



Best Practices at the Center Level to Safely Use Marginal Organs

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CUTTING EDGE OF
TRANSPLANTATION

AST | AMERICAN SOCIETY OF
TRANSPLANTATION

RESOLVING THE ORGAN SHORTAGE



PRACTICE |



POLICY |



POLITICS

FEBRUARY 25-27, 2016 • PHOENIX, ARIZONA

Liver Transplantation at Ochsner Clinic: Fracking Hard in the Big Easy



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Conflict of Interest Disclosure

- none

Liver Transplantation at Ochsner Clinic



Liver Transplantation at Ochsner Clinic

- Where we started



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- Where we are



Liver Transplantation at Ochsner Clinic

- Where we started
- Where we are
- What drives utilization



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- What is 'Liver Fracking'



Liver Transplantation at Ochsner Clinic

- Where we started
- Where we are
- What drives utilization
- Where are the aggressive liver centers
- What is 'Liver Fracking'
- Two real donor scenarios, one old, one new.





This Story Begins in August of 2005 with Hurricane Katrina

Where We Started

The week after Katrina we were notified by UNOS and the MPSC that our liver program was flagged for poor outcomes.

Both 1-yr patient and graft survival rates were significantly worse than expected. Performing 95/yr at that time.

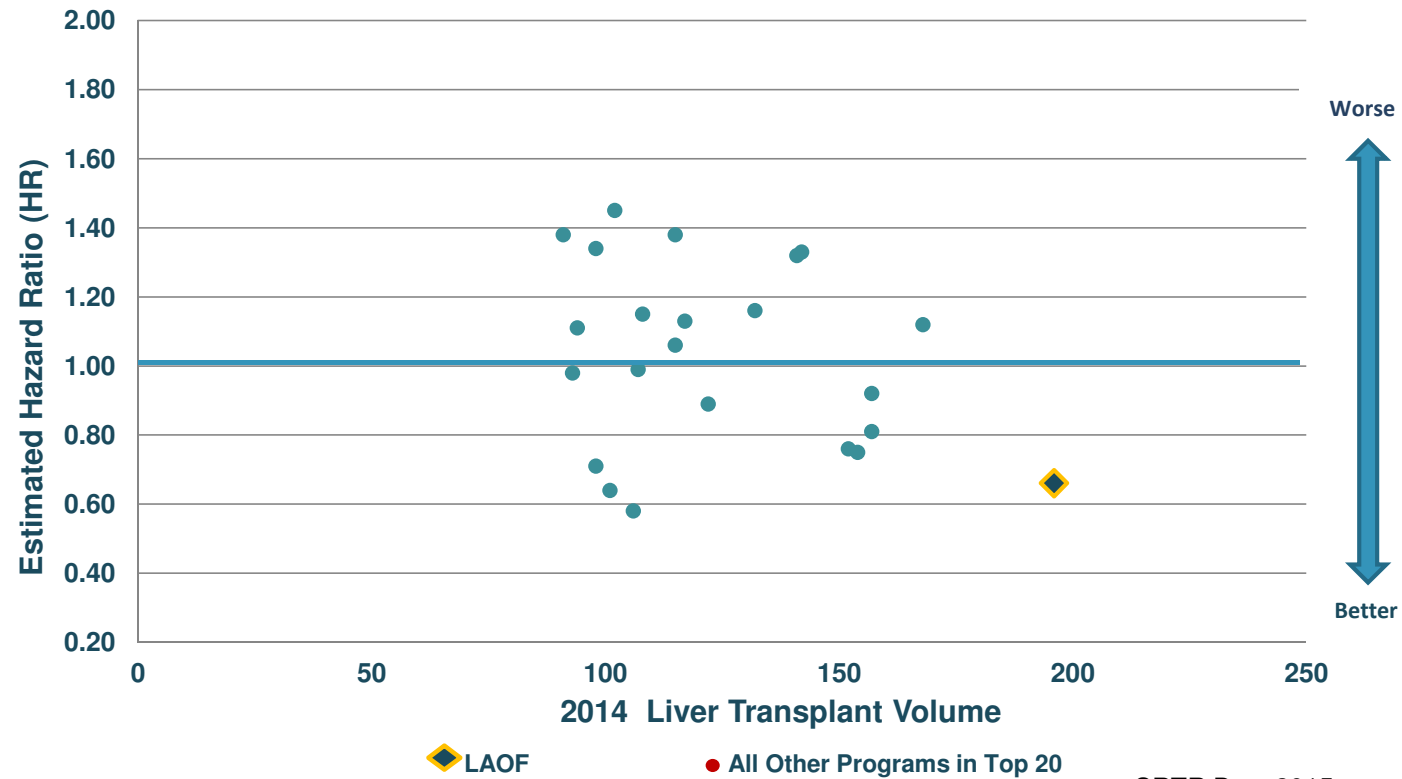


2014 Top 20 Liver Transplant Centers by Volume

2014 Volume Rank	Liver Transplants	2014 Tx Volume	2013 Tx Volume	2012 Tx Volume	1-yr patient survival
1	LAOF-TX1 Ochsner Foundation Hospital	196	175	174	Statistically Higher
2	CAUC-TX1 UCLA Medical Center	168	175	169	As Expected
3	FLSL-TX1 Mayo Clinic Florida	157	146	165	As Expected
3	CASF-TX1 Univ of CA San Francisco Med Ctr	157	146	139	As Expected
4	GAEM-TX1 Emory University Hospital	154	137	111	As Expected
5	TNVU-TX1 Vanderbilt Univ Med Ctr	152	119	98	As Expected
6	NYCP-TX1 New York-Presbyterian/Columbia	142	110	123	As Expected
7	INIM-TX1 Indiana University Health	141	114	133	As Expected
8	OHCC-TX1 Cleveland Clinic Foundation	132	128	143	As Expected
9	FLJM-TX1 Jackson Memorial Hospital	122	109	115	As Expected
10	PAUP-TX1 The Hosp of the Univ of PA	117	137	125	As Expected
10	TNMH-TX1 Methodist University Hospital	115	115	117	As Expected
11	MDUM-TX1 Univ of Maryland Med System	115	90	86	As Expected
12	ILNM-TX1 Northwestern Memorial Hospital	108	113	109	As Expected
13	NYMS-TX1 Mount Sinai Med Center	107	93	108	As Expected
14	KSUK-TX1 University of Kansas Hospital	106	114	77	Statistically Higher
15	DCGU-TX1 Georgetown Univ Med Ctr	102	91	116	As Expected
16	CAUH-TX1 Keck Hospital of USC	101	80	84	Statistically Higher
17	ALUA-TX1 Univ of Alabama Hospital	98	95	110	As Expected
17	MNMC-TX1 Rochester Methodist Hosp- Mayo Clinic	98	102	95	As Expected
18	NEUN-TX1 The Nebraska Medical Center	94	111	96	As Expected
19	MOBH-TX1 Barnes-Jewish Hospital	93	99	92	As Expected
20	TXTX-TX1 Baylor University Medical Center	91	98	88	As Expected

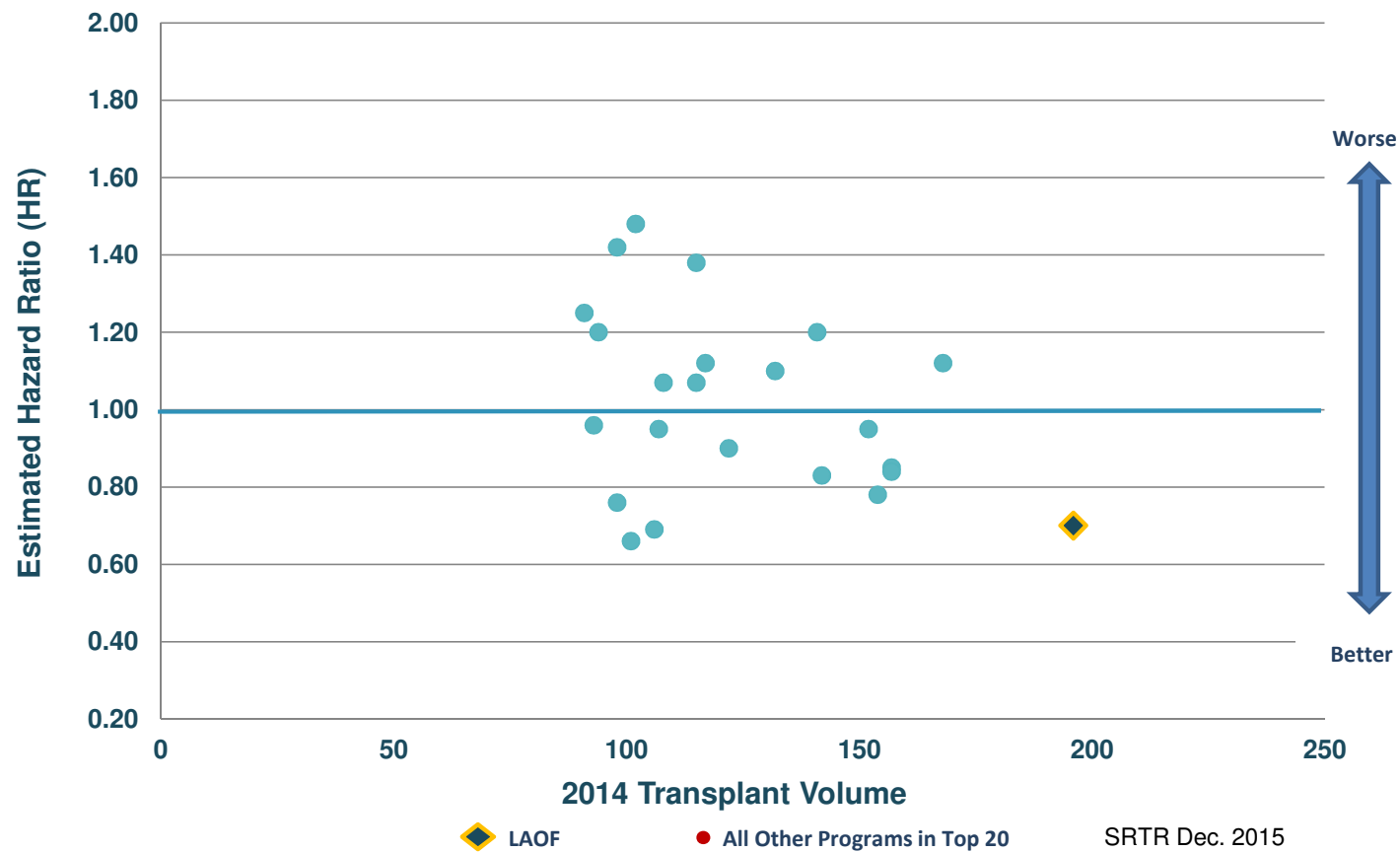
Source: OPTN/UNOS & Scientific Registry for Transplant Recipients Dec. 2015

Top 20 Liver Transplant Programs 1-Year Patient Survival Hazard Ratio Comparison



SRTR Dec. 2015

Top 20 Liver Transplant Programs 1-Year Graft Survival Hazard Ratio Comparison

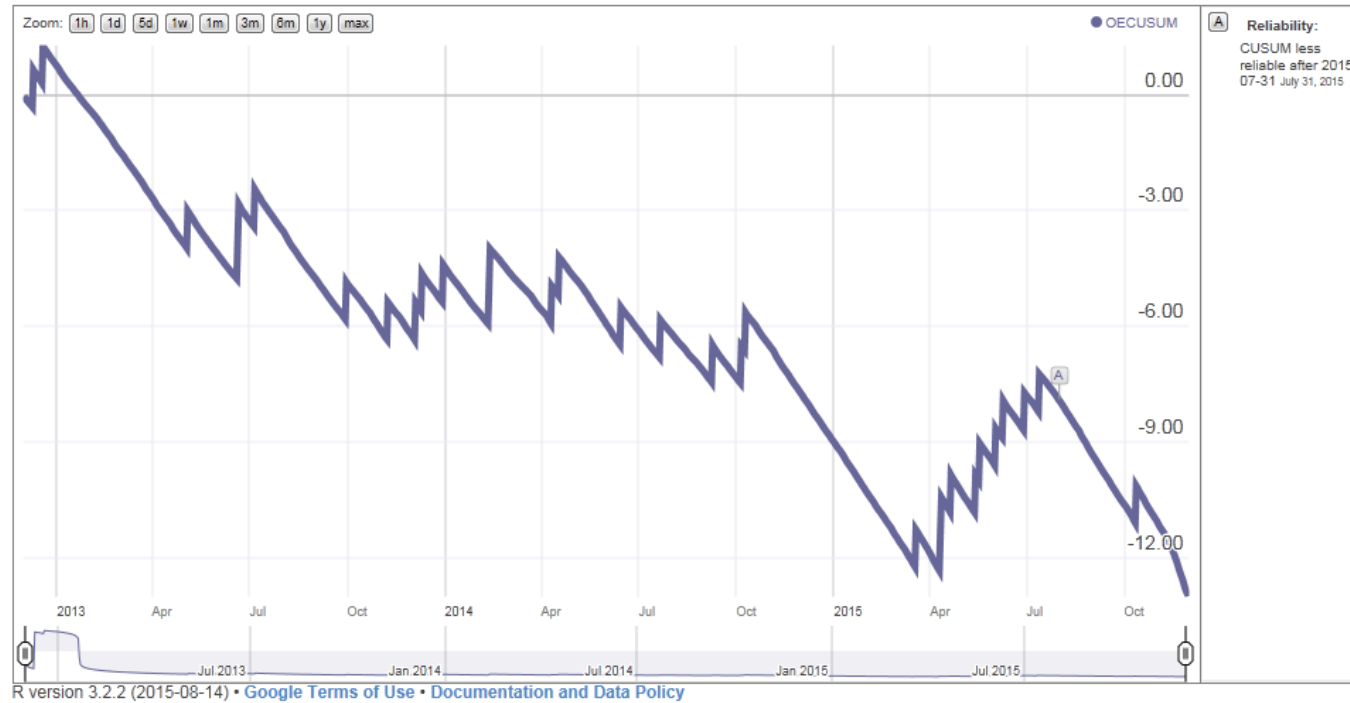


CUSUM Charts

LAOFTX1 LIVER PROGRAM CUSUM REPORT: ADULT ONE-YEAR PATIENT DEATH

2016-01-01

OBSERVED - EXPECTED CUSUM: ALL DONOR ADULT ONE-YEAR PATIENT DEATH



CUSUM Charts

LAOFTX1 LIVER PROGRAM CUSUM REPORT: ADULT ONE-YEAR GRAFT FAILURE

2016-01-01

OBSERVED - EXPECTED CUSUM: ALL DONOR ADULT ONE-YEAR GRAFT FAILURE



I Need to Tell You This So We Can Talk About Risk and Utilization

Over the last ten years we have more than doubled our liver transplant volume by increasing the number of imported livers. During this time our outcomes have improved from the bottom 5% in 2005 to the top 5% in the nation for the last 5 years in a row.

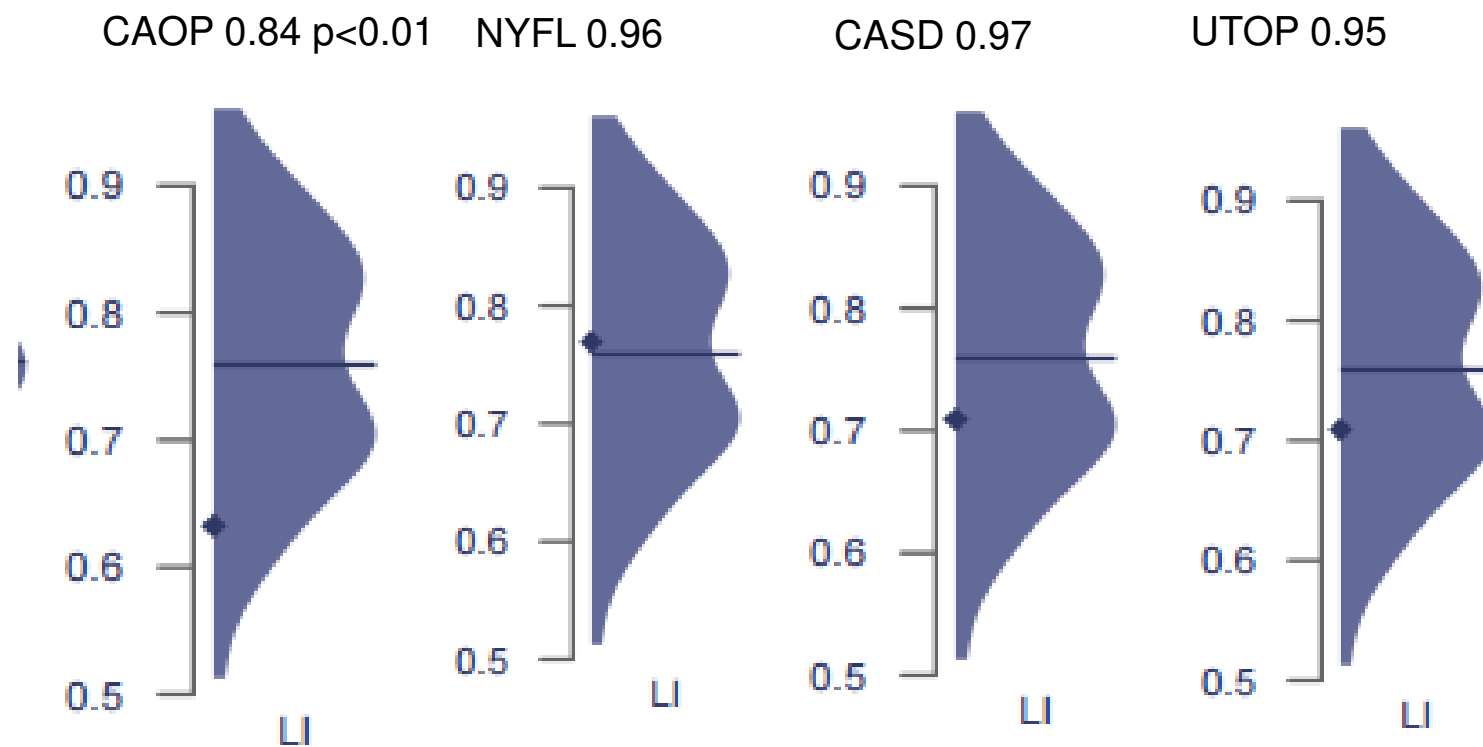
Our median wait time has ranged from 1.8 to 2.2 months during this time (Currently 2.1 months).



