Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Variation in Organ Donation Among Transplant Centers

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OBJECTIVE

The objective of this report is to describe variation in organ donation among transplant centers.

We analyzed data for 190 of the nation's 255 transplant centers on patients who were medically eligible to be organ donors and the number of donors for whom consent was given to donate. We found that the rate of consent for donation (the consent rate) varies widely among transplant centers at the national level, as well as within geographic regions and at the organ procurement organization (OPO) service area level. We found a slightly higher consent rate in hospitals with a larger number of transplant programs and operations.

However, of 190 transplant centers in our analysis, 18 had a consent rate below 30 percent, compared to a national average of 51 percent. Had these 18 transplant centers obtained consent at the average rate of the other 172 centers (54 percent), they would have realized 130 more donors beyond their current performance, resulting in an estimated additional 450 life saving organs.

BACKGROUND

More than 80,000 Americans are currently awaiting organ transplants, yet fewer than 25,000 people received a transplant in 2002. During that same year more than 6,400 people died while waiting for a transplant.[1] It is estimated that 12,000 to 15,000 deaths annually could yield organs for transplantation; however, fewer than half of those deaths led to such an outcome in 2002.[2]

Medicare requires that all hospitals receiving Medicare or Medicaid funding have an agreement with an OPO to coordinate organ donation efforts. Every hospital participating in Medicare and Medicaid must contact its OPO in a timely manner about patients whose deaths are imminent or who die while in the hospital.[3]

No specific requirements govern organ donation at hospitals that perform organ transplants. Hospitals that receive Medicare reimbursement for heart, liver, and heart-lung transplants must demonstrate "adequate plans for organ procurement meeting legal and ethical criteria, as well as yielding viable transplantable organs in reasonable numbers."[4] Although this criterion lays out a general expectation for transplant center performance in donation, it does not specify a minimum level of donation that a transplant center should achieve, and it applies only to heart, liver, and heart-lung transplant centers.

This analysis focuses on transplant centers because they are in a key position to take a leadership role in donation. Their staff are familiar with the life-saving benefits of organ transplantation. Operating a transplant program brings significant prestige in the medical community. These hospitals are at the forefront of implementing sophisticated medical procedures.

The Health Resources and Services Administration (HRSA) oversees the nation's organ procurement and transplantation system. Among its other responsibilities, HRSA funds the Organ Procurement and Transplantation Network (OPTN).[5] All transplant programs are members of the OPTN. The OPTN is charged with operating and monitoring an equitable system for allocating organs, maintaining a waiting list of potential recipients, matching potential recipients with donors, and increasing organ donation.

Since 1999, HRSA has funded demonstration and research projects to test and replicate interventions designed to increase organ donation. OPOs, hospitals (including transplant centers), and other organizations receive these grants. In the most recent round of grant projects, funded in September 2002, the agency funded 16 grants that test medical strategies and outreach efforts intended to increase the number of donors.

The Centers for Medicare & Medicaid Services (CMS) specifies organ procurement service areas, establishes conditions of coverage for the nation's 59 OPOs, and certifies those organizations for participation in Medicare. CMS also establishes the conditions that a transplant center must meet in order to receive Medicare reimbursement for organ transplants.

OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of this analysis is to present data on variation in organ donation among transplant centers. This data presentation is part of our continuing work toward helping to increase organ donation. Documenting variation among transplant centers can help identify centers with potential for increasing the number of donors, as one step in closing the gap between the need for and the availability of organs.

Our analysis uses hospital-specific data that OPOs submit to the OPTN. The OPTN provides these data to HRSA's Division of Transplantation. The requirement for submission of these data is HRSA's response to OIG's 2000 recommendation that it "require OPOs to submit hospital-specific data on referrals and on organ recovery" to help the Department assess the effectiveness of efforts to increase organ donation. (Office of Inspector General, "Medicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule," OEI-01-99-00020, August 2000.)

The data report the number of eligible donors and the number for whom consent to donate was given, from August 2001 through November 2002. An eligible donor is defined as a patient aged 70 or younger whose death is determined by neurological criteria (brain death) and who does not have clinical conditions, such as tuberculosis, HIV, or hepatitis.[6] From this data set, which covers all hospitals in the United States, we created a subset of data for transplant centers by using the OPTN list of hospitals that were operating a transplant program in February 2003. The total number of transplant centers is 255.

