

# Methods for Achieving and Maintaining Adequate Study Subject Participation for a Multi-Site Time-Series Trial



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## Background

- Opioid dependence (OD) occurs among people who abuse legal or illegal opiates in increasing quantity and frequency resulting in physical dependence
- In the United States, there has been a steady increase in the number of people who abuse and become dependent upon opioids (SAMHSA, 2007; SAMHSA, 2009)
- As a result, medications such as Buprenorphine have become more widely available through non-traditional healthcare venues such as family practitioners, internal medicine, and psychiatric practice offices (Carrieri et al., 2006; Kastelic et al., 2009)
- As the population of patients who are treated in these office based models grows, the generalizability of existing study results to these patients as well as their physicians will likely decline creating a knowledge gap for addiction treatment researchers
- Access to and identification of these patients for enrollment in research projects is a challenge for the field and will likely require innovative approaches for participant recruitment, enrollment, data collection, and study retention
- The purpose of this study was to describe the procedures and sample of an ongoing, large scale, national study on the effects of a telephonic support intervention for Buprenorphine patients recruited from physicians' offices across the U.S.

## Methods

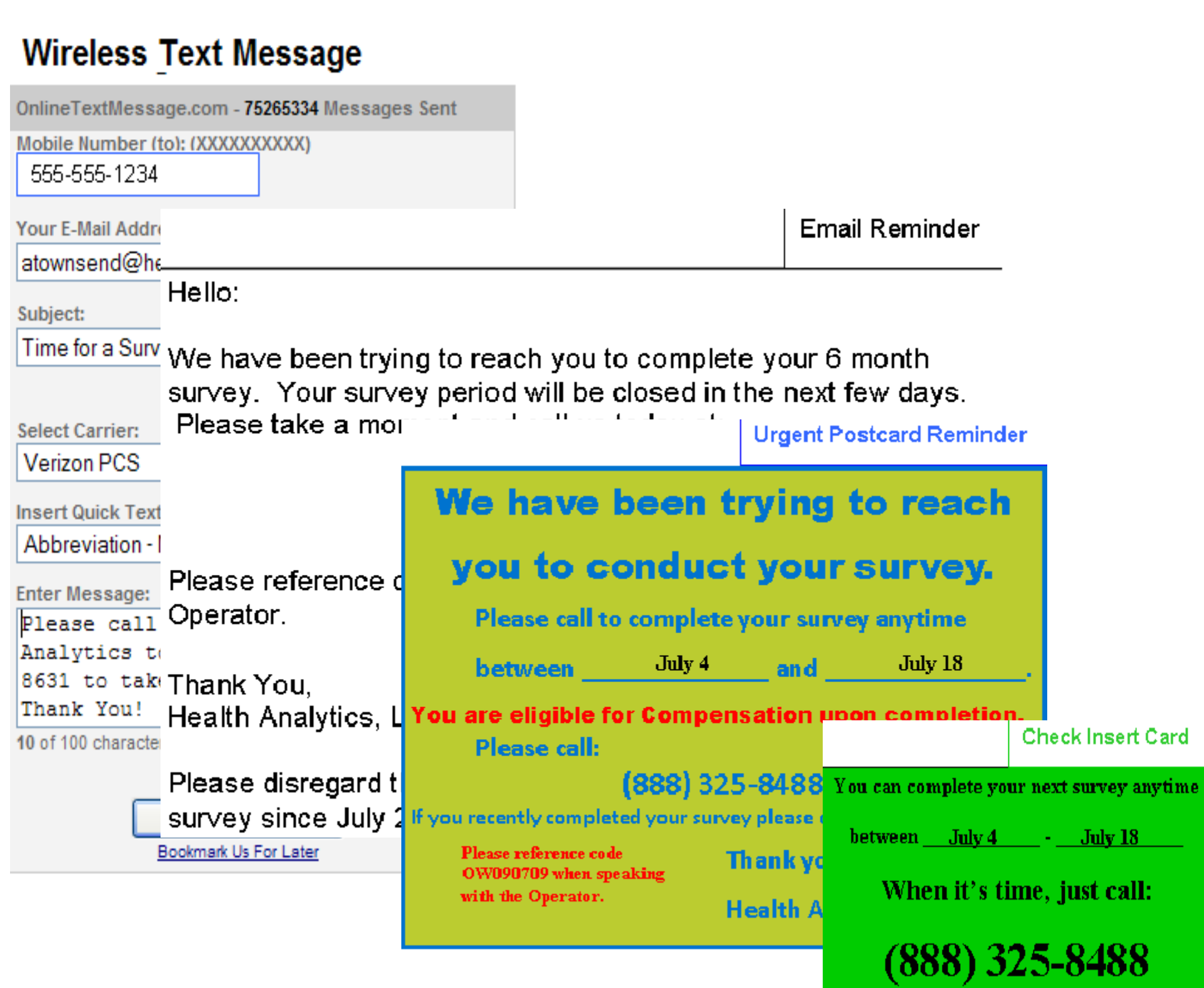
### Physician Recruitment

- Target population of active Buprenorphine-waivered physicians (SAMHSA published list; n = 10,000)
  - identify appropriate physicians
  - must treat  $\geq 5$  OD patients per month
- Bi-weekly enrollment progress report sent to each physician's office

### Subject Recruitment

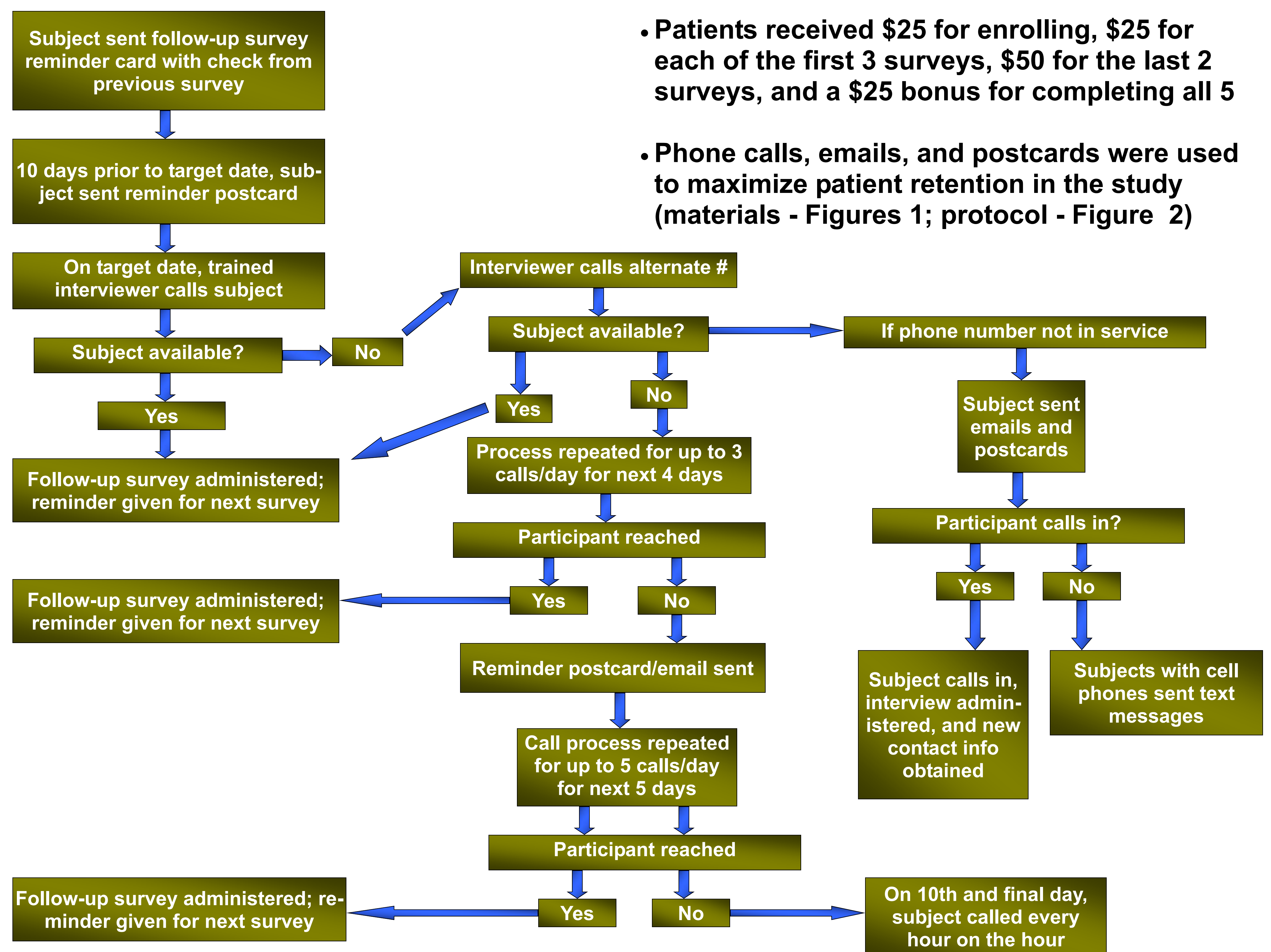
- Physicians recruit OD patients new to Buprenorphine
  - present idea
  - review cost/benefit
  - gauge interest
  - present study information
- Interested patients enrolled via the web

