

Claims-based Clinical Follow-up

Achieving Operational Efficiency

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Disclosures

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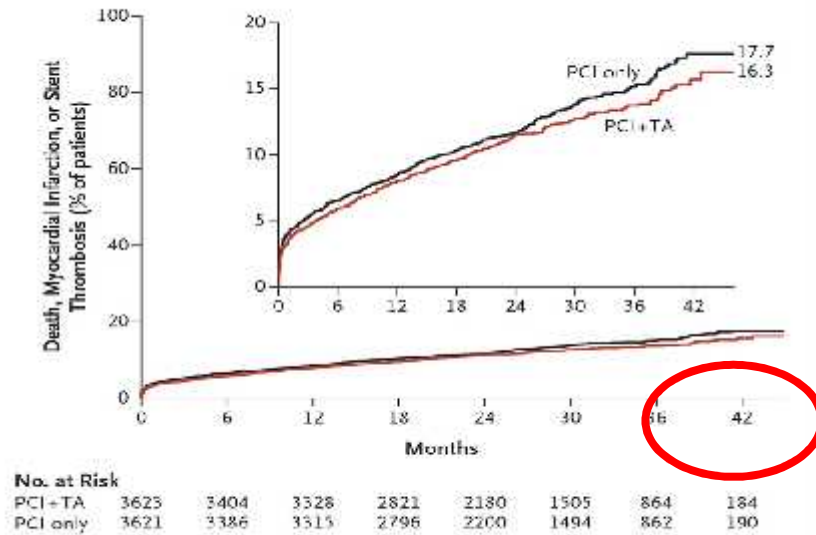
No significant industry relationships.



Claims-based Patient Follow-up STEMI Thrombectomy Story



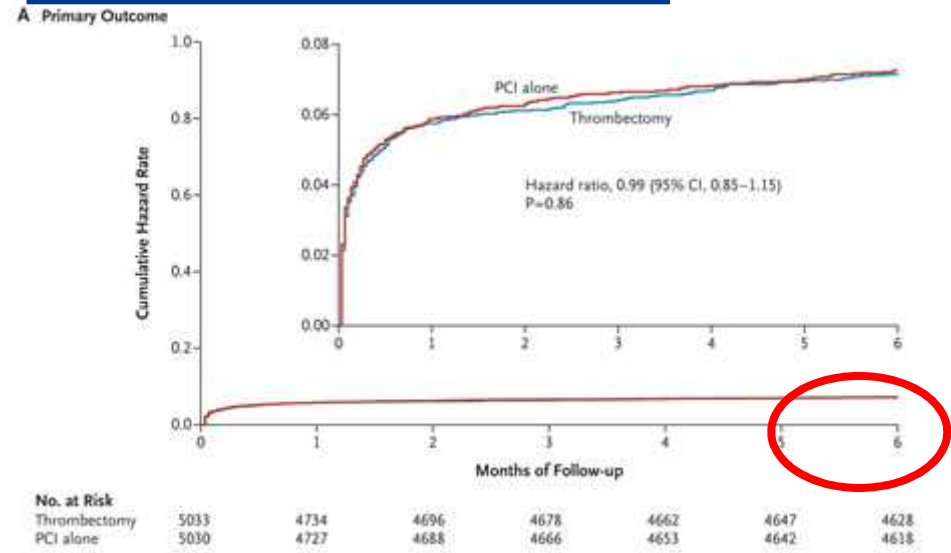
Claims-based Follow-up



1st patient: June 2010
 30 centers
 33 months to full enrollment
 7500 patients

Lagerqvist B et al. N Engl J Med 2014;371:1111-1120

Site-based Follow-up



1st patient: August 2010
 87 centers
 48 months to full enrollment
 10,700 patients

