

## Background

- To ensure appropriate antipsychotic use and psychiatric-care quality in nursing homes (NH), CMS added antipsychotic (AP) Medication Review (AP-MR) questionnaire to long-term care (LTC) Minimum Data Set 3.0 (MDS) mandatory surveys of NH residents in October 2017.<sup>1,2</sup>
- The AP-MR questionnaire included categorical (Yes/No) questions that clinicians are required to complete regarding whether patients have:
  - Clinical contraindication to Gradual Dose Reduction (GDR) for chronic and enduring conditions such as Parkinson's Disease Psychosis (PDP).
  - GDR attempts.<sup>2,3</sup>
- To date, pimavanserin is the only atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with PDP.<sup>4</sup>
- Primary objective was to investigate role of AP-MR documentation quality and treatment-continuity on discharge-to-community. Secondary objective was to estimate the clinical outcomes (falls, hip fractures, pelvic/femur fractures) among LTC patients treated with pimavanserin.

## Methods

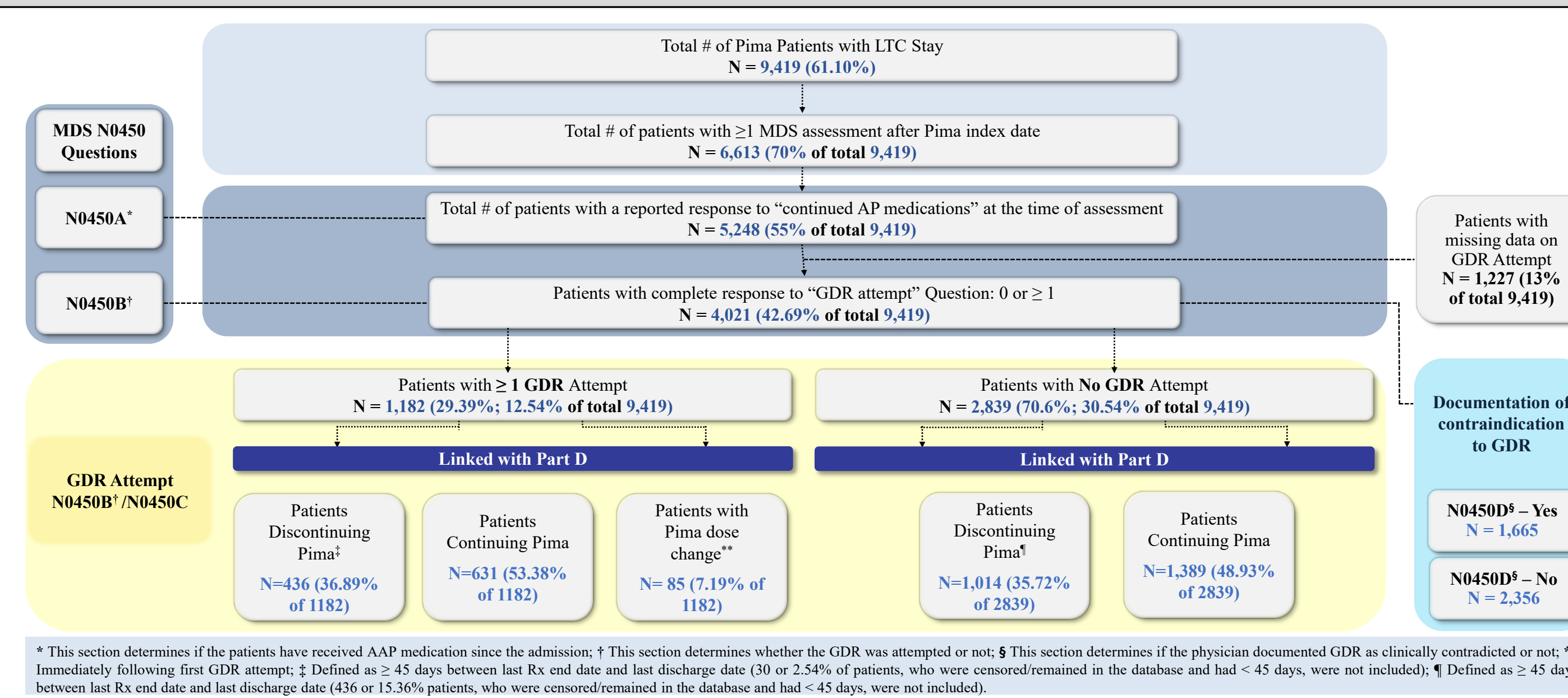
- A retrospective cohort analysis using Parts A, B, and D claims from Medicare 100% sample linked with MDS from June 2016-December 2018 was conducted.
- Patients with >100-day LTC-stay and ≥1 pimavanserin prescription with completed MDS question on AP use were selected.
- AP-MR documentation quality measures (i.e., GDR attempts, clinical contraindication to GDR), and clinical outcomes (e.g., falls, fractures) was assessed from Part D claims.
- Frequency, proportions, and chi-square tests reported categorical measures and means (SD) reported continuous measures.
- Logistic regression model, adjusted for demographics, hospitalizations, and LTC-admission, reported association between pimavanserin treatment-continuity and discharge-to-community using odds ratios with 95% confidence intervals (CI).

