

Introduction

- COVID-19 presented unique challenges for the care of immunocompromised individuals.
- Patients with suppressed immune systems lack the ability to mount a robust response to vaccines, leading to an increased likelihood of developing severe COVID-19 responses and increased mortality.
- Astra-Zeneca developed Evusheld, a monoclonal antibody (Tixagevimab/cilgavimab) as a COVID-19 prophylaxis to target the SARS-CoV-2 spike protein. ¹
- In December 2023, the FDA enacted an Emergency Use Authorization (EUA) for Evusheld in immunocompromised individuals and TJUH developed a roll-out plan. ²
- Thomas Jefferson University Health (TJUH) distributed the drug using a tiering system that ranked the degrees of immunocompromising conditions for priority administration.

Research Question: *How effective was the TJUH roll out program at distributing a medication in limited supply under the constraints of a pandemic?*

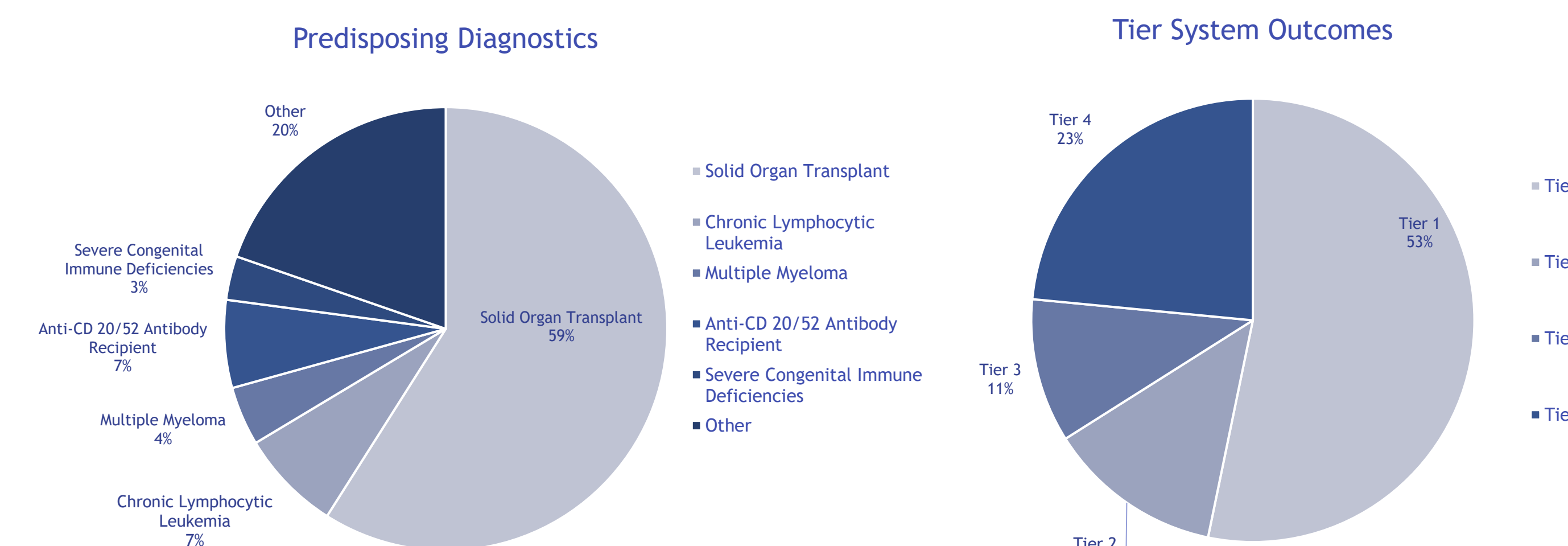
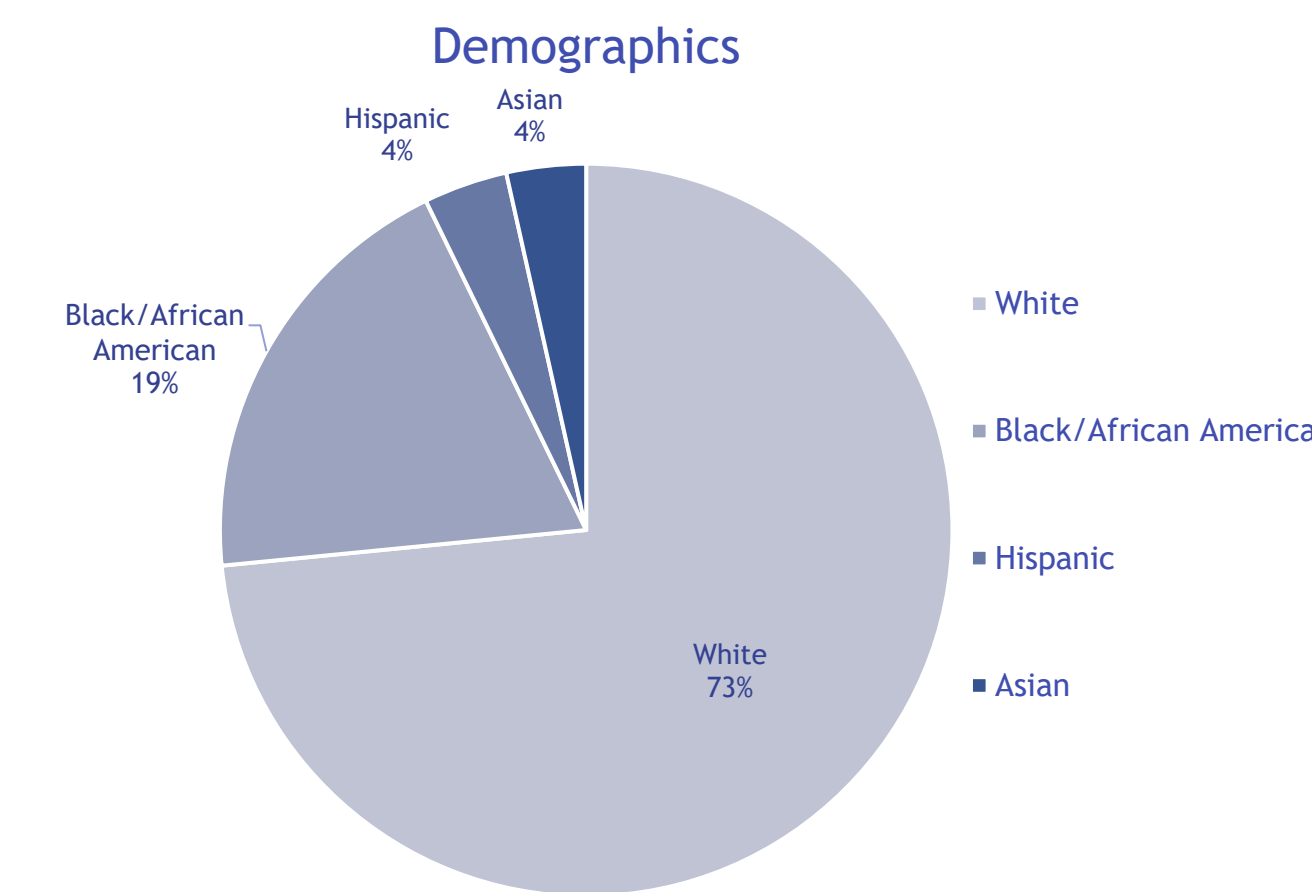
Hypothesis: **The tiering system will successfully allocate immunocompromised patients Evusheld for Covid-19.** Analyzing the program for supplying Evusheld to TJUH will provide insights for effective novel drug rollout plans for future pandemics.

Methods

- Retrospective cohort study comprised of immunocompromised patients eligible for Evusheld at TJUH.
- Patients were recommended to receive Evusheld via their medical provider through the “Evusheld Prioritization Request” order.
- Requests prioritized based on a tiering system developed by a multidisciplinary team, including members from the departments of Transplant Surgery, Infectious Diseases, Hematology, Medical Oncology, Gastroenterology, Rheumatology and Pharmacy services.
 - The lower the numbered Tier correlated to a greater degree of immune function weakness.
- Efficacy of the Tier System is evaluated by the ability to allocate Evusheld to immunocompromised patients. Additional data collected included demographics, vaccine status, COVID-19 infections, and hospitalizations from COVID-19.
- The data points were manually collected from patient’s electronic medical records in EPIC and analyzed for descriptive statistics in Stata.

