

Quality Insights Renal Network 3 Transplant Education Collaborative

Presented By:

Saint Barnabas Medical Center
Renal and Pancreas Transplant Division

October 1, 2020

Faculty



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Program Highlights

- Kidney
- Pancreas
- Pediatric

- 351 Transplants in 2019
 - 159 Living Donor Transplants

- Living Donor Institute
 - Altruistic Donation
 - Paired Exchange
 - Incompatible Transplant
 - Compatible Share

SBMC Renal & Pancreas Transplant Division



Saint Barnabas Medical Center
Livingston, NJ

Convenient Satellite Locations

W. Long Branch,
NJ

Pre-Transplant
Evaluations



Edison, NJ

Pre-Transplant
Evaluations

Coming Soon

Opening
10-8-20

The Renal and Pancreas Transplant Division at Saint Barnabas Medical Center

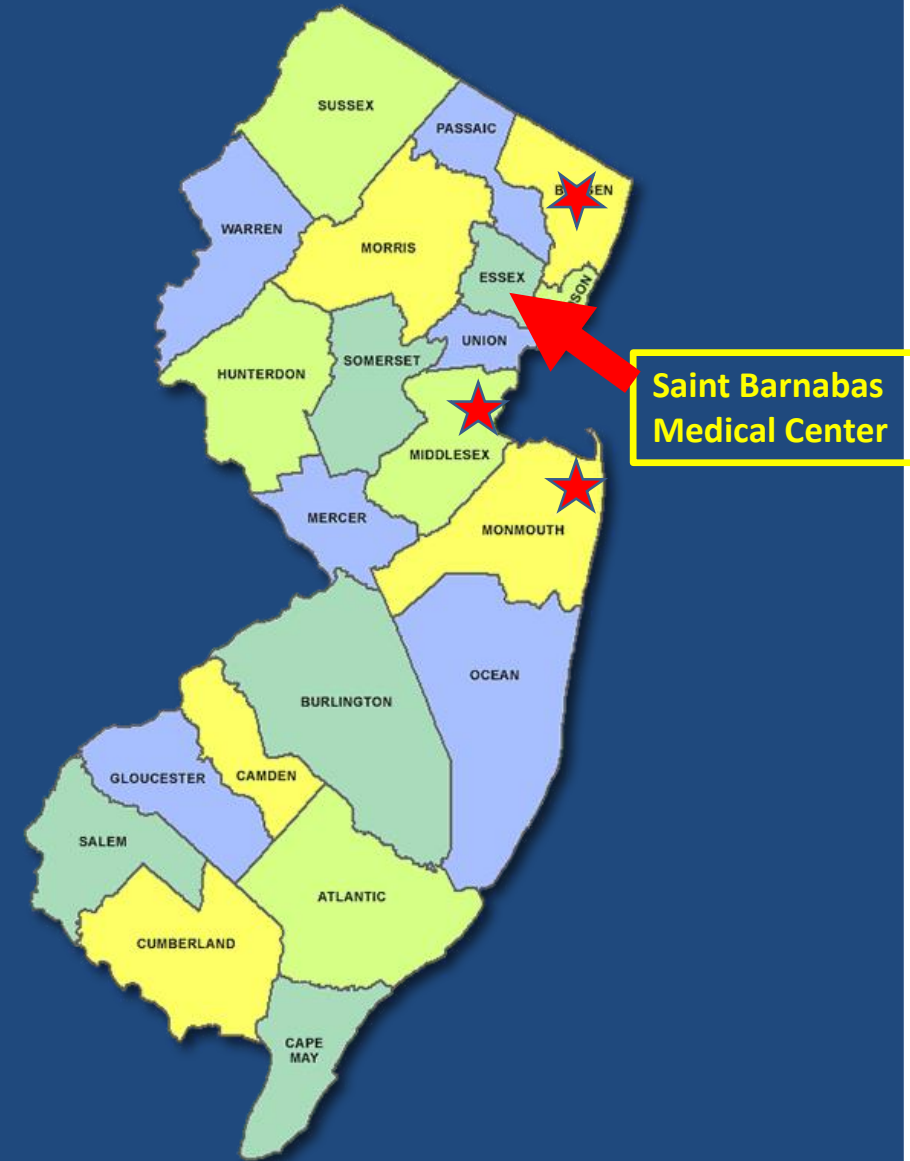
Announces the Grand Opening of their River Edge Transplant Satellite Unit

10 Elizabeth Street
Third Floor, Suite 303
River Edge, NJ 07661

The Renal and Pancreas Transplant Division's Satellite Unit is located at 10 Elizabeth Street next to the New Bridge Landing Railway Station in River Edge, New Jersey. This new satellite is available to help make kidney and pancreas transplantation more accessible to residents living in Bergen and Passaic Counties in New Jersey and in Rockland and Westchester Counties in New York. The River Edge Satellite offers the identical education and evaluation experience available at Saint Barnabas Medical Center in Livingston, New Jersey. Individuals may complete their pre-transplant evaluation in River Edge without having to travel to Saint Barnabas Medical Center.

The Renal and Pancreas Transplant Division at Saint Barnabas Medical Center in Livingston, New Jersey, is one of the largest kidney transplant programs in the country, performing more than 350 transplants each year. The Transplant Division's Living Donor Institute is among the leading living donor kidney programs in the United States. Our team offers an array of innovative options, allowing patients with chronic kidney disease to receive kidney transplants from living donors and deceased donors as soon as possible.

Transplanting kidneys. Transforming lives.



REFERRAL PROCESS

- We accept all major payers

Multiple Ways to Refer Patients for Transplant Evaluation



Fax
Referral
(Minimal)

On-site Dialysis Unit Referral
(5%)



Goals

- Streamlined
- Easy connections
- Personal touch
- Reduce barriers
- Increased automation

2019

1,949 total
referrals



Phone
Referral
(64%)



On-line Referral
(32%)

www.rwjbh.org/kidneytransplantreferralfarm

TRANSPLANT
EVALUATION

The Renal and Pancreas Transplant Division at Saint
Barnabas Medical Center

Online Referral Form

The Renal and Pancreas Transplant Division is now taking
appointment requests from patients and dialysis staff members
online at www.rwjbh.org/kidneytransplantreferralfarm.

This new link replaces the referral forms currently sent via
facsimile to the Transplant Division.

**Effective March 1, 2018, the Transplant Division will no
longer be accepting referrals via facsimile. Referrals from
dialysis centers should be submitted ONLINE ONLY.**

This new system allows the Transplant Division to respond to

Referral Received Now What?

- Referral Packet sent



**World Leaders in
Kidney Transplant**

**Saint Barnabas
Medical Center** | **RWJBarnab
HEALTH**
Renal and Pancreas
Transplant Division


Welcome to The Renal and Pancreas Transplant Division

Welcome to The Renal and Pancreas Transplant Division at Saint Barnabas Medical Center in Livingston, New Jersey. The Renal and Pancreas Transplant Division at Saint Barnabas Medical Center is one of the largest kidney transplant programs in the country. We take pride in offering compassionate and comprehensive care, along with the most advanced technology and approaches to kidney transplantation.

This packet contains important information about your visit, including forms that you should complete and bring to your evaluation appointment.

Sincerely,


Francis L. Wong, MD, MSCE
Chief, Transplant Division


Stuart Gellner, MD, MS-HCM, FACS
Director, Transplant Surgery

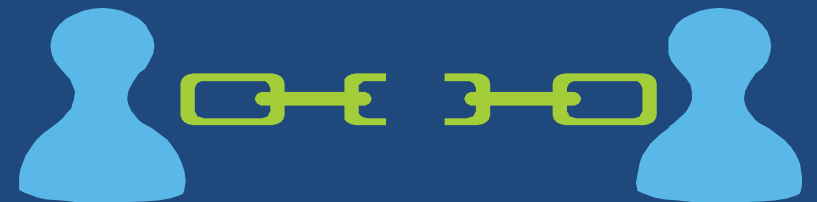
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HEALTH**
Renal and Pancreas
Transplant Division

We strongly encourage you to come to your evaluation appointment with a family member(s) or significant other. During the evaluation day and throughout the transplant process, a reliable support system is very important. Thank you for choosing Saint Barnabas Medical Center for your transplant services.

