Entrepreneurial Ventures and Whole-Body Donations:
A Regional Perspective from the United States

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Abstract

Human cadavers are crucial to medical science. While the debate on how to secure sufficient cadavers has focused primarily on donors' behaviors, procuring organizations' roles in increasing donations remains less explored. The United States offers an interesting setting to examine this question since entrepreneurial ventures supplying cadavers for medical science have recently emerged alongside traditional academic-housed programs, raising both hopes and fears about their impact on whole-body donations.

To assess their potential impact, an archival survey of voluntary, in-state whole-body donors to two programs procuring in the same U.S. state was conducted. The programs' specimen recipients were also analyzed. One program is academic-housed; the other is an entrepreneurial venture. Both offered equal levels of financial support to donating parties. Eighty donations and 120 specimen shipping invoices from 2005 were analyzed in each program.

Donations to the two programs did not significantly differ in terms of donors' gender, marital status, maximum educational level, and estimated hourly wage. The entrepreneurial venture's donors were, however, significantly younger, more likely to be from a minority group, and more likely to have died from cancer. For-profit organizations, continuing medical training organizations, and medical device companies were more likely recipients of the entrepreneurial venture's specimens. Non-profit and academic organizations were more likely recipients of the academic-housed program's specimens.

These findings suggest that although the programs procured from a somewhat similar pool of donors, they also complemented one another. The entrepreneurial program procured donations that the academic-housed program did not attract. Specimen recipients' distinct demands partly explain these procurement behaviors. Thus, organizational efforts to meet demands seem to shape the supply. Examining organizations, alongside donors, might perhaps provide new answers to increase donations.

Introduction

Human cadavers are crucial to numerous health care areas, such as the initial and continuing training of medical doctors or other health professionals and, more broadly, medical research. All of these areas depend upon an adequate supply of cadavers to operate (Boulware, Ratner, Cooper, LaVeist, & Powe, 2004). Because procurement in the United States primarily relies on a system of voluntary donation, maintaining an adequate supply of cadavers has often been a concern (Baumel, 1968; Dasgupta, 2004). Similar concerns have also been voiced in other countries, such as in Canada, the United Kingdom, and Thailand (Agthong & Wiwanitkit, 2002; Assemblée Nationale du Québec, 2004; U.K. Department of Health, 2005).

There are many possible answers to this concern: many of which traditionally focus on donors' behaviors. As an illustration, the impact of using financial incentives for donors or their families to encourage anatomical donations is regularly debated (Delmonico, Arnold, Scheper-Hugues, Siminoff, Kahn, & Youngner, 2002; Harrington & Sayre, 2006; Obermann, 1998). Similarly, surveys of potential whole-body donors seek insight into the reluctance to donate and how to better educate potential donors (Boulware et al., 2004; Richardson & Hurwitz, 1995; Sanner, 1994).

Instead of focusing on donors, some answers might, however, lie with the procuring organizations' roles in securing donations. Specifically, the efforts that procuring organizations deploy to meet their specimen recipients' demands might impact donations. Moreover, recent research on organ donation shows that organizational attributes, not only donors' demographics, explain variations in donation rates across geographies (Healy, 2004). One answer might, therefore, reside in encouraging organizations serving distinct demands to act as match-makers between donors and health care areas.

The 1987 Uniform Anatomical Gift Act, governing anatomical donations in the United States, makes it a felony to "knowingly, for valuable consideration, purchase or sell a [body] part for transplantation or therapy, if removal of the part is intended to occur after the death of the descendent," but excludes from this consideration "the reasonable payment [by the health care areas] for the removal, processing, disposal, preservation, quality control, storage, transportation, or implantation of a part;" thus allowing operators to procure and supply body parts for these purposes (National Conference of Commissioners on Uniform State Laws, 1987). Besides, the purchase or sale of whole bodies (as opposed to parts) and body parts for purposes other than transplantation or therapy (such as education) are absent from this provision.

In this context, legal for-profit and non-profit entrepreneurial ventures, alongside the traditional academic-housed programs, have started supplying U. S. medical schools, medical training centers, and medical device companies with human cadavers and remains. The United States is, to our knowledge, the only country with such legal entrepreneurial ventures. Though welcomed by those dependant on this supply, these ventures also conjure fears around the creation of a market for cadavers and the potential for predatory behavior (for assumptions on markets, see Fourcade & Healy, 2007 and Zelizer, 2005). Historical images of body-snatchers and recent accounts of illegal commerce of human remains fuel these fears (Cheney, 2006; Goodwin, 2006; Sappol, 2002). Documented predatory practices around organ procurement add to these fears (Fox & Swazey, 1992).

