

# Data Extraction Form adapted from the Cochrane Collaboration

**Title of the systematic review:** The impact of clinical registries on quality of patient care and health outcomes

**Trial Registration no:** CRD42015017319

This form has been developed by adopting and customizing the “Data collection form for intervention review – RCTs and non-RCTs” of The Cochrane Collaboration. Some new sections have been added into this tool and the irrelevant sections have been removed from the original form. Information included on this form should be comprehensive, and may be used in the text of the review.

## Notes on using this data extraction form:

- Be consistent in the order and style you use to describe the information for each included study
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.
- You will need to protect the document in order to use the form fields (Tools / Protect document)

<b>Title of the paper/article/report</b>
<b>Study ID</b> ( <i>surname of first author and year first full report of study was published e.g. Smith 2001</i> )
<b>Report IDs of other reports of this study</b> ( <i>e.g. duplicate publications, follow-up studies</i> )
<b>Notes:</b>

## 1. General Information

1. <b>Date form completed</b> ( <i>dd/mm/yyyy</i> )	
2. <b>Name/ID of person extracting data</b>	
3. <b>Report title</b> ( <i>title of paper/abstract/ report that data are extracted from</i> )	

4. <b>Report ID</b> ( <i>if there are multiple reports of this study</i> )	
5. <b>Reference details</b>	
6. <b>Report author contact details</b>	
7. <b>Publication type</b> ( <i>e.g. full report, abstract, letter</i> )	
8. <b>Study funding source</b> ( <i>including role of funders</i> )	
9. <b>Possible conflicts of interest</b> ( <i>for study authors</i> )	
10. <b>Notes:</b>	

## 2. Eligibility

<b>Study Characteristics</b>	<b>Review Inclusion Criteria</b> ( <i>Insert inclusion criteria for each characteristic as defined in the Protocol</i> )	<b>Location in text</b> ( <i>pg &amp; ¶/fig/table</i> )
11. <b>Type of study</b>		
12. <b>Participants</b>		
13. <b>Types of Registry</b> <i>Describe either a clinical registry or a CQR which collects data on a procedure, disease or health care resource</i>		
14. Collect data systematically and on ongoing basis from the population being investigated		
15. <b>Types of outcome measures</b> (mortality/survival, measures outcome that reflects a process or outcome of health care utilization or cost)		
16. <b>Is registry used as an intervention</b> (based on inclusion)		

Study Characteristics	Review Inclusion Criteria <i>(Insert inclusion criteria for each characteristic as defined in the Protocol)</i>	Location in text <i>(pg &amp; ¶/fig/table)</i>
and exclusion criteria in table -1)		
17. <b>Decision</b> <i>(with reasons for either inclusion or exclusion)</i>		
18. <b>Notes:</b>		

**DO NOT PROCEED IF STUDY IS EXCLUDED FROM REVIEW**

### 3. Population and setting

	<b>Description</b> <i>[include comparative information for each group (i.e. intervention and controls) if available]</i>	<b>Location in text</b> (pg & ¶/fig/table)
19. <b>Population description</b> <i>(from which study participants are drawn)</i>		
20. <b>Setting</b> <i>(including location and social context)</i>		
21. <b>Inclusion criteria</b>		
22. <b>Exclusion criteria</b>		
23. <b>Method/s of recruitment of participants</b>		
24. <b>Notes:</b>		

### 4. Methods

	<b>Descriptions as stated in report/paper</b>	<b>Location in text</b> (pg & ¶/fig/table)
25. <b>Aim of study</b>		
26. <b>Design</b> <i>(e.g. RCT, comparative study with concurrent controls i,e non-randomised, experimental trial, cohort study, case-control study, interrupted time series with a control group or a comparative study without concurrent controls)</i>		

27. <b>Study start date</b>		
28. <b>Study End date</b>		
29. <b>Duration of participation</b> <i>(from recruitment to last follow-up)</i>		
30. <b>Notes:</b>		

## 5. Participants

Provide overall data and, if available, comparative data for each intervention or comparison group.

	Description as stated in report/paper	Location in text <i>(pg &amp; ¶/fig/table)</i>
31. <b>Total no. participants</b>		
32. <b>Clusters</b> <i>(if applicable, no., type, no. people per cluster)</i>		
33. <b>Baseline imbalances</b>		
34. <b>Withdrawals and exclusions</b> <i>(if not provided below by outcome)</i>		
35. <b>Age</b>		
36. <b>Sex</b>		
37. <b>Race/Ethnicity</b>		
38. <b>Severity of illness</b>		
39. <b>Co-morbidities</b>		
40. <b>Other treatment received</b> <i>(additional to study intervention)</i>		
41. <b>Other relevant socio-demographics</b>		

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
42. Notes:		

## 6. Outcomes

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
43. Process outcomes		
44. Patient reported outcomes		

Copy and paste table for each outcome.

