

**Report to the Washington State Legislature on  
Strategies for Increasing Organ Donation  
Senate Bill 5386**

**Introduction and Purpose**

This report summarizes the deliberations and recommendations of the workgroup assembled to discuss strategies for increasing organ donation in Washington as described in Senate Bill 5386 sponsored by Senator Craig Pridemore (D-Vancouver). This workgroup met on three separate occasions in 2011. While the workgroup fully recognizes the value of tissue and cornea donation, and of organ donation from living donors (e.g. kidney), the specific focus of this report is on strategies aimed towards increasing organ donation from deceased donors in Washington.

**Workgroup Process**

Members from various stakeholder groups were selected to serve on the workgroup, including the following:

Dr. Jorge Reyes, Chief of Transplant Surgery, Seattle Children's Hospital & University of Washington Medical Center

Dr. Michael Souter, Chief of Anesthesiology, Harborview Medical Center

Geoff Austin, Associate Administrator, University of Washington Medical Center

Deborah Swets, Vice-President, Membership, Washington State Hospital Association

Denny Maher, Director of Legal Affairs, Washington State Medical Association

Monty Montoya, President & CEO, SightLife

Maria Elena Geyer, Executive Vice-President, Marketing & Communication, Puget Sound Blood Centers

Dr. Leanna Tyshler, Chronic Kidney Disease Medical Advisor, NW Kidney Center

Stephen Zieniewicz, Executive Director, University of Washington Medical Center

John Barr, General Manager, Beck's Funeral Home

Dr. Louise Harder, Intensivist, Providence Health & Services

Senator Craig Pridemore, D-Vancouver, Washington State Senate

Jim LaMunyon, Community Member and Kidney Recipient

John Mitterholzer, Community Member and Donor Family Member

George Taniwaki, Community Member and Living Kidney Donor

Vicki Christophersen, Lobbyist, Christophersen, Inc.

Jenna McKenzie, Lobbyist, Christophersen, Inc.

Mike Seely, Executive Director, Pacific Northwest Transplant Bank

Megan Clark, Vice-President, Program Development & External Affairs, LifeCenter Northwest

Kevin O'Connor, President & CEO, LifeCenter Northwest

Meetings: Three two hour meetings were held, as follows:

July 19, 2011 - Naegeli Reporting, Seattle

September 15, 2011 - LifeCenter Northwest, Bellevue

October 11, 2011 - LifeCenter Northwest, Bellevue

Transcripts:

Each meeting was transcribed by a court reporter provided by Naegeli Reporting, and transcripts were furnished to the workgroup leaders. These transcripts served as the basis for this final report. They are available to legislators upon request.

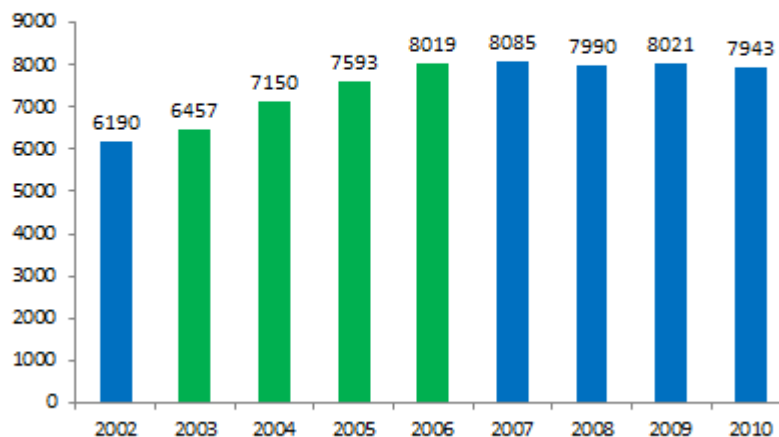
## Background Information

Organ transplantation has evolved into a highly effective, life-saving therapy for patients with end-stage organ failure. Consequently, demand for organs has increased steadily over the past two decades, with over 110,000 patients on the national waiting list at the end of 2011. The majority of these patients are in need of replacement kidneys, while others await life-saving hearts, lungs, livers, and pancreata. Nationwide, over 6000 patients die each year while waiting for transplantation. Others continue to wait for many years to receive the gift of life.

