TECHNICAL REPORT NO. UKR-2

Economic Evaluation of Pregnancy Screening in Chernivtsi, Ukraine

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Economic Evaluation of Pregnancy Screening in Chernivtsi, Ukraine

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PREFACE

As part of the U.S. Agency for International Development (USAID) program of support to Ukraine, the Zdrav*Reform* Program was asked in mid-1994 to assist with health sector management, organization, and financing reforms. Zdrav*Reform* provides technical assistance, training, information dissemination, and, in some places, but not Ukraine, grant support for such health reforms to selected countries of the former Soviet Union. To begin Zdrav*Reform*'s work in Ukraine, several "rapid response" activities were identified, as follows:

- Drohobych—Conduct an evaluation of an innovative system used to allocate state budget funds to hospitals, similar to diagnosis-related groups (DRGs).

- Chernivtsi—Using cost-effectiveness techniques, perform an analysis of a pregnancy screening program conducted by the Chernivtsi Diagnostic Center.

- Kiev—Assist with curriculum development, teaching short courses, and transfer of teaching methodologies to the newly established School of Health Administration of the Institute of Public Administration.

- National—Conduct a study tour to the United States for the Verkhovna Rada's (National Parliament) health commission, staff, and key health leaders from around the country.

This particular project, the economic evaluation of a pregnancy screening process in Chernivtsi, was one of those activities identified.

TABLE OF CONTENTS

ANNEXES

ACRONYMS

CBA	Cost-benefit analysis
CEA	Cost-effectiveness analysis
CMA	Cost-minimization analysis
CUA	Cost-utilization analysis
DALY	Disability-adjusted life years
DRGs	Diagnostic-related groups
NIH	National Institutes of Health
NIS	New Independent States
QALY	Quality-adjusted life years
RMDC	Regional Medical Diagnostic Center
USAID	U.S. Agency for International Development
USFDA	U.S. Food and Drug Administration
ZRP	Zdrav*Reform* Program

EXECUTIVE SUMMARY

The health sector in Ukraine is suffering from drastically reduced budgets. While the amount of available resources for health is shrinking, the demand for health services is rising. Policymakers are therefore faced with difficult decisions on how to allocate their budgets among competing needs.

One characteristic of the current transition in the government of Ukraine is the move from centralized to decentralized decision-making styles. While decentralized decision-making can improve efficiency and encourage innovation, it requires decision-making abilities at the local level. Such skills are not currently available in Ukraine's health sector since local managers are accustomed to a top-down decision-making style. Without tools for decision-making, local managers will not be able to contribute much to reform in the sector.

This report documents the application of cost-effectiveness analysis on a pregnancy screening process at a medical diagnostic center in Chernivtsi. By applying cost-effectiveness methodology to a diagnostic process in one facility in Ukraine, the Zdrav*Reform* Program (ZRP) introduced the use of economic evaluation tools to local health officials. This exercise in economic evaluation was meant to incite local officials in health and reproductive health to think about resource use and about using economic tools to maximize the effectiveness of public programs.

Another outcome of applying cost-effectiveness analysis in Ukraine is to learn from the experience and to put the lessons to use in the future. Admittedly, the economic and structural realities in Ukraine—and in the New Independent States (NIS) in general—may create difficulties in applying market-based tools. This application allows ZRP to identify areas of difficulty for the implementation of these tools, and to gauge the appropriateness of and opportunities for the use of economic evaluation methods in the NIS.

The focus of this technical assistance was to gather data to introduce economic evaluation methods, such as cost-benefit or cost-effectiveness analysis, to local officials at the Chernivtsi Regional Medical Diagnostic Center (RMDC). The ZRP team sought to determine what cost and results data were available on a pregnancy screening process at the center. Available data allowed the ZRP team to calculate the cost-effectiveness of the screening process as measured by the cost-per-pregnancy abnormality detected.

Pregnancy screening in the Chernivtsi region can be described as a two-level process. The first level is a long list of tests that every pregnant woman undergoes at the local polyclinic. The list includes general blood analysis, HLA blood group, resis analysis, syphilis test, HIV/AIDS test, biochemical blood test, urine test, stool analysis, pap smear, vaginal smear, EKG, and an ultrasound sonogram test.[1] This first level of screening takes place at least once during a pregnancy

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[1] In Ukraine, counterparts used "ultrasound sonogram test," "ultrasonogram," and "ultrasound" interchangeably; however, for the purposes of this paper the term "ultrasound sonogram test" will be used.

but usually twice. If the gynecologist suspects problems with the pregnancy or with the pregnant woman, the woman is referred to RMDC in Chernivtsi for a second level of screening and further tests. At the diagnostic center, at least four types of tests are requested by the doctors: ultrasound sonogram test, hormonal tests, clinical blood tests, and biochemical blood tests.

Ukraine's system treats most pregnancies as uniform risk and is not cost conscious. The use of the ultrasound sonogram test, in particular, is very high. This finding carries cost implications—especially considering the shrinking budget of the Ukrainian government. Furthermore, some evidence in the medical literature suggests that excessive use of the ultrasound sonogram test may have a negative effect on the growth of the fetus.

The pregnancy screening process, especially the first level, follows rigid rules and does not take into account factors that may make some women more likely to have complications with their pregnancies. By not using risk assessment tools, doctors are implicitly treating most women as high risk and subsequently spending considerable resources in screening. Some technical assistance on risk assessment methods could be very useful in developing national standards and could save resources.

The interaction between the health facilities and RMDC in the Chernivtsi region regarding the two levels of pregnancy screening is weak and has led to redundant testing. When a woman is referred to RMDC by her gynecologist, a number of tests (ultrasound sonogram test and blood tests, for example) are automatically repeated. When asked why they repeat the tests, the doctors at the diagnostic center, two answers were given: (1) said that either the patients did not have the test results with them, or the doctors were not sure about the quality of the tests that had been given outside the center. If the tests are repeated simply because one level of the system is not transferring the right information to the next level, then resources are being wasted.

RMDC has an excellent computerized setup for keeping patient files and test results. Unfortunately, the information is not being used to track the effectiveness of different tests or to produce reports on utilization breakdowns and resource use. The data are not imputed and stored to statistical research and analysis. Center staff are aware of this problem and have started redesigning the data imputing instrument. Some technical assistance in the area of information systems could help staff improve their system and could serve as a model for other centers in the country and the region. The diagnostic center staff are highly intelligent and dedicated, making them excellent candidates for training in this field.
Much information exists on cost identification and quantification of the diagnostic center activities. RMDC administrative staff have determined the costing of all the tests provided. They have ensured that all costs were considered and that overhead and joint costs were divided among activities. Should ZRP provide training on advanced cost estimation methodologies, some of the diagnostic center staff should be invited to participate.

Information on health results was difficult to collect. The organization of the computerized system was part of the problem, combined with the medical staff's misunderstanding the need to collect, organize, and analyze aggregate data. The doctors believe their job is simply to observe patients—not to perform statistical analysis in order to look at effectiveness or financial benefits. While this attitude is not unique to Ukraine, it nevertheless makes performing an economic analysis difficult.

Chapter 1

INTRODUCTION

Ukraine is transitioning from a Soviet-style command economy with centralized decision-making to a more market friendly and decentralized decision-making style. The health sector is suffering from drastically reduced budgets, hyperinflation of local currency, and a limited supply of hard currencies to purchase essential imported drugs and equipment. In an environment of structural transition and shrinking budgets, making decisions on how to spend limited resources becomes critical. It is therefore useful to introduce economic evaluation methods into the decision-making process at both the state and local levels.

While the transitional state of Ukraine's health sector presents an opportunity to try new approaches to decision-making, the regional authorities lack the tools and experience needed to make difficult changes. In the area of reproductive health, for example, doctors and facilities still follow rigid rules on screening and risk assessment set by the central authorities before the breakup of the Soviet Union. Decisions on setting priorities on spending are not linked to local need or to an analysis of the cost-benefit or cost-effectiveness of alternative approaches to care.

The Zdrav*Reform* Program (ZRP) team collected available data on the costs and results of the screening process for pregnant women in the Chernivtsi region from the Regional Medical Diagnostic Center (RMDC) of Chernivtsi and from the Chernivtsi Regional Health Authority. Data on the costs of four groups of tests commonly administered twice to pregnant women were collected in terms of quantities of all inputs to the process as well as estimated prices in 1993 koupons. The four groups of tests are ultrasound sonogram test of the fetus, hormonal tests, clinical blood tests, and biochemical blood tests. The team collected data on the results of the tests for the entire region, as well as for the RMDC. A detailed description of data collection methods and data collected is presented in chapter 3.

