ABSTRACT

Retrospective medical record review is often used to answer the “why” questions that statistical modeling cannot. In addition to its utility as an explanatory tool, it can be used to generate hypotheses using available retrospective data and so is a convenient guide for developing future prospective studies. A recent review of articles that used the retrospective medical record review method listed 10 best practices that ought to be followed. However, an issue that is not listed is the use of sampling weights, which are important when one can only conduct retrospective medical record review for a sample of the target population. Although that review acknowledged the importance of carefully selecting a sampling strategy for such a scenario and indeed had outlined 3 commonly used sampling methods (convenience, simple random, and systematic), the authors say nothing of the use of sampling information at the data analysis stage. This article aims to fill that gap and to demonstrate why the use of sample weights ought to be another best practice to add to the list by reviewing well-known theoretical details and some published data analysis examples.

INTRODUCTION

In the current era of electronic health records and big data analytics, there is still a place for retrospective medical record review (RMRR). RMRR is often used to answer the “why” questions that structured data and statistical modeling usually cannot. RMRR can also be used to capture ill-defined or nondiscrete variables, validate structured data, and generate hypotheses based on qualitative data. It is also used to validate phenotypes and outcomes that have been ascertained via International Classification of Diseases codes using administrative databases or from natural language processing methods. There are explicit RMRR best practices, such as the use of standardized data abstraction forms and assessment of interrater reliability when multiple reviewers are involved. These RMRR guidelines also acknowledge the importance of considering sampling issues a priori as well as conducting a power analysis in the design of a sampling strategy. Unfortunately, no recommendations are available to guide the use of the sampling information at the data analysis stage of a RMRR study. We focus on addressing this gap, demonstrating why the use of sample weights should be added to the list of best practices.

Many studies have performed sampling from well-defined target populations for RMRR; many of these studies report sample statistics and tests to compare subgroups of the population while ignoring the sampling strategy in the analysis. Of the commonly used sampling methods, the most obvious choice is for RMRR studies to conduct a simple random sample (SRS) to select records for review. However, summary data are often not presented with measures of sampling variability to report the uncertainty in the sample statistics. Moreover, not applying the sampling weights in a descriptive analysis might be, for example, calculating a weighted mean for each of several strata in a stratified random sample. A general approach to constructing such weights is the well-known Horvitz-Thompson estimator, which has been extended to the analysis of health survey data in cancer research. This article provides 2 pragmatic examples of how to account for the sampling strategy in the analysis stage, using long-standing methods from the survey sampling literature, and demonstrates the potential consequences of reporting sample statistics without accounting for the sampling weights. Although the

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methods presented in this article are specific to estimating population frequencies and proportions, analogous methods exist that apply to means, ratios, regression, and differences.14,15

PRAGMATIC EXAMPLES AND THE BASIC PRINCIPLE

Example 1

Our first example deals explicitly with sampling weights of clinical encounters for acute sinusitis (AS). RMRR was used to assess the rates of guideline-concordant care for patients treated in 3 different care settings: Emergency Department, Primary Care Department, and Urgent Care.13 For this study, the investigators used a stratified random sampling approach by which they randomly selected 100 medical records to review from each of the 3 care settings to ascertain whether recommended care had been delivered for specific “AS encounters . . . which resulted in antibiotics filled, the performance of CT [computed tomography] imaging or both.” It was important to estimate the proportions of length of symptoms (LOS) in the patients presenting at the 3 care settings because that was a variable that indicated a recommendation for antibiotic treatment (ie, LOS ≤ 7 days). The study followed best practice recommendations10 for RMRR and showed excellent interrater reliability (93.3% agreement) with both raters using the same protocol and data abstraction forms. In addition, the study team knew the sampling weights based on the design and incorporated them when conducting descriptive analyses.

