Recruitment Hurdles for a Phase 3 Clinical Trial of Relapsed/Refractory Multiple Myeloma (RRMM) at a Safety-Net Health Care System

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Context

- RRMM remains a significant clinical challenge. The phase 3 SUCCESSOR-2 trial evaluates mezigdomide, a novel cereblon-E3 ligase modulator, and dexamethasone versus carfilzomib and dexamethasone in this high-need population.

Objective

- To describe real-world experience and challenges in recruiting patients with RRMM at a public hospital participating in the SUCCESSOR-2 (NCT05552976) trial after its activation on January 14, 2025.

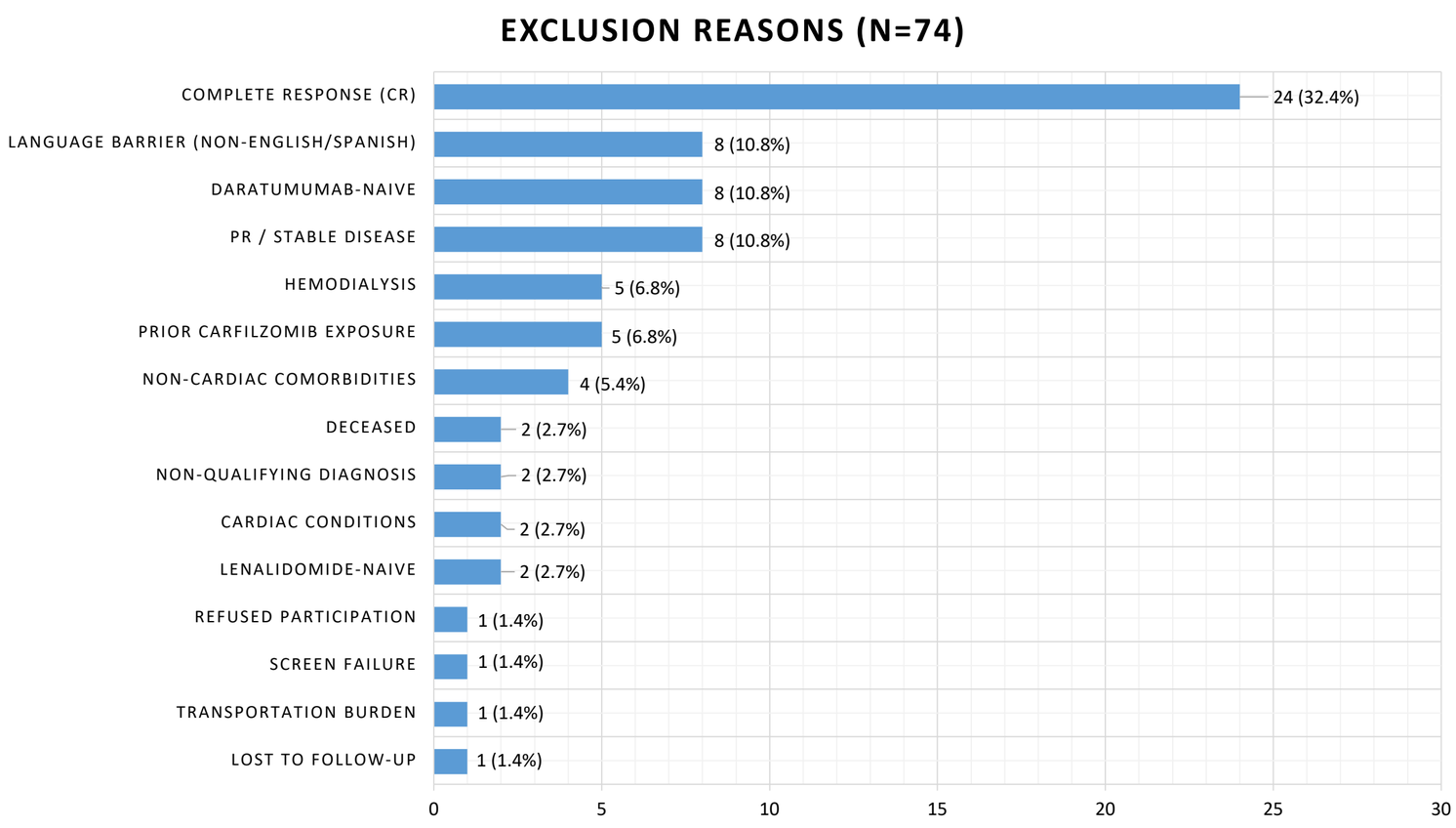
Design and Setting

- Observational study at the JPS Health Network, a safety-net health care system in North Texas serving a diverse patient population.
- In December 2024, we used Epic Slicer Dicer, a self-service tool within Epic electronic medical records (EMRs), to apply diagnosis-based filters and generate a list of potential eligible participants.
- We subsequently queried the Epic Clarity database using structured query language (SQL) development studio with eligibility criteria and myeloma-specific ICD10 codes (C90.00, C90.01, C90.2).
- Participants were verified manually by the research coordinator and the principal investigator.

Patients

- From January 1, 2024, to November 30, 2024, 74 patients were identified and were serially evaluated for study enrollment.
- Median age at diagnosis, 62 years; median time from diagnosis to review, 2 years (mean, 3 years; range, 0–12). 42 patients were male (56.8%), and 21 (28.4%) were Black.
- Languages included English (n=45), Spanish (n=19), and others (n=10). Consent forms were available in English and Spanish only. Other languages included Nepali (1), Serbo-Croatian (1), Lingala (1), Vietnamese (2), Urdu-Pakistan (2), Arabic (1) and un-named (2)

Results



- All 74 screened patients were excluded. The most common reasons were complete response/stable disease (32 patients, 43%), prior therapy eligibility issues (carfilzomib/daratumumab/lenalidomide, 15 patients, 20%), comorbidities (11 patients, 15%), and language barriers (8 patients, 11%).
- Among 3 patients with progression, none enrolled (transportation, screening failure, refusal). Of the 32 without progression, most were in complete remission on first- or second-line therapy.

Conclusion

- High response rates from effective therapies can limit RRMM recruitment.
- Having consent forms in patients' preferred language could help with recruitment at safety-net settings. It is cumbersome to do this currently; artificial intelligence may help in creating consent forms in multiple languages in the future.
- Effective ways of identifying lines of therapy in EMRs could reduce time spent on manual chart checks.

References

- Clinicaltrials.gov. Published 2025. Accessed August 21, 2025. https://clinicaltrials.gov/study/NCT05552976#more-information

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