

**“The third wheel in the relationship. Why a theory-driven framework need not add complexity to an already complex intervention”**

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# Introduction to the topic

Yesterday's session:

- “Relationship advice for trial teams integrating qualitative inquiry alongside randomised controlled trials of complex interventions”

Today's session:

- Theory as the “third wheel” in the relationship





# Background to the topic

- UK Medical Research Council's report on methods for developing and evaluating RCTs for complex interventions has been credited with stimulating ongoing debate about appropriate methods and concepts in healthcare evaluation.
  - The potential is understated
  - Need for a good theoretical understanding of how an intervention leads to change is acknowledged BUT
  - they do not provide practical guidance or recommendation in applying such theory driven approaches.





# Presentation objectives

Respond to the paucity of practical guidance & recommendations in applying theory driven approaches to developing and evaluating **complex interventions** by:

- Providing a practical example of the application of theory-driven evaluation.
- Showing how theory driven frameworks can add value to a complex intervention





# Why is this topic important?

A well guided theory driven approach can result in the development and evaluation of complex interventions in healthcare that are likely to be **more effective, sustainable and scalable.**







# Before we start: a quick recap

- a) Randomised controlled trial (RCT)
- b) Complex intervention





## a. Randomised Controlled Trials (RCTs)

### Take home messages

- RCTs tell us about changes but nothing about causal mechanism of the change (hows and whys)
- RCTs are not always suitable for population-based health interventions (because they are more *complex*)

We need an integral **process evaluation** to compliment the RCT

“Hows” and “whys” are answered by **qualitative inquiry**

If RCTs *must* be used at population level, we need to treat them as “complex interventions”; thus need an appropriate design







## b. Complex interventions

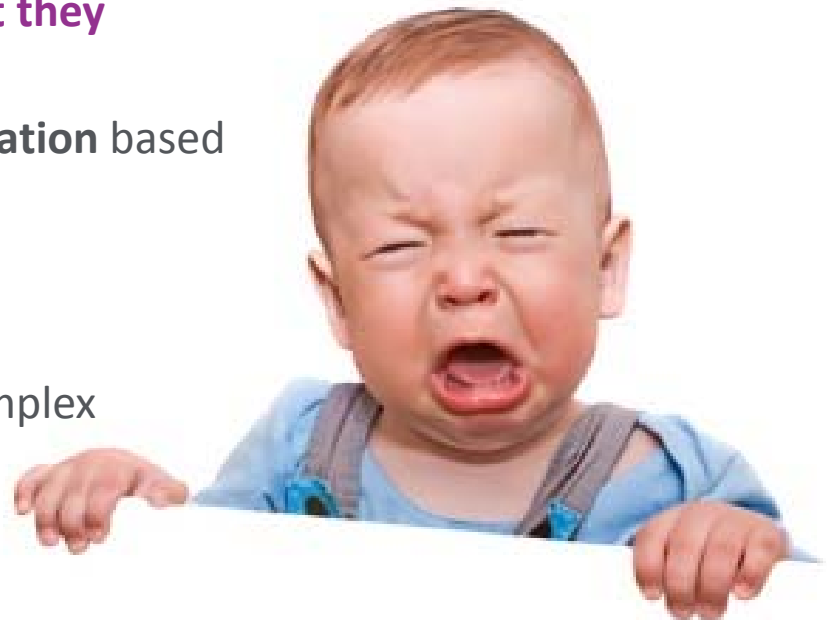
### Take home messages

### Complex interventions = complex evaluations

There is likely to be too much 'noise' in the application of the RCT to complex interventions to meet standards of good science. However, this does not mean that we should disregard RCTs entirely, but **rather that they should be modified:**

- adding a comprehensive **contextual evaluation** based on mixed methods to the design, and
- using multiple sites.

(Wolff 2001 "Randomised trials of socially complex interventions: promise or peril?" )





# Complex intervention example

- The problem:
  - Poor medication compliance for rheumatic heart disease prevention (*injection every 21-28 days for 10 years or until the age of 21*)
- The aim:
  - To improve medication compliance by implementing and evaluating a sustainable, transferable, **systems-based** intervention at 10 Northern Territory health centres
- The intervention:
  - model of care designed to optimise health systems and community resources



## EVALUATION CRITERIA

### PROCESS & FIDELITY:

- What was the completeness and acceptability of implementation of the intervention package, and of individual items?
- What were the barriers and enablers of Implementation?