1.1 Describing the Pregnancy Screening Process

In Ukraine, the state mandates that each pregnant woman must pass two screening tests, in or around the 16th and 26th weeks of pregnancy. The head of the Department of Gynecology and Obstetrics at the Chernivtsi Regional Health Authority and the heads of the Departments of Medical Genetics and Ultrasonography at the Chernivtsi RMDC outlined the norms of screening pregnant women in the Chernivtsi region. The process described shows gynecologists prescribing a list of tests for pregnant women at two stages of the pregnancy. The list of tests for each woman may include the following:

- general blood analysis;
- HLA blood group;
- resis analysis;
- syphilis test;

- HIV/AIDS test;
- biochemical blood test;
- urine test;
- stool analysis;
- pap smear;
- vaginal smear;
- EKG; and
- sonogram.

If the gynecologist at one of the 13 clinics in the region suspects problems with the pregnancy or with the pregnant woman upon the conclusion of the first-level screening, then the pregnant woman is referred to RMDC in Chernivtsi for a second-level screening. At RMDC, at least four types of tests are requested by the doctors:

- sonogram;
- hormonal tests;
- clinical blood tests; and
- biochemical blood tests.

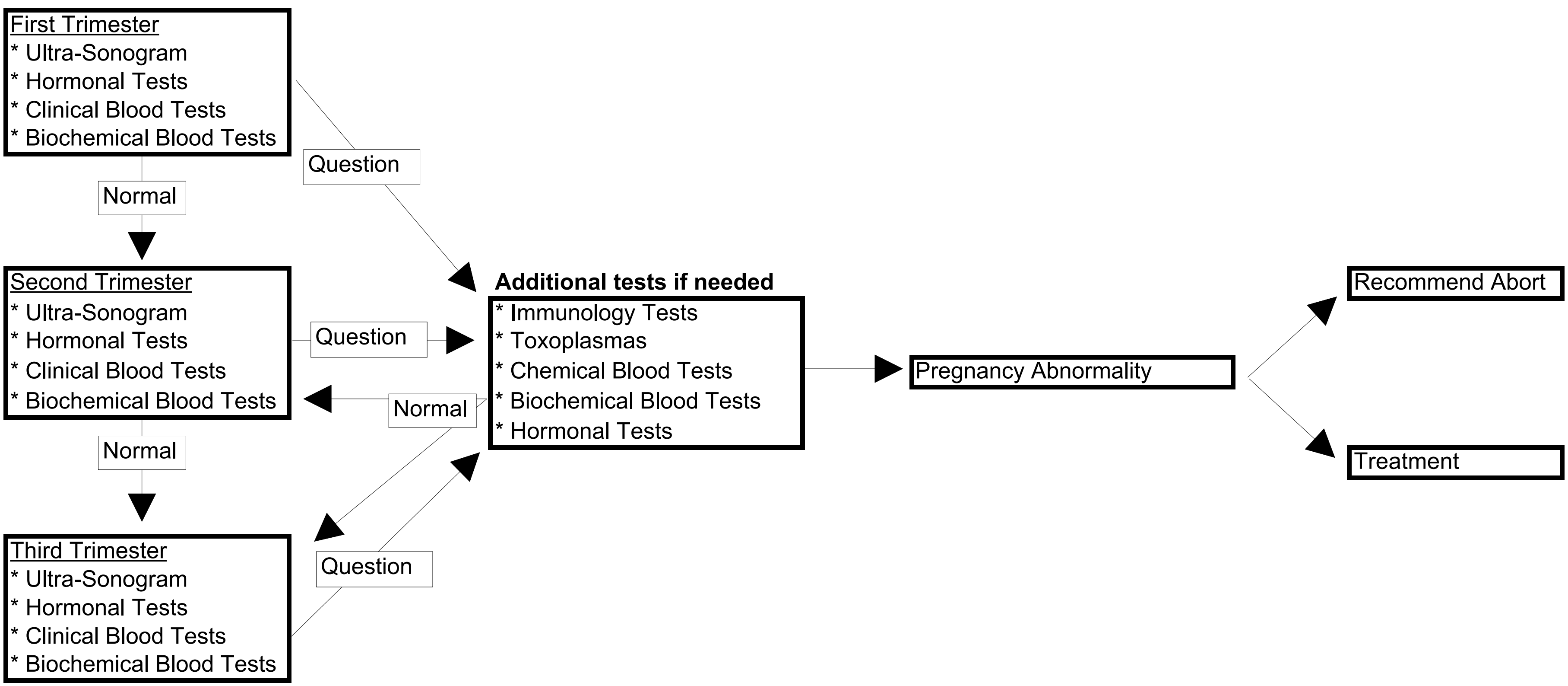
Of the four tests, the sonogram of the fetus is the only test administered to every pregnant woman. The doctors at the diagnostic center estimated that only 50 percent of the women receive the hormonal tests because of the high costs involved and the restricted hours that they are administered. Clinical blood tests are not always administered because the referral forms usually include the results of blood tests taken before the woman was referred. In addition to the four tests described above, other tests can be requested and performed at RMDC.

A diagrammatic description of the screening process at RMDC is presented in figure 1. If a gynecologist at RMDC suspects a potential abnormality with the pregnancy or with the health of the mother, then the pregnant woman undergoes selected additional tests, such as immunology tests, toxoplasmas tests, and/or more chemical blood, biochemical blood, and hormonal tests. If one of these additional tests reveals an abnormality, then RMDC recommends either the abnormality be medically treated or the pregnancy be aborted.

1.2 Organization of the Report

Chapter 2 of this report presents a brief overview of the methodological approach taken in the economic analysis. The third chapter describes the data collection activities and the findings from the cost-effectiveness application. Recommendations and lessons learned are presented in chapter 4. For interested readers, annex A provides an introduction to economic evaluation tools and the methodological approach taken in using them, and annex B broaches the issue of uncertainty surrounding ultrasound sonogram testing by citing evidence found in medical literature on the efficacy and safety of sonograms.

Figure 1
Pregnancy Screening at the Chernivtsi Medical Diagnostic Center



Chapter 2

METHODOLOGY

To perform an economic evaluation of the pregnancy screening process, the ZRP team gathered data on both the costs and results of the process. The team identified, measured, valuated, and analyzed the costs, and identified and analyzed the results. Economic evaluation methods help individuals and decision-makers find appropriate answers to the questions of allocating scarce resources among competitive needs and wants. Of the four primary types of economic analysis described in annex A, available data directed the team to use cost-effectiveness analysis. Cost-effectiveness analysis measures the cost involved in performing a process to achieve a particular consequence. It provides decision-makers with a framework for organizing information about the viability of a program. The cost-effectiveness of a process is measured in cost-per-positive effect achieved. Available data from the pregnancy screening process yielded a measure of cost-effectiveness in terms of cost-per-pregnancy abnormality detected.

Chapter 3

DATA COLLECTION AND FINDINGS

3.1 Costs Data

3.1.1 Identification

The ZRP team was concerned with identifying costs RMDC incurred in its pregnancy screening process. To accomplish this, the ZRP team first needed to identify what types of costs were involved in the four tests (sonogram, hormonal, biomedical, and clinical) administered. The center's chief engineer and economist had already identified six broad categories of inputs/costs, which are listed below:

- labor;
- materials;
- building space;
- equipment;
- office furniture and supplies; and
- administrative labor and supplies.

3.1.2 Measurement

The chief engineer gave the team the results of RMDC's costing exercise—a facility accounting computer printout of a table of 1993 costs (in Ukrainian koupons) per investigation to the center. These costs were broken down into six input or cost categories for all of the different types of tests (93 total) administered at the diagnostic center, across the five departments. (For example, the ultrasound sonogram test is administered in the sonography department; the hormonal, biochemical, and clinical blood tests are all performed in the clinical laboratories department.

Expressing the costs in terms of per investigation provides a uniform measure across the four test components. The total cost per unit of time, rather than per investigation, could differ across the four test components of the comprehensive screening for reasons beyond simply costs alone. For instance, the ultrasound sonogram test component of the screening can perform approximately one investigation per hour, but the clinical blood testing component of the screening process can accommodate three investigations in the same amount of time. Hence, if the cost information is expressed in per-hour figures, this will upwardly bias the true cost of a clinical blood investigation.

The ZRP team worked with the diagnostic center staff to identify the itemized inputs of all four test components and to quantify these inputs by expressing them in real, or natural, units (i.e. hours, kilograms, square meters, etc.). Again, the chief engineer was instrumental in identifying these inputs and their quantities for the six broad cost categories. Tables 1-4 display both the input categories in nominal units and the itemized inputs in natural units for the ultrasound sonogram test, the hormonal test, the biomedical test, and the clinical blood tests, respectively. When exact itemized input quantities could not be found, such as for the number of sheets of paper RMDC used daily, the team relied on the chief engineer's educated guesses. Most of the capital inputs, such as the diagnostic machines and computers, carry five-year warranties. For analysis purposes, these inputs were then considered as five-year capital investments. Consequently, the costs for these inputs were spread over five years, making the per-investigation cost relatively small. Similarly, the building space costs were amortized over 59 years—the financial life span of the clinic's physical structure.

