## **Overdiagnosis** :

## What we know so far from epidemiological aspect

Overdiagnosis can be defined as a screen-detected cancer that would not have become clinically significant during the patient's lifetime. It is not meaning the cases that pathologically non-malignant tumor are incorrectly diagnosed as malignant (True positive, not false positive cases). It is determined by two factors, namely, growth speed of cancer and individual remaining lifetime. Different from other harms, there is no incorrect judgement during the process. It is difficult to determine for individual case whether it is overdiagnosis case or not.

Overdiagnosis was recognized by the fact that cancer incidence increases above the expected level, such as findings from randomized controlled trials for evaluating prostate cancer screening (PSA) or lung cancer screening (low-dose CT). Increasing time trends for prostate or breast cancer incidence after nation-wide introduction of cancer screening also suggest overdiagnosis. Specific case in Japan is neuroblastoma screening. In 1985, nationwide mass screening program for neuroblastoma at age six months was introduced in Japan (screening rate was >80%). In 2002, however, Canadian and German studies reported that neuroblastoma mass screening did not reduce mortality. In 2003, Japanese government halted the program. Time trends after the program cessation indicated rapid decrease in incidence, while no change in mortality. This will be strong evidence of overdiagnosis.

Although overdiagnosis has been shown qualitatively, it is still under progress to certify methodology how quantitively evaluate the magnitude of overdiagnosis. Estimating incidence for unscreened reference population and adjusting lead time will be two major components.

Overdiagnosis is one of the most important harms caused by cancer screening. Since overdiagnosis is difficult to recognize as harm not only for laypersons but also health professionals, special efforts are needed for explanation