PD25 Use Of Real-World Evidence In The Reimbursement Assessment Of Medical Devices

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Introduction. Randomized controlled trials (RCTs) are typically considered the gold standard source of clinical evidence for reimbursement submissions, but they can often be resource-intensive, expensive, and may not always be appropriate. For example, it may be unethical to assign patients to an untreated or undiagnosed control group, or blinding may not be feasible when assessing medical devices. Evidence for medical devices is therefore often limited to nonrandomized studies. We explored the use and value of real-world evidence (RWE) in the reimbursement of medical devices across several health technology assessment (HTA) agencies.
Methods. A narrative review was completed to compare the acceptability of RWE for the HTA evaluation of medical devices across a convenience sample of countries. English-language published guidance documents were reviewed, and study design preferences extracted.
Results. In Australia, France, Germany, Ireland, Norway, and Scotland, HTA agencies prefer RCT evidence but accept RWE as supporting data. In England, there is no preferred study design, with directly observed clinical outcomes, evidence syntheses, nonclinical, and modelling studies accepted. Notably, methods and processes for HTA programs are being reviewed and are expected to place a greater emphasis on RWE. In Australia, pseudo-randomized trials, comparative cohort studies, case series, and other study designs are permitted. In France, nonrandomized or nonblinded trials, patient preference cohorts, prospective comparative observational studies, and propensity score matched cohorts are permitted, accompanied by justification. In Scotland, lived experiences, RWE, and systematic reviews are accepted. In Germany, nonrandomized studies are deemed to provide "minimum", "very low" or "low" certainty of results. In Norway, RWE may be accepted if no RCT data are available, or to support RCTs.
Conclusions. In the assessment of medical devices, where RCTs are unsuitable, RWE can form a feasible alternative. Real-world evidence is increasingly being recognized as a valuable source of evidence for medical interventions and is accepted by a number of HTA agencies.
No funding was received for this study.

PD26 Overscreening For Older Women In Cervical And Breast Cancer Screening In Japan

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Introduction. Appropriate resource utilization is crucial for cancer screening programs. Overscreening is defined as screening provided beyond the upper age limit of the target age or at a shorter interval than recommended in national programs. In Japan, there are no upper age limits set for cancer screening programs, and the recommended screening interval for cervical and breast cancer screening is 2 years. To examine the efficient use of resources for cervical and breast cancer screening, we investigated how often overscreening occurred in both programs.
Methods. The target age for this study was defined as 20-69 years for cervical cancer screening and 40-69 years for breast cancer screening. We used the national report for cancer screening in 2017 in Japan and estimated the number of participants over 70 years old or those who participated in screening annually. The percentage of overscreening was compared between cervical cancer and breast cancer screening by chi-square test.
Results. The number of participants was 4,294,127 for cervical cancer screening and 3,087,781 for breast cancer screening in 2017. The percentage of overscreening in total participants was 38.0 percent for cervical cancer screening and 35.7 percent for breast cancer screening ($p<0.01$). The percentage of screening at overage was higher in breast cancer screening than in cervical cancer screening (21.1% vs. 13.9%, $p<0.01$), whereas more frequent screening was seen more often in cervical cancer screening than in breast cancer screening (29.7% vs. 19.6%, $p<0.01$). If the resources used in overscreening could be used for the target population, it was estimated that the participation rate could increase by 4.1% for cervical cancer screening and 4.3% for breast cancer screening.
Conclusions. In Japan, screening for overage participants and short intervals may have contributed to unnecessary screening for cervical cancer and breast cancer. These resources used for overscreening could be allocated to screening for the target population.

PD28 Cost-Effectiveness Of Selective Internal Radiation Therapy Using Y-90 Resin Microspheres For Unresectable Hepatocellular Carcinoma In Brazil

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Introduction. Hepatocellular cancer (HCC) is a severe condition with poor prognosis and a significant burden. Selective internal radiation therapy (SIRT) is recommended as an alternative treatment option to overcome some limitations of current treatments. This analysis estimated the cost-effectiveness of SIRT using Y-90 resin microspheres for the treatment of unresectable HCC in Brazil.

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