### Outcome 1

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
45. Outcome name		
46. Time points measured ( <i>specify whether from start or end of intervention</i> )		
47. Time points reported		
48. Outcome definition		
49. Unit of measurement ( <i>if relevant</i> )		
50. Scales: upper and lower limits ( <i>indicate whether high or low score is good</i> )		
51. Is outcome/tool validated? ( <i>Yes/No/Unclear/Not mentioned</i> )		
52. Assumed risk estimate ( <i>e.g. baseline or population risk noted in Background</i> )		
53. Notes:		

## 7. Information describing registry as intervention

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
54. <b>Which type of organization hosting the registry</b> (University, research institute, professional organization, hospital)		
55. <b>Reference population</b> (this could be a group of countries, a single country, a state or territory)		
56. <b>Coverage</b> (what extent the eligible population representative of the country)		
57. <b>How data are being collected</b> (Computerised, Electronic, paper based or web based)		
58. <b>Diseases/conditions cover</b> (Diabetic, Stroke, Cancer, Surgery etc)		
59. <b>Who are involved in the management of database</b> ( Doctor, nurses, epidemiologist, statistician, IT specialist, General manager, consumer/patients, administrative staff, data collector, data manager)		
60. <b>Source of data and whether data is linkage with other database</b>		
61. <b>Availability of data dictionary</b>		
62. <b>Quality assurance mechanism</b>		
63. <b>Involvement of professional bodies/industries</b>		

## 8. The feedback mechanism and frequency of reporting

	Description as stated in report/paper	Location in text <i>(pg &amp; ¶/fig/table)</i>
64. <b>Follow up method</b>		
65. <b>Presence of any audit system</b>		
66. <b>Reporting mechanism</b>		
67. <b>Frequency of reporting</b>		
68. <b>Nature of reporting</b>		
69. <b>To whom feedback mechanism is provided</b> (clinicians, hospital, funders, government departments, industry, patients and consumers)		

## 9. Results and findings

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

### For randomised or non-randomised trial - Dichotomous outcome

	Description as stated in report/paper	Location in text <i>(pg &amp; ¶/fig/table)</i>
70. <b>Comparison</b>		
71. <b>Outcome</b>		
72. <b>Subgroup</b>		
73. <b>Time point</b> ( <i>specify whether from start or end of intervention</i> )		



	Description as stated in report/paper				Location in text (pg & ¶/fig/table)
74. <b>Results</b> <i>Note whether:</i>  ... <i>post-intervention</i> <i>OR</i>  ... <i>change from baseline</i>  <i>And whether</i>  ... <i>Adjusted OR</i>  ... <i>Unadjusted</i>	<b>Intervention</b>		<b>Comparison</b>		
	No. events	No. participants	No. events	No. participants	
75. <b>Baseline data</b>	<b>Intervention</b>		<b>Comparison</b>		
	No. events	No. participants	No. events	No. participants	
76. <b>No. missing participants and reasons</b>					
77. <b>No. participants moved from other group and reasons</b>					
78. <b>Any other results reported</b>					
79. <b>Unit of analysis</b> <i>(e.g. by individuals, health professional, practice, hospital, community)</i>					
80. <b>Statistical methods used and appropriateness of these methods</b> <i>(e.g. adjustment for correlation)</i>					
81. <b>Reanalysis required?</b> <i>(if yes, specify why, e.g. correlation adjustment)</i>	...				
82. <b>Reanalysis possible?</b>	...				

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
83. Reanalysed results		
84. Notes:		

**For randomised or non-randomised trial - Continuous outcome**

	Description as stated in report/paper						Location in text (pg & ¶/fig/table)
85. Comparison							
86. Outcome							
87. Subgroup							
88. Time point <i>(specify whether from start or end of intervention)</i>							
89. Post-intervention or change from baseline?							
90. Results <i>Note whether:</i>  ... <i>post-intervention OR</i>  ... <i>change from baseline</i>  <i>And whether</i>  ... <i>Adjusted OR</i>  ... <i>Unadjusted</i>	Intervention			Comparison			
	Mean	SD (or other variance)	N	Mean	SD (or other variance )	N	
91. Baseline data	Intervention			Comparison			
	Mean	SD (or other variance)	N	Mean	SD (or other variance )	N	

	Description as stated in report/paper		Location in text (pg & ¶/fig/table)
92. <b>No. missing participants and reasons</b>			
93. <b>No. participants moved from other group and reasons</b>			
94. <b>Any other results reported</b>			
95. <b>Unit of analysis</b> (e.g. by individuals, health professional, practice, hospital, community)			
96. <b>Statistical methods used and appropriateness of these methods</b> (e.g. adjustment for correlation)			
97. <b>Reanalysis required?</b> (if yes, specify why)	... Yes/No/Unclear		
98. <b>Reanalysis possible?</b>	... Yes/No/Unclear		
99. <b>Reanalysed results</b>			
100. <b>Notes:</b>			

