National Office of Clinical Audit

POTENTIAL DONOR AUDIT DEVELOPMENT PROJECT REPORT

PREPARED BY THE POTENTIAL DONOR AUDIT DEVELOPMENT PROJECT WORKING GROUP WITH ASSISTANCE FROM THE POTENTIAL DONOR AUDIT DEVELOPMENT PROJECT

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With the assistance of the Potential Donor Audit Feasibility Study Steering Committee

NATIONAL OFFICE OF CLINICAL AUDIT

The National Office of Clinical Audit (NOCA) was established in 2012 to create sustainable clinical audit programmes at national level. NOCA is funded by the Health Service Executive Office of the Chief Clinical Officer and operationally supported by the Royal College of Surgeons in Ireland.

The National Clinical Effectiveness Committee defines national clinical audit as "a cyclical process that aims to improve patient care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards on a national basis" (National Clinical Effectiveness Committee, 2015, p. 2). NOCA supports hospitals to learn from their audit cycles.

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This report uses data collected by healthcare providers as part of their normal care process. NOCA thanks all participating hospitals for their valuable contributions, in particular the organ donation nurse managers and clinical leads in organ donation. Without their continued support and input, this audit could not produce meaningful analyses of organ donation practices in participating hospitals. NOCA greatly appreciates the ongoing commitment and support received from Organ Donation Transplant Ireland.

The NOCA Potential Donor Audit Development Project Steering Committee would like to thank all those who were involved in the early stages of development of the Potential Donor Audit and all those who continue to be involved in additional data collection. These include, but are not limited to: the NOCA Irish National Intensive Care Unit Audit clinical lead, audit managers and audit coordinators; Intensive Care Unit personnel in participating hospitals; MEG, the Potential Donor Audit Development Project information technology application partner; and international advisers at National Health Service Blood and Transplant in the United Kingdom, DonateLife in Australia, and Professor Michael O'Leary, Co-State Medical Director, New South Wales Organ and Tissue Donation Service in Australia.

The NOCA Potential Donor Audit Development Project Steering Committee acknowledges the patients who died in participating Intensive Care Units during the audit time frame. We would like to offer our sympathies to their families.

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POTENTIAL DONOR AUDIT DEVELOPMENT PROJECT REPORT

Dr Alan Gaffney
Clinical Lead
Potential Donor Audit Development Project
National Office of Clinical Audit
2nd Floor, Ardilaun House
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5th July 2023

Dear Dr Gaffney,

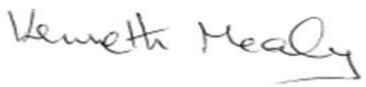
I wish to acknowledge receipt of the *Potential Donor Audit Development Project.*

Following your presentation to the NOCA Governance Board on the 22nd June 2023 and feedback garnered from our membership, we are delighted to endorse this report.

I wish to congratulate you, Project Manager, Dr Maria Kehoe, PhD and your governance committee in the development of this report which is a valuable quality improvement initiative.

Please accept this as formal endorsement from the NOCA Governance Board of the *Potential Donor Audit Development Project* and we wish you every success in your ongoing commitment to improving the care of patients and their families.

Yours sincerely,



Mr Ken Mealy

Chair

National Office of Clinical Audit Governance Board

FOREWORD

We are delighted to welcome the publication of this National Office of Clinical Audit (NOCA) *Potential Donor Audit Development Project Report* and wish to congratulate the writers and team at NOCA. This report is a significant milestone for the Irish healthcare service. It contains results from the newly developed Potential Donor Audit (PDA) in six participating Intensive Care Units (ICUs) and represents NOCA's first national clinical audit development project. These findings demonstrate that a PDA should be deployed nationally as soon as possible in order to support and enhance a service that is of immense benefit to patients and their families.

We would like to thank all participating hospitals for their valuable contributions, in particular the organ donation nurse managers acting as PDA coordinators, clinical leads in organ donation, and their colleagues throughout the ICUs. Without their dedication and commitment, this audit could not have produced meaningful data. We would like to thank the PDA Development Project Steering Committee and all those at NOCA with the audit development expertise to create a high-quality PDA that is relevant to the Irish context and suitable for international benchmarking. Finally, we would like to acknowledge the families and those patients who died in participating ICUs during the audit time frame.

Organ donation is 'the gift of life'. The benefits for the families of both deceased organ donors and transplant recipients cannot be measured. As healthcare professionals, we are committed to offering organ donation as an option at the end of life, where appropriate. A national potential donor audit is recognised as an international standard that forms an integral pillar of an organ donation and transplant service. This has been long recognised in other countries, such as the United Kingdom, Australia, the United States of America, and Spain – the world leaders in organ donation.

By identifying potential missed opportunities, the PDA Development Project highlights areas where we are doing well, while also bringing attention to opportunities for improvement. It provides us with meaningful information we can use to improve our practice. Given the breadth of health service provision and fluctuations in staffing resources, there is a critical educational value in the audit. High-quality data will inform the allocation of educational and infrastructural resources to support ICUs and Emergency Departments to meet the needs of patients.

Organ donation and transplant is a service born through the vision of pioneers in medicine, as well as the generosity of donors and their families. A national potential donor audit offers a mechanism to continue this good work and to build a system that offers the best possible end-of-life care to our patients and their families.

Professor Jim Egan
Director of Organ Donation Transplant Ireland
Consultant in Respiratory Medicine and Transplant Physician,
Mater Misericordiae University Hospital

Dr Catherine Motherway
Former Consultant in Anaesthesia and Intensive Care, UL Hospital Group
Organ Donation Clinical Specialist, Organ Donation Transplant Ireland

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GLOSSARY OF TERMS AND DEFINITIONS

Term	Definition
CIS	clinical information system
CLOD	clinical lead in organ donation
CT ICU	Cardiothoracic Intensive Care Unit
DBD	donation following brain death
DCD	donation following circulatory death
DPIA	data privacy impact assessment
DSMP	Data Specification Management Process
ED	Emergency Department
GICU	General Intensive Care Unit
HDU	High Dependency Unit
HIQA	Health Information and Quality Authority
ICU	Intensive Care Unit
ICSI	Intensive Care Society of Ireland
INICUA	Irish National Intensive Care Unit Audit
NHSBT	National Health Service Blood and Transplant
NOCA	National Office of Clinical Audit
NOPS	National Organ Procurement Service
ODNM	organ donation nurse manager
ODP	Organ donation personnel. This includes Hospital Group personnel (i.e. the clinical lead in organ donation and/or the organ donation nurse manager) and/or the National Organ Procurement Service.
ODTI	Organ Donation Transplant Ireland
PMP	per million population
PDA	Potential Donor Audit
PDA development project	an umbrella term for the entire work completed over the one year development phase
PDA pilot study	refers to the undertaking of the newly developed PDA in six hospitals for three months on a pilot basis
QI	quality improvement
SNOD	specialist nurse in organ donation
SNOMED-CT	Systematized Nomenclature of Medicine – Clinical Terms
WLST	withdrawal of life-sustaining therapy

Definitions

The definitions provided below have been adapted from "The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation" (Domínguez-Gil et al., 2011).

Term	Explanation
absolute medical contraindications	Absolute medical contraindications (to organ donation) are medical conditions in a potential organ donor which preclude organ donation due to the risk of harm to transplant recipients. To operationalise the development project, medical conditions were Identified by organ donation personnel based on McGowan's (2019) and the European Directorate for the Quality of Medicines & HealthCare's (2022) guidelines for the operation of the audit.
potential donor after brain death	A patient whose clinical condition is suspected to fulfil the brain death criteria (i.e. a patient who met the criteria for brainstem testing).
potential donor after circulatory death	A person who: a) has had life-sustaining therapy withdrawn following a neurological cause of death b) in the case of a non-neurological cause of death, was assessed as having the potential to become a donor after circulatory death.
eligible donor after brain death	A medically suitable person who has been declared dead based on neurological criteria.
eligible donor after circulatory death	A medically suitable person who: a) has had life-sustaining therapy withdrawn following a neurological cause of death b) in the case of a non-neurological cause of death, was assessed as having the potential to become a donor after circulatory death.

EXECUTIVE SUMMARY

The aim of a potential donor audit is to ensure that every person who is approaching the end of life in an Intensive Care Unit (ICU) or Emergency Department (ED) is offered the possibility of becoming an organ donor, where this is appropriate. Arising from a recommendation from the *Potential Donor Audit Feasibility Study Report* (National Office of Clinical Audit, 2022), Organ Donation Transplant Ireland commissioned the National Office of Clinical Audit to develop a Potential Donor Audit (PDA) for Irish hospitals. The feasibility study demonstrated the need for a national clinical audit of organ donation practices and recommended the development of a national PDA.

The PDA was developed using 15 methodological steps. These included setting quality improvement-focused aims and objectives, as well as involving frontline stakeholders throughout the process in order to ensure that the PDA provided the necessary information to drive improvement in organ donation practices with a focus on the Health Information and Quality Authority (HIQA) (2018) dimensions of data quality and appropriate ethical and information governance frameworks. Data were collected on a pilot basis by organ donation nurse managers who were clinically supported by clinical leads in organ donation for 3 months in one hospital in each of the six included Hospital Groups. The development process included a communications strategy to increase engagement with and by hospital and clinical communities, as well as to raise public awareness of the PDA. Important learning from the development process was recorded for the future.