## Results

- Overall, 9,419 pimavanserin patients with LTC stay were identified. MDS assessment after post-index pimavanserin were reported by 6,613 patients.
- Among 5,248 LTC patients that reported AP use, 4,021 eligible patients had a reported response about GDR attempts (Figure 1).
- The mean age of the patients (n = 4,021) was 76.57 years, 50% were male, 86% were white Americans, 44% were married, 79% came from an acute hospital, and only 40% experienced hallucinations.
- In the eligible patient sample (n=4,021), 66% (n=2,635) patients initiated pimavanserin during their LTC stay; about 90% (n=2,352) of those reported a LTC stay of ≥150 days (Figure 2).
- Among patients with a GDR attempt, the mean (SD) and median days to first GDR were 220.1 (184.4) days and 175 days, respectively among 1152 (of 1182) patients.
- About 73% (n=62) of 85 patients with dose change had dose reduction (Figure 3).
- For 59% (n=2,356) of the total number of patients, clinicians had documented that GDR is not clinically contraindicated; remaining 41% (n=1665) had documentation showing GDR was clinically contraindicated, yet 39% (n=645) still attempted GDR (Figure 4).
- In our study population, a small proportion of LTC-stay patients had discharge-to-community overall. However, higher (14.94%) proportion of patients that continued pimavanserin had discharge-to-community compared to those who discontinued (11.84%) pimavanserin (p<0.05).
- Pre-index PD diagnosis status data was available in 74% (n=2,993) of eligible patients; of 2,993 patients, 83% (n=2,474) patients had pre-index PD diagnosis.

## Results (Cont.)

Figure 1. Patient Disposition, GDR and Documentation Status



\* This section determines if the patients have received AAP medication since the admission; † This section determines whether the GDR was attempted or not; ‡ This section determines if the physician documented GDR as clinically contraindicated or not; \*\* Immediately following first GDR attempt; ‡ Defined as ≥ 45 days between last Rx end date and last discharge date (30 or 2.54% of patients, who were censored/retained in the database and had < 45 days, were not included); † Defined as ≥ 45 days between last Rx end date and last discharge date (436 or 15.36% patients, who were censored/retained in the database and had < 45 days, were not included).

