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Zero-Inflated and Hurdle Models of Count Data with Extra Zeros: Examples from an HIV-Risk Reduction Intervention Trial

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Background: **In clinical trials of behavioral health interventions, outcome variables often take the form of counts, such as days using substances or episodes of unprotected sex. Classically, count data follow a Poisson distribution; however, in practice such data often display greater heterogeneity in the form of excess zeros (zero-inflation) or greater spread in the values (overdispersion) or both. Greater sample heterogeneity may be especially common in community-based effectiveness trials, where broad eligibility criteria are implemented to achieve a generalizable sample.** ***Objectives:*** **This article reviews the characteristics of Poisson model and the related models that have been developed to handle overdispersion (negative binomial (NB) model) or zero-inflation (zero-inflated Poisson (ZIP) and Poisson hurdle (PH) models) or both (zero-inflated negative binomial (ZINB) and negative binomial hurdle (NBH) models).** ***Methods:*** **All six models were used to model the effect of an HIV-risk reduction intervention on the count of unprotected sexual occasions (USOs), using data from a previously completed clinical trial among female patients (N = 515) participating in community-based substance abuse treatment (Tross et al. Effectiveness of HIV/AIDS sexual risk reduction groups for women in substance abuse treatment programs: Results of NIDA Clinical Trials Network Trial. J Acquir Immune Defic Syndr 2008; 48(5):581–589). Goodness of fit and the estimates of treatment effect derived from each model were compared.** ***Results:*** **The ZINB model provided the best fit, yielding a medium-sized effect of intervention.** ***Conclusions and Scientific Significance:*** **This article illustrates the consequences of applying models with different distribution assumptions on the data. If a model used does not closely fit the shape of the data distribution, the estimate of the effect of the intervention may be biased, either over- or underestimating the intervention effect.**

Keywords: overdispersion, extra zeros, Poisson, negative binomial, hurdle model

INTRODUCTION

In controlled clinical trials, outcome variables often take the form of integers or counts, such as number of symptoms or number of risk behaviors during some defined time period (e.g., episodes of drug use, episodes of risky sex per month). Generally, these are not normally distributed. Ordinary least squares models, of which *t*-tests, ANOVA and ANCOVA are special cases, assume that the outcome is normally distributed and may yield a biased estimate of the effect of a treatment (and of other factors) if that assumption is violated. This means, in practical terms, that the size of the effect of treatment and its statistical significance are either over- or underestimated, neither of which is good.

The last several decades have therefore seen the growing availability in standard statistical packages of parametric models (i.e., Mplus, R, SAS, Splus, Stata) for nonnormally distributed data, including Poisson, negative binomial (NB), zero-inflated negative binomial (ZINB), and negative binomial hurdle (NBH) models. These models have all the flexibility and power of parametric models, handling repeated measures, multiple covariates, and various configurations of fixed and random effects, while assuming that the outcome is different than that of the normal distribution (Poisson, NB, etc.). Previous reports have compared Poisson, NB, ZINB, and NBH models applied to various outcomes, including the counts of adverse events related to a vaccine (1), hospital stays (2,3), and traffic accidents (4). The purpose of this article is to illustrate the differences between these distributions and models and to explore how to compare different models using data from a multisite clinical trial of behavioral interventions to reduce episodes of HIV-risk behavior (CTN-0019) conducted through the National Institute on Drug Abuse Clinical Trials Network (5).

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Poisson, Negative Binomial, Zero-Inflated, and Hurdle Models

The shape of distribution of data appropriate for the Poisson, zero-inflated Poisson (ZIP), and Poisson hurdle (PH) models are illustrated in Figure 1. Data appropriate for the NB, ZINB, and NBH models are distributed similarly as the distribution of the three corresponding models with Poisson distribution in Figure 1 with extreme values spread further away from 0.

Poisson Distribution

The number of events occurring in a fixed period of time by definition follows the Poisson distribution. The classic example of such a distribution is a count. When the mean count is low, then the data consist of mostly low values (e.g., counts of 0, 1, 2) and less frequently higher values (illustrated by a long right tail). As the mean count increases, the skewness diminishes, and the distribution becomes approximately normal. For nonnegative count outcomes, a model with Poisson distribution is much more appropriate than an ordinary least squares linear model (6).

