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ABSTRACT

Objectives Increases in obesity and cardiovascular diseases contribute to rapidly growing healthcare expenditures in many countries. However, little is known about whether the population-level health guidance intervention for obesity and cardiovascular risk factors is associated with reduced healthcare utilisation and spending. The aim of this study was to investigate the effect of population-level health guidance intervention introduced nationally in Japan on healthcare utilisation and spending.

Design Retrospective cohort study, using a quasiexperimental regression discontinuity design.

Setting Japan's nationwide employment-based health insurers.

Participants Participants in the national health screening programme (from January 2014 to December 2014) aged 40–74 years.

Predictors Assignment to health guidance intervention (counselling on healthy lifestyles, and referral to physicians as needed) determined primarily on whether the individual's waist circumference was above or below the cut-off value in addition to having at least one cardiovascular risk factor.

Primary and secondary outcome measures Healthcare utilisation (the number of outpatient visits days, any medication use and any hospitalisation use) and spending (total medical expenditure, outpatient medical expenditure and inpatient medical expenditure) within 3 years of the intervention.

Results A total of 51 213 individuals within the bandwidth (± 6 cm of waist circumference from the cut-off) out of 113 302 screening participants (median age 50.0 years, 11.9% woman) were analysed. We found that the assignment to the national health guidance intervention was associated with fewer outpatient visit days (-1.3 days; 95% CI, -11.4 to -0.5 days; $p=0.03$). We found no evidence that the assignment to the health guidance intervention was associated with changes in medication or hospitalisation use, or healthcare spending.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ First study to investigate the effect of a national health guidance intervention on healthcare spending and utilisation of care, using a robust quasiexperimental causal design.
- ⇒ Nationwide health screening data and medical claims data in Japan.
- ⇒ Some variations in the national health guidance intervention.
- ⇒ Secondary outcome of any hospitalisation including hospitalisations due to non-cardiovascular diseases.

Conclusion Among working-age, male-focused Japanese from a health insurer of companies of civil engineering and construction, the national health guidance intervention might be associated with a decline in outpatient visits, with no change in medication/hospitalisation use or healthcare spending.

INTRODUCTION

Obesity and obesity-related diseases, such as diabetes and hypertension, are the major causes of disease burdens and increasing health expenditures in many countries. In the USA, annual health expenditures relating to obesity, diabetes and hypertension are US\$ 147 billion,¹ US\$ 237 billion² and US\$ 131 billion,³ respectively. In addition, individuals with obesity have a higher risk of coronary heart disease, stroke and cancer, further contributing to higher disease burdens and health expenditures. At the global level, the prevalence of obesity has been increasing in most countries, regardless of their sociodemographic indices,⁴ causing 4 million deaths annually, two-thirds of which are due to cardiovascular diseases. Despite

the magnitude of this public health problem and major efforts to address this issue, no policies or interventions that effectively reduce the rate of obesity at the population level have been discovered.

Policy-makers in many countries are turning to preventive care as a promising intervention for curbing the rapidly growing disease burdens of obesity and related health expenditures. Among existing interventions, population-level health screening programmes for obesity and cardiovascular risk factors have attracted attention and have been implemented in many countries, including China,⁵ Denmark⁶ and Japan.⁷ The underlying assumption is that the identification of high-risk populations and the provision of interventions to improve their lifestyles or referring them to a physician for medical treatment may reduce future healthcare spending on the treatment of cardiovascular diseases. However, evidence showing the effectiveness of such programmes on healthcare utilisation and spending is weak and mixed. Existing research is limited to studies conducted in a single district in Denmark^{8,9} (therefore, of limited generalisability) or observational studies lacking sufficient consideration of unmeasured confounding^{10,11} (eg, studies that compared individuals who self-selected to receive interventions vs those who did not). Therefore, it remains unclear whether lifestyle interventions targeted at high-risk populations identified through population-level health screening are effective for lowering healthcare spending in the long term.

The purpose of this study is to examine the effects of population-level health guidance intervention on healthcare utilisation and spending. In doing so, we compared individuals whose waist circumference values were just above and below the eligibility cut-off level using the quasiexperimental regression discontinuity (RD) design. The RD design allows us to examine the causal impact of the national health guidance intervention, because individuals just above and below the cut-off value were very similar in many characteristics, and the only major difference among them was whether or not they received the intervention.

