

# Reliability of Medicaid Claims Versus Medical Record Data In a Cost Analysis of Palivizumab

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## Abstract

**Background:** Palivizumab is one of the most costly paediatric medications for Medicaid and other health plans. It is uncertain whether the costs of palivizumab administration are justified in specific risk groups. Ongoing investigations of palivizumab require identification of reliable data sources.

**Objective:** To estimate the reliability between Medicaid paid claims data and medical records documentation in a cost analysis of palivizumab.

**Study design:** A cross-sectional study of data reliability was performed within a cost analysis study of palivizumab in a cohort of at-risk patients during the US 2002/3 respiratory syncytial virus season. Exposure classification (to palivizumab prophylaxis) was compared using Medicaid claims and medical records data.

**Methods:** The study was performed in 28 widely dispersed paediatric medical practices serving North Carolina, USA Medicaid patients within the AccessCare/Community Care of North Carolina (CCNC) Program, an enhanced primary care case management programme. Patients were eligible if they were born between 1 March 2002 and 28 February 2003 at 32–35 weeks estimated gestational age, were enrolled in the North Carolina primary care case management Medicaid programme during the study period and were patients of the participating practices. Medicaid healthcare claims were obtained in December 2003 for services provided between October 2002 and May 2003. Medical records were abstracted by community-based case managers. Primary variables included frequency, dates and dose of palivizumab injections. The main outcomes measures were agreement in the number of palivizumab injections, dates of administration and doses of palivizumab between Medicaid paid claims and medical record data.

**Results:** Injection frequencies matched between medical record and Medicaid claims data for only 46.2% of study participants. Congruence in injection service dates occurred between data sources for only 1% of injections. Doses were similar between data sources for 81.9% of injections.

**Conclusions:** In Medicaid recipients receiving palivizumab injection, Medicaid claims data were inconsistent with medical records data. Use of multiple data sources and validation are recommended to identify temporal relationships between drug administration and endpoints of interest.

Medicaid and other administrative (e.g. claims) databases are valuable sources of data for health services research such as pharmacoepidemiological studies and cost analyses.<sup>[1-6]</sup> Claims databases frequently offer the advantages of relatively low acquisition cost, access to large numbers of study participants, the option to track people over time and computer readability.<sup>[1,4,7-10]</sup> Use of claims data may allow investigators to avoid the potential for provider or patient recall bias and eliminate the need to contact patients directly.<sup>[10-13]</sup> Medicaid databases specifically offer the advantage of the prescription drug benefit, which provides data accessibility for large pharmacoepidemiological studies.<sup>[11,14,15]</sup>

There are also potential limitations with the use of Medicaid claims as a source of research data. Historically, problems with Medicaid claims data have included missing data, inaccuracies and lack of standard reporting conventions.<sup>[1,6,16]</sup> Medicaid data may also not be useful for identifying potential confounders,<sup>[4,11,17]</sup> and identification of patient data can be difficult if participant Medicaid identification (MID) numbers change over time.<sup>[4]</sup> Furthermore, there is often a 6-month lag time between the date of service and the presence of complete information in the claims dataset.<sup>[18]</sup>

The objective of this study was to examine the reliability between Medicaid paid claims data and documented data in medical records in a US direct cost analysis of palivizumab. Agreement in exposure classification to palivizumab prophylaxis between the two distinct data sources is quantified. Further, the reliability of drug claims service dates between data sources is assessed, which is critical for establishing temporal relationships between drug exposure and primary clinical outcomes.<sup>[11]</sup>

The need for this assessment is evidenced by the unique attributes of palivizumab administration and utilisation. First, ongoing cost assessments of palivizumab are likely to occur because of the high cost per dose and overall costs of palivizumab to health plans. During the 2004/5 respiratory syncytial virus (RSV) season, North Carolina, USA, Medicaid expenditures for palivizumab exceeded \$US15 million.<sup>[19]</sup> Palivizumab expenditures exceeded \$US99 million in Medicaid programmes within a seven-state area in south-eastern USA during that same time period.<sup>[20]</sup> In 2004, palivizumab sales exceeded