OPO	median_lab_meld	median_match_meld
MAOB-OP1 New England Organ Bank	17	31
CTOP-OP1 LifeChoice Donor Services	17	24
FLWC-OP1 LifeLink of Florida	17	23
NYRT-OP1 New York Organ Donor Network	17	31
DCTC-OP1 Washington Reg Transplant Community	17.5	25
ORUO-IO1 Pacific NW Transplant Bank	18	28
OHLP-OP1 Lifeline of Ohio	18	25
INOP-OP1 Indiana OPO	18	22
MIOP-OP1 Gift of Life Michigan	19	25
PADV-OP1 Gift of Life Donor Program	19	30
NEOR-OP1 Nebraska Organ Recovery System	19	22
VATB-OP1 LifeNet Health	19	24
NCCM-IO1 LifeShare of the Carolinas	19	23
OHLB-OP1 LifeBanc	19.5	25
KYDA-OP1 KY Organ Donor Affiliates	20	25
CADN-OP1 CA Transplant Donor Network	20	34
IAOP-OP1 Iowa Donor Network	20	22
FLMP-OP1 Life Alliance Organ Recovery Agency	20	24
AZOB-OP1 Donor Network of Arizona	20	28
NCNC-OP1 Carolina Donor Services	20	27
MWOB-OP1 Midwest Transplant Network	20	24.5
ALOB-OP1 Alabama Organ Center	21	25
TXSA-OP1 Texas Organ Sharing Alliance	21	29
CORS-OP1 Donor Alliance	21	30
MOMA-OP1 Mid-America Transplant Svcs	21	27
PATF-OP1 Center for Organ Recovery and Educ	21	29
FLUF-IO1 LifeQuest Organ Recovery Services	21	28
TNMS-OP1 Mid-South Transplant Foundation	21	23
OHOV-OP1 LifeCenter Organ Donor Network	21	24
TNDS-OP1 Tennessee Donor Svcs	21	25
AROR-OP1 Arkansas Reg	21	22.5
MNOP-OP1 LifeSource Upper Midwest OPO	21	31
LAOP-OP1 Louisiana Organ Procurement Agency	21	24
NJTO-OP1 NJ Organ and Tissue Sharing Network	22	28
WALC-OP1 LifeCenter Northwest	22	29
TXGC-OP1 LifeGift Organ Donation Ctr	22	31
SCOP-OP1 LifePoint, Inc	22	23
FLFH-IO1 TransLife	23	25
WIUW-IO1 UW Health Organ and Tissue Donation	23	28
GALL-OP1 LifeLink of Georgia	23	25
ILIP-OP1 Gift of Hope	23	29
OKOP-OP1 LifeShare Transplant Donor Svcs of OK	23	30.5
TXSB-OP1 Southwest Transplant Alliance	24.5	29
MDPC-OP1 The Living Legacy Foundation of MD	25	29
WIDN-OP1 Wisconsin Donor Network	26.5	34.5
UTOP-OP1 Intermountain Donor Services	28	34
CASD-IO1 Lifesharing - A Donate Life Org	29	34.5
NYFL-IO1 Finger Lakes Donor Recovery Network	30	34
CAOP-OP1 OneLegacy	31	37

OLTs from
1/1/13-9/30/14

What Drives Aggressive Utilization? Below Depicts the Chance that a Donor will Result in a Liver Transplant by OPO. O/E Ratio Shown

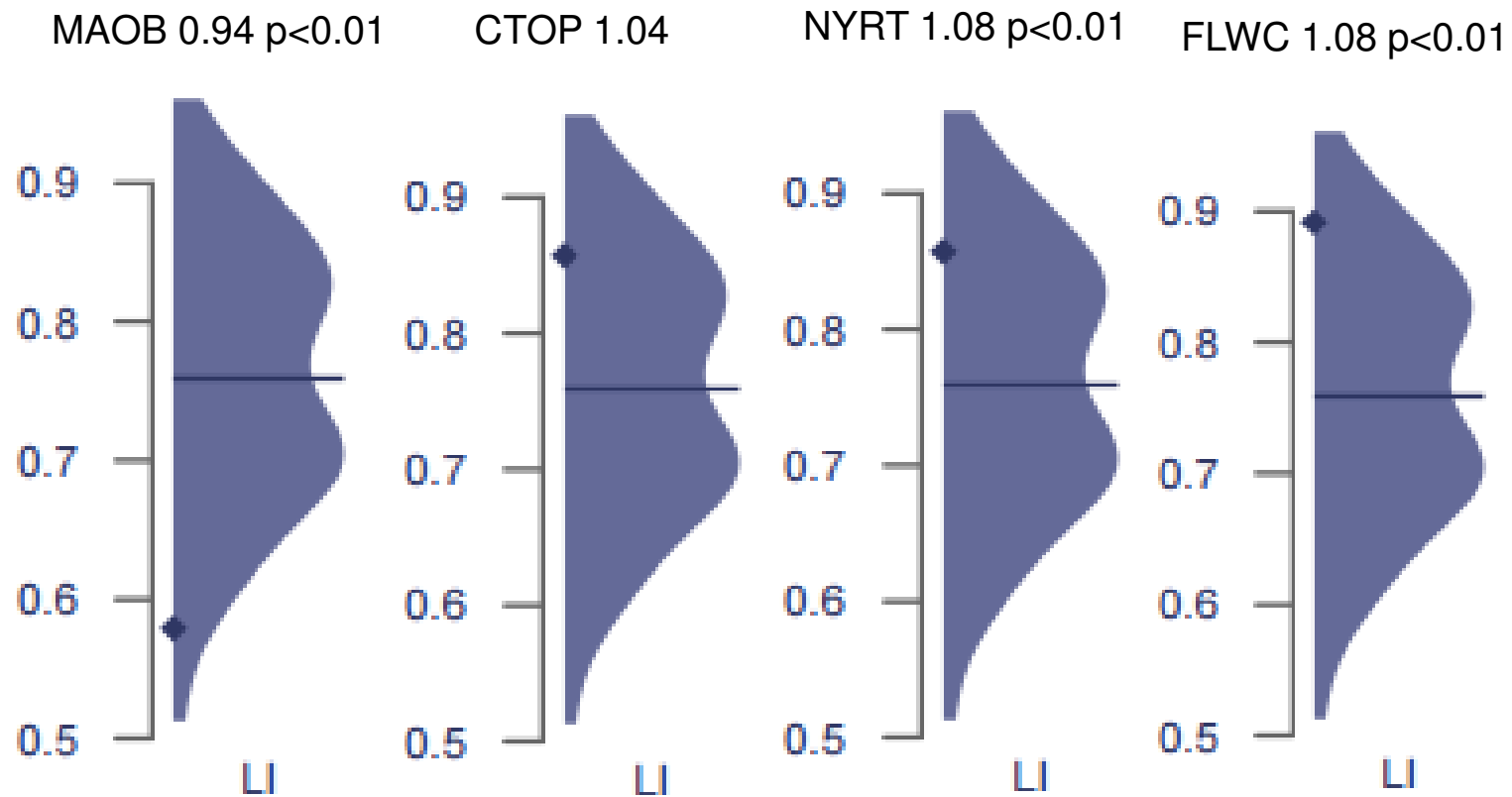


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SRTR Dec. 2015

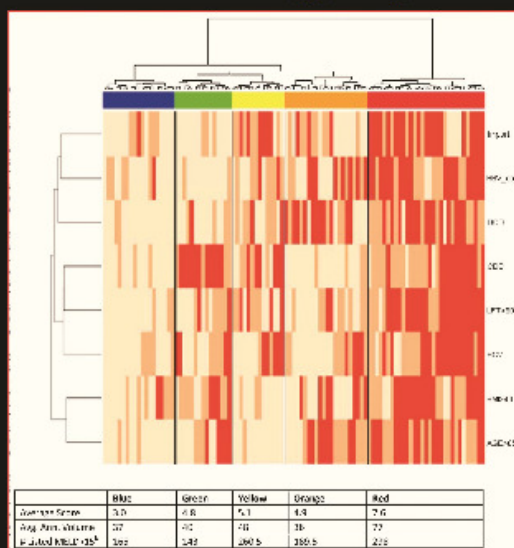
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AND THE AMERICAN SOCIETY OF TRANSPLANT SURGEONS

ASTS
PUBLISHED BY WILEY-BLACKWELL

Turning up the Heat!



What is
appropriately
aggressive
organ
utilization?

WILEY Blackwell

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TRANSPLANTATION

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RESOLVING THE ORGAN SHORTAGE
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Aggressive Centers Use Livers from Donors with the Following Characteristics

- HBV core
- DCD
- CDC
- LFT>500
- HCV
- BMI>40
- Age>65
- Import



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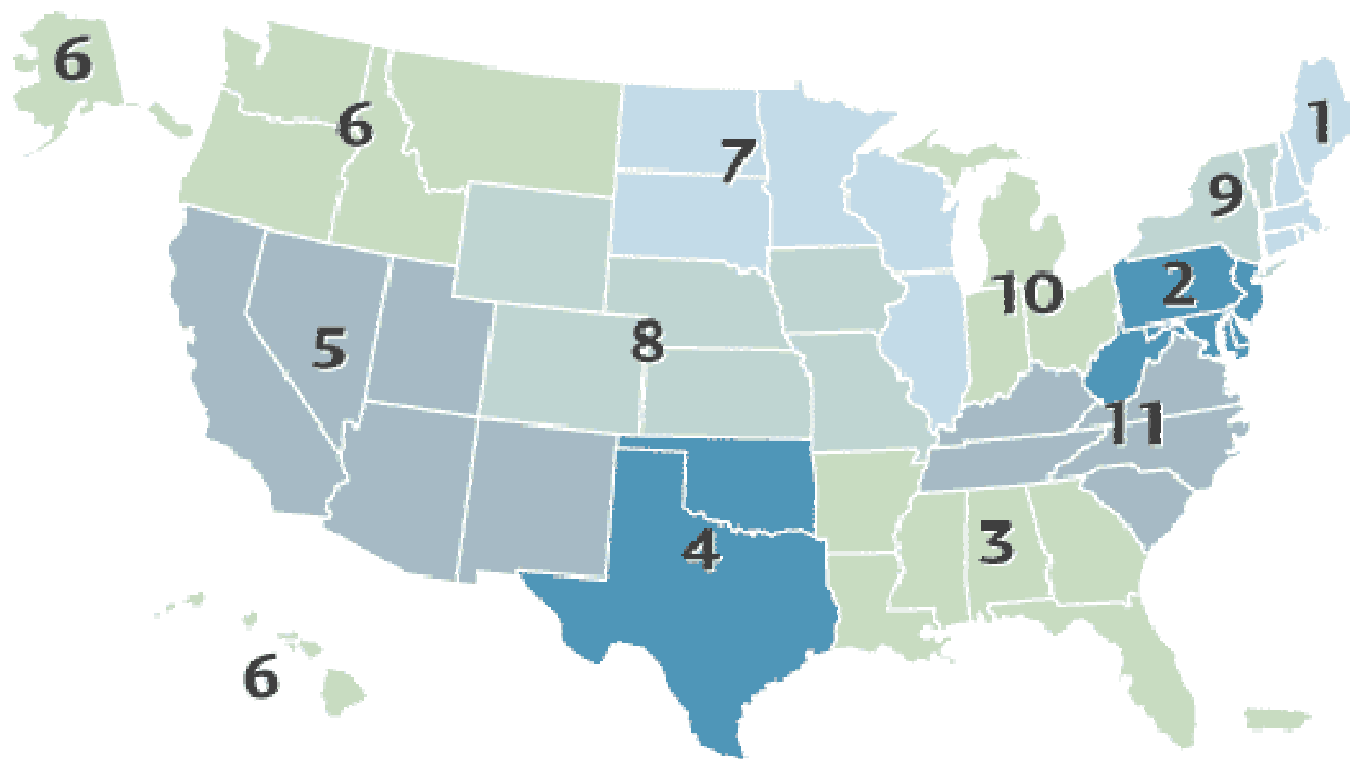
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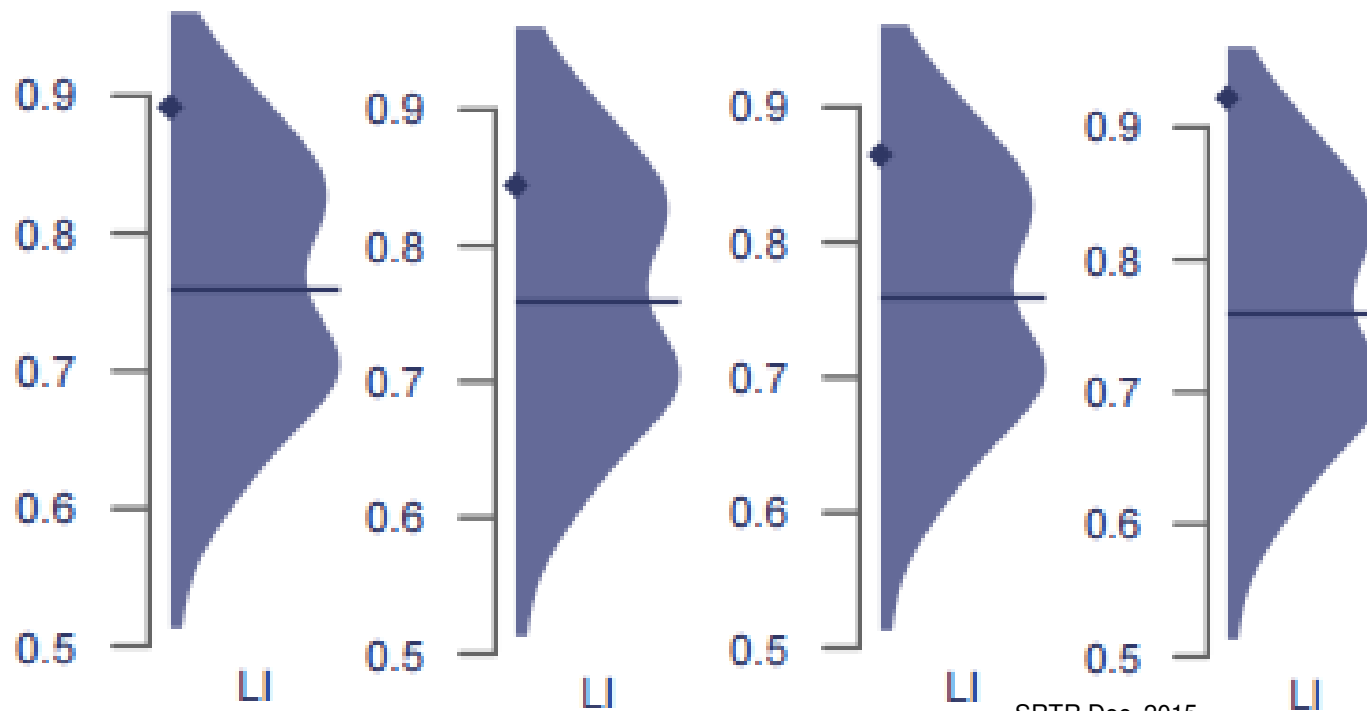
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- HCV ✓
- BMI>40 ✓
- Age>65 ✓
- Import ✓





What Drives Aggressive Utilization?

FLUF 1.15 $p < 0.01$ GALL 1.11 $p < 0.01$ ALOB 1.07 $p < 0.01$ LAOP 1.13 $p < 0.01$



SRTR Dec. 2015

What is the Imperative?

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- Death on the list

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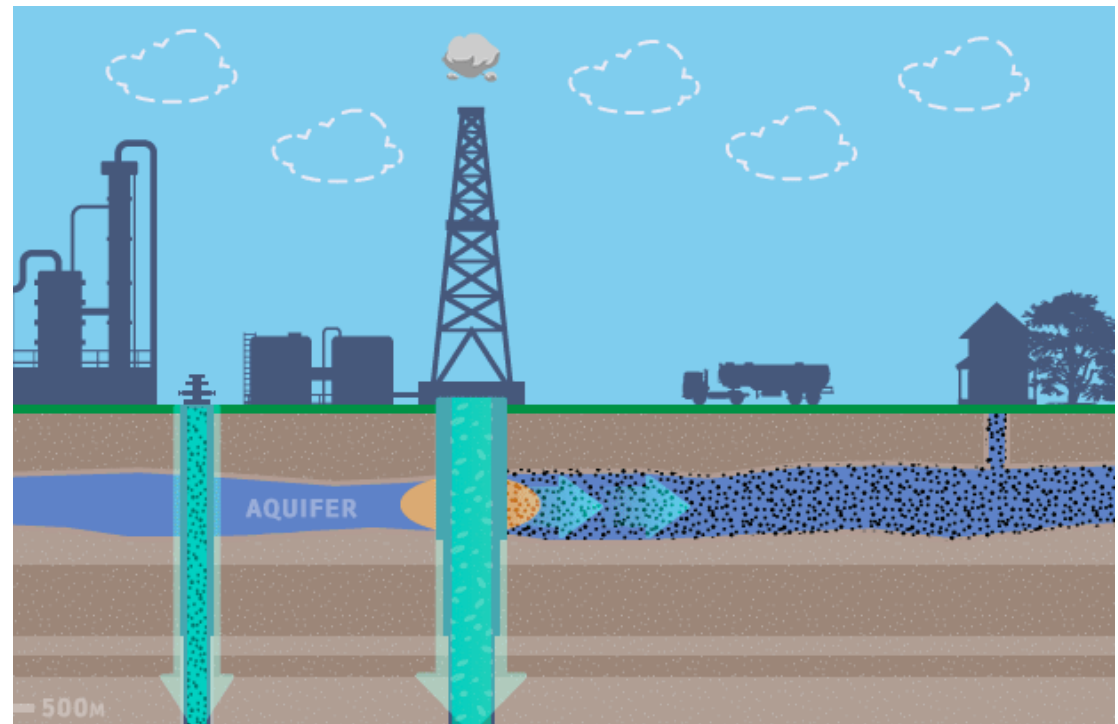
- Death on the list
- 2011 nearly 25% of our listed patients died while waiting

What is the Imperative?

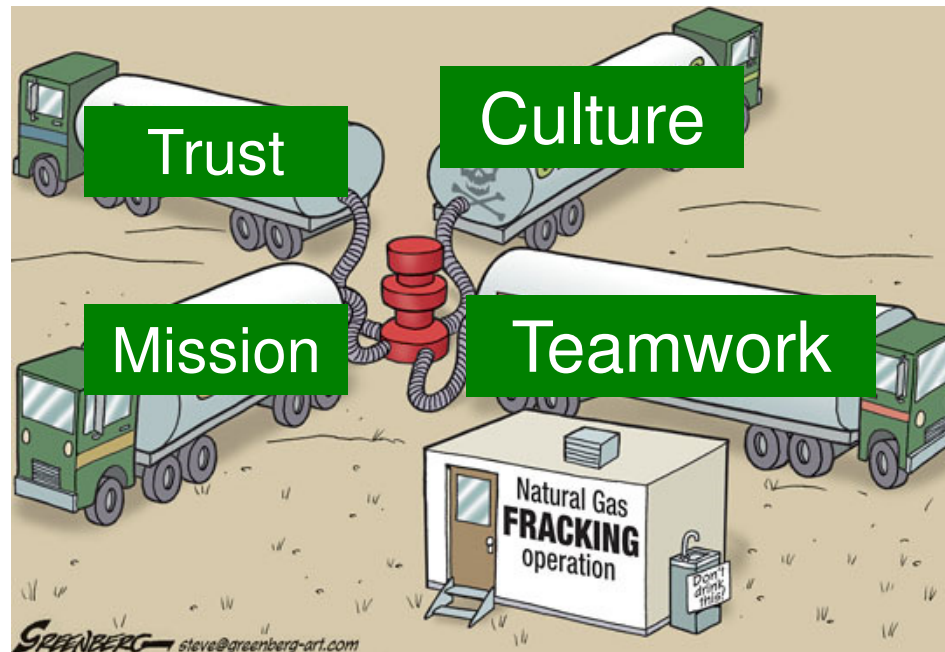
- Death on the list
- 2011 nearly 25% of our listed patients died while waiting
- 50% with MELD < 21, 50% \geq 21

Fracking

Fracking, or hydraulic fracturing, is the process of extracting natural gas from shale rock layers deep within the earth. Fracking makes it possible to extract resources that were once unreachable with conventional technologies.

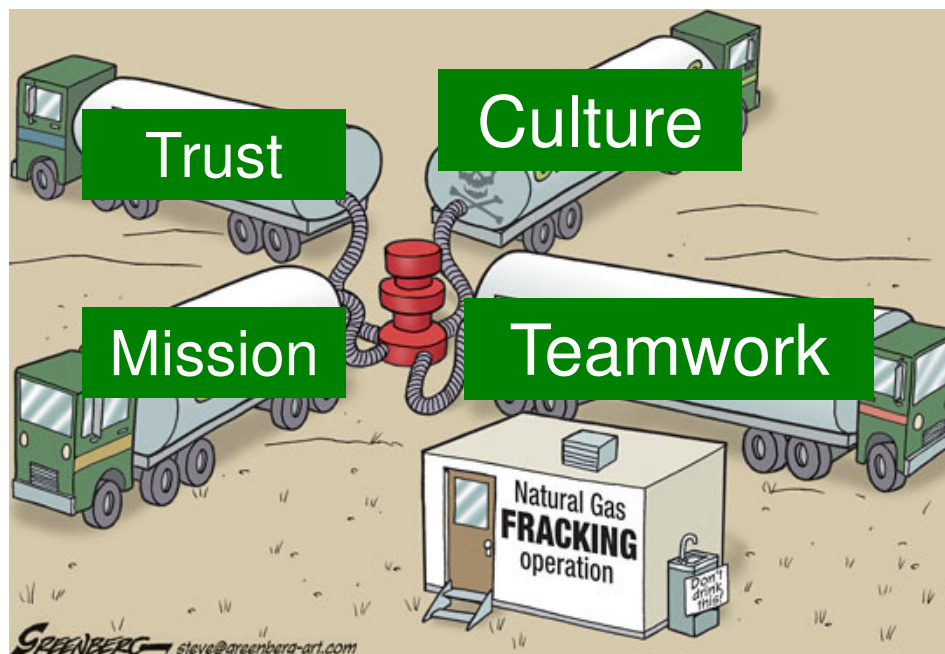


Liver Fracking



Extracting Livers that were Once Unreachable

Liver Fracking



Using the sheer power of our shared commitment to the dual missions of organ donation and transplantation, we work with dedicated professionals from OPOs across the nation and with remote surgeon partners to prevent livers from being buried.

