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Focusing the question

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Session aims

- To define question formulation for aggregative and interpretive reviews
- To provide an overview of the limitations of aggregative effectiveness reviews
- To demonstrate how and when qualitative research findings can be used to inform the development of questions for reviews of effectiveness
- To identify the issues and challenges in formulating different types of qualitative questions to promote interpretive evidence synthesis



Aggregative versus interpretive

- Aggregative synthesis locates similar research evidence for the purposes of formulating conclusions that are generalisable across different populations and settings
 - Listing, compiling, accumulating
- Interpretive synthesis integrates diverse evidence to generate theories/explanations for a particular population, setting or situation
 - Cross comparison, integrating – the whole is greater than the sum of the parts



Question formulation for aggregative synthesis

- Aggregative synthesis is typically used in systematic reviews of effectiveness
- Question formulation helps to focus the elements of the aggregative question
 - Population
 - Intervention
 - Comparison
 - Outcome



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Effectiveness reviews are conducted when

- a body of research has accumulated in a particular field, and findings need to be aggregated
- there is uncertainty about a common strategy or treatment
- there is uncertainty about relative effectiveness of two or more commonly offered interventions so a comparison is needed



Effectiveness reviews are dependent upon primary research (usually RCTs) where

- Problem definition guides the research that is funded
- Artificial, controlled environments limit transferability
- There may be implicit problems with implementation fidelity



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Scoping searches map existing research

- A scoping search for a systematic review “should typically search for **existing** reviews and major trials and other studies. Results from these searches can refocus or focus the review.... This process can involve several iterations. Scoping searches are also used to estimate the size of the literature and by extension the cost of the review.”

Centre for Reviews and Dissemination
<http://www.york.ac.uk/inst/crd/revsint.htm>



Limiting your review to existing RCTs is sometimes risky, because published research reflects

- The predominant interest of the funder
- Researchers' and funders' formulation of the problem may be limited to a particular perspective or discipline, neglecting factors in the surrounding environment or characteristics of the participants that can affect outcomes
- Many health problems are investigated within the confines of a randomised controlled trial conducted under artificial conditions. As a result, it is difficult to successfully transfer the trial intervention to other contexts

