

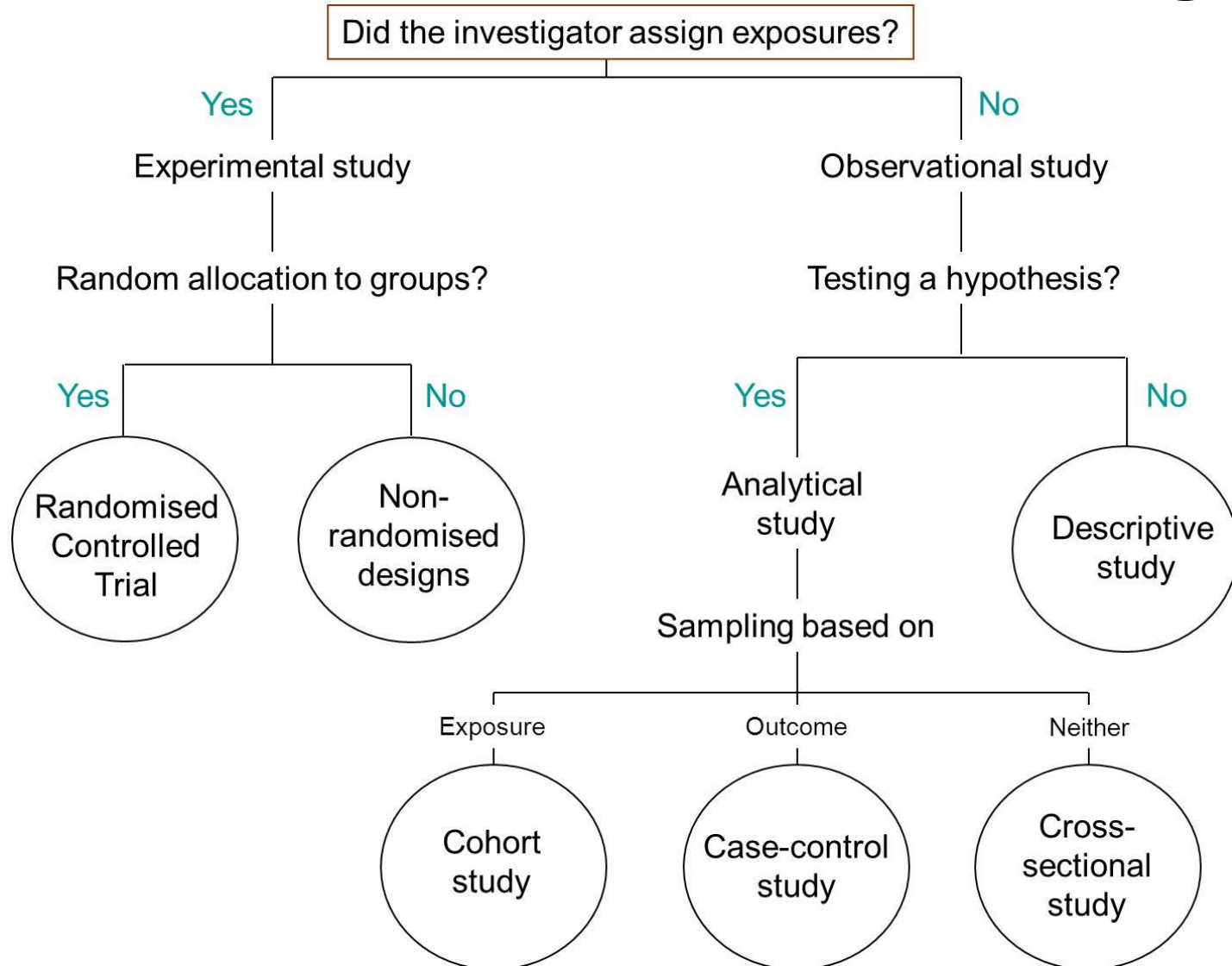
# National ICU registries

## The use of registry data in research

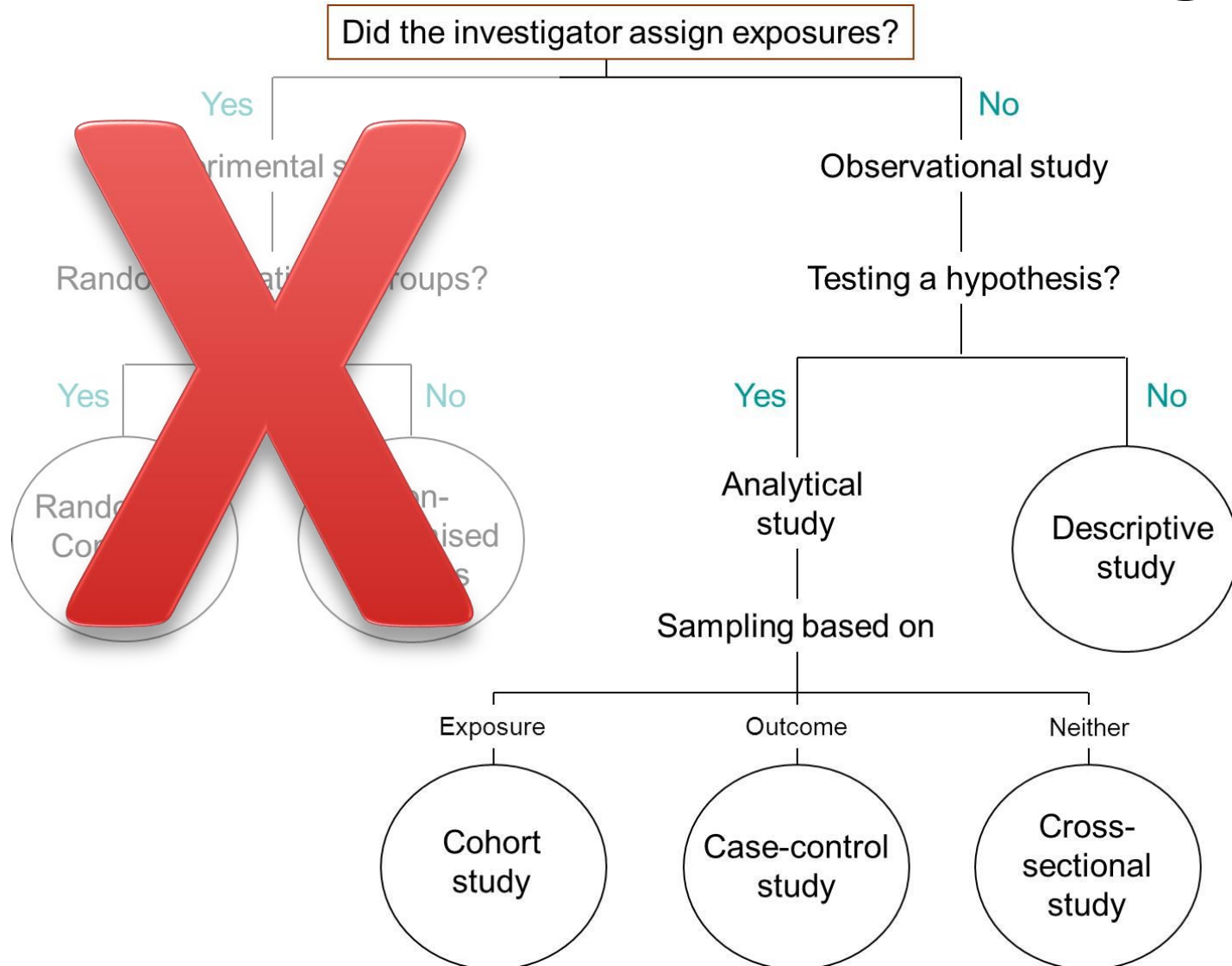
### *Outline*

- The present state
- The current research paradigm
- The next step in registry research

# Quantitative research designs



# Quantitative research designs





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A multifaceted feedback strategy alone does not improve the adherence to organizational guideline-based standards: a cluster randomized trial in intensive care.

de Vos ML, van der Veer SN, Wouterse B, Graafmans WC, Peek N, de Keizer NF, Jager KJ, Westert GP, van der Voort PH.