Overdispersion and Zero-Inflation

Unlike the normal distribution, the variance of a Poisson random variable depends on the mean, with the mean equal to the variance. Count data frequently depart from the Poisson distribution due to a larger frequency of extreme observations resulting in spread (variance) greater than the mean in the observed distribution. This is called "overdispersion."

In practice, the distribution of counts, such as episodes of substance use or other risk behaviors, often has a much larger than expected number of observed zeros than that assumed by Poisson distribution, called "zero-inflated." For instance, many patients may already be abstaining or not having unprotected sexual occasions (USOs). This may be particularly common in effectiveness trials, where the effort is to maximize generalizability of the study by minimizing exclusionary criteria that might otherwise put a floor on the severity of problems at baseline.

Negative Binomial Distribution

The NB distribution is an alternative to the Poisson model (6,7) and is especially useful for count data whose sample variance exceeds the sample mean (i.e., data with overdispersion). The NB distribution looks superficially similar to the Poisson but with a longer, fatter tail to the extent that the variance exceeds the mean. If the observed outcome is suspected to have variance larger than the mean, the NB distribution of the outcome is more appropriate than either the Poisson or normal distributions.

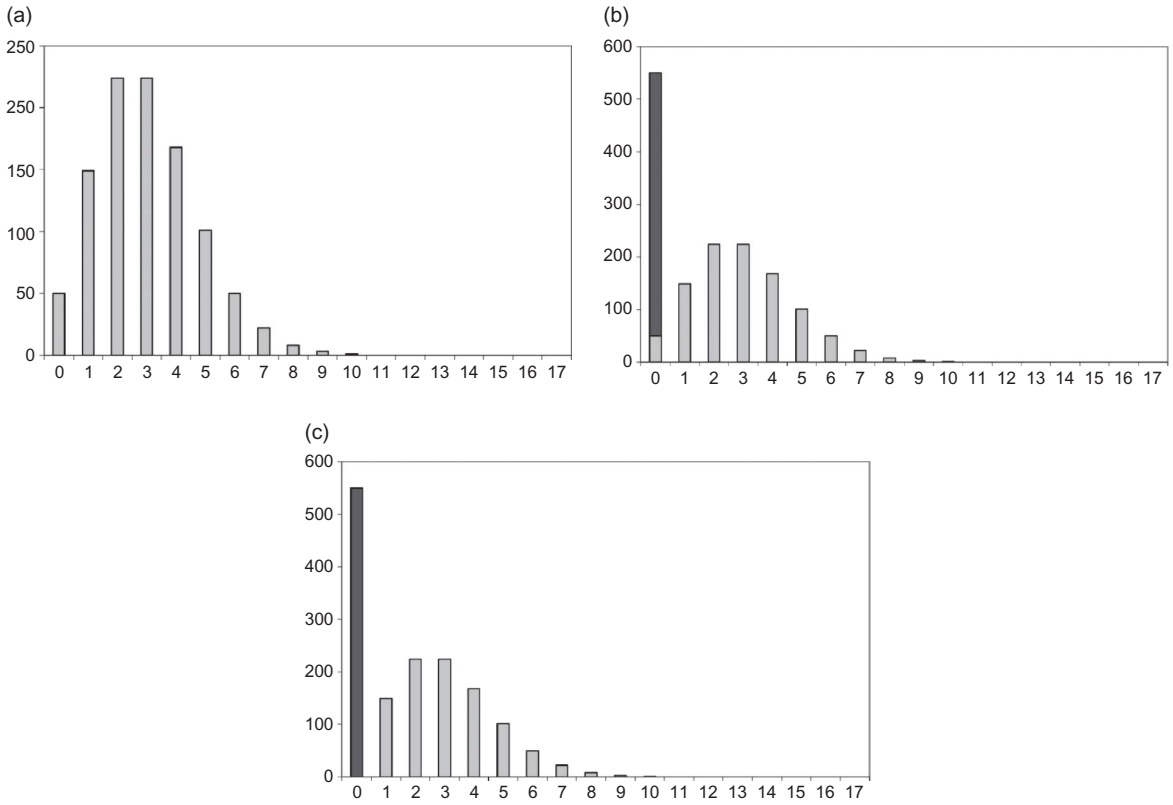


FIGURE 1. Example of models with Poisson distribution. (a) Data appropriate for Poisson model ($n = 1000$, mean = 3, variance = 3). (b) Data appropriate for ZIP model ($n = 1500$, with 500 "structural" and 50 "sampling" zeros). (c) Data appropriate for PH model ($n = 1500$, with 550 "structural" and no "sampling" zeros).

Notes: Three models with the NB distribution were not shown because they would appear similar to the corresponding models with Poisson distribution and would be hard to distinguish visually from the Poisson distribution. NB, negative binomial; ZIP, zero-inflated Poisson; PH, Poisson hurdle.

Zero-Inflated and Hurdle Models

Zero-inflated (8) and "hurdle" (7) models (each assuming either the Poisson or NB distribution of the outcome) have been developed to cope with zero-inflated outcome data with overdispersion (NB) or without (Poisson distribution) (see Figure 1b and 1c). Both (zero-inflated and hurdle) models deal with the high occurrence of zeros in the observed data but have one important distinction in how they interpret and analyze zero counts.