- Appointment Given
 - Evaluation site confirmed
 - Directions provided
- Encouraged to bring support
 - No small children please
- Confirmation letter sent
- Attends education session
- Multi-disciplinary evaluations
 - MD
 - RN
 - MSW
 - RD

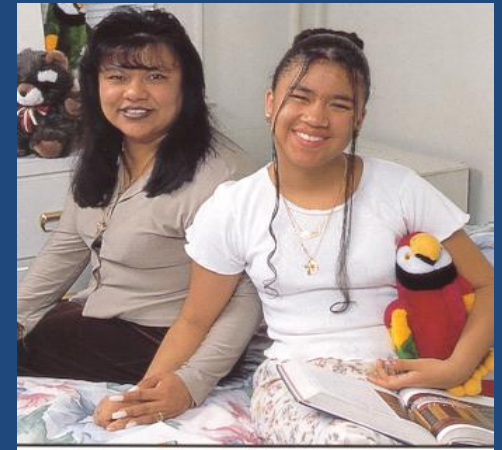
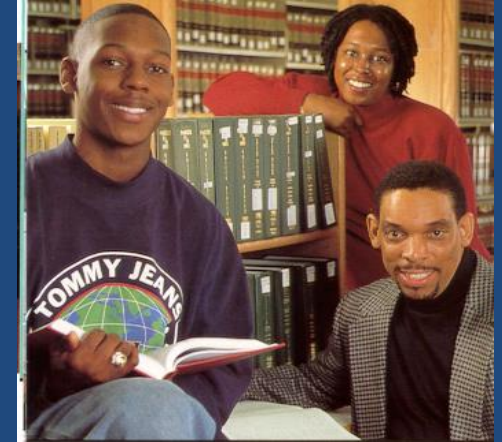
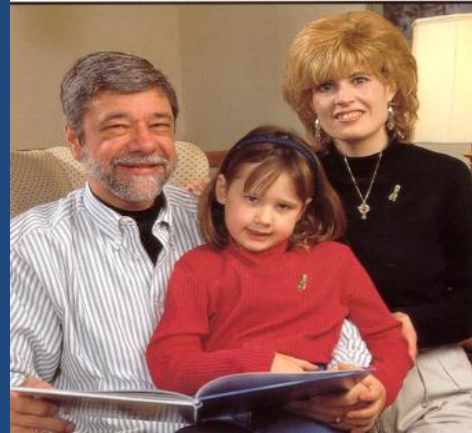
Dialysis Center Transplant Surgeon Designees and Social Workers

- A critical link between the patient and the transplant center
- Always communicate important changes in the patient's status including psychosocial status
- We may never know about serious non-compliance



Talk to your patients about living donation?

- Better Outcomes
- Less medication
- Eliminates Wait Time
- Planned, scheduled surgery
- Can sometimes avoid dialysis altogether



Saint Barnabas Medical Center Transplant Surgeon Designee Symposium 2021

- West Orange, NJ – 4/22/21
- Eatontown, NJ -4/29/21

Kidney Transplant in Times of Uncertainty: Updates from Saint Barnabas

Francis L. Weng, MD, MSCE

Chief, Renal & Pancreas Transplant Division
Saint Barnabas Medical Center
Livingston, NJ

