



Calculating Adjusted Survival Functions for Complex Sample Survey Data and Application to Vaccination Coverage Studies with National Immunization Survey

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Abstract

Background: In vaccination studies with complex sample survey, survival functions have been used since 2002. Recent publications have proposed several methods for evaluating the adjusted survival functions in non-population-based studies. However, alternative methods for calculating adjusted survival functions for complex sample survey have not been described.

Objectives: Propose two methods for calculating adjusted survival functions in the complex sample survey setting; apply the two methods to 2011 National Immunization Survey (NIS) child data with SUDAAN software package.

Methods: The inverse probabilities of being in a certain group are defined as the new weights and applied to obtain the inverse probability weighting (IPW) adjusted Kaplan-Meier (KM) survival function. Survival functions are evaluated for each of the unique combination of all levels of predictors in complex sample survey obtained from Cox proportional hazards (PH) model, and the weighted average of these individual functions is defined as the Cox corrected group (CCG) adjusted survival function.

Results: The IPW and CCG methods were applied to generate adjusted cumulative vaccination coverage curves across children's age in days receiving the first dose of varicella by family mobility status. The IPW adjusted cumulative varicella vaccination coverage curves could be consistent estimates of the true coverage curves, the IPW adjustment made the curve for moved family closer to the curve for not-moved family, and the IPW method significantly reduced the standard errors of the cumulative vaccination coverage across children age in days receiving the first dose of varicella comparing to the unadjusted KM method. The Cox PH assumption is not valid for 2011 NIS data.

Conclusions: If the Cox PH assumption is not met, then the IPW adjusted KM method is the only good choice, if adjusted survival estimates are desired. If the Cox PH assumption is valid, either the IPW or CCG methods can be used.

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1 Introduction

In vaccination studies with complex sample survey data, survival functions have been applied to account for time to vaccination to estimate cumulative vaccination coverage, assess the timeliness of vaccination, and compare cumulative vaccination coverage curves between any two levels of selected covariate [1-11]. It is important to develop alternative methods for generating covariate adjusted survival functions accounting for the complex sample survey design, such that we could reduce bias and increase the precision when evaluating the effect of a particular “exposure” factor on cumulative vaccination coverage over time. In published literature, several methods for calculating adjusted survival functions in the context of noncomplex sample survey have been proposed. The average covariate adjusted method is frequently used in biomedical papers, which applies the parameter estimates obtained from the Cox proportional hazards model to the average value of the covariates of interest in the groups being compared [12]. The major problem of the average method is that for categorical covariates, the meaning of the *adjusted* survival for individuals with the average covariate value is quite difficult to explain [13]. The corrected group prognosis method [14-16] was proposed to overcome the limitation of the average covariate adjusted method. This method calculates the survival functions for each unique combination at all levels of the covariates with a Cox proportional hazards model and obtains the adjusted survival function as a weighted average of these individual survival functions, in which weights are based on the sample sizes in each combinations. Recently an adjusted Kaplan–Meier estimator using inverse probability of treatment weighting was proposed [17] and it was shown to be a consistent estimate of the survival function. A non-parametric covariate-adjusted survival function approach was also introduced [18], but this method involves a loss of efficiency and power especially when the proportional hazards assumption was valid. A direct adjustment method based on the Kaplan-Meier survival estimates calculates a weighted average of the strata-specific Kaplan-Meier estimates, weighting according to the baseline sample size of the study population in each stratum [19]. However this method produces very similar survival functions to those generated by the unadjusted Kaplan-Meier method.

Many national public health surveys employ complex sampling schemes, such as the National Immunization Survey (NIS), Behavioral Risk Factor Surveillance System (BRFSS), National Health and Nutrition Examination Survey (NHANES), and the National Health Interview Survey (NHIS). Brogan [20,21] has discussed the impact of sample survey design on data analysis and has illustrated the possible consequences of ignoring the survey design in analysis of national health survey data. Bieler et al. [22] pointed out that complex sample surveys are designed to yield population-based estimates and inferences, and they typically involve some combination of sample weighting, stratification, multistage sampling, clustering, and perhaps finite population adjustments. They also emphasized that special statistical methods are needed to account for these complex sample designs in order to obtain unbiased estimates of population parameters, appropriate standard errors and confidence intervals, and valid population inferences. Here the weighting is not just to account for unequal selection, rather in complex sample survey, weighting process play much more critical role such as to adjust sample-frame non-coverage, interview non-response, post-stratification of weights, raking adjustment and trimming of post-stratified weights, propensity score weighting adjustment for provider nonresponse etc. [23]. The covariate adjusted methods described above are intended to be used for non-population-based studies and are

