

## Appendix 2 (as supplied by the authors): Study design features of non-observational studies

<b>Article</b>	Fraser LK et al 2013 <sup>1</sup>	
<b>Allocation</b>	Individual level	
<b>Study design</b>	RCS	
<b>Study design features</b>	<b>Support for judgment</b>	
<i>Was there a comparison:</i>		
Between two or more groups of clusters receiving different interventions?	Y	Children referred to a hospice service compared to those not referred within a health authority involving all hospitals in the area. Regression model also allowed for comparison within groups overtime
Within the same group of clusters over time?	Y	
<i>Were participant/clusters allocated to groups by:</i>		
Concealed randomization?	N	Record of program acceptance from the Pediatric Hospice. It's unknown why in the same period only 1/3 of the cohort was referred to the hospice program (family preferences, stigma, distance to the hospice, etc)
Quasi-randomization?	N	
By other action of researchers?	N	
Time differences?	N	
Location differences?	U	
Policy/public health decisions?	Y	
Cluster preferences?	U	
Some other process? (specify)	U	
<i>Which parts of the study were prospective:</i>		
Identification of participating clusters?	N	Administrative database analysis - entirely retrospective
Assessment of baseline and allocation to intervention?	N	
Assessment of outcomes?	N	
Generation of hypotheses?	U	
<i>On what variables was comparability between groups assessed:</i>		
Potential confounders?	Y	"- The regression model controlled for confounders including the covariates: age at diagnosis, disease category, gender and deprivation category."
Baseline assessment of outcome variables?	N	
<i>Other potential sources of bias/confounding/limitations/comments</i>		
<p>-There was no comparison of the outcome variable before the "referral" point between the groups to check for baseline differences.</p> <p>- Whether the patients were still in disease-directed treatment in both groups was not measured and/or controlled, and could be an explanatory factor for decrease in planned admissions.</p> <p>- The authors did not include days spent in hospice for the referred group to complement the total number of admissions for that group. It might conceal some shifting in resource utilization important to be measured in terms of healthcare resources consumption.</p> <p>- In the hospice group, median time from the diagnosis date to referral was calculated by cancer category and then applied to the same category in the control group, to create a point for comparison before/after referral. Interquartile range for time to referral varied widely between categories from 85 to over 1100 days.</p> <p>- Negative binomial regression modeling was used including each person's post referral period in the model as an exposure term.</p> <p>- The patients who did not link to the NHS hospital admission system (10.1%) differed from the patients included in this analysis and tended to be male, diagnosed under age of 5, and diagnosed towards the beginning of the study period.</p> <p>- Among the patients included in the analysis, the groups did differ in some demographics such as smaller % of patients between 15-19 referred to the hospice services, and disease category of Central Nervous System being the largest group disease among those referred to the hospice.</p>		

<b>Article</b>	<b>Keele L et al 2013 <sup>2</sup></b>	
<b>Allocation</b>	Individual level	
<b>Study design</b>	RCS	
<b>Study design features</b>	<b>Support for judgment</b>	
<i>Was there a comparison:</i>		
Between two or more groups of clusters receiving different interventions?	Y	Database from >40 hospital across USA. Other than the proportion of patients accessing PC services, no other characteristics were compared over time.
Within the same group of clusters over time?	N	
<i>Were participant/clusters allocated to groups by:</i>		
Concealed randomization?	N	Based on billing code, which changed overtime according to PC guidelines
Quasi-randomization?	N	
By other action of researchers?	N	
Time differences?	N	
Location differences?	N	
Policy/public health decisions?	Y	
Cluster preferences?	U	
Some other process? (specify)	U	
<i>Which parts of the study were prospective:</i>		
Identification of participating clusters?	N	Administrative database analysis - entirely retrospective
Assessment of baseline and allocation to intervention?	N	
Assessment of outcomes?	N	
Generation of hypotheses?	N	
<i>On what variables was comparability between groups assessed:</i>		
Potential confounders?	Y	LOS and Cost were not adjusted for by possible confounders, other than geography. Differences in the distribution of certain characteristics were presented (age, health insurance, race, diagnosis)
Baseline assessment of outcome variables?	N	
<i>Other potential sources of bias/confounding/limitations/comments</i>		
<ul style="list-style-type: none"> <li>- Children who received PC consultations in the last admission before death were different in some characteristics such as older age, race distributions with less access by blacks, having more private insurance, and increase access along the years.</li> <li>- Diseases categories varied significantly. In a subgroup analysis of complex chronic conditions (CCCs) patients (85% of the entire cohort) compared to those not having CCCs, patients with CCCs were more likely to have had a PC consultation (RR 2.2; 95% CI 1.7–2.8).</li> <li>- Comparison included all causes of death, no subgroup analysis for CCC group were presented on the differences in demographics and clinical characteristics.</li> <li>- The authors discussed limitations of the study regards to exclusion of patients discharged under hospice program and admissions &lt; 5 days, which may have underestimated the total numbers.</li> <li>- Changes in coding practices and maturation of PPCP also represent a potential bias because it cannot be measured.</li> </ul>		