\$US900 million in the US.<sup>[21]</sup> The average computed prophylaxis costs of palivizumab in the North Carolina cost analysis study sample were \$US1214 per injection and \$US4996 per person receiving prophylaxis.<sup>[22]</sup> Second, the primary healthcare utilisation outcome (RSV-attributed hospitalisation) was relatively rare in the study sample, accentuating the need for accurate palivizumab prophylaxis exposure classification.<sup>[22]</sup> Third, palivizumab is provided to physician practices by pharmacy providers/wholesale distributors within all or most state Medicaid programmes. The drug is billed directly by the pharmacy providers/wholesale distributors rather than by healthcare providers who actually administer palivizumab. Fourth, guidelines for administration of palivizumab to 32- to 35-week estimated gestational age (EGA) infants continue to evolve as additional research is performed and published.<sup>[23-25]</sup>

It was concluded from the cost analysis that the prophylaxis costs of palivizumab injections in infants born at 32–35 weeks EGA far exceeded the estimated direct costs of averted hospitalisations for RSV-related illnesses.<sup>[22]</sup> The average seasonal costs of inpatient hospitalisation for RSV-related illness was \$US250.08 in the comparison (non-prophylaxis) group. The average per-person total direct seasonal cost of RSV-related care and prophylaxis in the intervention (palivizumab) group ( $n = 185$ ) was \$US5117, compared with \$US371 in the non-prophylaxis group ( $n = 182$ ).<sup>[22]</sup> The computed net cost of prophylaxis to prevent one RSV hospitalisation in the study sample was \$US102 073.<sup>[22]</sup>

This report of palivizumab data sources may guide the selection of data sources in future cost and effectiveness studies of this drug.

## Methods

### Study Design

A cross-sectional study of data reliability was performed within a cohort study and direct cost analysis study of palivizumab use in a cohort of infants born at 32–35 weeks EGA. Medicaid claims data and medical record data were compared. In the cost analysis, a cohort study was designed to compare healthcare utilisation and costs associated with serious RSV infections and bronchiolitis between

patients receiving (exposed) and not receiving (non-exposed) palivizumab during the 2002/3 RSV season in North Carolina, USA.<sup>[26]</sup> The observational study period was 1 October 2002–31 May 2003; palivizumab was typically administered monthly as an intramuscular injection during this period.

Participating practices used the North Carolina Medicaid prior authorisation guidelines, which allowed for up to six doses of palivizumab per eligible patient between October 2002 and the end of March 2003. Under special circumstances (e.g. if prophylaxis began late in the RSV season), some doses were administered during April 2003. The study design was reviewed and approved by the University of North Carolina, School of Medicine Human Subjects Institutional Review Board and the East Carolina University and Medical Center Institutional Review Board.

### Study Participants

Study participants were selected from all 28 paediatric practices serving Medicaid patients throughout North Carolina within the AccessCare/Community Care of North Carolina (CCNC), an enhanced primary care case management (E-PCCM) programme. Patients were eligible if born between 1 March 2002 and 28 February 2003 at 32–35 weeks EGA, and enrolled in the North Carolina primary care case management Medicaid programme during the study period.

Potential study participants were identified at participating practices by community-based case managers and practice-based palivizumab nurses through review of palivizumab prior authorisation forms, Medicaid claims, birth lists and medical records. Potential participants were then screened for eligibility based on the date of birth, EGA, AccessCare enrolment and co-morbidities. Patients were excluded from this study when they had a diagnosis of chronic lung disease and/or haemodynamically unstable congenital heart disease. Unique study identifiers were sequentially assigned to study participants at the time enrolment data were entered into a Microsoft SQL server database.

### Data Collection

Medicaid healthcare claims were obtained in December 2003 for healthcare services provided to study participants during the study period. Claims were obtained 6 months after the study period ended to allow for lag-time in claims submission and processing. Claims were selected based on participants' MID numbers and dates of service. Investigators surveyed the participating practices to identify the billing codes used when palivizumab injections were administered in the clinic. Wide variations existed between the practices with regard to the use of procedure/service codes (Current Procedural Terminology, 4th edition; CPT-4), diagnostic codes (International Classification of Disease, 9th edition; ICD-9), and combinations of procedure and diagnostic codes when billing for palivizumab injections. These injection claims did not provide a feasible alternative data source to palivizumab Medicaid drug claims. Following this inquiry, investigators obtained a third source of palivizumab injection data. AccessCare community-based case managers, affiliated with participating practices and located throughout North Carolina, abstracted ambulatory and inpatient medical records, using a standardised abstraction tool, to obtain palivizumab injection data (service dates and doses). These data included injections provided during inpatient hospital stays.

