JOHNS HOPKINS
MEDICINE
TRANSPLANT ONCOLOGY
INFECTIOUS DISEASES CLINICAL
RESEARCH CENTER

HIV-HCV: Perspectives and New Frontiers in Solid Organ Transplantation

Christine Durand, MD
Assistant Professor of Medicine and Oncology
Johns Hopkins University, School of Medicine

Disclosures

- Scientific advisor for Gilead Sciences,

Merck Pharmaceuticals, Bristol Myers Squibb

- Research support, paid to Johns Hopkins from Merck Pharmaceuticals, Viiv.

JOHNS HOPKINS
MEDICINE
TRANSPLANT ONCOLOGY
INFECTIOUS DISEASES CLINICAL
RESEARCH CENTER

Outline

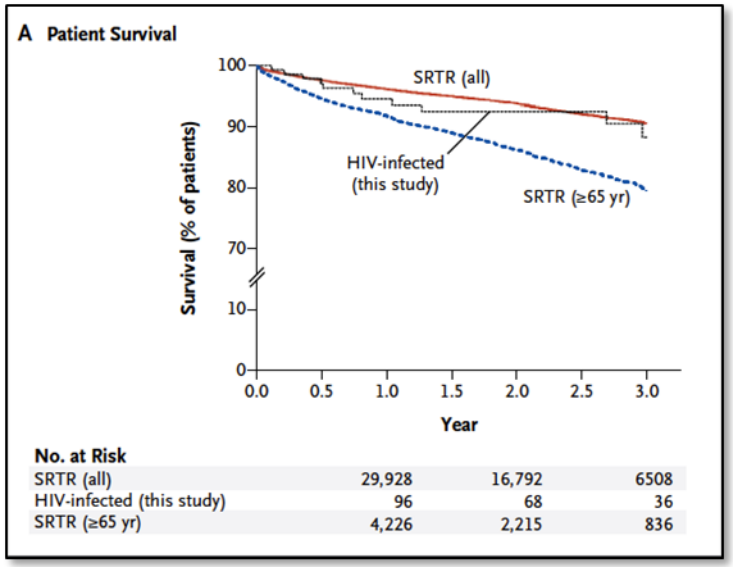
JOHNS HOPKINS
MEDICINE
TRANSPLANT ONCOLOGY
INFECTIOUS DISEASES CLINICAL
RESEARCH CENTER

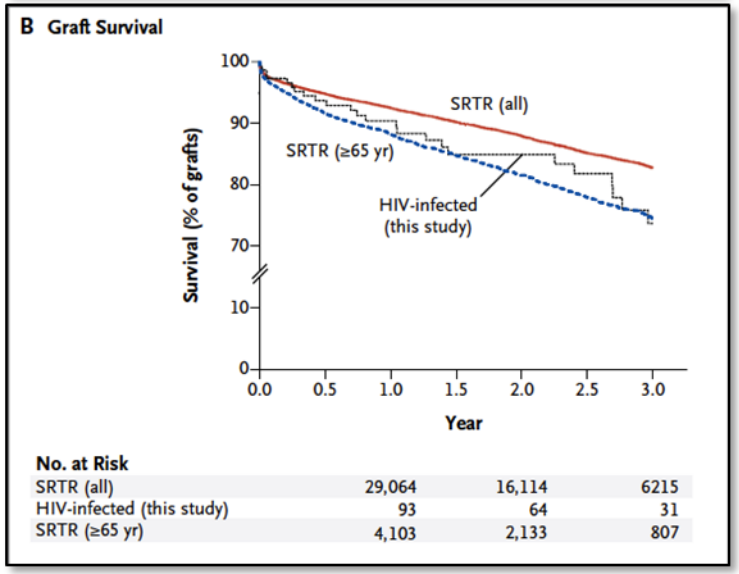
- HIV/HCV co-infection
- Outcomes in HIV/HCV transplant recipients
- HCV treatment in co-infected individuals
- New frontier: HCV+ donors for HCV- recipients

HIV/HCV co-infection and SOT

- Co-infection leads to increased liver- and non-liver morbidity and mortality (Lo-Re 2014, Chen 2009)
- Differences persist in modern ART era (Kirk 2013)
- End stage liver and kidney disease are a growing cause of morbidity and mortality in HIV-infected patients in the era of ART (Lucas 2014; Smith 2014)
- ≈ 1-2% of individuals on dialysis and liver transplant waitlist are HIV+, ≈ 20-40% HIV+ transplant candidates are HCV+

HIV Kidney Transplant (KT)





ORIGINAL ARTICLE

Outcomes of Kidney Transplantation in HIV-Infected Recipients

Peter G. Stock, M.D., Ph.D., Burc Barin, M.S., Barbara Murphy, M.D., Douglas Hanto, M.D., Ph.D., Jorge M. Diego, M.D., Jimmy Light, M.D., Charles Davis, M.D., Emily Blumberg, M.D., David Simon, M.D., Ph.D., Aruna Subramanian, M.D., J. Michael Millis, M.D., G. Marshall Lyon, M.D., Kenneth Brayman, M.D., Doug Slakey, M.D., Ron Shapiro, M.D., Joseph Melancon, M.D., Jeffrey M. Jacobson, M.D., Valentina Stosor, M.D., Jean L. Olson, M.D., Donald M. Stablein, Ph.D., and Michelle E. Roland, M.D. for the HIV-TR Investigators

Kidney

N = 150

Patient survival

1 yr: 95%

3 yr: 91%

4 yr: 89%

Graft survival

1 yr: 90%

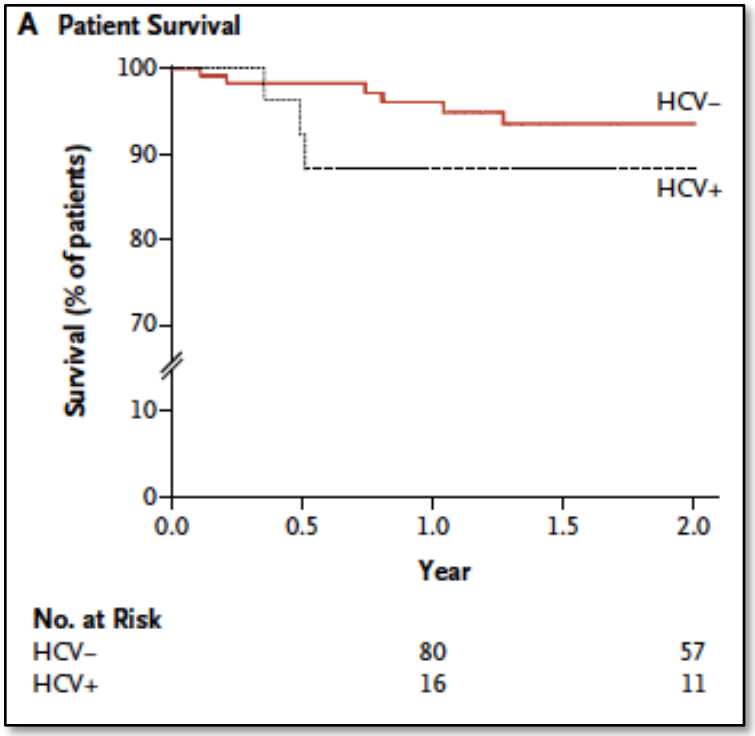
3 yr: 77%

4 yr: 70%

Stock PG/Roland M et al NEJM 2010;363:2004-2014.

Roland M et al AIDS 2016.

HIV/HCV KT survival



	HIV+	> 65 years
1 yr:	95%	92%
3 yr:	91%	79.5%

	HIV+/HCV+	HIV+	
1 yr:	86%	94%	p=.09

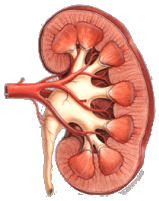
Stock PG et al. NEJM 2010; 363: 2004-2014.

4 year follow-up

- Hazard of death for HCV/HIV = $_{0.8}1.9_{41}$ (p = .19)

Roland M et al AIDS 2016.

HIV/HCV KT outside the NIH trial

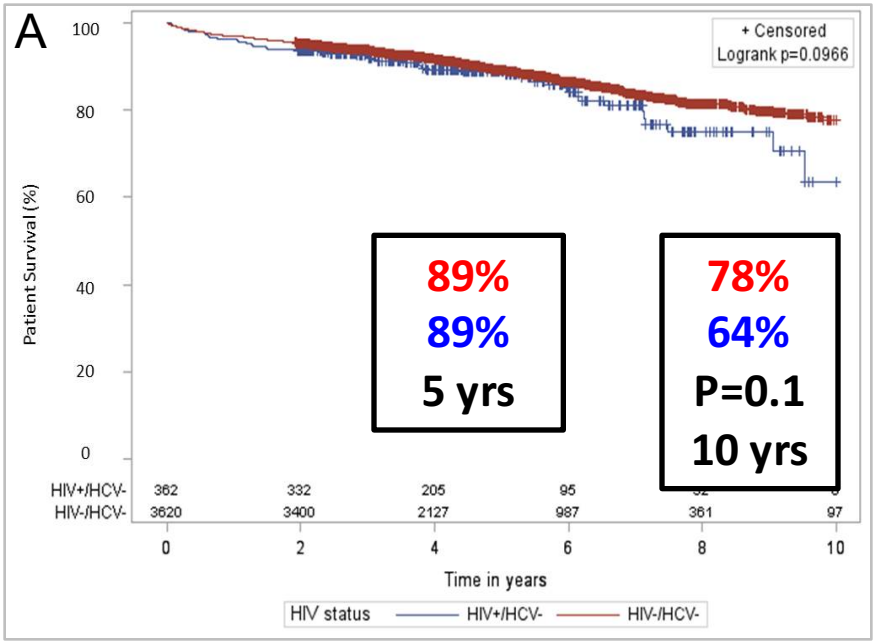


- 514 HIV+ KT recipients in SRTR, 2002-2011
- Matched 1:10 HIV- controls on race, age, sex, BMI, PRA, ATG induction, receipt of steroids, donor age, cold ischemia time
- Graft survival, patient survival through 10 years

