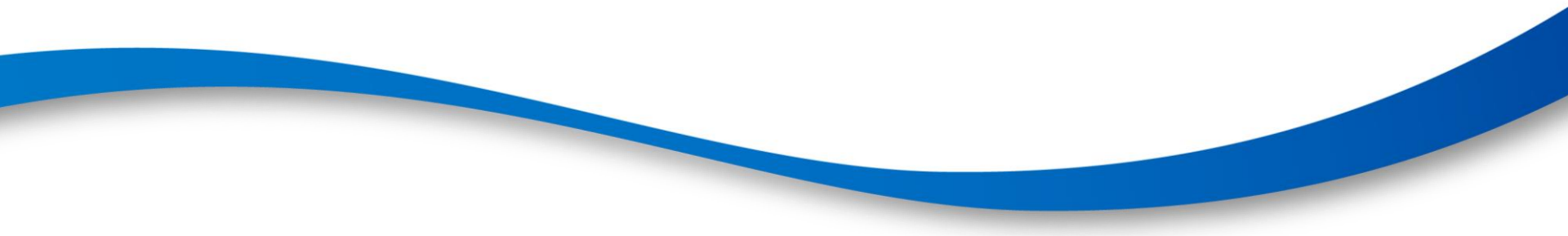


Communication of Risk and Consent in Transplantation

02/10/2018



Objectives

- Describe the projects within the ‘Communication of Risk and Consent in Transplantation’ working group
 - Transplant Risk/benefit Assessment and Communication (TRAC) tool
 - Best practice consent videos
- 

Background

- Changing donor demographics has led to increasing use of 'marginal' donors
- Greater need for individual assessment of risks/benefits of transplant due to large variability in recipient and donor population
- Perception that more 'risky' transplants are taking place and continued evaluation of outcomes is required
- How can we improve communicating this risk / benefit relationship to both patients and clinicians?

