November 5, 2021 and had an email address on file, were eligible to receive the survey. Exclusion criteria included receipt of an anti-spike neutralizing monoclonal antibody, receipt of convalescent plasma, use of remdesivir under other study protocols, and transition from an outside facility during remdesivir treatment. Patients who were incarcerated or Minnesota residents who declined research authorization were excluded. The Mayo Clinic Institutional Review Board approved the survey as quality improvement.

2.4. Survey design

The electronic survey was conducted from June 20, 2022, through July 22, 2022. The survey instrument was developed by a multidisciplinary team, including clinical pharmacists and physicians involved in COVID-19 management, experts in survey research, and statisticians.[14] The survey was developed to include four COVID-19 symptom-based questions, seven remdesivir-based questions, and four additional potential questions (three related to COVID-19 symptoms and one related to remdesivir) that was dependent on the responses, for a total of 15 questions. A final open-ended question invited the survey responders to offer additional information about their experiences with COVID-19 and/or our institution. The remdesivir-based questions were designed to assess the patient experience with remdesivir infusions in the outpatient setting, and one question aimed to determine potential adverse drug effects from remdesivir. Before distribution, the survey questions were independently reviewed by RRR, CGR, and the Mayo Clinic Survey Center staff. A copy of the survey instrument is available as **Supplemental Material**.

2.5. Data collection and survey distribution

Demographic and clinical information on the study population was collected via the Mayo Clinic Electronic Health Records (EHR) system, including age at the time of remdesivir administration, sex at birth, race, ethnicity, Monoclonal Antibody Screening Score (MASS) and World Health Organization (WHO) ordinal clinical severity scale[15–17] as a measure of clinical severity for each patient. Patient-reported data was collected via a survey that was deployed electronically by the Mayo Clinic Survey Center using the Qualtrics Online Survey Platform (Qualtrics, Provo, UT) to patient-provided email addresses. The parameters of study participation were provided in an introductory email, which outlined the purpose of the survey, the approach to protecting respondent confidentiality, and the voluntary nature of involvement. After the initial distribution email, four automated reminder emails were sent. Each email invitation contained a link that allowed individuals to opt out of future communications related to this study. No participant remuneration was offered. Participants could leave questions unanswered. Any surveys left unfinished at the date of closure were still collected, and available answers were included in the data analysis.

2.6. Economic evaluation and analysis

Cost data for the patients were abstracted from the Mayo Clinic Cost Data Warehouse, which has been described elsewhere.[18] In summary, professional service costs were estimated using Medicare reimbursement rates for the corresponding codes (Healthcare Common Procedure

Coding System, HCPCS or Current Procedural Terminology, CPT), and hospital services were costed by multiplying the charges with Medicare cost-to-charge ratio. All costs were then inflation-adjusted to the most recent year using the gross domestic product implicit price deflator for eligible patients in the study.

2.7. Statistical analysis

Descriptive statistics: count (n) and proportion (%) were calculated for demographic and clinical characteristics of the response population and by survey question. Missing variables were left as missing and reported as such throughout all tables. Assessment for non-response bias was completed by comparing the distribution of our response population against the sampled population. Differences in distribution between those who responded and those who did not respond to our survey were estimated using the Mann-Whitney *U* test of continuous variables and the Chi-Square (χ^2) Test of Independence for categorical variables. The Fisher exact test was used when the assumptions of the χ^2 test were unmet. Significance was assumed if our p-value was below 0.05. Since healthcare cost data are known to be skewed (non-normally distributed), cost data were also adjusted for potential confounding variables including gender, MASS, and WHO ordinal clinical severity scale using generalized linear modeling (GLM).[19] All costs were inflation-adjusted to the year 2022. Statistical analyses were performed using Statistical Analysis Software (SAS) version 9.2 (Cary, NC) and Stata version 17 (College Station, TX).

