# The Final Interim Report by the Work Group for Studying the Effects of the Specific Health Checkups and Specific Health Guidance on Health Care Expenditures

# March 2015

The Work Group for Studying the Effects of the Specific Health Checkups and Specific Health Guidance on Health Care Expenditures

Translation by Akiko S. Hosler (ホスラー晃子)

University at Albany (SUNY) School of Public Health

	Table of Contents	
Part 1	Introduction	1
1-1	Overview of SHCSHG	2
1-2	Status of SHCSHG.	5
Part 2	The First Interim Report (April 2014)	6
2-1	Changes in Clinical and Behavioral Indicators	6
(1)	Study Subjects	6
(2)	Statistical Analysis	7
(3)	Results (Graphs are for the FY 2008-09 data only)	7
а	Intensive HG Intervention vs Control	7
b	Motivational HG Intervention vs Control	16
(4)	Discussion – Changes in Clinical and Behavioral Indicators	25
2-2	Changes in Health Guidance Eligibility.	27
(1)	Study Subjects	27
(2)	Statistical Analysis	27
(3)	Results (Graphs are for the FY 2008-09 data only)	29
а	Participants Who Completed Intensive HG	29
b	Participants Who Completed Motivational HG	31
(4)	Discussion – Changes in Health Guidance Eligibility	33
2-3	Changes in Metabolic Syndrome Status	34
(1)	Study Subjects	34
(2)	Statistical Analysis	34
(3)	Results (Graphs are for the FY 2008-09 data only)	36
а	Participants Who Completed Intensive HG	36
b	Participants Who Completed Motivational HG	38
(4)	Discussion – Changes in Metabolic Syndrome Status	40
Part 3	The Second Interim Report (November 2014)	41
3-1	Overall Methods	41
(1)	Data	41
(2)	Definitions of Intervention and Control Groups	42
(3)	Method for Calculating Per Capita Outpatient Health Care Costs	42
3-2	Analytic Methods	43
(1)	Per Capita Outpatient Health Care Costs for Hypertension, Dyslipidemia, and	40
(2)	Diabetes One Year After Health Guidance	43
. ,	and Control Groups	43
3-3	Results	46

(1)	Per Capita Outpatient Health Care Costs for Hypertension, Dyslipidemia, and Diabetes One Year After Health Guidance	46
а	Intensive Health Guidance (40 to 64 years of age)	46
b	Motivational Health Guidance (40 to 64 years of age)	46
С	Motivational Health Guidance (65 to 73 years of age)	47
(2)	Analysis to Examine Baseline Health Care Cost Differences Between Intervention and Control Groups	52
а	Analysis of Per Capita Outpatient Health Care Costs Associated with Hypertension, Dyslipidemia, and Diabetes for the Year Subjects Became Eligible for HG	52
b	Analysis Without Subjects Who Were Billed for Hypertension, Dyslipidemia, or Diabetes During the Year Prior To Heath Guidance	52
3-4	Discussion	63
(1)	Per Capita Outpatient Health Care Costs for Hypertension, Dyslipidemia, and Diabetes One Year After Health Guidance	63
(2)	Analysis to Examine Baseline Health Care Cost Differences Between Intervention and Control Groups	65
Part 4	The Third Interim Report	66
4-1	Study Subjects	66
4-2	Methods	66
(1)	Longitudinal Analysis of Clinical Indicators Following Health Guidance	66
(2)	Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance	69
(3)	Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance (Follow-up Analysis of Baseline Cohort)	70
4-3	Results	72
(1)	Longitudinal Analysis of Clinical Indicators Following Health Guidance	72
а	Intensive Health Guidance (40 to 64 years of age)	72
b	Motivational Health Guidance (40 to 64 years of age)	119
С	Motivational Health Guidance (65 to 74 years of age)	166
(2)	Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance	213
а	Intensive Health Guidance (40 to 64 years of age)	213
b	Motivational Health Guidance (40 to 64 years of age)	213
С	Motivational Health Guidance (65 to 74 years of age)	214
(3)	Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance (Follow-up Analysis of Baseline Cohort)	228
а	Intensive Health Guidance (40 to 64 years of age)	228
b	Motivational Health Guidance (40 to 64 years of age)	228

4-4	Discussion.	240
(1)	Longitudinal Analysis of Clinical Indicators Following Health Guidance	240
(2)	Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance	241
(3)	Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance (Follow-up Analysis of Baseline Cohort)	242
Part 5	Closing Remarks	243

## Part 1. Introduction

The Work Group for Studying the Effects of the Specific Health Checkups and Specific Health Guidance on Health Care Expenditures (the **Work Group** hereafter) was convened by the Committee for Specific Health Checkups and Specific Health Guidance by Health Insurers to conduct scientific studies on the effects of the Specific Health Checkups and Specific Health Guidance (the **SHCSHG** hereafter) on national health care expenditures and other critical health indicators. The Work Group is spearheaded by experts of public health and epidemiology, and utilizes information generated from the National Insurance Claims Database (**NDB**).

The Work Group is charged to investigate whether the SHCSHG had any impact on 1) the changes in clinical and behavioral indicators, 2) the savings in national health care expenditures, and 3) other major health indicators. The Work Group began its activity on March 1<sup>st</sup>, 2013, and to date, a total of 19 meetings have been held.

In the First Interim Report published on April 22, 2014, the Work Group analyzed the effects of the SHCSHG on changes in clinical and behavioral (i.e. smoking) indicators, and found that subjects who completed intensive health guidance (HG) had statistically significant improvements in waist circumference, body weight, blood pressure, lipids, and blood glucose at the following year's examination compared to those who did not participate or complete the intensive HG.

In the following Second Interim Report published on September 22, 2014, the Work Group examined outpatient health care costs associated with hypertension, dyslipidemia, and diabetes. It was found that subjects who had completed intensive HG during fiscal year (FY) 2008 had 34% lower health care costs in the following year compared to those who did not participate in intensive HG. This result suggested that individuals who had completed HG improved their lifestyle and lost body weight, which subsequently led to reduction in per capita outpatient health care costs for hypertension, dyslipidemia, and diabetes.

After the publication of the Second Interim Report, the SHCSHG held a total of 4 meetings. Incorporating suggestions by the health insurers' committee on health checkups and health guidance, the Work Group investigated the SHCSHG's effects on the savings in national health care expenditures over multiple years. The present report serves as the Work Group's Final Report, which combines two previously published interim reports and the Third Interim Report containing findings from the most recent investigation.

## 1. Overview of SHCSHG

The rapid aging of the population in Japan brought an increasing burden of lifestyle-related chronic diseases, including cancer, cardiovascular disease, cerebrovascular disease, and diabetes. To improve the quality of life across the life span, and to curb the upward trends of health care expenditures, the Health Care Systems Reform Plan of 2006 introduced the SHCSHG. This legislation went into effect in April 2008 under the Act of Financing Health Care for the Elderly.

The SHCSHG requires all health care insurers (administrators of the National Health Insurance and the Employees' Insurance) to provide annual, systematic health examinations to all enrollees and their dependents aged 40 to 74 years. The health examination features laboratory tests and a physical examination to evaluate metabolic risk factors.

By focusing on visceral obesity, the examination allows physicians to identify individuals who are at risk for developing lifestyle-related chronic diseases and also detect those who have already developed a chronic disease. Under the SHCSHG, the former group will be refereed to special health guidance, and the latter group will be recommended to receive immediate medical care.

**Table 1** depicts the standard health examination items all participants must receive.

Table 1. Items for the standard health examination

Item	Comments
Health history	Includes questionnaire for medication history and smoking behavior
Subjective and objective symptoms	Physiological (physical) examination
Height, weight, and waist circumference	Based on the Ministry of Health, Labour and Welfare Guidelines, physicians can waive waist circumference measurement for certain individuals. (To receive a waiver, the participant must be BMI<20kg/m², or BMI<22kg/m² and able to self-report waist circumference measurement.) Measurement of visceral fat can substitute waist circumference measurement.
Body Mass Index (BMI)	BMI=weight(kg)/height(m²)
Blood pressure	n/a
Liver function	Serum glutamic oxaloacetic transaminase (SGOT) or aspartate transaminase (AST), serum glutamate-pyruvate transaminase (SGPT) or alanine transaminase (ALT), and gamma-glutamyl transpeptidase (Y-GT, Y-GTP)
Blood cholesterol	Quantification of serum triglycerides, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol
Blood glucose	Fasting glucose or hemoglobin A1c (HbA1c)
Urinalysis	Detection of glucose and protein in urine

The SHCSHG also requires all health care insurers to evaluate the results of health examinations, and provide annual, systematic health guidance to individuals who are deemed to require health improvement. There are two types of health guidance (HG) - intensive HG and motivational HG.

An algorithm for evaluating examination results is used to classify participants into groups, and type of HG is determined by group membership. (Participants are initially classified by obesity indicators, then by the number of additional metabolic risk factors, smoking status, and age.) Individuals who are on pharmacological therapy for diabetes, dyslipidemia, or hypertension are not eligible for HG. Individuals who do not fall into any of the groups are deemed to be low risk and receive health information resources (brochures) only.

Table 2 details participant classification, and Table 3 describes contents of HG.

Table 2. Participant classification for health guidance eligibility

Waist circumference/ BMI	Additional risks (Glucose, Lipid, BP)	Smoking	Age 40-64	Age 65-74
≥85cm (men) ≥90cm (women)	2 or more risks	Yes or No	- Intensive HG	
		Yes	Motivat	Motivational HG
	1 risk	No	Motivational HG	
<85cm (men) <90cm (women)	3 risks	Yes or No	Intensive HG	
but BMI≥25kg/m²		Yes	Intensive no	Motivational HG
		No	Motivational	
		Yes or No	HG	

The definitions of blood glucose, lipid, and blood pressure risks are as follows:

**Blood glucose**: Fasting glucose≥100mg/dl or HbA1c≥5.6% by the NGSP. If both fasting blood glucose and HbA1c are measured, use the fasting glucose value. Note that HbA1c tests done on or before March 31, 2013 are reported in the JDS unit (Japanese standard). HbA1c tests done after March 31, 2013 are reported in the NGSP unit (International standard). (In this report, all HbA1c values are reported in the JDS unit, and the cutoff value for blood glucose risk is HbA1c≥5.2%.)

Lipid: Triglycerides≥150mg/dl or HDL<40mg/dl

Blood Pressure: Systolic≥130mmHg or Diastolic≥85mmHg

**Note**: Individuals who are already taking medication for diabetes, dyslipidemia, or hypertension are not eligible for health guidance. Only motivational health guidance is available for those aged 65 to 74 years.

Table 3: Description of intensive and motivational health guidance

Intensive health guidance				
Duration and frequency	<ul> <li>Initial counseling* and continuous support for 3 months or longer.</li> <li>Progress evaluation after 3 months and final outcome evaluation after 6 months.</li> </ul>			
Content of support	<ul> <li>Health examination results, smoking status, physical activity, dietary habit, sleep/resting, and other aspects of lifestyle are evaluated, and individualized lifestyle modification plans are provided at the initial counseling.</li> <li>Lifestyle modification support is provided through face-to-face contacts and other means.</li> </ul>			
Motivational health guid	lance			
Duration and frequency	Initial counseling*.     Final outcome evaluation after 6 months.			
Content of support	<ul> <li>Health examination results, smoking status, physical activity, dietary habit, sleep/resting, and other aspects of lifestyle are evaluated, and individualized lifestyle modification plans are provided at the initial counseling.</li> <li>Each participant sets his/her own behavioral goals and makes an effort to modify lifestyle on his/her own</li> </ul>			

<sup>\*</sup>The initial counseling can be face-to-face counseling for at least 20 minutes, or group counseling (8 participants or fewer) for at least 80 minutes. A trained health care professional (physician, nurse, or dietitian) provides counseling.

## 1-2. Status of SHCSHG

The total number of adults eligible for health examination during the fiscal year (FY) 2011 was approximately 52.5 million, or virtually all of the adult population 40 to 74 years of age in Japan. (Japan has universal health care coverage.) The total number of eligible adults who participated in the health examination during FY 2011 was approximately 23.5 million, with a participation rate of 44.7%. It is an increase by 5.8% from the participation rate in 2008 (38.9%). Although the 2011 rate it is still far below the 2017 national goal of 70%, the annual participation rates show a constant upward trend since the inception of the SHCSHG in 2008 (see **Table 4**).

Table 4. Status of health examination participation

Year (FY)	Total eligible adults (aged 40-74 years)	Participated in health exam	Participation rate (%)	Participation rate goal by 2017
2008	51,919,920	20,192,502	38.9	
2009	52,211,735	21,588,883	41.3	700/
2010	52,192,070	22,546,778	43.2	70%
2011	52,534,157	23,465,995	44.7	

Of those who received health examinations in FY 2011 (approx. 23.5 million), about 4.3 million had elevated metabolic risk factors (but not on pharmacological therapy) and were determined to be eligible for HG, with an eligibility rate of 18.2%. Among the 4.3 million adults who were eligible for HG, about 643,000 completed HG, with a completion rate of 15.0%. It is an increase by 7.3% compared to the completion rate for 2008 (7.7%). Again, although the 2011 rate is still far below the 2017 national goal of 45%, annual completion rates have been increasing incrementally since 2008 (see **Table 5**).

Table 5. Status of health guidance eligibility and completion

Year (FY)	Adults eligible for HG	Eligibility rate for HG (%)	Completed HG	Completion rate (%)	Completion rate goal by 2017
2008	4,010,717	19.9	308,222	7.7	
2009	4,086,952	18.9	503,712	12.3	450/
2010	4,125,690	18.3	540,942	13.1	45%
2011	4,271,235	18.2	642,819	15.0	

# Part 2. The First Interim Report (April 2014)

# 2-1. Changes in Clinical and Behavioral Indicators

A series of analyses was conducted to examine changes in key clinical and behavioral indicators from baseline to the following year among intervention and control groups, using health examination data for FY 2008 to FY 2011. All analyses were stratified by type of HG, FY, gender, and age group.

# (1) Study Subjects

**Inclusion criteria:** Adults from 40 to 74 years of age who 1) had a health examination in Time 1 (FY 2008, 2009 or 2010), 2) became eligible to receive HG because of elevated metabolic risk factors, and 3) had a health examination again in the following year (Time 2) (i.e. had health examination data for two consecutive years)

Intervention and control subjects were selected based on the following criteria.

**Intervention**: Those who participated in HG for the first time in Time 1, remained in the program, and completed the final outcome evaluation at the end of the 6<sup>th</sup> month.

**Control**: Those who had not participated in HG prior to Time 1, and also chose not participate in HG in Time 1 (non-participants) or those who received initial counseling for the first time in Time 1, but did not remain in the program (dropouts).

Individuals who began pharmacological therapy prior to health examination in Time 2 were excluded from analysis.

The numbers of study subjects are summarized in **Table 6**.

Table 6. Number of study subjects

Intensive health guidance						
Time 1 to Time 2	Control	Total				
FY 2008 – FY 2009	74,663	1,274,292	1,348,955			
FY 2009 – FY 2010	93,350	899,565	992,915			
FY 2010 – FY 2011	109,444	1,266,110	1,375,554			
Motivational health guidance						
Time 1 to Time 2	Intervention	Control	Total			
FY 2008 – FY 2009	119,218	938,875	1,058,093			
FY 2009 – FY 2010	124,508	711,048	835,556			
FY 2010 – FY 2011	127,965	871,520	999,485			

# (2) Statistical Analysis

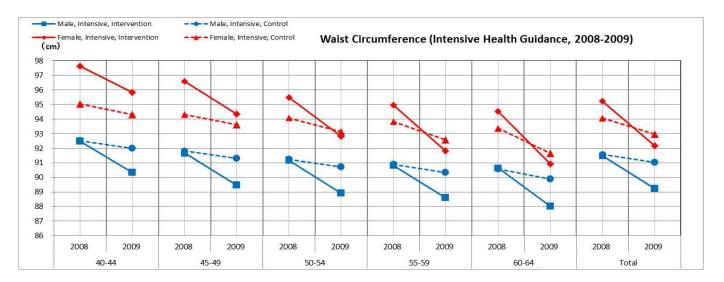
Analyses focused on changes in the clinical and behavioral indicators that were used in the algorithm for evaluating health examination results and determining HG eligibility. These indicators included waist circumference, BMI (also body weight), fasting glucose, HbA1c, systolic blood pressure, diastolic blood pressure, triglycerides, HDL cholesterol, and smoking status. LDL-cholesterol, ALT (GPT), and Y-GT (Y-GTP) were also analyzed for reference purposes only. Changes in these indicators from Time 1 to Time 2 were averaged and compared for intervention and control groups, using the Student's t-test for testing statistical significance (p < 0.05).

# (3) Results (Graphs are for the FY 2008-09 data only)

**Note:** In the results section, all graphs are for the FY 2008-09 data. Other years are described without graphs. All numbers are rounded.

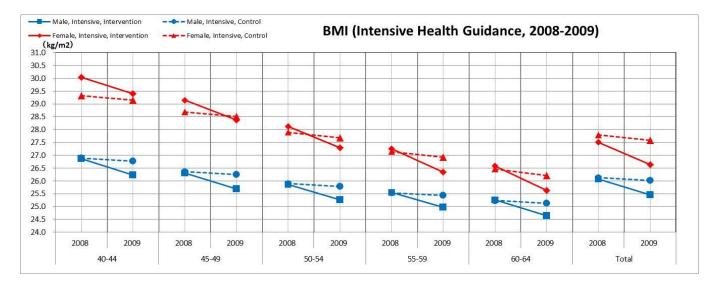
#### a. Intensive HG Intervention vs Control

## a-1. Waist Circumference



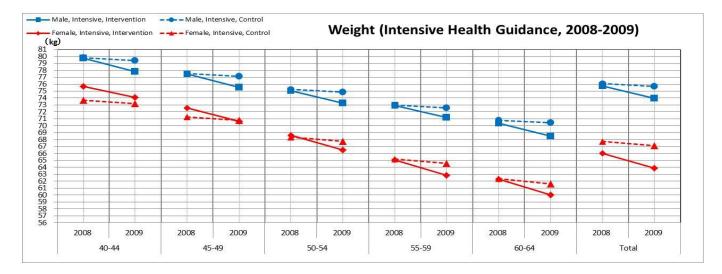
- In the intensive HG intervention group, waist circumference decreased from 91.5cm to 89.2cm (a decrease of 2.2cm) in men, and from 95.2cm to 92.2cm (a decrease of 3.1cm) in women (FY 2008-09).
- In the control group, decreases of waist circumference were only 0.6cm in men and 1.1cm in women.
   The differences of decreases between intervention and control groups were statistically significant in both men (1.7cm) and women (2.0cm) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in decreases in waist circumference between intervention and control groups were 1.2cm in men and 1.1cm in women (FY 2009-10), and 1.0cm in men and 0.9cm in women (FY 2010-11).
- o For all gender and age groups, the intervention group had significantly larger decreases of waist circumference than the control group.

#### a-2. BMI



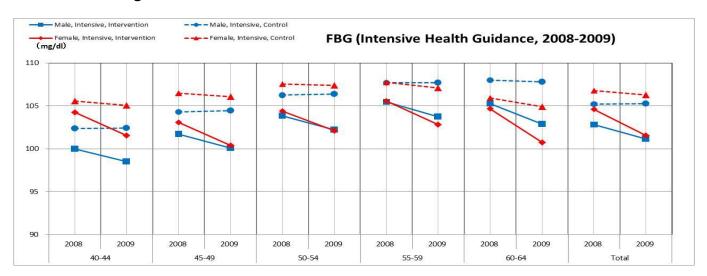
- In the intensive HG intervention group, BMI decreased from 26.1kg/m² to 25.5kg/m² (a decrease of 0.6kg/m²) in men, and from 27.5kg/m² to 26.6kg/m² (a decrease of 0.9kg/m²) in women (FY 2008-09).
- In the control group, decreases of BMI were only 0.1kg/m² in men and 0.2kg/m² in women (FY 2008-09).
- The differences in decreases between intervention and control groups were statistically significant in both men (0.5kg/m²) and women (0.7kg/m²) (FY 2008-09).
- Similar results were observed for FY 2009-10 and FY 2010-11: the differences in decreases in BMI between intervention and control groups were 0.3kg/m² in men and 0.4kg/m² in women (FY 2009-10), and also 0.3kg/m² in men and 0.4kg/m² in women (FY 2010-11). These differences were all statistically significant.
- At baseline, younger subjects had higher BMI compared to older subjects in both intervention and control groups. Women in particular had a very visible inverse relationship between BMI and age.

# a-3. Body Weight



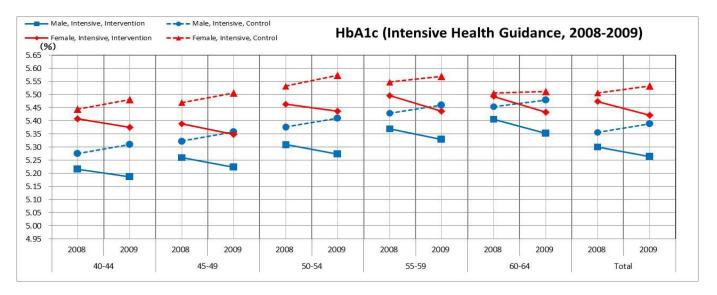
- o In the intensive HG intervention group, men lost 1.9kg (2.5% reduction of baseline weight) and women lost 2.2kg (3.3% reduction of baseline weight) within a year (FY 2008-09).
- In the control group, decreases in weight were only 0.4kg in men and 0.6kg in women. The
  differences in decreases between intervention and control groups were statistically significant in both
  men (1.5kg) and women (1.6kg) (FY 2008-09).
- Similar trends were observed for FY 2009-10 and FY 2010-11: the differences in weight reductions between intervention and control groups were 1.0kg in men and 1.1kg in women (FY 2009-10), and 0.8kg in men and 0.9kg in women (FY 2010-11). These differences were all statistically significant.
- For all gender and age groups, the intervention group had significantly larger decreases in weight than the control group.

## a-4. Fasting Glucose



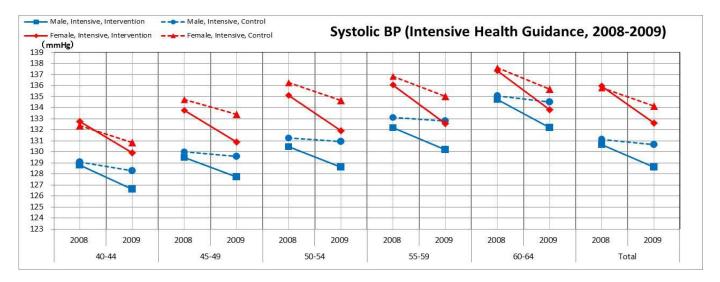
- In the intensive HG intervention group, fasting glucose decreased from 102.8mg/dl to 101.2mg/dl (a decrease of 1.7mg/dl) in men, and from 104.6mg/dl to 101.5mg/dl (a decrease of 3.1mg/dl) in women (FY 2008-09).
- o In the control group, fasting glucose increased by 0.1mg/dl in men, but decreased by 0.5mg/dl in women (FY 2008-09). Among men 45 to 49 and 50 to 54 years of age, fasting glucose increased.
- o Differences in changes in fasting glucose between intervention and control groups were statistically significant in both men (1.7mg/dl) and women (2.5mg/dl) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in changes in fasting glucose between intervention and control groups were 1.1mg/dl in men and 1.4mg/dl in women (FY 2009-10), and 1.1mg/dl in men and 1.7mg/dl in women (FY 2010-11). These differences were all statistically significant.

# a-5. HbA1C (JDS unit)



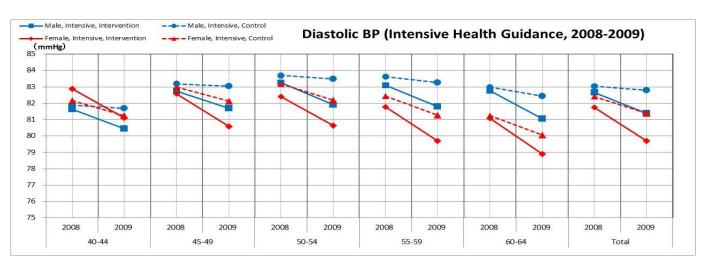
- o In the intensive HG intervention group, HbA1c decreased from 5.30% to 5.26% (a decrease of 0.04%) in men, and from 5.47% to 5.42% (a decrease of 0.05%) in women (FY 2008-09).
- o In the control group, HbA1c increased by 0.03% in both men and women. A small increase of HbA1c was found in all age groups in men and women (FY 2008-09).
- The differences in changes in HbA1c between intervention and control groups were statistically significant in both men (0.07%) and women (0.08%) (FY 2008-09).
- Similar trends were found for FY 2009-10 and FY 2010-11: the differences in changes in HbA1c between intervention and control groups were 0.04% in men and 0.05% in women (FY 2009-10), and 0.04% in men and 0.05% in women (FY 2010-11). These differences were all statistically significant.
- Baseline HbA1c increased with age in both intervention and control groups.

## a-6. Systolic Blood Pressure



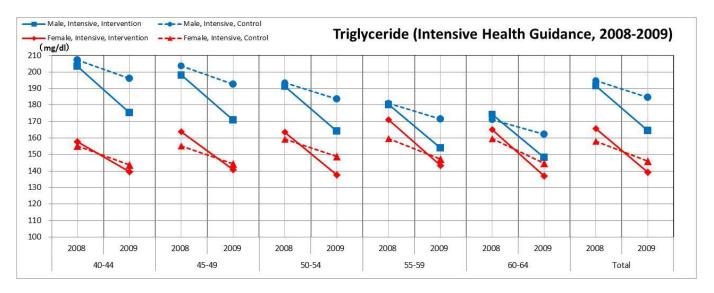
- o In the intensive HG intervention group, systolic blood pressure (BP) decreased from 130.7mmHg to 128.6mmHg (a decrease of 2.0mmHg) in men, and from 136.0mmHg to 132.6mmHg (a decrease of 3.4mmHg) in women (FY 2008-09).
- In the control group, systolic BP decreased by only 0.5mmHg in men and 1.7mmHg in women. The
  differences in decreases between intervention and control groups were statistically significant in both
  men (1.6mmHg) and women (1.7mmHg) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: differences in decreases in systolic BP between intervention and control groups were 1.0mmHg in men and 1.4mmHg in women (FY 2009-10), and 0.9mmHg in men and 1.1mmHg in women (FY 2010-11). These differences were all statistically significant.
- Baseline systolic BP increased with age in both intervention and control groups.

#### a-7. Diastolic Blood Pressure



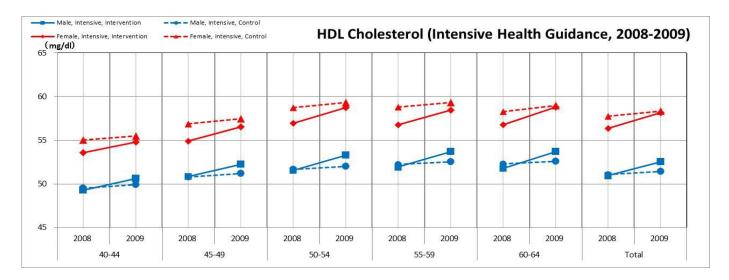
- In the intensive HG intervention group, diastolic blood pressure (BP) decreased from 82.7mmHg to 81.4mmHg (a decrease of 1.3mmHg) in men, and from 81.8mmHg to 79.7mmHg (a decrease of 2.0mmHg) in women (FY 2008-09).
- In the control group, diastolic BP decreased by only 0.2mmHg in men and 1.0mmHg in women. The
  differences in decreases between intervention and control groups were statistically significant in both
  men (1.0mmHg) and women (1.0mmHg) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in decreases in diastolic BP between intervention and control groups were 0.7mmHg in both men and women (FY 2009-10), and 0.6mmHg in both men and women (FY 2010-11). These differences were all statistically significant.

## a-8. Triglycerides



- In the intensive HG intervention group, triglycerides dropped from 191.7mg/dl to 164.5mg/dl (a decrease of 27.2mg/dl) in men, and from 165.7mg/dl to 139.3mg/dl (a decrease of 26.4mg/dl) in women (FY 2008-09).
- In the control group, triglycerides decreased by only 10.4mg/dl in men and 12.1mg/dl in women. The
  differences in decreases between intervention and control groups were statistically significant in both
  men (16.8mg/dl) and women (14.3mg/dl) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in deceases of triglycerides between intervention and control groups were 11.5mg/dl in men and 9.9mg/dl in women (FY 2009-10), and 7.7mg/dl in men and 8.3mg/dl in women (FY 2010-11). These differences were all statistically significant.

#### a-9. HDL Cholesterol

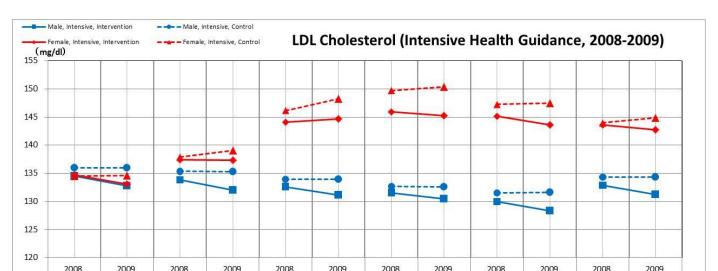


- In the intensive HG intervention group, HDL cholesterol increased from 51.0mg/dl to 52.5mg/dl (an increase of 1.6mg/dl) in men, and from 56.4mg/dl to 58.2mg/dl (an increase of 1.8mg/dl) in women (FY 2008-09).
- In the control group, HDL cholesterol increased by 0.4mg/dl in men and 0.6mg/dl in women.
   Differences in increases in HDL cholesterol between intervention and control groups were statistically significant in both men (1.2mg/dl) and women (1.3mg/dl) (FY 2008-09).
- Similar trends were observed for FY 2009-10 and FY 2010-11: the differences in changes in HDL cholesterol between intervention and control groups were 0.8mg/dl in both men and women (FY 2009-10), and 0.8mg/dl in men and 1.0mg/dl in women (FY 2010-11). These differences were all statistically significant.

## a-10. Smoking Status



- For smoking status assessment, smoking cessation rates (percentages of non-smokers in Time 2 among current smokers in Time 1) were assessed.
- The intensive HG intervention group had higher smoking cessation rates compared to the control group in both men and women in all study years.



#### a-11. LDL Cholesterol - additional indicator

45-49

40-44

In the intensive HG intervention group, LDL cholesterol decreased from 132.9mg/dl to 131.3mg/dl (a decrease of 1.6mg/dl) in men, and from 143.6mg/dl to 142.7mg/dl (a decrease of 0.9mg/dl) in women (FY 2008-09).

55-59

60-64

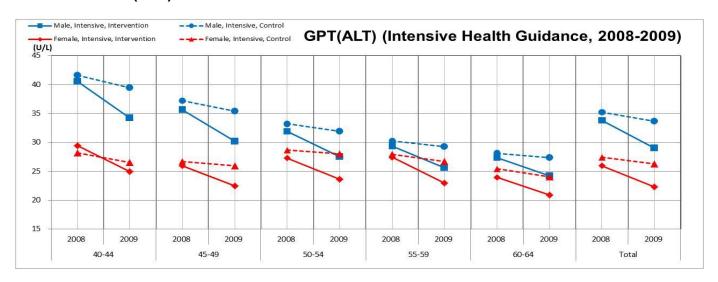
Total

- In the control group, LDL cholesterol decreased by 0.04mg/dl in men but increased by 0.9mg/dl in women. The differences in changes in HDL cholesterol between intervention and control groups were statistically significant in both men (1.5mg/dl) and women (1.7mg/dl) (FY 2008-09).
- At baseline, LDL cholesterol was elevated in women aged 50 years and older (FY 2008-09).

50-54

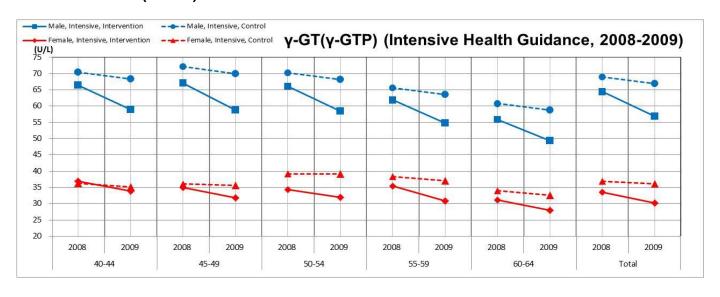
 Similar trends were observed for FY 2009-10: the differences in changes in LDL cholesterol between intervention and control groups were 1.1mg/dl in men and 1.4mg/dl in women. These differences were all statistically significant.

# a-12. ALT (GTP) - additional indicator



- o In the intensive HG intervention group, ALT decreased from 33.9U/L to 29.0U/L in men (a decrease of 4.9U/L), and from 26.0U/L to 22.3U/L in women (a decrease of 3.7U/L) (FY 2008-09).
- In the control group, ALT decreased by only 1.5U/L in men and 1.1U/L in women. The differences in decreases in ALT between intervention and control groups were statistically significant in both men (3.3U/L) and women (2.6U/L) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in decreases in ALT between intervention and control groups were 2.3U/L in men and 1.7U/L in women (FY 2009-10), and 1.6U/L in men and 2.1U/L in women (FY 2010-11). These differences were all statistically significant.

# a-13. Y-GT (Y-GTP) - additional indicator

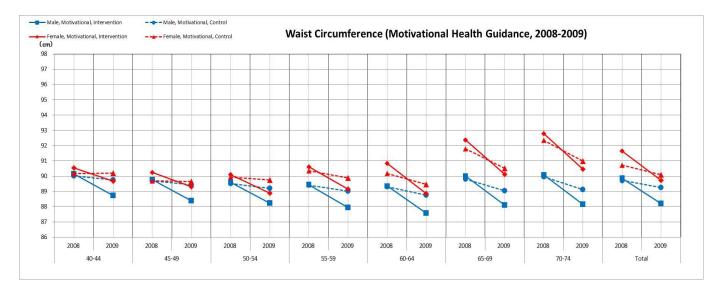


In the intensive HG intervention group, Y-GT decreased from 64.5U/L to 57.0U/L in men (a decrease of 7.6U/L), and from 33.5U/L to 30.1U/L in women (a decrease of 3.4U/L) (FY 2008-09).

- In the control group, Y-GT decreased by only 2.1U/L in men and 0.9U/L in women. The differences in decreases in ALT between intervention and control groups were statistically significant in both men (5.4U/L) and women (2.5U/L) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in decreases in Y-GT between intervention and control groups were 3.7U/L in men and 1.7U/L in women (FY 2009-10), and 2.8U/L in men and 2.0U/L in women (FY 2010-11). These differences were all statistically significant.

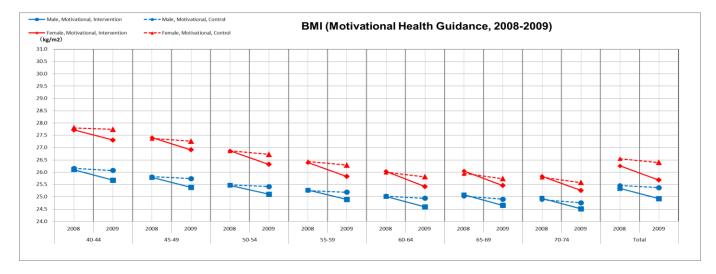
## b. Motivational HG Intervention vs Control

#### b-1. Waist Circumference



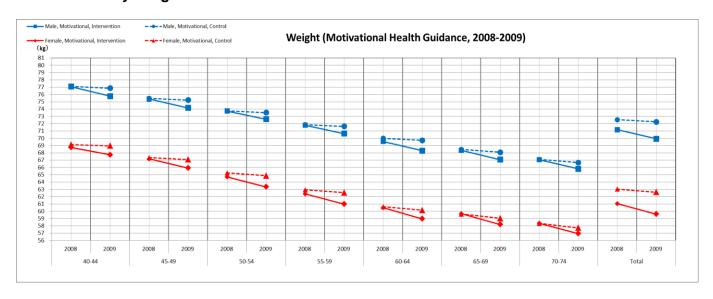
- In the motivational HG intervention group, waist circumference decreased from 89.9cm to 88.2cm (a decrease of 1.7cm) in men, and from 91.7cm to 89.7cm (a decrease of 1.9cm) in women (FY 2008-09).
- In the control group, decreases in waist circumference were 0.5cm in men and 0.6cm in women. The
  differences in decreases between intervention and control groups were statistically significant in both
  men (1.2cm) and women (1.3cm) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in decreases in waist circumference between intervention and control groups were 0.9cm in both men and women (FY 2009-10), and 0.7cm in men and 0.8cm in women (FY 2010-11).

#### b-2. BMI



- In the motivational HG intervention group, BMI decreased from 25.3kg/m² to 24.9kg/m² (a decrease of 0.4kg/m²) in men, and from 26.3kg/m² to 25.7kg/m² (a decrease of 0.6kg/m²) in women (FY 2008-09).
- o In the control group, decreases in BMI were only 0.1kg/m² in men and 0.2kg/m² in women. The differences in decreases between intervention and control groups were statistically significant in both men (0.3kg/m²) and women (0.4kg/m²) (FY 2008-09).
- Similar trends were observed for FY 2009-10 and FY 2010-11: the differences in decreases in BMI between intervention and control groups were 0.2kg/m² in men and 0.3kg/m² in women (FY 2009-10), and 0.2kg/m² in both men and women (FY 2010-11). These differences were all statistically significant.

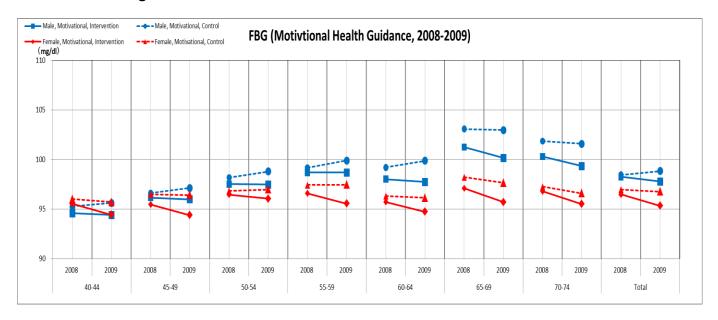
## b-3. Body Weight



 In the motivational HG intervention group, men lost 1.2kg (1.7% reduction of baseline weight) and women lost 1.4kg (2.3% reduction of baseline weight) within a year (FY 2008-09).

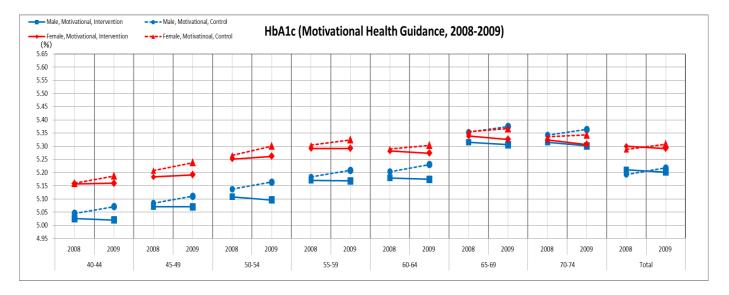
- In the control group, decreases in weight were only 0.3kg in men and 0.4kg in women. The
  differences in decreases between intervention and control groups were statistically significant in both
  men (1.0kg) and women (1.0kg) (FY 2008-09).
- Similar trends were observed for FY 2009-10 and FY 2010-11: the differences in weight reductions between intervention and control groups were 0.7kg in both men and women (FY 2009-10), and 0.6kg in both men and women (FY 2010-11). These differences were all statistically significant.

## b-4. Fasting Glucose



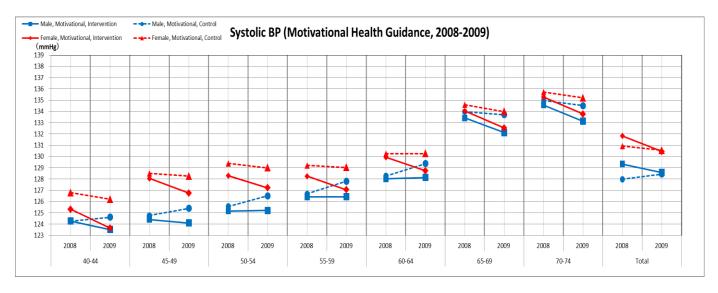
- In the motivational HG intervention group, fasting glucose decreased from 98.3mg/dl to 97.8mg/dl (a decrease of 0.5mg/dl) in men, and from 96.5mg/dl to 95.3mg/dl (a decrease of 1.1mg/dl) in women (FY 2008-09).
- In the control group, fasting glucose increased by 0.4mg/dl in men, but decreased by 0.2mg/dl in women. The differences in changes in fasting glucose between intervention and control groups were statistically significant in both men (0.9mg/dl) and women (1.0mg/dl) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in changes in fasting glucose between intervention and control groups were 0.7mg/dl in men and 0.6mg/dl in women (FY 2009-10), and 0.6mg/dl in men and 0.7mg/dl in women (FY 2010-11). These differences were all statistically significant.

# b-5. HbA1C (JDS unit)



- In the motivational HG intervention group, HbA1c decreased from 5.21% to 5.20% (a decrease of 0.01%) in men, and from 5.30% to 5.29% (a decrease of 0.01%) in women (FY 2008-09).
- In the control group, HbA1c increased by 0.02% in both men and women. The differences in changes in HbA1c between intervention and control groups were statistically significant in both men (0.03%) and women (0.03%) (FY 2008-09).
- Similar trends were observed for FY 2009-10 and FY 2010-11: the differences in changes in HbA1c between intervention and control groups were 0.02% in both men and women (FY 2009-10), and 0.02% in men and 0.03% in women (FY 2010-11). These differences were all statistically significant.

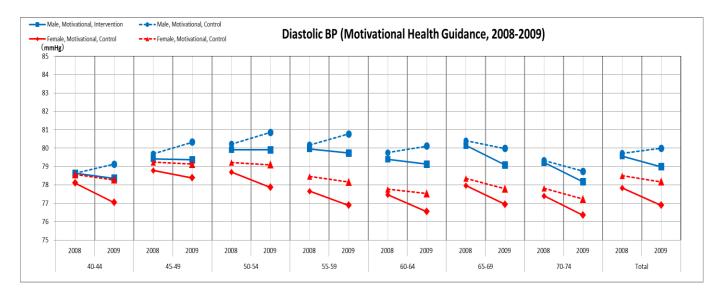
# b-6. Systolic Blood Pressure



In the motivational HG intervention group, systolic blood pressure (BP) decreased from 129.3mmHg to 128.6mmHg (a decrease of 0.8mmHg) in men, and from 131.8mmHg to 130.4mmHg (a decrease of 1.4mmHg) in women (FY 2008-09).

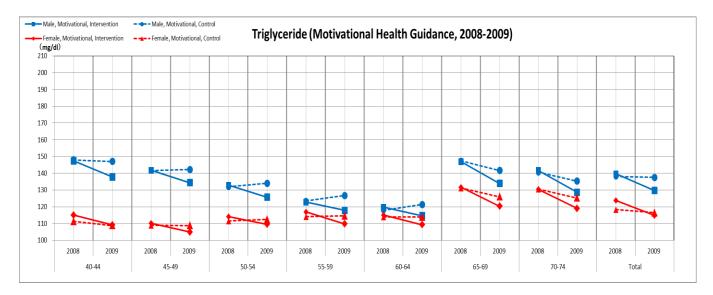
- In the control group, systolic BP decreased by 0.5mmHg in men and 0.4mmHg in women. The
  differences in decreases between intervention and control groups were statistically significant in both
  men (1.2mmHg) and women (1.0mmHg) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in decreases in systolic BP between intervention and control groups were 0.9mmHg in men and 0.7mmHg in women (FY 2009-10), and 0.7mmHg in men and 0.8mmHg in women (FY 2010-11). These differences were all statistically significant.

#### b-7. Diastolic Blood Pressure



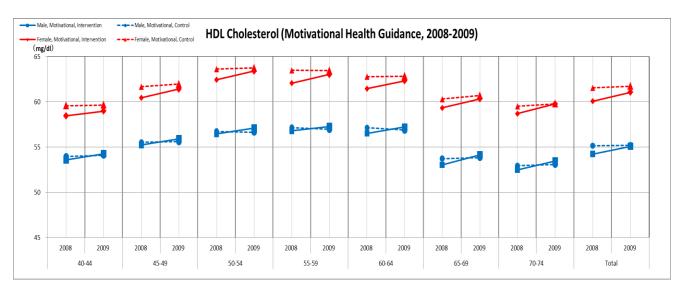
- In the motivational HG intervention group, diastolic blood pressure (BP) decreased from 79.6mmHg to 79.0mmHg (a decrease of 0.6mmHg) in men, and from 77.8mmHg to 76.9mmHg (a decrease of 0.9mmHg) in women (FY 2008-09).
- In the control group, diastolic BP increased by 0.3mmHg in men, but decreased by 0.3mmHg in women. The differences in decreases between intervention and control groups were statistically significant in both men (0.8mmHg) and women (0.6mmHg) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in decreases in diastolic BP between intervention and control groups were 0.6mmHg in men and 0.5mmHg in women (FY 2009-10), and 0.4mmHg in both men and women (FY 2010-11). These differences were all statistically significant.

# b-8. Triglycerides



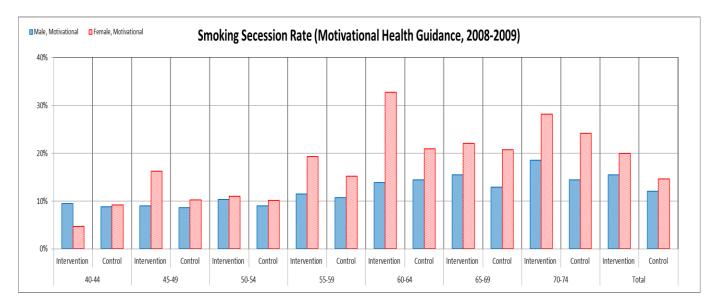
- In the motivational HG intervention group, triglycerides dropped from 139.6mg/dl to 129.8mg/dl (a decrease of 9.9mg/dl) in men, and from 123.8mg/dl to 114.9mg/dl (a decrease of 8.9mg/dl) in women (FY 2008-09).
- In the control group, triglycerides decreased by only 0.6mg/dl in men and 1.8mg/dl in women. The
  differences in decreases between intervention and control groups were statistically significant in both
  men (9.3mg/dl) and women (7.0mg/dl) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in deceases of triglycerides between intervention and control groups were 7.2mg/dl in men and 5.0mg/dl in women (FY 2009-10), and 5.5mg/dl in men and 3.9mg/dl in women (FY 2010-11). These differences were all statistically significant.

# b-9. HDL Cholesterol



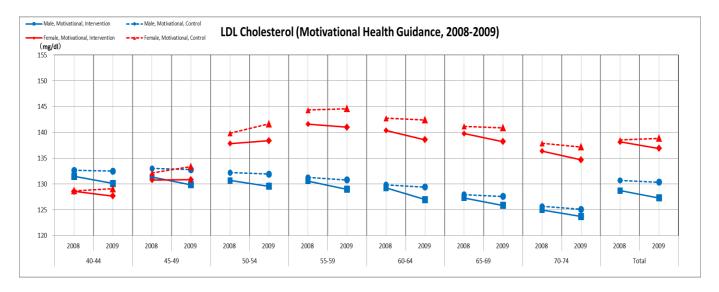
- In the motivational HG intervention group, HDL cholesterol increased from 54.3mg/dl to 55.1mg/dl (an increase of 0.8mg/dl) in men, and from 60.1mg/dl to 61.1mg/dl (an increase of 1.0mg/dl) in women (FY 2008-09).
- In the control group, HDL cholesterol increased by only 0.03mg/dl in men and 0.2mg/dl in women.
   The differences in increases in HDL cholesterol between intervention and control groups were statistically significant in both men (0.8mg/dl) and women (0.8mg/dl) (FY 2008-09).
- Similar trends were observed for FY 2009-10 and FY 2010-11: the differences in changes in HDL cholesterol between intervention and control groups were 0.7mg/dl in men and 0.4mg/dl in women (FY 2009-10), and 0.7mg/dl in men and 0.6mg/dl in women (FY 2010-11). These differences were all statistically significant.

## b-10. Smoking Status



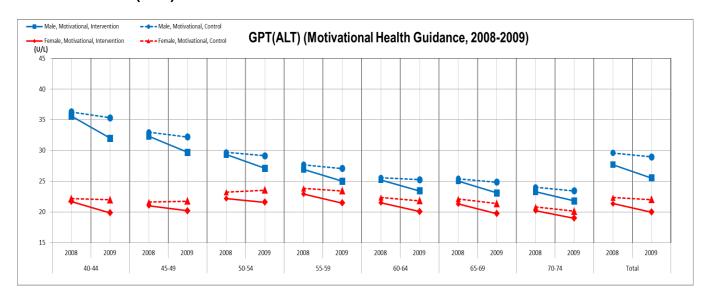
- For smoking status assessment, smoking cessation rates (i.e. percentages of non-smokers in Time 2 among current smokers in Time 1) were assessed. The motivational HG intervention group generally had higher smoking cessation rates compared to the control group in both men and women in all study years.
- In men in their 40s and 50s, the differences in smoking cessation rates between intervention and control groups tended to be small.
- Similar trends were observed for FY 2009-10 and FY 2010-11.

### b-11. LDL Cholesterol - additional indicator



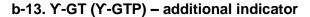
- In the motivational HG intervention group, LDL cholesterol decreased from 128.8mg/dl to 127.3mg/dl (a decrease of 1.4mg/dl) in men, and from 138.2mg/dl to 136.9mg/dl (a decrease of 1.3mg/dl) in women. (FY 2008-09)
- In the control group, LDL cholesterol decreased by 0.3mg/dl in men but increased by 0.32mg/dl in women. The differences of changes in HDL cholesterol between intervention and control groups were statistically significant in both men (1.1mg/dl) and women (1.6mg/dl). (FY 2008-09)
- Similar trends were observed for FY 2009-10: the differences of changes in LDL cholesterol between intervention and control groups were 1.1mg/dl in men and 1.2mg/dl in women. These differences were all statistically significant.

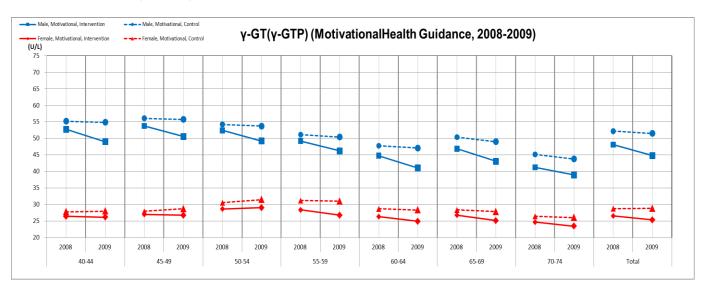
## b-12. ALT (GTP) - additional indicator



o In the motivational HG intervention group, ALT decreased from 27.7U/L to 25.5U/L in men (a decrease of 2.2U/L), and from 21.4U/L to 20.0U/L in women (a decrease of 1.4U/L) (FY 2008-09).

- In the control group, ALT decreased by only 0.7U/L in men and 0.3U/L in women. The differences in decreases in ALT between intervention and control groups were statistically significant in both men (1.5U/L) and women (1.1U/L) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in decreases in ALT between intervention and control groups were 1.2U/L in men and 1.1U/L in women (FY 2009-10), and 0.9U/L in men and 0.7U/L in women (FY 2010-11). These differences were all statistically significant.





- o In the motivational HG intervention group, Y-GT decreased from 48.1U/L to 44.8U/L in men (a decrease of 3.3U/L), and from 26.5U/L to 25.3U/L in women (a decrease of 1.2U/L) (FY 2008-09).
- In the control group, Y-GT decreased by 0.7U/L in men but increased by 0.04U/L in women. The
  differences in changes in ALT between intervention and control groups were statistically significant
  in both men (2.6U/L) and women (1.3U/L) (FY 2008-09).
- Similar results were found for FY 2009-10 and FY 2010-11: the differences in decreases in Y-GT between intervention and control groups were 2.0U/L in men and 1.2U/L in women (FY 2009-10), and 1.5U/L in men and 0.8U/L in women (FY 2010-11). These differences were all statistically significant.

