Using HCV Viraemic Organs for HCV Negative Recipients

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Brighton 2018

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Outline of Talk

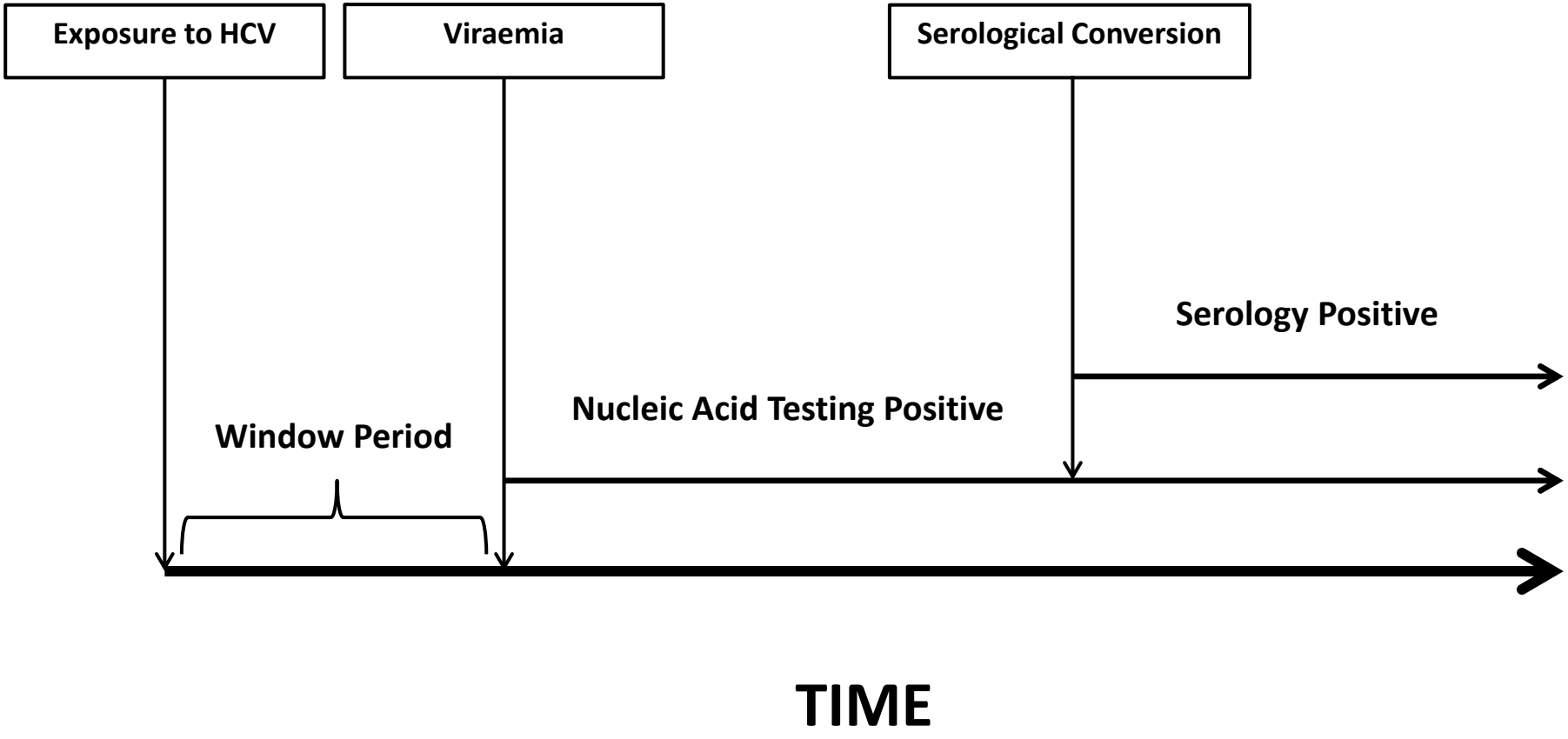
- Which donors are we talking about?
- Why is it time to move on?
- What is the evidence that this approach is safe?
- What are the dangers of adopting a new approach?
- National Position Statement – launching today
- Next Steps

Which donors are we talking about?

Increased Infectious Risk Donors

- Known HCV viraemic patients
- Recent intravenous drug use
- Commercial sex workers
- Individuals engaged in unprotected anal intercourse with multiple partners
- Untested sexual partners of individuals known to be infected with HBV/HCV/HIV
- Incarcerated in last 12 months
- Non-sterile tattooing or piercing in last 12 months