3. Results

3.1. Characteristics of the survey population

During the one year study period from November 6, 2020, to November 5, 2021, a total of 3,029 patients were hospitalized for COVID-19 and received at least one dose of remdesivir treatment. Among them, 542 (17.9 %) were assessed by hospital providers to have clinically improved to allow for early dismissal and continue remdesivir treatment in the outpatient setting. The clinical outcomes of all the patients have been recently reported.[9]

Among 542 patients dismissed from the hospital to complete treatment in the outpatient setting, the electronic survey was sent to 470 patients (86.7 %); the remaining 72 patients did not have electronic means of communication. Of the 470 surveyed patients, 93 (19.8 %) responded. Except for age, where responders were significantly older than non-responders (median, 63 vs. 58 years), there were no statistically significant differences between survey responders and non-responders in terms of sex, race, ethnicity, and composite measures of comorbidity (Table 1).

Table 1
Demographics and Risk Profiles of Patients who Received Intravenous Remdesivir in the Hospital-based Outpatient Infusion Facilities.

Variable	Responders (n = 93)	Non-responders (n = 377)	P-value
Age, years [median (Q1, Q3)]	63 (53, 71)	58 (45, 70)	0.0145
Sex, % male	57 %	61 %	0.4782
Race, n (%)			0.1933
• Asian	1 (1.1 %)	10 (2.7 %)	
• Black	1 (1.1 %)	8 (2.1 %)	
• Others	0	13 (3.4 %)	
• White	91 (97.8 %)	346 (91.8 %)	
Ethnicity, n (%)			0.3589
• Hispanic	1 (1.1 %)	15 (4.0 %)	
• Not Hispanic	92 (98.9 %)	357 (94.7 %)	
• Others	0	3 (0.8 %)	
• Unspecified	0	2 (0.5 %)	
Monoclonal Antibody Screening Score, median (Q1, Q3)	3.0 (1.0, 5.0)	3.0 (1.0, 5.0)	0.9014

Among 93 survey responders, the median number of days of COVID-19 symptoms was 20 [IQR, 10, 60] days. The majority (70.5 %) had their symptoms completely resolved by the time of the survey. However, ten patients (11.4 %) remained with symptoms that were perceived to be still related to COVID-19, while another 16 (18.2 %) were unsure if their symptoms were related to COVID-19. The most common symptoms that were attributed to long COVID-19 were brain fog (23.7 %), fatigue (30.1 %), and insomnia (18.3 %). Other common symptoms were dizziness, shortness of breath, and pain syndrome (Table 2).

3.2. Patient's perception of the outpatient remdesivir program

Seventy-four percent of the survey responders were excited to learn about the availability of an outpatient remdesivir program where they could continue treatment. Most patients (82.5 %) knew right away that they would accept or decline the outpatient treatment option, while a small proportion (15.1 %) felt they needed more time before agreeing to the outpatient treatment option. The majority (60.7 %) felt that COVID-19 put their lives in danger, and the majority (67.5 %) felt sick enough to continue treatment. The majority of patients (79.5 %) had enough support to continue treatment at home, and they felt that completing treatment at home was the right decision for them (81 %) (Table 3).

Communication with the staff before their visit to the ITC and during their outpatient remdesivir infusion led to positive patient experiences. About 80.5 % of patients were satisfied with the communication received during infusion. Eighty percent of patients were satisfied with the explanation of the treatment, but only 58.5 % were satisfied with the explanation of potential side effects. More than 80 % of patients had a positive experience with the quality of care received. Eighty-nine

Table 2
Clinical course of COVID-19 among 93 survey responders[a].

Variable	Number of patients (%), unless otherwise specified
Resolution of clinical symptoms	
Yes	62 (70.5 %)
No	10 (11.4 %)
Unsure	16 (18.2 %)
Total number of days of COVID-19 symptoms, median (Q1, Q3)	20 (10.0, 60.0)
New symptoms after remdesivir infusion	
Yes	12 (14.5 %)
No	61 (73.5 %)
Unsure	10 (12.0 %)
New symptoms after start of IV remdesivir	
Chills	6 (6.5 %)
Diarrhea	8 (8.6 %)
Dizziness	8 (8.6 %)
Fever	4 (4.3 %)
Headache	11 (11.8 %)
Itching	5 (5.4 %)
Nausea	8 (8.6 %)
Shortness of breath	16 (17.2 %)
Skin rash	5 (5.4 %)
Vomiting	2 (2.2 %)
Others[b]	24 (25.8 %)
Long-term symptoms	
Brain fog	22 (23.7 %)
Dizziness	12 (12.9 %)
Fatigue	28 (30.1 %)
Gastrointestinal upset	7 (7.5 %)
Heart palpitations	4 (4.3 %)
Insomnia	17 (18.3 %)
Pain syndrome	10 (10.8 %)
Shortness of breath	13 (14.0 %)
Others[c]	11 (11.8 %)

[a] Not all patients responded to all questions of the survey.
[b] Includes: pain syndromes, fatigue, weakness, hair loss, constipation, neuropathy.
[c] Includes: lack of energy, anxiety, hair loss, and altered sense of tase and smell.

