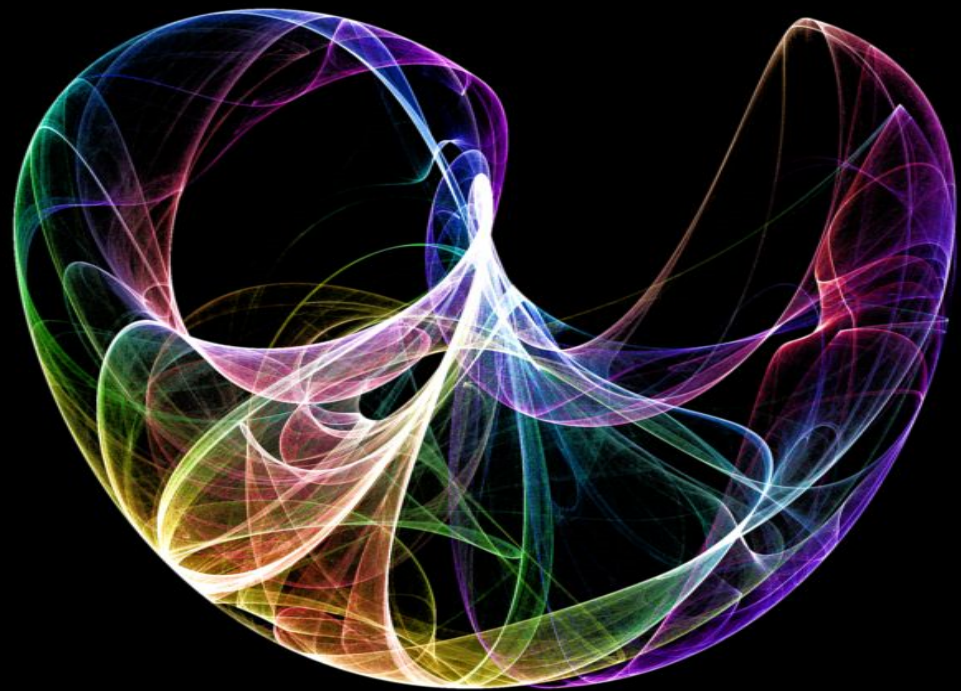
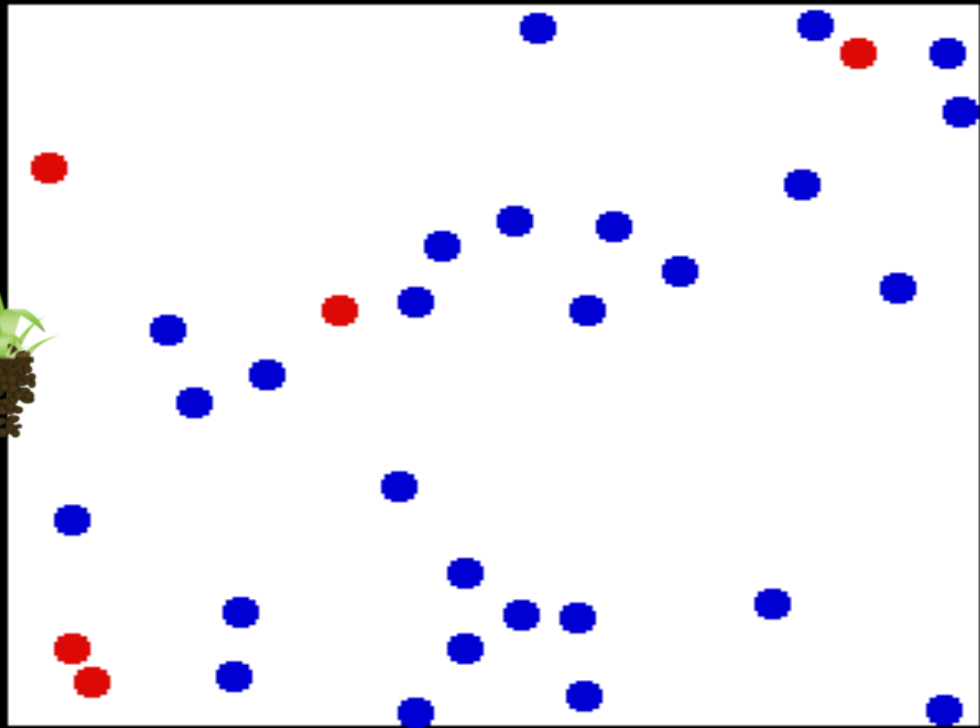


Learning from adverse events is an obligation, not an option!

Kim Lyngby Mikkelsen, MD, Ph.D.
National Agency for Patients' Rights
and Complaints, Denmark

NSQH 2012



- Anthill
- Brownian motion
- Strange attractors in chaotic system

2 points of view!

- The epidemiologist's point of view
 - Learning from adverse events?
 - Do case-crossover studies!
- The interventionist's point of view
 - Acting on adverse events?
 - Do feasibility studies!

The epidemiologist's point of view

Learning from adverse events?

- From adverse event data, **we get hypotheses of the exposures when things go wrong**
- Therefore we need to supplement that with insights into the exposures when things go right
- In other words, we simply need to test the hypotheses we get
 - Use the case-crossover design!