Figure 1. Patient Retention Materials



## Methods

Figure 2. Follow-up Survey Collection



- Surveys were collected at baseline, and at 1, 2, 3, and 6 month post-baseline
- Patients received \$25 for enrolling, \$25 for each of the first 3 surveys, \$50 for the last 2 surveys, and a \$25 bonus for completing all 5
- Phone calls, emails, and postcards were used to maximize patient retention in the study (materials - Figures 1; protocol - Figure 2)

## Results

- A total of 470 physicians in 40 states were contracted and trained for participation in the study
- A total of n = 2,194 Buprenorphine patients were recruited between 10/6/08- 2/10/09
- Of those who were eligible and enrolled, n = 1599 completed a baseline assessment, which comprised the study sample
- Nearly 90% of the sample was recruited between Nov '08 - Feb '09, with a near 70% follow-up survey capture rate (Figure 3)
- A total of 631 subjects completed all 5 surveys (Figure 4)
- Approximately 50% of the 6 month surveys were collected within 10 calls (Figure 5)

Figure 3. Follow-Up Survey Completion Rate

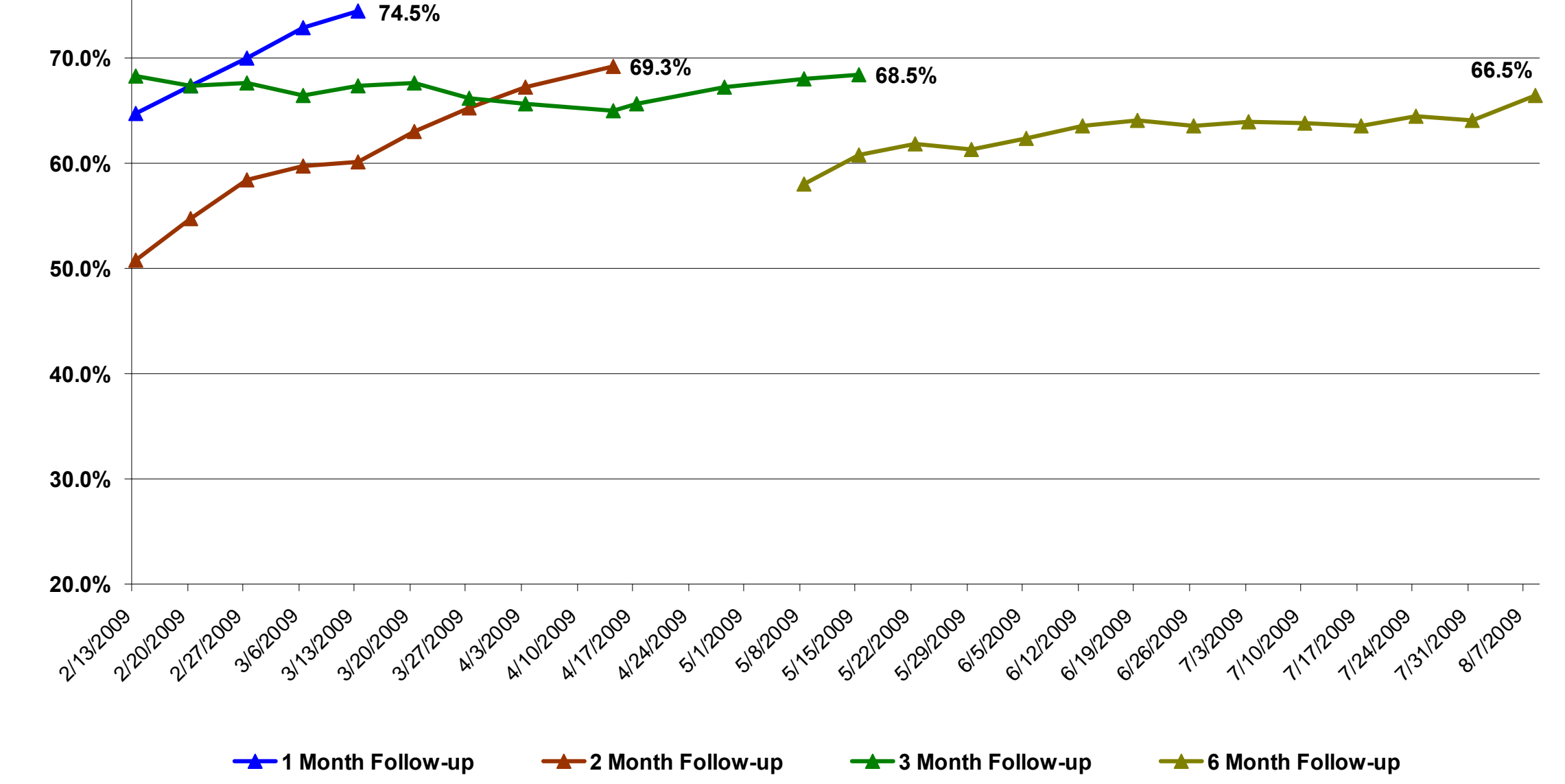


Figure 4. Survey Completion Results

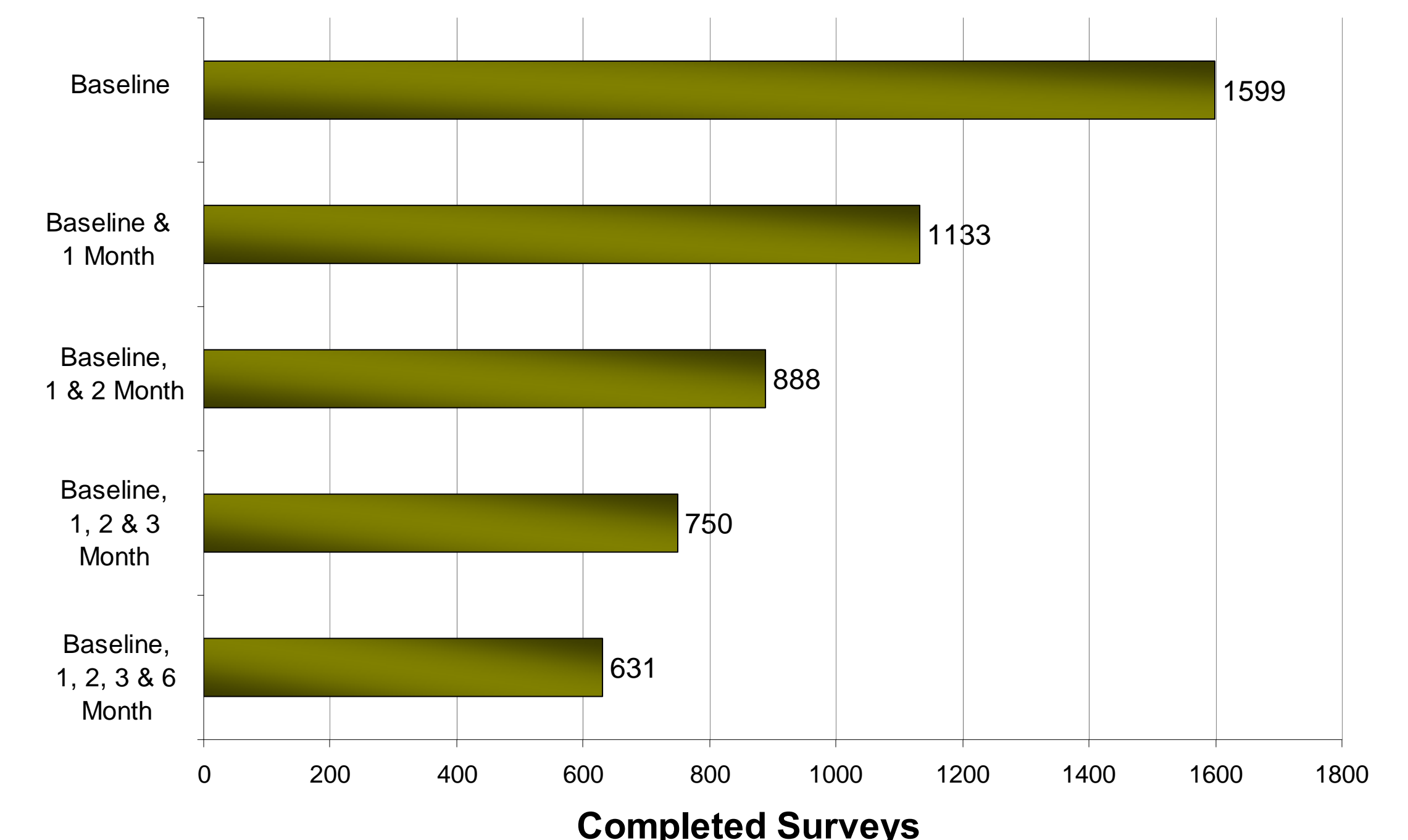
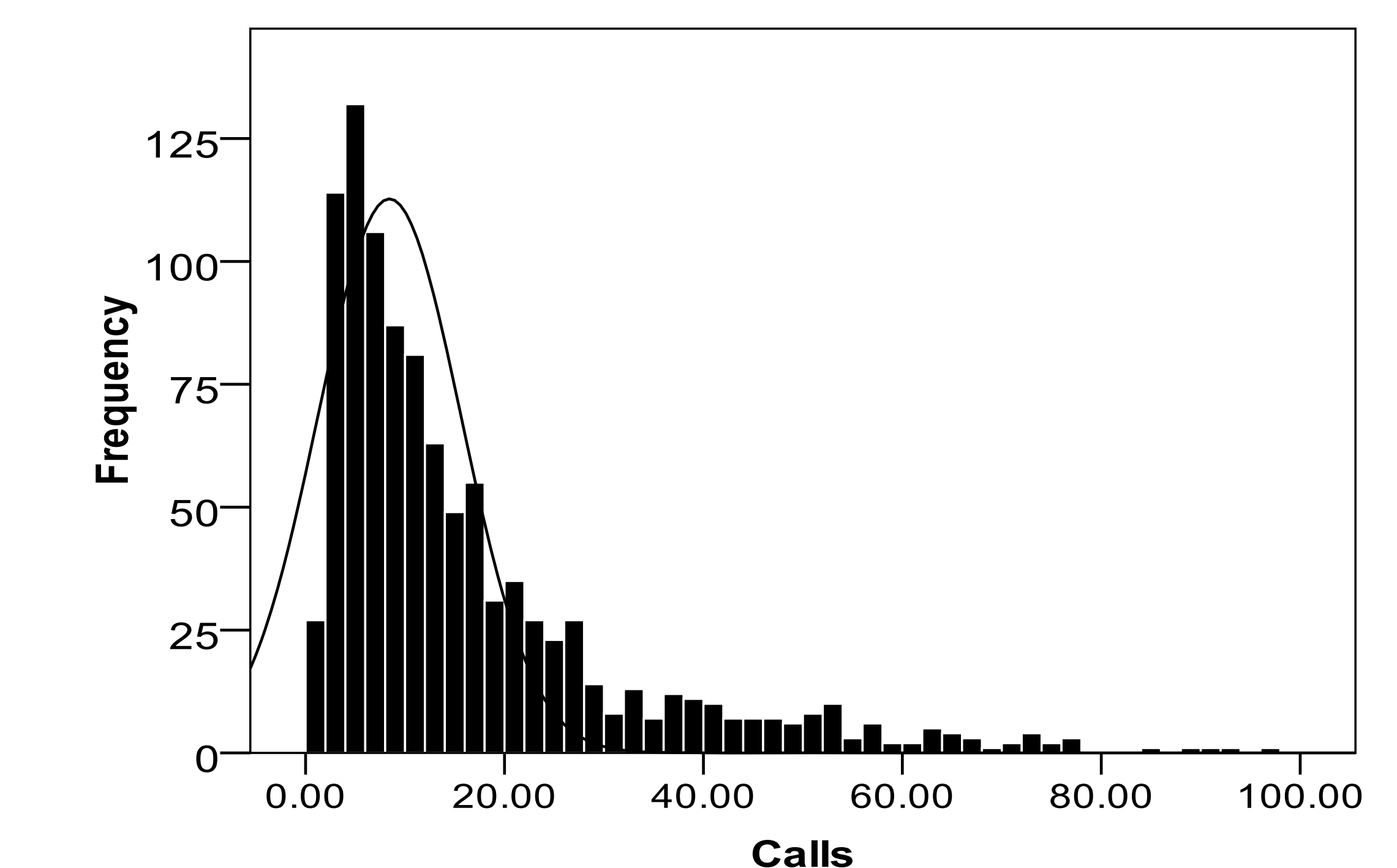


Figure 5. Calls Attempts for 6 Month Data



## Conclusions

- Collecting self-reported outcomes data from a sample of opioid dependent patients who are new to Buprenorphine in the U.S. presented several challenges
- Internet-based sample recruitment and data collection tools have shown to be time and cost efficient in survey research (East et al., 2008; Katz et al., 2008)
- In the present study, n = 2,194 opioid dependent patients were enrolled within a 5 month window, clearly demonstrating the effectiveness of combination recruitment methods employing doctors and the web
- Future studies should test similar web-based methods on other clinical samples

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