<b>Article</b>		<b>Dussel V et al 2009<sup>3</sup></b>
<b>Allocation</b>		Individual level
<b>Study design</b>		RCS
<b>Study design features</b>		<b>Support for judgment</b>
<i>Was there a comparison:</i>		
Between two or more groups of clusters receiving different interventions?	Y	Cross-sectional survey with retrospective chart review + retrospective cohort comparison.
Within the same group of clusters over time?	Y	
<i>Were participant/clusters allocated to groups by:</i>		
Concealed randomization?	N	Based on survey responses, children from 2 clusters were separated in to 2 groups (had or had not planned the LOD by their parents).
Quasi-randomization?	N	
By other action of researchers?	Y	
Time differences?	N	
Location differences?	N	
Policy/public health decisions?	Y	
Cluster preferences?	U	
Some other process? (specify)	U	
<i>Which parts of the study were prospective:</i>		
Identification of participating clusters?	N	<ul style="list-style-type: none"> <li>• Retrospective chart review</li> <li>• Cross-sectional survey</li> </ul>
Assessment of baseline and allocation to intervention?	N	
Assessment of outcomes?	N	
Generation of hypotheses?	U	
<i>On what variables was comparability between groups assessed:</i>		
Potential confounders?	Y	<ul style="list-style-type: none"> <li>• For the determinants of having or not having planned LOD, there was some control for confounders. For the health resource utilization, no confounding was addressed.</li> <li>• The impact of LOD planning on healthcare resources was a secondary outcome and was not controlled for any confounder, nor was it further explored.</li> </ul>
Baseline assessment of outcome variables?	N	
<i>Other potential sources of bias/confounding/limitations/comments</i>		
<p>- Eligibility of the families depended upon physician's consent, which was declined for 19 families. It might introduce some selection bias.</p> <p>- Only one parent was interviewed which might have introduced some non-response bias.</p> <p>- Some interviews were done long time after the fact which might represent some recall bias (median 3 years).</p> <p>- Response rate 64%. The non-respondents were similar at child's age at death and diagnosis.</p> <p>- The study used regression with stepwise approach to study the determinants of planning LOD and control for confounders. The authors run sensitivity analysis for missing data and by physicians cluster. No differences in the results were shown.</p> <p>- Children with hematological cancer, those who died from treatment related complications, those families who were very religious were less likely to have planned LOD.</p> <p>- Children who had private insurance, families who had experience previous losses, those who reported that oncologist clearly explained treatment options and those who access home care were more likely to have planned LOD.</p>		