SRTR

Locke JE/Segev. JASN, 2015

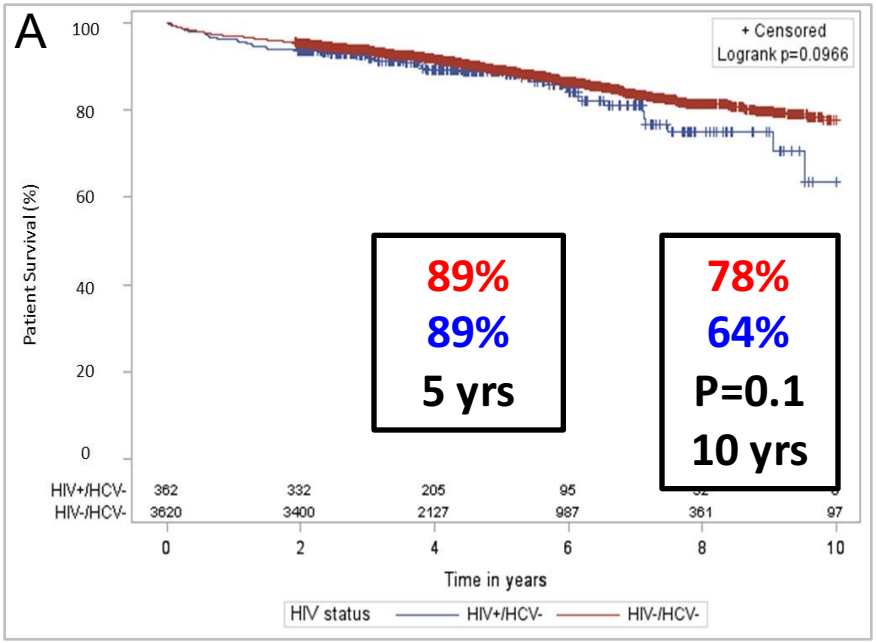
Overall survival out to 10 years

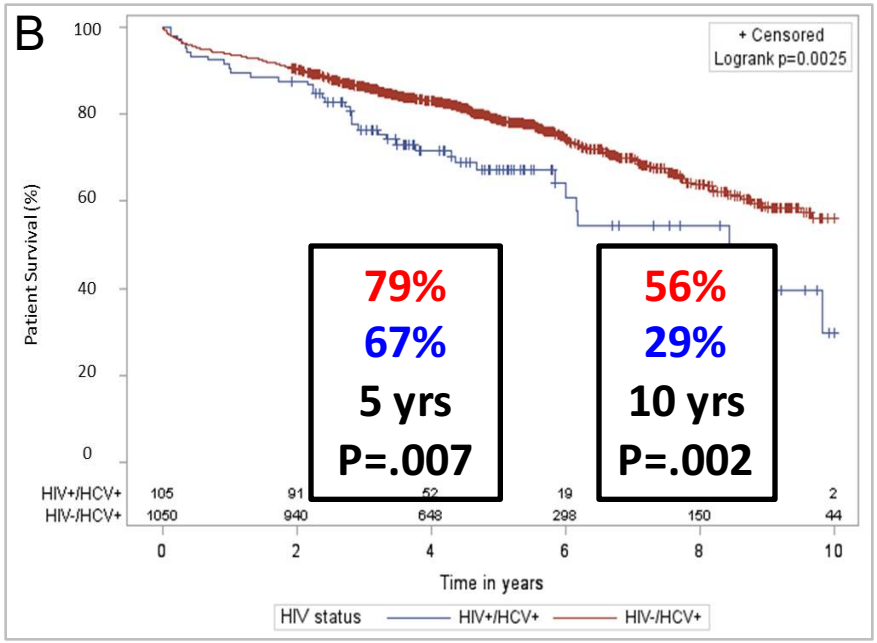


HIV+ compared matched HIV-

Locke JE/Segev. JASN, 2015

Overall survival out to 10 years



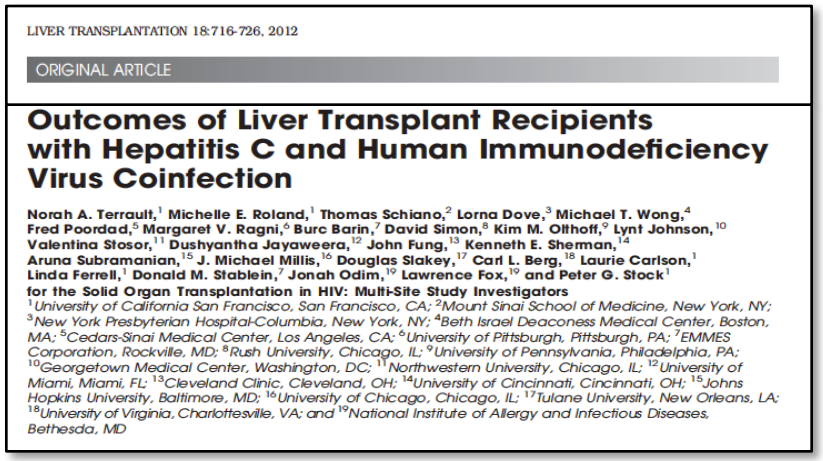


HIV+ compared matched HIV-

HIV/HCV compared matched HCV+

Locke JE/Segev. JASN, 2015

HIV/HCV Liver Transplant (LT)



LIVER TRANSPLANTATION 18:716-726, 2012

ORIGINAL ARTICLE

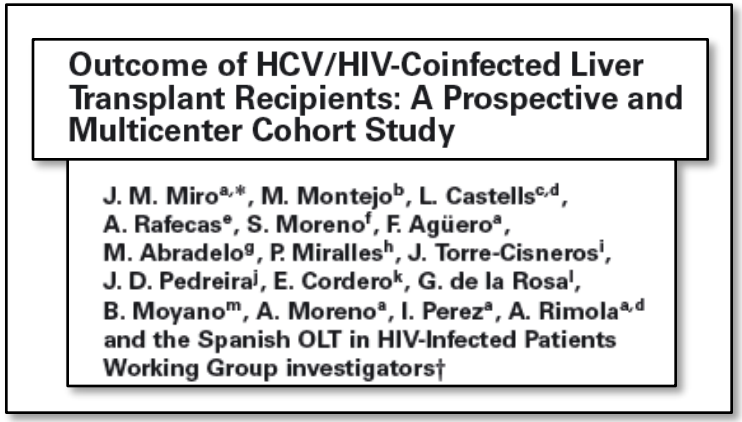
Outcomes of Liver Transplant Recipients with Hepatitis C and Human Immunodeficiency Virus Coinfection

Norah A. Terrault,[1] Michelle E. Roland,[1] Thomas Schiano,[2] Lorna Dove,[3] Michael T. Wong,[4] Fred Poordad,[5] Margaret V. Ragni,[6] Burc Barin,[7] David Simon,[8] Kim M. Olthoff,[9] Lynt Johnson,[10] Valentina Stosor,[11] Dushyantha Jayaweera,[12] John Fung,[13] Kenneth E. Sherman,[14] Aruna Subramanian,[15] J. Michael Millis,[16] Douglas Slakey,[17] Carl L. Berg,[18] Laurie Carlson,[1] Linda Ferrell,[1] Donald M. Stablein,[7] Jonah Odim,[19] Lawrence Fox,[19] and Peter G. Stock[1]
for the Solid Organ Transplantation in HIV: Multi-Site Study Investigators
[1]*University of California San Francisco, San Francisco, CA;* [2]*Mount Sinai School of Medicine, New York, NY;* [3]*New York Presbyterian Hospital-Columbia, New York, NY;* [4]*Beth Israel Deaconess Medical Center, Boston, MA;* [5]*Cedars-Sinai Medical Center, Los Angeles, CA;* [6]*University of Pittsburgh, Pittsburgh, PA;* [7]*EMMES Corporation, Rockville, MD;* [8]*Rush University, Chicago, IL;* [9]*University of Pennsylvania, Philadelphia, PA;* [10]*Georgetown Medical Center, Washington, DC;* [11]*Northwestern University, Chicago, IL;* [12]*University of Miami, Miami, FL;* [13]*Cleveland Clinic, Cleveland, OH;* [14]*University of Cincinnati, Cincinnati, OH;* [15]*Johns Hopkins University, Baltimore, MD;* [16]*University of Chicago, Chicago, IL;* [17]*Tulane University, New Orleans, LA;* [18]*University of Virginia, Charlottesville, VA; and* [19]*National Institute of Allergy and Infectious Diseases, Bethesda, MD*

US NIH study

HIV/HCV+ N = 89

Terrault et al. Liver Transp 2012;18:716-726.



Outcome of HCV/HIV-Coinfected Liver Transplant Recipients: A Prospective and Multicenter Cohort Study

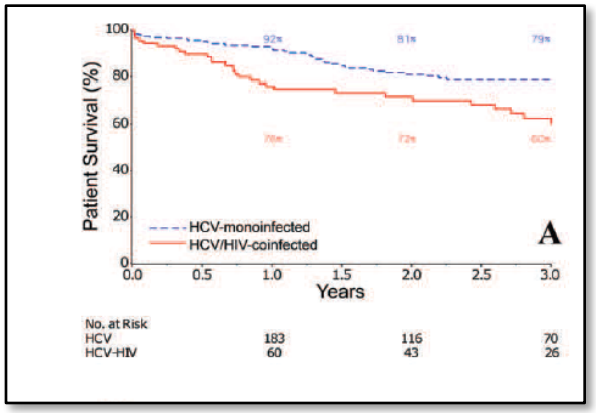
J. M. Miro[a,*], M. Montejo[b], L. Castells[c,d], A. Rafecas[e], S. Moreno[f], F. Agüero[a], M. Abradelo[g], P. Miralles[h], J. Torre-Cisneros[i], J. D. Pedreira[j], E. Cordero[k], G. de la Rosa[l], B. Moyano[m], A. Moreno[a], I. Perez[a], A. Rimola[a,d] and the Spanish OLT in HIV-Infected Patients Working Group investigators†

Spanish study

HIV/HCV+ N = 84

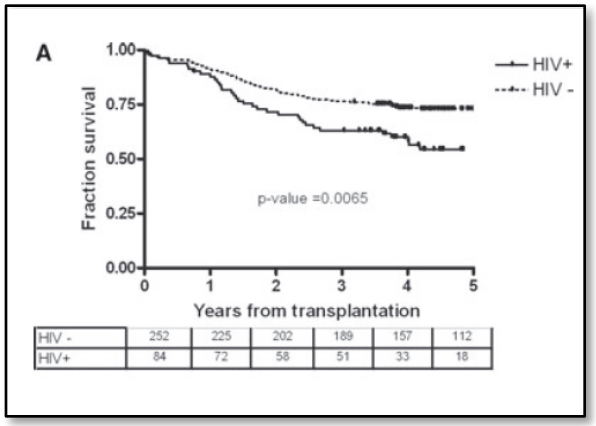
Miro et al. Am J of Trans 2012;12:1866-76.

