

Economic Analysis and Policy Suggestions for Prenatal Screening and Diagnosis on Down's Syndrome in China

Yi-jhan Hsieh*

Shanghai Experimental School International Division, Shanghai, 200125, China

*Corresponding author: 161847231@masu.edu.cn

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Abstract: Down Syndrome is a disease that can cause a significant economic burden on both society and individual families. It has a relatively high incidence compared to other conditions, but it can be detected with the proper use of prenatal screening and diagnostic tests. This paper conducted a cost-benefit analysis, cost-effectiveness analysis with the Incremental Cost-Effectiveness Ratio (ICER), a Criteria Importance through Intercriteria Correlation (CRITIC) model. Through using a Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS) model to evaluate and compare the three different prenatal diagnostic tests for DS, amniocentesis, noninvasive prenatal testing (NIPT), and chorionic villus sampling (CVS). The result showed that amniocentesis and CVS are both cost-benefit and cost-effective, ranking the first in the CRITIC and TOPSIS models, with amniocentesis having a more significant lead. In contrast, NIPT has a negative net benefit and is not cost-effective, ranking third in both models. Amniocentesis should be compulsory in China, with the government covering \$402 and individual families paying \$98. Choices should be given to individual families if they are willing to pay more to take NIPT if they are worried about the risk of invasive amniocentesis. People with autoimmune diseases and other diseases that can increase the risk of miscarriage with an invasive test should be provided with NIPT with the government covering the extra fee. A selection system with the prenatal test for DS as the default choice is another option for policy implementation based on the nudge theory. This policy can release around \$8,265,075,000 economic burden on the society and \$1,100,000,000 on individual families annually in China, creating more economic value for the rapidly growing country.

1. Introduction

1.1 Research background

Down's Syndrome (DS), also known as trisomy 21, is a genetic chromosome disorder some people are born with [1]. It is caused by all or part of the third copy of chromosome 21 [2]. It causes learning disabilities and an increased risk of developing medical issues, including heart defects, vision problems, and growth problems. DS is a lifelong problem that cannot be cured.[1] Life expectancies for DS patients are around 50 to 60 years with proper healthcare in developed countries [3]. DS is one of the most common chromosome abnormalities [3]. It is present in 5.4 million individuals globally [4]. The estimated incidence of DS is 1 in 1000 newborns [5]. Therefore, DS is a prevalent problem all around the world. These DS populations also create a substantial economic burden for society and the family. It was estimated that a DS patient costs society \$15311 to care for annually, accounting for 24% of the US GDP per capita in 2019 [6]. For individual families, the figure is \$47000 for the whole lifetime [7]. These high economic costs can cause severe social inefficiencies and financial burdens from a societal point of view. It can also worsen income and wealth inequality as poorer families are usually less educated about DS, reducing the possibility of an early diagnosis.

Even though DS cannot be cured, early screening and diagnosis can help reduce the number of newborns with DS. If test results are positive, parents can choose to end the pregnancy, and thus the DS baby will not be born. According to the organization Patient, options of screening include nuchal translucency scan (NT) and maternal serum screen, while options of diagnostic tests include

amniocentesis and chorionic villus sampling (CVS) [1]. The diagnosis tests are invasive, while the screening tests are not. The four methods have the accuracy of 70%, 75%, 99.4% and 99% respectively [10] [11-13]. Even though screening tests have low accuracy, combined screening can increase accuracy between 83 and 96 percent [13]. Therefore, these prenatal screening and diagnostic tests have high accuracy, which can help reduce the DS population, decreasing the economic burden they have on individual families and society. Due to this, the prenatal tests are products with positive consumption externalities, which there will be significant underconsumption if the market is left to the free market mechanism. Thus, there is a need to evaluate the best method that can be implemented by the government and whether or not the method is cost-beneficial for society and individuals.

In China specifically, the incidence of DS is 14.7 per 10000 live births, with an annual birth number of approximately 23000 – 25000 newborns [8]. There is a decreasing perinatal prevalence ratio and increasing prenatally diagnosed DS cases [9]. The societal, economic burden for the lifetime of a DS patient in China is \$55000, apart from the \$47000 individual costs [7]. In terms of the prenatal tests, the capital of China, Beijing, had announced to include the noninvasive prenatal testing (NIPT) into its health insurance of the China Health Security (CHS) [14]. Therefore, there must be an increasing awareness of the DS problems and the importance of prenatal screenings and diagnosis of DS.

