

Does recommending to resubmit really enhance the quality of SBIR/STTR applications?

Victor Prikhodko, MBA; Tamara Slipchenko, PhD; Irina Sazonova, PhD; Elena Koustova, PhD, MBA
Office of Translational Initiatives and Program Innovations (OTIPI), National Institute on Drug Abuse (NIDA), NIH, Rockville, MD

Rationale and Objectives

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are the largest sources of early-stage capital for small business concerns (SBC) in the US. In FY 2016, NIH's SBIR/STTR programs invested \$870M into life science companies that are creating innovative technologies that align with NIH's mission to enhance health, lengthen life, and reduce illness and disability. A key objective of this work is enabling life-saving innovations to reach the consumer market.

NIDA allocates approximately \$36M/Y to the SBIR /STTR programs. The program support for SBCs attempting to commercialize their product is quite different from the assistance to the academic applicants typically provided by program staff. Writing and submitting the grant applications is not a core capability and function of the SBCs.

Due to a limited number of employees (n=3, on average) and little administrative and institutional support, which is common for academicians, SBCs do not fare well in the review process. The poor grantsmanship contributes to poor peer-review outcomes, including inadequate priority scores and high percentage of non-discussed applications. For NIDA, the percentage of non-discussed applications is reported to be as high as 62% (Fig.1). To improve the priority score, resubmission of the application is often advised.

The time lag between the SBIR/STTR grant submission and the possible award is 9-12 months. Awaiting the results of the grant application resubmission for many SBCs is literally the question of life and death. Thus, we conducted the analysis to inform NIDA SBIR/STTR program staff on whether to encourage the resubmission (A1) or fund the original scored application (A0) with the goal of providing a thorough pre- and post-funding programmatic oversight.

Materials and Methods

We conducted a retrospective analysis of new, resubmitted, and unscored SBIR/STTR grant applications submitted for review in FY 2010-2015. We identified n=513 original (A0) and n=106 resubmitted (A1) applications. Application data were extracted from QVR database. Analysis was performed using SAS 9.4 for Windows and MS Excel 2010.