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Intensive care admission of cancer patients: a comparative analysis.

Bos MM, Verburg IW, Dumaij I, Stouthard J, Nortier JW, Richel D, van der Zwan EP, de Keizer NF, de Jonge E.

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Why Did Poisoned Patients Eventually Die Long After Their ICU Stay? The authors reply.

Brandenburg R, Brinkman S, de Keizer NF, Meulenbelt J, de Lange DW.

CRITICAL CARE MEDICINE 43(1), 2015, p.e26-.

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How to Assist Intensive Care Units in Improving Healthcare Quality. Development of Actionable Quality Indicators on Blood use.

Roos Blom Marie José, Dongelmans Dave, Arbous M. Sesmu, de Jonge Evert, de

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### PUBLICATIONS

Order By Year ▼

#### Critical care network (8)

**Nursing intensive care skills training: A nurse led, short, structured, and practical training program, developed and tested in a resource-limited setting**

October 29, 2014    NICS, PBCN, MOH & MEDARC



Nursing Intensive Care Skills Training was highly rated by participants and was effective in improving the knowledge of the participants. This sustainable short course model may be adaptable to other resource-limited settings.

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## Nursing Intensive Care

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L'attività scientifico-divulgativa del gruppo comprende una serie di lavori pubblicati su riviste nazionali ed internazionali, numerose comunicazioni scientifiche a congressi nazionali ed internazionali e due opere monografiche.

ANNO									
						<a href="#">2015</a>	<a href="#">2014</a>	<a href="#">2013</a>	<a href="#">2012</a>
<a href="#">2011</a>	<a href="#">2010</a>	<a href="#">2009</a>	<a href="#">2008</a>	<a href="#">2007</a>	<a href="#">2006</a>	<a href="#">2005</a>	<a href="#">2004</a>	<a href="#">2003</a>	<a href="#">2002</a>
<a href="#">2001</a>	<a href="#">2000</a>	<a href="#">1999</a>	<a href="#">1998</a>	<a href="#">1997</a>	<a href="#">1996</a>	<a href="#">1995</a>	<a href="#">1994</a>	<a href="#">1993</a>	<a href="#">1992</a>
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## CORE - Publications

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# ...in addition to observational studies

Registries may be used

- generation of hypotheses
- to aid design of RCTs
- to detect/adjudicate end-points in RCTs
- for 'piggyback' research studies



# Piggyback research studies

- Piggy-back research studies link case report forms to registry data from same patient/admission
- Registry data may provide sociodemographics, physiology data, standardised severity scores, comorbidities, diagnoses, receipt of organ support, mortality, length of stay and more.....
- Unique person identifier – if available - may be used for linkage to health care registries, vital statistics and more (i.e. education, employment, income, residence)
- ....



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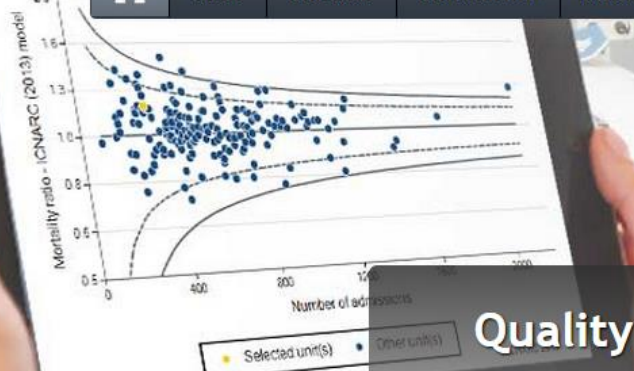
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Quality data for quality care

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### Board of Management - Trustee

We are seeking to appoint Trustees with clinical experience to join our Board of Management.