Key finding 1: In the six participating hospitals, the PDA pilot study:

→	Quantified the potential for organ donation in six Irish hospitals where there was a long-established culture of organ donation. The pilot study findings provided information which acknowledges the work of ICU personnel and specialist organ donation personnel (ODP) in participating hospitals. Thirty percent (69/231) of ICU deaths met the PDA Development Project potential donor criteria.
→	Identified some potential missed opportunities for organ donation through a determination of medical eligibility.
→	Demonstrated the degree to which best practice standards in organ donation were met. These were: brainstem testing rate (68%; 17/25), referral rate (67%; 46/69), approach rate (83%; 19/23) and assent rate (68%; 13/19). Thirty-seven percent (7/19) of families of eligible donors were approached with the Hospital Group ODP present, and 53% (10/19) of families were approached at the recommended time. These findings provided baseline information upon which, future trends can be monitored.
→	Identified specific medical (e.g. absolute medical contraindications), process (e.g. reluctance to approach family) and family (e.g. family dissatisfied with patient care) reasons for a non-donation outcome.

Key finding 2: The PDA development project demonstrated:

The feasibility of collecting the required data elements for the PDA in participating ICUs
The degree to which the proposed PDA met the aim and objectives of the PDA development project
Excellent data quality using the HIQA dimensions of data quality (HIQA, 2018)
The value and necessity of a specialist Hospital Group ODP for PDA data collection
Areas for improvement in the proposed audit design for national implementation.

The findings of the PDA pilot study provided the necessary information to drive improvement in participating hospitals, ensuring that every person who was approaching the end of life in ICU or ED was offered the possibility of becoming an organ donor, where this was appropriate.

The PDA development project made four key recommendations:

Implement the PDA nationally in all acute hospitals with ICUs and/or EDs
Provide an agreed list of contraindications that can be operationalised for clinical practice in order to support the PDA.
Use the findings from the PDA Development Project to inform a set of national guidelines for organ donation.
Develop a clinically led quality improvement forum dedicated to improving organ donation and transplantation. Improvement activities may include, but are not limited to: reviewing cases that did not proceed to organ donation sharing examples of best practice and improvement activities developing quality improvement plans

These recommendations are key pillars of improvement from which donor families can find some solace and lives can be saved.

WHAT THIS PROJECT MEANS TO ME: INSIGHTS FROM PUBLIC AND PATIENT INTEREST REPRESENTATIVES

Martina Goggin
Strange Boat Donor Foundation
Public and Patient Interest Representative, PDA Development Project Steering Committee

When our son died following a road crash, my husband and I would have been devastated if we had not been given the opportunity to donate his organs. The comfort and consolation we felt in knowing that our son performed the noblest act of generosity by giving the gift of life to others is like a light that continues to shine even on the darkest days.

Being the parent of an organ donor, I did not hesitate when asked to participate in the Potential Donor Audit (PDA) Development Project Steering Committee as a public and patient interest representative. I feel that it is so important that every person approaching the end of life in hospital is offered the possibility of becoming an organ donor.

The data in this report highlight the value of the PDA in ensuring that this is the practice in Irish hospitals, which will, hopefully, increase the number of organ donors in the future.

The findings of this report took into account my views and experience, and reflect the process of organ donation from the perspective of the donor family. Important issues, such as the most appropriate and compassionate time to raise the question of organ donation with the family, were discussed and included. The report also stresses the importance of clear, honest and sensitive communication between trained medical staff and the family throughout the process, and the fact that the family should never feel left out of the decision-making process or feel that they are superfluous in the organ donation/transplantation proceedings.

The benefits of organ donation to the donor family cannot be overemphasised.

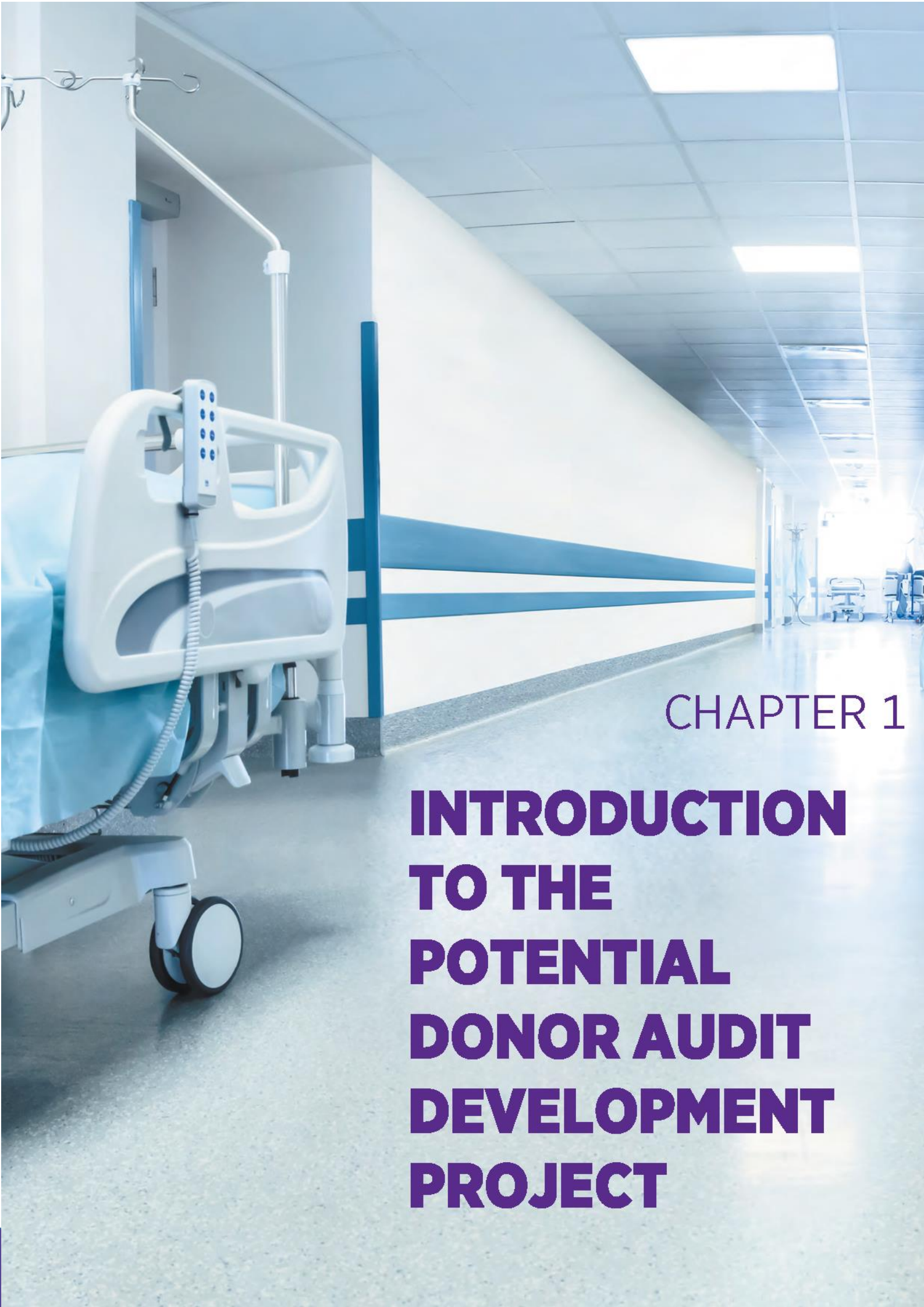
WHAT THIS PROJECT MEANS TO ME: INSIGHTS FROM PUBLIC AND PATIENT INTEREST REPRESENTATIVES

Louise Galvin
Public and Patient Interest Representative,
PDA Development Project Steering Committee

Through my personal and professional life, I have experienced the organ donation process in Ireland first-hand. As a chartered physiotherapist, I have worked directly with patients with cystic fibrosis who have at times been awaiting and received transplants. More pertinently, however, I have lived the devastating experiences of the donor family. I was asked to be a public and patient interest representative for the PDA Development Project and was glad to accept the role.

Throughout this process, I have felt a real desire from all stakeholders for the donor family perspective to be taken into consideration. I felt it provided an opportunity to effect change in a positive way, through sharing that lived experience. Organ donation is a profoundly difficult question for all involved, and it must be acknowledged that time is a precious commodity throughout this process. Practically speaking, information must be delivered unambiguously, empathetically and by experienced healthcare professionals who are available to answer questions from the donor family. It is crucial to the process that this information is delivered by the best-placed professionals at the recommended time.

The PDA pilot study has shown that at times, there were missed opportunities for potential organ donation to have occurred, and that these opportunities were missed for a variety of reasons. It is hugely important that the recommendations from this development project are adhered to and that we strive to meet best practice standards. This will lead to a reduction in the number of missed opportunities in the future. Having the potential organ donor pathway streamlined and standardised nationwide will lead to a more holistic experience for the donor families, and will ultimately maximise the procurement of organs. Finally, although nothing prepares you – or consoles you – for the sudden loss of a loved one, there is some solace in knowing that their passing has provided others with the gift of life.



CHAPTER 1

INTRODUCTION TO THE POTENTIAL DONOR AUDIT DEVELOPMENT PROJECT

CHAPTER 1 INTRODUCTION TO THE POTENTIAL DONOR AUDIT DEVELOPMENT PROJECT

Background

Organ Donation Transplant Ireland (ODTI) is the competent authority responsible for the oversight of donation and transplant services in Ireland. A key national objective is to increase the availability of organs for transplantation in Ireland. In seeking to achieve this objective, ODTI commissioned a feasibility study in 2021 to ascertain the need for a national clinical audit of organ donation practices (National Office of Clinical Audit, 2022). This study found clear guidance from countries that are leading in organ donation on what should be included in a potential donor audit. It found strong evidence that improvement can be achieved in all aspects of the organ donation process and that such improvement can be continuous, even 15 or 20 years into the future. This study also found considerable room for improvement in Ireland. The datasets of existing national audits fail to identify all missed opportunities for organ donation and fail to empower the relevant organ donation personnel (ODP) with the information necessary in order to drive improvement. The findings of this study included a recommendation for the National Office of Clinical Audit (NOCA) and ODTI to develop a Potential Donor Audit (PDA) in Ireland within 1 year of the feasibility study (March 2022), and to implement the PDA in one hospital in each of the six included Hospital Groups prior to expanding the implementation to all acute hospitals, including paediatric hospitals.