METHOD

Data source

Data were obtained from one of Japan's largest employment-based health insurers (a national sample of employees of a civil engineering and construction company) collected between January 2014 and December 2019, and developed by linking three databases: annual health screening data, enrolment data and medical claims data. The health screening data included information on demographics (age (continuous) and gender (binary)), weight (continuous), body mass index (BMI) (continuous), waist circumference (continuous), systolic and diastolic blood pressure (continuous), haemoglobin A1c (HbA1c) (continuous), triglyceride (continuous), high-density lipoprotein cholesterol (continuous),

medication use (binary) and smoking status (binary). Baseline variables were measured using the results of the first screening in 2014. Visit days for outpatient care, medical expenditure (including medications) and any hospitalisation were measured by medical claims data in subsequent years (2015–2019). Medication use was measured by a self-reported questionnaire at a health screening in subsequent years (2015–2019).

National health guidance intervention

If a participant had one or more cardiovascular risk factors (hypertension, hyperglycaemic and dyslipidaemia), and a waist circumference larger than the cut-off value (85 cm for men and 90 cm for women) or a BMI higher than or equal to 25, he/she was assigned to the health guidance intervention. Those who were assigned to the health guidance intervention were notified by the health insurer and received health guidance from trained instructors (many of whom were qualified dietitians or public health nurses). Participants with medication use (antihypertensives, antidiabetics or antihyperlipidemic drugs) were not assigned to health guidance. All subjects who underwent the health screening received a summary report of their screening results in the mail, regardless of whether they were assigned to the health guidance.

The national health guidance intervention in Japan consists of an initial interview (at least 20 min of individual support or 80 min of group support), followed by continuous support for 3–6 months. The instructor provides explanations about lifestyle improvements (mainly exercise and diet) and recommends medical treatment if it is needed. The health guidance intervention assignment process is shown in online supplemental efigure 1. Detailed information about the national health guidance intervention is described in the previous study.¹²

Participants

A total of 113 418 individuals, between 40 and 74 years old, received baseline health screening during the period from January 2014 to December 2014. After excluding those whose waist circumference measurements were missing from the data (n=116), we analysed 113 302 participants.

Healthcare utilisation and healthcare spending

Healthcare utilisation and spending were defined as visit for outpatient care (days), medication use (hypertension, diabetes and dyslipidaemia), hospitalisation, total medical expenditure (dollars), medical expenditure for outpatient care (dollars) and medical expenditure for inpatient care (dollars), using medical claims data and follow-up screening results from January 2015 to December 2019. To convert the Japanese yen to US\$, we used the rate on 8 January 2021 (1 US\$=103.92 Japanese yen). Our main outcomes were the sum of those outcomes for 3 years (from January 2015 to December 2017). We also examined those outcomes from year 1 (2015) to year 5 (2019). Note that lifestyle consultations provided by

health insurers are not medical treatments and thus not covered by public health insurance. Therefore, they are not included in our utilisation and spending measures.

Statistical analysis

To estimate the effect of health guidance intervention on healthcare utilisation and spending, we used an RD design, which uses a clinical or policy decision rule that participants are differentially assigned to the intervention or control group according to an arbitrarily defined cut-off value for a continuous variable.¹³ In our RD analysis, waist circumference was used as the assignment variable. In the national health guidance intervention, participants with a waist circumference above the cut-off value (85 cm in men and 90 cm in women) were more likely to receive the health guidance intervention than those below it. The RD analysis compares individuals whose values of the assignment variable (waist circumference) are just above and below the cut-off level. The RD analysis allows us to estimate causal effects because individuals just above or below the cut-off value were very similar in most characteristics, except whether or not they received the intervention. In our main analyses, we used the data-driven approach to determine the optimal bandwidths for each outcome variable in the RD analyses.¹⁴ We used a fuzzy RD analysis, which allows for situations in which the assignment variable does not completely determine the intervention but is determined probabilistically.