# ICNARC Clinical Trials Unit

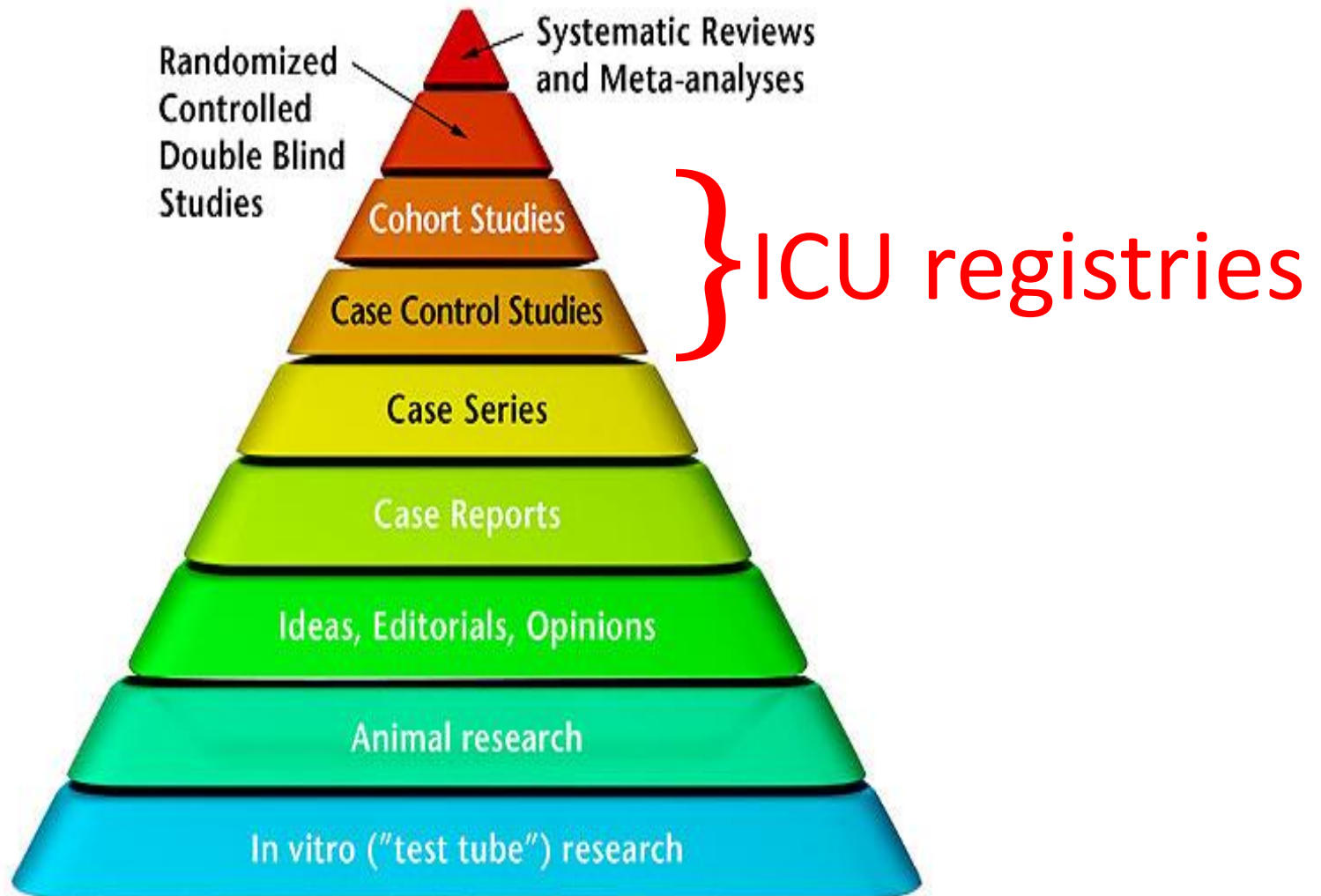
- Specific remit to design, conduct, analyse and publish rigorous experimental, observational and methodological studies
- Core disciplines/skills to centrally coordinate multicentre studies
- Resources to provide an adequate, robust, secure and stable infrastructure
- Good multi-disciplinary working relationships