Frackable Livers

HBV core

DCD

CDC

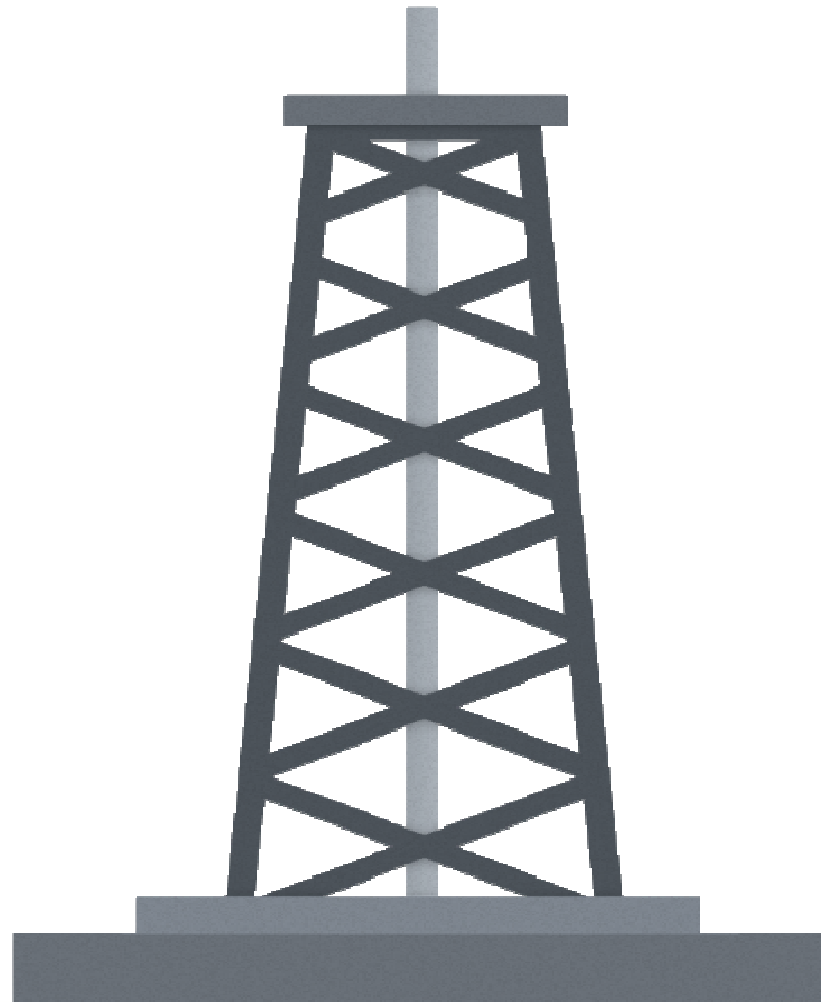
LFT>500

HCV

BMI>40

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Import



Frackable Livers

HBV core



DCD

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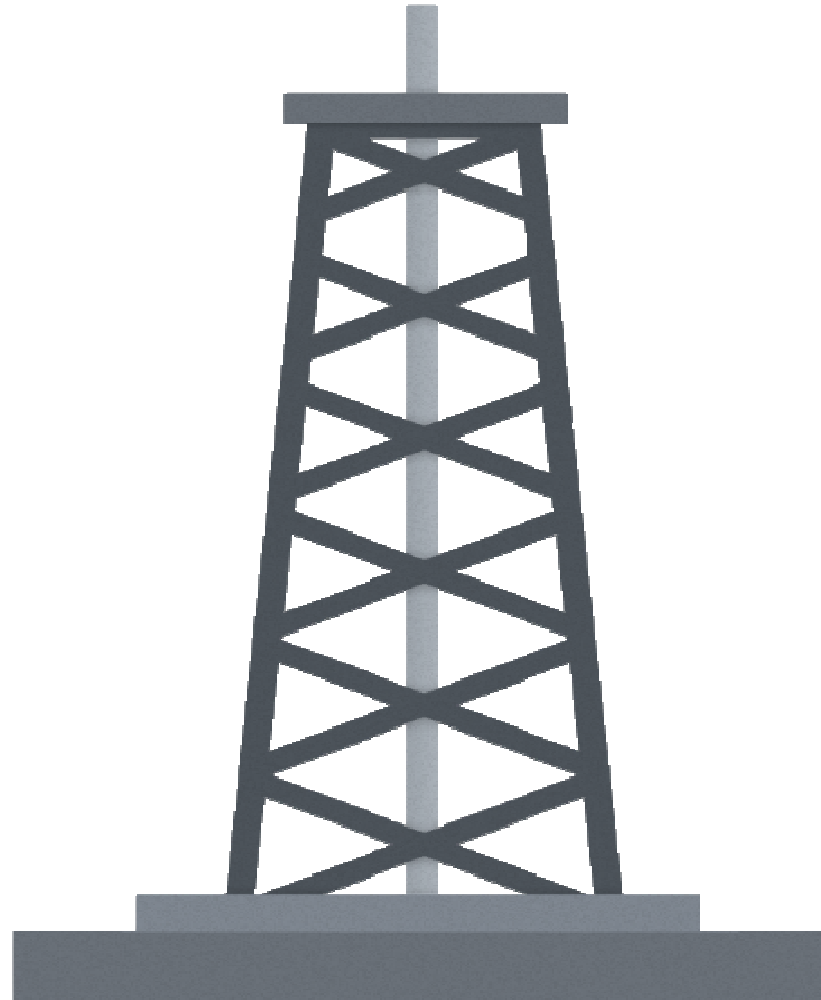
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Frackable Livers

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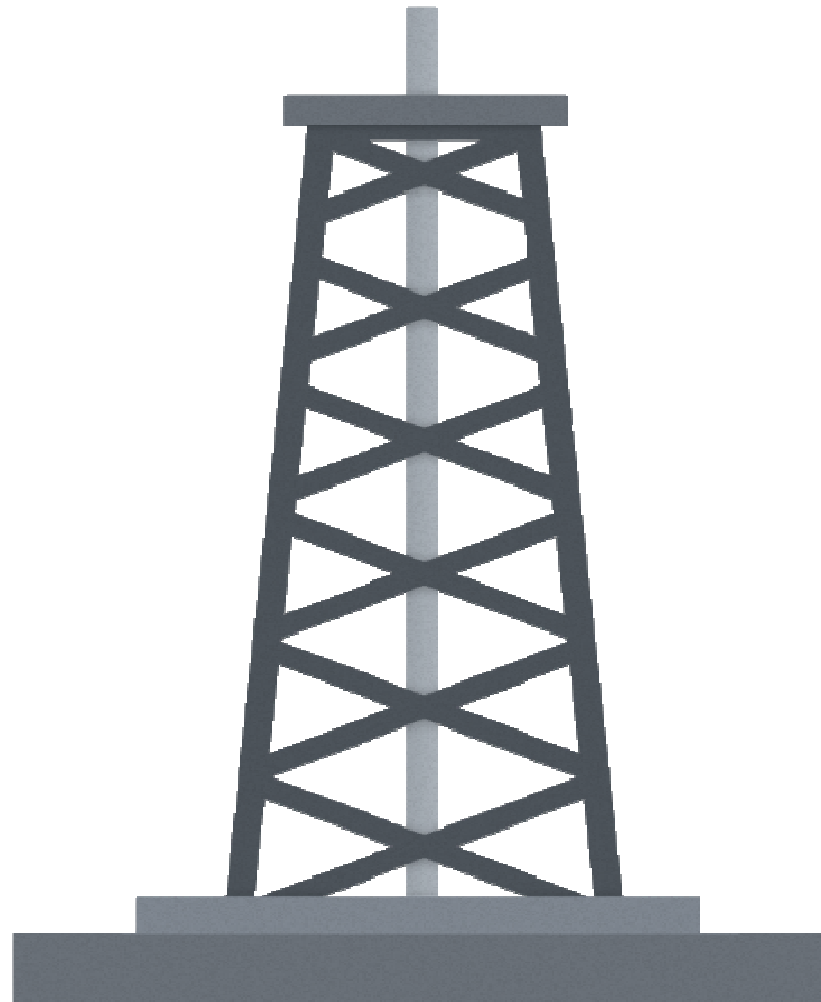
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Import



Frackable Livers

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HCV

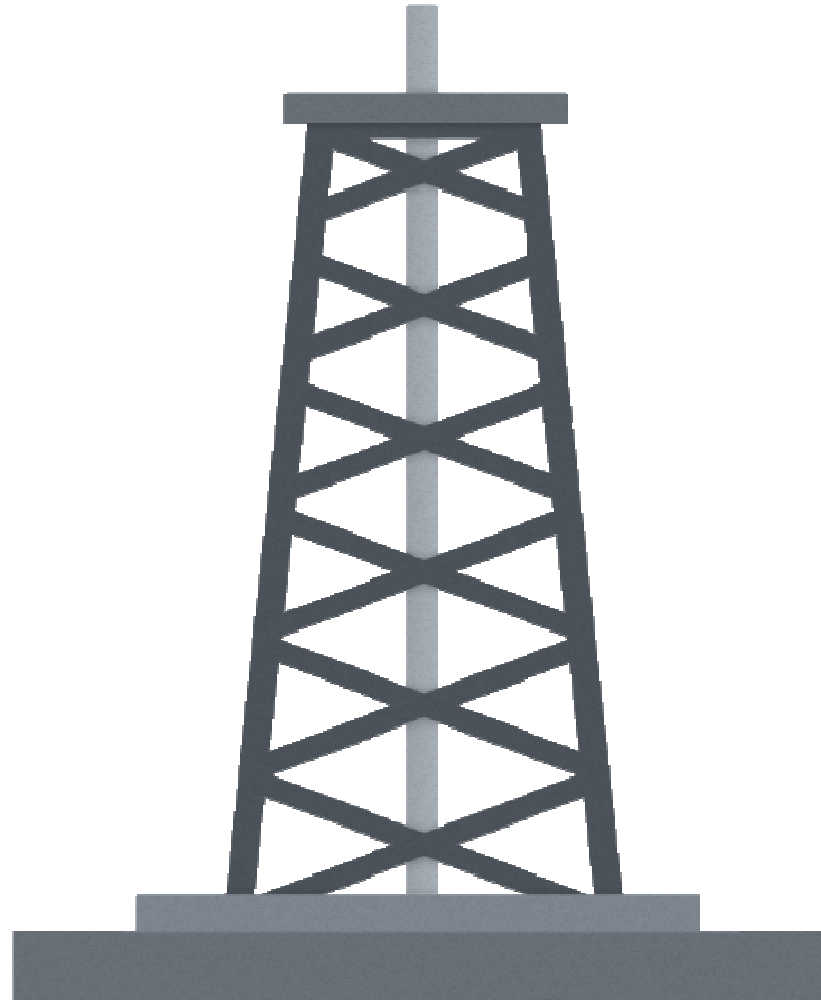
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Age>65



Import



Frackable Livers

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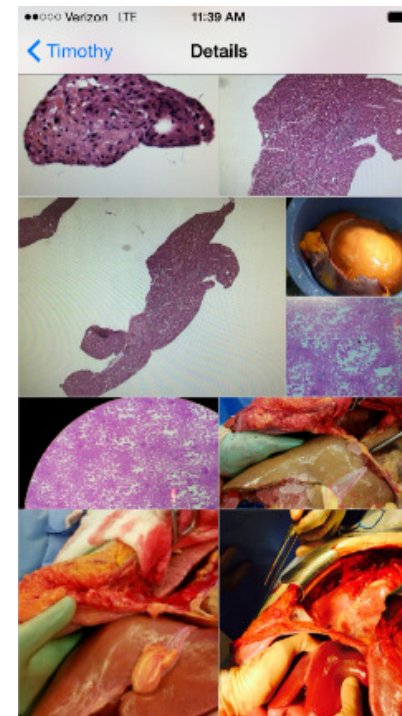
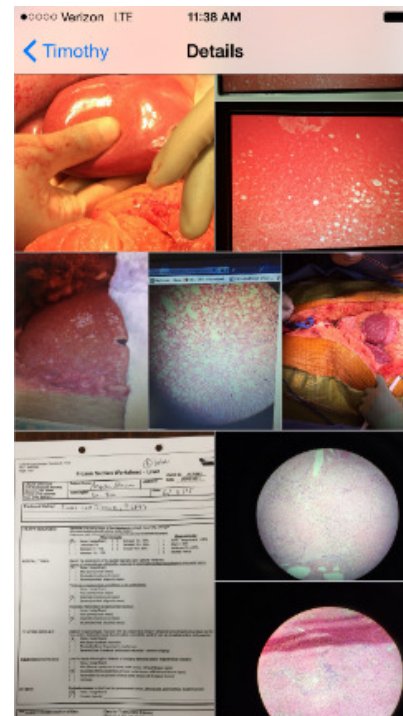
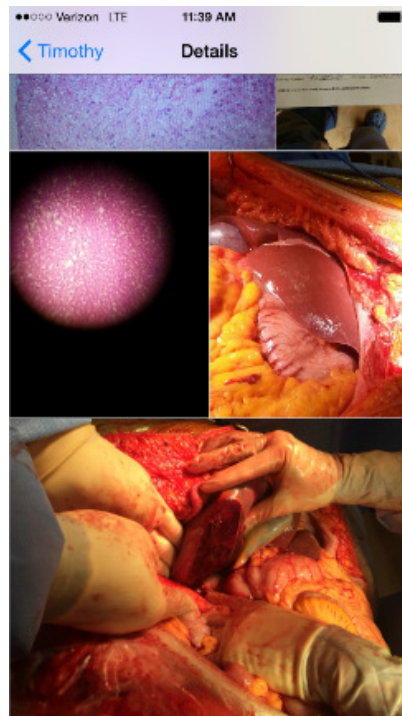
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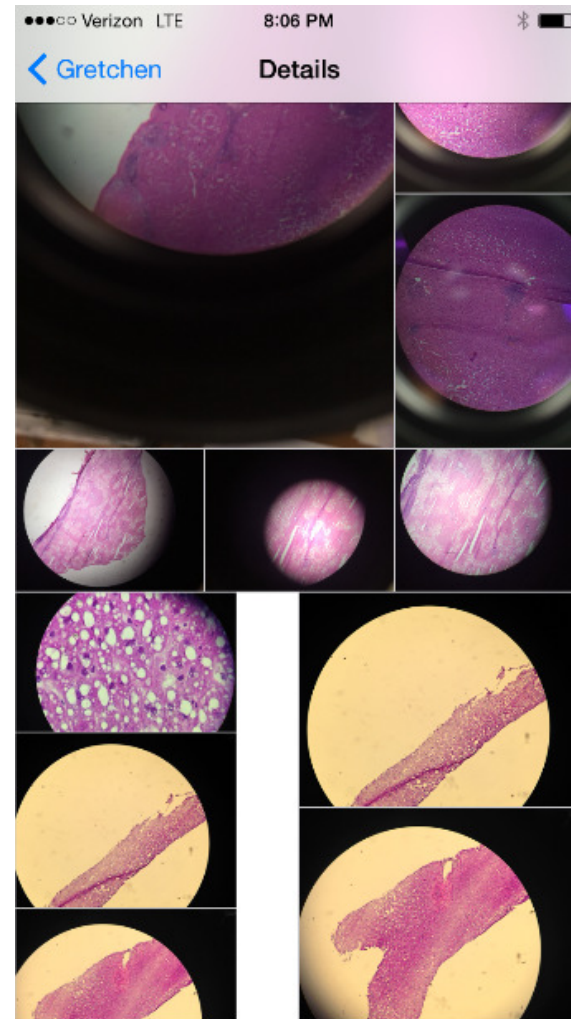
iPhone Screen Shots

iPhone Screen Shots

Smartphone cameras can be used to take pictures through the eyepiece and ocular lens. Takes about 90 seconds to teach a surgeon how to do this.

We do not believe a written report if we are not forced to. We always try to look at the slides ourselves.

Fat content is most often overcalled.

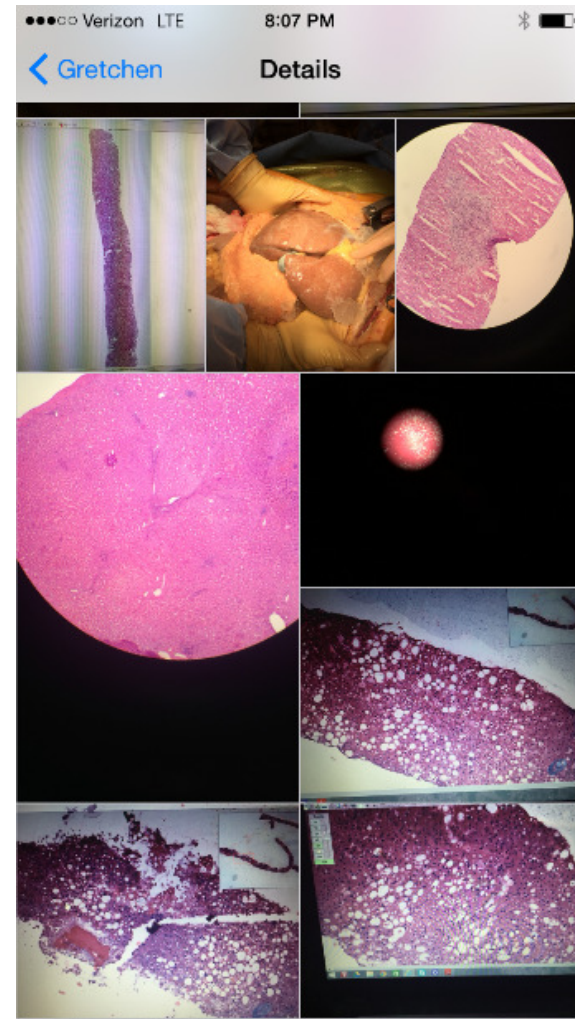


iPhone Screen Shots

Our method of estimating fat is to pretend we have a squeegee. We squeegee all of the fat globules to one side of the slide. If our squeegeed globules occupy less than 50% of the slide, all is right with the world.

Livers can look very yellow and have very little macro fat present histologically.

Livers that look only mildly steatotic can have a surprisingly large amount of macrovesicular fat present histologically.

