Society of Black Academic Surgeons

The Organ Donation Breakthrough Collaborative: has it made a difference?

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Abstract

BACKGROUND: The Organ Donation Breakthrough Collaborative (ODBC) was established in 2003 to increase the number of transplantable organs in the United States. However, recent publications have suggested that the ODBC has not impacted donation conversion rates at local organ procurement organizations (OPOs). We sought to determine the impact, if any, of our becoming part of the ODBC on organ donation rates in our OPO or in our institution (Carolinas Medical Center [CMC]), particularly among minority donors.

METHODS: This is a retrospective review of data entered concurrently into a patient referral database maintained by our local OPO. Donation approach and consent rates were calculated. They were then analyzed by race and institution, and trends were analyzed over the study period of 2002 to 2010. Statistical differences between the various patient groups were determined by the chi-square test or the Fisher exact test. Statistical differences over time were determined by the Cochran-Armitage trend test.

RESULTS: From 2002 to 2010, 10,855 patients were screened by our OPO for potential organ donation. The overall approach rate was 13.4%, and the consent rate was 57.6%. An increase in approach and consent rates was noted beginning in 2004, but this increase was not sustained. Consent rates in general were higher for white patients than for black and Hispanic patients. Consent rates for CMC did increase significantly (*P* = .02), but they did not increase for the non-CMC hospitals. When analyzed by race, no significant changes were noted in consent rates over time. When analyzed by race and institution, the only statistically significant increase in consent rates occurred for white patients at CMC.

CONCLUSIONS: Since joining the ODBC, we have noted an increase in consent rates at a single institution (CMC), but no other significant changes. Greater emphasis should be placed on methods to increase and sustain consent rates for all racial groups in general, with a special emphasis on increasing consent rates in minority patients.

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The currently existing supply of transplantable organs in the United States is woefully inadequate to meet the needs of patients awaiting organ transplantation. Currently, in the United States there are 110,586 patients on the transplant waiting list, and each day 18 patients on that list die awaiting an organ that never arrives. Several large-scale national initiatives have been developed to address this pressing need, with limited success. The Organ Donation Breakthrough Collaborative (ODBC) is one such initiative, funded by the Division of Transplantation in the Health Resources and Services Administration of the US Department of Health and Human Services and developed in...
collaboration with the Institute for Healthcare Improvement. It was launched in September 2003 with the expressed intent of increasing the number of organs available for transplantation in the United States. Our local Organ Procurement Organization (OPO), LifeShare, and our own institution, Carolinas Medical Center (CMC), joined the ODBC in 2004. As a result, significant resources, both financial and human, were invested with the hope of improving donation rates and organs transplanted within our region. Specific changes within our OPO and our hospital that were brought about through participation in the ODBC include the following:

- The establishment of clinical triggers, which are simple physiologic and anatomic criteria that allow easier and more timely identification of potential organ donors
- Dedicated support coordinators ("24/7") for families of potential organ donors
- Dedicated critical care support (personnel, protocols) for potential organ donors and those who have consented to be organ donors
- Institution of a "death by neurologic criteria" guideline designed to achieve a more timely and more standardized declaration of brain death
- Institution of extensive educational programs for physicians, nurses, and other hospital personnel
- New policies and protocols for donation after cardiac death
- Establishment of several oversight committees to monitor compliance with, and success of, instituted changes

The increased focus on organ donation improvement has indeed improved conversion rates (number of organ donors per number of patients eligible to become organ donors) and organs transplanted per donor within our institution, as well as within our OPO, and several other institutions and OPOs have documented similar increases in donation activity coincident with their participation in the ODBC. However, some recent publications have suggested that the ODBC has not impacted donation conversion rates at their local OPOs. We therefore became interested in determining the overall impact of our participation in the ODBC as well as what specific phase or phases of the consent process (identification of potential donors, screening of potential donors, approaching families of potential donors, and obtaining actual consent for donation) had been impacted, particularly among minority donors. Therefore, this study examines donation consent rates for our OPO by institution and by race between 2002 and 2010. Our hypothesis was that consent rates for minority patients had increased in our own institution, as well as within the entire OPO, as a result of participating in the ODBC.