HIV/HCV Liver Transplant (LT)



US NIH study

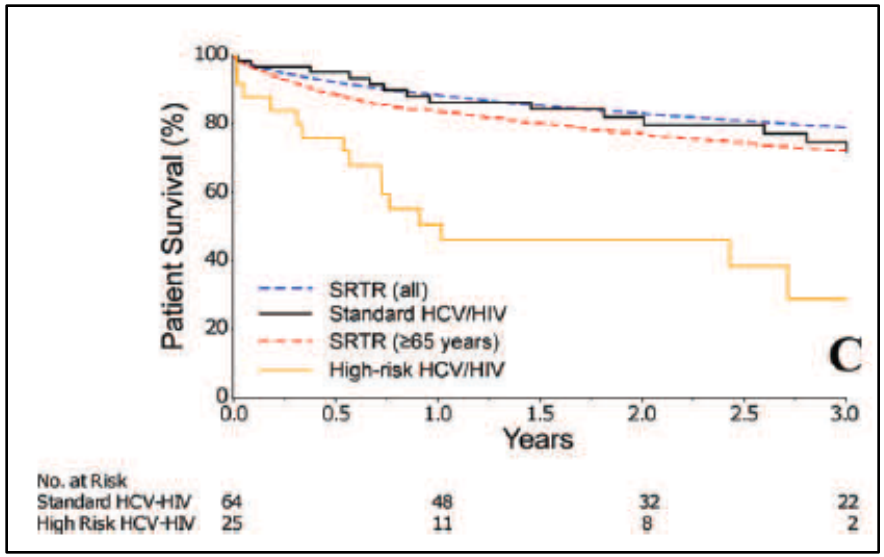
	HIV+/HCV+	HCV+
3 yr:	60%	79%



Spanish study

	HIV+/HCV+	HCV+
5 yr:	54%	71%

Selected lower risk individuals HCV+/HIV+



US NIH Study

HCV negative donor

BMI > 21

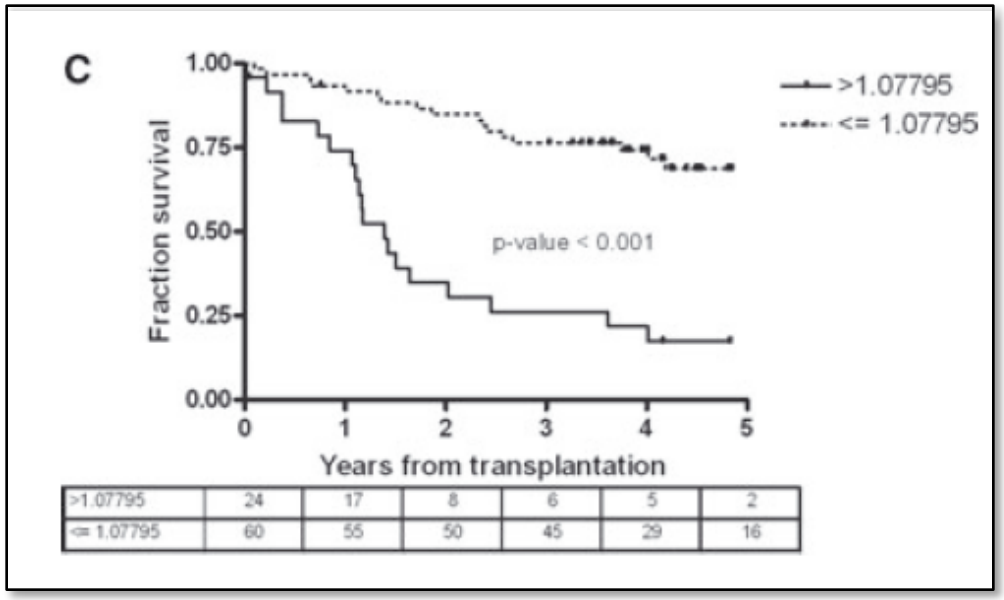
No combined kidney transplant

3 year survival

HIV+/HCV+	low	high	HCV+
60%	72%	29%	79%

Terrault et al Liver Transp 2012;18:716-726.

Selected lower risk individuals HCV+/HIV+



Spanish Study

Favorable HCV genotype

Lower MELD

Experienced hospital

5 year survival

HIV+/HCV+	low	high	HCV+
54%	69%	17%	71%

Miro et al. Am J of Trans 2012;12:1866-76.

SRTR: HIV D-/R+ LT, impact of HCV

N =180 LT recipients 1:10 matched HIV – controls
HIV+/HCV-, HIV+/HCV+, HIV-/HCV+, HIV-/HCV-

TABLE 2.

Survival rates by HIV and HCV status

	Patient survival				Graft survival			
	1 y	3 y	5 y	10 y	1 y	3 y	5 y	10 y
HIV+	77.2%	62.2%	55.8%	41.0%	73.3%	58.2%	50.7%	35.4%
HIV– general	88.2%[a]	79.6%[a]	73.4%[a]	60.9%[a]	85.4%[a]	76.5%[a]	70.1%[a]	57.8%[a]
HIV– matched	87.7%[b]	78.8%[a]	72.1%[a]	57.1%[a]	84.9%[b]	75.3%[a]	68.4%[a]	53.7%[a]
HIV+/HCV–	81.4%	71.9%	64.8%	43.9%	76.3%	66.6%	59.3%	35.1%
HIV–/HCV–	88.8%	82.6%[b]	77.3%[b]	65.3%[b]	85.9%[b]	79.3%[b]	73.8%[b]	62.2%[b]
HIV+/HCV+	77.1%	58.5%	51.8%	44.1%	73.4%	54.8%	46.4%	41.1%
HIV–/HCV+	87.5%[a]	76.3%[a]	69.1%[a]	55.9%[a]	84.9%[a]	73.4%[a]	66.0%[a]	53.0%[a]
HIV+/HCV–	81.4%	71.9%	64.8%	43.9%	76.3%	66.6%	59.3%	35.1%
HIV+/HCV+	77.1%	58.5%	51.8%	44.1%	73.4%	54.8%	46.4%	41.1%

SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Locke JE, Durand CM, Segev DL. Transplantation, 2016.

HCV Treatment in Transplant

- Direct acting antivirals cure HCV in 95-100% of patients
- Effective and tolerated with minimal drug interactions in transplant recipients

HCV Treatment in Transplant

- Direct acting antivirals cure HCV in 95-100% of patients
- Effective and tolerated with minimal drug interactions in transplant recipients

- Pre-transplant or post transplant?
- HCV+ donor organs for HCV+ candidates
- Wait times for organ: weeks vs years

DAA Treatment for HIV/HCV

- ALLY-2: GT1,2,3,4; DAC SOF 12 wks (Wyles 2014)
- C-EDGE: GT1,4,6; EBR GZR 12 wks (Rockstroh 2015)
- ION-4: GT1,4; LDV SOF 12 wks (Naggie 2015)
- TURQUOISE1: GT1; PrOD 12 vs 24 wks (Sulkowski 2015)
- ASTRAL5: GT1,2,3,4; SOF VEL 12 wks (Wyles 2016)

HIV/HCV co-infected individuals

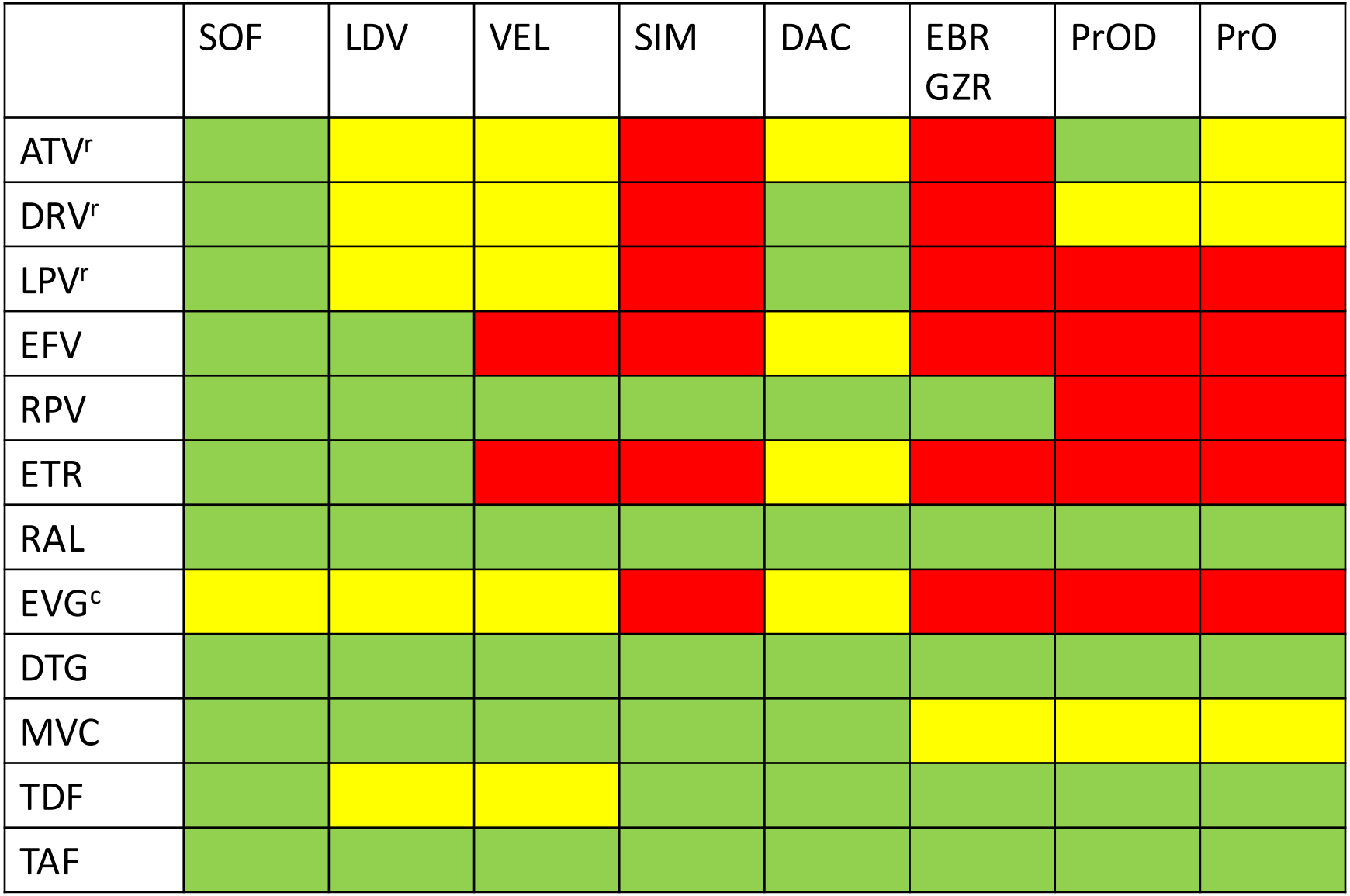
Recommended Regimens for HIV/HCV-Coinfected Individuals

Listed in order of level of evidence, then within group alphabetically.

