



# Medical & healthcare, Big Data/Real-World Data

# Creation and evaluation of real-world evidence based on the NDB (National Database of Health Insurance Claims and Specific Health Checkups of Japan)

Division of Health Sciences, Graduate School of Medicine

Specially Appointed Associate Professor Makoto Fujii QResearchmap https://researchmap.jp/m-fujii?lang=en

Specially Appointed Researcher Asuka Ikeda

Professor Mai Kabayama



Researchmap https://researchmap.jp/kabayama?lang=en



#### Abstract

The rising number of dialysis patients due to diabetes presents a significant economic burden and policy challenge for developed nations, including Japan. This study leverages Japan's National Database (NDB) to identify public health priorities for preventing diabetic nephropathy and assess the effectiveness of Japan's current prevention program.

Data from 29,393,195 individuals revealed that 20.83% of diabetic patients experience a rapid decline in kidney function annually. Key risk factors include elevated systolic blood pressure, suboptimal or excessively stringent diabetes management, increased urinary protein levels, low hemoglobin, and detrimental lifestyle habits such as skipping breakfast, smoking, physical inactivity, late-night eating, and insufficient sleep. The program was found to be more effective among insurers who fully adhered to its implementation guidelines.

Utilizing real-world NDB data is expected to enhance the effectiveness of prevention strategies and improve health outcomes while optimizing healthcare resource allocation.

### **Background & Results**

The rising number of dialysis patients due to diabetes presents a serious economic issue and policy challenge in developed countries, including Japan. This study utilized the NDB (National Database of Health Insurance Claims and Specific Health Checkups of Japan) to identify key targets for preventing diabetic nephropathy and assess the effectiveness of the Ministry of Health, Labour, and Welfare's prevention program. Data from 29,393,195 individuals who underwent health checkups revealed that 20.83% of diabetic patients experienced a rapid kidney function decline of 10% or more annually. Key risk factors included high systolic blood pressure, poor or excessively strict diabetes management, increased urinary protein excretion, and reduced hemoglobin levels. Lifestyle factors such as skipping breakfast, smoking, lack of regular exercise, late-night meals, and insufficient sleep were also identified as risks. Furthermore, the effectiveness of the diabetic nephropathy prevention program was significantly higher among National Health Insurance providers who met all program requirements compared to those who did not fully participate.

## Significance of the research and Future perspective

In the global shift toward big data analysis, generating real-world evidence from the NDB, which has supported Japan's universal health insurance system for over 50 years, is essential. By utilizing NDB data, preventive measures can be better guided, and the impact of public health interventions more accurately evaluated, leading to improved health outcomes and more efficient resource use. This research supports comprehensive strategies to prevent diabetic nephropathy progression, with the goal of reducing the economic burden of dialysis treatment. It also provides a model for other developed nations facing similar public health challenges, showing how big data can inform healthcare decisions for improved outcomes.



Figure1. Relationship between rapid decline in renal function and specific health checkup

Setting & Participants	Results			
Japan NDB (national database)	40–59 ages			
29,396,195 individuals	Adjusted OR (95%CI)			
= underwent specific health	Lifestyle factors	eGFR 60-85	eGFR 30–59	eGFR < 30
checkups in FY 2018	Non-refreshing sleep	1.14 (0.99, 1.31)	1.19 (1.00, 1.42)	<b>1.36</b> (1.00, 1.85)
M	Regular smoking	<b>1.29</b> (1.12, 1.50)	1.45 (1.21, 1.73)	1.42 (1.00, 2.02)
<b>m</b> 573,860	Skipping breakfast	<b>1.57</b> (1.34, 1.84)	<b>1.18</b> (0.96, 1.46)	<b>0.82</b> (0.57, 1.19)
- HbA1c >5 6%	Lack of habitual exercise	<b>1.10</b> (0.92, 1.32)	<b>0.96</b> (1.77, 1.18)	<b>0.96</b> (0.64, 1.45)
	Late-night dinners	<b>1.05</b> (0.91, 1.22)	<b>1.08</b> (0.91, 1.29)	<b>1.26</b> (0.92, 1.75)
- Available for follow-up 2 years	High alcohol intake	<b>0.98</b> (0.83, 1.17)	<b>0.75</b> (0.48, 0.95)	<b>0.77</b> (0.48, 1.23)
- eGFR <85	60–74 ages			
Exposure & Outcomes	Adjusted OR (95%CI)			
Rapid decliner	Lifestyle factors	eGFR 60-85	eGFR 30-59	eGFR < 30
a relative decrease	Non-refreshing sleep	1.14 (0.99, 1.31)	1.08 (0.92, 1.28)	0.94 (0.66, 1.34)
In eGFR of 210% per follow-up	Regular smoking	<b>1.40</b> (1.20, 1.63)	1.84 (1.55, 2.17)	1.12 (0.76, 1.67)
	Skipping breakfast	<b>1.32</b> (1.07, 1.63)	<b>1.35</b> (1.06, 1.70)	<b>1.88</b> (1.15, 3.09)
	Lack of habitual exercise	<b>1.21</b> (1.06, 1.39)	1.48 (1.26, 1.74) ·	1.18 (0.84, 1.65)
	Late-night dinners	<b>1.01</b> (0.87, 1.18)	<b>1.22</b> (1.03, 1.45)	<b>1.01</b> (1.69, 1.48)
	High alcohol intake	<b>1.14</b> (0.96, 1.35)	1.12 (0.90, 1.38) <sup>•</sup>	<b>1.14</b> (1.68, 1.92)

Figure2. Relationship between rapid decline in renal function and lifestyle factors

Patent Treatise	F a L a I I u
URL	
Keyword	

ujii, Makoto; Ohno, Yuko; Ikeda, Asuka et al. Current status of the rapid decline in renal function due to diabetes mellitus and its associated factors: nalysis using the National Database of Health Checkups in Japan. Hypertension Research. 2023, 46, 1075–1089. doi: 10.1038/s41440-023-01185-2 i, Yaya; Fujii, Makoto; Ohno, Yuko et al. Lifestyle factors associated with a rapid decline in the estimated glomerular filtration rate over two years in older dults with type 2 diabetes–Evidence from a large national database in Japan. PLOS ONE. 2023, 18(12), e0295235. doi: 10.1371/journal.pone.0295235 keda, Asuka; Fujii, Makoto; Ohno, Yuko et al. Effect of the Diabetic Nephropathy Aggravation Prevention Program on medical visit behavior in individuals nder the municipal national health insurance. Journal of Diabetes Investigation. 2023, 14, 782–791. doi: 10.1111/jdi.14006

ne NDB (National Database of Health Insurance Claims and Specific Health Checkups of Japan), diabetic nephropathies, real-world evidence