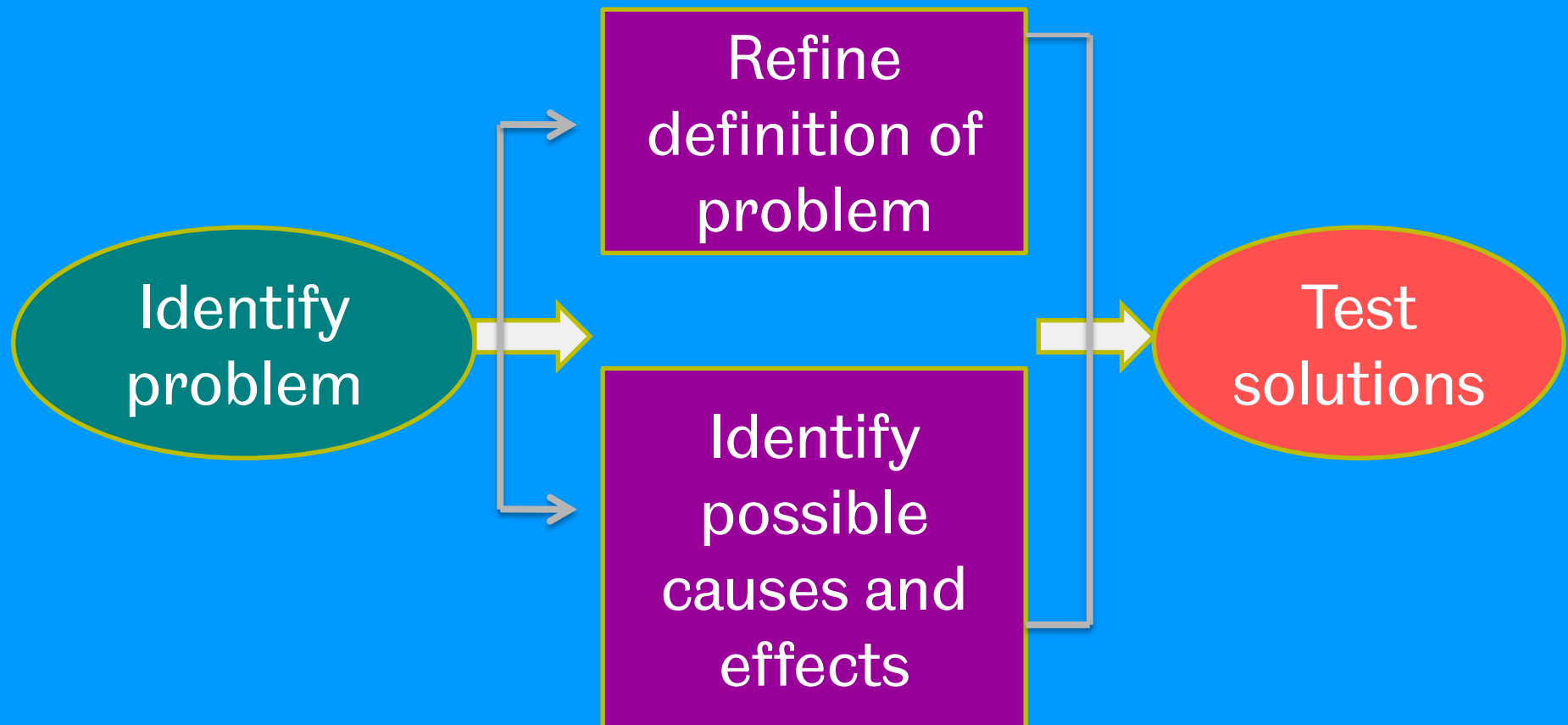


Problems with replication

- Successful replication of the results of a trial depends on
 - The amount of contextual information that was captured during the original trial
 - The amount of information collected on each component of the intervention
 - Reporting of how the intervention was delivered (implementation fidelity)
- In order to promote transferability, we need to know
 - Important characteristics of participants
 - Important characteristics of the setting
 - Important characteristics of the people who delivered the intervention
 - The various components that make up the intervention
- If these characteristics are similar to our situation, then we can be reasonably confident that we can obtain a similar effect
- BUT if the complexity of the intervention has not been captured, analysed and reported, then we have problems with transferability

Most effectiveness questions identify a limited number of causes and effects

Qualitative questions can identify additional factors that may influence cause and effect





Developing questions for reviews of effectiveness: When should qualitative research be considered?

- Qualitative research should be considered if
 - Your review question is about a complex intervention
 - More information is needed on the components of an intervention – what are various elements of the intervention how do they work together?
 - Information is needed on the surrounding context – the setting, the environment, that may influence the relative success of the intervention
 - Information is needed on why the intervention works or doesn't work in different settings, for different populations



What is a complex intervention?

- Complex interventions in health care, whether therapeutic or preventative, comprise a number of separate elements which seem essential to the proper functioning of the interventions although the 'active ingredient' of the intervention that is effective is difficult to specify... Complex interventions are built up from a number of components, which may act both independently and interdependently. The components usually include behaviors, parameters of behaviors (e.g. frequency, timing), and methods of organizing and delivering those behaviors (e.g. type(s) of practitioner, setting and location).'
- Medical Research Council: *A framework for development and evaluation of complex interventions to improve health*. London: Medical Research Council; 2000.



Where can we find information on the components of a complex intervention?

- Some RCTs collect qualitative information either within the study. This is called a 'process evaluation'
- In other cases, qualitative research is conducted alongside an RCT
- The question for the effectiveness review may find these studies, as long as you don't limit on study type
- BUT What if there aren't any process evaluations or parallel qualitative studies to inform the effectiveness question?



Formulating qualitative questions to inform effectiveness review protocols

- Qualitative questions can be formulated to explore characteristics of
 - P: are there important differences in Population that might influence effectiveness?
 - I: is the Intervention delivered in different ways?
 - C: is the Comparator delivered in different ways?
 - O: do the Outcomes reflect the values of the Population and are they directly related to the Intervention?

Qualitative questions during protocol development are useful because they help to refine the PICO

Effectiveness question

P: Women eligible for breast cancer screening

I: Letter plus telephone invitation to screening

C: Letter only

O: Uptake of screening

Refined

- P: who have not completed secondary school education
- I: delivered by nurses experienced in working with patients with low literacy
- C: letter only
- O: Uptake of screening PLUS
 - Ability to read letter
 - Ability to understand information and follow instructions



How do you formulate qualitative questions that will help to identify the components of a complex intervention?