- **HIV/HCV-coinfected persons should be treated and retreated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications (see Initial Treatment of HCV Infection and Retreatment of Persons in Whom Prior Therapy Has Failed).**
  Rating: Class I, Level B

- **Daily daclatasvir (refer above for dose) plus sofosbuvir (400 mg), with or without ribavirin (refer to Initial Treatment of HCV Infection and Retreatment of Persons in Whom Prior Therapy Has Failed sections for duration) is a Recommended regimen when antiretroviral regimen changes cannot be made to accommodate alternative HCV direct-acting antivirals.**
  Rating: Class I, Level B

SOF=sofosbuvir; LDV=ledipasvir; VEL=velpatasvir; SIM=simeprevir; DAC=daclatasvir; EBV GZR=grazoprevir elbasvir; PrOD=paritaprevir ritonavir ombitasvir dasabuvir; PrO=paritaprevir ritonavir ombitasvir



ATV=atazanavir; r=ritonavir; DRV=darunavir; LPV=lopinavir; EFV=efavirenz ; RPV=rilpivirine; ETR=etravirine; RAL=raltegravir EVG=elvitegravir; c=cobicistat; DTG=dolutegravir; MVC=maraviroc; TDF= tenofovir disoproxil fumarate; TAF=tenofovir alafenamide fumarate;

SOF=sofosbuvir; LDV=ledipasvir; VEL=velpatasvir; SIM=simeprevir; DAC=daclatasvir; EBV GZR=grazoprevir elbasvir; PrOD=paritaprevir ritonavir ombitasvir dasabuvir; PrO=paritaprevir ritonavir ombitasvir

		SOF	LDV	VEL	SIM	DAC	EBR GZR	PrOD	PrO
PIs	ATV^{r}								
	DRV^{r}								
	LPV^{r}								
	EFV								
	RPV								
	ETR								
	RAL								
	EVG^{c}								
	DTG								
	MVC								
	TDF								
	TAF								

ATV=atazanavir; r=ritonavir; DRV=darunavir; LPV=lopinavir; EFV=efavirenz ; RPV=rilpivirine; ETR=etravirine; RAL=raltegravir EVG=elvitegravir; c=cobicistat; DTG=dolutegravir; MVC=maraviroc; TDF= tenofovir disoproxil fumarate; TAF=tenofovir alafenamide fumarate;

SOF=sofosbuvir; LDV=ledipasvir; VEL=velpatasvir; SIM=simeprevir; DAC=daclatasvir; EBV GZR=grazoprevir elbasvir; PrOD=paritaprevir ritonavir ombitasvir dasabuvir; PrO=paritaprevir ritonavir ombitasvir

	SOF	LDV	VEL	SIM	DAC	EBR GZR	PrOD	PrO
ATV^{r}								
DRV^{r}								
LPV^{r}								
NNRTIs EFV								
NNRTIs RPV								
NNRTIs ETR								
RAL								
EVG^{c}								
DTG								
MVC								
TDF								
TAF								

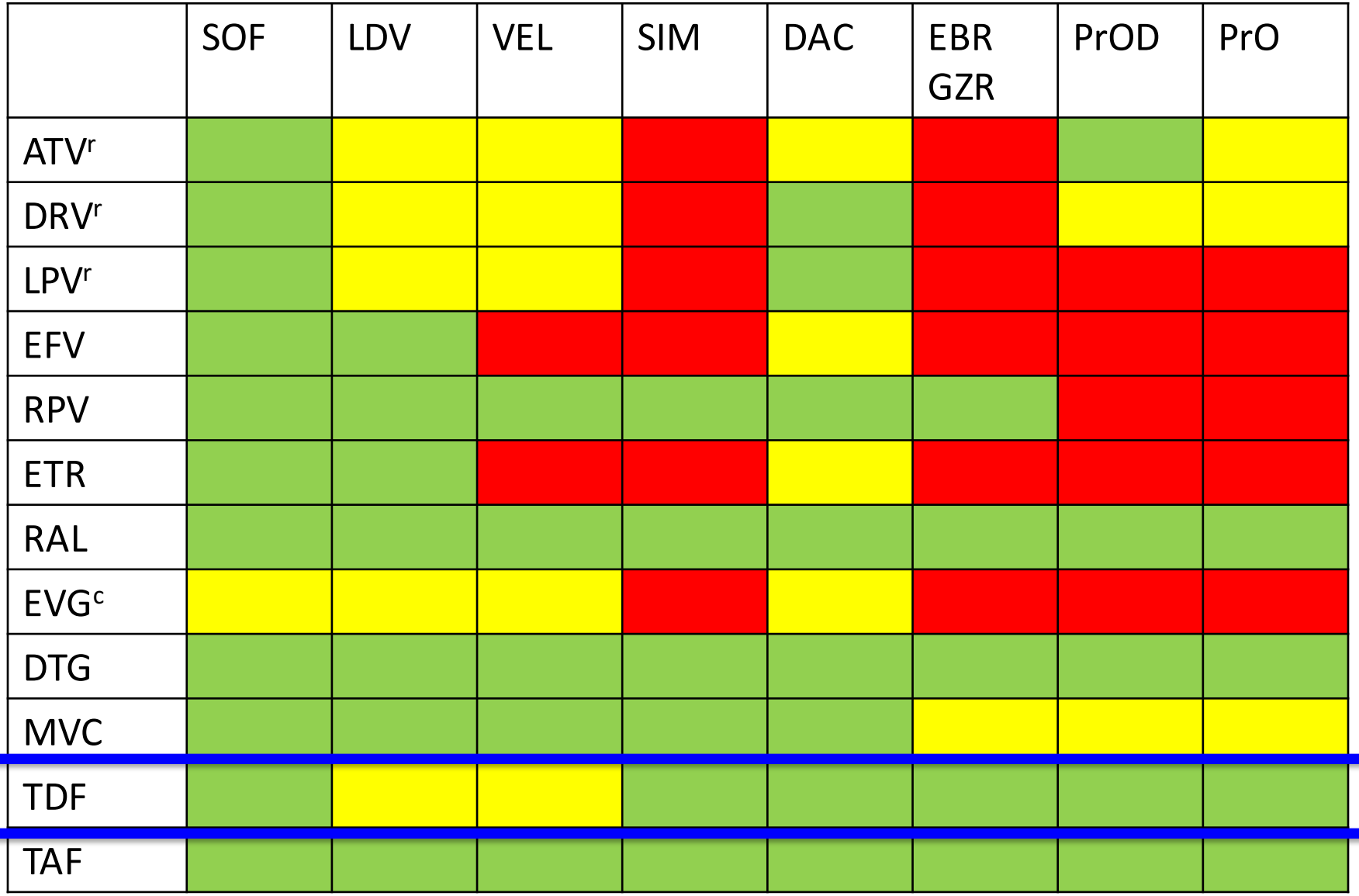
ATV=atazanavir; r=ritonavir; DRV=darunavir; LPV=lopinavir; EFV=efavirenz ; RPV=rilpivirine; ETR=etravirine; RAL=raltegravir EVG=elvitegravir; c=cobicistat; DTG=dolutegravir; MVC=maraviroc; TDF= tenofovir disoproxil fumarate; TAF=tenofovir alafenamide fumarate;

SOF=sofosbuvir; LDV=ledipasvir; VEL=velpatasvir; SIM=simeprevir; DAC=daclatasvir; EBV GZR=grazoprevir elbasvir; PrOD=paritaprevir ritonavir ombitasvir dasabuvir; PrO=paritaprevir ritonavir ombitasvir

	SOF	LDV	VEL	SIM	DAC	EBR GZR	PrOD	PrO
ATV^{r}								
DRV^{r}								
LPV^{r}								
EFV								
RPV								
ETR								
INSTIs RAL								
INSTIs EVG^{c}								
INSTIs DTG								
MVC								
TDF								
TAF								

ATV=atazanavir; r=ritonavir; DRV=darunavir; LPV=lopinavir; EFV=efavirenz ; RPV=rilpivirine; ETR=etravirine; RAL=raltegravir EVG=elvitegravir; c=cobicistat; DTG=dolutegravir; MVC=maraviroc; TDF= tenofovir disoproxil fumarate; TAF=tenofovir alafenamide fumarate;

SOF=sofosbuvir; LDV=ledipasvir; VEL=velpatasvir; SIM=simeprevir; DAC=daclatasvir; EBV GZR=grazoprevir elbasvir; PrOD=paritaprevir ritonavir ombitasvir dasabuvir; PrO=paritaprevir ritonavir ombitasvir



ATV=atazanavir; r=ritonavir; DRV=darunavir; LPV=lopinavir; EFV=efavirenz ; RPV=rilpivirine; ETR=etravirine; RAL=raltegravir EVG=elvitegravir; c=cobicistat; DTG=dolutegravir; MVC=maraviroc; TDF= tenofovir disoproxil fumarate; TAF=tenofovir alafenamide fumarate;

SOF=sofosbuvir; LDV=ledipasvir; VEL=velpatasvir; SIM=simeprevir; DAC=daclatasvir; EBV GZR=grazoprevir elbasvir; PrOD=paritaprevir ritonavir ombitasvir dasabuvir; PrO=paritaprevir ritonavir ombitasvir