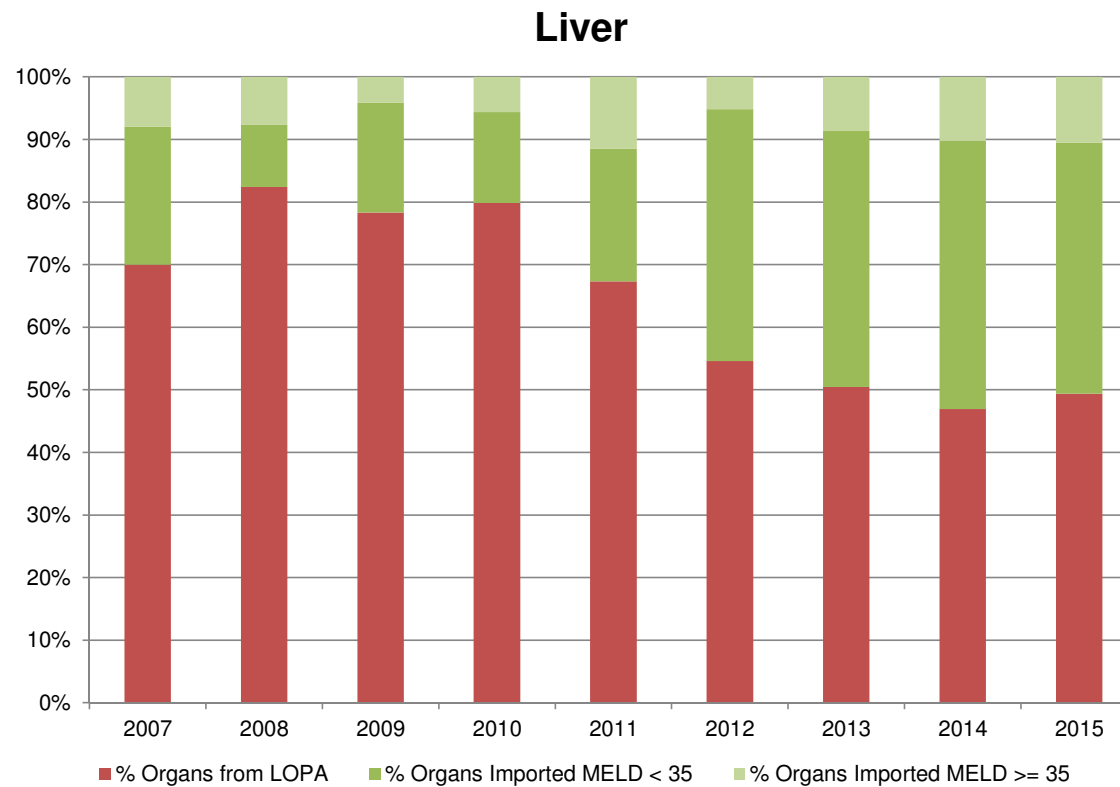


LOPA: Total Organs Recovered vs. Organ Received



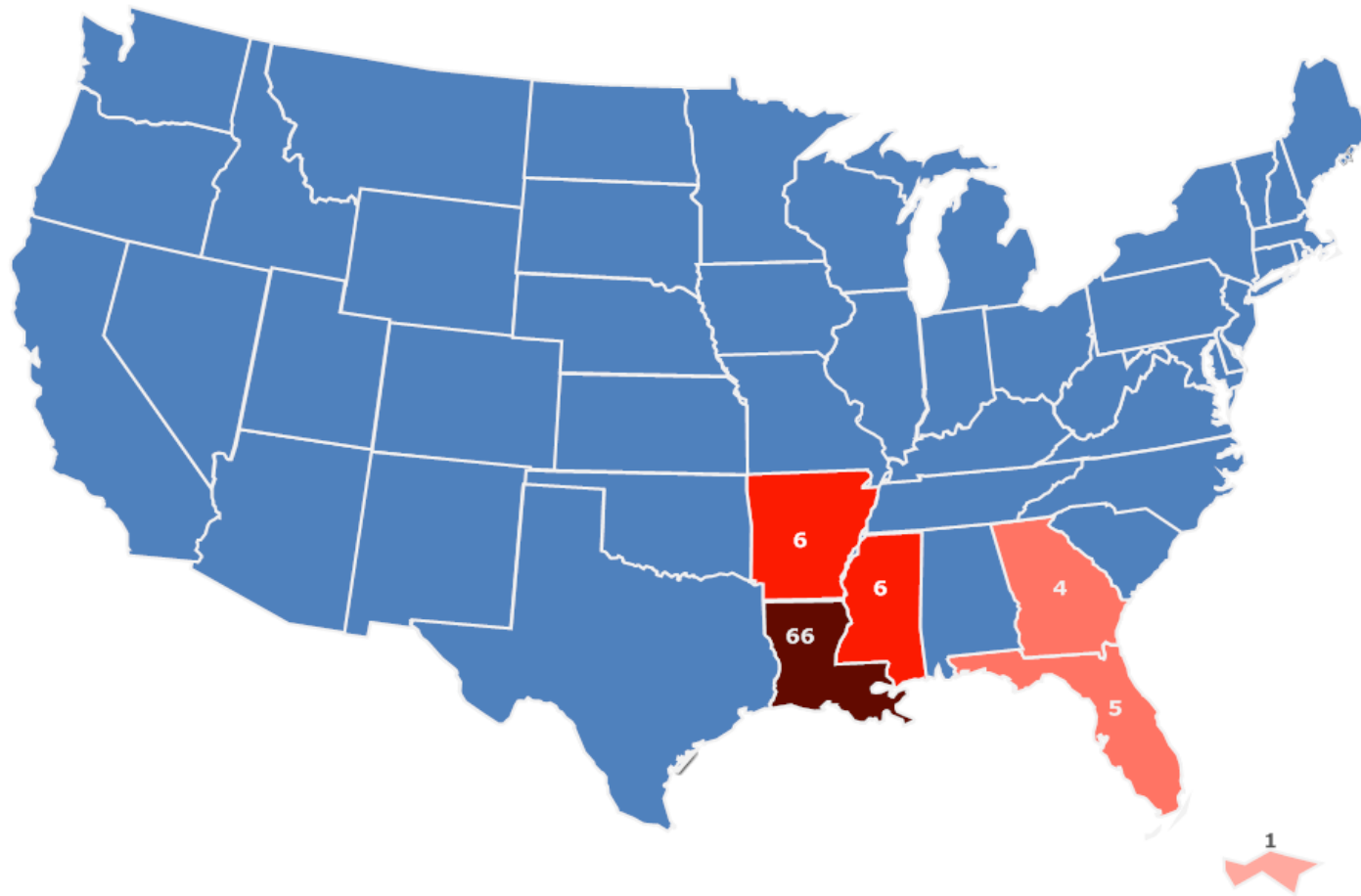
Data from LOPA annual reports

Organs Used: Importing Over 50%, but only 10% for MELD > 35

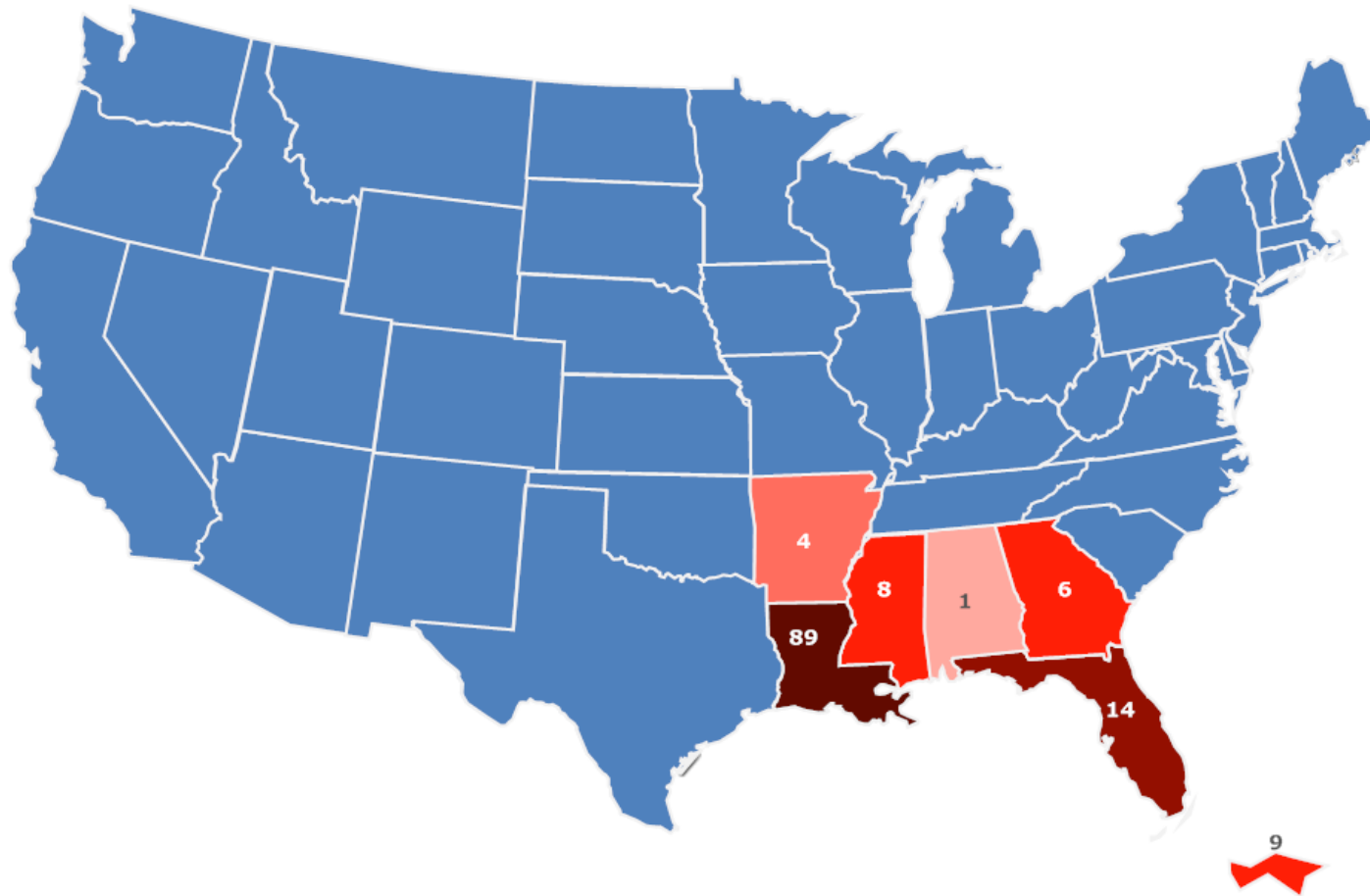


Internal Ochsner Data

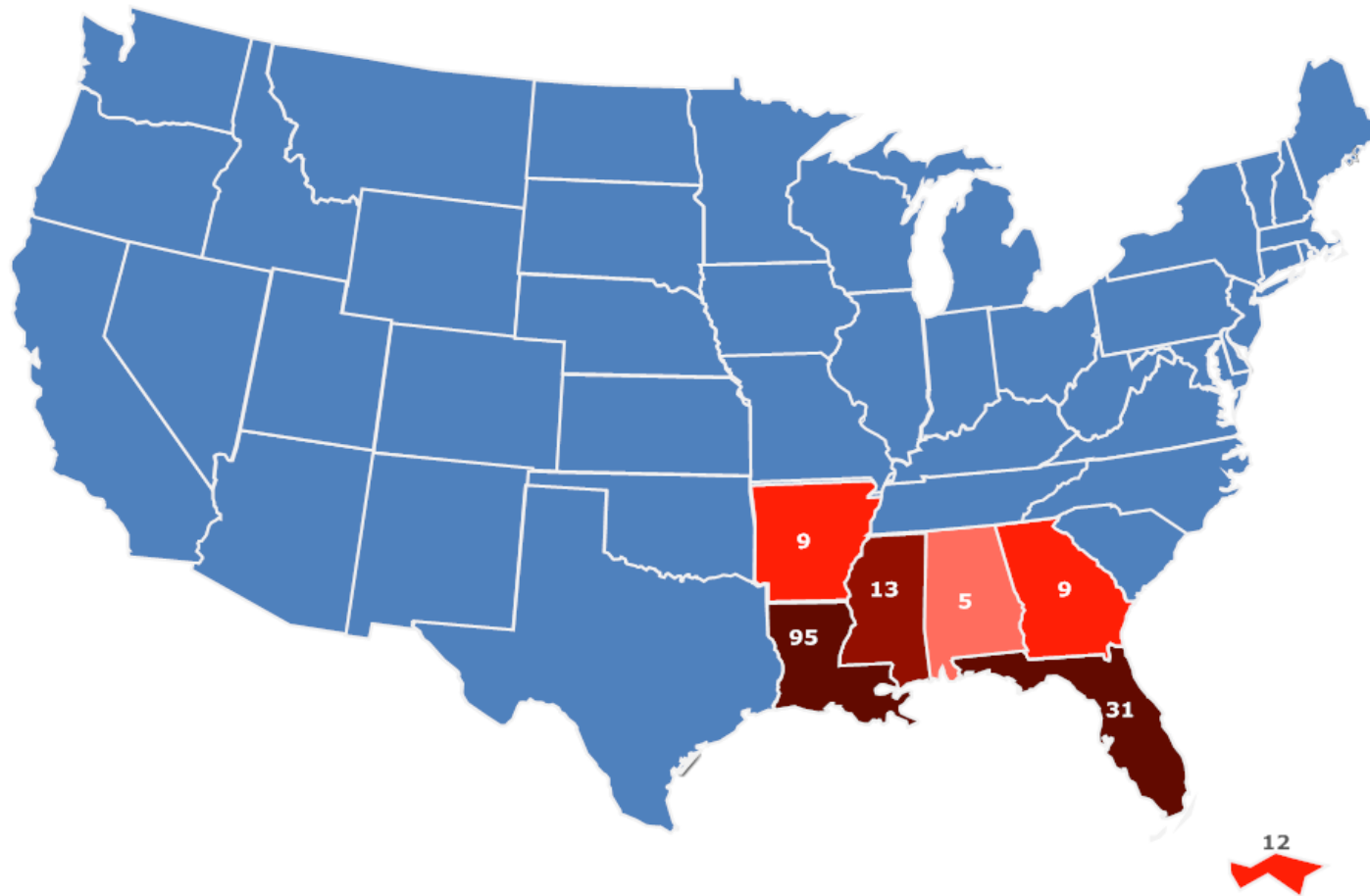
Organ Donors by State 2006



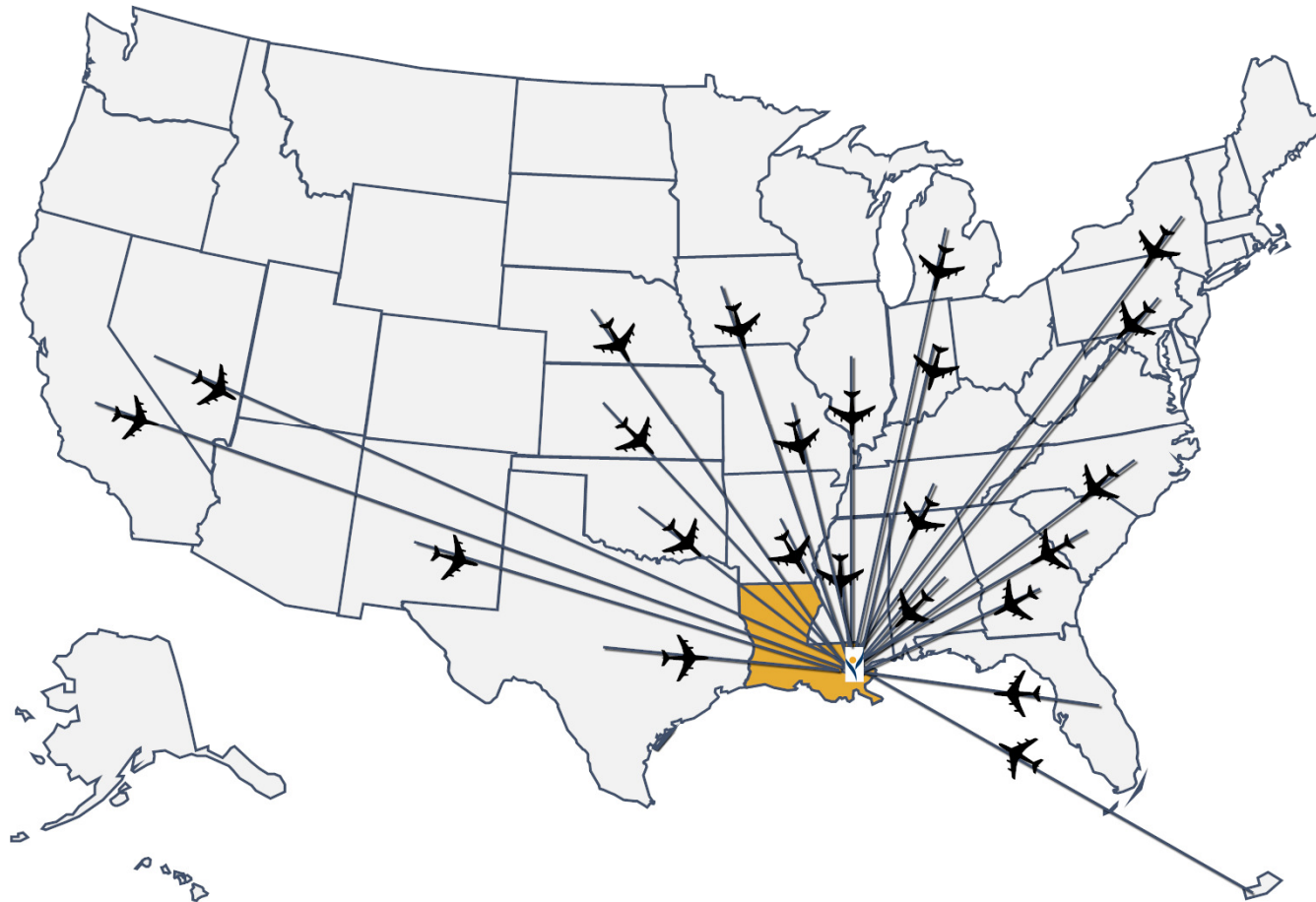
Organ Donors by State 2011



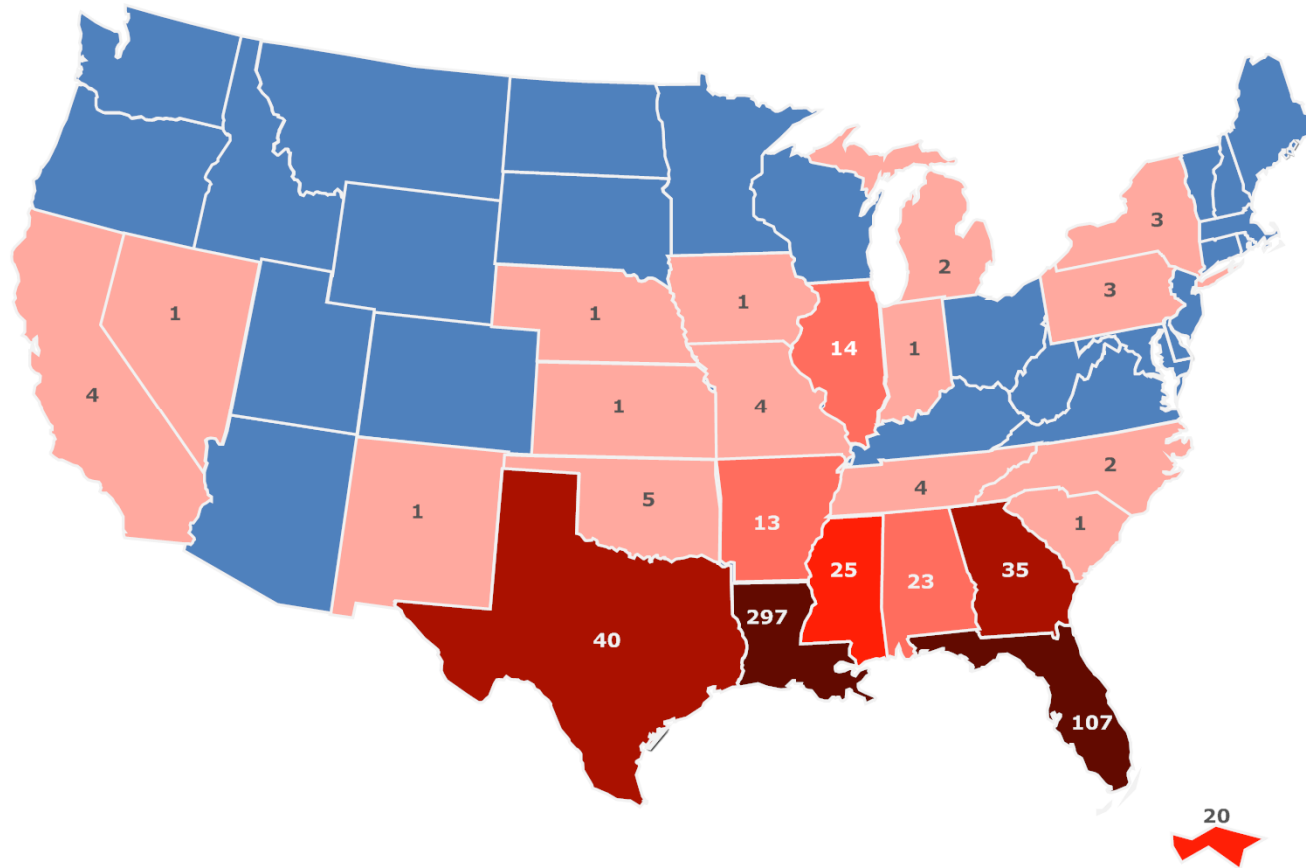
Organ Donors by State 2012



Liver Donors 2013-2015



Organ Donors by State 2013 - 2015



Liver Donors 2013-2015

Distance from New Orleans (miles)