Commissioning the PDA Development Project

The PDA Development Project was commissioned by ODTI, with funding secured through the Health Service Executive (HSE) National Service Plan 2022. This key national development builds on the National Service Plan 2021 investment, which delivered the feasibility study.

Organ Donation Transplant Ireland

ODTI was established by the HSE in 2014. Since then, ODTI has acted as a joint competent authority, in conjunction with the Health Products Regulatory Authority, with responsibility for the oversight of donation and transplant services nationally. ODTI is responsible for the maintenance of a robust quality management system which monitors and tracks the end-to-end process of the identification, approach and procurement of organs for donation up to their safe transfer to transplant hospitals. In addition, ODTI maintains ongoing tracking of outcomes post-transplantation of organs and is responsible for organ donor family support, including acting as an indefinite confidential intermediary between donor families and recipients following organ transplant. Included in ODTI's remit is operational oversight for the National Organ Procurement Service.

The National Office of Clinical Audit

NOCA was established in 2012 to create sustainable national clinical audit across the Irish healthcare system. It is funded by the HSE Office of the Chief Clinical Officer, is governed by an independent voluntary board, and is operationally supported by the Royal College of Surgeons in Ireland (RCSI).

NOCA advocates for change at a national level, arising from key findings of national audits. This is done by working with senior decision-makers at both policy and operational levels within the Irish healthcare system. NOCA promotes transparent reporting and publishes annual reports for each of its audits, in addition to providing regular reports to hospitals.

Purpose of this report

The purpose of this report is to:

- Describe the methodological approach to the development of the PDA, which included a number of steps (Chapter 2, p. 18), one of which was the roll-out of a 3-month pilot study during the development project in six participating hospitals (Chapter 3, p.24).
- Present the findings from the PDA pilot project (Chapter 5, p.32). This includes the data from the pilot project and learnings across the full development project (Chapter 6, p.43).
- Make recommendations arising from the findings of the PDA development project (Chapter 7, p.51).

Who is this report aimed at?

This report is intended for a range of audiences, including commissioners; healthcare policy-makers and providers; patients; and the public at large.

CHAPTER 2

AUDIT DEVELOPMENT

CHAPTER 2 AUDIT DEVELOPMENT

Introduction

The purpose of this chapter is to describe the process used in developing the PDA. The PDA development project commenced in May 2022, following the publication of the Potential Donor Audit Feasibility Study Report (NOCA, 2022). Web links to the related publicly available information are provided throughout this chapter. Readers of the print format of this report can access this information by downloading a QR code reader on their smartphone and using it to scan the QR code at the end of this report.

Methodology for the development of a PDA

The PDA development project consisted of a series of methodological steps, which are detailed in Table 2.1.

TABLE 2.1: POTENTIAL DONOR AUDIT DEVELOPMENT PROJECT METHODOLOGY

Methodological steps	PDA development process
Governance of the project	This project was clinically led by Dr Alan Gaffney, Clinical Lead in Organ Donation at the RCSI Hospital Group and Consultant Anaesthesiologist and Intensivist at Beaumont Hospital. The PDA development project steering committeehttps://www.noca.ie/pda-governance (Appendix 1, p. 65), chaired by Dr Philip Crowley, HSE National Director for Strategy and Research, was established to oversee this project, with clear terms of reference. (NOCA, n.d.(a)).
Operational management of the project	The PDA development project working group comprising subject matter experts (from the HSE and ODTI, as well as hospital-based ODP) working with NOCA and with clear responsibilities was established in order to deliver the work plan. The PDA development project working group members are the authors of this report and had the relevant subject matter and audit development expertise to carry out the PDA development project.
Quality improvement–focused aim and objectives of the PDA are clearly defined	The aim and objectives of the audit were developed with a quality improvement (QI) focus. The aim of the PDA is to ensure that every person who is approaching the end of life in an Intensive Care Unit (ICU) or Emergency Department (ED) is offered the possibility of becoming an organ donor, where this is appropriate. The objectives are to: • Quantify the potential for organ donation in acute Irish hospitals. • Assess if the PDA identifies opportunities for improvement in organ donation and where in the patient journey these opportunities occur. • Identify the reasons for a non-donation outcome. • Systematically assess the degree to which best practice standards in organ donation are met.
Scope of the development study	The scope of the PDA development project included only the ICUs of participating hospitals.
Stakeholder involvement in audit development	A thorough stakeholder assessment was conducted at the beginning of the audit's development. There was continuous consultation and engagement with stakeholders throughout the development process, including: • setting the QI-focused aims and objectives of the audit • developing process flows • identifying data elements that were:

Methodological steps	PDA development process
	○ measurable ○ amenable to improvement. • developing the complete PDA dataset • public and patient interest representatives reviewing the draft dataset • considering ethical issues • holding a workshop, which included ODP and members of the PDA Development Project Steering Committee, in order to discuss the face and content validity, threats, problems, solutions and value of the PDA.
Development of the PDA dataset	• Licensing models used with other well-established national PDA, were explored particularly those that are used in the United Kingdom (UK). This focus on the UK was due to its similar patient population demographics, organ sharing arrangements between the UK and the rest of Europe, the possibility of a unified approach to potential donor audit across the full Island of Ireland, a supportive working relationship with National Health Service Blood and Transplant (NHSBT), and templates of successful licensing arrangements with other UK audits being available within NOCA. However, many questions were identified in the NHSBT dataset which would have required significant changes in order to suit the Irish context due to differences in processes, roles and legislation. Furthermore, there were technical challenges that could not be overcome in order to effectively deliver a national clinical audit within the set development timelines. Other options were also explored, but these had practical operational challenges (e.g. significant time differences between Ireland and other countries or dataset languages other than English). Thus, a new national clinical audit was developed to suit the Irish context. • Individual and complete PDA datasets were developed following a detailed review of data collection tools. These tools were from other jurisdictions identified in the *Potential Donor Audit Feasibility Study Report* (NOCA, 2022), where there was strong evidence of improvement following the implementation of a PDA in other countries in Spain, the UK, Australia, France and Italy). The development of the PDA dataset was informed by available guidelines (e.g. Dwyer et al., 2020, National Transplant Organisation, 2011)., a comparison of international datasets, as well as a line-by-line review of questions and response options, definitions (where available), and reporting metrics (e.g., De la Rosa et al., 2012, National Health Service Blood and Transplant, 2020). • Available publications and reports were examined in order to determine their approach to reporting, and consultations were held with local and international subject matter experts. International approaches agreed broadly on data elements pertaining to patient information, end-of-life care, referral, approach, and family assent. The terminology used in the questions and the level of detail used in response options varied slightly across audits. • International peer review was conducted in order to evaluate the face and content validity of the newly developed PDA. There was a review by subject matter experts and established potential donor audit personnel, including Professor Michael O'Leary, DonateLife in Australia, and NHSBT in the UK. This was greatly appreciated, and suggestions and amendments were made by the PDA Working Group. This consultation highlighted similarities in the approaches for the donation following brain death (DBD) pathway and raised the challenges of auditing the donation following circulatory death (DCD) pathway.

Methodological steps	PDA development process
	• The resulting dataset underwent further external review following the HSE Data Specification Management Process (DSMP) Group (HSE, 2022) and the National Release Centre for Systematized Nomenclature of Medicine – Clinical Terms (SNOMED-CT) international review guidelines. **Quality improvement focus** The PDA dataset was finalised, ensuring that it met the QI objectives of the audit (NOCA, n.d.(b)). The dataset contained questions which were relevant to the quality of care being measured. The flow of the dataset was designed to reflect the patient care pathway.
Development of the data collection protocol	Chapter 3, p.24 details the approach to data collection the PDA pilot study.
Information governance	The development of an information governance framework consisted of the following steps: • A data privacy impact assessment (DPIA) was completed and relevant risks were identified. • A design change was implemented in the data collection tool to support the DPIA recommendations, whereby no data could be entered until the patient's date of death was entered. • A data flow was developed to illustrate the flow of audit data. • Data protection officers at participating sites were consulted. • A Potential Donor Audit Information Leaflet was developed and available at all audit sites, as well as via NOCA communication channels (NOCA, n.d.(c)). • A data sharing agreement was put in place for all participating hospitals.
Information technology	• The information technology (IT) requirements were defined. • Security, accessibility and interoperability were assessed. • The PDA audit coordinator's IT requirements were identified. • An IT information leaflet was developed to support hospitals with the relevant technical information about the PDA and the hosting platform. • A frequently asked questions log was created to support hospitals with technical/learning issues regarding using the data collection tool.
Testing of the PDA dataset and electronic IT tool	A comprehensive approach to testing the data collection tool before 'going live' was adopted. This approach included: • accessing the electronic data collection tool from hospitals • testing the dataset from both the NOCA and user (ODP) side • testing the access to and accuracy of reports for both NOCA and users (ODP).
Communications	The purpose of the PDA communications plan was to increase awareness and understanding among healthcare professionals and the public. The communications plan included: • a virtual presentation on the PDA Development Study in participating hospitals • Development of a dedicated web page on the NOCA website (NOCA, n.d.(d) • a promotional video on the benefits of the PDA hosted on that web page (NOCA, n.d.(e)) • a social media presence on the NOCA Twitter account, @noca_irl • engagement with the media (i.e. *The Medical Independent* [Reilly, 9 August 2022]) • publications and conferences, including poster presentations at the National Patient Safety Office Conference (held at The Printworks, Dublin Castle on 11

