

## A framework for proactive detection of child maltreatment risk using linked municipal data in Japan

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To grasp the welfare needs of children and families, municipalities in Japan often rely on passive notifications from families or community members. This approach is often insufficient for timely child protection, especially in maltreatment cases where early intervention is critical. We collaborate with a Japanese city to develop a support system using linked municipal data to proactively detect children and families in need. Our presentation aims to share our experience utilizing epidemiological expertise to enhance the use of this data for child welfare.

Our target population was registered residents of city A, aged 3–6 not in childcare (n=3,300) and those in grades 1–2 (n=28,000) as of November 30, 2023. We used anonymized municipal data—covering household demographics, maternal/child health, school, and confirmed maltreatment records—merged from separate systems with individual and household IDs. Our university team provided epidemiological support for data management, handling missing values, and analysis. Using XGBoost, we modeled the similarity to confirmed maltreatment cases in 2023 (AUC=0.72), identifying 541 children with higher scores (315 for the first group, 226 for the second). As part of the municipal project, city staff reviewed these cases and conducted home visits for 120 of them to confirm safety and caregiving environment. These visits revealed some families had economic difficulties or caregiver resource instabilities, which can be risk factors for maltreatment.

The system is designed to help the city reach families who might otherwise remain unsupported, such as those missing kindergarten enrollment procedures or facing financial hardship. Integrating municipal data with epidemiological expertise offers a feasible way to identify vulnerable children. This project framework shows that linked municipal data can provide municipal staff with decision-making support for welfare provision, and has potential for application in other municipalities.

## Municipal Sports Plans and Residents' Sports Participation Rates: Findings from JAGES

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**Background :** Since 2011, The Japan Sports Agency has urged local governments to adopt sports promotion plans under the national Basic Plan. In 2018, 55.4% of municipalities (excluding designated cities) still lacked a stand-alone plan. However, whether implementation increases residents' participation in sports groups remains unclear. We examined the association between the plan implementation and sports-group participation over time.

**Methods :** We analyzed repeated cross-sectional data from 16 municipalities participating in the Japan Gerontological Evaluation Study (JAGES) in 2010, 2013, 2016, and 2019, excluding core cities. The outcome was the age-standardized proportion of physically independent residents aged  $\geq 65$  participating in a sports group  $\geq$  weekly. The exposure was the presence of a municipal plan between 2011–2013. We used simple linear regression to estimate year-specific differences by plans. An interaction model between plan status and survey year was used to assess changes in the difference over time.

**Results :** Five municipalities implemented plans; 11 did not. The female proportion among adults  $\geq 65$  was 54.4% in plan municipalities vs 52.1% in non-plan municipalities. At baseline (2010), the four municipalities that would adopt plans already had a 2.2 percentage points (pp; 95% CI: 0.3–4.1) higher than the 12 municipalities that would not. The gap widened to 3.7 pp (2013; 1.7–5.8), 4.9 pp (2016; 2.8–7.1), and 4.7 pp (2019; 2.3–7.0). The interaction term between plan status and survey year was statistically significant, indicating that the gap in participation proportions between the two groups grew significantly over the study period.

**Conclusion :** Municipalities with sports promotion plans consistently had higher participation, and the gap widened after plans introduction. Although these findings suggest plan development may help sustain and expand residents' sports participation. More rigorous designs are needed to assess causal impact.

## Interaction of Job Insecurity and Diabetes Mellitus Severity on the Risk of Cardiovascular Disease

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**Background :** Diabetes mellitus, a key risk factor for cardiovascular disease (CVD), is increasingly prevalent due to westernized lifestyles. Low socioeconomic status, particularly employment instability, is a critical but understudied factor that may heighten CVD risk in diabetic patients. This study aims to investigate the impact of employment instability on CVD risk among individuals with diabetes.

**Methods :** Using Korean National Health Insurance Service data, we identified diabetic workers aged 40–50 years with continuous employment in 2009–2010. Job insecurity was categorized annually from 2012–2016. The primary endpoint, incident CVD or all-cause mortality, was tracked from January 2011 to December 2023. Cox proportional hazards models estimated adjusted hazard ratios (HRs) with 95% confidence intervals (CIs). The interaction between the number of oral antidiabetic drug classes last taken and job insecurity on the composite outcome was assessed using the additive interaction approach via relative excess risk due to interaction (RERI).

**Results :** After exclusions, 128,704 individuals (107,071 men, 21,633 women; mean age 49.1 and 50.0 years, respectively) were analyzed. Over a 13-year median follow-up, employment instability interacted significantly with diabetes severity (by oral antidiabetic medication count). In men with unstable jobs, CVD risk HRs were 1.41 (95% CI: 1.33–1.48) for 1–2 agents and 2.19 (95% CI: 1.99–2.42) for  $\geq 3$  agents compared to stable employment, with a synergistic RERI of 0.34 (95% CI: 0.11–0.57). In women, HRs were 1.48 (95% CI: 1.29–1.70) and 2.63 (95% CI: 2.11–3.28) for 1–2 and  $\geq 3$  agents, respectively, but RERI was non-significant (0.36, 95% CI: -0.26–0.99).

**Conclusions :** Job instability markedly increases CVD risk in diabetic patients, especially men with advanced diabetes on multiple oral antidiabetic agents, highlighting the need to integrate medical and socioeconomic factors into cardiovascular prevention strategies.

## Impact of Enhanced Clinical Trial Regulation on Clinical Trial Conduct in Japan

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**Background :** Major antihypertensive drug trial misconduct in Japan during the 2010s undermined public trust in clinical research. To restore this trust and ensure research quality, the Clinical Research Act was enacted in April 2018. The Act imposed stricter requirements on researchers. Reports showed that the number of clinical trials decreased during short-term observations after implementation. However, how this impact evolved over time remains unclear.

**Objective :** This study aimed to quantify the impact of the Act by distinguishing between immediate effects, representing abrupt changes immediately after implementation, and sustained effects, representing transitions to new steady states, and to track their changes over time. **Methods** We analyzed monthly new interventional trial registrations (April 2015 to March 2024) obtained from the University Hospital Medical Information Network Clinical Trials Registry and Japan Registry of Clinical Trials, stratified by randomized controlled trials (RCTs) and non-RCTs. A local linear trend state-space model with persistent intervention effects was employed to estimate immediate and sustained effects of the Act's implementation using Bayesian inference.

**Results :** The analysis included 22,837 trials: 10,855 RCTs (47.5%) and 11,982 non-RCTs (52.5%). For RCTs, the immediate effect was -4.8 trials (95% Bayesian credible interval: -25.5 to 13.7) and the sustained effect was -11.8 (-62.6 to 21.1). For non-RCTs, the immediate effect was -52.4 (-77.5 to -29.1) and the sustained effect was -68.7 (-94.3 to -45.3). The percentage change for immediate effects was -2% (-25% to 25%) for RCTs and -35% (-58% to -15%) for non-RCTs.

**Conclusion :** Implementation of the Act exerted immediate and sustained suppressive effects on non-RCT registrations but did not demonstrate clear impact on RCTs. This likely reflects researchers' strategic allocation of limited resources toward higher-evidence-level studies in response to the regulatory changes.