Palivizumab injection data obtained from medical record abstraction were entered into the SQL server enrolment database. Injection data entry was verified for a 35.5% sample, with 99.6% reliability. Medical record and claims datasets were combined and matched based on MID numbers. Injection data for each respective participant were matched between the two data sources based on sequential service dates and timeline proximities.

### Statistical Methods and Hypothesis Testing

Three hypotheses were explicitly tested to compare palivizumab injection data from medical records versus Medicaid healthcare claims data. The first null hypothesis was that the number of palivizumab injections given to a study participant as reported in the medical record agreed with palivizumab drug claim data. This hypothesis was tested using the kappa statistic,  $\kappa$ , a measure of inter-

rater agreement, and was expressed as  $H_0: \kappa = 0$ .<sup>[27]</sup> If there is complete agreement, then  $\kappa$  equals 1; if the observed agreement is greater than or equal to chance agreement then  $\kappa \geq 0$ ; and if the observed agreement is less than or equal to chance agreement, then  $\kappa \leq 0$ . Landis and Koch<sup>[28]</sup> have characterised ranges of values for  $\kappa$  as follows: values  $>0.75$  may represent excellent agreement beyond chance; values  $<0.40$  may represent poor agreement beyond chance; and values between 0.40 and 0.75 may represent fair-to-good agreement beyond chance. Comparisons between data sources were also made to determine if at least one injection was noted for each participant from both data sources.

The second hypothesis was that palivizumab administration dates in the medical records for an individual study participant were the same as the service dates for palivizumab drug claims. Injection dates were assumed to be correlated within a study participant. Because the data arose from independent clusters, a multi-level model with two levels and a random intercept for each study participant was used to account for this correlation. The two levels were the study participant level and the injection level, and the clusters were the injections given to the same individual study participant. The injection level is nested within the study participant level. Singer<sup>[29]</sup> described this model in detail. Using Singer's terminology and notation, hypothesis two was tested in an unconditional means model. The null hypothesis was expressed in the context of this model as  $H_0: \gamma_{0,0} = 0$  (i.e. the overall mean difference in injection dates is zero). The calculations were performed using the SAS<sup>®</sup> system.<sup>[30]</sup>

The third hypothesis was that the dose of palivizumab injections, expressed in 50mg increments (as the drug is supplied), were equivalent between the two data sources. This hypothesis was tested and the confidence interval was constructed using a bias-corrected bootstrap method.<sup>[31,32]</sup> A total of 100 000 bootstrap samples were drawn with replacement from the sample of 139 study participants who had at least one injection of palivizumab recorded in both the medical record and claims files. Doses were assumed to be correlated within a study participant.

To test the accuracy of the service data matching process, the dates of service analyses were repeated

for the study participants with equal numbers of injections documented in both data sources.

## Results

### Study Participant Injection Status

Of the 374 study participants included in the cost analysis, 208 (55.6%) had evidence (in either data source) of receiving at least one palivizumab injection and were eligible for inclusion in the data reliability assessment. Of these 208 participants, 139 patients had at least one injection of palivizumab recorded in both the medical record and claims files.

### Frequency of Palivizumab Injections by Data Source

In aggregate, 795 palivizumab injections were documented in the medical records, compared with 768 recorded in the claims database. Agreement in the number of injections per participant between the data sources was achieved in only 46.1% of study participants with any evidence in medical records, claims data, or both (either data source) of receiving a palivizumab injection; this accounted for a total of 430 injections (table I). In 23.6% of infants, the per-participant number of palivizumab injections was greater in the medical records than in the claims database. In 30.3% of infants, the number of palivizumab injections per individual participant was greater in the claims database than in the medical records. Of the 208 participants with a record of at least one palivizumab injection recorded in either data source, 87% had at least one injection documented in both data sources (table I).

The estimate of the  $\kappa$  statistic,  $\kappa = 0.37$  (95% CI 0.29, 0.44), indicated poor agreement in the frequency of injections beyond chance, using Landis and Koch's<sup>[28]</sup> criterion (see Statistical Methods and Hypothesis Testing section).

### Dates of Palivizumab Injections by Data Source

Of the 875 injections documented in the medical records, drug claims records or both, 689 (78.7%) were recorded in both data sources. In  $>90\%$  of the 689 matched injections, the date of service listed in

the claims records preceded the date of service listed in the participant's medical records (table I). For 52 of the injections (7.5%), the injection date in the medical record preceded the claim date. The service dates were the same in both data sources for only 1% (7) of the matched injections.