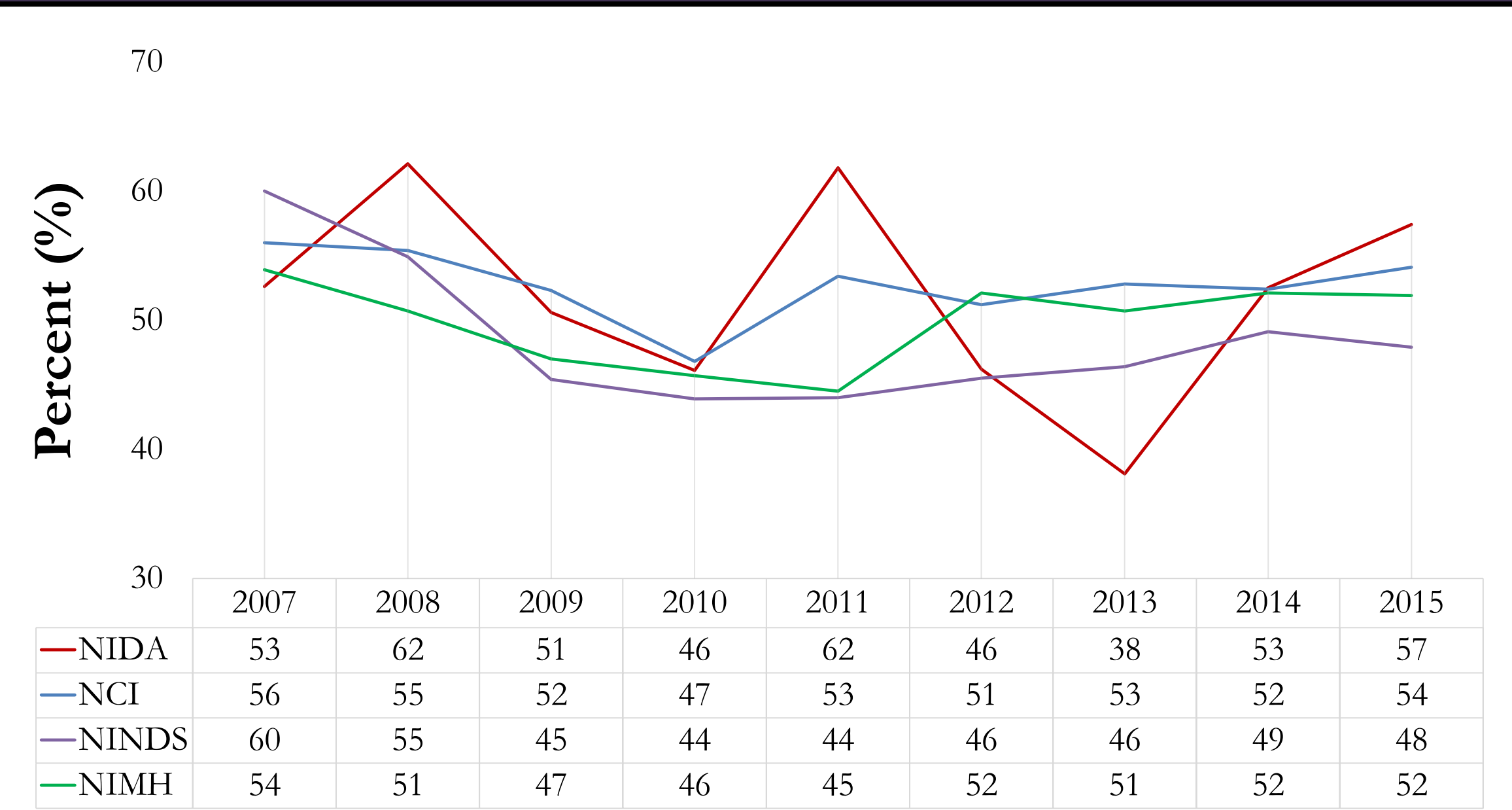
Study Questions

- Q1: Do we lose SBC-applicants in the resubmission process? How many SBCs with unscored applications resubmit?
- Q2: Is there an improvement in priority score after resubmission?
- Q3: How many A0 SBCs would get unscored A1?

Analysis

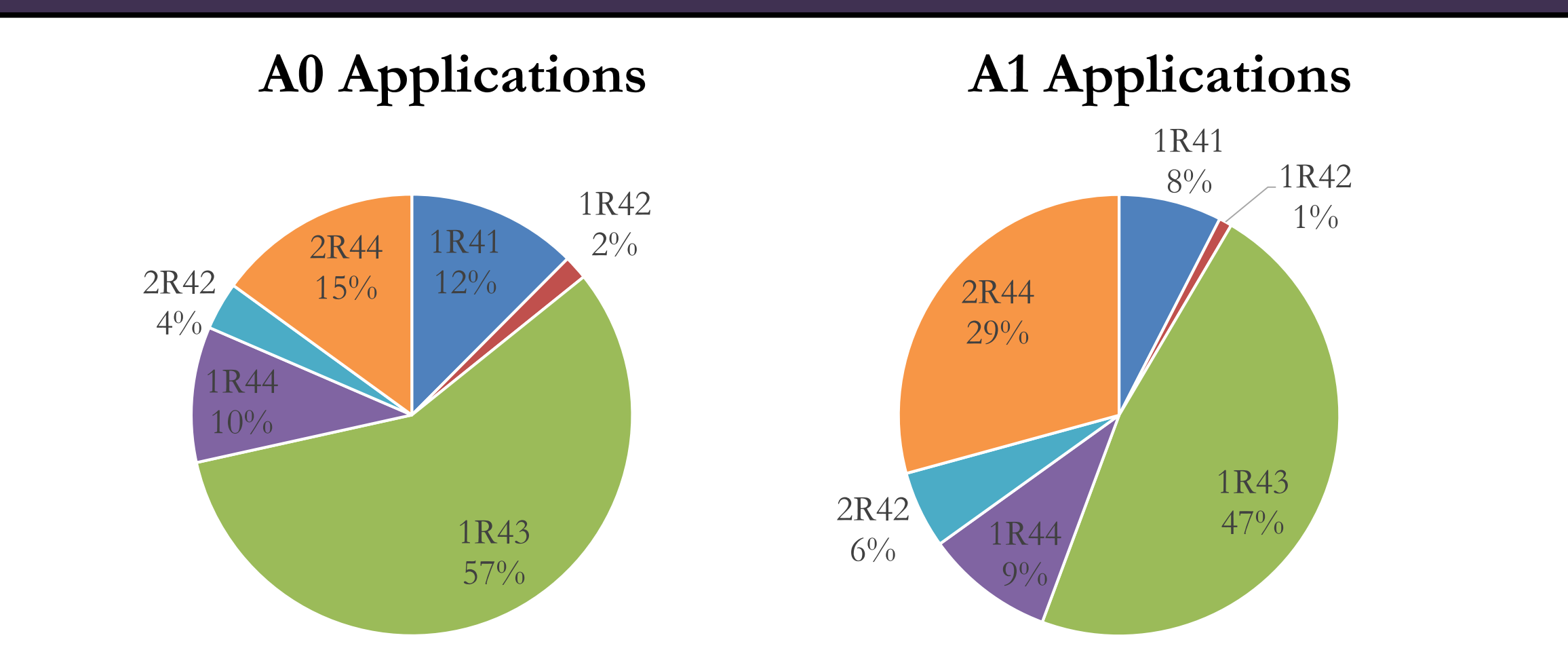
- Analyzed changes in individual Priority Scores (PS) after resubmission for n=106 applications with paired scores (Fig. 3)
- Calculated difference in mean PS for Scored applications only (n=46) using both parametric paired t-test and non-parametric Wilcoxon Sign Rank test ¹.
- Calculated outcomes for each step of review process for all applications (n=513), grouped by funding mechanism (Fig. 4)
- Calculated success after resubmission for SBIR Phase I (Fig. 5) and Phase II (Fig. 6) applications. We tested for differences in success using two-sided proportion test.