# (4) Discussion – Changes in Clinical and Behavioral Indicators

This study examined the effects of health guidance on clinical and behavioral indicators using the SHCSHG health examination data from FY 2008 to FY 2011. Study subjects were adults 40 to 74 years of age who became eligible to receive intensive or motivational HG because of elevated metabolic risk factors. Health examination data from baseline (Time 1) and one year later (Time 2) were compared for the intervention group (those who completed HG) and the control group (those who did not participate in HG or dropped out from HG), stratified by type of HG, FY, gender, and age group.

Overall and for each stratum, the intervention groups achieved greater reductions in waist circumference, BMI, and body weight, and also had greater improvements in blood glucose, blood pressure, and lipid compared to their respective control groups. The magnitudes of improvements however, have become incrementally smaller in each year since 2008. One could argue that this was because highly motivated individuals participated in HG in the initial year, and the proportions of less motivated and/or hard-to-improve individuals became higher in later years. Nonetheless, continuous training of health care professionals to improve health guidance technique is warranted.

In terms of the HG's effects on individual obesity-related indicators, waist circumference decreased about 2 to 3cm in the intensive HG group, and about 1 to 2cm in the motivational HG group. For body weight, men in the intensive HG group achieved 2.5% reduction of baseline weight, and women in the same group achieved 3.3% reduction of baseline weigh, both in one year. These results were close to, or exceeding, the body weight reduction goal of 3.0% for the improvement of metabolic syndrome [1]. Among the motivational HG group, weight reduction was 1.7% in men and 2.3% in women. The magnitudes of weight reduction in the motivational HG group were smaller compared to the intensive HG group, but still significantly larger compared to the control group.

In terms of the HG intervention's effects on blood glucose, blood pressure, and lipid indicators, the following observations are worth discussing further.

First, in the intensive HG group, there were major cardiovascular risk reductions, including decreases of triglycerides by 25 to 30mg/dl, and reductions of systolic blood pressure by 2 to 4mmHg. Healthy Japan 21 set a goal to reduce systolic blood pressure by 4mmHg for the entire Japanese population [2]. This study provided evidence that the systolic blood pressure goal can be achieved by lifestyle modification alone.

Second, fasting glucose and HbA1c decreased in both intensive and motivational HG groups, but increased in their respective control groups. It appears that providing health examination without intervention exacerbated glycemic control in adults who had or were at risk for metabolic syndrome. The motivational HG was able to stop worsening glycemic control, and the intensive HG actually improved glycemic control. It seems that the modification of lifestyle and reduction of body weight attributed to the HG intervention improved insulin resistance, and also contributed to the prevention of type 2 diabetes.

Lastly, among women in their 50s, LDL cholesterol levels improved among the intervention groups, but worsened in their respective control groups. Menopausal women tend to experience a surge in HDL cholesterol due to hormonal changes, and so they are more likely to be on medication to control dyslipidemia [3]. The result of this study suggests that modification of lifestyle can also improve LDL cholesterol in menopausal women.

[1] A Muratomo, M Matushita, A Kato, N Yamamoto, G Koike, N Nakamura, T Numata, A Tamakoshi, K Tsushita. Three percent weight reduction is the minimum requirement to improve health hazards in obese and overweight people in Japan. Doi.Org/10.1016/j.orcp.2013.10.003

[2] Japanese Ministry of Health, Labour and Welfare. Healthy Japan 21 Resources for the Second Campaign (厚生労働省 「健康日本 21(第二次)の推進に関する参考資料」) <a href="http://www.mhlw.go.jp/bunya/kenkou/dl/kenkounippon21\_02.pdf">http://www.mhlw.go.jp/bunya/kenkou/dl/kenkounippon21\_02.pdf</a>

[3] Comprehensive Survey of Living Conditions (国民生活基礎調査)

# 2-2. Changes in Health Guidance Eligibility

Another series of analyses was conducted to examine how adults who had completed HG intervention for the first time fared in the health examination in the following year, by tracking shifts in health guidance eligibility. Health examination data for FY 2008 through 2011 were used. All analyses were stratified by type of HG, FY, gender, and age group.

# (1) Study Subjects

**Inclusion criteria:** Adults from 40 to 74 years of age who 1) had a health examination in Time 1 (FY 2008, 2009 or 2010), 2) became eligible to receive HG because of elevated metabolic risk factors, 3) completed HG for the first time and received the final outcome evaluation at the end of the 6<sup>th</sup> month, and 4) had a health examination again in the following year (Time 2).

The numbers of study subjects are summarized in **Table 7**.

Table 7. Number of study subjects

Intensive health guidance						
Time 1 to Time 2	Men	Women	Total			
FY 2008 – FY 2009	70,610	9,420	80,030			
FY 2009 – FY 2010	101,595	10,683	112,278			
FY 2010 – FY 2011	134,217	10,333	144,550			
Motivational health guidance	9	•	•			
Time 1 to Time 2	Men	Women	Total			
FY 2008 – FY 2009	82,765	48,125	130,890			
FY 2009 – FY 2010	105,035	52,942	157,977			
FY 2010 – FY 2011	122,509	47,134	169,643			

# (2) Statistical Analysis

Analyses focused on changes in eligibility for health guidance from Time 1 to Time 2 among adults who completed HG interventions for the first time in Time 1. All analyses were stratified by type of HG, FY, gender, and age group.

For instance, among adults who completed the intensive HG for the first time, the following year's health examination can classify them into 4 categories: 1) No health guidance required (denoted as "Information only"), because several clinical and behavioral indicators have improved and they are no longer considered to be at high risk, 2) Motivational HG, because improvements in some indicators reduced overall metabolic risk factors, 3) Intensive HG, because no or little metabolic risk reduction was achieved, and 4) Ineligible for health guidance because pharmacological therapy started (denoted as "Drug therapy").

## (Reference) Participant classification for health guidance eligibility (reprinted)

Waist circumference/ BMI	Additional risks (Glucose, Lipid, BP)	Smoking	Age 40-64	Age 65-74
≥85cm (men) ≥90cm (women)	2 or more risks	Yes or No	Intensive HG	
		Yes	Motiva	Motivational HG
	1 risk	No	Motivational HG	
<85cm (men) <90cm (women)	3 risks	Yes or No	Intensive HG	
but BMI≥25kg/m²	/ll≥25kg/m² 2 risks	Yes	intensive ng	Motivational HG
		No	Motivational	
	1 risk	Yes or No	HG	

The definitions of blood glucose, lipid, and blood pressure risks are as follows:

**Blood glucose**: Fasting glucose≥100mg/dl or HbA1c≥5.6% by the NGSP unit. If both fasting blood glucose and HbA1c are measured, use the fasting glucose value. Note that HbA1c tests done on or before March 31 2013 are reported in the JDS unit (Japanese standard). HbA1c tests done after March 31 2013 are reported in the NGSP unit (International standard). (In this report, all HbA1c values are reported in the JDS unit, and the cutoff value for blood glucose risk is HbA1c≥5.2%.)

Lipid: Triglycerides≥150mg/dl or HDL<40mg/dl

Blood Pressure: Systolic≥130mmHg or Diastolic≥85mmHg

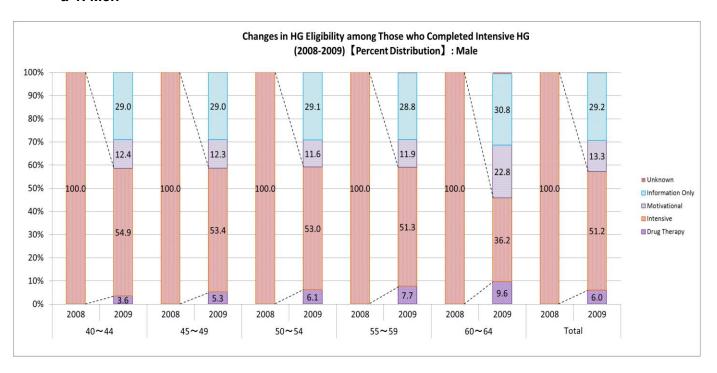
**Note**: Individuals who are already taking medication for diabetes, dyslipidemia, or hypertension are not eligible for health guidance. Only motivational health guidance is available for those aged 65 to 74 years.

# (3) Results (Graphs are for the FY 2008-09 data only)

**Note:** In the result section, all graphs are for the FY 2008-09 data. Other years are described without graphs. All numbers are rounded.

# a. Participants Who Completed Intensive HG

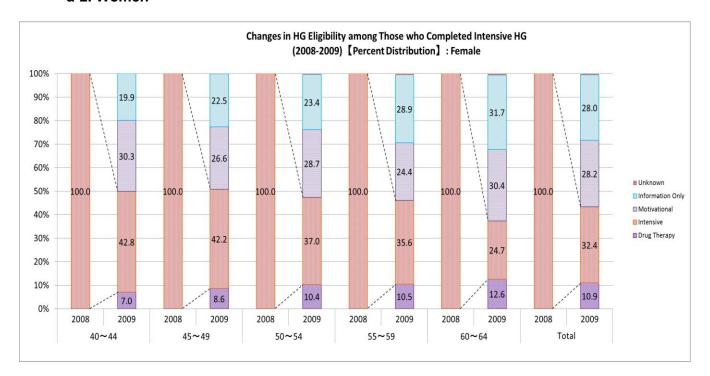
## a-1. Men



The following sections describe men who completed the intensive HG for the first time.

- From FY 2008 to 2009, 29.2% moved to the information only category, 13.3% moved to the motivational HG category, 51.2% remained in the Intensive HG category, and 6.0% shifted to the drug therapy category.
- From FY 2009 to 2010, 25.6% moved to the information only category, 12.6% moved to the motivational HG category, 55.2% remained in the intensive HG category, and 6.5% shifted to the drug therapy category.
- From FY 2010 to 2011, 22.7% moved to the information only category, 13.2% moved to the motivational HG category, 57.5% remained in the intensive HG category, and 6.6% shifted to the drug therapy category.

## a-2. Women

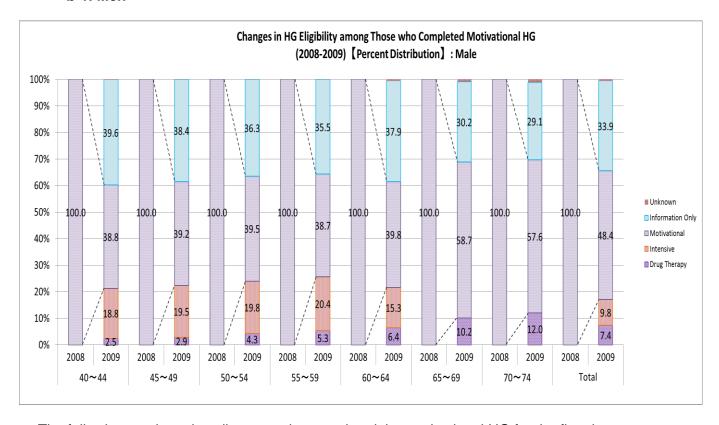


The following sections describe women who completed the intensive HG for the first time.

- From FY 2008 to 2009, 28.0% moved to the information only category, 28.2% moved to the motivational HG category, 32.4% remained in the intensive HG category, and 10.9% shifted to the drug therapy category.
- From FY 2009 to 2010, 23.1% moved to the information only category, 25.7% moved to the motivational HG category, 39.0% remained in the intensive HG category, and 11.9% shifted to the drug therapy category.
- From FY 2010 to 2011, 19.7% moved to the information only category, 26.0% moved to the motivational HG category, 43.4% remained in the intensive HG category, and 10.7% shifted to the drug therapy category.

# b. Participants Who Completed Motivational HG

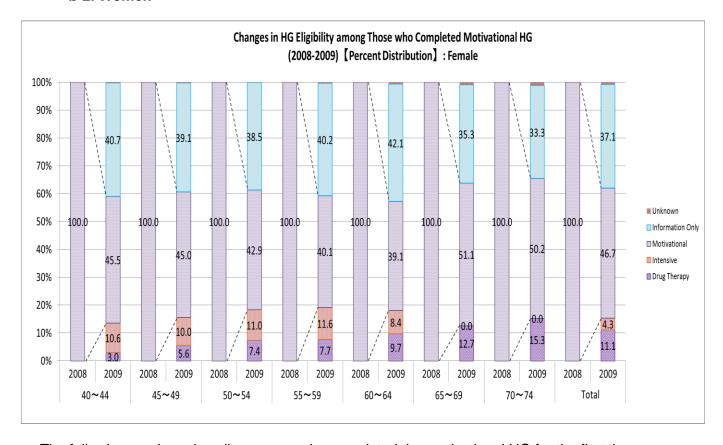
## b-1. Men



The following sections describe men who completed the motivational HG for the first time.

- From FY 2008 to 2009, 33.9% moved to the information only category, 48.4% remained in the motivational HG category, 9.8% moved to the intensive HG category, and 7.4% shifted to the drug therapy category.
- From FY 2009 to 2010, 31.9% moved to the information only category, 48.7% remained in the motivational HG category, 12.0% moved to the intensive HG category, and 7.2% shifted to the drug therapy category.
- From FY 2010 to 2011, 31.5% moved to the information only category, 46.9% remained in the motivational HG category, 15.3% moved to the intensive HG category, and 6.1% shifted to the drug therapy category.

b-2. Women



The following sections describe women who completed the motivational HG for the first time.

- From FY 2008 to 2009, 37.1% moved to the information only category, 46.7% remained in the motivational HG category, 4.3% moved to the intensive HG category, and 11.1% shifted to the drug therapy category.
- From FY 2009 to 2010, 33.4% moved to the information only category, 49.4% remained in the motivational HG category, 5.6% moved to the intensive HG category, and 11.2% shifted to the drug therapy category.
- From FY 2010 to 2011, 32.9% moved to the information only category, 50.1% remained in the motivational HG category, 7.3% moved to the intensive HG category, and 9.5% shifted to the drug therapy category.

## (4) Discussion - Changes in Health Guidance Eligibility

The analyses of the shifts in health guidance eligibility before and after intervention revealed that approximately 40% of men and 50% of women who had completed the intensive HG improved their metabolic risk factors in the following year. Furthermore, nearly 20% of those who had completed the intensive HG made large enough improvements to move up to the information only category. However, about 6% of men and 10% of women who had completed the intensive HG began pharmacological therapy before the following year's health examination.

Among those who had completed the motivational HG, approximately 30% of men and women saw improvements and moved up to the information only category. However, around 25% of men younger than 65 years of age worsened their metabolic risk factors and moved down to the intensive HG category.

In general, adults who completed the intensive HG tended to move up to a lighter health guidance category, indicating that intensive HG is an effective approach to improve metabolic risk factors. The magnitudes of improvements tended to be larger in women than in men, most likely because women achieved greater reductions in body weight than men. The fact that women's waist circumference cut-off (90cm) is 5cm larger than men's cut-off (85cm) might have played a role in their greater body weight reductions. In terms of age differences, the positive effects of the intensive HG were seen uniformly in all age groups.

With regard to the motivational HG, while some individuals achieved improvements in their metabolic risk factors, a similar proportion of others got worse, suggesting a need to improve the motivational HG curriculum.

For both types of HG, the magnitudes of improvements tended to become incrementally smaller over the years, suggesting that highly motivated individuals might have participated in HG as soon as they became eligible and improved quickly, while less motivated and/or hard-to-improve individuals gradually became over-represented as years passed by. Continuous training of health care professionals to improve HG technique is warranted.

Finally, data for individuals who did not participate or dropped out from HG were not analyzed. In order to show the true effects of HG, comparisons between intervention and control groups are needed. It is important to note that not all the metabolic risk improvements seen in this study were attributed to the HG intervention, because a small proportion of individuals in the control groups were believed to have similar improvements without intervention.

## 2-3. Changes in Metabolic Syndrome Status

The last series of analyses evaluated the extent of changes in metabolic risk factors in adults who had completed HG intervention for the first time, using the existing metabolic syndrome diagnostic criteria. Health examination data for FY 2008 through 2011 were used. All analyses were stratified by type of HG, FY, gender, and age group.

## (1) Study Subjects

**Inclusion criteria:** Adults from 40 to 74 years of age who 1) had a health examination in Time 1 (FY 2008, 2009 or 2010), 2) became eligible to receive HG because of elevated metabolic risk factors, 3) completed HG for the first time and received the final outcome evaluation at the end of the 6<sup>th</sup> month, and 4) had a health examination again in the following year (Time 2). The numbers of study subjects are summarized in **Table 8**.

Table 8. Number of study subjects

Intensive health guidance			
Time 1 to Time 2	Men	Women	Total
FY 2008 – FY 2009	70,771	9,469	80,240
FY 2009 – FY 2010	101,772	10,708	112,480
FY 2010 – FY 2011	134,434	10,354	144,788
Motivational health guidance	•		
Time 1 to Time 2	Men	Women	Total
FY 2008 – FY 2009	83,082	48,275	131,357
FY 2009 – FY 2010	105,255	53,075	158,330
FY 2010 – FY 2011	122,832	47,218	170,050

#### (2) Statistical Analysis

Analyses focused on changes in group designations based on metabolic syndrome diagnostic criteria from Time 1 to Time 2 among adults who completed an HG intervention for the first time in Time 1. All analyses were stratified by type of HG, FY, gender, and age group.

Evaluation of health examination results can classify individuals into three groups: 1) the metabolic syndrome (**Met S**) group, 2) the pre-metabolic syndrome (**Pre-Met S**) group, and 3) the no metabolic syndrome (**no Met S**) group.

The metabolic syndrome diagnostic criteria used in this study were the criteria based on the joint consensus statement published in April 2005 by eight major Japanese medical organizations, including the Japanese Society of Internal Medicine. The details of the diagnostic criteria are shown in **Table 9**.

Table 9. Japanese metabolic syndrome diagnostic criteria

Waist circumference	Additional risks (Glucose, Lipid, BP)	Diagnosis
≥85cm (men)	2 or more risks	Metabolic syndrome
≥90cm (women)	1 risk	Pre-Metabolic syndrome

The definitions of blood glucose, lipid, and blood pressure risks are as follows:

Blood glucose: Fasting glucose≥110mg/dl

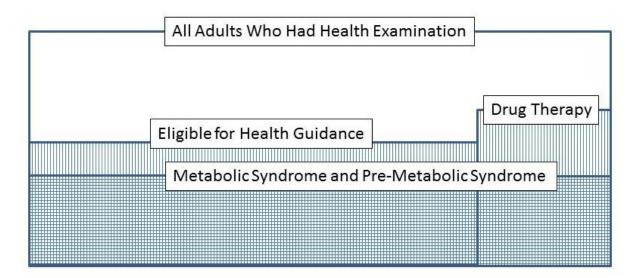
Lipid: Triglycerides≥150mg/dl or HDL<40mg/dl

Blood Pressure: Systolic≥130mmHg or Diastolic≥85mmHg

**Note**: Individuals who are already taking medication for diabetes, dyslipidemia, or hypertension are also considered at risk.

There are notable differences between the Japanese metabolic syndrome diagnostic criteria and the algorithm used to determine HG eligibility (also see the visualization chart below):

- The HG eligibility algorithm excludes those who are on pharmacological therapy
- The HG eligibility algorithm includes the following as metabolic risk factors: BMI≥25kg/m²
  - Fasting glucose 100-109mg/dl
- The HG eligibility algorithm used smoking status and age for determining HG type



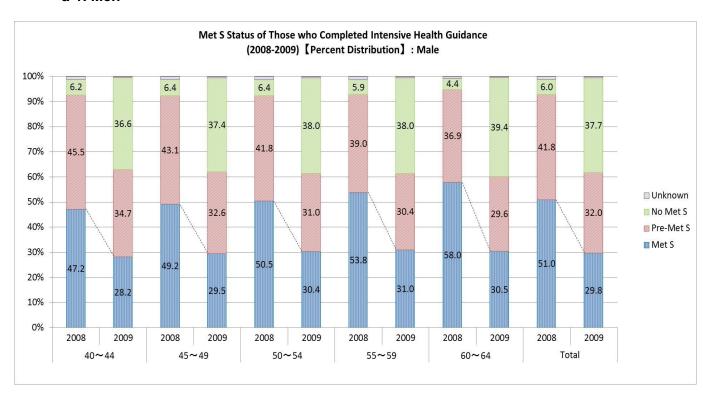
Also note that the Japanese metabolic syndrome diagnostic criteria are different from the WHO criteria or the NCEP-ATPIII criteria.

## (3) Results (Graphs are for the FY 2008-09 data only)

**Note:** In the results section, all graphs are for the FY 2008-09 data. Other years are described without graphs. All numbers are rounded.

## a. Participants Who Completed Intensive HG

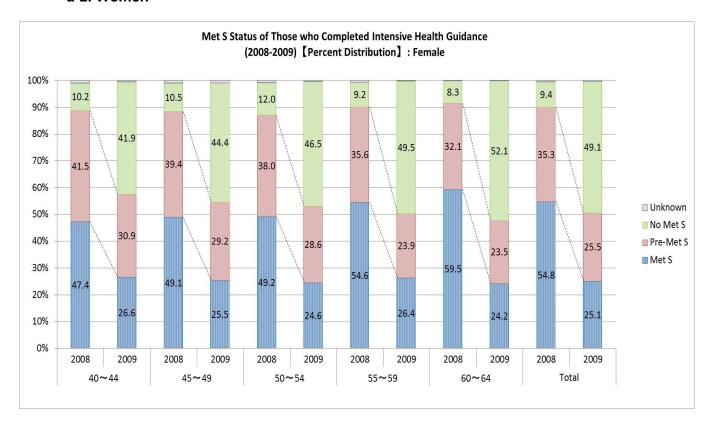
#### a-1. Men



The following sections describe men who completed the intensive HG for the first time.

- From FY 2008 to 2009, the Met S group decreased from 51.0% to 29.8%, and the pre-Met S group also decreased, from 41.8% to 32.0%. The no Met S group increased from 6.0% to 37.7%.
- o From FY 2009 to 2010, the Met S group decreased from 49.8% to 33.1%, and the pre-Met S group also decreased, from 43.7% to 32.8%. The no Met S group increased from 6.3% to 34.0%.
- From FY 2010 to 2011, the Met S group decreased from 49.0% to 34.7%, and the pre-Met S group also decreased, from 44.0% to 34.4%. The no Met S group increased from 6.8% to 30.7%

#### a-2. Women



The following sections describe women who completed the intensive HG for the first time.

- o From FY 2008 to 2009, the Met S group decreased from 54.8% to 25.1%, and the pre-Met S group also decreased, from 35.3% to 25.5%. The no Met S group increased from 9.4% to 49.1%.
- From FY 2009 to 2010, the Met S group decreased from 52.9% to 29.1%, and the pre-Met S group also decreased, from 35.7% to 27.2%. The no Met S group increased from 11.3% to 43.7%.
- From FY 2010 to 2011, the Met S group decreased from 50.9% to 30.6%, and the pre-Met S group also decreased, from 37.0% to 29.4%. The no Met S group increased from 11.9% to 39.8%.

## b. Participants Who Completed Motivational HG

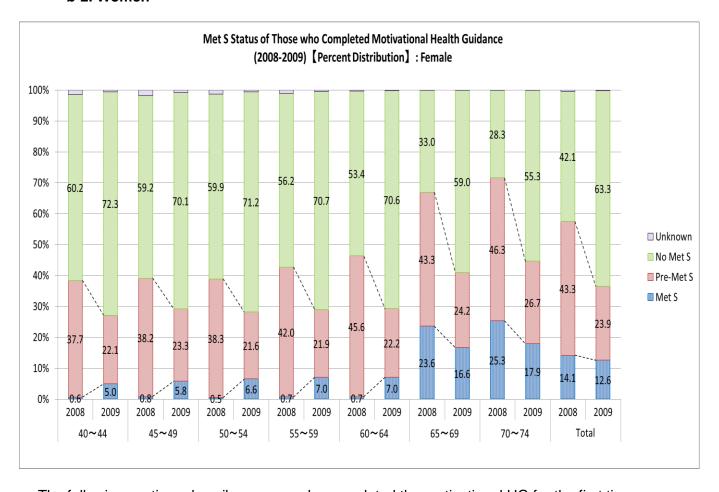
#### b-1. Men



The following sections describe men who completed the motivational HG for the first time.

- From FY 2008 to 2009, the Met S group increased slightly from 18.5% to 19.1%, but the pre-Met S
  decreased from 60.3% to 35.5%. The no Met S group increased from 20.1% to 45.1%.
- o From FY 2009 to 2010, the Met S group increased from 14.9% to 19.1%, but the pre-Met S group decreased from 62.0% to 36.4%. The no Met S group increased from 23.1% to 44.3%.
- From FY 2010 to 2011, the Met S group increased from 9.2% to 16.8%, but the pre-Met S group decreased from 63.3% to 38.5%. The no Met S group increased from 27.2% to 44.4%.

b-2. Women



The following sections describe women who completed the motivational HG for the first time.

- o From FY 2008 to 2009, the Met S group decreased from 14.1% to 12.6%, and the pre-Met S group also decreased, from 43.3% to 23.9%. The no Met S group increased from 42.1% to 63.3%.
- From FY 2009 to 2010, the Met S group increased slightly from 11.6% to 13.0%, but the pre-Met S group decreased from 41.1% to 24.5%. The no Met S group increased from 47.3% to 62.4%.
- From FY 2010 to 2011, the Met S group increased from 8.3% to 11.0%, but the pre-Met S group decreased from 39.5% to 25.1%. The no Met S group increased from 52.0% to 63.6%.

## (4) Discussion – Changes in Metabolic Syndrome Status

Among individuals who completed the intensive HG for the first time, the proportions of the Met S groups decreased by 14% to 21% in men and by 20% to 30% in women. The proportions of pre-Met S groups also decreased, by 10% to 11% in men and by 8% to 10% in women. As a result, the no Met S groups increased by 24% to 32% in men and 28% to 40% in women. It is remarkable to observe that 20% to 30% of men and 30% to 40% of women no longer had metabolic syndrome or pre-metabolic syndrome after the completion of the intensive HG.

Among those who had completed the motivational HG, the proportions of the Met S groups increased by 1% to 8% in men, and increased or decreased by 2% to 3% in women. The proportions of pre-Met S groups decreased by 25% in men and by 14% to 19% in women. Consequently, no Met S groups increased by 17% to 25% in men and 12% to 21% in women. In terms of age differences, among men and women 40 to 64 years of age, the proportions of Met S groups were nearly 0 at baseline but increased to around 10% a year later. This indicates that metabolic risk factors worsened even after the completion of the motivational HG intervention.

However, decreases of the proportions of Met S groups were seen among men and women 65 to 74 years of age. The HG eligibility algorithm classifies all adults aged 65 to 74 years into the motivational HG group even though their metabolic risk factors may be highly elevated. Further research is needed to closely monitor the changes of metabolic syndrome status before and after intervention by incorporating the severity of baseline metabolic risk factors for this oldest age group. Nevertheless, it is reasonable to say that the motivational HG was effective, evidenced by the reductions of the proportions of pre-Met S by 25% in men and by 14% to 19% in women. It is also important to point out that 20% to 30% of men and 10% to 20% of women who had pre-Met S at baseline improved and no longer had the condition after the motivational HG intervention.

On a final note, data for individuals who did not participate or dropped out from HG were not analyzed in this study. In order to show the true effects of HG, comparisons between intervention and control groups are needed. It is important to note that not all the metabolic risk improvements seen in this study were attributed to the HG intervention, because a small proportion of individuals in the control groups were believed to have similar improvements without intervention.

## Part 3. The Second Interim Report (November 2014)

This study used the available health examination/health guidance data and the health insurance claims data to obtain per capita outpatient health care costs for hypertension, dyslipidemia, and diabetes during the one-year period following the health examination. These figures were compared between intervention and control groups. All analyses were stratified by type of HG, age group, and gender. The Wilcoxon rank sum test was used to test statistical significance (p <0.05).

#### 3-1. Overall Methods

### (1) Data

Currently the National Insurance Claims Database (the NDB hereafter) contains all enrollees' health examination and health guidance data under the SHCSHG (SHCSHG data hereafter) for FY 2008 to 2012, and health insurance claims data (HIC data hereafter) for FY 2009 to 2012.

In this study, SHCSHG and HIC data were linked, and SHCSHG data from FY2008 to FY 2011, and HIC data from FY2009 to FY 2012 were used for analysis. Data matching rates were monitored, and only the data from the insurers who had a data matching rate of 80% or higher in all years from FY2009 to FY2011 were included. The insurers who met the data matching standards were 365 in total, including 321 insurers of the National Health Insurance, 2 insurers of the Health Insurance Societies, and 42 insurers of the Mutual Aid Associations. The age distribution of eligible and total enrollees for FY 2011 is presented in **Table 10**.

Table 10. Age distribution of eligible and total enrollees (FY 2011)

	40-44	45-49	50-54	55-59	60-64	65-69	70-74	Total
Eligible enrollees	29,728	25,125	26,966	32,891	35,774	35,750	35,170	221,404
(age distribution)	(13.4%)	(11.3%)	(12.2%)	(14.9%)	(16.2%)	(16.1%)	(15.9%)	(100%)
Total enrollees, in	9,338	7,903	7,536	8,139	10,348	7,567	6,787	57,618
1000s	(16.2%)	(13.7%)	(13.1%)	(14.1%)	(18.0%)	(13.1%)	(11.8%)	(100%)
(age distribution)	,	,	,	,	,	,	,	,

(Source: The Ministry of Health, Labour and Welfare "Basic Information of Health Insurance" December, 2013)

When data were entered in the NDB, personal identifiers were stripped from both SHCSHG and HIC data, but unique information was kept to permit matching. Due to some technical issues in the process, the overall data matching rate is currently only around 30% (though the rates vary widely by insurers). An improvement project is under way to address the problem.

Based on the Survey on Medical Care Benefit Expenditures in FY2011, it is estimated that approximately 85% of all health insurance enrollees would use any type of health care in a given year. Therefore, the eligibility criteria were set to include only data with a matching rate of 80% or higher. Enrollees who had SHCSHG data, but without matching HIC data, were regarded as non-health care users.

## (2) Definitions of Intervention and Control Groups

Intervention and control subjects were selected based on the following criteria.

**Intervention**: Adults 40 to 74 years of age who became eligible for health guidance (HG) due to elevated metabolic risks, participated in HG for the first time in Time 1 (FY 2008, 2009 or 2010), remained in the program, and completed the final evaluation at the end of the 6<sup>th</sup> month.

**Control**: Adults 40 to 74 years of age who became eligible for health guidance (HG) due to elevated metabolic risks, but never participated in HG, including Time 1 and prior to Time 1 (never-participants). Those who received initial counseling, but did not complete the program (dropouts), were NOT included in the analysis.

## (3) Method for Calculating Per Capita Outpatient Health Care Cost

To obtain per capita outpatient health care costs, eligible subjects' total monthly medical care and prescription drug points\* were summed. (\*Each medical care, dental care, and prescription drug covered by any health insurance has fixed points used for claims. 1 point equals 10 yen, or approximately 8.5 cents of a health care fee charged.) The Work Group identified specific diagnostic codes and drug codes associated with hypertension, dyslipidemia and diabetes, and monthly claims containing both diagnostic AND drug codes for at least one of these diseases were included for calculation.\*

The Work Group used simple sums of monthly total points containing specific codes for hypertension, dyslipidemia, and diabetes, even though sizable subjects might have other co-morbidities. This decision was made because it was technically very difficult to separate points for individual diseases. Therefore, existence of co-morbidities could influence total health care costs, and when costly co-morbidities were included, they would even inflate the overall averaged figures. This was a major limitation for using this method.

To remedy this methodological limitation, this study excluded any monthly claims containing diagnostic codes for malignant neoplasms from analysis. This decision was made based on the fact that 1) Incidence of malignant neoplasms was relatively high among adults 40 to 74 years of age, 2) malignant neoplasms were associated with high health care costs and likely to inflate the average costs, and 3) the SHCSHG was unlikely to prevent malignant neoplasms, particularly in the short run. In addition, one particular subject who did not have a malignant neoplasm, but had very large total points (an outlier), was excluded from analysis.

\*See Appendix for diagnostic codes and drug codes associated with hypertension, dyslipidemia and diabetes (Page 244)

## 3-2 Analytic Methods

## (1) Per Capita Outpatient Health Care Costs for Hypertension, Dyslipidemia, and Diabetes One Year After Health Guidance

Using the methodology explained in the previous section, per capita outpatient health care costs for hypertension, dyslipidemia, and diabetes one year after HG were analyzed for intervention and control groups. Subjects who were 74 years of age at the time of HG were excluded from the analysis, because their following year's health insurance claims information was collected by the Late-stage medical care system for the elderly, a separate insurance system for adults 75 years and older.

Table 11. Data for the analysis of per capita health care costs one year after health guidance

Study subjects	HIC data for comparison
FY 2008 HG eligible enrollees (intervention vs. control)	FY 2009 health care costs
FY 2009 HG eligible enrollees (intervention vs. control)	FY 2010 health care costs
FY 2010 HG eligible enrollees (intervention vs. control)	FY 2011 health care costs
FY 2011 HG eligible enrollees (intervention vs. control)	FY 2012 health care costs

The numbers of study subjects (intervention and control) are summarized in **Table 12**.

Table 12. Number of eligible study subjects

Intensive health guidance				
Year	Intervention	Control	Total	
FY 2008	11,771	87,653	99,424	
FY 2009	9,832	79,382	89,214	
FY 2010	8,945	80,574	89,519	
FY 2011	8,746	82,978	91,724	
Motivational health gui	dance			
Year	Intervention	Control	Total	
FY 2008	20,211	112,969	133,180	
FY 2009	19,707	100,429	120,136	
FY 2010	15,744	101,638	117,382	
FY 2011	15,655	107,831	123,486	

# (2) Analysis to Examine Baseline Health Care Cost Differences Between Intervention and Control Groups

It was important to examine whether the differences in per capita outpatient health care costs between intervention and control groups were due to heath guidance intervention, or some other intrinsic characteristics of study subjects, such as health care seeking behavior and existence of co-morbidities.

Therefore, this study also analyzed health care costs for the year the subjects became eligible for HG (i.e. baseline).

Table 13. Data for the analysis to examine baseline health care cost differences between intervention and control groups

Study subjects	HIC data for comparison
FY 2009 HG eligible enrollees (intervention vs. control)	FY 2009 health care costs
FY 2010 HG eligible enrollees (intervention vs. control)	FY 2010 health care costs
FY 2011 HG eligible enrollees (intervention vs. control)	FY 2012 health care costs

The numbers of study subjects (intervention and control) for this analysis are summarized in **Table 14**.

Table 14. Number of eligible study subjects

Intensive health guidance					
Year	Intervention	Control	Total		
FY 2009	9,832	79,382	89,214		
FY 2010	8,945	80,574	89,519		
FY 2011	8,746	82,978	91,724		
Motivational health gui	Motivational health guidance				
Year	Intervention	Control	Total		
FY 2009	20,839	106,179	127,018		
FY 2010	16,596	106,944	123,540		
FY 2011	16,478	113,202	129,680		

Individuals who were taking medication for hypertension, dyslipidemia, and diabetes were not eligible for HG. However, some might have reported erroneous medication information due to a lack of understanding of their medication. The proportion of subjects with incorrect medication information might differ between intervention and control groups. In order to eliminate the information bias, analysis was conducted without subjects who had been billed for hypertension, dyslipidemia, and diabetes during the year prior to HG. Subjects who were 74 years of age at the time of health guidance were excluded from the analysis, because their following year's health insurance claims information was collected by the Late-stage medical care system for the elderly system.

Table 15. Data for the analysis to examine baseline health care cost differences without subjects who had been billed for hypertension, dyslipidemia, and diabetes during the year prior to HG

J [	
Study subjects	HIC data for comparison
Those who were eligible to receive HG during FY 2010	FY 2010 and 2011 health care
AND not billed for hypertension, dyslipidemia or diabetes	costs
during FY 2009 (intervention vs. control)	

The numbers of study subjects (intervention and control) for this analysis are summarized in **Table 16**.

Table 16. Number of eligible study subjects

Intensive health guidance					
Year	Intervention	Control	Total		
FY 2010 health care costs	8,621	76,155	84,776		
FY 2011 health care costs	8,621	76,155	84,776		
Motivational health guidance					
Year	Intervention	Control	Total		
FY 2010 health care costs	15,383	99,022	114,405		
FY 2011 health care costs	14,610	94,412	109,022		

#### 3-3. Results

## 3-1. Per Capita Outpatient Health Care Costs for Hypertension, Dyslipidemia, and Diabetes One Year after Health Guidance

### a. Intensive Health Guidance (40 to 64 years of age) (Figure 11 on page 49)

Among men who became eligible for intensive HG during FY 2008, the per capita outpatient health care costs during FY 2009 were 1,002 points for the intervention group and 1,536 points for the control group. The difference (534 points) was statistically significant (P<0.01) (**Figure 11-1** left side). The health care costs for the intervention group were 34.8% lower than for the control group. Furthermore, for every age group, the intervention subjects had significantly lower health care costs compared to their controls. Therefore, among men, those who had completed intensive HG had uniformly lower health care costs for hypertension, dyslipidemia, and diabetes in the following year compared to those who had not participated in intensive HG.

During the same time period, women who had completed intensive HG had per capital heath care costs of 1,466 points in the following year, compared to 2,221 points for women who had not participated in intensive HG (a difference of 755 points, P<0.01). The intervention group's health care costs were 34.0% lower than the control group (**Figure 11-1** right side). In terms of age differences (grouped by 5-year increments), the intervention groups had significantly lower health care costs in the 55 to 59 and 60 to 64 age groups. In younger age groups, the intervention groups also tended to have lower health care costs than their controls, though the differences were not statistically significant.

Similar results were found for FY 2009 through FY 2011 (**Figures 1-1-2 to 1-1-4**). Among men, intervention groups had significantly lower heath care costs than their controls overall and in almost every age group. Among women, intervention groups tended to have lower health care costs than control groups in most age groups. However, the differences were not significant for women who became eligible for HG during FY 2010 and 2011. It should be noted that none of the intervention groups had significantly higher health care costs than their controls.

## b. Motivational Health Guidance (40 to 64 years of age) (Figure 12 on page 50)

Among men 40 to 64 years of age who became eligible for motivational HG during FY 2008, the per capita outpatient health care costs during FY 2009 was 745 points for the intervention group and 1,131 points for its control. The difference (386 points) was statistically significant (P<0.01) (**Figure 12-1** left side). The health care costs for the intervention group were 34.1% lower than for the control group. In terms of age differences, the intervention groups had consistently lower health care costs than control groups, although these differences were statistically significant only in a few age groups. Furthermore, the magnitude of these differences tended to be smaller compared to the differences found in the comparisons between intensive HG groups and their controls.

Among women who became eligible for motivational HG in FY 2008, the health care costs in the following year were 1,057 points for the intervention group and 1,321 points for its control, with a difference of 264 points. The health care costs for the intervention group were 20.0% lower than for the control group (P<0.01) (**Figure 12-1** right side). In terms of age differences, the intervention groups had significantly lower health care costs than their controls in the 55 to 59 and 60 to 64 age groups. In the younger age groups, the intervention groups also tended to have lower health care costs than their controls, though the differences were not statistically significant. Similar to men, the magnitude of these differences tended to be smaller compared to the differences found in the comparisons between intensive HG groups and their controls.

In terms of years, the intervention groups had significantly lower health care costs among both men and women in FY 2008 and men only in FY2009. However, only one age group had a significant difference among women in FY 2009, and no significant differences were found among men and women in FY 2010 and 2011 (Figures 1-2-2 to 1-2-4).

## c. Motivational Health Guidance (65 to 73 years of age) (Figure 1-3 on page 51)

Among men 65 to 73 years of age who became eligible for motivational HG during FY 2008, the per capita outpatient health care costs during FY 2009 were 2,046 points for the intervention group and 2,680 points for the control group. The difference (634 points) was statistically significant. (P<0.01) (**Figure 1-3-1** left side). The health care costs for the intervention group were 23.7% lower than for the control group. Furthermore, the intervention groups had significantly lower health care costs than their controls in the age groups for 65 to 69 and 70 to 73.

Among women who became eligible for motivational HG in FY 2008, the health care costs in the following year were 2,434 points for the intervention group and 3,164 points for the control group, with a difference of 730 points. The health care costs for the intervention group were 23.1% lower than for the control group (P<0.01) (**Figure 1-3-1** right side). Just as among men, the intervention groups had significantly lower health care costs than their controls in the age groups for 65 to 69 and 70 to 73.

In terms of years, the intervention groups had consistently and significantly lower health care costs than their controls, in all gender and age groups throughout the 4 year period (**Figures 1-3-2 to 1-3-4**).

To summarize the findings presented in the sections a through c, among the subjects who were eligible for HG during FY 2008, the following year's health care costs for the <u>intervention groups</u> were as follows:

Health care costs expressed in percentile, supposing that the health care costs for their respective control groups are 100%:

Intensive HG (40-64 years of age)	Men 65.2%	Women 66.0%
Motivational HG (40 to 64 years of age)	Men 65.9%	Women 80.0%
Motivational HG (65 to 73 years of age)	Men 76.3%	Women 76.9%

In every category, intervention groups had lower health care costs than their controls.

<u>Differences in the average health care costs between intervention and control groups:</u>

Intensive HG (40-64 years of age)	Men 534 points	Women 755 points
Motivational HG (40 to 64 years of age)	Men 386 points	Women 264 points
Motivational HG (65 to 73 years of age)	Men 634 points	Women 730 points

Likewise, intervention groups had uniformly lower health care costs than their controls.

For both men and women in the 40 to 64 age group, the differences in health care costs between intervention and control groups were smaller for motivational HG groups than for intensive HG groups.

Significant differences were found in men and women aged 40 to 64 years who became eligible for motivational HG in FY 2008. However, similarly significant differences were not found in men in FY 2010 and 2011 or in women in FY 2009 through FY 2011 (**Figures 1-2-2 through 1-2-4**). However,

significant differences were observed in men and women aged 65 to 73 years who became eligible for motivational HG in FY 2008 through FY 2011 (**Figures 1-3-1 through 1-3-4**).

Figure 1. Per Capita Outpatient Health Care Costs for Hypertension, Dyslipidemia, and Diabetes One Year After Health Guidance

Figure 11. Intensive Health Guidance (40-64 years old)

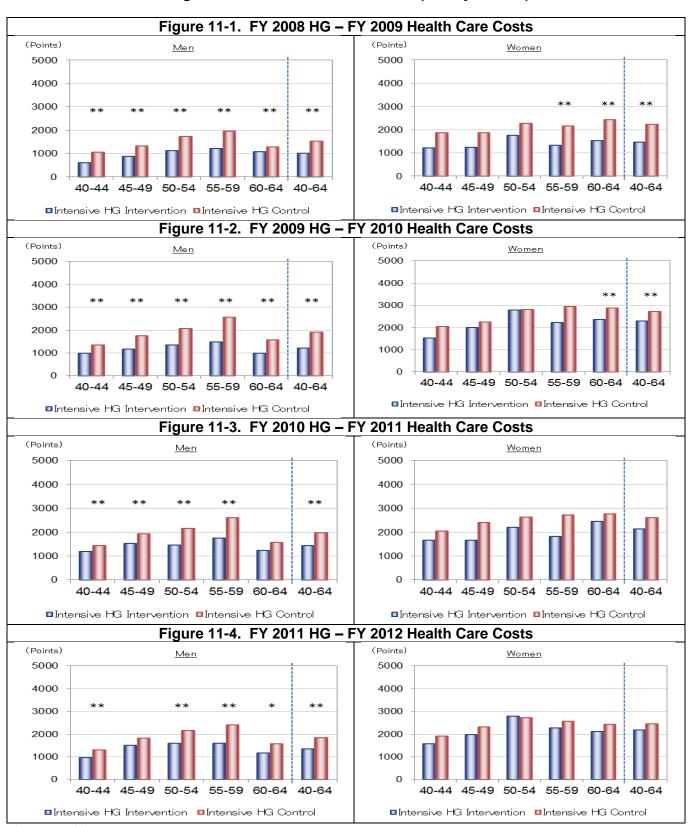


Figure 12. Motivational Health Guidance (40-64 years old)

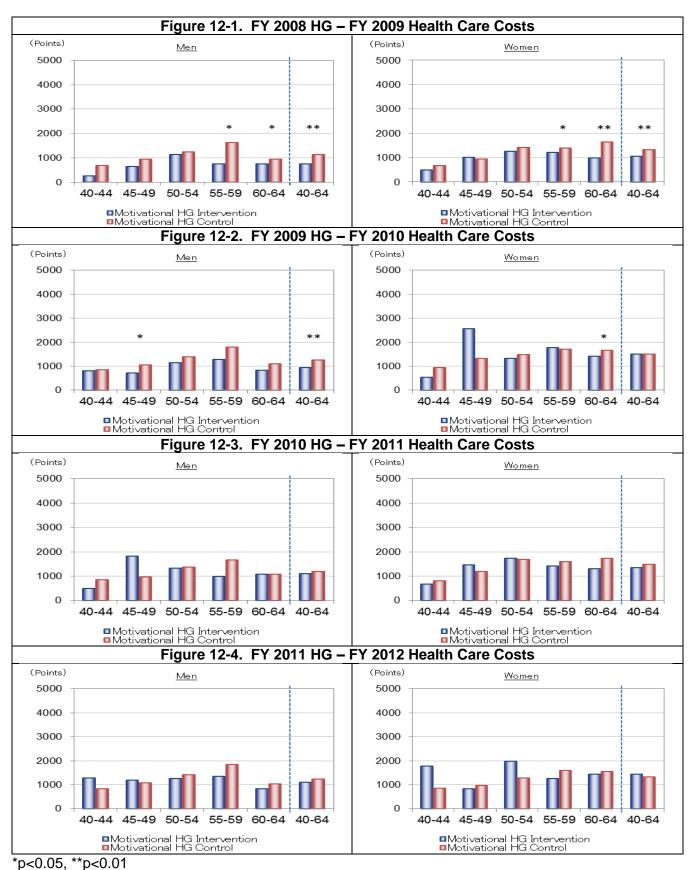
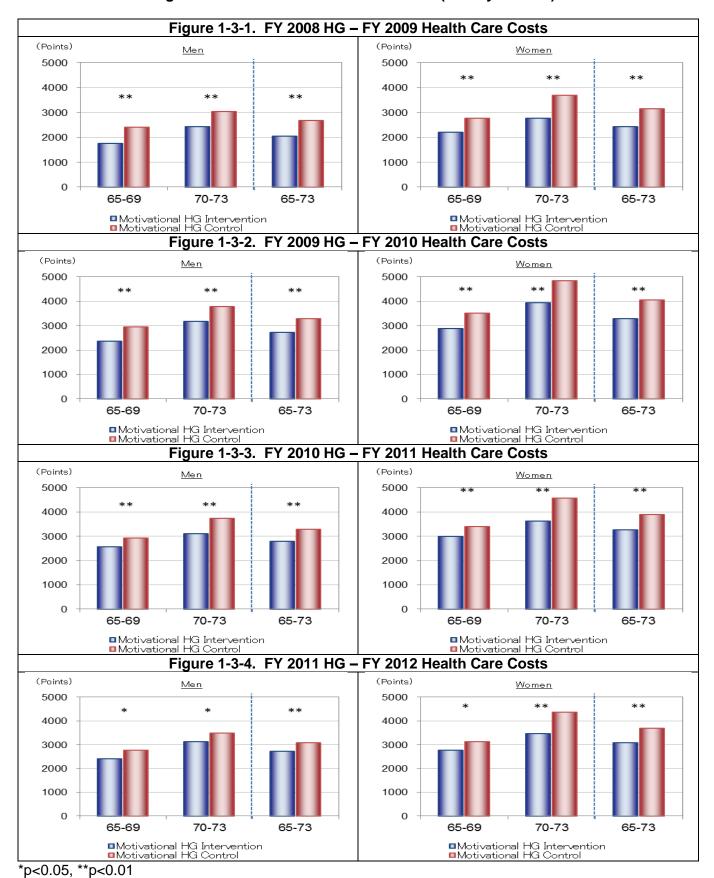


Figure 1-3. Motivational Health Guidance (65-73 years old)



# (2) Analysis to Examine Baseline Health Care Cost Differences Between Intervention and Control Groups

# a. Analysis of Per Capita Outpatient Health Care Costs Associated with Hypertension, Dyslipidemia, and Diabetes for the Year Subjects Became Eligible for HG

This study has demonstrated that outpatient health care costs one year after HG were significantly lower in intervention groups compared to their controls, but further research is needed to examine whether the lower health care costs were attributed to HG. To find out whether intervention and control subjects had different baseline characteristics such as health care seeking behavior or co-morbidities, health care costs associated with hypertension, dyslipidemia, and diabetes for the same year that subjects became eligible for HG were analyzed (**Figure 2-1** on page 54).

Outpatient health care costs for FY 2008 among subjects who became eligible for intensive HG in the same year were as follows: 497 points for men with intervention and 826 points for their controls: 755 points for women with intervention and 1,131 points for their controls. Overall, intensive HG intervention groups had significantly lower health care costs compared to control groups (**Figure 2-1-1**). Similarly, motivational HG intervention groups tended to have lower health care costs in the same year they became eligible for HG than their controls (**Figure 2-2-1**).

There was a possibility that the HG intervention's effects were immediate and able to reduce health care costs in the same year. It was also possible that control groups included higher proportions of subjects who had erroneously reported that they had not been taking medication for hypertension, dyslipidemia, or diabetes and thus became eligible for HG.

To eliminate the effects of subjects who might have been on pharmacological therapy, an auxiliary analysis was performed without subjects who were treated for hypertension, dyslipidemia, or diabetes during the year prior to HG.

# b. Analysis Without Subjects Who Were Billed for Hypertension, Dyslipidemia, or Diabetes During the Year Prior To Heath Guidance

This study was conducted with subjects who were not billed for hypertension, dyslipidemia, or diabetes during FY 2009. Their per capita outpatient health care costs during the year they became eligible for HG (FY 2010), and the following year (FY 2011) were examined (**Figure 3** on page 57).

The total number of eligible subjects in the previous analysis (section a) was 206,901, but in this study the number of eligible subjects who had completed HG in the previous year was 193,798. The proportion of subjects who were excluded from this study was 6.3%.

Even after eliminating subjects who had been billed for hypertension, dyslipidemia, or diabetes one year earlier, intensive HG intervention groups, both men and women, still had lower health care costs in the following year (year of HG) compared to their controls. This tendency was consistent in all age groups (**Figures 3-1-A, 3-2-B**). Among men in particular, the intervention groups had significantly lower health care costs in most age groups.

Among subjects who became eligible for motivational HG, the intervention groups had significantly lower health care costs in men and women 65 years of age and older (**Figures 3-3-A, 3-3-B**). However, in younger age groups (40 to 64 years of age), not all differences in health care costs were statistically significant (**Figures 3-2-A 3-2-B**).

These results were generally congruent with the results obtained from the analyses in section a.

In addition, the proportions of subjects excluded from analysis were 3.6% for the intensive HG intervention group, 5.5% for its control group, 7.2% for the motivational HG intervention group, and 7.1% for its control group. Among the subjects who became eligible for intensive HG, their control group had a higher proportion of subjects who were taking medication during the previous year. In terms of age groups, the proportions of excluded subjects were small in both men and women in 40 to 44 years of age (2.6% and 1.9%, respectively). The proportions of excluded subjects tended to increase with age. For instance, the proportions were 6.5% in men and 6.1% in women 55 to 59 years of age, and 10.2% in men and 12.7% in women 70 to 73 years of age.

