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The Human Tissue (Authorisation) (Scotland) Act 2019: Five year Monitoring and Evaluation Plan



HEALTH AND SOCIAL CARE



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Abbreviations

CLOD	Clinical Lead for Organ Donation
ED consultant	Emergency Department consultant
ICU consultant	Intensive Care Unit consultant
ICU senior nurses	Intensive Care Unit senior nurses
NHSBT	NHS Blood and Transplant
ODR	Organ Donation Register
SNBTS	Scottish National Blood Transfusion Service
SNOD	Specialist Nurse for Organ Donation
TDCs	Tissue Donation Coordinator

Introduction

This document outlines a five year monitoring and evaluation plan of the organ and tissue donation opt-out system. The requirement for monitoring and evaluation was stipulated by the 'The Human Tissue (Authorisation) (Scotland) Act 2019' (hereafter referred to as 'the Act') which introduces the opt-out system. This plan outlines:

- The outcomes (short, medium and long term) that the Act is aiming to influence
- The evaluation logic model
- The data sources and indicators that will be used to monitor progress
- A proposed monitoring and evaluation timeline

This is a working document, and therefore time points and activities may be changed over the monitoring and evaluation period as necessary.

Policy Context

The Act introduced a system of 'deemed authorisation' for organ and tissue donation for transplantation, changing the current 'opt-in' system to an 'opt-out' system. This means that if someone dies in circumstances where they potentially could become a donor, and they have not recorded a donation decision, they would be presumed to be willing to donate unless their family provides information that the potential donor was unwilling to do so. The Act is predicated on the views of the donor taking primacy.

The implementation of this legislation in Scotland included a package of implementation activities, such as training targeted at NHS staff, public information aimed at raising public awareness, and stakeholder engagement. This approach is supported by research conducted in other European contexts where there has been a change to an opt-out system, which demonstrated the importance of a broader package of implementation activities to support the efficacy of the shift to an opt-out system.

Approach to Developing the Plan

The Scottish Government (Health and Social Care Analysis Division) developed a draft evaluation plan in 2018, in collaboration with NHS Health Scotland, who

facilitated an evaluability assessment workshop¹. The result was an initial logic model outlining the various implementation activities and intended outcomes of the changed legislation, a draft set of evaluation questions and proposed methods for answering each. This version of the monitoring and evaluation plan builds on this previous work and was informed by further discussions with the Act implementation team.

This plan is based on a theory-based evaluation design. Theory-based designs address the challenges of attribution and impact within complex policy and delivery landscapes. The aim of most evaluations is to determine whether a new intervention or policy has produced the intended long-term changes. However, attributing changes to any one intervention or policy is challenging, as longer term outcomes are influenced by a wide number of external and contextual factors. This makes it difficult to assess the impact of the intervention activities.

In the context of organ and tissue donation, a challenge will be to evaluate the extent to which the legislative change to an opt-out system – alongside the supporting implementation activities – have impacted on a number of the long-term potential outcomes. This is particularly the case for outcomes related to numbers of organ and tissue donations and transplants in Scotland. This is because there are a number of contingencies between gaining authorisation to proceed to donation and successful donation and/or transplantation, which are largely clinical in nature. An opt-out system cannot impact on these contingencies. As such, whilst increased donation and transplantation is the ultimate aim of the legislation, these measures do not provide a direct read-across by which to understand the success of the change to an opt-out authorisation system, or its package of implementation activities.

Outcomes and Logic Model

Outcomes

The theory-based evaluation framework for the Act identified 16 potential outcomes, listed below. These outcomes underpin the data that will be collected on the donation process for the purposes of monitoring and evaluation.

It should be noted that Outcome 11 – increased donation authorisation rate – is a priority outcome to achieve the ultimate aim of the legislation to increase donation and transplantation. The other intended outcomes of the Act work to support the fruition of this outcome, for example, by supporting a positive donation culture in the

¹ Evaluability Assessment is a systematic and collaborative approach to deciding whether and how an evaluation should be done. For more information see: [Policy briefing – Evaluability Assessment: A collaborative approach to planning evaluations | What Works Scotland](#)

public sphere and within the NHS, as well as supporting an infrastructure which supports donation as a normalised end-of-life care choice.