Example 2

A second example involved the assessment of guideline-concordant use of imaging for staging of early-stage breast cancer in patients at low risk for metastasis14 as recommended by the American Society of Cancer Oncology.15 The authors also used stratified random sampling, but this time the population stratum corresponded to 3 different types of imaging, with different numbers of medical records randomly sampled from each group of imaging within each study site: CT only and radionuclide bone scan or positron emission tomography. As with the study above, the authors carefully vetted the target population and incorporated the known sampling weights in descriptive analyses.

CALCULATING WEIGHTS FOR A STRATIFIED RANDOM SAMPLE

We demonstrate the basic principle here by using the above AS example, and all calculations can be performed by hand or in any spreadsheet program (we used Microsoft Excel, Microsoft Corp, Redmond, WA), and the following notation illustrates how simple it can be to incorporate sampling weights.

1. \( p_j = \frac{\sum_{i=1}^{n_j} w_i}{n_j} \)
2. \( \hat{p}(\bar{p}_j) = \left( \frac{N_j - n_j}{N_j - 1} \right) \left( \frac{\sum_{i=1}^{n_j} (\bar{p}_j - \bar{p})}{\bar{p}_j} \right) \)
3. \( \bar{p}_{overall} = \frac{1}{N} \sum_{j=1}^{c} n_j \bar{p}_j \)
4. \( \hat{v}(\bar{p}_{overall}) = \frac{1}{N^2} \sum_{j=1}^{c} N_j^2 \hat{v}(\bar{p}_j) \)

Starting with equation 1, let \( n_j \) denote the sample size for population stratum \( j \) and \( x_j \) be an indicator of the outcome of interest for person \( i \) in stratum \( j \) (eg, \( x_j = 1 \) if LOS ≤ 7 and 0 otherwise). If we let \( j \) index the different care settings, \( p_j \) denotes the sample proportion of the outcome in care setting \( j \). Viances of the \( p_j \) are estimated using equation 2, where \( N_j \) and \( n_j \) are the population and sample sizes for group \( j \), respectively. The 95% confidence intervals (CIs) can then be computed for each care setting using the normal approximation to the Binomial distribution given by

\[ p \pm 1.96 \cdot \sqrt{(V(p_j) / n_j^{1/2})} \]

where 1.96 is the 97.5th percentile of a standard normal distribution (ie, with a mean of 0 and a variance of 1), and the stratum-specific variances are weighted by a ratio of \( N \) and \( n_j \). The weighted overall sample proportions and variances for the population strata are estimated using equations 3 and 4, respectively. Estimates of population parameters are accentuated with carets (ie, \( \hat{\cdot} \)).

Although the same formulas apply to SRS, in either case the weights are determined by the sampling fractions of a properly conducted sampling scheme as discussed elsewhere.7 Instead of sampling from different population strata \( j = 1 \ldots c \), one simply modifies equations 1 to 4 by dropping the index \( j \). Thus, the weights are the same as for a stratified random sample with \( c = 1 \), and equations 1 and 3 become redundant because \( p_{overall} = \bar{p} \). Such a strategy would be relevant, for example, had the AS study only been interested in the primary care setting.

RESULTS

Table 1 gives the raw sample proportions that ignore the sampling weights in the AS study, where the \( j \) from the above equations index the 3 care settings. The sampling fractions \( (N_j / n_j) \) are 6.7 for Emergency Department, 390.4 for Primary Care Department, and 93.9 for Urgent Care. This means, for example, that each patient selected from primary care presents approximately 391 other Primary Care patients and contributes approximately 4 times more weight (or, alternatively, information) to the population proportion than one seen in urgent care. To obtain the weighted population proportion of LOS of 7 days or less, for example, one divides the sum of the product of the care-specific totals and their weights by the total population size: 74×(601/90) + 37×(32,400/83) + 64×(9114/97) = 20,924/42,115 = 0.49. Repeating this for the other categories gives the weighted proportions (and 95% CIs) of LOS for randomly selected patients with AS treated in different care settings, shown in Table 2. Comparing those proportions between Tables 1 and 2 clearly illustrates that the overall proportion of LOS of 7 days or more should be closer to the Primary Care Department proportion, despite the Emergency Department proportion being nearly double, because of the underlying distribution of visits across settings.

