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## Background

Guidance on trial reporting outlines that primary and secondary outcomes should be presented with the estimated effect size and its range (CONSORT Statement [1]).

**In oncology trial reports:** the primary outcomes are mainly time-to-event outcomes (such as overall survival and progression-free survival) that are presented in the form of survival curves. **CONSORT recommends that the effect size be expressed as the Hazard Ratio (HR) or difference in median survival time and its Confidence Interval (CI) [1].**

**In systematic reviews:** it is preferred that time-to-event outcome data are pooled using HRs for meta-analyses [2].

## Objective

To conduct a case study on whether or not oncology trial reports comply with CONSORT by providing appropriate effect sizes and ranges for time-to-event outcomes.

## Methods

1. A Cochrane review update on Taxane-containing regimens for metastatic breast cancer was selected as the case study
2. Only the included trials with a full-text publication were eligible for data extraction
3. For each included trial, each key point below was coded by one author as present or absent:
  - Type of time-to-event outcome reported i.e. overall survival, progression-free survival (PFS) or time-to-failure (TTF)
  - A Kaplan-Meier curve
  - An effect size: HR, difference in median survival or risk ratio (RR)
  - Range: either CI or standard error (SE)
4. Data were presented as the frequency of reporting key event data

## Conclusions & Recommendations

### In this case study:

- The majority of articles reported an estimated effect size (i.e. HR, difference in median survival or RR) irrespective of whether the article was published in 1995 or 2011
- The associated CIs for the effect size were not consistently reported, that is, 58.3% of the time for overall survival and 78.3% for PFS/TTF
- Only 25% to 34.8% of the included trials reported HRs associated with the survival curve

### Recommendations:

Trial authors should consider:

- Reporting CIs for effect sizes, as is required by the CONSORT statement
- Reporting meaningful effect sizes such as HRs for time-to-event outcomes to facilitate uptake into meta-analyses in systematic reviews

## Results

- 24 full-text trial reports were eligible
- **For overall survival (OS)** (see Table 1): all 24 articles reported OS data
  - 23 out of 24 articles presented an estimated effect size while their range was absent in 10 out of 24 articles
  - HRs were provided in 6 out of 24 articles
  - HRs and CIs were absent in articles published in 1995 and 2009

**Table 1.** Reporting of key event data for overall survival

Trial publication & year	Kaplan Meier curve presented?	HR reported?	CI reported?	P value reported?	Other effect size reported?	Range of other effect size?
Pub1, 1995	✓	X	X	✓	✓: Median (months)	X
Pub2, 1999	✓	X	X	✓	✓: Risk Ratio	✓
Pub3, 1999	✓	X	X	✓	✓: Risk Ratio	X
Pub4, 1999	✓	X	X	✓	✓: Median (months)	✓
Pub5, 2000	✓	X	X	✓	✓: Risk Ratio	X
Pub6, 2001	✓	✓	✓	✓	X	X
Pub7, 2002	✓	✓	✓	✓	X	X
Pub8, 2002	X	X	X	X	✓: Median (months)	✓
Pub9, 2002	✓	X	X	✓	✓: Median (months)	X
Pub10, 2003	✓	X	X	✓	✓: Median (months)	X
Pub11, 2003	✓	X	X	✓	✓: Median (months)	X
Pub12, 2003	✓	X	X	✓	✓: Median (months)	✓
Pub13, 2004	✓	X	X	X	✓: Median (months)	X
Pub14, 2004	✓	X	X	X	X	X
Pub15, 2005	✓	✓	✓	✓	X	X
Pub16, 2005	X*	X*	X*	✓	X*	X
Pub17, 2005	✓	X	X	✓	✓: Median (months)	✓
Pub18, 2005	✓	✓	✓	✓	X	X
Pub19, 2007	✓	X	X	✓	✓: Median (months)	✓
Pub20, 2008	✓	X	X	✓	✓: Duration (days)	✓
Pub21, 2009	✓	X	X	✓	✓: Median (months)	✓
Pub22, 2009	✓	X	X	✓	✓: Median (months)	✓
Pub23, 2010	✓	✓	X	✓	X	X
Pub24, 2011	✓	✓	✓	✓	X	X
<b>Total (% of 24 articles):</b>	<b>22 (91.6%)</b>	<b>6 (25%)</b>	<b>5 (20.8%)</b>	<b>22 (91.6%)</b>	<b>16 (66.6%)</b>	<b>9 (37.5%)</b>

\* Immature data;  
Abbreviations: Pub = publication

- **For PFS or TTF** (see Table 2): 23 articles reported PFS or TTF data
  - All articles reported either an HR, RR or difference in median survival
  - 5 out of 23 articles (21.7%) did not present CIs or SEs

**Table 2.** Reporting of key event data for PFS or TTF

Key data	Kaplan Meier curve presented	HR reported	CI reported	P value reported	Other effect size reported	Range for other effect size reported
No. of articles presenting data on PFS or TTF	22	8	7	21	15 (Median= 12; Risk Ratio= 3)	11
% of total no. of articles	95.7%	34.8%	30.4%	91.3%	65.2%	47.8%