October 1, 2020



**Saint Barnabas
Medical Center**

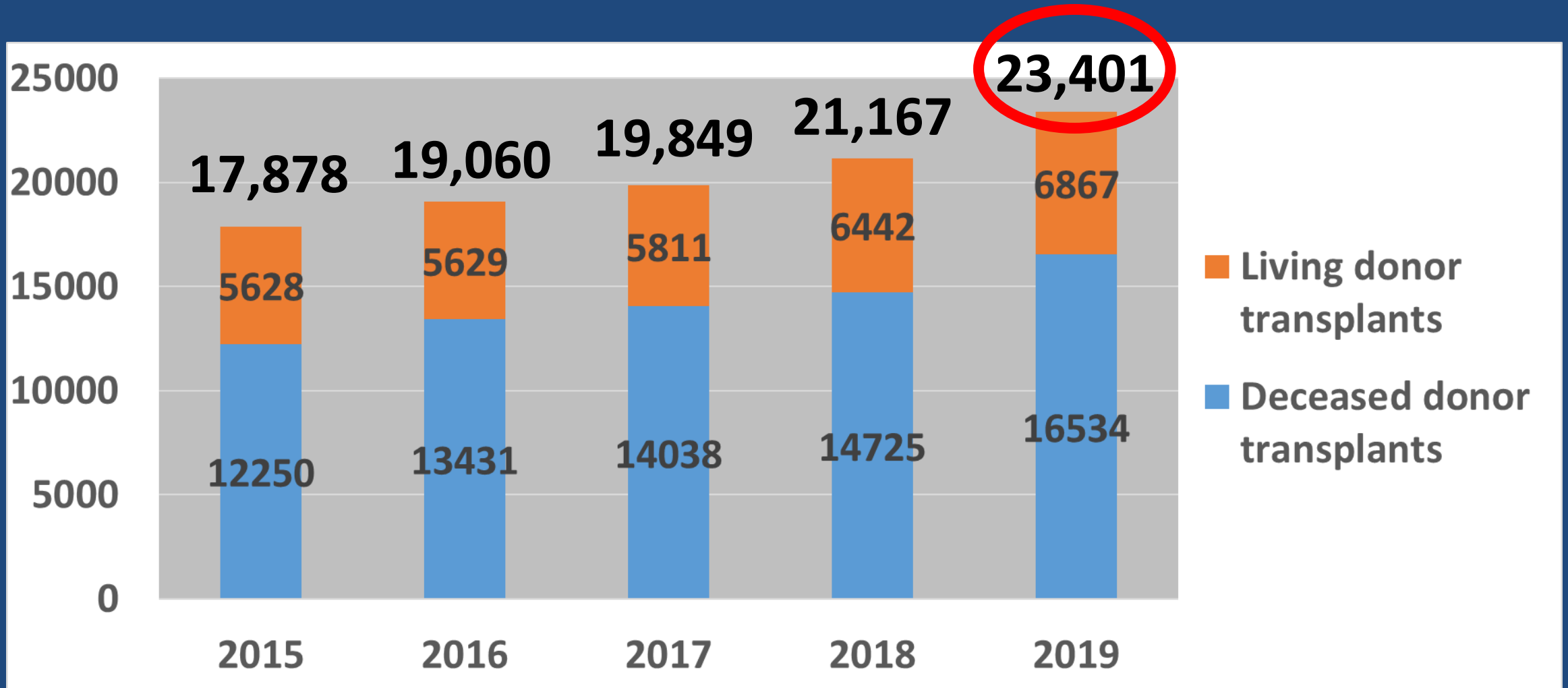
**RWJBarnabas
HEALTH**

Outline and overview

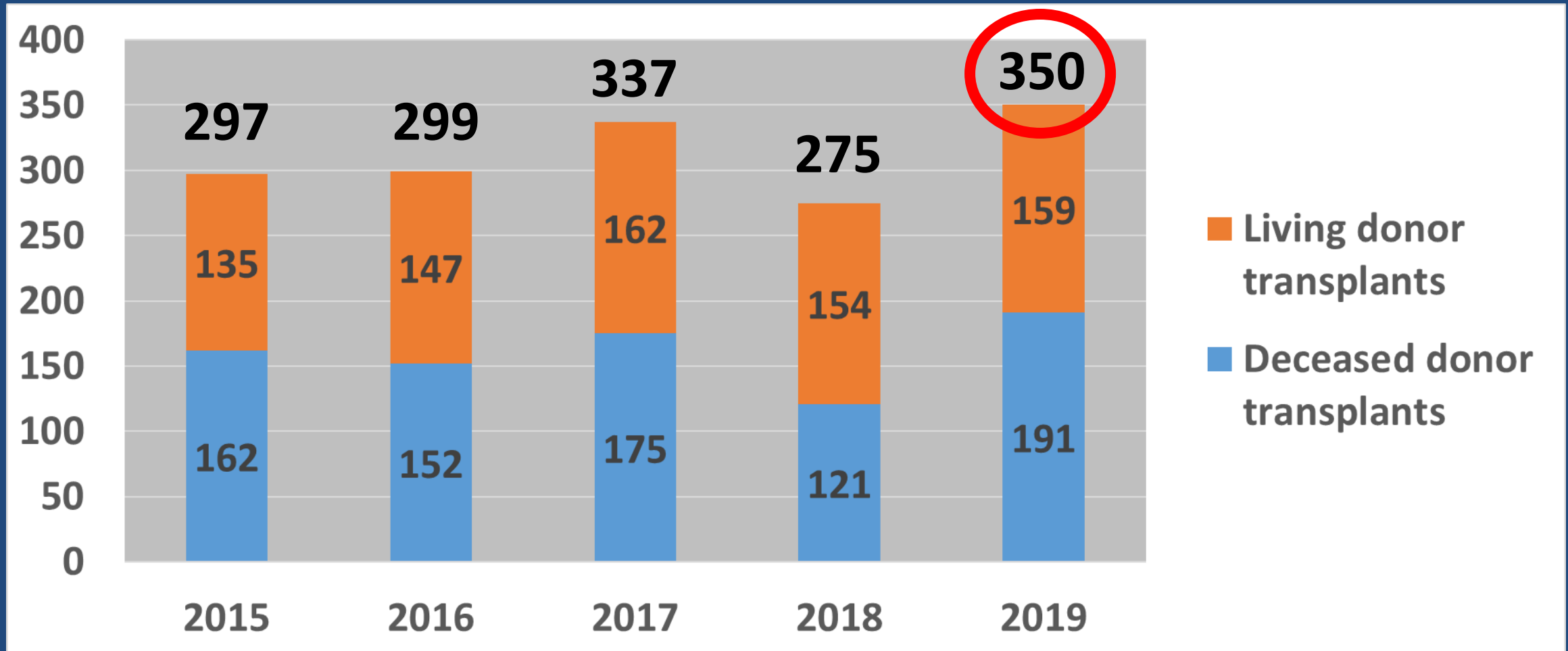
- Early 2020: Pre-COVID-19
 - Kidney transplant, nationally and at Saint Barnabas
- March-April 2019: Local peak of COVID-19
 - Impact upon transplant
- Summer/fall 2019 (after the local peak of COVID-19)
 - Resumption of transplant activities
- Upcoming changes to the kidney transplant allocation system

Early 2020: Before the COVID-19 pandemic

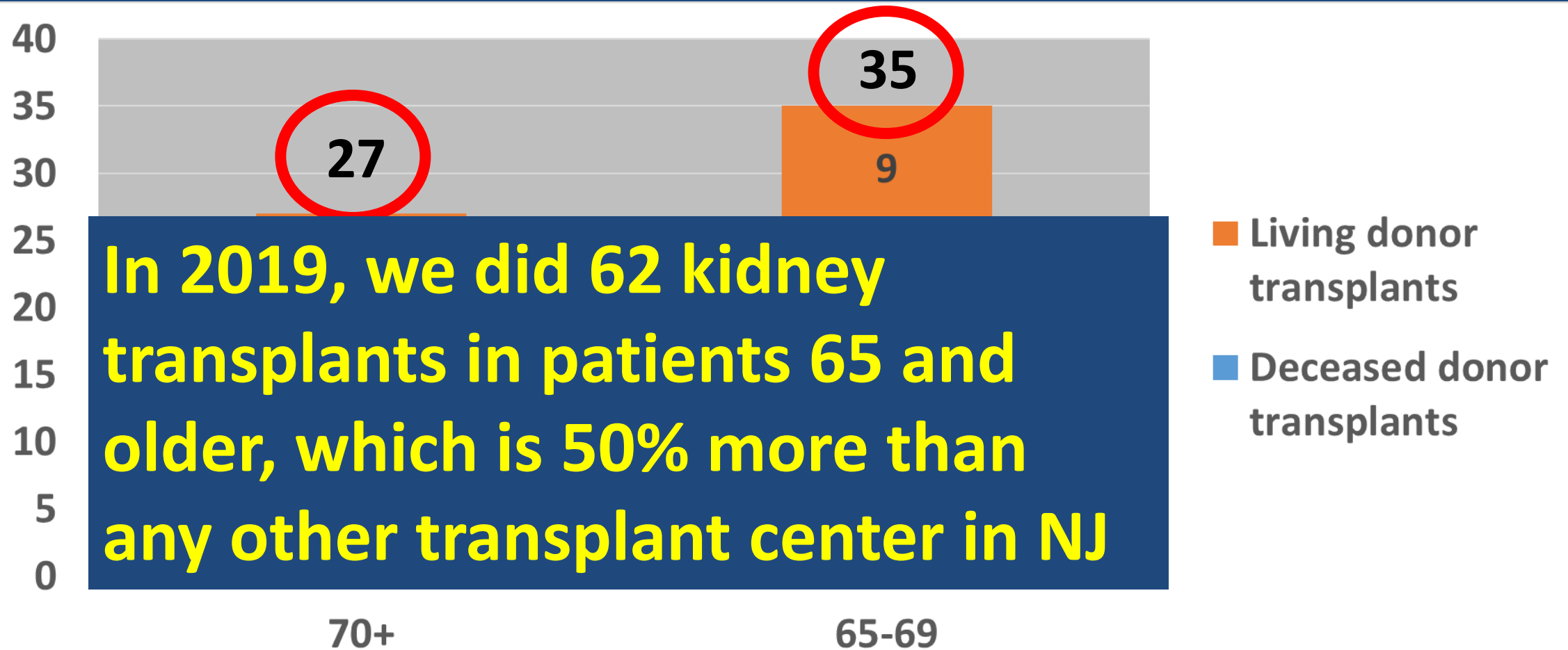
Nationally in 2019, a record number of kidney transplants was performed