Table 3
Experience and perspectives of 93 hospitalized patients about COVID-19 coronavirus disease-2019 and on transitioning intravenous remdesivir to an outpatient infusion therapy center.

Statements	Agree	Neutral	Disagree
I was excited to learn about the outpatient remdesivir infusion	**73.8 %**	23.8 %	2.5 %
I knew right away whether I'd accept or decline	**82.5 %**	13.8 %	3.8 %
I felt like COVID-19 put my life in danger	**60.7 %**	17.7 %	21.5 %
I thought it unlikely I'd need to be hospitalized again	**53.5 %**	36.3 %	10.1 %
I was confident I could recover without completing treatment	10.2 %	**43.0 %**	**46.8 %**
I did not think I was sick enough to need the rest of the treatment	7.6 %	25.0 %	**67.5 %**
I wish I had more time to decide about completing treatment	15.1 %	**41.3 %**	**43.8 %**
I wish I could wait to determine needing to finish treatment	8.8 %	31.3 %	**60.0 %**
I felt there were benefits to being home and completing the treatment	**79.5 %**	12.8 %	7.7 %
I knew the risks of completing treatment at home	**60.2 %**	25.6 %	14.1 %
I had enough support from others to complete treatment at home	**79.5 %**	14.1 %	6.4 %
I felt sure completing the treatment at home was best for me	**67.9 %**	25.6 %	6.4 %
It was the right decision to receive treatment in the outpatient setting	**81.0 %**	12.7 %	6.3 %

percent of the patients were satisfied with the time spent at ITC, and 87.6 % felt they could keep a safe distance from others while receiving treatment. The overall experience was positive in 76 % of patients (Fig. 1).

Among the responders, the benefits of continued treatment were very important (82.5 %) while also appreciating the associated risk (Fig. 2). The cost of treatment, the inconvenience, and the discomfort of daily infusions were unimportant to most of the responders (Fig. 2).

3.3. *Cost considerations of outpatient remdesivir program*

The hospitalization cost of 530 patients who transitioned the treatment course of remdesivir to the outpatient setting was compared to 2,290 patients who continued treatment in the inpatient setting. In unadjusted analysis, the mean cost between the groups was significantly different at $16,524 (inpatient) and $8,961 (outpatient). After adjusting for gender, MASS, and WHO ordinal clinical severity scale, the predicted cost for the groups were $16,544 (inpatient) and $9,097 (outpatient) per patient (cost difference of $7,447; $p < .01$). Based on the total number of remdesivir infusion in the outpatient setting during this period, we estimated a total of 1,077 hospital bed-days were made available to other patients who needed hospitalization for any indication.

4. Discussion

During the height of the COVID-19 pandemic, our institution established an outpatient remdesivir program that allowed for the early dismissal of stable, improving patients while still completing the full course of remdesivir therapy. This study demonstrated that the program was favorably perceived by patients, particularly regarding the communication received during a stressful period of their life and overall experience. Moreover, the program led to substantial cost savings and the ability to reallocate hospital resources to other patients with acute care needs or other critical conditions.

The model of transitioning remdesivir from the hospital to the outpatient setting was adopted from a well-established Outpatient Antimicrobial Therapy (OPAT) program, which continues to administer intravenous antimicrobials to patients after being dismissed from the acute care hospital setting.[20,21] Previous studies have demonstrated that receiving antimicrobial therapy at home or at the ITC is effective and