Our RD analysis estimated causal effects of the intervention on healthcare utilisation and spending for 3 years (from 2015 to 2017), using a local polynomial (cubic function) regression-discontinuity estimation with robust bias-corrected CIs to avoid overfitting of the data and misinterpretation of the effect. To further control for potential confounders, we included age, gender, current smoking status (yes/no) and baseline medication use as covariates in the model. We used a triangular kernel function that gives more weight to subjects near the threshold. Because only 0.05% (25 individuals) have missing data with covariates of smoking status and baseline medication use, we conducted complete case analysis. We estimated both the effect of assignment to the intervention (ie, intention-to-treat (ITT) effects) and the effect of receipt of the intervention (ie, the treatment-on-the-treated (ToT) effect). For all analysis, we used Stata V.17.0 (StataCorp, College Station, Texas, USA). To conduct RD analysis, we used the `rdrobust` command in Stata.

Secondary analysis

We conducted several secondary analyses. First, we described a histogram of waist circumference and tested whether waist circumference changed smoothly at the cut-off value by McCrary's density test.¹⁵ Second, we described the proportion of participants assigned to the health guidance intervention based on the values of their waist circumferences to show how the probability of the assignment changed discontinuously around the cut-off value of the waist circumferences. Third, to test the smooth

continuity of observed covariates at the cut-off of waist circumference, we described the RD plots using covariates as the outcome variable and waist circumference as the running variable. Fourth, we examined the effect of health guidance intervention on healthcare utilisation and hospitalisation spending in each year from 2015 (year 1) to 2019 (year 5). Fifth, we conducted subgroup analysis according to gender. Finally, to examine whether the estimated effects were sensitive to the selection of bandwidths, we conducted RD analyses using different bandwidths.

Patient and public involvement

This research was performed without patient involvement.

RESULTS

Participant characteristics

We analysed 51 213 individuals within the bandwidth of waist circumference (± 6 cm from the cut-off) out of 113 302 health screening participants. The median age was 50 years, and 11.9% were woman. [Table 1](#) shows participant characteristics within the bandwidth.

Effect of the health guidance intervention on healthcare utilisation and hospitalisation

[Figure 1](#) shows RD plots of healthcare utilisation and spending. According to those RD plots, we did not find significant discontinuity of outcomes at the cut-off of waist circumference. [Table 2](#) shows that assignment to the health guidance intervention (ITT effect) was associated with fewer visit days for outpatient care (-1.3 days, 95% CI: -11.4 to -0.5 , p value= 0.03). We found no evidence that assignment to health guidance intervention was associated with medication use, hospitalisation, total medical expenditure, medical expenditure for outpatient care or medical expenditure for inpatient care.

[Table 3](#) shows that the effect of receipt of the health guidance intervention (ToT effect) was greater on visit days for outpatient care (-10.6 days, 95% CI: -42.7 to $+18.7$, p value= 0.45), compared with that of assignment to the intervention (ITT effect). We found no evidence that the receipt of health guidance intervention was associated with medication use, hospitalisation or total medical expenditure.

Secondary analysis

We found no evidence of discontinuity of waist circumference at the cut-off (online supplemental efigure 2). Around the cut-off of waist circumference, the proportion of participants assigned to the health guidance intervention dramatically increased from 19.6% (-1 to 0 cm from the cut-off) to 80.2% (0 to 1 cm from the cut-off). The proportion of those who received the intervention increased from 4.2% (-1 to 0 cm from the cut-off) to 12.7% (0 to 1 cm from the cut-off) (online supplemental efigure 3). We found no evidence of discontinuity of observed covariates at the cut-off of waist circumference

Table 1 Characteristics of participants in the national health screening programme