Figure 1. Not Discussed (ND) rate (%) for NIDA, NCI, NINDS, and NIMH 1R43 applications by FY, 2007-2015



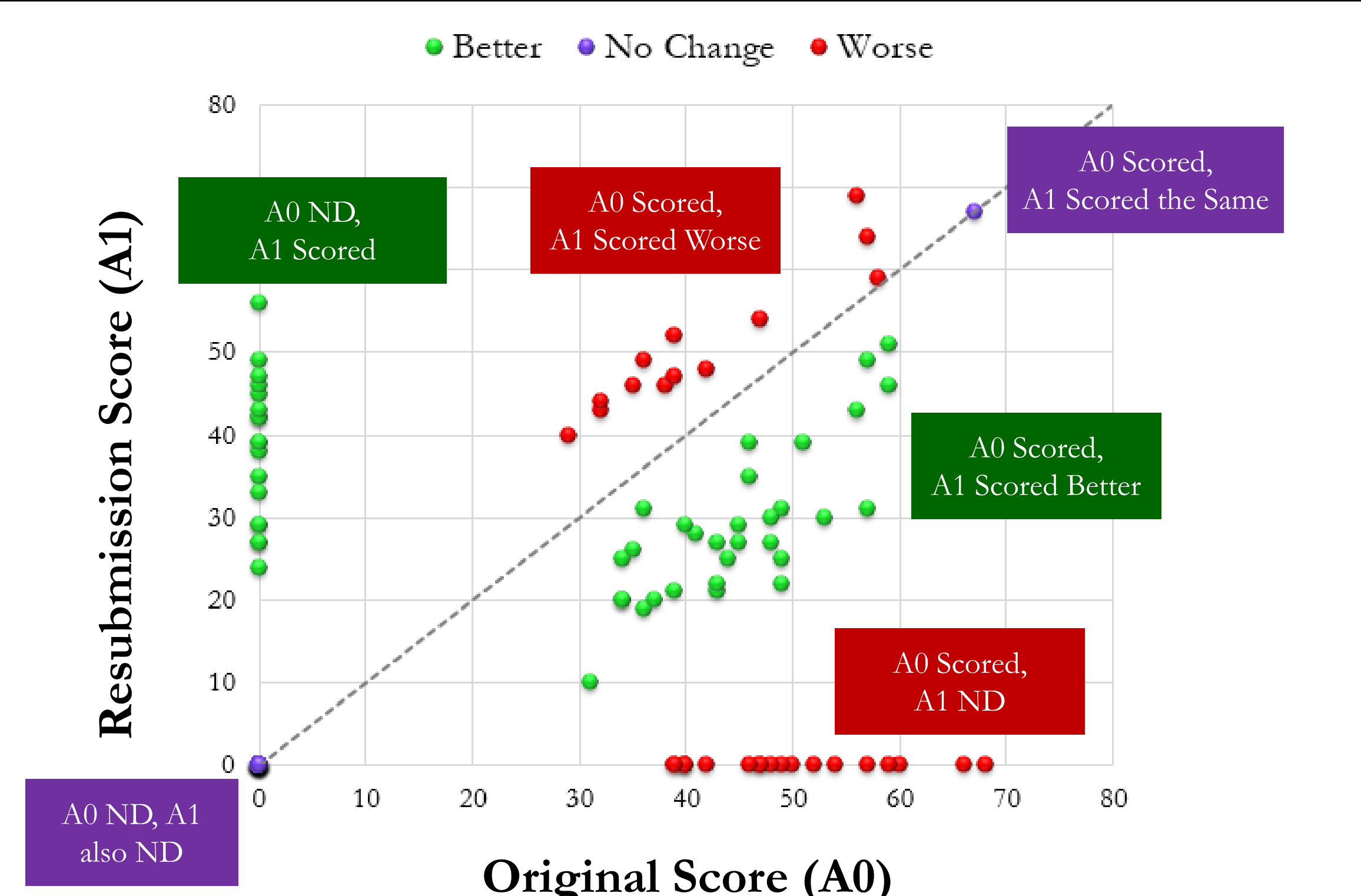
NIDA has an extremely volatile Not-Discussed rate for 1R43 applications compared to other NIH Institutes. From 2007 through 2015, the high for ND rate was 62%, with a 9Y average of 52%.