We then narrowed the data set to include only those transplant centers for which data were reported for at least 14 of the 16 months from August 2001 through November 2002. We also chose to include only those transplant centers with a minimum of 4 eligible donors

during this 16-month period. We made this decision to avoid skewing the rates with extreme percentages for hospitals that saw few eligible donors. We also excluded data from one OPO that identified reporting errors in its initial data submission.

All told, our analysis includes 190 of the 255 transplant centers (approximately 75 percent), and 51 of the 59 OPOs (approximately 86 percent). For these hospitals and OPOs we calculated the consent rate as the number of eligible donors for whom consent was given divided by the number of eligible donors.

We identified three limitations to these data. First, although OPOs use uniform definitions for identifying potential donors, the data are self-reported by the OPO. OPOs could vary in how they apply these definitions, although we would expect consistency within each OPO.

Second, these data have not been independently verified. Although each OPO has validated its own submission, neither we at OIG, nor HRSA or the OPTN has independently audited these data for accuracy.

Finally, as noted above, some gaps in reporting exist among 8 of the country's 59 OPOs. Seven OPOs did not provide data for at least 14 of the 16 months in the reporting period, and 1 OPO discovered errors during its validation process. We excluded these eight OPOs from our analysis. As these OPOs submit data, our analysis can be easily updated for the additional transplant centers involved.

Our analysis is based on the consent rate at each transplant center. The consent rate is the number of patients for whom consent to donate organs was given, as a percentage of all patients at the hospital who were medically eligible to donate organs. A medically eligible donor is defined as a patient aged 70 or younger whose death is determined by neurological criteria (brain death) and who lacks certain clinical conditions, such as cancers, tuberculosis, HIV, or hepatitis, among other diseases. Our analysis covers a 16-month period, from August 2001 through November 2002.

FINDINGS

National Variation in Donation Rates at Transplant Centers

Table 1 shows the variation in consent rates among transplant centers. Nationally, these 190 transplant centers obtained consent from a mean of 51 percent of potential donors, with a median of 52 percent. Thirty centers (16 percent) had consent rates of 70 percent or higher.

However, at 18 of the 190 centers the consent rate fell below 30 percent. These centers averaged 22 eligible donors during this 16-month period. Ten of the 18 centers had at least 1 eligible donor per month; in some centers, the number was considerably higher. Yet they still had a low consent rate, despite multiple opportunities for donation.

Table 1 National Variation in Consent Rate Among Transplant Centers (8/01-11/02)		
Consent Rate	**Number of Centers**	**Percentage of Total**
0 - 9.9%	2	1.1%
10% - 19.9%	4	2.1%
20% - 29.9%	12	6.3%
30% - 39.9%	22	11.6%
40% - 49.9%	35	18.4%
50% - 59.9%	45	23.7%
60% - 69.9%	40	21.1%
70% - 79.9%	17	8.9%
80% - 89.9%	8	4.2%
90% - 100%	5	2.6%
Total	190	100.0%
source: OIG analysis of OPO data submitted to OPTN and HRSA		

Although Medicare and the OPTN have no minimum requirement for consent rates, this level presents substantial opportunity for improvement. For example, had these 18 transplant centers achieved a consent rate of 40 percent, they would have realized 75 additional donors, resulting in about 260 more organs for transplantation. Omitting these 18 centers, the national mean consent rate was 54 percent. Had these 18 centers achieved that 54 percent rate, they would have obtained consent for 130 more donors beyond their current performance, resulting in an additional 450 life saving organs.