In order to examine the potential role of entrepreneurial ventures on the supply for cadavers, this study compares donor and specimen recipient profiles from one such venture to those from a more established academic–housed program. Both programs operate in the

same U.S. state. To further understand their positions, donor profiles are also compared to age and geographically relevant segments of the broader U.S. population.

Methods

The archived profiles of donors and specimen recipients in two whole-body donation programs (labeled A and B) were accessed. Program A is the State Anatomy Board, housed at the University of Maryland — the dominant historical operator in Maryland, where only one other, much smaller, academic-housed program exists. The official goal of program A is to supply cadaveric needs of in-state medical institutions. By contrast, program B is a newer (active since 2002), independent entrepreneurial venture, called Anatomy Gifts Registry. Incorporated as a non-profit, it supplies in- and out-of-state health care areas.

Both programs offered comparable levels of material help and financial support to ease the donation process: covering all in-state transportation costs and cremation costs (after the cadaver's use), and returning ashes to a designated party, when requested. (The only minor financial disparity between programs was a $15 shipping fee, charged by program B for returning ashes.) The process of voluntary donation at these programs was slightly different. While both programs sought mutual consent from donors and their family members (though mutual consent is not legally required), almost all donors in program A (91% of our sample) had registered before death, based on their own volition. Program A relied mainly on word-of-mouth to secure donations and did not advertise beyond an Internet presence. In program B, though donors were also encouraged to pre-register (49% of our sample did), legally authorized agents (such as spouses or children) were often the ones approving the donations upon death. Program B's staff visited hospital chaplains and retirement homes to advertise services. Moreover, whereas program A only

procured cadavers in-state, program B also procured cadavers out-of-state. For the purpose of this analysis, out-of-state donors were excluded. Similarly, the analysis only included voluntary donations to both programs — meaning those received with the donor's or a legally authorized agent's consent. Unclaimed cadavers that program A received were excluded. Thus, the comparison was between donors from a potentially similar pool: voluntary in-state whole-body donations.

Eighty in-state voluntary donations from the year 2005 were analyzed at each program. This sampling includes all voluntary in-state donations for program B or 18% of their total (in- and out-of-state) donations that year (444), and a random sample corresponding to 17% of the total voluntary in-state donations for program A (462). Data were gathered from donors' death certificates and tracking sheets. Data regarding use of specimens were obtained by a random sampling of 120 shipping invoices from 2005, collected at each program. Each invoice corresponded to a shipment of one or more specimens. (Specimens included whole cadavers and parts.) This sample represents 25% of program A's invoices from 2005 (474) and 20% of program B's invoices from 2005 (600). Access to all data was obtained by permission of program directors and the confidentiality of donors' and recipients' data was ensured.

To further understand what types of donations these programs received, donor profiles were compared to age and/or geographically relevant segments of the U.S. population. Since most donations came from individuals above 65 years old, and given that both programs were located in Maryland, a comparative sample of the elderly population (65 and above) living in the U.S. Middle-Atlantic region was used for gender, race, marital status, and educational attainment comparisons (U.S. Census Bureau, 2006). When

examining causes of death, the programs were separately compared to segments of the U.S. population dying at a similar age to each program's donors' mean age at death. Also, the estimated mean hourly wage of donors, as a proxy for their economic standing, was compared to the mean found in the U.S. population living in the Middle-Atlantic region.

To further comprehend the specimen recipients that each program supplied, the party appearing on the shipping invoice as reimbursing the procurement costs was, first, coded according to its legal status — either for-profit, non-profit, or government — and was also coded according to the main organizational goals it pursued — "academic," "training," or "medical device development." Recipients coded as academic focused on research and initial medical education; recipients classified as training focused primarily on continuing medical education; and recipients coded as medical device development focused essentially on the development and sales of medical devices, such as surgical instruments or implants. Key informants from each program with strong knowledge of the recipients reviewed the coding to ensure that recipients were assigned to the proper categories.

Differences were assessed using 2-tailed t-tests of differences in means and chi-square tests of differences in proportion. All tests were conducted at the 5% significance level. For mean values, 95% confidence intervals were calculated.

