V.1.4. Discussion

(1) Evaluation of Estimation Results

From Table 3, showing the average shot rate and average copayment, we can see that the price elasticity of shot rate is −0.2606. It appears to be higher than the results of the previous study. That is, the study based on the conjoint analysis which is the most reliable technique with a hypothetical questionnaire indicates −0.02 to −0.04 for the elasticity, and the actual behavior in the '01/'02season indicates −0.1 for the elasticity[4]. Hence, the result in this paper shows that the shot rate is very elastic against price.

There are two main reasons for these differences. Firstly, this study focus on the metropolitan and big cities and so it may be biased toward extremely urban areas, whereas the previous studies cover the whole of Japan. If the residents in the urban areas have higher price elasticity to vaccination than rural areas, our results here may be reasonable. In this sense, the previous studies seem to be more general than this research.

Conversely, the data in this paper covers all residents in an area, while the previous study relied on survey by mail and it did not cover all the residents, of course, and they may not be representative. If the respondents of the questionnaire tend to have inclination toward vaccination for influenza compared with non-respondents, the shot rate may be insensitive to price. In this sense, the result in this study seems to be more reliable than the previous one. Though, it is not certain which estimate and reasoning is more reasonable, We have to remind ourselves that our final goal, namely the analysis with the BCR, is independent of price elasticity of shots as explained before.

On the other hand, the shot rate elasticity of mortality rate is −2.48, and thus mortality is elastic against shot rate. Combining these two estimation results, if copayment would be cut by a thousand yen (eight dollars), it raises the shot rate by 7 percentage points, and reduces the mortality rate due to pneumonia and influenza by .029 percentage point. It seems like a very small number, but since the average mortality rate due to pneumonia and influenza is very small, the effect certainly is quite high. In fact, this means this policy can reduce about 423 death in an average big city.

Since F statistics in the first equation is higher than ten, the fitted variables seems to be good instrument[5]. In other words, the reason of insignificance of the shot rate in the crude weighted least square can be inferred as positive simultaneous bias which offsets the shot rate effect on the mortality rate. Therefore, the instrument variable can solve this bias and it is a more appropriate method for this problem.

(2) Evaluation for BCR

The obtained BCR, 22.4, is quite high compared with the other countries or other vaccinations. In some other countries, since it is 1.93[6] for children before school and 1.81[7] or 2.92[8] for healthy adults, the obtained IBCR is much higher. Compared with other diseases, it is 2.5[9] for measles in Japan and it is just 1.4[10] in the case of hepatics B for all infants in China where there are epidemic areas. Overall, the policy of subsidy for shots for the elderly is quite cost-effective and there is concrete evidence for this.

(3) Problem and limitation in this analysis

At first, there are some differences in the definition of population among areas for the policy targeting or/and for the shot rate calculation. Especially, this policy also subsidizes the non-elderly, i.e. between 60 and 64 years old, who have heart, kidney, and respiratory problem or HIV career. Moreover, each city sometimes extend the target population more than the national policy requirement. Typically, some cities subsidize the institutionalized elderly even if they are younger than 65. These additional target populations are included in the denominator in some cities, but are not in other cities. The subsidized number in the numerator of the shot rate include such additional targeting populations, and thus the shot rate may be different depending on whether the denominator include such additional targeting populations or not. However, these additional target populations are quite small compared with the elderly, and it is less than just one percent. Therefore, such an inconsistency in the denominator of the shot rate may not substantially affect the result.

Moreover, the starting date of subsidy is not the same among areas. In particular, it is remarkable in the first season of this policy, i.e. the '01/'02 season. Our data of shot rate only includes those who received the subsidy, and does not include those who did not receive subsidy but received shots. So the shot rate may be lower than the actual rate in the area where the starting date of subsidy was delayed. In this sense, the data of shot rate is always lower than the actual shot rate among the elderly. This measurement error may lead to upper bias of the estimated coefficient of the shot rate in the second estimation. Hence, it also lead upper bias in IBCR. However, it is not sure how many elderly people received a shot but were not subsidized, and so we cannot evaluate this effect in detail.

On the other hand, it is questionable whether our sample in the metropolitan and big cities represents the whole of Japan or not. The coverage of the elderly population in our data is 21% of Japan, but it may not be the average population. Especially, there may be big differences from those in the rural areas as mentioned before. So as to check the robustness of the obtained result, we should extend our analysis to the other areas.

