Can administrative data predict chemotherapy adverse events?

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Introduction

Adverse event (AE) rates in clinical practice differ from those in clinical trials. However, AE rates from clinical trials are often used to populate models of chemotherapy cost effectiveness, as rates in clinical practice are difficult to obtain.

The aim of this study was to determine whether Australian administrative data could identify the incidence of selected chemotherapy AEs in clinical practice.

Methods

The Elements of Care study (EoC) was a prospective study of individuals in New South Wales, Australia, undergoing chemotherapy for breast, colorectal or lung cancer. Primary data, including self-reported rates of AEs experienced, were collected through questionnaires and medical record reviews.

Linked administrative data of prescriptions and medical services for each participant were available from the Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS). This data was used to develop a proxy for an AE based on whether an individual was treated for one of the selected AEs (diarrhoea, vomiting, anaemia and neutropenia) up to three days after a chemotherapy dose.

The self-reported AE rates were compared to the proxy-identified AE rates using 2x2 contingency tables, with significance of any differences calculated using odds ratios and chi-square statistics.

Results

There were 482 individuals in EoC study. In general, the demographic and clinical characteristics of the sample are similar to those seen in a NSW population of individuals with cancer.

The proxy identified much lower rates of AEs than were self-reported, capturing:

- 30% of self-reported cases of nausea and vomiting,
- 1.3% of self-reported diarrhoea, and
- less than 1% of self-reported anaemia and neutropenia.

Additional analyses did not identify a pattern in the grade of AEs or type of treatment received that the proxy was more likely to identify.

Table 1. Sample demographics

Demographics	%	Demographics	%
Gender		**Cancer site**	
Male	26	Breast	54
Female	74	Colorectal	33
		Lung	13
Age group (years)		**Cancer stage**	
Less than 50	23	Stage I	6
50 to 60	26	Stage II	19
60 to 70	35	Stage III	23
Over 70	16	Stage IV	52

Figure 1. Rates of self-reported AEs

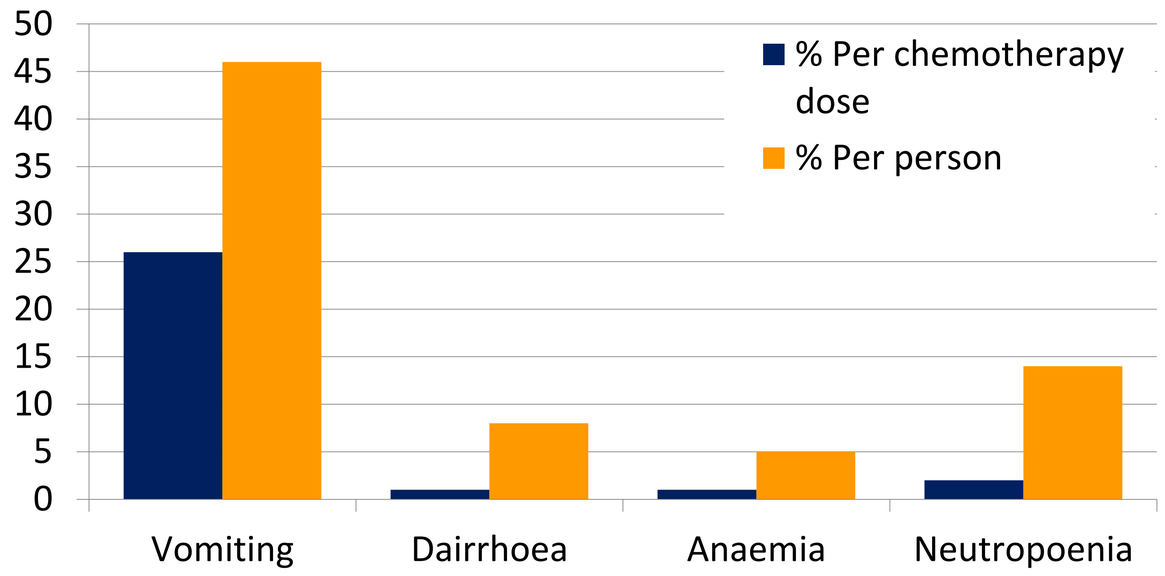

Table 2. Self-reported vs proxy-identified rates of AEs

Diarrhoea	Self-reported		
Proxy-identified	No	Yes	Total
No	12,268	1,473	13,741
Yes	79	20	99
Total	12,347	1,493	13,840

Odds ratio (95% CI): 2.11 (1.29, 3.45)

Nause & Vomiting	Self-reported		
Proxy-identified	No	Yes	Total
No	8,520	850	9,370
Yes	2,912	365	3,277
Total	11,432	1,215	12,647

Odds ratio (95% CI): 1.26 (1.10, 1.13)

Anaemia	Blood-test-identified		
Proxy-identified	No	Yes	Total
No	14,107	3,387	17,494
Yes	38	20	58
Total	14,145	3,407	17,552

Odds ratio (95% CI): 2.12 (1.27, 3.77)

Neutropoenia	Blood–test-identified		
Proxy-identified	No	Yes	Total
No	16,825	205	17,030
Yes	272	1	273
Total	17,097	206	17,303

Odds ratio (95% CI): 0.30 (0.04, 2.16)

Conclusions

Overall there was poor concordance between the two measures of AE rates. This may be due to low treatment rates for AEs, poor capturing of AE treatments by the proxy, or over-reporting of adverse event by participants. Regardless, it would appear that **administrative data such as the MBS and PBS are not suitable for estimating the incidence of AEs in clinical practice**, and bottom up data collection techniques such as the EoC study are essential.

Further information

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