Figure 2. Analysis of Per Capita Outpatient Health Care Costs Associated with Hypertension, Dyslipidemia, and Diabetes for the Year Subjects Became Eligible for HG Figure 2-1. Intensive Health Guidance (40-64 years old)

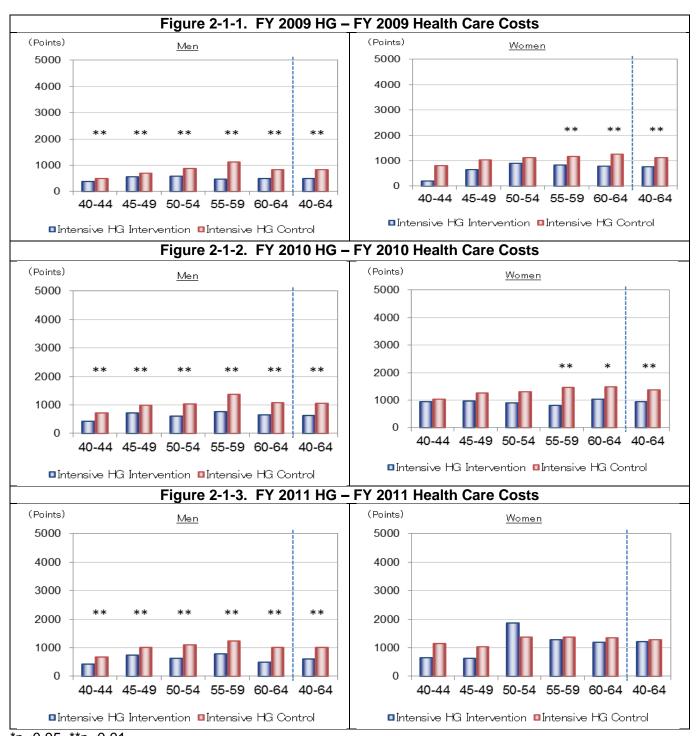


Figure 2-2. Motivational Health Guidance (40-64 years old)

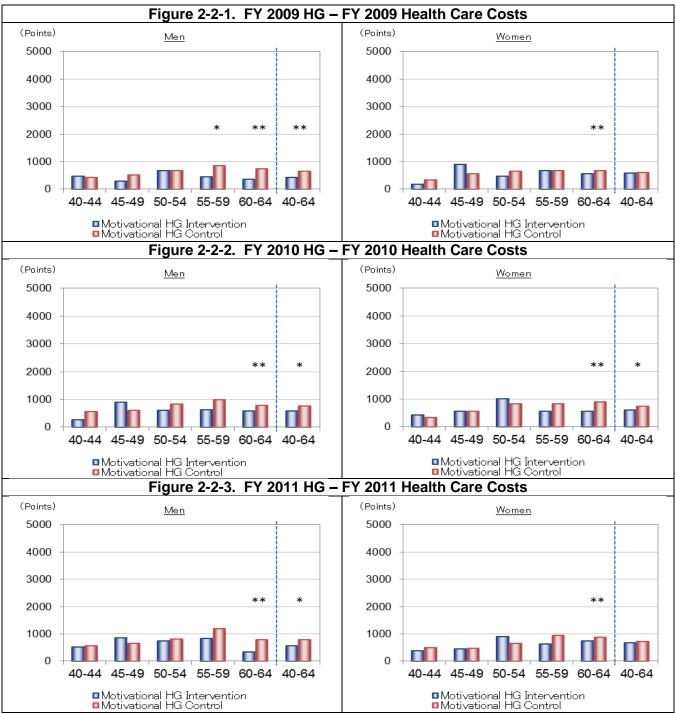


Figure 2-3. Motivational Health Guidance (65-74 years old)

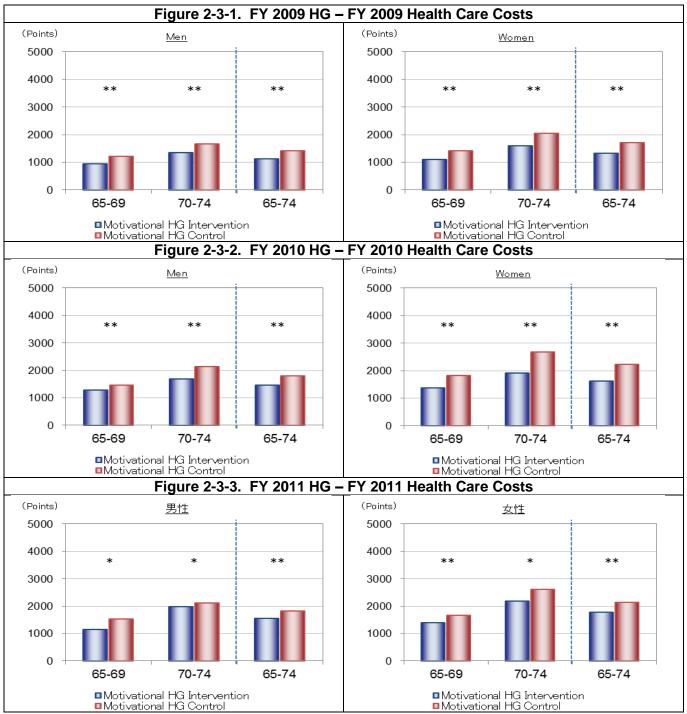


Figure 3. Analysis without Subjects Who Were Billed for Hypertension, Dyslipidemia, or Diabetes During the Year Prior To Heath Guidance

Figure 3-1. Intensive Health Guidance (40-64 years old)

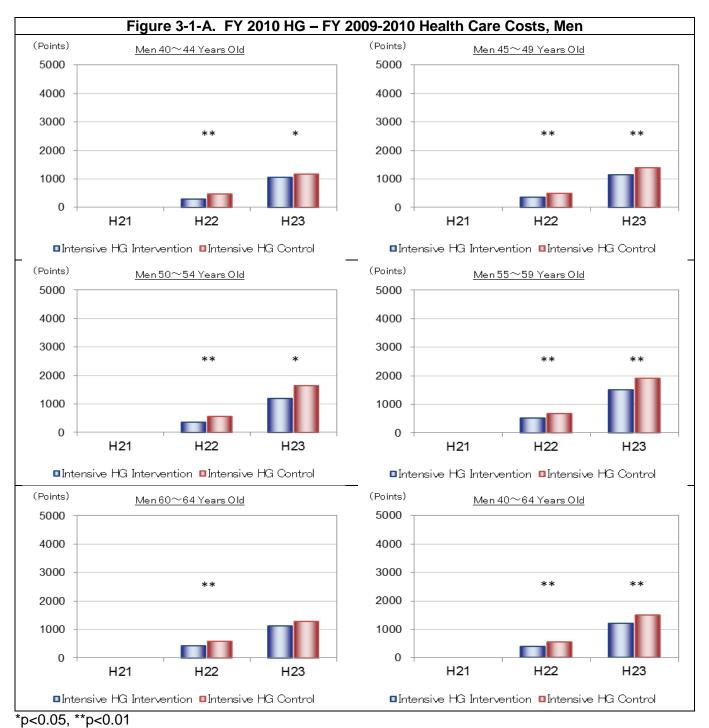


Figure 3-1-B. FY 2010 HG - FY 2009-2010 Health Care Costs, Women (Points) (Points) Women 40∼44 Years Old Women 45∼49 Years Old 5000 5000 4000 4000 3000 3000 2000 2000 1000 1000 0 0 H21 H21 ■Intensive HG Intervention ■Intensive HG Control ■Intensive HG Intervention ■Intensive HG Control (Points) (Points) Women 50∼54 Years Old Women 55∼59 Years Old 5000 5000 4000 4000 3000 3000 2000 2000 1000 1000 0 0 H21 H22 H21 H22 H23 ■Intensive HG Intervention ■Intensive HG Control ■Intensive HG Intervention ■Intensive HG Control (Points) (Points) Women 60∼64 Years Old Women 40∼64 Years Old 5000 5000 4000 4000 3000 3000 \*\* 2000 2000 1000 1000 0 0 H21 H22 H23 H21 H22 H23

Figure 3-1. Intensive Health Guidance (40-64 years old)

■Intensive HG Intervention ■Intensive HG Control

■Intensive HG Intervention ■Intensive HG Control

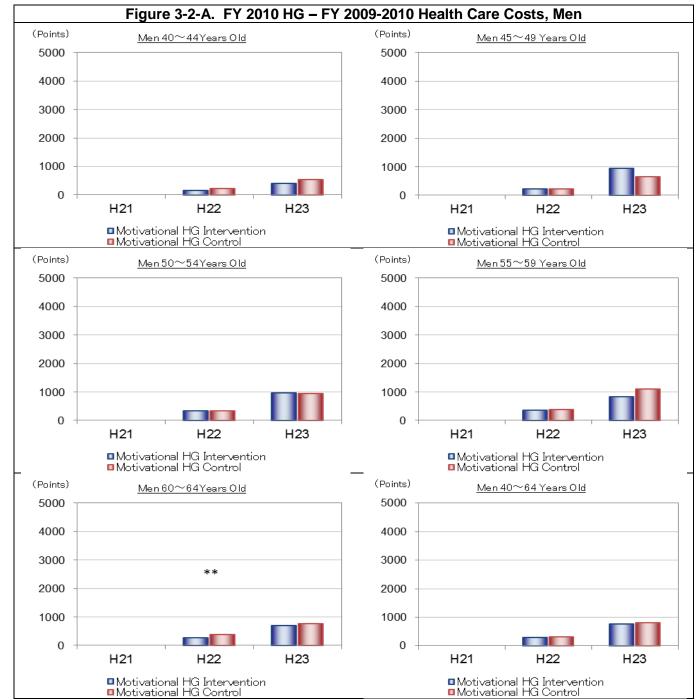


Figure 3-2. Motivational Health Guidance (40-64 years old)

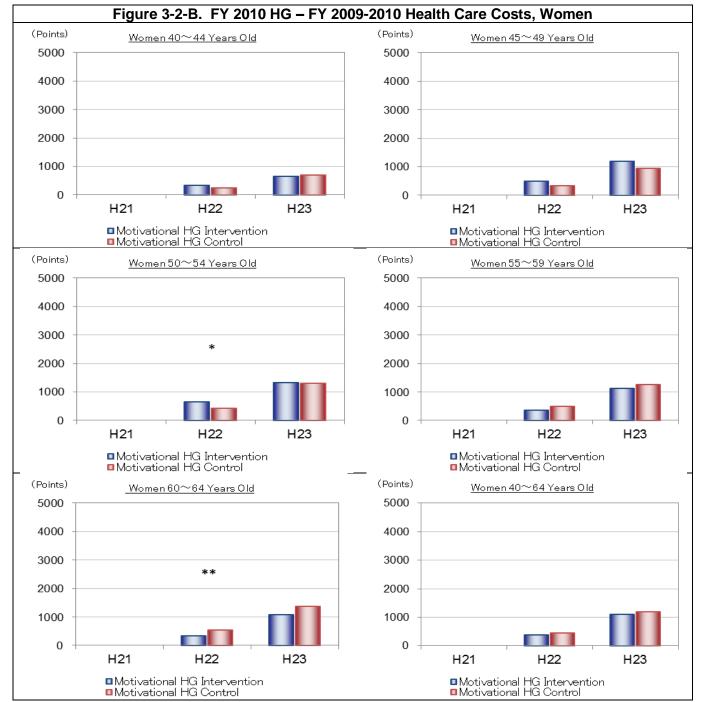


Figure 3-2. Motivational Health Guidance (40-64 years old)

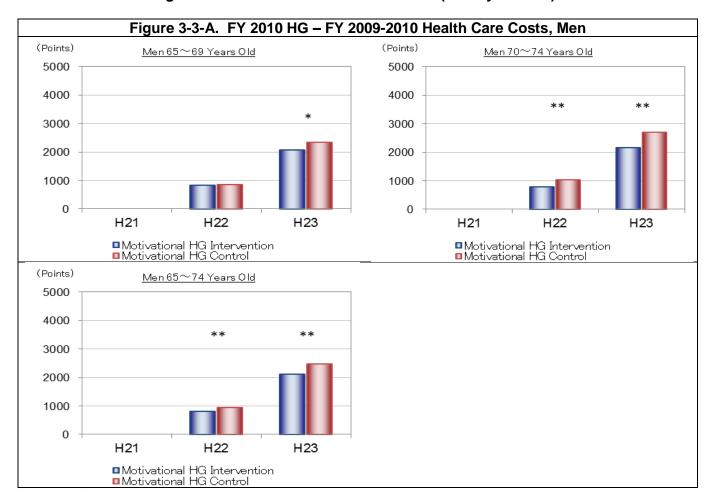


Figure 3-3. Motivational Health Guidance (65-74 years old)

\*p<0.05, \*\*p<0.01

FY2011 analysis does not include those who were 74 years of age in the year they became eligible for HG.

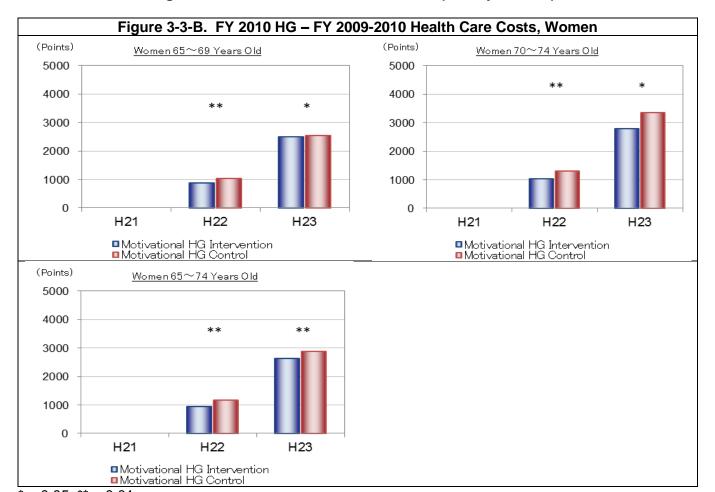


Figure 3-3. Motivational Health Guidance (65-74 years old)

\*p<0.05, \*\*p<0.01

FY2011 analysis does not include those who were 74 years of age in the year they became eligible for HG.

#### 3-4. Discussion

## (1) Per Capita Outpatient Health Care Cost for Hypertension, Dyslipidemia, and Diabetes One Year after Health Guidance

The current study examined the impacts of health guidance (HG), which began in 2008 under the Specific Health Checkups and Specific Health Guidance (SHCSHG), on the costs of lifestyle-related chronic disease care during the year following HG, using data from the National Insurance Claims Database (NDB). The primary objective of this study was to examine how the completion of HG would affect per capita outpatient health care costs for hypertension, dyslipidemia, and diabetes in the following year. The SHCSHG data and health insurance claims (HIC) data were linked for the analysis.

For subjects 40 to 64 years of age who were eligible for intensive HG, both men and women in intervention groups had uniformly lower health care costs compared to their controls. In particular, men who had completed intensive HG had significantly lower health care costs for metabolic syndrome-related diseases (hypertension, dyslipidemia, and diabetes) than their controls in almost all age categories, suggesting that completing intensive HG could lead to health care cost containment. The previous study by the Work Group published in April 2014 has found that intervention groups achieved greater reductions in waist circumference and body weight, and also had significant improvements in blood pressure, lipids, and blood glucose compared to their controls. Together with the results from the current study, it is feasible to assume that men who completed intensive HG were able to improve their lifestyle and reduce body weight, and subsequently the upward trend of men shifting to a pharmacological therapy was at least partially reversed.

Women who had completed intensive HG had similar results as their male counterparts, but statistically significant reductions in health care costs were found only for those who became eligible for HG during FY 2008 and 2009. The magnitudes of heath care cost reductions became smaller and non-significant in FY 2010 and later years. For women, the waist circumference cut-off for metabolic risk was set at 90cm (5cm greater than men's cut-off), therefore intensive HG eligible women tended to have higher BMI than their male counterparts. The study published in April 2014 also found that female subjects had higher baseline (prior to HG) BMI, systolic blood pressure, fasting blood glucose, and HbA1c than male subjects. The reduced effects of HG in women could be attributed to their more severe metabolic risks at baseline. Additional possible explanations include: 1) Reduced statistical power because women had a smaller sample size, 2) Women were more likely to be on dyslipidemia medication because their cholesterol levels were elevated due to menopause, and 3) Female control subjects made efforts to improve their lifestyle that were comparable to their peers in intervention.

For subjects who were eligible for motivational HG, two age groups (40 to 64 years of age and 65 to 73 years of age) were reviewed separately because HG eligibility differed by age groups.

Subjects 40 to 64 years of age who had completed motivational HG had smaller differences in health care costs between intervention and control groups, compared to the differences found between comparable intensive HG groups and their controls. Furthermore, some age groups did not have significant differences between HG subjects and their controls. It appeared that as years passed, the reductions of health care costs became smaller, suggesting a possibility of waning effects of HG over time. For instance, not all subgroups of intervention subjects who had demonstrated significant reduction in health care costs in FY 2008 had similar significant results in FY 2010 and FY 2011. Possible reasons for the reduced effects of motivational HG include: 1) Motivational HG subjects had lower metabolic risks at baseline compared to intensive HG subjects, therefore their health care costs were also lower at baseline, 2) Frequency of intervention for motivational HG was minimal, evidenced by their smaller impacts on the improvements of clinical indicators compared to intensive HG, and 3)

There was a possibility that motivational HG was given in an even more simplified, expedited manner in order to increase participation rate.

For reason 1 above, motivational HG eligible subjects were less likely to receive health care involving pharmacological therapy in the following year, because they had fewer metabolic risk factors and their pathophysiological conditions were less severe compared to intensive HG eligible subjects.

Reason 2 stemmed from programmatic limitations. Motivational HG provided subjects with initial counseling to set individualized behavioral goals, and conducted evaluations at the end of the 6th month. But there was no system for continuous support for the length of the program. Some HG intervention sites reported increased effectiveness by adding unique efforts of insurers and HG providers, or combining existing worksite wellness programs. As the insurer-level data analysis results become available, discussions of ways to improve motivational HG will become a priority.

Regarding reason 3, the current computation algorithm for HG participation rates weighed intensive HG and motivational HG equally. Therefore, it was possible that some insurers who wanted to increase the overall participation rate might have chosen to cut corners and gave simplified HG. It would be necessary to re-evaluate methodology for computing participation rates, and a system to improve HG effectiveness along with participation rates should be incorporated in program evaluation.

Among older subjects (65 to 73 years of age) who completed motivational HG, the health care costs for the intervention groups were approximately 76% of the health care costs for their controls. The differences in health care costs between intervention subjects and their controls were 634 points for men and 730 points for women. These differences were much larger than the differences found in the 40 to 64 age groups (386 points for men and 264 points for women). Furthermore, differences were statistically significant in all age groups and intervention years.

Possible reasons for the large reduction in health care costs include: 1) Health care costs were normally higher in adults 65 years and older, therefore it was easy to see the impact, 2) Adults 65 years and older who were not on pharmacological therapy were generally healthier and more health conscious, and 3) Initial counseling introduced them to municipal public health centers and other existing local health improvement resources, so that they were able to improve their lifestyles on their own (synergetic effect of population-based health promotion).

As people age, they become more health conscious. It was likely that the initial counseling offered by motivational HG taught older adults, who had had health examinations, but had not been educated about lifestyle change, which is an important aspect of their health management. Subsequently, they became motivated to improve their lifestyle before moving on to pharmacological therapy. Increased health consciousness was also related to the fact that older adults were more likely to spend time in their communities, so they had increased opportunities to utilize community-based health improvement resources. It was also likely that the short-term reduction of health care costs was achieved because interventions were offered right before subjects were shifted to a pharmacological therapy.

# (2) Analysis to Examine Baseline Health Care Cost Differences Between Intervention and Control Groups

This analysis examined health care costs for the year subjects became eligible for HG. It was found that health care (primarily pharmacological therapy) for hypertension, dyslipidemia, and diabetes were already present during the year of HG. Health care costs for intensive HG and motivational HG subjects, both men and women, tended to be lower compared to their controls.

Possible reasons for the presence of health care utilization of during the year of HG include: 1) Some subjects were already taking medications for hypertension, dyslipidemia, or diabetes at the time of health examination, but did not report their current medication, so they became eligible for HG, and some subjects received health examinations when their pharmacological therapy for the metabolic conditions were temporary suspended, so they reported not taking any medication, or 2) Subjects began pharmacological therapy immediately after they became eligible for HG.

Reasons for the lower same-year health care costs for intervention groups include: 3) Higher proportions of those who misreported their medication information (reason 1 above) were found in control groups, 4) Some subjects who had completed HG improved their clinical conditions immediately, resulting in health care cost reductions in the same year, 5) Subjects who had completed HG were more likely to be health conscious and motivated to practice self-care, therefore regardless of the effect of HG, they were less likely to utilize health care, and 6) Some control subjects did not participate in HG because their health examination results were worse than they expected and they chose to receive medical care immediately.

Additional analyses were conducted to eliminate the possible effects of underreported medication information (reason 1). Even after eliminating subjects who had been billed for hypertension, dyslipidemia, and diabetes during the year prior to HG, intervention groups still had lower health care costs than their controls in the year of HG, as well as the following year. This suggested that there would be a need to examine reason 4 (immediate improvement), although factors associated with reason 5 (health consciousness) and reason 6 (control's tendency to choose medical care) would be difficult to eliminate.

## 4. The Third Interim Report

## 4-1. Study Subjects

In this study, SHCSHG and HIC data were linked, and SHCSHG data from FY 2008 to FY 2011, and HIC data from FY 2009 to FY 2012 were used for analysis. Similar to the analyses in the Second Interim Report, data matching rates were monitored, and only the data from the insurers who had a data matching rate of 80% or higher in all years from FY 2009 to FY 2011 were included. The insurers who met the data matching standards were 365 in total, including 321 insurers of the National Health Insurance, 2 insurers of the Health Insurance Societies, and 42 insurers of the Mutual Aid Associations.

From the eligible enrollee data, enrollees who became eligible for specific health guidance (HG) due to elevated metabolic risks in FY 2008 were selected as study subjects. Using the SHCSHG data for FY 2008-FY 2011 and HIC data for FY 2009-FY 2011, longitudinal trends of average values for clinical indicators, per capita outpatient health care costs, and outpatient health care utilization rates were compared between intervention and control groups, stratified by sex and age groups.

Intervention and control subjects were selected based on the following criteria.

**Intervention**: Subjects who became eligible for HG due to elevated metabolic risks in FY 2008, participated in HG for the first time in the same fiscal year, and completed the final evaluation at the end of the 6<sup>th</sup> month. (Whether the subject participated in HG in FY 2009 and later years did not matter in this study)

**Control**: Subjects who became eligible for HG due to elevated metabolic risks in FY 2008, but did not participate in HG at all between FY 2008 and 2011. (Subjects who dropped out from HG were not included in the analysis)

#### 4-2. Methods

## (1) Longitudinal Analysis of Clinical Indicators Following Health Guidance

Longitudinal trends of major clinical indicators used in the HG eligibility algorithm were analyzed for each year from baseline (FY 2008) to 3 years later (FY 2011) for intervention and control groups. Averaged differences from baseline (i.e. the average of clinical value at *n* years later minus baseline clinical value) were also analyzed.

In this analysis, for each year between FY 2009 and FY 2011, only subjects who participated in health examination and had clinical data in the same year were included (see **Table 17**). Subjects who had missing clinical values and those who moved to the Late-stage medical care system for the elderly (those who turned 75 years of age) during the study period were excluded.

The Student's t test was used to test statistical significance (p <0.05) in differences between intervention and control groups. (Note: The Student's t test is a statistical method to compare averaged values between two population samples)

Table 17. Data used for longitudinal analysis of clinical indicators after health guidance

participation

	Subjects	Data for analysis
Baseline (FY 2008)	Individuals who became eligible for HG in FY	Clinical values in FY
Baseline (FT 2008)	2008 (intervention & control groups)	2008
1 year later (FY 2009)	Individuals who became eligible for HG in FY 2008 (intervention & control groups), and participated in health examination in FY 2009	Clinical values in FY 2009
2 years later (FY 2010)	Individuals who became eligible for HG in FY 2008 (intervention & control groups), and participated in health examination in FY 2010	Clinical values in FY 2010
3 years later (FY 2011)	Individuals who became eligible for HG in FY 2008 (intervention & control groups), and participated in health examination in FY 2011	Clinical values in FY 2011

Table 18 reports numbers of intervention, control, and total subjects (n) in each year

Table 18. Numbers of subjects for longitudinal analysis of clinical indicators after

health guidance participation

nealth guidance participation						
Intensive health guidance	Intervention	Control	Total			
Baseline	10,942	78.072	89,014			
1 year later	9,246	54,268	63,514			
2 years later	8,607	50,312	58,919			
3 years later	7,956	48,026	55,982			
Motivational health guidance	Intervention	Control	Total			
Baseline	20,848	111,654	132,502			
1 year later	15,498	71,391	86,889			
2 years later	13,575	63,965	77,540			
3 years later	12,051	57,663	69,684			

## Additional analysis - setting upper limits

The analyses described in section (1) found that control groups tended to have significantly higher baseline values for HbA1c, systolic blood pressure, and diastolic blood pressure compared with intervention groups. It was most likely that control groups included higher proportions of individuals who were subject to pharmacological treatment based on various clinical guidelines, therefore additional analyses were conducted without such individuals. Specifically, additional analyses were conducted with subjects whose baseline (FY 2008) clinical values were lower than specific cutoff values: HbA1c below 7.0%, systolic blood pressure below 160mmHg, and diastolic blood pressure below 100mmHg. Those who had baseline clinical values higher than these cutoff values were excluded. (See Table 19 for proportions of subjects who were excluded)

**Table 19** reports numbers of intervention, control, and total subjects (n) for the additional analyses in each year.

Table 19. Numbers of subjects for additional longitudinal analysis of clinical indicators following health guidance \* Excluding those who had higher than the cutoff baseline clinical values from subjects described in Table 18

#### <HbA1c>

Intensive HG	Intervention	% excluded	Control	% excluded	Total	% excluded
Baseline	10,680	2.4	74,047	5.2	84,727	4.8
1 year later	8,770	5.1	49,648	8.5	58,418	8.0
2 years later	8,108	5.8	45,628	9.3	53,736	8.8
3 years later	7,455	6.3	43,007	10.5	50,462	9.9
Motivational HG	Intervention	% excluded	Control	% excluded	Total	% excluded
Baseline	20,567	1.3	109,113	2.3	129,680	2.1
1 year later	15,128	2.4	68,448	4.1	83,576	3.8
2 years later	13,229	2.5	61,115	4.5	74,344	4.1
3 years later	11,714	2.8	54,641	5.2	66,355	4.8

<Systolic blood pressure>

Intensive HG	Intervention	% excluded	Control	% excluded	Total	% excluded
Baseline	10,322	5.7	71,518	8.4	81,840	8.1
1 year later	8,470	8.4	48,195	11.2	56,665	10.7
2 years later	7,862	8.7	44,250	12.0	52,112	11.6
3 years later	7,227	9.2	41,700	13.2	48,927	12.6
Motivational HG	Intervention	% excluded	Control	% excluded	Total	% excluded
Baseline	19,513	6.4	102,343	8.3	121,856	8.0
1 year later	14,396	7.1	64,777	9.3	79,173	8.9
2 years later	12,618	7.0	57,850	9.6	70,468	9.1
3 years later	11,194	7.1	51,785	10.2	62,979	9.6

<Diastolic blood pressure>

Colastolic blood pressure/						
Intensive HG	Intervention	% excluded	Control	% excluded	Total	% excluded
Baseline	10,212	6.7	70,958	9.1	71,170	8.8
1 year later	8,358	9.6	47,575	12.3	55,933	11.9
2 years later	7,733	10.2	43,624	13.3	51,357	12.8
3 years later	7,105	10.7	41,029	14.6	48,134	14.0
Motivational HG	Intervention	% excluded	Control	% excluded	Total	% excluded
Baseline	20,286	2.7	106,614	4.5	126,900	4.2
1 year later	14,918	3.7	66,928	6.3	81,846	5.8
2 years later	13,060	3.8	59,652	6.7	72,712	6.2
3 years later	11,536	4.3	53,285	7.6	64,821	7.0

# (2) Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance

Using the same study subjects in the previous analysis (longitudinal analysis of clinical indicators following health guidance), longitudinal analyses of per capita outpatient health care costs and outpatient care utilization rates for hypertension, dyslipidemia, and diabetes were conducted, using the data for one to three years after health guidance (FY 2009 to FY 2011) (see **Table 20**).

Rationale for using the same subjects from the previous analysis in this analysis is to investigate association with changes in clinical indicators obtained from the analysis (1). (Therefore, numbers of intervention, control, and total subjects for each analysis year were same as the numbers reported in Table 15. Note that HIC data were not included in the NDB in FY 2008, therefore no analyses were conducted at baseline (FY 2008).

The Wilcox t test was used to test statistical significance (p <0.05) in differences between intervention and control groups. (Note: The Wilcox t test is a statistical method to compare between two sample populations without assuming that population is normally distributed.)

To obtain per capita outpatient health care costs, eligible subjects' total medical care and prescription drug points for hypertension, dyslipidemia, and diabetes ("three targeted diseases") were summed, using the same method employed in the Second Interim Report. (See page 42 for details). This study excluded any claims containing diagnostic codes for malignant neoplasms from analysis, because malignant neoplasms have relatively high incidence rates in adults 40 to 74 years of age; even one case of a malignant neoplasm would inflate the overall average costs due to its high treatment costs; and it is unlikely to expect that the development of a malignant neoplasm is prevented as an immediate effect of specific health guidance. In addition, one subject who had very large total points (an obvious outlier) was excluded from analysis.

Outpatient care utilization rates were computed as follows, based on the definition used in the Survey on Medical Care Benefit Expenditures.

Outpatient care utilization rate = total number of health insurance claims associated with outpatient care for the three target diseases in a specific group in a specific year / total number of subjects in the same group in the same year

(Reference) Definition of health care utilization rate by the Survey on Medical Care Benefit Expenditures.

Health care utilization rate = total number of health care visits during a specific period of time (total number of health insurance claims) / average number of health insurance enrollees for the same time period

Table 20. Data used for longitudinal analysis of per capita outpatient health care costs and outpatient health care utilization rates

	Subjects	Data for analysis
Baseline (FY 2008)	Individuals who became eligible for HG in FY 2008 (intervention & control groups)	n/a
1 year later (FY 2009)	Individuals who became eligible for HG in FY 2008 (intervention & control groups), and participated in health examination in FY 2009	Outpatient health care costs and care utilization rates in FY 2009
2 years later (FY 2010)	Individuals who became eligible for HG in FY 2008 (intervention & control groups), and participated in health examination in FY 2010	Outpatient health care costs and care utilization rates in FY 2010
3 years later (FY 2011)	Individuals who became eligible for HG in FY 2008 (intervention & control groups), and participated in health examination in FY 2011	Outpatient health care costs and care utilization rates in FY 2011

# (3) Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance (Follow-up Analysis of Baseline Cohort)

In order to examine associations among changes in clinical indicators, per capita outpatient health care costs, and outpatient health care utilization rates, the same study subjects were used in the analysis (1) and (2). Specifically, for each year, only subjects who participated in a health examination and had clinical data in the same year were included. Therefore, subjects were unique in each year (see **Table 21**).

In the analysis (3), the focus is changes in per capita outpatient health care costs and outpatient health care utilization rates in the same subject over time. Therefore, the costs and utilization rates at 1 to 3 years later (FY 2009 to FY 2011) were analyzed by following up intervention and control subjects who became eligible for HG in FY 2008 regardless whether they had clinical indicator data.

When subjects turn 75 years of age, they are transferred to the Late-stage medical care system for the elderly and their data will no longer be available. (Note: Intensive HG is for adults 40 to 64 years of age only, but motivational HG includes adults 40 to 74 years of age) Because of this, for motivational HG-eligible subjects, only those who were 40 to 69 years of age in FY 2008 were included in analysis.

The Wilcox t test was used to test statistical significance (p <0.05) in differences between intervention and control groups. The methods to compute per capita outpatient health care costs and outpatient health care utilization rates used were same as the ones used in the analysis (2).

Table 21. Data used for longitudinal analysis of per capita outpatient health care costs and outpatient health care utilization rates (follow-up analysis of baseline cohort)

	Subjects	Data for analysis
Baseline (FY 2008)		n/a
1 year later (FY 2009)	Individuals who became eligible for HG in FY 2008 (intervention & control groups)	Outpatient health care costs and health care utilization rates in FY 2009
2 years later (FY 2010)	*Note: for motivational health guidance-eligible individuals, only	Outpatient health care costs and health care utilization rates in FY 2010
3 years later (FY 2011)	those who were 40 to 69 years of age were included	Outpatient health care costs and health care utilization rates in FY 2011

Table 22 reports numbers of intervention, control, and total subjects (n) in each year.

Table 22. Numbers of subjects for longitudinal analysis of per capita outpatient health care costs and outpatient health care utilization rates (follow-up analysis of baseline cohort)

conorty			
Intensive health guidance	Intervention	Control	Total
Baseline	11,771	87,653	99,424
1 year later	11,771	87,653	99,424
2 years later	11,771	87,653	99,424
3 years later	11,771	87,653	99,424
Motivational health guidance	Intervention	Control	Total
Baseline	13,869	86,775	100,644
1 year later	13,869	86,775	100,644
2 years later	13,869	86,775	100,644
3 years later	13,869	86,775	100,644

#### 4-3. Results

#### (1) Longitudinal Analysis of Clinical Indicators Following Health Guidance

#### a. Intensive Health Guidance (40 to 64 years of age)

#### **I.** Waist Circumference (Page 75, Figures 4-I-A~D)

Among men, there were no statistically significant differences in baseline waist measurements between intervention and control groups in all age groups except for the 45 to 49 age group and overall (40 to 64 years of age). However, intervention groups had significantly smaller waist measurements at one year later (FY 2009), two years later (FY 2010), and three years later (FY2011). The reduction of waist measurement from baseline was 2.34cm by one year later, 1.92cm by two years later, and 1.48cm by three years later in intervention groups overall. The extent of these waist measurement reductions was significantly greater compared with control groups overall (0.66cm, 0.69cm, and 0.51cm, respectively).

Among women, baseline waist measurements were significantly larger in intervention groups than in control groups in the 40 to 44 age group and overall, but other age groups had no significant baseline differences. The intervention groups had greater reductions in waist measurements in subsequent years. By one year later, the intervention groups had significantly smaller waist measurements in the 55 to 59 and the 60 to 64 age groups, and overall. The reduction of waist measurement from baseline was 2.98cm by one year later, 2.80cm by two years later, and 2.66cm by three years later in intervention groups overall. The amounts of these waist measurement reductions were significantly greater compared with control groups overall (1.59cm, 1.71cm, and 1.55cm, respectively).

#### II. BMI (Page 79, Figures 4-II-A~D)

In both men and women there were no baseline differences in BMI between intervention and control groups in all age groups and overall (40 to 64 years of age). In each subsequent year, intervention groups had lower BMI than control groups in almost all age groups. Furthermore, the intervention groups had significantly lower BMI in both men overall and women overall in each year. Among the intervention groups, BMI reduction was the greatest in one year later, then it gradually got smaller, but even at three years later, their BMI was still lower compared with baseline BMI and control groups' BMI.

#### III. Body Weight (Page 83, Figures 4-III-A~D)

Among men, there was no significant baseline body weight difference between intervention and control groups in each age group, but the control group overall (40 to 64 years of age) had significantly higher baseline body weights. In subsequent years, intervention groups had significantly lower body weights than control groups in almost all age groups. Among male intervention groups overall, the reduction of body weight from baseline was 1.98kg by one year later, 1.53kg by two years later, and 1.25kg by three years later. The amounts of these body weight reductions were significantly greater compared with the control groups overall (0.42kg, 0.43kg, 0.43kg, respectively).

Among women, there was also no significant baseline body weight difference between intervention and control groups in each age group, but control groups overall (40 to 64 years of age) had significantly higher baseline body weights, and differences in body weights increased in subsequent years. Among the female intervention groups overall, the reduction of body weight from baseline was 2.25kg by one year later, 1.83kg by two years later, and 1.65kg by three years later. The amounts of these body weight reductions were significantly greater compared with control groups overall (0.68kg, 0.85kg, and 0.81kg, respectively).

#### IV. HbA1c (in the JSD unit) (Page 87, Figures 4-IV-A~H)

Baseline HbA1c was 5.37% in male intervention groups overall (40 to 64 years of age), 5.48% in male control groups overall, 5.51% in female intervention groups overall, and 5.63% in female control groups overall, and the differences in HbA1c between interventions and control groups were all statistically significant. Similarly, in each age group, control groups had significantly higher baseline HbA1c than intervention groups. In subsequent years, HbA1c tended to gradually increase in control groups, but in intervention groups, HbA1c either decreased or increased only slightly.

Because baseline HbA1c was significantly higher in control groups than in intervention groups in all age groups in both men and women, additional analyses were performed with subjects whose baseline HbA1c was below 7%. In new analyses, baseline differences between groups almost entirely disappeared. It was found that the difference of HbA1c from baseline to one year later was a decrease of 0.01% in male intervention groups overall and a decrease of 0.05% in female intervention groups overall. However, HbA1c increased by 0.06% by two years later and 0.07% by three years later in male intervention groups overall. Similarly, HbA1c increased by 0.01% by two years later and 0.02% by three years later in female intervention groups overall. Among control groups, HbA1c increased even more greatly in all subsequent years. The increase was 0.04% by one year later, 0.09% by two years later, and 0.10% by three years later in male control groups overall, and 0.02%, 0.07%, and 0.09%, respectively, in female control groups overall. In other words, intervention groups had smaller increases in HbA1c compared with control groups.

#### V. Systolic Blood Pressure (Page 95, Figures 4-V-A~H)

Among men, baseline systolic blood pressure was 132.40mmHg in intervention groups overall (40 to 64 years of age), and 133.82mmHg in control groups overall. The difference was statistically significant. In all age groups except for the 40 to 44 age group, the control groups also had significantly higher baseline systolic blood pressure than their intervention groups. Among women, baseline systolic blood pressure was 136.85mmHg in intervention groups overall, and 138.95mmHg in control groups overall. The difference was also statistically significant. The control groups had significantly higher baseline systolic blood pressure than their intervention groups in all age groups greater than 50 years.

Because baseline systolic blood pressure was significantly higher in control groups than in intervention groups, additional analyses were performed with subjects whose baseline systolic blood pressure was below 160mmHg. Baseline differences among groups were diminished, and intervention groups tended to have lower systolic blood pressure in subsequent years in both men and women. It was found that among male intervention groups overall, the decrease of systolic blood pressure from baseline was 2.12mmHg by one year later, 1.19mmHg by two years later, and 0.72mmHg by three years later. Among male control groups overall, the decrease was 0.87mmHg, 0.39mmHg, and 0.13mmHg, respectively. Among female intervention groups overall, the decrease of systolic blood pressure from baseline was 3.31mmHg by one year later, 3.16mmHg by two years later, and 2.95mmHg by three years later. These decreases were significantly greater compared to female control groups overall.

#### VI. Diastolic Blood Pressure (Page 103, Figures 4-VI-A~H)

Among men, baseline diastolic blood pressure was 83.24mmHg in intervention groups overall (40 to 64 years of age), and 84.06mmHg in control groups overall. The difference was statistically significant. In all age groups except for the 40 to 44 age group, control groups also had significantly higher baseline diastolic blood pressure than intervention groups. Among women, baseline diastolic blood pressure was 81.86mmHg in intervention groups overall, and 83.23mmHg in control groups overall. The difference was also statistically significant. Control groups had significantly higher baseline diastolic blood pressure than intervention groups in all age groups greater than 55 years.

Because baseline diastolic blood pressure was significantly different between intervention and control groups, additional analyses were performed with subjects whose baseline diastolic blood pressure was below 100mmHg. Baseline differences among groups were diminished, and intervention groups tended to have lower diastolic blood pressure and greater reduction from baseline in subsequent years in almost all age groups.

#### VII. Triglycerides (Page 111, Figures 4-VII-A~D)

Among men, there were no significant baseline triglyceride differences between intervention and control groups in all age groups except the 50-54 age group and overall (40 to 64 years of age). In subsequent years, intervention groups had lower triglycerides compared with control groups in all age groups. Triglycerides were significantly lower in intervention groups overall compared with control groups overall by one, two, and three years later. Also, intervention groups in every age group had significantly lower triglycerides by one year later. The reduction from baseline was 35.75mg/dl by one year later, 29.43mg/dl by two years later, and 31.27mg/dl by three years later in intervention groups overall, indicating that intervention subjects steadily kept a lower triglyceride level for three years. Control groups also had generally lower triglycerides in subsequent years, but the amounts of reduction were smaller compared with intervention groups.

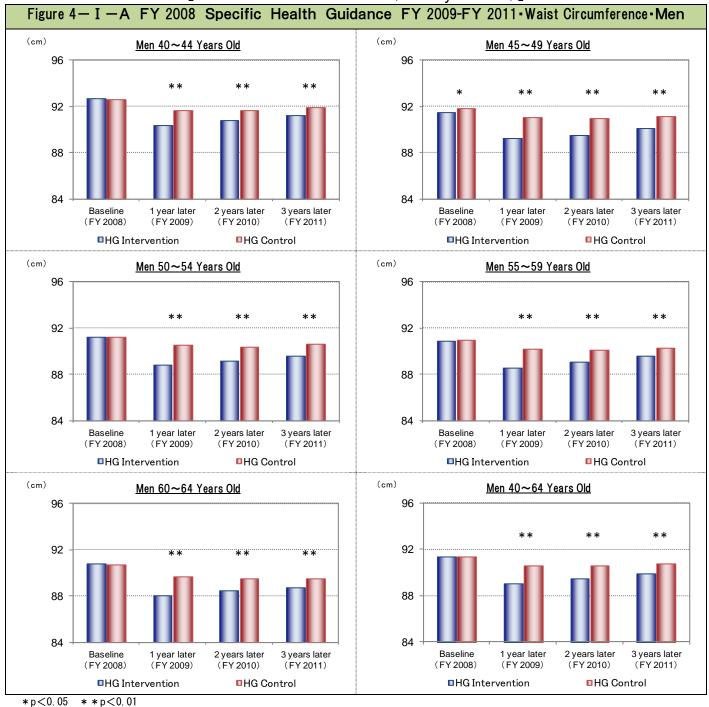
Among women, there were also no significant baseline triglyceride differences between intervention and control groups in all age groups. In subsequent years, intervention groups had lower triglycerides than control groups in almost all age groups, with statistically significant differences in women overall and in the 60 to 64 age group. Among intervention groups overall, the reduction of triglycerides from baseline was 27.51mg/dl by one year later, 26.81mg/dl by two years later, and 26.17mg/dl by three years later. These reductions were significantly greater compared to control groups overall.

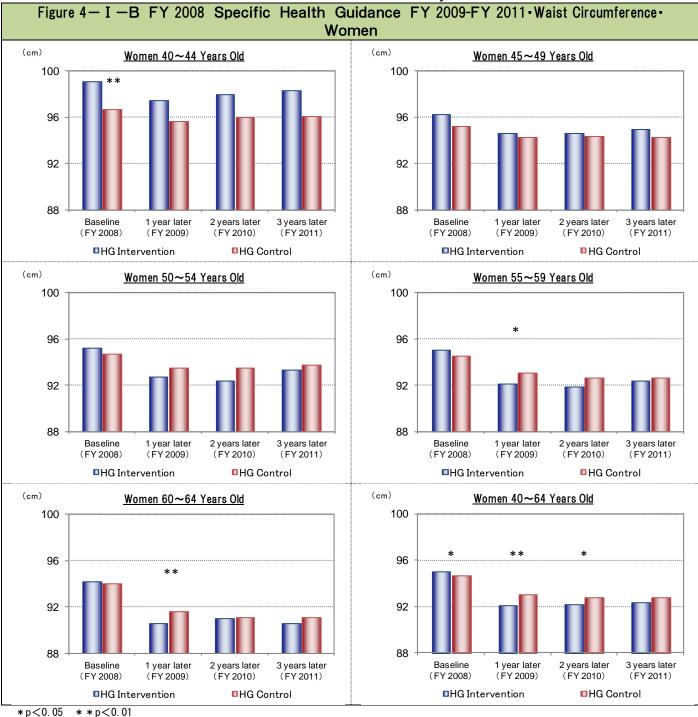
#### VIII. HDL Cholesterol (Page 115, Figures 4-VIII-A~D)

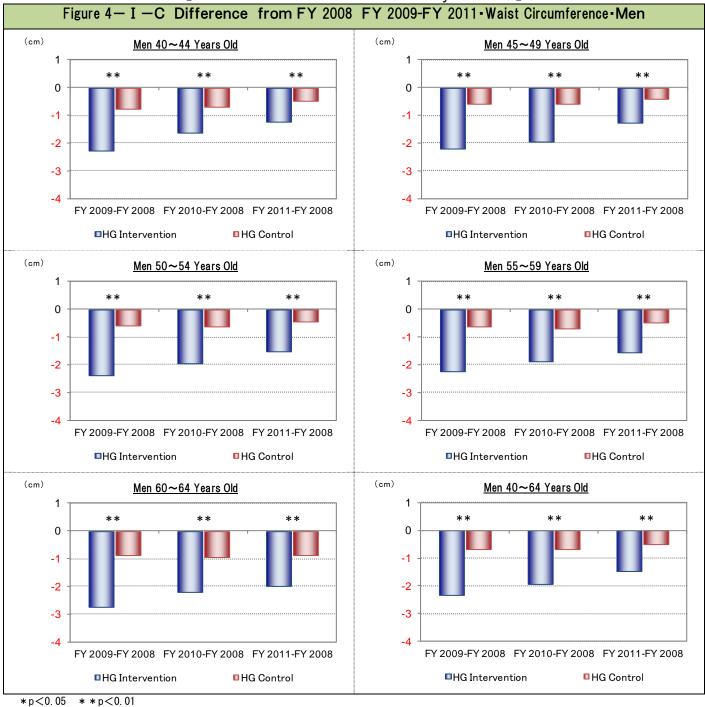
Among men, intervention groups overall (40 to 64 years of age) had significantly lower baseline HDL cholesterol, but by one year later their HDL cholesterol was higher than control groups overall. Similarly, in every age group, intervention groups had lower baseline HDL cholesterol, but in later years they tended to have generally higher (*i.e.* more favorable) HDL cholesterol. The increase from baseline was 1.93mg/dl by one year later, 2.10mg/dl by two years later, and 2.37mg/dl by three years later in intervention groups overall, indicating that they improved HDL cholesterol incrementally every year for three years. Control groups also tended to have increased HDL cholesterol in subsequent years, but the amounts of increase from baseline were smaller compared to intervention groups.

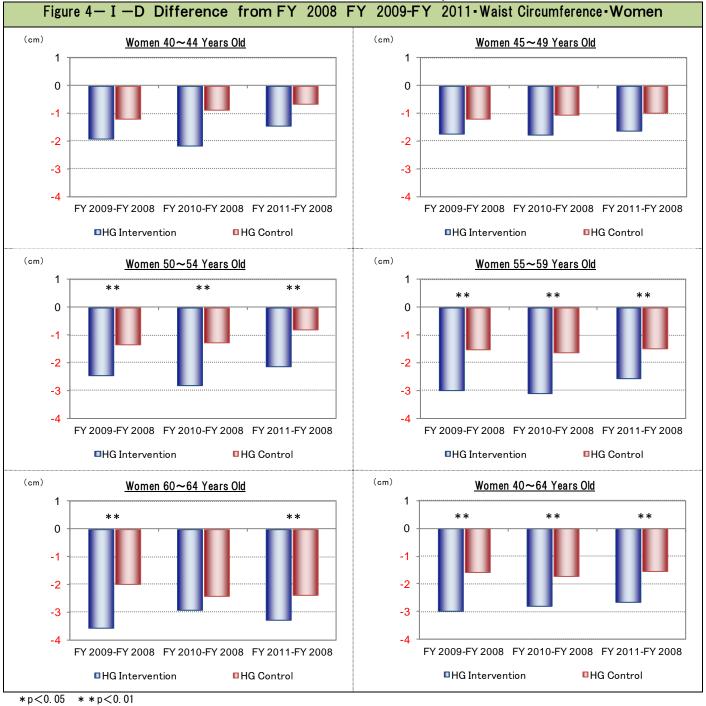
Among women, intervention groups overall also had significantly lower baseline HDL cholesterol, but in subsequent years their HDL cholesterol increased, and group differences disappeared. Similarly, in every age group, intervention groups had generally lower baseline HDL cholesterol but in later years they tended to have generally higher (*i.e.* more favorable) HDL cholesterol. The increase from baseline was 1.69mg/dl by one year later, 2.00mg/dl by two years later, and 2.33mg/dl by three years later in intervention groups overall, indicating that they improved HDL cholesterol incrementally every year for three years. Control groups also tended to have increased HDL cholesterol in subsequent years, but the amounts of increase from baseline were smaller compared with intervention groups.