Figure 2. Patient Disposition: Distribution of Patients According to LTC Stay (N=4,021)

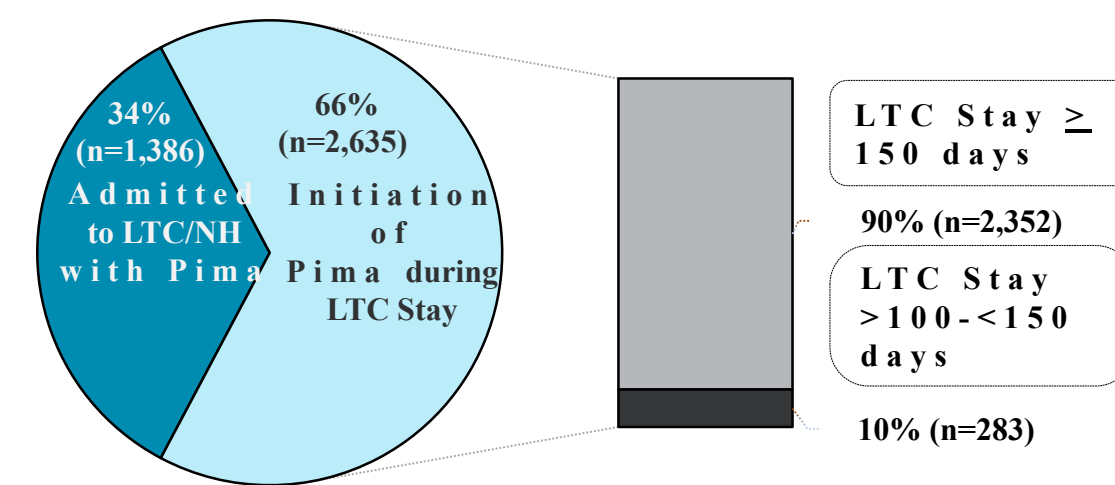


Figure 3. Patient Disposition: Patients who Underwent ≥1 GDR Attempt (N=1,182)

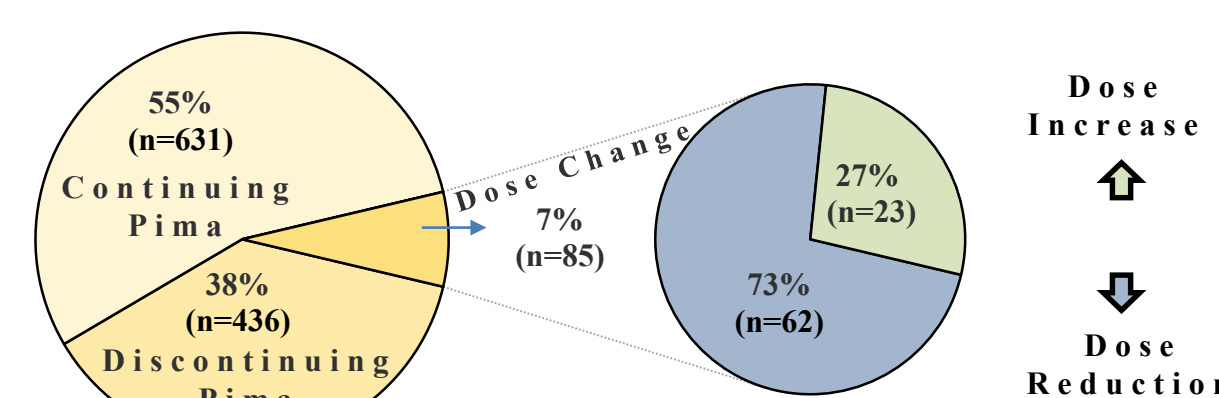


Figure 4. Patient Disposition: Accuracy of Clinical Contraindication Documentation Status by GDR (N=4,021)

