

NHSBT Board Meeting

March 2019

Organ Donation Consent Legislation – Progress Report

1. Status – Official

2. Executive Summary

The Government is supporting a change in the law on organ and tissue donation to move to an opt-out system in England. The Government's ambition is that the change in the law will lead to 700 additional transplants per year.

The Organ Donation (Deemed Consent) legislation, known as Max and Keira's Law, received Royal Assent on March 15th 2019 and is anticipated to come into effect in Spring 2020. The Department of Health and Social Care (DHSC), NHS Blood and Transplant (NHSBT), NHS England and the Human Tissue Authority (HTA) will lead a set of workstreams that will implement the legislation.

Detailed implementation planning is in progress and funding arrangements have now been confirmed by DHSC for the operational implementation and communications campaign. However, it falls short of NHSBT funding requirements and as a result, the programme is assessing options to undertake the implementation activity within the allocated funding.

Legislation in Scotland has also moved forward. The Health and Sport Committee did not recommend any amendments and the Bill received overwhelming support for progressing to the next stages. Subject to further Parliamentary activity, it may be enacted later this year.

3. Action Requested

- **Note the law in England will come into effect in Spring 2020 and that implementation planning is underway.**
- **Note the challenges arising from DHSC funding constraints and that the programme will proceed with reduced implementation activity.**

4. Purpose of the paper

This paper outlines the current position of primary and secondary legislation and progress to date regarding Operational, Communications and Digital activity.

5. Legislation

5.1 England

The Organ Donation (Deemed Consent) Act 2019 successfully passed through parliament in England, with Royal Assent on March 15th 2019.

DHSC are working on secondary legislation which will focus on exemptions from the Act and on novel / rare transplants (e.g. limb, face). Subject to Ministerial clearance, the draft secondary legislation will be released for a 12-week public consultation.

The DHSC are working with our Communications planning teams to identify a suitable time for the consultation launch. The secondary legislation needs to be in place before the implementation date therefore there are some time pressures to take in to consideration.

5.2 Scotland

The Health and Sport Committee published their report in February and whilst they made some recommendations to inform implementation, they did not make any amendments to the Bill. The legislation passed a major milestone in late February with a landslide vote of 107 in favour, 1 against and 2 abstentions. Subject to further Parliamentary activity, it is anticipated that the Bill will be enacted in Summer 2019 and come in to force in late 2020.

The Scottish Government are setting up an implementation team which is expected to be in place from May 2019 onwards.

5.3 Crown Dependencies

Jersey has already introduced legislation and we are working with them to agree an implementation date which could potentially be summer 2019. The Isle of Man is progressing legislation and may also wish to implement in 2019. Guernsey is unlikely to introduce legislation before 2020.

6. Operational Implementation

6.1 Activity this period has focused on building the programme implementation team (see item 10) and preparing the National Contact Centre, Organ Donor Register and Clinical Enquiries teams for increased activity following Royal Assent.

6.2 The operations infrastructure business case was approved on Feb 28th 2019 but falls £900k short of our funding requirements. The operational implementation workstreams are being reviewed to consider options for reducing implementation activity. These implications and risks are still being worked through. Funding for Financial Years 2020/21 to 2022/23 is agreed in principle but is indicative at this stage and will be subject to the Spending Review.

7. Communications

- 7.1 The Government has committed to an £11.5m campaign over two years with the option of extending the campaign to three years if the results are not achieving the policy objectives. This is £7.5m short of the campaign requirements put forward by NHSBT, with the removal of a household mailing (£1.8m), some targeted media spend and all year 3 activity. Despite this, campaign planning is progressing and the team are recruiting to additional key roles for delivery. The funding allocation will support a 2-year media campaign which will deliver mass reach at sustained frequency over 2 years at a good return on investment alongside some specific behaviour change interventions for BAME / young people / hard to engage groups.
- 7.2 Stakeholder mapping and plans are in place to maintain contact with all key stakeholders as the legislation progresses across the UK and Crown Dependencies. The NHSBT Website has been updated to provide FAQs and further updates will coincide with launch of campaign in April. Two phases of awareness tracking are complete and awareness of the law change was 37% of the population in January 2019 (vs. 54% in the previous wave). The campaign advisory group continues to convene monthly to scrutinise the campaign planning and development.
- 7.3 NHSBT have been clear with DHSC that we cannot be accountable for delivery of the 80% public awareness target set by Government. Raising awareness to this level is challenging based on comparative spend levels in Wales and will place a high reliance on cross government partnerships to drive expected reach.
- 7.4 Contact with BAME / Faith groups is continuing and we are discussing plans with National BAME Transplant Alliance (NBTA). The team are starting to pull together PR plans for the campaign. The main campaign leaflet in England and information sheets are in design.

8. Digital

- 8.1 The planned release date of 24th April for the NHS App Integration Solution remains feasible. However, the risk level remains high due to there being no time or cost contingency to absorb any significant issues that may be identified during testing. Development is progressing to schedule and the testing phase is in full flight.
- 8.2 Some data and process issues will need to be addressed before live use, while others such as de-duplication of ODR records will continue to be worked on beyond the April release. Integrated end-to-end testing has started and some minor functional defects are being resolved through fixes and minor changes.
- 8.3 The testing undertaken so far has identified a number of important IT infrastructure requirements / non-compliances that require investment to fully resolve. These were not included in the NHS App project scope or budget and are therefore a cost pressure to ODT.