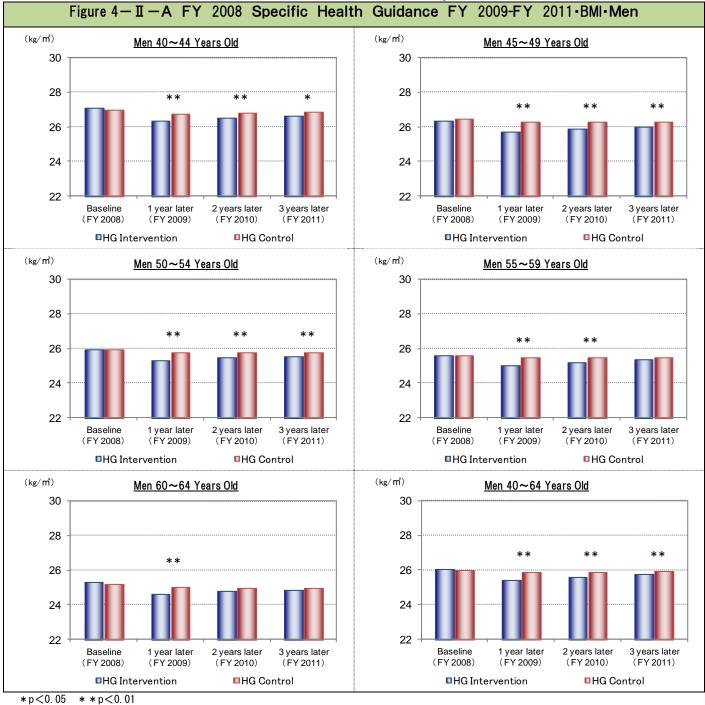
Figure 4. Longitudinal Analysis of Clinical Indicators Following Health Guidance [Intensive Health Guidance (40-64 years old)]