Jolly SS et al. N Engl J Med 2015;372:1389-1398

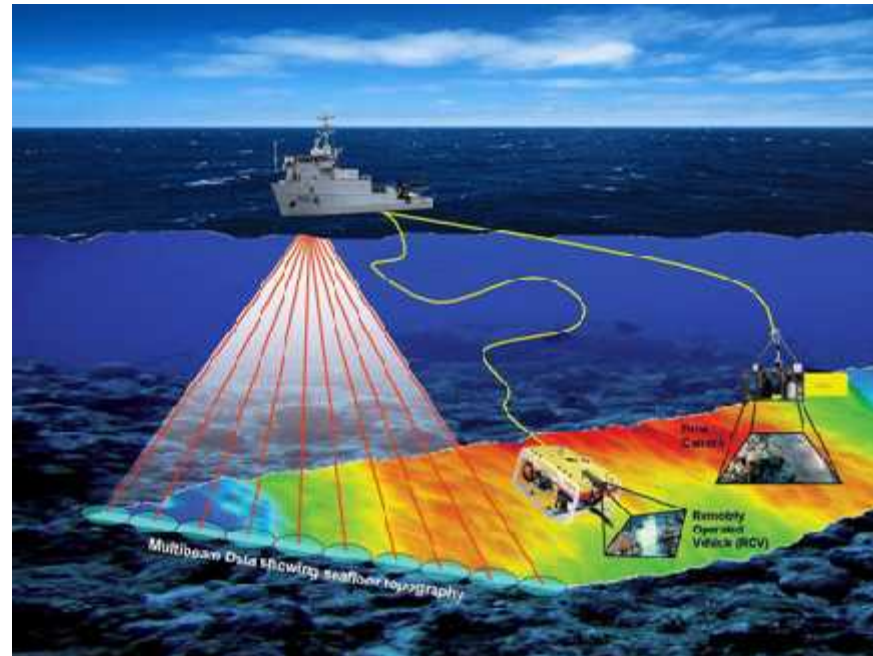


Claims-based Patient Follow-up

Where does it fit in the toolbox?



Stand-Alone



Trigger for 'Deeper Dive'



Claims-based Patient Follow-up Strengths and Weaknesses





Claims-based Patient Follow-up

1. Index
2. Open
3. Not
4. Sta
5. Up
6. Au

ICD



Intelligence





Claims-based Patient Follow-up

The Weaknesses

1. Limited detail (e.g., mechanism of failure)
2. May not capture 'silent' or clinically irrelevant events
3. 'Covered lives'
4. Timeliness
5. Data ownership and portability
6. ~~Data Accuracy~~



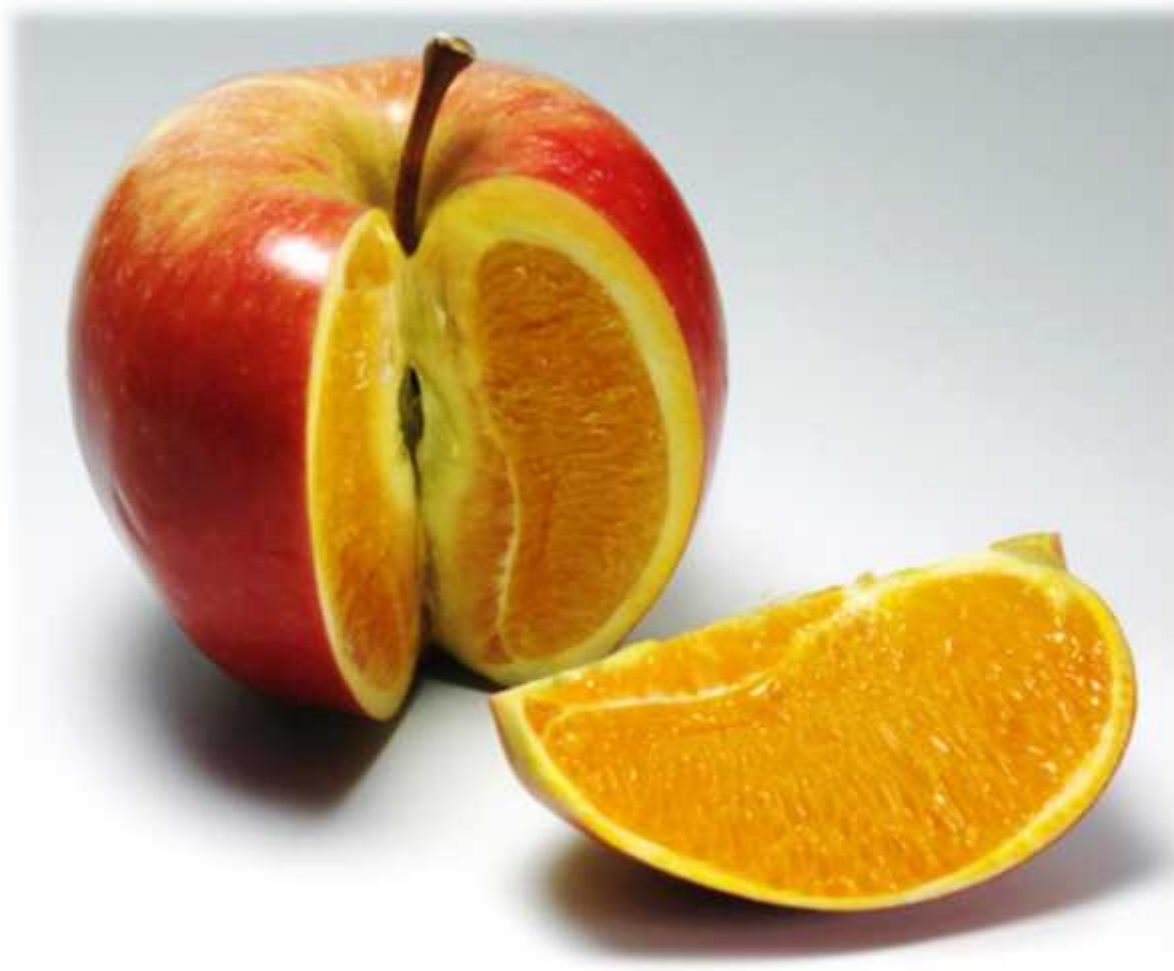
Claims-based Patient Follow-up Accuracy Matters