Additionally, the effect of the influenza epidemic on the mortality rate is measured by excess mortality which is defined by the difference between the actual number of deaths and the hypothetical number in the case of no influenza epidemic[11-14]. Therefore, we have to replace the mortality definition from the crude number of death to the excess mortality. In particular, excess death should be defined regardless of the cause of death[14] because it is very well known that the influenza epidemic raises the mortality rate from other causes than pneumonia or influenza and these death can be prevented by the vaccination and control of the influenza epidemic. Moreover, if we can limit the number of deaths to those of more than 65 years old, it would be a more precise measure. In this sense, the excess mortality of those older than 65 years old in all causes of death is the best measure to evaluate the vaccination effect.

At the same time, we also need more explanatory variables which affect the shot rate or mortality. For example, the hortative measure for vaccination may be much different among local governments and it may affect the shot rate. Even in this case, if such a measure did not change in an area in the two season, this effect can be controlled out completely by the area dummies and it does not affect the estimated coefficient.

On the other hand, there are many implicit assumptions in BCR. First of all, since we limit the effect of vaccination to the prevention of death, and thus it is certainly a finer measurement than the prevention of the severe conditions like hospitalization as emphasized. Since it is difficult to obtain the data of the number of patients and the hospitalized, these numbers would be based on the similar estimation. Hence, these are far less precise than the number of death. In other words, we choose preciseness rather than broadness in the definition of effectiveness. Obviously, this limitation lower BCR. If we take the effects of vaccination on the number of patients and the hospitalized into consideration, BCR definitely becomes higher than the BCR discussed in this paper. It strengthens our conclusion in favor of the subsidy and has never change it.

Conversely, the ignorance of opportunity cost for vaccination or side effects certainly raises BCR. However, almost all of them are retired, and suffered from chronic disease and thus they usually visit a doctor, their additional opportunity cost for vaccination seems to be small. Concerning side effects, on 28 August, 2003, the Ministry of health and welfare reported only two fatal cases and 18 severe side effects from 1998 to 2003. Therefore, we can safely ignore these cost and the obtained conclusion is probably not affected by the introduction of these costs.

Finally, we can extend the effectiveness of vaccination to the number of patients or the medical cost. The data limitations of these variables are already mentioned. Moreover, since the primary purpose of vaccination is the prevention of severe cases, if we extend to these aspects, the results may not be clear and BCR may decline. In extreme case, the fatal case may use less medical resources compared with severe cases where the patients survives. In this sense, the limitation of effectiveness on the number of deaths seems to be more appropriate for considering the vaccination policy. Nevertheless, the research on the number of patients and medical cost are unambiguously important and we need to overcome the data limitations.

V.2. Example 2: Smoking Cessation Program

We show *ex ante* policy evaluation for smoking cessation program as another example of cost-effectiveness analysis in policy for medicine or public health which is originally in Ohkusa and Sugawara(2005a).

V.2.1. Objective

There are many programs to cease smoking, such as group therapy, individual therapy by professional staff such as medical doctors or nicotine replacement therapy. The Tobacco Use and Dependence Clinical Guideline Panel, Staff, and Consortium Representatives (2000) recommend the use of nicotine replacement therapy for nicotine dependence. In Japan, nicotine replacement therapy uses nicotine patch or nicotine gum, but the former requires a prescription written by a medical doctor. The later does not require it and we can buy it as an OTC (Over-the-counter) drug at any pharmacy without consultation by medical doctors. The Nicotine patch is used in more than 60 countries, and is an OTC in more than 30 countries. However, it has not switched to the OTC, yet in Japan. On the other hand, individual consultation by a medical doctor is not covered by health insurance in Japan.

This paper tries to conduct an ex ante cost effective analysis to evaluate new policies for smoking cessation, such as switching the nicotine patch to OTC (PO) and insurance coverage for individual therapy by medical doctors (PI).

V.2.2. Material and Method

The survey collected information through the web site in December 2004. The respondents were limited to smokers aged 20 to 59, and randomly drawn stratified are, age, and gender which replicate the national average from the list of the contracted members with the survey company.

It employs the hypothetical questionnaire which is used in the Conjoint analysis (Halpern, Berns and Israni(2004), Ratcliffe, Buxton, McGarry, Sheldon and Chancellor(2004), Maddala, Phillips and Johnson(2003) Schwappach(2003), Phillips, Maddala and Johnson(2002), Gyrd-Hansen and Slothuus(2002), Aristides, Chen, Schulz, Williamson, Clarke and Grant(2002), Bryan, Roberts, Heginbotham and McCallum(2002), Ratcliffe, Van Haselen, Buxton, Hardy, Colehan and Partridge(2002), Telser and Zweifel(2002), Gabriel, leung, Chan, Chau and Chua(2001), Johnson, Banzhaf and Desvousges(2000), Ratcliffe(2000), Tilley and Chambers(2000)). It asks the respondent to choose visiting a doctor or going to a pharmacy under the hypothetical situations: about cost of medical services and OTC, traveling time to visit a doctor, insurance coverage of individual consultation by a medical doctor, and explanation by a pharmacist on now to use the OTC drug.