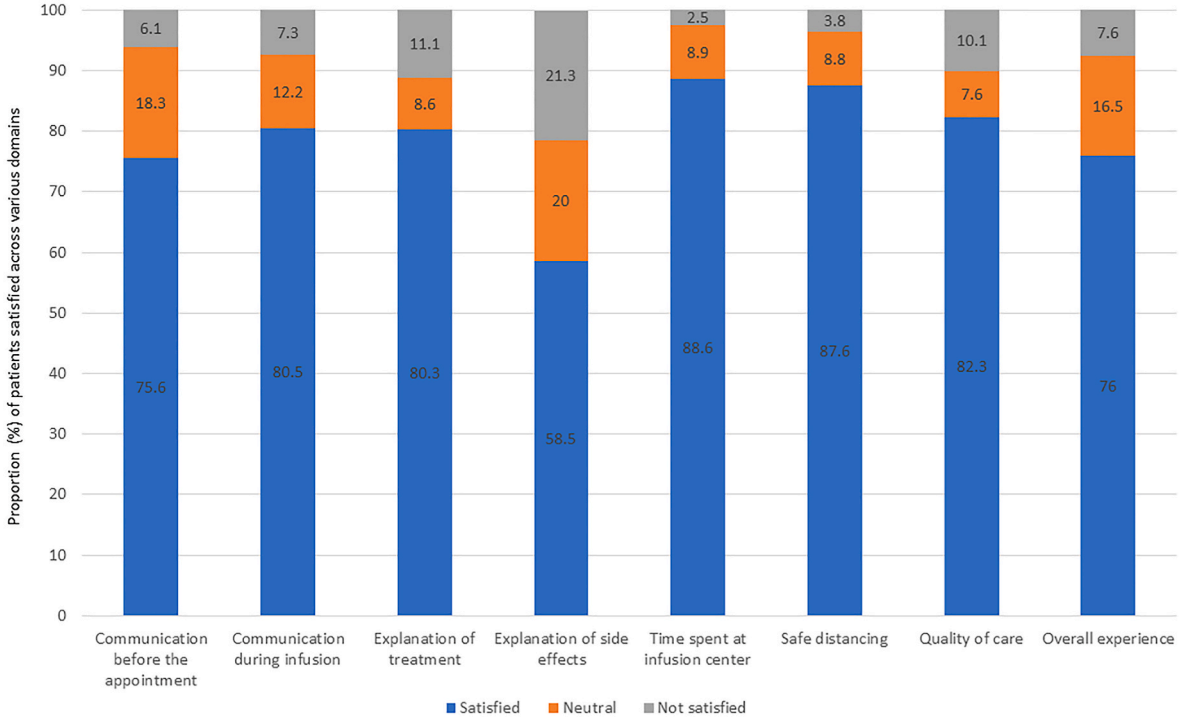

Fig. 1. Experience of Patients who Transitioned Intravenous Remdesivir Treatment from Hospital to Outpatient Infusion Center.
Fig. 1 legend: This chart illustrates the percentage of patients expressing satisfaction, neutrality, or dissatisfaction with various aspects of their treatment experience after transitioning from inpatient hospital care to an outpatient setting. Each bar represents the patient responses across critical domains such as communication, treatment explanation, and safety measures. Notably, 76 % of patients reported a positive overall experience.