Methodological steps	PDA development process
	October 2022) and at the Foundations and Future of Organ Donation Conference (held at the Midlands Park Hotel in Portlaoise on 24 May 2023) • three hospital site visits.
Pilot testing of the dataset and audit methodology	A 3-month pilot of the PDA was conducted in order to test the dataset in participating ICUs (see Chapter 3 for pilot project methodology, p.24).
Developing reporting from audit development	Reporting metrics were developed in conjunction with the relevant stakeholders. These included: • review of national and international guidelines on organ donation practices • identification of common metrics, standard accepted terminology, and questions included in international datasets and reports that have led to improvement • identification of opportunities for benchmarking • engagement with the Intensive Care Society of Ireland (ICSI). Hospitals identified that access to real-time information was a priority for the PDA. Preliminary basic metrics were defined and made available through the electronic data collection tool used for the PDA. Aggregate findings for all participating ICUs are presented in Chapter 5, p.32. of this report. A hospital-level report was sent to participating hospitals. Reports included included: • a data flow illustrating all patients captured in the PDA (Figure 5.1, p.34, which was adapted from the NHSBT's *Annual Report on the Potential Donor Audit* (2022) (this presentation is widely understood by the organ donation community and provides relevant, meaningful information that can drive improvement) • the reporting metrics on potential and eligible donors, which were developed by the PDA Development Project Working Group (Table 5.6, p.40. Some observations on metrics can be utilised from UK data for learning, and comparisons may be possible for some DBD metrics in the future. Direct comparisons with findings from the PDA pilot study should be avoided. There are some key differences between the NHSBT's potential donor audit and the newly developed NOCA PDA, as follows: • Data in this PDA report come from only participating ICUs in six participating hospitals – they are not national data. The NHSBT report is a national report covering all ICUs and EDs in the UK. • Furthermore, the DCD pathway is different in Ireland and in the UK, due to different processes in the two healthcare systems. • All deaths in ICU are included in this PDA report, whereas the NHSBT excluded the deaths of those aged over 80 years from its PDA report.
Learning	Learning from the PDA development project is described (Chapter 6, p.43).
Recommendations	The rationale and evidence base are provided for recommendations for national implementation, in addition to actions, action owners, and timelines (Chapter 7, p.51). An indicative costing of the implementation of a national PDA is provided (Appendix 2, p.66).

Methodology for developing data quality

The data quality processes which were applied during the PDA Development Study are described using the data quality assessment pro forma. This template describes the development processes through the prism of the dimensions of data quality (Health Information and Quality Authority, 2018). The rest of this section briefly summarises the approach to data quality using these dimensions.

Relevance

The PDA dataset and reporting metrics were co-developed with ODP in order to ensure that the data captured in this audit provided relevant information to support ODP in driving improvement in organ donation practices.

Accuracy and reliability

The Irish National Intensive Care Unit Audit (INICUA) is the gold standard in terms of data collection for ICU activity and outcomes in participating ICUs in Ireland, and supported the PDA. The INICUA audit coordinators worked closely with the PDA audit coordinators (who are organ donation nurse managers) in order to ensure full data coverage for participating sites. The ICU clinical information systems provided additional information on patient admissions and discharges. Data validation was conducted at the point of data entry within the electronic IT tool, and an external data validation report was developed by NOCA.

Timeliness and punctuality

PDA audit coordinators were advised to collect data as soon as possible following a patient's death. This ensured that data were current, and that preliminary 'real-time' basic report metrics were available through the PDA electronic data collection tool.

Coherence and comparability

A careful review of terminology by ODP ensured that terminology was consistent with accepted contemporary clinical practice in organ donation. A placeholder was reserved for when the individual health identifier becomes available. The data dictionary was positively evaluated by the HSE DSMP Group (HSE, 2022) in order to promote comparability with other national and international datasets The National Release Centre for SNOMED-CT was consulted and informed of the response options used for the 'Neurological Cause of Death' field. PDA audit coordinators worked locally with INICUA audit coordinators in order to ensure dataset comparability and validation of the appropriate data elements in both the INICUA and the PDA datasets.

Accessibility and clarity

Reporting metrics were co-developed with ODP following a review of international evidence and local and international guidelines. The PDA is the first audit within the NOCA portfolio to have a complete data dictionary available publicly.

CHAPTER 3

METHODOLOGY FOR THE PDA PILOT STUDY

CHAPTER 3 METHODOLOGY FOR THE PDA PILOT STUDY

Pilot aims

A pilot was carried out as a proof of concept in order to assess:

- The feasibility of collecting the required data elements for the PDA in participating ICUs
- The degree to which the PDA meets its aim and objectives
- Any areas for improvement in the proposed audit design.

Setting

The PDA pilot study took place from 14 November 2022 to 10 February 2023 (12 weeks) in the ICUs of six participating hospitals. Units that had the ability to admit and care for ventilated patients were included. Sites were selected based on whether they had the required resources in place (i.e. an organ donation nurse manager (ODNM). In 2022, the six hospitals participating in the PDA pilot study accounted for 50% (43/86) of all organ donors in Ireland (J Walsh 2023, personal communication, 17th February 2023).

Characteristics of participating hospitals

Table 3.1 describes the characteristics of hospitals who participated in the PDA pilot study.

TABLE 3.1: CHARACTERISTICS OF PARTICIPATING HOSPITALS DURING THE POTENTIAL DONOR AUDIT PILOT PROJECT

Unit	Description
Beaumont Hospital General ICU	A General ICU (GICU) for medical and surgical patients, with a significant number of neurosurgical patients as overflow from the hospital's neurosurgical ICU.
Beaumont Hospital Richmond ICU (Neuro)	A specialist ICU for neurosurgical patients, with a number of general medical/surgical patients as overflow from the Beaumont Hospital General.
St James's Hospital GICU	A GICU for medical and surgical patients.
National Burns Unit	A burns unit in St James's Hospital with allocated burns ICU beds.
St James's Hospital High Dependency Unit (HDU)	Patients from the St James's Hospital GICU may overflow to the HDU.
University Hospital Galway ICU	A general critical care service for medical and surgical patients.
University Hospital Galway Cardiothoracic Intensive Care Unit (CT ICU)	A CT ICU primarily caring for critically ill cardiothoracic patients.
University Hospital Limerick ICU	A GICU for medical and surgical patients.

Unit	Description
Cork University Hospital CT ICU	A specialist CT ICU for patients following cardiothoracic surgery, with some GICU patients.
Cork University Hospital ICU	This GICU is a tertiary referral centre catering for critically ill medical and surgical patients via a range of specialties, including neurosurgery.
Mater Misericordiae University Hospital ICU	A GICU for medical and surgical patients. Significant influences on case mix include cardiothoracic surgery, heart and lung transplantation, and extracorporeal life support.

Note: The St James's Hospital Keith Shaw Unit (Cardiothoracic ICU) was not included in the PDA pilot study.

PDA data collection tool

The development of the PDA data collection tool and methods for ensuring data quality were described in Chapter 2, p.18. The resulting complete PDA dataset consisted of six individual datasets, as follows:

- Patient information
- End-of-life care
- Referral
- Approach
- Assent
- Organ donation outcomes.

Each dataset asked a series of questions to gather information describing the patient, processes of care, and reasons for decision-making relating to organ donation.

Modifications to the dataset

Immediately after commencing the PDA pilot study, it was identified that the date and time of death were not recorded for all patients due to the conditional branching in PDA dataset. This variable is necessary in order to quantify the potential for organ donation in any given time frame. This was initially excluded for patients who died without the potential for organ donation (e.g. patients who were not ventilated) in order to minimise the burden of data collection.

This issue was rectified quickly and the modification was inserted into the audit dataset. Data were entered retrospectively for the small number of audit entries concerned. Further changes to the dataset were not made during the development stage in order to fully test the original PDA and avoid confusion in the approach to data collection. However, all suggested changes were noted and are included in the learnings for national implementation (Chapter 6, p.43).

Personnel involved in the PDA

PDA coordinators (ODNMs)

The PDA was coordinated in the six participating hospitals by an ODNM. ODNMs are clinical experts in the specialist area of organ donation, and they act as advocates for patients, donors and their families. In addition to being involved in obtaining family assent (along with the multidisciplinary team), the ODNM continues to work with families throughout the process and help staff appropriately support and enhance end-of-life care for each patient and their family. They are an integral part of the ICU team and are a resource, in conjunction with the clinical lead in organ donation (CLOD), in identifying and managing the patient in order to ensure the best outcome for organ donation. The ODNMs' role also includes the promotion of organ donation education and training among clinical personnel and the wider hospital community.

ODNMs were critical for the success of the PDA pilot project. Their role included informing and educating ICU healthcare professionals and patients' families about the PDA, data collection and validation, as well as sharing and disseminating the final hospital PDA report.

Clinical leads in organ donation

The CLODs provide clinical leadership across each Hospital Group in order to champion and promote the value of deceased organ donation. They focus on minimising missed opportunities for organ donation through establishing good working relationships and promoting the implementation of national guidelines. The CLODs provided clinical leadership for the PDA in participating sites.