	SOF	LDV	VEL	SIM	DAC	EBR GZR	PrOD	PrO
ATV^{r}								
DRV^{r}								
LPV^{r}								
EFV								
RPV								
ETR								
RAL								
EVG^{c}								
DTG								
MVC								
TDF								
TAF								

ATV=atazanavir; r=ritonavir; DRV=darunavir; LPV=lopinavir; EFV=efavirenz ; RPV=rilpivirine; ETR=etravirine; RAL=raltegravir EVG=elvitegravir; c=cobicistat; DTG=dolutegravir; MVC=maraviroc; TDF= tenofovir disoproxil fumarate; TAF=tenofovir alafenamide fumarate;

hcvguidelines.org

- UNIQUE PATIENT POPULATIONS: PATIENTS WITH HIV/HCV COINFECTION
- UNIQUE PATIENT POPULATIONS: PATIENTS WITH DECOMPENSATED CIRRHOSIS
- UNIQUE PATIENT POPULATIONS: PATIENTS WHO DEVELOP RECURRENT HCV INFECTION POST–LIVER TRANSPLANTATION
- UNIQUE PATIENT POPULATIONS: PATIENTS WITH RENAL IMPAIRMENT

American Association for the Study of Liver Diseases

AASLD

Recommendations for Testing, Managing, and Treating Hepatitis C

IDSA

Infectious Diseases Society of America

HCV treatment in liver transplant

Recommended Regimens for Treatment-naïve and -Experienced Patients with HCV Genotype 1 or 4 Infection in the Allograft, Including Those with Compensated Cirrhosis

Recommended regimens are listed in groups by level of evidence, then alphabetically.

- **Daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) with weight-based ribavirin for 12 weeks is a Recommended regimen for patients with HCV genotype 1 or 4 infection in the allograft, including those with compensated cirrhosis.**
  Rating: Class I, Level A

- **Daily daclatasvir (60 mg) plus sofosbuvir (400 mg) with low initial dose of ribavirin (600 mg, increased as tolerated) for 12 weeks is a Recommended regimen for patients with HCV genotype 1 or 4 infection in the allograft, including those with compensated cirrhosis.**
  Rating: Class I, Level B

Recommended Regimens for Treatment-naïve Patients with HCV Genotype 1 or 4 Infection in the Allograft and with Compensated Liver Disease, Who Are Ribavirin Ineligible

Recommended regimens are listed in groups by level of evidence, then alphabetically.

- **Daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) for 24 weeks is a Recommended regimen for treatment-naïve patients with HCV genotype 1 or 4 infection in the allograft and with compensated liver disease, who are ribavirin ineligible.**
  Rating: Class I, Level B

- **Daily daclatasvir (60 mg) plus sofosbuvir (400 mg) for 24 weeks is a Recommended regimen for patients with HCV genotype 1 or 4 infection in the allograft and with compensated liver disease, who are ribavirin ineligible.**
  Rating: Class II, Level C

For HIV+/HCV+ transplant recipients…

- UNIQUE PATIENT POPULATIONS: PATIENTS WITH HIV/HCV COINFECTION
- UNIQUE PATIENT POPULATIONS: PATIENTS WITH DECOMPENSATED CIRRHOSIS
- UNIQUE PATIENT POPULATIONS: PATIENTS WHO DEVELOP RECURRENT HCV INFECTION POST–LIVER TRANSPLANTATION
- UNIQUE PATIENT POPULATIONS: PATIENTS WITH RENAL IMPAIRMENT

hcvguidelines.org

American Association for the Study of Liver Diseases

AASLD

Recommendations for Testing, Managing, and Treating Hepatitis C

IDSA

Infectious Diseases Society of America

Clinical case: HIV/HCV SOT

- 55 year old African American with HIV infection on efavirenz, abacavir, lamivudine
- Renal transplant, 2 months prior
- Chronic hepatitis C, genotype 1a
- Treatment naive
- F3 disease on biopsy

Clinical case: HIV/HCV SOT

- 55 year old African American with HIV infection on efavirenz, abacavir, lamivudine
- Renal transplant, 2 months prior
- Chronic hepatitis C, genotype 1a
- Treatment naive
- F3 disease on biopsy
- LDV/SOF for 12 weeks

Clinical case: HIV/HCV SOT

- LDV/SOF for 12 weeks
- Baseline viral load 1.2 million
- Week 4 viral load < 15 IU/mL
- Remained < 15 IU/mL on treatment

Clinical case: HIV/HCV SOT

- LDV/SOF for 12 weeks
- Baseline viral load 1.2 million
- Week 4 viral load < 15 IU/mL
- Remained < 15 IU/mL on treatment
- Week 4 off treatment: 550,000 IU/mL

Clinical case: HIV/HCV SOT

- LDV/SOF for 12 weeks
- Baseline viral load 1.2 million
- Week 4 viral load < 15 IU/mL
- Remained < 15 IU/mL on treatment
- Week 4 off treatment: 550,000 IU/mL
- Genotype: Q80K positive, NS5A resistance

Relapse in HIV/HCV SOT

- Reasons for failure?
  - Multiply immunocompromised (transplant, HIV)
  - African American, on EFV, ION4 study lower SVR12 rates unexplained by PK data
- Retreatment options – June 2015
  - Sofosbuvir + Paritaprevir ritonavir ombitasvir dasabuvir + ribavirin for 24 weeks
  - February 2016 confirmed SVR12

JOHNS HOPKINS
MEDICINE

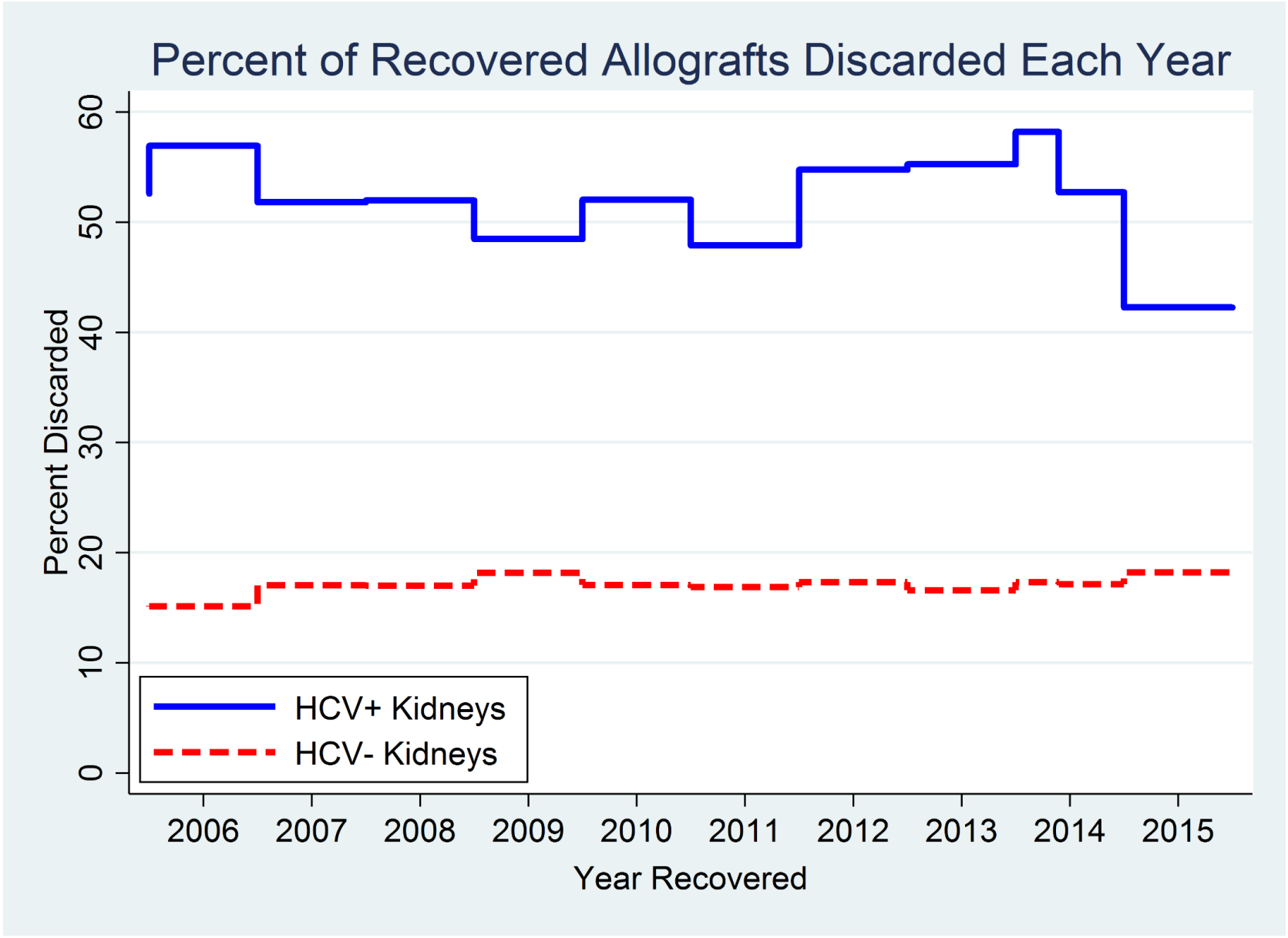
EPIDEMIOLOGY
RESEARCH GROUP IN
ORGAN TRANSPLANTATION

EXPANDER: Exploring Transplants Using Hepatitis-C Infected Donor Kidneys for HCV-Negative Recipients