- What were the barriers and enablers of organisational change?

### EFFICIENCY: Degree to which inputs have been converted to outputs

- To what extent did health centres change their delivery of RHD care to align with the systems-based intervention?

### PERFORMANCE:

- What were the factors associated with success in achieving organisational and client level improvements in SP for RHD?

### EFFECTIVENESS: Degree to which project purpose has been achieved by the project outputs

- To what degree did adopting the systems-based intervention improve processes of RHD care and adherence to SP?
- Which elements of the intervention were most effective in activating change?

### RELEVANCE & IMPACT: Degree to which the program design was right

- Did the intervention, (a model of care designed to optimise health systems), improve overall adherence to SP for RHD and minimise 'days at risk'?

## STUDY LOGIC MODEL

### BASELINE (3 months):

2-week site visit, interviews & development of customised action plans

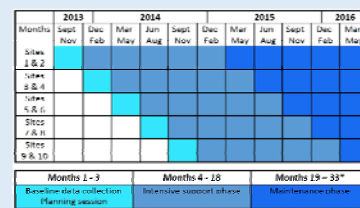
### INTENSIVE (15 months):

Monthly site visits, review of action plan progress

### MAINTENANCE (up to 15 months):

Monthly follow up, review of action plan progress

**IMPLEMENTATION:** Health centres commence the study at 3-monthly steps in random order

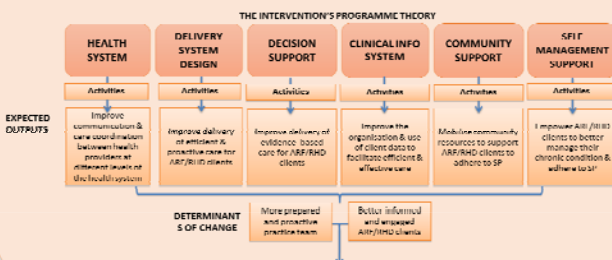


IMPLEMENTATION (Input)

MODERATORS  
(factors that condition the intervention's effect on outcome)

### THE INTERVENTION PACKAGE:

- Project Officers support health centres to develop and implement a customised set of activities aimed at improving penicillin delivery
- Activities are aligned under the elements of the Chronic Care Model (CCM)
- The intervention's Programme Theory is organised under the streams of the CCM & aim to activate "determinants" allowing for achievement of outcomes



INTERVENTION (Activities & outputs)

DETERMINANTS

### OUTCOMES:

- Measured with generalised linear mixed models; Primary outcome with a logit link
- Outcomes measured at community level: McNemar's test for binary outcomes or a paired t test for normally distributed continuous outcomes

- OUTCOME MEASURES
- Proportion of clients receiving 80% or more of scheduled BPG injections over a minimum 12 month period
  - The proportion of scheduled injections that a client receives over a minimum 12 month period
  - The average number of days at risk
  - Proportion of clients receiving at least 90% of scheduled BPG injections over a minimum 12 month period
  - Proportion of clients receiving 50-79% and <50% of scheduled BPG injections over a minimum 12 month period
  - Recurrence rate and proportion of acute rheumatic fever (ARF) episodes that are recurrences, compared to non-participating communities and to the whole jurisdiction
  - Improvement in delivery of other services for RHD clients
  - Effect of the programme on delivery of other routine services
  - Impact of the intervention on RHD clients' experience of care including their perception and understanding of the disease and its management

OUTCOMES  
Improved delivery and uptake of SP by ARF/RHD clients

IMPACT  
Reduction in ARF recurrence

## THEORY-DRIVEN EVALUATION SUCCESSES

### 1. Implementation success

When there is evidence that the intervention is appropriately implemented in the field

Occurs only when an intervention appropriately activates a change process

### 2. Action theory success

When activities to optimise health systems for RHD care DO lead to a more prepared practice team & more engaged clients

(when there is evidence that intervention activities DO affect the determinants of change)

### 3. Conceptual theory success

When prepared practice teams & engaged clients DO positively affect delivery and uptake of SP by ARF/RHD clients)

(when there is evidence that the determinants DO affect outcomes)

### SUSTAINABILITY: Durability of the benefits produced by the project after its completion

- Which of the activities and streams of the Chronic Care Model were sustained during maintenance phase?