Key questions

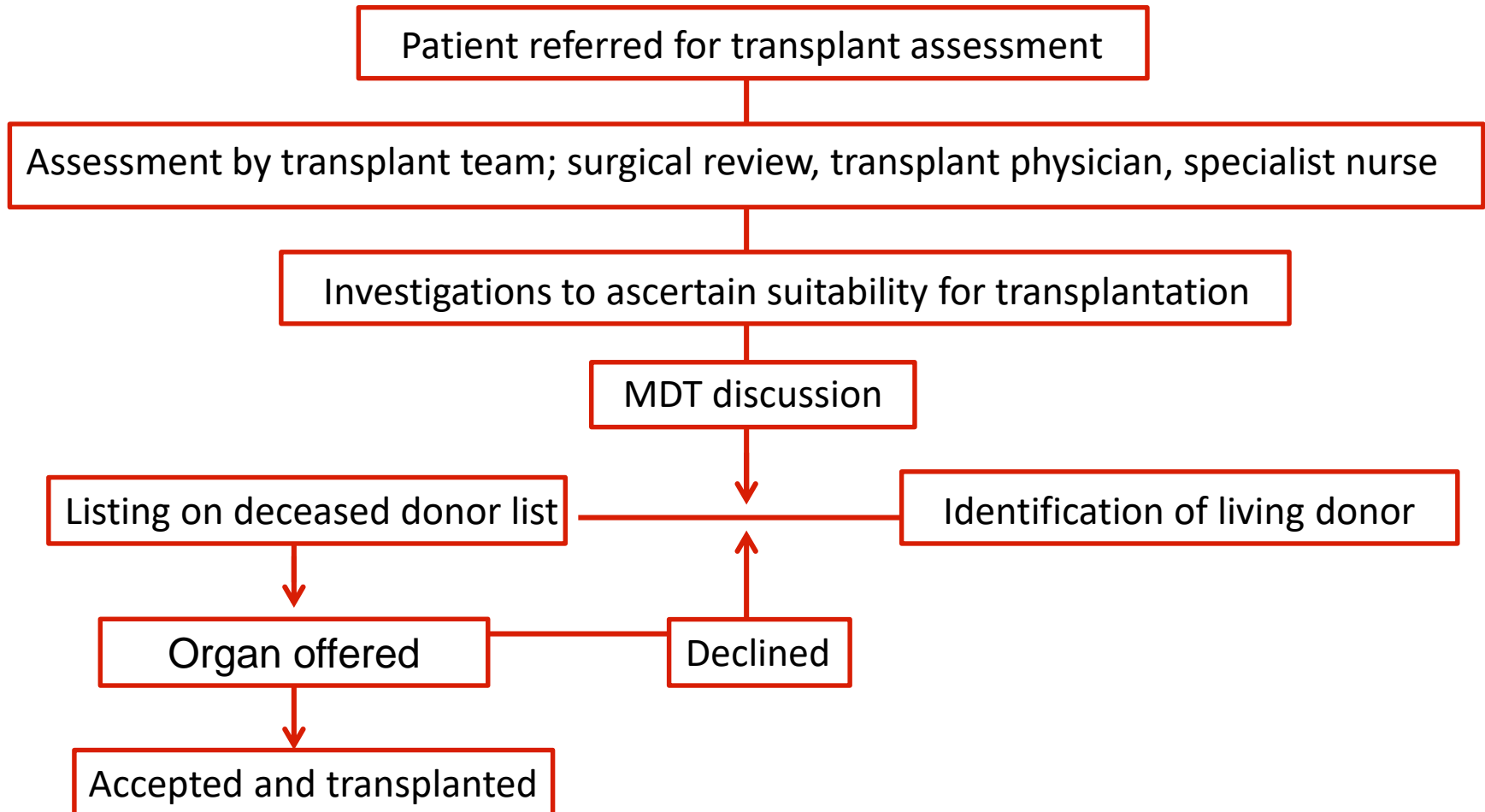
- How do we currently communicate transplant risk / benefit to our patients?
 - Patient information leaflets, videos etc.
 - Communication with healthcare professionals in clinic
 - Limited tools available for individualised communication of risk
 - How *should* we be communicating risk/benefit to our patients?
- How well do we as clinicians know the risk of transplantation and which variables are of significance?
- What information is relevant when consenting patients?

General principles

- Tool must be (relatively) easy to use and interpret
 - Must consider variation in literacy and numeracy rates amongst patient groups
 - Note: current NHS literature aimed at a literacy age of 11
- Should be trustworthy and statistically sound
 - Absolute risk should be clearly demonstrated to avoid misinterpretation
 - Methodology should be transparent and easily accessible
- Should act as a helpful aid to clinicians when making clinical decisions
 - Clear indicator that 'acceptable tolerable risk' will vary for each individual patient, tool itself not to include clinical recommendations
 - Can demonstrate to clinicians which variables are of statistical significance

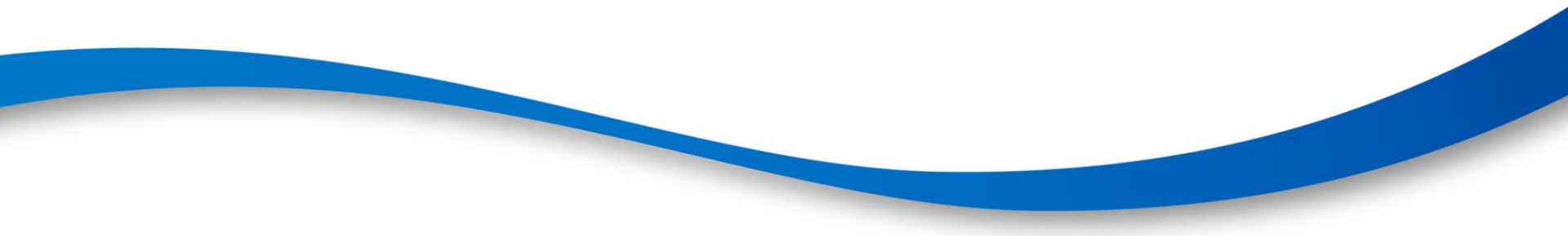
A Patient Journey

(Example for an elective kidney transplant recipient)



At what points could use of a risk/benefit tool developed using NHSBT data be most clinically useful?