There are two sources of organs for transplantation, living donors, and deceased donors. Each year approximately 6000 US patients receive kidneys from living donors, and about 250 receive segments of livers from living donors. At the same time, about 24,000 US patients receive life-saving transplants from deceased organ donors. In spite of intensive efforts to increase organ donation, the number of donors nationwide has remained flat since 2006, as shown below.



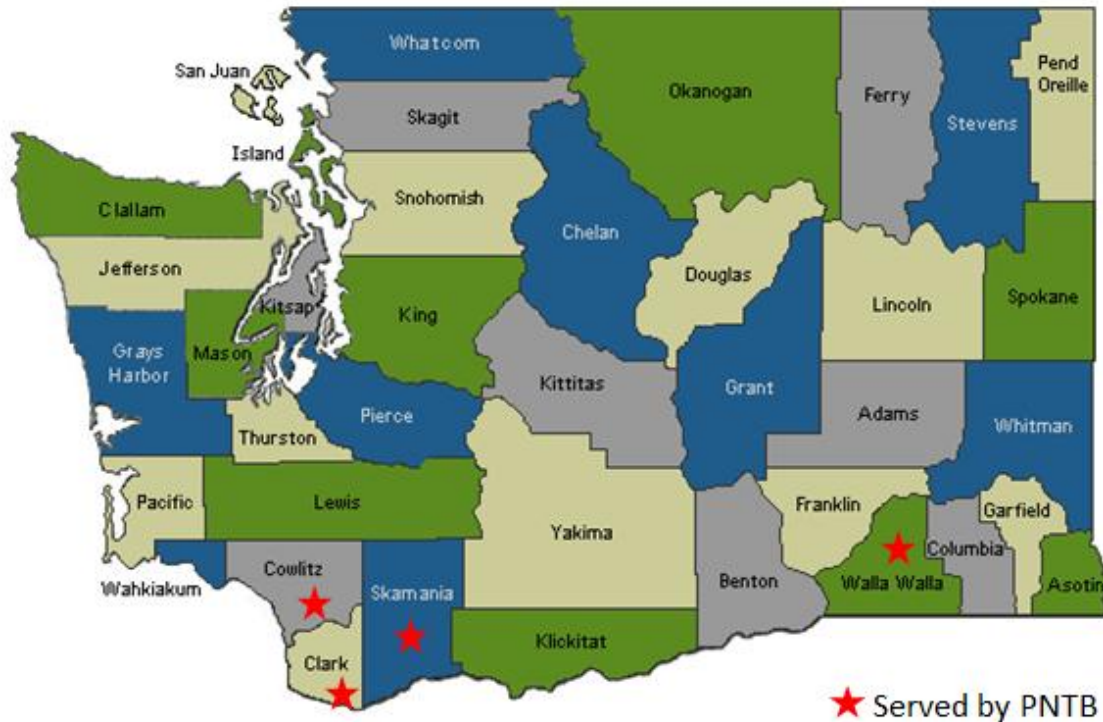
### US Deceased Donors: 2002 to 2010



Two federally designated Organ Procurement Organizations (OPOs) serve the state of Washington: LifeCenter Northwest (LCNW), located in Bellevue, serves the majority of the

state, and the Pacific Northwest Transplant Bank (PNTB), located in Portland, OR serves the remaining four counties as shown below.

*All WA counties are served by LCNW except Cowlitz, Clark, Skamania, and Walla Walla (served by PNTB, marked with red star)*



Organ donation in Washington has increased slightly in recent years, from 89 donors in 2009 to 113 in 2010, but the demand for organs in the state far exceeds the supply. On average, each deceased donor results in three organs transplanted.

Organ transplants are performed at five hospitals in Washington:

- University of Washington Medical Center (Seattle)
- Seattle Children's Hospital (Seattle)
- Virginia Mason Medical Center (Seattle)
- Swedish Medical Center (Seattle)
- Providence Sacred Heart Medical Center (Spokane)

In 2010, there were over 1700 patients awaiting transplantation at these hospitals, and less than 600 organ transplants were performed. Many of these organs came from donors in other states, such as Alaska or Montana, where there are no transplant programs. Each year, the number of patients on the waiting list grows larger.

## **Strategies for Increasing Organ Donation**

### **Presumed Consent**

Most of the first meeting was devoted to a discussion of this strategy, which featured a comprehensive presentation by a legal expert, Alexandra Glazier, Vice President and General Counsel for the New England Organ Bank, and Chair of the United Network for Organ Sharing Ethics Committee. Key points of this discussion, and conclusions, are described in the following section (which also draws from background analysis and commentary provided by the Association of Organ Procurement Organizations)

The growing demand for organs has prompted three linked questions.