The presence of significant inflation in Ukraine gives minimal meaning to the nominal cost columns in tables 1-4. In 1993 alone, the value of the koupon in December was worth only 2 percent of its value in January of that year. Similarly, the exchange rate of koupons per U.S. dollar multiplied 29 times over that same timespan.

3.1.3 Valuation

Since the cost values (in koupons) of the input categories had already been presented to the team in the form of a computer printout provided by the Chief Engineer, the ZRP team did not have to go through the exercise of placing cost values (in koupons) on each itemized input and then summing these values to obtain the total costs. An interesting exercise, however, would be to place Western, or European, prices on the input quantities. Such an exercise could circumvent the analytical challenge of placing koupon values on itemized inputs. As a result of set wages, subsidized prices, and foreign exchange difficulties, input prices in Ukraine do not reflect true economic costs.

3.1.4 Analysis

Figure 2 displays the cost structures of the four components of the pregnancy screening process. The top two pies represent the costs of the ultrasound sonogram test and the hormonal tests, which require four to five times the cost of the biochemical and clinical tests. One obvious reason for these cost discrepancies is the cost makeup of the tests with respect to the six input categories listed in tables 1-4. The ultrasound sonogram test is capital intensive; the equipment accounts for one-half of the total cost. The hormonal test can also be considered to be capital intensive since the material—a laboratory system imported from Finland—accounts for 85 percent of the total cost. In the RMDC, much of the capital inputs are imported, and imported goods are often more expensive relative to labor in an economy with high inflation, such as Ukraine experienced in 1993.

The clinical test, on the other hand, is much more labor intensive, with labor accounting for approximately one-half of the total cost. Equipment is a sizeable portion (34 percent), but, in referring to table 4, it is evident that the radiological and immune investigation equipment is Ukrainian, and hence less expensive.
TABLE 1

Table 1
INPUTS/COSTS OF SONOGRAM TESTING
(per investigation)

CATEGORY	ITEM	QUANTITY	TIME	UNIT COST	TOTAL COST (koupons)	TOTAL COST (dollars)
Labor					2089	$2.38
	doctor	1/office, 4 total * 2 shifts	0.83 hr/invest.			
	nurse	10 total				
Material					350	$.39
	jelly	158.68 L/investigation				
	alcohol	40 kg, Ukrainian				
	photography paper	960 m				
Building/Space					252	$.29
	4 offices	18 sq. m. each	amortized 59 yrs yrs			
Equipment					4959	$5.64
	sonogram machine	1/office	5 yr warrantee			
	eko camera SSD630	1/office				
	386 computer	1/office				
	eye saver on computer	1/office				
	printer	1/office				
	refrigerator	1/office				
	lamp	1/office				
Office Furniture and Supplies					48	$.05
	bed	1/office				
	desks	2/office				
	chairs	2/office				
	table for equipment	1/office				
	phones	2/office				
	shelf	1/office				
	cabinet	1/office				
	air conditioner	1/office				
	lamps	2/office (3 lights each lamp)				
Administrative Labor and Supplies					2276	$2.59
	secretaries, etc.	14 total				
	service workers (drivers, janitors)	17 total				
	maintenance of building and offices	5278.6 sq. m total				
	maintenance of grounds					
	maintenance of automobiles	parts for 2 Ladas, 1 Jeep				
	security	4 policeman/day				
	fire safety	centralized system				
	technical servicing of equipment					
	cleaning of equip. (incl. laundry)					
	water	20 cu. m/day total (15 cold, 5 hot)				
	water supply and drainage	$/sq m				
	electricity (light & AC)	23,000 kwhrs/month				
	telephone	1.5/day Ukraine, 2/wk NIS, 2.5/mo Europe				
	radio	5000 coupons/month				
	folders					
	paper	400/day				
	pens					
	glue					
Total					9974	$11.36

NOTES:
ultrasonography department has 4 offices, and can maintain 18 tests; 1055.7 sq. meters in sonography dept; January 1993 exchange rate: 878 koupons = $1 US

Table 2

INPUTS/COSTS OF HORMONAL TESTING

(per investigation)

CATEGORY	ITEM	QUANTITY	TIME	UNIT COST	TOTAL COST (koupons)	TOTAL COST (dollars)
Labor					935	$1.06
	lab technician	1/test	30 min/invest			
Material					10009	$11.40
	Kone (Finland) system					
Building/Space					22	$.02
	1 shared office	36 sq. m. each	amortized 59 yrs			
Equipment					540	$.62
	biochemical analyzers	2	5 yr warrantee			
	Beckman E2A ion measuring system	1	5 yr warrantee	$15,000		
	distillers (Soviet made)	2	5 yr warrantee			
	Elga (England) deionization machine	1	5 yr warrantee	$540		
	printer	3				
	refrigerator	1				
	thermostat	1				
	Sartorius scales (German)	2				
	centrifuge (Soviet made)	1	5 yr warrantee	$14,000		
Office Furniture and Supplies					3	$.00
	desks	5				
	chairs	5				
	phones	1				
	air conditioner	1				
Administrative Labor and Supplies					273	$.31
	secretaries, etc.	14 total				
	service workers (drivers, janitors)	17 total				
	maintenance of building and offices					
	maintenance of grounds					
	maintenance of automobiles	parts for 2 Ladas, 1 Jeep				
	security	4 policeman/day				
	fire safety	centralized system				
	technical servicing of equipment					
	cleaning of equipment (incl. laundry)					
	water	20 cu. m/day total (15 cold, 5 hot)				
	water supply and drainage	$/sq m				
	electricity (light & AC)	23,000 kwhrs/month				
	telephone	1.5/day calls to Ukraine, 2/wk to NIS, 2.5/mo. to Europe				
	radio	5000 coupons/month				
	folders					
	paper	400/day				
	pens					
	glue					
Total					11782	$13.42

NOTES:
hormonal tests consist of 14 mini-tests which take 2 minutes each
each test requires 20 minutes of intensive work, and then a long wait for the results
January 1993 exchange rate: 878 koupons = $1 US

Table 3

INPUTS/COSTS OF BIOCHEMICAL TESTING

(per investigation)

CATEGORY	ITEM	QUANTITY	TIME	UNIT COST	TOTAL COST (koupons)	TOTAL COST (dollars)
Labor					165	$.19
	lab technician	1/test	20 min/invest			
Materials					1138	$1.30
	physiological solution	1.5 tons		$12,000/yr		
	paper					
Building/Space					5	$.00
	office	1	amortized 59 yrs			
Equipment					405	$.46
	Celtrak 11 Nova System	2	5 yr warrantee	$6689.51 (in 1991 dollars)		
	Biolan microscopes (Soviet)	2	5 yr warrantee	$15,000		
	distiller (Soviet made)	1 (shared w/ biochem)	5 yr warrantee			
	computer					
	printer	1				
	refrigerator	1				
	thermostat	1				
	Sartorius scales (German)	2				
	centrifuge (Soviet made)	1 (shared w/ biochem)	5 yr warrantee	$14,000		
Office Furniture and Supplies					1	$.00
	desks	7				
	chairs	6				
	phones	2 (only one calls out)				
	cabinets	3				
	air conditioner	1				
Administrative Labor and Supplies					1053	$1.20
	secretaries, etc.	14 total				
	service workers (drivers, janitors)	17 total				
	maintenance of building and offices	5278.6 sq. m total				
	maintenance of grounds					
	maintenance of automobiles	parts for 2 Ladas, 1 Jeep				
	security	4 policeman/day				
	fire safety	centralized system				
	technical servicing of equipment					
	cleaning of equipment (incl. laundry)					
	water	20 cu. m/day total (15 cold, 5 hot)				
	water supply and drainage	$/sq m				
	electricity (light & AC)	23,000 kwhrs/month				
	telephone	1.5/day calls within Ukraine, 2/wk to NIS, 2.5/mo to Europe				
	radio	5000 coupons/month				
	folders					
	paper	400/day				
	pens					
	glue					
Total					2767	$3.15

NOTES:
11 mini-tests total, 2 minutes each; 2 systems run in one room; 430,000 investigations take place per year; Kone system includes vials, flasks and cuvettes
January 1993 exchange rate: 878 koupons = $1 US

Table 4
INPUTS/COSTS OF CLINICAL TESTING
(per investigation)

