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Collecting Direct Non–Health Care and Time Cost Data: Application to Screening and Diagnosis of Cervical Cancer

Scott B. Cantor, PhD, Lawrence B. Levy, MS, Marylou Cárdenas-Turanzas, MD, DrPH, Karen Basen-Engquist, PhD, Tao Le, BS, J. Robert Beck, MD, Michele Follen, MD, PhD

Background. Data on direct non-health care and time costs are rarely collected, though the incorporation of such data is essential for performing cost-effectiveness analyses according to established guidelines. **Objectives**. To explore the challenges involved in collecting and analyzing these data from patients enrolled in a clinical trial. Methods. Through the use of a pilot study, the authors designed a questionnaire to collect these costs. They used this questionnaire in a clinical trial conducted at a comprehensive cancer center and a public community hospital. Patients in the trial were undergoing screening or diagnostic procedures through a clinical protocol designed to measure the effectiveness of fluorescence and reflectance spectroscopy for detecting cervical precancers. Direct non-health care costs were adjusted to 2003 constant dollars. Results. The authors successfully collected direct non-health care and time cost data, thus demonstrating the feasibility of acquiring such data. Compared to patients receiving diagnostic services for cervical cancer, those receiving screening services for the same condition

in both settings incurred lower direct non-health care costs and time costs, as defined in the questionnaire. Compared to patients receiving either service at the comprehensive cancer center, those seeking either service at the public community hospital incurred lower direct non-health care costs and time costs. When outliers were removed, total direct non-health care costs and time costs substantially decreased for diagnostic patients in the comprehensive cancer center; total direct non-health care costs and time costs for other subgroups remained essentially unchanged. Conclusions. Direct non-health care and time cost data can be collected within a large-scale clinical trial. The setting (community v. specialty hospital) and population (patients receiving screening v. diagnostic examination) makes a difference regarding the cost totals. The order of magnitude of the final result depends on the context in which the non-health care and time cost data will be used. Key words: cervical cancer; costs and cost analysis; diagnosis; screening; time costs. (Med Decis Making 2006;26:265–272)

Cost-effectiveness analysis is used to analyze the tradeoff between economic costs and health benefits of medical interventions. Such information can be applied when evaluating screening practices, choosing the best treatment strategy, and determining the appropriate pharmaceutical to prescribe.

In 1996, the US Panel on Cost-Effectiveness in Health and Medicine synthesized recommendations and published guidelines for performing cost-effectiveness analyses.¹ An important recommendation of the panel is to perform cost-effectiveness analyses from a societal perspective. The potential implications of the choice of the societal perspective were recognized in the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force on

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Good Research Practices–Modeling Studies.² The societal perspective recognizes that societal resources are finite and considers many societal investments, in addition to health, to have merit (e.g., education, quality of the environment, law enforcement, etc.). From this perspective, no single factor always supersedes other components of expenditures or other components of benefit.¹

Costs that are pertinent in the economic evaluation of health care programs have been classified into 4 categories: 1) direct health care costs, which are either directly attributable to an intervention or attributable to a consequence of the intervention; 2) costs of non-health care resources, including costs of child care, elder care, transportation, and parking; 3) costs for an unpaid caregiver's assistance; and 4) costs associated with the time spent seeking and receiving medical care.³ Most economic evaluations of health care interventions focus on direct health care costs that consist of the more obvious components, including physician and nursing services, pharmaceuticals, diagnostic tests, inpatient and outpatient care, food, and supplies. However, direct health care costs also include overhead costs, which are commonly overlooked, such as those associated with the clinical site, facilities, equipment, and utilities.

The societal perspective, however, also considers the impact of costs other than those of direct health care when analyzing the cost-effectiveness of medical interventions. Costs that may not be borne by the payor or provider of health care services but that are incorporated in the societal perspective include opportunity costs of resources used, such as the time patients spend seeking and receiving care, and direct costs borne only by the patient, such as transportation costs, parking fees, and caregiver fees if required in the patient's absence while seeking health care services. This point was reiterated by Weinstein and others⁴ in their attempt to decrease the confusion regarding incorporating productivity costs (i.e., that the lack of conventional measurements for certain costs or consequences does not justify their omission in cost-effectiveness analyses).

Some studies⁵⁻¹¹ have collected direct non-health care costs or time costs, whether alone or as part of a cost-effectiveness analysis (CEA), but no established methodologies currently exist for the collection of direct non-health care cost data. Moreover, many analysts consider the collection and standardization of such data to be a difficult endeavor that may not be worth the time, effort, and money required.