1. *Would more organs be available for transplant in the U.S. if all were considered donors (presumed consent) unless we specifically opt-out, as in some European countries?*

The facts suggest otherwise. Today, under our voluntary, opt-in system, 75% of Americans who meet the criteria to donate actually become organ donors after their death (by comparison, only 7% of people who are eligible to donate blood actually do so). This results in over 25 organ donors per million population, which is the second highest organ donation rate in the world after Spain. Contrary to common belief, Spain also relies on an opt-in, voluntary donation system. Major European countries with opt-out laws have donation rates that range from 11.4 to 20.6 organ donors per million, which is well below the U.S. rate of 26 donors per million, as shown in the following table.

Country	Consent Practice	Donors per Million Population
Spain	VC	34.4
Belgium	PC	25.3
France	PC	24.7
Austria	PC	23.0
Italy	VC	21.3
United Kingdom	VC	15.5
Germany	VC	14.9
Denmark	PC	13.9
Sweden	VC	13.8
Netherlands	PC	12.8
<b>United States</b>	<b>VC</b>	<b>25.4</b>

(VC = Voluntary Consent Practice, PC = Presumed Consent Practice)

The data suggests that social, cultural, and operational factors, rather than legal structures, are the key to increased donation rates. For example, there is a positive correlation between high organ donation rates in European countries where the population of Roman Catholics is greater than 50%, regardless of whether the country has opt-in or opt-out laws.

Simply put, the international data and a review of international practice show quite clearly that opt-out donation laws are not responsible for increases in donation and are not the answer to the organ shortage in the U.S.

## 2. *What are the legal challenges that opt-out donation laws may face?*

The Uniform Anatomical Gift Act (UAGA) is the shared model language that 50 separate state donation laws are founded on across the U.S., and each state has adopted a version of this

model to govern how organs can be donated after death in our uniformly voluntary opt-in system. Organ donation under the UAGA is based on gift law principles. Changing to an opt-out system would conflict with the UAGA because evidence of donor “intent” is a required legal element for a gift to be binding. In an opt-out system, however, the default is that an individual is a donor if no action is taken. The legal issue is whether “donor intent” can be met on the basis of inaction. This conflict with gift law could lead to legal challenges to anatomical gifts made under an opt-out system. One could consider restructuring the organ donation laws outside of gift law principles but this would be a fundamental legal change that could not be accomplished with a simple statutory amendment to the UAGA. Further, eliminating gift law as the basis for organ donation could have unintended consequences such as undermining the legal foundation that prohibits the buying and selling of organs.

Other legal issues could include constitutional challenges, such as whether an opt-out donation law would amount to government “takings” or violate substantive due process by interfering with the fundamental right to burial. As a more general matter, the laws in our country are built heavily on the core concepts of individual rights and liberties. Opt-out donation may be contrary to these fundamental legal principles and unprecedented in U.S. law.

The need for uniformity and legal clarity regarding how organ donation can be authorized and the binding nature of an anatomical gift has been recognized since the UAGA was first enacted in 1968. Legal uncertainty and challenges to US organ donation law would be complex, time-consuming and could undermine confidence in our system of organ donation and transplantation with tremendous potential for harm.

*3. Would there be unintended consequences in the U.S. if the country changed to an opt-out donation system?*

One of the benefits of our voluntary opt-in system is that it allows, but does not require, an individual to make a donation decision prior to death. If an individual does not register as an organ donor (or document a refusal to be a donor), the individual’s family can make a donation decision at the time of his or her death. What this means is that there are two opportunities for donation to be authorized under our voluntary opt-in system; either by the individual’s prior donor registration or by the family’s decision to donate at the time of death. This accounts for the

difference between the 37% of Americans who register to be donors through their respective state registries and the 75% who actually become organ donors at the time of death.

When confronting the need to make final decisions, the vast majority families choose to donate. This is a significant difference from opt-out donation systems where there is no such opportunity to sensitively address misinformation and inspire families to donate; and uniquely in the US, the decision to opt-out is a legally binding refusal to donate that family cannot override.