Training

A detailed training plan for PDA audit coordinators was developed and delivered for ODNMs and CLODs. This included pre-recorded sessions on the aim and objectives of the audit; the role of NOCA; the role of ODTI; mandatory training on HSeLanD (the HSE's national online learning and development portal) on data quality, information governance and cybersecurity; and a detailed user manual and data dictionary in which there were clear instructions on the completion of the data collection questionnaire/interview in order to ensure consistency. A virtual training session included an introduction to the user manual, demonstration of the IT tool, and an opportunity to practise entering data and answer any questions in real time. Follow-up training, including facilitated group discussions, was provided in order to ensure consistency in the approach to data collection across sites.

Data sources

As part of their normal role, the expertise of the ODNM is sought by the ICU team as part of normal end-of-life care. ODNMs review clinical information systems and patient healthcare records as part of their normal clinical processes. They are involved in family meetings and in the workup of the patient for potential donation; are informed of

potential organs for donation; and seek post-donation feedback via email or telephone on outcomes from the National Organ Procurement Service (NOPS), including reasons for organs not being accepted or being deemed unsuitable by transplant teams. While audit information is available concurrent to clinical practice, for the purpose of the PDA pilot project, it was not entered into the electronic data collection tool for the PDA until the patient had died. Following the death of the patient, ODNMs reviewed the clinical information system/patient healthcare record for any further information, documenting the process in order to complete data collection for the PDA.

Where the patient had not been referred to ODP, a retrospective approach was taken to data collection. PDA audit coordinators reviewed a list of deceased patients on the clinical information system/ICU admission book or liaised with INICUA audit coordinators, as INICUA is considered the gold standard reference point for ICU activity and outcomes in Ireland. PDA audit coordinators reviewed the clinical information system/patient healthcare record and identified the healthcare staff involved in each patient's care, including medical and nursing staff. They also reviewed conversations that took place around organ donation decision-making/interactions with family members and reverted to INICUA audit coordinators to fill in any outstanding information gaps.

Analytical methods

A patient flow diagram and cascade analysis were developed illustrating where in the patient pathway opportunities for organ donation may have been missed. These were used to inform a reporting specification for 'missed opportunities'. The data for cases demonstrating missed opportunities were reviewed across a number of variables, including religion, ethnicity, nationality, processes of care, and reasons for a non-donation outcome at every point in the patient pathway (i.e. reasons for not undertaking brainstem testing; reasons why referral, approach or assent did not occur; or reasons why organ donation did not proceed after assent was given). Reasons for a non-donation outcome were explored for the patients identified and were classified as 'medical reasons' or 'process reasons'. Any process reasons identified were further reviewed in order to understand the nature of the non-donation outcome.

Reporting metrics were calculated to reflect whether a patient was a potential donor for the DBD pathway or a potential donor for the DCD pathway:

- Metrics for potential donors for the DBD pathway were calculated for patients who met the criteria for brainstem testing.
- Metrics for potential donors for the DCD pathway were calculated for patients who had life-sustaining therapy withdrawn following a neurological cause of death, or, in the case of non-neurological death, for patients who were assessed as having the potential to become a donor after circulatory death.

Calculations were made to determine the total number of all potential donors. A small number of patients met the definitions of both a potential donor after brain death and a

potential donor after circulatory death. These patients were only counted once for the purpose of calculating the total potential donor pool. Metrics for brainstem testing and referral were based on the definition of the 'potential donor'.

Reporting metrics for approach, assent and proceed rates were based on the definition of the 'eligible' (i.e. medically suitable) donor. This was done through the use of an aggregate 'dummy' variable representing patients who were identified as having either an absolute medical contraindication or a transplant centre-determined contraindication at any point in the organ donation process. This approach was based on international reporting metrics and allowed for benchmarking. Frequency tables described the reasons for a non-donation outcome. Simple descriptive statistics and frequencies were used to describe the demographics of potential donors.

CHAPTER 4
DATA QUALITY FOR POTENTIAL DONOR AUDIT REPORT

Coverage of Data Release

Completeness of Data Release

Accuracy of Data Release

CHAPTER 4 DATA QUALITY FOR THE PILOT PDA STUDY

The PDA pilot study relied on capturing data on all eligible organ donation patients. Data were considered to be of good quality when accurate and reliable data became available in a timely manner. Table 4.1 describes the context of the data quality statement. Tables 4.2 and 4.3 present and assess the quality of the data released in this report.

TABLE 4.1: CONTEXT OF THE DATA QUALITY STATEMENT

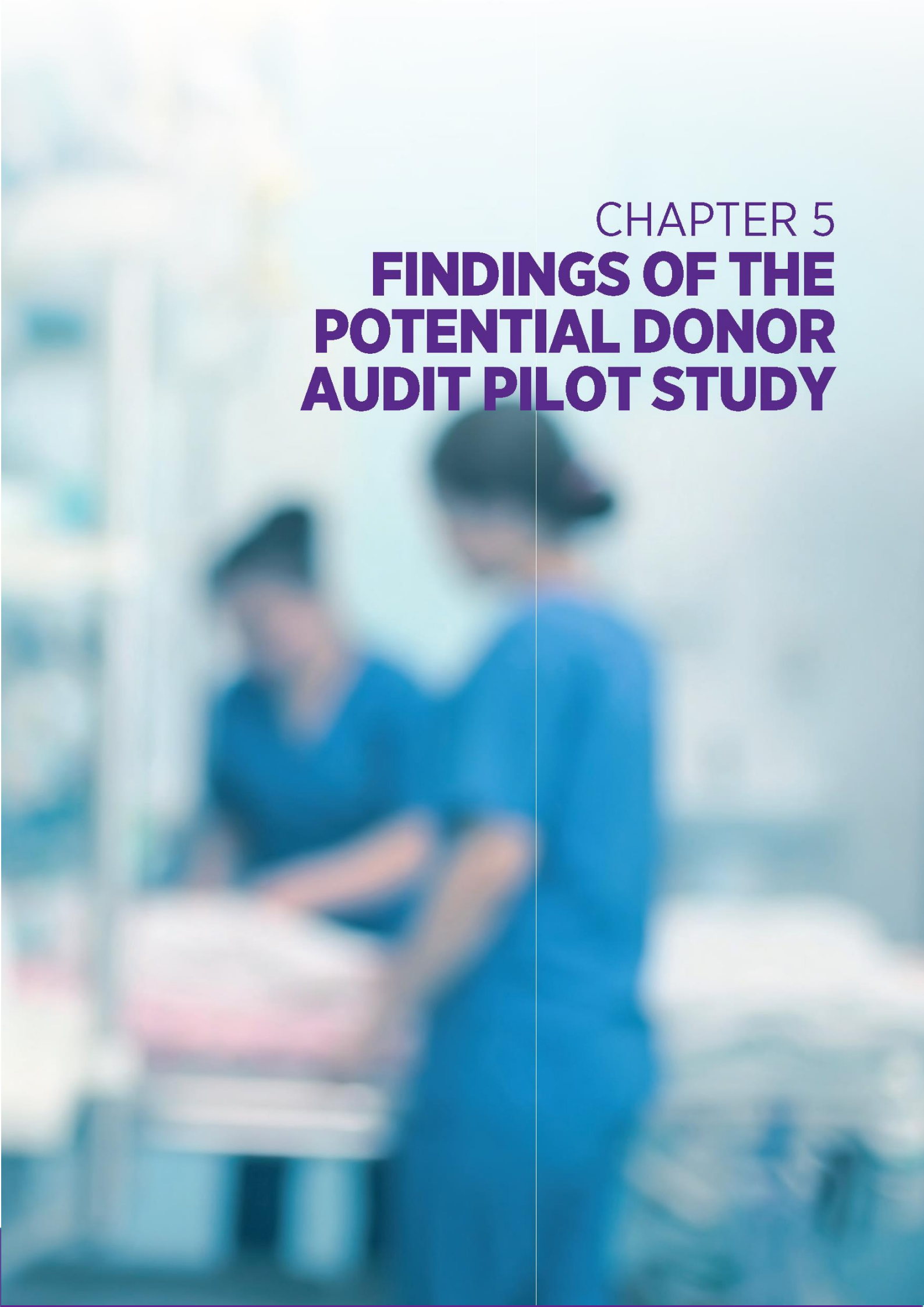
Scope	This data quality statement provides an assessment of the data released for this report.
Purpose	This data quality statement is designed to help the reader decide whether the data are fit for their specific purpose.
Data source	The source of data for individual figures and tables is the PDA pilot study.
Time frame of data	14 November 2022 to 10 February 2023
Type of data	Final data

TABLE 4.2: DATA QUALITY STATEMENT FOR THE DATA RELEASE

Coverage	100% for six participating hospitals
Completeness	100%
Data accuracy	All discrepancies were resolved in the data validation report.

TABLE 4.3: ASSESSMENT OF DATA IN THE POTENTIAL DONOR AUDIT DEVELOPMENT PROJECT REPORT

Strengths of the data in this report	• An empirical approach was taken in the development of the dataset. • The data collected are grounded in the needs of data users. • The approach to developing data quality was described in the 'Methodology for developing data quality' section of Chapter 2, p.23.
Limitations of the data in this report	• There was potential for the introduction of bias as ODNMs audited their own practice for some questions in the dataset, such as "When was the family formally approached" and "Who was present for the formal approach". This limitation was mitigated by the data dictionary providing precise information on definitions and response items. The inclusion of self-audit styles of questions is minimal, and data were documented in the patient healthcare record. Furthermore, some of the structural aspects of the organ donation process (e.g. "Who was present for the formal approach") were outside of the control of the ODNMs; thus, there was no incentive for overrating this element. • The subjective nature of some of the data (e.g. reasons for not following organ donation processes) may also have introduced some potential for bias and inconsistency. Data obtained through discussions were collected in as close to real time as possible in order to minimise recall bias. This limitation was also mitigated by the data dictionary providing guidance and examples in relation to response options. Ongoing PDA project lead support and follow-up group training sessions facilitated discussions to standardise these response options, and data validation rules were developed in order to assess consistency across response options and between hospitals.