The case-crossover design

- What it is
- An example

The case-crossover design

What it is

Case-control design



The case-crossover design

What it is

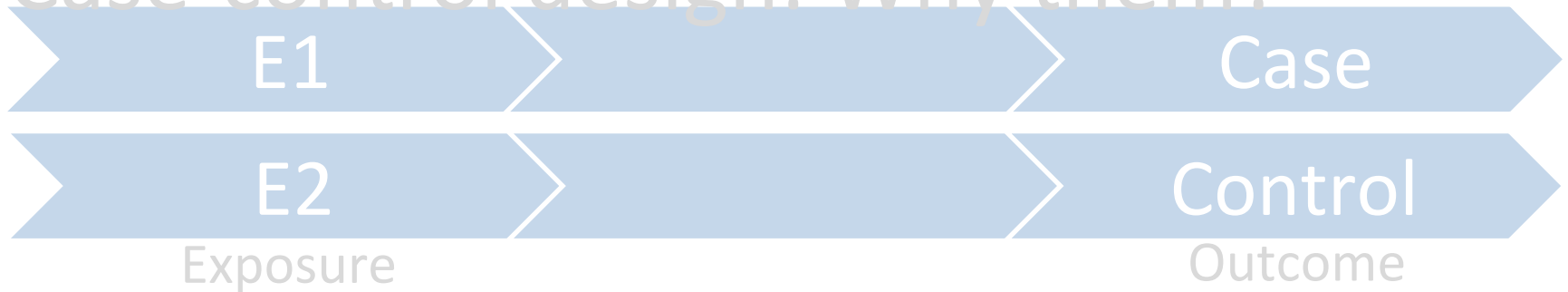
Case-control design: Why them?



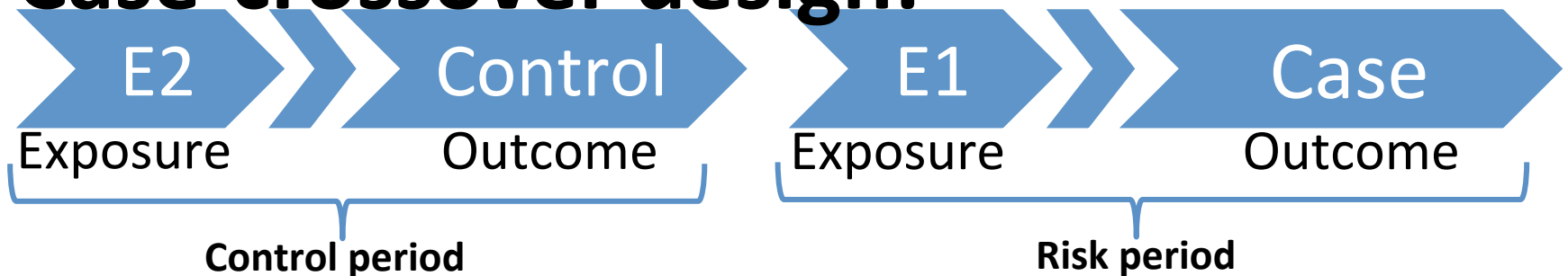
The case-crossover design

What it is

Case-control design: Why them?



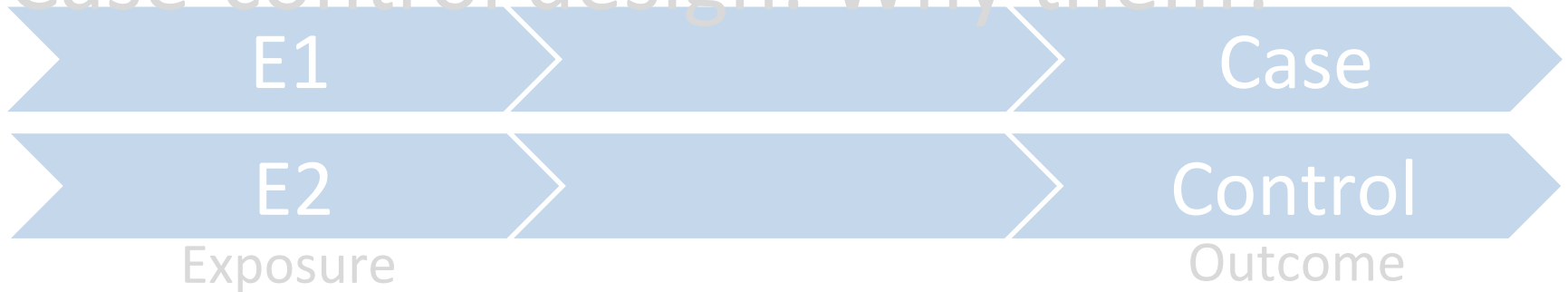
Case-crossover design:



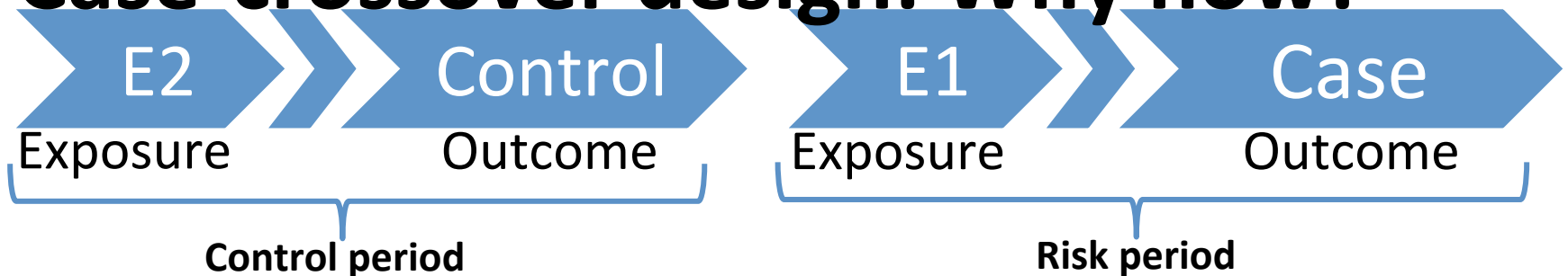
The case-crossover design

What it is

Case-control design: Why then?