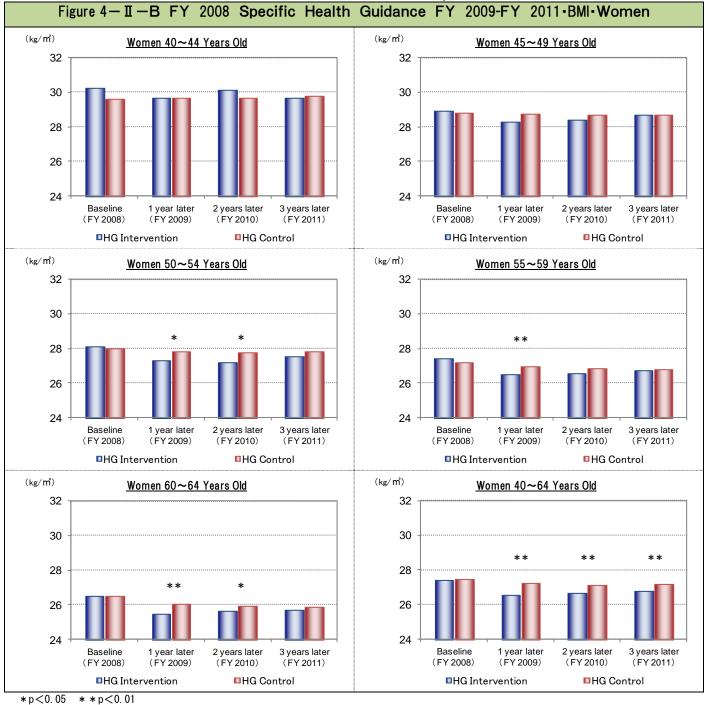


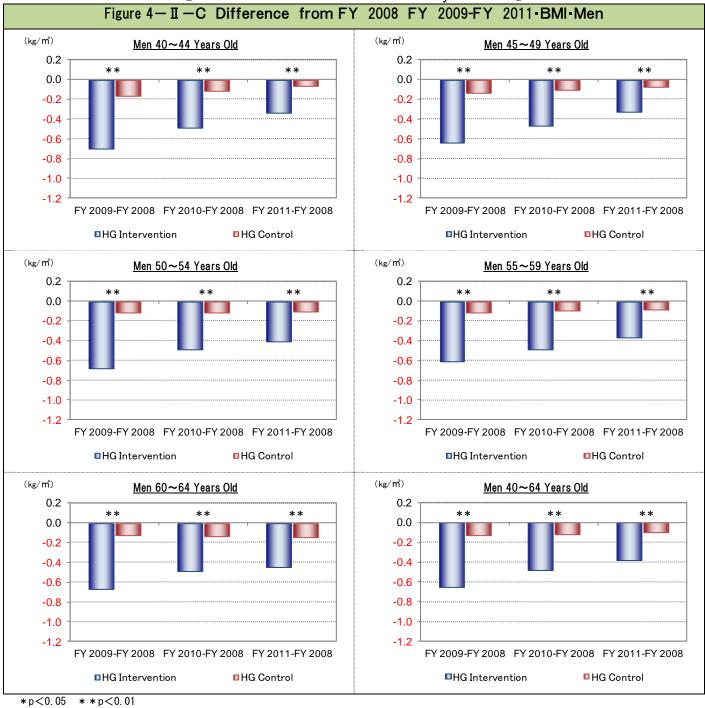


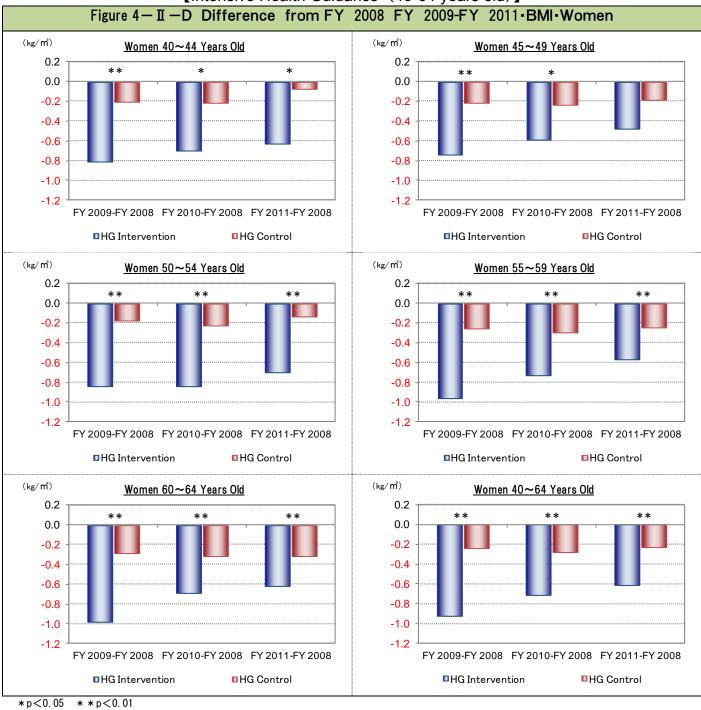


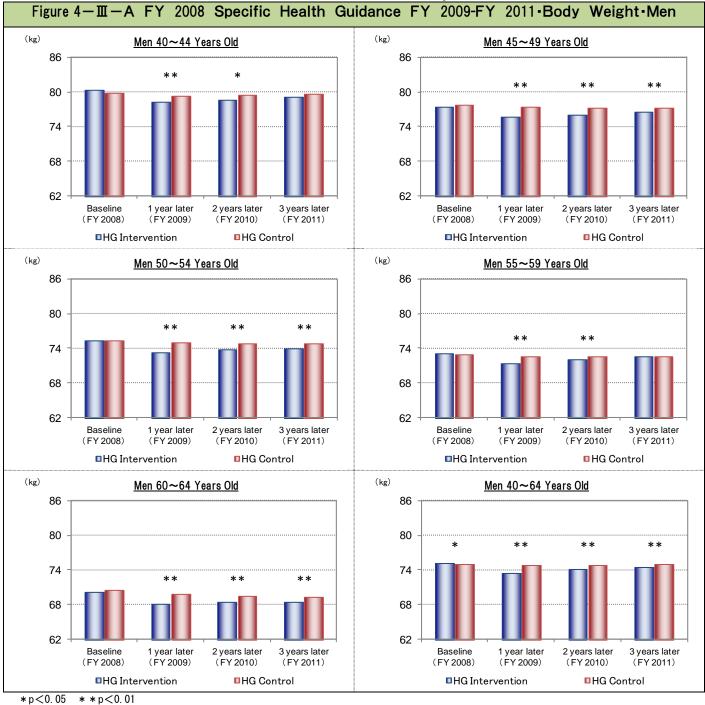


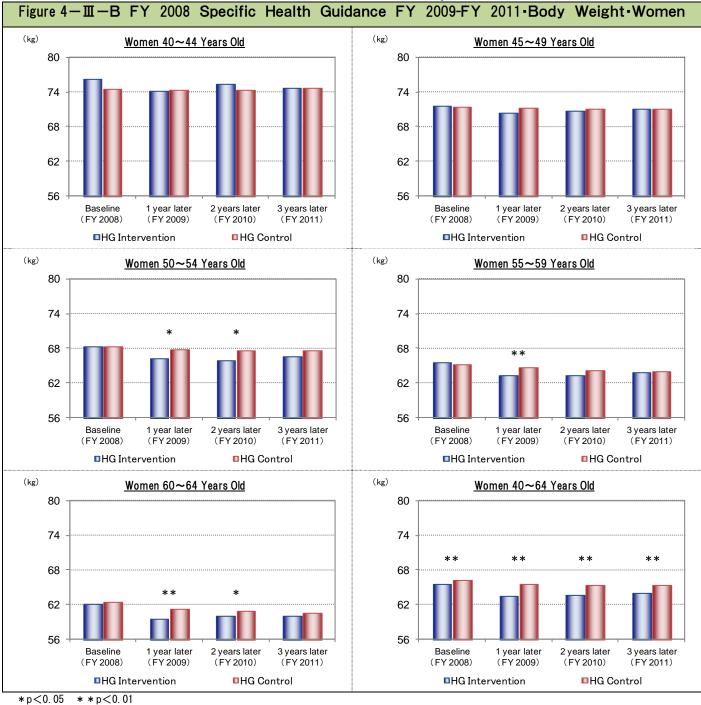


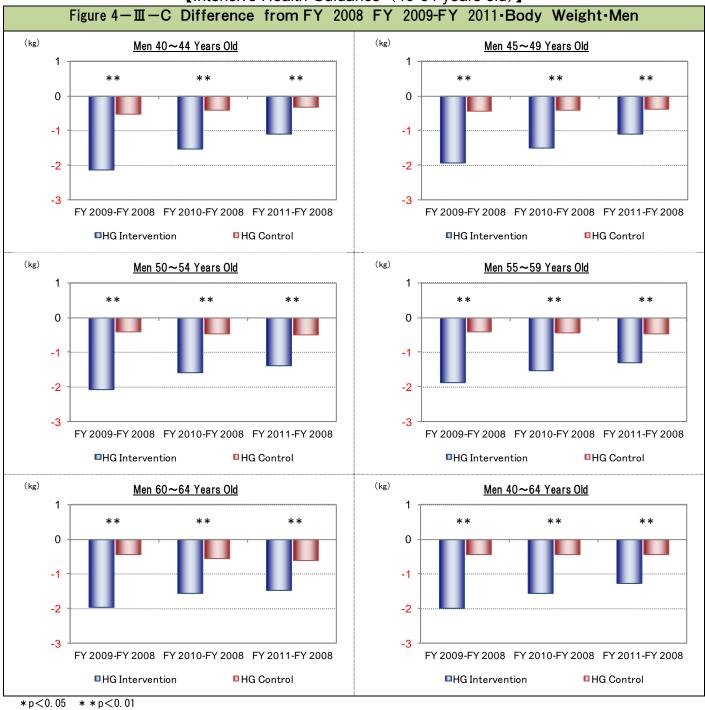


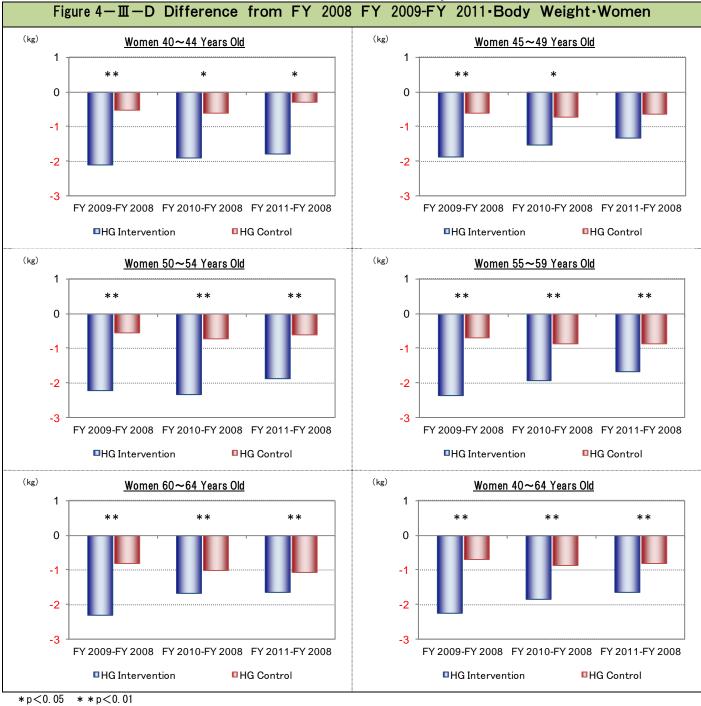


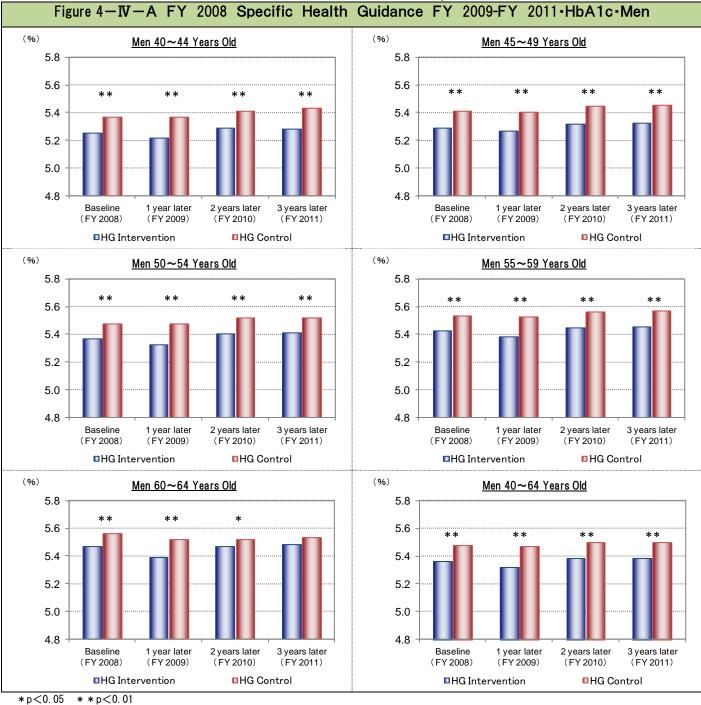


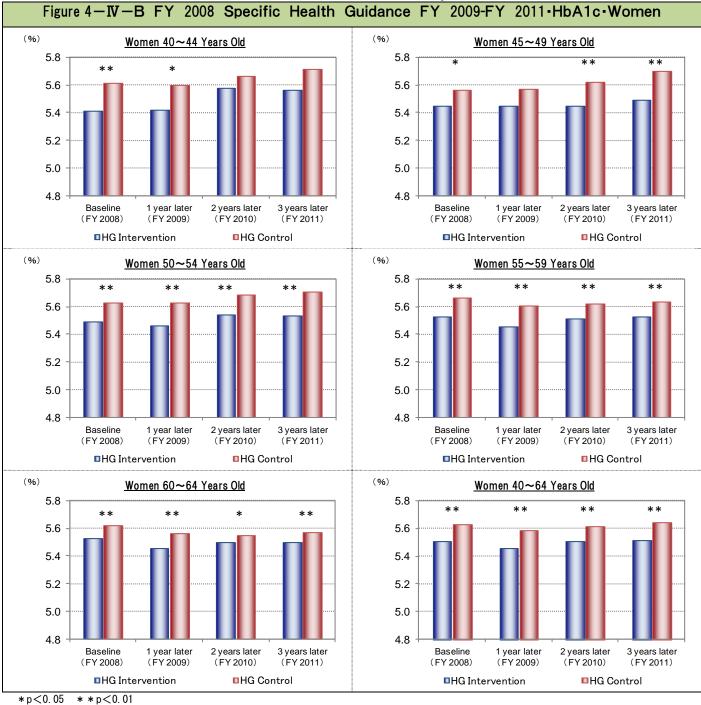


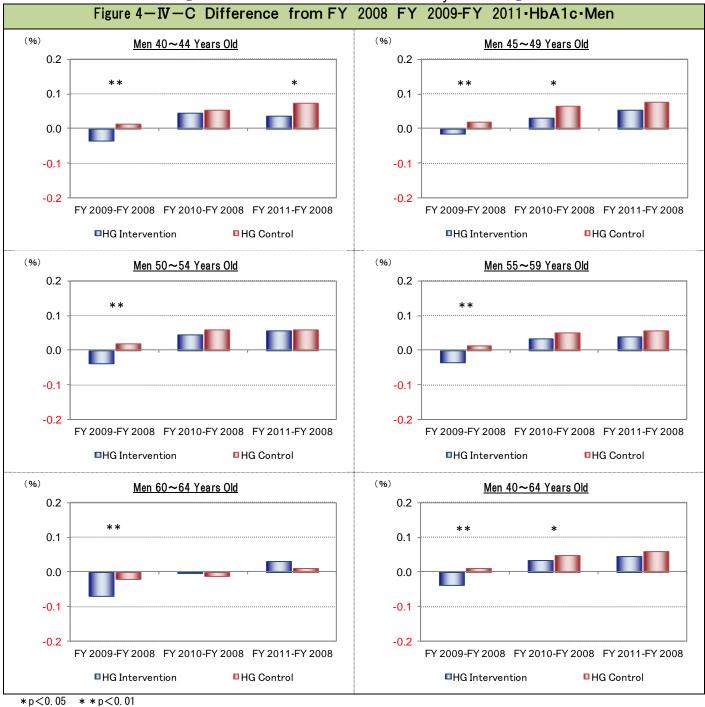


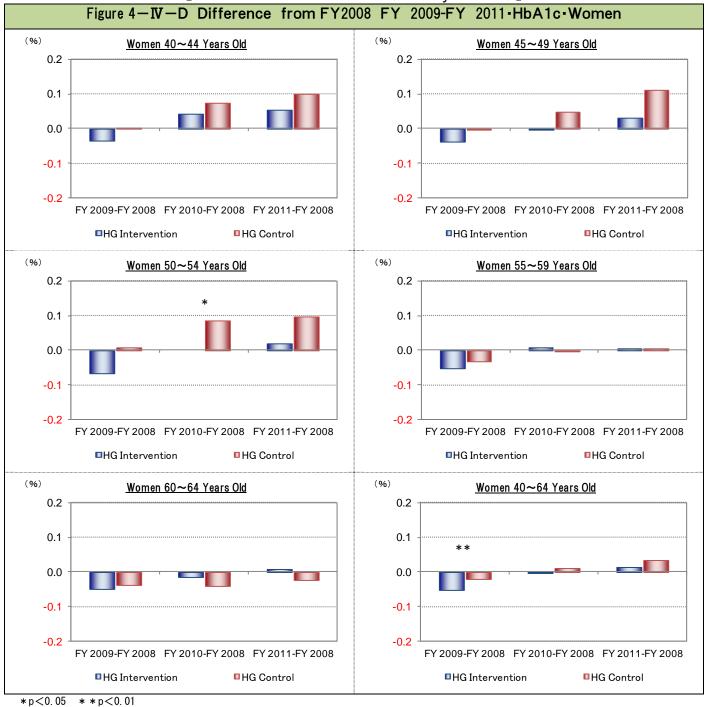


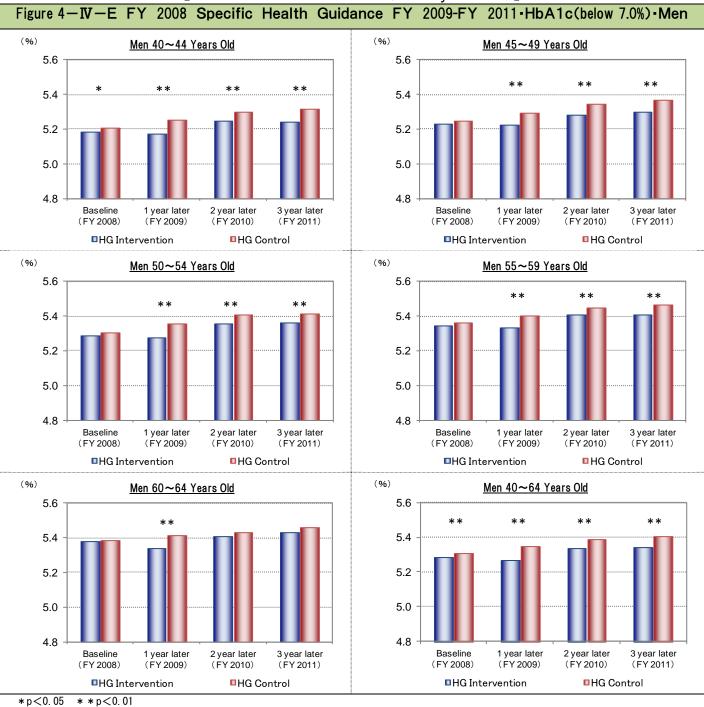


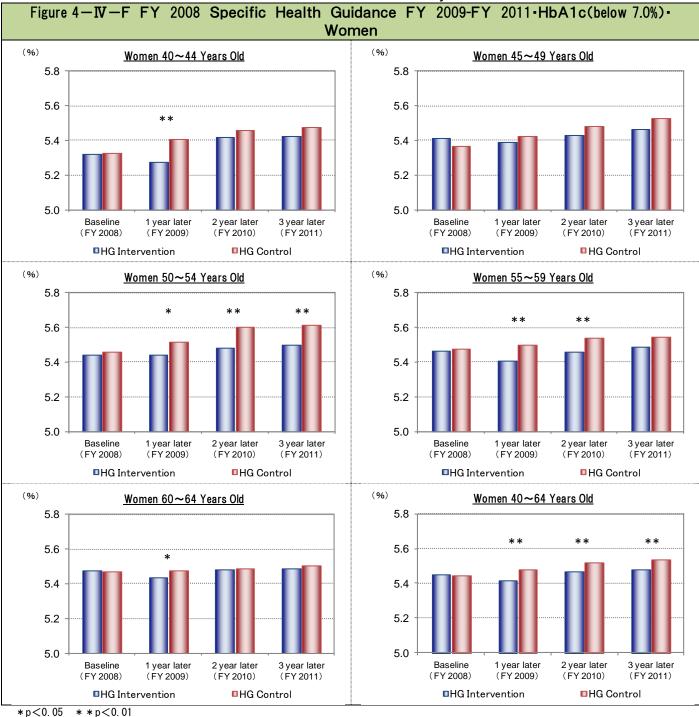


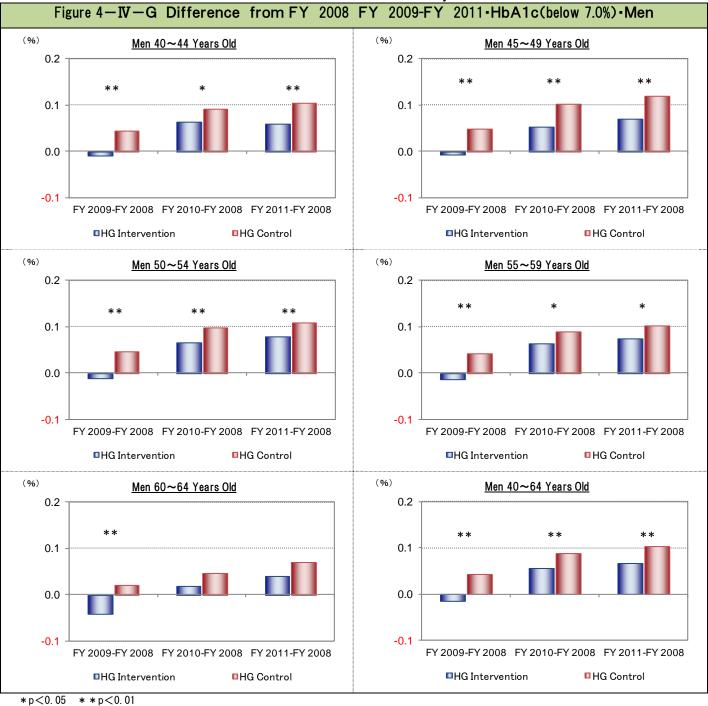


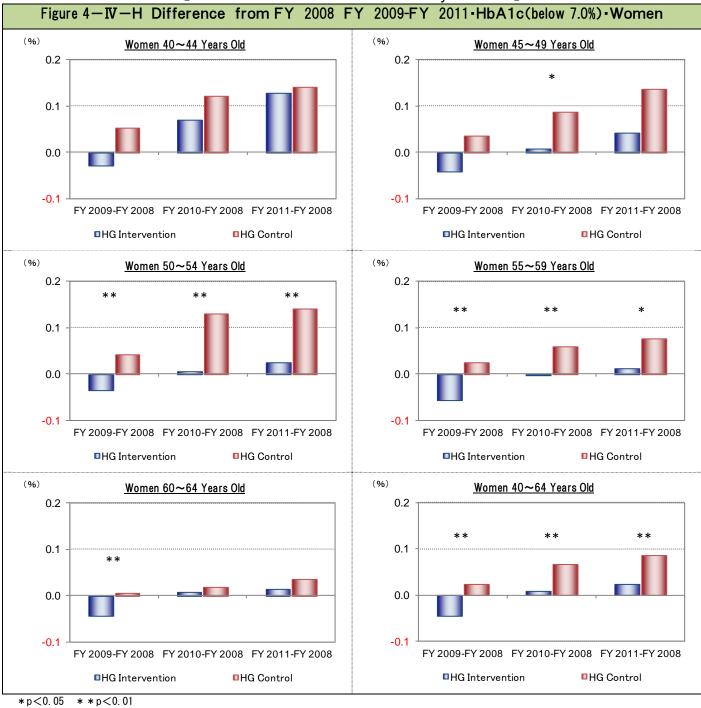


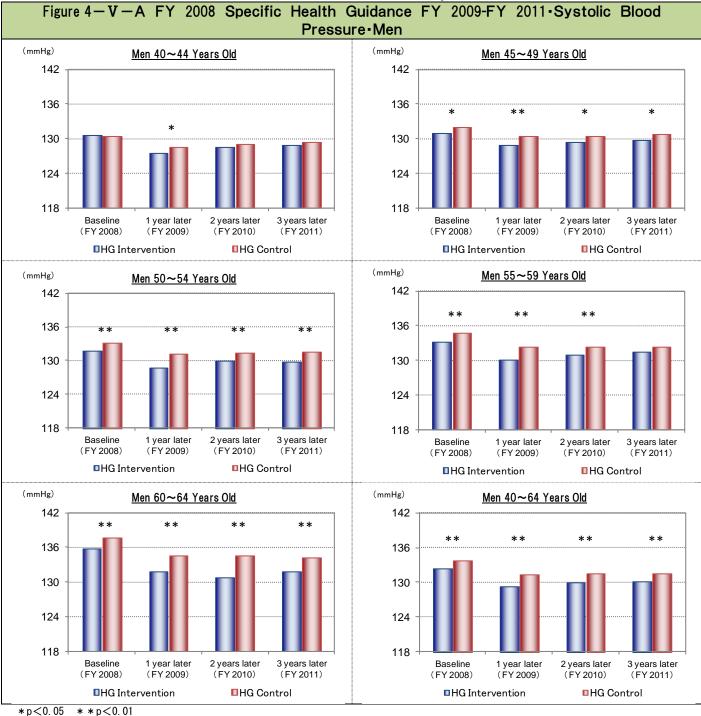


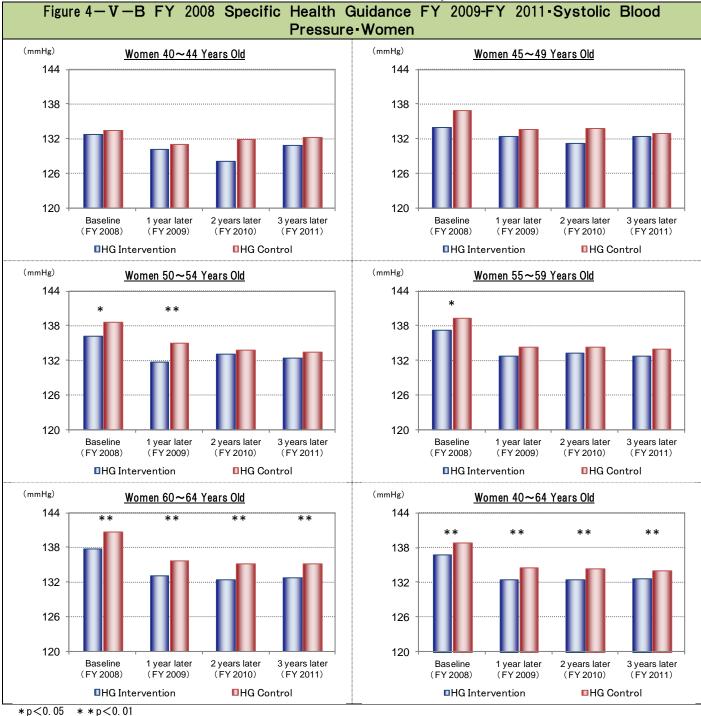


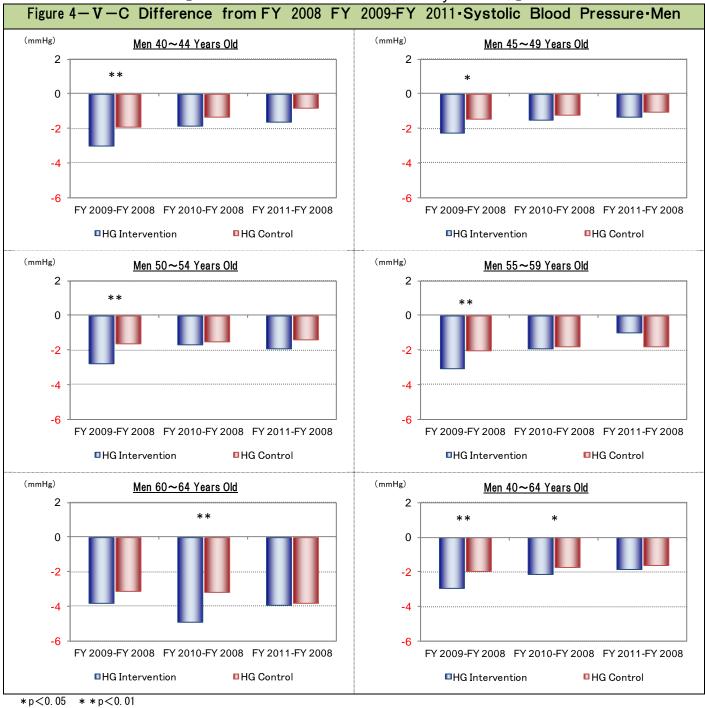


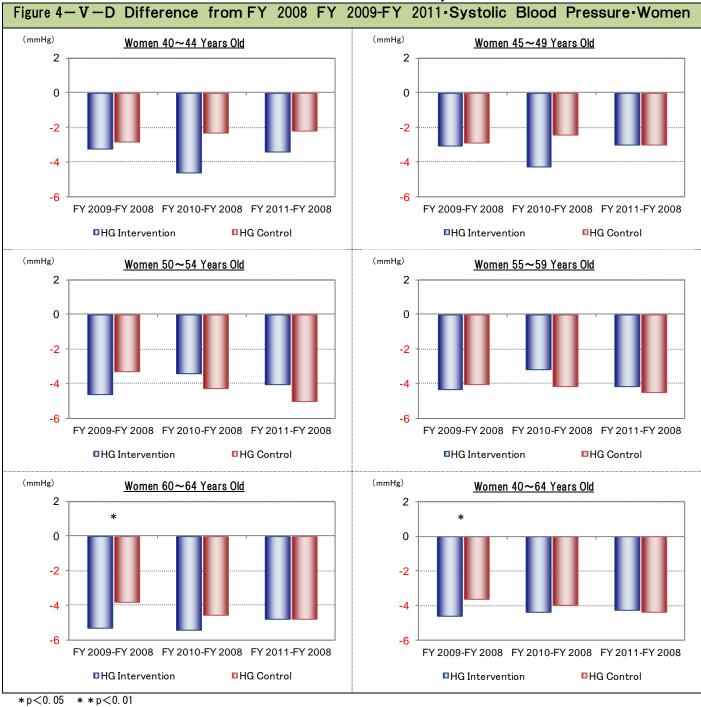


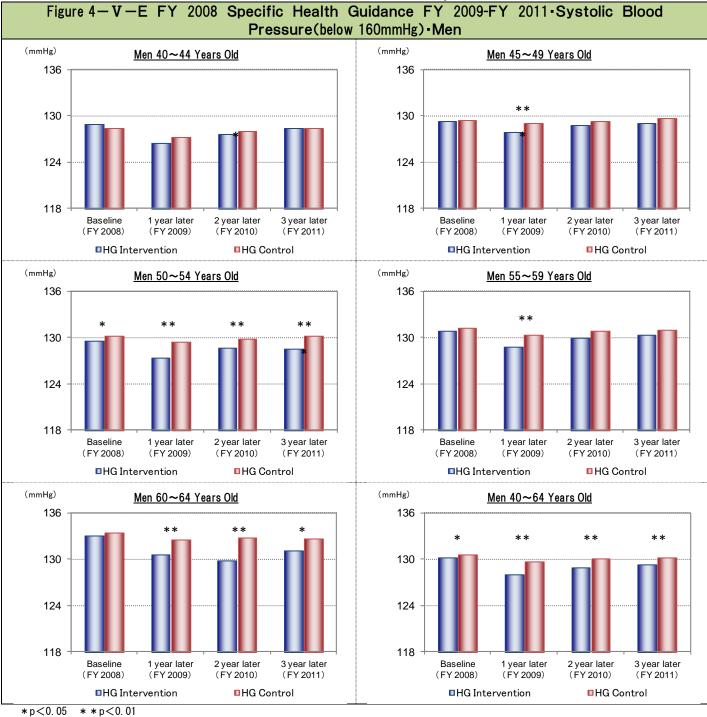


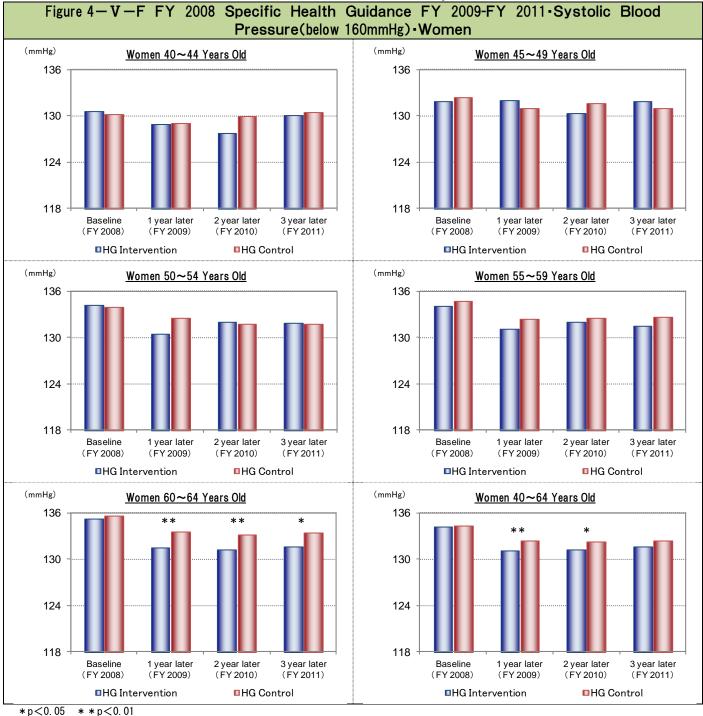


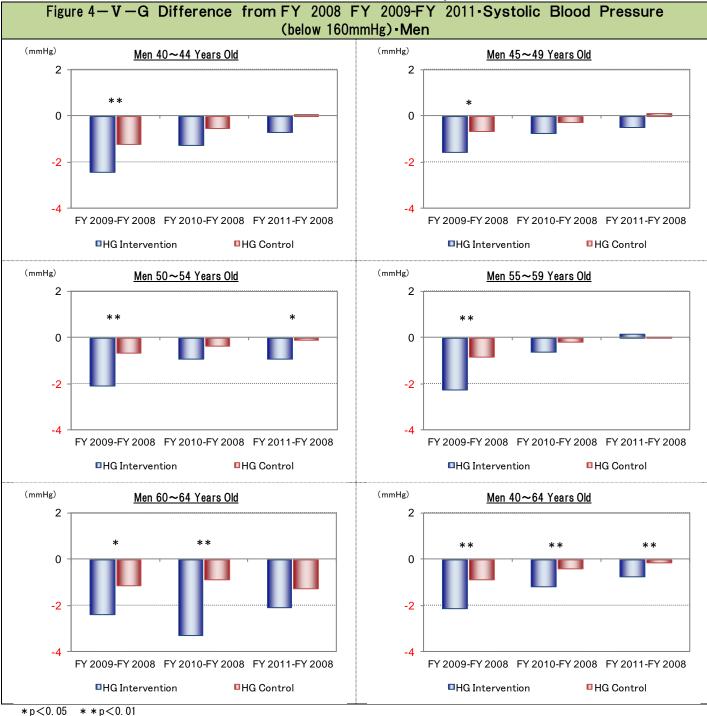


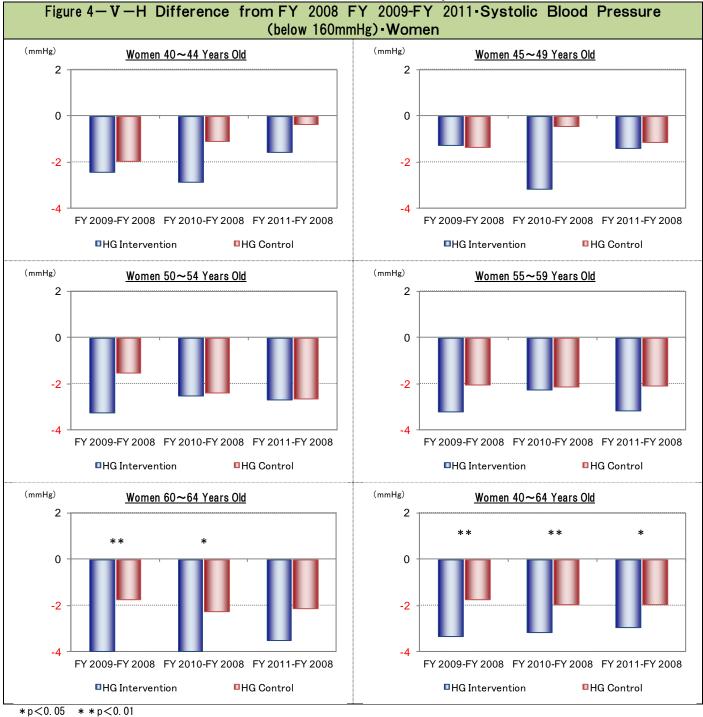


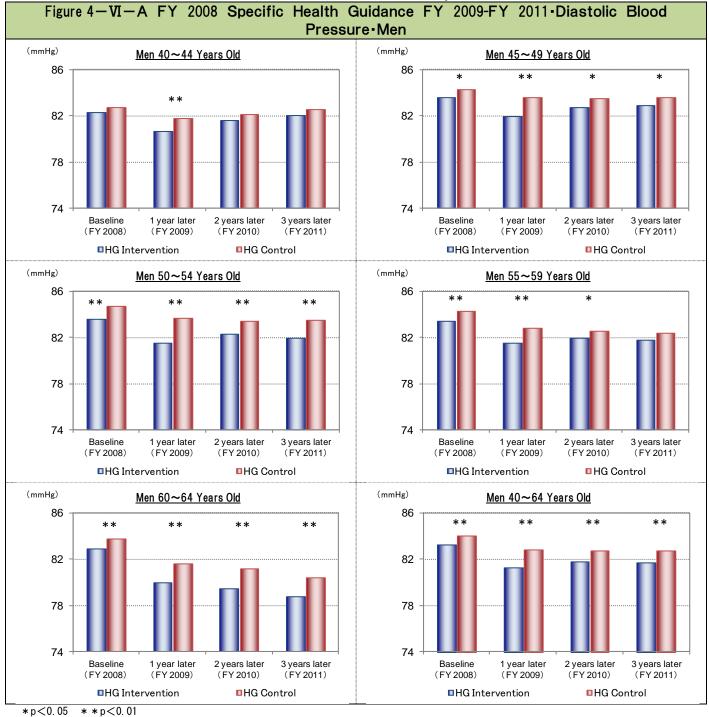


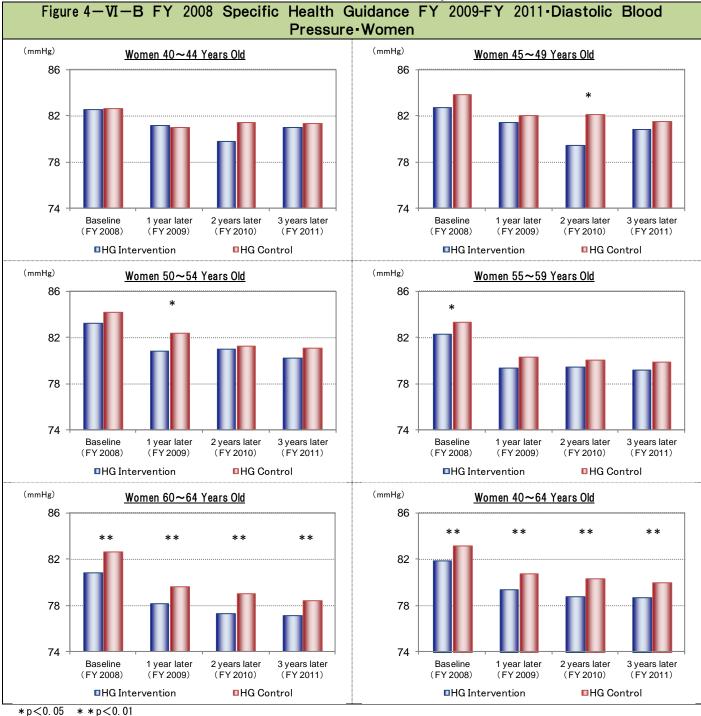


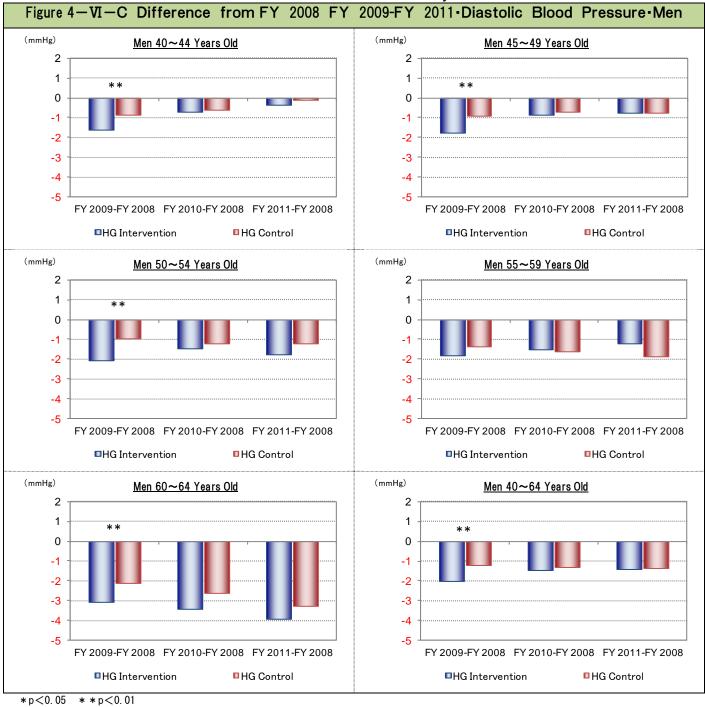


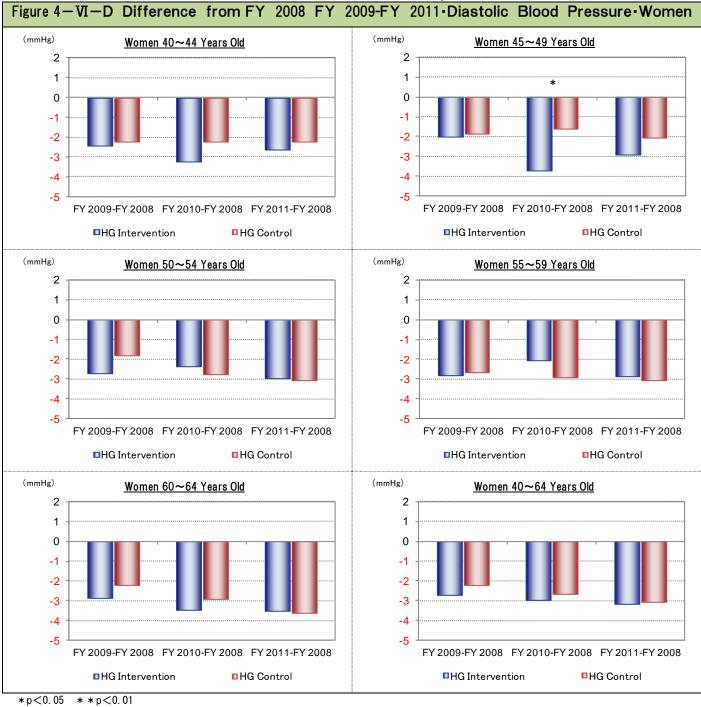


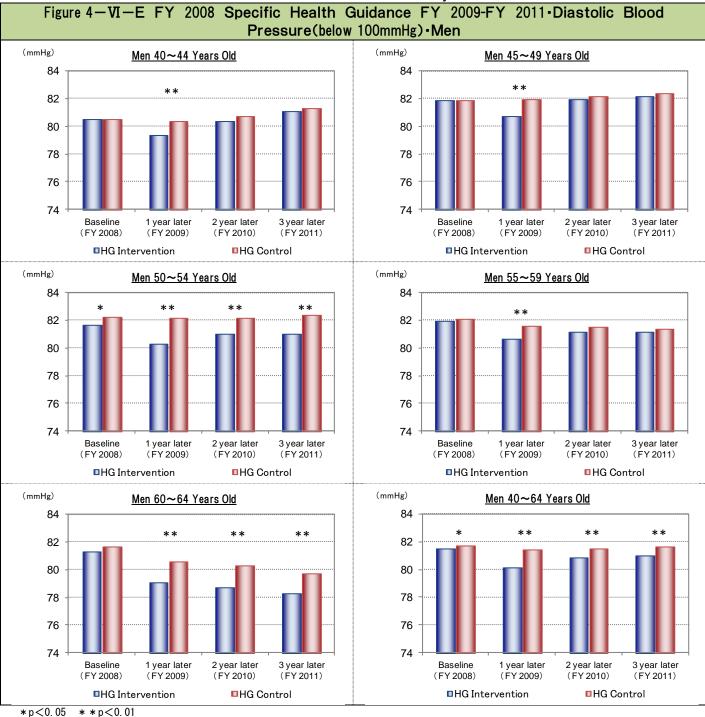


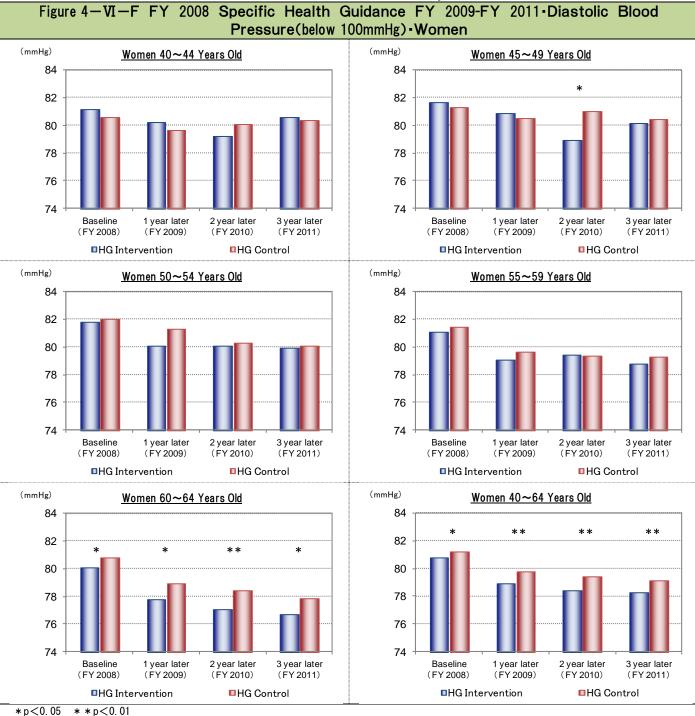


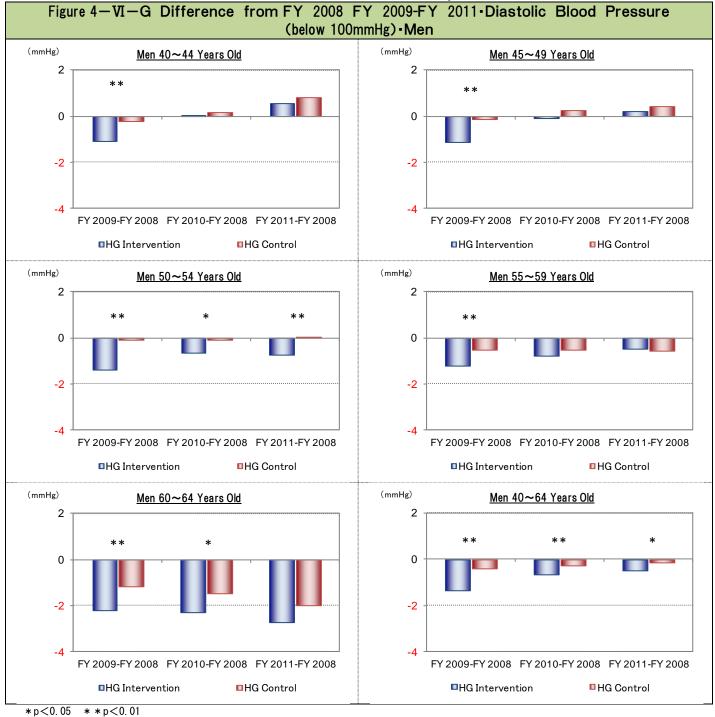


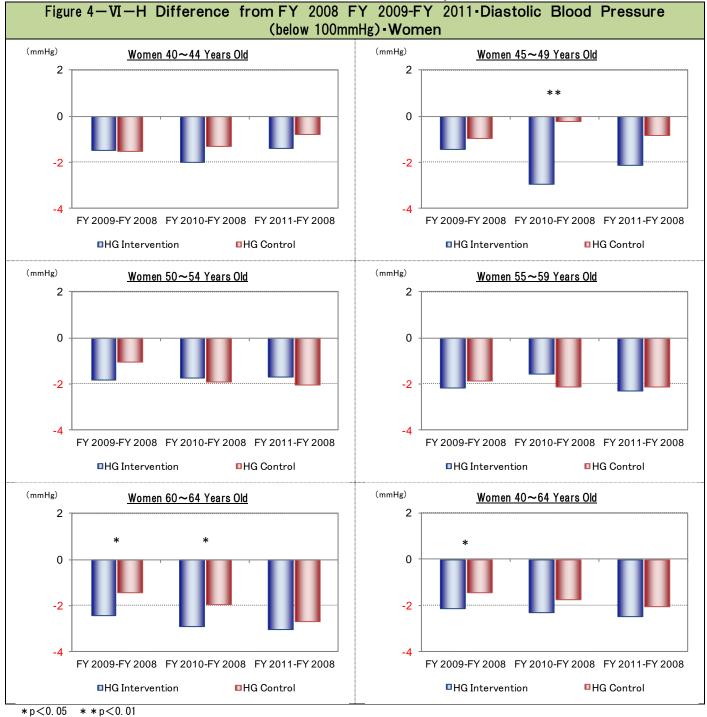


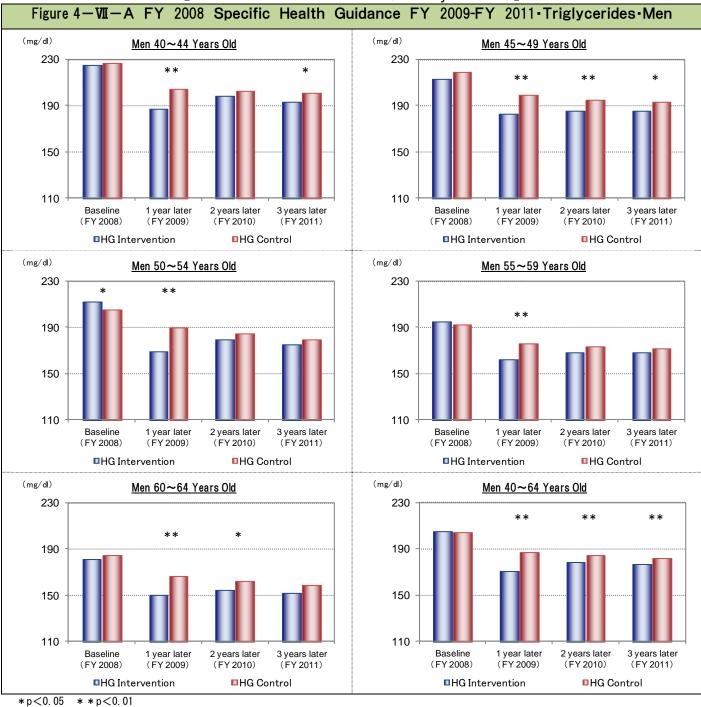


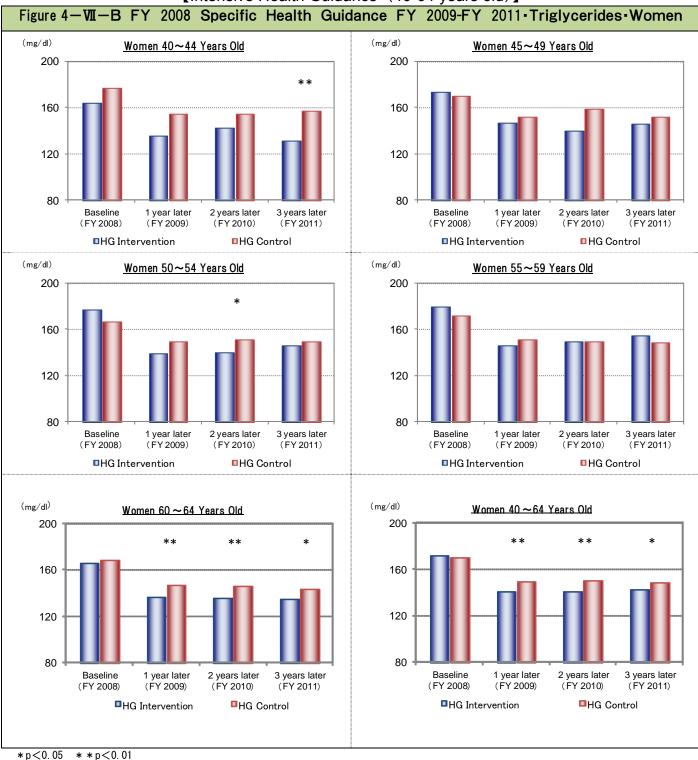


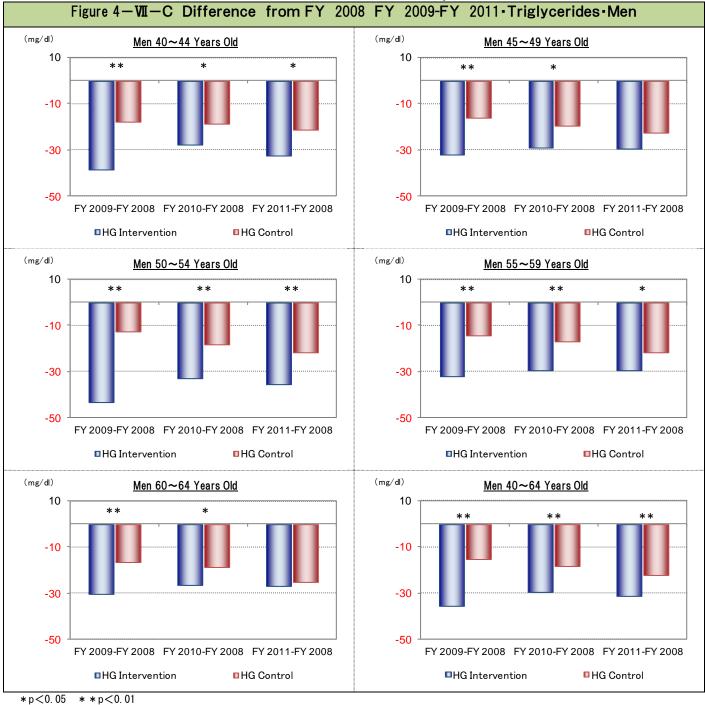


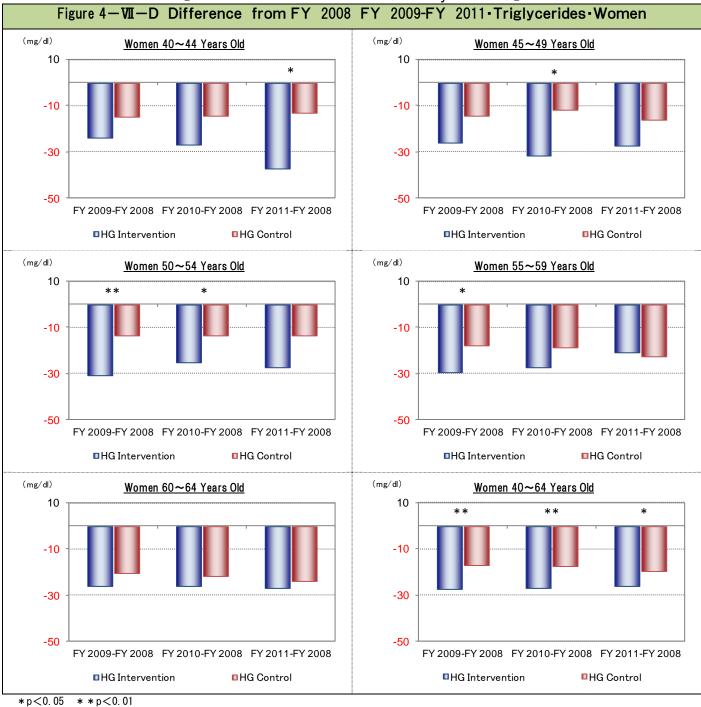


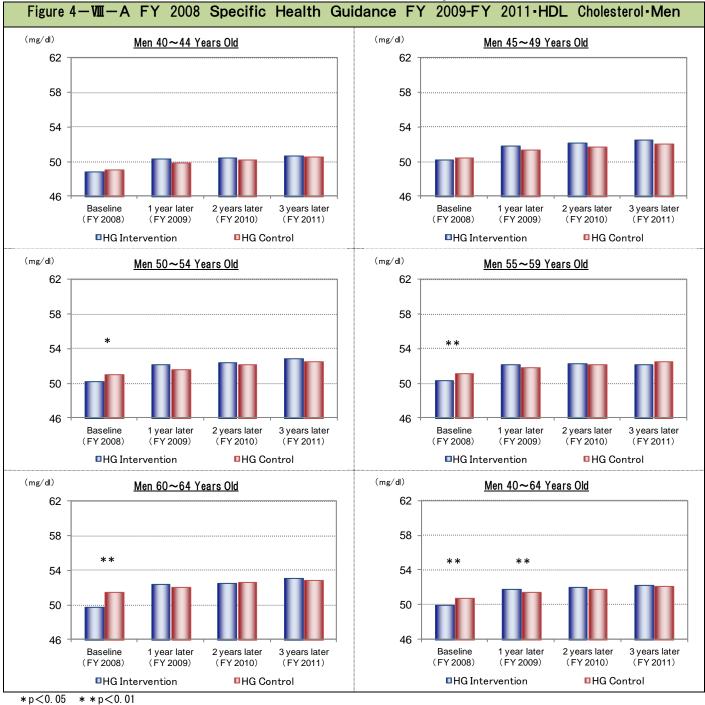


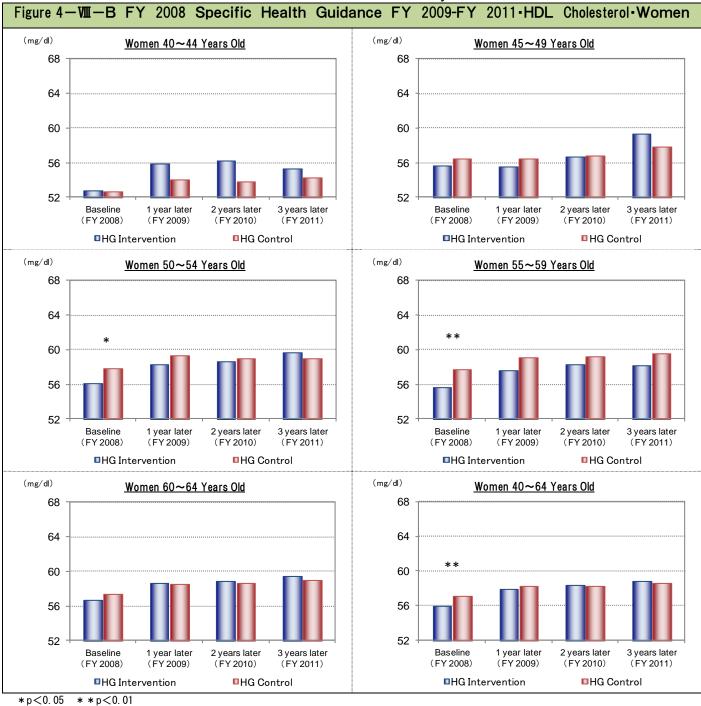


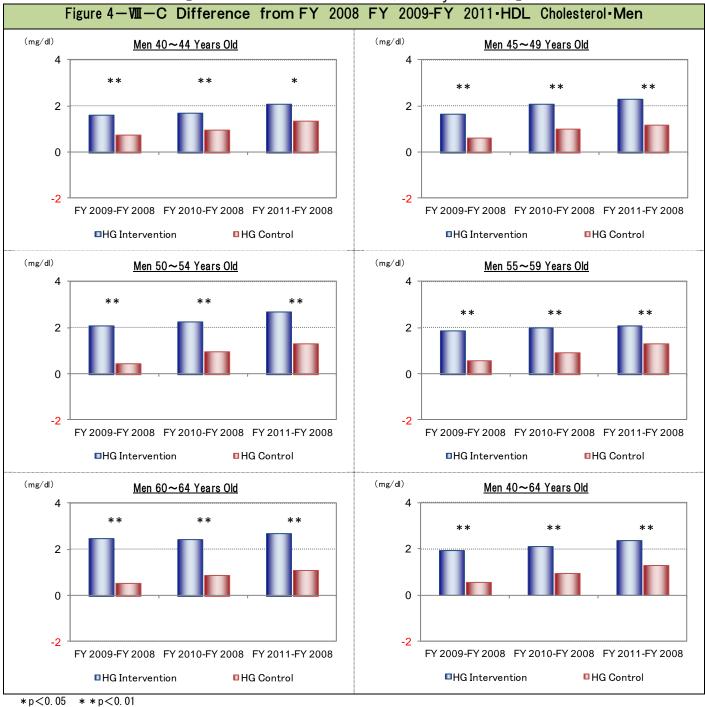


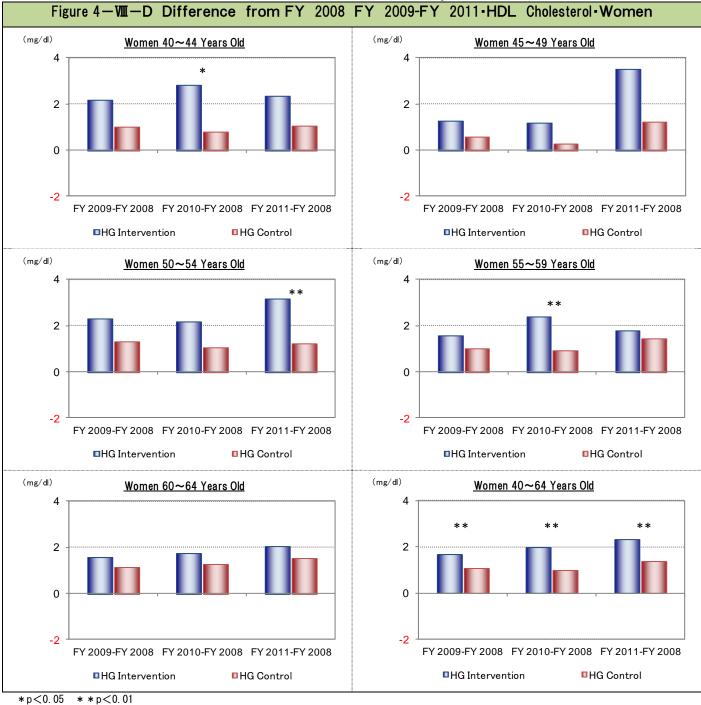












### b. Motivational Health Guidance (40 to 64 years of age)

#### I. Waist Circumference (Page 122, Figures 5-I-A~D)

Among men, intervention groups had significantly larger baseline waist measurements compared with control groups in the 40 to 49 age group and overall (40 to 64 years of age). However, intervention groups overall had significantly smaller waist measurements by one, two, and three years later. The reduction of waist measurement from baseline was 1.87cm by one year later, 1.73cm by two years later, and 1.54cm by three years later. The amounts of these waist measurement reductions were significantly greater compared with control groups overall (0.44cm, 0.49cm, and 0.31cm, respectively).

Among women, baseline waist measurements were significantly larger in intervention groups than in control groups in all age groups except the 40 to 44 age group and overall, but one year later nearly all control groups had larger waist measurements. The reduction of waist measurement from baseline was 1.70cm by one year later, 1.69cm by two years later, and 1.54cm by three years later in intervention groups overall. The amounts of these waist measurement reductions were significantly greater compared with control groups overall (0.54cm, 0.55cm, and 0.35cm, respectively).

In both men and women, the reductions of waist measurements were smaller compared with intensive HG intervention groups.

#### II. BMI (Page 126, Figures 5-II-A~D)

Among men, intervention groups overall (40 to 64 years of age) had significantly lower baseline BMI compared with control groups overall, and the difference in BMI tended to increase in subsequent years. Intervention groups had significantly lower BMI in the 55 to 59 and 60 to 64 groups by one, two and three years later.

Among women, intervention groups overall also had significantly lower baseline BMI compared with control groups overall, and the difference in BMI tended to increase in subsequent years as well.

#### III. Body Weight (Page 130, Figures 5-III-A~D)

Among men, intervention groups overall (40 to 64 years of age) had significantly lower baseline body weight compared with control groups overall, and the difference in body weight tended to increase in subsequent years. The reduction of body weight from baseline was 1.40kg by one year later, 1.21kg by two years later, and 1.09kg by three years later in intervention groups overall, indicating that they kept lower body weight for three years. Intervention groups had significantly greater reductions of body weight in all three years compared with control groups in the 55 to 59 and 60 to 64 age groups.

Among women, intervention groups overall also had significantly lower baseline body weight compared with control groups overall, and the difference in body weight tended to increase in subsequent years. The reduction of body weight from baseline was 1.53kg by one year later, 1.40kg by two years later, and 1.34kg by three years later in intervention groups overall. Intervention groups had significantly greater reductions of body weight in all age groups in all three years compared with control groups.

#### IV. HbA1c (in the JSD unit) (Page 134, Figures 5-IV-A~H)

Among men, there was no baseline HbA1c difference between intervention and control groups overall (40 to 64 years of age). HbA1c decreased 0.01% from baseline in one year later, but increased by 0.02% and 0.03% in two and three years later in intervention groups. In control groups, the increase of HbA1c from baseline was 0.02% in one year later, 0.06% in two years later, and 0.06% in three years

later. The amounts of HbA1c increases were significantly greater in control groups compared with intervention groups.

Among women, there was no baseline HbA1c difference between intervention groups and control groups overall. HbA1c decreased by 0.01% from baseline by one year later, but it increased by 0.01% by two years later and again by 0.01% by three years later in intervention groups overall. In control groups, HbA1c increased from baseline by 0.02% by the one year later, by 0.05% by two years later, and again by 0.05% by three years later. The amounts of the HbA1c increases were significantly greater in control groups compared with intervention groups.

In additional analyses with subjects whose baseline HbA1c was below 7%, the amounts of HbA1c increases were significantly greater in control groups compared with intervention groups.

#### V. Systolic Blood Pressure (Page 142, Figures 5-V-A~H)

Among men, there was no significant baseline systolic blood pressure difference between intervention and control groups overall (40 to 64 years of age), but in the 45 to 49 age group, the control group had significantly higher baseline systolic blood pressure. In intervention groups, systolic blood pressure decreased below baseline in subsequent years, but in control groups, systolic blood pressure tended to increase after two years.

Among women, there was also no significant baseline systolic blood pressure difference between intervention and control groups overall, but in the 60 to 64 age group, the control group had significantly higher baseline systolic blood pressure. In subsequent years, there were no significant differences in systolic blood pressure between intervention and control groups overall. In both groups, systolic blood pressure decreased by one year later and tended to slightly increase by two years later, but even by three years later it was still below baseline.

In additional analyses with subjects whose baseline systolic blood pressure was below 160mmHg, it was found that among men, intervention groups had significantly lower systolic blood pressure compared with control groups, and among women, intervention groups had significantly greater reductions of systolic blood pressure from baseline compared with control groups.

#### VI. Diastolic Blood Pressure (Page 150, Figures 5-VI-A~H)

Among men, baseline diastolic blood pressure was significantly higher in intervention groups than in control groups in the 40 to 49 age group, 60 to 64 age group, and overall (40 to 64 years of age). In subsequent years, control groups had higher diastolic blood pressure compared with intervention groups. In intervention groups overall, diastolic blood pressure decreased by 0.69mmHg by one year later, 0.44mmHg by two years later, and 0.90mmHg by three years later. In control groups overall, there was no change in diastolic blood pressure by one year later, but it increased by 0.03mmHg by two years later and by 0.15mmHg by three years later.

Among women, baseline diastolic blood pressure was significantly higher in control groups than intervention groups in the 60 to 64 age group and overall. In subsequent years, control groups generally had higher diastolic blood pressure.

Because baseline diastolic blood pressure was significantly different between intervention and control groups, additional analyses were performed with subjects whose baseline diastolic blood pressure was below 100mmHg. Baseline differences among groups were diminished in both men and women. Among men, diastolic blood pressure decreased from baseline by 0.21mmHg by one year later, 0.04mmHg by two years later, and 0.48mmHg by three years later in intervention groups overall. In

contrast, intervention groups overall incrementally increased diastolic blood pressure from baseline by 0.45mmHg by one year later, 0.57mmHg by two years later, and 0.77mmHg by three years later.

Among women, intervention groups tended to decrease diastolic blood pressure from baseline, and control groups increased diastolic blood pressure by three years later, but group differences were not statistically significant.

### **VII. Triglycerides** (Page 158, Figures 5-VII-A~D)

Among men, there were no significant baseline triglyceride differences between intervention and control groups overall (40 to 64 years of age). In subsequent years, intervention groups overall had significantly lower triglycerides compared with control groups overall. In subsequent years, triglycerides decreased from baseline by 7.77mg/dl by one year later, 11.33mg/dl by two years later, and 8.79mg/dl by three years later in intervention groups overall. Intervention groups steadily kept a lower triglyceride level for three years, but the amounts of decrease were smaller compared with intensive intervention groups. Control groups slightly increased triglycerides by 0.78mg/dl by one year later, then decreased them by 0.70mg/dl by two years later and 1.87 mg/dl by three years later.

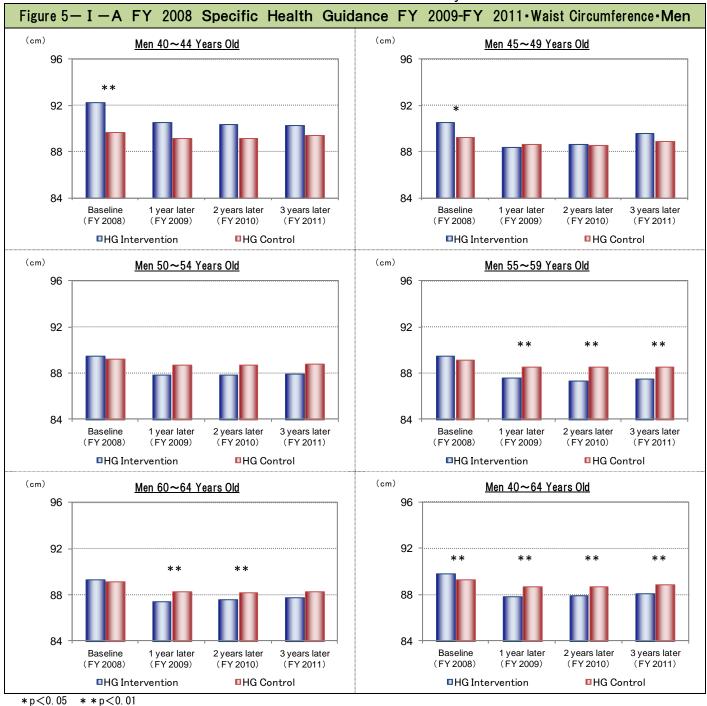
Among women, there were also no significant baseline triglyceride differences between intervention and control groups overall, but in subsequent years, intervention groups had significantly lower triglycerides than control groups. Among intervention groups overall, the reduction of triglycerides from baseline was 7.03mg/dl by one year later, 6.41mg/dl by two years later, and 6.46mg/dl by three years later. These reductions were significantly greater compared with control groups overall, but the amounts of decrease were smaller compared with intensive intervention groups.

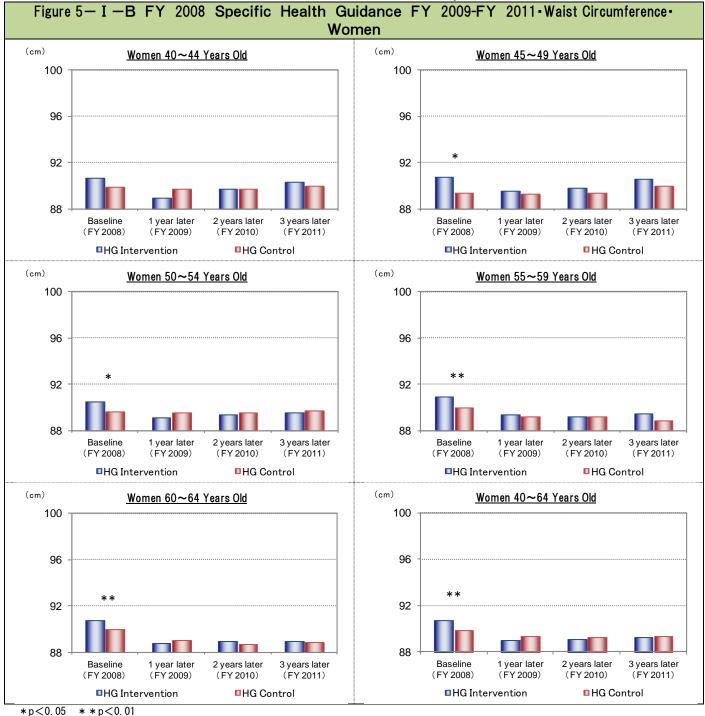
#### VIII. HDL Cholesterol (Page 162, Figures 5-VIII-A~D)

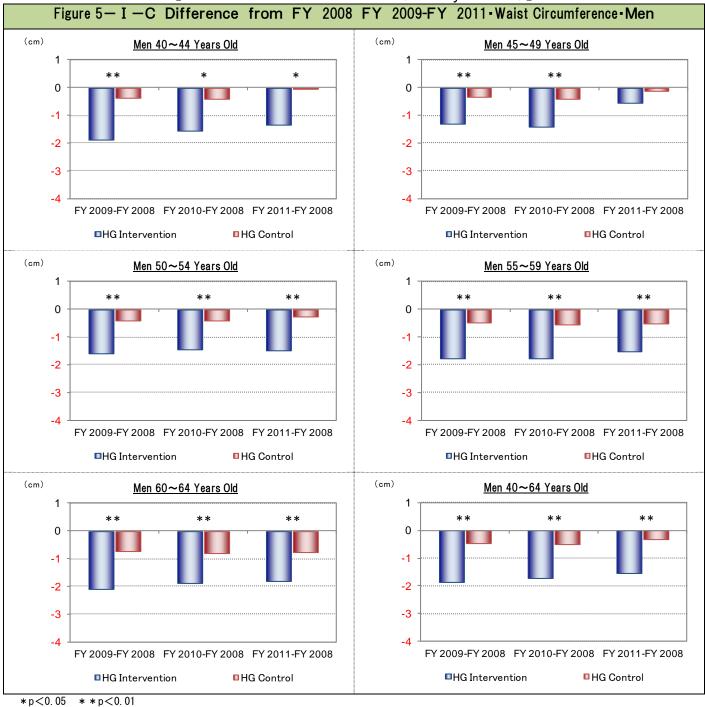
Among men, there were no significant HDL cholesterol differences between intervention and control groups overall (40 to 64 years of age) at baseline and in all subsequent years. Intervention groups overall increased HDL cholesterol from baseline by 0.97mg/dl by one year later, 1.23mg/dl by two years later, and 1.21mg/dl by three years later. Control groups overall also increased HDL cholesterol from baseline by 0.18mg/dl by one year later, 0.38mg/dl by two years later, and 0.66mg/dl by three years later. The amounts of the increases in HDL cholesterol from baseline were significantly greater in intervention groups than in control groups in all years.

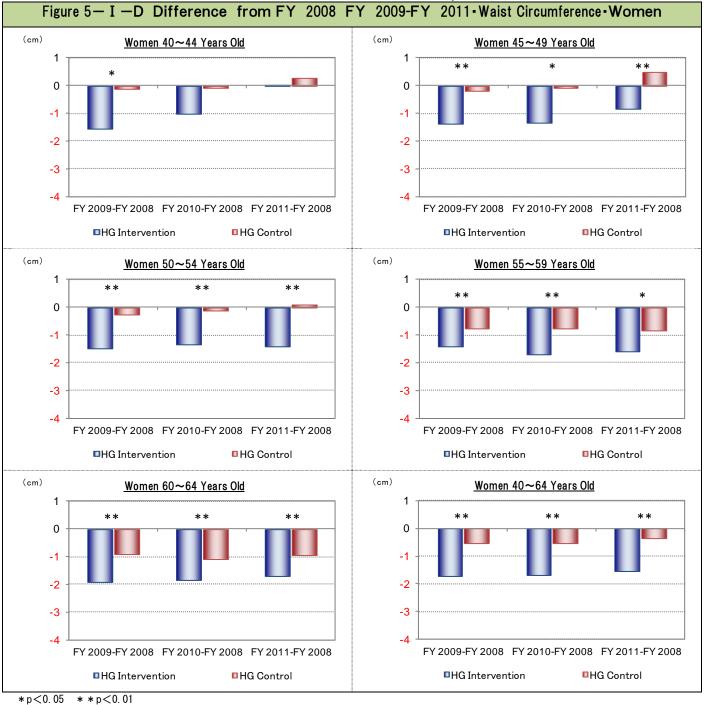
Among women, intervention groups had significantly lower baseline HDL cholesterol than control groups in the 60 to 64 age group and overall, but in subsequent years there were no group differences at all. Intervention groups overall increased HDL cholesterol from baseline by 0.98mg/dl by one year later, again by 0.98mg/dl by two years later, and by 1.33mg/dl by three years later. Control groups overall also increased HDL cholesterol from baseline by 0.24mg/dl by one year later, 0.38mg/dl by two years later, and 0.70mg/dl by three years later. The amounts of the increases in HDL cholesterol from baseline were significantly greater in intervention groups than in control groups in all years.

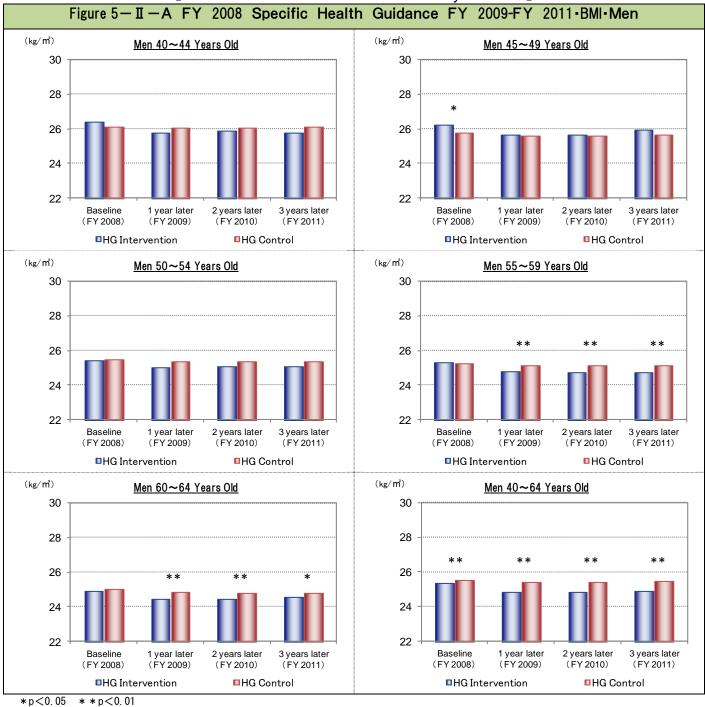
Figure 5. Longitudinal Analysis of Clinical Indicators Following Health Guidance [Motivational Health Guidance (40-64 years old)]