HCV Virology and Serology

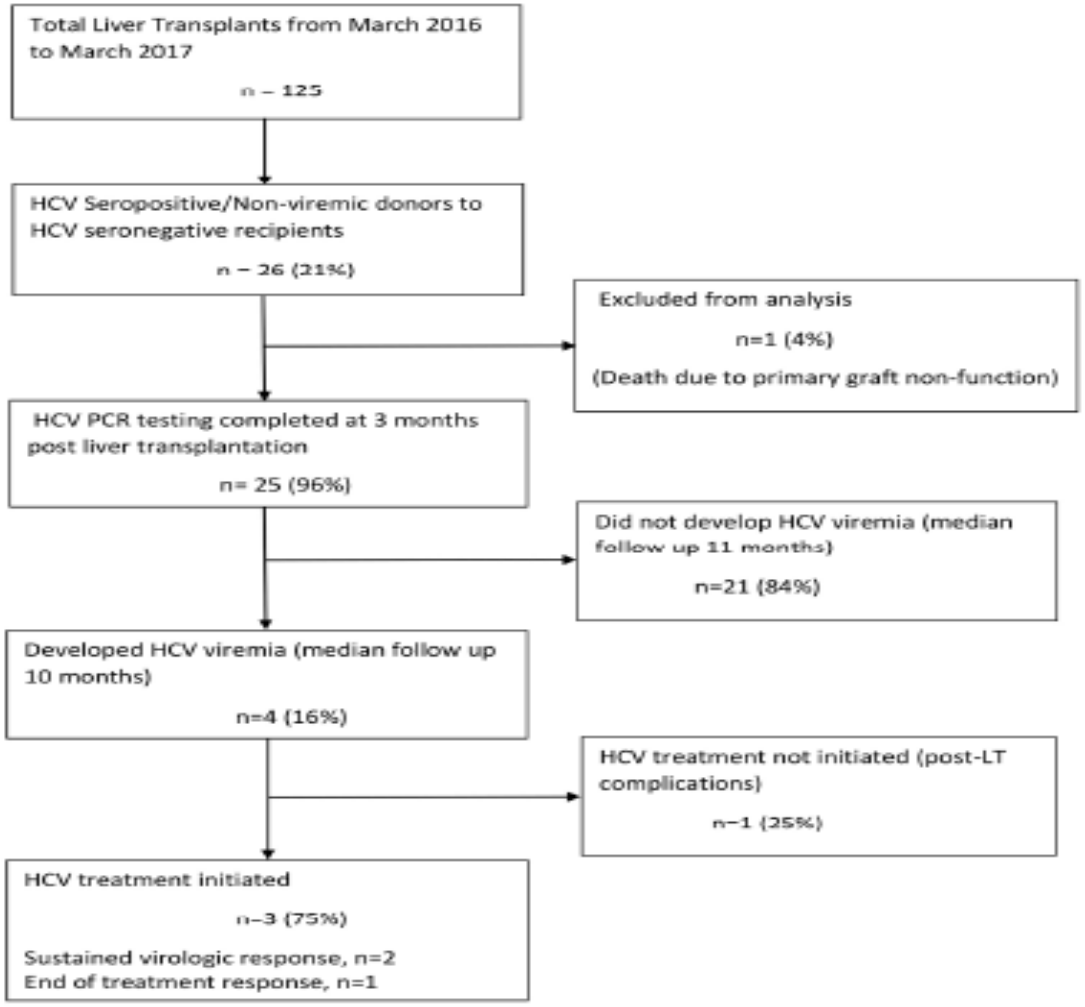


Nomenclature Definition

- Essentially talking about known HCV viraemic donors or those with the potential to be
- Literature is poor at differentiating antibody and PCR positive donors
- Best to consider all increased infectious disease risk donors and HCV Ab positive donors as potentially viraemic

Hepatitis C Transmission from Seropositive, Non-Viremic Donors to Non-Hepatitis C Liver Transplant Recipients

Khurram Bari, MD;[1] barikm@ucmail.uc.edu; no conflicts of interest



Liver Transplant recipient flow diagram

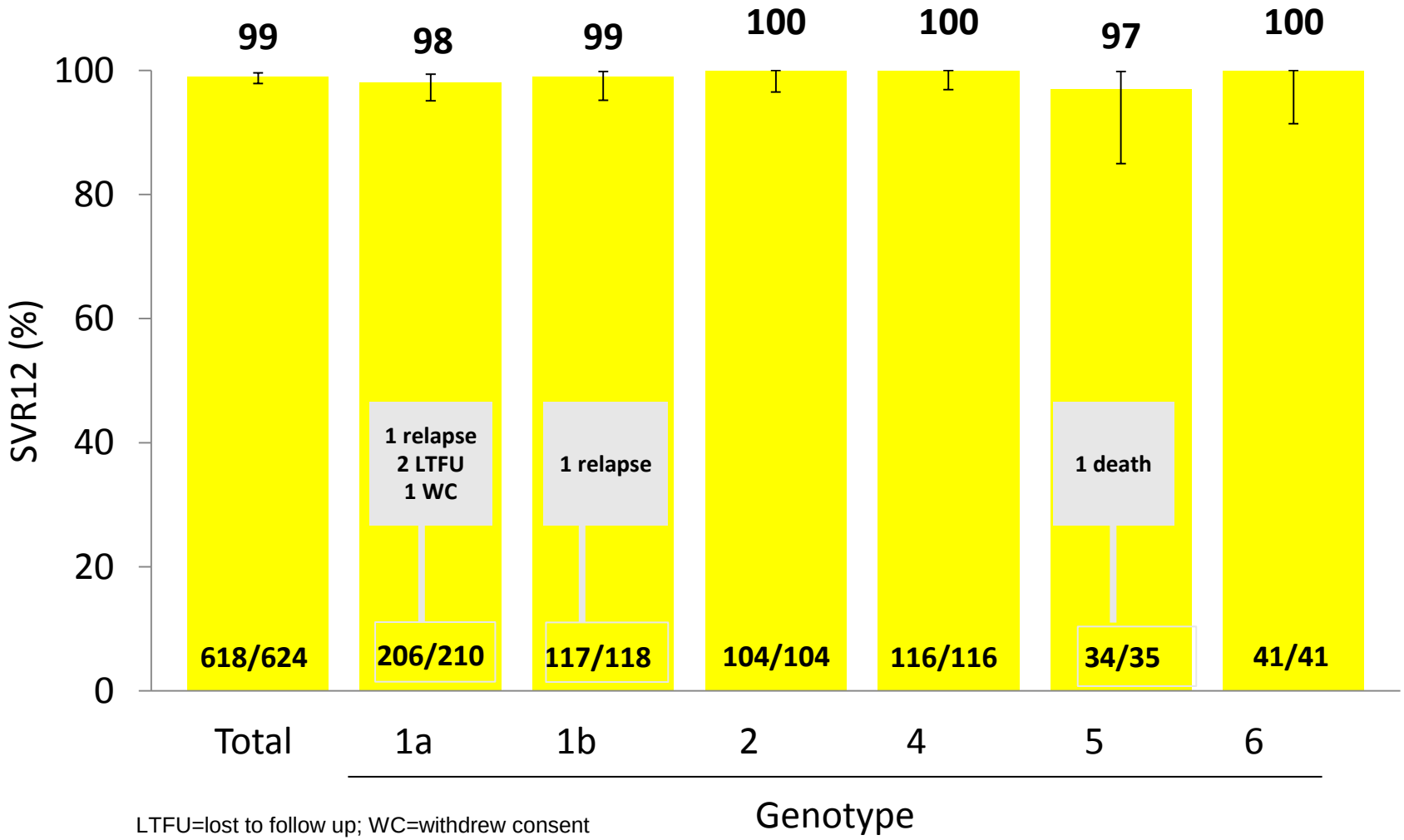
Hepatology (in press)

Why is it time to move on?

Numerous Reasons

- The number of HCV viraemic transplant recipients is falling
- HCV positive donor organ discard rates are unacceptably high – reversing this is both **life and cost-saving**
- There is some evidence that drug overdose related deaths are on the increase in England
- Modern DAA therapy will allow us to cure virtually everyone post-transplant
- We already intentionally infect patients with viruses if the risk benefit-ratio is right – CMV is a prime example

ASTRAL-1: SOF/VEL for 12 Weeks in GT 1, 2, 4, 5, 6 HCV-Infected Patients



LTFU=lost to follow up; WC=withdrew consent

Feld, AASLD, 2015, LB-2. Feld JJ, et al. *N Engl J Med*. 2015. DOI: 10.1056/NEJMoa1512610