# Current research paradigm



# Current research paradigm



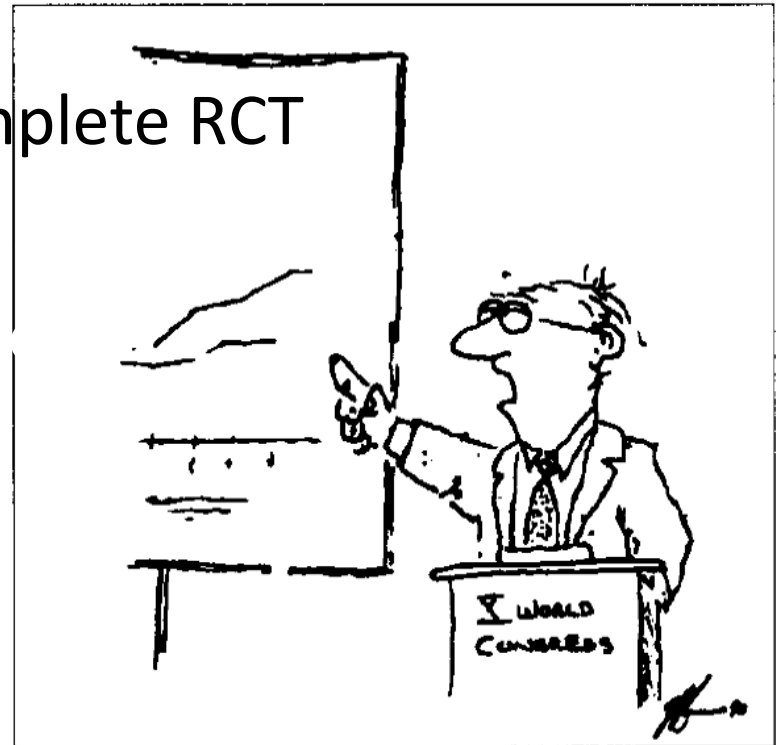
# Current paradigm

- Has served us well (Djulbegovic et al, Nature 2013)
  - Generated incremental advances that translate into improved health and lifespan (i.e. childhood leukemia from 0 % to 80 % cure)
  - But, waste in design, conduct and reporting



# Current paradigm

- Has served us poorly
  - Long time to plan and complete RCT



*"This randomized, double-blind trial involving over 20,000 patients was conducted over a 10 year period. Unfortunately we've forgotten why."*

# Current paradigm

- Has served us poorly
  - Long time to plan and complete
  - Highly selected populations
  - Often selected study centres
  - Often surrogate endpoints
  - Expensive