Previous efforts in collecting direct non-health care or time cost data have shown the feasibility of collecting such data. Data collection methods include self-administered mailed questionnaires,⁵ self-administrated questionnaires at the clinic,⁷ event diaries and personal interviews in the subjects' homes,¹⁰ and retrospective phone interviews.⁹ Nearly all identified studies on time cost data collection were performed in the United States, but some studies were performed in other countries, including the United Kingdom¹⁰ and Tanzania.¹¹ Validity and reliability of data collection methods are not usually evaluated. However, Stringer⁶ demonstrated test-retest reliability by comparing written and oral responses to survey questions, and Kowalewski and others¹¹ validated data by comparing the waiting and treatment times reported in patient interviews with that recorded at the clinics.

Previous studies typically did not address whether neglecting direct non-health care or time cost data might produce significant bias in evaluating the cost-effectiveness of health care interventions. Time costs can be a significant cost component in screening⁷ or treatment⁸ programs. These costs can affect adherence, which may be a barrier to obtaining health care and potentially affect the results of economic evaluations.^{7,9,11}

Because many perceive direct non-health care costs as having little or no impact on the "bottom line," little has been done to standardize collection methods for and ascertain the true impact of these costs. In light of this, we conducted a study to demonstrate a method for collecting such data in an interview format. First, we note the challenges associated with collecting these data, as observed in a pilot study, and provide suggestions for dealing with some of the more controversial questions of accounting. Second, we present the results of a study that collected cost data other than direct health care cost data. This was part of a larger study to determine the effectiveness and costs of emerging technologies for cervical intraepithelial neoplasia and cancer screening and diagnosis.

METHODS

Pilot Study

As part of a larger questionnaire concerning the pain and anxiety experienced during a clinic visit

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for diagnostic testing for cervical cancer, 20 patients were asked about costs other than direct health care costs. The variables of interest were transportation to and from the clinic, child care costs, elder care costs, parking costs, and the time spent away from work to visit the clinic. The data were ascertained in an open, rather than closed, question format (e.g., "How far did you travel to come to the clinic today?").

Interviewers discussed their concerns about the questionnaire with the project leaders, resulting in modification of the questionnaire. The revised questionnaire is presented in the appendix. Concerns about accounting included issues of inconsistent estimations of time away from work, free parking at an initial visit, transportation provided at no charge to the patient, and unusual distances or modes of travel. Three patients had traveled significant distances by plane, train, or car; although the mode of transportation of distance traveled was somewhat unusual, we decided to retain the data for these patients in the main analysis. Three other patients had been driven to the clinic by friends or significant others. We collected sufficient information in these latter cases to estimate the time cost of the friend or significant other for incorporation into the cost calculation. For a patient who had been dropped off by a friend who traveled home before returning to pick up the patient, we doubled the usual round-trip cost to more accurately reflect the total resources expended. Similarly, for a patient who stated that her parking fee was waived because it was her first visit, we considered this to be an opportunity cost to the hospital and counted it as a non-health care cost. We also considered the time patients lost from nonworking hours, such as vacation time or study time (if a student), to be opportunity costs of missed work or leisure time. Finally, we considered a case in which the interviewer knew that the patient had given an inconsistent answer regarding time away from work. As we knew this patient's response was incorrect, we excluded it from the analysis. However, this situation demonstrated the difficulties of collecting such data; had the interviewer not known that the patient's answer was inconsistent, the data would have been included in our analysis.

Exploratory Study

We incorporated the changes arising from the concerns in the pilot study into a cost questionnaire to be used in the exploratory study. This cost questionnaire was part of a larger questionnaire given to patients who participated in 1 of 2 clinical trials that tested fluorescence and reflectance spectroscopy of the cervix for cancer screening or diagnosis. Questions about non-health care costs were asked of each patient only after her clinical examinations had concluded.

The inclusion criteria for patients in the screening protocol were age of 18 years or older, no current pregnancy, and having an intact cervix (i.e., posthysterectomy patients were excluded). Patients in the diagnostic study had to meet the previous inclusion criteria and had to have been referred on the basis of an abnormal Papanicolaou smear or to have had a history of an abnormal Papanicolaou smear. The institutional review boards at The University of Texas M. D. Anderson Cancer Center ("M. D. Anderson") and Lyndon Baines Johnson Hospital ("LBJ") in Houston, Texas, approved both study protocols.

From the data, we identified 4 patient subgroups based on the study setting (public community hospital v. comprehensive cancer center) and population (patients undergoing screening v. diagnostic procedures). We hypothesized that the diagnostic study patients would have higher non-health care costs because their history of abnormal Papanicolaou smears would necessitate longer examinations. Furthermore, we hypothesized that the patients who visited the comprehensive cancer center would have higher non-health care costs because of the typically farther distances patients are willing to travel to visit such a center as compared to a community hospital.

