National, centralised hospital datasets can inform clinical trial outcomes in prostate cancer: a pilot study in the STAMPEDE trial

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AIM
Can routinely collected data be used to capture clinical trial events?

To develop a method to identify these major events in prostate cancer

To test if clustering of routinely collected NHS data correlates with major progressive disease events

ABSTRACT
Hospital Episode Statistics (HES) are routinely collected data describing National Health Service (NHS) hospital visits in England, with prevalent & disease codes. This study, embodied in STAMPEDE, aimed to build a model using HES linked to primary medical records & trial case report forms (CRFs) to identify progressive disease events (PDEs), including skeletal-related events (SREs).

METHOD
Data collection
JS, Smeeth L, 10
Identify possible study, case & HES not & codes
94
Procedure
B identified more events than traditional trial data (SREs), note
PDE
England, as
HES
of
compared patients (missed SREs isolated from routine hospital statistic data coding Jul
missed to
57
events PDEs
Progressive disease events (PDEs) isolated from clustering; manual model medical CRFs
An equal number of SREs to trial data (9/20)
positive
2
14
HES
predicted false
Episode use when
16
upgraded
patients were
Randomised to original arms A
Hence
Identified the majority of events nearer additional (false
Number events PDEs found
HES to
a
Skeletal Related Events (SREs)
& detected missed events 98 using Statistics identified PDEs
recorded records of
This
interval
PDEs
outcome -
primary &
HES
CRFs
trial
to

Faster, cheaper clinical trials on population data

CONCLUSION
Clustered identified progression events
Routine hospital statistic data:
• detected missed events
• identified more events than traditional trial data
• identified the majority of events added the collection of SRE data
• missed some events however more identified than trial data
For this purpose routine data seems to have sufficient accuracy

Algorithms seem feasible to detect progression events and SREs in prostate cancer

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Methods
Analysis of S STAMPEDE patients (men) in 5 stages ( iota to Jul 14): 1: Detailed manual review of 5 pt PDEs were compared to HES & CRFs to build model; 2: Unused model used to test if identify possible PDEs in 2 pt, test if noted by note review & compared to CRFs. Created algorithm rules to identify PDEs for 5 pt interval plus further analysis of HES coding

Results
Prostate cancer PDEs coinciding with clustering of HES events. HES found 4 PDEs related to the CRFs: prostate cancer (II), bladder cancer (II), kidney cancer (II), & pituitary (II). HES found 3 false positives in CRFs: prostate cancer (II), bladder cancer (II), & pituitary (II).

CONCLUSION
Hospital review validated, site plan may miss reporting major clinical efficacy outcomes on CRFs, especially rare end-of-life. HES accurately identified SREs (often found as a cluster of SREs), plus additional trial events not reported on CRFs compared to note review. As PDEs are important as prior history can impact accuracy.

METHOD – Data collection - Stage 1
Data analysed
Routine hospital statistic data

HospitaI administration system incl. clinical records, correspondences, & laboratory (clinical note review).

STAMPEDE Clinical trial Case Report Forms
Collect information for trial analysis

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