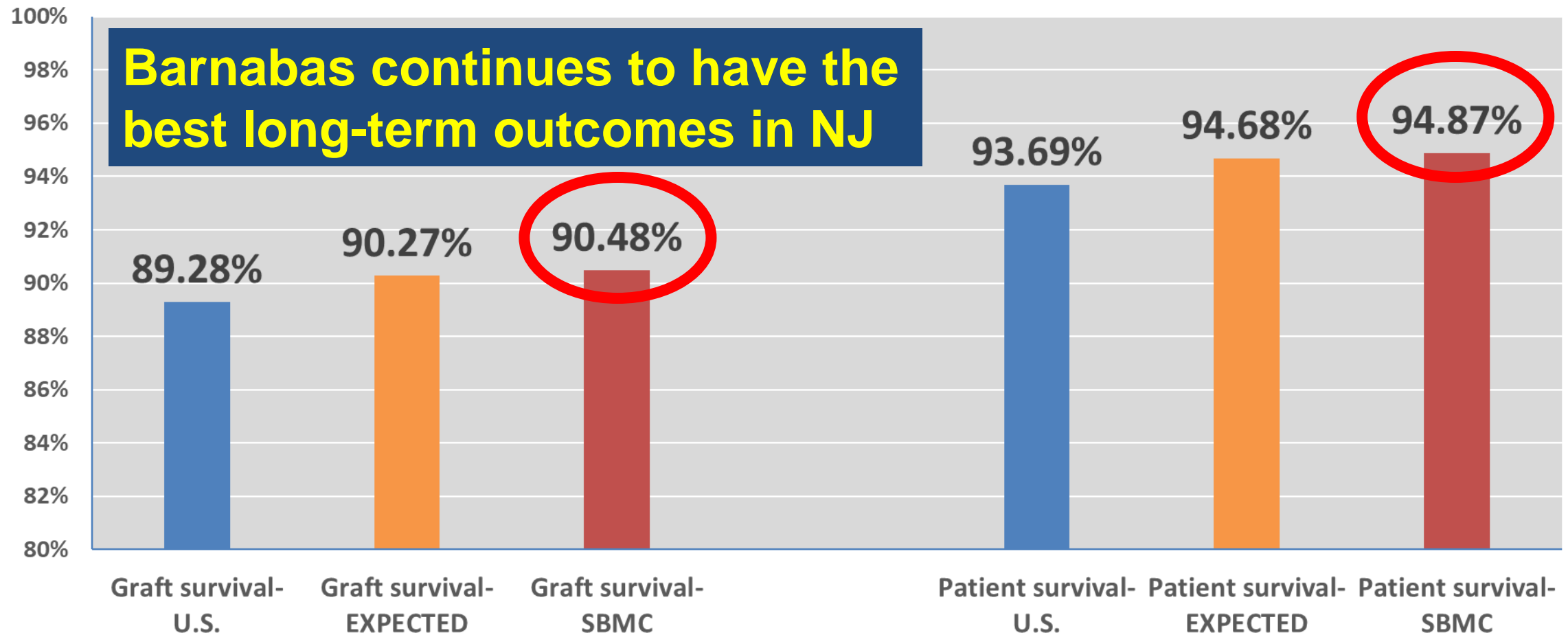
Regionally, Saint Barnabas was again the largest kidney transplant center in the Northeast



In 2019, Saint Barnabas also did the most kidney transplants in NJ in elderly recipients

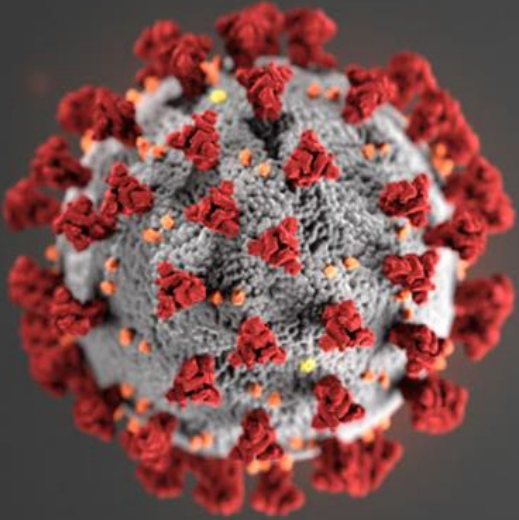


In addition to large volume, Saint Barnabas has the best long-term (3 year) results in New Jersey