Characteristics	Total N=113 302	Within bandwidth of 6 cm N=51 213
Age, years	49.4 (44.4–57.4)	50.0 (44.8–58.4)
Female, n (%)	30 263 (26.7%)	6111 (11.9%)
Waist circumference, cm	83.5 (77.3–90)	85.1 (82.5–88)
Above the cut-off, n (%)	46 701 (41.2%)	24 214 (47.3%)
Body mass index*	23.5 (21.3–25.8)	24 (22.8–25.3)
Systolic blood pressure (SBP), mm Hg	124 (113–134)	125 (115–135)
Diastolic blood pressure (DBP), mm Hg	77 (69–85)	78 (71–86)
Triglyceride, mg/dL	98 (68–149)	109 (78–159)
High-density lipoprotein (HDL) cholesterol, mg/dL	60 (50–72)	57 (49–67)
Haemoglobin A1c (HbA1c), %	5.5 (5.3–5.7)	5.5 (5.3–5.7)
Fasting blood glucose (FBG), mg/dL	94 (87–102)	95 (88–103)
Current smoking, n (%)	34 186 (30.2%)	17 233 (33.7%)
Antihypertensive drug, n (%)	18 414 (16.3%)	8860 (17.3%)
Antidiabetic drug, n (%)	5241 (4.6%)	2325 (4.5%)
Antihyperlipidemic drug, n (%)	10 556 (9.3%)	4987 (9.7%)
SBP \geq 130 mm Hg, DBP \geq 85 mm Hg or antihypertensive drug	50 963 (45.0%)	24 934 (48.7%)
FBG \geq 100 mg/dL, HbA1c \geq 5.6% or antidiabetic drug	52 559 (46.4%)	24 651 (48.1%)
Triglyceride \geq 150 mg/dL, HDL cholesterol $<$ 40 mg/dL or antihyperlipidemic drug	36 613 (32.3%)	18 842 (36.8%)

*Calculated as weight in kilograms divided by height in metres squared.

(online supplemental efigure 4). These results support the validity of our RD analysis. Except for visit days for outpatient care in year 2 (-1.0 days, 95% CI: -4.7 to -0.5 , p value=0.01), we did not find significant associations of the assignment to the national health guidance intervention with healthcare utilisation and spending in each year from 2015 (year 1) to 2019 (year 5) (online supplemental eTable 1). According to the subgroup by gender, the point estimates of the effect of assignment to the intervention were larger in women than those in men, with larger CIs (online supplemental eTable 2). The estimated effects

were qualitatively unaffected when we used different bandwidths (online supplemental eTable 3).

DISCUSSION

Using nationwide claims data linked with information from the national screening programme, we found that Japan's national health guidance intervention was associated with fewer outpatient visit days. On the other hand, we found no evidence that the health guidance intervention was associated with medication use, hospitalisations

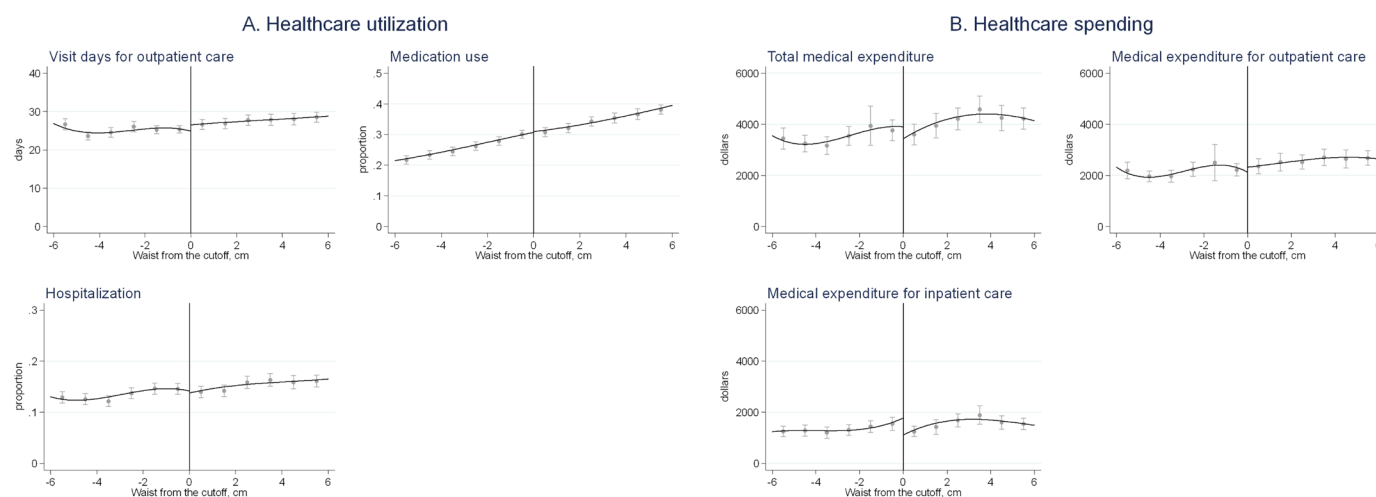


Figure 1 Healthcare utilisation and spending for 3 years according to assignment to health guidance intervention: regression discontinuity plots. The dots and error bars indicate sample means and 95% CIs, respectively. The vertical solid line indicates the cut-off of waist circumference, which is an assignment variable for health guidance intervention.