Methods

LifeShare of the Carolinas is a not-for-profit OPO designated by the federal government to serve 40 hospitals in a 22-county area of southwestern North Carolina. All potential organ donors referred to LifeShare are entered concurrently into Transplant Connect, a prospective database that captures basic demographic information as well as the outcome of the donor assessment process and the donation outcome. Our study is a retrospective review of Transplant Connect data for the years 2002 through 2010. In addition to basic demographic information, we also recorded whether the patient’s family was approached for consent to organ donation and whether consent was obtained. Approach rates and consent rates were then calculated for each year of the study (2002 to 2010) for the entire OPO, CMC, and all other institutions in our OPO in aggregate (non-CMC hospitals). The following definitions were used to analyze our data:

- Approach rate: number of patients approached for donation per number of patients screened for donation
- Consent rate: number of patients who consented for donation per number of patients approached for donation

The rationale for performing a separate analysis of outcomes at CMC stems from the fact that this institution is the largest hospital served by the OPO, it is the only transplant center in the region, and it is located in the most ethnically and racially diverse city within the OPO service area. CMC is the flagship facility of the Carolinas Healthcare System with an 874-bed hospital in Charlotte that includes a level I trauma center and numerous specialty services, including organ transplantation. Thus, we felt that any increases in organ donation rates, particularly among minority patients, would more likely occur at this institution and might be obscured by less substantial increases (or even decreases) experienced by non-CMC hospitals. Finally, approach rates and consent rates were analyzed by race (white, black, and Hispanic) for the entire OPO, for CMC only, and for the non-CMC institutions during each year of the study.

![Figure 1](image-url)
Statistical analysis

Statistical differences in approach and consent rates between the various patient groups were determined by the chi-square test or the Fisher exact test (for predicted values of \( \leq 5 \)), with significance established at the \( P \) less than .05 level. Statistical differences in approach and consent rates over time were determined by the Cochran-Armitage trend test, with significance established at the \( P \) less than .05 level. All statistical analyses were performed with SAS, version 9.2 (SAS Institute, Cary, NC).

Results

Between January 1, 2002 and December 31, 2010, 10,855 patients were entered into the LifeShare Transplant Connect database as potential organ donors. CMC accounted for 43% of the patients referred to LifeShare, the largest number of patients of any single institution in the OPO’s service area. Overall, 1,450 patients, or 13.4% of the patients referred for donation, actually fulfilled appropriateness criteria for organ donation, and their families were approached for consent to organ donation. Consent for donation was obtained for 836 patients, for an overall consent rate of 57.6% (Fig. 1).

Data for the total numbers of patients who were referred or approached for donation and those who were consented for donation are shown in Table 1. There was a marked increase in the number of patients referred to LifeShare beginning in 2004, our first year of participation in the ODBC.

We also noted an increase in the number of patients who were approached and who consented beginning in 2004, but this increase was not sustained. Because of the large increase in the number of patients referred, with no accompanying increase in the number of patients approached, the approach rate decreased steadily from 25.9% in 2002 to 15.2% in 2010. Approach rates were consistently higher at CMC than at non-CMC hospitals, statistically significantly so in 6 of the 9 years of the study (Fig. 2).

Consent rates for the entire OPO (CMC and non-CMC hospitals) are shown in Table 2 and Fig. 3. No differences were noted between consent rates for CMC and for non-CMC hospitals. Consent rates for LifeShare overall appeared to increase over time beginning in 2006, but this increase was not sustained and did not reach statistical significance (\( P = .30 \)) (Fig. 3). However, as opposed to overall OPO consent rates, consent rates for CMC alone did demonstrate a statistically significant increase between 2002 and 2010 (\( P = .02 \)). No statistically significant changes or trends in consent rates occurred for the non-CMC hospitals over time (\( P = .61 \)).

Racial demographic information was available for 10,439 of the 10,885 patients identified for this study. The remaining 446 patients were excluded from the analysis of the impact of race on the consent process. The racial composition of the 3 patient populations (referred approached, and consented) is shown in Fig. 4. No significant differences were noted in the composition of the 3 groups. White, black, and Hispanic patients were approached for and consented to organ donation in the same proportions they represented in the referral population.

Table 3 shows consent rates analyzed by race, irrespective of institution. In general, OPO-wide consent rates were higher for white patients than for black or Hispanic patients, and they showed little institutional variation except for 3 years when the consent rates for white patients at CMC exceeded those rates at the non-CMC institutions (2007, 2009, and 2010) and 1 year (2004) when the consent rates for Hispanic patients at CMC exceeded those rates at the non-CMC institutions (Table 4).