implemented with *Lifetest* and *Phreg* Procedures in SAS (SAS Institute Inc., Cary, North Carolina, USA). Alternative methods of calculating covariate adjusted survival functions for complex sample survey data have not been described.

Because the Kaplan-Meier product limits estimate and Cox proportional hazards model are two popular procedures in survival data analysis, we propose and describe two approaches for calculating covariate adjusted survival functions in the context of complex sample survey: the inverse probability weighting (IPW) adjusted Kaplan-Meier method and the Cox corrected group (CCG) adjusted method. The two methods are implemented with SUDAAN [24] software package which is an international recognized statistical software package that specializes in providing efficient and accurate analysis of data from complex sample surveys since SUDAAN procedures properly account for complex sample survey design features, such as correlated observations, clustering, complex weighting, stratification, and multiple stages. Data from 2011 National Immunization Survey are used to illustrate the procedures of our proposed methods.

2 Methods

2.1 Inverse Probability Weighting (IPW) Adjusted Kaplan-Meier Survival Functions for Complex Sample Survey Data

Let $(T_i, \delta_i, X_i, Z_i)$, $i=1, 2, \dots, N$, denotes a survival data from a complex sample survey, where T_i is the possibly right-censored survival time, δ_i is the censoring indicator, X_i is the group index variable, $X_i=1, \dots, K$ for K different groups, and Z_i is the covariate vector. The IPW method has been implemented with 3 steps. First, the non-parametric censored linear rank test might be used to obtain the group variable and the covariates which are significantly associated with the survival time [25].

Second, a logistic regression analysis was conducted to obtain the predicted probability of an individual being in a target group for which the adjusted survival function will be evaluated. We assumed that all of the variables, except the event time, considered in a complex sample survey survival data analysis were categorical. Let p_{ik} be the predicted probability for the i th individual being in the k th group of the complex sample survey data, which was calculated by use of the *Logistic* Procedure in SUDAAN [24,26-27] with the original complex survey weights. These probabilities may depend on the covariate vector Z_i , i.e. $p_{ik} = P(X_i=k|Z_i)$, where X_i is the group index for the i th individual and Z_i the covariates to be controlled in order to obtain the IPW adjusted Kaplan-Meier survival function for the k th group.

Third, in order to reduce the confounding effects for different groups by controlling the covariates and accounting for the complex sample survey design scheme, we assigned a new weight $W_{ik} = 1/p_{ik}$ for the i th individual in group k , then applied the new weights W_{ik} to SUDAAN *Kapmeier* Procedure to obtain the inverse probability weighting (IPW) adjusted Kaplan-Meier survival function for the k th group.

2.2 Cox Corrected Group (CCG) Adjusted Survival Functions for Complex Sample Survey Data

The Cox corrected group (CCG) adjusted method has been implemented with 7 steps. First, Cox proportional hazard assumption is assumed to be valid for the survival data in the complex sample survey, evaluation of the proportional hazards assumption is needed. Also we assume that all of the variables in the survival data, except the survival time, are categorical. Second, the backward-selection method [28-29] was applied to the Cox proportional hazards model in SUDAAN *Survival* Procedure for complex sample survey survival data, to obtain the final model which contains the significant predictors including the group variable for which the adjusted survival functions will be evaluated for each level of the group variable, and the covariates to be controlled. Third, the individual cumulative hazards functions $H(t)$ were obtained for each of the unique combination at all levels of the predictors including the group variable and the covariates in the final Cox model by applying SUDAAN *Survival* Procedure and output the estimated cumulative hazard functions [24]. Fourth, the estimated individual survival functions $S(t)$ were calculated by $S(t) = \text{Exp}[-H(t)]$. Fifth, the weighted sample sizes for each of the individual survival functions were calculated using SUDAAN *Crosstab* Procedure, weighted sample size is the weighted count in each table cell of cross tabulation of all predictors in the complex sample survey. Sixth, when the group variable had m levels, all of the individual survival functions were separated into m subgroups. Finally, the CCG adjusted survival functions for each of the group level were estimated as a weighted average of those individual survival functions within each of the m subgroups with weights equal to the weighted sample sizes obtained in the fifth step.