A *zero-inflated model* assumes that the zero observations have two different origins: "structural" and "sampling." Figure 1b shows a ZIP model with the zero observations split due to their structural (dark gray portion of the zero bar called "structural zeros") or sampling origin (light gray portion of the zero bar called "sampling zeros"). The sampling zeros are due to the usual Poisson (or NB) distribution, which assumes that those zero observations happened by chance. Zero-inflated models assume that some zeros are observed due to some specific structure in the data. For example, if a count of high-risk sexual behaviors is the outcome, some participants may score zero because they do not have a sexual partner; these are the structural zeros since they cannot exhibit unprotected sexual behavior. Other participants have sexual partners but score zero because they have eliminated their high-risk behavior. That is, their risk behavior is assumed to be on a Poisson or NB distribution that includes both zero (the "sampling zeros") and nonzero counts.

In contrast, a *hurdle model* (see Figure 1c for illustration of a PH) assumes that *all* zero data are from one "structural" source. The positive (i.e., nonzero) data have "sampling" origin, following either truncated Poisson (Figure 1c) or truncated NB distribution (7). For example, consider a study of cocaine users in which a secondary outcome is a number of tobacco cigarettes smoked during last month. In this case, it is safe to assume that only nonsmokers will smoke zero cigarettes during the last month and smokers will score some positive (nonzero) number of cigarettes during last month. Hence, the zero observations can come from only one "structural" source, the nonsmokers. If a subject is considered a smoker, they do not have the "ability" to score zero cigarettes smoked during the last month and will always score a positive number of cigarettes in a hurdle model with either truncated Poisson or truncated NB distributions.

The distinction between structural and sampling zeros, and hence between zero-inflated and hurdle models, may seem subtle. However, one or the other models may be more appropriate depending on the nature of the experimental design and the outcome data being observed (1). The different models can yield different results with very different interpretations.

METHODS

Participants

Data were drawn from a national, multisite randomized clinical trial (CTN-0019) conducted through the National Institute on Drug Abuse Clinical Trials Network to test the effectiveness of a five-session safer Sex Skills Building (SSB) group intervention compared against a one-session standard HIV education (HE) intervention. Details of the methods and the primary outcome analysis have been previously published (5). The participants were 515 women recruited from community-based drug treatment programs who met eligibility criteria for being at heightened risk for HIV/STI heterosexual transmission, defined as having at least one unprotected occasion with a male partner in the prior 6 months.

Measurement

Primary Outcome

The primary outcome was the number of USOs with male partner(s) in the 3 months prior to each assessment. Sexual risk behaviors were collected via an audio computer-assisted self-interview (ACASI) format version of the Sexual Experiences and Risk Behavior Assessment Schedule (SERBAS; 9).