The full list of outcomes of the Act are:

Short term (1-2 years)

1. Increasing public awareness of the legislation regarding:
 - a. implications of opt out/deemed authorisation
 - b. how to register to opt in/opt out for tissue and organ donation
 - c. the role of family in authorisation processes
2. Increasing awareness of donation and the (implications of) legislation change among groups that are currently under-represented among organ and tissue donors, in particular ethnic minority groups.
3. Increasing proportion of people who report having a conversation with their family members about their decisions in regards to tissue and organ donation.
4. Increasing awareness of, knowledge about, and support for the legislation among NHS staff involved in organ and tissue donation, to support timely referral to specialist organ donation nurses or tissue donor coordinators.
5. Infrastructure in place for early identification and referral of potential donors.

Medium term (3-4 years)

6. Increasing public trust in the NHS organ and tissue donation system.
7. Increased number of people that feel they are able to make an informed decision about organ and tissue donation.
8. Increased registrations of a decision about organ and tissue donation on the Organ Donor Register.
9. Increased proportion of families supporting donor's decisions.
10. Increased trust and skills in the NHS donation system within the NHS professional culture.
11. Increased donation authorisation rate².
12. Reductions in missed donation opportunities.

Long term (5 years)

13. Permanent culture change within the public and NHS professional culture, to include shifts such as: normalisation of donation as part of end of life care, and increased cultural willingness to discuss donation decisions.
14. Increased percentage of people becoming donors from the potential donors group (in Scotland).³

² Although increased donation and transplantation rates are the ultimate aim of the Act, an increased donation *authorisation* rate is a priority outcome according to the aims of the legislation.

³ 'Potential donors' are defined as patients who met the criteria for neurological death tests i.e. those for which neurological death was suspected or patients for whom treatment was withdrawn and death was anticipated within four hours.

- 15. Increased percentage of transplants (from donors in Scotland).
- 16. Support available for relatives of persons who have authorised, or who have been deemed to have authorised organ and/or tissue donation (both before and after organ/tissue retrieval takes place).⁴

Notes:

- Outcomes 14 and 15: Whilst increased donation and transplantation is the ultimate aim of the legislation, there are a number of factors (often clinical) which mean that authorisation does not always lead to successful donation or transplantation. The move to an opt out system does not change these contingencies.
- Outcome 16: Availability of support for donor’s relatives is not a specific aim of the Act. However support for donor families is an important part of the donation process and so this outcome is included as part of the evaluation requirements, but is one which is not dependent on the other outcomes for fruition. This outcome is already supported by current, NHS Blood and Transplant (NHSBT) and Scottish National Blood Transfusion Service (SNBTS) practice.

Outcome strands

The outcomes fall within three main strands:

Strand	Refers to	Outcomes
A. Public Attitudes	Public’s views on, attitudes toward and behaviours associated with donation	1-3, 6-9, 13-15
B. Workforce	Views, confidence, and practice of NHS Scotland staff members involved in donation processes	4, 5, 10, 12, 13 - 15
C. Monitoring Data	Data currently collected by NHSBT and SNBTS on referral, authorisation, donation and transplantation rates	11, 12, 14-16

Logic Model

The logic model below (Figure A) illustrates the relationships and dependencies between the outcomes. It demonstrates which outcomes are projected to impact on the achievement of other outcomes. In addition, the logic model illustrates the

⁴ This outcome is a stipulated aspect of the legislation but one which is not dependent on the other outcomes for fruition. This outcome is already supported by current Specialist Nurse for Organ Donation (SNOD) operations.