3 Results

3.1 Data Source

In this study, the 2011 National Immunization Survey (NIS) Child data was used to calculate adjusted cumulative vaccination coverage curves accounting for the complex sample survey design of NIS and controlling for the selected socio-demographic factors. The NIS is conducted annually by the U.S. Centers for Disease Control and Prevention (CDC) to provide national, state, and selected urban-area estimates of vaccination coverage among U.S. children aged 19-35 months [30]. The NIS is a stratified clustered random-digit-dialed telephone survey of households with age-eligible children. The NIS landline sample was used in this illustrative example. Data for 19,534 children who had adequate provider vaccination information were analyzed. In 2011, the NIS landline household survey response rate based on Council of American Survey and Research Organizations (CASRO) guidelines was 61.5%.

3.2 Adjusted Cumulative Vaccination Coverage Curves for the First Dose of Varicella Vaccination

The IPW and CCG methods were applied to generate the adjusted cumulative vaccination coverage curves across children's age in days upon receiving the first dose of varicella vaccination stratified by children's family mobility status (whether the state of family residence at child birth is different from current residence state: moved vs. not moved), and controlling for three other significant covariates: parental attitude of delay/refusal vaccination (yes vs. no);

mother's age group (≤ 29 years vs. ≥ 30 years); and children first born status (yes vs. no). The association of family mobility status, parental attitude, mother's age, and children first born status with time in days of children receiving the first dose of varicella vaccination was examined by non-parametric censored linear rank tests [25], all of the four predictor are significantly associated with the vaccination time ($P < 0.05$) based on the 2011 NIS child data. Also, using the method recommended by Kleinbaum [12], the Cox proportional hazards assumption was evaluated graphically and found to be invalid for all of the four predictors. For comparison purpose, the unadjusted cumulative vaccination coverage curves were estimated using the original unadjusted Kaplan-Meier (KM) method in SUDAAN, abbreviated as unadjusted KM method, with the original sampling design weights in NIS.

Essentially the IPW method that we proposed for complex sample survey survival data is the extension of the AKME (Adjusted Kaplan-Meier Estimator) method proposed by Xie and Liu [17] for observation studies. The AKME method applied the inverse probability weighting to adjust the covariates; our IPW method applied both the inverse probability weighting to adjust the covariates and the SUDAAN software to implement the complex sample survey design characteristics. Therefore IPW method is both an extension and a promotion of the AKME method. Xie and Liu conducted both a theoretical and a computer simulation studies. They show that the AKME is a consistent estimate of the survival function, i.e. the AKME estimate is closer to the true survival function; simulated AKME survival curves centered at the true survival curve; the limit of survival curves by AKME is different from the limit of survival curves by unadjusted KM method; and the two target group survival curves by the unadjusted KM method are separate, whereas the two target group survival curves by AKME method are closer. The AKME reduces the confounding effect of covariates, and therefore provides a better estimation of survival functions for the two target groups [17].

Because the IPW method is an extension of the AKME method, the IPW method should possess the favorable property of AKME as mentioned above, i.e. the IPW could generate consistent estimate of the survival function and the estimated survival function may be closer to the true survival function. Comparison of the first dose of cumulative varicella vaccination coverage curves for children whose family moved vs. not-moved by IPW and unadjusted KM methods are shown in Fig. 1. The vaccination coverage curves among children whose family were not-moved by both IPW and unadjusted KM methods were higher than the corresponding vaccination coverage curves among children whose family were moved, as expected. The IPW adjustment made the curve for moved family closer to the curve for not-moved family and both IPW adjusted curves are positioned between the corresponding unadjusted KM curves, this movement of curves might be explained as follows: the socio-demographic factors act as confounders, therefore the association of mobility with status of vaccination is attenuated when controlling for those factors via adjusted survival curves [16-17]. Therefore the IPW method in this illustrative example generated better adjusted cumulative varicella vaccination coverage curves than the unadjusted KM method. Furthermore, we calculated the standard errors of the first dose varicella cumulative vaccination coverage across children age in days receiving the first dose of varicella by children whose family moved vs. not-moved and by the IPW vs. unadjusted KM method. Fig. 2 shown that the IPW method results in much smaller standard errors than the unadjusted KM method: the standard errors of the IPW methods are approximately 50% less than the standard errors of unadjusted KM method among children whose family moved; the standard errors of the unadjusted KM methods are about 45% higher than the standard errors of IPW method among children whose family not moved. The significant reductions in standard errors were not found alone in our IPW method. Jiang et al. obtained remarkable reductions in standard errors by using