Results

Demographics of donors

The programs did not significantly differ in terms of donors' gender (d.f. =1, p=.64): program A recruited 54% females donors and program B 50%. The gender divide for all surveyed donors yielded 83 females (51.9%) and 77 males (48.1%). This combined gender divide was not significantly different from that of the elderly population residing in the

Middle-Atlantic region (58.7% female and 41.3 % male; d.f.=1, p=.08). The average age at death of program A's donors (76 years old) was significantly higher than program B's donors (65 years old) (t=-4.87, d.f.=158, p<.001). The average age at death of all donors (70 years and 10 months) was significantly lower, by 7 years, than that of the general U.S. population (t=-5.89, d.f.=159, p<.001) (Miniño, Heron, & Smith, 2006).

Donors' marital status did not vary significantly between programs A and B (d.f.=3, p=.10). When pooled together, 43.4% of all surveyed donors were married, 27.7% were widowed, 21.4% divorced, and 7.5% never married. The distribution differed, however, significantly from the elderly U.S. population (d.f.=3, p<.001): donors were significantly less likely, at the time of death, to be widowed (27.7% vs. 32.5%) or married (43.4% vs. 52%), and were more likely to have been never married (7.5% vs. 6.2%) or divorced (21.4% vs. 9.3%). Though the overall racial composition of all 160 donors was predominantly white (93.1%), program B attracted more non-white donors (11.2% vs. 2.5%) than program A (d.f.=1, p=.03). Non-white donors were defined as all donors who were not categorized as "white" on their death certificate. Compared to the elderly population living in the same geography, the racial profile of combined donors showed a significant under-representation of non-white donors (d.f.=1, p=.002).

Educational and occupational backgrounds of donors

The maximum level of educational attainment between donors in the two programs was not significantly different (Table 1). In order to compare donors to the broader relevant U.S. population, several educational attainment categories listed on the death certificates were combined to match the categories used in the U.S. census. The combined donors from both programs were significantly more highly educated than the corresponding segment of the

U.S. population, with 43.5% of combined donors having completed grade 13 or higher, versus 33.1% in the elderly population living in that region.

Death certificates provide little data about a donor's economic standing, but they do capture the donor's main occupation prior to retirement. To approximate the economic standing of donors, each donor's occupation was matched with the estimated mean hourly wage for that given occupation in the Middle-Atlantic region (U.S. Department of Labor, 2006). (Our approximation captures only part of donors' economic standing. Household data, for instance, was unavailable.) Donors for whom it was not immediately obvious to which category their listed occupation corresponded (17% of cases) were independently coded by the two authors. The coding of these cases yielded a 75% inter-rater reliability, and the remaining cases' categories were agreed upon through discussion. The programs did not significantly differ in terms of estimated mean hourly wage of their donors (Table 1). The mean hourly wage of the combined sample was, however, significantly higher than that which prevailed in the Middle-Atlantic region.

Causes of death and bequest interval

Donors in program B were significantly more likely to have died from cancer than donors in program A (71% vs. 21%) (Table 2). More generally, variations in causes of death were significant between programs A and B. Whereas a significant proportion of donors in program A were identified as having died from "heart disease, stroke, or other cerebrovascular disorders" (25%), "chronic respiratory disease, influenza, and pneumonia" (15%), and "Alzheimer's" (13%), program B received significantly fewer donors in these categories (respectively 10%, 8%, and 5%). The distribution of causes of death among donors from program A did not differ significantly from those who died at a similar age in

the U.S. population (Centers for Disease Control and Prevention, 2003). However, the distribution of causes of death in donors from program B differed significantly from those who died at a similar age in the U.S. population. Although cancer is the leading cause of death among individuals dying at the age of 65, in the United States, more donors in program B than expected died of cancer (71% vs. 36.7%). Also, far fewer donors from program B died of "heart disease, stroke, or other cerebrovascular disorders" than did individuals in the broader U.S. population corresponding in age at death (10% vs. 29.4%).

The bequest intervals, or the amount of time that separates the moment a donor registers and the actual donation time, differed significantly between the programs. Program A's average bequest interval was 131 months, whereas program B's amounted to only 2 months ($t=-7.527$, $d.f.=157$, $p<.001$).