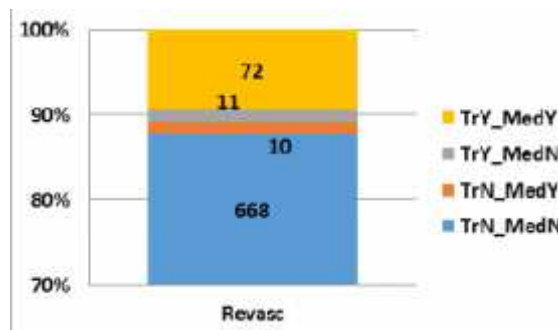
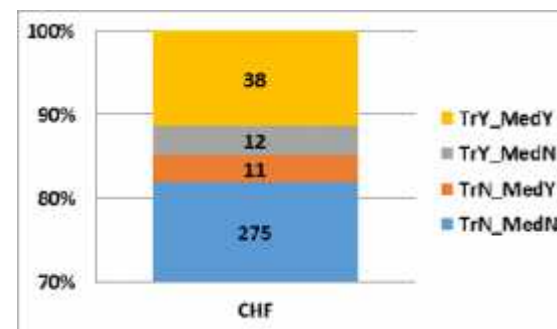
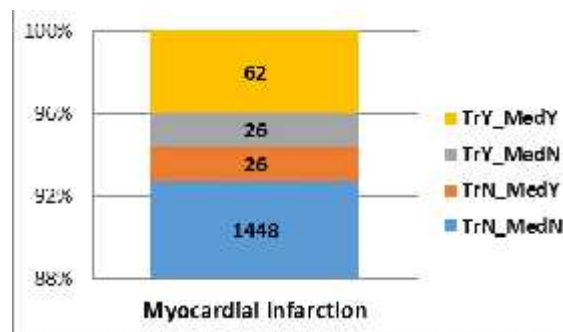
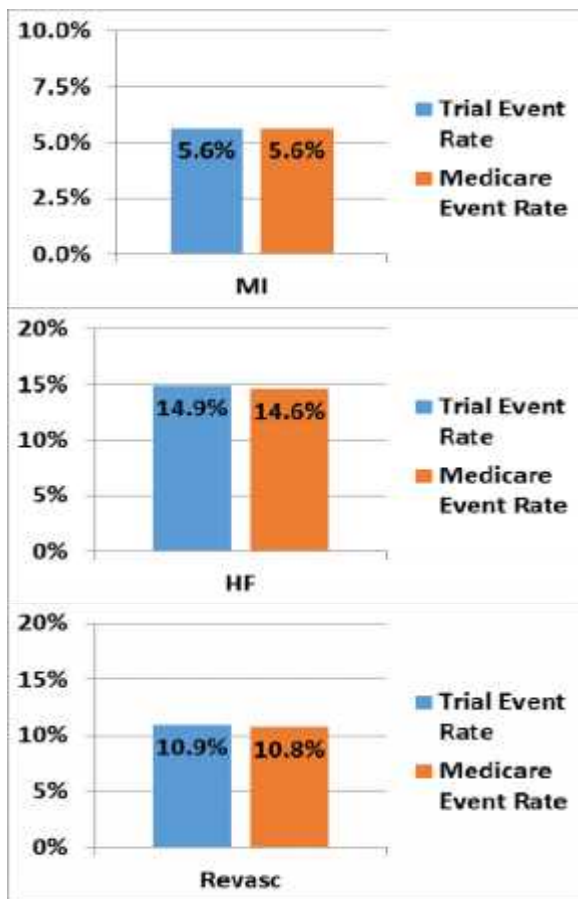
Claims-based Patient Follow-up