of their covariate-adjusted non-parametric method [18]. In general covariate adjustment has been demonstrated to reduce bias, and increase estimation efficiency [31-37]. In summary, the adjusted cumulative varicella vaccination coverage curves by IPW method could be consistent estimates to the true coverage curves, the IPW adjustment made the curve for moved family closer to the curve for not-moved family and both IPW adjusted curves are positioned between the corresponding unadjusted KM curves, and the IPW method significantly reduces the standard errors of the cumulative varicella vaccination coverage across children age in days receiving the first dose of varicella comparing to the unadjusted KM method, therefore IPW method is the better choice over the unadjusted KM method for calculating adjusted survival curves in the context of complex sample survey.

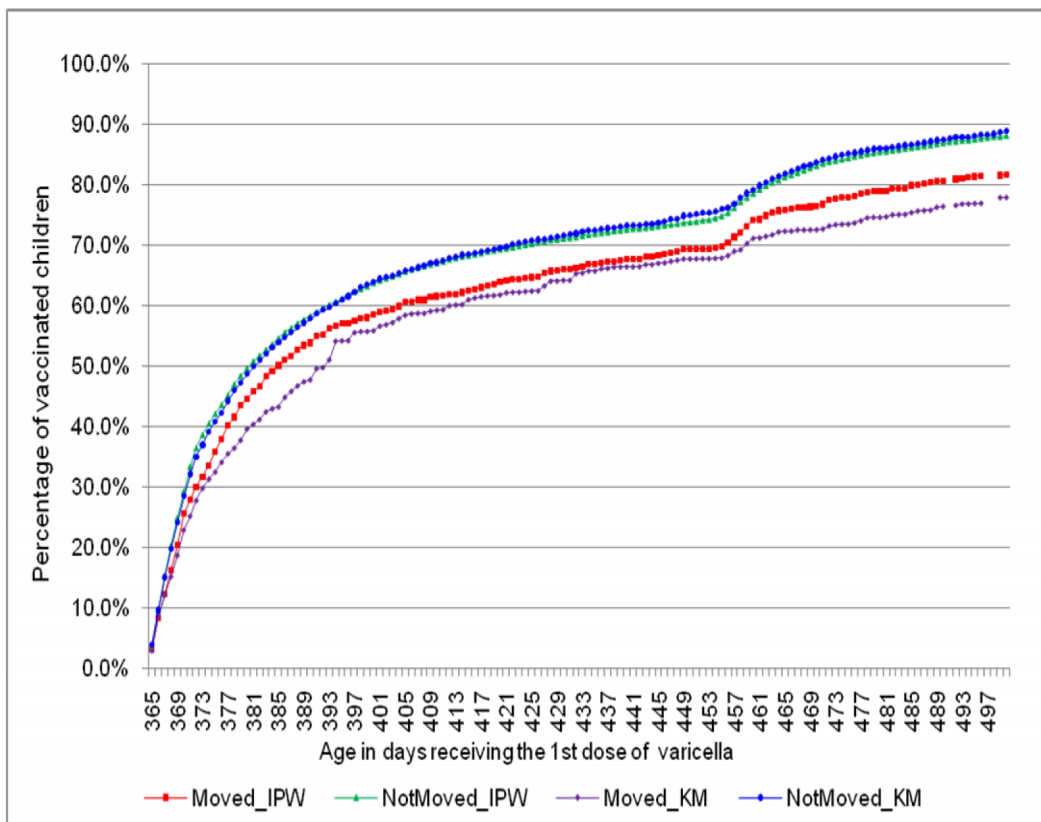


Fig. 1. Comparison of the first dose varicella cumulative vaccination coverage curves for children whose family moved vs. not-moved by IPW and unadjusted KM methods, 2011 National Immunization Survey (NIS)

Moved_IPW: Cumulative varicella vaccination coverage curve for children whose family moved by Inverse probability weighting (IPW) adjusted Kaplan-Meier method.