<b>Article</b>	<b>Knapp CA et al 2009<sup>4</sup></b>
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<b>Allocation</b>		Individual level
<b>Study design</b>		RCS
<b>Study design features</b>		<b>Support for judgment</b>
<i>Was there a comparison:</i>		
Between two or more groups of clusters receiving different interventions?	Y	Included children from several hospitals and hospice catchment areas within province
Within the same group of clusters over time?	Y	
<i>Were participant/clusters allocated to groups by:</i>		
Concealed randomization?	N	The authors allocated the 2 groups based on claims for hospice services. Limitations from unbilled and unpaid services existed as 5 patients in the non-hospice user group died in hospice.
Quasi-randomization?	N	
By other action of researchers?	Y	
Time differences?	N	
Location differences?	N	
Policy/public health decisions?	Y	
Cluster preferences?	U	
Some other process? (specify)	U	
<i>Which parts of the study were prospective:</i>		
Identification of participating clusters?	N	Administrative database entirely retrospective
Assessment of baseline and allocation to intervention?	N	
Assessment of outcomes?	N	
Generation of hypotheses?	U	
<i>On what variables was comparability between groups assessed:</i>		
Potential confounders?	N	There was subgroup analysis per diagnosis group but no regression was carried to control for other covariates (e.g. gender, race, length of enrollment in the insurance, etc.) to determine differences in healthcare expenditures between groups. No statistical test was applied to check significant differences between groups in healthcare expenditures.
Baseline assessment of outcome variables?	N	
<i>Other potential sources of bias/confounding/limitations/comments</i>		
<p>- Although the authors found some patients' characteristics to be associated to more or less hospice use, when analyzing the expenditures, only subgroup analysis by diagnostic category were presented. No other factor was control as confounders (gender, race and time enrolled in the Medicaid program, place of death).</p> <p>- The authors discussed the limitations of the study such as the limited generalizability for children with private insurance or uninsured, which represents 2/3 of the pediatric population dying in the province.</p>		

<b>Article</b>		<b>Arland LC et al 2013<sup>5</sup></b>	
<b>Allocation</b>		Group Level	
<b>Study design</b>		ChBA	
<b>Study design features</b>		<b>Support for judgment</b>	
<i>Was there a comparison:</i>			
Between two or more groups of clusters receiving different interventions?	N	Children with brain tumors from a single pediatric-oncology department that implemented an EOL program	
Within the same group of clusters over time?	Y		
<i>Were participant/clusters allocated to groups by:</i>			
Concealed randomization?	N	Study Before/after the implementation of a standardized EOL program carried by a hospital	
Quasi-randomization?	N		
By other action of researchers?	N		
Time differences?	Y		
Location differences?	N		
Policy/public health decisions?	Y		
Cluster preferences?	na		
Some other process? (specify)	na		
<i>Which parts of the study were prospective:</i>			
Identification of participating clusters?	N	Chart review entirely prospective	
Assessment of baseline and allocation to intervention?	N		
Assessment of outcomes?	N		
Generation of hypotheses?	U		
<i>On what variables was comparability between groups assessed:</i>			
Potential confounders?	N	Authors disclosed not having addressed any potential confounders, and difficulties with missing data (demographics), unclear EOL periods before the program was implemented, and changes in treatment course/disease management	
Baseline assessment of outcome variables?	na		
<i>Other potential sources of bias/confounding/limitations/comments</i>			
<p>- The groups had different criteria to determine EOL period. Several individuals in the historical control had EOL determined based on radiology reports of the disease progression, which does not mean they had been treated as EOL patients. The intervention group had a date for EOL discussion, referral to hospice or complete DNR order. The historical control cohort period was reduced because there was no formal onco-pediatric program previous to this date compromising the quality of data quality.</p> <p>- Authors explain exclusion of only 22/52 patients excluded from the initial cohort of 166 patients.</p> <p>- The authors aimed to measure symptoms but did not present any data on that other than hospitalizations. Likewise, they stated fewer complication after the implementation of the program but did not show any data.</p> <p>- No demographic data comparison was presented. No ethics approval was mentioned.</p> <p>- Although the authors extensively stated the limitations for the study such as temporality, demographics information missing, no symptom measurement scale available, maturation of the disease management and EOL care, changes in health insurance policies, no statistical analysis were applied to some presented outcomes.</p>			