What are we currently working on?

- Transplant Risk/benefit Assessment and Communication (TRAC) tool
 - Best practice consent videos
- 

Development of the TRAC tool

Ascertain aims and objectives of TRAC tool for each organ type

MODEL DEVELOPMENT

Statistical:

What models are available?
What further development is needed?
Do we have the data?
Is it feasible from a resource point of view?

Clinical:

What do clinicians want from the TRAC tool?
What do patients want from the TRAC tool?
Review by clinical and patient working groups

Other considerations:

Liaison with NHSBT Digital Research ethics application
Medical device registration

Model shared with Winton Centre for development of user interface

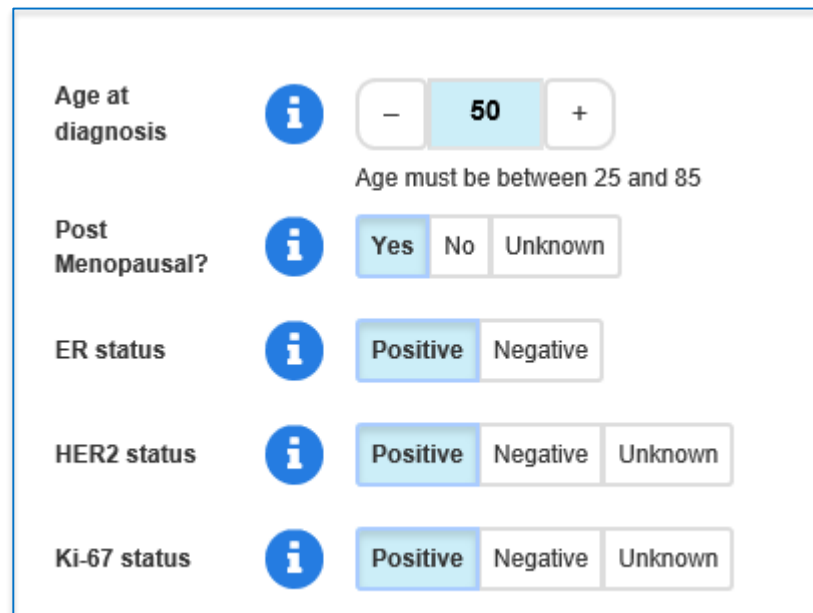
IMPLEMENTATION OF TRAC TOOL ON WEBSITE HOSTED BY NHSBT

Validation study e.g. RCT to determine effectiveness






Annual or 2-yearly update and review of tool

TRAC development

Examples from breast cancer 'NHS Predict' website, developed by Winton Centre:



The screenshot shows a form with five input fields, each with an information icon (i) to its left. The fields are: 'Age at diagnosis' with a numeric input set to 50 and a note 'Age must be between 25 and 85'; 'Post Menopausal?' with radio buttons for 'Yes', 'No', and 'Unknown'; 'ER status' with radio buttons for 'Positive' and 'Negative'; 'HER2 status' with radio buttons for 'Positive', 'Negative', and 'Unknown'; and 'Ki-67 status' with radio buttons for 'Positive', 'Negative', and 'Unknown'. The 'Positive' options are selected in each case.

Age at diagnosis		<input type="text" value="50"/>	Age must be between 25 and 85
Post Menopausal?		<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	
ER status		<input checked="" type="radio"/> Positive <input type="radio"/> Negative	
HER2 status		<input checked="" type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Unknown	
Ki-67 status		<input checked="" type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Unknown	

Input:

TRAC development

Output:

Results

Table Curves Chart Texts Icons

These results are for women who have already had surgery. This table shows the survival percentages based on the information you have provided

5 10 15 years after surgery.