NotMoved_IPW: Cumulative varicella vaccination coverage curve for children whose family not moved by Inverse probability weighting (IPW) adjusted Kaplan-Meier method.

Moved_KM: Cumulative varicella vaccination coverage curve for children whose family moved by original unadjusted Kaplan-Meier method in SUDAAN.

NotMoved_KM: Cumulative varicella vaccination coverage curve for children whose family not moved by original unadjusted Kaplan-Meier method in SUDAAN

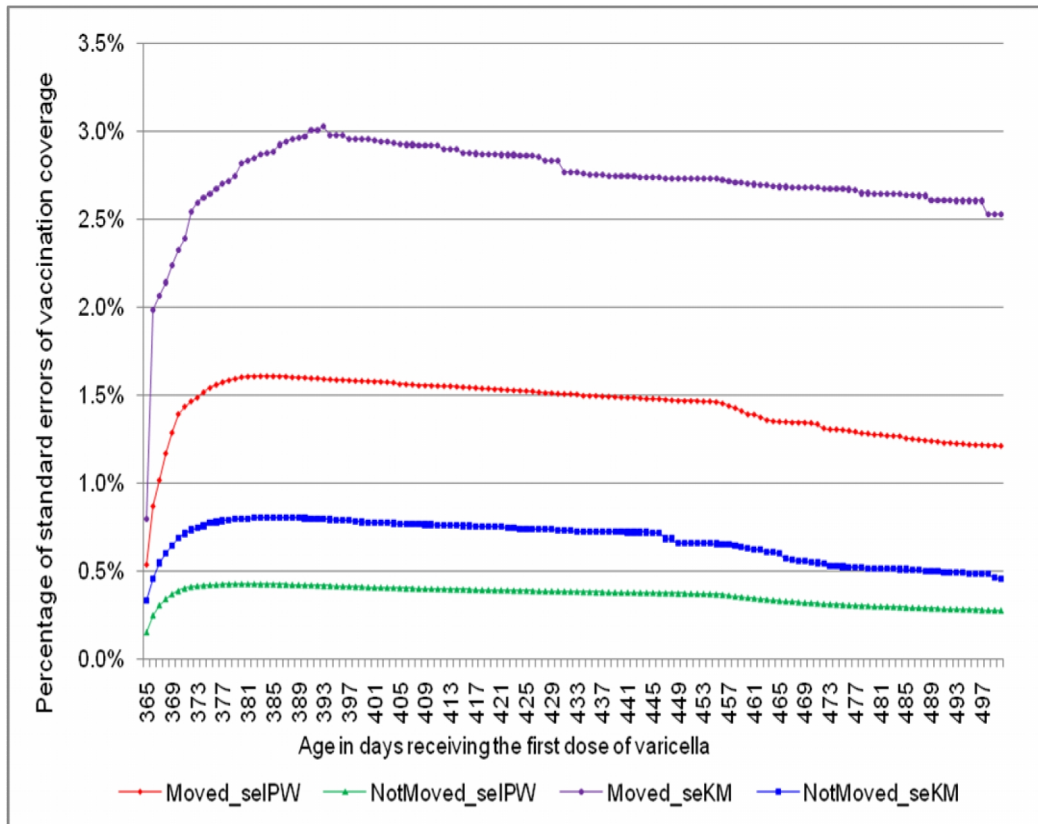


Fig. 2. Comparison of standard errors of the first dose varicella cumulative vaccination coverage across age in days receiving the first dose of varicella for children whose family moved vs. not-moved by IPW and unadjusted KM methods, 2011 National Immunization Survey (NIS)

Moved_selPW: Standard error of cumulative varicella vaccination coverage for children whose family moved by Inverse probability weighting (IPW) adjusted Kaplan-Meier method.