Using the Singer<sup>[29]</sup> model, the second primary hypothesis was rejected ( $p = 0.0016$ ); the overall mean was greater than zero. On average, the injection was administered 7.5 days (95% CI 4.2, 10.7) after the billing date.

In the 96 participants for whom equal numbers of injections were documented in the two data sources, billing service dates preceded the medical record injection date for 95.1% (409) of the injections; these results were similar to those for the full study sample.

#### Palivizumab Dose by Data Source

The dose of palivizumab injections was abstracted from the medical records for 584 palivizumab injections ( $n = 139$  study participants); 515 of these injections were also identified in the claims records. In 81.9% (422) of matching palivizumab records, the dose in the medical records was consistent with the vial size (charge) in the Medicaid paid claims database (table I).

## Discussion

Performing cost analyses to aid the development of evidence-based health coverage policies that have the potential to optimise health outcomes requires the selection of valid and reliable data sources.

As hypothesised in this study, the dates of service for palivizumab paid drug claims varied significantly from dates in the medical records and were shown to be unreliable for identifying dates of administration of palivizumab injections. This was expected within an administrative system in which distributors pre-bill for palivizumab. Therefore, the use of service dates from palivizumab Medicaid drug claims is likely to alter the assessment of temporal relationships between prophylaxis and outcomes. In our cost study, RSV hospitalisations were documented for five palivizumab prophylaxis participants and 12 non-prophylaxis participants. Use of palivizumab service dates from the Medicaid claims data could lead to exposure misclassification for participants who experienced outcomes and endpoints of interest such as RSV-related hospitalisation. Misclassification in our study had the potential to reduce the cost differential between the study groups and alter the relative risk of hospitalisation; however, misclassification would not have altered the overall cost-related study conclusions given the relatively low occurrence and inpatient case-based

**Table I.** Comparison of documentation of palivizumab injections between claims and medical records: 208 infants were eligible for inclusion in the data reliability assessment; 689 injections were recorded in both databases

Hypothesis/measure	Number	Percent
<b>Hypothesis 1: agreement in the number of injections per infant between the data sources (n = 208)</b>		
Agreement in the number of injections (no. of infants)	96	46.1
More injections documented in the medical record (no. of infants)	49	23.6
More injections documented in the claims records (no. of infants)	63	30.3
Agreement in the presence of at least one injection per data source (n = 208):		
injections in both data sources (no. of infants)	181	87.0
injections in medical records only (no. of infants)	14	6.7
injections in claims records only (no. of infants)	13	6.2
Statistical significance for hypothesis 1: $\kappa = 0.37$		
<b>Hypothesis 2: agreement in injection service dates between the data sources</b>		
Average number of days between the injection date and the drug billing date	7.5	NA
Service dates matched (no. of injections)	7	1.0
Medical record service date preceded claims date (no. of injections)	52	7.5
Claims date preceded medical record service date (no. of injections)	630	91.4
Statistical significance for hypothesis 2: $p = 0.0016$ (95% CI 4.2, 10.7)		
NA = not applicable.		

North Carolina Medicaid reimbursement of hospitalisations in our study sample.

If exposure misclassification were to occur in a study of palivizumab prophylaxis in a higher risk group (e.g. patients with chronic lung disease) with higher rates of RSV-related hospitalisations and longer and more costly hospitalisations, the impact on costs may be more significant. For example, if the costs and hospitalisation rates reported in the Farina et al.<sup>[33]</sup> study of infants with bronchopulmonary dysplasia who received palivizumab prophylaxis are applied to a hypothetical sample of 100 prophylaxis patients and 100 non-prophylaxis patients, the total direct costs of prophylaxis and treatment for RSV-bronchiolitis could shift from being approximately 27% higher in the prophylaxis group to being  $\leq 45\%$  higher in the non-prophylaxis group.