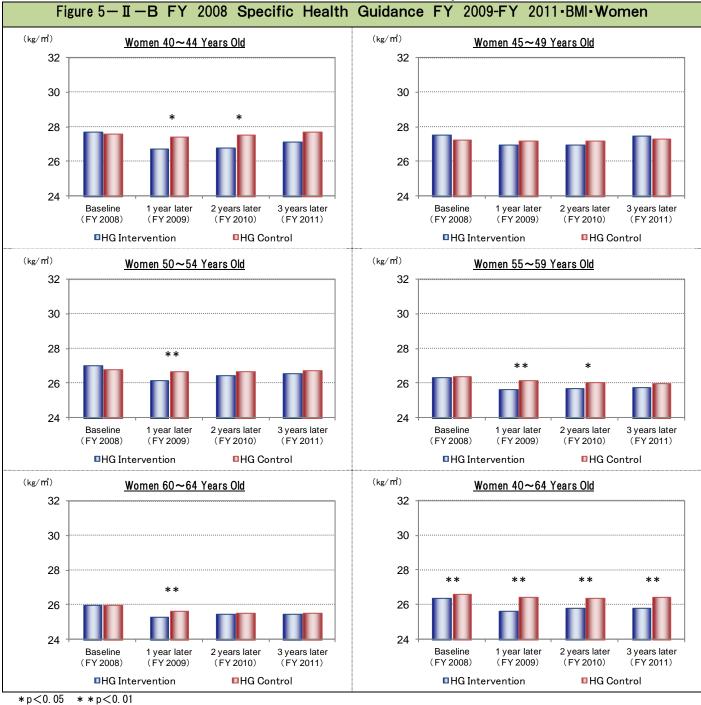


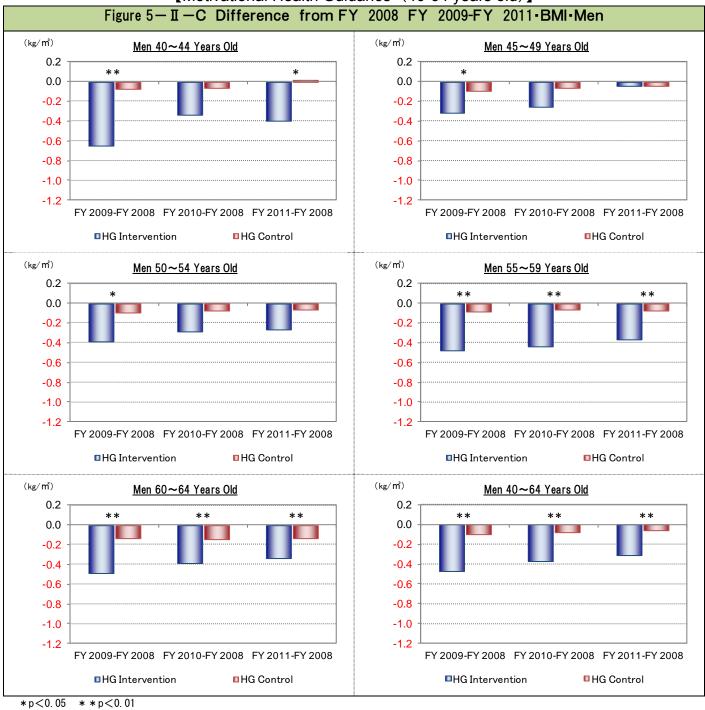


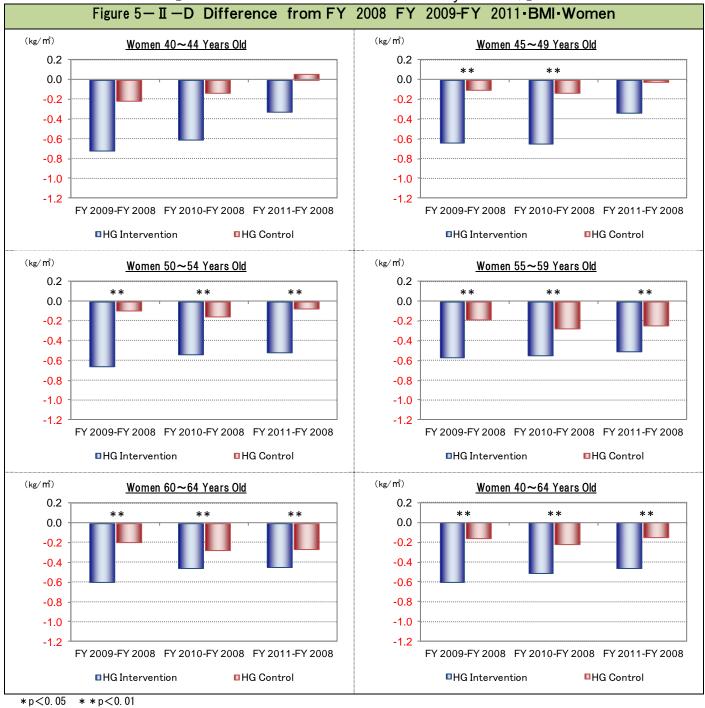


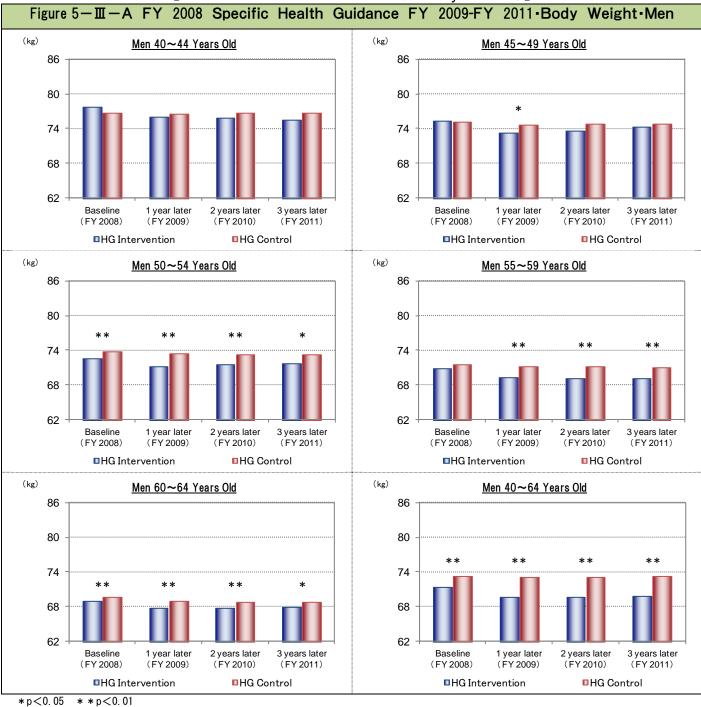


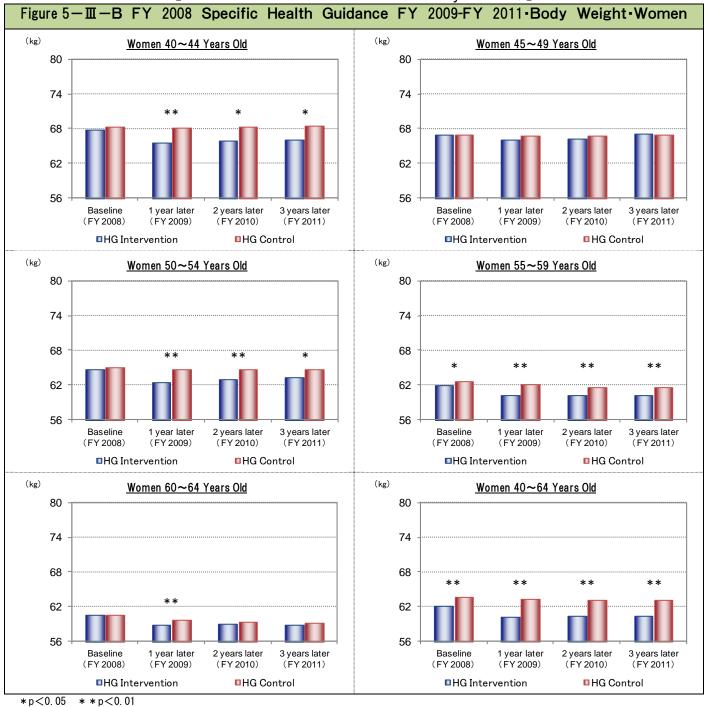


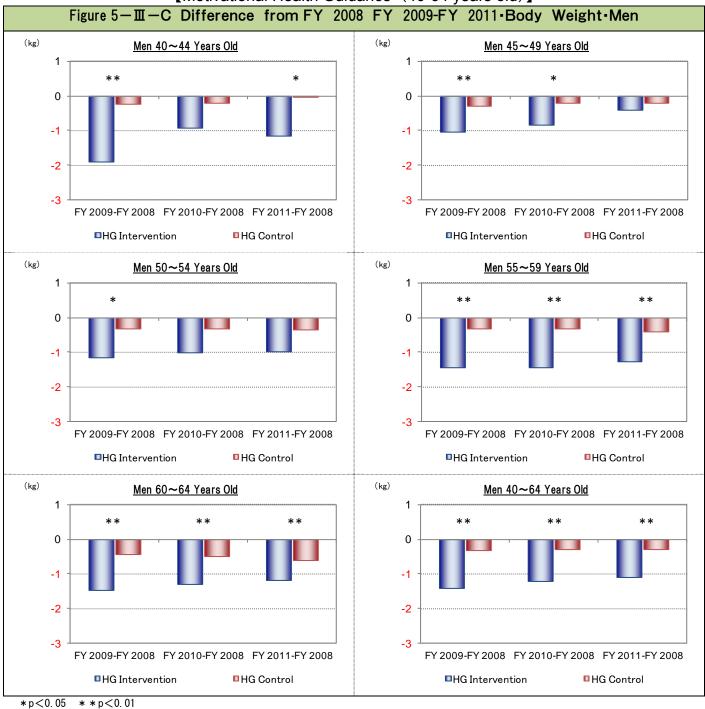


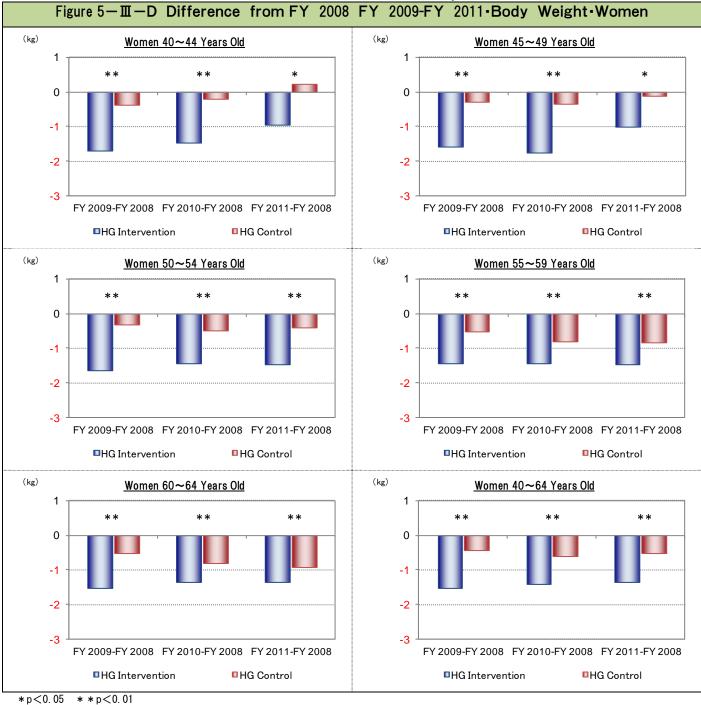


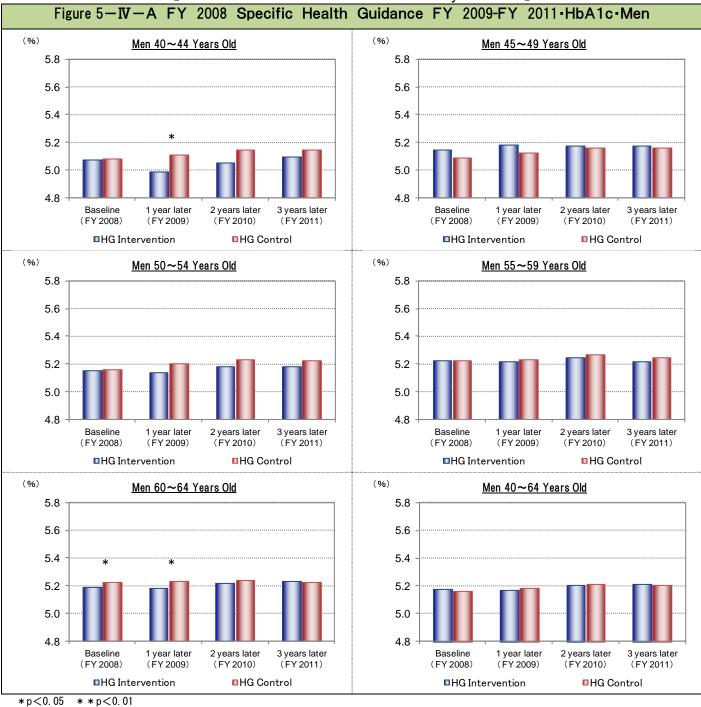


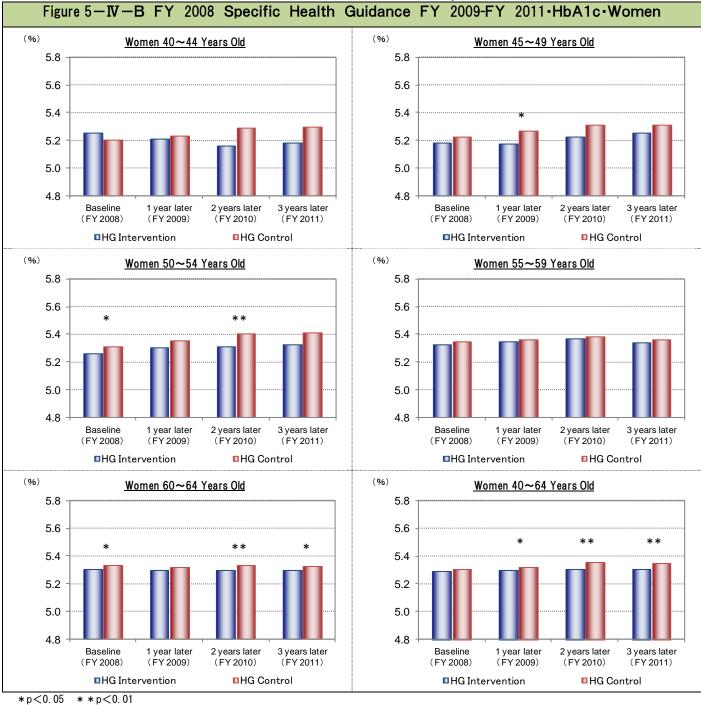


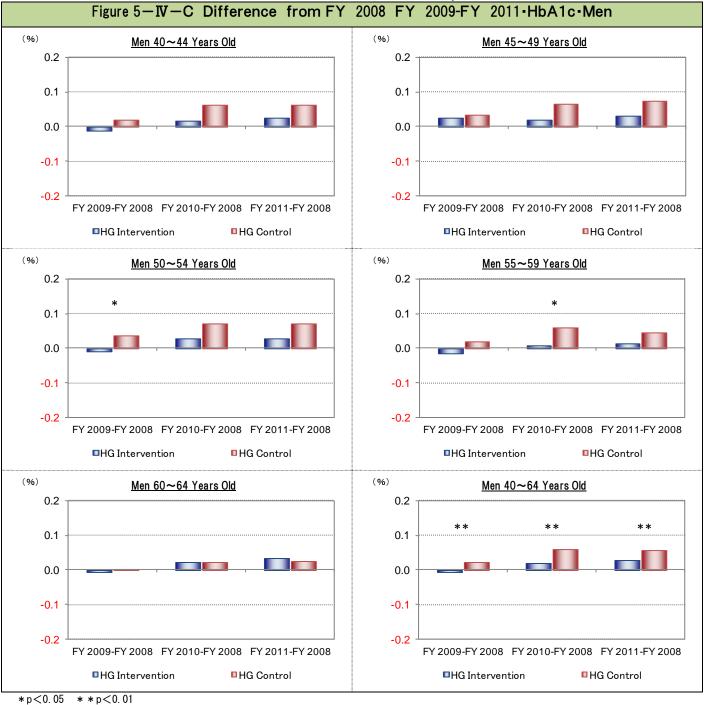


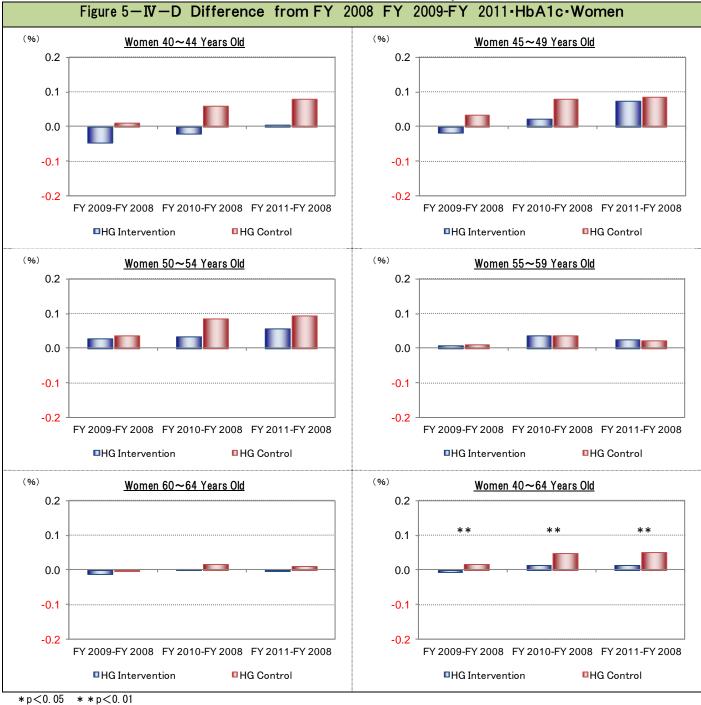


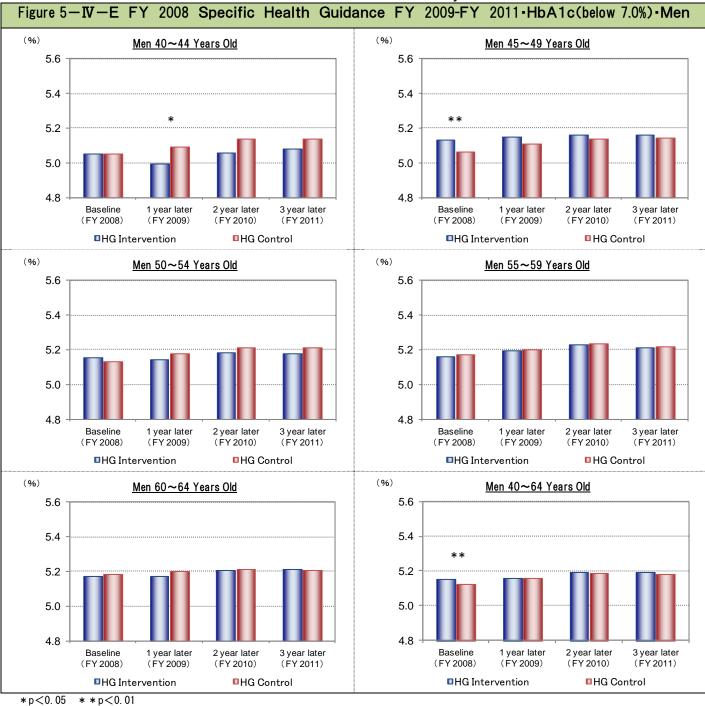


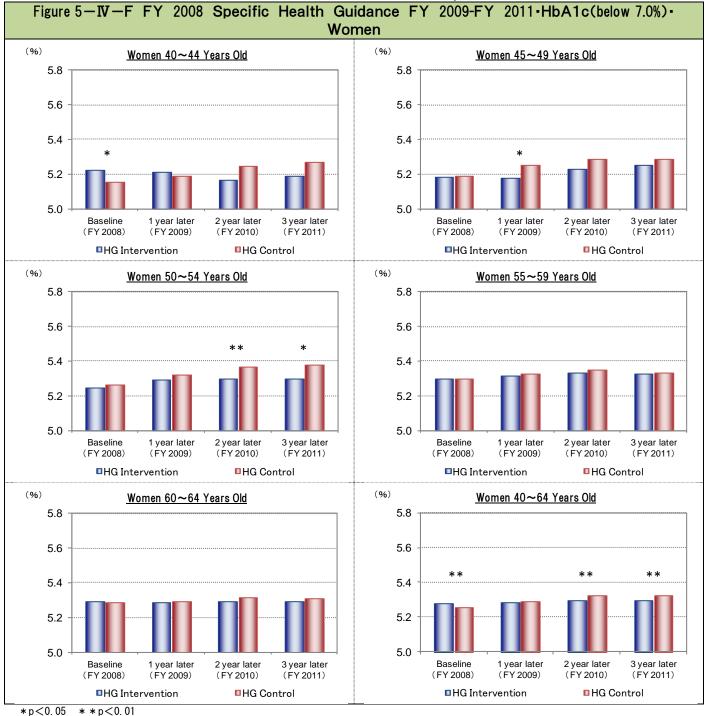


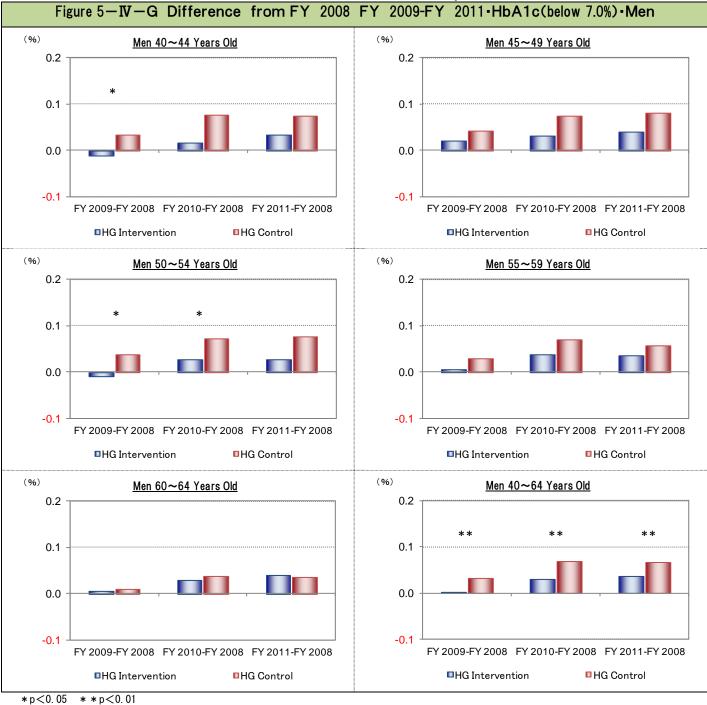


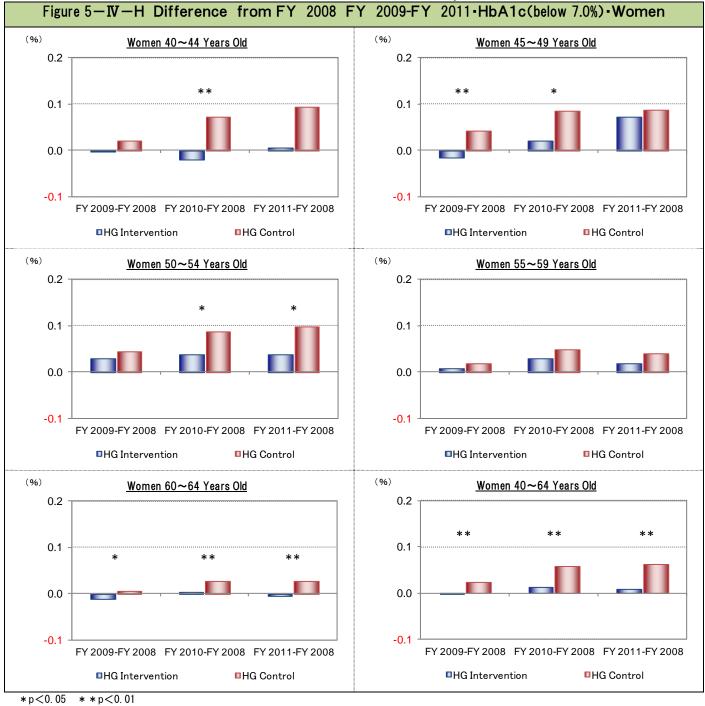


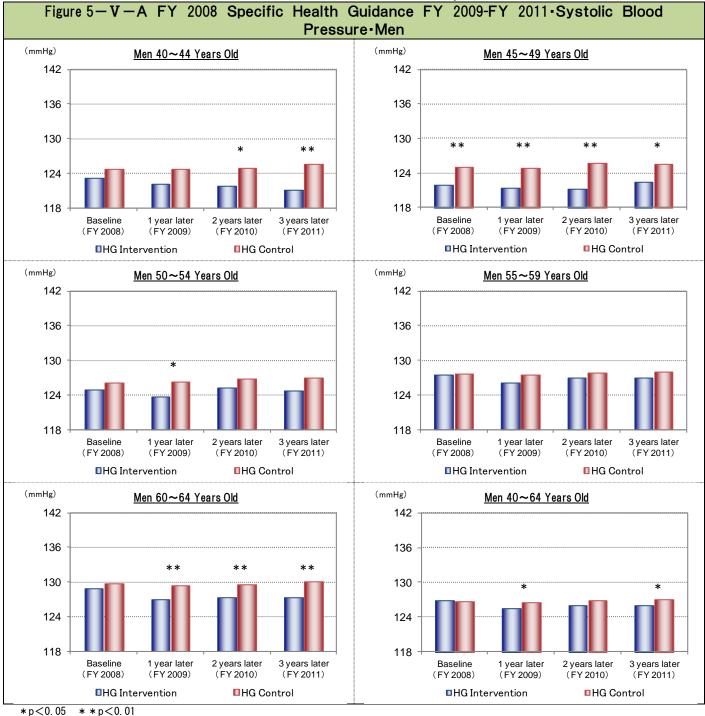


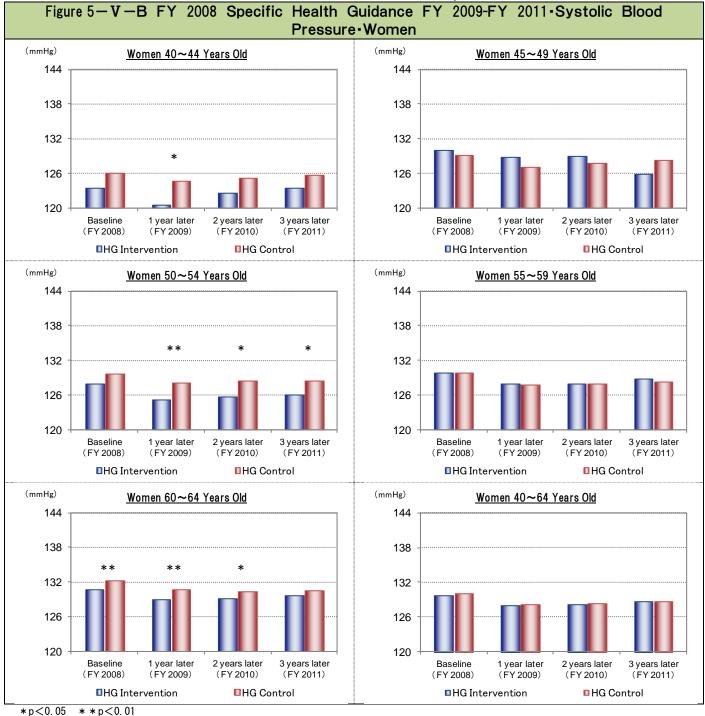


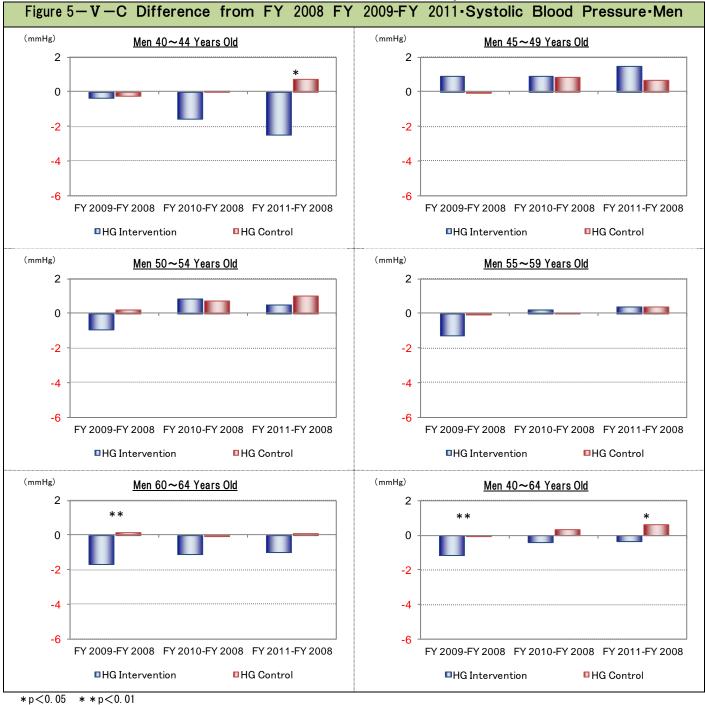


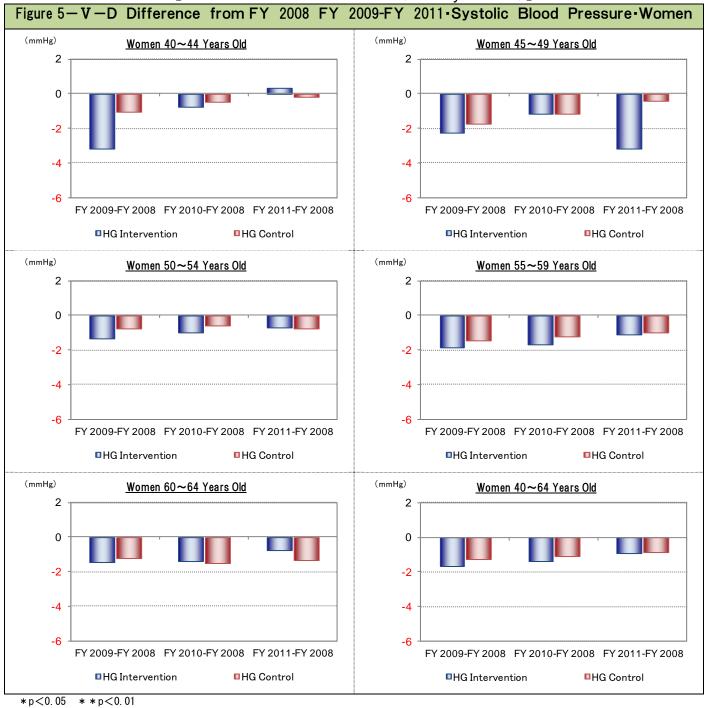


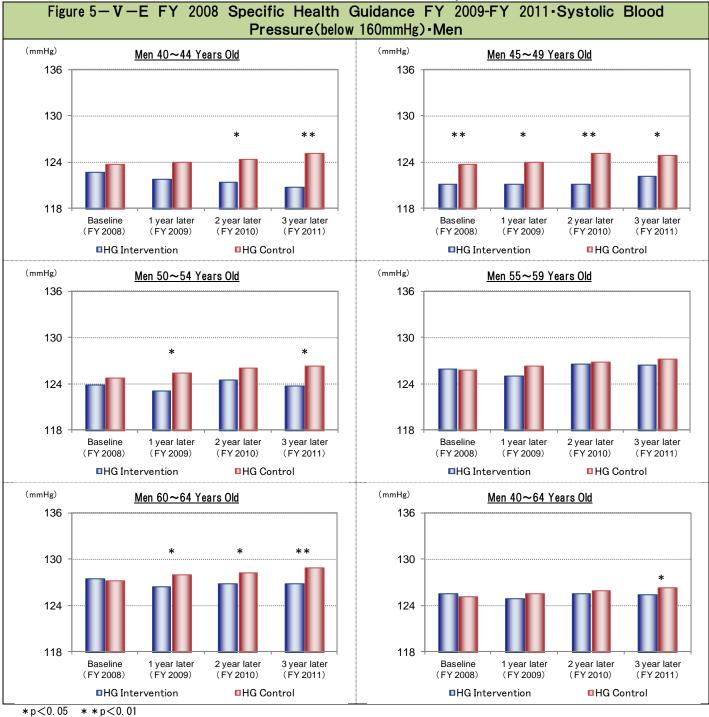


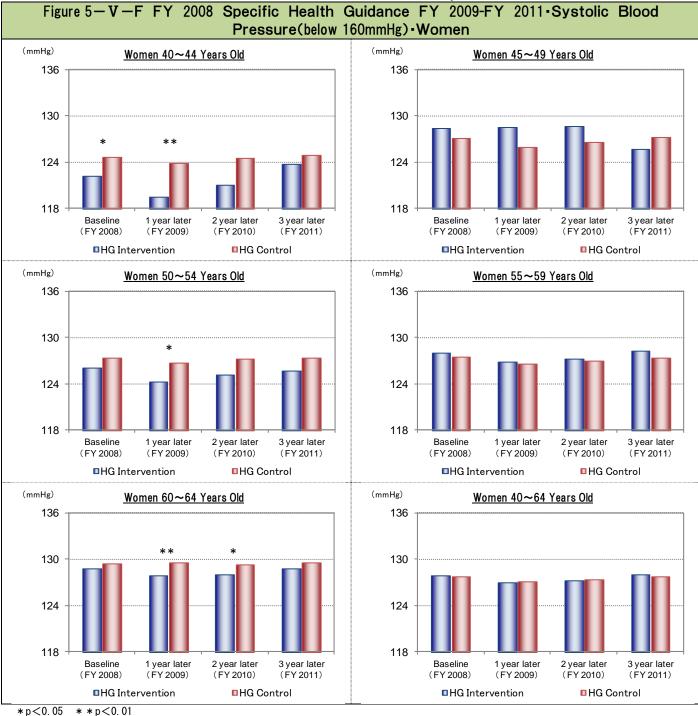


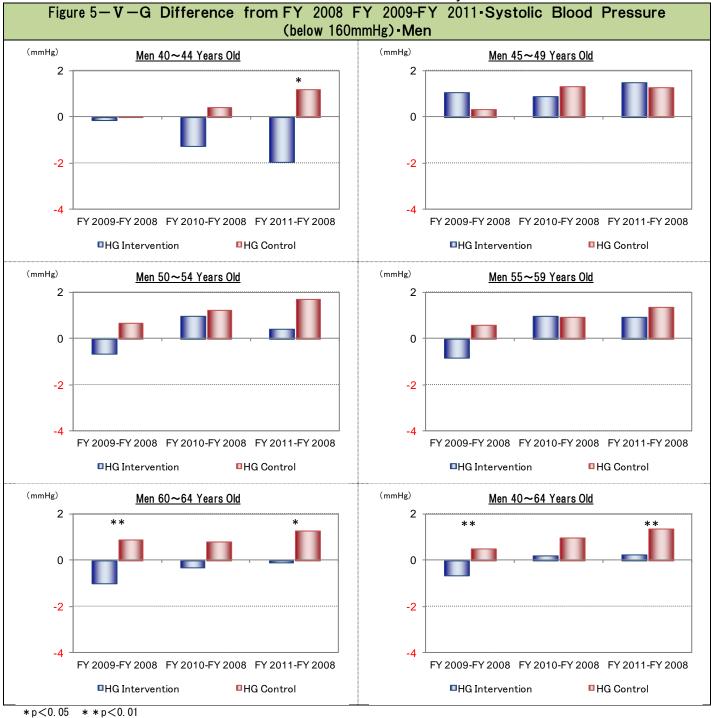


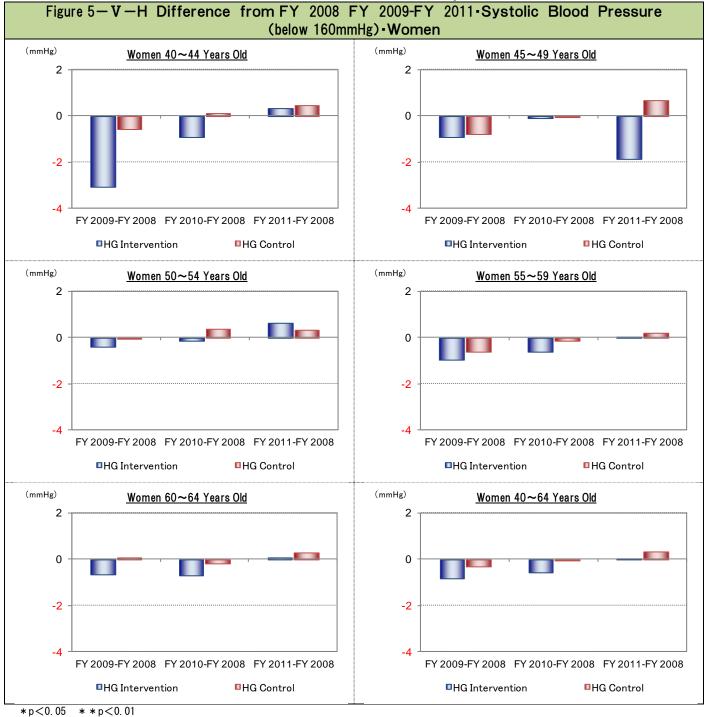


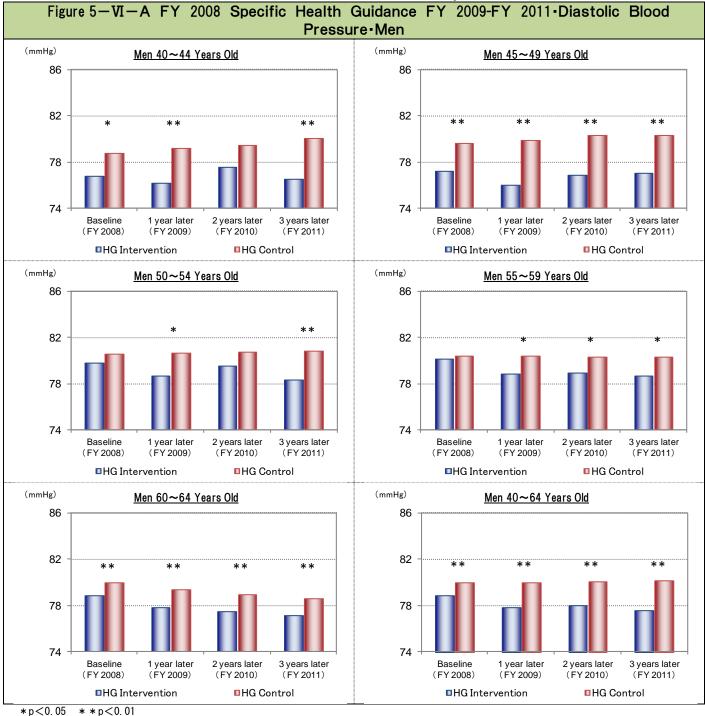


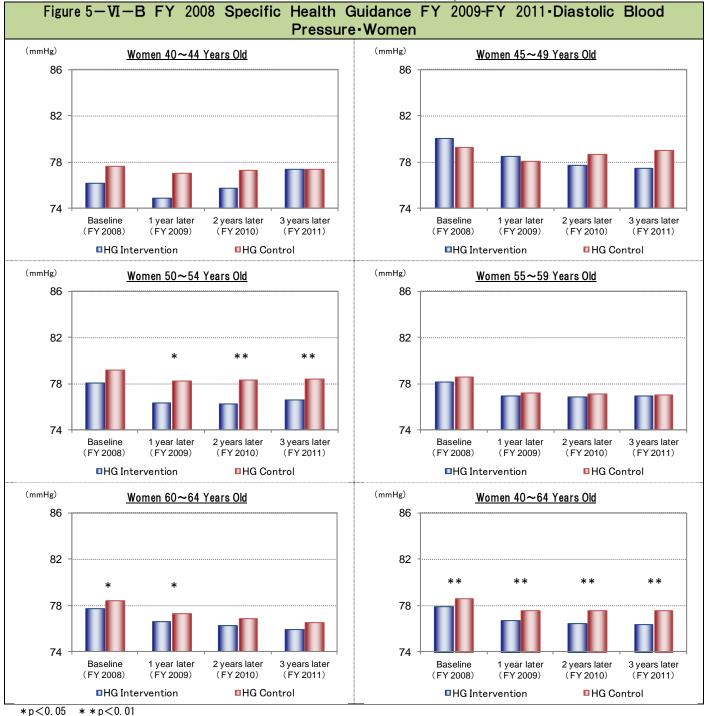


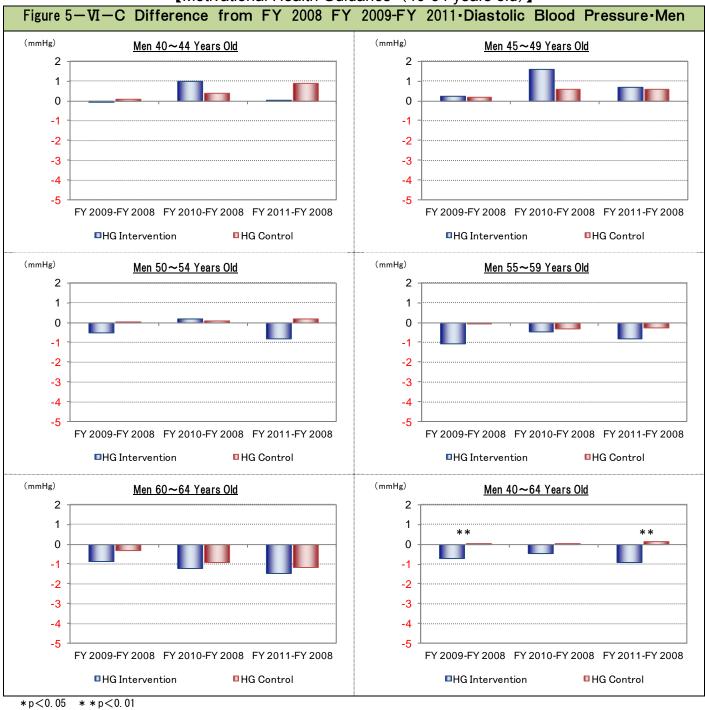


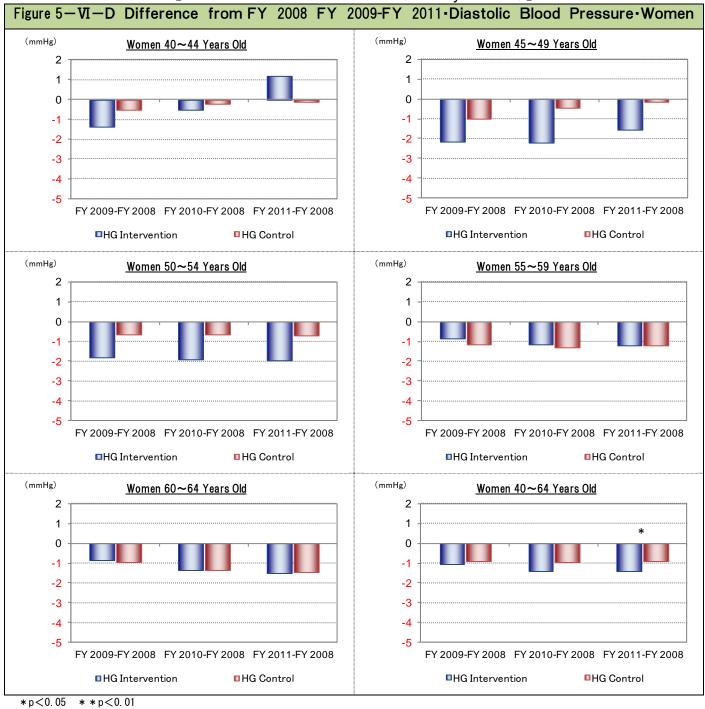


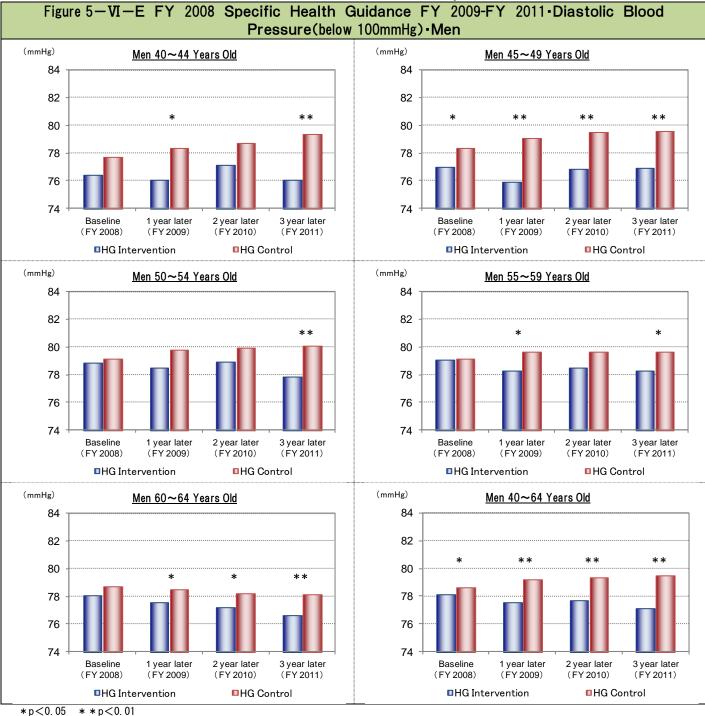


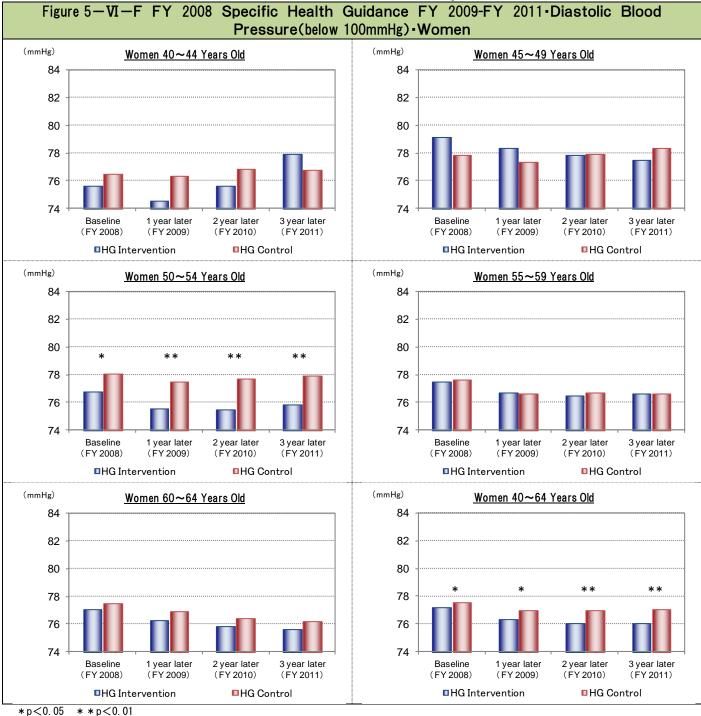


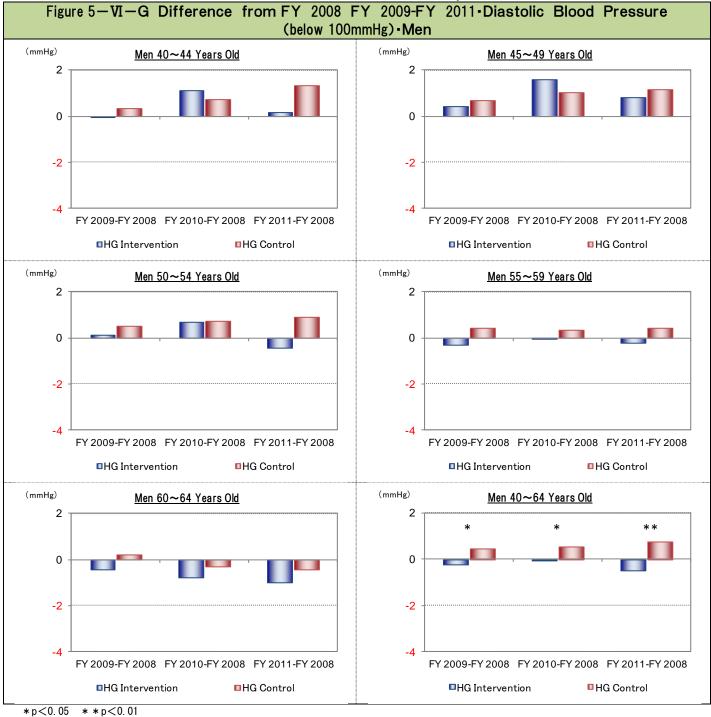


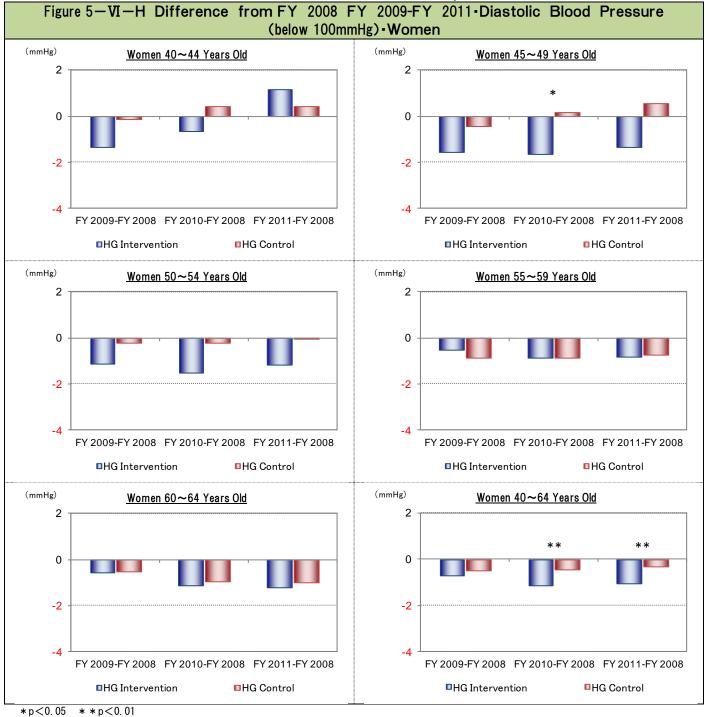


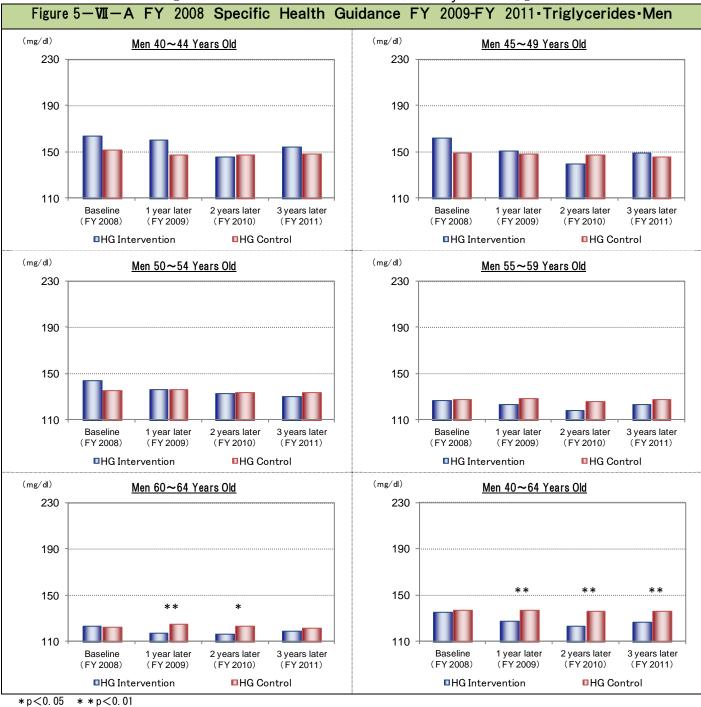


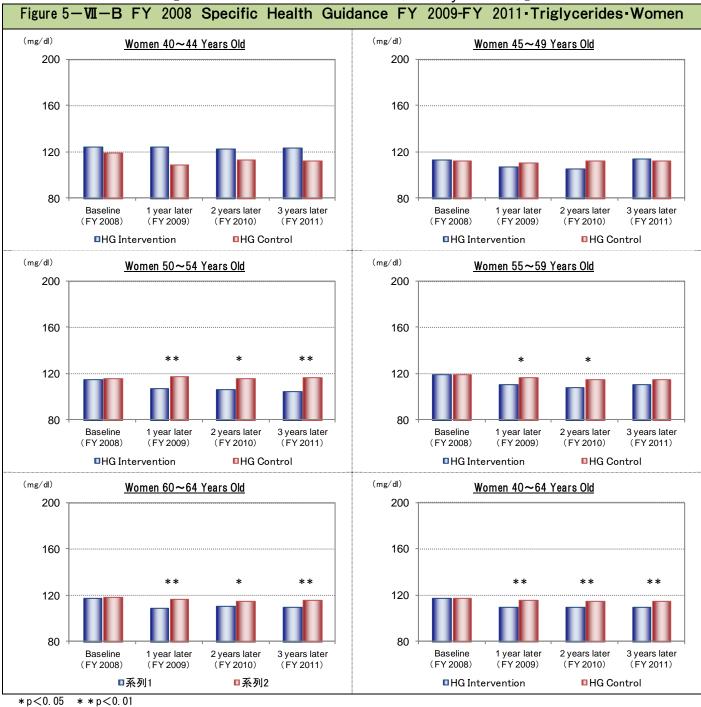


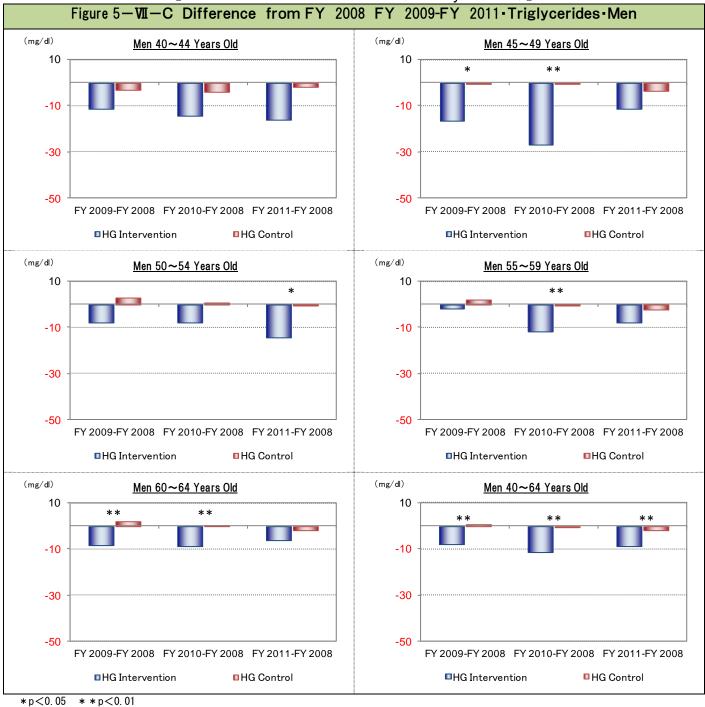


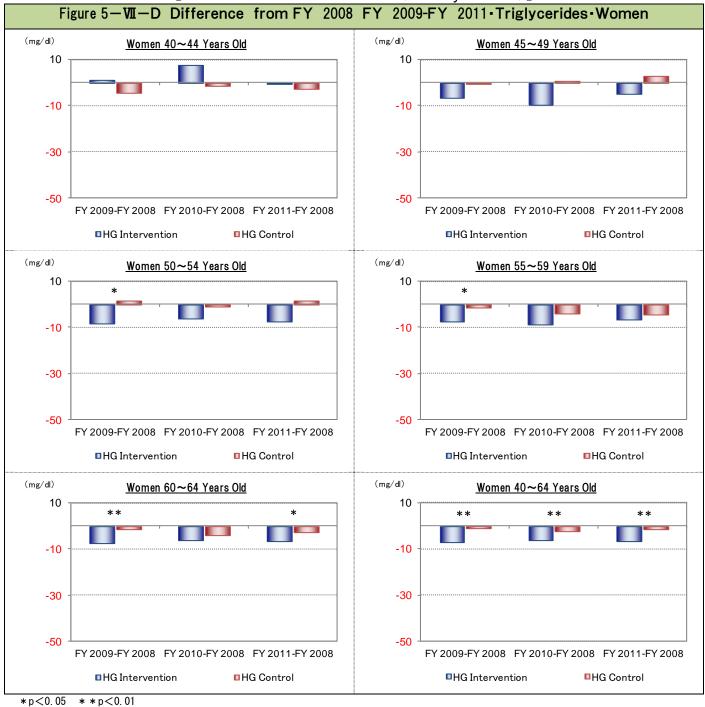


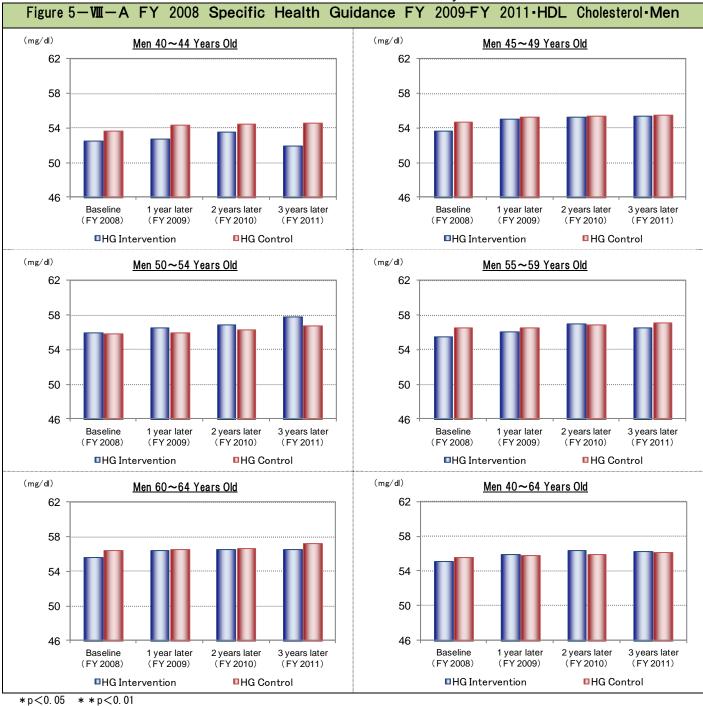


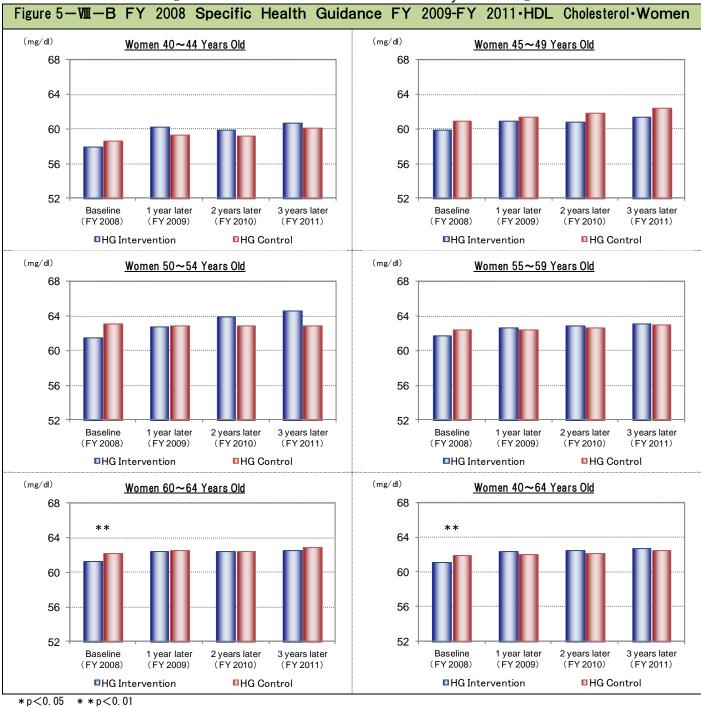


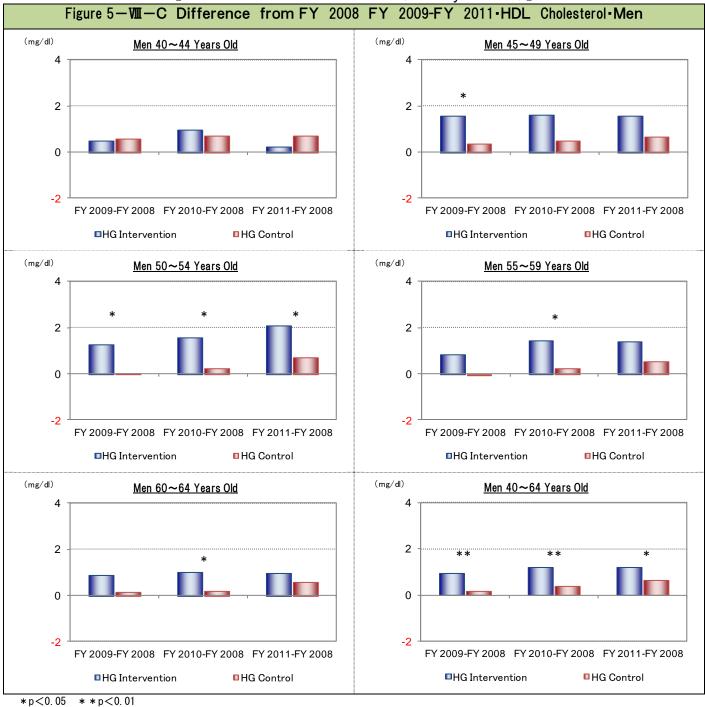


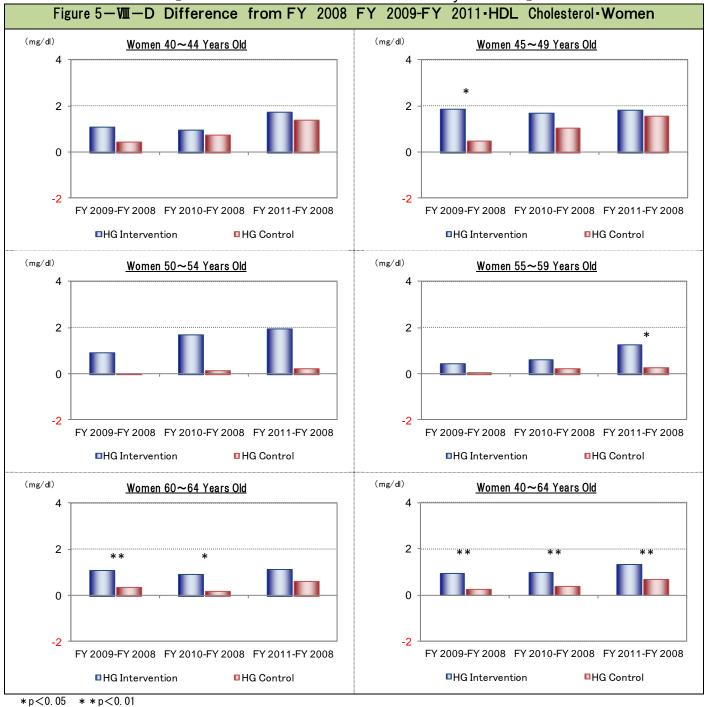












#### c. Motivational Health Guidance (65 to 74 years of age)

#### I. Waist Circumference (Page 169, Figures 6-I-A~D)

Among men, there were no baseline waist measurement differences between intervention and control groups overall (65 to 74 years of age), but intervention groups had significantly lower waist measurements than control groups in subsequent years. Intervention groups overall reduced waist measurements from baseline by 1.95cm by one year later, 1.78cm by two years later, and 1.65cm by three years later. The amounts of these waist measurement reductions were significantly greater compared with control groups overall (0.95cm, 1.06cm, and 0.97cm, respectively).

Among women, there were no baseline waist measurement differences between intervention and control groups in all age groups, but in one year later, intervention groups had significantly lower waist measurements compared with control groups. The reduction of waist measurement from baseline was 2.36cm by one year later, 2.44cm by two years later, and 2.23cm by three years later in intervention groups overall. The amounts of these waist measurement reductions were significantly greater compared with control groups overall (1.45cm, 1.85cm, and 1.75cm, respectively).

#### II. BMI (Page 173, Figures 6-II-A~D)

Among men, control groups had significantly lower baseline BMI compared with intervention groups in the 70 to 74 age group and overall (65 to 74 years of age).

Among women, there were no baseline BMI differences between intervention and control groups in all age groups.

In both men and women, intervention groups had significantly greater BMI reductions in all subsequent years in all age groups.

#### III. Body Weight (Page 177, Figures 6-III-A~D)

Among men, there were no baseline body weight differences between intervention and control groups in all age groups. The intervention group overall (65 to 74 years of age) reduced body weight from baseline by 1.30kg by one year later, 1.20kg by two years later, and 1.22kg by three years later. Control groups overall also reduced body weight from baseline by 0.43kg by one year later, 0.62kg by two years later, and 0.74kg by three years later. The amounts of body weight reductions were significantly greater in intervention groups than in control groups in all years.

Among women, there were also no baseline body weight differences between intervention and control groups in all age groups. Intervention group overall reduced body weight from baseline by 1.51kg by one year later, 1.48kg by two years later, and 1.49kg by three years later. Control groups overall also reduced body weight from baseline by 0.64kg by one year later, 0.90kg by two years later, and 1.02kg by three years later. The amounts of body weight reductions were significantly greater in intervention groups than in control groups in all years.

#### IV. HbA1c (in the JSD unit) (Page 181, Figures 6-IV-A~H)

In both men and women, intervention groups had significantly lower baseline HbA1c than control groups in all age groups.

When additional analyses were performed with subjects whose baseline HbA1c was below 7%, baseline Hba1c differences between intervention and control groups decreased. In subsequent years, HbA1c incrementally increased in control groups, but it only slightly increased in intervention groups.

#### V. Systolic Blood Pressure (Page 189, Figures 6-V-A~H)

In both men and women, baseline systolic blood pressure was significantly lower in intervention groups than in control groups. Therefore, additional analyses were performed with subjects whose baseline systolic blood pressure was below 160mmHg. Both intervention and control group decreased systolic blood pressure in subsequent years, but intervention groups had greater amounts of reductions compared with control groups.

#### VI. Diastolic Blood Pressure (Page 197, Figures 6-VI-A~H)

In both men and women, baseline diastolic blood pressure was significantly lower in intervention groups than in control groups. When additional analyses were performed with subjects whose baseline diastolic blood pressure was below 100mmHg, baseline diastolic blood pressure differences between intervention and control groups decreased. In subsequent years, both intervention and control groups tended to decrease diastolic blood pressure, but intervention groups generally had lower values.

#### **VII. Triglycerides** (Page 205, Figures 6-VII-A~D)

Among men, intervention groups had significantly lower baseline triglycerides in the 65 to 69 age group and overall (65 to 74 years of age) compared with control groups, and the differences in triglycerides between the two groups increased in subsequent years. Triglycerides decreased from baseline by 13.46mg/dl by one year later, 15.72mg/dl by two years later, and 16.10mg/dl by three years later in intervention groups overall. Control groups also decreased triglycerides from baseline by 7.93mg/dl by one year later, 10.40mg/dl by two years later, and 12.40 mg/dl by three years later. The amounts of triglyceride reductions were significantly greater in intervention groups than in control groups in all years.

Among women, intervention groups had significantly lower baseline triglycerides in all age groups compared with control groups, and the differences in triglycerides between the two groups increased in subsequent years. Triglycerides decreased from baseline by 11.33mg/dl by one year later, 12.47mg/dl by two years later, and 12.02mg/dl by three years later in intervention groups overall. Control groups also decreased triglycerides from baseline by 7.28mg/dl by one year later, 9.48mg/dl by two years later, and 10.86 mg/dl by three years later. The amounts of triglyceride reductions were greater in intervention groups than in control groups in all years.

In both men and women, the amounts of triglyceride reductions were greater compared with younger age groups (40 to 64 years of age) who completed motivational HG.

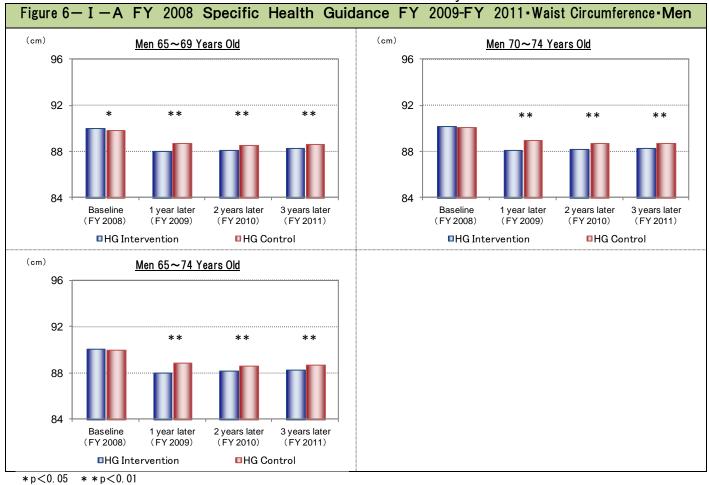
#### VIII. HDL Cholesterol (Page 209, Figures 6-VIII-A~D)

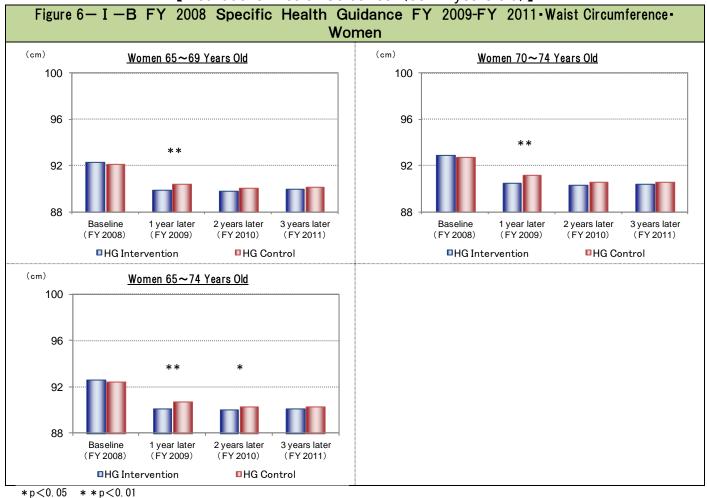
Among men, baseline HDL cholesterol was significantly lower in intervention groups than in control groups in all age groups, but in subsequent years, intervention groups increased HDL cholesterol and differences between the two groups disappeared. The increase of HDL cholesterol from baseline was 1.13mg/dl by one year later, 1.25mg/dl by two years later, and 1.59mg/dl by three years later in intervention groups overall (65 to 74 years of age). Control groups overall also increased HDL cholesterol from baseline by 0.14mg/dl by one year later, 0.17mg/dl by two years later, and 0.56mg/dl by three years later. The amounts of the increases in HDL cholesterol from baseline were significantly greater in intervention groups than in control groups in all years.

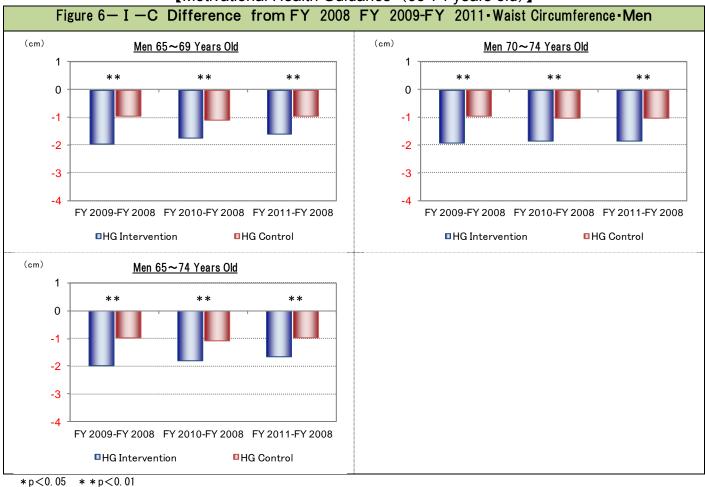
Among women, there were also no significant baseline HDL cholesterol differences between intervention and control groups in all age groups. In subsequent years, intervention groups had significantly higher HDL cholesterol in the 70 to 74 age group by one year and three years later.

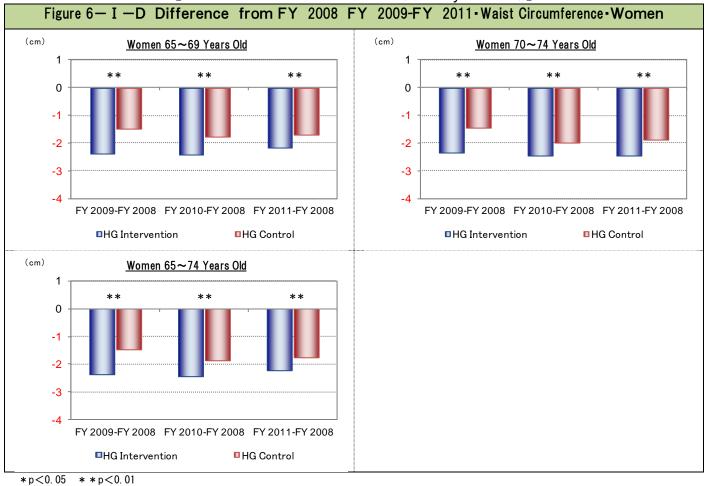
Intervention groups overall increased HDL cholesterol from baseline by 1.01mg/dl by one year later, also 0.96mg/dl by two years later, and 1.58mg/dl by three years later. Control groups overall also increased HDL cholesterol from baseline by 0.54mg/dl by one year later, 0.55mg/dl by two years later, and 1.07mg/dl by three years later. The amounts of increases in HDL cholesterol from baseline were significantly greater in intervention groups than in control groups.

