

The RECORD statement – checklist of items, extended from the STROBE statement, that should be reported in observational studies using routinely collected health data.

	Item No.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Title and abstract					
	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	The title states that the study is looking at the “prevalence, nature and risk factors of medication administration omissions” and that the design is “a retrospective multi-centre” (page 1, Lines 1-3).	<p>RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included.</p> <p>RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract.</p> <p>RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.</p>	<p>The title states that “Medication Safety Thermometer data” has been used. (Page 1, Lines 1-3)</p> <p>Data were from hospitals in England and this is stated in the title (Page 1, Lines 1-3)</p> <p>N/A</p>
Introduction					
Background rationale	2	Explain the scientific background and rationale for the investigation being reported	The background highlights the issue of medication administration omissions, and the variation in rates and collection methods reported by previous studies (pages 4, lines 99-212). The background also explains the standardised methodology by which the Medication Safety Thermometer data is collected and how it can be used to learn		

			about the rate of patients with medication administration omissions (pages 4-5, lines 124-153).		
Objectives	3	State specific objectives, including any prespecified hypotheses	Aim of study stated (page 6, lines 155-159). Exploratory study with no hypothesis.		
Methods					
Study Design	4	Present key elements of study design early in the paper	The study design is described in the methods section, after context about the data used, and related definitions have been described (page 7, lines 216-228).		
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	The study involved secondary analysis of previously collected data and this is stated in the methods. How the data were collected has been described according to the tool's guidance document and previous research about NHS staff trusting the data collected in hospitals (page 6, line 163-174).		
Participants	6	<p>(a) <i>Cohort study</i> - Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up</p> <p><i>Case-control study</i> - Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls</p> <p><i>Cross-sectional study</i> - Give the eligibility criteria, and the</p>	N/A as this study involves secondary analysis of data already collected. However, inclusion criteria are described in study design and population (page 8, lines 224-228).	<p>RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided.</p> <p>RECORD 6.2: Any validation studies of the codes or algorithms used to select the population</p>	<p>6.1. Data from all hospital inpatients who have been prescribed one or more medicines included (page 8, lines 224-228).</p> <p>6.2 N/A</p>

		<p>sources and methods of selection of participants</p> <p><i>(b) Cohort study</i> - For matched studies, give matching criteria and number of exposed and unexposed</p> <p><i>Case-control study</i> - For matched studies, give matching criteria and the number of controls per case</p>		<p>should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided.</p> <p>RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage.</p>	6.3 N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	Predictors were the patient variables available from Medication Safety Thermometer data e.g. age groups (page 9, lines 251-260). Potential confounders were the hospital and ward, accounted for in multi-level modelling (page 9, lines 254-260).	RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided.	N/A
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	N/A		
Bias	9	Describe any efforts to address potential sources of bias	Multi-level modelling was used to account for the hierarchical nature of the data, this is stated (page 9, lines 254-260).		
Study size	10	Explain how the study size was arrived at	Data from the January 2015 were used as the highest number of		

			<p>patients had been surveyed in this month. Additionally, as it was also in the early implementation of the MedsST v16 where there was more guidance with MedsST data collection, including a national launch event that most hospitals had attended about how to use the MedsST, monthly WebExes, national guidance packages available online and a dedicated MedsST team based at Haelo to answer queries. (page 8, lines 217-224).</p>		
Quantitative variables	11	<p>Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why</p>	<p>Groupings provided by the Medication Safety Thermometer were used. This is stated (page 9, lines 251-260).</p>		
Statistical methods	12	<p>(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> - If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> - If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> - If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses</p>	<p>a) Statistical methods have been described (Pages 8-9, lines 230-255). b) Regression Models used to examine sub-group interactions (pages 238-241 and Tables 3 & 4). c) Missing data were excluded because the number of missing values was very small (55 cases out of 5763, less than 1%) (page 9, page 271-274) d) N/A. e) Sensitivity analyses was conducted by excluding omissions due to patient refusals (page 9, lines 253-255).</p>		

Data access and cleaning methods		..		<p>RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population.</p> <p>RECORD 12.2: Authors should provide information on the data cleaning methods used in the study.</p>	<p>All data are available online; however, raw data were requested from Haelo who facilitated data management at the time. Stated (page 6, lines 176-180 and page 19, lines 594-603).</p> <p>Data cleaning methods included excluding community organisations, patients prescribed 0 medicines or with incomplete data. Furthermore, one organisation with only 1 patient surveyed. Stated (Pg 6, lines 162-174).</p>
Linkage		..		<p>RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided.\</p>	
Results					
Participants	13	(a) Report the numbers of individuals at each stage of the study (<i>e.g.</i> , numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed)	N/A – secondary analysis.	<p>RECORD 13.1: Describe in detail the selection of the persons included in the study (<i>i.e.</i>, study population selection) including filtering based on data quality, data availability and linkage. The selection of</p>	

		(b) Give reasons for non-participation at each stage. (c) Consider use of a flow diagram		included persons can be described in the text and/or by means of the study flow diagram.	
Descriptive data	14	(a) Give characteristics of study participants (<i>e.g.</i> , demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) <i>Cohort study</i> - summarise follow-up time (<i>e.g.</i> , average and total amount)	a) Demographic information provided as patient sub-groups/variables (page 7, lines 182-186). b) Fifty-five patient submissions were excluded due to incomplete data, stated (Page 7, line lines 264-265). c) N/A		
Outcome data	15	<i>Cohort study</i> - Report numbers of outcome events or summary measures over time <i>Case-control study</i> - Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> - Report numbers of outcome events or summary measures	Outcomes events (patients with omissions) reported in results. Overall omissions reported (page 9, lines 266-274) and then omissions due to various reasons in Table 1.		
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (<i>e.g.</i> , 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	a) Unadjusted estimates given (Table 3). Multi-level regression model adjusted for variation, including the following levels: hospital-ward-patient (see pages 9-11, lines 312-358 and Table 4). b) N/A no continuous variables. c) N/A.		

Other analyses	17	Report other analyses done— e.g., analyses of subgroups and interactions, and sensitivity analyses			
Discussion					
Key results	18	Summarise key results with reference to study objectives	Key results discussed with respect to aims: -Prevalence of overall omissions summarised (page 9, lines 266-274). -Nature of omissions (Table 1) -Predictors for patients having omissions (Table 4 [adjusted] and discussed page 12, lines 361-and 373-378)		
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Limitations summarised in the article summary and discussed in more detail in the strengths and limitations (pages 16-18, lines 508-575).	RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported.	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	This has been given in the discussion, and strengths and limitations.		
Generalisability	21	Discuss the generalisability (external validity) of the study results	Generalisability mentioned in article summary and discussed (page 18, lines 570-575).		
Other Information					

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Funding information is provided (page 18, lines 584-586).		
Accessibility of protocol, raw data, and programming code		..		RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code.	Information about how to see data online, has been provided and it has been stated that the Quality Observatory team at South, Central and West Commissioning Support Unit can be contacted for more recent raw data. (pages 18, lines 594-603)

*Reference: Benchimol EI, Smeeth L, Guttman A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, the RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLoS Medicine* 2015; in press.

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