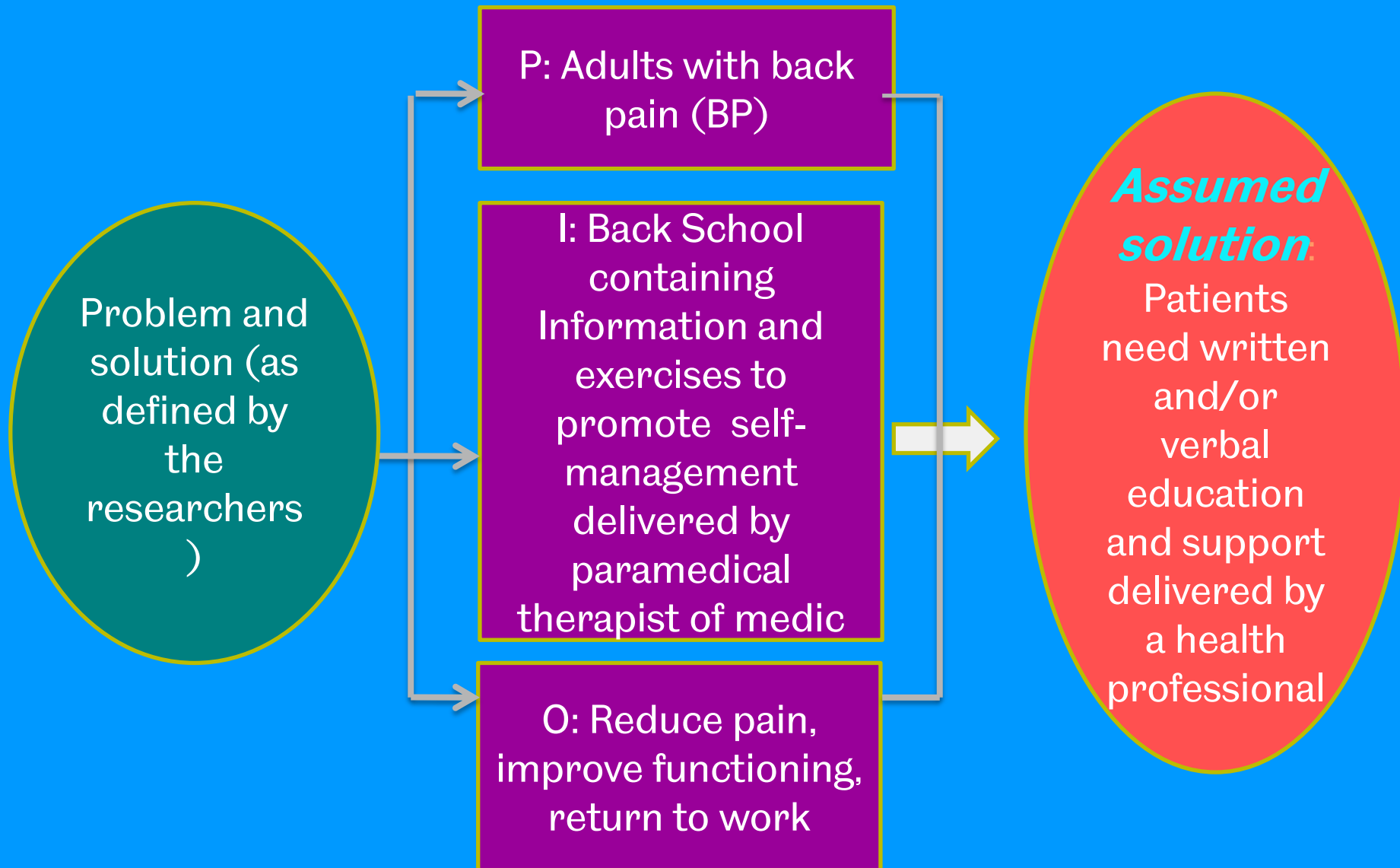
- We'll use an example to illustrate how this can be done
 - *For people who suffer from low back pain, are back schools effective in reducing pain, improving functioning, and promoting return to work?*
- A search showed that there were no qualitative studies on patients' experiences of participating in back schools
- So qualitative questions need to be formulated, in areas related to the phenomenon of interest



Back pain schools for non-specific back pain (Heymanns et al, 2010)

- This Cochrane review was unable to perform a meta analysis due to the heterogeneity of the studies included in the review.
 - *'A back school was defined as consisting of an educational and skills acquisition program, including exercises, in which all lessons were given to groups of patients and supervised by a paramedical therapist or medical specialist. Additional interventions were allowed.'*
- *What are the components of the intervention?*

Effectiveness question: In adults with Low Back Pain does provision of education via Back Schools reduce pain, improve functioning and promote return to work?