<b>Article</b>	<b>Postier et al 2014<sup>6</sup></b>	
<b>Allocation</b>	Individual level	
<b>Study design</b>	ChBA	
<b>Study design features</b>	<b>Support for judgment</b>	
<i>Was there a comparison:</i>		
Between two or more groups of clusters receiving different interventions?	N	Children enrolled in the PPCP carried by a tertiary provider Pre/Post cost and hospital admissions comparison
Within the same group of clusters over time?	Y	
<i>Were participant/clusters allocated to groups by:</i>		
Concealed randomization?	N	Authors classified the pre/post period based on the first day of PPCP/hospice program utilization
Quasi-randomization?	N	
By other action of researchers?	Y	
Time differences?	N	
Location differences?	N	
Policy/public health decisions?	N	
Cluster preferences?	U	
Some other process? (specify)	U	
<i>Which parts of the study were prospective:</i>		
Identification of participating clusters?	N	Administrative database entirely retrospective
Assessment of baseline and allocation to intervention?	N	
Assessment of outcomes?	N	
Generation of hypotheses?	N	
<i>On what variables was comparability between groups assessed:</i>		
Potential confounders?	Y	Multivariate regression accounting for exposure to the program, disease group and study period
Baseline assessment of outcome variables?	Y	
<i>Other potential sources of bias/confounding/limitations/comments</i>		
<ul style="list-style-type: none"> <li>- As any other pre/post design without a control group for comparison, it's unclear whether the observed decrease in LOS and charges are due to the PPCP or a natural trend among those type of patients.</li> <li>- It is not clear the proportion of patients who died at the hospital/home, which would deeply affect charges closer to death.</li> <li>- Selection bias regards to referral are always present in this type of program.</li> <li>- Charges with home care were not accounted for.</li> <li>- Non-parametric test applied to compare the outcomes pre/post does not take into account the different time of exposure to the program which may overestimate the differences between pre/post.</li> <li>- Authors do not report the estimates from the regressions.</li> </ul>		

<b>Article</b>	<b>Gans D et al 2012<sup>7</sup></b>	
<b>Allocation</b>	Individual level	
<b>Study design</b>	ChBA	
<b>Study design features</b>	<b>Support for judgment</b>	
<i>Was there a comparison:</i>		
Between two or more groups of clusters receiving different interventions?	Y	Children enrolled in the community palliative care program in California, using several healthcare providers in different counties
Within the same group of clusters over time?	Y	
<i>Were participant/clusters allocated to groups by:</i>		
Concealed randomization?	N	Before-after enrollment in the program criteria not clearly stated. It seems to be a registry for the enrollees.
Quasi-randomization?	N	
By other action of researchers?	N	
Time differences?	Y	
Location differences?	N	
Policy/public health decisions?	Y	
Cluster preferences?	U	
Some other process? (specify)	U	
<i>Which parts of the study were prospective:</i>		
Identification of participating clusters?	N	Administrative database entirely retrospective
Assessment of baseline and allocation to intervention?	N	
Assessment of outcomes?	N	
Generation of hypotheses?	N	
<i>On what variables was comparability between groups assessed:</i>		
Potential confounders?	N	Authors did not address confounders that could influence the outcomes such as diagnosis type, city, age, availability of services, proximity to death, etc.
Baseline assessment of outcome variables?	N	
<i>Other potential sources of bias/confounding/limitations/comments</i>		
<ul style="list-style-type: none"> <li>- The enrollment in the program depended on financial criteria to be covered by MediCal. Which included life-threatening conditions and were expanded to all conditions expected to consume more than 30 days/year of hospital admissions.</li> <li>- Not clear if all the patients enrolled in the same point in time, and if the before and after expenditures were flagged as such, independent of how long they were under the program.</li> <li>- Unbilled or unpaid claims were excluded from the data, possibly overestimating cost savings.</li> <li>- Survey used a likert scale of 4 points the author's called quality of life. No validation mentioned.</li> <li>- No control group was used to compare natural trends in shift of healthcare resources utilization.</li> <li>- The authors briefly mention certain limitations of the study and the need to use full administrative data with control, to better estimate the differences suggested by this report on the shift of healthcare resource allocation.</li> </ul>		