CATEGORY	ITEM	QUANTITY	TIME	UNIT COST	TOTAL COST (koupons)	TOTAL COST (dollars)
Labor					590	$.67
	doctor	1/office	10 min/invst.			
	lab technician	1/office	10 min/invst.			
Material					0	$.00
	packet of reagents (inc. chloromine)	1 packet yields 45 invtgs		$10.00/packet		
Building/Space					17	$.02
	2 offices	18 sq. m. each	amortized over 59 yrs			
Equipment					418	$.48
	Gamma 12 system for radiological & immune investigation (Kiev)	1/office, 2 total	5 year warrantee			
	386 computer	1				
	eye saver on computer	1				
	printer	1				
	refrigerator	1				
	thermostat	1/office, 2 total				
	special safe	1				
	centrifuge	1				
Office Furniture and Supplies					2	$.00
	desks	1/office				
	chairs	1/office				
	phones	1/office				
	cabinet	1				
	air conditioner	1/office				
Administrative Labor and Supplies					173	$.20
	secretaries, etc.	14 total				
	service workers (drivers, janitors)	17 total				
	maintenance of building and offices	5278.6 sq. m total				
	maintenance of grounds					
	maintenance of automobiles	parts for 2 Ladas, 1 Jeep				
	security	4 policeman/day				
	fire safety	centralized system				
	technical servicing of equipment					
	cleaning of equipment (incl. laundry)					
	water	20 cu. m/day total (15 cold, 5 hot)				
	water supply and drainage	$/sq m				
	electricity (light & AC)	23,000 kwhrs/month				
	telephone	1.5/day calls to Ukraine, 2/wk to NIS, 2.5/mo to Europe				
	radio	5000 coupons/month				
	folders					
	paper	400/day				
	pens					
	glue					
Total					1200	$1.37

NOTES:
January 1993 exchange rate: 878 koupons = $1 US

3.2 Results Data

3.2.1 Identification

Identifying the consequences from pregnancy screening was considerably more difficult than identifying the costs. The doctors in charge are not accustomed to reporting results at an aggregate level and see no need to justify the screening process. In addition although the diagnostic center uses an extensive computer network to store all information, the data inputing instrument does not allow for data manipulation for analysis.

To identify the results of the pregnancy screening process, the ZRP team consulted with the chief of the Department of Medical Genetics at RMDC, who provided specific information on the 11 most common pregnancy abnormalities diagnosed by the screening process. The following is a list of these abnormalities, as classified by the RMDC:

- hereditary problems;
- water (amniotic fluid) surrounding the fetus;
- danger of interrupting the pregnancy;
- underdeveloped pregnancy;
- invasion of the fetus;
- extra-uterus (i.e. fallopian) pregnancy;
- general abnormality in obstetrics;
- fetal placenta insufficiency (hypoxia of the fetus);
- intra-uterus death of the fetus;
- hypotrophy of the fetus; and
- abnormality of the umbilical cord.

As a result of these diagnoses, either the abnormalities were treated or the pregnant woman received a recommendation to abort the pregnancy.

In Ukraine, the state mandates that each pregnant woman must pass two screening tests, in or around the 16th and 26th weeks of pregnancy. Not all of the pregnant women in the Chernivtsi region receive this screening process at RMDC. In fact, most women in the Chernivtsi region receive their pregnancy screening tests at one of the 13 other diagnostic clinics, which each own a sonography machine. If an abnormality is diagnosed, the mother is automatically referred to the Chernivtsi RMDC for subsequent screening processes.

Unfortunately, the data that the ZRP team received did not consist solely of referrals to the Chernivtsi RMDC. Some of the observations represent women who came to RMDC for their first screening test. Since all patient data were aggregated into a central computer, the data records provided no means for ferreting out these "first screening" observations. However, this number is small relative to the number of women who received the screening in another district before being referred to the Chernivtsi RMDC.

The ZRP team received a matrix listing the number of cases by diagnosed type of pregnancy abnormality and by trimester, across the 12 districts in the Chernivtsi medical region. Data on the results of the pregnancy screening process are listed by trimester in table 5. Most of the types of abnormalities are only intermediate consequences, since RMDC's suggestion to abort or treat follows the abnormality diagnosis. Even this is not the final stage, since the pregnant woman decides whether to abort or treat the abnormality after hearing the RMDC recommendation. However, the abnormality "intra-uterus death of the fetus" obviously is not an intermediate consequence.

3.2.2 Description of Results Data

There is some sample selection bias in the data contained in table 5. The sample contains observations of women with diagnosed pregnancy abnormalities who were referred to the Chernivtsi RMDC from one of the 13 other diagnostic clinics as well as observations of women who attended RMDC for their first screening process. Because limitations in the data records prevented the ZRP team from separating these two groups of observations, the sample of women who attended the center for their first screening process negatively affects the probability of an abnormality ultimately being identified. Also, since some of the women in the sample were referred from 13 other health clinics, diagnostic ability must be assumed constant across the referring clinics. Realistically, this assumption may not be tenable.

The second problem with the results data is that it contains observations across the trimesters of pregnancy, such that one woman's pregnancy might be screened in more than one trimester. According to data obtained from Dr. Verbulya, 2,899 pregnant women visited RMDC in 1993; 1,862 of these women returned at least once during their pregnancy, for a total of 4,761 screening observations. The presence of the sample of "return visitors" most likely biases the probabilities of detection, but it is unclear whether this bias exists and to what extent. For instance, if a potential abnormality is diagnosed earlier in the pregnancy, the woman will most likely receive at least one screening process, if not more later in the pregnancy. If the abnormality is treated and corrected between the investigations, then the probability of detection upon the second investigation will not be biased. But if the abnormality is not treated, then the probability of detection upon the second investigation will be biased upward. Since not every abnormality is treated upon detection (some are left to work themselves out naturally), it could be suspected that the overall sample selection bias is slightly positive as a result of the data containing observations on some women across trimesters.

The ZRP team also encountered data challenges in linking results to costs. Although the four test components are applied individually so that a specific test may detect an abnormality, RMDC does not keep data on which component of the process detected the abnormality. Nor does RMDC record which additional tests (immunology, toxoplasmas, chemical, biochemical, and hormonal) it gave to a pregnant woman after a question arose from the first level of screening. Specific results, therefore, cannot be linked to specific tests, and hence to costs. This limits the extent to which an economic analysis can be performed. For example, a cost-

Table 5

RESULTS OF PREGNANCY SCREENING PROCESS, BY TRIMESTER

FIRST TRIMESTER	
Total Number of Pregnant Women Tested	836
Observed Pathology	583 (p=.697)
Hereditary (detected via amniocentisis)	6
Amniotic Fluid	146
High Probability of Miscarriage	169
Underdeveloped Fetus	5
Foreign Invasion of the Uterus	1
Extra-Uterus Pregnancy	0
Health Complication of Mother (i.e. placenta, multi-embryo)	90
Other Pathologies	166
SECOND TRIMESTER	
Total Number of Pregnant Women Tested	2703
Observed Pathology	1773 (p=.656)
Hereditary	28
Amniotic Fluid	13
High Probability of Miscarriage	570
Fetal Placenta Insufficiency	609
Foreign Invasion of the Uterus	7
Death of Fetus	10
Health Complication of Mother (i.e. placenta, multi-fetus)	278
Other Pathologies	258
THIRD TRIMESTER	
Total Number of Pregnant Women Tested	1222
Observed Pathology	678 (p=.555)
Hereditary	11
Amniotic Fluid	4
High Probability of Miscarriage	150
Fetal Placenta Insufficiency	287
Fetal Nourishment Insufficiency - Small Fetus	3
Complications with the Umbilical Cord	1
Death of Fetus	4
Health Complication of Mother During Labor (i.e. placenta, multi-fetus)	75
Other Pathologies	143
TOTALS	4761

effectiveness analysis can be performed only on the pregnancy screening process, not on the individual test components.