CHAPTER 5

FINDINGS OF THE POTENTIAL DONOR AUDIT PILOT STUDY

CHAPTER 5 FINDINGS OF THE PDA PILOT STUDY

This chapter presents the results of the 3-month PDA pilot project and discusses the implications of the findings.

Key findings

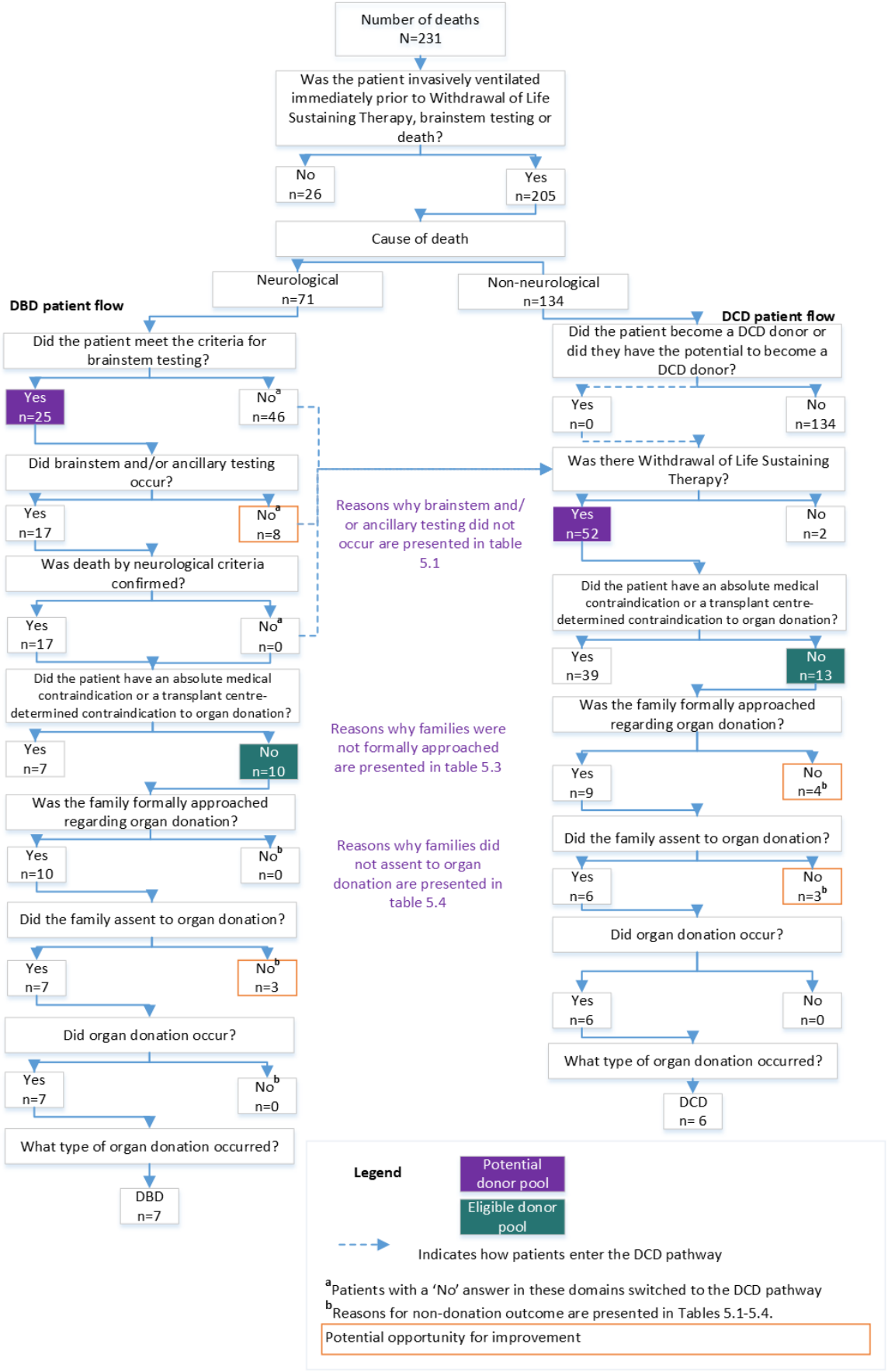
Figure 5.1, p.34 presents a data flow of patients captured in the PDA pilot study. Reasons for a non-donation outcome are presented in Tables 5.1 to 5.4. Reporting metrics are summarised in Table 5.5. Table 5.6 presents the profile of potential donors identified during the PDA pilot study. Together, these findings meet the objectives of the PDA.

After accounting for absolute medical contraindications or transplant centre-determined contraindications, 10 cases were initially considered as potential missed opportunities for organ donation when the data were analysed. Of these, three cases would not have proceeded to organ donation (one patient sustained cardiac arrest before brainstem testing, and two potential DCD patients were deemed unlikely to die within 90 minutes of withdrawal of life-sustaining therapy (WLST) and subsequently did not die within 90 minutes).

Of the remaining seven cases (10.1% of all potential donors), four fulfilled the criteria for brainstem testing but did not undergo testing. In one case, there was reluctance to approach the family, and in the three other cases, organ donation was discussed either prior to a discussion about brainstem testing or during the prognosis conversation. In these final three cases, where the criteria for brainstem testing were fulfilled and brainstem testing was carried out, organ donation was discussed during the prognosis conversation in one case; in the other two cases, families were approached by senior intensivists and/or ODNMs at the correct time (following international best practice organ donation processes) but did not assent to organ donation.

In summary, there were five cases where best practice organ donation processes were not followed. While it could be speculated that some of these cases might have resulted in donation episodes had best practice been followed, this is not guaranteed – overall, the family consent rate was as good as that in the UK.

FIGURE 5.1: DATA FLOW RELATING TO PATIENTS CAPTURED IN THE POTENTIAL DONOR AUDIT



Reasons for a non-donation outcome

Tables 5.1 to 5.4 describe the reasons for a non-donation outcome at different points in the patient pathway. In interpreting these findings, it is important to note that one patient can have more than one reason for not being referred for organ donation. Thus, the sum of reasons can be greater than the number of patients not referred.
Tables 5.1 and 5.2 relate to potential donors. Tables 5.3 and 5.4 relate to eligible donors (i.e. they exclude patients with a verified absolute medical contraindication or transplant centre-determined contraindication). This approach facilitates international comparison and benchmarking.

Brainstem testing

In order to maximise the potential for organ donation, all patients who met the criteria for brainstem testing should have been brainstem tested and referred to ODP to evaluate their eligibility for organ donation. Seventeen of 25 patients (68%) underwent brainstem and/or ancillary testing.
Importantly, Table 5.1 demonstrates that a number of these patients would never have proceeded to organ donation anyway due to medical reasons. The nine reasons identified relate to eight people in total, as more than one response option could be selected for each patient.

TABLE 5.1: REASONS WHY BRAINSTEM TESTING AND/OR ANCILLARY TESTING WERE NOT COMPLETED

Reasons why brainstem testing and/or ancillary testing were not completed (multiple reasons can be selected)	n	Percentage of reasons
Absolute medical contraindication(s)	4	44%
Family had already expressed a wish not to donate	1	11%
Not identified as potentially brain dead	1	11%
Patient did not wish to become an organ donor	1	11%
Reluctance to approach family	1	11%
Cardiorespiratory instability	1	11%
Total (reasons)	9	100%

This finding suggests that the full potential for DBD may not have been fully realised in a very small number of cases; DBD results in a greater number of organs per donor than DCD does. In the eight cases where there was an opportunity to carry out brainstem testing, four had an absolute medical contraindication to organ donation. The PDA reports a rate of brainstem testing of 68%. This is lower than what was reported in the UK for the 1st April 20221 – 31st March 2022 (79.7%) (NHSBT, 2022). It is, however, not directly comparable, as the Irish PDA represents only a small proportion of Irish hospitals and includes patients aged over 80 years (n=2). The National Health Service Blood and Transplant (NHSBT) Potential Donor Audit represents national data and excludes patients aged over 80 years.

Referral

Forty-six out of 69 (67%) potential donors were referred (DBD: 22/25, 88%; DCD: 29/52, 56%). Analysis of the reasons why potential donors were not referred to ODP suggests that the most frequently occurring reason for non-referral was 'absolute medical contraindications' (Table 5.2). These were independently verified by ODNMs at the point of data entry, with a conservative list of internationally recognised absolute medical contraindications used for the purposes of the PDA. An examination of referral rates for eligible donors demonstrated a DBD referral rate of 100% (10/10) and a DCD referral rate of 77% (10/13), with an overall referral rate of 87% (20/23) of all eligible donors.

This approach of local ICU teams making decisions without the input of ODP or the transplant centres risks the possibility of potential donors being missed in the future, as what counts as an 'absolute medical contraindication' may change over time.

TABLE 5.2: REASONS FOR NOT REFERRING TO ORGAN DONATION PERSONNEL

Reasons for not referring to ODP (multiple reasons can be selected)	Potential DBD donors[1]		Potential DCD donors[2]		All potential donors[3]	
	n	Percentage of reasons	n	Percentage of reasons	n	Percentage of reasons
Absolute medical contraindication(s)	1	33%	20	83%	20	83%
Patient was not expected to die within the time frame compatible with organ donation	0	0%	2	8%	2	8%
Family had already expressed a wish not to donate	1	33%	1	4%	1	4%
Reluctance to approach family	1	33%	1	4%	1	4%
Total (reasons)	3	100%	24	100%	24	100%

Please note: Percentages may not sum to 100% due to rounding.
[1]Patients who met the criteria for brainstem testing.
[2]Patients who had life-sustaining therapy withdrawn following a neurological cause of death or, in the case of non-neurological death, who were assessed as having the potential to become a DCD donor.
[3]All potential donors: The total number of all potential donors is less than the number of potential DBD donors and potential DCD donors combined. This is because eight patients who met the criteria for brainstem testing crossed over from the DBD pathway to the DCD pathway, as they did not undergo brainstem testing, and three of these were not referred to ODP. These patients are only counted once for the purpose of calculating the total potential donor pool.