Apples and Oranges





Claims-based Patient Follow-up Absolute Event Rates



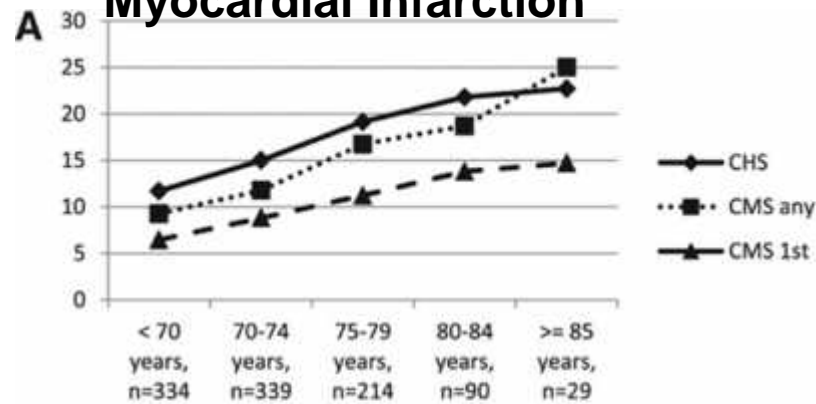
Similar event rates, but different patients with Claims-based vs Trials-based AE detection for select CV endpoints.



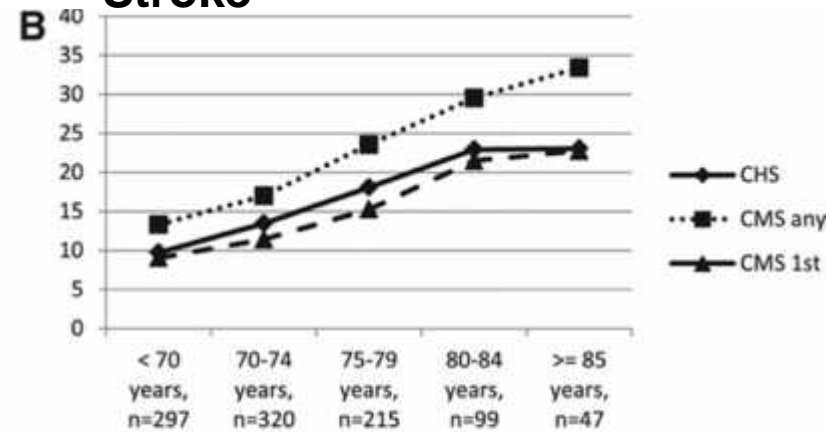
Claims-based Patient Follow-up Outcome Definitions Matter