3.3 Findings

3.3.1 Detection of Pregnancy Abnormalities

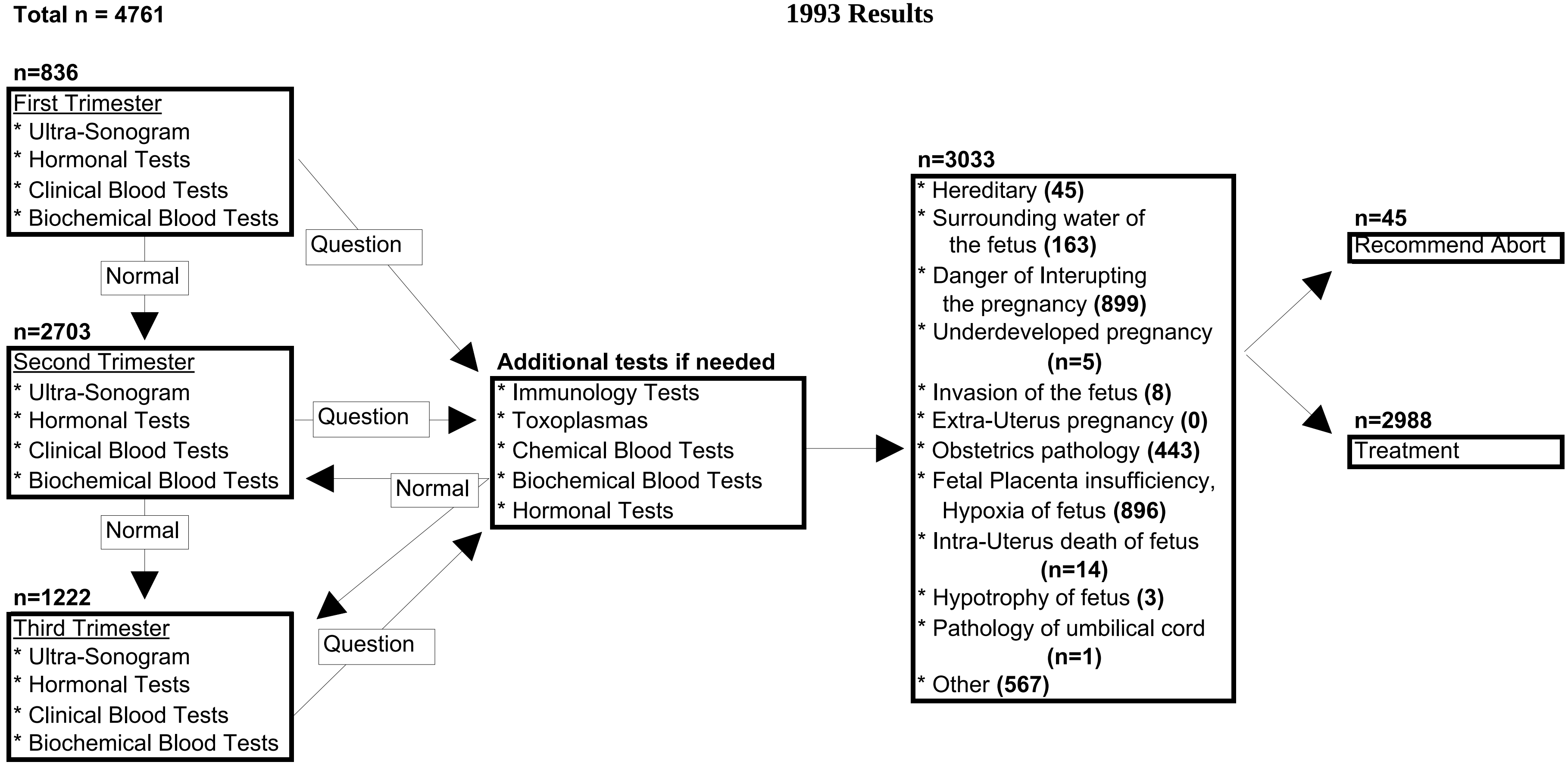
All pregnant women in the Chernivtsi region undergo a comprehensive screening process at one of the 14 clinics. If an abnormality is suspected, the woman is referred to the Chernivtsi RMDC for another comprehensive pregnancy screening. As shown in figure 3, a woman at RMDC may undergo an ultrasound sonogram test (100 percent of cases), clinical blood tests (75 percent of cases), biochemical blood tests (75 percent of cases), and hormonal tests (about 50 percent of cases). When a specific test detects an abnormality, RMDC does not record which component of the test detected the abnormality because the process is considered a package of four components.

If a concern is raised during these tests, the woman undergoes one or more of a second-stage battery of tests that can include immunology tests, toxoplasmas tests, chemical blood tests, biochemical blood tests, and hormonal tests. Unlike the first stage of tests applied at RMDC, these are not a package, but are applied as the particular case demands. These tests provide the final diagnosis, but unfortunately for analysis purposes, RMDC does not record which specific test detected the abnormality.

Figure 3 shows that 4,761 pregnancy cases, mostly referrals, were observed at RMDC with 836 pregnant women observed in the first trimester, 2703 in the second trimester, and 1,222 in the third trimester. Of these 4,761 cases, 3,033 abnormalities were detected: 583, 1,773, and 678 abnormalities in the first, second, and third trimesters, respectively. Of the 3,033 total abnormalities detected in 1993, 45 cases were recommended for abortion and 2,988 cases were recommended for treatment.

Table 5 outlines the number of pregnant women tested at RMDC, the total number of observed pathologies, and the number of diagnoses by pathology for each trimester. The probability of an abnormality being diagnosed within a trimester is the number of observed pathologies divided by the number of pregnant women tested. Since Ukrainian women are recommended to undergo screening processes in the 16th and 26th weeks of pregnancy, it is not surprising that the total number of observations is greatest in the second and third trimesters. From table 5 it is clear that the most common abnormalities are fetal placenta insufficiency and health complications of the mother, such as with the placenta or with the incidence of two or more fetuses present. It is noteworthy that diagnosed problems with the water surrounding the fetus are much more prevalent in the first trimester than in either the second or third trimesters. Also, the likelihood of an abnormality being detected by the screening process decreased with each trimester. These two findings, in particular, suggest that (holding the likelihood of detection due to natural reasons constant) the screening process is effective in detecting abnormalities early in the pregnancy so that they can be treated. This is concurrent with the

Figure 3
Pregnancy Screening at the Chernivtsi Medical Diagnostic Center
1993 Results



evidence cited in annex B regarding the efficacy of ultrasound sonogram tests, in particular, in detecting defective fetuses.

Since only one-half of the women undergo the hormonal tests, an obvious focus of analysis would be to run marginal analysis on the number of abnormalities detected across different probabilities of women undergoing the hormonal tests. This analysis would show the diagnostic effect of the hormonal tests in detecting abnormalities. Data over a number of different years would be necessary, however, to run this analysis; and only data for 1993 were available. Running the marginal analysis by monthly data is possible, but the sample sizes would, in some cases, be too small for meaningful analysis.

3.3.2 Cost-effectiveness Analysis

In attempting to measure the effectiveness of the pregnancy screening process, it is important to distinguish between the functional (or technical) efficacy of the specific test components and the clinical (or economic) efficacy of the screening process as a whole. Economic analysts, in general, are not qualified to investigate the functional efficacy of specific tests (such as the sonogram, biochemical, clinical, and hormonal) or machines in accurately diagnosing problems. But analysts can measure the clinical efficacy of a medical process by calculating the costs involved in a process against the consequences that the process yields.

The standard cost-effectiveness measure in health service delivery is the cost-per-positive health outcome achieved (in this case, maternal or infant death averted). But with the existing limitations of the results data, and with no legitimate method for determining which abnormalities would lead to infant or maternal death, such a measure would be imprecise. The cost-effectiveness measure used in this analysis (cost per abnormality detected) was a function of the data available. The authors recognize, however, that the more standard measure of cost-effectiveness is desirable in future analysis, provided relevant and accurate data exist.

Since not every pregnant woman receives all four tests, it makes sense to compute the total cost for one average pregnancy screening observation.

$$TC = p_s*C_s + p_h*C_h + p_b*C_b + p_c*C_c$$

Where TC = total cost

p_i = probability that test i is implemented

C_i = total cost of test i

s = sonogram test

h = hormonal test

b = biochemical test

c = clinical test

The total cost for the average screening observation is simply the weighted average of the costs of the four components, or the sum of the products of the total cost of each component and the probability that test will be applied. The probabilities mentioned above yield a baseline total cost of 18,840 koupons for the whole process.

Since 4761 pregnant women underwent the screening process at RMDC in 1993, this number is multiplied by 18,840 koupons, the average per-investigation cost, to yield the total 1993 cost of performing the screening process. This total cost is divided by the number of abnormalities (3033) to obtain the average cost of detecting an abnormality, 29,574 koupons. This figure is the cost-effectiveness of the RMDC pregnancy screening process because it gives the cost involved in achieving the desired effect—detecting a pregnancy abnormality.

Since RMDC receives its budget directly from the Regional Health Authority, the Authority is interested in RMDC spending its money wisely and making good use of its available resources. As it stands, the cost-effectiveness measure above can be used over time to make decisions regarding operation of the pregnancy screening process at both RMDC and the 13 regional clinics under the direction of the Regional Health Authority.