1.2 Literature review

Several types of research have been done on evaluating different prenatal screening and diagnostic tests on DS. In their research paper "A Cost-Effectiveness Analysis of prenatal Screening Strategies for Down Syndrome", Odibo et al. carried out a cost-effectiveness analysis using decision analysis models for nine different prenatal screening strategies. They found that sequential screening can detect more cases. Still, it is associated with high costs, while integrated serum is the most cost-effective strategy [15]. Okem et al. also developed a decision-analytic model to evaluate the cost-effectiveness of seven different prenatal screening strategies and calculated the Incremental Cost-Effectiveness Ratio (ICER) for these strategies, respectively. Results showed that the NIPT has relatively high costs despite its high effectiveness, and the researchers proposed decreasing the price for NIPT [16]. In their research paper published in the Chinese Journal of Medical Genetics, Liu et al. analyzed population-based prenatal screening and diagnosis in Jiangsu province, China. Their results showed that 9 DS cases were detected with a positive prenatal screening rate of 67%. They concluded that these strategies are beneficial to reduce the birth of DS patients and improve the population's quality. Still, the accuracy of the tests should be improved to get more precise results [17]. Gekas et al. carried out a cost-effectiveness analysis and calculated the ICER for three different prenatal screening strategies for DS. The results are that the contingent screening method is the most cost-effective strategy compared with integrated screening and sequential screening [18]. Ward examined which prenatal test is right to choose from the various options and concluded that there are no simple conclusions to the topic and proposed further research interests [19].

1.3 Research gap

Most scholars and their research papers discussed the cost-effectiveness of the different prenatal screening methods, and not much was done on the diagnostic tests. The proposed optimal prenatal screening strategies and suggested that future research interests and problems be solved. However, a few evaluated the prenatal screening and diagnostic tests on DS with the relief on the societal and individual costs this population brings. Therefore, there was a lack of cost-benefit analysis of the prenatal tests. Moreover, few policy suggestions were proposed to discuss what the government should do to help reduce the DS incidence with prenatal screening and diagnostic tests. Therefore, there is a need to evaluate the economic perspectives of prenatal testings to construct a comprehensive government policy to reduce DS.

1.4 Research framework

To evaluate different prenatal screening and diagnostic tests for DS and give policy implementation suggestions, this paper will first find data on DS in China, including the population, birth rate, economic burden, and the costs of each different prenatal test with its accuracy. Then, this paper will carry out a cost-benefit analysis by identifying the costs of each method and the benefit that can be gained from the testing methods. After that, several models will evaluate the best prenatal testing method. This includes cost-effectiveness analysis and multi-criteria decision-making models. Finally, with the optimal strategy being found, policy suggestions for the Chinese government will be proposed with the optimal method and the implementation.

2. Methods

2.1 Literature Review

A literature review is a research method by surveying scholarly sources on a specific topic [20]. In this paper, through the research on scholarly articles and references, data including population, birth rate, and economic burden of DS in China and the costs and accuracy of different prenatal screening and diagnostic tests for DS are gathered for further analysis.

2.2 Cost-Benefit Analysis

A cost-benefit is the process of analyzing the business and economics of a project by comparing the projected and estimated costs and benefits associated with it [21]. In this paper, the cost of the prenatal tests for DS will be calculated and the relief of economic burden that the prenatal tests can bring. The results will then be used for policy implementation suggestions.

2.3 Incremental Cost-Effectiveness Ratio (ICER)

The Incremental Cost-Effectiveness Ratio (ICER) is a cost-effectiveness analysis by comparing the ratio between the effectiveness of an intervention and the costs for different interventions to evaluate the most cost-effective intervention [22]. In this paper, the ICER for each prenatal test for DS will be calculated. The most cost-effective option will be found, which can be used for future policy implementation suggestions.

2.4 Criteria Importance through Intercriteria Correlation (CRITIC)

The Criteria Importance through Intercriteria Correlation (CRITIC) is a multi-criteria decision-making model that can calculate the weight of different criteria for evaluating other decisions and find the relatively optimal option by calculating each option using the calculated weight of the criteria [23]. In this paper, CRITIC will be used to calculate the weight of different criteria for the various prenatal tests for DS and find the relatively optimal testing method that will be used to interpret policy implementation suggestions.