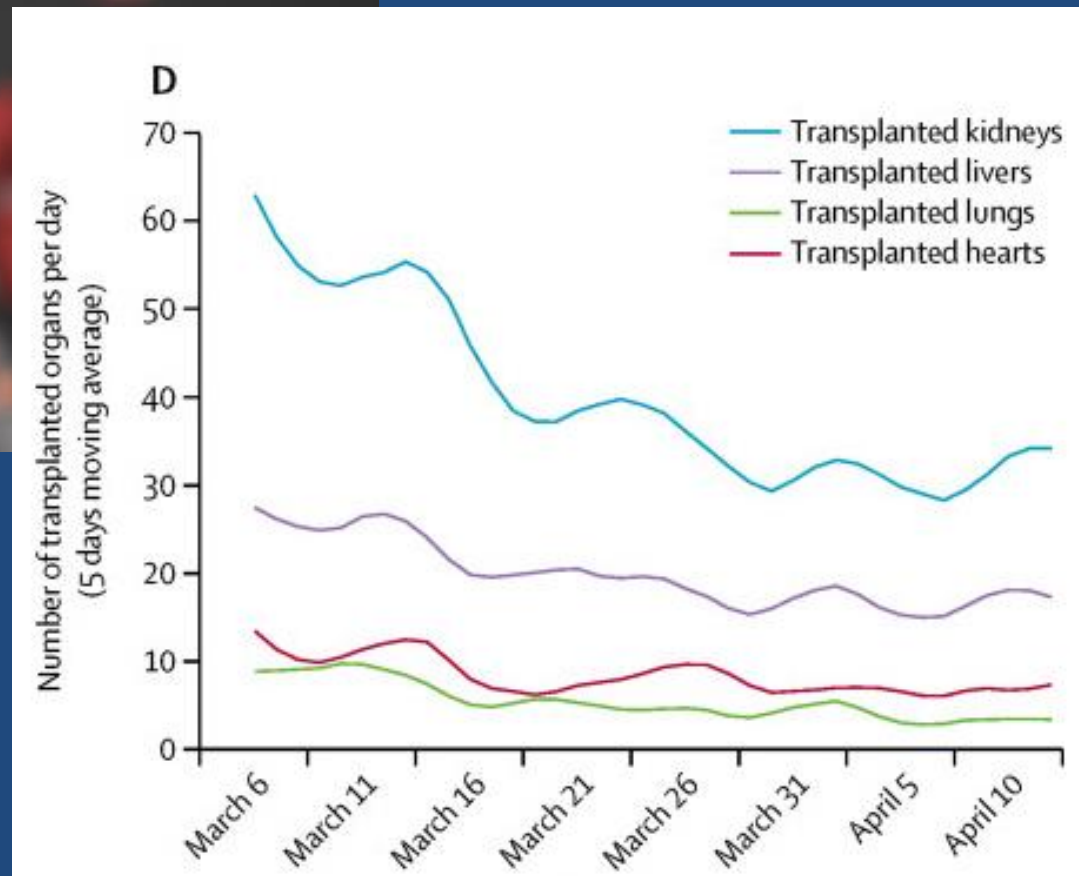


Spring 2020: Impact of COVID-19

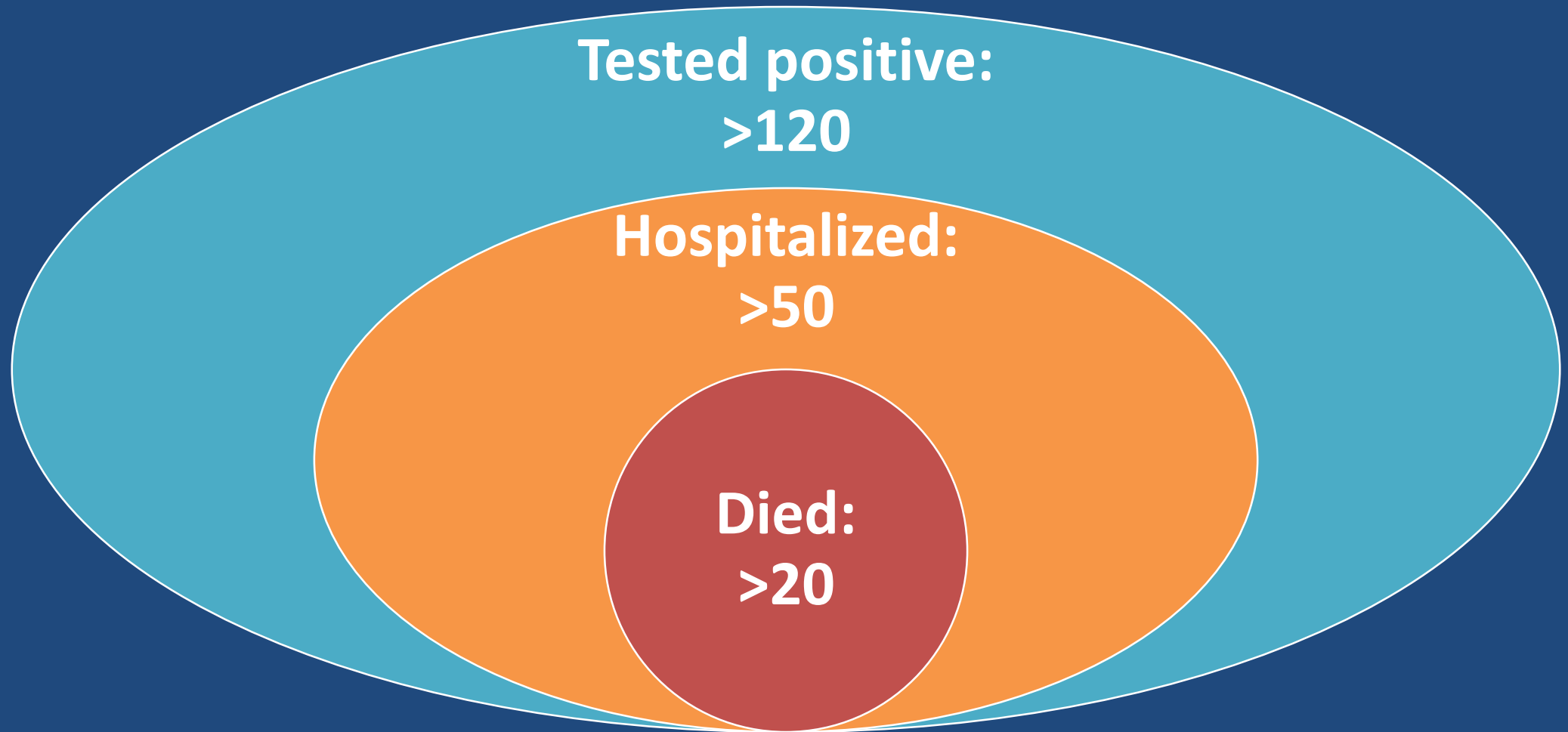
During the local peak of COVID-19 in March-May, SBMC stopped performing transplants



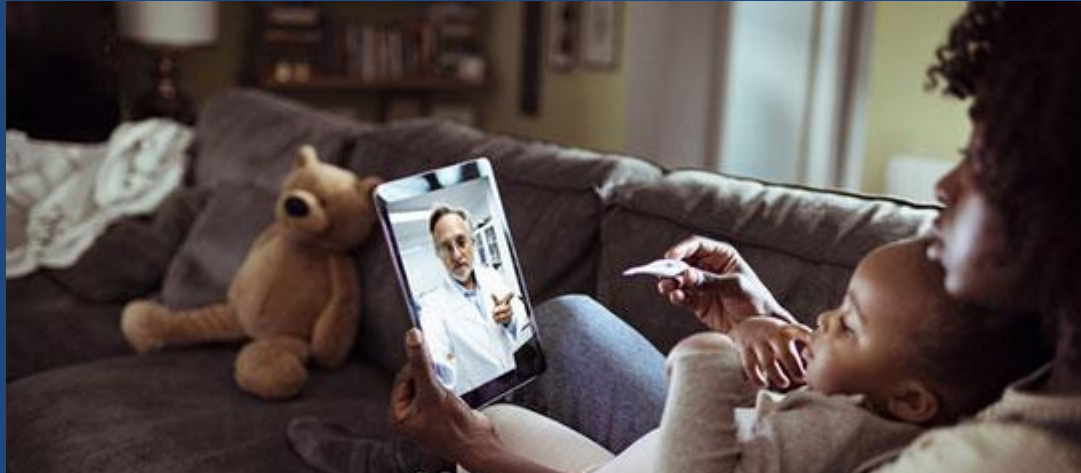
- Nationally, kidney transplant decreased a lot, mostly in areas hit hard by COVID-19



In March-April 2020, many transplant recipients fell ill, were hospitalized, and even died from COVID-19



For patient and staff safety, SBMC shifted to mostly Telemedicine visits



- Pre-transplant
 - New evaluations
 - Re-evaluations
 - Post-transplant
 - Living donor evaluations
-
- >2500 Telemed visits in March-August
 - Patients continued to be listed for transplant
 - 60 in March-April
 - 128 in June-August

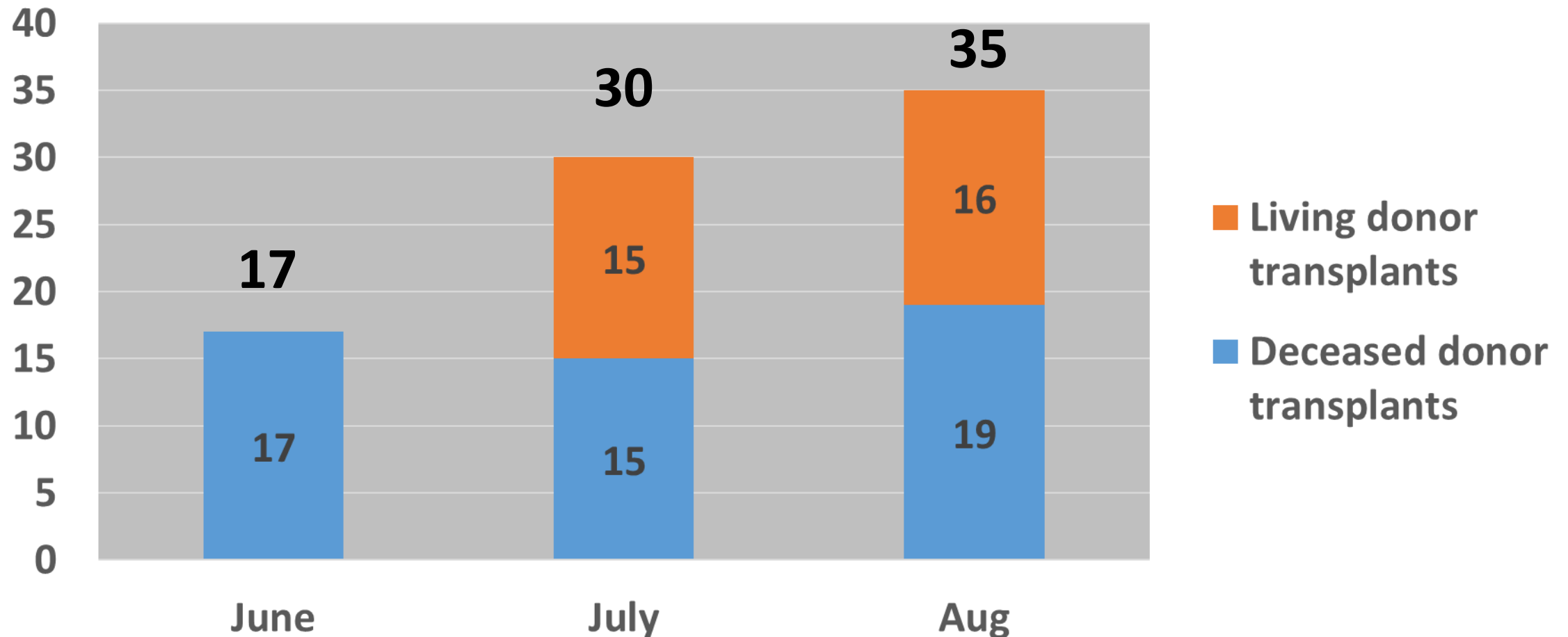
Summer/Fall 2020 (after the local peak of COVID-19): Resumption of transplants

Before re-starting performing transplants, SBMC instituted policies to ensure patient safety

- All new transplant recipients are tested for SARS-CoV-2 PCR by nasal swab
 - DDKT: On admission to hospital
 - LDKT: 2 days prior to surgery
- All living donors are tested 2 days prior to donation surgery