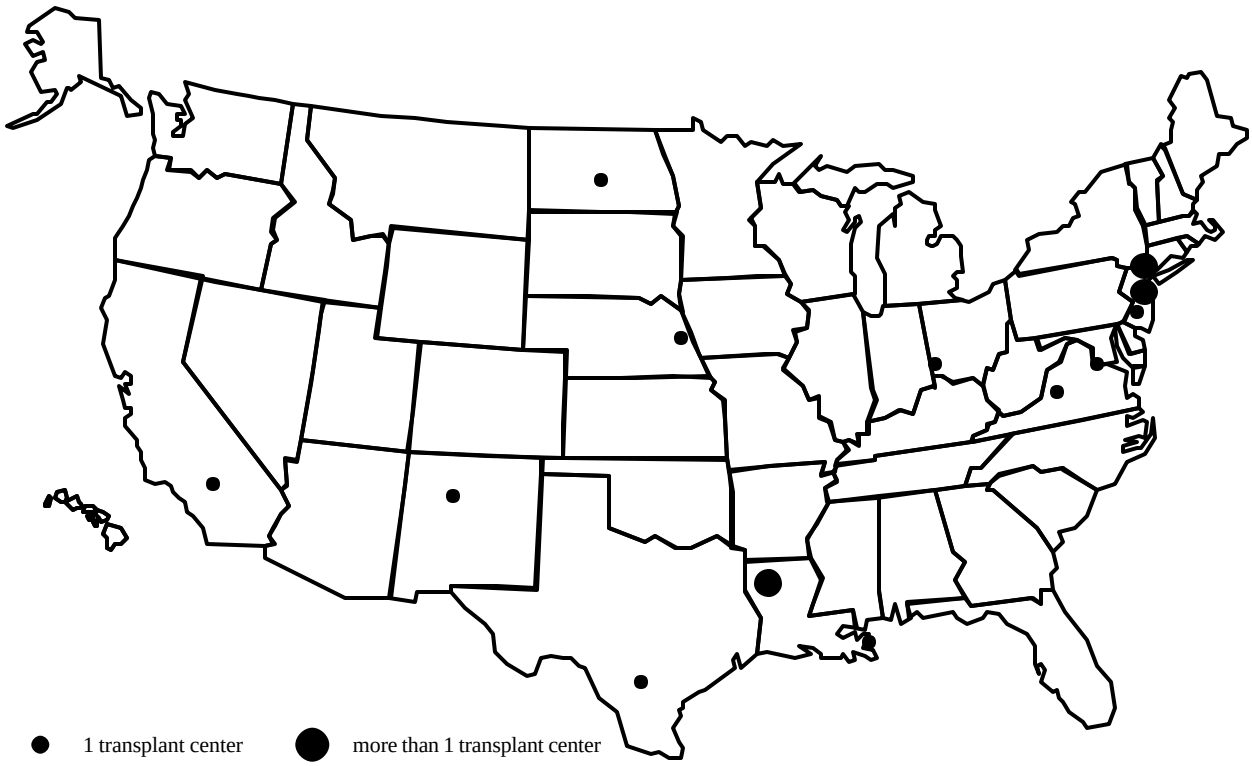
Figure 1 shows the geographic distribution of those transplant centers with a consent rate of less than 30 percent. The 18 transplant centers that fell below 30 percent consent rates are distributed among 12 OPO service areas.

Undoubtedly, there are factors in addition to being a transplant center that can explain some portion of this variation. For example, many of the centers with lower consent rates are located in urban areas that traditionally have had difficulty in obtaining donors. It is important to note that overall, transplant centers have a slightly higher consent rate than do other hospitals. For the service areas in this analysis, the consent rate for transplant centers averages 51 percent, versus 47 percent for other hospitals.

The OPO service areas contain 1 to 11 transplant centers. For the 51 OPO service areas included in this analysis, variation is widest in those service areas with the largest numbers of transplant centers.

Figure 1.

Location of Transplant Centers with Consent Rates Below 30 Percent



Variation by Number of Transplant Programs at a Center

Transplant centers can operate between one and eight transplant programs. Almost all transplant centers (243 of 255) perform kidney transplants, while fewer centers have other programs.[7] Table 2 displays consent rates by number of transplant programs that a transplant center operates. Larger programs show slightly higher consent rates. For example, the 21 centers that operate either 7 or 8 transplant programs had a combined consent rate of 55 percent. The 87 centers operating either 1 or 2 programs had a combined rate of 48 percent.

Among the 18 transplant centers with consent rates below 30 percent, 5 had only one transplant program, but 6 had 4 or more transplant programs.