San Juan., PR: 1,700
Miami: 864
Jacksonville: 546
Philadelphia: 1,221
Syracuse: 1,380
Detroit: 1,065
Nashville: 532
Chicago: 925
St. Louis: 677
OKC: 709
Albuquerque: 1,152
Las Vegas: 1,723
Sacramento: 2,231
San Francisco: 2,277



Strategies

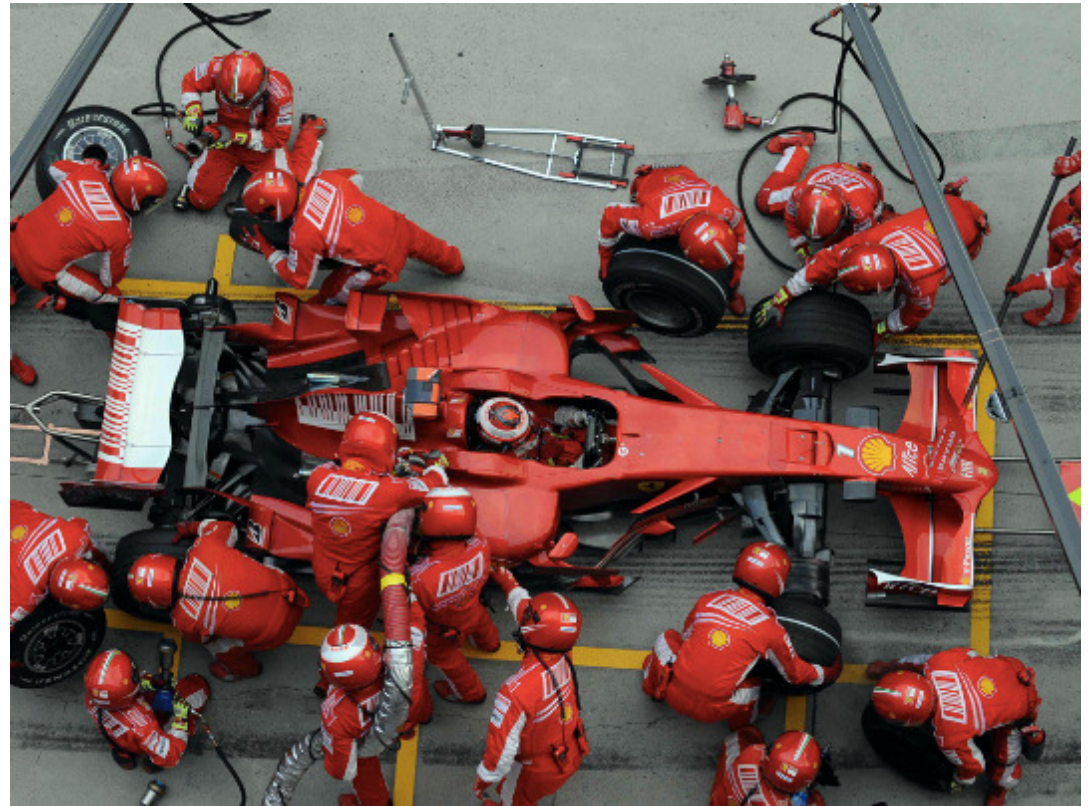
Collaborate: more than 50% imports and 20% from out of region.

Culture/Teamwork: avoid making decisions when tired.

Perform a good operation: 2 staff surgeons per case and 3 for redos and dense PVT

Keep CIT short (< 5 hours for local 95% vs 54%; imports 58% vs 33%) and WIT short (median 27 min)

Purpose/Mission: remember why we do this—avoid death on the list.



Strategies

Be Creative/Mitigate financial risk.

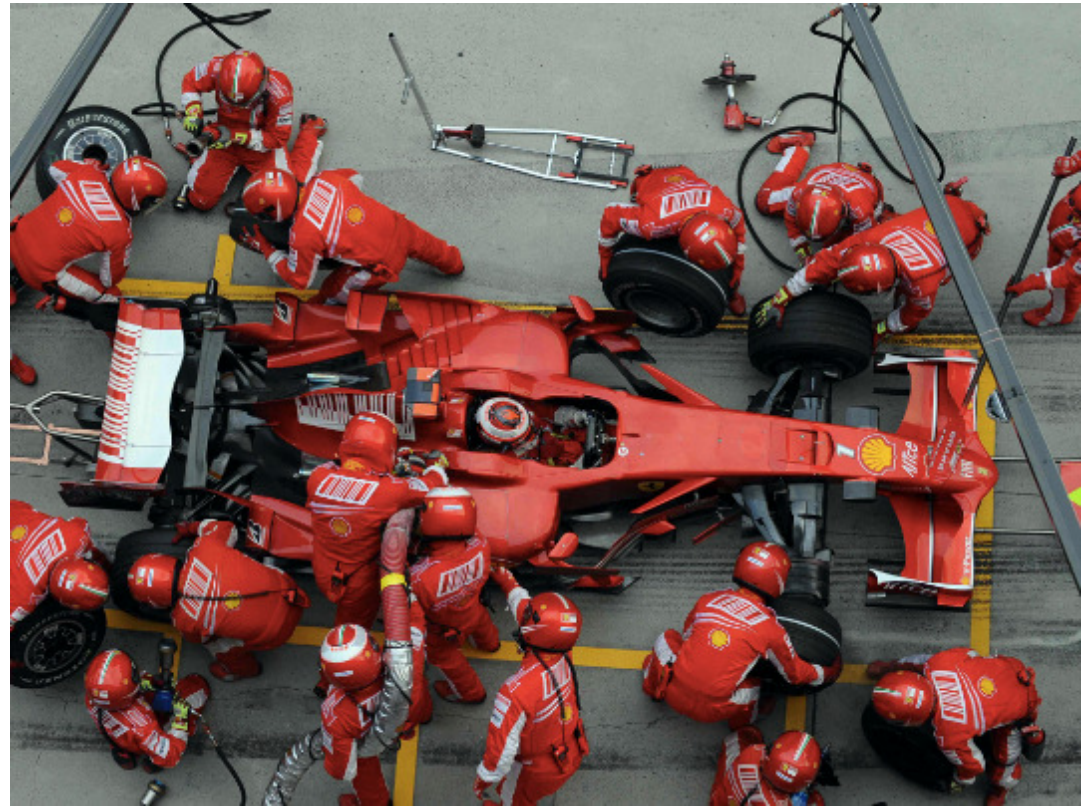
Export Nothing—liver sluts—“if Ochsner won’t use it why should we?”—Stingiest OPO in our region

Use Geography to Your Advantage/Build distant relationships.

Don’t Believe the Dogma.

Strive to continuously improve and find an edge.

Ask the next question.



Tuesday 3 am, Dan
(procurement coordinator)
calls:

Out of region 62 yr old
Caucasian female donor with a
BMI of 53.4 who died of
stroke. Bedside biopsy shows
40-60% macro-fat. Minimal
micro steatosis. Hx of HTN.

Not yet a primary offer

About 1000 miles away.

ABO: O

Serologies all negative

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About 1000 miles away.

ABO: O

Serologies all negative

Who is In, Who is Out?

If you are in, what do you want to
know next?

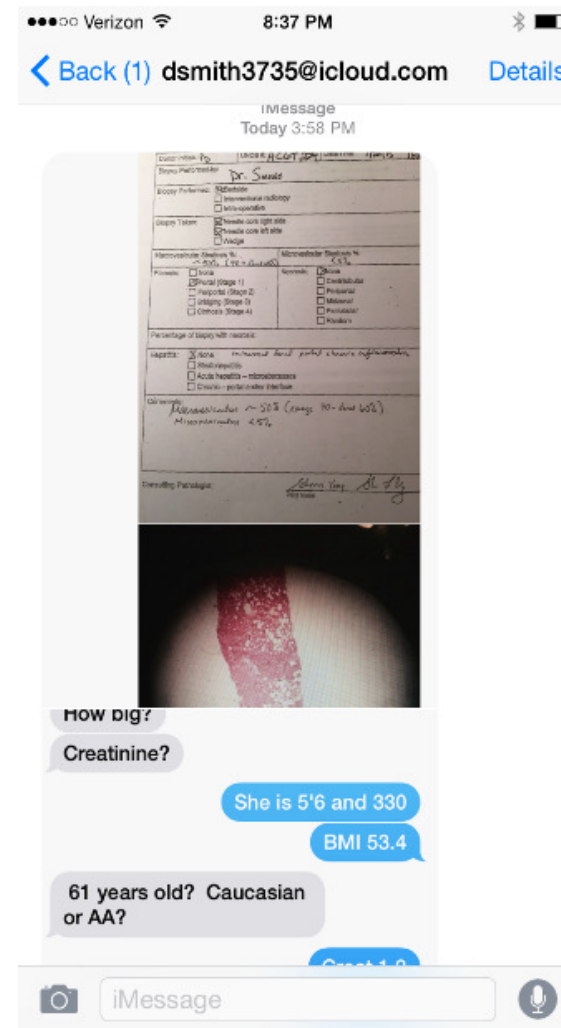
Tuesday 3 am, Dan calls and texts:

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About 1000 miles away.

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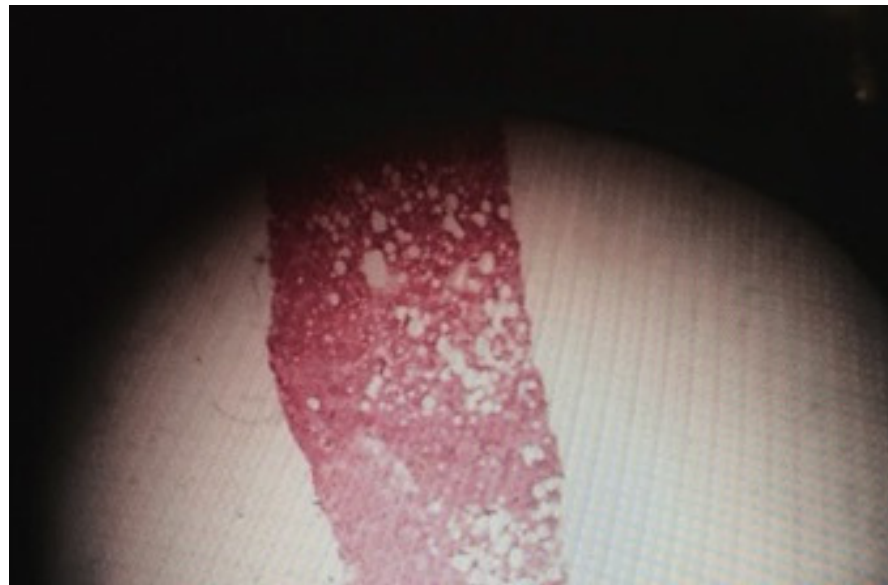
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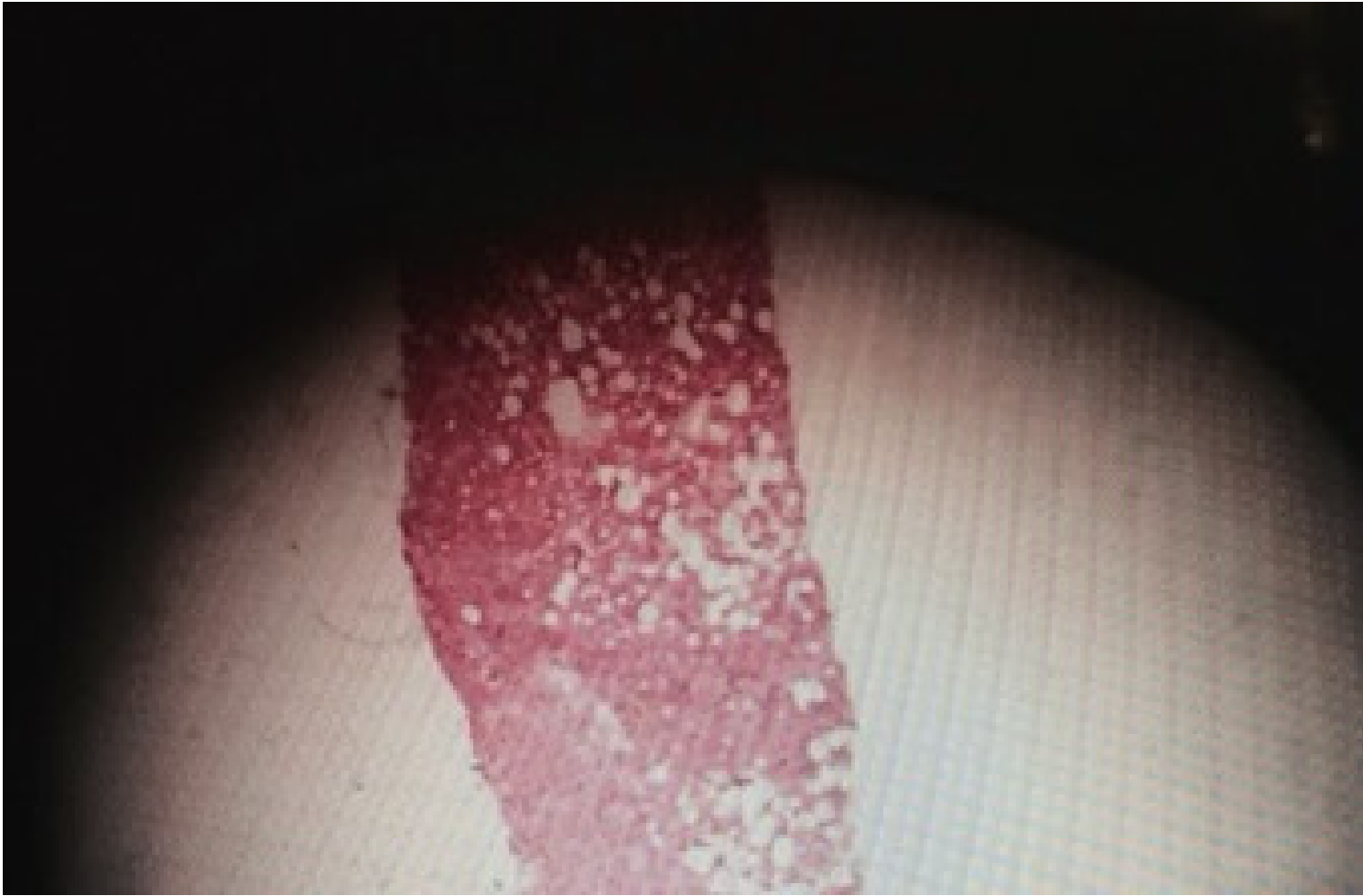


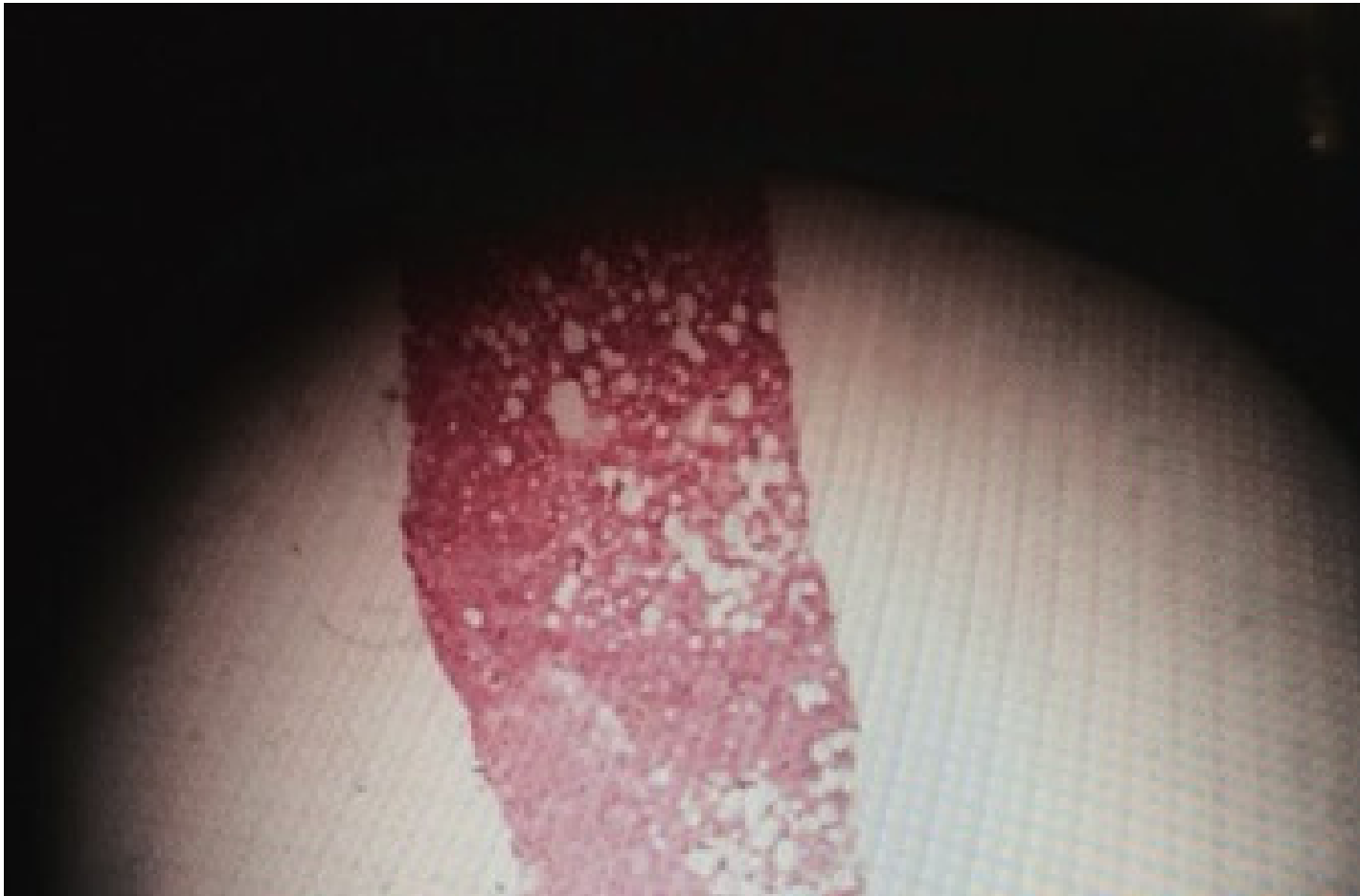
Pathology report and biopsy

Called 40-60% macrosteatosis
and less than 5% microsteatosis

Hepatitis:	<input checked="" type="checkbox"/> None	minimal focal portal chronic inflammation
	<input type="checkbox"/> Steatohepatitis	
	<input type="checkbox"/> Acute hepatitis – microabscesses	
	<input type="checkbox"/> Chronic – portal and/or interface	
Comments:	Macrovesicular ~ 50% (range 40-60%) Microvesicular < 5%	





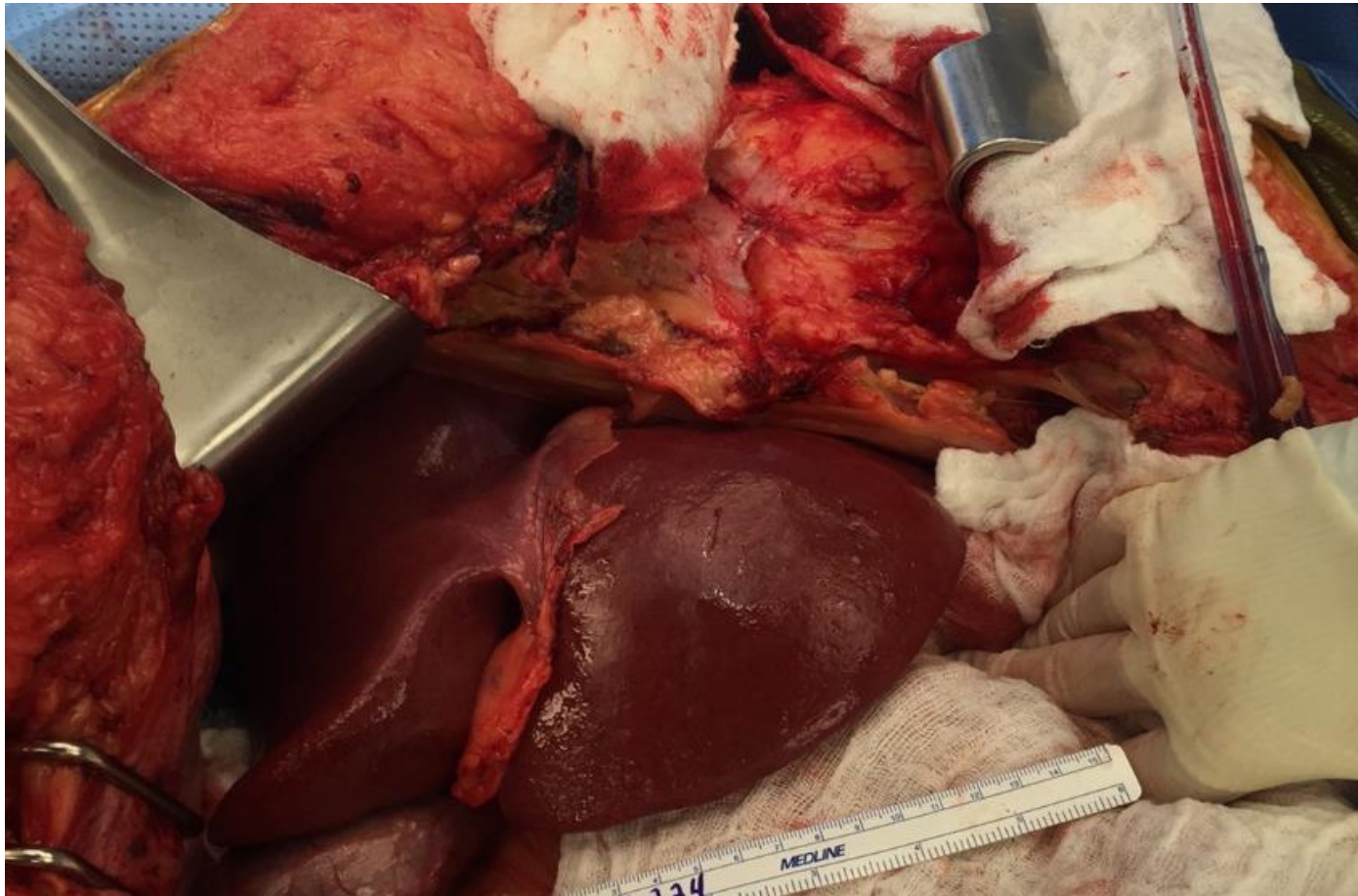


Who wants this liver?