When a patient did not provide a particular associated cost, we used the mean cost for others who had such an expense within her setting-population subgroup. To determine an overall mean cost for each of the 4 setting-population subgroups, we averaged total expenses across all participating patients within each subgroup.

Some cost components did not involve an actual payment. We made additional assumptions to estimate these costs. For example, when a patient identified the use of caretaker services for which she did not pay, we considered the caretaker costs to be the product of the number of hours missed times the average wage rate for that caretaker's age and sex.¹² This value would represent the opportunity cost, from the societal perspective, of the caretaker's time. A similar calculation could be made for a person accompanying a patient to the clinic visit.

We also considered the requirement of assumptions when determining transportation costs, such as applying the US government standard of \$0.31 per mile to estimate transportation costs by automobile for patients using that mode of travel. We proposed

	Companies I DI Companies M D. Anderson		Diamania I DI	D'and M D Andrew	
	(n = 113)	(n = 373)	(n = 122)	(n = 321)	
Age					
\overline{X}	46.6	44.4	39.4	38.1	
Range	24-77	18-80	19-73	18-85	
Education, <i>n</i> (%)					
≤ High school	26 (23.0)	65 (17.4)	39 (32.0)	91 (28.3)	
Some college	36 (31.9)	168 (45.0)	49 (40.1)	113 (35.2)	
≥ College graduate	51 (45.1)	140 (37.5)	34 (27.9)	114 (35.5)	
Missing	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.0)	
Race, <i>n</i> (%)					
White	45 (39.8)	190 (50.3)	62 (50.4)	198 (60.9)	
Hispanic	40 (35.4)	83 (22.0)	40 (32.5)	49 (15.1)	
Black	26 (23.0)	63 (16.7)	16 (13.0)	58 (17.8)	
Asian	2 (1.8)	28 (7.4)	3 (2.4)	9 (2.8)	
Native American	0 (0.0)	7 (1.9)	1 (0.8)	5 (1.5)	
Other	0 (0.0)	7 (1.9)	1 (0.8)	5 (1.5)	
Missing	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	

Table 1 Demographic Characteristics of Study Sample

validating the distance traveled by comparing the patient's estimate of distance traveled with the round-trip distance between the patient's stated point of origin and the clinic site, as computed by the online mapping service at http://www.mapquest. com. For the few patients in this survey who indicated that they had traveled to their clinic visit by plane, we proposed to use an industry estimate of \$0.25 per mile, based on the estimated distance between the city of origin and the city in which the clinic was located.

We followed the panel's recommendations by using a standardized index year. All costs were converted into constant 2003 dollars using the general Consumer Price Index.

RESULTS

A total of 929 patients answered the cost questionnaire: 486 from the screening study and 443 from the diagnostic study. Table 1 gives the demographic characteristics of the 4 subgroups. The diagnostic sample consisted of more white patients than did the screening sample, and more white patients were seen at M. D. Anderson than at LBJ. This was true both in the screening and in the diagnostic populations.

The patients in the screening study were older (mean age of 46.6 years for those from LBJ and 44.4 years for those from M. D. Anderson) compared to the diagnostic patients (mean age of 39.4 years for those from LBJ and 38.1 years for those from M. D. Anderson). Patients in the screening study had completed more years of education, with 81.3% having attended at least some college, compared to 70.0% of those in the diagnostic study. This may be accounted for by the fact that a portion of the screening patient population came from employees at the hospitals where the studies were conducted. In addition, the patients from M. D. Anderson, the comprehensive cancer center, had received slightly more years of education than the patients from LBJ, the community hospital.

The majority of patients traveled to their clinic appointments by car (Table 2), consistent with the primary means of transportation in Houston, Texas. Twice as many M. D. Anderson patients in the screening study walked to their appointments, as did patients in the diagnostic study; again, this may reflect the number of participants in the screening study who were employees of M. D. Anderson. For those who traveled by car, Figure 1 shows the distribution of distances traveled in miles, and Table 3 shows the median distance traveled and associated costs. These distributions are similar across both study setting and population.