Table 2 Consent Rate By Number Of Transplant Programs (8/01-11/02)						
				Transplant Center Consent Rates (eligible donors / consents)		
Number of Programs	**Number of Hospitals**	**Eligible Donors**	**Consents**	**Mean**	**High**	**Low**
8	7	215	139	64.7%	95%	28%
7	14	513	261	50.9%	76%	21%
6	25	800	425	53.1%	73%	35%
5	20	487	271	55.6%	93%	13%
4	20	359	207	57.7%	89%	38%
3	17	526	259	49.2%	80%	0 %
2	36	788	372	47.2%	90%	0%
1	51	1,391	671	48.2%	100%	28%
Total/ Mean	190	5,079	2,605	51.3%		
source: OIG analysis of OPO data submitted to OPTN and HRSA						

Variation by Number of Transplant Operations Performed

We ranked centers by the number of transplant operations they had performed between 1987 and 2001. The volume of transplant operations is highly concentrated into a few centers. Ten of the 190 centers in our analysis had performed 25 percent of all the transplants, and 30 had performed 50 percent of the transplants.

As with the number of transplant programs in a hospital, these data show that the large programs exhibit a somewhat higher mean consent rate. At the same time, however, the variance around that mean is quite large, for all sizes of programs.

Table 3 Consent Rate by Number of Transplant Operations (8/01-11/02)							
Quartile	**Number of Hospitals**	**Number of Transplants (1987-2001)**	**Eligible Donors**	**Consents**	**Transplant Center Consent Rates (eligible donors / consents)**		
					Mean	**High**	**Low**
0-25%	10	40,488	347	202	58%	95%	21%
26-50%	20	41,259	670	396	59%	93%	32%
51-75%	34	39,211	1,162	593	51%	82%	0%
76-100%	126	40,388	2,900	1,414	49%	100%	0%
Totals	190	161,346	5,079	2,605	51%		
source: OIG analysis of OPO data submitted to OPTN and HRSA							

Among the 18 transplant centers with consent rates below 30 percent, one was included in the quartile of the 10 largest hospitals that perform 25 percent of all transplants.

SUMMARY

Our objective was to describe variation among transplant centers, which, because of their role in organ transplantation, can be potential national leaders in donation.

These data illustrate the wide variation among transplant centers in procuring organ donors. In documenting this variation, our analysis highlights the existing potential to increase the number of organ donors.

Undoubtedly, there are factors in addition to being a transplant center that can explain some share of this variation. For example, many of the centers with low consent rates are located in urban areas that traditionally have had difficulty in obtaining donors. Our aim here is not to explain these differences, but rather to identify areas in which there is broad opportunity for increasing organ donation.

We recognize the limitations to these data. They are self-reported and we have not independently verified them. The data do not cover 8 of the 59 OPOs; they also exclude 65 of the 255 transplant centers. Nevertheless, even with these limitations, the data highlight the variation among transplant centers in donor consent rates. As additional data are submitted, this analysis could be replicated to determine whether more comprehensive data reveal any changes in consent rates.

No specific criteria exist either in Medicare or in the OPTN governing organ donation and consent rate expectations at transplant centers. However, if those transplant centers with lower consent rates can rise toward the mean, many more transplantable organs will become available, and the gap between the need for organs and their availability will begin to close. With the shortage of transplantable organs growing, any steps that can help reduce that gap should be examined.

HRSA, in its ongoing oversight of the OPTN, can work with the transplant center community to increase consent rates. HRSA could encourage the OPTN to focus on transplant centers with lower consent rates, where substantial unmet potential exists. All centers are members of the OPTN, giving that organization access to and particular credibility in the transplant community.

HRSA funds grant programs that focus on clinical interventions and social/ behavioral strategies to increase organ donation. Recipients of these grant funds include OPOs, hospitals, and other organizations. HRSA might choose to give special attention to project proposals that focus on transplant centers with lower consent rates.

HRSA might also choose to make hospital-specific data on donation publicly available. We previously had recommended that CMS make such data public, and the agency agreed that this idea has merit and should be considered.[8] In that report, we also recommended

that HRSA require OPOs to submit hospital-specific data on referrals of potential donors and on organ recovery. The agency concurred with our recommendation; in its contract with the OPTN, HRSA required the submission of those data and it began collecting them. As a result, HRSA appears to be the more appropriate agency to make the data public. In fact, HRSA plans to make these data publicly available in the summer of 2003.