# Theory-driven Evaluation

## Why choose theory-driven evaluation?

- ♥ Will assess whether an intervention works or not – and *how and why* it does so.
- ♥ Will take the underlying causal mechanisms and the implementation processes into account when assessing a program.
- ♥ Will provide an understanding of whether a program is reaching its goals and document the *hows and whys* of a program success or failure.

The success of a program in reaching its goals depends on the validity of its **program theory**.



# Program theory explained

**What is a program theory?** explains why, how, and under what conditions the program effects occur, predict the outcomes of the program, and specify the requirements necessary to bring about the desired program effects (Sidani & Sechrest, 1999).

**Assumptions** underlying a program

1. **Prescriptive assumptions** (**action model**) prescribe the program components and activities that will enable a program to function:

- ✓ How are the contextual factors and program activities organized to implement the intervention and support the change process?
- ✓ What actions are required to solve a social problem

2. **Descriptive assumptions** (**change model**) describe causal processes that lead to goal attainment:

- ✓ Why does the intervention affect the outcome?
- ✓ Why the problem will respond to these actions (Chen, 2004)



The diagram illustrates the 'ACTION MODEL' for a community-based intervention. It shows the flow of resources, information, and implementation across various components. A large green circle highlights the central components of the model.

- RESOURCES**: An arrow points down into the 'Implementing Organisations' box.
- Implementing Organisations**: A box that receives resources and interacts with 'Intervention and Service Delivery Protocols' and 'Peer Organisations and Community Partners'.
- Intervention and Service Delivery Protocols**: A box that interacts with 'Implementing Organisations' and 'Program Implementors'.
- Peer Organisations and Community Partners**: A box that interacts with 'Implementing Organisations' and 'Ecological Context'.
- Program Implementors**: A box that interacts with 'Intervention and Service Delivery Protocols' and 'Target Group'.
- Ecological Context**: A box that interacts with 'Peer Organisations and Community Partners' and 'Target Group'.
- Target Group**: The final recipients of the intervention, interacting with 'Program Implementors' and 'Ecological Context'.