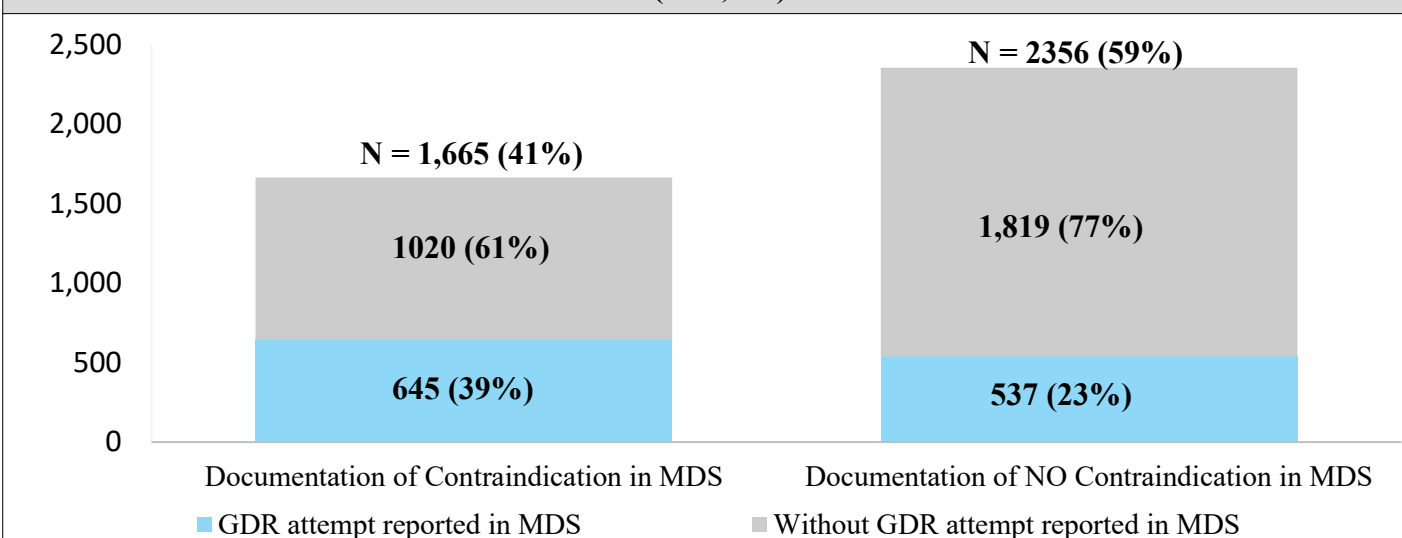
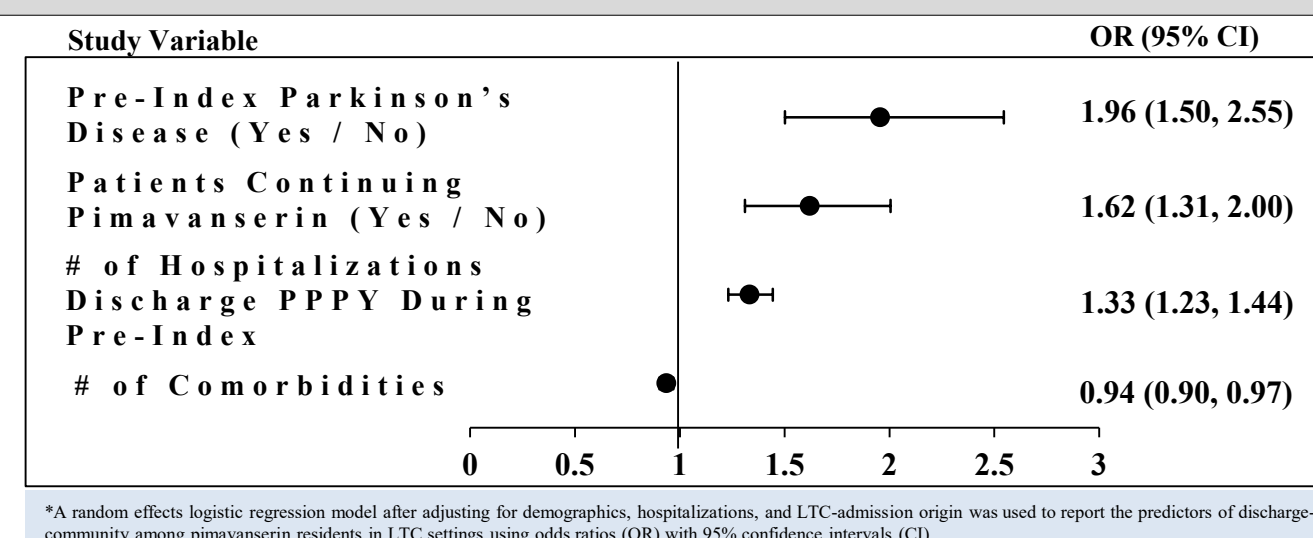