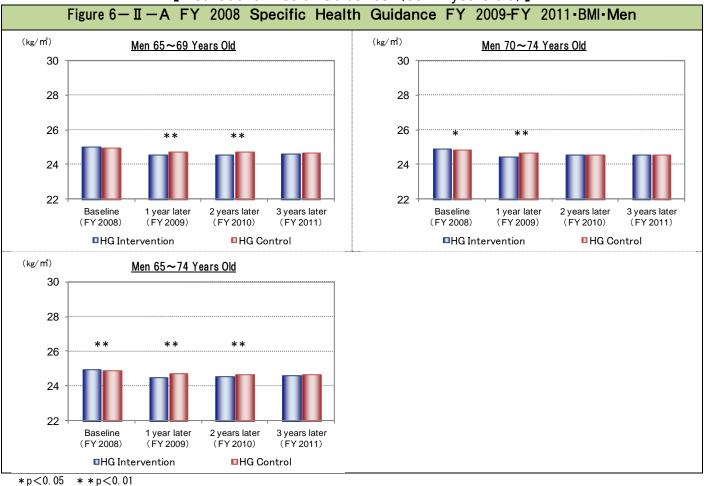
Figure 6. Longitudinal Analysis of Clinical Indicators Following Health Guidance [Motivational Health Guidance (65-74 years old)]

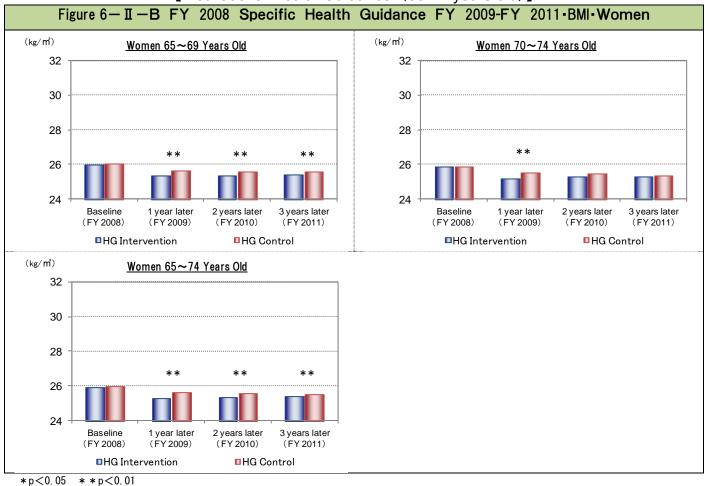


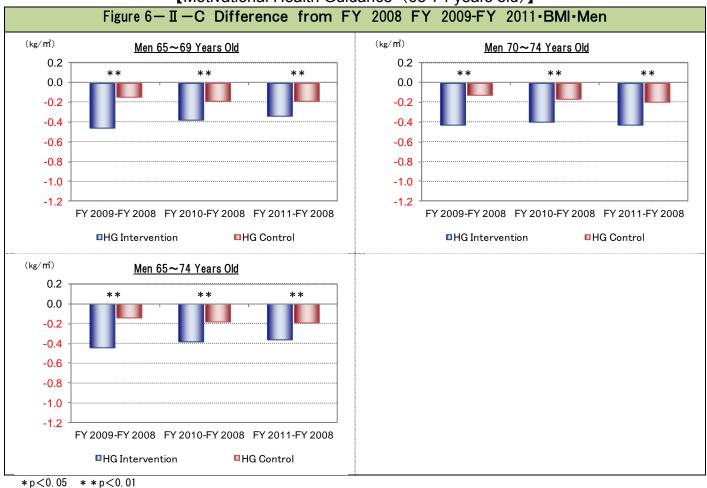


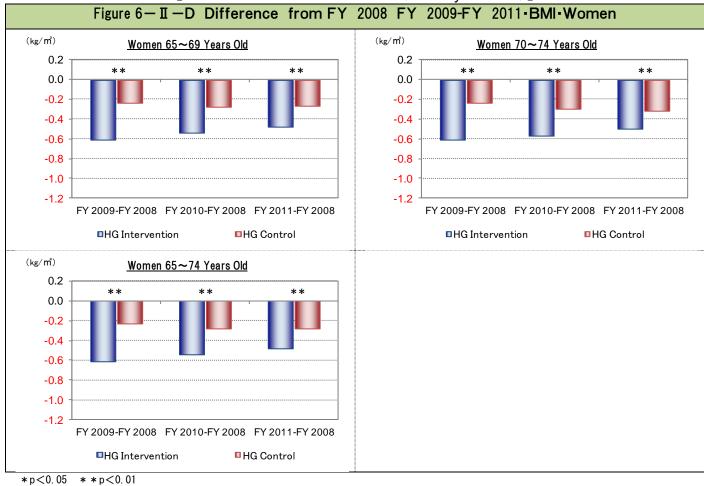


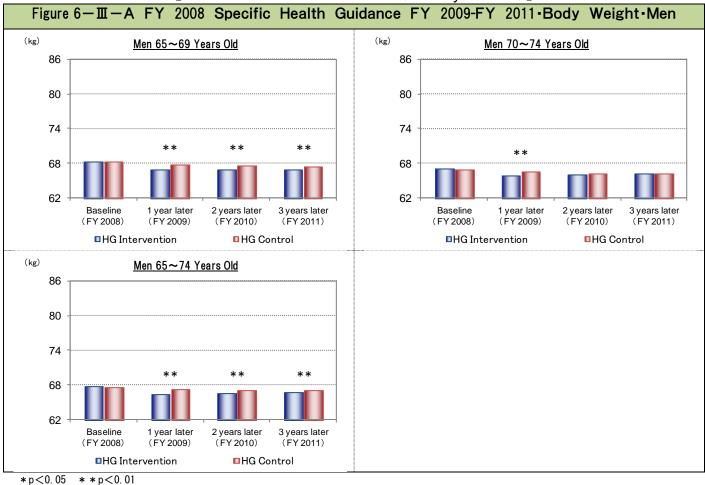


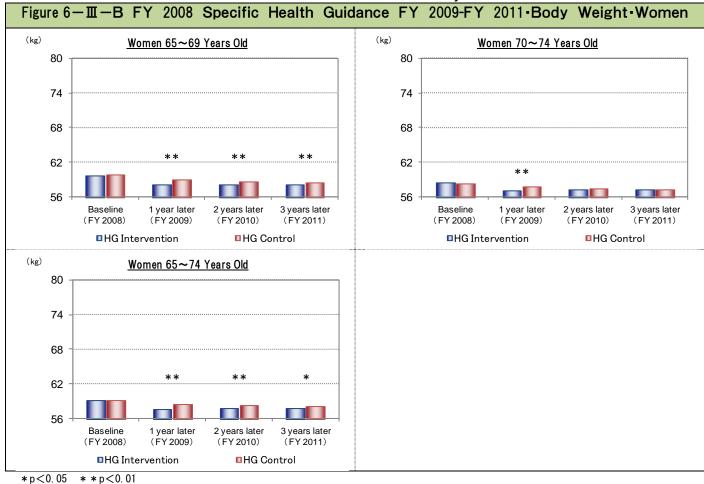


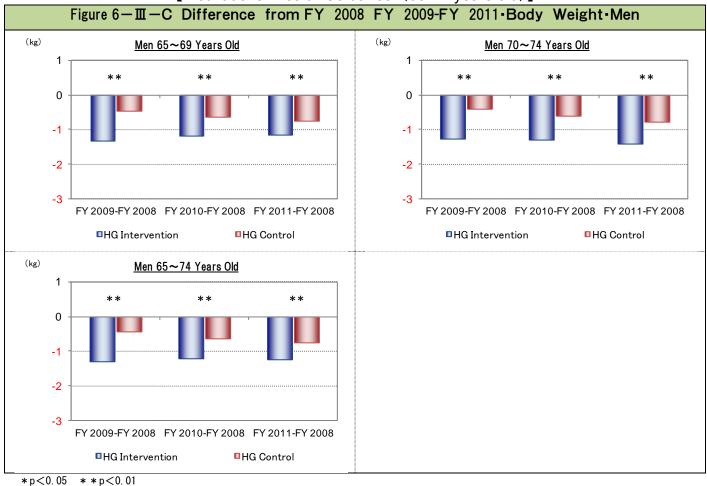


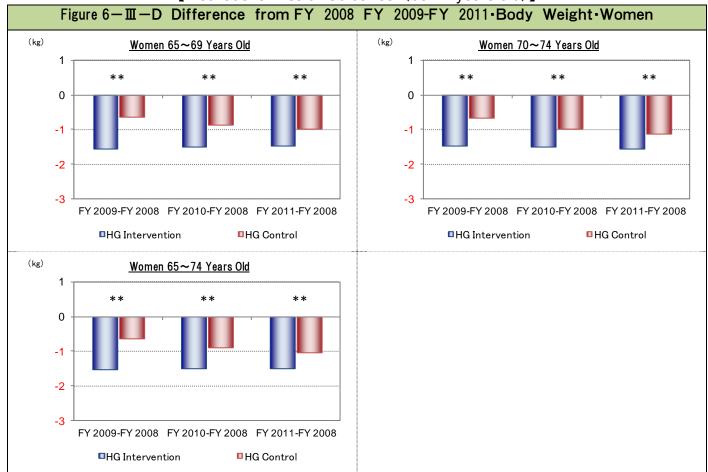




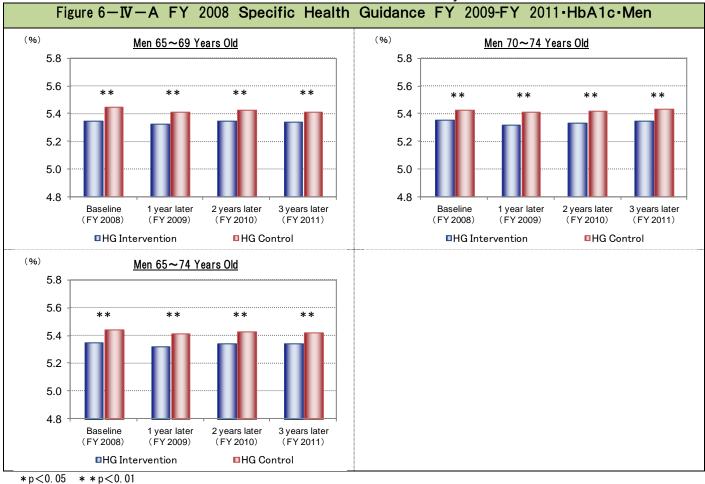


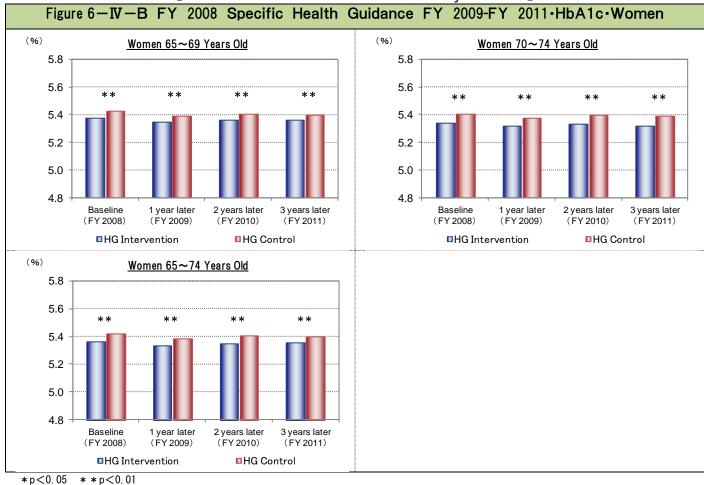


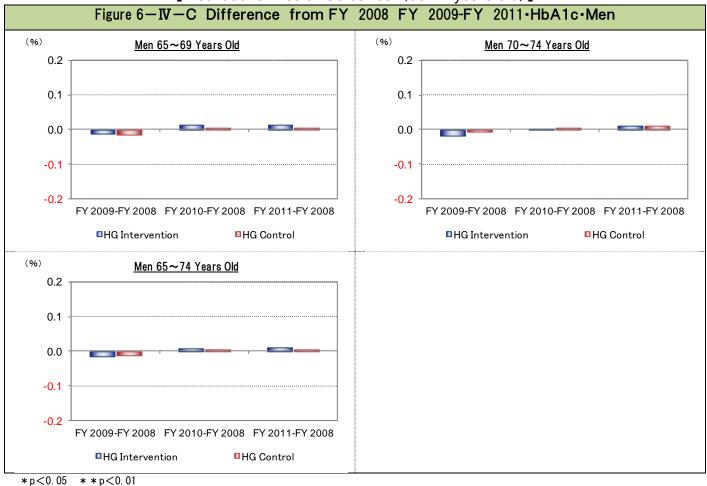


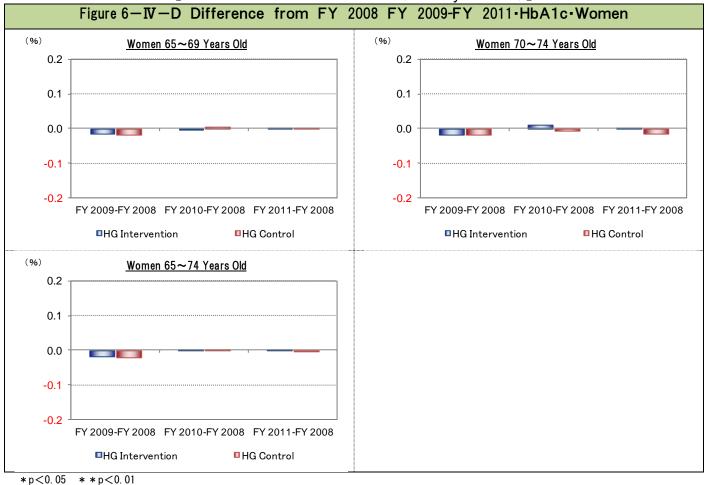


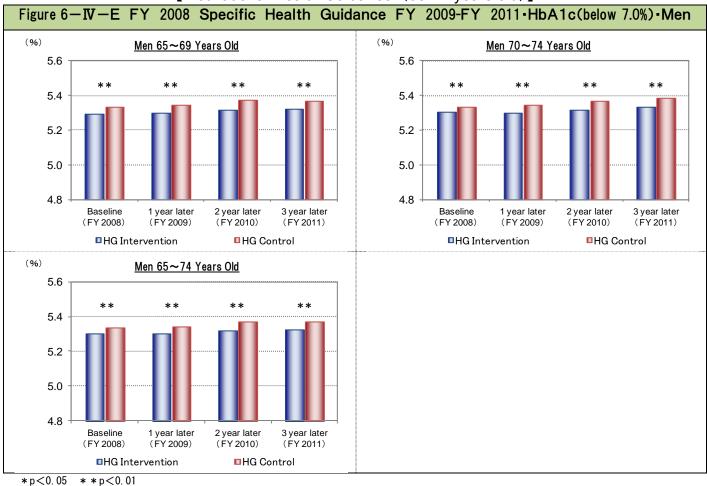
\*p<0.05 \*\*p<0.01

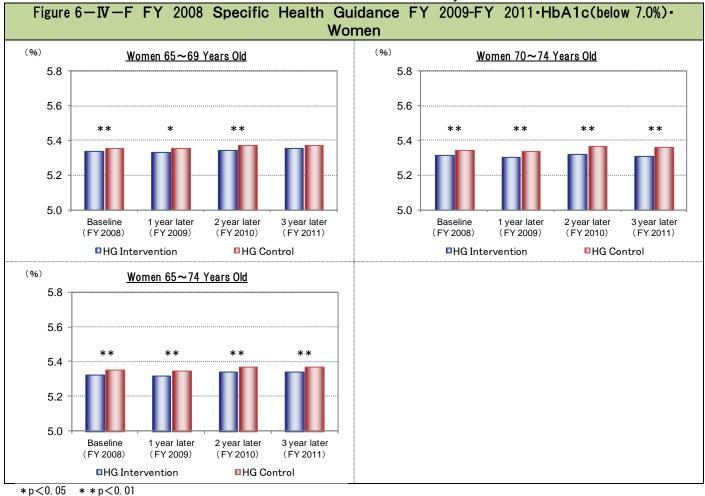


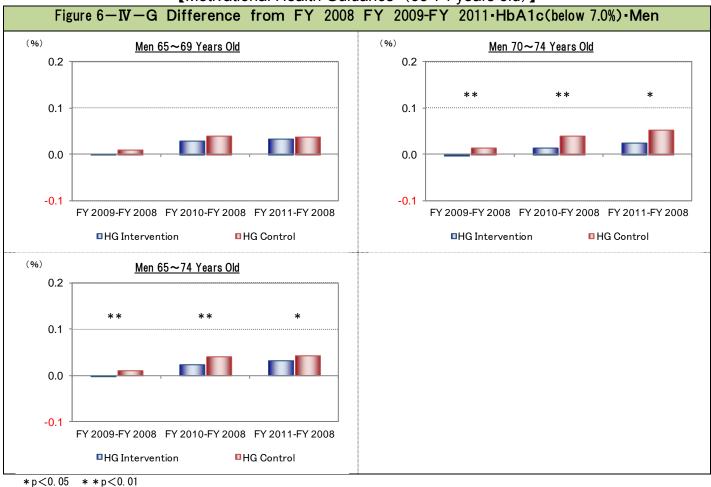


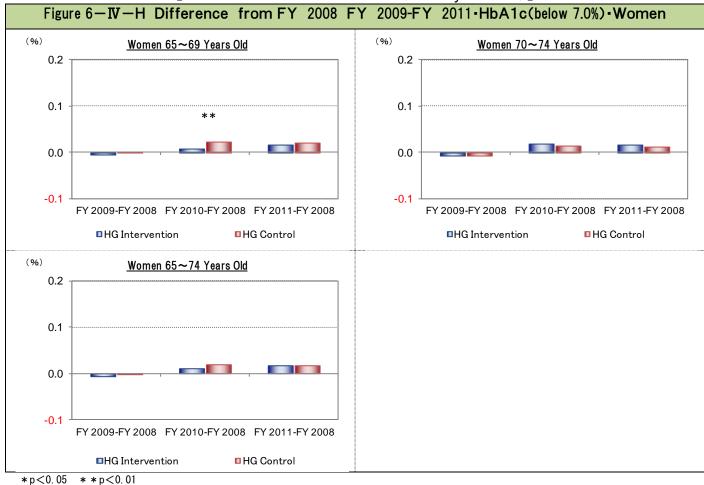


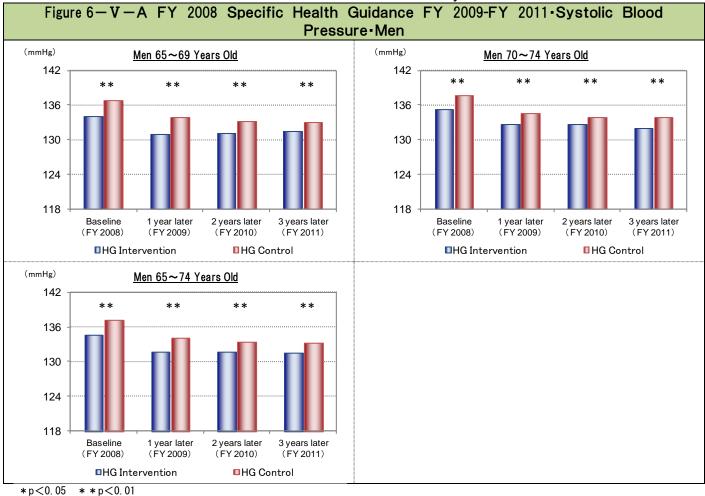


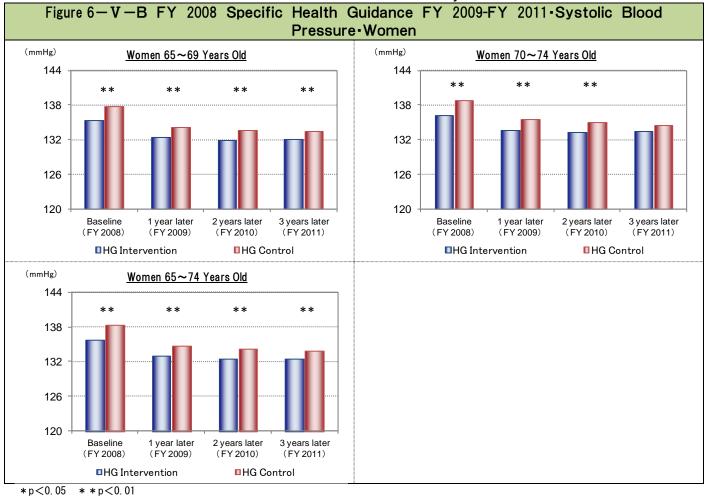


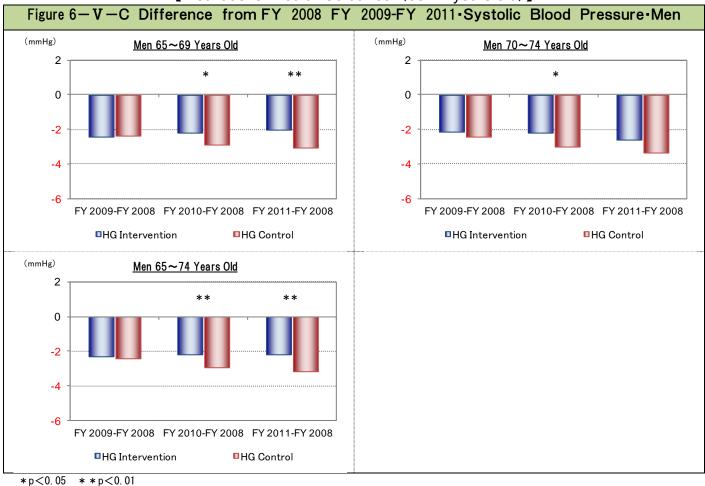


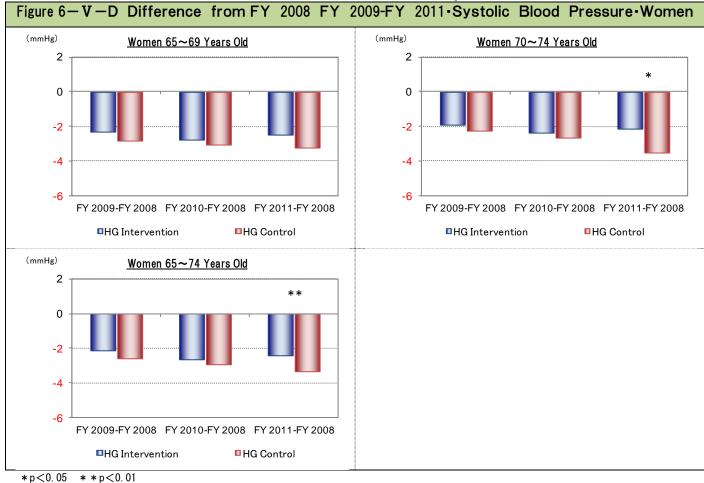


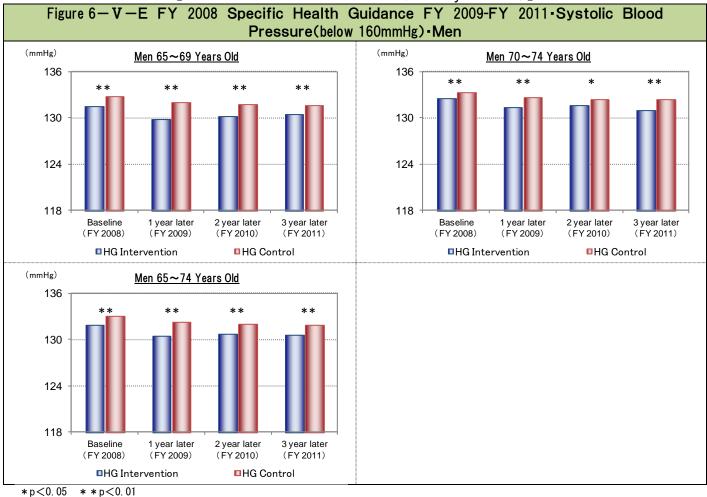


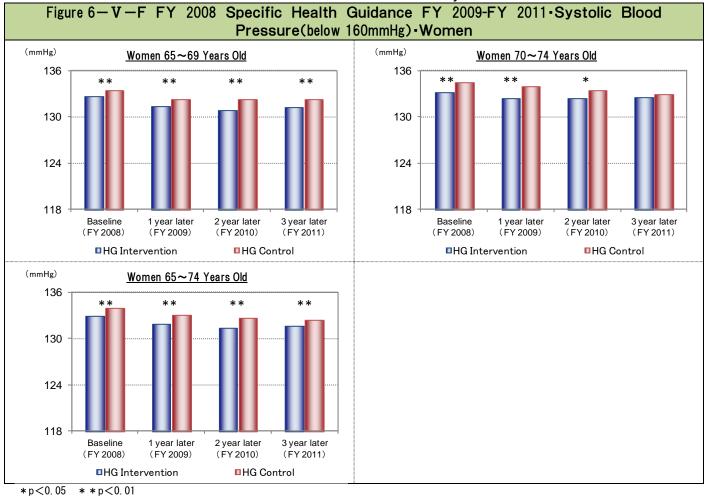


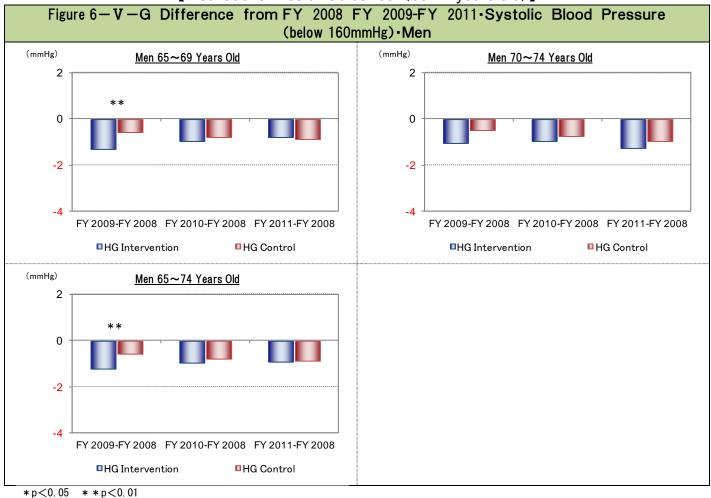


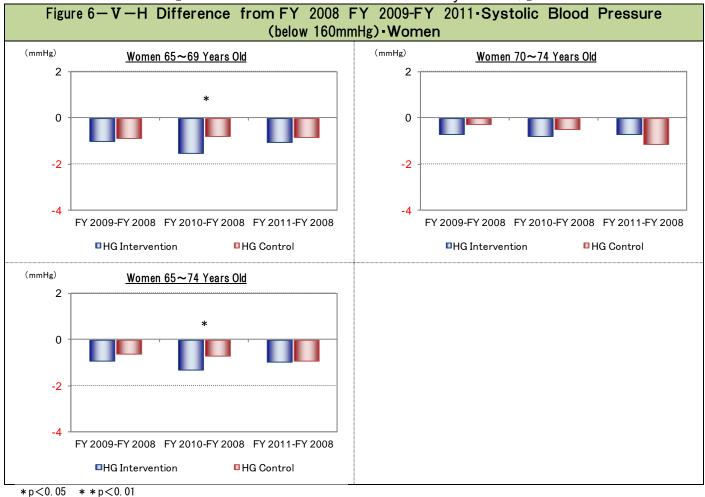


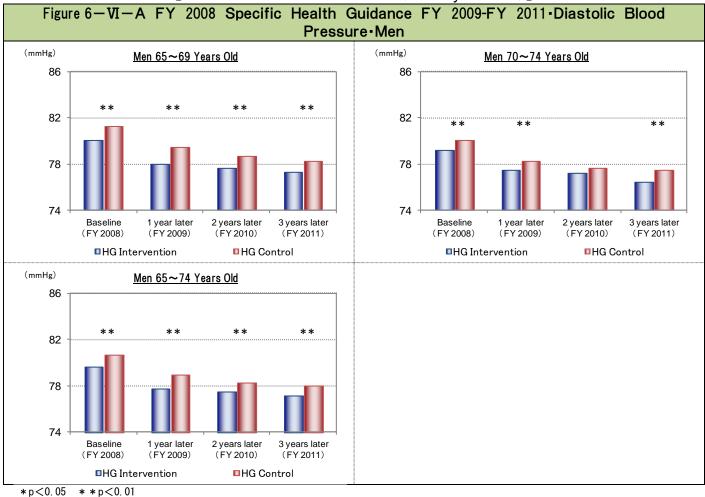


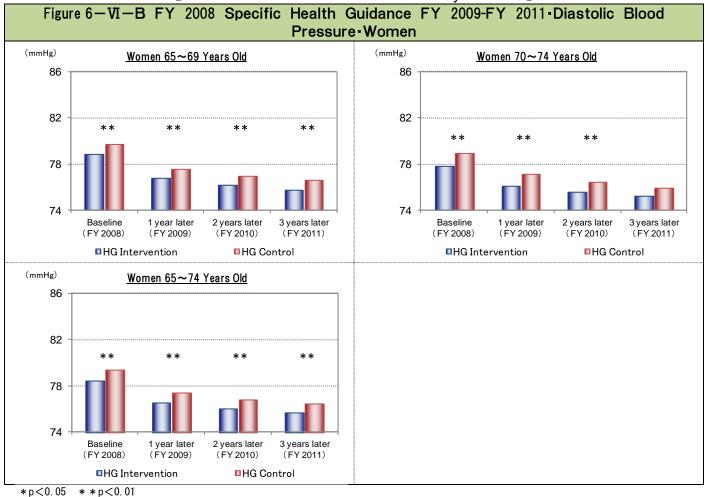




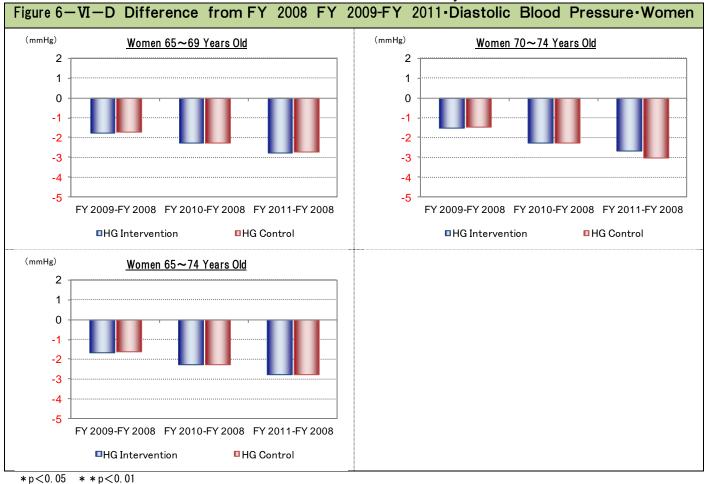


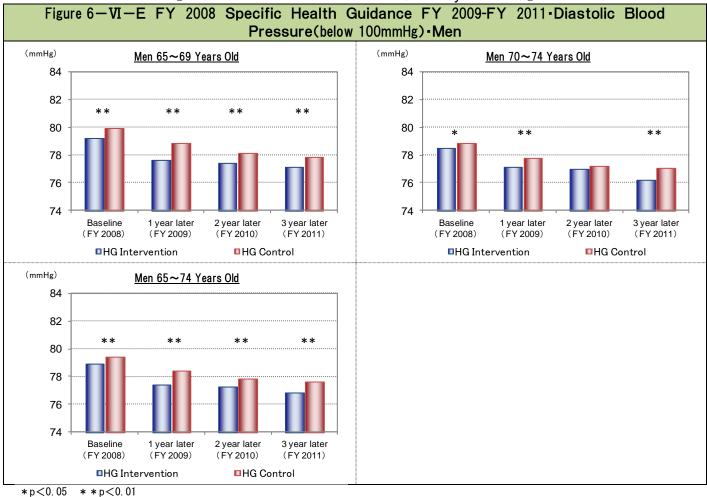


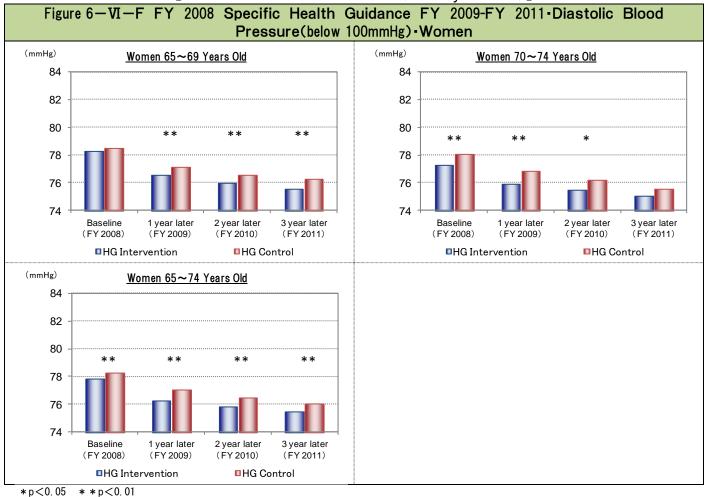


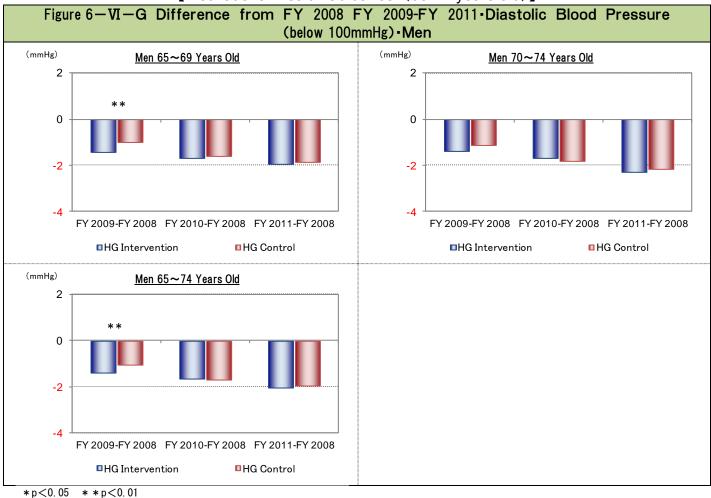


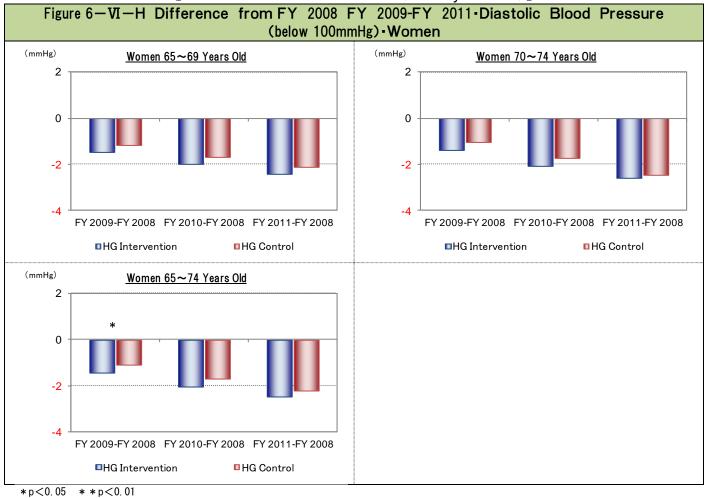


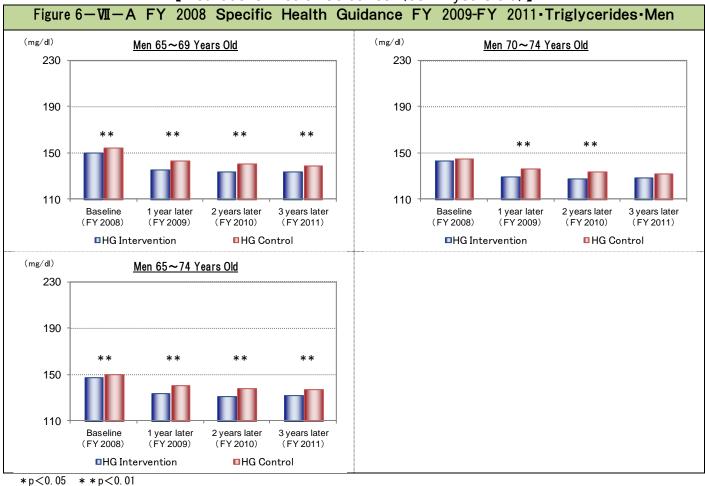


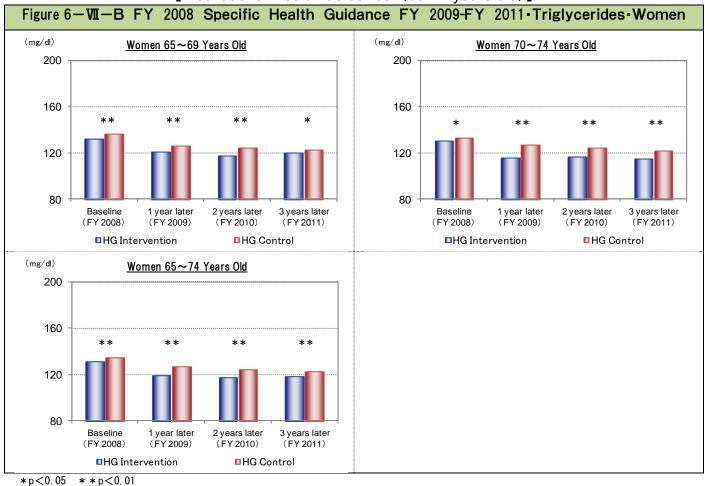


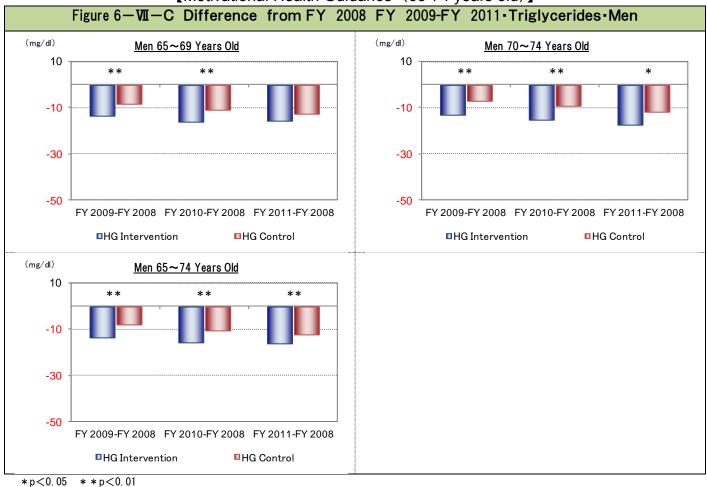


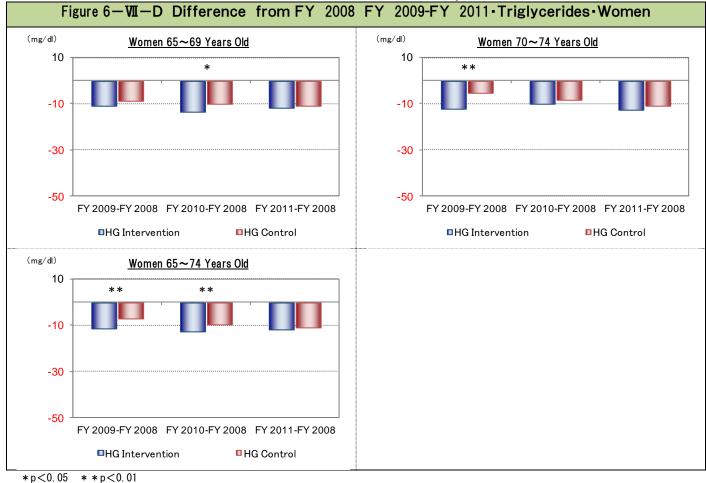


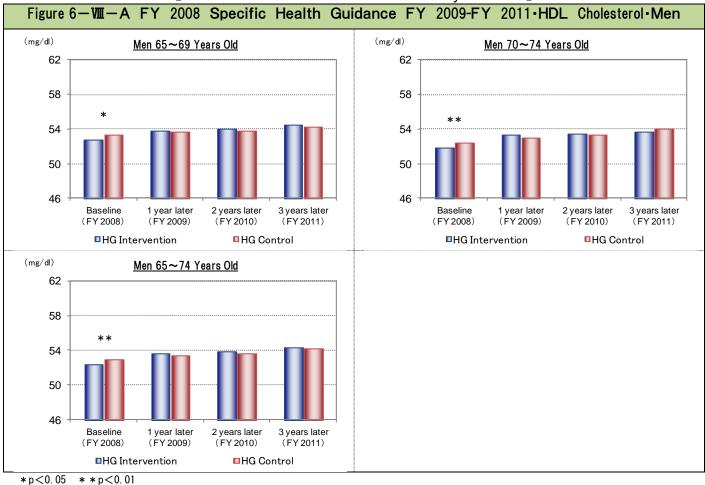


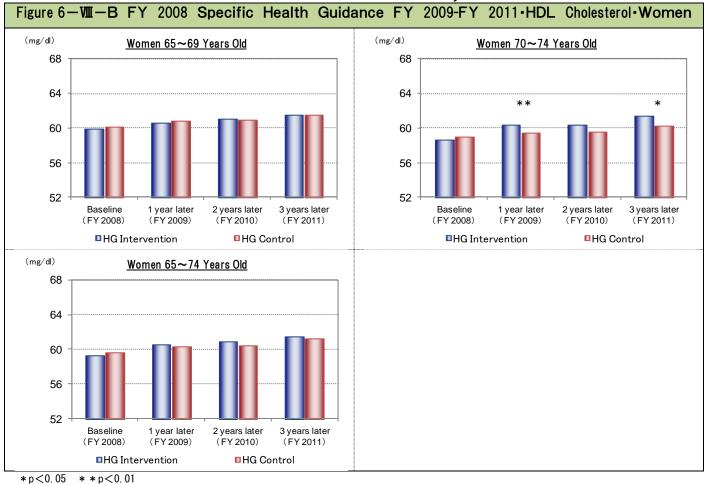


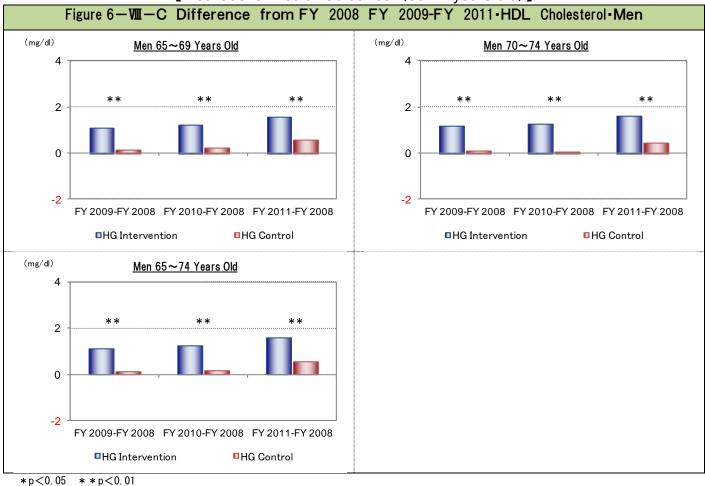


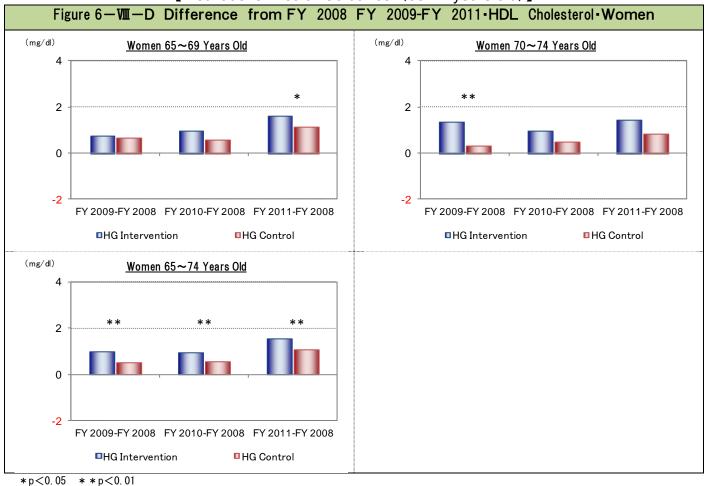












# (2) Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance

#### a. Intensive Health Guidance (40 to 64 years of age)

#### I. Per Capita Outpatient Health Care Costs (Page 216, Figures 7-I-A~B)

Among men, intervention groups had significantly lower per capita outpatient health care costs for hypertension, dyslipidemia and diabetes than control groups in all age groups and overall (40 to 64 years of age) by one, two, and three years later. Intervention groups overall had cumulative points of 6,011 for the three year period, whereas control groups overall had cumulative points of 8,526 in the same time period, and the difference was 2,515 points (intervention groups had 29.5% fewer points than control groups).

Among women, intervention groups overall also had significantly lower per capita outpatient health care costs for hypertension, dyslipidemia and diabetes than control groups overall by one, two, and three years later. Intervention groups overall had cumulative points of 8,604 for the three year period, whereas control groups overall had cumulative points of 12,003 in the same period, and the difference was 3,399 points (intervention groups had 27.4% fewer points than control groups).

#### II. Outpatient Health Care Utilization Rates (Page 218, Figures 7-II-A~B)

Among men, intervention groups had significantly lower outpatient health care utilization rates for hypertension, dyslipidemia and diabetes than control groups in all age groups greater than 45 years of age and overall (40 to 64 years of age) by one, two, and three years later. Intervention groups overall had a cumulative outpatient health care utilization rate of 3.45 visits per 3 years, whereas control groups overall had a cumulative rate of 4.74 visits per 3 years, and the difference was 1.29 visits (intervention groups had 29.7% fewer visits than control groups).

Among women, intervention groups had significantly lower outpatient care utilization rates for hypertension, dyslipidemia and diabetes than control groups in the 55 to 59 age group, the 60 to 64 age group, and overall by one, two, and three years later. Intervention groups overall had a cumulative outpatient care utilization rate of 5.39 visits per 3 years, whereas control groups overall had a cumulative rate of 7.20 visits per 3 years, and the difference was 1.81 visits (intervention groups had 25.1% fewer visits than control groups).

#### b. Motivational Health Guidance (40 to 64 years of age)

#### I. Per Capita Outpatient Health Care Costs (Page 220, Figures 8-I-A~B)

Among men, intervention groups overall (40 to 64 years of age) had significantly lower per capita outpatient health care costs for hypertension, dyslipidemia and diabetes than control groups by one, two, and three years later. Intervention groups overall had cumulative points of 4,180 for the three year period, whereas control groups overall had cumulative points of 5,700 for the same time period, and the difference was 1,520 points (intervention groups had 26.7% fewer points than control groups).

Among women, intervention groups had generally lower per capita outpatient health care costs for hypertension, dyslipidemia and diabetes than control groups in all age groups and overall by one, two, and three years later. Intervention groups overall had cumulative points of 6,171 for the three year

period, whereas control groups overall had cumulative points of 7,345 for the same period, and the difference was 1,174 points (intervention groups had 16.0% fewer points than control groups).

When compared with intensive HG groups, motivational HG groups had lower absolute outpatient health care costs in all age groups, but percentages of cost reduction were slightly smaller in motivational HG groups.

#### II. Outpatient Health Care Utilization Rates (Page 222, Figures 8-II-A~B)

Among men, intervention groups had significantly lower outpatient health care utilization rates for hypertension, dyslipidemia and diabetes than control groups in the 60 to 64 age group and overall (40 to 64 years of age) by one, two, and three years later. Intervention groups overall had a cumulative outpatient health care utilization rate of 2.61 visits per 3 years, whereas control groups overall had a cumulative rate of 3.27 visits per 3 years, and the difference was 0.66 visits (intervention groups had 20.2% fewer visits than control groups).

Among women, intervention groups had lower outpatient health care utilization rates for hypertension, dyslipidemia and diabetes than control groups in the 60 to 64 age group and overall by one, two, and three years later. Intervention groups overall had a cumulative outpatient health care utilization rate of 3.99 visits per 3 years, whereas control groups overall had a cumulative rate of 4.60 visits per 3 years, and the difference was 0.61 visits (intervention groups had 13.3% fewer visits than control groups).

When compared with intensive HG groups, motivational HG groups had lower absolute outpatient health care utilization rates in all age groups, but percentages of rate reduction were slightly smaller in motivational HG groups.

#### c. Motivational Health Guidance (65 to 74 years of age)

#### I. Per Capita Outpatient Health Care Costs (Page 224, Figures 9-I-A~B)

Among men, intervention groups had significantly lower per capita outpatient health care costs for hypertension, dyslipidemia and diabetes than control groups in all age groups and overall (65 to 74 years of age) by one, two, and three years later. Intervention groups overall had cumulative points of 9,661 for the three year period, whereas control groups overall had cumulative points of 12,538 for the same time period, and the difference was 2,877 points (intervention groups had 22.9% fewer points than control groups).

Among women, intervention groups also had significantly lower per capita outpatient health care costs for hypertension, dyslipidemia and diabetes than control groups in all age groups and overall by one, two, and three years later. Intervention groups overall had cumulative points of 11,644 for the three year period, whereas control groups overall had cumulative points of 15,137 for the same period, and the difference was 3,493 points (intervention groups had 23.1% fewer points than control groups).

When compared with younger motivational HG groups (40 to 64 years of age), older control groups had higher outpatient health care costs and percentages of cost reduction were also greater in older intervention groups.

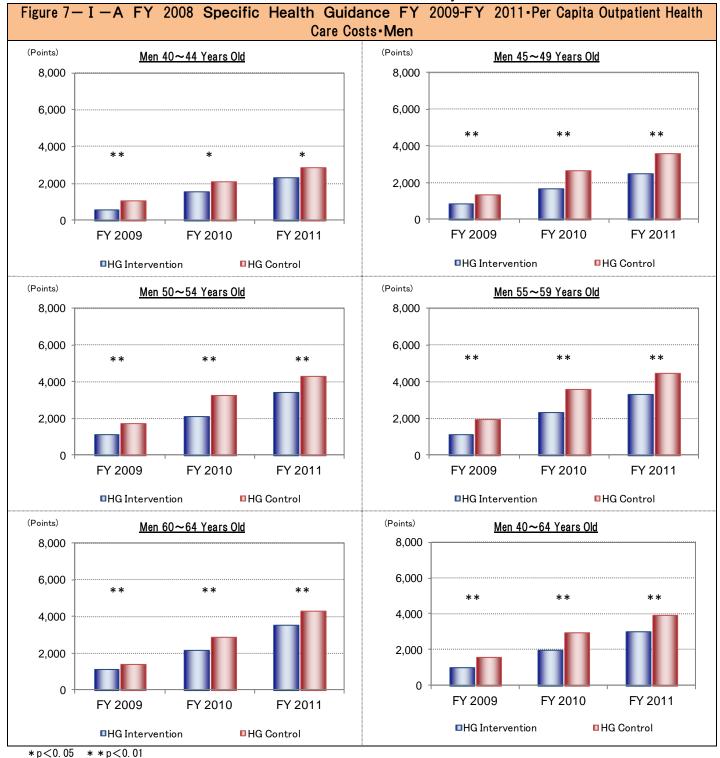
#### II. Outpatient Health Care Utilization Rates (Page 226, Figures 9-II-A~B)

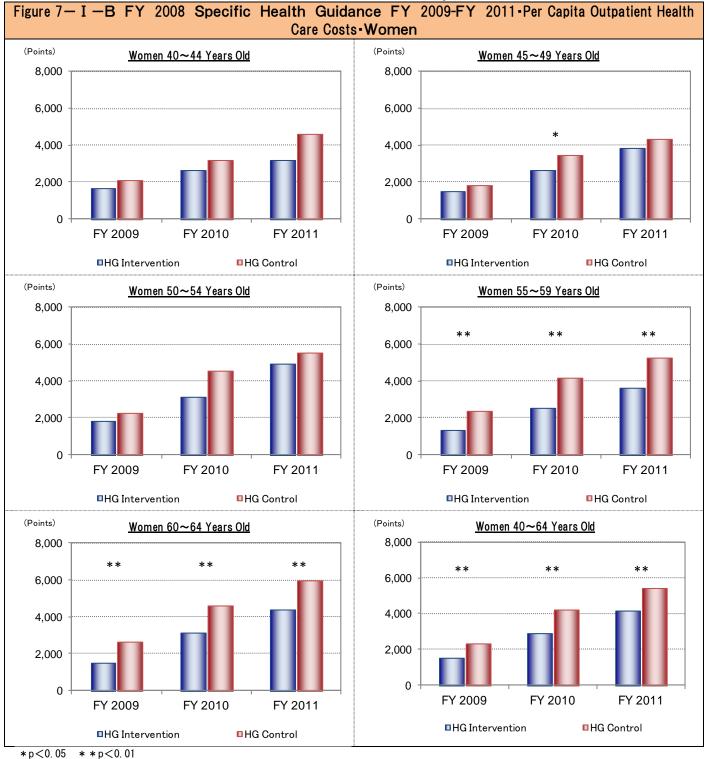
Among men, intervention groups had significantly lower outpatient health care utilization rates for hypertension, dyslipidemia and diabetes than control groups in all age groups and overall (40 to 64

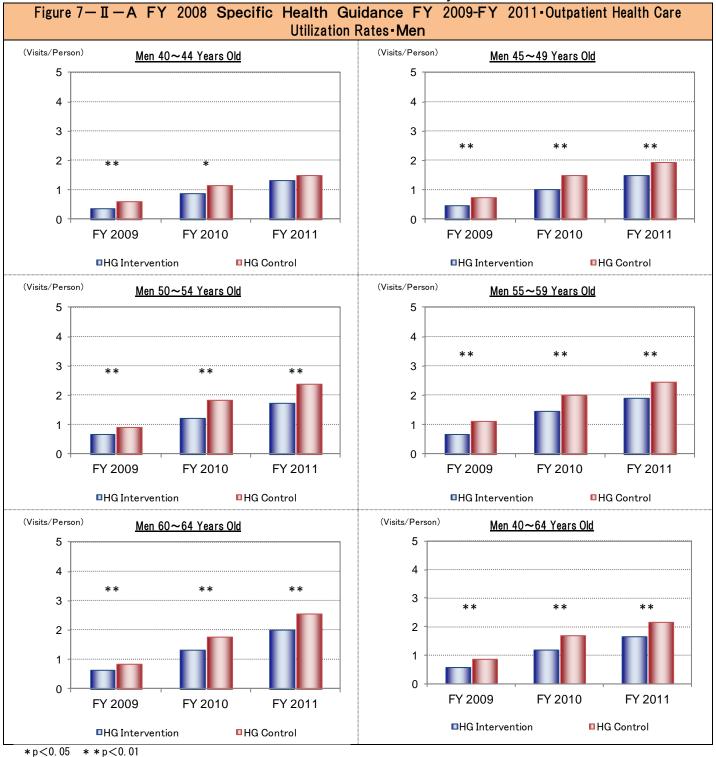
years of age) by one, two, and three years later. Intervention groups overall had a cumulative outpatient health care utilization rate of 5.60 visits per 3 years, whereas control groups overall had a cumulative rate of 7.22 visits per 3 years, and the difference was 1.62 visits (intervention groups had 22.4% fewer visits than control groups).