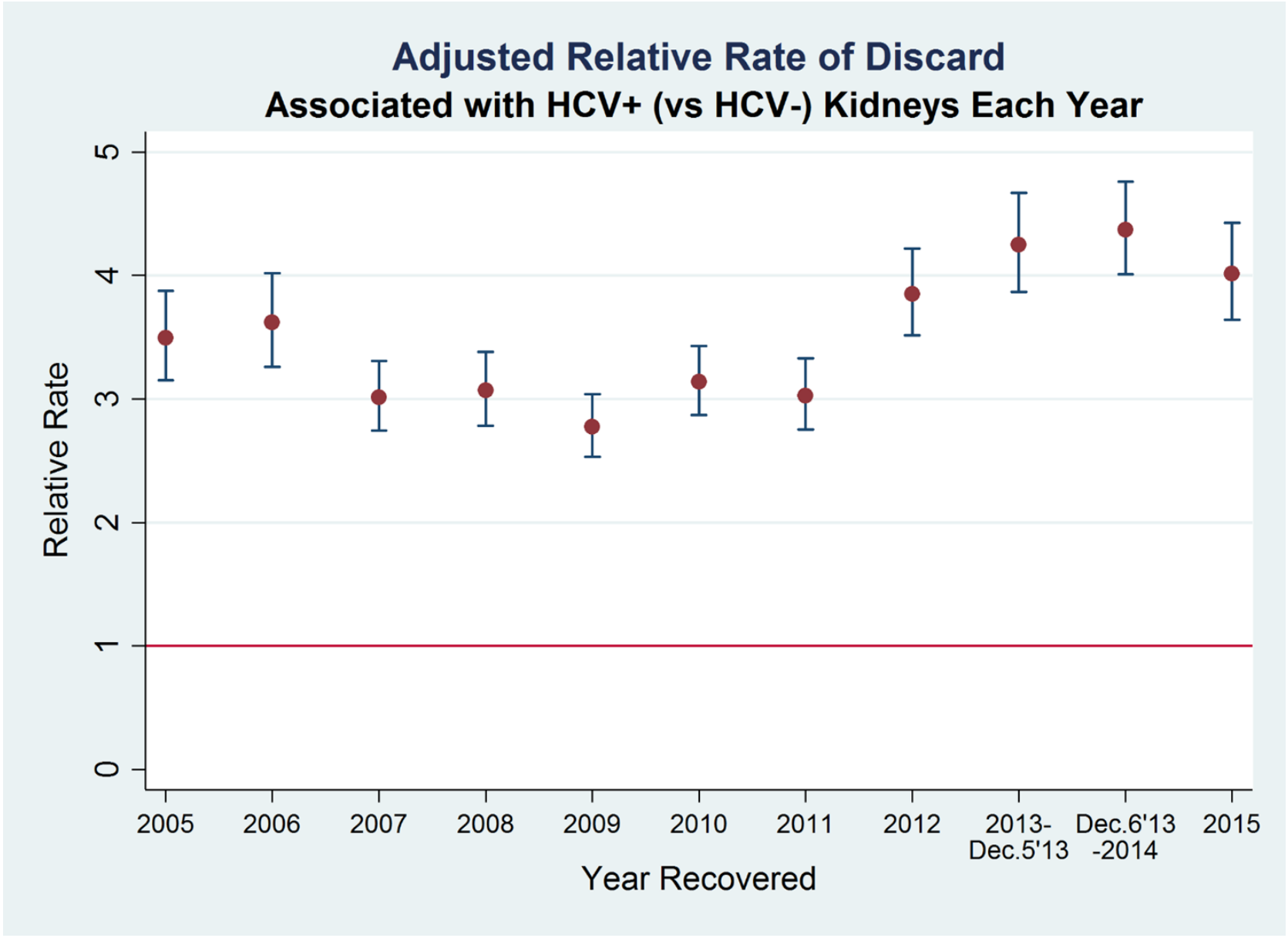
Christine M. Durand, Diane Brown, Nicole Bair, Russell Wesson, Michael A. Chattergoon, Guido Massaccesi, Ashraf Reyad, Fizza Naqvi, Darin Ostrander, Mary Grace Bowring, Samantha Halpern, Allan B. Massie, Sarah Rasmussen, Jeremy Sugarman, Dorry L. Segev, Mark Sulkowski, **Niraj M. Desai**

HCV+ Donors

- Number of HCV+ donor kidneys exceeds number of HCV+ kidney transplant candidates



Bowring/Durand ASTS 2016

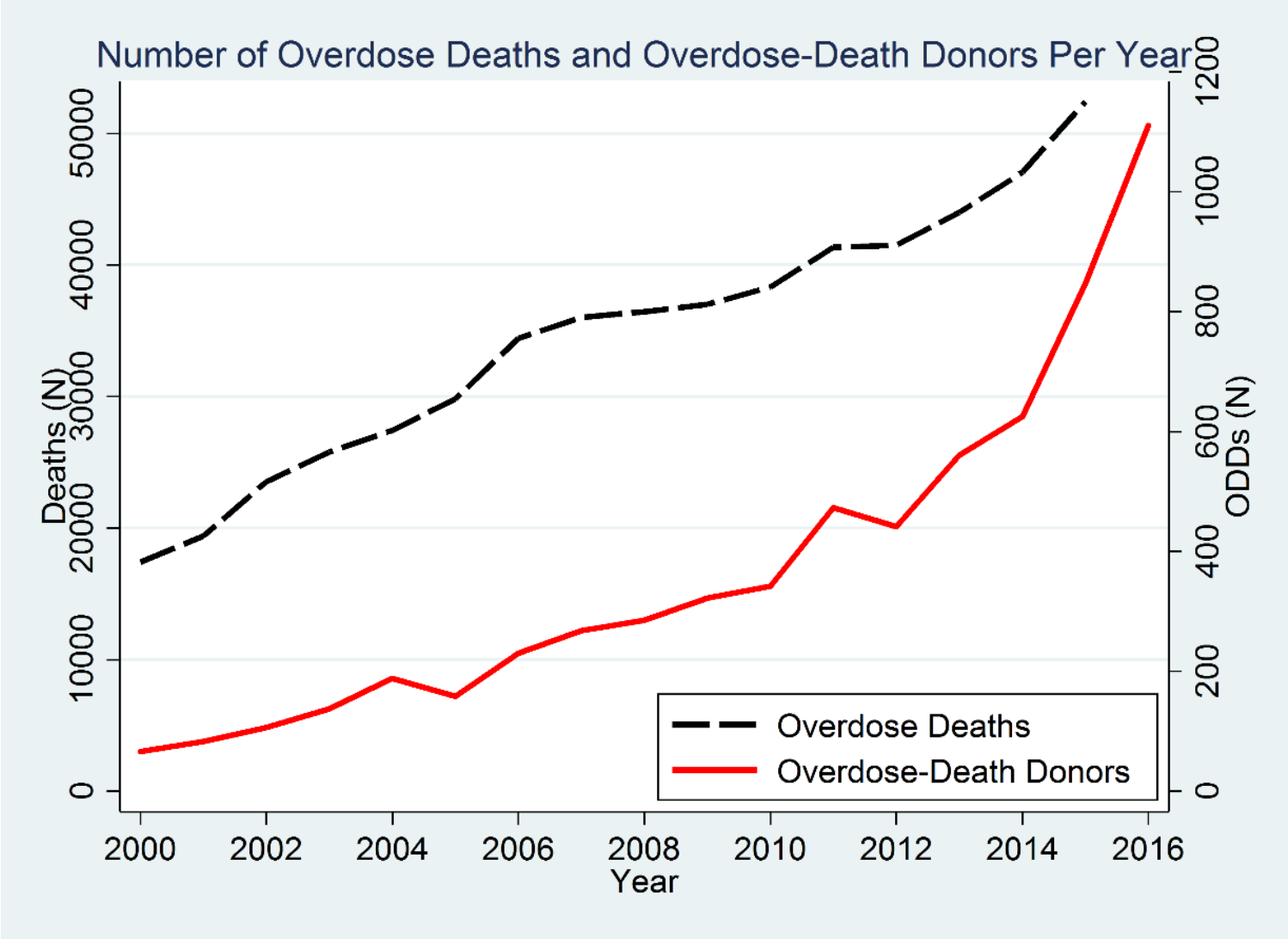


Bowring/Durand ASTS 2016

HCV+ Donors

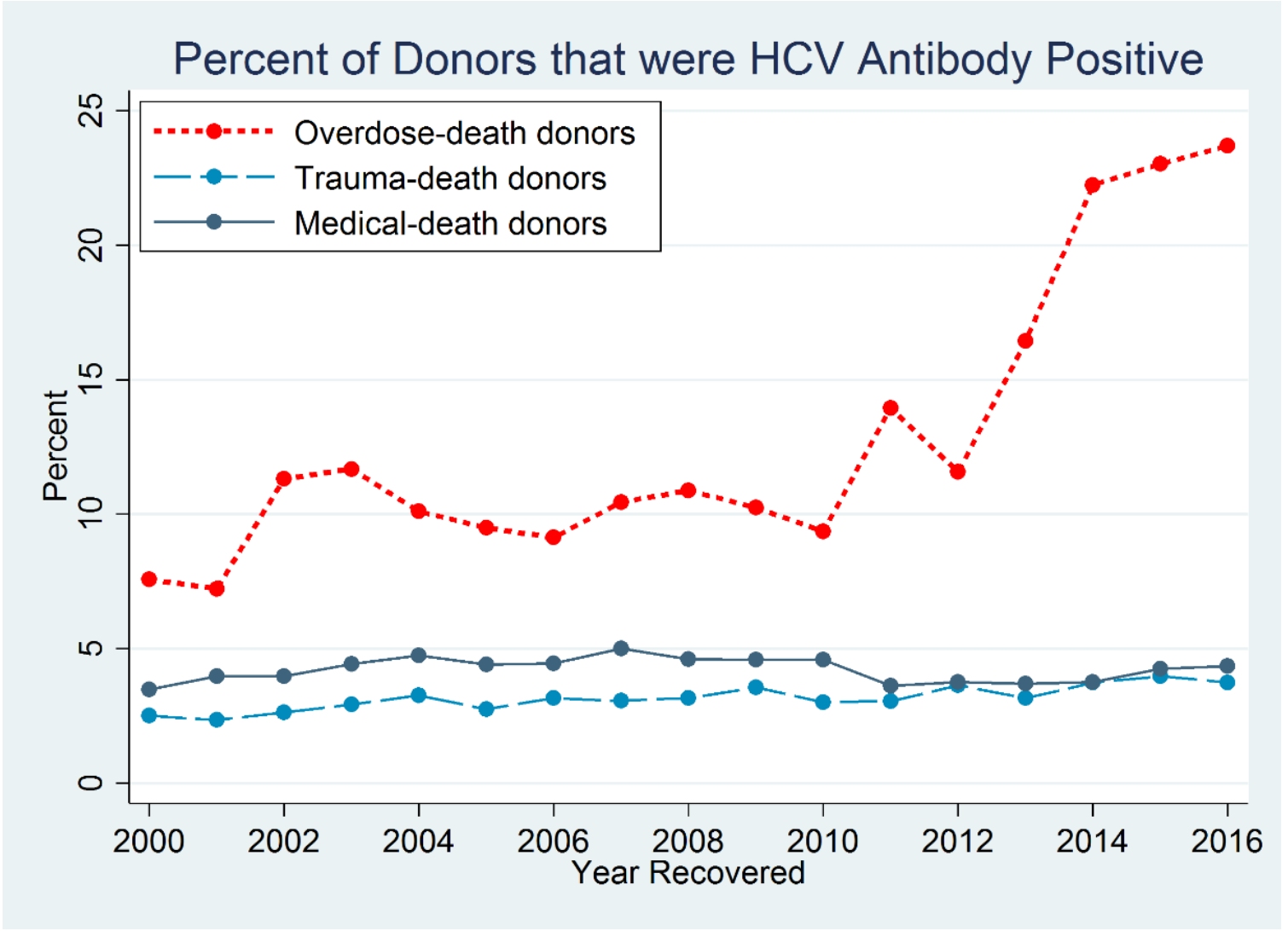
- Number of HCV+ donor kidneys exceeds number of HCV+ kidney transplant candidates
  - > 40% of recovered HCV+ kidneys discarded
  - 4X discard rate compared to HCV-
- Potential pool of HCV+ kidneys may be larger since not all HCV+ kidneys are recovered