Problems with poor reporting

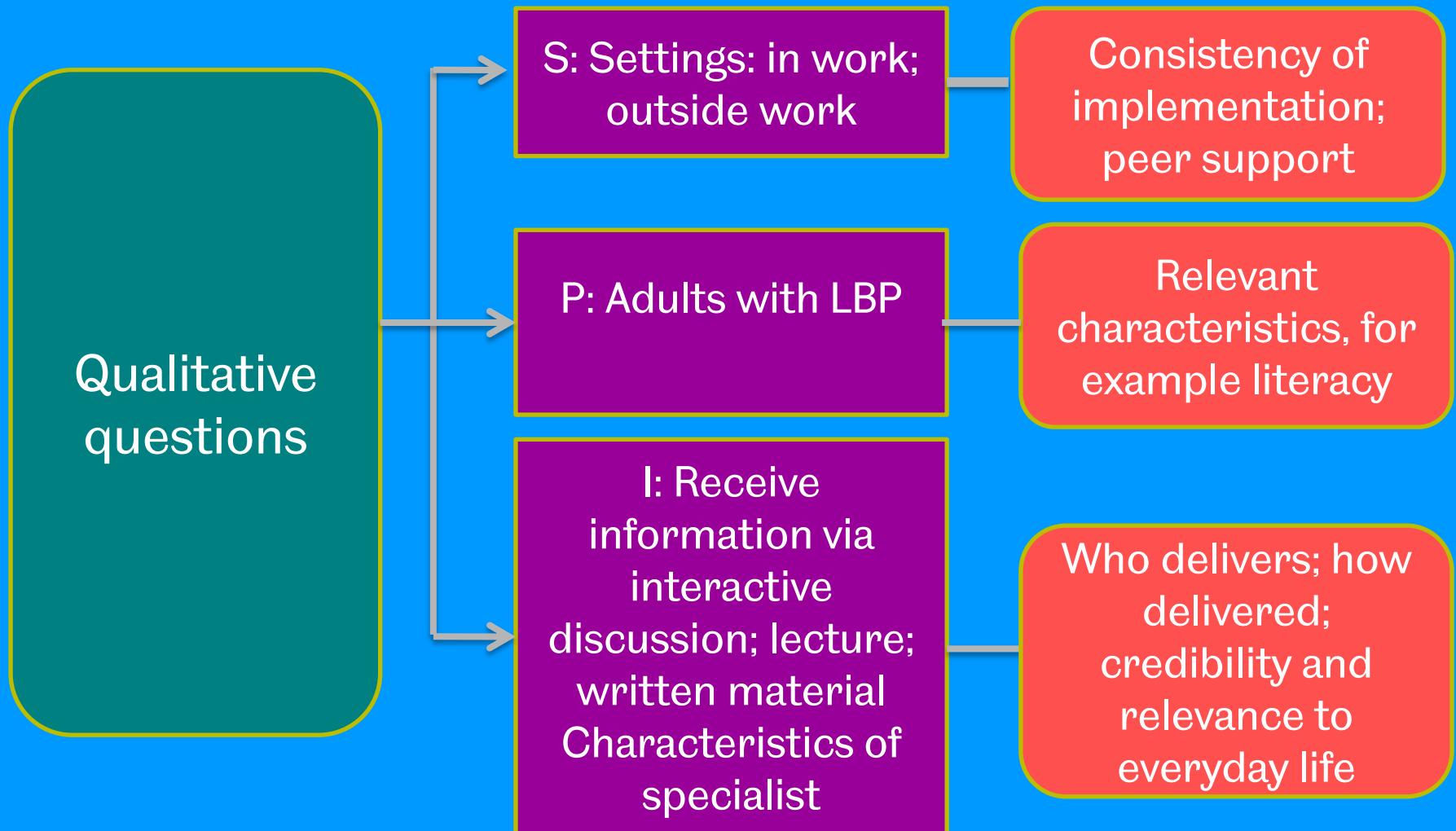
- ‘RCTs either reported briefly about the content of the intervention or failed to report essential information about the **type, intensity or performance of the exercises.**’
- Reporting of the various **treatment settings** was poor or non-existent
- If the components of the intervention are not described, then we cannot know which components were responsible for the effect