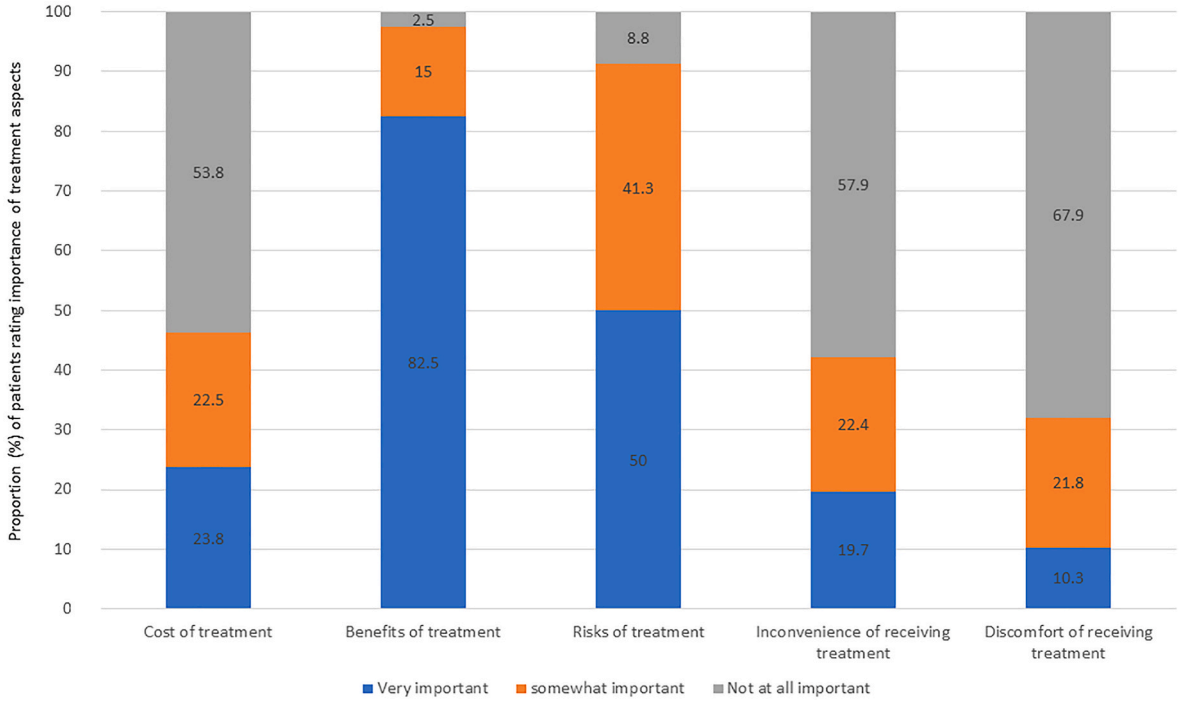

Fig. 2. Patient perception on receiving intravenous remdesivir in the outpatient infusion center.
Fig. 2 legend: This chart depicts the distribution of patient perceptions regarding the importance of various aspects of receiving intravenous remdesivir at an outpatient infusion center. Each bar indicates the percentage of patients who rated aspects such as the cost of treatment, benefits of treatment, risks associated, and the inconvenience and discomfort of treatment as 'Very Important,' 'Somewhat Important,' or 'Not at All Important.' Notably, a majority found the benefits of continued treatment to be very important, while aspects like the cost, inconvenience, and discomfort of daily infusions were considered unimportant by most respondents.

safe for patients.[22–24] The patients' overall satisfaction was high, especially with the home infusion.[25] Additionally, it demonstrated that the health care cost was significantly reduced with the OPAT program compared to those who continued antimicrobial therapy in the hospital.[22,26]

However, even though most tertiary care centers in the US have a well-established OPAT program, several factors hinder the widespread implementation of the OPAT model for outpatient remdesivir administration. First, remdesivir administration must be performed safely in a dedicated ITC with specialized equipment and training because of the contagious nature of COVID-19. Infection prevention and control strategies were implemented to reduce the risk of SARS-CoV-2 transmission to staff and others.[27] At the ITC, proper use of personal protective equipment (PPE), physical distancing, avoidance of companions and accompanying visitors, and other infection control measures were implemented. Second, scheduling remdesivir infusion was logistically challenging, as it required once daily ITC appointments for 1–4 days. It was, therefore, critical that the ITC was open daily, including weekends and holidays, to provide remdesivir infusions without interruption. Third, transitioning patients from inpatient to outpatient care requires a multi-disciplinary approach. Close coordination between treating providers, nurses, pharmacists, and ITC personnel ensures a smooth and seamless transition.

The overall satisfaction and positive experience with outpatient remdesivir administration for most patients aligned with previous surveys of COVID-19 patients who received monoclonal antibody therapy.[14] Patient-centered care is a core construct in developing new clinical care models, and assessment of patient experience is important to continue to evolve these new models.[28] This observation reflects the successful establishment of an excellent patient-clinician relationship and rapport, which was achieved through effective communication. However, not all the processes are perfect, as a small proportion of patients thought that receiving outpatient remdesivir therapy was not the right decision. The reason for dissatisfaction in the minority of patients was not included in the survey, but some possible explanations could be speculated. First, completing the course of outpatient remdesivir may not have resolved lingering symptoms of COVID-19, which could have led to dissatisfaction and disappointment. Second, some patients may have experienced symptoms that were perceived to be adverse effects of remdesivir. These are only assumptions, but future qualitative studies to explore these reasons may provide the answer to these experiences to improve the future outpatient infusion process.