Recent UK Wide Data

- Analysis by NHSBT of donors from 2000 to 2015
- 244 HCV +ve donors identified
- Only 65 (27%) provided organs for 93 recipients (63 livers and 30 other organs)
- Organs from 146 HCV +ve consented organs were declined with 71.4% being because of positive virology
- The median eGFR of declined HCV+ve donors was 103 ml/min/m2 (IQR 70-144)
- 49% had a UK donor risk index score of <1.02, suggesting at least 77% of potential transplanted kidneys from such donors would be functioning at 5 years
- Transplanting D+ kidneys into R- recipients was estimated to be cost neutral with dialysis after 4 years of transplant

Courtesy of James Neuberger

We are already behind the curve

American Journal of Transplantation 2017; 17: 2790–2802
Wiley Periodicals Inc.

doi: 10.1111/ajt.14381

Meeting Report

The American Society of Transplantation Consensus Conference on the Use of Hepatitis C Viremic Donors in Solid Organ Transplantation

J. Levitsky[1,*,†], R. N. Formica[2,†], R. D. Bloom[3], M. Charlton[4], M. Curry[5], J. Friedewald[1], J. Friedman[6], D. Goldberg[3], S. Hall[7], M. Ison[1], T. Kaiser[8], D. Klassen[9], G. Klintmalm[7], J. Kobashigawa[10], A. Liapakis[2], K. O'Conner[11], P. Reese[3], D. Stewart[9], N. Terrault[12], N. Theodoropoulos[13], J. Trotter[7], E. Verna[14] and M. Volk[15]

need for scientific study and consensus, the American Society of Transplantation convened a meeting of experts to review current data and develop the framework for the study of using HCV viremic organs in solid organ transplantation.

Abbreviations: CDC, Centers for Disease Control and Prevention; ChLIA, chemiluminescence assay; CKD, chronic kidney disease; DAA, direct-acting antiviral agent; EIA, enzyme immunoassay; ESRD, end-stage renal disease; FDA, Food and Drug Administration;

AJT 2017

SaBTO Guidelines

Test result(s) suggesting possible donor HCV infection	Organs	Tissues	HSPC, TC and Human embryonic stem cells	Gametes and embryos

1.1.6 HCV infection in the potential donor does not amount to an absolute contra-indication to donation of material for life-preserving transplantation, however the net benefit of transplantation must be considered against the risk of not receiving that specific transplant. This risk/benefit analysis allows for the potential use of a transplant from a HCV infected donor to a non-infected recipient.

* EUTCD prohibits donation from individuals with a "history, clinical evidence, or laboratory evidence of HIV, acute or chronic hepatitis B (except in the case of persons with a proven immune status), hepatitis C and HTLV I/II, transmission risk or evidence of risk factors for these infections."

**EUTCD prohibits non-partner donation of gametes and embryos if Anti-HCV antibody is positive

Courtesy of James Neuberger

Cost equation

- The annual cost of haemodialysis is c.£30,000
- The annual cost of a renal transplant (after the first year) is c.£5,000

- Therefore, each extra year of dialysis costs £25,000
  - For highly sensitized patients the cost may reach £250,000.

- More importantly these patients face the prospect of being consigned for many years on dialysis, with poor QoL, limited ability to work or travel, and a considerable risk of death on dialysis.

- Opening up a pool of HCV (+) kidneys, that would otherwise be discarded, specifically to patients who would otherwise have a high mortality will offers such patients significantly improved health outcomes

Courtesy of Mark Harber

What is the evidence that this approach is safe?

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Trial of Transplantation of HCV-Infected Kidneys into Uninfected Recipients

- >500 kidneys with HCV discarded annually in US
- Open label, single group pilot trial – THINKER trial at U Penn (n=10)
- Geno 1 +RNA,
- Post-transplantation elbasvir-grazoprevir
- Inclusion: HD, predicted long wait time
- Exclusion: Condition increasing likelihood of liver disease
- IS: Steroids, ATG
- HCV RNA day 3
  - once positive – 12 weeks elbasvir-grazoprevir

Goldberg et al, NEJM 2017

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Trial of Transplantation of HCV-Infected Kidneys into Uninfected Recipients

- Median age 59, M:F 1:1, 2 black
- Median wait for HCV + organ 58 days
- HCV RNA detectable in all on day 3, 9 Geno 1a, none NS5A RAS

- SVR12 100%
- Median eGFR 68ml/min (51-83)
- Complications: Delayed graft function (n=1), elevated ALT (n=2), transient class I DSA (n=1), proteinuria & FSGS (n=1)
- Overall: Excellent allograft function

Goldberg et al, NEJM 2017

EXPANDER-1: Exploring Renal Transplants Using Hepatitis-C Infected Donors for HCV-Negative Recipients

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

GT1a

NS5a resistant variants

Yes

Add ribavirin
Treat for 16 weeks

No

GT1b, 4

No change

GT2, 3

Add sofosbuvir
Treat for 12 weeks

HCV-infected donors (*n* = 10)	
Median age (IQR), *y*	30 (23-35)
Female, *n (%)*	5 (50)
White race, *n (%)*	10 (100)
Cause of death, *n (%)*	
Overdose	6 (60)
Trauma	3 (30)
Cardiovascular	1 (10)
Median KDPI score (IQR), %	45 (41-50)
Nonreactive to hepatitis B total core IgG antibodies, *n (%)*	9 (90)

HCV = hepatitis C virus; IQR = interquartile range; KDPI = Kidney Donor Profile Index; NSAID = nonsteroidal anti-inflammatory drug.

N. *Am J Transplant.* 2017;17 (suppl 3). American Transplant Congress 2017, Abstract no 2.

EXPANDER-1 Results

Table 2. Donor HCV Characteristics and Recipient HCV Status After Transplant

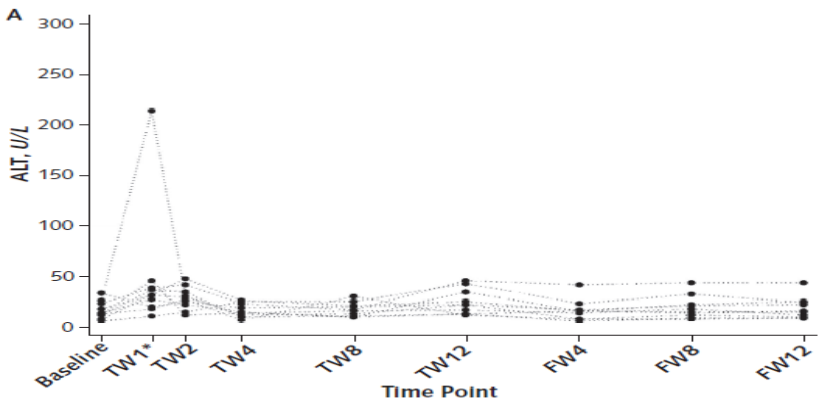
Donor-Recipient Pair	Genotype	Donor		Recipient						
		HCV RNA Level, *IU/mL*	HCV Antibody Status	HCV RNA Level, *IU/mL*				HCV Antibody Status at FW12	Positive PPs, *n*	
				POD1	TW1	TW12	FW12		Baseline	FW8
1	ND*	467	Positive	<15	<15	<15	<15	Negative	0	0
2	ND*	104	Positive	<15	<15	<15	<15	Positive	0	0
3†	ND*	<15‡	Positive	<15	<15	<15	<15	Negative	2	1
4	1a/3	46 733	Positive	<15‡	<15	<15	<15	Negative	0	0
5†	1a	62 400	Positive	<15	<15	<15	<15	Positive	4	8
6	1a	4 645 289	Positive	94	<15	<15	<15	Negative	1	0
7	3	2 090 042	Positive	<15‡	<15	<15	<15	Positive	0	0
8	2	1 760 000	Positive	136	55	<15	<15	Positive	5	2
9	ND	131	Positive	<15	<15	<15	<15	Negative	3	6
10	1a	1 140 000	Positive	32	<15	<15	<15	Positive	1	2