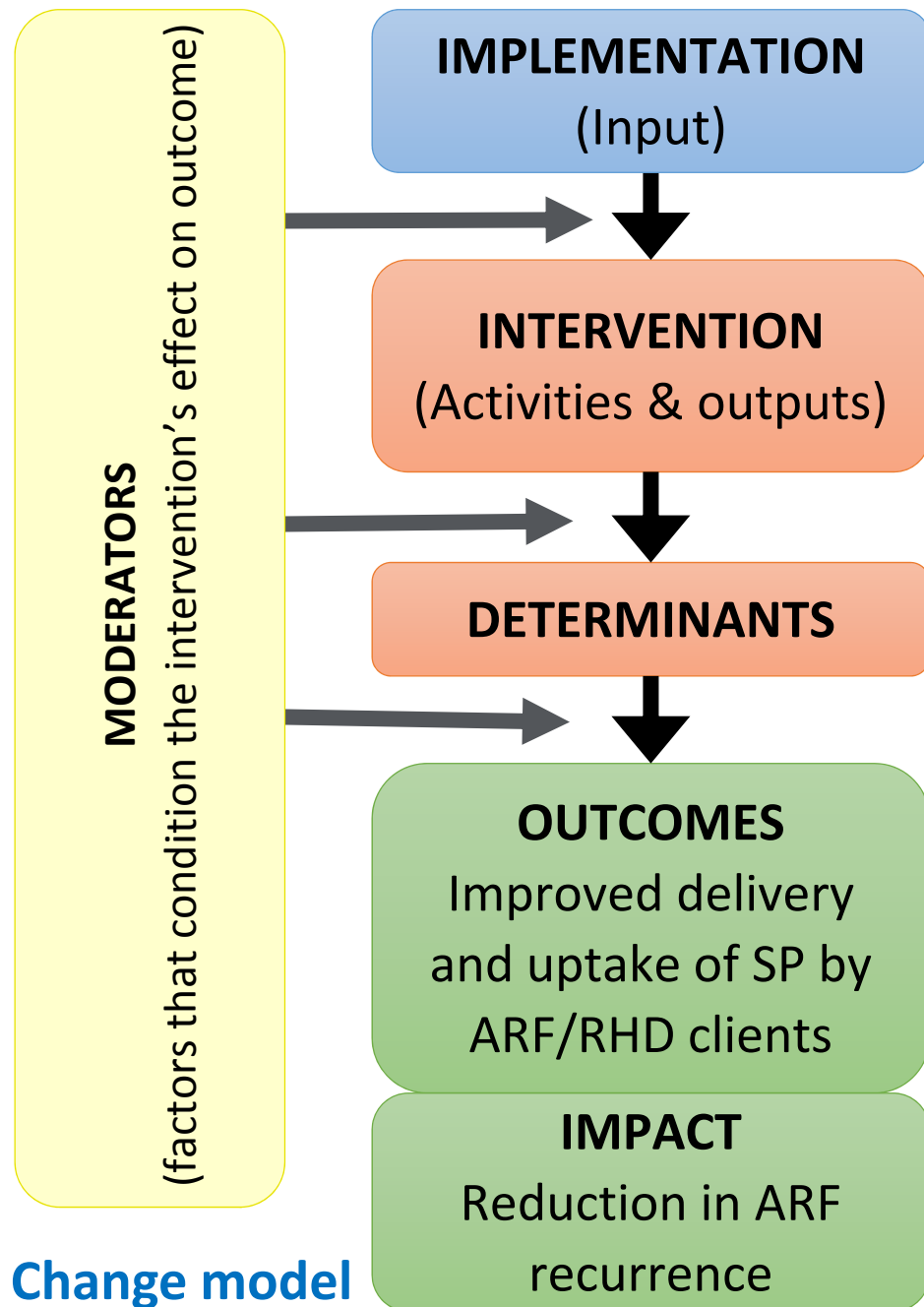
The diagram uses solid arrows for primary flows and dashed arrows for secondary or feedback flows. A large green circle highlights the central components of the model, and a blue line indicates a feedback loop from the 'Target Group' back to the 'Implementing Organisations'.

### 3. Evaluation transfer

```

graph LR
    Intervention --> Determinants
    Determinants --> Outcome
    Outcome --> Determinants
    Determinants --> Intervention
    subgraph Loop
        Intervention
        Determinants
        Outcome
    end
    ChangeModel[CHANGE MODEL] --> Intervention
  
```







# Theory-driven Evaluation

It is important to note that different models (n=4) of theory-driven evaluations can be constructed depending on which part of the conceptual framework of program theory the evaluation is focused (Chen, 2004).

- The simple theory driven evaluation framework **applied in this study** is a hybrid of Chen's models including:

1. **Intervening mechanism evaluation:** assessing the **change model** component of the program theory conceptual framework
2. **Moderating mechanism evaluation:** assessing one or more factors in program implementation that conditions or **moderates** the intervention's effect on an outcome

Addresses the causal mechanisms!

Addresses the contextual factors!

These two models are priority for explaining a result – but the most comprehensive approach would be applying the other two models