OPO-wide consent rates for white patients appeared to increase between 2006 and 2009, but this trend was not statistically significant (\( P = .28 \)) (Fig. 5). Consent rates for black patients exhibited no discernable pattern over time, whereas the number of Hispanic patients referred for

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**Table 1** Number of patients OPO-wide analyzed for trends for each year of the study

<table>
<thead>
<tr>
<th>Year</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. patients referred</td>
<td>437</td>
<td>454</td>
<td>885</td>
<td>1,294</td>
<td>1,472</td>
<td>1,003</td>
<td>1,414</td>
<td>1,768</td>
<td>2,128</td>
</tr>
<tr>
<td>No. patients approached</td>
<td>113</td>
<td>121</td>
<td>143</td>
<td>187</td>
<td>206</td>
<td>107</td>
<td>139</td>
<td>111</td>
<td>323</td>
</tr>
<tr>
<td>No. patients consented</td>
<td>60</td>
<td>63</td>
<td>76</td>
<td>109</td>
<td>118</td>
<td>77</td>
<td>85</td>
<td>81</td>
<td>167</td>
</tr>
</tbody>
</table>

OPO = Organ Procurement Organization.

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**Figure 2** Approach rates by CMC and non-CMC institutions and OPO-wide.
donation was too small to detect any trends. However, when analyzed by race and institution, consent rates for white patients at CMC did increase significantly from 2002 to 2010 ($P < .001$) (Table 4). No other statistically significant changes in consent rates were noted for any other racial group at either CMC or non-CMC institutions.

**Comments**

Currently, there are more than 111,000 patients in the United States on the waiting list for organ transplantation, and every 16 minutes a new patient is added to that list. In the past 10 years, the waiting list has grown from 18,000 to more than 100,000, whereas the number of organs transplanted annually has only increased from 13,000 to 28,000. Approximately 18 patients per day die awaiting an organ. Although minorities compose nearly 55% of the patient population in need of organ transplants, minority donation accounts for only 27% of the donor population. Because organ matching is more likely to occur between individuals who are racially (and hence immunologically) similar, minority patients awaiting transplantation are, to a great extent, dependent upon minority donors. Therefore, as a result of the relatively low numbers of minority donors, only 34% of transplant recipients are minorities. The statistics are overwhelming and demonstrate a pressing need to increase consent rates and to maximize every opportunity for organ donation, particularly within the minority community.

HRSA, through the Division of Transplantation of the U.S. Department of Health and Human Services, has undertaken several initiatives to improve organ donation rates in the United States. Examples of these programs include the National Donor Sabbath (http://www.organdonor.gov), which focuses on raising public awareness of organ donation through a faith-based approach, and the Gift of Life Initiative, which seeks to promote donation by partnering with more than 10,000 employers, unions, and other employer organizations across the country. Part of HRSA’s Gift of Life initiative was the ODBC, which was launched in 2003 with the goal of achieving donor conversion rates of 75% or higher across the country. Since its inception, the ODBC has reported that more than 180 hospitals have met or exceeded this 75% goal. A second collaborative study that is currently under way is focusing on increasing the number of organs donated per donor.

In joining the collaborative, we had hoped to see a significant increase in consent rates and consequently an increase in the overall number of transplantable organs. However, our initial hypothesis that minority consent rates would increase after participating in the ODBC was not proved. Consent rates at our own institution (CMC), however, did increase over the course of the study, driven by an increase in the rate for white patients without a concomitant increase in rates for minority donors. Whether this overall increase results from participation in the ODBC is not clear, but other institutions have noted similar increases after

<table>
<thead>
<tr>
<th>Year</th>
<th>OPO</th>
<th>CMC</th>
<th>Non-CMC</th>
<th>Black</th>
<th>Hispanic</th>
<th>White</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>53.10</td>
<td>52.27</td>
<td>53.62</td>
<td>42.86</td>
<td>0.00</td>
<td>60.27</td>
</tr>
<tr>
<td>2003</td>
<td>52.07</td>
<td>44.44</td>
<td>60.34</td>
<td>23.81</td>
<td>36.36</td>
<td>61.45</td>
</tr>
<tr>
<td>2004</td>
<td>53.15</td>
<td>51.35</td>
<td>55.07</td>
<td>41.38</td>
<td>75.00</td>
<td>56.66</td>
</tr>
<tr>
<td>2005</td>
<td>58.29</td>
<td>59.41</td>
<td>56.98</td>
<td>42.86</td>
<td>42.86</td>
<td>61.24</td>
</tr>
<tr>
<td>2006</td>
<td>57.28</td>
<td>58.88</td>
<td>55.56</td>
<td>38.78</td>
<td>54.55</td>
<td>65.25</td>
</tr>
<tr>
<td>2007</td>
<td>71.96</td>
<td>77.61</td>
<td>62.50</td>
<td>56.52</td>
<td>60.00</td>
<td>76.32</td>
</tr>
<tr>
<td>2008</td>
<td>61.15</td>
<td>61.90</td>
<td>60.00</td>
<td>36.36</td>
<td>50.00</td>
<td>71.43</td>
</tr>
<tr>
<td>2009</td>
<td>72.97</td>
<td>78.08</td>
<td>63.16</td>
<td>60.00</td>
<td>75.00</td>
<td>80.30</td>
</tr>
<tr>
<td>2010</td>
<td>51.70</td>
<td>55.15</td>
<td>48.10</td>
<td>42.17</td>
<td>20.00</td>
<td>58.22</td>
</tr>
</tbody>
</table>