<b>Article</b>	<b>Pascuet E et al 2010<sup>8</sup></b>	
<b>Allocation</b>	Individual level	
<b>Study design</b>	ChBA	
<b>Study design features</b>	<b>Support for judgment</b>	
<i>Was there a comparison:</i>		
Between two or more groups of clusters receiving different interventions?	N	Children who used the respite admission at least once, had their total hospital/hospice admissions measured before and after access to first respite
Within the same group of clusters over time?	Y	
<i>Were participant/clusters allocated to groups by:</i>		
Concealed randomization?	N	It is not clear whether the groups were determined by the date of hospice opening or the date of first utilization of respite services from a pediatric hospice
Quasi-randomization?	N	
By other action of researchers?	N	
Time differences?	N	
Location differences?	N	
Policy/public health decisions?	Y	
Cluster preferences?	U	
Some other process? (specify)	U	
<i>Which parts of the study were prospective:</i>		
Identification of participating clusters?	N	Administrative database entirely retrospective
Assessment of baseline and allocation to intervention?	N	
Assessment of outcomes?	N	
Generation of hypotheses?	N	
<i>On what variables was comparability between groups assessed:</i>		
Potential confounders?	N	Authors did not address confounders that could influence outcomes such as different types of inpatient utilization, diseases categories, age or proximity to services.
Baseline assessment of outcome variables?	N	
<i>Other potential sources of bias/confounding/limitations/comments</i>		
<ul style="list-style-type: none"> <li>- The authors stated that the cost for inpatient admissions at the hospital had a fixed cost per day (based on 2007 cost), based on the interprovincial billing rate (including direct healthcare cost and overhead costs). Costs were not differentiated per type of admission - general, critical care.</li> <li>- Not clear if costs included emergency and outpatient visits, and how their costs were addressed.</li> <li>- Cost for hospice care was calculated by average cost per day, being the annual hospice budget divided by number of beds per year. It seems that hospice only provided respite care.</li> <li>- Not clear if all patients included had 24 months of observation period. Not clear, in case of shorter period, if the outcomes were weighted by time in the study.</li> <li>- The authors recognize the limitations of different cost analyses across institutions.</li> </ul>		



<b>Article</b>	<b>Smith A et al 2013<sup>9</sup></b>	
<b>Allocation</b>	Individual level	
<b>Study design</b>	ChBA/RCS	
<b>Study design features</b>	<b>Support for judgment</b>	
<i>Was there a comparison:</i>		
Between two or more groups of clusters receiving different interventions?	N	Children discharged from a single tertiary care provider
Within the same group of clusters over time?	Y	
<i>Were participant/clusters allocated to groups by:</i>		
Concealed randomization?	N	Authors classified groups based on utilization of PC consultation
Quasi-randomization?	N	
By other action of researchers?	N	
Time differences?	Y	
Location differences?	N	
Policy/public health decisions?	Y	
Cluster preferences?	na	
Some other process? (specify)	na	
<i>Which parts of the study were prospective:</i>		
Identification of participating clusters?	na	Abstract does not bring enough information on the methods
Assessment of baseline and allocation to intervention?	na	
Assessment of outcomes?	na	
Generation of hypotheses?	na	
<i>On what variables was comparability between groups assessed:</i>		
Potential confounders?	N	Authors did not control for any confounders
Baseline assessment of outcome variables?	N	
<i>Other potential sources of bias/confounding/limitations/comments</i>		
<p>- Abstract presented at a conference. It does not bring enough information about the methods applied in this research. We are unable to evaluate risk of bias, selection and identification of participants, intervention definition.</p> <p>- The authors did not control for differences in the population found in the research such as gender, comorbidities, technology dependence.</p>		