An overall referral rate of 92.5% was found in the UK from 1st April 20221 – 31st March 2022 (NHSBT, 2022). The DCD referral rate in the UK was 90.4% (NHSBT, 2022). The DCD referral rate in Ireland (56%; 29/52) is not comparable as the UK potential donor audit includes national data for both the ICU and ED and excludes patients aged over 80 years. Furthermore, in the NHSBT report, the DCD pathway captures all patients in whom imminent death was anticipated (i.e. a patient receiving assisted ventilation, a clinical decision to withdraw treatment has been made and death is anticipated within a time frame to allow donation to occur). The NOCA PDA DCD pathway includes all

patients who died following WLST. The NHSBT (n.d.(a)) provides clear guidance on who should be referred to a specialist nurse in organ donation (SNOD). This includes patients for whom neurological death is suspected or for whom imminent death is anticipated, i.e. those receiving assisted ventilation for whom a clinical decision to withdraw life-sustaining therapy has been made and death is anticipated. DonateLife in Australia advises referral of all patients for whom there is planned end-of-life care (Organ and Tissue Authority, 2021). The DCD referral process in Ireland may benefit from specific guidance on precisely who should be referred to ODP, particularly for the DCD pathway, and/or to define a standardised process that determines donor eligibility within the ICU. Internationally, this is managed by key donation personnel at hospital level.

Family approach

Nineteen out of 23 families of eligible donors (83%) were approached (DBD: 10/10, 100%; DCD: 9/13, 69%). The reasons for non-approach are outlined in Table 5.3; the majority of reasons were clinical in nature (e.g. cardiac arrest, or anticipated time to death not being compatible with organ donation).

TABLE 5.3: REASONS FOR NOT APPROACHING THE FAMILY ABOUT ORGAN DONATION

Reasons for not formally approaching the family about organ donation	Eligible DBD donors[1]		Eligible DCD donors[2]		All eligible donors[3]	
	n	Percentage of reasons	n	Percentage of reasons	n	Percentage of reasons
Patient was not expected to die within the time frame compatible with organ donation	0	0%	2	50%	2	50%
Cardiac arrest occurred before approach was made	0	0%	1	25%	1	25%
Reluctance to approach family	0	0%	1	25%	1	25%
Total (reasons)	0	0%	4	100%	4	100%

[1]Medically suitable patients who had been declared dead based on neurological criteria.
[2]Medically suitable patients who had life-sustaining therapy withdrawn following a neurological cause of death or, in the case of non-neurological death, who were assessed as having the potential to become a DCD donor.
[3]All eligible donors: The total number of all eligible donors represents the number of DBD and DCD donors combined. Eligibility is determined based on the absence of absolute medical contraindications or transplant centre-determined contraindications to organ donation.

Post-hoc analysis of patients who were not expected to die within the time frame required for organ donation (i.e. within 90 minutes of WLST) demonstrated that these patients did ultimately die outside of this time frame. The British Transplant Society suggests a stand down time for kidneys at 120mins which can be extended by a further 120mins in selected donors depending on logistics. If the time frame required for organ donation had been extended to up to 4 hours, one more patient would have become eligible to become an organ donor.

Family assent

Thirteen out of 19 families of eligible donors (68%) assented to organ donation (DBD: 7/10, 70%; DCD: 6/9, 69%). Process reasons accounted for the majority of the reasons why families did not assent to organ donation (Table 5.4).

TABLE 5.4: REASONS WHY FAMILIES DID NOT ASSENT

Reasons why the family did not assent	Eligible DBD donors[1]		Eligible DCD donors[2]		All eligible donors[3]	
	n	Percentage of reasons	n	Percentage of reasons	n	Percentage of reasons
Patient did not wish to become an organ donor	0	0%	2	67%	2	33%
Family was dissatisfied with patient care	1	33%	0	0%	1	17%
Family was uncomfortable with the organ donation process (including who receives the organs)	0	0%	1	33%	1	17%
Strong refusal – probing not appropriate	1	33%	0	0%	1	17%
Other - the family felt the process would be too traumatic for the patient's children	1	33%	0	0%	1	17%
Total (reasons)	3	100%	3	100%	6	100%

[1]Medically suitable patients who had been declared dead based on neurological criteria.
[2]Medically suitable patients who had life-sustaining therapy withdrawn following a neurological cause of death or, in the case of non-neurological death, who were assessed as having the potential to become a DCD donor.
[3]All eligible donors: The total number of all eligible donors represents the number of DBD and DCD donors combined. Eligibility is determined based on the absence of absolute medical contraindications or transplant centre-determined contraindications to organ donation.

The National Institute of Clinical Excellence (2011) and the Intensive Care Society of Ireland (ICSI) DCD guidelines (2016) provide some guidance on family approach, including on the timing of discussions and communication with families. The NHSBT (2022) Potential Donor Audit data demonstrated that the rate of families who assent to organ donation doubles (DBD: from 35% to 71% of audit cases; DCD: from 19% to 67% of audit cases) when there is a SNOD involved in the family approach. The rate of families approached with Hospital Group ODP present reported in the PDA pilot study was 37%.

In Ireland, Hospital Group ODP are organised at Hospital Group level and are not a 24/7 service. Approaches to families may be undertaken outside the routine working hours of the Hospital Group ODP. The UK system is different in that there is a dedicated, embedded SNOD in most hospitals. Data from NHSBT repeatedly reveal higher family assent rates for both DBD and DCD when SNODs are involved at an early stage (NHSBT, n.d.(b)). It is not appropriate to directly compare these findings due to different processes and resource allocations. Until there is an ODNM resource available in every participating Irish hospital, it will not be possible to significantly improve this metric. There is considerable room for improvement in the rate of families approached at the recommended time (which was 53% in the PDA pilot study). This is a learning point for all participating hospitals in providing the best standard of care for families in a position to consider organ donation, and may influence the rate of family assent.

Number (rate) of assented eligible donors who became actual donors

All assented eligible donors became actual donors (13/13; 100%). In some cases, eligibility was determined by the transplant centres at the end of the patient journey. These patients (n=7: DBD=5, DCD=2) are captured within the patient flow diagram (Figure 5.1, p.34).

Table 5.5 summarises the reporting metrics of the PDA. The total number of all potential donors is less than the number of potential DBD donors and potential DCD donors combined; this is because eight patients who met the criteria for brainstem testing crossed over from the DBD pathway to the DCD pathway, as they did not undergo brainstem testing and had life-sustaining therapy withdrawn. These patients were only counted once for the purpose of calculating the referral rate for the total potential donor pool.

TABLE 5.5: REPORTING METRICS

Reporting metrics on potential donors	Potential DBD donors			Potential DCD donors			All potential donors		
	n	N	%	n	N	%	n	N	%
Number of potential donors	25	231	11%	52	231	23%	69	231	30%
Number (rate) of patients who had brainstem and/or ancillary testing[1]	17	25	68%	N/A (only relates to DBD)					
Number of patients who presented in both the DBD and DCD pathways	8	25	32%	N/A (only relates to DBD)					
Number of patients who were referred to ODP[2]	22	25	88%	29	52	56%	46	69	67%
Reporting metrics on eligible donors[3]	**Eligible DBD donors**			**Eligible DCD donors**			**All eligible donors**		
	n	N	%	n	N	%	n	N	%
Number of eligible donors	10	25	40%	13	52	25%	23	69	33%
Number (rate) of patients who were referred to ODP (eligible donors)	10	10	100%	10	13	77%	20	23	87%
Number (rate) of families approached[4]	10	10	100%	9	13	69%	19	23	83%
Number (rate) of families approached with Hospital Group ODP present	2	10	20%	5	9	56%	7	19	37%
Number (rate) of families approached at the recommended time	6	10	60%	4	9	44%	10	19	53%
Number (rate) of families who assented to organ donation[5]	7	10	70%	6	9	67%	13	19	68%
Number (rate) of assented eligible donors who became actual donors	7	7	100%	6	6	100%	13	13	100%

[1]See Table 5.1 for reasons why brainstem and/or ancillary testing were not completed
[2]See Table 5.2 for reasons for not referring to ODP
[3]A potential DBD donor becomes an eligible DBD donor after neurological death is confirmed and there are no absolute medical contraindications or transplant centre-determined contraindications. A potential DCD donor becomes an eligible DCD donor following exclusion of absolute medical contraindications or transplant centre-determined contraindications.
[4]See Table 5.3 for reasons why families were not approached. Hospital Group ODP are not a 24/7 service, and these approaches may take place outside their routine working hours.
[5]See Table 5.4 for reasons why families did not assent

Profile of potential donors

Table 5.6 presents the profile of potential donors identified during the PDA pilot study. The profile of potential donors can be monitored over time. These metrics are presented by different demographic profiles in order to understand where specific challenges may occur.