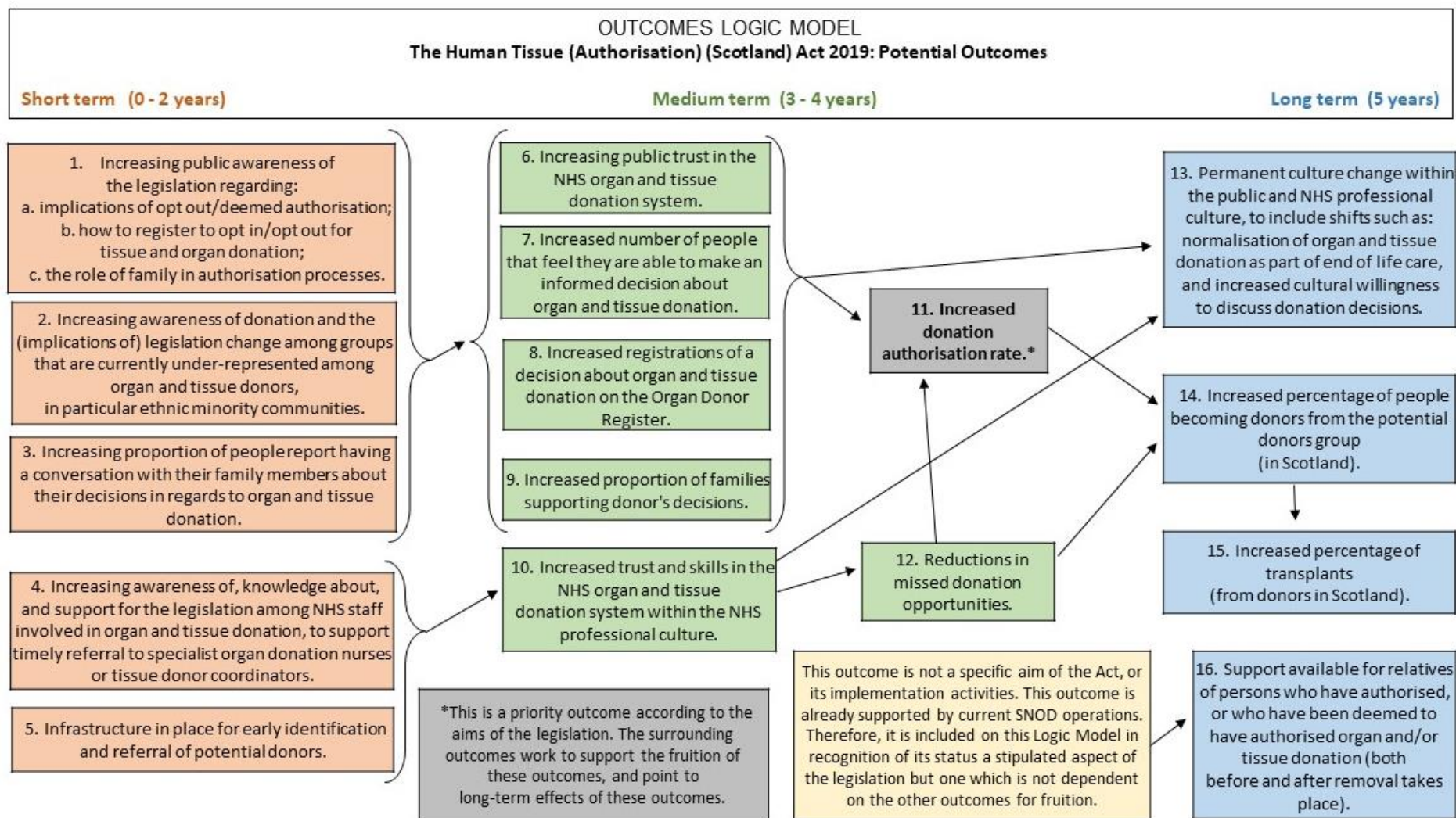
anticipated timeframes within which impacts may be seen as a result of the implementation of the Act and its package of implementation activities.

For example, the success of increasing authorisation rates (Outcome 11), a priority outcome of the Act that is linked to donation and transplantation rates, is projected to be a measureable trend toward the end of the five year monitoring and evaluation period. An increase in authorisation rates is likely to be supported by the success of Outcomes 6-9 and 12, measurable at the midway point of the period. In turn, these are largely impacted by Outcomes 1-3, which are likely to show first signs of impact from the implementation of the Act and its package of supporting activities.

Furthermore, authorisation rates (Outcome 11) are positioned to impact on Outcome 14, and in turn Outcome 15.

Three further logic models are included in Annex 1 to illustrate which outcomes fall within each of the three strands (Public Attitudes; Workforce; and Monitoring Data).

Figure 1: Outcomes Logic Model



Data Sources, Indicators, and Implementation Activities

Background

This section gives an overview of different data sources (indicators) that the monitoring and evaluation program intends to draw upon over the five year period, to track potential impacts on the Act's intended outcomes. It is organised according to the three strands: Public Attitudes, Workforce, and Monitoring Data.