Treatment

The SSB intervention in an HIV prevention program for women was previously demonstrated to be effective by Exner, Seal, and Ehrhardt (10). The SSB intervention consists of five group sessions cultivating HIV-risk assessment, problem-solving to overcome obstacles to safer sex, condom use, negotiation skills, and assertiveness. The HE control intervention consists of one 60-minute informational group session designed to simulate standard HIV prevention offered within substance abuse treatment programs.

Data Analysis

Poisson, NB, ZIP, ZINB, PH, and NBH models were each fitted into the data with mixed-effects modeling (MEM), using PROC NLMIXED in SAS 9.2 (SAS Institute Inc., Cary, NC, USA; 11) on the intent-to-treat sample of all randomized participants. The dependent variable was the count of USOs, measured at 3- and 6-month follow-up points. Independent variables were the intervention condition (SSB vs. HE), time (assumed to be categorical variable), count of USOs at baseline, and age. Because other demographic variables, such as racial/ethnic group, education, and marital status, were not significantly associated with the outcome variable in the primary outcome paper (5), they were not included in this analysis. The interaction of time-by-treatment was included in all the models. Missing outcomes were assumed to be missing at random, while random effects estimated within-subject correlation from repeated measurements (12,13).

Various statistical tests were applied to evaluate overdispersion and compare model fit. Overdispersion in the Poisson regression was tested by the Lagrange multiplier statistic (14). For NB models, the dispersion parameters were tested for difference from zero with *t*-statistics. To compare the goodness of fit between pairs of models, likelihood ratio (LR) tests (for full and nested models),

Akaike's information criterion (AIC; for nonnested models) (15,16), and Vuong statistics (for nonnested models) (17) were calculated.

RESULTS

Of the 515 randomized patients, 250 were assigned to safer SSB and 265 to the HE control condition. At baseline, the average number of USOs in the past 3 months was 18.6 (SD = 27.8, range = 0–191) for SSB and 20.0 (SD = 33.4, range = 0–325) for HE. As previously reported (5), neither the covariates nor the follow-up rates differed by treatment group.

The observed mean and variance in the number of USOs across all participants and time points were 13.6 and 744.6, respectively. The observed variance to mean ratio is 54.8, clearly indicating overdispersion. After controlling for covariates (treatment, time, age, baseline USO, interaction between time and treatment) in the Poisson model, the Lagrange multiplier remained highly significant ($\chi^2 = 8753.6$, df = 1, $p < .0001$), suggesting overdispersion.

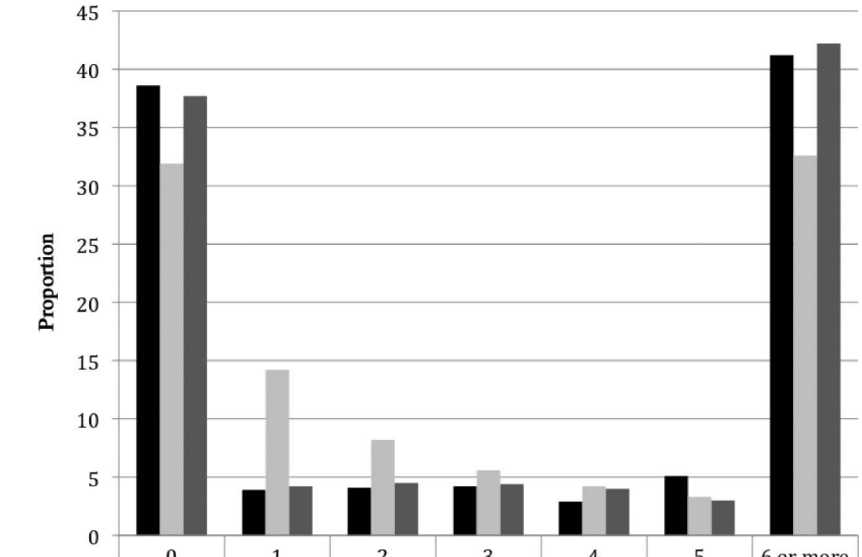
To explore zero-inflation in the outcome data, we first examined the observed distribution of the count of USO (see Figure 2). On inspection, the NB model appears to underestimate zero counts, overestimate counts of 1–3, and underestimate counts in the higher ranges of 6 or more. In contrast, the ZINB model fits the data closely in terms of the higher count of zeros and the greater dispersion of nonzero values.