FW = follow-up week; HCV = hepatitis C virus; ND = not determined; POD = postoperative day; PP = peptide pool; TW = treatment week.
* Because of insufficient viral RNA.
† The donor received substantial blood products, and the specimen being tested may have been hemodiluted.
‡ The target was detected but not quantifiable.

Durand et al Ann Int Med 2018

EXPANDER-1 Safety

Figure 2. Posttransplantation liver function tests in non–HCV-infected recipients of kidneys from HCV-infected donors.



Appendix Table 2. Recipient Urinary Protein–Creatinine Ratio or Standard Dipstick Result

Donor-Recipient Pair	1 Month	2 Months	3 Months	6 Months
1	0.38	0.27	0.17	0.07
2	0.15	0.09	0.14	0.11
3	0.26	0.67	0.37	0.22
4	0.12	0.11	0.1	0.13
5	0.14	0.12	0.09	0.11
6	0.29	0.2	0.18	0.17
7	0.28	0.24	0.14	0.08
8	Dipstick 1+	Dipstick 1+	Dipstick 1+	0.09
9	Dipstick 0	0.17	0.13	0.11
10	0.29	0.21	0.36	0.23

Appendix Table 1. Donor Biopsy Findings

Donor	Biopsy Finding
1	4% glomerulosclerosis, no arterial hyalinosis, minimal arterial sclerosis, minimal interstitial fibrosis and inflammation
2	4% glomerulosclerosis, minimal arterial hyalinosis, no arterial sclerosis, minimal interstitial fibrosis and inflammation, focal cortical scar
3	No glomerulosclerosis, minimal arterial hyalinosis, minimal arterial sclerosis, minimal interstitial fibrosis, no interstitial inflammation, no cortical scar
4	No glomerulosclerosis, minimal arterial hyalinosis, minimal arterial sclerosis, minimal interstitial fibrosis, no interstitial inflammation, no cortical scar
5	No glomerulosclerosis, no arterial hyalinosis, no arterial sclerosis, mild focal interstitial fibrosis and interstitial inflammation, no cortical scar
6	No glomerulosclerosis, no arterial hyalinosis, no arterial sclerosis, no interstitial fibrosis, no interstitial inflammation
7	No glomerulosclerosis, no arterial hyalinosis, no arterial sclerosis, mild interstitial fibrosis, no interstitial inflammation, no cortical scar
8	No glomerulosclerosis, no arterial hyalinosis, no arterial sclerosis, no interstitial fibrosis, no interstitial inflammation, no cortical scar
9	No glomerulosclerosis, no arterial hyalinosis, no arterial sclerosis, no interstitial fibrosis, mild interstitial inflammation, focal cortical scar
10	No glomerulosclerosis, no arterial hyalinosis, no arterial sclerosis, no interstitial fibrosis, no interstitial inflammation