This section also provides an overview of some of the activities conducted to support implementation of the Act. These activity overviews provide context to understand how potential impacts on particular outcomes might occur. They also serve as potential monitoring tools for particular outcomes. For example, Outcome 2 (increasing awareness of donation and legislation change among under-represented groups) is currently not evidenced by data sources, but it is being addressed through implementation activities centred around stakeholder engagement and media marketing about the Act.

Baseline Data

Baseline data was gathered (up to February 2020) to underpin this Monitoring and Evaluation Plan, so that the five year monitoring and tracking data can be compared to a 'pre' legislation implementation context. An overview of the baseline data can be found in Annex 2 and full details are in the [Baseline Report](#).

Impacts of the COVID-19 Pandemic on Data

The Act was originally planned for implementation in Autumn 2020, however due to the COVID-19, implementation was postponed to March 2021. The pandemic appears to have had impacts on organ and tissue donation and transplantation activity in the UK. The NHSBT [Annual Organ Donation and Transplantation Activity Report 2020/2021](#) reported significant drops in donation and transplantation rates in 2020, which were not consistent with activity trends prior to March 2020. Therefore, the baseline data against which this monitoring and evaluation plan will be measured covers the period prior to the onset of the COVID-19 pandemic, namely up until 29 February 2020.

As implementation of the Act was postponed to March 2021, this does create a missing year of data (March 2020 - March 2021), however given the significant contextual changes created by the pandemic, exclusion of this data will provide a more accurate baseline view. It should be noted that the implementation of the legislation (March 2021) occurred during continued COVID-19 pandemic restrictions, and that the pandemic may continue to impact donation activities during the monitoring and evaluation period.

Potential Monitoring and Evaluation Data Sources

A. Public Attitudes

Data: Public attitudes survey

- At baseline, The Scottish Government commissioned the Scottish Health Council to survey members of the public about organ and tissue donation, using the Our Voice Citizen's Panel⁵. This provided an understanding of public awareness, understanding, and views on donation in general and about the legislation, as well as behaviours in relation to organ and tissue donation.
- The Scottish Government will undertake similar surveys at approximately two and five years post implementation.

Data: Marketing surveys

- The baseline data drew on five omnibus surveys that were undertaken to monitor impacts of a media marketing campaign (see below). The surveys looked at public attitudes towards the change to an opt-out system, as well as impacts of the media campaign.
- Future marketing campaigns will also be evaluated, although the specific timing of these surveys is yet to be determined.

Implementation Activity: Media marketing campaigns

- These activities included broader awareness raising work during the baseline period and the 'Big Change' marketing campaign, from January 2021. The aim of these activities was to inform the public of the donation law change and encourage people to register a donation decision on the NHS Organ Donor Register and tell their family members about their decision.
- Scottish Ministers are under an ongoing duty to raise awareness about the opt out system and donation in general, so there will be ongoing campaigns which will continue to be evaluated. These are likely to be run annually, although the specific timing and content of these campaigns is yet to be determined.

Implementation Activity: Stakeholder engagement

- The aim of this workstream is to raise awareness with harder-to-reach groups, and groups with specific interests in relation to the opt-out system, to incorporate their views into the implementation of the Act. The bulk of these activities have taken place from July 2019 to implementation.
- Future stakeholder engagement will be scoped as part of business as usual activities. Any activities will be recorded and monitored over the five year monitoring and evaluation period in order to contextualise outcomes within the Public Attitudes strand.

⁵ [Our Voice Citizen's Panel: October 2019](#)

- This workstream offers the best potential monitoring information for Outcome 2 (increasing awareness of donation and legislation change among under-represented groups).

B. Workforce

Data: [Qualitative research with NHS Scotland staff](#)

- At baseline, a Scottish Government researcher conducted qualitative research (via interviews and focus groups) with NHS Scotland staff⁶ involved in donation. This gathered views on donation generally, the move to a deemed authorisation system, and what could help ensure it is a success.
- A scaled down version of this qualitative research is recommended during the five year monitoring and evaluation period to track changes in workforce attitudes and views.. Two potential options include:
 - Telephone or video interviews with a sample of NHS Scotland staff involved in donation.
 - An online survey sent to all NHS Scotland staff involved in donation (matching the staff groups listed).