**For randomised or non-randomised trial - Other outcome**

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
101. <b>Comparison</b>		

	Description as stated in report/paper				Location in text (pg & ¶/fig/table)
102. <b>Outcome</b>					
103. <b>Subgroup</b>					
104. <b>Time point</b> <i>(specify whether from start or end of intervention)</i>					
105. <b>Type of outcome</b>					
106. <b>Results</b>	Intervention result	SD (or other variance)	Control result	SD (or other variance)	
	Overall results		SE (or other variance)		
107. <b>No. participant</b>	Intervention		Control		
108. <b>No. missing participants and reasons</b>					
109. <b>No. participants moved from other group and reasons</b>					
110. <b>Any other results reported</b>					
111. <b>Unit of analysis</b> <i>(e.g. by individuals, health professional, practice, hospital, community)</i>					
112. <b>Statistical methods used and appropriateness of these methods</b>					
113. <b>Reanalysis required? (if yes, specify why)</b>	...				
114. <b>Reanalysis possible?</b>	...				

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
115. <b>Reanalysed results</b>		
116. <b>Notes:</b>		

**For controlled before-after study**

	Description as stated in report/paper				Location in text (pg & ¶/fig/table)
117. <b>Comparison</b>					
118. <b>Outcome</b>					
119. <b>Subgroup</b>					
120. <b>Time point</b> <i>(specify whether from start or end of intervention)</i>					
121. <b>Post-intervention or change from baseline?</b>					
122. <b>Results</b>	Intervention result	SD (or other variance)	Control result	SD (or other variance)	
	Overall results		SE (or other variance)		
123. <b>No. participants</b>	Intervention		Control		
124. <b>No. missing participants and reasons</b>					

	Description as stated in report/paper		Location in text (pg & ¶/fig/table)
125. <b>No. participants moved from other group and reasons</b>			
126. <b>Any other results reported</b>			
127. <b>Unit of analysis</b> <i>(individuals, cluster/ groups or body parts)</i>			
128. <b>Statistical methods used and appropriateness of these methods</b>			
129. <b>Reanalysis required?</b> <i>(specify)</i>	... <i>Yes/No/Unclear</i>		
130. <b>Reanalysis possible?</b>	... <i>Yes/No/Unclear</i>		
131. <b>Reanalysed results</b>			
132. <b>Notes:</b>			

**For interrupted time series or repeated measures study**

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
133. <b>Comparison</b>		
134. <b>Outcome</b>		
135. <b>Subgroup</b>		
136. <b>Length of time points measured</b> <i>(e.g. days, months)</i>		

	Description as stated in report/paper		Location in text (pg & ¶/fig/table)
<b>Total period measured</b>			
<b>137. No. participants measured</b>			
<b>138. No. missing participants and reasons</b>			
<b>139. No. time points measured</b>	<b>140. Pre-intervention</b>	<b>141. Post-intervention</b>	
<b>142. Mean value (with variance measure)</b>			
<b>143. Difference in means (post – pre)</b>			
<b>144. Percent relative change</b>			
<b>145. Result reported by authors (with variance measure)</b>			
<b>146. Unit of analysis (individuals or cluster/groups)</b>			
<b>147. Statistical methods used and appropriateness of these methods</b>			
<b>148. Reanalysis required? (specify)</b>	... <i>Yes/No/Unclear</i>		
<b>149. Reanalysis possible?</b>	... <i>Yes/No/Unclear</i>		

	Description as stated in report/paper				Location in text (pg & ¶/fig/table)
150. <b>Individual time point results</b>					
151. <b>Read from figure?</b>	...				
152. <b>Reanalysed results</b>	<b>Change in level</b>	<b>SE</b>	<b>Change in slope</b>	<b>SE</b>	
153. <b>Notes:</b>					

## 10. Discussion

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
154. <b>Key discussion points</b> ( <i>with references in detail</i> )		
155. <b>Notes:</b>		

## 11. Limitation and mitigation strategy

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
156. <b>Limitation</b>		
157. <b>Strategies to overcome the limitation</b>		
158. <b>Notes:</b>		



## 12. Recommendations

	Description as stated in report/paper	Location in text <i>(pg &amp; ¶/fig/table)</i>
159. <b>Recommendations related to registry system</b>		
160. <b>Notes:</b>		

## 13. Other information

	Description as stated in report/paper	Location in text <i>(pg &amp; ¶/fig/table)</i>
161. <b>Key conclusions of study authors</b>		
162. <b>References to other relevant studies</b>		
163. <b>Correspondence required for further study information</b> <i>(what and from whom)</i>		
164. <b>Further study information requested</b> <i>(from whom, what and when)</i>		
165. <b>Correspondence received</b> <i>(from whom, what and when)</i>		
166. <b>Notes:</b>		