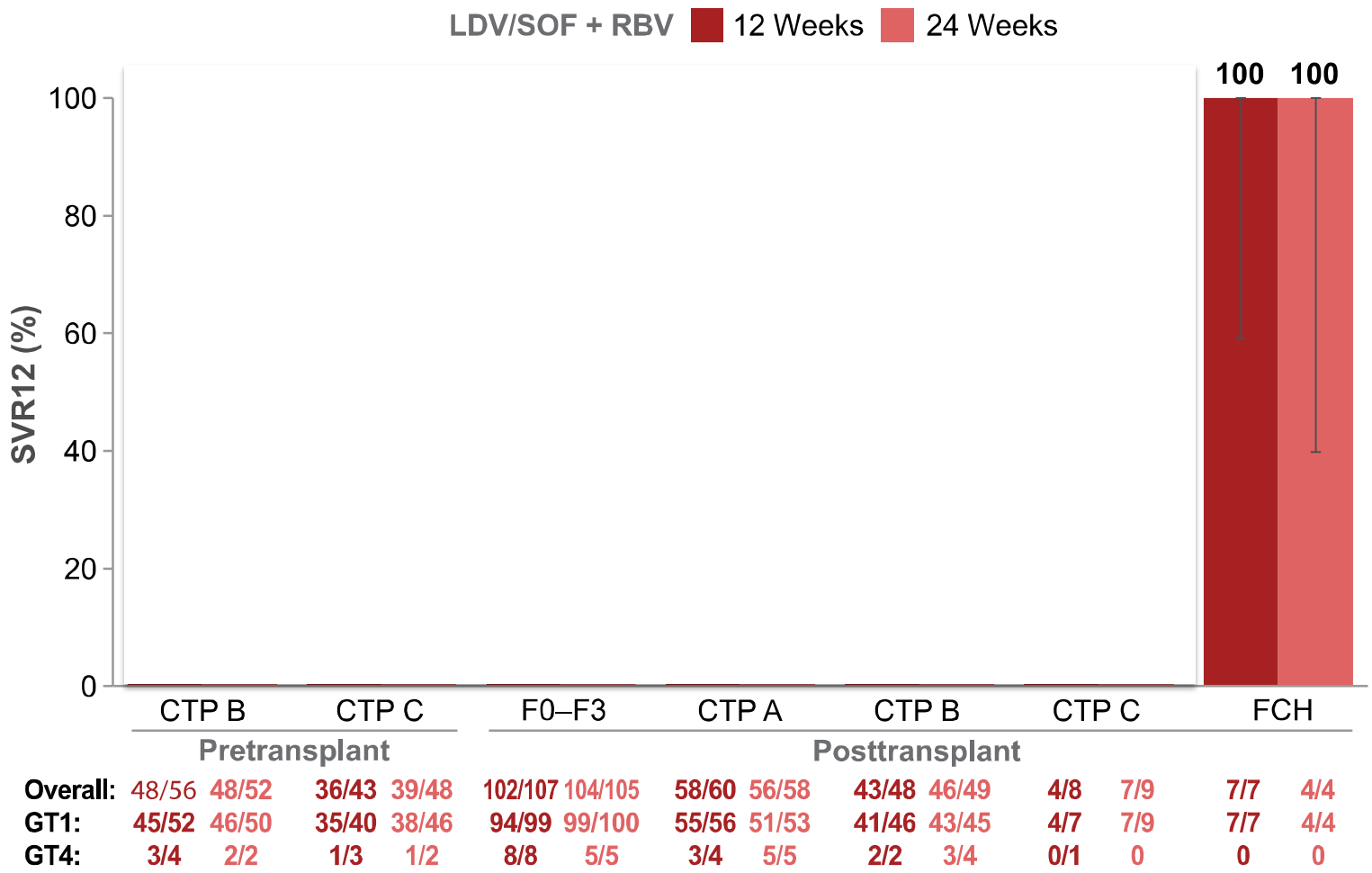
Durand et al Ann Int Med 2018

What are the dangers of adopting a new approach?

Potential Dangers

- Fibrosing cholestatic hepatitis
- Treatment failure post transplant with development of difficult to treat RAS – choice and length of regimen should mitigate this
- Extra-hepatic manifestations of HCV such as cryoglobulinaemic vasculitis or potential increased rates in blood derived malignancy such as PTLD- can be mitigated by curative treatment
- Sexual transmission of HCV to a partner – can be mitigated by simple lifestyle advice
- Transmission of HBV and HIV – risk very low and there is a lot of experience of management of these viruses post-transplant with excellent results

Efficacy of DAAs in FCH



Analysis excluded 13 patients transplanted prior to posttreatment Week (FU) 12 with HCV RNA <LLOQ at last measurement prior to transplant, and 3 pretransplant patients who were CTP A at baseline. *Error bars* represent 95% confidence intervals (CIs).

Gane, AASLD, 2015, 1049

Transmission of Other Viruses

Transplant International

ORIGINAL ARTICLE

Organ transplantation from "increased infectious risk donors": the experience of the Nord Italia Transplant program — A retrospective study

Paolo Antonio Grossi[1], Daniela Dalla Gasperina[1], Domenico Lombardi[1], Andrea Ricci[2], Giuseppe Piccolo[3] & Alessandro Nanni Costa[2]

Transplant International 2018; 31: 212–219

Table 1. Organs offered and refusal reasons according to the type of organ

Type of organ offered	Number of organs offered	Number of organs accepted	Number of organs refused	Refusal reasons		
				IRD-related reasons	Poor quality of organs	Other factors
Kidney	150	89 (59.3%)	61 (40.7%)	48 (78.7%)	11 (18%)	2 (3.3%)
Lung	86	14 (16.3%)	72 (83.7%)	28 (38.9%)	40 (55.6%)	4 (5.6%)
Heart	65	36 (55.4%)	29 (44.6%)	11 (37.9%)	18 (62.1%)	–
Liver	59	43 (72.9%)	16 (27.1%)	2 (12.5%)	13 (81.3%)	1 (6.3%)
Pancreas	18	3 (16.7%)	15 (83.3%)	7 (46.7%)	6 (40%)	2 (13.3%)
Pancreatic islets	1	–	1 (100%)	1 (100%)	–	–
Total	379	185 (48.8%)	194 (51.2%)	97 (50%)	88 (45.4%)	9 (4.6%)

- 174 organs from IIRD donors transplanted
- FU data on 152 recipients
- No cases of transmission of HBV, HIV or syphillis
- 2 cases of transmission of HCV from known HCV viraemic donors

UK National Position Statement

Working Group for the UK Position Statement

List of Stakeholders

- British Viral Hepatitis Group (Lead)
- Advisory Committee on the Safety of Blood, Tissues and Organs
- British Association for the Study of Liver Disease
- British Liver Transplant Group
- British Transplantation Society
- Clinical Virology Network
- National Health Service Blood and Transplant
- National Health Service Scotland
- National Health Service Wales
- Operational Delivery Networks for HCV in England
- Skipton Fund (Special Category Mechanism)
- Renal Association

Members of the Working Group

Ahmed Elsharkawy (Chair)

Will Gelson

Mary Cannon

Mark Harber

Rachel Hilton

Colin Wilson

Varuna Aluvihare

Chris Callaghan

Stephen Large

Pedro Catarino

Kosh Agarwal

Matthew Cramp

Derek Manas

John Forysthe

James Neuberger

Graham Foster

Lynne Vernon

Sarah Matthew

William Irving

Andy Bathgate

Graham Lipkin

Brendan Healey

Geoff Dusheiko

Chris Watson

Thamara Perera

Moira Perrin

Alice Workman

The Final Report

BVHG British Viral Hepatitis Group

BASL British Association for the study of the Liver

UK Position Statement on the use of Organs from Hepatitis C Viraemic Donors and Increased Infectious Risk Donors in Hepatitis C Negative Recipients