2.5 Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS)

Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS) is also a multi-criteria decision-making model that finds the relatively optimal solution by calculating the similarity of each solution to the ideal solution [24]. In this paper, with the weight calculated by the CRITIC model, TOPSIS will be used to find the relatively optimal prenatal testing method and give policy suggestions for which to be used.

3. Results

3.1 Cost-Benefit Analysis

To analyze the cost and benefit to implement prenatal tests for DS in China, the cost and benefit of different prenatal testings need to be found. The benefit of having prenatal testing for DS is the

economic burden that can be reduced due to cases of DS being identified and avoided. The cost of doing so is the cost of having the prenatal tests. Both of them are calculated every year. Furthermore, as for determining the benefit and designing the implementation policy, the individual family benefit and coverage and the governmental coverage and societal benefit need to be classified separately. With the separated consideration, we can then determine how much the individual family would be willing to pay and how much the government would pay and the respective coverage. Lastly, to specify, the prenatal screening and diagnostic tests being evaluated are noninvasive prenatal testing (NIPT), amniocentesis, and chorionic villus sampling (CVS).

To begin with, the cost for the three prenatal tests for DS is being calculated. Since policies are being implemented, every pregnant woman will have to take the test, so the policy's total cost will be the prenatal test times the yearly newborn. In 2020, the birth rate in China is 8.52 per 1000 people [25], and the total population that year is 1,402,112,000 [26]. Therefore, the yearly newborn will be estimated as 11,945,994.24. The price of the three prenatal tests is \$1500, \$500, and \$450, respectively [27] [28]. So, the cost for each plan is shown in the following table 1.

Table 1. Price and Total Cost for Different Prenatal Tests for Implementation in China

Price/Total Cost	NIPT	Amniocentesis	CVS
Price in \$	1500	500	450
Total Cost in \$	17,918,991,360	5,972,997,120	5,375,697,408

In addition, the benefit of getting prenatal tests is determined. Since the benefit of getting the prenatal tests is reducing the economic burden, the benefit should be calculated separately for the government and individual families. The first thing that needs to be clarified is the accuracy of the three different prenatal tests, NIPT, amniocentesis and CVS, and the yearly DS born. Their accuracy is 99%, 99.4% and 99%, respectively [29] [30] [31] while every year in China, 25,000 DS patients are born [32]. According to research on the economic burden of DS patients in China, the economic burden on the individual family with a DS patient is \$47,000 [33]. However, as getting a DS baby is not a usual case, the average benefit on the individual families should be the risk of having the economic burden if a DS patient is born that is avoided. Therefore, the average benefit for individual families should be calculated as the total cases that can be detected by the prenatal tests divided by the total birth in a year time the economic burden that is released, or in the following equation where A is the accuracy of one prenatal test, N is the number of DS children born in a year, B is the total number of births in a year, and C is the economic burden on individual families with a DS patient.

$$Benefit = \frac{A \times N}{B} \times C$$

However, the total benefit for both the government and all individual families is much simpler to calculate. The benefit can be determined by multiplying the number of cases that can be detected and the economic burden that is eliminated minus the cases that are not detected multiplied by the financial burden they brought. The governmental and societal benefit is calculated by adding the DS case's economic burden on society and the healthcare system, which are \$55,000 and \$275,603, respectively [34] [35]. The benefit of the different prenatal tests for the government and individual families is shown below.

Table 2. Benefits for Policy Implementation of Different Prenatal Tests

Benefits in \$	NIPT	Amniocentesis	CVS
Governmental Benefit	8,099,773,500	8,165,894,100	8,099,773,500
Individual Family Benefit	1,151,500,000	1,160,900,000	1,151,500,000
Average Individual Family Benefit	97.376	97.769	97.376

The result shows that rational individual families will not choose to do the tests since their benefit is only less than \$100. However, it is beneficial for the government to pay for amniocentesis and CVS

since the benefit exceeds the costs. It is not the case for NIPT. However, further investigation is needed to evaluate the cost-effectiveness of each of the different prenatal tests. Moreover, as the NIPT is noninvasive, the benefit cannot be simply assessed. Some people may choose to take the noninvasive method, and others may not be suitable and safe to take the invasive techniques. The combined results of the cost-benefit analysis are shown in the following.