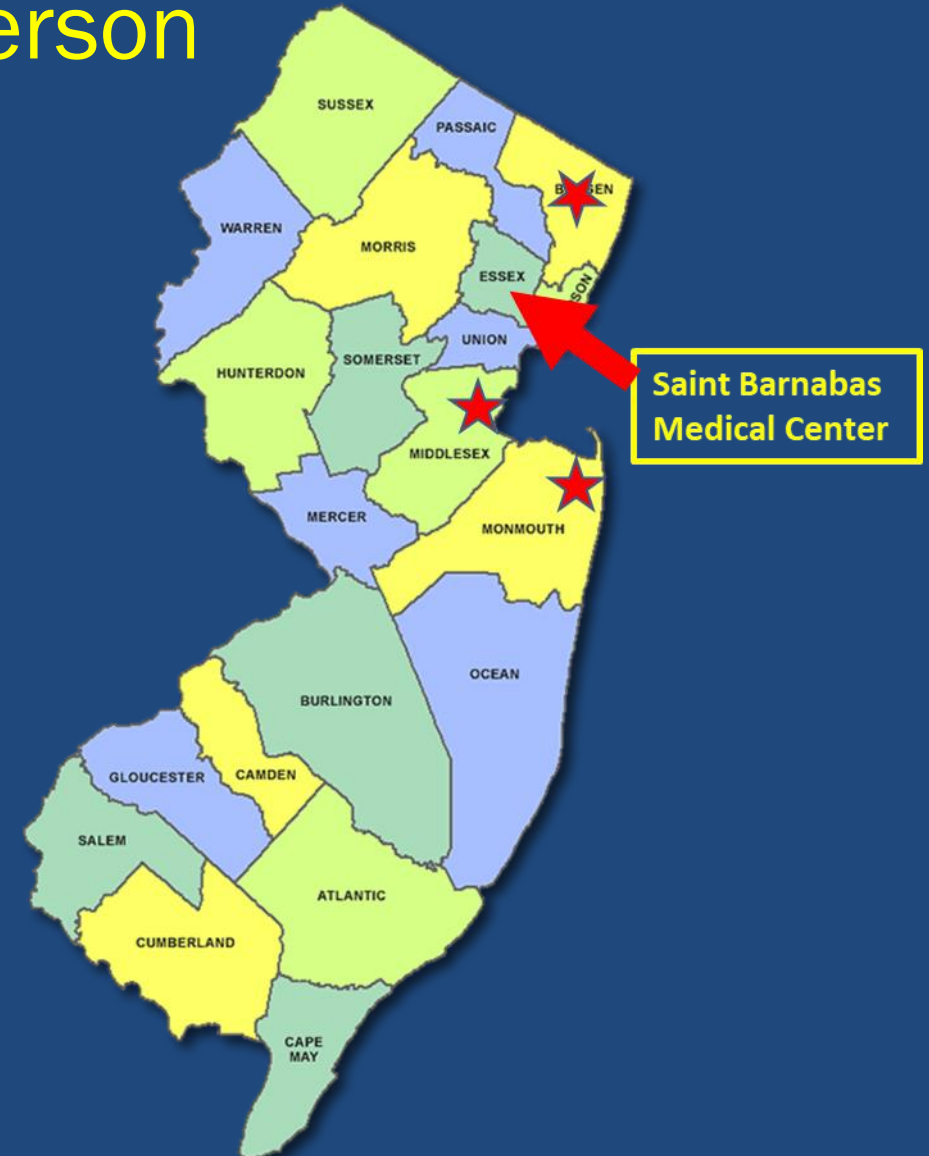


Saint Barnabas resumed deceased donor transplants in June and living donor transplants in July



In summer 2020, Saint Barnabas transplant resumed seeing patients in-person

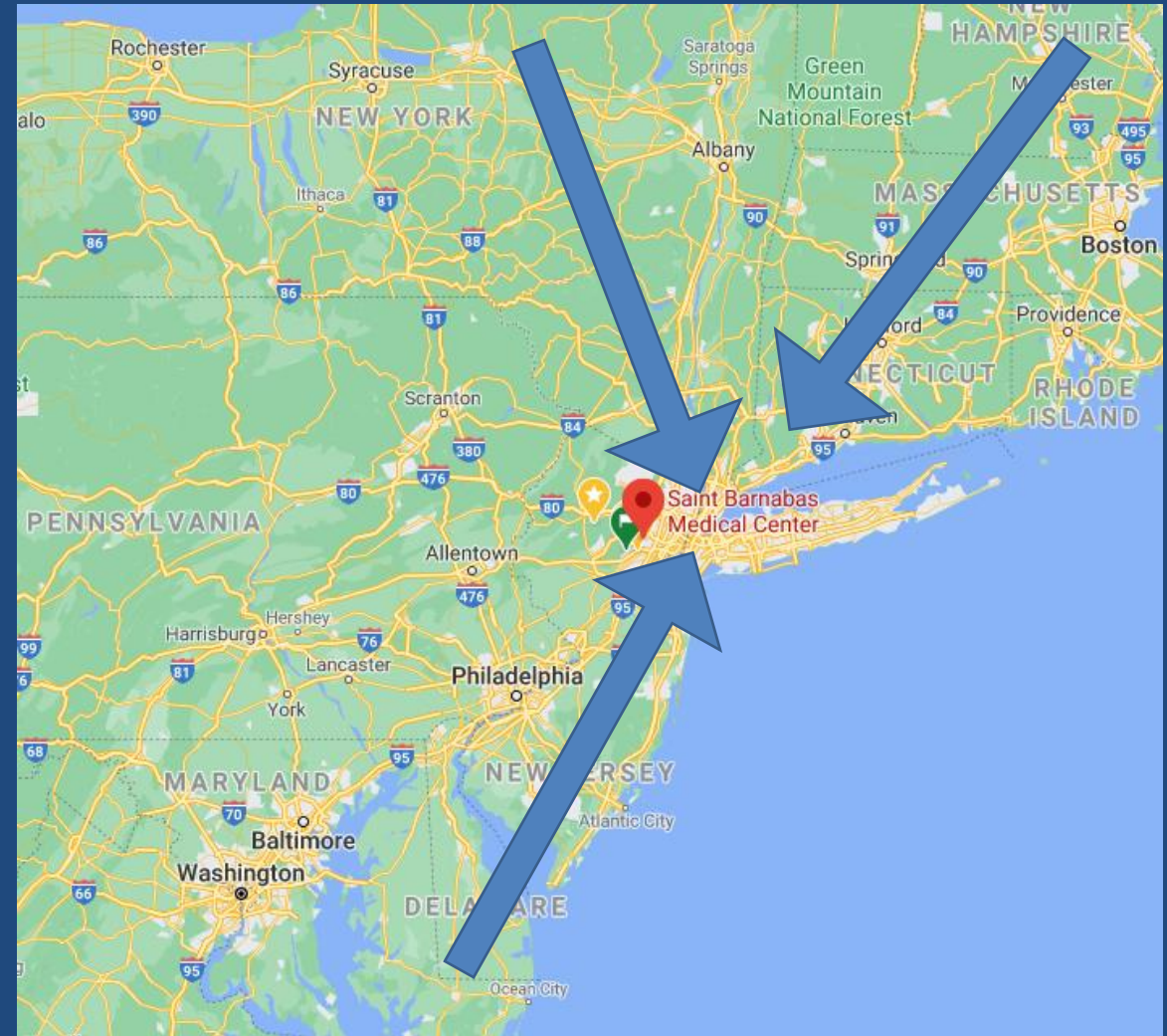
- Pre-transplant
 - New evaluations
 - Re-evaluations
 - Satellite locations
 - Edison
 - West Long Branch
 - River Edge (coming soon)
- Post-transplant
- Living donor evaluations



Upcoming changes: A major shift in how deceased donor kidneys will be allocated

Starting in Dec 2020, changes to kidney allocation will greatly increase waiting times in New Jersey

- Deceased donor kidneys will be shared more broadly
 - Kidneys from NJ and PA will be shared with patients in NY
- Most patients listed in NY have been waiting a VERY long time
- Most patients listed in NJ have not been waiting as long as NY patients



Starting in Dec 2020, changes to kidney allocation will greatly increase waiting times in New Jersey

- What will be the end-result?
 - This is good news for patients listed in NY who have been waiting awhile
 - This is bad news for patients within ~250 miles of New York
- **Bottom line:**
 - **For a few years, until waiting times in NY decrease and “even out” with NJ, patients in NJ will be less likely to receive a DDKT**

What can our patients do?