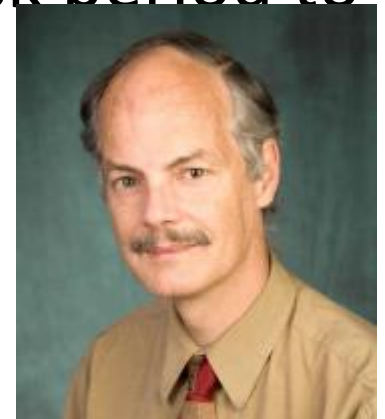
Case-crossover design: Why now?



The Case-crossover design

What it is

- Popular tool for studying transient effects on the risk of acute events (Why now?)
- Same person taken as its own control
 - Only cases are sampled
 - No between-persons confounding
- Compare within-subject exposure in a risk period to one or more control periods
- Exposure
 - must vary over time



Professor Malcolm Maclure,
UBC Chair in Patient Safety

The case-crossover design

An example

- JAMA. 2006 Sep 6;296(9):1055-62. Extended work duration and the risk of self-reported percutaneous injuries in interns. Ayas NT et al.



- **CONTEXT:**
In their first year of postgraduate training, interns commonly work shifts that are longer than 24 hours.
- **DESIGN, SETTING, AND PARTICIPANTS:**
National prospective cohort study of 2737 interns. Comprehensive Web-based surveys asked about work schedules and the occurrence of percutaneous injuries in the previous month. Case-crossover within-subjects analyses were performed.

The case-crossover design

An example

- JAMA. 2006 Sep 6;296(9):1055-62. Extended work duration and the risk of self-reported percutaneous injuries in interns. Ayas NT et al.



MAIN OUTCOME MEASURES:

Comparisons of rates of percutaneous injuries

during day work (6:30 am to 5:30 pm) after working overnight (extended work)
vs day work that was not preceded by working overnight (nonextended work).

RESULTS:

Percutaneous injuries were more frequent during extended work compared with nonextended work odds ratio [OR], 1.61; 95% confidence interval [CI], 1.46-1.78).

The case-crossover design

An example

Hi Kim,

I spoke with Dr. Najib Ayas by phone just now. His JAMA paper resulted in limits on work-hours in graduate education effective last July.

Also his current institution is limiting shifts of nurses following a pilot case-crossover study of insulin dosing errors in relation to nurse sleep deprivation. The association was strong enough to be detected in a small feasibility pilot study.

I'm interested in facilitating use of case-crossover studies in patient safety, so keep in touch.

