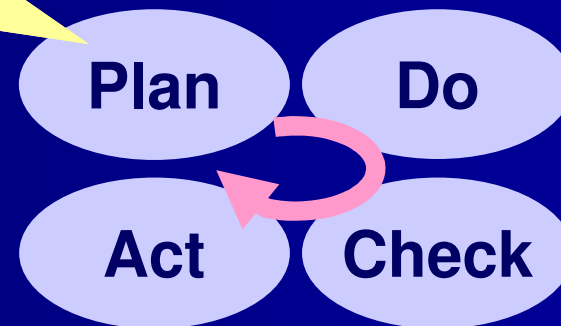


Quantitative evaluation of exhaustive failure mode identification of FMEA applied to health-care processes

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FMEA (Failure mode and effects analysis) is frequently used as **proactive risk analysis** of health-care processes at **Plan** in the PDCA cycle for process improvement.

For effective analysis, failure modes of health-care processes should be **exhaustively enumerated** by FMEA.

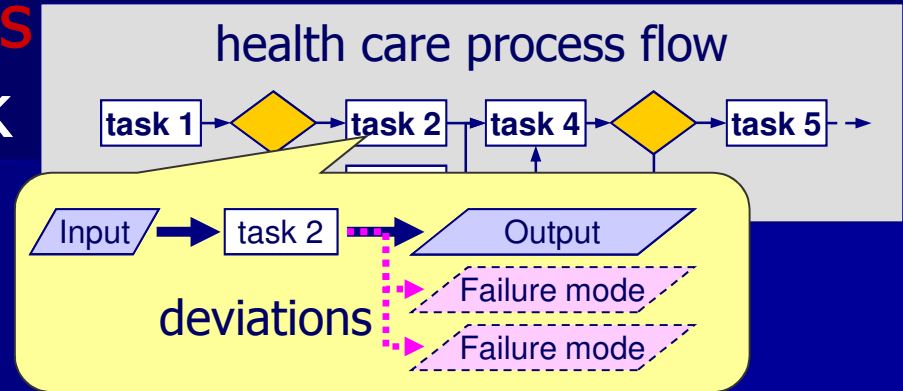


If some failure modes of a health-care process are not identified, and are high-risk, the process will not be improved adequately and remain high-risk before the failure modes really happen and cause severe accidents.

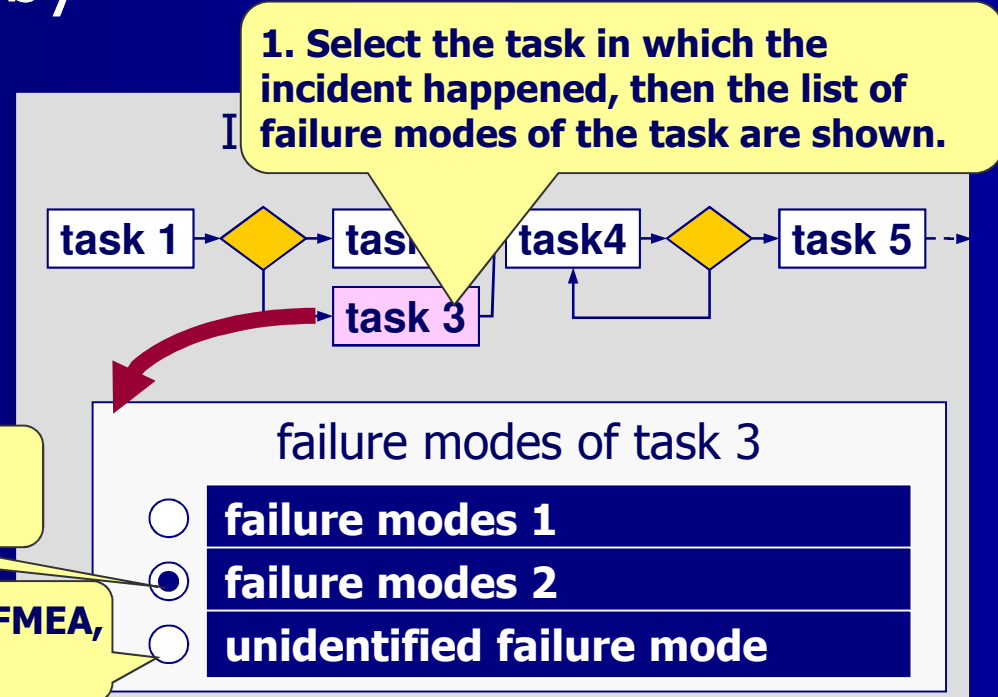
How can we exhaustively enumerate failure modes by FMEA at Plan, and verify it at Do?

Our new approach

1. Identification of all **inputs and outputs** of each task in a health-care process, and enumeration of **failure modes as deviations of outputs** by FMEA at Plan



2. Collection of incident reports related with failure modes at Do



2. Select the corresponding failure mode from the list.

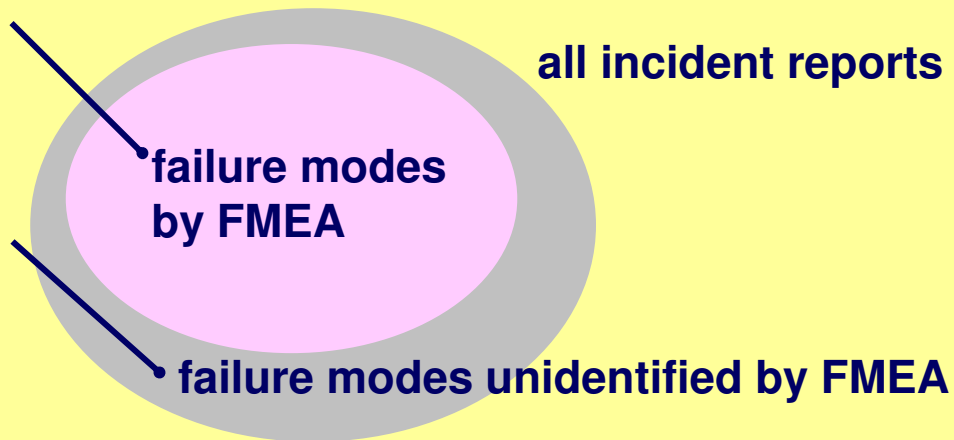
3. If appropriate failure mode is not listed by FMEA, report "unidentified failure mode".

Result and Conclusion

- We applied the approach for these two processes:
 - Injection medication process, Oral medication process

A. reports in which failure modes by FMEA are selected

B. reports in which “unidentified failure mode” is selected



$$\text{Coverage} = \frac{\text{the number of incident reports of type A}}{\text{the number of all incident reports (A+B)}} = \text{about 99\% for both processes}$$

- Conclusion
 - By identifying all inputs and outputs of tasks and considering deviations of them, we can exhaustively enumerate failure modes in health-care processes,
 - and FMEA can be effective for proactive risk analysis.