Figure 5. Logistic Regression: Factors Associated with Discharge to Community\*



- Odds ratio for treatment-continuity, pre-index Parkinson's disease diagnosis, and comorbidities were 1.96 (95% CI: 1.50-2.55), 1.62 (95% CI: 1.31-2.00), and 0.94 (95% CI: 0.90-0.97), respectively (Figure 5).
- Patients continuing pimavanserin had lower incidence of falls (2.8% vs 9.4%), hip fractures (0.29% vs 0.69%) and pelvic/femur fractures (0% vs 0.92%) vs. those who discontinued pimavanserin.

## Limitations

- As with any retrospective database analysis that involves claims and surveys linked analysis, this research too may be limited by coding errors, transcription errors, & other documentation errors.
- Claims information were obtained from recorded information at the time of event occurrence (e.g., prescription fill, discontinuations, hospitalization, pre-index PD diagnosis, etc.), clinical contraindication documentation, and rates of discharge to the community are collected at quarterly intervals or at time of discharge/readmission. Thus, potential biases in temporal associations demonstrated in this analysis is plausible, although unlikely due to appropriately assessing outcomes during follow-up.
- Notwithstanding the limitations, this analysis is the first-of-its-kind real-world study of Medicare patients to evaluate pimavanserin prescribing patterns, GDR and dose change patterns as well documentation patterns of clinical contraindication of GDR.

## Conclusions

- Of the total number of LTC patients with > 100 day stay, 41% had a reported documentation that GDR is clinically contraindicated.
- Among these patients, 61% had no GDR attempts and approximately 40% had GDR attempt despite documentation of clinical contraindication.
- Results from this analysis suggest that GDR-attempts among pimavanserin treated patients was relatively low despite higher inaccurate documentation rates regarding clinical contraindication to GDR.
- Interestingly, pimavanserin treatment-continuity, and PD diagnosis prior to initiation in LTC setting had 96%, and 62% greater likelihood of discharge-to-community, respectively.
- Patients continuing pimavanserin showed improved outcomes in terms of discharge-to-community, falls and fractures compared to those who discontinued the treatment.
- These results suggest a significant need for continued GDR-policy education and mandatory documentation training as it relates to treatment-continuity to ensure appropriate AP use in LTC/NH settings.

## References

- Campanelli, Christine M. "American Geriatrics Society updated beers criteria for potentially inappropriate medication use in older adults: the American Geriatrics Society 2012 Beers Criteria Update Expert Panel." *Journal of the American Geriatrics Society* 60, no. 4 (2012): 616.
- Tjia, Jennifer, Marcus M. Reidenberg, Jacob N. Hunnicutt, Kelli Paice, Jennifer L. Donovan, Abir Kanaan, Becky A. Briesacher, and Kate L. Lapane. "Approaches to gradual dose reduction of chronic off-label antipsychotics used for behavioral and psychological symptoms of dementia." *The Consultant Pharmacist* 30, no. 10 (2015): 599-611.
- Centers for Medicare and Medicaid Services. State Operations Manual: Guidance to Surveyors for Long Term Care Facilities. Available from: [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltc.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltc.pdf)
- Cummings J., Isaacson S., Mills R., et al. Pimavanserin for patients with Parkinson's disease psychosis: a randomised, placebo-controlled phase 3 trial. *The Lancet*. 2014;383(9916):533-540. doi:10.1016/s0140-6736(13)62106-6.