9. Funding

- 9.1 Table 1 and 2 below outlines the funding requirement provided by NHSBT for implementation over 5 years and the funding confirmed by DHSC. We are awaiting clarification on some points, particularly regarding the operational budget so that we can revise our implementation plans.
- 9.2 DHSC have indicated that any funding after 2019/20 for the operational budget will be confirmed following the Spending Review. We have also had no confirmation regarding recurrent funding.
- 9.3 A breakdown of the Comms spend is provided at Appendix A.

Table 1 Funding Requirement

Funding Requirement	2018/19	2019/20	2020/21	2021/22	2022/23	Recurrent
	£000's	£000's	£000's	£000's	£000's	£000's
Faith Declaration*	80	-	-	-	-	-
NHS App Integration**	590	237	102	102	102	102
Operations	780	5,094	4,657	4,486	5,525	11,131
Communications	200	9,500	6,300	3,000	-	-
Total	1,650	14,831	11,059	7,588	5,627	11,233

Table 2 Confirmed DHSC Funding

Confirmed Funding	2018/19	2019/20	2020/21	2021/22	2022/23	Recurrent
	£000's	£000's	£000's	£000's	£000's	£000's
Faith Declaration	80	-	-	-	-	-
NHS App Integration	0	237	-	-	-	-
Operations	0	4,200	-	-	-	-
Communications	200	6,500	5,000	-	-	-
Total	280	10,937	5,000	0	0	0

* Capital Spend

** Capital & Revenue

10. Capacity to Deliver

- 10.1 Activity in this period has focused on building the implementation team to deliver the operational change and communications campaign. Details of the current positions filled / under offer / vacant and the funding basis for the posts are provided at Appendix B.

11. Risks and Issues

There are the following new risks and issues, in addition to those highlighted in previous Board papers:

- a. The operational implementation funding falls £900k short of our requirements. Funding for Financial Years 2020/21 to 2022/23 is agreed in principle but is indicative at this stage and will be subject to the spending review. These implications and risks of reducing implementation activity are being worked through by the team.
- b. DHSC have not confirmed funding for the Machine Perfusion and DCD Hearts, both of which are collectively required to support the Government's aim of 100 additional donors and 700 additional transplants. The team are working with Statistics and Clinical Studies and DHSC to define realistic and achievable transplant projections with the programme Board.
- c. There is no formal financial governance structure in place with DHSC and it is unclear what the process is for raising budget issues and seeking approval. This has been raised as an issue and the DHSC Finance team are reviewing this matter.
- d. The communications budget falls short of our recommendation. This will constrain our ability to deliver sustained public awareness over a longer time period leading to some risk of public confusion in some areas and potential decrease in donor referrals and consent due to some loss of Medical and Nursing confidence. We are exploring with Government what more can be done to provide ongoing awareness to those who reach the age of 18.
- e. Overall the planned release date of 24th April for the NHS App remains feasible but the risk level remains high due to there being no time or cost contingency to absorb any significant issues.

12. Conclusion

The new Act in England marks a major milestone in organ donation history in the UK and will be followed in the coming months by legislation in Scotland, Jersey, Guernsey and the Isle of Man. NHSBT has been commended by Ministers and in the House of Lords for our activity to inform the legislation as it progressed through Parliament and our work to reassure stakeholders. We will continue with this collaborative approach through the implementation programme.

NED Scrutiny

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Appendix A – Communications: Summary and breakdown of spend for 2019/20

Description	2019/20 (£m)
Mass reach media campaign	£4.00
Community engagement with black, Asian and minority communities through grant scheme, faith engagement, development of a Fatwa, bespoke BAME and faith assets needed for communities (includes multi-language)	£0.40
Ongoing evaluation and research - quarterly trackers, bi-annual wave attitudinal trackers	£0.20
Production of TV ad, radio ads (2019/20), ongoing content development (storytelling, real people stories, myth-busting content, through time period covered by the costs for paid, owned and earned channels	£0.45
Materials (posters, leaflets, merchandise), storage and distribution and a targeted Household Mailing	£0.25
Targeted household mailing	£0.10
3rd party agency costs to engage partners to disseminate the campaign message	£0.20
Teaching resources/young people outreach. Paid media partnership (e.g. UCAS)	£0.10
Healthcare promotion (posters and leaflets in GP surgeries	£0.20
Team resource	£0.60
Total	£6.50

Appendix B - Capacity and implementation roles

Role Type	Role	Status	Funding
Implementation	Accountable Executive	Appointed	TBC
Implementation	Programme Manager	Appointed	Baseline
Implementation	Project Lead for Nursing	Appointed	TBC
Implementation	Project Lead for Education and Governance	Appointed	DHSC
Implementation	Project Manager for Operations	Under offer	TBC
Implementation	Project Manager for Communication's	Under offer	TBC
Implementation	PMO Coordinator	Under offer	TBC
Implementation	Workforce	Appointed	TBC
Implementation	Quality Assurance	tbc	TBC
Operations	NHS Organ Donor Line Call Agents	Appointed	
Operations	Professional Development Staff	Recruit March	DHSC
Operations	Specialist Nurses for Organ Donation	Recruit April	DHSC
Operations	NORS Team	tbc	DHSC
Operations	Complaints Team	tbc	DHSC
Operations	Statistician	tbc	DHSC
Operations	Donor Records Administrators	tbc	DHSC
Communications	Media and PR Manager	Recruit March	DHSC
Communications	Stakeholder Manager	Recruit March	DHSC
Communications	Administrators	Recruit March	DHSC
Communications	Deputy Head Organ Donation Marketing	Recruit March	DHSC
Communications	Senior Marketing and Campaigns Officer	Recruit March	DHSC