Sign up for all types of deceased donor kidney transplants

Strongly consider living donor kidney transplant

Be prepared for possibly longer waiting times for DDKT for a few years

Conclusions



Saint Barnabas continues to be one of the country's leading kidney transplant programs

During COVID-19, Saint Barnabas temporarily stopped doing new transplants

Starting June 2020, transplants resumed at their previous pace

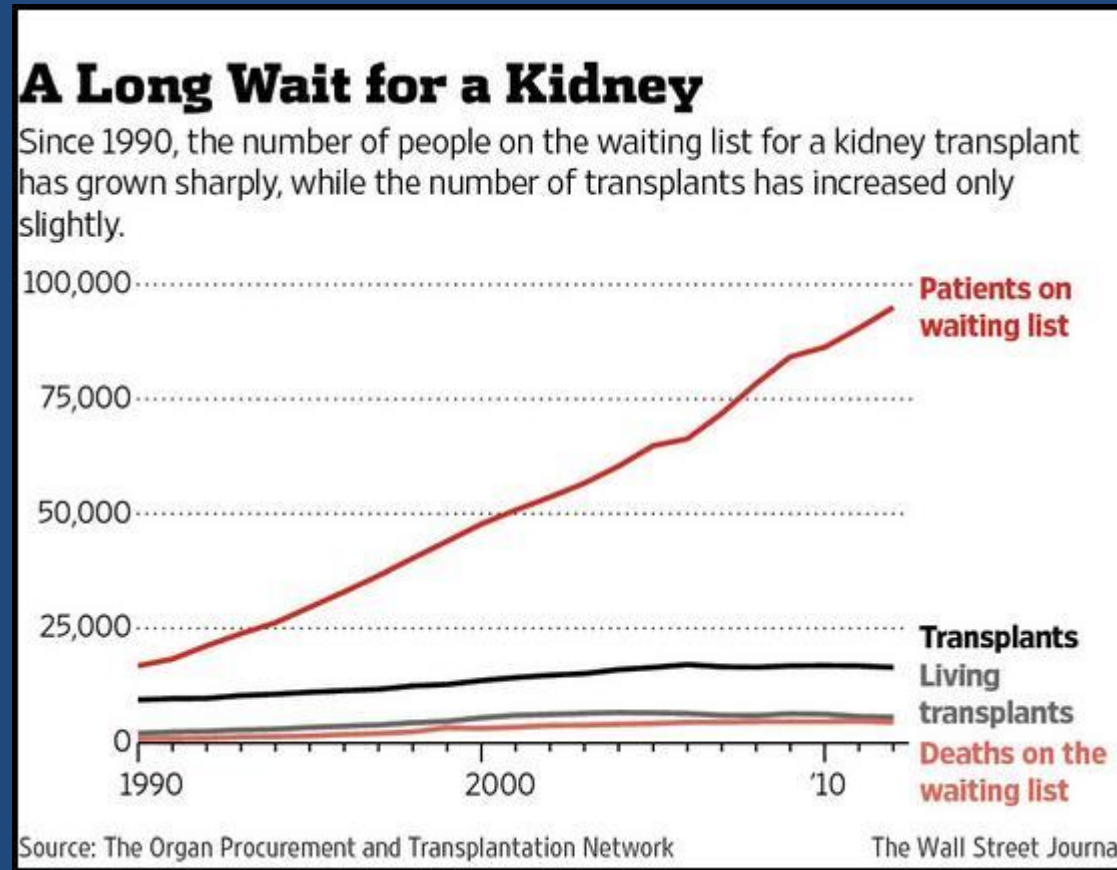
Starting December 2020, national changes will impact deceased donor transplants in NJ

Hepatitis C donor kidneys and update on clinical trials at Saint Barnabas Medical Center

Anup Patel, M.D.
Director of Transplant Research
Saint Barnabas Medical Center
Livingston, New Jersey

October 1, 2020

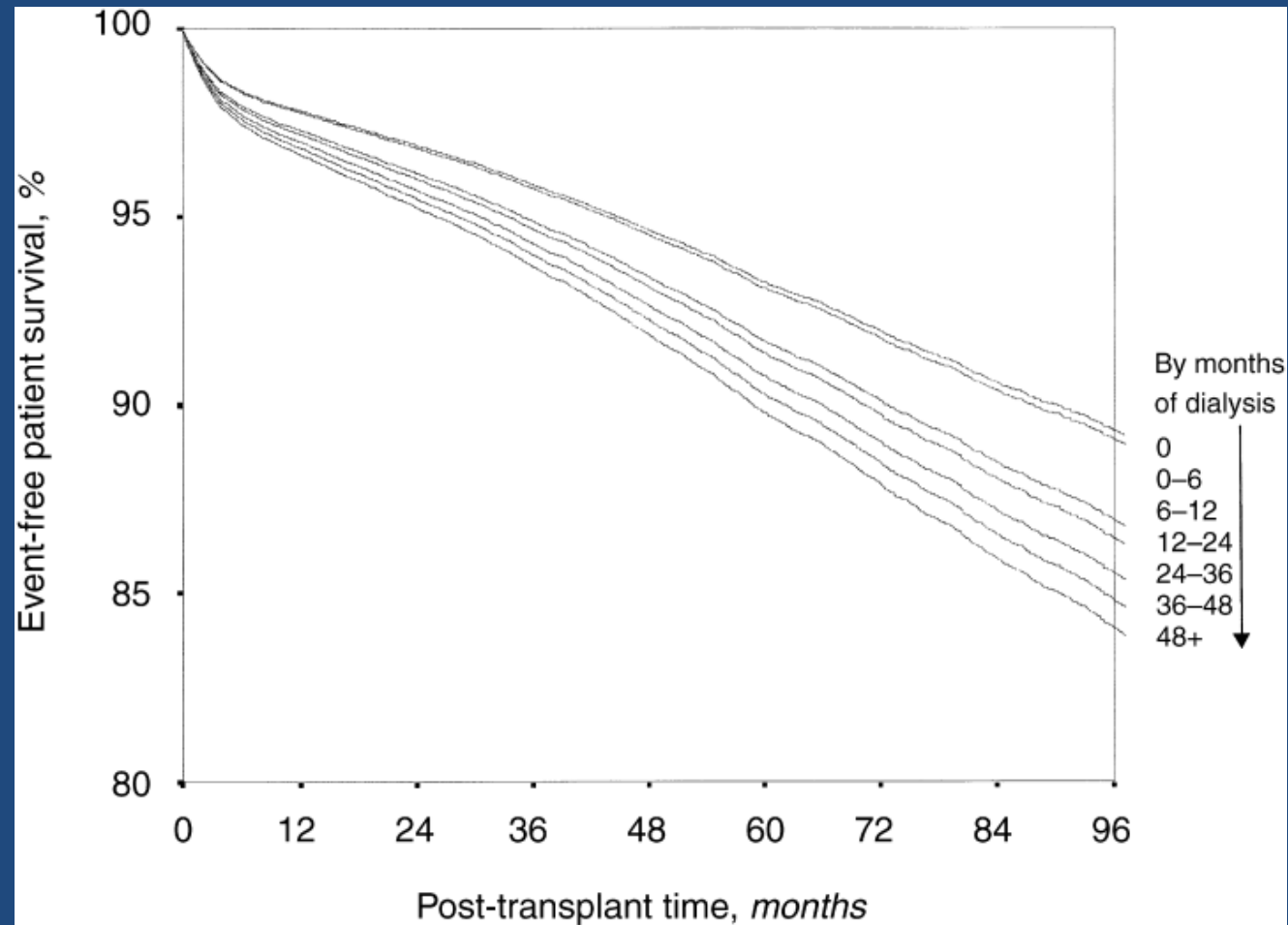
The wait-time for a deceased donor kidney transplant is increasing



What happens to patients on the wait-list?