Data: Confidence rating surveys pre- and post- training with NHS Scotland staff

- At baseline, online surveys were sent to staff to evaluate the impact of training undertaken in preparation for the implementation of the Act. These surveys were sent pre- and post- training, and measured changes in reported confidence around key areas of practice, as well as key learning sought by and gained through the training.
- In order to track levels of confidence over the five year monitoring and evaluation period, a survey replicating the baseline staff questionnaire will be needed. The key areas of practice to be tracked include:
 - Staff understanding of the new legislation
 - Explaining changes to an opt-out authorisation system to fellow colleagues
 - Following the correct procedures to ensure new legislative requirements are followed
 - Understanding of the changes being made around Pre Death Procedures in the Human Tissue (Authorisation) (Scotland) Act 2019
 - Explaining Pre Death Procedures to peers
 - Explaining the changes in legislation to patients and patient families

⁶ Staff interviewed included: Clinical Leads for Organ Donation; Specialist Nurses for Organ Donation; Tissue Donation Coordinators; ICU consultants; Emergency Department clinicians and senior nurses.

Implementation Activity: Training aimed at NHS Scotland staff involved in donation processes*

- The aim of this workstream is to ensure compliance and confidence with new legislative requirements among all operational staff involved in donation processes in Scotland.
- *It is unclear in what form these training activities will continue, beyond an online tool. An overview of training activities will be recorded and monitored over the five year monitoring and evaluation period in order to contextualise outcomes within the Workforce strand.

Implementation Activity: Donor family support

- Routine, informal support is offered to donor and potential donor families by SNODs as part of practice prior to the implementation of the Act. However, these activities are not tracked by SNODs, NHSBT or SNBTS therefore there is no published data source for this information.
- One approach for gathering information on this is to gather information from the Lead SNOD about the range of support offered to donor families in the year prior, or a short survey to be sent to all SNODs gathering this information anonymously. It is important to note that this would serve as monitoring information, not evidence against which to measure the success of outcome 16.

C. Monitoring Data

Data: Organ donation data

- Routine data is collected by NHSBT on referral, family approach, authorisation, donation, and transplantation rates.
- The NHSBT Scotland Organ Donation Services Team release statistical reports providing a summary of data relating to potential and actual organ donors, as recorded by NHSBT via the Potential Donor Audit (PDA), the accompanying Referral Record and the UK Transplant Registry:
 - Scotland Organ Donation Services Team: Detailed Report Actual and Potential Deceased Organ Donation 1 April 2019 - 31 March 2020
 - Organ Donation and Transplantation Activity Report 2019/2020
 - Organ Donation and Transplantation data for Black, Asian and Minority Ethnic (BAME) communities: Report for 2019/2020

Data: Tissue Donation Data

- Some routine data is collected by SNBTS on referral, family approach, authorisation, donation, and transplantation rates.
- Currently, this data is not routinely published, but SNBTS will seek to collect and share this data with Scottish Government for monitoring and evaluation purposes.

Data: Organ Donor Register data on opt-in and opt-out registrations and withdrawals

- Routine data collected by NHSBT and published within the Organ Donation and Transplantation Activity Report 2019/2020.
- Detailed Scottish specific data will be made available by NHSBT for Scottish Government monitoring and evaluation purposes.

Table A lays out which data sources address which outcomes. This shows that there is at least one source of potential data or information from implementation activities to monitor progress towards most outcomes. However, there is also uncertainty over the future availability of some sources of information, particularly for outcomes two and 16.

Table A: Measuring and Contextualising Outcomes by Information Source

Strand	Information Source	Outcomes															
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Public Attitudes	Public Attitudes Survey																
	Marketing Surveys*																
	Academic and Public Sector Research**																
Workforce	Qualitative research with NHS Scotland staff																
	Surveys with NHS Scotland Staff																
Monitoring Data	NHSBT: Organ Donation Data																
	SNBTS: Tissue Donation Data																
	Organ Donation Register data																
Implementation (and potentially ongoing) activities	Activities in the section below offer monitoring information or contextual information about potential impact on the outcome, not data against which to measure impact.																
	Media marketing campaign*																
	Engagement with partners and stakeholders*																
	Training aimed at NHS Scotland staff involved in donation processes*																
	Routine, informal support offered to donor families by SNODs*																

NOTES:

The specific details of information sources marked with an asterisk () are still be determined, as long-term business planning within Scottish Government and the NHS is still underway.