Figure 2. Percent (%) Original A0 (n=513) and Resubmitted A1 (n=106) NIDA SBIR/STTR Applications by Funding Mechanism.



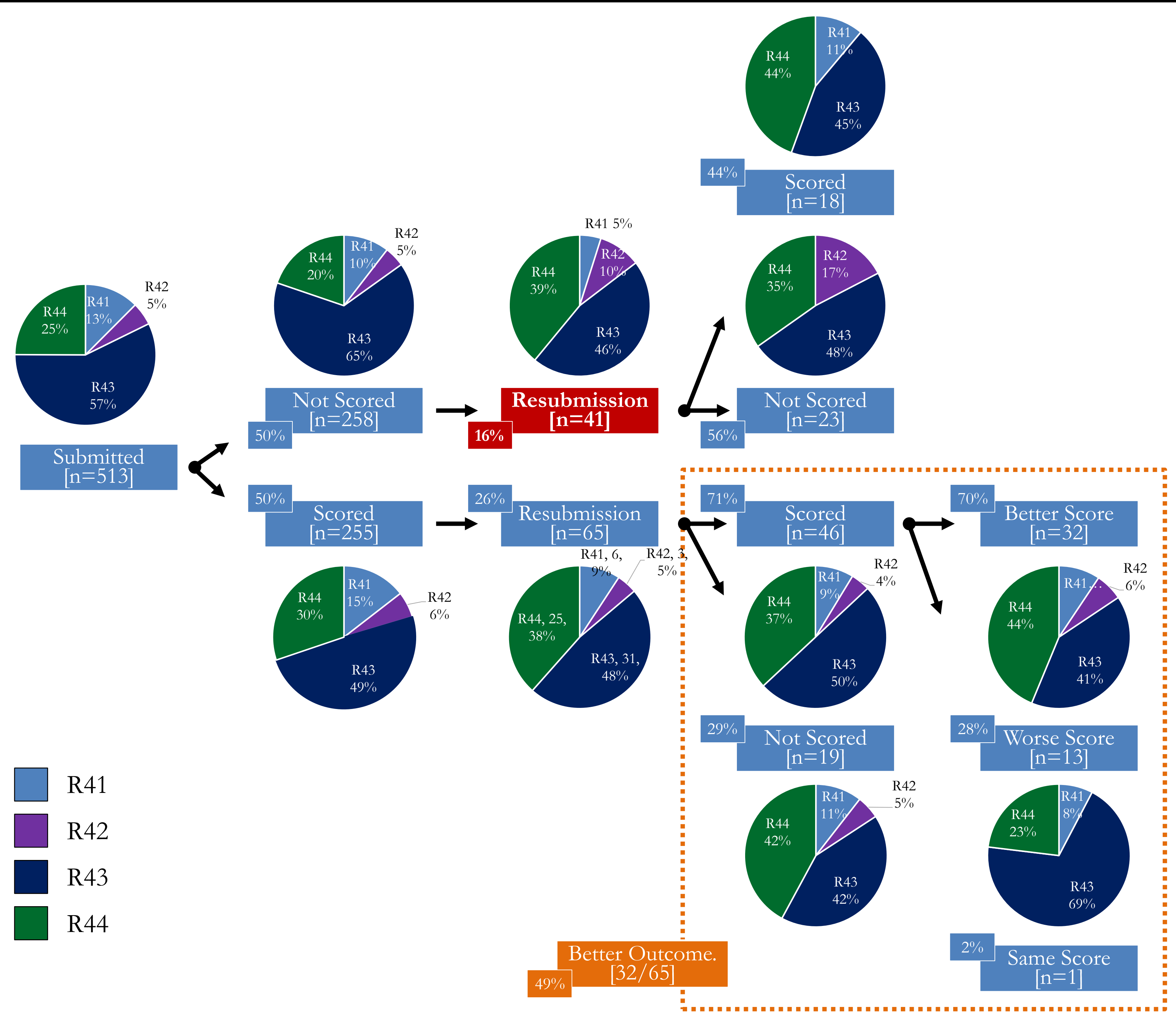
N=513 original and n=106 (21%) resubmission NIDA SBIR/STTR applications were submitted between 2010 and 2015. 1R43 and 2R44 comprised of the SBIR/STTR portfolio, 72% of A0 and 76% of A1 applications.