SaBTO Advisory Committee on the Safety of Blood, Tissues and Organs

BLTG British Liver Transplant Group

BTS British Transplantation Society

NHS Blood and Transplant

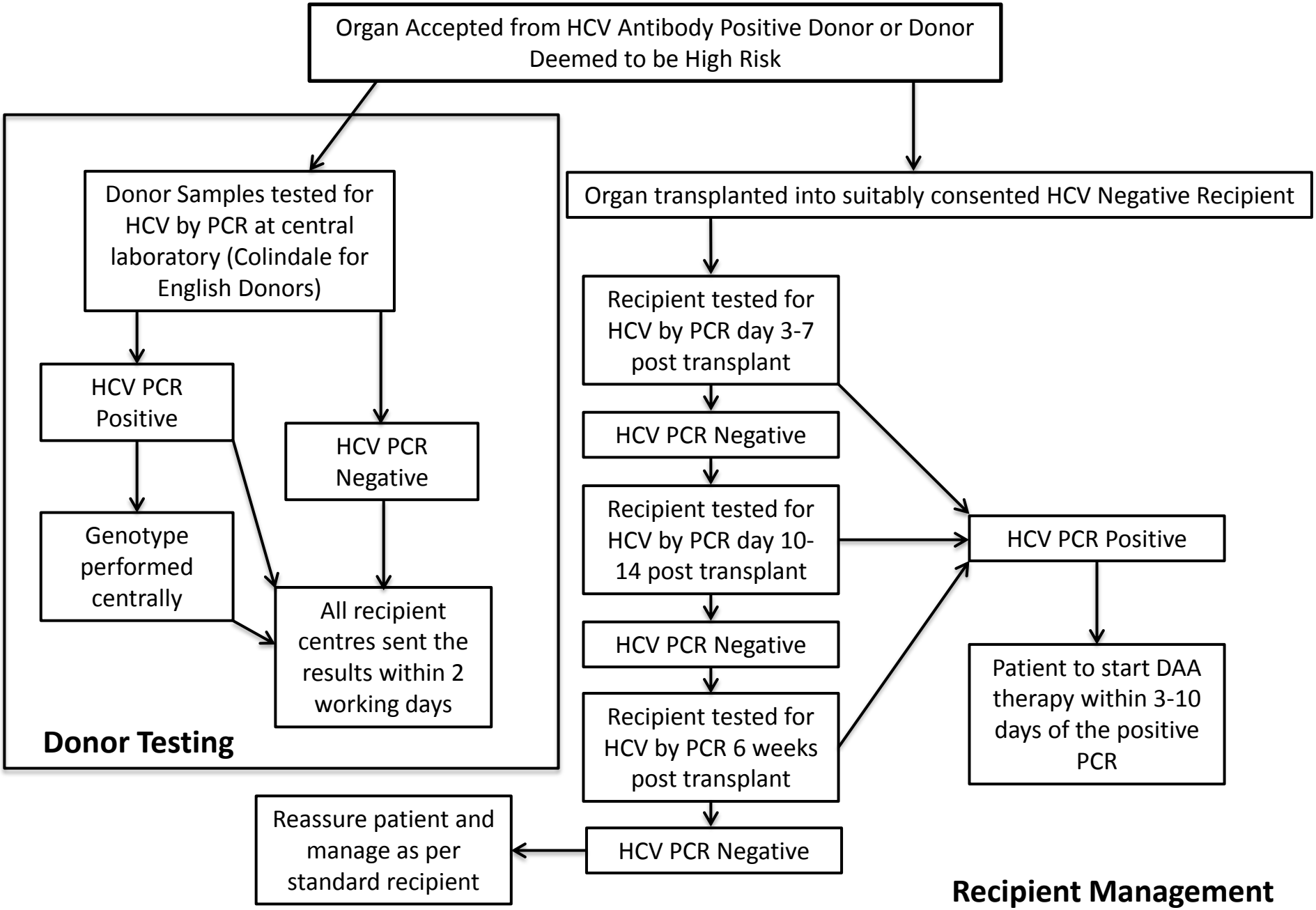
Contents

List of Stakeholders 4
Executive Summary 5
Introduction 7
Introduction to HCV and Clarification of Nomenclature 7
Changes in the treatment of hepatitis C over the past five years 9
Current discard rates for hepatitis C positive donor organs in the UK 10
Experience from outside the UK 11
Why HCV D+ to R- transplantation should be cost effective 14
What are the risks of HCV D+ to R- transplantation? 15
The Practicalities of Implementing this Policy in the United Kingdom 16
- Patient Consent 17
- Patient and Unit Requirements Pre-Transplant 17
- Allocation of HCV D+ Organs on the Waiting List 18
- Management of the Recipient of a HCV D+ Organ 18
- Special Additional Considerations 20
- Oversight of the Programme in its Early Days 21

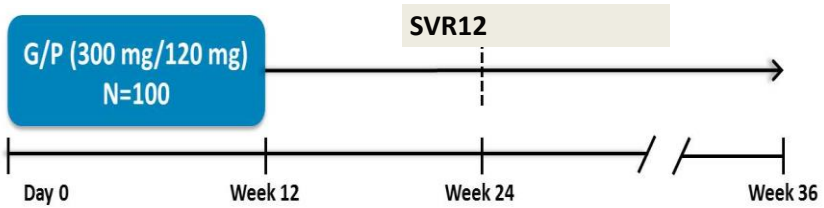
Next Steps in the Process 21
References 22
Appendix 1 - Patient Information Leaflet for the Use of Hepatitis C Infected Organs in Hepatitis C Negative Recipients 26
- Introduction 26
- What is hepatitis C? 26
- Why am I being offered a hepatitis C infected (insert organ here)? 26
- What are the advantages to me of receiving a hepatitis C infected (insert organ here)? 27
- What are the risks to me if I receive a hepatitis C infected (insert organ here)? 27
- What is the experience of patients who have been infected with hepatitis C at the time of an organ transplant? 28
- How do I know that the hepatitis C infected (insert organ here) has not been damaged by the virus? 28
- What are the risks to my family if I receive a hepatitis C Infected (insert organ here)? 29
- How will I be treated if I receive a hepatitis C infected (insert organ here)? 29
- What happens to me if I refuse to accept a hepatitis C infected (insert organ here)? 30
- Will I be entitled to compensation if I accept a hepatitis C infected (insert organ here)? 30
- Where can I find out more information? 31

Donor Acceptability

Acceptable Within Proposed Policy	Not Recommended Within Proposed Policy
HCV Ab positive with no history of treatment of HCV	Previously failed DAA therapy with on-going viraemia
HCV Ab positive with documented SVR after treatment	DAA therapy within last year without documented SVR (unless the recipient is at imminent risk of death)
Any HCV Ab negative donor who has exposed themselves to risk but who does not fulfill any of the unacceptable criteria	Multiple documented re-infection with HCV
Any HCV Ab positive donor whose HCV treatment history is unknown – **proceed with caution**	