Holding the cost-per-screening figures (tables 1-4) constant, an increasing cost-per-abnormality figure indicates a higher "total number of pregnant women tested to total number of abnormalities" ratio. If this ratio continues to rise over time, it may be that RMDC is receiving false-positive referrals, or patients who were incorrectly diagnosed with a pregnancy abnormality (the language of empirical study refers to this functional efficacy problem as a "type II error"). Conversely, if this ratio falls over time, it may be that the 13 other clinics in the region are holding back true-negative patients, or women who were not diagnosed with a pregnancy abnormality when one did exist (type I error). In these cases, the Regional Health Authority may insist on more careful first screenings in the other clinics around the region, or a more narrowly or more broadly defined set of abnormality classifications (for example, either tightening or relaxing the standards of what qualifies as an abnormality worthy of a referral to RMDC). Fortunately, RMDC keeps records on which referrals came from which of the other 13 clinics in the Chernivtsi region. Resources could ultimately be saved if RMDC monitors these records to see if a specific clinic(s) is referring an inordinate amount of "false positives" or holding back a high number of "true negatives."

Improved management information systems would allow this cost-effectiveness measure to be used for other analyses as well. If results data were available for the individual tests in the pregnancy screening process, such that specific results could be linked to specific costs, then this cost-effectiveness measure could be used to look at the intensity of first-level screenings, to decide whether to screen low-risk pregnancies, and to compare the cost-effectiveness of the four individual test components of the screening process.

3.3.3 Sensitivity Analysis

Since the ZRP team could not be sure of the precise probabilities of application for the hormonal, biochemical, and clinical test components in the screening process, a sensitivity analysis was performed. Tables 6, 7, and 8 detail how the total cost of an average screening process, and hence the cost-effectiveness of the process, is affected by changes in the probabilities of the respective components being applied. The probability of the particular component is altered slightly from the baseline probability (in bold) while holding the probabilities of the other components constant at their baseline figures. An in-depth analysis will reveal that the total cost figures and the cost-effectiveness figures vary linearly. This can be expected, since each set of figures represents one alteration in the linear total cost equation.

Table 6

SENSITIVITY ANALYSIS WITH RESPECT TO THE PROBABILITY OF THE HORMONAL TEST BEING APPLIED

P_h	TC (kpns)	Cost-effectiveness (kpns/abnormality detected)
.40	17,662	27,725
.45	18,251	28,649
.50	**18,840**	**29,574**
.55	19,429	30,498
.60	20,018	31,423

Table 7

SENSITIVITY ANALYSIS WITH RESPECT TO THE PROBABILITY OF THE BIOCHEMICAL TEST BEING APPLIED

P_b	TC (kpns)	Cost-Effectiveness (kpns/abnormality detected)
.65	18,564	29,140
.70	18,702	29,357
.75	**18,840**	**29,574**
.80	18,979	29,792
.85	19,117	30,009

Table 8

SENSITIVITY ANALYSIS WITH RESPECT TO THE PROBABILITY OF THE CLINICAL TEST BEING APPLIED

P_c	TC (kpns)	Cost-Effectiveness (kpns/abnormality detected)
.65	18,720	29,385
.70	18,780	29,480
.75	**18,840**	**29,574**
.80	18,900	29,668
.85	18,960	29,762

Chapter 4

RECOMMENDATIONS

The health care system of Ukraine treats most pregnancies as uniform risk, neglecting the cost considerations that diagnosing these patients entails. In light of the shrinking budget of the Ukrainian government, such use of medical resources carries very real cost implications. Furthermore, medical literature now suggests that excessive use of the ultrasound sonogram test, a component of Ukraine's screening process, may have a negative effect on the growth of the fetus. An Australian study released in 1993 found that fetuses subjected to multiple ultrasound sonogram tests were more than twice as likely as those tested only once to be small for their gestational age, as well as at birth (Newnham, et.al.). And in 1989, a U.S. Food and Drug Administration panel of outside experts recommended that ultrasound sonogram testing should not be performed routinely during fetal development. (See annex B for details on the efficacy and safety of ultrasound screening).

The pregnancy screening process of Ukraine follows very rigid rules by mandating that each pregnant woman pass at least two screenings. This mandate implicitly avoids accounting for factors that may make some women more likely to experience complications with their pregnancies. By not employing risk assessment tools, doctors are treating most women as high risk and potentially spending unwarranted resources. By developing risk groups, doctors can apply pregnancy screening more intensively to those women at higher risk for pregnancy abnormalities. Some technical assistance on risk assessment methods in health care could be very useful in developing national standards and could certainly save resources.

The weak interaction between the first two stages of pregnancy screening leads to redundant testing. In the Chernivtsi region, when a pregnant woman's gynecologist refers her to RMDC, a number of tests are automatically repeated. Doctors at RMDC say they repeat the tests because the quality of tests administered outside RMDC is uncertain and the patients often do not have the initial test results with them. Resources could be saved by improving informational transfer between medical centers. Technical assistance on improving management information systems across health facilities could help alleviate this communication problem.

RMDC has the potential to produce important data and information beyond that specific to pregnancy screening, such as data on general preventive care and health outcomes. The commitment and professionalism of the center's staff, combined with an excellent information-gathering ability, provide the two most important elements for achieving this potential. A number of additional factors would help realize this potential:

- The center needs to improve the data inputing instrument for health quality assurance and cost-effectiveness reasons. Currently the computer is used as a filing cabinet, where data input can be copied, from paper in blocks of information but it does not allow the information to be sorted and manipulated. If the center inputs each piece of information (such as patient characteristics, referral information, and findings from each test) in a separate cell that is consistent across all patients, generating statistics on outcomes and linking results to tests and characteristics will be easy. At the time of this report, center staff were in the process of improving this element of data gathering. Some technical assistance or training in this area could be useful.

- The center can improve the costing methodologies employed. The ZRP team although impressed with the costing exercise the RMDC staff conducted, concluded that newer methodologies could be used to improve the estimates. To that end, the ZRP team is sending RMDC a report on cost estimation methodologies developed by ZRP for the NIS region and applied in Kazakhstan (Telyukov and Hildebrand).

Once data inputing issues are addressed, RMDC can take advantage of the wealth of information to produce policy-relevant statistics, such as the following:

- population profiles for persons with high risk of health problems;

- test-specific outcomes (for example, technical efficacy—how accurate are different tests in diagnosing different health abnormalities?) for all the diagnostic tests in RMDC; and

- cost-effectiveness of each diagnostic test.

Once these data inputing methods have been implemented, RMDC could easily use information pertaining specifically to pregnancy screening to perform the following:

- From the population profiles of health, develop risk groups for women according to varying levels of risk for pregnancy problems. Higher risk women would be recommended to receive more first-level screenings than those of lower risk.

- Investigate the appropriate intensity of first-level screenings (one versus two, or two versus three screenings), including the decision whether or not to screen low-risk pregnancies (vis-à-vis physician-appointed only screenings).

- Calculate and compare the cost-effectiveness of the four individual test components of the screening process. The more cost-effective test components would be used more intensively.

Annex A

ECONOMIC EVALUATION METHODS

Conditions of limited resources with unlimited needs are not unique to the field of health care. Individuals interested in maximizing satisfaction are faced with choices of how to spend or invest their wealth. Businesses interested in maximizing profits or sales are faced with choices such as hiring or purchasing within set budgets. Similarly, government agencies are faced with spending choices against set budgets. It is important therefore to have tools that assist decision-makers in making such spending choices. Economic evaluation methods help individuals and decision-makers find appropriate answers to the questions of allocating scarce resources among competitive needs and wants.

In any evaluation process, costs and consequences (usually benefits) must be identified. Costs are the resources used in a process; consequences are the outcomes or results. Costs are usually expressed in monetary terms, but often it is not possible to place numerical measures on consequences. For instance, attaching a monetary benefit to extending a terminal cancer patient's life two years as a result of radiation therapy is extremely subjective.

Types of Evaluation Methods

The four primary types of economic analysis are as follows:

- cost-minimization analysis;
- cost-effectiveness analysis;
- cost-benefit analysis; and
- cost-utilization analysis.

Cost-minimization analysis (CMA) is the easiest to use of the economic evaluation methods and the only one that focuses solely on costs and not on consequences. CMA can be used to investigate the cheapest way to produce identical consequences. If there is no significant difference between the consequences of two or more processes, the one that incurs the lower cost would be desirable. For example, if a person can reach a destination in approximately the same time by car or train, then the means of transportation with the lower fare will most likely be chosen. When the activities being evaluated produce different consequences, CMA should not be used since differences in consequences are not considered.