How important are the variations

- 'Also apparent were the wide variations in the content and components of the interventions. This may explain the differences in interpretation of the items between the two authors, reflected by the disagreement score of 34%
- Can variations be statistically controlled?
- Or should heterogeneity be dealt with by 'lumping and splitting'?
- These questions are especially important when dealing with complex interventions

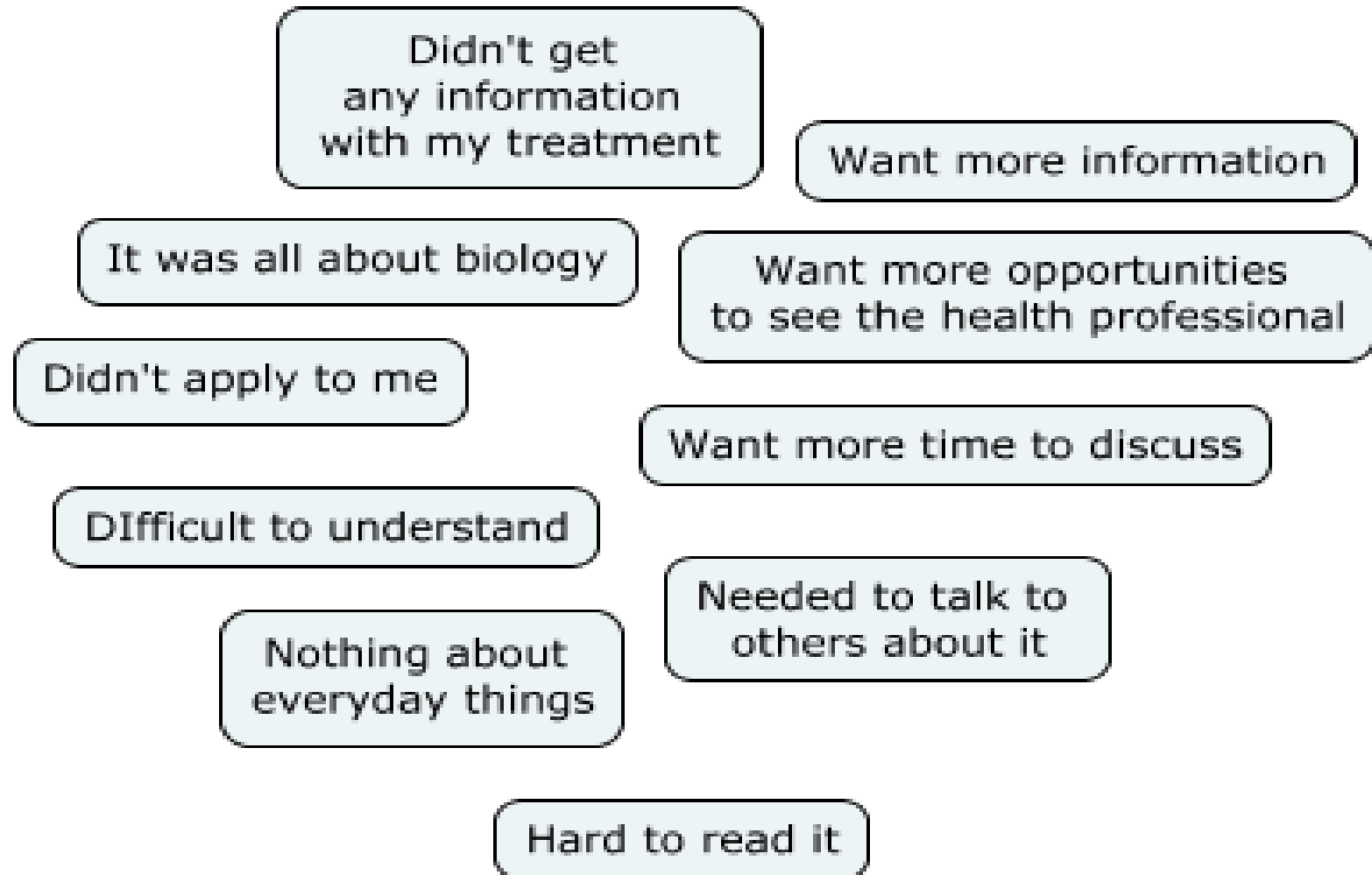
Explore assumptions with qualitative questions



A qualitative question that explores components of the intervention

What are adults' experiences of receiving information in different formats, in different settings, from different providers?