Figure 3. Changes in Priority Scores (PS) after resubmission for n=106 NIDA SBIR/STTR applications, FY 2010-2015



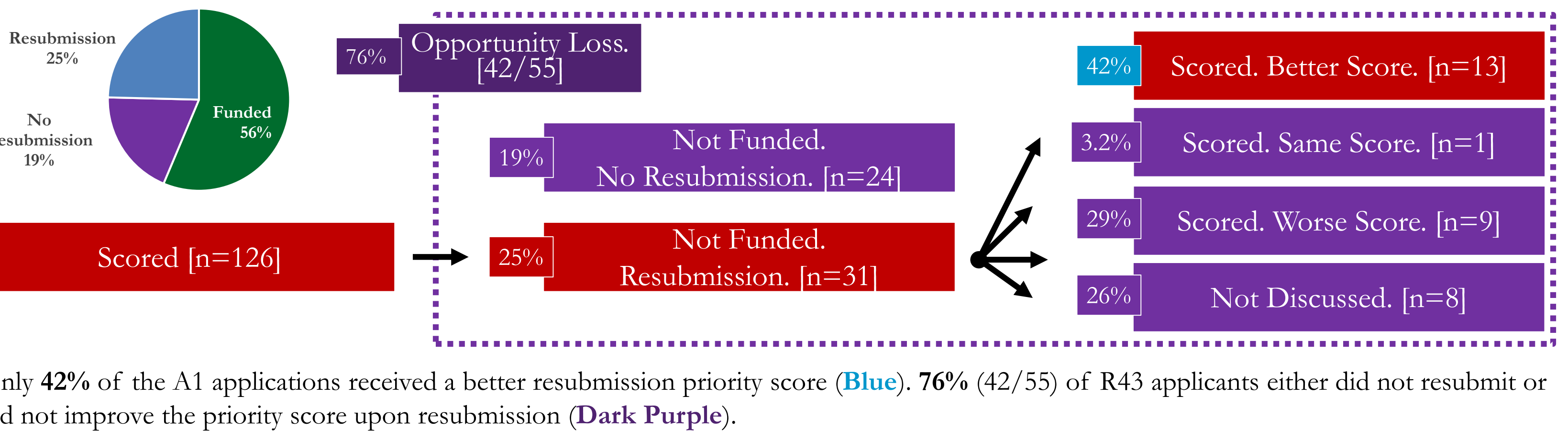
Individual resubmission outcomes were mixed. Each dot represents an individual application with paired scores (n=106). X-axis: Original (A0), Y-axis: Resubmission (A1) score. Each dot is colored by outcome: Better (n=50), Worse (n=32), No Change (n=24). Mean priority score improved by 9 points after resubmission.