Best wishes,
Malcolm

From: Malcolm Maclure []
Sent: Tuesday, January 31, 2012 11:28 AM

The case-crossover design

An example

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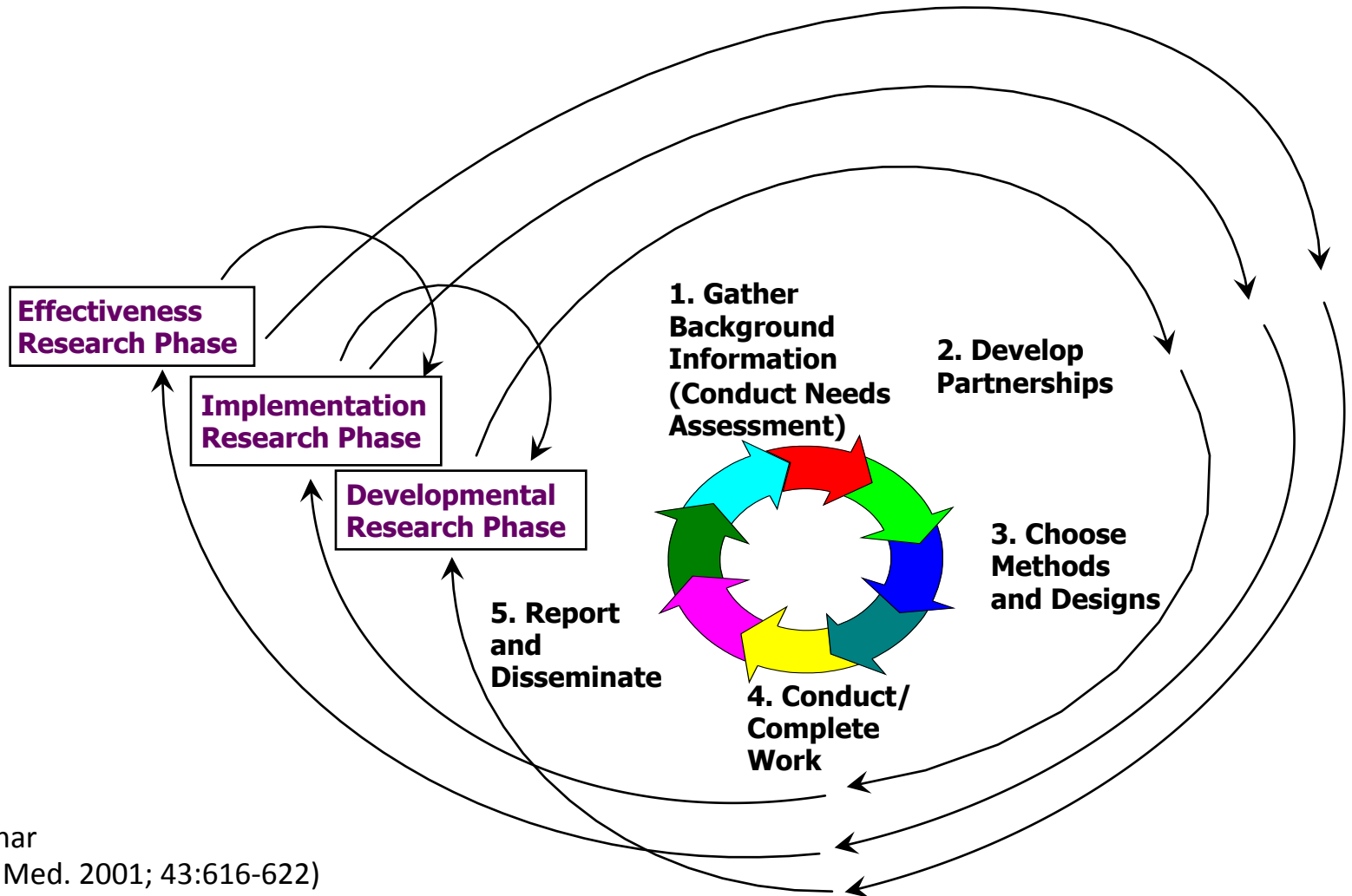


The interventionist's point of view

Acting on adverse events?

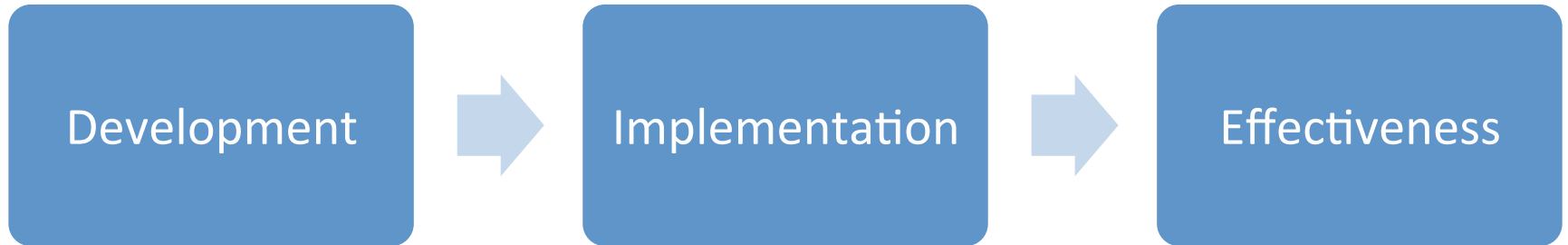
- Most patient safety professionals feel **an obligation to act** when confronted with adverse events, and many action plans are initiated
 - intuition and experience?
 - evidence?
- **Do we know if these initiatives are effective?**
 - First do **'Feasibility studies'**

The Intervention Framework

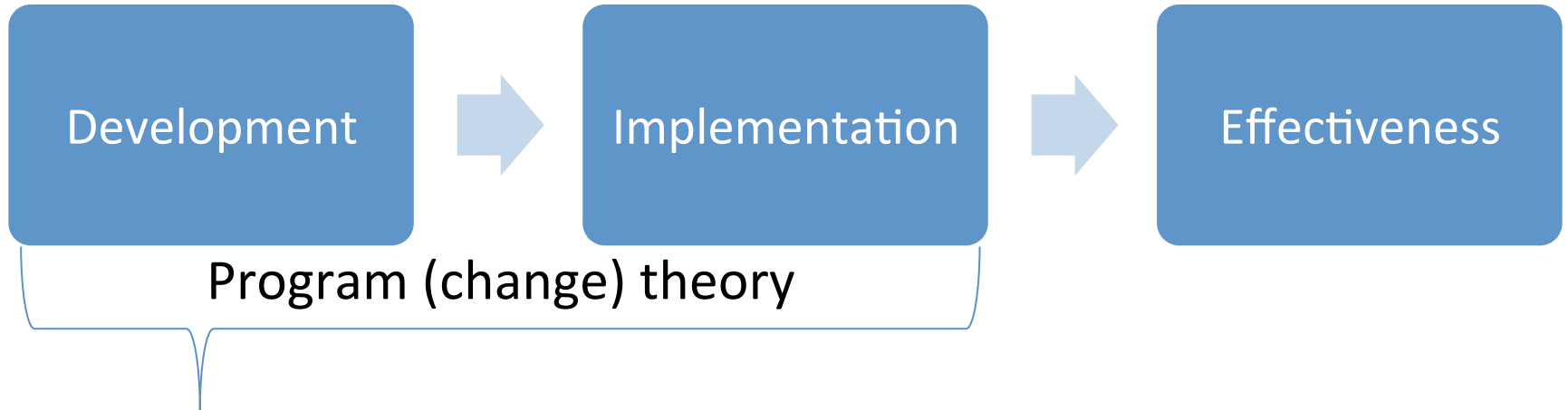


From:
NORA
Intervention
Effectiveness
Research Team,
Linda M. Goldenhar
(J Occup Environ Med. 2001; 43:616-622)