We see a similar story in the breast cancer example.14 In the breast cancer example, sampling fractions correspond to the different sets of imaging types that defined the strata in the sample, which were 15.6 for CT, 13.6 for positron emission tomography or bone scan, and 15.8 for multiple imaging techniques. Similarly, for example, each medical record reviewed from the set of records from all patients who underwent CT represented approximately 16 other patients. Unlike the AS example, however, the patient medical records sampled from each imaging type are all roughly equally weighted and informative. Following the same procedure as in equations 1 to 4
Table 1. Raw counts and unweighted proportions (95% CIs) of LOS for randomly selected patients with acute sinusitis treated in different care settings, determined from medical record review, Kaiser Permanente Southern California, 2012 (N = 100 per setting)

<table>
<thead>
<tr>
<th>LOS, d</th>
<th>ED (n = 601)</th>
<th>PC (n = 32,400)</th>
<th>UC (n = 9114)</th>
<th>Sample proportion (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 7</td>
<td>74 (0.62)</td>
<td>37 (0.14)</td>
<td>64 (0.66)</td>
<td>0.65 (0.59-0.71)</td>
</tr>
<tr>
<td>8-13</td>
<td>6 (0.07)</td>
<td>14 (0.07)</td>
<td>9 (0.09)</td>
<td>0.11 (0.07-0.14)</td>
</tr>
<tr>
<td>≥ 14</td>
<td>10 (0.11)</td>
<td>32 (0.38)</td>
<td>24 (0.25)</td>
<td>0.25 (0.19-0.30)</td>
</tr>
<tr>
<td>Total</td>
<td>90</td>
<td>83</td>
<td>97</td>
<td>0.11 (0.07-0.14)</td>
</tr>
</tbody>
</table>

CI = confidence interval; ED = Emergency Department; LOS = length of symptoms; PC = Primary Care; UC = Urgent Care.

Table 2. Weighted proportions (and 95% CIs) of LOS for randomly selected patients with acute sinusitis treated in different care settings, determined from medical record review, Kaiser Permanente Southern California, 2012 (n = 100 per setting)

<table>
<thead>
<tr>
<th>LOS, d</th>
<th>ED (n = 601)</th>
<th>PC (n = 32,400)</th>
<th>UC (n = 9114)</th>
<th>Weighted proportion (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 7</td>
<td>0.82 (0.75-0.89)</td>
<td>0.45 (0.34-0.55)</td>
<td>0.66 (0.56-0.76)</td>
<td>0.49 (0.41-0.58)</td>
</tr>
<tr>
<td>8-13</td>
<td>0.07 (0.02-0.12)</td>
<td>0.17 (0.09-0.25)</td>
<td>0.09 (0.03-0.15)</td>
<td>0.15 (0.09-0.22)</td>
</tr>
<tr>
<td>≥ 14</td>
<td>0.11 (0.05-0.17)</td>
<td>0.38 (0.28-0.49)</td>
<td>0.25 (0.16-0.34)</td>
<td>0.35 (0.27-0.44)</td>
</tr>
</tbody>
</table>

CI = confidence interval; ED = Emergency Department; LOS = length of symptoms; PC = Primary Care; UC = Urgent Care.