Figure 4. NIDA SBIR/STTR A0 and A1 applications transition rates



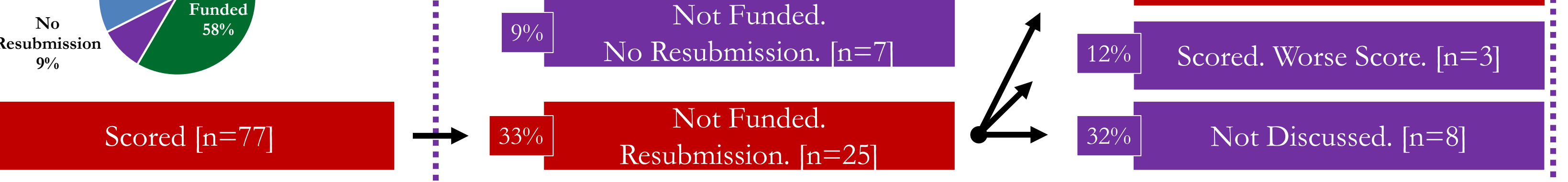
Only 16% (41/258) of companies whose original application were Not Discussed, resubmitted their application (Red). Of the 65 originally scored A0 applications that were initially discussed, only 49% (32/65) received a better score than the original application (Orange).

Figure 5. Decreased probability of A1 success for R43 applications



Only 42% of the A1 applications received a better resubmission priority score (Blue). 76% (42/55) of R43 applicants either did not resubmit or did not improve the priority score upon resubmission (Dark Purple).

Figure 6. Decreased probability of A1 success for R44 applications



56% of the A1 applications received a better resubmission priority score (Blue). However, similar to R43 applications, majority of R44 applicants (56%) also did not resubmit or did not improve the priority score upon resubmission (Dark Purple).

Results

I. Not Discussed Rate for NIDA: From 2007 through 2015, NIDA's Not-Discussed rate for 1R43 applications ranged from 38% to 62% (Fig.1).

II. Study Population and Sample: **Study population:** Included n= 513 original (A0) and n=106 resubmitted (A1) NIDA SBIR/STTR FY 2010-2015 applications. Overall resubmission rate was 106/513=21%. Majority of original (72%) and resubmitted (76%) applications were 1R43 and 2R44 (Fig.2).

III. Changes in Priority Scores (PS) after resubmission **Individual scores:** Resubmission outcomes varied: 47% of A1 applications received better, 30% worse and 23% did not have a PS change (Fig.3).

Difference in Mean PS: Mean (STD) PS was: A0=45 (+/-10), range: 29 to 70; A1=36 (+/-14), range: 10 to 69. Overall, resubmission improved (lowered) PS by a mean of 9 points (95% CI: 5 to 13; t-test P<0.001; signed rank P<0.001) for n=46 scored applications (A0>0 and A1>0).

IV. Application Outcome: Decision Tree Only 16% of applicants whose initial application was Not Discussed, resubmit their application [n=41]. 44% of the resubmitted applications were discussed [n=18] (Fig.4). Of the 65 resubmitted applications which were initially Discussed, 49% (32/65) had better resubmission outcome (Fig.4).

IV. R43 and R44 Probability of A1 Application Success Post A0=1 76% of Discussed R43 applications [n=42] that were not funded, did not resubmit or did not improve their review score. Only 42% of R43 A1 applications [n=13] that were resubmitted, received a better review score (Fig.5). Similarly, 56% [n=18] of Discussed R44 applications that were not funded, did not resubmit or did not improve their review score (Fig.6).

Conclusions

- The resubmission process improved the priority score of NIDA SBIR/STTR applications by a mean of 9 points (95% CI: 5 to 13; P<0.001). However, individual resubmission outcomes varied, with less than half (50/106=47%) of A1 applications getting better scores.
- Only 16% of SBIR/STTR applicants, whose initial application was Not Discussed resubmit their application. This is an opportunity for NIDA to expand its portfolio by actively engaging with the SBCs post review, helping in addressing the review comments and encouraging the SBC to resubmit.
- Applicants with the originally scored A0s that were advised to resubmit, 76% (42/55) of R43 and 56% (18/32) of R44 applicants either did not resubmit or did not improve the priority score upon resubmission.
- Our result revealed that advice to resubmit merits thorough consideration. Program staff should be cognizant that the probability of not resubmitting, or not improving the priority score is high for small businesses working in NIDA mission space. Overall, the results provide the evidence for the informed risk-benefit assessment of the potential funding.

Limitations

- Impact of funding is based upon submission cycle.
- Applicants' communication with NIDA program before submission or resubmission of an application was not factored into the analysis. How well companies addressed reviewer's feedback in A0 applications was not evaluated.
- A larger study is needed to obtain more precise estimates (narrower confidence intervals) around the difference in priority scores
- SBIR/STTR resubmission success is NIDA portfolio specific