In each attribute, the levels are set as follows; traveling time to visit a doctor: 30 minutes, 60 minutes, and 120 minutes, cost for both medical service and OTC: 100 thousand yen (800 dollars) to 500 thousand yen (4000 dollars) by 100 thousand yen (800 dollars), explanation by pharmacist: none, 5 minutes and 10 minutes, insurance coverage and switching to OTC: yes or no.

In the case of insurance coverage for medical service, costs for medical services are reduced to be 30%, which is the coinsurance rate in Japan. The Cost for medical services and OTC are selected from estimations of cost in the current situation. Expected rate of those who quit smoking is supposed to be the same among programs.

Hence there are 900 possible scenarios. Of these, we select 50 scenarios orthogonally. Then we allocate 10 questions to each respondent and set 5 patterns.

We adopt random effects Probit model which is very common to estimate the Conjoint analysis. Especially, we estimate it separately, whether nicotine patch is switched or not, so as to fully evaluate its effect. In each estimation, the dependent variable is binary; if i th the individual choose OTC for j (j=1,2,...,10) th question, then $O_{i,t}$=1, and is zero otherwise. The estimation equation is

$$O^*_{i,j} = \alpha_0 + \alpha_M \log M_{i,j} + \alpha_T \log T_{i,j} + \alpha_I I_{i,j} + \alpha_C \log C_{i,j} + \alpha^5_E E^5_{i,j} + \alpha^{10}_E E^{10}_{i,j} + \mu_i + \varepsilon_{i,j}$$

$$O_{i,j} = \begin{cases} 1 & \text{if } O^*_{i,j} > 0 \\ 0 & \text{otherwise} \end{cases} \qquad (12)$$

where $M_{i,j}$, $T_{i,j}$, $I_{i,j}$, $C_{i,j}$, $E^5_{i,j}$, $E^{10}_{i,j}$ are respectively the cost for medical service, the traveling time to visit a doctor, dummy for insurance coverage, the cost for OTC, dummy for a five minute explanation by a pharmacist, and dummy for a ten minute explanation by pharmacist. μ_i is the random effect that captures individual effects and $\varepsilon_{i,j}$ is a stochastic disturbance term.

Next, we perform a cost effective analysis of these two new policies, PO and PI, based on the estimated demand curve. We calculate the incremental benefit cost ratio (IBCR) with and without such an externality among the current situation and switching the nicotine patch to OTC, insurance coverage for smoking cessation therapy by a doctor, and both of them. Moreover, we refer to net benefit in this policy so as to evaluate its amount of gain or loss in monetary term.

V.2.3. Results

We collected information from 2,839 individuals and the response rate was 51.9%. The estimation results are summarized in Table 5. It shows that all coefficients are significant and the variance of the random effect is significantly more than zero. Therefore, its consideration is important.

Table 5 :Demand for OTC and Medical Services which Assists Quit Smoking

	Nicotine Patch		Nicotine Gum	
	Marginal Effect	*p* value	Marginal Effect	*p* value
Medical Cost(log)	0. 09595611	. 000	0. 23414278	. 000
Traveling Time(log)	0. 08233906	. 002	0. 09190193	. 000
Insurance Coverage	-0. 06234507	. 021	-0. 03687187	. 001
OTC Cost(log)	-0. 33815518	. 000	-0. 23327342	. 000
Explanation(5 min.)[a]	0. 09684908	. 000	0. 01804711	. 089
Explanation(10 min.)[a]	0. 07527379	. 050	0. 08756433	. 000
# of sample	4725		7066	
# of individuals	2375		2377	
p-value for χ^2 test[b]	<0. 0000		<0. 0000	
Log Likelihood	-1531. 5		-3187. 5	
p-value for χ^2 test[c]	<0. 0000		<0. 0000	

Note:Dependent variable is binary variable whether they demand for OTC (nicotine patch or nicotine gum) or not.[a]:"Explanation (5 min.)" and "Explanation (10 min.)" means that how long pharmacist explain about nicotine gum or patch when the consumer buy it at pharmacy.[b]: Likelihood ratio test for estimation model against constant term only.[c]: Likelihood ratio test for estimation model against the model without random effects.