Cost-effectiveness analysis (CEA) is one way of addressing some of the difficulties involved in evaluating activities that produce different consequences. In the example used above, two modes of transportation are considered (cab or train), but the consequence is identical (equal travel time). The problem becomes more difficult if the time involved for each transportation mode differs. CEA can be applied in this case to measure the cost of transportation per unit time. CEA measures the cost involved in performing a process to achieve a particular consequence, or, conversely, CEA gauges the "productivity" in achieving a consequence, given a certain cost. Consequences in CEA are measured in natural units, or units of time, weight, length, number of occurrences, and so forth.

When evaluating health, CEA uses consequences such as life expectancy, mortality measures, and morbidity measures. CEA can address the problem of dissimilar consequences, but only if the consequences are of the same type. For example, if one intervention can prolong the life of a patient by two months (for example, applying radiation therapy to a terminal cancer patient) while another intervention cannot prolong life but can make the patient more comfortable by reducing pain (forgoing the radiation therapy), then CEA should not be used.

Cost-benefit analysis (CBA) can address the problem of having different types of consequences. Unlike CEA, CBA measures consequences in monetary terms and enables decision-makers to compare the value of consequences to the cost of activities. In the transportation example, CEA cannot be used if we are comparing the transportation of two individuals that have different costs of time, as measured by their salaries. But in CBA, the cost of the mode of transportation would be compared to the monetary value of time for each individual. CBA also allows for analysis when consequences are achieved over a period of time. Discounted costs over time are subtracted from the discounted benefits over time to project whether the process or project will be economically improving (positive difference) or economically hindering (negative difference). Typically, the process or project is undertaken if this difference is positive and foregone if this difference is negative. An example may be measuring the net social gain from constructing a dam; the discounted benefits, such as the value of the hydraulic energy produced and the value of the irrigation attained, are weighed against the enormous cost of financing and constructing the dam to determine whether building the dam is economically desirable.

When applied to health issues, CBA presents computational and ethical problems. Computational problems arise from the difficulty in estimating the economic costs and benefits of different medical conditions. Even if we can estimate the economic benefit of a consequence, we sometimes have to make subjective decisions such as determining the value of an averted death or the value of reduced morbidity. While placing monetary values on suffering and life is distasteful to some, the exercise can be worth the effort if the result is to maximize the health consequences of a group with limited resources.

Cost-utilization analysis (CUA) uses satisfaction or utility to measure the benefit in deciding between alternatives. Utility is defined as the level of happiness of an individual. In the transportation example, the preferences of the travelers would be considered. For instance, if the individual has an aversion to the noise of a train and prefers a cab (travel time and monetary cost being equal), then the cab ride would be the more desirable means of transportation. Even if the times or the costs are not equal, the individual may see this cost difference as worth the sacrifice to ride in a cab as opposed to the noisy train. Not surprisingly, the application of CUA is limited by information constraints. In this example, the analyst would need information on the preferences of the individual with respect to cab rides versus train rides.

In performing an economic analysis of health care issues, the figure of quality-adjusted life years (QALY) is often calculated. This figure is frequently matched with the cost of achieving a given increase in QALY as a measure of the program's productivity or effectiveness. Another measure used is disability-adjusted life years (DALY), which considers both mortality and morbidity in analyzing health consequences.

An example of cost-utilization applied to health care is when a person decides between having laser surgery or buying glasses. The person may have an aversion to wearing glasses, in which case, having the laser surgery performed will increase the measure of QALY. The cost of the surgery must be measured against the QALY benefit to facilitate making a thoughtful decision.

Steps in Economic Evaluation

The first step in any economic evaluation is to define the general problem and the specific objectives of the analysis. Will constructing the dam save or cost the state money over a long period of time? Which staffing strategy costs less money for a hospital in performing a medical procedure: employing two nurses or one doctor? The second step is to identify alternative programs for consideration with the help of an economic analysis. The third step is to calculate the net costs and net consequences of each alternative. Then the analyst can apply the decision rules pertaining to the particular type of evaluation method used. Finally, the analyst can perform sensitivity analysis to extract the impact that a particular variable has on the system.

Costs

Regardless of the type of economic evaluation method selected, costs need to be estimated for all alternative activities. Costing activities employs a three-step approach: identifying costs, quantifying costs, and valuating costs.

a. Identification of Costs

A useful exercise in identifying costs is to define the different types of costs. Costs can be classified in a number of ways: direct or indirect, joint or nonjoint, recurrent or capital, and program or user. Classifying costs ensures that all costs are identified, aids in projecting financial needs to identify problems and potential savings, and determines who is paying the bill. The latter will determine the viewpoint of the evaluation. For example, if it is a matter of choosing between health interventions to maximize the positive consequences within the government's budget, the patient's costs need not be considered.

Direct and Indirect Costs: Direct costs correspond to resources that can be explicitly identified with a service or product. Indirect costs cannot be explicitly identified but are related to supporting the direct activities. Indirect costs typically are incurred to administer or evaluate programs. Examples of direct costs involved in a surgical procedure are the cost of the anesthesia and the cost of the doctor's and nurse's time. Examples of indirect costs involved in a surgery are the cost of a hospital secretary's salary, the cost of the computer the secretary uses, and the cost of the paper upon which information regarding the surgery is written. (From the analysis of the pregnancy screening process in Ukraine, labor and materials are examples of direct costs, while building space, office furniture and supplies, and administrative labor and supplies are examples of indirect costs.)

Joint and Nonjoint Costs: Joint costs are the costs of clinic resources that are used for more than one activity or investigation. Nonjoint costs are costs of resources that are used for only one activity or investigation, and they are either fully consumed or discarded at the end of the investigation. Examples of joint costs surrounding a surgical procedure are the hospital bed and the surgical instruments used in the procedure, for these items may be used in other surgical procedures. Examples of nonjoint costs of a surgical procedure are the anesthesia, stitches, and the disposable gown worn by the patient. (From the analysis of the pregnancy screening process in Ukraine, administrative labor and supplies are examples of joint costs, while labor and materials are examples of nonjoint costs. The joint costs were allocated proportionately with respect to floor space at RMDC.)

Recurrent and Capital Costs: Recurrent costs are usually defined as the costs of inputs that will be consumed or replaced within one year, while capital costs are defined as the annual costs of inputs that have a life expectancy of more than one year. Recurrent and capital costs may be thought of as variable and fixed costs, respectively. In a soda bottling process, for example, the recurrent costs may be the costs of the bottles, the ingredients (such as sugar, starch, and food coloring) to make the soda syrup, and the chemical reagents used to test the quality of the soda. Examples of capital costs are the costs of the conveyer belts that transport the bottles, the filler machines, and the building. When evaluating programs to make funding decisions, donors often look closely at a program's recurrent and capital costs. Frequently, the donor will offer to cover the program's capital costs and incite the program to recover its costs that recur continually over time. If a program is able to recover its recurrent costs, it is seen as self-sufficient and generally worthy of receiving capital cost funding. (From the analysis of the pregnancy screening process in Ukraine, labor and materials are examples of recurrent costs, while building space, equipment, and office furniture and supplies are examples of capital costs.)

Program and User Costs: Program costs are those associated with the process, namely the cost of inputs. User costs are those borne by the individual using the goods or service. In health care, program costs are realized by the hospital or health clinic, and consist of the costs of the inputs (such as machines, medicine, and doctor's or nurse's time) required for a certain procedure to be performed. User costs include the fee for treatment, the cost of transporting the patient to and from the health facility, and the opportunity cost of the patient's time. (From the analysis of the pregnancy screening process in Ukraine, all of the costs involved are program costs.)

Opportunity Costs: The opportunity cost of the current use of some goods, input, or process is its worth or value in the next-best alternative use. The opportunity cost of constructing a dam is the value of the investment when this money is alternatively used to make improvements in roads, schools, and public parks. This notion of cost is broader than the financial cost framework, because it encompasses all resources consumed in the process, regardless of who pays for them.

b. Quantifying Costs

Measuring, or quantifying, costs in natural units allows the analyst to gain the real—not monetary—measure of an input. Costs should be expressed in units of time, length, area, volume, weight, and so forth. Some examples of natural units are hours, yards, square meters, cubic feet, and kilograms. Measuring costs in natural units is especially advantageous when the currency in the country in which the analysis is being conducted is experiencing significant inflation, such that the cost figures may be quite different over a relatively short period of time.
In performing economic evaluations, the analyst must also control for scale. Effectively, this means taking note how the per-unit cost of the process changes as the number of units produced changes.

When reliable cost data cannot be obtained, the analyst must rely on the educated guessing of an individual with the knowledge to make an informed estimate. (For the analysis of the pregnancy screening process in Ukraine, the ZRP team relied on the educated guessing of the RMDC's chief engineer for some of the itemized input costs, such as the number of sheets of paper RMDC used daily.)

c. Valuating Costs

After the analyst has collected and measured the costs in natural units, he or she must place value on these inputs by attaching currency figures to the inputs. This is done by multiplying the number of units of the input item used in the process times the unit price for that particular input item.