This work demonstrates how established survey sampling methods can be incorporated into a RMRR at the analysis stage of a study. We argue that this is a necessary step in RMRR studies that use some form of random sampling, which we have highlighted with practical examples. First, a simple method can use estimates of population parameters along with measures of variability for RMRR sample data to appropriately account for sampling design using sample weights. Second, the use of sample weights can offer more valid estimates of population parameters and variances. Third, stratified random sampling can afford certain efficiency advantages over SRS because more information can be obtained per unit sampled when there are important subgroups in the target population. For example, use of SRS may miss patients from clinically meaningful subgroups of the target population, resulting in findings that may not generalize to the target population as in the study by Belletti et al. However, even then one could still use the sampling fractions in the random sample in the data analysis assuming one had such information available (eg, in Table 1 of the AS study). In such situations, one can be easily misled by sample statistics that do not appropriately account for sampling design because they may not always reflect quantities of the target population or properly account for underlying population strata.

However, a few important limitations are worth stating. An important caveat is that we are working with the assumption that a binomial random variable (eg, number of patients with AS presenting with LOS ≤ 7 days) can be approximated using the normal distribution, although one could circumvent this assumption by computing exact binomial CIs. A related issue is that the stratum-specific variances depend explicitly on their proportions, and so if one performs SRS and then tries to construct post sampling stratified weights on the basis of underlying population strata, one must take care to use the correct variance formulas (ie, equations 2 and 4) to obtain an unbiased estimate of the population parameter. Lastly, the sampling method used may be constrained by the available resources or assume that the cost (in time and effort) of performing medical record reviews is the same for all population strata. In the AS case, this assumption would not be true if reviewing medical records for the Emergency Department setting was more complicated and required more time than for Primary Care Department, and the costs would therefore vary.

In that instance, the different costs across the 3 settings could be accounted for in the determination of sample size for each group so as to minimize the cost for a fixed level of variability or to minimize the variability for a fixed cost.

In addition to applying sample weights to the analysis of RMRR data arising from a given random sampling procedure, articles reporting results from such studies should also report complete information on the sampling frame, such as the total number of eligible participants. This information would allow others to assess the degree to which biases or imprecisions in sample statistics or measures of association and lack of generalizability to the target population may be attributable to sampling design. For example, existing methods from the survey sampling literature could allow one to make such assessments, such as the standardization methods used for the NHANES® or for health surveys in general. The same could be done to compare the study and target populations by applying sample weights as described above, the unweighted proportion of inappropriate imaging works out to 9% vs 16% when weighted.

For the AS example, had the unweighted proportions with LOS of 7 days or less been reported and the overrepresentation of Emergency Department and Urgent Care visits in the sample vs Primary Care been ignored, the population proportion would have been overestimated by roughly 32%. Notably, the 95% CIs for the weighted and unweighted proportions of patients with LOS of 7 days or less do not overlap, providing further evidence of the danger of ignoring the sampling design in the data analysis. In the breast cancer example, the unweighted sample proportion of all imaging performed for surveillance in the cohort appears to underestimate the population proportion by nearly half (9% unweighted vs 16% weighted). In both cases, assuming SRS and then reporting the unweighted sample proportions could be misleading because of ignoring the underlying distribution of the outcome across those population strata.

**DISCUSSION**

This work demonstrates how established survey sampling methods can be incorporated into a RMRR at the
we described or by comparing the sampled population to the target population as in 1 study that reported all details of the sampling frame.\textsuperscript{14}

This study has demonstrated that relatively straightforward applications of existing survey sampling methods can improve the quality of reporting for RMRR studies by providing more representative estimates of population parameters, along with corresponding estimates of variability. Our study also demonstrates how using such methods can help ensure that underlying population subgroups that may have been overrepresented or underrepresented in a SRS do not bias the parameter estimates, both in one’s own study and in the evaluation of others’ studies. As discussed earlier, such sampling information can even be used after data collection has already been completed to correct for having oversampled or undersampled from some population strata using SRS. It is especially helpful when one is only able to review a limited number of medical records because of resource or time limitations because one can use strategic sampling choices along with the corresponding weights to obtain as much possible information from a limited sample.

CONCLUSION

We recommend that future RMRR studies apply established survey sampling methods in the data analysis stage to improve the quality of their methods and the accuracy of their results. \textsuperscript{\textdagger}

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