As more data become available, HRSA may also wish to examine trends in for those centers with low consent rates to assess whether they have made improvements.

CMS is reexamining the conditions of coverage for OPOs and is also considering new conditions for participation for transplant centers. Both of these efforts provide an opportunity to implement more specific criteria governing organ donation. The data presented here give CMS a base line, which it might use in considering whether and how to incorporate criteria governing donation in transplant centers in these new conditions.

APPENDIX

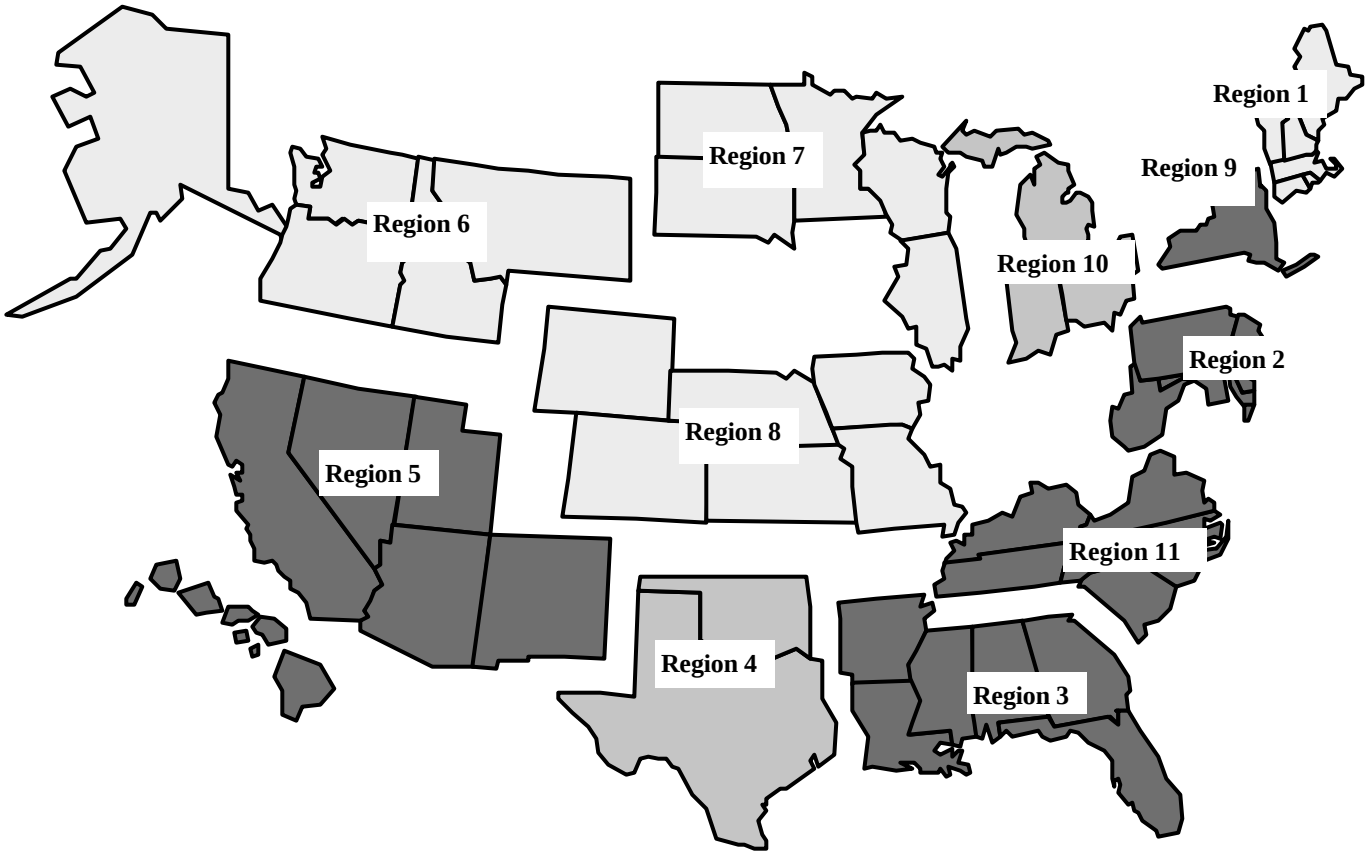
Table A-1
Variation in Consent Rate Among
Transplant Centers Across OPTN Regions (8/01-11/02)