NotMoved_selPW: Standard error of cumulative varicella vaccination coverage for children whose family not moved by Inverse probability weighting (IPW) adjusted Kaplan-Meier method.

Moved_seKM: Standard error of cumulative varicella vaccination coverage for children whose family moved by original unadjusted Kaplan-Meier method in SUDAAN.

NotMoved_seKM: Standard error of cumulative varicella vaccination coverage for children whose family not moved by original unadjusted Kaplan-Meier method in SUDAAN

On the other hand, as presented in Fig. 3, the CCG adjusted first dose of cumulative varicella vaccination coverage curves for moved and not-moved family were located approximately outside of the varicella vaccination coverage curves with unadjusted KM method for moved and not-moved family, and most time the CCG adjusted cumulative vaccination coverage curve for moved family was moved far below from the curve with unadjusted KM method for moved family. The CCG method requires the satisfaction of Cox proportional hazards assumption which is not met in this illustrative example with 2011 NIS child data.

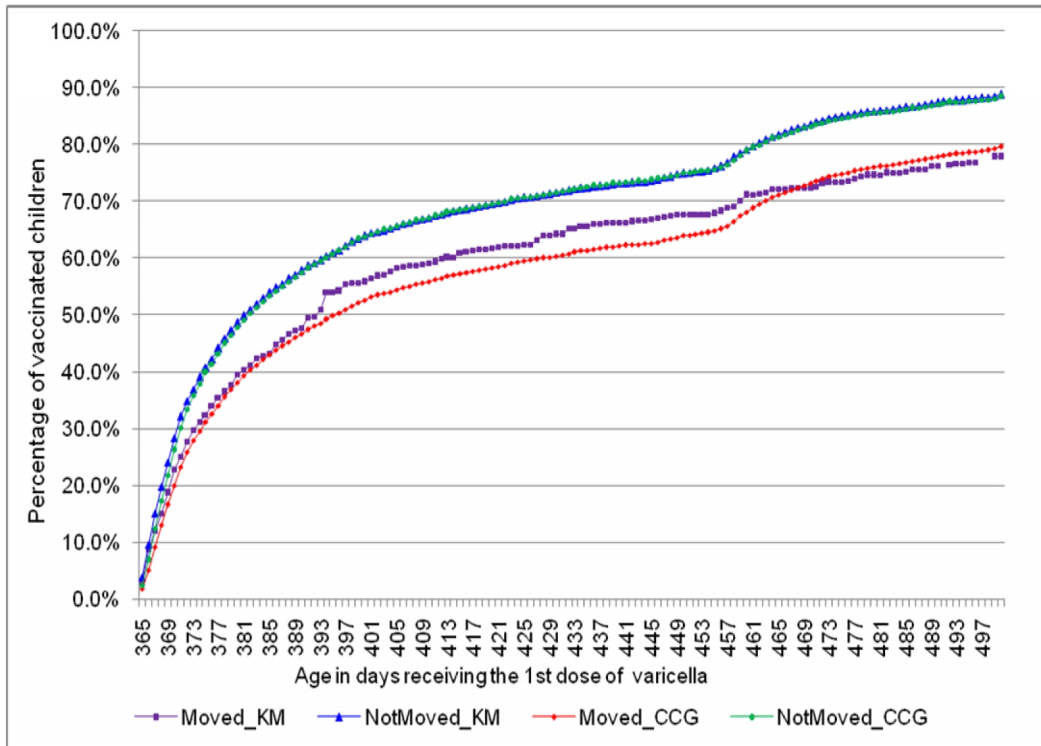


Fig. 3. Comparison of the first dose varicella cumulative vaccination coverage curves for children whose family moved vs. not-moved by CCG and unadjusted KM methods, 2011 National Immunization Survey (NIS)

Moved_KM: Cumulative varicella vaccination coverage curve for children whose family moved by original unadjusted Kaplan-Meier method in SUDAAN.

NotMoved_KM: Cumulative varicella vaccination coverage curve for children whose family not moved by original unadjusted Kaplan-Meier method in SUDAAN.

Moved_CCG: Cumulative varicella vaccination coverage curve for children whose family moved by Cox corrected group (CCG) adjusted method.

