Kidney Advisory Group
5th December 2016

Transplant consent form app

Background

The UK Supreme Court case of *Montgomery vs. Lanarkshire Health Board* has reinforced the need for best practice in obtaining consent for medical and surgical interventions, and arguably taken the legal systems of the UK more towards the American "prudent patient" model of what information need be disclosed for consent to be considered informed and valid.

In my own transplant unit in Glasgow, which happens to include the Lanarkshire Health Board area in its catchment, the clinical risk department had expressed to us the need to review our own consent processes for the complex procedure of renal transplantation, with the suggestion that a procedure-specific form be developed.

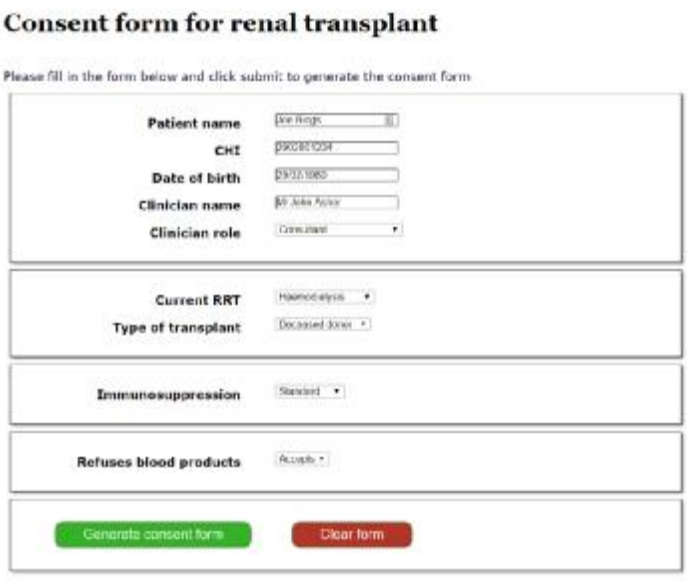
A proposed solution

A detailed consent form was developed by Neal Padmanabhan (consultant nephrologist), Marc Clancy (consultant transplant surgeon) and myself, but an obvious issue which arose was the sheer volume of information that the form had to communicate, including risks pertinent only to certain patient or kidney-specific circumstances. To deliver a form with an acceptable signal to noise ratio, it was clear that it would have to be customisable to fit the circumstances in hand. I therefore developed a web application to generate a bespoke form for each patient.

The pilot of the web application can be viewed at www.glasgowtransplant.com/pilot

There are separate versions of t form for use in the clinic at the time of listing and for use on admission; in the case of the transplant form this allows for additional information known about the transplant to be included, such as whether DBD or DCD and the side on which it is to be implanted.

The first screen takes some basic details, so this would be how it is filled in for a standard deceased donor transplant listing clinic:



The web app then generates a tailored consent form in the standard format used in Scotland, which can be printed out and signed by clinician and patient:

Consent for kidney transplantion

(transplant assessment clinic)

NHS Greater Glasgow and Clyde

PATIENT DETAILS

Patient name **Joe Blogs**
CHI number **2902801234**
Date of birth **29/02/1980**

STATEMENT FOR PRACTITIONER

(to be filled in by practitioner with appropriate knowledge of proposed procedure)

You are being asked to give your consent to the staff in the Glasgow Renal and Transplant Unit for kidney transplantation and the use of immunosuppressive drugs.