Profiles of recipients

The profiles of recipients of each program's specimens differed significantly, both with respect to their legal statuses and main organizational goals ($d.f.=2$, $p<.001$ both for status and goals). The proportion of recipients with a non-profit legal status was higher in program A than B (78% vs. 52.5%). In contrast, organizations with a for-profit legal status represented 40% of recipients in program B versus only 7% in program A. Although recipients with academic goals (regardless of legal status) were the most prevalent at both programs, they were more highly represented in program A than in B (74% vs. 47.5%). Recipients with continuing medical education goals were significantly more highly represented in program B (31.7% vs. 26%). Finally, whereas program B catered to recipients developing medical devices (20.2% of recipients), program A did not.

Discussion

There is no solution that will, alone, ensure an adequate supply of human cadavers for medical science. The introduction of entrepreneurial ventures, alongside academic-housed, oftentimes more established, programs might, however, impact donations. By examining how distinct organizations might pursue and attract different donors, this study identifies one possible approach.

This study is also a first attempt to empirically address the hopes and fears raised by the emergence of entrepreneurial ventures. Currently, there are approximately 150 academic-housed whole-body donation programs (University of Florida State Anatomical Board, 2004) and ten known, for- and non-profit, entrepreneurial ventures in the United States. The variation in organizational form (entrepreneurial versus academic) might not be the only driver of the observed procurement strategies and outcomes, but is assumed, in this study, to partly inform them. Because the study focused on two programs in one state, results may reflect state and program specificities. Other in-state and out-of-state entrepreneurial programs might also be procuring from this state. Although the design of the study does not account for all whole-body donations in the region, its focus on the two primary operators in the state ensures that the study accounts for most in-state donations.

This study found that the profiles of voluntary donations to an academic-housed program (A) and an entrepreneurial venture (B) procuring in the same U.S. state and offering similar level of financial support, did not significantly differ in terms of donors' gender, marital status, maximum educational level, and estimated hourly wages. Whereas it is sometimes assumed that entrepreneurial ventures are more likely to engage in predatory behavior to procure donations, the entrepreneurial venture did not attract less educated or less affluent donors. It did, however, attract donors more likely to have died from cancer

and their families: individuals potentially emotionally distressed at the time of the donation, given the relatively short bequest interval (2 months). This calls attention to the need to ensure that all donating parties are treated with due respect.

In addition, the entrepreneurial program catered to some recipients — for-profit organizations, continuing medical training, and medical device companies — that this, and many other academic-housed programs, traditionally did not fully cater to. (In the case of medical device companies, did not cater to at all.) Concurrently, while academic-housed programs are typically hesitant to use cadavers with certain diseases (such as cancer) for anatomical study, the entrepreneurial venture more readily accepted them, directing them toward other use. For example, medical device companies and continuing medical education organizations, often requiring only certain parts of the cadaver, might use specimens subject to refusal by other recipients. Thus, the two programs partly complemented one another.

While the data in our study cannot fully explain the impact of entrepreneurial ventures on whole-body donations, several explanations can be attempted. First, on the supply side, the entrepreneurial venture sourced in a somewhat similar pool to the one found in the academic-housed program (similar gender representation, marital status, educational attainment, and estimated hourly wages). But the entrepreneurial venture also attracted donors who were significantly younger, more likely to have died of cancer, and minorities. As such, entrepreneurial ventures might increase the supply of cadavers.

The academic-housed program's reluctance to let legally authorized agents donate in the absence of a donor's pre-registration probably made it easier for the entrepreneurial venture to secure some donations. But the entrepreneurial venture also increased the supply

by accepting some donations less appealing to the academic-housed program. Variations in donors' profiles suggest contrasted procurement strategies: one targeting seemingly healthy individuals (academic-housed) and the other focusing primarily on diseased individuals and their families (entrepreneurial). Though the novelty of the entrepreneurial program cannot be discounted as an explanation for its shorter bequest interval, the shorter bequest interval might also reflect these contrasted strategies.

Second, the different ways that the programs went about procuring cadavers appear linked to the types of recipients each program catered to. It is likely that recipients' demands informed the organization's efforts to secure donations. For instance, given that specimen recipients in the entrepreneurial venture used cancerous cadavers, it made sense for the entrepreneurial venture to reach out to those donors and their families. The academic-housed program also accepted them, but was not as eager to pursue them. By catering to different demands, the two programs deployed distinct efforts to match donations and recipients.