Opioid overdose death donors



Bowring/Durand ATC 2016

Overdose death donors: 25% HCV+



Bowring/Durand ATC 2016

Major advances in HCV Treatment

- Direct acting antivirals cure HCV in 95-100% of patients,[1] effective and tolerated with minimal drug interactions in studies of transplant recipients[2]
- In 2016, Grazoprevir/Elbasvir (GZR/EBR) approved for HCV treatment in chronic or end-stage renal disease[3]

[1]Sulkowski NEJM 2014
[2]Kwo NEJM 2014
[3]Roth Lancet 2015

EXPANDER: Objectives

- To explore the use of HCV D+ kidneys for transplant for HCV- recipients (HCV D+/R-)

EXPANDER: Objectives

- To explore the use of HCV D+ kidneys for transplant for HCV- recipients (HCV D+/R-)
- To use DAAs pre- and post-transplant prophylaxis to prevent HCV infection in HCV- recipients

EXPANDER: Objectives

- To explore the use of HCV D+ kidneys for transplant for HCV- recipients (HCV D+/R-)
- To use DAAs pre- and post-transplant prophylaxis to prevent HCV infection in HCV- recipients

EXPANDER Trial

HCV- Participant Inclusion Criteria

- On deceased donor transplant waitlist at JHU
- On dialysis or GFR < 15 ml/min
- ≥ 50 years old
- HCV-

EXPANDER Trial

HCV- Participant Inclusion Criteria

- On deceased donor transplant waitlist at JHU
- On dialysis or GFR < 15 ml/min
- ≥ 50 years old
- HCV-

HCV+ Donor Inclusion Criteria

- Age 13-50
- Creatinine < 3.0 mg/dL, normal renal biopsy
- **Qualitative** HCV NAT+, UNOS screening test
- HCV genotype sent to commercial lab

EXPANDER Trial

HCV- Participant Inclusion Criteria

- On deceased donor transplant waitlist at JHU
- On dialysis or GFR < 15 ml/min
- ≥ 50 years old
- HCV-

HCV+ Donor Inclusion Criteria

- Age 13-50
- Creatinine < 3.0 mg/dL, normal renal biopsy
- **Qualitative** HCV NAT+, UNOS screening test
- HCV genotype sent to commercial lab

EXPANDER Trial

HCV- Participant Inclusion Criteria

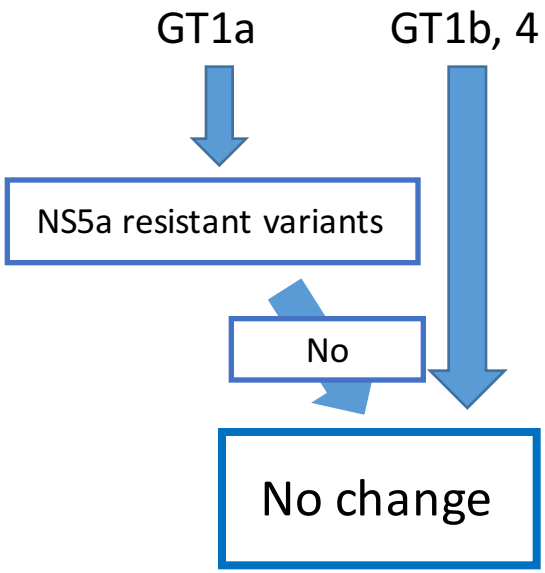
- On deceased donor transplant waitlist at JHU
- On dialysis or GFR < 15 ml/min
- ≥ 50 years old
- HCV-

HCV+ Donor Inclusion Criteria

- Age 13-50
- Creatinine < 3.0 mg/dL, normal renal biopsy
- **Qualitative** HCV NAT+, UNOS screening test
- HCV genotype sent to commercial lab

HCV D+/R- Transplant N =10

GZR EBR on call to OR
Daily for 12 weeks



EXPANDER Trial

HCV- Participant Inclusion Criteria

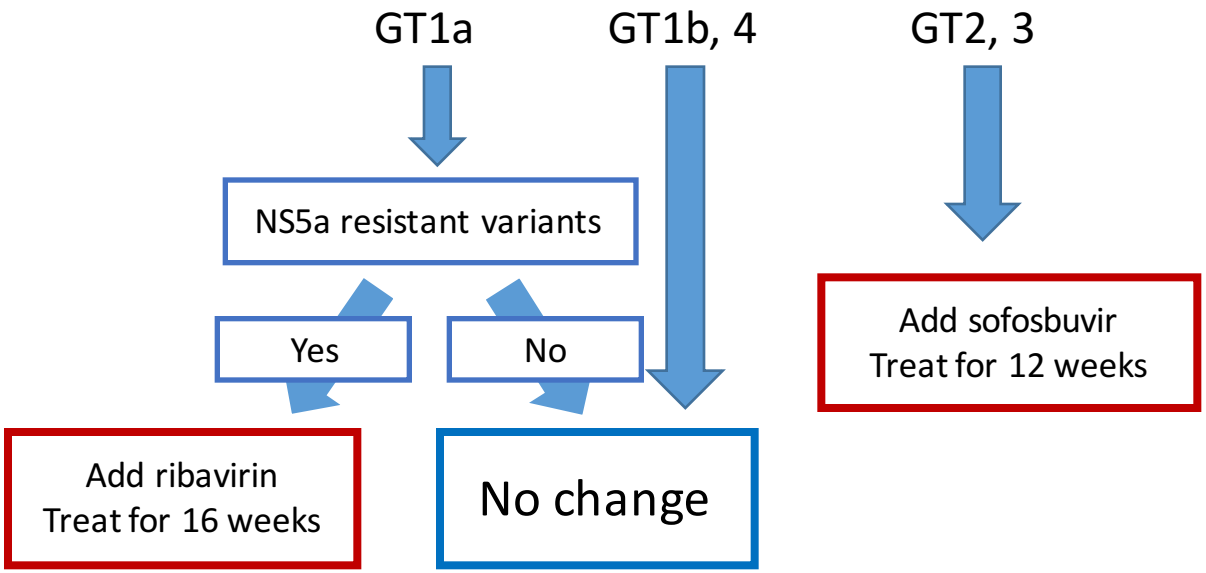
- On deceased donor transplant waitlist at JHU
- On dialysis or GFR < 15 ml/min
- ≥ 50 years old
- HCV-

HCV+ Donor Inclusion Criteria

- Age 13-50
- Creatinine < 3.0 mg/dL, normal renal biopsy
- **Qualitative** HCV NAT+, UNOS screening test
- HCV genotype sent to commercial lab

HCV D+/R- Transplant N =10

GZR EBR on call to OR
Daily for 12 weeks



Monitoring and Endpoints

Recipient HCV Plasma RNA

- Post-operative day (POD1)
- On treatment weeks (TW) 1, 2, 3, 4, 8, 12
- Follow up off treatment (FW) 2, 4, 8, 12

Primary endpoints

- Safety: adverse events related to GZR/EBR
- Efficacy: HCV RNA FW12 (definition of HCV cure)

Results

- From 8/2016 – 2/2017: 10 HCV D+/R- transplants
- 10/10 participants have completed treatment

- Safety: No adverse events related to treatment
- Efficacy: 6/10 have reached final endpoint (FW12)

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White

Age: median 30 (21-42)

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41

KDPI: median 45 (34-62)

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

*Donor qualitative nucleic acid test positive

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

*Donor qualitative nucleic acid test positive

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

*Donor qualitative nucleic acid test positive

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

*Donor qualitative nucleic acid test positive

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

*Donor qualitative nucleic acid test positive

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male

Age: median 71 (57-76)

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male
Wait time	36	4.1	12.2	4.4	0.8	2.3	34.6	0.9	0.8	18.3

Median time on the waitlist: 4.2 months (0.8-36)

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male
Wait time	36	4.1	12.2	4.4	0.8	2.3	34.6	0.9	0.8	18.3
From entry	0.5	0.7	1.0	1.0	0.4	1.4	4.0	2.0	0.9	2.7

Median time on the waitlist: 4.2 months (0.8-36)

Median wait from study entry to transplant: 1 month

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male
Wait time	36	4.1	12.2	4.4	0.8	2.3	34.6	0.9	0.8	18.3
From entry	0.5	0.7	1.0	1.0	0.4	1.4	4.0	2.0	0.9	2.7

HCV RNA on treatment (TW)

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male
Wait time	36	4.1	12.2	4.4	0.8	2.3	34.6	0.9	0.8	18.3
From entry	0.5	0.7	1.0	1.0	0.4	1.4	4.0	2.0	0.9	2.7

HCV RNA on treatment (TW)										
POD 1	<15	<15	<15	<15^{++}	<15	94	<15^{++}	136	<15	32

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male
Wait time	36	4.1	12.2	4.4	0.8	2.3	34.6	0.9	0.8	18.3
From entry	0.5	0.7	1.0	1.0	0.4	1.4	4.0	2.0	0.9	2.7

HCV RNA on treatment (TW)										
POD 1	<15	<15	<15	<15^{++}	<15	94	<15^{++}	136	<15	32