Results

- A total of 651 patients were recommended for Evusheld and of those, 430 (66.1%) received the drug.
- Out of the Evusheld recipients, 235 (54.4%) were male, and 195 (45.3%) were female. The majority, 315 (73.3%), identified as White. Black/African American patients accounted for 19.3%, Asians 3.5%, and Hispanics 3.7%. In terms of age, 53.5% of recipients were younger than 65, while 46.5% were 65 or older.
- 59% of patients that had received Evusheld at TJUH were transplant recipients. Other conditions that were likely to receive Evusheld were those with Chronic Lymphocytic Leukemia (7.4%), Multiple Myeloma (4.3%), anti-CD 20/52 antibody recipients (6.4%) and severe congenital immune deficiencies (3.2%).
- The Tier 1 cohort were the most likely to receive Evusheld (53.3%), while Tier 2 made up 12.8%, Tier 3 made up 10.5% and Tier 4 made up 23.5%.



Conclusion

- TJUH successfully distributed Evusheld to highly vulnerable patients, with 53.3% falling into the first Tier.
- The predominant recipients of Evusheld at TJUH were transplant patients. The success in supplying the transplant population at TJUH could be attributed to the strategic provision of Evusheld during the hospitalization period for their transplant surgery, facilitating a more seamless administration process.
- The distribution of Evusheld failed to achieve proportional representation among various racial groups relative to the population of Philadelphia, a point of improvement with future roll-out strategies.
- A critique of the Tier system involves the lack of consideration of ethical and socioeconomic factors that could play a role in a more severe COVID-19 course of infection.
- A study limitation was the inability to analyze the full function of the Tier system because the supply exceeded the demand at TJUH.
- The study's implications encompass the development of a prospective framework to inform future pandemic action plans, particularly in the context of administering medications under limited supply. This framework holds promise as a valuable guide, providing insights and strategic approaches to enhance the efficient allocation and distribution of resources during periods of scarcity.

References

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2. EUA, H. O. E. U. A. (2021). Fact Sheet for Healthcare Providers: Emergency Use Authorization for Evushel (Tixagevimab Co-Packaged with Cilgavimab). Food and Drug Administration

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Tier 1
<ul style="list-style-type: none"> • Allogeneic HSCT within the past year • Autologous HSCT within the past six months • CAR T-cell therapy recipient • Currently on therapy for leukemia • Solid organ transplant patients discharged or receiving specific agents in the past year • Anti-CD 20/52 antibody recipient in the past year • Cutaneous graft versus host disease on immunosuppression in the past six months • Solid organ transplant recipients with full COVID-19 vaccination and negative SARS-CoV2 spike antibody • Severe congenital immune deficiencies • Wiskott Aldrich syndrome • DiGeorge syndrome • HIV-positive patients with a CD4 count <50

Tier 2
<ul style="list-style-type: none"> • Allogeneic HSCT recipient (1-3 years post-transplant) • Autologous HSCT recipient (6-12 months post-transplant) • Multiple myeloma • Chronic lymphocytic leukemia (not on therapy) • Lymphoma on therapy • Myeloproliferative neoplasms • Aplastic anemia • HIV-positive with CD4 count <200 • Patients within six months of adjuvant cytotoxic chemotherapy post-surgery • Lung cancer on treatment • All solid organ transplant patients within one year of transplantation • All solid organ transplant patients on belatacept • All heart transplant recipients

Tier 3
<ul style="list-style-type: none"> • Patients on antimetabolites for non-transplant conditions • Unvaccinated HIV-positive patients with CD4 count >200 • Patients on cytotoxic chemotherapy without curative intent • Solid organ transplant recipients age 65 or older • Patients on antimetabolites or chronic corticosteroids (dose ≥ prednisone 20 mg/day) for non-transplant conditions

Tier 4
<ul style="list-style-type: none"> • All well-controlled, vaccinated HIV-positive individuals • All other solid organ transplant recipients • All other immunosuppressed patients as defined by the Evusheld EUA