OPTN Region	Number of Transplant Centers	Organ Procurement Organizations	Transplant Center Consent Rates		
			Mean	High	Low
Region 01	13	2	66.7%	90.0%	34.3%
Region 02	18	4	43.2%	67.0%	0.0%
Region 03	23	9	48.1%	93.0%	25.0%
Region 04	17	3	54.1%	80.2%	13.3%
Region 05	23	6	49.2%	100.0%	23.8%
Region 06	5	2	62.7%	75.0%	54.5%
Region 07	19	4	62.8%	90.0%	25.0%
Region 08	18	5	70.6%	88.9%	25.0%
Region 09	15	4	44.9%	61.5%	0.0%
Region 10	19	5	50.6%	85.7%	14.3%
Region 11	20	7	46.4%	73.3%	27.6%
Total / mean	190	51	51.3%	100.0%	0.0%

source: OIG analysis of OPO data submitted to OPTN and HRSA

Figure A-1
Regional Variation in Donation at Transplant Centers

Variation in Consent Rate
Among Transplant Centers by OPTN Region (8/01-11/02)



Key:

< 50 percent | 50-59 percent | 60 > percent

***source*: OIG analysis of OPO data submitted to OPTN and HRSA**

Endnotes

[1] According to the United Network for Organ Sharing, which holds the federal contract for the Organ Procurement and Transplantation Network, as of April 4, 2003, there are 80,953 candidates on the waiting list for an organ transplant. 24,866 people received a transplant in 2002; 6,608 of these transplants were from living donors (kidneys and livers), and 18,258 were from cadaveric donors. There were 6,184 cadaveric donors in 2002, and 6,818 living donors. (http://www.unos.org/data/default.asp?displayType=usData, accessed April 4, 2002)

[2] Steven Gortmaker, Carol Beasely, *et al.*, "Organ Donor Potential and Performance: Size and Nature of the Organ Donor Shortfall," *Critical Care Medicine*, 24: 432-439.

[3] 42 C.F.R., §283.45 was added at 63 Fed. Reg. 33,875, June 22, 1998, effective August 21, 1998.

[4] These criteria for coverage were established for heart transplants at 52 Fed. Reg. 10,935, April 6, 1987; for liver transplants at 56 Fed. Reg. 15,006, April 12, 1991; and for lung and heart-lung transplants at 60 Fed. Reg. 6,537, February 2, 1995. Medicare does not restrict which hospitals or physicians may perform pancreas transplants. Medicare bases certification of intestinal transplant centers on volume and survival criteria only. Medicare certification of kidney transplant centers, which dates to 1976, does not address donation.

[5] The OPTN contract is held by the United Network for Organ Sharing, based in Richmond, Virginia.

[6] Eligible donors are defined as "any patient who is aged 70 or younger meeting death by neurological criteria, based on the American Academy of Neurology Practice parameters for determining brain death, who does not have the following:

- Tuberculosis
- Human Immunodeficiency Virus Infection with Special Conditions
- Creutzfeldt-Jacob Disease
- Herpetic Septicemia
- Rabies
- Reactive Hepatitis B Surface Antigen
- Any Retro virus infection
- Active malignant Neoplasms, except Primary CNS tumors and skin cancers
- Hodgkin's Disease, Multiple Myeloma, Leukemia
- Miscellaneous Carcinomas
- Aplastic Anemia
- Agranulocytosis
- Fungal and Viral Meningitis
- Viral Encephalitis
- Gangrene of Bowel
- Extreme Immaturity
- Positive Serological or Viral Culture Findings for HIV"

[7] In addition to kidney transplants (243 hospitals), hospitals can perform transplants for hearts (139 hospitals), livers (120), lungs (72), heart-lung blocs (74), pancreata (136), pancreas islets (36), and intestines (39). In the 191 hospitals in this sample, the totals are: Kidneys-184; 109 hearts-109;

livers-90; lungs-59; heart-lung blocks-58; pancreata-99; pancreas islets-26; and intestines-33.

[8] Office of Inspector General, "Medicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule," OEI-01-99-00020, August 2000.

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