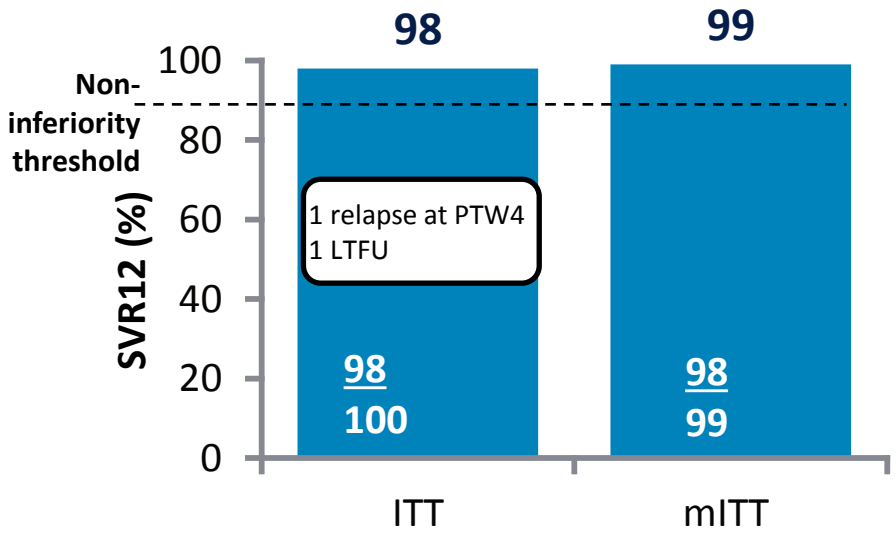

Organ Accepted from HCV Antibody Positive Donor or Donor Deemed to be High Risk
Donor Samples tested for HCV by PCR at central laboratory (Colindale for English Donors)
HCV PCR Positive
HCV PCR Negative
Genotype performed centrally
All recipient centres sent the results within 2 working days
Donor Testing
Organ transplanted into suitably consented HCV Negative Recipient
Recipient tested for HCV by PCR day 3-7 post transplant
HCV PCR Negative
Recipient tested for HCV by PCR day 10-14 post transplant
HCV PCR Negative
Recipient tested for HCV by PCR 6 weeks post transplant
HCV PCR Negative
Reassure patient and manage as per standard recipient
HCV PCR Positive
Patient to start DAA therapy within 3-10 days of the positive PCR
Recipient Management

MAGELLAN-2 Trial



Baseline: ≥3 Months since: Liver Transplant (n = 80), Renal Transplant (n = 20)
GT: 1 (57%), 2 (13%), 3 (24%), 4–6 (6%)
Fibrosis: F0–1 (80%), F2 (6%), F3 (14%)
Treatment naïve (66%) or experienced* (SOF±pegIFN±RBV) (34%)

Excluded: Coinfection HBV or HIV
ALT/AST >10 × ULN, albumin <3.5 g/dL, platelets <70,000, CrCl <30 mL/min
Acute renal failure / re-transplant / dual transplant
Experience with DAA other than SOF



BL immunosuppressant medication:
tacrolimus (68%), mycophenolic acid (30%), cyclosporine (13%), prednisone (13%), prednisolone (11%), everolimus (8%), azathioprine (6%), and sirolimus (7%)

Safety, n/%	G/P, 12 weeks N = 100
SAE	8
DAA-related SAEs*	2
AE leading to study drug discontinuation†	1
DAA-related AE leading to study drug discontinuation	0
Death	0
Transplant rejection	1

Patient with mild liver transplant rejection was considered unrelated to DDIs and did not lead to treatment interruption

Grade 3 laboratory abnormalities were rare

*Sinusitis (day 2); abnormal hepatic function (PTW4); †Cerebrovascular accident unrelated to G/P on week 6; patient achieved SVR12

Reau N, et al. EASL 2017, Amsterdam. #LBO-03

Patient Consent Form

Appendix 1 - Patient Information Leaflet for the Use of Hepatitis C Infected Organs in Hepatitis C Negative Recipients

Introduction

You are being asked to consider whether or not you would accept a (insert organ here) from a hepatitis C virus infected donor. This leaflet will explain why this option is being considered for you, and will explain the potential benefits and the potential risks that this may involve. It is important to emphasise that it is your choice whether or not you agree to accept a (insert organ here) from a hepatitis C virus infected donor.

What is hepatitis C?

Hepatitis C is a virus that is transmitted in infected blood and body fluids. It lives in the liver and blood of infected individuals and can cause inflammation and scarring of the liver. The scarring can be severe, although on average it takes 30 years for the scarring to become life-threatening in non-transplant patients. Severe scarring may develop more rapidly in transplant patients taking drugs that suppress the immune system.

Treatments for hepatitis C have changed greatly over recent years. It is now possible to cure over 95% of patients who are infected with the hepatitis C virus. Treatment requires taking tablets for 12 weeks. Once the virus is cleared it does not come back and does not affect your long term health.

What are the advantages to me of receiving a hepatitis C infected (insert organ here)?

If you agree to accept a (insert organ here) from a hepatitis C virus infected donor, you may receive a transplant more quickly. This may be very helpful if you would otherwise wait a very long time for a transplant. Also, because organ donors who are infected with hepatitis C virus are younger than average, and less likely to have other important health issues, their organs may be of higher quality and therefore more likely to work immediately and may last longer.

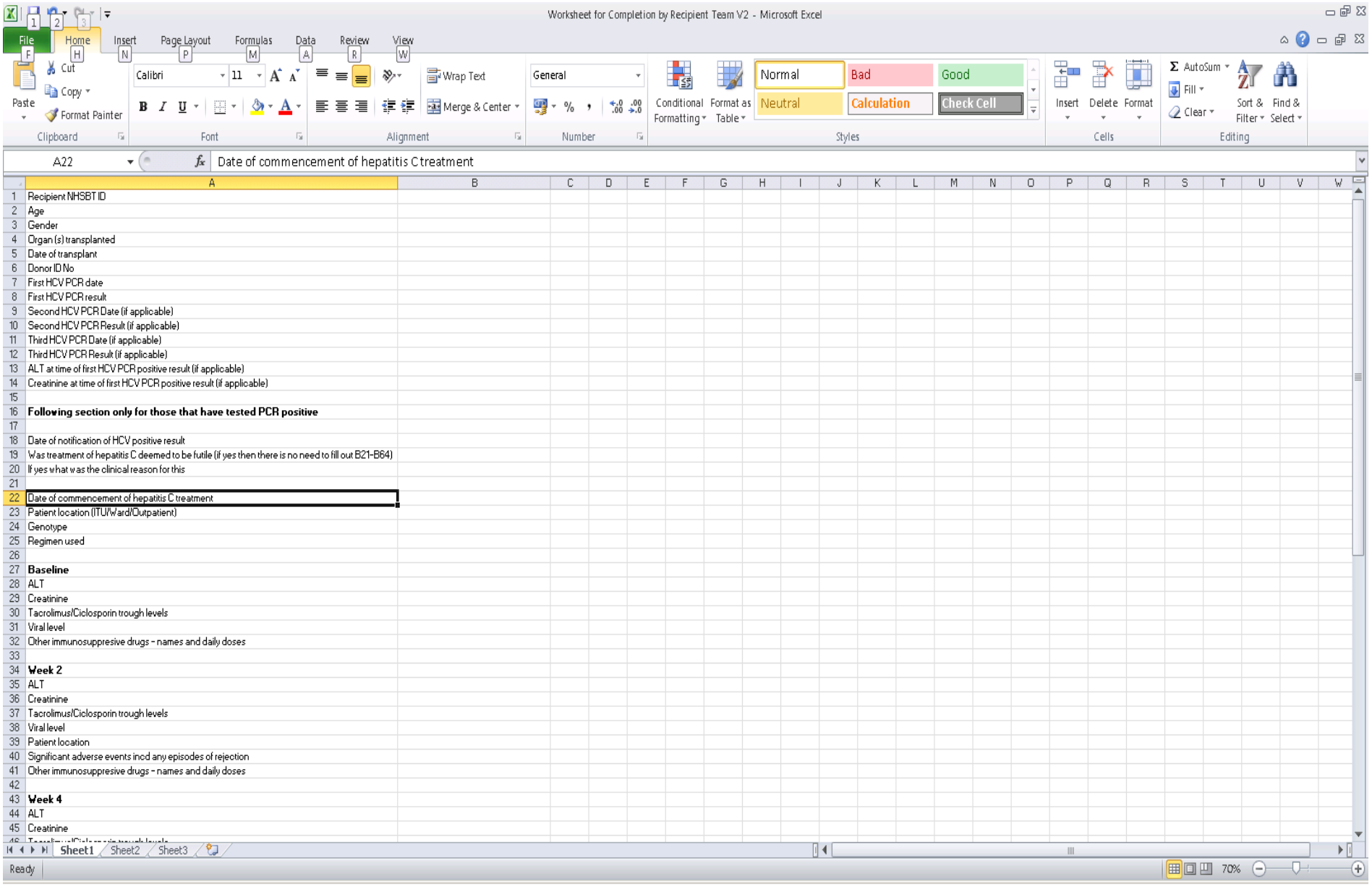
What are the risks to me if I receive a hepatitis C infected (insert organ here)?