- Mortality on the wait-list
 - Approximately 6% of wait-listed patients die each year while waiting for a deceased donor kidney transplant
- Removal from the wait-list
 - Approximately 7% of patients are removed from the wait-list each year
 - Medical condition deteriorates (ex- heart attack, stroke, newly diagnosed cancer)
 - Reach the age limit of 75

Effect of dialysis duration on transplant outcome



How can we reduce the wait-time for a kidney transplant?

- Living donation
 - 33 pre-emptive living donor transplants
 - Median wait-time of 6 months
- Accepting donors with hepatitis C (HCV) for recipients without hepatitis C
- In 2019, 236/350 (~67%) of our kidney transplant recipients received either a living donor kidney transplant or a deceased donor kidney transplant within 2 years of active listing or dialysis duration
 - Saint Barnabas Medical Center has the best 3 year patient and allograft survival rates in New Jersey

Why are HCV organs available?

- Fewer transplant candidates with (+)HCV viral load due to newer HCV medications
 - Historically, these were the only patients who could accept a HCV organ
- IVDA epidemic = increased HCV donors
 - Over 500 HCV donor kidneys discarded in USA annually

Trials of direct acting antiviral therapy (DAAT) in kidney transplant patients

- 10 HCV negative patients received HCV+ deceased donor kidneys
 - HCV treatment initiated once HCV viremia detected post-transplant
 - Treatment consisted of Zepatier x 12 weeks
- Results
 - 10/10 patients developed HCV viremia
 - 10/10 patients achieved sustained virologic response (SVR) with treatment
 - 2 cases of transient transaminitis

Trials of DAAT in kidney transplant patients

- 10 HCV negative patients received HCV+ deceased donor kidneys
- Treatment started pre-transplant with Zepatier
 - 5/10 patients never developed viremia
 - 10/10 patients developed SVR
 - No clinical hepatitis

Trials of DAAT in kidney transplant patients

- Study of 80 HCV+ liver transplant and 20 HCV+ kidney transplant organs into recipients who were HCV negative
 - Treated with Mavyret
 - 1/100 with virologic failure (liver transplant recipient)
 - 1 recipient lost to follow-up
 - 98/99 patients developed SVR

Trials of DAAT in kidney transplant patients

- Use of HCV+ deceased donors in HCV- recipients is feasible
 - Excellent sustained virologic response rate with DAAT (reported rates >98% with various regimens)
 - No increase in side effects vs. placebo in previous studies
 - Ok to use with our standard immunosuppressive medications
 - Issues
 - Ideally, would like to give DAAT prophylactically pre-transplant but not allowed by insurance companies
 - DAAT has only been FDA approved for treatment of HCV viremia, not prophylaxis
 - Cost of therapy
 - Insurance approval
 - Interactions with other medications

HCV+ donor into HCV- kidney transplant recipient

- Who should we consent?
 - All listed patients at their first re-evaluation
 - Ok to consent patients sooner if they specifically ask about the protocol
- Exclude:
 - Hepatitis B infection
 - HIV infection
 - Inability to stop one of the contraindicated medications during the first 8 weeks post-transplant
 - Baseline AST and/or ALT >1.5 times higher than the upper limit of normal
 - History of alcohol abuse
 - Complement-dependent cytotoxicity or flow cytometry crossmatch positive

Saint Barnabas experience with HCV+ kidney into HCV- recipient: 1st case

- 74yo male with ESRD due to type 2 diabetes
 - Listed since 9/2017
 - Type O blood
 - Anticipated transplant date: 9/2023
 - Anticipated age at time of transplant is 78 years old: not a candidate
 - 11/2/2018: consented for HCV(+) organ
 - 11/10/2018: received a HCV(+) kidney transplant
 - 11/19/2018: HCV PCR (+)
 - Mavyret x 8 weeks started on 11/23/2018
 - Patient achieved sustained virologic response
 - Doing well with a functioning kidney transplant

SBMC experience with HCV+ kidney into HCV- recipient: 1st 13 cases

Patient	Age at HCV listing	Wait-time at HCV listing (years)	Anticipated transplant date	Transplant date with HCV organ	Last serum Cr	HCV PCR negative?
1	74	1.2	9/2023	11/10/2018	2.0	yes
2	63	3.5	7/2020	2/15/2019	0.9	yes
3	74	1.1	2/2021	2/18/2019	0.8	yes
4	74	3.1	9/2019	3/20/2019	1.2	yes
5	47	5.5	8/2020	4/23/2019	1.4	yes
6	70	3.6	11/2021	5/16/2019	1.6	yes
7	60	0.4	1/2025	5/16/2019	1.1	yes
8	54	2.4	2/2023	5/23/2019	0.8	yes
9	59	5.7	10/2019	5/27/2019	1.2*	yes
10	59	0.6	11/2024	5/27/2019	1.1	yes
11	56	2.3	1/2022	5/30/2019	1.0	yes
12	62	1.3	7/2023	6/13/2019	1.4	yes
13	68	1.9	4/2023	6/13/2019	1.3	yes

*death with functioning graft (Aspergillus fungemia)

SBMC experience with HCV+ kidney into HCV-recipient

- Total of 59 cases from 8/2018-8/2020
 - Death-censored graft survival is 52/54 (96.3%)
 - no patients have HCV viremia after treatment
 - Median LOS =5 days
 - All patients received a HCV DDKT within one year of consenting to receive these offers

Clinical trials at SBMC

- Current trials
 - Non-invasive testing to help predict kidney transplant rejection
 - Novel therapy for CMV prophylaxis in high risk transplant recipients
 - Prevention of recurrent focal segmental glomerulosclerosis post-transplant
 - Novel therapy for treatment of refractory antibody-mediated rejection

Clinical trials

- Cellular immunotherapy for induction of immune tolerance in recipients of HLA-matched, living donor kidney transplants
 - Goal: complete withdrawal of immunosuppression at 1 year post-transplant
 - First patient enrolled 8/12/2019
 - Last dose of immunosuppression on 8/5/2020
 - Kidney transplant biopsy (8/2020): no rejection

Clinical trials

- Upcoming trials
 - Novel therapy for treatment of chronic antibody mediated rejection
 - Novel therapy for treatment of BK viremia after kidney transplantation
 - Use of T-regulatory cells (TREG) to reduce the risk of acute rejection and facilitate immunosuppression weaning in living donor kidney transplant recipients

TREG study

- No HLA matching required
- Goal is to wean down to everolimus monotherapy 12 months post-transplant
 - Typical immunosuppressive regimen consists of tacrolimus and mycophenolic acid with or without steroids
 - Tacrolimus is nephrotoxic and increases the risk of post-transplant diabetes mellitus
 - Mycophenolic acid causes bone marrow suppression and has gastrointestinal side effects

Conclusions

- HCV donor organs significantly reduce wait time for a DDKT
 - Current wait-time is less than one year
 - >98% chance of HCV eradication with a single course of treatment post-transplant
 - Excellent graft survival
- Multiple clinical trials at SBMC that offer novel therapies for our transplant patients which are not available at most transplant centers
 - Tolerance induction and minimization of immunosuppression have the potential to significantly improve kidney transplant survival and quality of life for our transplant recipients