The disease burden of smoking has been estimated as 3.7 to 7.3 trillion yen (Institute of Health Economics and Planning(1997), Ohkusa and Sugawara(2005b)). In this amount, externality is the insurance paid for the medical cost of treatment for smoking related disease. While it is not recognized as costs for smokers, it is actually the cost from the societal view point. Such externality is estimated as 0.88 to 1.12 trillion yen and rate of externality is estimated as 7.3/(7.3-1.12)-1=0.18.

The result of cost effective analysis is summarized in Table 6. It shows the results separately in terms of the externality considered. The first row indicates the case of switching nicotine patch to OTC. The second row presents the result of the case where the therapy by doctors does not become popular while it is covered by insurance, and where the traveling time is ninety minutes .The third and fourth rows summarize the result if the traveling time is reduced to be 60 or 30 minutes. Besides, the result if both PO and PI are implemented by traveling time is also shown. Table 7 shows the net benefit in OTC market and market of medical services.

Table 6:IBCR of Switching to OTC of Nicotine Patch and/or Insurance Coverage for Quit Smoking Therapy

Switching to OTC of Nicotine Patch	Insurance Coverage	Traveling Time (min.)	without Externality			with Externality		
				95% CI			95% CI	
			Median	Lower	Upper	Median	Lower	Upper
Yes	No	90	1.46	1.39	1.53	1.72	1.65	1.81
No	Yes	90	0.189	0.039	0.295	0.203	0.024	0.329
No	Yes	60	0.311	0.208	0.386	0.352	0.229	0.442
No	Yes	40	0.461	0.398	0.509	0.534	0.460	0.591
Yes	Yes	90	0.789	0.733	0.863	0.910	0.840	1.00
Yes	Yes	60	0.711	0.698	0.749	0.819	0.803	0.867
Yes	Yes	30	0.665	0.576	0.734	0.767	0.661	0.850

Table 7:Net Benefit of Switching to OTC of Nicotine Patch and/or Insurance Coverage for Quit Smoking Therapy by Doctor

Insurance Coverage	Traveling Time	After Switching		Before Switching	
		OTC	Medical Service	OTC	Medical Service
without Externality					
No	90	1321.0425 [929.8, 1805]	32.014884 [31.72, 32.27]	193.39717 [145.8, 252.9]	21.691252 [21.46, 21.92]
Yes	90	179.66613 [103.9, 207.5]	-211.5101 [-223.9, -198.7]	1.8866509 [1.193, .9411]	-712.20123 [-718.5, -705.7]
Yes	60	111.0619 [61.72, 191.2]	-214.41094 [-230.9, -197.6]	0.94754236 [.5874, 1.507]	-839.76731 [-848.4, -830.8]
Yes	30	44.870128 [23.23, 82.75]	-260.64714 [-288.6, -232.6]	0.27154143 [.1625, .4476]	-1013.9675 [-1028, -999.5]
with Externality					
No	90	2073.351 [1511, 2744]	47.488069 [47.23, 47.69]	303.77122 [231.9, 392.5]	36.81772 [36.55, 37.07]
Yes	90	340.16637 [206.1, 538.4]	-114.27436 [-128.1, -100.0]	3.4450426 [2.217, 5.282]	-571.11183 [-578.3, -563.7]
Yes	60	218.27756 [127.2, 358.7]	-106.47282 [-125.9, -86.70]	1.7637574 [1.112, 2.7599]	-654.23084 [-664.1, -644.0]
Yes	30	94.090628 [51.14, 165.4]	-9.1588703 [-39.45, 20.92]	0.52249262 [.3182, .8465]	-731.27581 [-747.5, -714.6]

These tables show obviously that the IBCR for PO exceeds one significantly and is 1.46 without externality, and is 1.72 with externality. The net benefit achieves 135 billion yen and it is higher than the current net benefit of 21 billion yen by more than 100 billion yen.

Conversely, the IBCR for PI is less than one, and thus it does not support the implementation of this reform. This policy reduces the net benefit in the OTC market to less than 0.2 billion yen due to the reduction in copayment by insurance coverage and the society loses 71.2 billion yen.

Moreover, if the number of medical institutions which provide smoking cessation therapy by doctors increases and traveling time is shortened to be 60 or 30 minutes, the net benefit in the OTC market is reduced to 30 million yen and the net loss in the market for medical service achieve more than 100 billion yen. Even if we take such an externality into consideration, it leads the negative net benefit amounts to 57 billion yen in the society as a whole. When we test PO and PI simultaneously, its IBCR is not larger than one significantly, even though the upper limit of a case reaches one.