Treatment	Additional Benefit	Overall Survival %
Surgery only	-	74%

If nobody died from breast cancer 96% would survive 10 years. **i**

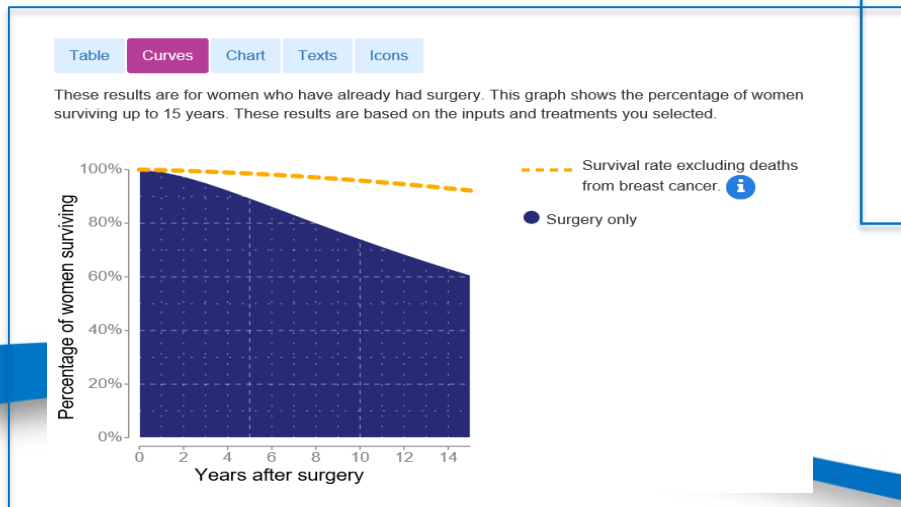
Show ranges? **i** Yes No

Table Curves Chart Texts Icons

These results are for women who have already had surgery. This display shows the outcomes for 100 women based on the inputs and treatments you have selected

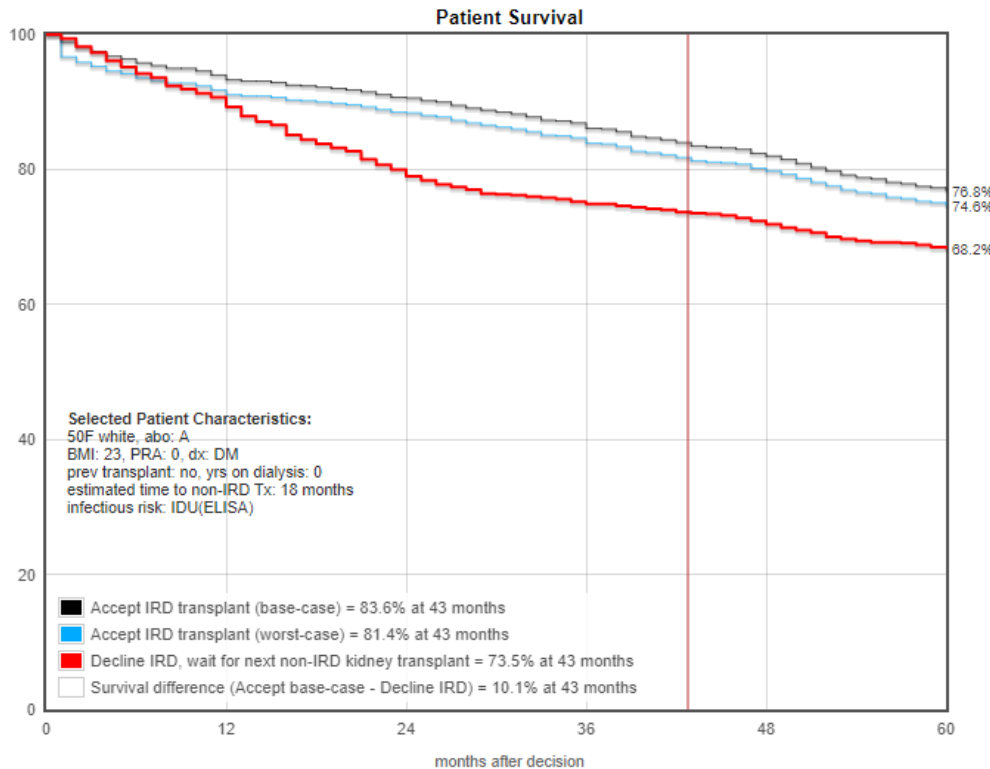
5 10 15 years after surgery.