Cr 1.2 AST 23 ALT 26 TB 1.8 INR 1.3 Na 144 pH 7.4—62 yr, BMI 53

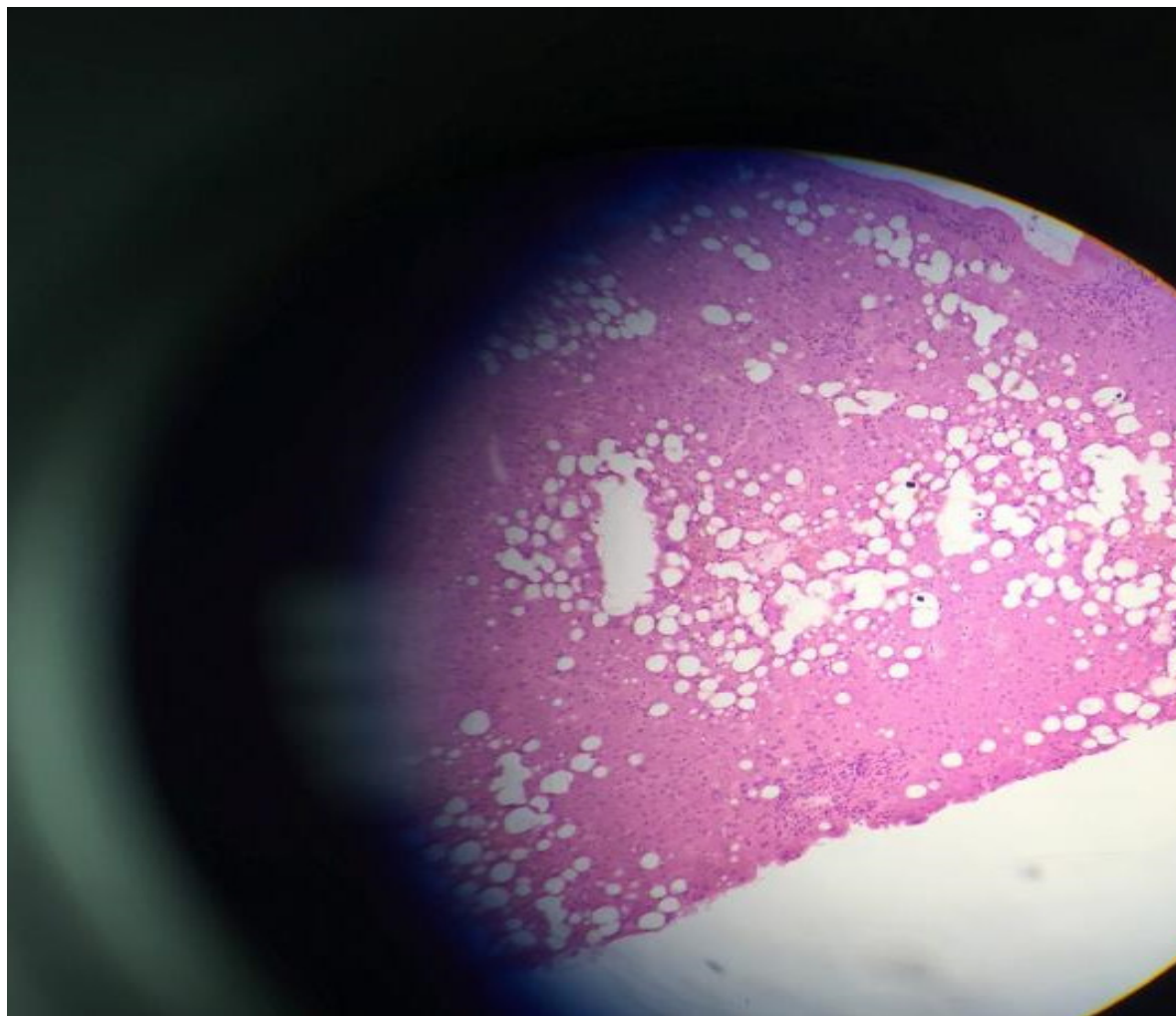
9 hours later they go to OR and take this photo



They Figured the iPhone Out!

Distance is 950 miles with a travel time of 3.5 hours including ground time.

How much macro fat do you think there is? 40-60%?

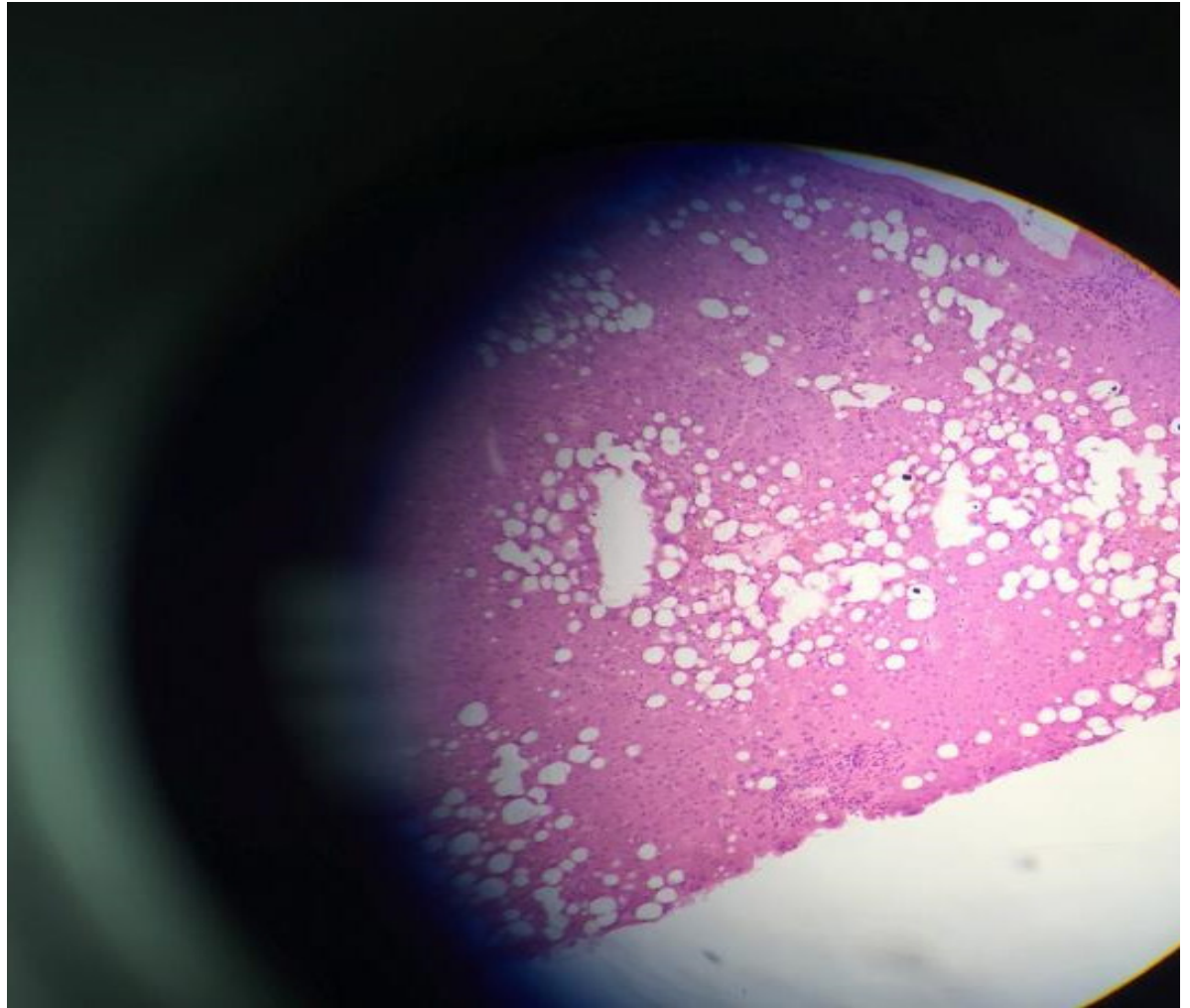


We Used It.

Liver arrived in our OR
4 hrs 15 min after
cross clamp.

Cold Ischemia Time
(CIT): 5 hrs 24 min

Warm Ischemia Time
(WIT): 22 min



Did it work?

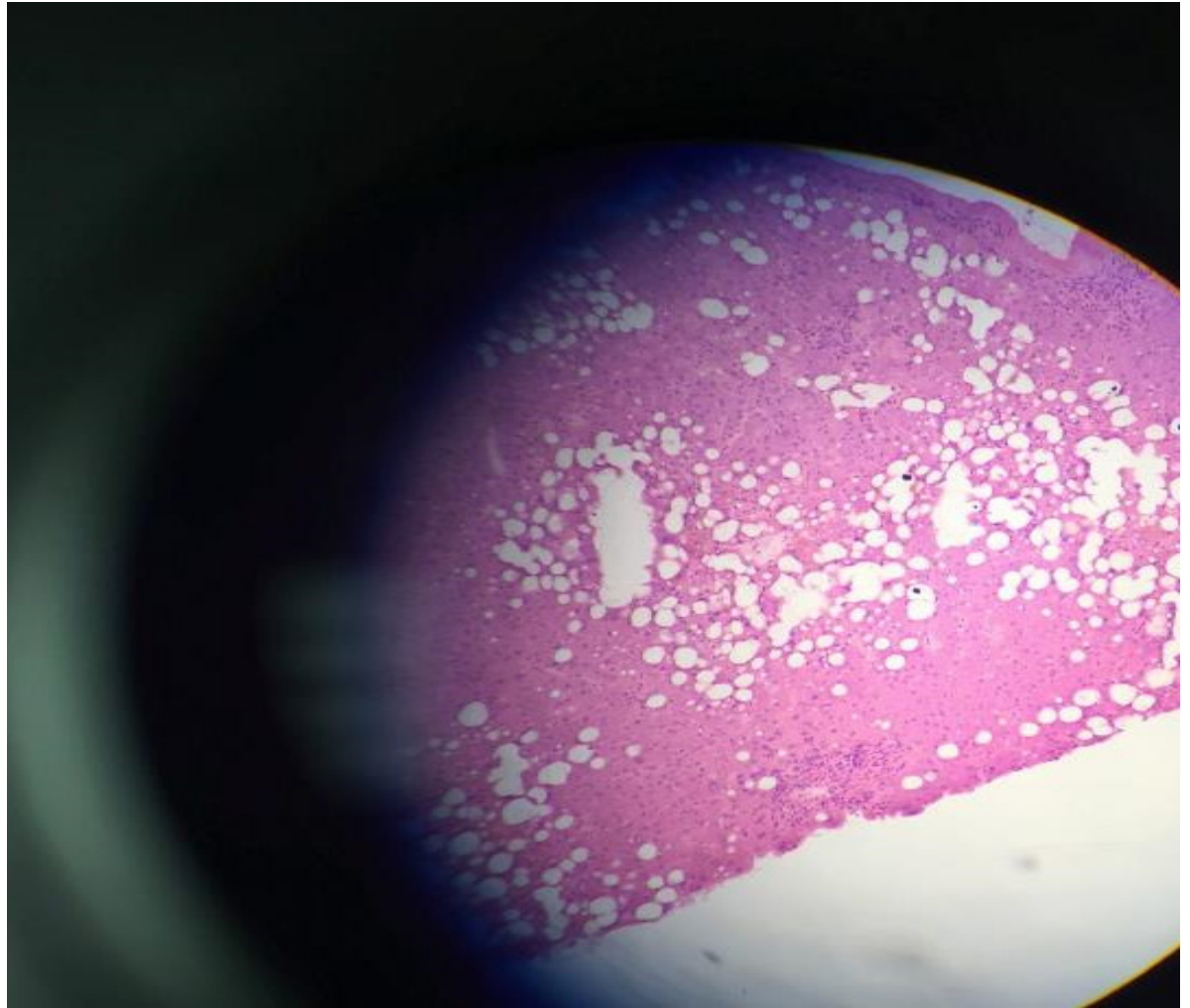
Recipient 6'2" 220 lb male
with a lab MELD of 14 and
listing MELD of 22 for HCC.

Intra-op (post-arterial) AST
2035, ALT 1450 and INR 2.1

OR time: 4 hrs

PRBCs: none. Extubated in
OR.

Initial Post-op Labs: AST
4244 (peak 5621), ALT
1751 (peak), INR: 1.5



Tim Calls at 8pm

Donor is an 18 yr old, 5'8",
160 lb, male, blood group
O, who died of anoxia from
a prescription drug
overdose combined with
EtOH with 41 minutes of
CPR. Terminal LFTs: AST
300 (peak 556), ALT 127
(peak 159), INR 1.1, pH 7.1

Tim Calls at 8pm

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Donor hospital is 2,275
miles away

Tim Calls at 8pm

Local Centers are running away because of biopsy results.

Bedside biopsy 80% macrosteatosis and diffuse microsteatosis, no fibrosis.

This is a call of interest only.

Tim Calls at 8pm

We saw the report and asked if we could see a photo of the biopsy slide.

Tim Calls at 8pm

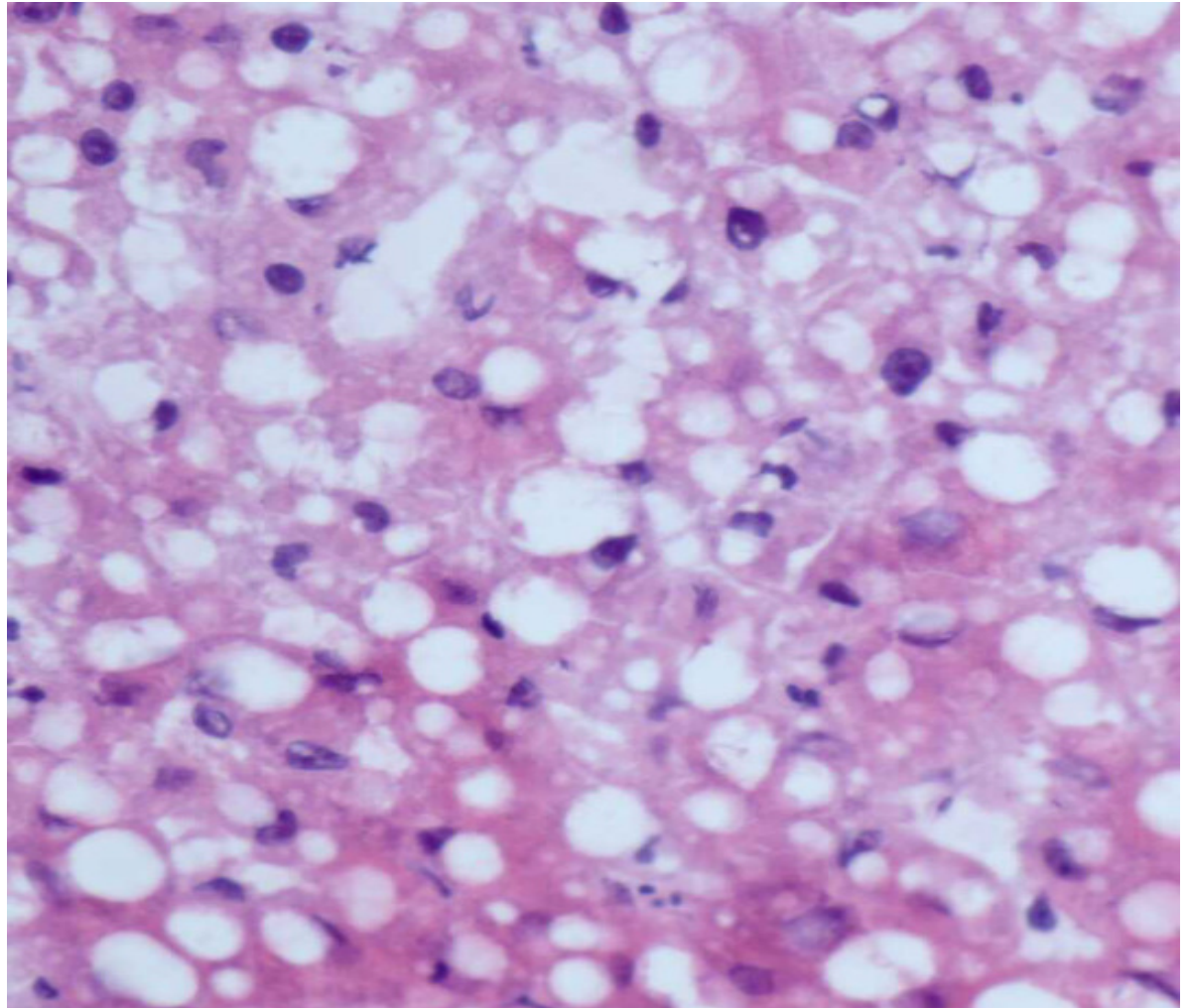
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Tim Calls at 8pm