V.2.4. Discussion

If we can assume that the expected benefit of quitting smoking is the same among smokers, the demand curve represents the subjective quit rate. In other words, the smokers who join the smoking cessation program are thought to have a higher subjective quit rate or have more aptitude of these programs than other smokers, those who do not join the program under the same price.

Conversely, almost all the cost effective analyses so far are usually based on the assumption of average individual or some artificial scenarios. Namely, the quit rate is assumed to be a certain level in all smokers in this case. It is true if we consider some nonexclusive public goods because the word "join" or "not join" does not make any sense. However it must not be true if we consider the private goods. In this sense, immunization, medical services or OTC drugs are exclusive private goods.

Even though there is heterogeneity among individuals, these studies ignore this clear fact and assume that they are homogenous. In our context, these typical cost effective analyses ignore the difference in the subjective quit rates which are represented by the demand curve for the smoking cessation program.

Especially, when we evaluate the policy with some subsidies including health insurance coverage, it is very important to recognized that such a policy enforces joining the programs whose subjected benefit is lower than those who join the program even though such a policy is not implemented. In other words, the average benefit among participants must be decreased by such a policy. It is very well known as a deadweight loss. Needless to say, such a policy for private goods must not be recommended because it worsens the welfare. Therefore the cost effective analysis must be based on the demand curve if we consider the policy for private goods, or the analysis leads to the wrong conclusion.

Moreover, almost all the cost effective analyses so far usually fail to consider externalities. As explained above, the cost effective analyses so far have been based on the average or hypothetical individual and summing them up into the aggregate benefit and cost. Hence the externality which does not count at the individual level may be ignored. This externality does not seem essential in the cost effective analyses and thus it can be incorporated in the analysis, but typically it is ignored.

On the other hand, we can easily take such an externality into consideration which is represented by the deviation of social benefit from the demand curve. This deviation is the only reasons for policy intervention. In the case of positive externality, since the deviation of social benefit other than individual's utility, the deadweight loss induced by the policy may be compensated. Hence, cost effectiveness analysis for private goods is not for considering whether such a positive externality is sufficiently large enough to compensate the deadweight loss. Therefore, externality is the most important and essential of cost effective analysis for private goods.

In our context, PI means to provide subsidy of 70% of the medical cost and thus it leads to some deadweight loss. Therefore, it needs some evidence that its externality is larger than the deadweight loss. On the other hand, switching the nicotine patch to OTC is a kind of deregulation and thus it does not lead to deadweight loss.

Table 6 and 7 imply that PI does not have evidence but PO has it to support implementation. The point to evaluate PI is whether the externality is so large that this deadweight loss can be compensated. Unfortunately, it cannot. Even if we perform PO and PI simultaneously, though the nicotine patch as OTC partially offset the demand for medical services, this strategy also does not have evidence to support implementation. Therefore we can conclude that PO is strongly recommended but PI is not.

If we calculate IBCR without using a demand curve, but assuming average individual even if a new policy is implemented, it should be as follows: Assume the quit rate is 30% in any program, PO and PI, and cost in both policies is 30 thousand yen (240 dollars), then the additional cost to quit per person is 70 thousand yen (560 dollars). On the other hand, the benefit of quitting smoking is supposed to be 3.7 to 7.3 as mentioned before, and its per capita term is 185-365 thousand yen (1.48-2.92 thousand dollars) if the smoking population is 20 million. We note that this number does not depend on how many person attend due to the new policy. Therefore IBCR is 2.6429(=185/70)- 5.2143(365/70).

Even though this extremely simple calculation ignores discounting, it does not seem to affect the its implication. It is clearly more than one, so this very simple calculation recommends the implementation of both PI and PO. However, we prove that PI make huge deadweight loss and externality cannot compensate it fully, so we cannot recommend it. This small example explain how such a simple cost effective analysis leads to a wrong conclusion.

However, we have some limitations. The most important of all would be environmental tobacco smoking (ETS). It must raise positive externality of quitting smoking. Even though its medical cost is very small compared with the medical costs of smokers, the bad smell of smoke worsen the QOL of non-smokers. Insurance coverage for smoking cessation therapy by doctors may be changed to be cost effective. Accumulation of knowledge about ETS in epidemiology and health economics is necessary as soon as possible so as to evaluate smoking cessation programs.

VI. Conclusion

As mentioned before,

In other countries, the smoking policy is based on the result of cost effectiveness analysis in the field of policy evaluation for medicine or public health. The more responsibility will be required for policy makers to explain for all citizens about the process of political decision they made. Taking this situation into consideration, additional research and discussion should be needed to respond this requirement.

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