<b>Article</b>	<b>Ward-Smith P et al <sup>10</sup></b>	
<b>Allocation</b>	Group Level	
<b>Study design</b>	CC	
<b>Study design features</b>	<b>Support for judgment</b>	
<i>Was there a comparison:</i>		
Between two or more groups of clusters receiving different interventions?	Y	Cases and controls from 1 hospital who carried the PPCP
Within the same group of clusters over time?	Y	
<i>Were participant/clusters allocated to groups by:</i>		
Concealed randomization?	N	Cases and controls were not chosen randomly, and were rather chosen to provide a range of diagnoses and enrollment in the PPCP within 6 months prior to death.
Quasi-randomization?	N	
By other action of researchers?	Y	
Time differences?	U	
Location differences?	N	
Policy/public health decisions?	N	
Cluster preferences?	U	
Some other process? (specify)	U	
<i>Which parts of the study were prospective:</i>		
Identification of participating clusters?	N	Administrative database entirely retrospective
Assessment of baseline and allocation to intervention?	N	
Assessment of outcomes?	N	
Generation of hypotheses?	N	
<i>On what variables was comparability between groups assessed:</i>		
Potential confounders?	N	None
Baseline assessment of outcome variables?	N	
<i>Other potential sources of bias/confounding/limitations/comments</i>		
<ul style="list-style-type: none"> <li>- Although the authors named the study as case-control, it is technically a cohort comparison, where the cohorts were distinct by the intervention – received services from the pediatric palliative care program.</li> <li>- Among the 133 possible cases identified under the inclusion criteria, the authors chose 9. This choice was not random but made by the authors to provide a range of diagnostics and because they had being enrolled in the PPCP within 6 months before death.</li> <li>- Do not state the matching criteria and if it was randomly selected or, as the cases, chosen by nurses.</li> <li>- Not clear if the controls were contemporary to the cases or if they were selected from the period before the implementation of the program.</li> <li>- Controls were slightly different in gender, and race.</li> <li>- It does not specify if the cost was adjusted to reflect the inflation, or if they incurred in the same period for cases and controls.</li> </ul>		

<b>Article</b>	Belasco JB et al <sup>11</sup>	
<b>Allocation</b>		
<b>Study design</b>	CR/CS	
<b>Study design features</b>	<b>Support for judgment</b>	
<i>Was there a comparison:</i>		
Between two or more groups of clusters receiving different interventions?	na	Case series with 3 patients
Within the same group of clusters over time?	na	
<i>Were participant/clusters allocated to groups by:</i>		
Concealed randomization?	N	Out of the 154 patients enrolled in the PPCP during the study period, some were selected by the author to reflect medically complicated patients, whose level of care at home was comparable to being in hospital, and differed only in palliative intent rather than intent to cure.
Quasi-randomization?	N	
By other action of researchers?	Y	
Time differences?	N	
Location differences?	N	
Policy/public health decisions?	N	
Cluster preferences?	U	
Some other process? (specify)	U	
<i>Which parts of the study were prospective:</i>		
Identification of participating clusters?	N	Administrative database entirely retrospective
Assessment of baseline and allocation to intervention?	N	
Assessment of outcomes?	N	
Generation of hypotheses?	N	
<i>On what variables was comparability between groups assessed:</i>		
Potential confounders?	na	None
Baseline assessment of outcome variables?	na	
<i>Other potential sources of bias/confounding/limitations/comments</i>		
<p>- Did not state how the patients were selected.</p> <p>- Did not describe how the number and types of procedures for charges comparison were measured and the comparison was created. It's not clear if the type of procedures were compared to a control, or if it was estimated to adapt to the home care model for the same patient, or if it was measured from the same patient in both settings.</p> <p>- The authors stated that for home care, because the way the insurances operate locally, charges per day did not included physicians home visit, social worker, coordinator of care, skilled nurse visits longer than 2 hours. Also, visits and procedures not authorized by insurance were not included, which may represent part of the out-of-pocket expenses for families, and not reflected in this comparison.</p> <p>- Charges do not appropriately reflect costs, introducing important measurement bias.</p>		

## References

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