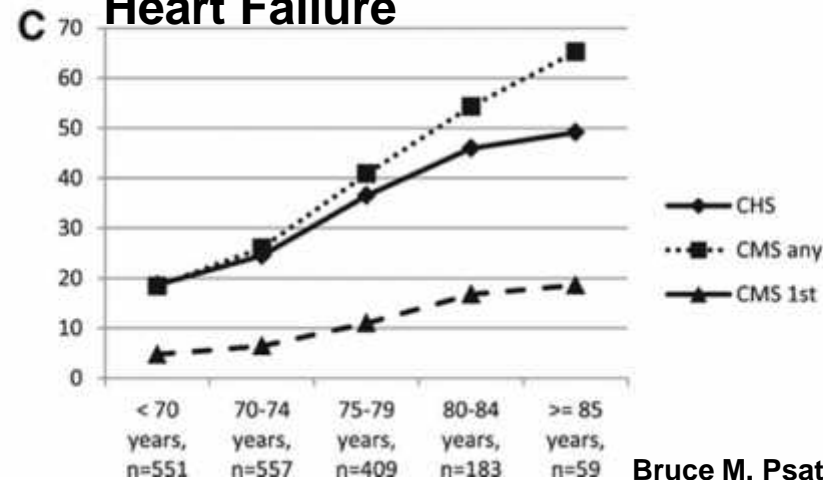
A Myocardial Infarction



B Stroke

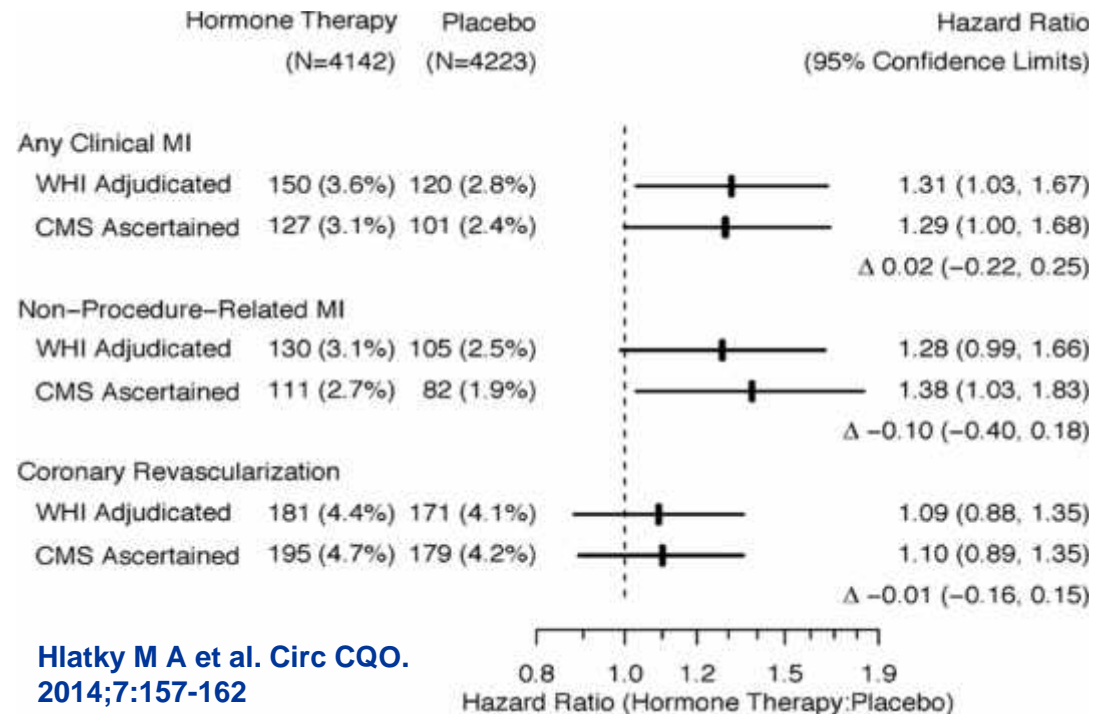


C Heart Failure





Claims-based Patient Follow-up Relative Treatment Effects



Similar treatment effects for
Claims-based vs site-based AE detection
for select CV endpoints.



Claims-based Patient Follow-up

Take-home Points

1. Claims-based follow-up is an **efficient** tool for patient follow-up in clinical research;
2. Event Rates may differ between Claims-based vs Site-based follow-up;
3. Treatment comparisons are similar across follow-up methods



Claims-based Patient Follow-up

Is it right for my study?

Checklist

1. Are clinical outcomes sufficient?
 - *Is the 'mechanism of failure' established?*
2. Is there an important nuance to the outcome definition that wouldn't be captured in the 'clinical definition'?
3. How likely are 'silent' events?
4. Is 'target population' covered?
5. What are the implications of 'data ownership' & 'data portability' rules?



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THANK YOU