** Relevant academic research will be used where appropriate.

A: SNBTS is currently reviewing how it will collect this information and the availability of this data source will be monitored.

B: There is no currently available evidence to address Outcome 2 (increasing awareness among under-represented groups) – the only available information comes from this stakeholder engagement workstream

C: Outcome 16 (support for relatives) is not impacted on by the Act's package of implementation activities.

Proposed Timeline

Table B presents a proposed timeline for the monitoring and evaluation of impacts of the implementation of the Act, with suggested time points at which data and information about areas of activity should be collected. This is a working plan, and therefore will be adjusted according to business planning, budget, staff capacity, data availability, and business planning. Decisions are still to be made about future reporting.

Table B: Proposed Timeline of Monitoring and Evaluation Activities

Strand	Information Source	Baseline	Act Implementation	Short term 1-2 years post		Medium Term 3-4 years post		Long Term 5 years post
		(until Feb 2020)	March 2021	2022	2023	2024	2025	2026
Public Attitudes	Public Attitudes Survey							
	Marketing Campaign Surveys*							
Workforce	Qualitative research with NHS Scotland staff							
	Confidence Rating Surveys with NHS Scotland Staff							
Monitoring Data	Organ Donation Data							
	Tissue Donation Data							
	Organ Donation Register data							

Strand	Information Source	Baseline	Act Implementation	Short term 1-2 years post		Medium Term 3-4 years post		Long Term 5 years post
		(until Feb 2020)	March 2021	2022	2023	2024	2025	2026
Implementation (and potentially ongoing) activities	The activities below offer information to contextualise potential impact, not data against which to measure impact.							
	Media marketing campaign*							
	Engagement with partners and stakeholders*							
	Training aimed at NHS Scotland staff involved in donation processes*							
	Routine, informal support offered to donor families by SNODs. The specifics of monitoring of this activity is still to be decided.							

* The specifics of these activities are still to be decided, according to business planning and future budgets