Table 3. Results of Cost-Benefit Analysis

Costs/Benefits	NIPT	Amniocentesis	CVS
Costs	17,918,991,360	5,972,997,120	5,375,697,408
Governmental Benefits	8,099,773,500	8,165,894,100	8,099,773,500
Individual Family Benefits	1,151,500,000	1,160,900,000	1,151,500,000
Average Individual Family Benefits	97.376	97.769	97.376
Net Governmental Benefit	-9,819,21,7860	2,192,896,980	2,724,076,092

3.2 Cost-Effectiveness Analysis

To evaluate the cost-effectiveness of the three prenatal tests for DS, the ICER is calculated for each prenatal test compared to no other interventions. The ICER of the three different prenatal tests is shown in the following.

Table 4. ICER for Prenatal Tests Compared with No Interventions Done

Prenatal Tests	NIPT	Amniocentesis	CVS
ICER (\$/per DS patient identified)	723,999.651	240,362.057	217,199.895

As we can see from the results, the overall trend of the ICER is the same as the net governmental benefit. NIPT has the worst result, with a negative net benefit and the highest ICER, and CVS has the best result with the highest net benefit and the lowest ICER. However, more is needed to be determined with the results. Even though NIPT has the worst results, its noninvasive characteristics can be favorable to some populations. Furthermore, as amniocentesis has a higher accuracy, which is more favorable for the government, the economic burden that isn't avoided due to the false negative result of the tests, which may affect the net governmental benefit. Therefore, a lot is needed to comprehensively evaluate the three different prenatal tests. Therefore, multi-criteria decision-making models are used to determine the relative optimal prenatal test that can be implemented as a policy in China provided for every citizen.

3.3 Critic

To comprehensively evaluate the three prenatal policies, the multi-criteria decision-making model CRITIC is first developed to further rank the three prenatal tests. Factors including price, total cost, accuracy, governmental (societal) benefit, individual family benefit, ICER, and the fact that it is invasive or not are being considered while modeling. Specifically, the NIPT, noninvasive prenatal testing methods are recorded as one while the invasive ones are 0. The result of the points and the rank of the prenatal tests are shown in the following.

Table 5. Result of CRITIC

Prenatal test	Points	Rank
Amniocentesis	0.638416	1
CVS	0.347974	2
NIPT	0.345236	3

3.4 TOPSIS

To further verify the result of the CRITIC model and evaluate the three prenatal tests, the multi-criteria decision-making model is used. The same factors as the CRITIC model are being considered

in this TOPSIS model. The result of the TOPSIS model, the points and the rank, is shown in the following.

Table 6. Result of TOPSIS

Prenatal test	Points	Rank
CVS	0.610082	1
Amniocentesis	0.597946	2
NIPT	0.389902	3

4. Discussion

From the cost-benefit analysis results, we can see that both amniocentesis and CVS are cost-benefit and cost-effective. They have a positive net benefit and an ICER more minuscule than the willingness to pay, which is the extra money spent on a DS patient. However, as NIPT has a negative net benefit and an ICER greater than the economic burden a DS case has on society and the healthcare system, it is not cost-beneficial and cost-effective to be implemented. Therefore, from the economic point of view, it is rational to implement CVS and amniocentesis as a policy to ensure minimum DS cases. As DS cases can cause a substantial financial and economic burden to society and individual families, there is a need to implement one of the two kinds of prenatal tests as a requirement that every woman in pregnancy needs to complete. However, which of these two methods to choose and how the policy should be implemented should be considered thoroughly.

To begin with, to choose the one to be implemented in the two prenatal tests, amniocentesis and CVS, the results from the CRITIC and the TOPSIS models should be examined. Even though both ranked the first in the two models, amniocentesis leads more in the CRITIC model than the lead CVS has against amniocentesis in the TOPSIS model. As in both of the models, the criteria being considered are normalized. The leading rank means that amniocentesis is more optimal than CVS. Furthermore, ignoring the criteria invasive or noninvasive as both prenatal tests are invasive, accuracy is the first ranking criteria in terms of weight calculated by the CRITIC model, which is 11.600. As amniocentesis is more accurate than CVS, amniocentesis seems to be the better prenatal testing method. This is reasonable as any DS cases not being detected will lead to an economic burden that is not considered and calculated in the cost-benefit and cost-effectiveness analyses. Therefore, to choose a prenatal test to implement, amniocentesis is the better choice overall.

Additionally, implementing the prenatal test for DS in China should be addressed. Several different plans can be chosen. Firstly, we need to determine the coverage of the testing fee for the government and the individuals. According to the homo economicus theory, people will behave rationally and think at the margin, considering the marginal costs and marginal benefits while making decisions [36]. According to this theory, individual families will be willing to pay \$98, the marginal benefit. The government should cover the rest with the China Health Security (CHS) health insurance, \$402 for each test being taken.