The Intervention Framework



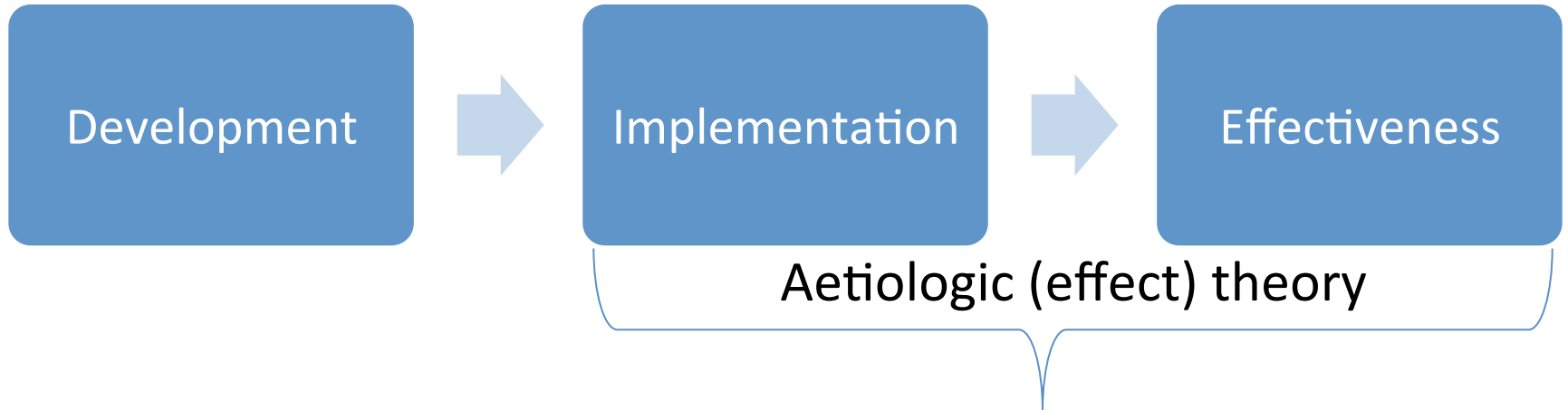
The Intervention Framework



Feasibility Studies

Did the intervention lead to the intended changes in exposure / behaviour?

The Intervention Framework



Effectiveness Studies

Did the changed exposure had the intended effect on adverse events?

Design Requirements

First do 'Feasibility studies'

- Small samples
- Endpoint: Expectation
- Removing exposure is the purpose
- Randomisation and blinding not needed
- Process important
- Effectiveness (RCT):
 - Large samples
 - Endpoint: Adverse events
 - Removing exposure is the purpose
 - Randomisation and blinding desirable
 - Results (endpoints) important

Feasibility Studies

Development phase

- Questions:
 - What changes are needed?
 - What are the best ways to bring about these changes?
 - What theories might apply?
 - What is the context of the intervention?
 - What barriers hinder the desired changes?
 - What is the knowledge, attitudes and beliefs of the target population?
 - What is the understanding of the needs for change?