**Table 2** Consent rates (%) analyzed for trend by institution and race for each year of the study.

CMC = Carolinas Medical Center; OPO = Organ Procurement Organization.
participation in this endeavor.\textsuperscript{7,9,10} Even if we assume that it was our participation in the ODBC that led to the increase in consent rates among white patients, it is still difficult to determine which of the 7 enhancements that we made to our organ donation program was responsible for this improvement. Certainly it is conceivable that the enhanced family support created an environment in which the family of the donor received greater support than in past years, thus facilitating the donation process and making it easier for the family to consent. It is also unclear why the increase in consent rates noted at our institution was not also seen OPO-wide, but perhaps this is a reflection of greater resource expenditure at CMC relative to the other institutions in our OPO.

It is important to note, however, that although our overall consent rate did not increase, the overall number of patients who were consented for donation did increase in the final year of our study. Hopefully, this trend of increased organ donation activity will continue.

Although our study reports consent rates, and not conversion rates, our results mirror those reported by Salim et al.\textsuperscript{4} in that participation in the ODBC did not have a significant impact on conversion rates when analyzed by race. The lack of improvement in consent rates for minority patients is troubling, particularly in light of the significant investments and improvements that we made in our organ donation procedures. It is well known that consent rates among minority groups are considerably lower than in the nonminority population, but we had hoped to note some improvement over time as a result of our system enhancements. The causes of these lower participation rates for minority patients are multifactorial and have been well studied. Bratton et al.\textsuperscript{5} found that this disparity between whites and blacks in particular is influenced by a lack of understanding about the transplant process and overall fear or distrust, or both, of the medical community. The need for public awareness and community outreach by The local OPO and transplant centers nationwide is apparent. Callender's report\textsuperscript{8} on the Organ Tissue Transplant Education Program, which details their success in doubling minority donation rates through community outreach programs and mass media, demonstrates the potential impact of efforts to improve community awareness.

Similar misconceptions and fears were noted by Salim et al.\textsuperscript{4} in a study of Hispanic Americans in southern California. From those surveyed, an overall misunderstanding about the organ donation process and allocation of organs was identified. It was discovered that within this community, Hispanics believed that organ donation disfigured the deceased and that organs were allocated only to wealthy patients. Similar outcomes were found in a study conducted by Brown et al.\textsuperscript{6} in 2010. Race, brain death, and delay in approach were independently associated with failure to consent for organ donation by family members. This reinforces the need for early contact by OPO support staff, community outreach, and further public awareness.

Our conclusions from this study are somewhat limited by its retrospective nature, the subjectivity of race, and the exceedingly small size of the Hispanic population within our OPO. Additionally, the study did not analyze actual organ donation numbers or the number of organs donated per patient. It is conceivable, therefore, that these other endpoints might have actually improved after our participation in the ODBC, but this possibility is beyond the scope of this analysis. Finally, our statistical methods may have obscured important changes that occurred over time that did not meet the $P$ less than .05 threshold. This appears to be especially true when we look at the changes in approach and consent rates that occurred between 2009 and 2010 as opposed to the changes seen in the years preceding 2009. Specifically, the Cochran-Armitage trend test would very
likely have detected a significant increase in consent rates had it not been for the heretofore unexplained downturn in consent rates between 2009 and 2010. The cause and significance of this downturn will likely become clear only after several more years of prospective data collection.

Conclusions

The ever-increasing need for transplantable organs has not been matched by a similar increase in organ donation rates. There remains a gap in public knowledge, most notably among minority groups, and looming misconceptions about the transplantation process. Our OPO’s involvement in the ODBC was associated with increased numbers of patients being referred to the OPO as well as an increase in the overall consent rate within a single institution that resulted from an increase in the rates for white patients at that institution. No corresponding increase was noted in system-wide consent rates for any patient population, or in consent rates among minorities, regardless of institution. Continued emphasis must be placed on methods to increase consent and subsequent donation rates in all patient populations, but especially within minority communities.

References