Lastly, issues of trust might also help explain our results. Distrust of established medical institutions has been shown to partly explain reluctance among minorities, particularly African-Americans, to donate their bodies (Boulware et al., 2004). It is possible that although entrepreneurial programs battle certain stigmas, such as popular associations with images of "body-snatchers," they may escape others, such as those which some minorities attach to more established medical institutions.

A greater availability of cadavers for medical science could accelerate the rate of discovery, and improve the quality of medical training and procedures. Whereas much of the debate on increasing the supply of cadavers, and more broadly of anatomical donations,

has focused on the supply side of the equation — or how to convince potential donors to donate, this study identifies another potential approach. Organizations might deploy their efforts differently to meet the unique demands of their specimen recipients. When large demands go unmet — in this instance, mainly demands from for-profit organizations, continuing medical education organizations, and medical device companies, opportunities for the deployment of organizational efforts to meet these demands abound. Entrepreneurial ventures seem to be answering this call.

The question of whether academic-housed programs might also serve this demand is probably, however, as important as the question of the entrepreneurial ventures' legitimacy. Choosing not to meet a demand opens up the door for others willing to do so. Irrespective of whether a legal market for cadavers might be considered a reason for sorrow or joy, market dynamics around whole-body donations de-facto operate in the United States. Understanding how and why these dynamics develop, and which organizations shape and react to what demand, might prove crucial to understanding how to potentially increase the supply of cadavers for medical science.

Table 1: Donors' maximum educational attainment and estimated hourly wage

	Program A (n = 80)	**Program B (n = 80)**	**P value (A and B)**	**Programs A and B combined (n = 160)**	**Elderly Middle-Atlantic population†**	**P value**
Maximum level of education	(n = 75)	(n = 79)	0.17	(n = 154)		<.001***
Completed grades 0-8	8%	6%		7.1%	12.3%	
Completed grades 9-11	7%	19%				
Completed grade 12	36%	37%				
Completed grades 9-12				*49.4%*‡	*54.6%*§	
Completed grades 13-15	11%	10%				
Completed grade 16	17%	18%				
Spent additional years studying for a graduate or professional degree	21%	10%				
Completed some years of college or greater				*43.5%*‖	*33.1%*¶	
					Middle-Atlantic Population#	**P value**
Estimated mean hourly wages ($ per hour)	(n = 65) 25 (12)‡‡	(n = 73) 23 (12)‡‡	0.28	(n = 138) †† 23.9 (1.05)§§	21.2 (0.3)§§	0.01*

* $p<.05$; ** $p<.01$; *** $p<.001$

† Data from U.S. Census Bureau. *2005 American Community Survey*.

‡ Death certificate categories of "completed grades 9-11" and "completed grade 12"

§ Census educational attainment categories of "9th to12th grade, no diploma" and "high school graduate (includes equivalency)."

‖ Death certificate categories of "completed grades 13-15," "completed grade 16," and "spent additional years studying."

¶ Census educational attainment categories of "some college, no degree," "associate's degree," "bachelor's degree," and "graduate or professional degree."

Data from U.S. Department of Labor, *National Compensation Survey: July 2005*.

†† Twenty two donors were dropped from the analysis because their occupations (such as "homemaker" or "unknown") could not be used to estimate their hourly wages.

‡‡ Values are expressed as mean (SD).

§§ Values are expressed as mean (SE).

Table 2: Donors' causes of death

	Program A (n = 80)	Program B (n = 80)	P value (A and B)	US population dying at 76 years old (similar to program A donors' average age at death)†	US population dying at 65 years old (similar to program B donors' average age at death)†	P value (program A compared to U.S. population dying at 76)	P value (program B compared to U.S. population dying at 65)
Cause of death			<.001***			0.30	<.001***
Heart disease, stroke, and cerebrovascular disease	25%	10%		23.2%	29.4%		
Cancer	21%	71%		28.9%	36.7%		
Chronic lower respiratory disease, influenza, and pneumonia	15%	8%		10.1%	7.6%		
Alzheimer's	13%	5%		‡			
All other causes of death	26%	6%		37.8%	26.3%		

* $p<.05$; ** $p<.01$; *** $p<.001$

† Data from Centers for Disease Control and Prevention. *Ten Leading Causes of Deaths, United States 2003.*

‡ Alzheimer's as a category was folded into the "other" category when comparing with the U.S. population dying at a similar age since the expected count for this category was less than 5.

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