Feasibility Studies

Implementation phase

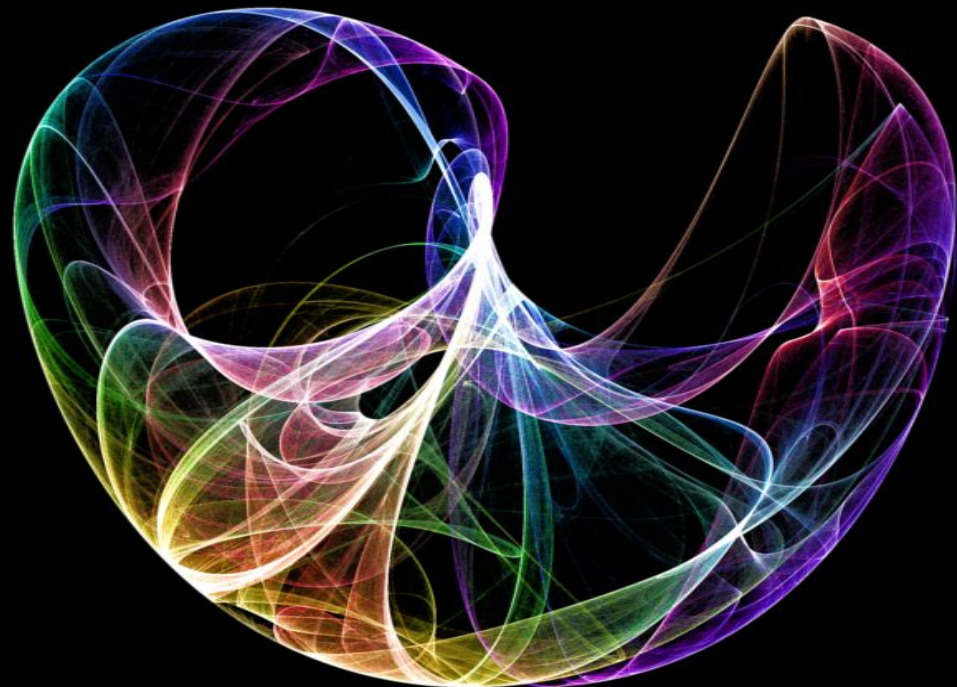
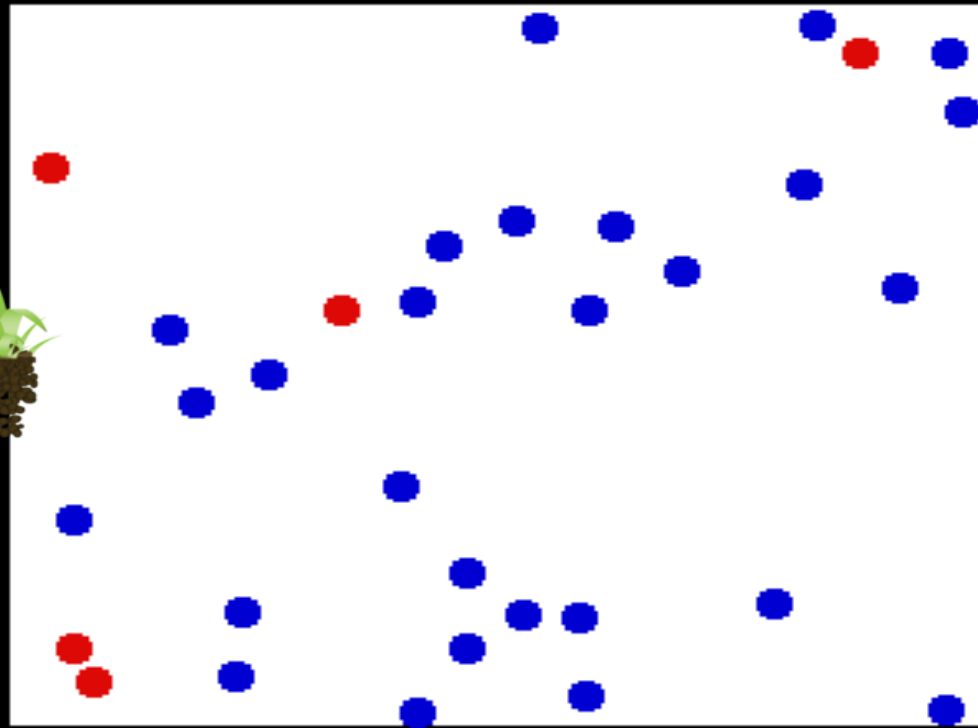
- “There is nothing more practical than a good theory” (Lewin 1951)
- A well-designed, theory-driven intervention is more likely to be effective
- Deciding on an intervention strategy, and developing, or adapting it, to fit the context of interest
 - Formative- or process-evaluation (qualitative methods)
- Document how an intervention is carried out
- Documenting how changes were or were not achieved
- Also use quantitative measures as much as you can
 - Set clear measurable implementation goals
 - Quality
 - Intensity
 - Frequency
 - Duration

Effectiveness Studies (Randomised controlled trials)





- Tell us the extent to which an intervention worked or did not work
 - impact, outcome or summative studies
- RCT is the optimal design
 - There is often practical, ethical, legal or other constraints
 - But there are no good reasons for ignoring the problems created by not applying such a design

2 points summary!