In this study, dates of palivizumab injections were abstracted from medical records for all participants in the prophylaxis group by case managers who worked directly with/at the widely distributed primary care practices. The practice of using medical records data to enhance the validity of palivizumab injection dates would obviously increase the costs of research. For example, medical record abstraction costs for a sample of approximately 200 patients receiving palivizumab prophylaxis may add an estimated \$US1250 (year 2005 values; using estimated costs/salaries from Human Resource data of approximately \$US25/hour and four charts per hour) to a research budget when local personnel are available for data abstraction services. If medical record abstraction of palivizumab injection dates was restricted to only those study participants in the Wegner et al.<sup>[22]</sup> study with a record of RSV hospitalisation (endpoint), abstraction costs could be reduced by approximately 97% to \$US38. For large-scale studies of palivizumab, the cost of medical record abstraction of injection dates could be minimised using the latter strategy.

Although this study provides a detailed comparison of medical record and Medicaid claims data, the generalisability of our results may be limited to specific drugs, supplies or services that are billed by suppliers who do not administer the medication/healthcare intervention. It is possible that the findings of this study may be unique to palivizumab; within Medicaid programmes this drug is billed

directly by the pharmacy provider, which is a wholesale distributor, rather than by the administering physician. As with other drugs purchased from a pharmacy provider, the record of a drug claim does not indicate patient compliance.<sup>[1,34]</sup>

A second limitation is that, although service dates were abstracted from medical records for all participants, the dose of palivizumab injections was abstracted for only 74% of the identified palivizumab injections with associated administration dates documented in the medical records. Sensitivity analysis demonstrated that, with complete dose information, the percentage of doses matching between the data sources (81.9% as reported in this study) could range from 61.8% to 86.2%.

A third potential limitation is the inability to validate the service date-matching process between data sources for individual study participants when the numbers of injections were not equivalent between sources for an individual. To test the accuracy of the service date-matching process, the dates of service analyses were repeated for the 97 study participants with equal numbers of injections in both data sources, with similar findings.

Fourth, this study assumed that medical records provide more accurate clinical information than claims data.<sup>[8,10,35]</sup> However, it is possible that medical record documentation of palivizumab injections, the abstraction process and data entry are subject to inaccuracies.<sup>[2]</sup> Injection data entry in this study was checked for reliability with 99.6% accuracy.

The methodological challenges of performing a cost analysis of palivizumab using Medicaid claims data have not been evident in other published economic studies of palivizumab because the majority of these studies used decision-analytic models with hypothetical cohorts and/or estimated cost data.<sup>[33,36-43]</sup> Additionally, several of these cost analyses were conducted within a small number of facilities, reducing the need for reliance on claims databases.<sup>[37,39]</sup> An economic study of palivizumab used Medicaid claims data; however, the potential limitations of using administrative data were not discussed.<sup>[44]</sup>

Non-palivizumab-related published evaluations of administrative databases were not directly comparable with this study; however, similar conclu-

sions were reached. One study that compared Maryland Medicaid claims with medical record documentation reported that 90% of ambulatory care visits according to paid claims were documented in the medical record; there was agreement between the data sources for date and diagnosis in 82%.<sup>[8]</sup> A study comparing diagnoses in medical records with those in an administrative database found that specificity was  $\geq 90\%$  for most diagnoses; the sensitivity of claims data was substantially lower, typically  $< 60\%$  for most diagnoses.<sup>[10]</sup> A third study reported a sensitivity of 67.3% for the exact service date when physician claims data for injury determination in the ED were compared with clinical records.<sup>[13]</sup>

## Conclusions

When performing a cost analysis of palivizumab, the use of North Carolina Medicaid drug claims data presented methodological challenges. The limitations of the drug claims data were addressed through the combined use of clinical and claims data, with dates of service being selected from the participants' medical records.

This approach was successful with the relatively small study sample and with community-based case managers being available at widely distributed practice sites to perform medical record abstraction. In larger studies, or in the absence of extensive data abstraction resources, our approach may not be feasible or cost effective. However, Medicaid claims data may be sufficient as the primary source of palivizumab injection data if supplemented with injection data from medical record abstraction for study participants identified as having rare endpoints or outcomes. In those participants it may be necessary to identify injection dates from clinical data, with consideration of the need for consistent data collection methods to help prevent some types of information bias.<sup>[4]</sup>

The results of this study support the use of medical records data when conducting future costs or effectiveness studies of palivizumab or other injectable medications.<sup>[4,7,45]</sup> However, when insufficient resources preclude the possibility of abstracting medical records data for all study participants, then the use of combined data sources (claims and medical records) may be sufficient if dates of palivizumab administration are abstracted from

medical records for those participants with endpoints of interest to determine temporal relationships between prophylaxis and the endpoints.

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