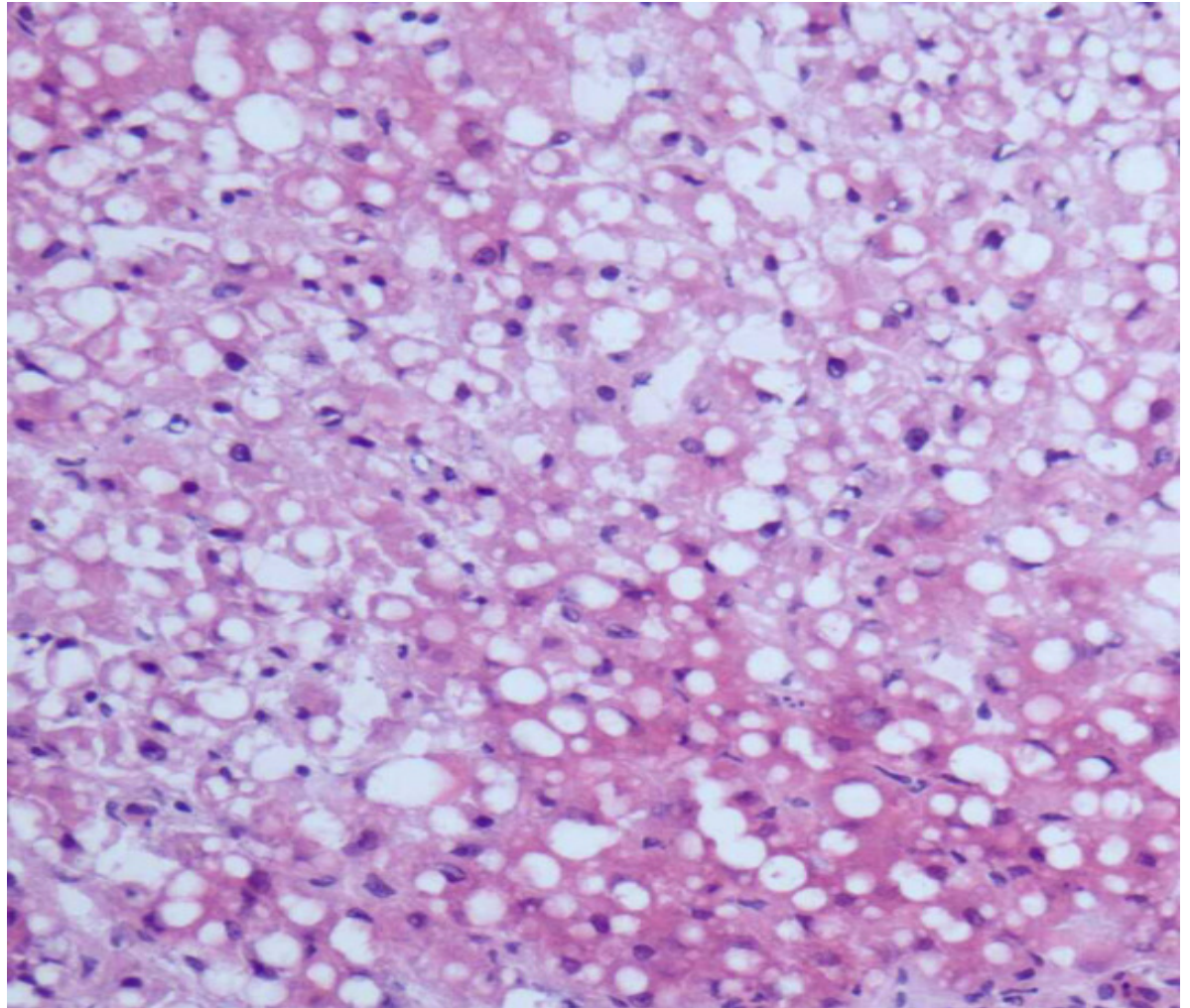
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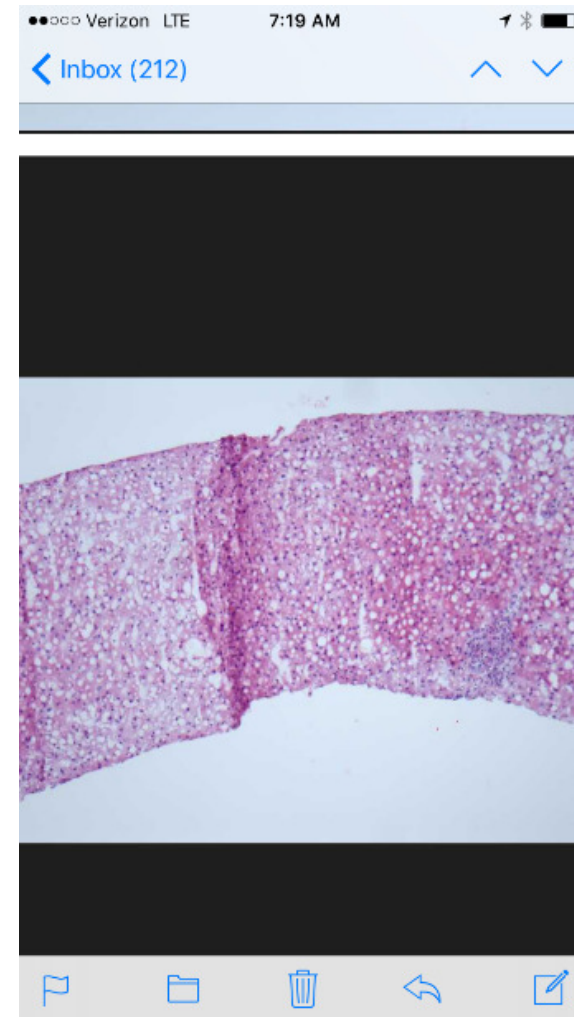
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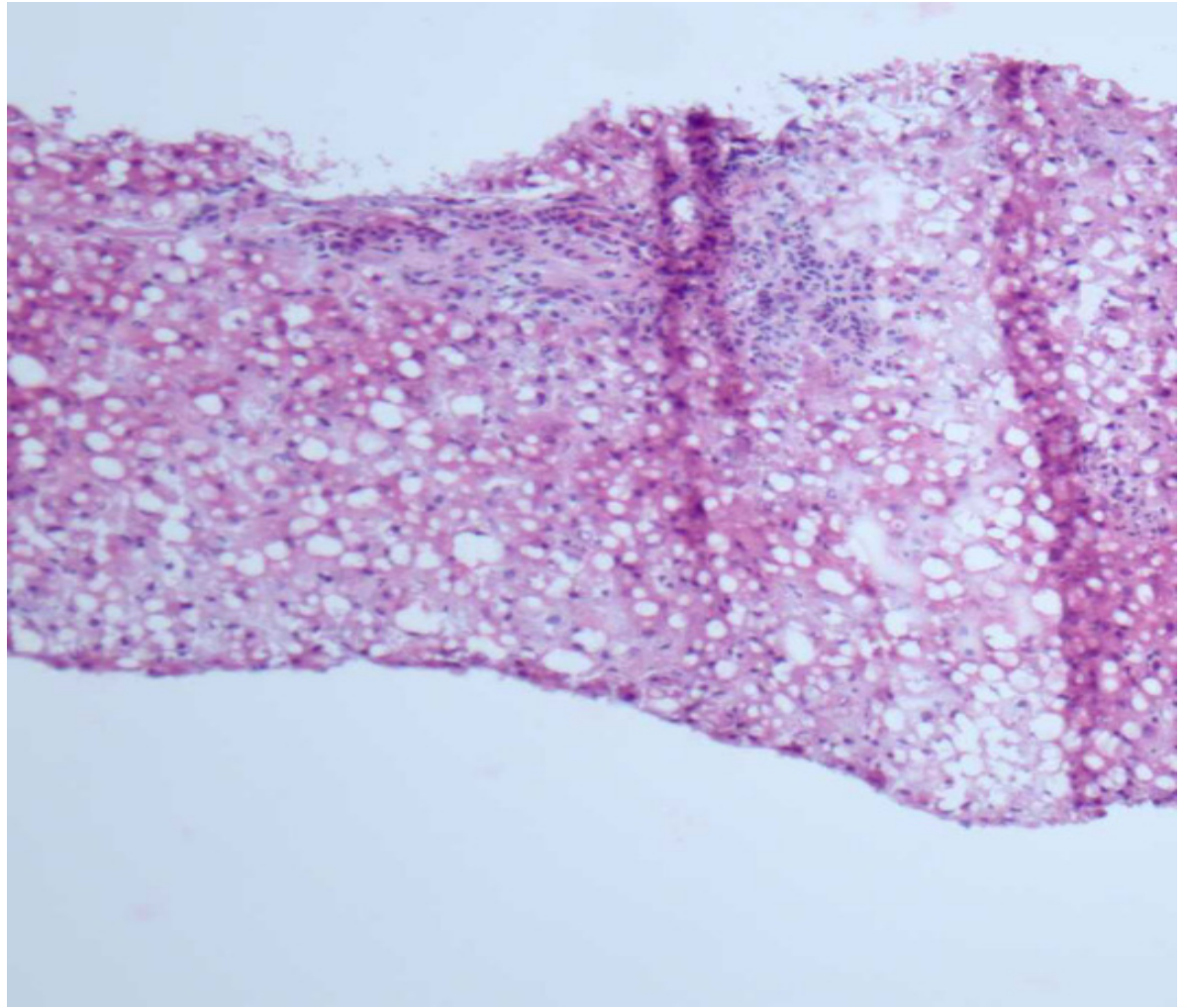
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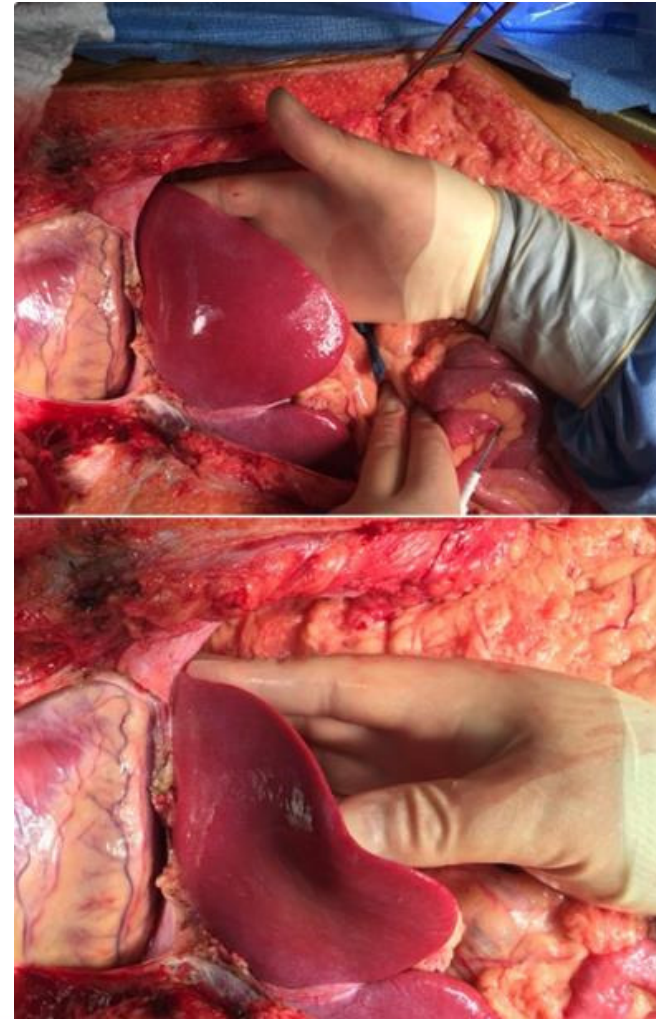


Bedside Biopsy

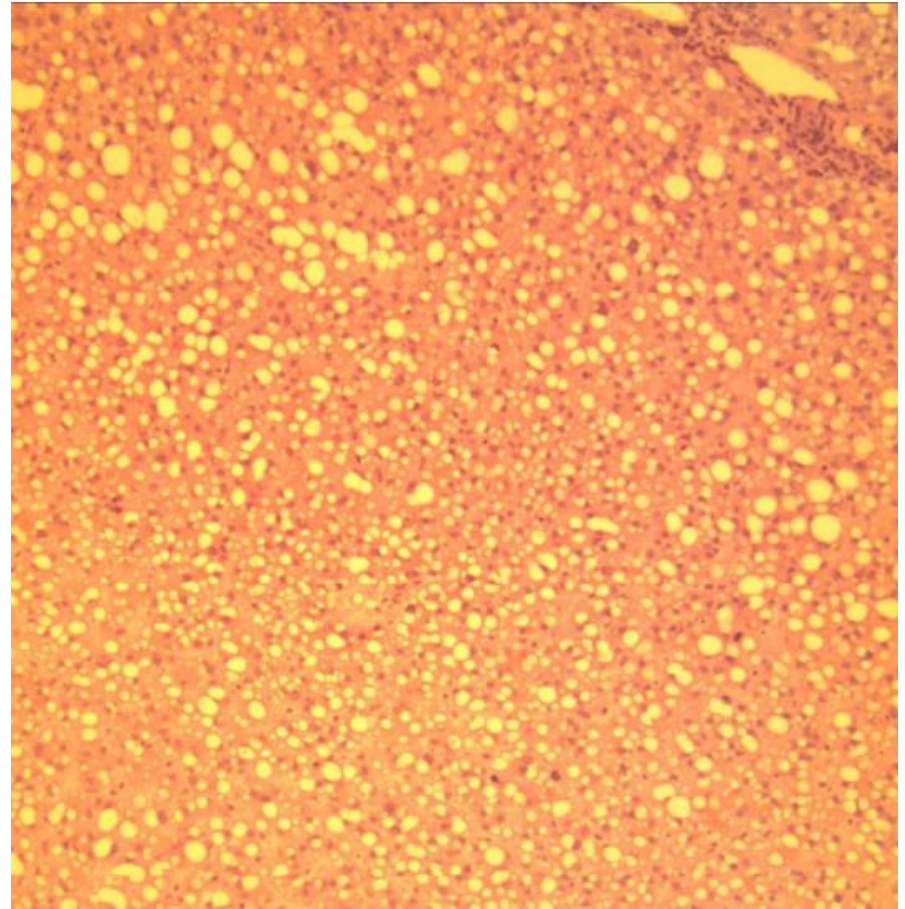
Our read was diffuse micro and 25-30% macro-steatosis.



Intra-op view of the liver



Intra-op wedge biopsy



We read this as diffuse micro and
20%-30% macro

Large Vacuolar Macrovesicular Steatosis to nearest 10%:	50
Total Steatosis to nearest 10%:	80

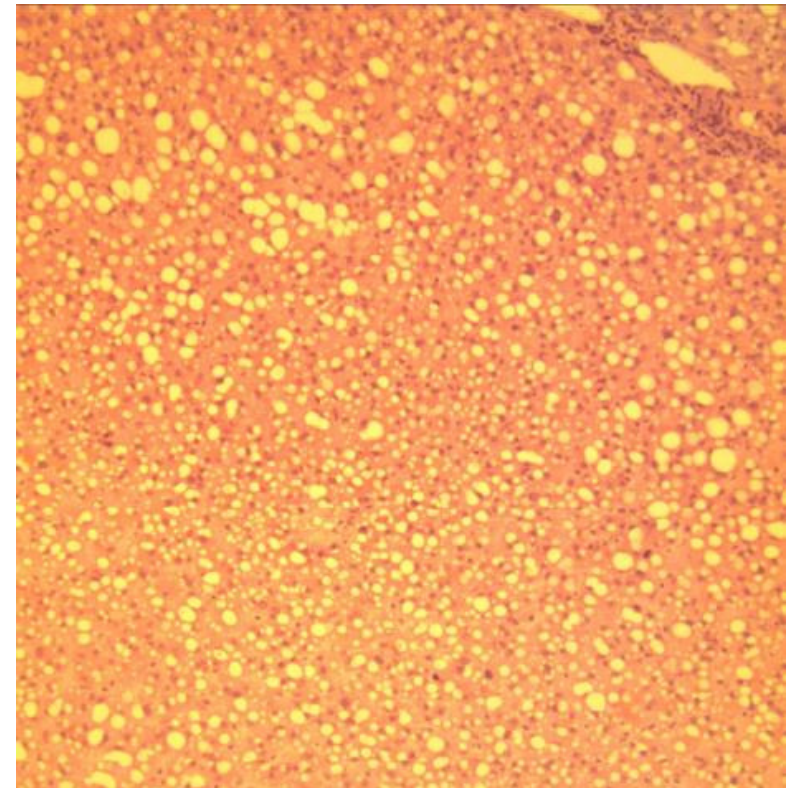
Chronic Hepatitis-related (circle one)	Score
No fibrosis	0
Portal/periportal fibrosis involving a minority of portal tracts	1
Periportal fibrosis involving a majority of portal tracts	2
Definite/Bridging fibrosis	3
Cirrhosis	4

Please check one choice for location and document percent involvement

Hepatocyte Necrosis (Location)	<input checked="" type="checkbox"/> None	<input type="checkbox"/> Centrilob
	<input type="checkbox"/> Periportal	
	<input type="checkbox"/> Midzonal	<input type="checkbox"/> Random

Percent of Biopsy Involved by Necrosis (estimate to nearest 10%):

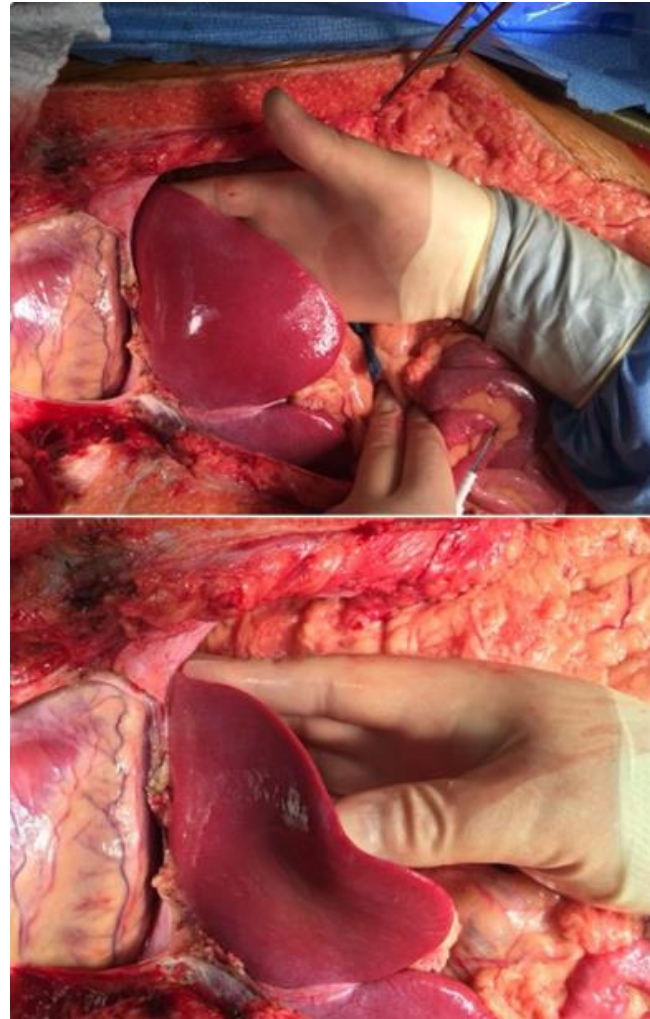
Portal and Lobular (circle one)	Score
None	0
Mild, some or all portal areas	1
Moderate, some or all portal areas	2
Moderate marked, all portal areas	3
Marked, all portal areas	4



Our Recipient

6', 174 lbs, BMI 23.7, 62 yr old male with HCC/CAHC cirrhosis with a low lab MELD and an allocation MELD of 22.

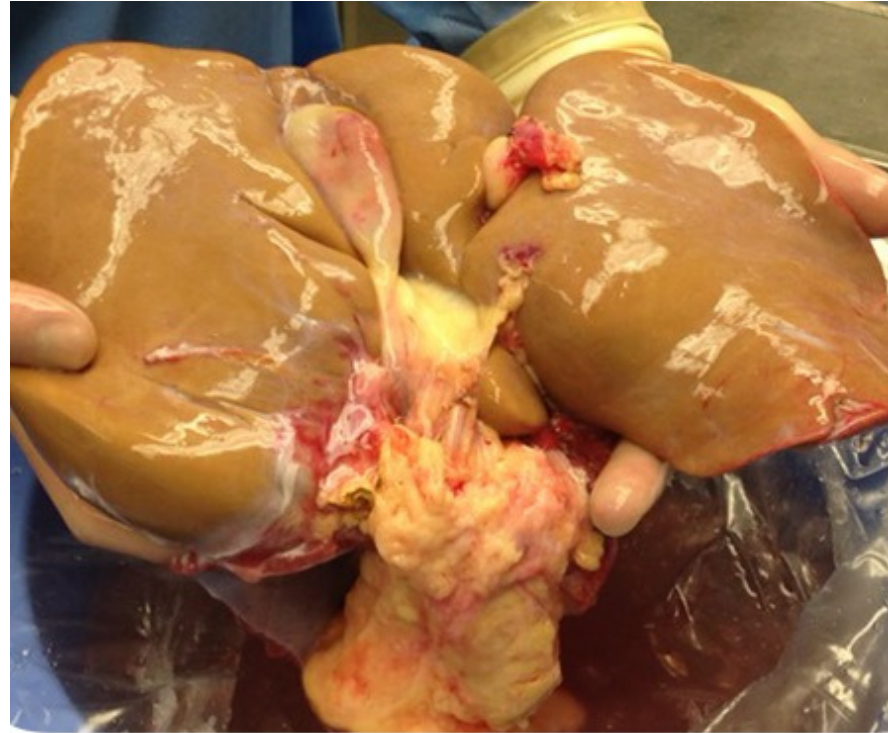
Patient was number 1,329 on the match run list.
Surgical risk A (no surgical challenges expected).
Medical risk A (no expected medical challenges).