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male
Wait time	36	4.1	12.2	4.4	0.8	2.3	34.6	0.9	0.8	18.3
From entry	0.5	0.7	1.0	1.0	0.4	1.4	4.0	2.0	0.9	2.7

HCV RNA on treatment (TW)										
POD 1	<15	<15	<15	<15^{++}	<15	94	<15^{++}	136	<15	32

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male
Wait time	36	4.1	12.2	4.4	0.8	2.3	34.6	0.9	0.8	18.3
From entry	0.5	0.7	1.0	1.0	0.4	1.4	4.0	2.0	0.9	2.7

HCV RNA on treatment (TW)										
POD 1	<15	<15	<15	<15++	<15	94	<15++	136	<15	32
TW1	<15	<15	<15	<15	<15	<15	<15	55	<15	<15

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male
Wait time	36	4.1	12.2	4.4	0.8	2.3	34.6	0.9	0.8	18.3
From entry	0.5	0.7	1.0	1.0	0.4	1.4	4.0	2.0	0.9	2.7

HCV RNA on treatment (TW)										
POD 1	<15	<15	<15	<15^{++}	<15	94	<15^{++}	136	<15	32
TW1	<15	<15	<15	<15	<15	<15	<15	55	<15	<15
TW4	<15	<15	<15	<15	<15	<15	missed	<15	<15	<15
TW8	<15	<15	<15	<15	<15	<15	<15	<15	<15	<15
TW12	<15	<15	<15	<15	<15	<15	<15	<15	<15	<15

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male
Wait time	36	4.1	12.2	4.4	0.8	2.3	34.6	0.9	0.8	18.3
From entry	0.5	0.7	1.0	1.0	0.4	1.4	4.0	2.0	0.9	2.7

HCV RNA on treatment (TW)										
POD 1	<15	<15	<15	<15++	<15	94	<15++	136	<15	32
TW1	<15	<15	<15	<15	<15	<15	<15	55	<15	<15
TW4	<15	<15	<15	<15	<15	<15	missed	<15	<15	<15
TW8	<15	<15	<15	<15	<15	<15	<15	<15	<15	<15
TW12	<15	<15	<15	<15	<15	<15	<15	<15	<15	<15

HCV RNA Follow up off treatment (FW)										
FW2	<15	<15	<15	<15	<15	<15	<15	<15	<15	<15
FW4	<15	<15	<15	< 15	<15	<15	<15	<15	<15	
FW8	<15	<15	<15	<15	<15	<15	<15	<15	<15	
FW12	<15	<15	<15	<15	<15	<15	<15			

DONORS	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Age, yrs	21	26	38	30	42	35	30	23	23	30
Sex	Female	Female	Female	Male	Male	Male	Female	Male	Male	Female
Race	White	White	White	White	White	White	White	White	White	White
Death	Trauma	Overdose	Trauma	Anoxia	Trauma	Overdose	Overdose	Overdose	Overdose	Overdose
KDPI	45	43	60	47	62	41	50	34	45	41
HCV Ab	+	+	+	+	+	+	+	+	+	+
HCV RNA	467	104	<15*	46,733	62,400	4,645,289	2,090,042	1,760,000	131	1,140,000
HCV GT	ND	ND	ND	1a/3a	1a	1a	3a	2	ND	1a

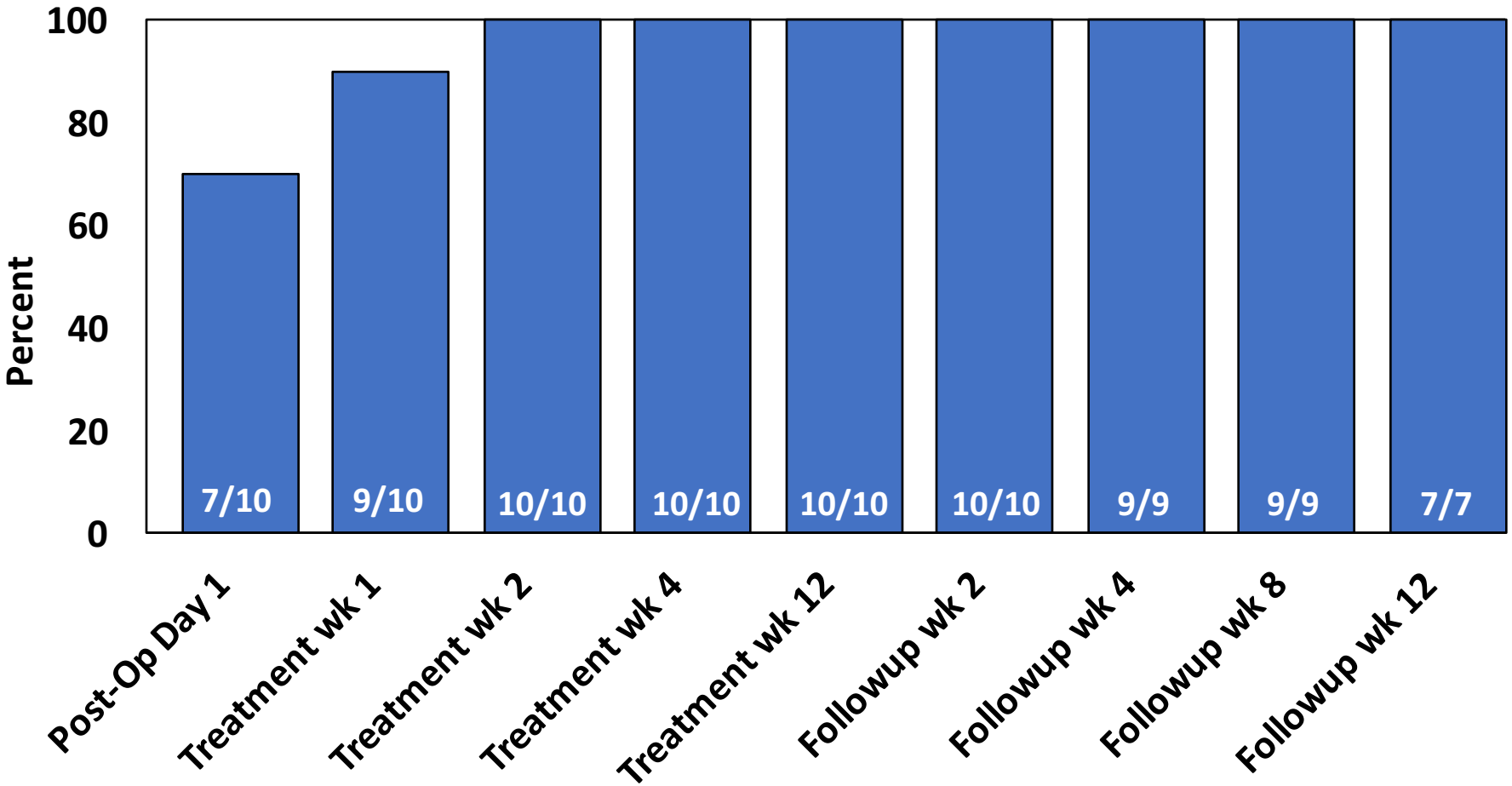
HCV R-	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
Age, yrs	71	71	65	57	72	71	74	61	76	66
Race	White	White	White	White	White	Asian	White	Black	White	White
Sex	Male	Female	Male	Male	Male	Male	Female	Male	Male	Male
Wait time	36	4.1	12.2	4.4	0.8	2.3	34.6	0.9	0.8	18.3
From entry	0.5	0.7	1.0	1.0	0.4	1.4	4.0	2.0	0.9	2.7

HCV RNA on treatment (TW)										
POD 1	<15	<15	<15	<15++	<15	94	<15++	136	<15	32
TW1	<15	<15	<15	<15	<15	<15	<15	55	<15	<15
TW4	<15	<15	<15	<15	<15	<15	missed	<15	<15	<15
TW8	<15	<15	<15	<15	<15	<15	<15	<15	<15	<15
TW12	<15	<15	<15	<15	<15	<15	<15	<15	<15	<15

HCV RNA Follow up off treatment (FW)										
FW2	<15	<15	<15	<15	<15	<15	<15	<15	<15	<15
FW4	<15	<15	<15	< 15	<15	<15	<15	<15	<15	
FW8	<15	<15	<15	<15	<15	<15	<15	<15	<15	
FW12	<15	<15	<15	<15	<15	<15	<15			

EXPANDER Results

Percent with undetectable HCV RNA at each visit



EXPANDER Conclusions

- Donors:
  - Young, Caucasians, 6/10 overdose death, low KDPI
  - 4/10 low HCV RNA, 3/10 non-GT1 HCV

EXPANDER Conclusions

- Donors:
  - Young, Caucasians, 6/10 overdose death, low KDPI
  - 4/10 low HCV RNA, 3/10 non-GT1 HCV
- Recipients:
  - GZR EBR and GZR EBR SOF was well-tolerated
  - 9/10 had low level HCV RNA only on POD1
  - 9/9 have undetectable HCV at FW4, (includes GT 2/3 donor)

EXPANDER Conclusions

- Donors:
  - Young, Caucasians, 6/10 overdose death, low KDPI
  - 4/10 low HCV RNA, 3/10 non-GT1 HCV
- Recipients:
  - GZR EBR and GZR EBR SOF was well-tolerated
  - 9/10 had low level HCV RNA only on POD1
  - 9/9 have undetectable HCV at FW4, (includes GT 2/3 donor)

HCV D+/R- transplant with DAAs as pre/post transplant prophylaxis may decrease HCV+ organ discard and safely expand the donor pool

Acknowledgements

Co-PI Niraj Desai, MD

Infectious Diseases:
Mark Sulkowski, MD
Diane Brown, MSN
Darin Ostrander, PhD
Shanti Seaman, BA
Michael Chattergoon, MD PhD
Guido Massaccesi, BS

Bioethics
Jeremy Sugarman, MD

Nephrology:
Fizza Naqvi, MD

EXPANDER Participants

EPIDEMIOLOGY RESEARCH GROUP IN ORGAN TRANSPLANTATION

Mary Grace Bowring, MPH
Samantha Halpern, BA
Sarah Rasmussen, BA
Allan B. Massie, PhD
Dorry L. Segev, MD PhD

Transplant Surgery
Nicole Bair, BSN
Russell Wesson, MD
Ashraf Reyad, MD