Table 2 Association of assignment to the national health guidance intervention with healthcare utilisation and healthcare spending (3 years cumulative) using fuzzy regression discontinuity design* (ITT effect)

	Bandwidth, † cm (number)	Average within bandwidth	Adjusted effects n=42 050	95% CI	P value
Healthcare utilisation					
Visit days for outpatient care, days ‡	6.1 (44 333)	26.4 days	-1.3 days	(-11.4 to -0.5)	0.03
Medication use, § percentage points (pp) ‡	6.8 (47 016)	30.0 %	-3.8 pp	(-9.0 to +1.4)	0.15
Hospitalisation, percentage points (pp) ‡	6.9 (47 726)	14.4 %	-1.2 pp	(-7.2 to +4.1)	0.59
Healthcare spending					
Total medical expenditure, dollars ‡	5.9 (42 050)	US\$3816	-US\$1138	(-4506 to +932)	0.20
Medical expenditure for outpatient care, dollars ‡	5.7 (41 081)	US\$2366	+US\$46	(-2063 to +1572)	0.79
Medical expenditure for inpatient care, dollars ‡	6.3 (44 986)	US\$1450	-US\$1214	(-2932 to +68)	0.06

*We used the data-driven approach to determine the optimal bandwidths for each outcome variables we have investigated.

†We selected optimal bandwidths for each outcome by data-driven approach.

‡We adjusted for age, gender, current smoking and baseline medication use.

§Any medication includes drugs for hypertension, hyperglycaemic and hyperlipidemia.

or healthcare spending. These findings indicate that the current structure of Japan's national health guidance intervention has a limited impact on growing health expenditures and highlights the importance of improving the design of the national health guidance intervention based on robust evidence to make it more effective.

There are several potential reasons why we found that the national health guidance intervention was associated with fewer outpatient visit days. First, participants who are under the health guidance intervention have opportunities to interact with an instructor, who may be able to solve minor health issues, thereby replacing physician visits. This hypothesis is supported by the Patient's Behavior Survey by the Japanese Ministry of Health, Labour and Welfare, which found that 25.8% of patients visited an outpatient clinic despite the lack of any symptoms because of concern, recommendations by family and friends, and referrals after undergoing a health screening programme.¹⁶ Second, a previous study¹² found a small

reduction in participants' weight due to the lifestyle intervention, which may have clinical benefits among those individuals near the cut-off value of waist circumference, possibly leading to fewer outpatient visit days. Lastly, the participants of the national health guidance intervention may have the chance to reflect on their lifestyles, which in turn may improve their health status and reduce outpatient visits.¹⁰

We found no evidence that the national health guidance intervention changed healthcare spending, and there are several mechanisms that may explain this finding. First, the implicit assumption behind promoting preventive care is that early interventions for individuals with a high risk of diseases could reduce future healthcare spending due to treatments of those conditions. However, the national health guidance intervention introduced in Japan may not be effective in preventing future incidences of cardiovascular diseases, and thereby leading to its lack of association with healthcare spending. This hypothesis

Table 3 Association of receipt of the national health guidance intervention with healthcare utilisation and healthcare spending (3 years cumulative) using fuzzy regression discontinuity design* (treatment-to-treat effect)

	Bandwidth, † cm (number)	Adjusted effects n=42 050	95% CI	P value
Healthcare utilisation				
Visit days for outpatient care, days ‡	8.2 (55 458)	-10.6 days	(-42.7 to +18.7)	0.45
Medication use, § percentage points (pp) ‡	8.8 (57 815)	-28.0 pp	(-56.7 to +6.5)	0.12
Hospitalisation, percentage points (pp) ‡	9.1 (60 250)	-14.7 pp	(-38.2 to +25.8)	0.70
Healthcare spending				
Total medical expenditure, dollars ‡	7.2 (50 273)	-US\$7638	(-23 672 to +7351)	0.30
Medical expenditure for outpatient care, dollars ‡	7.3 (50 940)	-US\$4	(-9549 to +11 022)	0.89
Medical expenditure for inpatient care, dollars ‡	6.7 (46 974)	-US\$7818	(-18 900 to +368)	0.06

*We used the data-driven approach to determine the optimal bandwidths for each outcome variables we have investigated.