The Operation

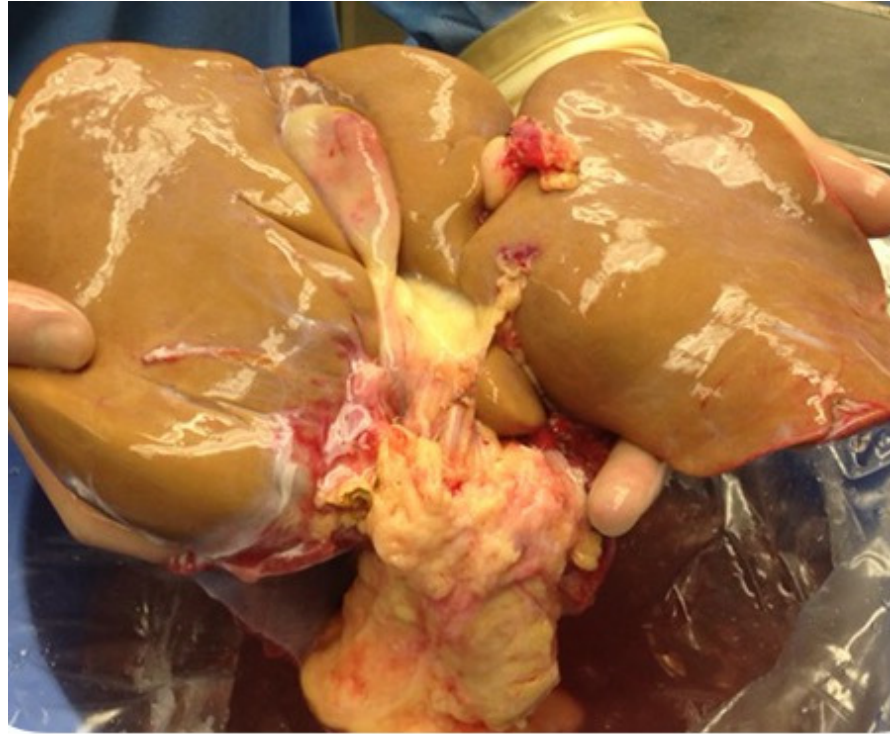
Liver arrived in our OR 7 hours after crossclamp.

CIT: 8 hrs 14 min and WIT 24 min. No PRBCs and cellsaver 695 cc.



Intra-op: AST 3,175 (peak 4,422 on POD 1), ALT 2,033 (intra-op was peak), INR 1.6 (1.1 on POD 2), Cr peaked at 1.5 on POD 0 and normalized to 1.1 on POD4, T. Bili peaked at 4.8 on POD 4.

Patient discharged POD 9.



One Month Later

AST: 37

ALT: 37

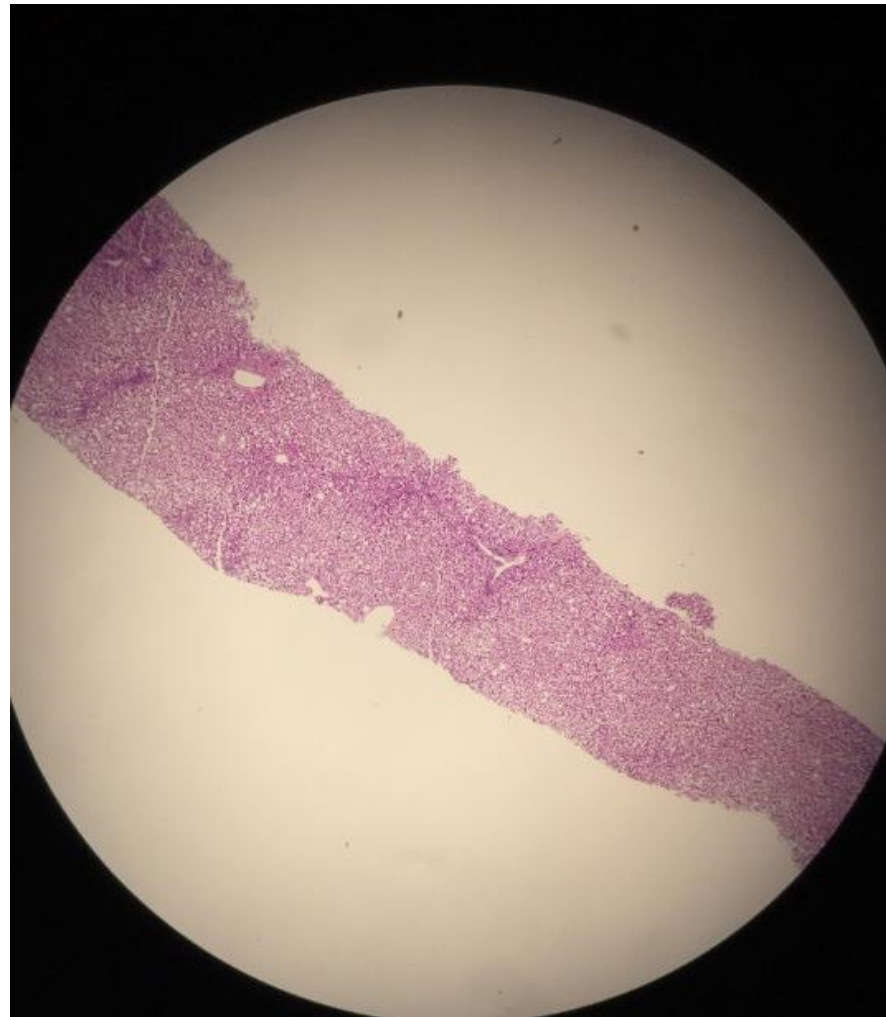
AP: 135

Tbili: 1.1

Reading of Permanent
Donor Biopsy:

40-50% macro

40% micro



Influencing Others

Call from over 2000 miles away

Backup call: 37 yr old died from CVA.

Bedside biopsy: read as 70% macro fat at community donor hospital.

All local centers out

We walked them through taking a photo.

Influencing Others

Call from over 2000 miles away

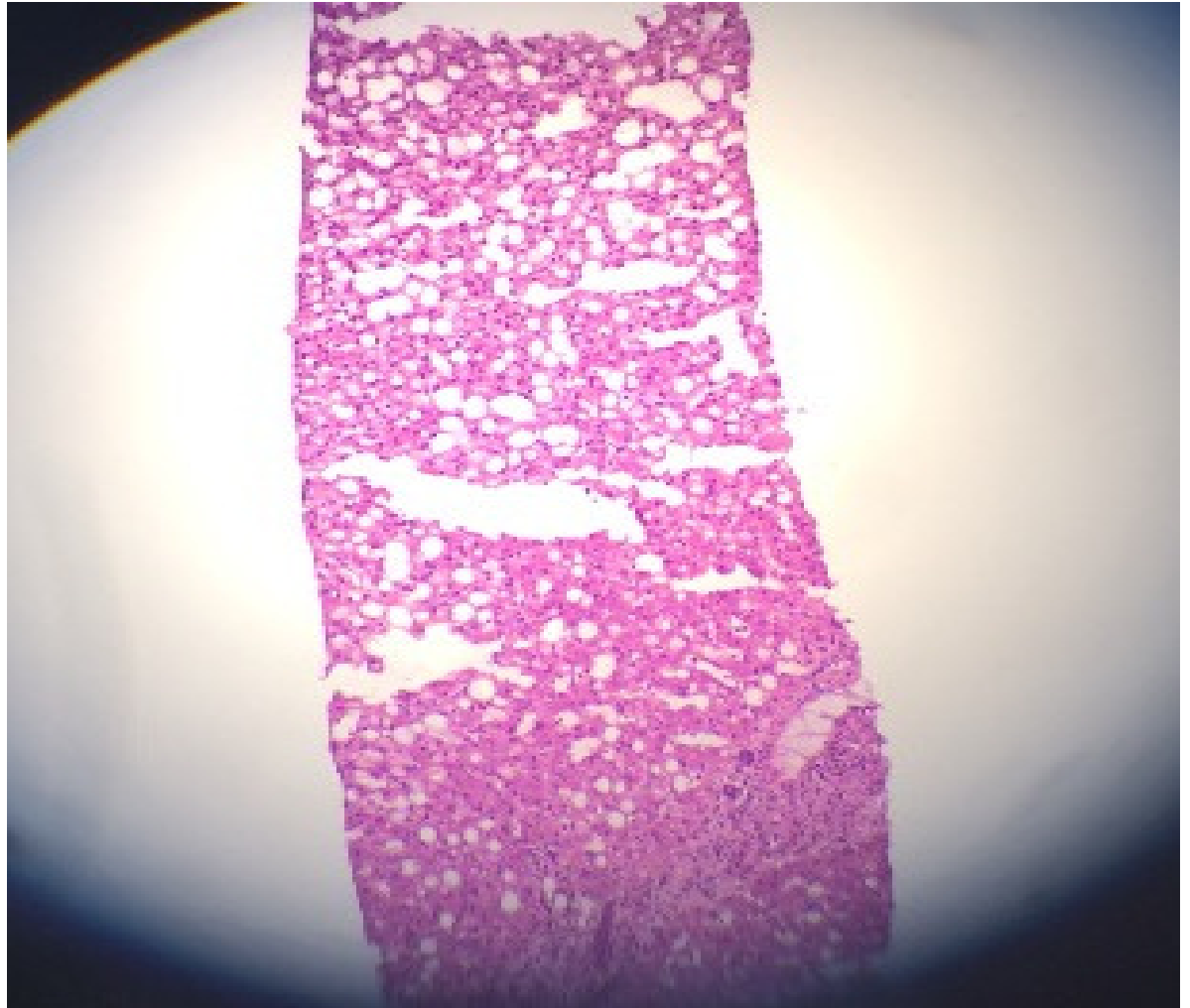
Backup call: 37 yr old died from CVA.

Bedside biopsy: read as 70% macro fat at community donor hospital.

All local centers out

We walked them through taking a photo.

We called it 25-30% macro



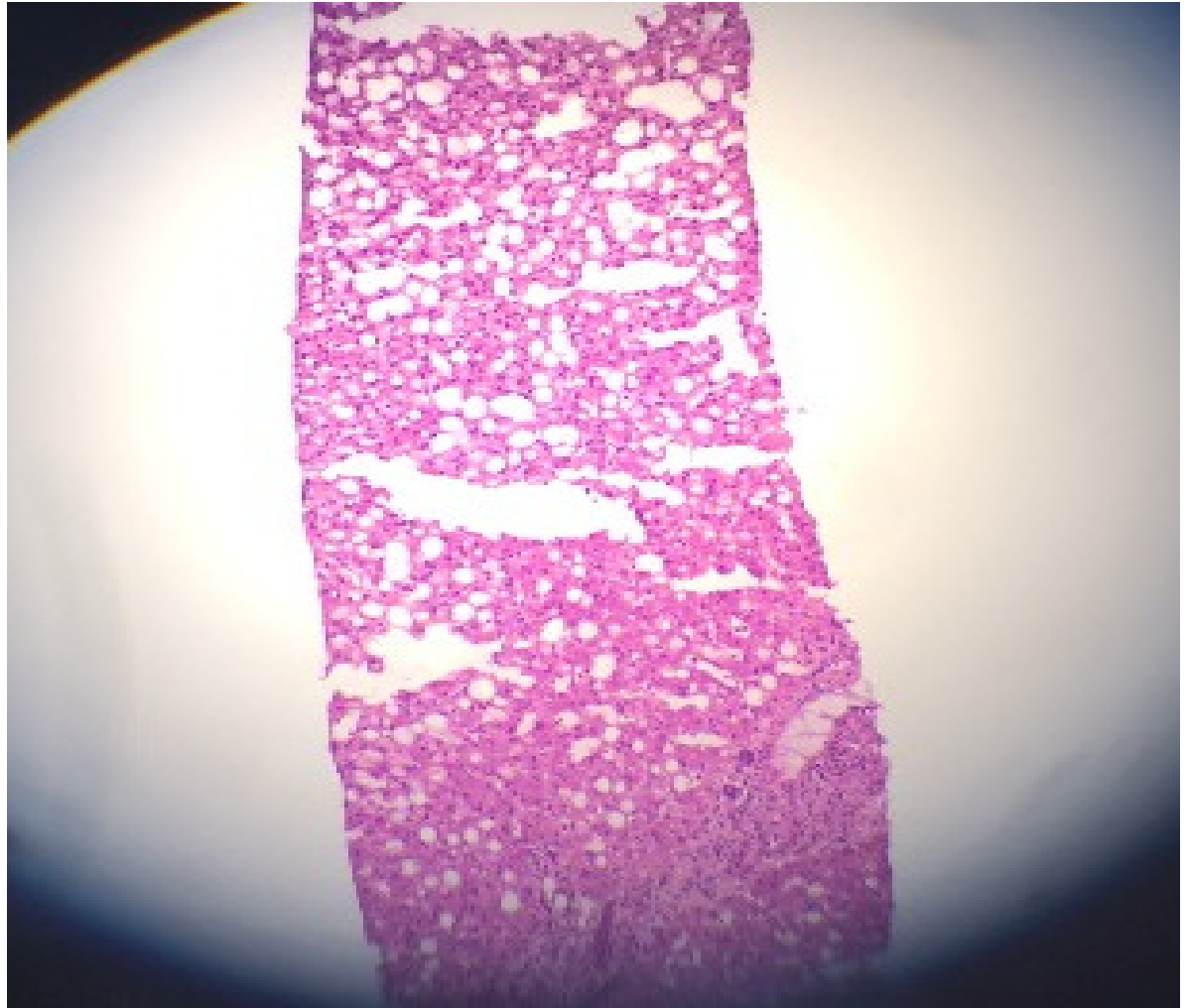
Influencing Others

The OPO emailed the photo to the largest local center.

Pathologist there read the iphoto and agreed with us: 25-30% macro.

They re-ran the list with the new information and the liver stayed locally.

That is fine with us.



We Don't Use Bad Livers; We Use Good Livers with Bad Stories

Graft survival significantly better than expected

Patient survival is significantly better than expected

Adult Primary Non-function (PNF) rate 0.1% (national rate still reported as 2-7%)

Transplant rate is significantly higher than expected (2.10 vs expected of 0.66)

Wait time is short (median 2.1 months vs national 15.6)

Mortality rate while on waitlist (0.15 vs expected of 0.19)

Over 100 consecutive DCD liver transplants performed without a graft loss from ischemic cholangiopathy in absence of late HAT.

1 yr Patient and Graft Survival Summary

Excludes patients with meld ≥ 35 —1 yr pt survival of this group 95.5% regardless of organ source

1 yr Patient and Graft Survival Summary

Transplants Performed 1/1/2012 - 12/31/2015	Observed 1-Year Patient Survival	Expected 1- Year Patient Survival	Observed 1- Year Graft Survival	Expected 1- Year Graft Survival
LOPA Donors n=264	96.5%	92.0%	95.1%	89.0%
Region 3 Donors (excl LOPA) n=211	92.5%	92.0%	91.6%	89.1%
non-Region 3 Donors n=74	91.3%	92.0%	90.1%	90.4%

Internal Ochsner Data

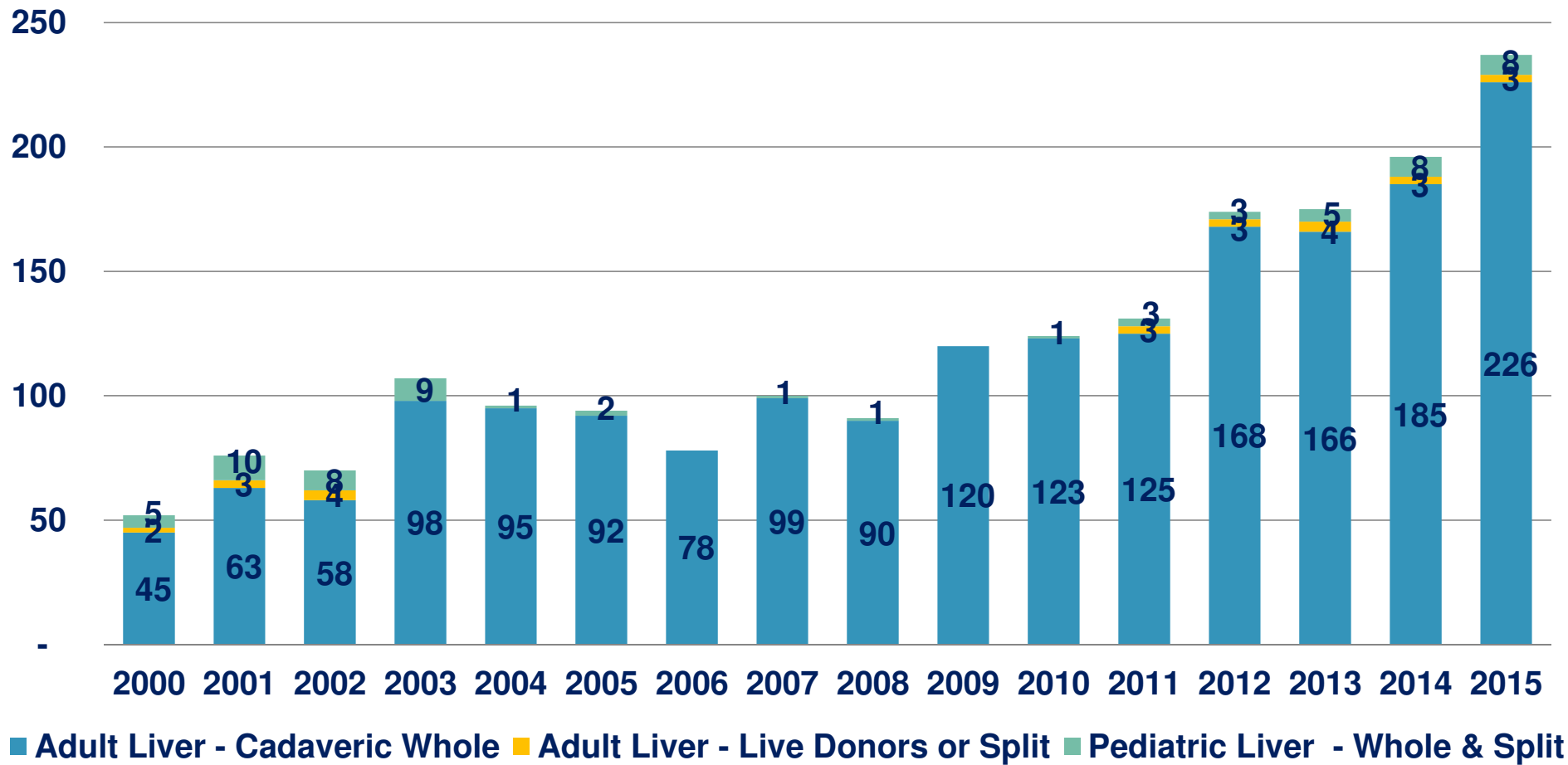
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Transplants Performed 1/1/2012 - 12/31/2015	Avg MELD	Median MELD
LOPA Donors	24	22
Region 3 Donors (excl LOPA)	24	22
non-Region 3 Donors	20	21

Internal Ochsner Data

Liver Transplant Volume 2000-2015



Ochsner MD Team

Hepatologists

- Nigel Girgrah
- George Therapondos
- Natalie Bzowej
- Shoba Joshi
- Gia Tyson

Surgeons

- Ari Cohen
- David Bruce
- Ian Carmody
- Humberto Bohoroquez
- Trevor Reichman
- Emily Ahmed
- John Seal
- Narendra Battula (fellow)

Thank You