Secondly, implementation plans should be proposed to promote amniocentesis tests to the public. To begin with, people should be allowed to take NIPT instead of amniocentesis as NIPT is noninvasive. Invasive prenatal tests on pregnant women have risks of miscarriage, infection, rhesus disease, and club foot, even though the risk is shallow [37]. People who have the economic ability and prefer the noninvasive prenatal test should be allowed to take NIPT. At the same time, the government still pays \$403 of the trial, with individual test-takers paying the rest (\$1-98).

On the other hand, there are higher risks of a miscarriage of autoimmune disease patients taking the invasive amniocentesis test [38]. Therefore, the government should cover the extra fee for NIPT to these pregnant to reduce the risk of miscarriage, covering \$1402 in total. In addition, there are several plans that the Chinese government can choose to deploy. Firstly, as the Chinese government has complete control over activities in its nation, the government can simply set prenatal tests for DS as a requirement, and unless you choose to pay more or you have diseases such as autoimmune diseases and other diseases that may increase the risk of miscarriage if an invasive test is taken, people

can only be allowed to choose amniocentesis. With the Chinese government's complete control, this can be quickly done. However, as the country continues to open up and turn its mixed economy more toward a free economy rather than planned, a nudging system can be applied in the policy. The nudge theory is a theory in behavioural economics which aims to help people make better decisions [39]. Constructing a sound selection system can be helpful in this case. For each family with a pregnancy, taking the prenatal test for DS should be a default choice that cannot be changed unless people are asked to answer ten to twenty questions on why they choose not to take the prenatal test. As it would be quite complicated to cancel the default choice and it is beneficial to take the prenatal test, most people will not change the default choice, and thus people will take the test. Moreover, this policy will show a better effect if the country advertises and educate people to take the prenatal test. As the Chinese citizens have a high level of obedience toward the policies promoted by the Chinese government, with the promotion of the prenatal tests with DS, the default choice of taking the test will be less likely to be changed by individuals.

5. Conclusion

This paper researched prenatal tests on DS and promoted possible policy implementations on the prenatal tests in China. Cost-benefit and cost-effective analyses are done on DS's three different prenatal diagnostic tests, amniocentesis, NIPT, and CVS. The result showed that both amniocentesis and CVS are cost-effective and cost-benefit, with amniocentesis having the highest net benefit and CVS having the lowest ICER. In contrast, NIPT has the highest ICER and a negative net benefit. Further investigation is done into these three prenatal tests using two different multi-criteria decision-making models, CRITIC and TOPSIS. The result is quite different, with amniocentesis ranking first in CRITIC and CVS ranking first in TOPSIS. However, NIPT ranks the last in both the models and the lead that amniocentesis has against CVS is greater than the lead CVS has against amniocentesis. Therefore, amniocentesis is determined as the relative optimal choice of the prenatal test of DS that should be implemented in China.

Furthermore, for policy implementation, the coverage and the policy are suggested. The government should cover \$402 for each test, with individual families paying \$98. Considering the risk associated with invasive amniocentesis, people can take NIPT voluntarily, paying \$1098 for the test. Two policies are suggested. The first one sets the prenatal test for DS compulsory. The second one constructed a selection system with the nudge theory setting taking the prenatal test for DS as default and making canceling the default choice complicated. And combined with advertisements and education, this policy can also ensure a very high level of prenatal tests for DS being taken.

Each year, an additional \$8,265,075,000 economic burden on society will be made due to the birth of around 25,000 DS patients, and \$1,100,000,000 will be made to individual families. There is a need to reduce the number of DS patients significantly. According to the money multiplier theory, this number attributes 0.0679% of the Chinese GDP, which means that releasing the economic burden can induce a more significant economic activity [41]. Therefore, there is a need to promote and implement prenatal tests for DS, considering the enormous financial burden that it can bring to society.

However, future research can be done to further promote more accurate estimations on the economic burden of DS patients on society in China. This paper used secondary data that may be outdated. Primary data can be obtained with the cooperation of the Chinese government to find the actual economic burden on the society and individual families in China currently. Moreover, as the Chinese government has vast bargaining power against its domestic firms, the price may be reduced for the prenatal tests for DS, which can be considered in future studies.

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