In most economic evaluation analyses—especially CBA—opportunity costs are discussed, if not added to the quantitative analysis. Whether the analyst acknowledges opportunity costs by including them in the actual quantitative analysis depends upon the analyst's perception of the impact, particularly on society, of the cost.

Consequences

Several types of consequences in economic evaluation methods exist: quantitative or qualitative, continuous or discrete, and those expressed monetarily or in natural units. The variability among consequence types is especially prevalent when applied to health care. Health consequences can be those of mortality, varying levels of morbidity and disability, monetary costs for treatment, discrete behavior choices regarding preventive care, as well as many others. The consequences can be intermediate as well as final. As an example, the intermediate consequences of a diagnosis of a cancerous tumor are that it is "benign" or "malignant" since the doctor's suggestion to either treat using radiation therapy or not to treat follows the diagnosis. And even the doctor's suggestion is not the final stage, since the cancer patient ultimately makes the treatment decision after hearing the recommendation.

Checklist for Economic Evaluation Methods

After performing an economic evaluation, the analyst can review his or her work by consulting a checklist of questions such as the following:

- Was a well-defined question posed in an answerable form?
- Was a comprehensive description of competing alternatives given?
- Was there noneconomic evidence of program effectiveness?
- Were all important costs and consequences identified?
- Were costs and consequences measured accurately in appropriate physical units?
- Were costs and consequences valued credibly?
- Were the costs and consequences adjusted for differential timing?
- Was an incremental analysis of costs and consequences of alternatives performed?
- Was a sensitivity analysis performed?

If all of these questions can be answered in the affirmative, then the analyst can be assured that he or she has conducted a sound evaluation.

Limitations of Economic Evaluation

The usefulness and accuracy of an economic evaluation is ultimately only as good as the data with which it begins. Conclusions drawn upon sketchy data will be sketchy themselves. An economic evaluation is also limited in the nature of its applicability: an economic evaluation is instrumental in making efficiency improvements, but not equity improvements. That is, an economic analysis can be used to make suggestions to use resources more effectively, but it cannot be used to make suggestions about how these resources may be distributed in a fairer or more equitable manner.

Furthermore, the economic evaluation does not guarantee that the resources will be used effectively. The analyst can only make suggestions for improvements. The burden of actual improvement falls on the individual or group in charge of the program (for example, the hospital or government). Finally, conducting an economic evaluation can be costly, especially with regards to the time costs of individuals.

Annex B

THE EFFICACY AND SAFETY OF SONOGRAM TESTING FOR PREGNANCY ABNORMALITIES GENERAL EVIDENCE

Ultrasound sonogram testing, in use since the mid-1970's, involves using sound waves to produce an image of the fetus that enables doctors to determine the fetus' age and growth, as well as to find birth defects. Sonograms are especially beneficial in the following:

- Determining multiple births;
- Clarifying gestational age (doctors often order the test about midway through a pregnancy because it provides a good estimate of the age of the fetus, thereby helping the doctor manage the rest of the pregnancy);
- Identifying an ectopic pregnancy (where the fertilized egg develops in the fallopian tube);
- Determining the proper placement of the needles in the amniocentesis procedure; and
- Caring for high-risk pregnancies.

However, in many Western countries doctors are considered to be overprescribing sonogram tests, especially in light of the uncertainty surrounding the use of ultrasound imaging during pregnancy. This uncertainty has focused on both efficacy (and hence economic) and health concerns.

Efficacy

To test the functional efficacy of sonograms in detecting pregnancy complications, the National Institute of Health (NIH) funded a study involving 15,151 pregnant women at 109 obstetrics and family practice facilities in six states between November 1987 and May 1991. Researchers at the Washington University School of Medicine in St. Louis, Missouri; Brigham and Women's Hospital in Boston; and George Washington University in Rockville, Maryland, collaborated on the study. This study was published in the September 16, 1993, issue of the *New England Journal of Medicine*.

One-half of the participants in the study (all of whom were considered at low-risk for problem births—over 16 years old, with no history of problem pregnancies) were randomly assigned to a treatment group that included two sonograms, one at 15-22 weeks into the pregnancy and the other at 31-35 weeks. In the control group, physicians ordered sonograms only when they considered them necessary. Women in the screening group averaged 2.2 sonograms while the control group averaged 0.6 tests. Fifty-five percent of the control group did not have any sonograms.

The results were surprising. Only 5 percent of babies born to mothers in the screening group had complications or adverse outcomes, compared with 4.9 percent of those mothers who did not undergo routine sonograms. (Adverse perinatal outcome was defined as fetal death, neonatal death, neonatal morbidity.) Also, the number of premature and low-weight babies were nearly identical in both groups. The routine ultrasound sonogram test did detect the more defective fetuses at an earlier stage, but the researchers said this made no significant difference to the outcome of the pregnancies. The study concluded that ultrasonography screening did not improve perinatal outcome as compared with the selective use of ultrasound sonogram test based on clinician judgment.

The efficacy of ultrasound sonogram testing is important when economic realities are taken into consideration. Considering the cost of sonograms ($250-$350 in the United States) and the growing hypothesis that routine ultrasound screening adds considerably to the cost of pregnancy care with no improvement in perinatal outcome, experts are questioning the appropriateness of such expensive testing in an environment of soaring health care costs. Dr. Bernard Ewigman of the University of Missouri at Columbia, the lead investigator of the NIH study, says, "This is an example of some of the unnecessary testing that is driving up health care costs" (Leary).

Safety

Sonogram testing is presumed to be safe, although conflicting evidence raises doubts. Ultrasound imaging works by transmitting high-frequency sound waves through body tissue. The sound waves bounce off the fetus and the mother's internal organs, creating an "echo." The echo is translated into an image, called a sonogram, which can be displayed on a monitor. The theoretical possibility exists that birth defects might result when fragile embryonic tissue is bombarded by sound waves.

This possibility was lent credence by an Australian study released in the October 9, 1993, issue of *Lancet*, which concluded that frequent ultrasound examinations may limit fetal growth. Babies subjected to multiple ultrasound sonogram tests were more than twice as likely as those tested only once to be small for their gestational age, as well as at birth. The fear that sound waves have the potential to cause subtle brain damage in the fetus was raised when a 1984 study indicated a possible link between prenatal ultrasound exposure and dyslexia, a type of learning disability in which children have difficulty reading.

On the other hand, a Norwegian study sampled 2,011 pregnancies between 1979-81 and found no link between in utero ultrasound exposure and the development of learning disabilities later in life. No connection between ultrasound exposure and birth defects has ever been demonstrated in humans, although some investigators have documented a rise in malfunctions among animals (Fackelman).

The scientific uncertainty surrounding sonograms led the U.S. Food and Drug Administration (USFDA) to recommend sonogram testing only in the case of bleeding, family history of birth defects, and advanced maternal age. The USFDA warns against frivolous use of the procedure, such as to determine the sex of the child or to have a picture of the fetus for the family photo album.

SELECTED BIBLIOGRAPHY

Crane, James P., et.al. "A Randomized Trial of Prenatal Ultrasonographic Screening: Impact on the Detection, Management, and Outcome of Anamalous Fetuses." *American Journal of Obstetric Gynecology*, vol. 171, no. 2: August 1994, pp. 392-399.

Ewigman, Bernard G., et.al. "Effect of Prenatal Ultrasound Screening on Perinatal Outcome." *New England Journal of Medicine*, vol. 329, no. 12: September 16, 1993, pp. 821-827.

Fackelmann, Kathy. "How Safe Is a Sonogram?" *Science News*, vol. 141: April 4, 1992, pp. 218-219.

Hildebrand, Stan and Alexander Telyukov. "Cost Centers and Step-Down Cost Allocation: Adjusting Hospital Cost Accounting in Issyk-kul Oblast, Kyrgyzstan to Internationally Accepted Methodology." Zdrav*Reform* Program Technical Report, October 28, 1994.

Leary, Warren E. "Study Finds Waste in Ultrasound Use." *New York Times*, September 16, 1993, p. A17:1.

Newnham, John P., et.al. "Effects of Frequent Ultrasound During Pregnancy: A Randomized Controlled Trial." *Lancet*, vol. 342, no. 8876: October 9, 1993, pp. 887-891.

Summary Minutes of the Thirty-Eighth Meeting of the Obstetrics-Gynecology Devices Panel, U.S. Food and Drug Administration, January 19, 1989.

Winslow, Ron. "Study Indicates Fetal Sonogram Is Overused Aid." *Wall Street Journal*, September 16, 1993, p. B1.