We validated the information regarding the round-trip distance between the patient's point of origin and the clinic by using data on the Web site http://www.mapquest.com. This allowed us to determine the actual distance between the patient's point of origin and the clinic. We then computed the ratio of what the patient stated as her distance traveled divided by the actual distance between the address of the patient's point of origin and the clinic. Thus,

	Screening LBJ		Screening M. D. Anderson		Diagnosis LBJ		Diagnosis M. D. Anderson	
Method of Travel	n	%	n	%	n	%	n	%
Walk	0	0.0	41	11.0	0	0.0	21	6.5
Bus	3	2.7	7	1.9	4	3.3	6	1.9
Car	110	97.3	320	85.8	117	95.9	290	90.3
Plane	0	0.0	0	0.0	0	0.0	2	0.6
Other	0	0.0	5	1.3	1	0.8	2	0.6
Total	113	100.0	373	100.0	122	100.0	321	100.0

Table 2Method of Travel

 Table 3
 Distance Traveled by Car and Travel Costs

	Screening LBJ	Screening M. D. Anderson	Diagnosis LBJ	Diagnosis M. D. Anderson
Number of patients who				
traveled by car	110	320	117	290
Median distance traveled				
in miles (first and third	32.7	31.6	32.6	30.6
quartiles in parentheses)	(22.8, 46.6)	(16.8, 45.4)	(21.4, 44.8)	(15.6, 52.0)
Median travel costs at				
\$0.31 per mile (first and	\$10.14	\$9.80	\$10.11	\$9.49
third quartiles in parentheses)	(\$7.07, \$14.45)	(\$5.21, \$14.07)	(\$6.63, \$13.89)	(\$4.84, \$16.12)



Figure 1 Round-trip distance (in miles) traveled by car.

if the patient gave accurate information, this ratio should equal 2.0, which would signify that the patient provided the round-trip distance accurately. We identified a sample of 50 patients from the study. Of these 50 patients, 9 (18.0%) did not provide a street address, leaving 41 patients who did provide a location. Of these 41 patients, we determined that 31 (75.6%) patients had computed ratios between 1.8 and 2.2, thus showing that the data provided by the patients were reasonably accurate.

As most patients traveled by car, transportation was a significant component of costs other than direct health care. The distribution of the round-trip distance driven and parking costs was typical for a major metropolitan area that lacks a well-developed public transportation system. As discussed above, there were a few outliers, the inclusion of which would have greatly increased the standard deviation of the miles traveled and the costs associated with transportation, especially at the comprehensive cancer center.

Child care and elder care were not major cost considerations for the patients in this study. Only 5 of 113 (4.4%) LBJ screening patients and 42 of 373

METHODOLOGY



Figure 2 Hours away from work associated with the time spent seeking and receiving medical care.

(11.3%) M. D. Anderson screening patients identified the requirement of a caretaker while they attended the clinic. Similarly, only 12 of 122 (9.8%) LBJ diagnostic patients and 50 of 321 (15.6%) M. D. Anderson diagnostic patients required a caretaker. Because the percentage of patients who indicated they required a caretaker was relatively small, these costs would amount to a much smaller contribution of the total non-health care costs when taken across the entire sample of patients. In this survey, almost all of the caretakers were required for child care services. Only 2 patients in the diagnostic study required elder care services in their absence; no patients in the screening study had this requirement.

Figure 2 shows the distribution of hours away from work. The median hours away from work for patients at LBJ and M. D. Anderson were 2.75 and 3.50 hours, respectively, for screening procedures and 3.00 and 4.00 hours, respectively, for diagnostic procedures. Patients undergoing diagnostic tests were away from work longer than those undergoing screening; similarly, patients at the comprehensive cancer center (M. D. Anderson) were away from work longer than those attending the communitybased hospital (LBJ).

Overall, the mean total direct non-health care and time costs for the LBJ and M. D. Anderson screening patients were \$47 and \$64, respectively; the mean total direct non-health care and time costs for the LBJ and M. D. Anderson diagnostic patients averaged \$53 and \$122, respectively. As hypothesized, the LBJ patients (i.e., from the community hospital) had lower costs than did the M. D. Anderson patients (i.e., from the comprehensive cancer center), and the screening patients had lower costs than the diagnostic patients.

However, these data contain a few outliers, especially in the M. D. Anderson and diagnostic populations that skew the distribution and disproportionately affect the means. Therefore, we determined the mean total direct non-health care and time costs per patient without the outliers. We defined outliers to be any patient who traveled by plane, traveled more than 200 miles by car, had a bus fare of more than \$100, or had time away from work of more than 48 hours. There was only 1 outlier identified in the LBJ (community-based) clinic. Thus, the mean total direct non-health care and time costs for the LBJ screening group remained at \$47, and the LBJ diagnostic group decreased slightly to \$52. However, there were 5 outliers found in the M. D. Anderson screening sample and 25 outliers identified in the M. D. Anderson diagnostic sample. When the outliers were excluded, the mean total direct non-health care and time costs for the M. D. Anderson screening and diagnostic groups decreased to \$60 and \$80, respectively.