Annex 1 - Logic models for the 3 outcome strands

Figure 2: Outcomes Logic Model: Public Attitudes Strand

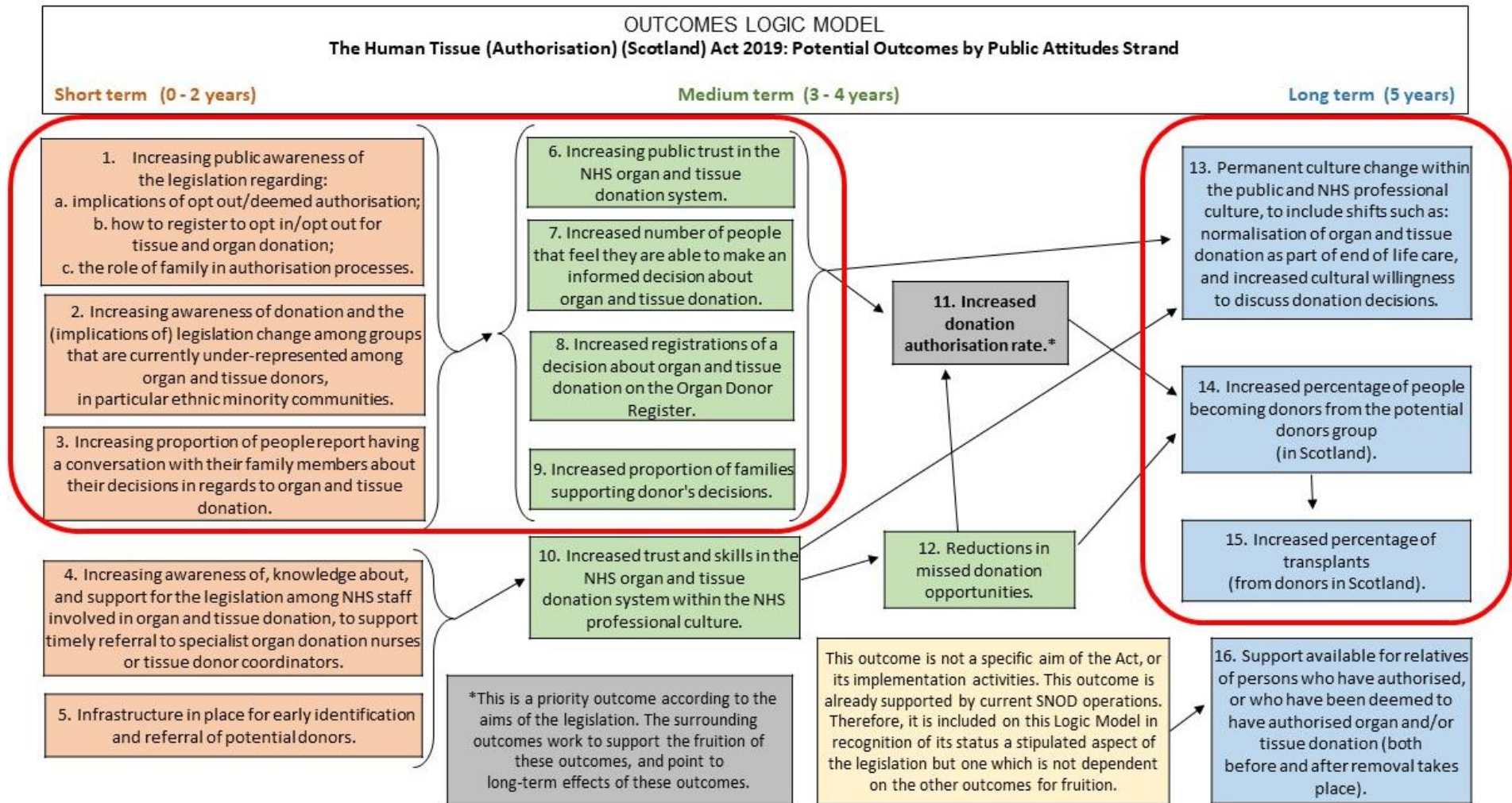
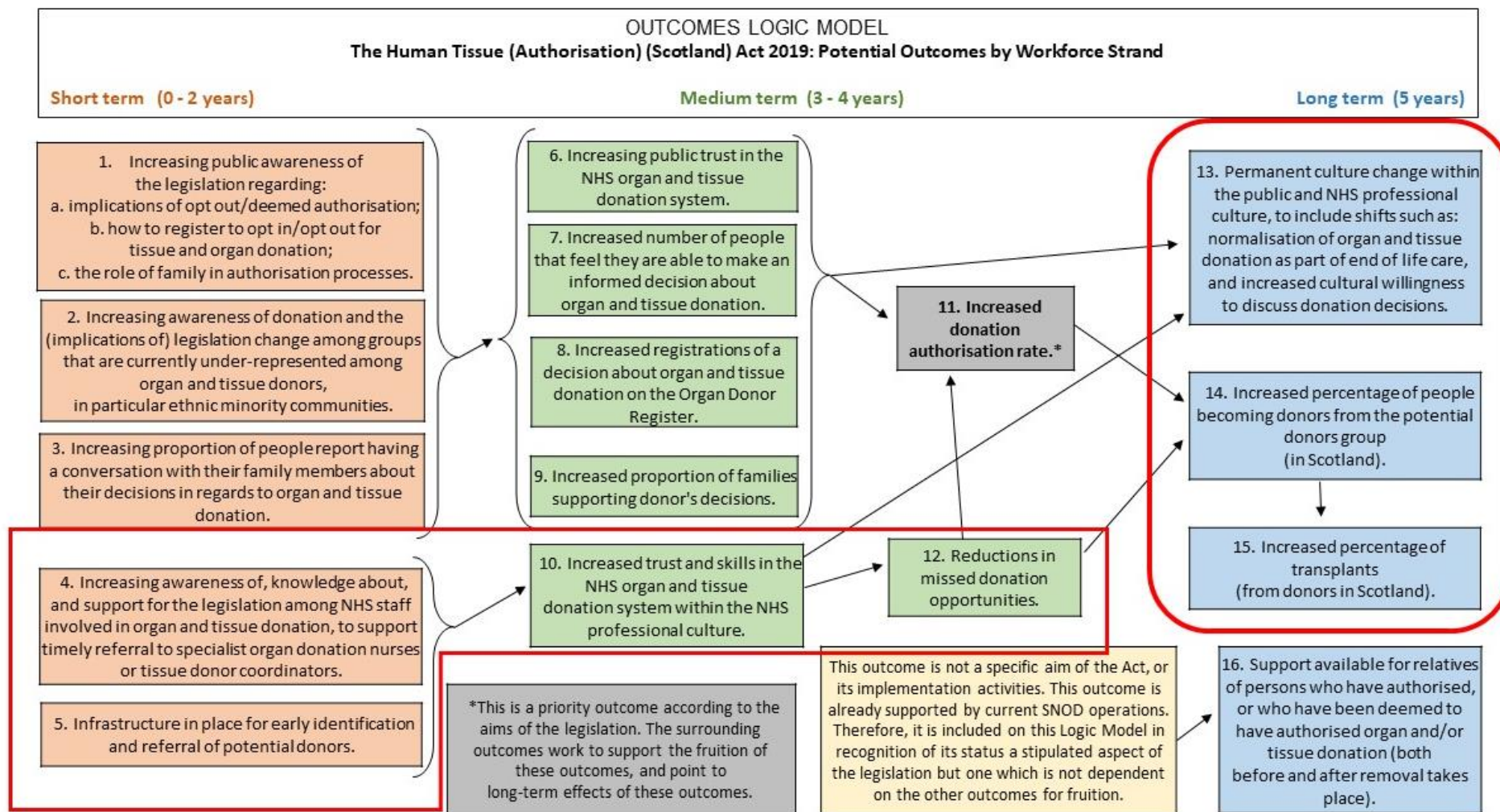