Table 1 summarizes the statistics comparing the goodness of fit of the models. The LR was used in χ^2 tests to compare pairs of full and nested models (i.e., NB vs. Poisson, ZINB vs. ZIP, and NBH vs. PH); the differences in AIC and Vuong statistics were computed for all pairs of nonnested models (i.e., PH vs. NB, NBH vs. ZINB). Significant values of χ^2 LR test (always positive) suggest that the model in the column fits the observed USO data significantly better than the model in the row. Positive differences in AIC and Vuong statistics suggest that the model in the column fits better than the model in the row. Negative differences mean that the model in the row fits better than the model in the column. Stars denote significance of one model better fitting over another.

Two main patterns emerge from Table 1:

(i) The ZINB model shows superior fit compared to the other models, with all positive numbers in its row and all negatives in its column; the Poisson distribution is inferior to the other models as shown by all negative numbers in its row and all positives in its column; and zero-inflated models fit better than their corresponding nonzero inflated counterparts; this suggests that the best-fitting model needs to account for both overdispersion and zero-inflation in the observed data.
(ii) Based on the AIC and Vuong tests, the ZIP and ZINB models fit better than their corresponding PH and NBH models; this suggests that the zero counts were best modeled as being due to both structural and sampling zeroes, not only from structural zeroes as in the hurdle models.

Tables 2–4 show the parameter estimates for independent predictors: treatment, time, the time-by-treatment interaction, and other covariates. For the zero-inflated and hurdle



	0	1	2	3	4	5	6 or more
Observed	38.6	3.9	4.1	4.2	2.9	5.1	41.2
NB	31.9	14.2	8.2	5.6	4.2	3.3	32.6
ZINB	37.7	4.2	4.5	4.4	4	3	42.2

FIGURE 2. Observed and modeled distribution of the count of USOs in a clinical trial of an HIV-risk reduction intervention, according to NB and ZINB models.
Note: USO, unprotected sexual occasion; NB, negative binomial; ZINB, zero-inflated negative binomial.

TABLE 1. Criteria for evaluating goodness of fit and model selection among six different models.

	Differences in fit statistics	Poisson	NB	ZIP	ZINB	PH	NBH
Poisson	χ^2 (LR)	–	1825.2**				
	AIC			880.6	1956.3	758.1	1873.6
	Vuong			4.25**	5.09**	2.61*	3.32**
NB	χ^2 (LR)		–				
	AIC			−942.6	133.1	−1065.1	50.4
	Vuong			−1.31	18.49**	−2.58*	−5.90**
ZIP	χ^2 (LR)			–	1075.7**		
	AIC					−122.5	993
	Vuong					−10.43**	.66
ZINB	χ^2 (LR)				–		
	AIC					−1198.2	−82.7
	Vuong					−4.22**	−27.27**
PH	χ^2 (LR)					–	1117.5**

Notes: Table 1 presents criteria for evaluating goodness of fit and model selection among six different models for analyzing the outcome of counts of high risk sexual behavior in a randomized clinical trial of an HIV-risk reduction intervention. Values in the table are chi-square (χ^2) statistics for LR comparing models, differences between AIC for models being compared, and Vuong statistics (referred to a standard normal distribution) comparing models. Positive numbers mean that the model in the column fits better than the model in the row. Negative numbers mean that the model in the row fits better than the model in the column. LR, likelihood ratios; AIC, Akaike's information criterion; NB, negative binomial; ZIP, zero-inflated Poisson; ZINB, zero-inflated negative binomial; PH, Poisson hurdle; NBH, negative binomial hurdle.
* and **Refer to significant difference at $p < .01$ and $p < .001$, respectively.