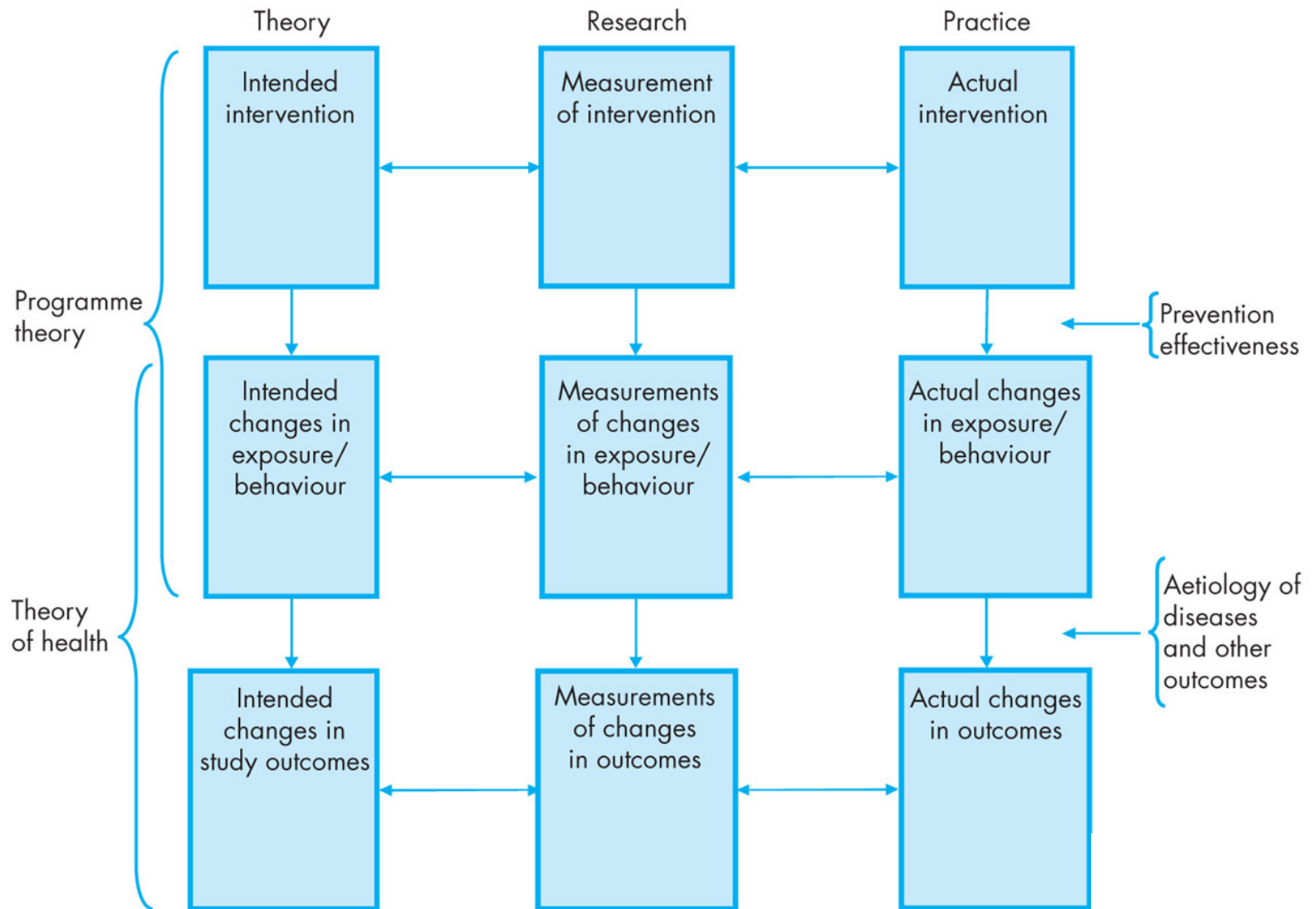
- From adverse events we get 2 things:
 - Hypothesis
 - Impetus to act
- The epidemiologist's point of view
 - If the hypotheses involves triggers?
 - Do case-crossover studies!
- The interventionist's point of view
 - Acting on adverse events?
 - First do feasibility studies!