Figure 3: Outcomes Logic Model: Workforce Strand



Annex 2 – Overview of the baseline data, by outcome strand

Public Attitudes

- Data: Public attitudes survey. In June and July 2019, the Scottish Health Council surveyed members of the public about organ and tissue donation, using the Our Voice Citizen's Panel. This survey collected information on awareness and understanding of the legislation, views on donation in general, as well as behaviours in relation to legislation and organ and tissue donation.
- Data: Marketing surveys. The Scottish Government's marketing unit commissioned five online omnibus surveys (in June 2019, September 2019, March 2020, September 2020, and January 2021) to monitor public views and attitudes towards the change to an opt-out system for donation, as well as the impacts of the media campaign to inform the public about the law change and to raise awareness about registering a decision on the Organ Donor Register.
- Implementation Activity: Media marketing campaign. The aim of this workstream was to inform the public about the donation law change and raise awareness about the importance of registering a donation decision on the Organ Donor Register.
- Implementation Activity: Engagement with partners and stakeholders. The aim of this workstream was to represent hard-to-reach groups and those with protected characteristics, and to incorporate their views into the implementation of the Act.

Workforce

- Data: Qualitative research with NHS Scotland staff. Between October 2019 and January 2020 a Scottish Government researcher undertook interviews and focus groups with staff involved in donation to gather their views.
- Data: Confidence rating surveys pre- and post- training with NHS Scotland staff, collected between Sept 2020 and March 2021.
- Implementation Activity: A variety of training sessions aimed at NHS Scotland staff involved in donation processes were run between Sept 2020 to Feb 2021, and an online resource was made available from Jan 2021. The aim of this workstream was to ensure compliance and confidence with new legislative requirements among all operational staff involved in donation processes in Scotland.

Monitoring Data

- Data: Routine organ donation data collected by NHSBT on referral, family approach, authorisation, donation, and transplantation rates.

- Data: Routine tissue donation data collected by SNBTS on referral, family approach, authorisation, donation, and transplantation rates.
- Data: Routine Organ Donation Register collected by NHSBT, on opt-in, opt-out registrations and withdrawals.



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This document is also available from our website at www.gov.scot.
ISBN: 978-1-80201-952-0

The Scottish Government
St Andrew's House
Edinburgh
EH1 3DG

Produced for
the Scottish Government
by APS Group Scotland
PPDAS1010759 (02/22)
Published by
the Scottish Government,
February 2022



Social Research series
ISSN 2045-6964
ISBN 978-1-80201-952-0

Web Publication
www.gov.scot/socialresearch

PPDAS1010759 (02/22)