TABLE 2. The Poisson and NB models on USO in a randomized clinical trial of an HIV-risk reduction intervention.

	Poisson		NB	
	β	SE	β	SE
USO at baseline	.68****	.08	.68****	.08
Age ≥ 40	−.57***	.22	−.60***	.21
Treatment (SSB vs. HE)	−.33	.22	−.41*	.24
Time (3-month vs. 6-month follow-up)	−.35****	.03	−.22	.15
Time-by-treatment interaction	.33****	.05	.46**	.23
Fit statistics				
Overdispersion			1.10****	.15
−2 Log-likelihood	5798.8		3973.6	
AIC	5812.8		3989.6	

Notes: Data derived at 3- and 6-month follow-up in a randomized clinical trial of an HIV-risk reduction intervention, safer SSB versus a HE control condition. USO, unprotected sexual occasion; HE, HIV Education; SSB, Sex Skills Building; AIC, Akaike's information criterion; NB, negative binomial.
*,**,***, and ****Refer to $p < .1$, $p < .05$, $p < .01$, and $p < .001$, respectively.

models (Tables 3 and 4), there are two sets of columns for each model, first showing the chances that the particular independent variable affected the "structural" zeros and the second showing the model for the "sampling" counts themselves. Across models, the effect of treatment manifests as a time-by-treatment interaction, consistent with the previously reported finding in the primary outcome paper in which a Poisson model was applied that the SSB intervention reduced episodes of unprotected sex compared to the HE intervention, mainly at the 6-month time point (5). The Poisson models (Poisson, ZIP, and PH) yield substantially greater time-by-treatment interactions compared to the corresponding NB models, possibly suggesting that failure to account for overdispersion by the Poisson models leads to overestimation of the effect of treatment. The NB and ZINB models yield similar estimates of the time-by-treatment interaction (both with p-value < 5%). Finally, the NBH model fails to detect a significant time-by-treatment interaction, suggesting that considering all zeros to be "structural" may bias against detecting an effect of treatment in this sample.

DISCUSSION

We considered six different models involving either the Poisson or NB distributions for analyzing clinical trial outcome data. The NB distribution better accommodates overdispersion in the outcome data compared to Poisson distribution. Zero-inflated and hurdle models account for overrepresentation of zero counts in the outcome data.

TABLE 3. The ZIP and ZINB models on USO in a randomized clinical trial of an HIV-risk reduction intervention.

	ZIP				ZINB			
	Probability on having 0 USO		Number of USO		Probability on having 0 USO		Number of USO	
	β (1)	SE (1)	β (2)	SE (2)	β (1)	SE (1)	β (2)	SE (2)
USO at baseline	−.61****	.14	.51****	.06	−.71****	.18	.49****	.06
Age	.48	.36	−.45***	.15	.53	.45	−.46***	.15
Treatment (SSB vs. HE)	.46	.42	−.31**	.15	.50	.52	−.30*	.17
Time (3-month vs. 6-month follow-up)	.06	.34	−.35****	.03	.12	.39	−.22**	.11
Time-by-treatment interaction	−.60	.50	.38****	.05	−.72	.59	.30**	.17
Fit statistics								
Overdispersion							.39****	.06
–2 Log-likelihood	4902.2				3824.5			
AIC	4932.2				3856.5			

Notes: Data derived at 3- and 6-month follow-up in a randomized clinical trial of an HIV-risk reduction intervention, safer SSB versus a HE control condition. SSB, Sex Skills Building; HE, HIV Education; ZIP, zero-inflated Poisson; ZINB, zero-inflated negative binomial; USO, unprotected sexual occasion; AIC, Akaike's information criterion.
*,**,***, and ****Refer to $p < .1$, $p < .05$, $p < .01$, and $p < .001$, respectively.

TABLE 4. The PH and NBH models on USO in a randomized clinical trial of an HIV-risk reduction intervention.