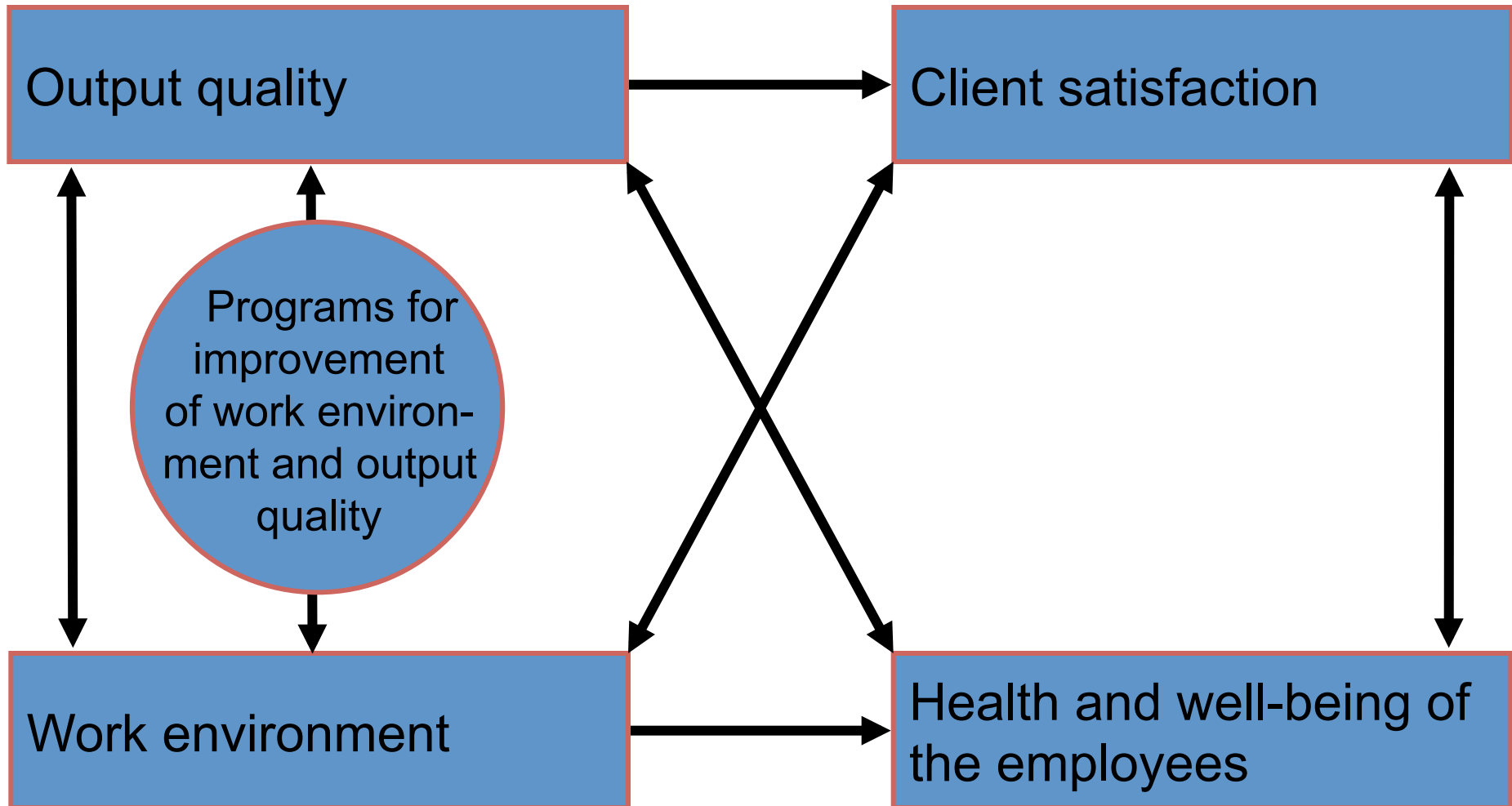
Program and or theory failure

		Program (Implementation)	
		Failure	Success
Theory	Failure		
	Success		

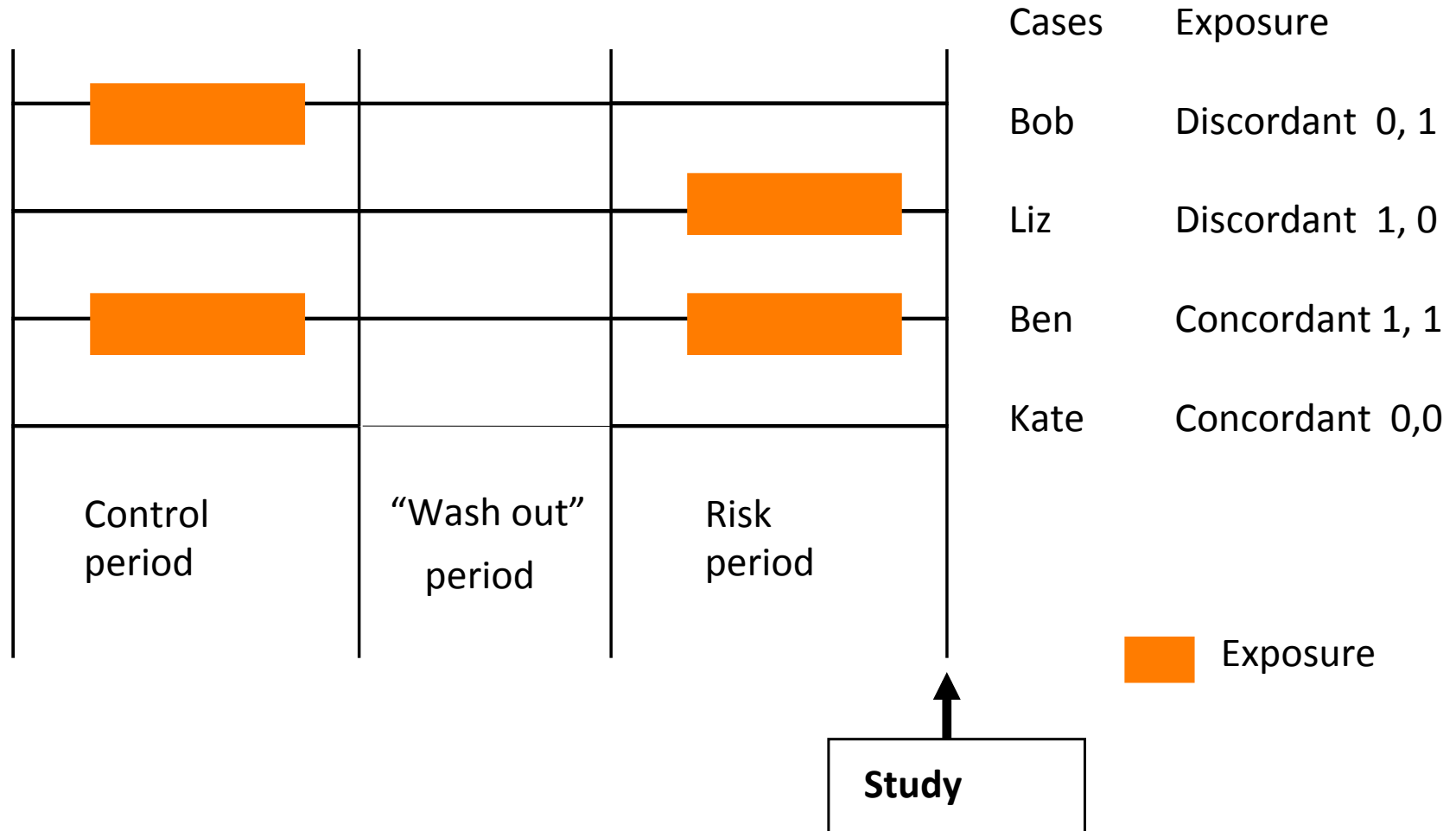
Theoretical model of key elements in intervention studies



The Sirdal model for work environment and output quality



Case-crossover design



The case-crossover design

References

- Maclure (1992) The case-crossover design: A method for studying transient effects on the risk of acute events, *Am J Epi* 133:144-153
- Mittleman, Maclure, Robinson (1995): Control sampling strategies for case-crossover studies :an assessment of relative efficiency, *Am J Epi* 142:91-98