The cost effectiveness of remdesivir therapy merits discussion. A systematic review and meta-analysis encompassing 12 studies from 12 countries concluded that remdesivir was cost-effective.[29] One study observed a similar average cost of $11,000 per patient for remdesivir therapy.[30] However, it is crucial to acknowledge that our study's estimated cost savings, which show a significantly lower cost for outpatient remdesivir therapy, do not represent a causal estimate. The higher expenses associated with inpatient care may reflect the increased medical complexity of these patients, likely leading to an upward bias in our cost estimates. Importantly, there is undeniable cost savings associated with non-hospitalization—suggesting that the true savings likely lie between the simple cost of occupying a hospital bed plus outpatient infusion expenses and our estimated savings. To provides a more comprehensive assessment, further analysis considering quality-adjusted life-years should be considered, allowing for a more holistic evaluation of the cost-effectiveness of outpatient remdesivir treatment.

While our study demonstrated the unique patient experiences in completing remdesivir as an outpatient, along with favorable cost analysis, our study has several limitations. First, due to our survey investigation's retrospective and cross-sectional nature, the results may suffer from recall bias in the recollection of information reported by survey participants, particularly as the survey was conducted many months after the participants' actual experience. Second, the low response rate to the survey is a limitation that could lead to another

potential threat: non-response bias; however, this is consistent with the declining national trend in survey responses within healthcare settings.[31] We believe the threat of non-response bias is limited upon investigation of the demographic and clinical factors of our responding population versus those who did not respond. Third, the majority of patients in our cohort were White and non-Hispanic, which may not fully represent the diverse populations significantly impacted by COVID-19. This limitation is noteworthy, especially considering the influence of social determinants of health and racial/ethnic disparities in COVID-19 access to care and clinical outcomes. Consequently, the generalizability of our results on patient satisfaction should be considered with caution, taking into account social, cultural and other factors that may vary across different populations. Fourth, while our analysis highlights the direct cost savings of the outpatient remdesivir treatment program, it may underestimate the total cost implications as it does not account for indirect costs such as travel and potential boarding expenses for caregivers. Additionally, start-up costs related to clinic space reconfiguration and staff training were not included in our financial analysis. This limitation should be considered when evaluating the cost-effectiveness of similar programs in settings with different resource availability.

In conclusion, our study delineated the complex process of establishing the outpatient remdesivir infusion therapy program that allowed for early hospital dismissal among hospitalized patients who have improved prior to completing five days of remdesivir. We illustrated that the patients who received intravenous remdesivir as outpatients reported a favorable experience. Furthermore, the program resulted in significant cost and resource savings. Specifically, the program freed up hospital beds for other patients who needed critical care during the height of the COVID-19 pandemic when large numbers of patients requiring hospitalizations overextended most healthcare system resources.

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CRediT authorship contribution statement

Supavit Chesdachai: Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Investigation, Data curation. **Christina G. Rivera:** Writing – review & editing, Writing – original draft, Validation, Investigation, Data curation, Conceptualization. **Jordan K. Rosedahl:** Writing – review & editing, Validation, Formal analysis, Data curation. **Lindsey M. Philpot:** Writing – review & editing, Validation, Methodology, Data curation, Conceptualization. **Ruchita Dholakia:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation. **Bijan J. Borah:** Writing – review & editing, Writing – original draft, Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Evan W. Draper:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation. **Richard Arndt:** Writing – review & editing, Methodology, Formal analysis, Data curation, Conceptualization. **Ravindra Ganesh:** Writing – review & editing, Supervision, Data curation, Conceptualization. **Jennifer J. Larsen:** Writing – review & editing, Validation, Methodology, Conceptualization. **Molly J. Destro Borgen:** Writing – review & editing, Validation, Methodology, Data curation, Conceptualization. **Raymund R. Razonable:** Writing – review & editing, Writing – original draft, Validation, Supervision, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Raymund R. Razonable reports financial support was provided by Gilead. RRR received research funds from Regeneron and Roche on projects unrelated to this study, as member of the DSMB for Novartis, and is on the American Society of Transplantation Board of Directors. CGR has served as member of advisory board for Gilead Inc. BJB is a Boehringer Ingelheim and Exact Sciences Corporation consultant on unrelated projects. Others declare no conflict of interest.

Data availability

The data that has been used is confidential.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.hjdsi.2024.100750.

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