# Cognitive patterns in pharmacovigilance assessments

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## Background/Introduction:

Assessments of pharmacovigilance case report series of drug–event combinations (DECs) have historically been carried out by experienced professionals using clinical reasoning, possibly supported by decision algorithms.[1] Analysis of clinical reasoning has previously been performed in medicine, e.g. to characterise and improve decision making in surgery [2], but to our knowledge has not yet been performed in pharmacovigilance assessments.

## Objective/Aim

To identify, characterise, and compare the reasoning by experienced pharmacovigilance assessors during assessments of DECs.

## Methods

Seven DECs were assessed by 5 medical assessors. Their reasoning was elicited and clarified by semi-structured interviews [3], which were transcribed, coded, and analysed using inductive thematic analysis. Related similar codes were grouped into subtasks indicative of cognitive patterns. Subtasks were iteratively grouped into tasks to match actions taken by participants in assessments and macrocognitive functions.[4] For every assessment, subtasks and tasks were qualitatively appraised for patterns and themes.

## Results

This analysis revealed 5 tasks comprised by 20 unique subtasks (Figure) being used by the assessors. Subtasks and tasks were arranged in a non-hierarchical assessment structure. Participants were found to transition from one task to another more than once before reaching a conclusion (indicated by "decide/choose option" subtask in Figure). Within each task, subtasks were not carried out in any consistent order. Before consulting the case series, participants generally started with a situation assessment, in which they appraised their knowledge of a given DEC and initially formed expectations of the case report series analysis yield. In the planning/re-planning task, goals were established according to initial expectations, which could lead to gathering information, analysing the case reports, or providing a final decision. No decisions were made only based on expectations. Information gathering consisted in consulting drug labelling or publications, leading to hypotheses. Case reports analysis yielded further hypotheses, competing or compatible with initial expectations. Participants addressed only a subset of their hypotheses before reaching a final conclusion. In most cases, assessors reached similar final conclusions on the DECs. Differences were partly explained by participants' depth of analysis [3], or choice of sources of information.

## References

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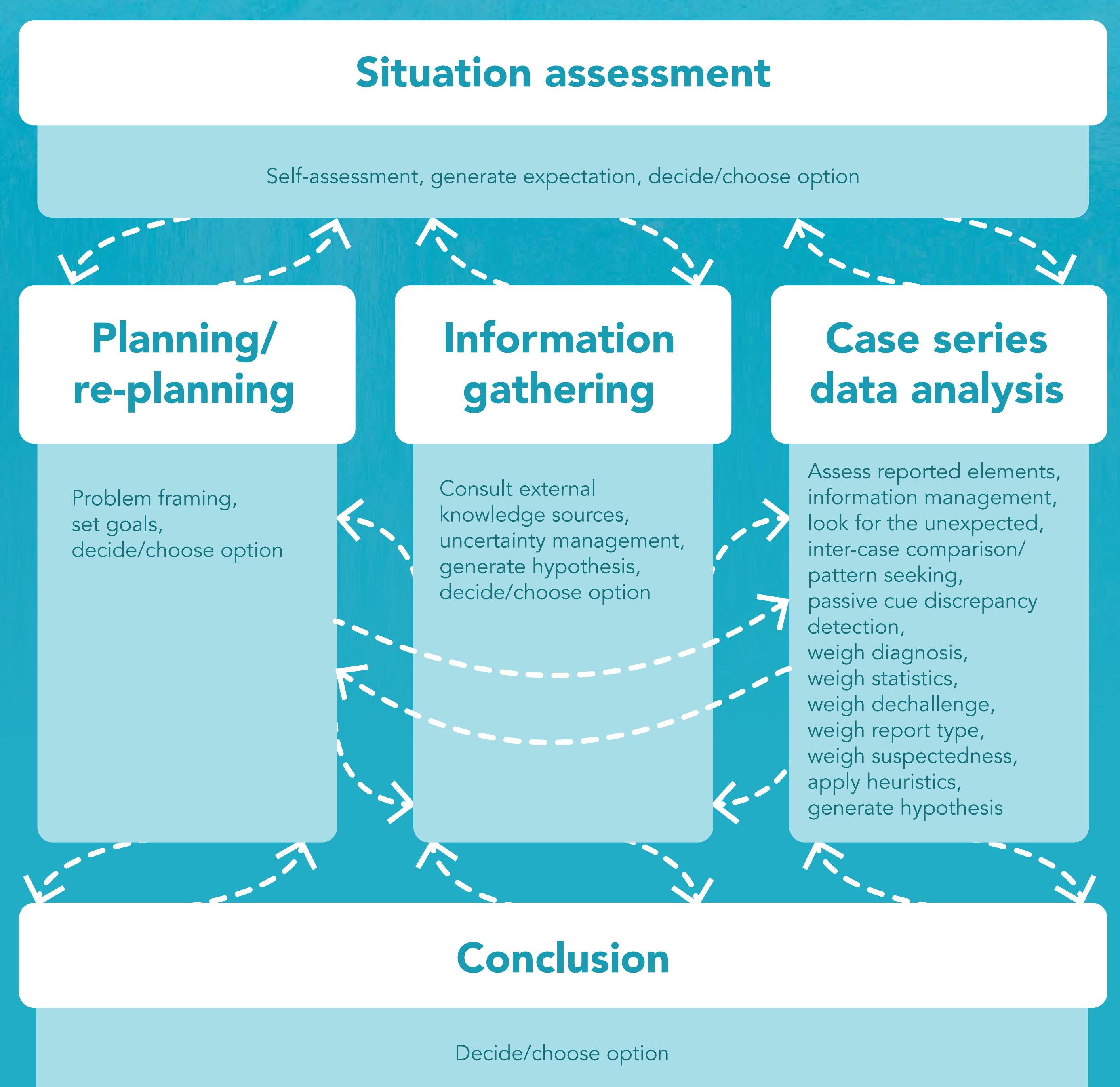
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**Situation assessment**

Self-assessment, generate expectation, decide/choose option

**Planning/ re-planning**

Problem framing, set goals, decide/choose option

**Information gathering**

Consult external knowledge sources, uncertainty management, generate hypothesis, decide/choose option

**Case series data analysis**

Assess reported elements, information management, look for the unexpected, inter-case comparison/ pattern seeking, passive cue discrepancy detection, weigh diagnosis, weigh statistics, weigh dechallenge, weigh report type, weigh suspectedness, apply heuristics, generate hypothesis

**Conclusion**

Decide/choose option

**Figure**. Overview of the identified 5 tasks and 20 subtasks, showing some of the potential transitions between tasks made by participants

## Conclusion

These results of inter- and intra-individual variations in cognitive patterns indicate a flexible approach to assessments, and may hold potential implications in informing the design of training programmes for pharmacovigilance assessment skills and decision support tools.