Among women, intervention groups also had lower outpatient health care utilization rates for hypertension, dyslipidemia and diabetes than control groups in all age groups and overall by one, two, and three years later. Intervention groups overall had a cumulative outpatient health care utilization rate of 7.08 visits per 3 years, whereas control groups overall had a cumulative rate of 9.01 visits per 3 years, and the difference was 1.93 visits (intervention groups had 21.4% fewer visits than control groups).

Figure 7. Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance







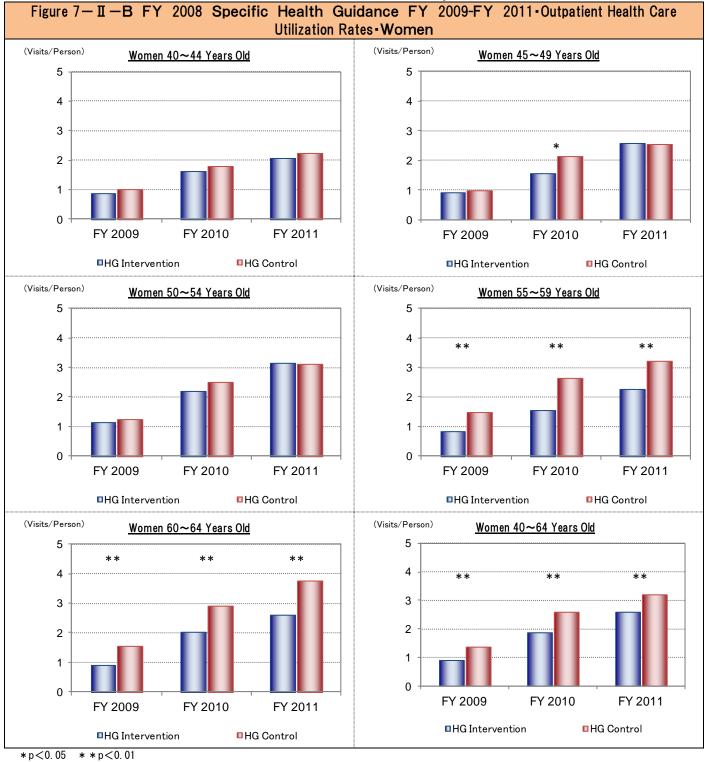
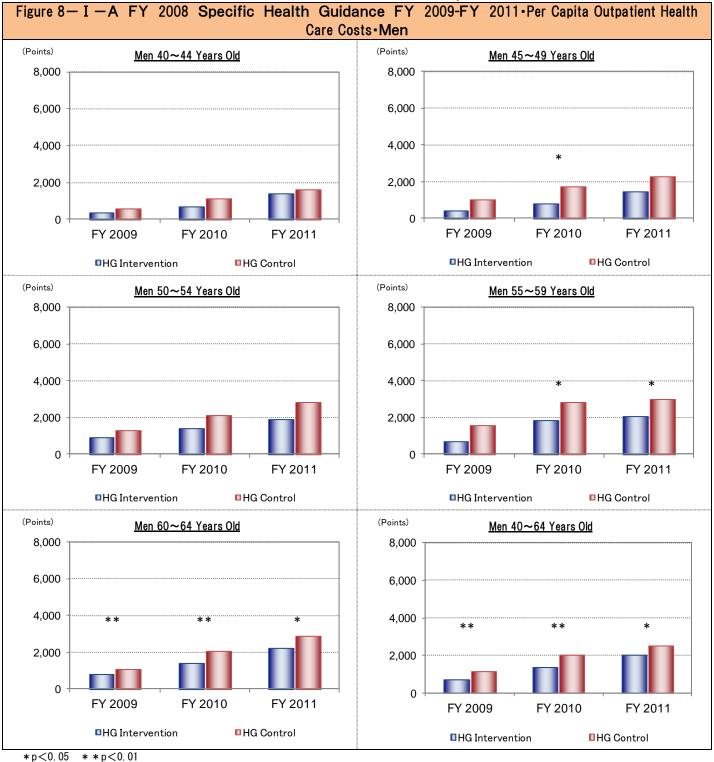
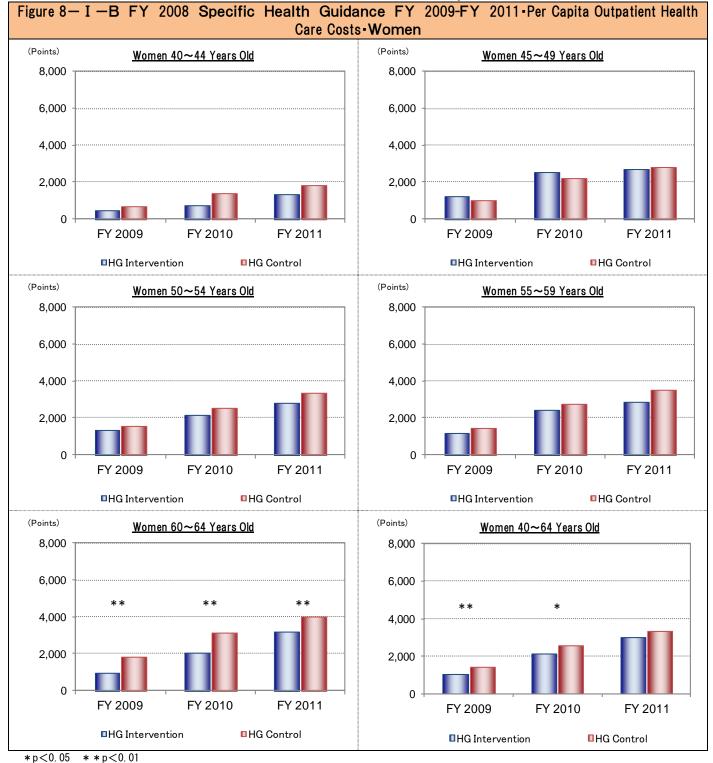
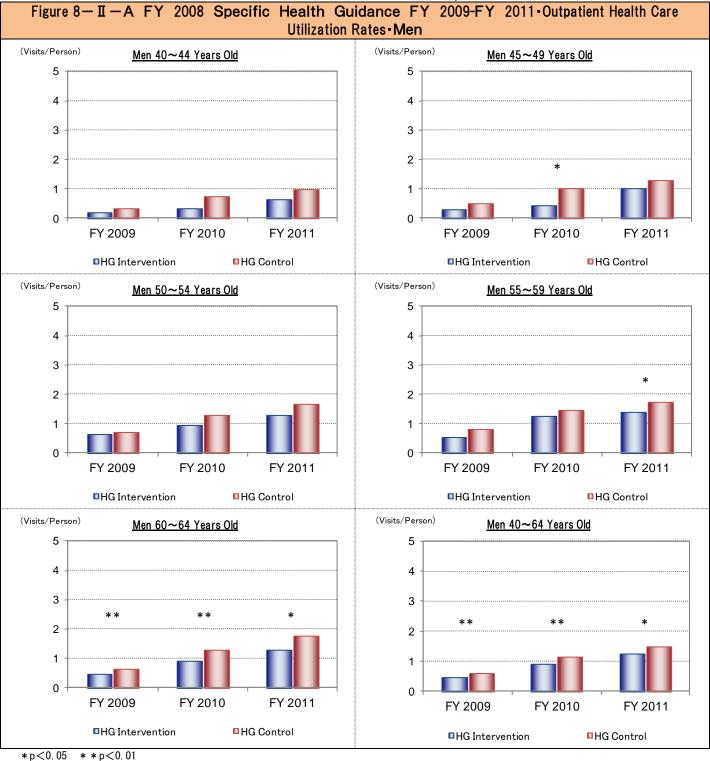


Figure 8. Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance







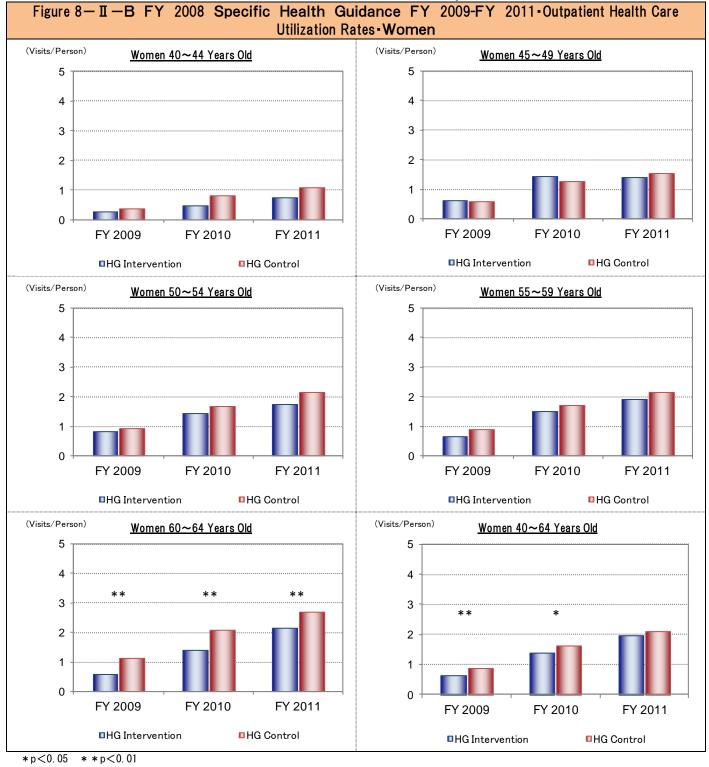
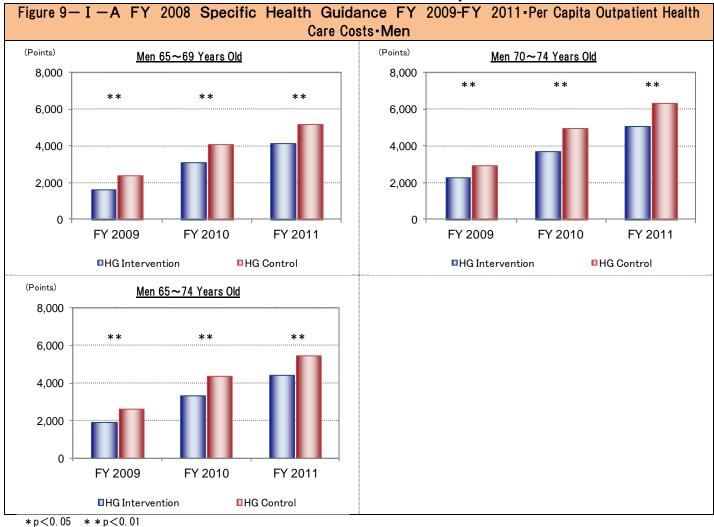
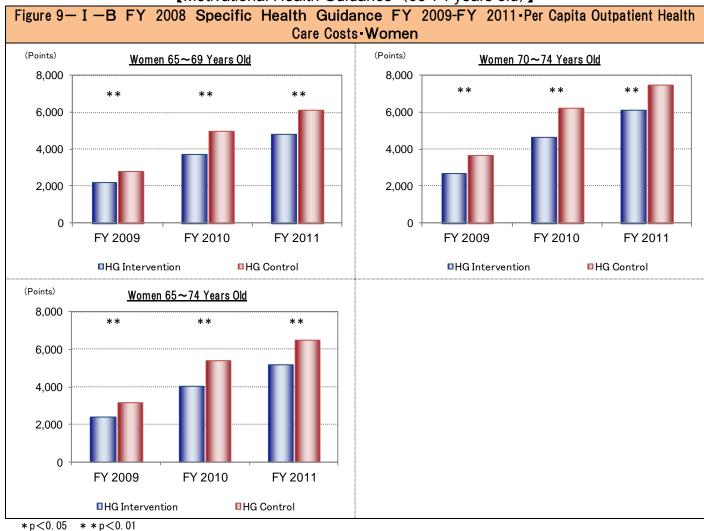
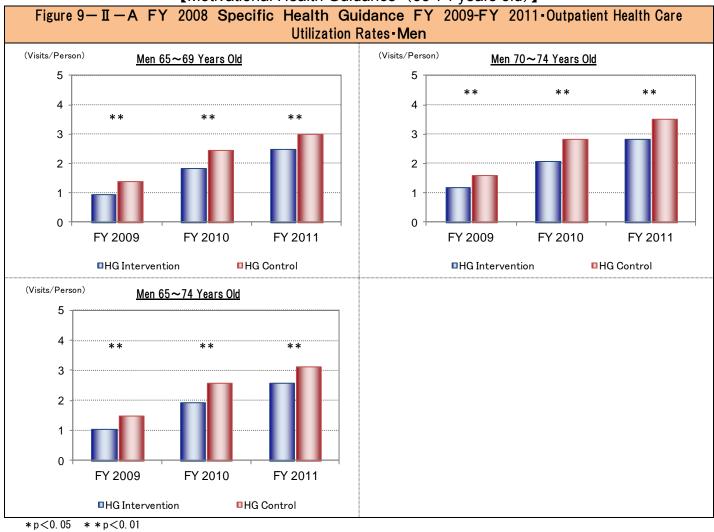
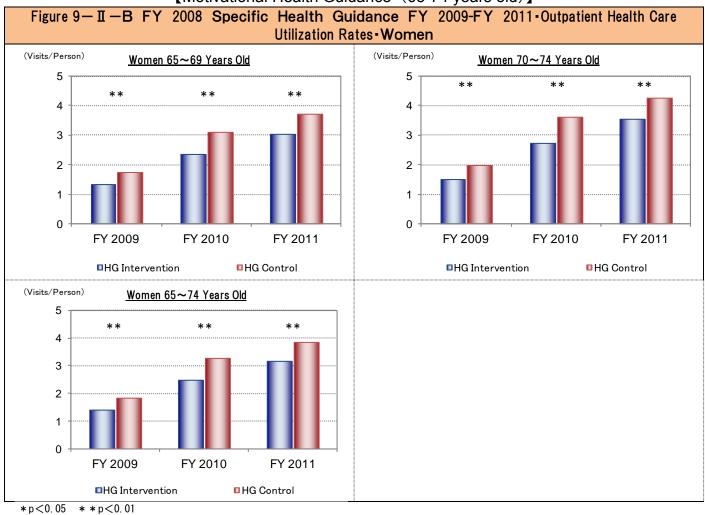


Figure 9. Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance









# (3) Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance (Follow-up Analysis of Baseline Cohort)

The following sections report longitudinal analysis of per capita outpatient health care costs and outpatient health care utilization rates for hypertension, dyslipidemia and diabetes by following up the same subjects for three years regardless of whether they have clinical indicator data. Overall results are nearly the same as the results reported in the section (2). Detailed analysis results are reported below.

#### a. Intensive Health Guidance (40 to 64 years of age)

#### I. Per Capita Outpatient Health Care Costs (Page 230, Figures 10-I-A~B)

In both men and women, intervention groups had significantly lower per capita outpatient health care costs for hypertension, dyslipidemia and diabetes than control groups in all age groups by one, two, and three years later. Among men, intervention groups overall (40 to 64 years of age) had cumulative points of 5,556 for the three year period, whereas control groups overall had cumulative points of 7,456 for the same time period, and the difference was 1,900 points (intervention groups had 25.5% fewer points than control groups). Among women, intervention groups overall had cumulative points of 7,856 for the three year period, whereas control groups overall had cumulative points of 9,977 for the same time period, and the difference was 2,121 points (intervention groups had 22.3% fewer points than control groups).

#### II. Outpatient Health Care Utilization Rates (Page 232, Figures 10-II-A~B)

In both men and women, intervention groups generally had lower outpatient health care utilization rates for hypertension, dyslipidemia and diabetes than control groups in all age groups by one, two, and three years later. Among men, intervention groups overall (40 to 64 years of age) had a cumulative outpatient health care utilization rate of 3.09 visits per 3 years, whereas control groups overall had a cumulative rate of 3.95 visits per 3 years, and the difference was 0.86 visits (intervention groups had 21.8% fewer visits than control groups). Among women, intervention groups overall had a cumulative outpatient health care utilization rate of 4.74 visits per 3 years, whereas control groups overall had a cumulative rate of 5.64 visits per 3 years, and the difference was 0.90 visits (intervention groups had 16.0% fewer visits than control groups).

#### b. Motivational Health Guidance (40 to 64 years of age)

#### I. Per Capita Outpatient Health Care Costs (Page 234, Figures 11-I-A~B)

Among men, intervention groups had generally lower per capita outpatient health care costs for hypertension, dyslipidemia and diabetes than control groups in all age groups by one, two, and three years later. Intervention groups overall (40 to 64 years of age) had cumulative points of 3,961 for the three year period, whereas control groups overall had cumulative points of 4,978 for the same time period, and the difference was 1,017 points (intervention groups had 20.4% fewer points than control groups). Among women, intervention groups had generally lower per capita outpatient health care costs, but intervention groups had higher costs in the 55 to 59 age group and intervention groups overall by three years later. Intervention groups overall had cumulative points of 6,010 for the three year period, whereas control groups overall had cumulative points of 6,167 for the same time period, and the difference was 157 points (intervention groups had 2.6% fewer points than control groups). The effect

of motivational HG was noticeably smaller in female motivational HG subjects, compared with male motivational HG subjects and intensive HG subjects overall.

#### II. Outpatient Health Care Utilization Rates (Page 236, Figures 11-II-A~B)

Among men, intervention groups generally had lower outpatient health care utilization rates for hypertension, dyslipidemia and diabetes than control groups in all age groups by one, two, and three years later. Intervention groups overall (40 to 64 years of age) had a cumulative outpatient care utilization rate of 2.40 visits per 3 years, whereas control groups overall had a cumulative rate of 2.70 visits per 3 years, and the difference was 0.30 visits (intervention groups had 11.1% fewer visits than control groups).

Among women, intervention groups overall had generally lower outpatient health care utilization rates, but similar to the per capita outpatient health care costs, intervention groups had higher outpatient health care utilization rates in the 55 to 59 age group (in two and three years later) and overall (in three years later). Intervention groups overall had a cumulative outpatient health care utilization rate of 3.70 visits per 3 years, whereas control groups overall had a cumulative rate of 3.69 visits per 3 years. Intervention groups overall had 0.01 more visit than control groups.

#### c. Motivational Health Guidance (65 to 69 years of age)

#### I. Per Capita Outpatient Health Care Costs (Page 238, Figures 12-I-A~B)

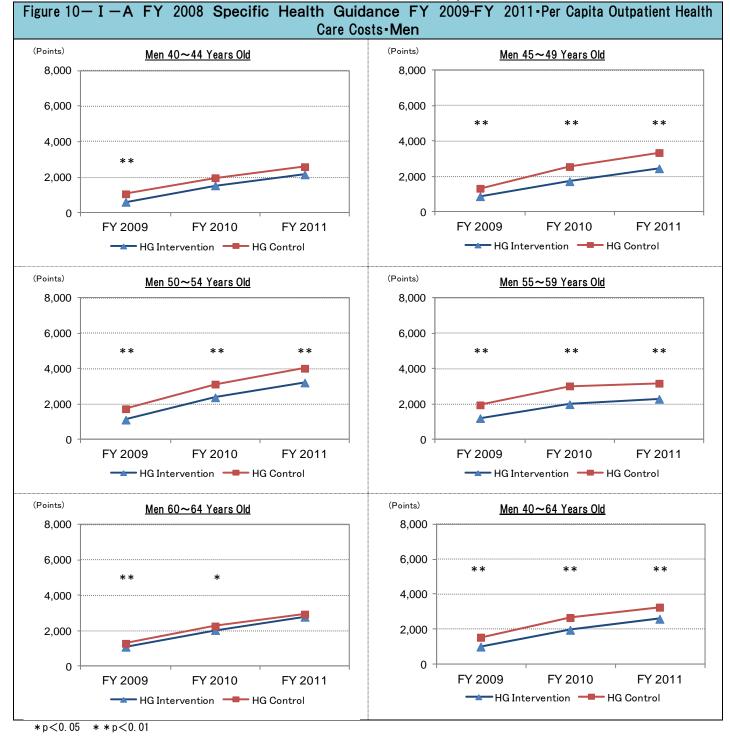
In both men and women, intervention groups had significantly lower per capita outpatient health care costs for hypertension, dyslipidemia and diabetes than control groups in all age groups by one, two, and three years later. Among men, intervention groups overall (65 to 69 years of age) had cumulative points of 9,138 for the three year period, whereas control groups overall had cumulative points of 11,556 for the same time period, and the difference was 2,418 points (intervention groups had 20.9% fewer points than control groups). Among women, intervention groups overall had cumulative points of 10,896 for the three year period, whereas control groups overall had cumulative points of 13,377 for the same time period, and the difference was 2,481 points (intervention groups had 18.5% fewer points than control groups).

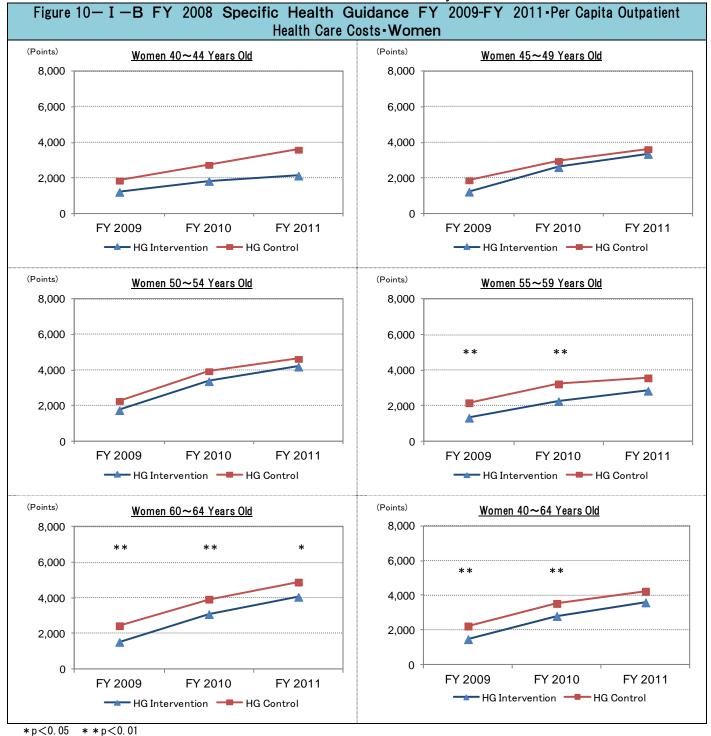
#### II. Outpatient Health Care Utilization Rates (Page 239, Figures 12-II-A~B)

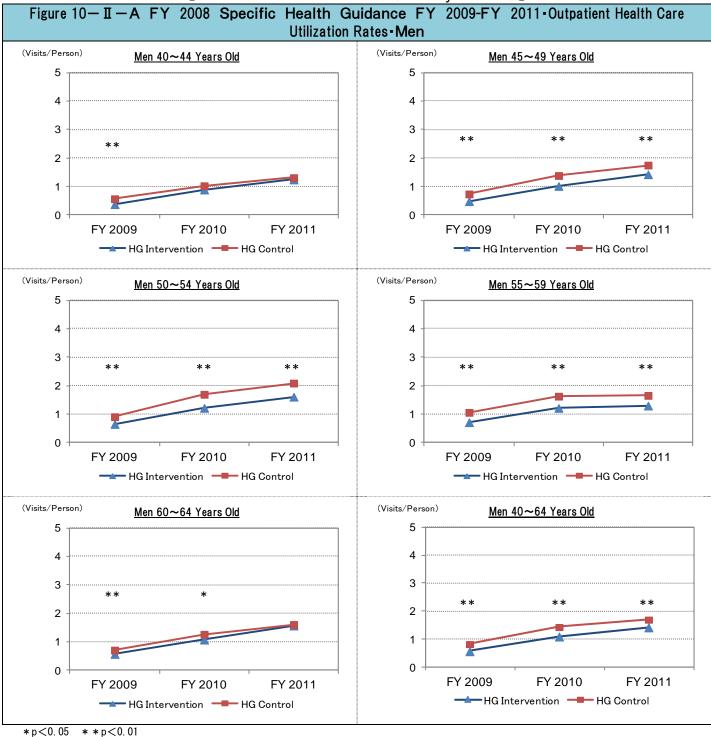
In both men and women, intervention groups had significantly lower outpatient health care utilization rates for hypertension, dyslipidemia and diabetes than control groups in all age groups by one, two, and three years later. Among men, intervention groups overall (40 to 69 years of age) had a cumulative outpatient care utilization rate of 5.19 visits per 3 years, whereas control groups overall had a cumulative rate of 6.33 visits per 3 years, and the difference was 1.14 visits (intervention groups had 18.0% fewer visits than control groups). Among women, intervention groups overall had a cumulative outpatient health care utilization rate of 6.55 visits per 3 years, whereas control groups overall had a cumulative rates of 7.73 visits per 3 years, and the difference was 1.18 visits (intervention groups had 15.3% fewer visits than control groups).

Figure 10. Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance

(Follow-up Analysis of Baseline Cohort)







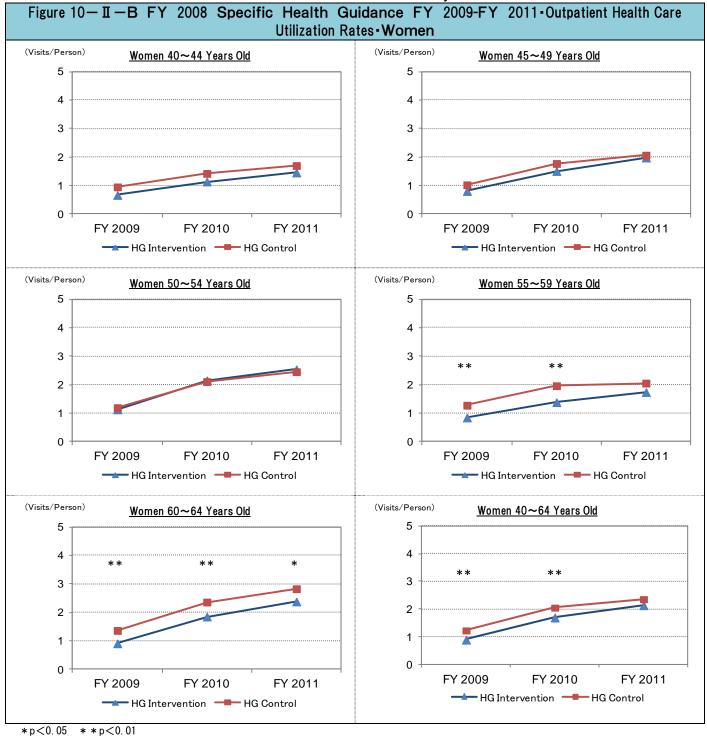
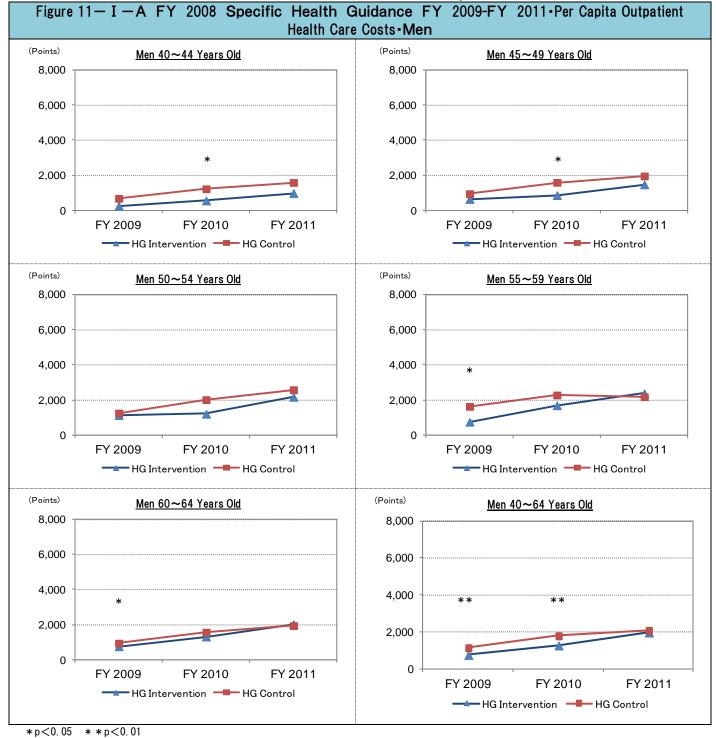
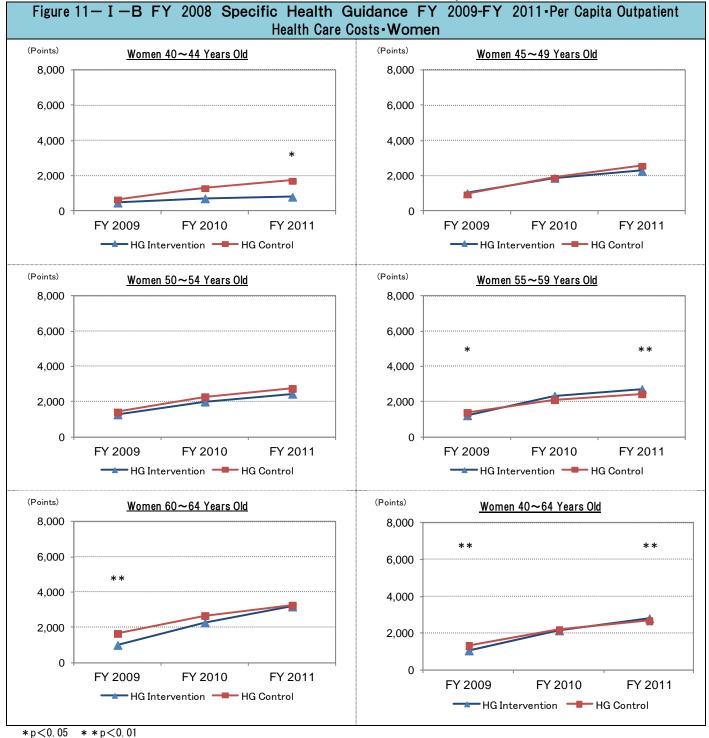
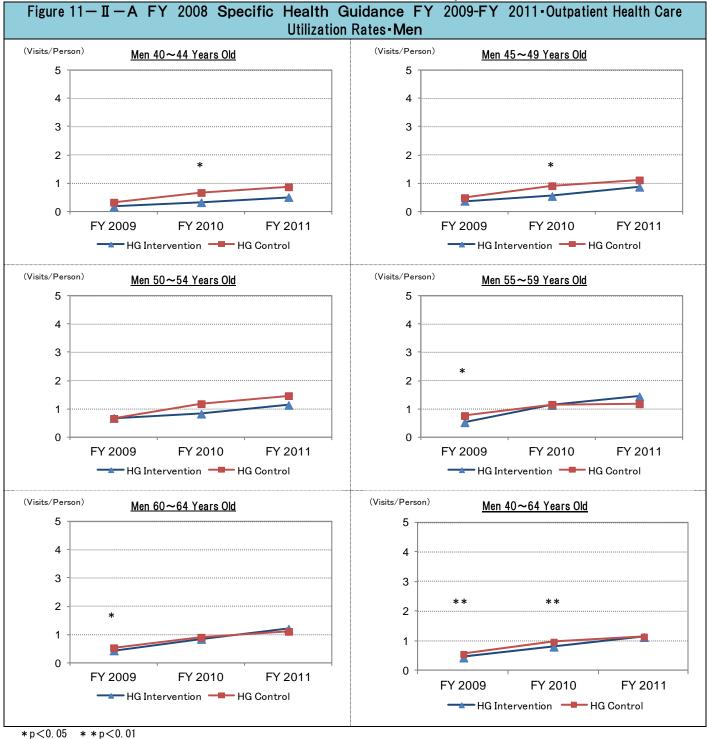


Figure 11. Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance

(Follow-up Analysis of Baseline Cohort)







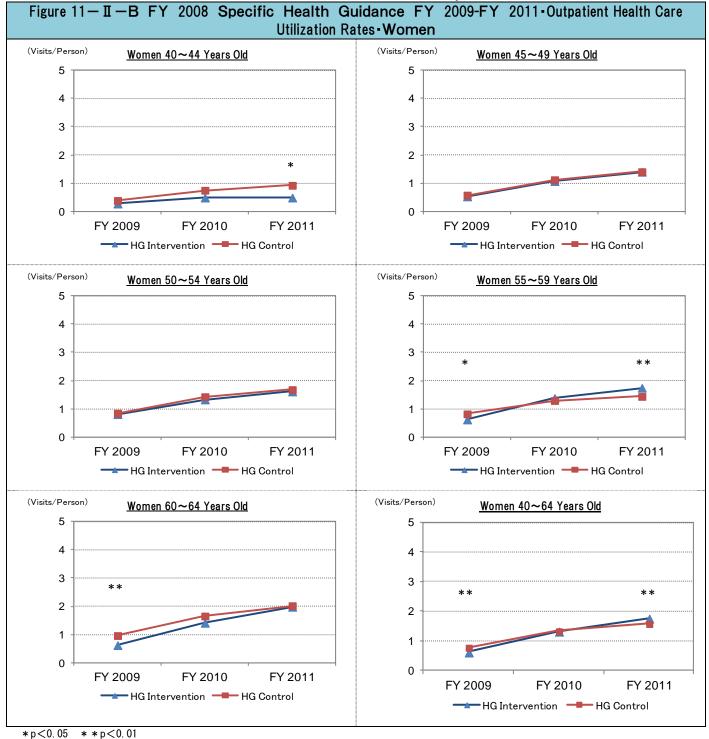
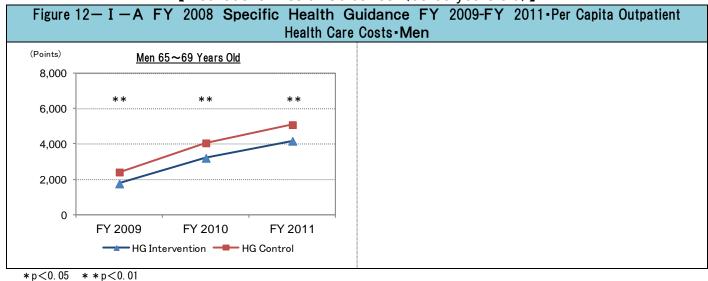
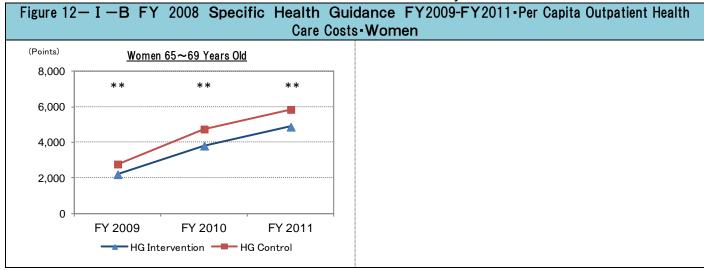


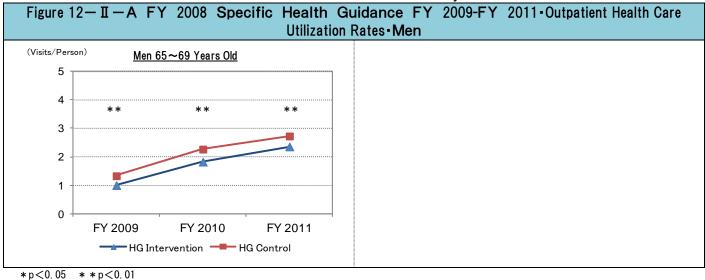
Figure 12. Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance

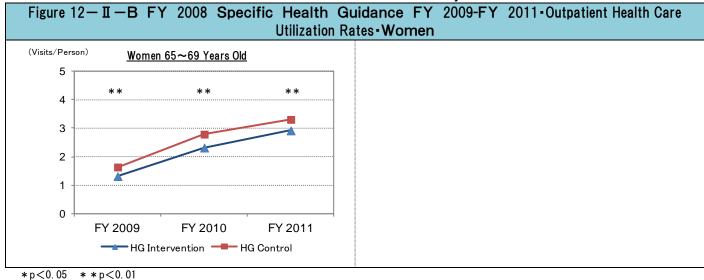
(Follow-up Analysis of Baseline Cohort)

[Motivational Health Guidance (65-69 years old)]









#### 4-4. Discussion

This Third Interim Report investigated changes in clinical indicators, per capita outpatient health care costs, and outpatient health care utilization rates associated with hypertension, dyslipidemia, and diabetes over a three-year period. Study subjects were enrollees who became eligible for specific health guidance (HG) due to elevated metabolic risks in fiscal year (FY) 2008. Those who completed HG in FY 2008 (intervention) and those who did not participate in HG in the same year (control) were compared.

In the analyses (1) and (2), health examination data, outpatient health care costs, and outpatient health care utilization rates were compared between intervention and control groups. In both analyses, subjects were those who had health examination data and health care utilization/expenditure data in the same fiscal year, therefore researchers were able to investigate associations between clinical indicators and health expenditures. Readers should note, however, that outpatient health care utilization/costs of those who did not participate in health examinations were not included in these analyses, and that numbers of study subjects were unique in each year.

To address these issues, in the analysis (3), per capita outpatient health care costs and outpatient health care utilization rates were examined by following up the same subjects over time, regardless of whether the subjects participated in health examinations or not in subsequent years. In these analyses, associations between clinical indicators and health expenditures could not be examined due to inclusion of subjects who did not participate in health examinations, but how health care costs and utilization changed over time in the same subjects were captured due to the cohort design.

These two types of analyses have both strengths and weaknesses, but results that are shared by both types of analyses should be regarded as important findings.

# (1) Longitudinal Analysis of Clinical Indicators Following Health Guidance

For the analysis of intensive HG, a total of 10,948 intervention and 78,072 control subjects were included and their clinical indicators were monitored for three years. It was found that intervention groups significantly improved obesity-related clinical indicators including waist circumference, BMI, and body weight, as well as triglycerides and HDL cholesterol, indicating that intensive HG was effective in reducing metabolic health risks. Intervention groups also had generally lower/better values in these indicators than control groups in most age groups during the three year period. Intensive HG provided lifestyle modification goals that focused on energy balance. It appears that after 6 months of continuous support, intensive HG participants learned how to manage their weight effectively. Intensive HG participants also maintained significantly lower triglyceride levels throughout the follow-up period. This indicates that participants maintained an ideal energy balance by regulating energy intake from food and increasing energy expenditure by physical activity even after they had completed HG.

It was also found that blood glucose (HbA1c) increased incrementally in subsequent years among control groups, but it decreased by one year later and tended to stay at a lower level among intervention groups. It became clear that when intensive HG-eligible subjects did not participate in HG, their blood glucose would increase, causing a potentially dangerous health situation. As results of this study suggest, intensive HG could prevent increases of blood glucose levels. It seems that rigorous health guidance is feasible for preventing diabetes.

As for blood pressure, significant baseline differences were detected between intervention and control groups. To minimize baseline differences, additional analyses were performed with subjects whose systolic blood pressure was below 160mmHg, and with subjects whose diastolic blood pressure was below 100mmHg. The additional analyses reduced baseline differences in blood pressure values, and

found that intervention groups generally maintained lower blood pressure than control groups in subsequent years.

To summarize, this study demonstrated that intensive HG-eligible subjects who had completed intensive HG significantly reduced waist circumference, BMI, body weight, and triglycerides, and maintained the lower values for three years. Intervention groups also maintained generally lower blood glucose (HbA1c) levels and blood pressure than control groups, suggesting that intensive HG could be effective to prevent diabetes and hypertension.

These improvements in clinical indicators were likely the results of lifestyle modification, but it is important to consider if pharmaceutical treatment had any role in them. As the analysis (2) demonstrated, subjects who had completed intensive HG had lower outpatient health care utilization rates and also lower outpatient health care costs for hypertension, dyslipidemia and diabetes compared with their controls. Therefore, intervention groups were less likely to be influenced by pharmaceutical treatment than control groups. Furthermore, reductions in body weight and waist circumference in intervention subjects strongly suggest reduction of visceral fat. It is feasible to think that intensive HG brought improvement in lifestyle and subsequent visceral fat reduction, which in turn contributed to improvements of other metabolic risk factors including blood pressure, blood glucose and lipids.

For the analysis of motivational HG, subjects were split into the 40 to 64 age group and the 65 to 74 age group. Subjects in the latter group had elevated metabolic risks that would qualify for intensive HG, but because of their older age, they were assigned to motivational HG.

Among the 40 to 64 age group, subjects who had completed motivational HG had lower waist circumference, BMI, body weight, and triglycerides compared to baseline by three years later. Although the amounts of reductions were not as great as those who had completed intensive HG, motivational HG was effective to reduce metabolic health risks.

Among the 65 to 74 age group, subjects who had completed motivational HG had greater improvements in clinical indicators compared with the 40 to 64 age group. Because baseline blood pressure and HbA1c were significantly different between intervention and control groups, additional analyses without subjects with elevated blood pressure and glucose values were conducted. These additional analyses confirmed that motivational HG was effective in reducing metabolic health risks.

Compared with intensive HG, motivational HG is simpler and with lower frequencies of in-person contacts, but participants receive detailed explanations of health examination results, and learn the importance of setting lifestyle modification goals. Because motivational HG does not involve follow-up support, it is not as effective as intensive HG, but this approach can be more cost effective as it can reach a large number of eligible subjects with minimal personnel and resources.

# (2) Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance

In the analysis of intensive HG, intervention groups had significantly lower outpatient health care costs and outpatient health care utilization rates for hypertension, dyslipidemia and diabetes compared with control groups. The difference in three-year cumulative points between intervention and control groups was 2,515 points (29.5% reduction in outpatient health care costs) in men, and 3,399 points (27.4% reduction in outpatient health care costs) in women. Furthermore, intervention groups had significantly lower outpatient health care costs and utilization rates in all age groups in men, and age groups greater than 55 years in women.

In the analysis of motivational HG, the difference in three-year cumulative points between intervention and control groups was 1,520 points (26.7% reduction in outpatient health care costs) in men, and 1,174 points (16.0% reduction in outpatient health care costs) in women. The amounts of reduction were not as great as those in intensive HG.

In the 65 years and older age group, the difference in three-year cumulative points between intervention and control groups was 2,877 points (22.9% reduction in outpatient health care costs) in men, and 3,493 points (23.1% reduction in outpatient health care costs) in women. The absolute amounts of costs reductions were greater in the older age group. As subjects age, they tend to have multiple health risks and higher prevalence of chronic disease. Therefore, outpatient health care costs would increase in both older intervention and older control subjects, but this study demonstrated that motivational HG was able to suppress cost increases.

To summarize, results of the analyses (1) and (2) suggest that participation in HG would improve metabolic health indicators and reduce the needs for prescription drugs, leading to reduction in outpatient health care costs.

# (3) Longitudinal Analysis of Per Capita Outpatient Health Care Costs and Outpatient Health Care Utilization Rates for Hypertension, Dyslipidemia, and Diabetes Following Health Guidance (Follow-up Analysis of Baseline Cohort)

In this analysis, the same subjects were followed up for three years after the completion of HG to examine the effects of HG on outpatient health care costs and utilization. The reductions in outpatient health care costs attributed to completion of HG were as follows: Intensive HG (40 to 64 years of age), 1,900 points (25.5% reduction) in men and 2,121 points (21.3% reduction) in women. Motivational HG (40 to 64 years of age): 1,017 points (20.4% reduction) in men and 157 points (2.6% reduction) in women. Motivational HG (65 to 69 years of age): 2,418 points (20.9% reduction) in men and 2,481 points (18.5% reduction) in women.

These results of the analysis (3) were very similar to the results of analyses (2) for subjects with intensive HG and older subjects (65 years of age and older) with motivational HG. For younger (40 to 64 years of age) subjects with motivational HG, results of the analysis (3) were also generally similar to the analyses (2), but in some age groups, the effects of HG were smaller in the analysis (3).

Based on the results from analyses (2) and (3), it became evident that subjects who had completed HG had lower outpatient health care costs than non-participants in following three years.

### 5. Closing Remarks

This Work Group was convened to investigate the effects of the Specific Health Checkups and Specific Health Guidance (SHCSHG) on the savings in national health care expenditures using the SHCSHG data and the health insurance claims (HIC) data deposited in the National Insurance Claims Database (NDB).

The Work Group began its activity in March 2013, and published the First Interim Report, which summarized the SHCSHG's effects on clinical indicators, and the Second Interim Report, which summarized the SHCSHG's effects on health care costs. This report contains the results of the most recent investigation regarding the SHCSHG's effects on clinical indicators and health care costs over multiple years. By combining the Third Interim Report with the First and Second Interim Reports, this document serves as the Final Report to describe all findings of the investigations the Work Group has worked on.

The Work Group faced several technical difficulties. The NDB contained data for only a limited time period: the SHCSHG data for FY 2008 to 2012, and the HIC data for FY 2009 to FY2013. Furthermore, linking these two datasets at the individual level had many technical problems. Despite limitations, the Work Group came up with analytic methods for measuring the SHCSHG's effects on clinical indicators and health care costs. The Work Group was also able to demonstrate that health guidance intervention groups had better outcomes compared with control groups in the short-term (using the following year's data) and in the long-term term (using the three-year longitudinal data). The results generated from the series of investigations were very valuable for improving participations in future health examinations and health guidance.

The Work Group will disseminate the results of these investigations to health insurers to help them improve participation rates of health examinations and health guidance. As the data deposited in the NDB expands, the Work Group will continue to investigate the effects of SHCSHG using the analytic techniques it developed in the most recent investigation. Furthermore, along with national-level macro studies using the NDB, the Work Group plans to conduct micro-level studies that would directly support individual health insurers' performance. These include development of a simulation tool for investigating savings in health expenditure, and more effective health guidance methods. The Work Group will share results of new investigations with health insurers.

# Appendix: Diagnostic Codes and Drug Codes Associated with Hypertension, Hyperlipidemia, and Diabetes

The diagnostic codes and drug codes associated with the three diseases (hypertension, hyperlipidemia and diabetes) were selected by the Work Group using the criteria described below.

#### Diagnostic Codes Associated with the Three Diseases (30 codes in total)

Based on the ICD-10 classification (WHO) in the published Master Directory of Diseases, codes for hypertension (I10–I15), hyperlipidemia (disorder of metabolism of lipoprotein and other blood lipids: E78), diabetes (E10-E14), and unspecified abnormal blood test results (R739, R740, R81) were selected. However, diseases that are not caused by lifestyle behavior were excluded (*i.e.* type 1 diabetes, secondary hypertension, familial hypercholesterolemia and others)

#### Drug Codes Associated with the Three Diseases (2,809 codes in total)

Based on the ATC classification (WHO) and the classification of drug efficacy (Ministry of Health, Labour and Welfare) in the published Master Directory of Drugs, drugs used for hypertension, hyperlipidemia and diabetes were selected (A10 drugs used in diabetes, B01 antithrombotic agents, C02-C09 drugs used in cardiovascular diseases). Among drugs classified as coronary vasodilators, ones that are used to treat hypertension were included. Among drugs classified as pancreatic hormones, inulin and others used to treat diabetes were also included. For drugs that were classified as "other XX agents", their eligibility for selection was determined individually by examining their drug efficacy.

#### Diagnostic Codes Associated with Malignant Neoplasms (1,612 codes in total)

For this analysis, the number of individuals/cases that actually developed the diseases was measured by specifying the relevant month claims that contained a diagnostic code as well as a drug code associated with the three diseases. Monthly claims containing diagnostic codes for malignant neoplasms that could greatly impact total health care costs were excluded from analysis.

\*As for the Master Directory of Diseases (Ministry of Health, Labour and Welfare), diagnostic codes were selected after all codes (including codes that were added or discontinued) that existed between April 1<sup>st</sup> 2008 and February 28<sup>th</sup> 2014 (the time of the latest revision) had been consolidated. Furthermore, each disease was individually scrutinized. In addition, because filling in a disease name in monthly claims does not affect calculation of medical care points, there is a possibility that discontinued diagnostic codes are still in use.

\*As for the master directory of drugs (Ministry of Health, Labour and Welfare), selection of drug codes based on the ATC classification (WHO) and the classification of drug efficacy (Ministry of Health, Labour and Welfare) was conducted after all codes (including codes that were added or discontinued) that existed between April 1st 2008 and February 3rd 2014 (the time of the latest revision) had been consolidated. Furthermore, each drug was individually scrutinized. In addition, because revision of drug classifications accompanies revision of medical care points (drug costs), it is less likely that discontinued drug codes are still in use.

※ The diagnostic codes associated with the three diseases (30 codes in total), the drug codes associated with the three diseases (2,809 codes in total), and the diagnostic codes associated with malignant neoplasms (1,612 codes in total) are published on the Ministry of Health, Labour, and Welfare's web site. URL: http://www.mhlw.go.jp/stf/shingi2/0000066373.html

# **Work Group Meeting Schedule and Agenda**

The Work Group for Studying the Effects of the Specific Health Checkup and Specific Health Guidance on Health Care Expenditures

Meeting #	Date	Agenda
1	March 1, 2013	Methods of studies
2	September 17, 2013	Progress of the SHCSHG's effects on health indicators
3	December 10, 2013	Progress of the SHCSHG's effects on health indicators
4	February 7, 2014	The SHCSHG's effects on health care expenditures
5	March 10, 2014	Interim report (draft)
6	March 17, 2014	Interim report (draft)
7	May 23, 2014	Study of the SHCSHG's effects on health care expenditures
8	August 28, 2014	Study of the SHCSHG's effects on health care expenditures
9	September 12, 2014	Study of the SHCSHG's effects on health care expenditures
10	September 22, 2014	Results of health examination and health guidance results for the first term
11	October 9, 2014	Study of the SHCSHG's effects on health care expenditures
12	October 22, 2014	Study of the SHCSHG's effects on health care expenditures
13	October 27, 2014	Study of the SHCSHG's effects on health care expenditures
14	November 10, 2014	Study of the SHCSHG's effects on health care expenditures
15	December 22, 2014	Study of the SHCSHG's effects on health care expenditures
16	February 18, 2015	Study of the SHCSHG's effects on health care expenditures
17	March 6, 2015	Study of the SHCSHG's effects on health care expenditures
18	March 18, 2015	Study of the SHCSHG's effects on health care expenditures
19	March 31, 2015	Study of the SHCSHG's effects on health care expenditures

# **Work Group Members (in alphabetical order)**

The Work Group for Studying the Effects of the Specific Health Checkup and Specific Health Guidance on Health Care Expenditures

FUKUDA, Takashi	福田敬	Research Managing Director, National Institute of Public Health (国立保健医療科学院統括研究官)
ITO, Yukiko	伊藤由希子	Associate Professor, Tokyo Gakugei University (東京学芸大学准教授)
KITAMURA, Akihiko	北村明彦	Associate Professor, Osaka University Graduate School of Medicine (大阪大学大学院医学系研究科准教授)
MIURA, Katsuyuki	三浦克之	Professor, Shiga University of Medical Science (滋賀医科大学教授)
TATARA, Kozo	多田羅浩三	President, Japan Public Health Association(一般財団法人日本公衆衛生協会会長)
TSUSHITA, Kazuyo	津下一代	Director, Aichi Health Plaza Comprehensive Health Science Center(あいち健康の森健康科学総合センター 長)

# Consultant

HOSLER, Akiko S. ホスラー晃子 Associate Professor, University at Albany (SUNY) School of Public Health