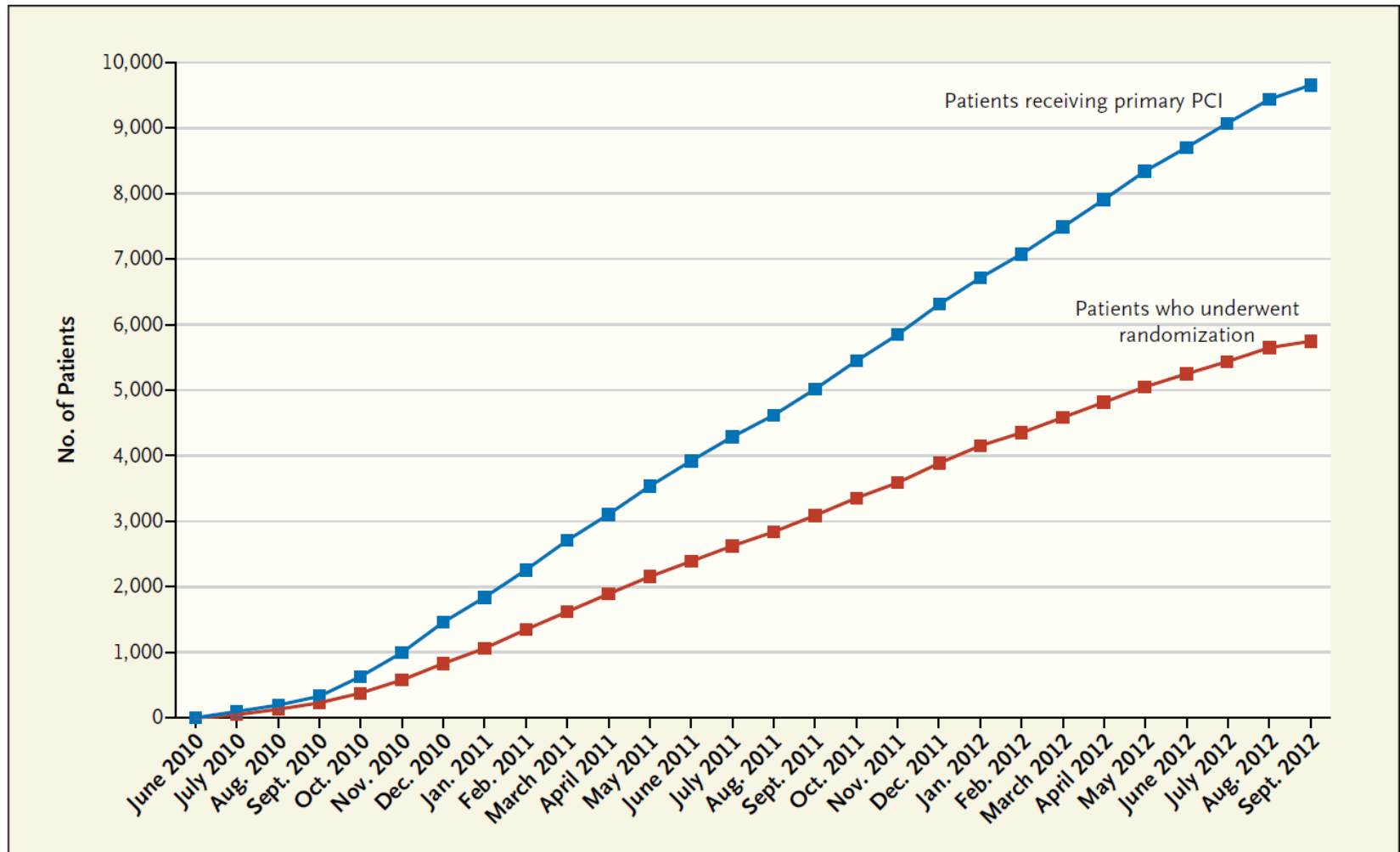
# Novel/Less used trial designs

- Paired availability design
  - Baker et al, Ann Intern Med 2014; 161: 240-41 (Letter)
- Cluster cross-over trials
- Adaptive trial designs
  - Group sequential trials
  - Response-adaptive randomization trials
  - Platform trials
- Registry-based randomized clinical trials (RRCT)

# Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia (*TASTE* trial)

- TASTE introduced the Registry-based Randomized Clinical Trial (RRCT) concept
- Online health quality registries (SCAAR and SWEDHEART) served as on-line platforms for:
  - randomization
  - case record forms
  - follow-up





**Rapid Randomization in the TASTE Trial, with Enrollment of Most Patients Receiving Primary Percutaneous Coronary Intervention (PCI).**

Adapted from the Institute of Medicine ([www.iom.edu/~media/Files/Activity%20Files/Quality/VSRT/LST%20Workshop/Presentations/Granger.pdf](http://www.iom.edu/~media/Files/Activity%20Files/Quality/VSRT/LST%20Workshop/Presentations/Granger.pdf)). The incremental cost of the Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia (TASTE) trial was \$300,000, or \$50 for each participant who underwent randomization.

# Registry-based randomized clinical trial

The registry can be used to

- Identify patients
- Assist collection of consent
- Randomize patients
- Collect case report forms
- End-point identification
- Adjudication of clinical end-points
- .....

# RCT vs. RRCT

	RCT	RRCT
Device – CE approved, already in use		Yes
Device, 'first in man'	Yes	
Drug in clinical practice		Yes
Old drug, new indication		Yes
New drug	Yes	

# Registry-based randomized clinical trial

## Strengths

- Unselected populations improves external validity
- Large cohorts of consecutive patients allow collection of infrequent events
- Quick enrolment
- Less expensive than conventional RCT

## Weaknesses

- Data quality may not be as good
- Less complete monitoring
- Less opportunity for mechanistic substudies and follow-up on secondary endpoints





} ICU registries



## Registry data in research

- Observational studies
  - Hypothesis generation
  - Aid in study design and power calculations
- Piggyback research
- Registrybased randomized controlled trial (RRCT)