†We selected optimal bandwidths for each outcome by data-driven approach.

‡We adjusted for age, gender, current smoking, and baseline medication use.

§Any medication includes drugs for hypertension, hyperglycaemic and hyperlipidemia.



is supported by a previous work showing that the national health guidance intervention had no impact on cardiovascular risk factors, such as blood pressure, HbA1c level and low-density lipoprotein cholesterol level.¹² Second, the cut-off value of waist circumference used to determine the population who received the health guidance intervention may be relatively low. Our data show that the current waist circumference cut-off values are close to the median waist circumferences for men (online supplemental efigure 2), indicating that a large number of healthy individuals received the intervention. It is possible that focusing the intervention on a population at higher risk may be more effective in lowering healthcare utilisation and spending. Lastly, the current intervention may not effectively incentivise payers to improve health outcomes or reduce health expenditures. The current intervention incentivises payers based on the quantity of support provided, such as initial interviews and telephone follow-ups, while being agnostic about changes in individual health outcomes. Incentivising the performance achieved (eg, improvements in cardiovascular risk factors) may be more effective than incentivising the quantities of inputs used.

Our findings provide valuable evidence regarding the impact of health guidance interventions. A randomised control study conducted in one region in Denmark found that regular preventive health checks did not have any effects on primary and secondary healthcare utilisation,^{8,9} but rate ratios for daytime outpatient visits initially increased and gradually decreased. Another quasiexperimental study in Austria used regional variations in the exposure to screening recommendations as an instrumental variable and concluded that no association between health screening and health expenditure existed in the long run.¹⁷ However, prior studies were limited in that they evaluated regional programmes (as opposed to the evaluation of a national programme in our study), and used observational designs that could not account for unmeasured confounders.^{11, 18} To our knowledge, no study to date has investigated the effect of a national health guidance intervention on healthcare spending and utilisation of care using a robust quasiexperimental causal design.

Our study has limitations. First, we did not evaluate how different types of interventions affect health expenditure and utilisation. For example, an eligible participant begins the national health guidance intervention with an interview, either as part of a group or as an individual. Participants are designated to receive either active or motivational support, and there is a difference in the frequency of interventions between those types of support. The association between the intervention and outcomes might vary by the type of intervention that participants receive. Second, we defined secondary hospitalisation utilisation as any hospitalisation, which included hospitalisations due to non-cardiovascular diseases such as pneumonia and pyelonephritis. This might have led to an overestimation of the secondary hospitalisation utilisation. Third, as

is the case with any studies using the RD analysis, the estimates calculated in our analyses are only interpretable as causal effects for those individuals near the cut-off values we used ('local average treatment effect'). Therefore, our findings may not be generalisable to individuals whose waist circumference are far away from our cut-off values. In particular, it is possible that the intervention may be more effective among those who are more obese (partially due to the regression to the mean), but the causal effect of the intervention is challenging to evaluate in this population using the quasiexperimental design. Fourth, we should be careful about the generalisability of the results, because we analysed male-focused, working-age population from a specific industry area (civil engineering and construction) in Japan. Only 11.9% were woman in the bandwidth. There may be differences of the estimated effects between gender because of different cut-off value of waist circumference between them. Future studies will need to further examine this in populations that include more women. We analysed employees and their family members from more than 1700 civil engineering and construction companies. These companies consist of various sizes (small construction companies and large general constructors), and the occupations are expected to be diverse (white-collar workers, blue-collar workers, etc). Although the healthcare spending per enrollee is very close to the national average for employment-based health insurance when adjusted for age, gender and employee or family, the associations may differ based on some factors such as socioeconomic status, education and work type. The limitation of our study includes the lack of those variables in our data. Finally, our findings are based on a relatively intensive health guidance intervention in Japan. Our findings may not be generalisable to the population in other contexts.

Conclusions

In summary, we found that the national health guidance intervention in Japan was associated with fewer outpatient visit days, but was not associated with changes in healthcare spending, medication use or hospitalisations. Ultimately, the effectiveness of these interventions hinges on the actual designs and structures of the interventions, and these findings suggest that the national health guidance intervention needs to be re-evaluated to improve its efficiency and effectiveness.

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