- 4 deaths due to other causes
- 22 breast cancer related deaths
- 74 survivors with surgery alone



Example of survival graphs: John Hopkins IRD **NHS** Blood and Transplant Kidney Transplant Calculator

CTAGH(18)22



Recipient Characteristics:

Age: (20-75)

Gender:

ABO:

Ethnicity:

BMI: (19-39)

PRA: (0-100)

Renal failure diagnosis:

Previous transplant:

Years on waitlist:

Estimated time remaining until non-IRD transplant *:

* This is time in addition to the time the patient may have already waited. eg: if a patient has spent 1 year on the waitlist, and the estimated time remaining until a non-IRD transplant is 18 months, the patient is expected to have waited 30 months since listing, before a non-IRD transplant.

Donor Characteristics:

Infectious Risk Behavior:

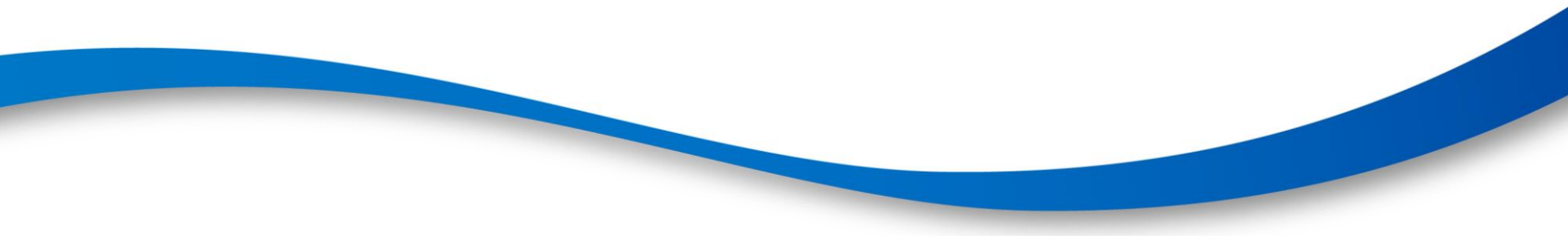
Serology Testing Used:

base-case estimate: mortality risk (if seroconverted) increased by 4.12% HIV, 3.42% HCV per year
 worst-case estimate: mortality risk (if seroconverted) equivalent to immediate (100% chance) death

Survival curves clearly interpretable, shows change over time

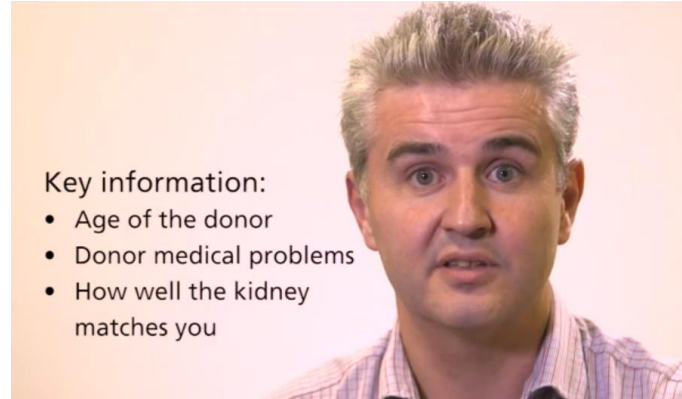
Lay representative feedback: useful for interpretation for clinicians in conjunction with patients