The significance of misinformation is not merely anecdotal; the 2010 Donate Life America/Astellas independent poll found that 52% of people incorrectly believe that doctors may not try as hard to save their lives if the doctor knows the patient wishes to be an organ or tissue donor, and that a remarkably high 61% mistakenly believe it may be possible for a brain dead person to recover from his or her injuries. With these serious misconceptions among a large proportion of the US population, it is a realistic concern that changing to an opt-out donation system may lead to millions of ill-informed decisions to opt-out with no chance to address these misconceptions when the opportunity to donate actually occurs. Furthermore, research shows that there is very little public support for an opt-out organ donation law. Implementing opt-out/PC system would remove the critically important opportunity to help families address misconceptions and fears at the time of their loss, and as a result donation would quite possibly decrease.

### **Financial Incentives**

There was little discussion of financial incentives, since, the current federal National Organ Transplant Act (NOTA) expressly prohibits the exchange of valuable consideration for purposes of organ transplantation. Some members of the workgroup felt that this strategy had merit and therefore might be worth pursuing as a pilot study, but the general consensus of the group was that this was not a strategy worth exploring in Washington at this time.



**Public Education**

Most workgroup members were supportive of efforts to educate the general public on the benefits of organ donation and transplantation, and to highlight the urgent need and life-saving potential. At the same time, it was generally agreed that this type of activity would have a relatively low return on investment, at least in the near future, since the death rate of the overall population is low, and only a small fraction of people who die meet the stringent criteria for organ donation. These criteria include suitable age at the time of death, absence of significant transmissible disease such as cancer, etc. Nonetheless, especially in areas where donation rates are lower than average, there was support for public education as a strategy to increase organ donation.

**Professional Education**

Several workgroup members felt strongly that mandatory education of health care providers would be an effective and worthwhile strategy. Comparisons were drawn to the mandatory training required to perform certain functions in the hospital setting, where proficiency and demonstrated knowledge are associated with superior clinical outcomes and patient safety. Lifecenter Northwest and the Pacific Northwest Transplant Bank shared information that suggested intensive targeted professional education of physicians, nurses, and other hospital staff involved in the organ donation process were correlated with high rates of organ donation and transplantation. Physician representatives from two high-performing WA hospitals (Harborview and Sacred Heart) agreed that this strategy had merit. While both OPOs are currently active in providing professional education, the general consensus was that additional efforts to increase the education of healthcare professionals in this area would be effective.

**Donor Designation (the Donor Registry)**

All states now have legislation in place that enables individuals to designate themselves as donors in the event of their death and to record this designation in an electronic donor registry. This information is accessible by the OPO staff, through a secure password protected portal, upon the referral of the impending death from the donor hospital. Over 65% of the licensed drivers in Washington are designated as donors, making WA one of the states with the highest

donor designation rates in the US. This is an attribute to the staff of the WA Department of Licensing and organ procurement organization staff who have worked together for many years to achieve this high rate of donor registration, which is almost twice as high as the US average. In recent years, this has translated into a high rate (over 60%) of actual organ donors in WA authorized via designation. Organ donation provides great comfort to a decedent's family members and to the healthcare team, knowing that they are honoring the wishes of the patient by enabling organ and tissue donation. The workgroup was unanimous in supporting continued efforts to maintain and increase this commendable high rate of donor designation, especially for those demographics underrepresented in the registry.

### **Recommendations:**

Most of the strategies mentioned above were discussed at length, with attention given to the strengths, the weaknesses, and the feasibility of each strategy. The workgroup concluded that activities (including legislative action) supportive of the following would be beneficial in terms of increasing the supply of organs for transplantation:

- *Raising awareness of the need for and benefits of organ donation and transplantation*
- *Increasing donor registration through the statewide electronic donor registry*
- *Education of health care providers on practices proven to optimize the organ donation process*

The workgroup concluded that activities (including legislative action) supportive of the following would not be beneficial and therefore should not be pursued at this time:

- *Presumed consent (or opt-out) systems of donor authorization*
- *Financial incentives*

**Further Consultation on Related Matters**

All of the organ and tissue recovery agencies serving the State of Washington are firmly committed to increase the supply of organs, tissues, and corneas for people in need of life-saving and life-enhancing transplants. The workgroup recognizes that the healthcare environment is continuously evolving and while these recommendations represent a current point of view, these and other strategies will need to be revisited in the future. Workgroup members pledge to be available as needed to offer additional information and guidance to increase organ donation in Washington.

For further information, please contact:

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<b>Mike Seely, Executive Director, Pacific Northwest Transplant Bank</b>	<b>503-494- 6096</b>