	PH				NBH			
	Probability on having 0 USO		Number of USO		Probability on having 0 USO		Number of USO	
	β (1)	SE (1)	β (2)	SE (2)	β (1)	SE (1)	β (2)	SE (2)
USO at baseline	−.49****	.08	.30****	.05	−.46****	.07	.35****	.05
Age	.44*	.23	−.30**	.14	.39*	.21	−.35**	.15
Treatment (SSB vs. HE)	.40	.29	−.33**	.14	.39	.27	−.26	.17
Time (3-month vs. 6-month follow-up)	.08	.26	−.35****	.03	.09	.25	−.23*	.12
Time-by-treatment interaction	−.51	.38	.38****	.05	−.49	.36	.28	.18
Fit statistics								
Overdispersion							.54****	.09
−2 Log-likelihood	5028.7				3911.2			
AIC	5054.7				3939.2			

Notes: Data derived at 3-month and 6-month follow-up in a randomized clinical trial of an HIV-risk reduction intervention, safer SSB versus a HE control condition. SSB, Sex Skills Building; HE, HIV Education; PH, Poisson hurdle; NBH, negative binomial hurdle; USO, unprotected sexual occasion; AIC, Akaike's information criterion.
*,**,***, and ****Refer to $p < .1$, $p < .05$, $p < .01$, and $p < .001$, respectively.

We fit each of these models to the data from a controlled clinical trial of a skill-oriented HIV-risk reduction intervention (5), in which the outcome variable was the count of USOs. Inspection of the observed data, as well as fit statistics, suggested that the distribution of the outcome variable was both overdispersed and zero-inflated. The fit statistics for the models (Table 1) showed that the ZINB model provided the best fit. Models using the NB distribution fit better than their corresponding models using the Poisson distribution, while zero-inflated and hurdle models fit better than their respective counterparts (Poisson, NB). Taken together, these suggest the importance of accounting for both overdispersion and zero-inflation in modeling the outcome data.

The estimates of the effect of treatment, in the form of the time-by-treatment interactions, differed in magnitude between models. Of particular note, the Poisson models estimated larger effects of treatment than the corresponding NB models, suggesting that failure to account for overdispersion in the model results in overestimation of the treatment effect in this particular case. This makes intuitive sense since ignoring greater dispersion in the data, in essence, suppresses variance. This illustrates the risk of falsely identifying a significant effect of treatment if the model chosen does not model the spread of the data correctly.

Across both zero-inflated and hurdle models, effects of time-by-treatment interaction or main effect of treatment were not detected to significantly influence the chances of "structural" zero outcomes. Thus, treatment reduced the magnitude of counts of high-risk sex but not the frequency of scoring 0. This illustrates the potential advantage of such models to provide a more precise interpretation of the data when the process that generates zero values differs from the process that generates nonzero counts. In this example, it may mean that the SSB treatment affected the number of USOs of some participants but did not significantly affect the number of those participants who had no sexual partners.

Zero-inflated models fit better than the corresponding hurdle models. Zero-inflated models consider two sources of zero observations: "sampling zeros" that are part of the underlying sampling distribution (Poisson or NB) and "structural zeros" that cannot score anything other than 0. In this example, it may be that while some participants scored zero USOs because they had no sexual partners, others had sexual partners but scored zero because they did not engage in high-risk sex. The SSB intervention focuses on promoting safe sex among those with partners and should, if effective, drive the rate of unsafe sex to zero in at least some of those participants. The hurdle model considers all zeros to be "structural zeros." The NBH model failed to detect a significant treatment effect, suggesting that truncating such "sampling" may have biased against finding treatment effect, perhaps by diluting the ability to show that SSB drove high-risk sex to zero in some at-risk participants.

Taken together, the data suggest the importance for any given data set of finding the most appropriate model for outcome data in order to arrive at the most accurate estimate of the effect of a treatment intervention and how an inadequately fitting model can bias in the direction of either overestimating or underestimating an effect of treatment. The process illustrated here of finding the best fit can proceed empirically without an a priori hypothesis about the distribution of the data. However, investigators designing clinical trials should be encouraged to hypothesize in advance the distribution of the outcome counts based on their knowledge of the population and the intervention being tested, as well as prior data. This could then guide the choice of model in the event that fit statistics does not identify a clear best fit.

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Declaration of Interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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