NotMoved_CCG: Cumulative varicella vaccination coverage curve for children whose family not moved by Cox corrected group (CCG) adjusted method

4 Discussion

Because the IPW method is the extension of the AKME method, the IPW method should possess the favorable property of AKME, i.e. the IPW could generate consistent estimate of the survival function and the estimated survival function may be closer to the true survival function. In addition, the IPW method significantly reduced the standard errors of cumulative vaccination coverage comparing to the unadjusted KM method. The IPW adjusted Kaplan-Meier method accounts for the complex sample survey design and adjusts the confounding by using the inverse probability weights and SUDAAN software. It is a non-parametric method and easy to implement. In addition, the IPW method provides marginal survival function estimates, does not require the validity of the Cox proportional hazards assumption which may not be satisfied sometimes, and

does not assume any semi-parametric or parametric survival model [17]. Thus, if the Cox proportional hazards assumption is not met, as in the illustrative example presented in this study, the IPW adjusted Kaplan-Meier method is the only appropriate choice among the two proposed methods with regard to calculating adjusted survival functions. Kleinbaum [12] pointed out that “the Cox proportional hazards model is a “robust” model, reasonable estimates of adjusted survival functions can be obtained for a wide variety of data situations, and the results from using the Cox model will closely approximate the results from the correct parametric model”. The CCG adjusted method is also a flexible tool for adjusting important covariates [18]. If the Cox proportional hazards assumption is valid, either IPW and CCG adjusted methods can be used, or the two methods could be used in combination (e.g., IPW as the primary method and CCG for subsequent adjustment). In practice, we recommend presenting the unadjusted survival curves first. The objectives of the study will determine if adjusted survival curves are needed. For example, in a study of disparities by race/ethnicity, the unadjusted curves are most important and need to be shown first. If researchers want to explain the disparity in terms of causal factors, the adjusted survival curves may be useful.

One limitation of these two proposed methods for calculating adjusted survival functions with complex sample survey data is the assumption that all variables considered in the analysis are categorical. Estimation and group comparison of survival curves are two very common issues in survival analysis [17]. The purpose of our study is to propose the IPW and CCG methods for calculating adjusted survival function in the context of complex sample survey for EACH LEVELS OF THE GROUP VARIABLE. Therefore the group index variable must be a categorical variable. For IPW method, at the time of estimating the predicted probability of p_{ik} for the i th individual being in the k th group adjusting the covariates Z_i which could contains the continuous elements. For CCG method, in order to evaluate the individual cumulative hazards functions $H(t)$ for each of the unique combination at all levels of the predictors including the group variable and the covariates in the final Cox model by applying SUDAAN *Survival Procedure* and output the estimated cumulative hazard functions [24], SUDAAN requires that all of the predictors including the group variable and the covariates must be categorical variable. In fact in the U.S. national public health surveys, almost all of the variables are categorical. Some variables such as mother’s age, education levels, or family income etc. might be treated as continuous variables, however they have been categorized to make the variable more informative and easier to use in the subsequent data analysis.

Another limitation might be the large number of variable combinations for which individual survival functions must be calculated if models contain many covariates by using CCG method. In these cases, researchers may apply stepwise survival analysis if Cox proportional hazards assumption is valid for all covariates, and adopt multicollinearity test, to get a small number, for example ≤ 10 , of significant predictors associated with survival time for calculating adjusted survival functions. This study is a statistical practice report that proposes and describes two methods for calculating adjusted survival functions in the context of complex sample survey; the two methods are implemented with procedures in SUDAAN v11 software [24] and are illustrated using 2011 NIS child data. Comprehensive theoretical researches and sophisticated computer simulation for evaluating the performance of both IPW and CCG methods might be needed in the future.

5 Conclusion

If the Cox PH assumption is not met, then the IPW adjusted KM method is the only good choice, if adjusted survival estimates are desired. If the Cox PH assumption is valid, either the IPW or CCG methods can be used.

Disclaimer

The findings and conclusions in this article are solely the responsibility of the authors and do not necessarily represent the official view of Centers for Disease Control and Prevention.

Competing Interests

Authors have declared that no competing interests exist.

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