DISCUSSION

We propose that the cost of resources used other than those involved with direct health care can be determined in a controlled setting such as the one we studied. We identified subgroups for which we anticipate differences in such costs and a possible scenario where outliers may result in sizable variations in cost.

Costs other than direct health care costs are not usually incorporated in cost-effectiveness analyses, even when the authors state the intention of conducting the report from the societal perspective. Very often, direct non-health care costs and time costs are simply ignored. Sometimes, authors state that these costs are not incorporated because they would be too small compared to the direct costs of health care; however, this is not a legitimate reason for their exclusion. For incremental cost-effectiveness analysis, in particular, costs other than direct health care costs can make a difference.

In the case of cost-effectiveness analyses of screening strategies for cervical cancer, differences in life expectancy between strategies are typically in the order of magnitude of days (the second or third decimal place when using life years or quality-adjusted life years as the outcome measure), producing a very small difference in the denominator of the incremental cost-effectiveness ratio. Suppose that a patient bears the direct non-health care cost of \$50 to \$80 per visit for cervical cancer screening or diagnostic procedures (covering transportation costs, parking fees, and the equivalent of time lost from work) and that cost is repeated on several visits over a conventional 2-year follow-up period. This results in an important difference in the costs, which is the numerator in the incremental cost-effectiveness ratio. For example, a difference of \$500 for 0.01 quality-adjusted life years (QALYs) would lead to an incremental costeffectiveness ratio of \$50,000 per QALY.

Our study has important limitations. In particular, we recognize that our direct non-health care costs were collected under a highly regimented protocol within a research study. Thus, for example, the required time away from work for patients seeking similar services at a clinical practice site would usually be much lower. Ironically, it would be nearly impossible to create a study that would accurately measure the direct non-health care costs involved in usual care: any research procedure added to usual clinical practice would artificially inflate the time spent at the clinic and thus inflate the true direct non-health care costs of health care.

Another major limitation is that our study populations are representative of a restricted geographic region. Transportation costs in a metropolitan area with a limited mass transportation system may be very different from those in a metropolitan area that has an extensive mass transportation system. Suburban and rural community practice settings are likely to show similar differences. Thus, the collection and estimation of direct non-health care costs may be more or less difficult, depending on the geographic region of the population studied.

We did not directly ask the patients for their specific salaries to compute the costs associated with time missed from work. We decided that this question was too intrusive and did not wish to diminish participation in the study.

In Shireman and others,⁷ the researchers demonstrated the differences in time costs when they were calculated based on actual clinical experiences rather than using average clinic appointment lengths. They found that the time a patient spent at a clinic appointment plus the time spent traveling was nearly 20 minutes longer than what was previously assumed, which increased the direct costs per visit by 22% to 32%. Although our study was conducted in a clinical trial and the appointments were longer than usual (especially for the screening patients), we can still apply our data to clinical trials, elucidating the direct non-health care costs involved in conducting a large-scale clinical trial.

We have described a method for collecting direct non-health care and time cost data. Whether the process of data collection is worth the effort is unclear, given the likely inaccuracies that may occur, the number of assumptions needed, and the difficulties of making policy prescriptions based on it. However, such a data collection process may be worth the effort when non-health care costs are a significant portion of the overall costs or when the considered strategies in the cost-effectiveness analysis may be greatly affected by the inclusion of such costs. Ideally, a decision-analytic model should be developed and executed to perform a sensitivity analysis. If the amounts of the direct nonhealth care and time costs are sufficiently large enough to make a difference in the cost-effectiveness analysis under investigation, then such data should certainly be collected and included in the analysis.

APPENDIX Questionnaire of Cost Data

- How did you get to the clinic today? _____
 Walk: How long did it take you to get to the clinic? ______
 Bus: What was the fare? ______
 Car: What address did you drive from? (Street and nearest cross street, if not known) ______
 Where did you/they park? ______
- 2. If you are accompanied to your appointment by someone who missed work, what is the gender and age of this person? (If not accompanied, skip to 3)

Gender: M F Age: _____

3. Did you have to get a caretaker for today to attend to your children and/or an elderly person living in your household in order to come to your appointment?

YES NO

How much do you expect to pay the caretaker for today? (If no payment, skip to 4)

Children_____ Elderly person_

4. Did the person taking care of the children and/or elderly person in your household miss work in order to help you? What is the gender and age of this person?

YES NO Gender: M F Age: _____

5. How much time will you miss from your usual activities because of this appointment?

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