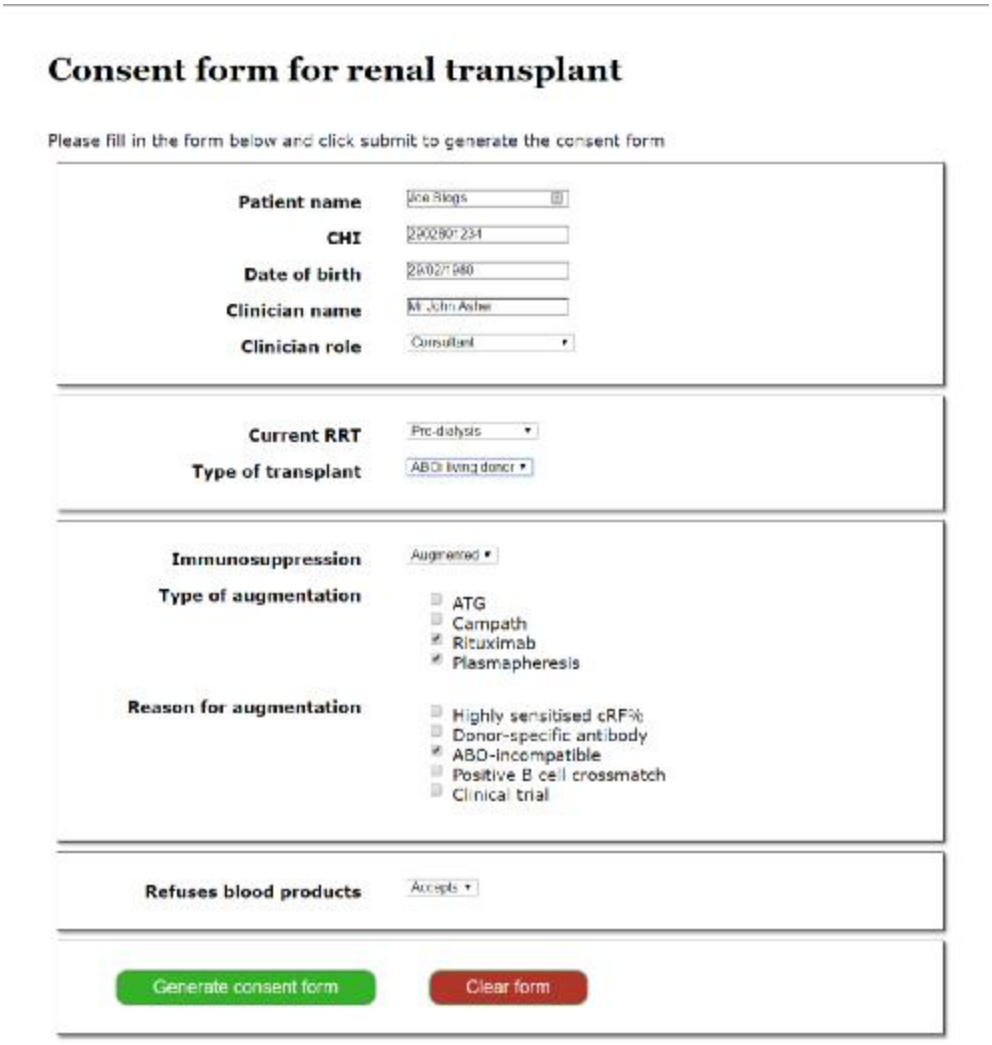
General information about kidney transplants

This procedure is being offered as a treatment of kidney disease, and is an alternative to dialysis. Treatment with medicines that affect the immune system will be required for the duration of the transplant and you should understand that there are risks associated with this treatment. Your attention is particularly drawn to the following:

- You will need to take medicines to prevent the kidney from being rejected. These may include steroid tablets or injections and drugs such as tacrolimus, mycophenolate, azathioprine and sirolimus. The side effects of these medicines can include kidney dysfunction, high blood pressure, diarrhoea, hair growth, or hair loss and a low white cell or platelet count. Regular attendance at the clinic is essential to monitor these medicines.
- Occasionally "rejection" occurs despite taking prescribed medicines and it is more likely if they are missed. This is usually treated with steroid injections and sometimes with antibody or other therapies. Rejection rarely (<5% of patients in the first year) causes the transplant to fail.
- Immunosuppressive medicines increase the risk of infection, especially urine infections and chest infections. Sometimes serious infections occur which are not common in people with normal immunity, such as viral infections (e.g. CMV) and pneumocystis infection. You may be asked to take preventative medicine to reduce the risk of infection.
- There is a small risk of infection being transmitted with the kidney. This can include bacterial, viral, fungal or other infections which were not apparent at the time of donation. Very rarely cancer can be transmitted with the kidney. Extremely rarely allergies can be passed from the donor, including serious allergies such as peanut allergy.
- In the long term immunosuppression increases the chance of cancer. The most common cancers in transplant patient are skin cancers and precautions to avoid sun exposure are recommended. After a successful transplant

The full information screen is too long to include in full here, but can be seen by visiting the pilot site.

There is provision for more complex circumstances, such as listing for an ABOi living donor transplant:



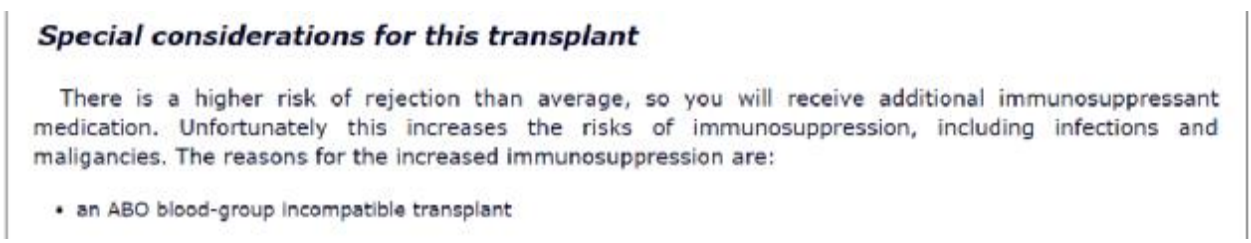
Consent form for renal transplant

Please fill in the form below and click submit to generate the consent form

Patient name	Joe Blogs
CHI	2902807234
Date of birth	29/02/1980
Clinician name	Mr John Asher
Clinician role	Consultant
Current RRT	Pre-dialysis
Type of transplant	ABOi living donor
Immunosuppression	Augmented
Type of augmentation	☐ ATG ☐ Campath ☑ Rituximab ☑ Plasmapheresis
Reason for augmentation	☐ Highly sensitised cRF% ☐ Donor-specific antibody ☑ ABO-incompatible ☐ Positive B cell crossmatch ☐ Clinical trial
Refuses blood products	Accepts

Generate consent form | Clear form

In this case, selecting the ABOi option automatically changed the immunosuppression from “standard” to “augmented” and ticked the relevant boxes. For other types of transplant where augmented immunosuppression is anticipated, the selector drop down can be changed manually and the boxes ticked as appropriate. This adds further information to the consent form generated:



Special considerations for this transplant

There is a higher risk of rejection than average, so you will receive additional immunosuppressant medication. Unfortunately this increases the risks of immunosuppression, including infections and malignancies. The reasons for the increased immunosuppression are:

- an ABO blood-group incompatible transplant

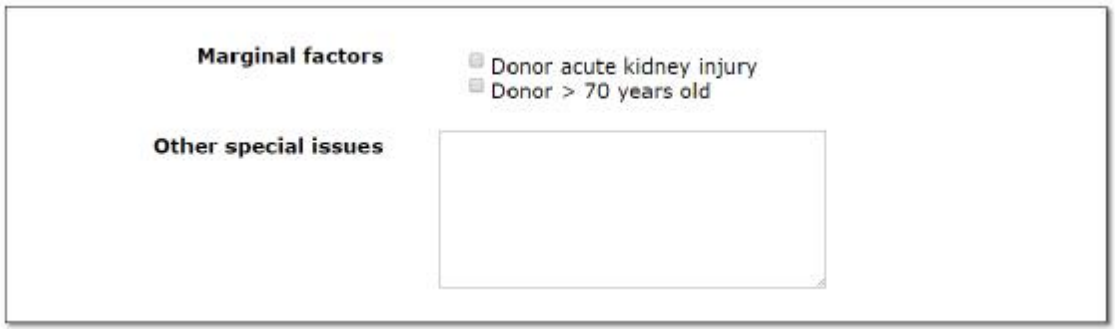
Other patient-specific risks can be included, such as the potential for requiring post-op dialysis if a transplant fails or experiences delayed graft function in a pre-dialysis recipient (in this case for a transplant with a DBD kidney):

- In the rare event that the kidney transplant fails, you may need to start long-term dialysis immediately and may require further operations or procedures to establish access for dialysis.
- In about 90% of transplants of this type the kidney is slow to work and a period of dialysis may be required before it does. A temporary haemodialysis catheter may be needed to provide access for dialysis. This is usually inserted into a large vein in the neck, and can usually be done while you are under the anaesthetic for the transplant. Complications due to insertion of a temporary haemodialysis catheter are rare, but can include bleeding and the formation of a pneumothorax.

Another very specific risk is that of an established peritoneal dialysis patient requiring a switch to haemodialysis if there is delayed graft function (in this case with a living donor kidney):

- In about 10% of transplants of this type the kidney is slow to work and a period of dialysis may be required before it does. It may be possible to perform your usual peritoneal dialysis during this period, but it is sometimes necessary to convert to haemodialysis. A temporary haemodialysis catheter may be needed to provide access for dialysis. This is usually inserted into a large vein in the neck, and can usually be done while you are under the anaesthetic for the transplant. Complications due to insertion of a temporary haemodialysis catheter are rare, but can include bleeding and the formation of a pneumothorax.

The version of the form for hospital admission also includes options to record special circumstances that should be documented on the consent form:



Taking this forward

The Glasgow pilot is still under development and cannot be used with patient identifiable information as it is hosted on a server outwith the NHS network. Locally we are still finalising the wording, then need formal sign off from our clinical risk department and arrangements to host it within the network. A similar customisable form is also under development for donor nephrectomy.

Once this is developed and functional, we are happy to provide the source files to other transplant centres to develop their own versions, probably under a Creative Commons Attribution Share-Alike type licence. Alternatively, if a solution of this type is widely supported by KAG, then I will look into the feasibility of ODT being able to host this for use nationally.

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