The main risk of accepting a (insert organ here) from a hepatitis C virus infected donor is that you will become infected with the virus yourself. If hepatitis C virus infection is not treated you may become jaundiced (yellow) and may develop severe inflammation in the liver (fulminant cholestatic hepatitis). In the longer term (3-6 months) hepatitis C may result in kidney injury. However, you will be offered treatment to cure you of the hepatitis C virus as soon as is has been confirmed that you have been infected. This will minimise the risk of any damage to you.

Checklist for Individual Units

	Yes	No
Recipient Specific		
Are you able to calculate APRI scores in your unit (requires measurement of AST and platelet count)?		
Are you able to perform high quality liver ultrasounds on potential recipients?		
Does your organisation have a specific consent form for transplantation and if so does it need to be modified to include transplantation of a HCV positive organ?		
Is there a plan to consent your recipients ahead of transplantation?		
Pharmacy Issues		
Does your pharmacy know how to order the HCV DAA drugs and how they get rebated for this?		
Do the HCV drugs need to be on your formulary prior to prescribing? If yes, have they been added to the formulary?		
Is your pharmacy able to get the drugs within the time frames outlined within the position statement?		
Will the whole treatment course be supplied by the transplant unit pharmacy if the patient is repatriated back to the referring centre early? If no have arrangements been made for continuous supply to be provided to the recipient for the duration of the course?		
Does your Trust have access to Blueteq in order to apply for approval of DAAs (England only)?		
Personnel Issues		
Has a lead clinician for this service development been identified? If this individual has not got personal experience of the management of hepatitis C has he/she got easy access to clinicians that do for advice on individual cases?		
Has the clinical lead provided training to your transplant co-ordinators, pharmacy, transplant surgeons, junior doctors and transplant physicians on this proposed service development?		
Does the wider team have a grasp of the following concepts 1. Blood tests to be performed post-transplantation 2. Referral pathway to local HCV MDT 3. Treatment regimens for HCV that are recommended and the importance of consistently checking for drug to drug interactions whilst on DAA therapy 4. Sustained virologic response and definition of "cure" 5. Risks of HCV transmission while patient is viraemic		
Will the clinical lead ensure that the mandatory blood tests are taken post transplantation and that results are actioned within the timelines stipulated within this document?		
Have you reached out to your referral networks to inform them of this potential development? Would your referrers be happy to supervise/delegate management of HCV post-transplant if the patient is repatriated early?		
Do you know who the clinical lead for the local operational delivery network is (England only)? If so, has the lead clinician in your organisation reached out to them and are they able to respond to treatment advice requests within the time frame required in the position statement? Has a formal pathway for management of potential recipients been agreed with the local ODN (England) or Hepatitis C Oversight Committee (in Wales and Scotland)? Has the local ODN lead agreed to report the data on individual recipients to the oversight committee facilitated by BVHG (see above)? For Scotland and Wales have the main oversight HCV committees agreed to report data on individual recipients to the oversight committee facilitated by BVHG (see above)?		
Laboratory Issues		
Have mechanisms been put in place to ensure timely testing of potential recipients within the time frames outlined in the national position statement? Is the lab able to provide a 3-5 day turnaround for HCV PCR results?		
Does the virology lab understand the need for repeated testing in a short time frame in the same patient?		
Is there a robust reporting mechanism in place to ensure timely communication to the relevant members of the transplant team?		

Data to be collected by HCV Team



	A
1	Recipient NHSBT ID
2	Age
3	Gender
4	Organ (s) transplanted
5	Date of transplant
6	Donor ID No
7	First HCV PCR date
8	First HCV PCR result
9	Second HCV PCR Date (if applicable)
10	Second HCV PCR Result (if applicable)
11	Third HCV PCR Date (if applicable)
12	Third HCV PCR Result (if applicable)
13	ALT at time of first HCV PCR positive result (if applicable)
14	Creatinine at time of first HCV PCR positive result (if applicable)
15	
16	**Following section only for those that have tested PCR positive**
17	
18	Date of notification of HCV positive result
19	Was treatment of hepatitis C deemed to be futile (if yes then there is no need to fill out B21-B64)
20	If yes what was the clinical reason for this
21	
22	Date of commencement of hepatitis C treatment
23	Patient location (ITU/Ward/Outpatient)
24	Genotype
25	Regimen used
26	
27	**Baseline**
28	ALT
29	Creatinine
30	Tacrolimus/Ciclosporin trough levels
31	Viral level
32	Other immunosuppresive drugs - names and daily doses
33	
34	**Week 2**
35	ALT
36	Creatinine
37	Tacrolimus/Ciclosporin trough levels
38	Viral level
39	Patient location
40	Significant adverse events incd any episodes of rejection
41	Other immunosuppresive drugs - names and daily doses
42	
43	**Week 4**
44	ALT
45	Creatinine

Future Steps

- We have set a ‘Go Live’ date of September 2017 and will continue to work with NHSBT on the logistics and operationalisation of this
- Dissemination and education about the scheme
- There are on-going discussions with NHSE on the issue of re-imbursement of drug costs
- NHS Scotland and NHS Wales have agreed to drug funding
- Setting up an oversight committee (hosted by BVHG)

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- All members of the UK Working Group
- Mary Cannon (in particular)
- Niraj M. Desai

- Full position paper will be available on the BVHG/BASL website by the end of next week https://www.basl.org.uk

Questions and Feedback Please

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