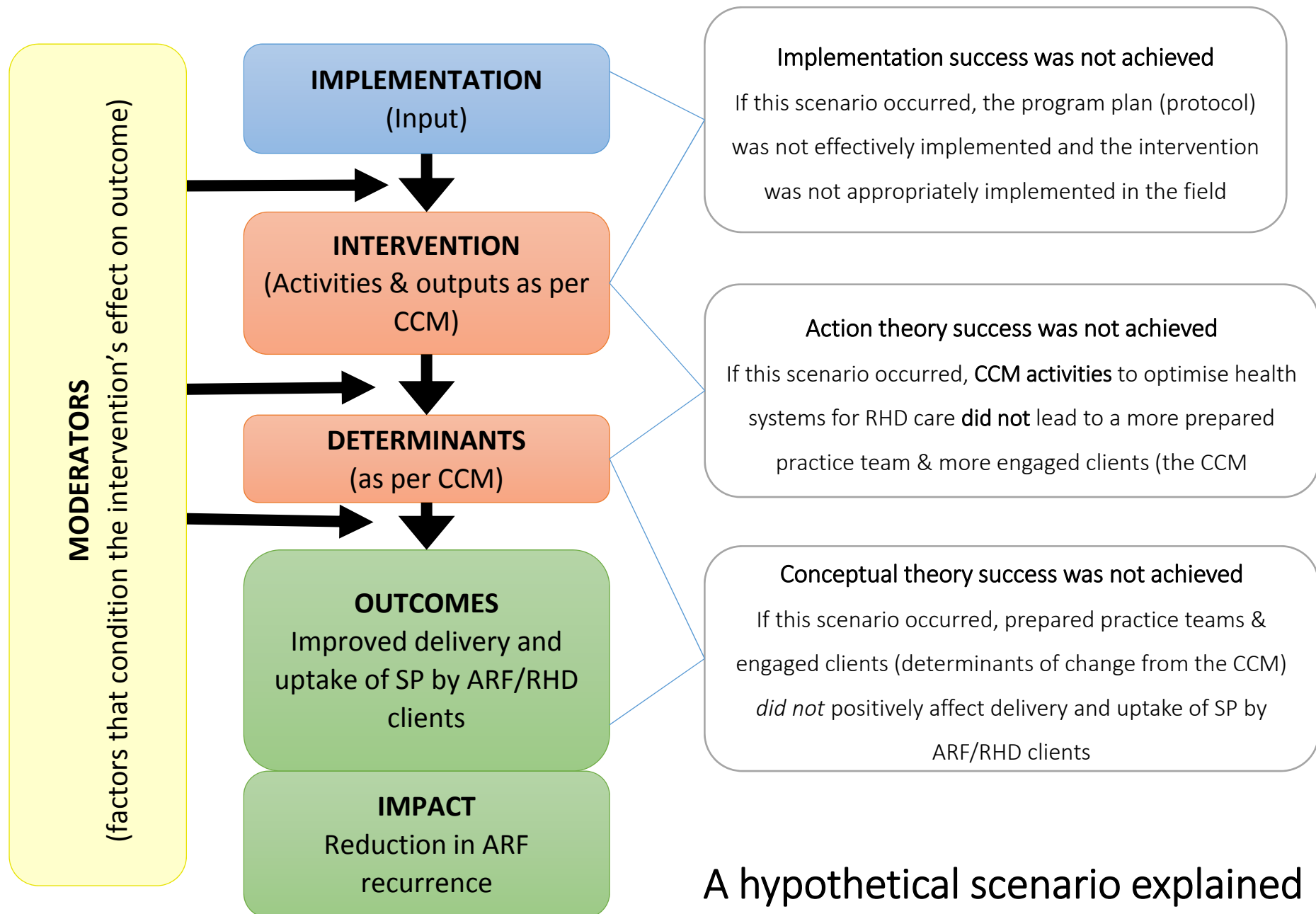




# A hypothetical scenario explained

What if the intervention DID NOT achieve the intended outcomes?





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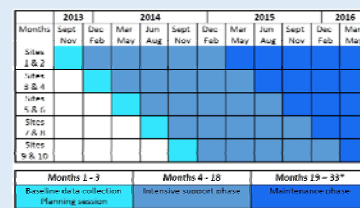
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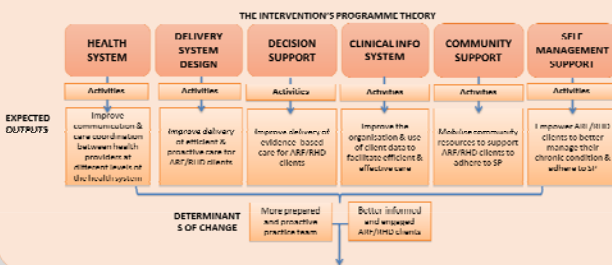


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# Take home messages

- RCT design for complex intervention is possible but should integrate:
  - Process AND context evaluations
- A theory driven evaluation framework can be instrumental in packaging the “whole story”
  - theory driven evaluation is a dense concept but can be simplified
- Once an RCT produces findings on effectiveness (whether there has been a change in the outcome)... we can use our theory driven framework to EXPLAIN the outcome
- We need QUALITATIVE RESEARCH to provide us with the hows and whys of success or failure of an intervention







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