Back pain patients' experiences of receiving education for self management



Patients' experiences of receiving back pain information in a physiotherapy-led back school

'Before, I had pain so I would lie down. Then I had more pain. But now after the course, when I have pain, I no longer lie down. I see that I must continue to go on moving and the pain will be gone. if I lie down the pain will come back. Before I was ill, now I am not.'

'It is important to be taken seriously.'

'My husband wasn't believed. [at the hospital].'

Here in the physiotherapy clinic, you can bring up all sorts of weird things, thoughts and theories because there's no time limit'.



Emerging theory from qualitative research

- **Sender:** People need to receive health information from that is relevant to their concerns and everyday problems with functioning. People need to feel that their condition is acknowledged.
- **Message:** People need an opportunity to discuss whether the health information applies to them. Time to reflect and opportunities to discuss are critical.
- **Receiver:** People need to accept that their condition is chronic, and understand that they need to take an active approach to manage their own condition (Michie, 2008)



Qualitative research can inform the effectiveness question by identifying

- Information from 'essential components' that needs to be aggregated
- For example, the search on experiences with back pain education identified issues with
 - Appropriateness and relevance of information
 - Importance of acknowledging the condition
 - Amount of time for discussion
 - Ability to use information to actively manage condition
- These issues could be used to reformulate the review question, in terms of
 - The type of information offered
 - The approach to providing information



What kinds of questions can be formulated for interpretive qualitative evidence synthesis?

- Qualitative evidence synthesis questions may be prompted by
 - Cross cutting issues that are relevant for a number of conditions, for example
 - Medication taking (Pound et al, 2005)
 - Chronic pain (a worked example)



Example of QES question: What are patients' experiences of taking medication?

- Pound et al, 2005 Resisting medicines: A synthesis of qualitative studies of medicine taking
 - Worried about harm, dependence, masking other symptoms
 - Significant impact on identity, posed problems in terms of disclosure and stigma
 - Modified regimens – symptomatic or strategic medicine taking, or adjusting doses to minimise unwanted consequences
 - Desire to minimise the intake, echoed in some peoples' use of non-pharmacological treatments to either supplant or supplement
 - Few discussed regimen changes with their doctors.
 - 'We conclude that the main reason why people do not take their medicines as prescribed is not because of failings in patients, doctors or systems, but because of concerns about the medicines.'



Example of QES question: Patient-defined outcomes for chronic pain

- Most of the chronic pain research defines outcomes as reduced pain, improved functioning and promoting return to work
- Qualitative research with patients who have chronic pain (Harris, Williams, Hart, et al in progress) indicates that they define important outcomes as
 - Better able to manage pain by recognising onset and timely use of medication – patients note that this is not the same as reducing pain
 - Ability to manage some of the everyday things that I did before, by doing them differently – this is not the same as improved physical functioning
 - Able to participate in social activities, volunteer activities – this is different from returning to work
 - Able to physically return to the workplace, but need to make work adjustments or do a different job
- The currently used biopsychosocial outcomes may not be measuring what is important
- How would you formulate a qualitative question for this sort of QES?



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A structure for formulated questions

Cochrane Reviews use **PATIENT-INTERVENTION-COMPARISON-OUTCOME (PICO)** structure

Within qualitative evidence syntheses the following may be more appropriate:

SETTING

PERSPECTIVE

INTERVENTION/INTEREST

COMPARISON

EVALUATION



Let us consider SPICE

S	Setting – Where? In what context?
P	Perspective – For who?
I	Intervention (Phenomenon of <i>Interest</i>) – What?
C	Comparison – What else?
E	Evaluation – How well? What result?



SPICE: A tool for question formulation

S	Setting – Where? In what context? In primary care
P	Perspective – For who? Adults who are unable to work
I	Intervention (Phenomenon of <i>Interest</i>) – What? Provision of cognitive behavioural support to self manage pain
C	Comparison – What else? Usual treatment
E	Evaluation – How well? What result?