Best practice consent videos

- Development of digital educational videos
 - Aim to be realistic, informative and easily interpretable
 - Dialogue between clinicians and patients
 - Potential use of animation
- 

Best practice consent videos

Royal Free Hospital:
(kidney transplantation)

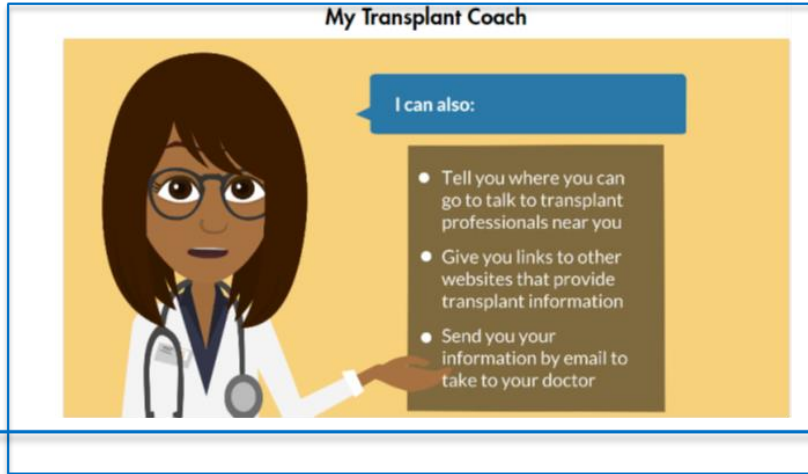


John Hopkins:
(pancreas transplantation)



Best practice consent videos

University of Emory:



My Transplant Coach

Height Feet Inches

Weight Pounds

Age Years

Gender **MALE** FEMALE

Race

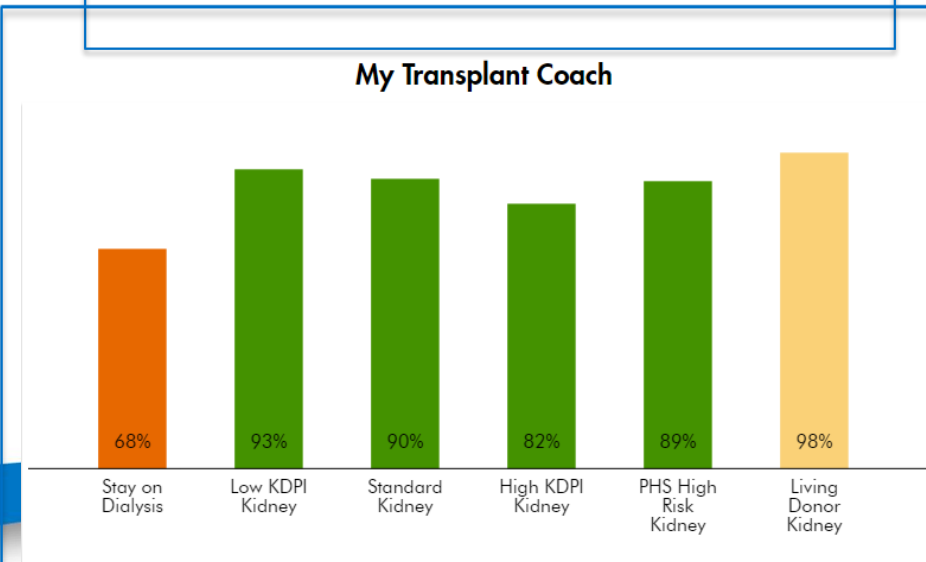
Blood Type

Time on Dialysis Years Months

Check if you have diabetes

Check if you have Polycystic kidney disease

Check if you have had a previous transplant



Graph 3: Expected outcome after kidney transplant

NEXT SCENE

Summary

- Scope for expansion of current UK risk/benefit communication tools
- Variety of mechanisms by which this can be achieved
- Key clinically important communication messages to be identified
- Optimisation of shared decision making