TABLE 5.6: PROFILE OF POTENTIAL DONORS

Demographic variable	Potential DBD donors[1]		Potential DCD donors[2]		All potential donors[3]	
Age in years: median/mean (standard deviation)	45.0/47.0 (19.5)		65.5/61.0 (16.6)		59.0/56.6 (18.5)	
Age group	**n**	**%**	**n**	**%**	**n**	**%**
<16 years	0	0%	0	0%	0	0%
16–18 years	~	*	0	0%	~	*
19–62 years	19	76%	24	46%	38	55%
63–79 years	~	*	21	40%	*	*
≥80 years	~	*	~	*	7	10%
Total	25	100%	52	100%	69	100%
Sex at birth						
Female	13	52%	16	31%	27	39%
Male	12	48%	36	69%	42	61%
Total	25	100%	52	100%	69	100%
Cause of death						
Neurological	25	100%	52	100%	69	100%
Non-neurological	0	0%	0	0%	0	0%
Total	25	100%	52	100%	69	100%
Neurological cause of death						
Anoxic brain injury	8	32%	25	48%	31	45%
Haemorrhagic stroke (including subarachnoid haemorrhage)	6	24%	13	25%	17	25%
Infectious disease	~	*	~	*	~	*
Ischaemic stroke	~	*	~	*	6	9%
Other	~	*	~	*	~	*
Space-occupying lesion of brain	~	*	~	*	~	*
Traumatic brain injury	~	*	~	*	10	14%
Unknown	~	*	~	*	~	*
Total	25	100%	52	100%	69	100%
Religion						
Church of Ireland	0	0%	0	0%	0	0%
Islam	0	0%	~	*	~	*
Orthodox	~	*	0	0%	~	*
Roman Catholic	18	72%	43	83%	55	80%
No religion	0	0%	~	*	~	*
Other	~	*	~	*	~	*
Unknown	~	*	~	*	7	10%
Total	25	100%	52	100%	69	100%
Ethnicity						

Demographic variable	Potential DBD donors[1]		Potential DCD donors[2]		All potential donors[3]	
Asian or Asian Irish (any other Asian background)	~	*	~	*	~	*
Asian or Asian Irish (Indian/Pakistani/Bangladeshi)	0	0%	0	0%	0	0%
White (any other White background)	~	*	~	*	9	13%
White (Irish)	16	64%	46	88%	57	83%
Total	25	100%	52	100%	69	100%
Country of birth						
Australia	0	0%	~	*	~	*
Bulgaria	0	0%	~	*	~	*
Ireland	16	64%	46	88%	57	83%
Latvia	~	*	~	*	~	*
Mongolia	~	*	0	0%	~	*
Netherlands	0	0%	~	*	~	*
Philippines	~	*	0	0%	~	*
Poland	~	*	~	*	~	*
Ukraine	~	*	0	0%	~	*
Total	25	100%	52	100%	69	100%

~Denotes five cases or fewer.

*Further suppression required in order to prevent identification of five cases or fewer.

[1]Patients who met the criteria for brainstem testing.

[2]Patients who had life-sustaining therapy withdrawn following a neurological cause of death or, in the case of non-neurological death, who were assessed as having the potential to become a DCD donor.

[3]All potential donors: The total number of all potential donors is less than the number of potential DBD donors and potential DCD donors combined. Eight patients who met the criteria for brainstem testing crossed over from the DBD pathway to the DCD pathway, as they did not undergo brainstem testing. These patients were only counted once for the purpose of calculating the demographics for the total potential donor pool.

Reflections from ODNMs who participated in the PDA pilot project

We are a team of six ODNMs based in each participating Hospital Group (pictured in Figure 5.2). We are advanced clinical experts in the specialist area of organ donation. We work with the clinical leads in organ donation (CLODs) to create relationships with hospital staff throughout our Hospital Groups, raising the profile of organ donation and ensuring that organ donation is a routine consideration in end-of-life decisions, both in the Emergency Department (ED) and ICU. We act as advocates for both the donors and their families throughout their end-of-life journey. We were involved in the pilot of the PDA in each of our base hospitals within the six Hospital Groups from 14 November 2022 to 10 February 2023.

Introducing the PDA in the ICU and informing staff of its purpose gave us an opportunity to re-engage with staff on the topic of organ donation. It refocused the multidisciplinary teams within each Unit to consider organ donation as a routine option at the end of life for their patients and families. Outlining the questions involved in order to complete the PDA increased reflection on current practices and reiterated best practice.

One of the key issues highlighted when completing the PDA was that the nuances of the conversations or decision-making around organ donation are not always documented. There was a need to have conversations with staff involved from various teams over a number of days in order to accurately complete the data collection. Like all audit data, the information gathered enabled consideration of potential areas for improvement in current practices. The access to real-time data provided a meaningful opportunity for reflection with the staff involved. The presentation of the PDA findings closer to the time of the donation episode ensured that staff could remember the cases that the findings related to, and that the learnings had more impact.

Data gathered during the PDA pilot study have shown that the majority of patients who die in ICU do not meet the criteria for organ donation. Therefore, it is vital that all potential opportunities are recognised and explored. The use of the PDA as part of routine clinical practice for donation staff will quickly identify key areas of improvement and will focus educational needs within each hospital.

FIGURE 5.2: HOSPITAL GROUP ORGAN DONATION NURSE MANAGERS

From left to right: Bernie Nohilly, UL Hospital Group; Breda Doyle, South/South West Hospital Group; Karen Healy, RCSI Hospital Group; Nikki Phillips, Dublin Midlands Hospital Group; Gillian Shanahan, Saolta University Health Care Group; and Orla Cradock, Ireland East Hospital Group.

CHAPTER 6

LEARNINGS FOR THE FUTURE

CHAPTER 6 LEARNINGS FOR THE FUTURE

Introduction

The purpose of this chapter is to outline the learnings from the development and pilot of the PDA for the future.

Learnings

Table 6.1 outlines what went well during the development project, as well as learning that can be carried forward for the national implementation of the PDA. As a result of learning from the development phase, improvements can be made to the data collection tool and the corresponding reporting filters used for real-time reporting. The positive momentum for national clinical audit established during the development project needs to be maintained, and a robust approach to assessing data coverage for the long term must be sustained.

TABLE 6.1: REFLECTION AND LEARNINGS FROM THE POTENTIAL DONOR AUDIT DEVELOPMENT PROJECT

Methodological steps	What went well	Learning for national implementation
Governance and operational management of the project	There was strong commitment and support from the PDA Development Project Steering Committee and PDA Development Project Working Group.	Continue with broad stakeholder representation and focused working groups as required.
Quality improvement-focused aim and objectives of the PDA are clearly defined	There was a quality improvement (QI) focus to the aim and objectives. They were Specific Measurable Achievable Relevant and Timely (SMART) and future-proof.	The focus on improving patient care and outcomes is an integral component of clinical audit, as outlined in the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023.
Scope of the development study	The project scope was agreed and adhered to. The scope of the PDA Development Project included ICUs only in the PDA pilot study.	The PDA should extend to all hospitals with ICUs and EDs in order to capture the true potential for organ donation in Irish hospitals. In order to benchmark against other jurisdictions, patients aged 80 years and over should be considered for exclusion from reporting.
Stakeholder involvement in audit development	A continuous consultation process was applied, with engagement and support from all stakeholders: • PDA information sessions were well attended by representatives across the hospital system, including	The momentum and level of consultation of the PDA should be maintained.

Methodological steps	What went well	Learning for national implementation
	those from ED, ICU, and quality and safety functions. • Stakeholder workshops were held (e.g. with ICSI representatives in order to peer review the dataset, and with Irish National Intensive Care Unit Audit (INICUA) audit coordinators in order to support data validation). • The PDA was positively received across ICUs, which was evidenced during three hospital site visits. • There was engagement from Children's Health Ireland at clinical and executive level.	
	The PDA dataset meets the QI objectives of the audit. The PDA dataset contains questions which are relevant to the quality of care being measured. Face and content validity were assessed and were deemed valid and accurate.	A full review of the dataset by the National Release Centre for Systematized Nomenclature of Medicine – Clinical Terms (SNOMED-CT), with the aim of creating an Irish SNOMED-CT reference set specifically for the PDA, would increase the potential for interoperability with electronic health records and allow for an international common understanding of the PDA. Minor amendments to the dataset and corresponding metrics and filters will reduce the burden of data collection for audit coordinators, enhance data accuracy and provide more meaningful preliminary metrics in real time for eligible donors. Minor amendments include: • two potential changes to the conditional branching in order to minimise the burden of data collection for patients who do not fulfil potential donor or eligible donor criteria • minor amendments to the dataset (e.g. additional response options in order to ensure that all circumstances are captured) • the implementation of an improved approach to the filtering and real-time reporting of the dataset

Methodological steps	What went well	Learning for national implementation
		through the addition of an aggregate question on medical contraindications, which is not currently in place. The dataset may evolve with the enactment of the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill 2022. Continued engagement with the Health Service Executive (HSE) Data Specification Management Process (DSMP) and relevant groups will ensure the ongoing critical review of the dataset as it evolves over time. Future implementation plans should include an objective assessment of reliability.
Development of the data collection protocol	PDA audit coordinators found that the training they received met the learning outcomes of the training programme and that the user manual supported them in their role as audit coordinator.	A library of case studies and frequently asked questions should be developed for training purposes. Initial training on the data collection and functionality of the tool should be followed by training on report interpretation at an agreed later time.
	Data sharing agreements were agreed in six sites. Engaging with Data Protection Officers in participating hospitals allowed for a full exploration of information governance issues and will inform future agreements, particularly in the context of IT advances.	There were some challenges in obtaining consensus on the data sharing agreement in one participating hospital. There was no ODNM in that hospital's Hospital Group. An embedded ODNM may have contributed to the hospital-wide understanding and acceptance of organ donation as a normal part of end-of-life care in participating hospitals. Consultation on the draft data sharing agreements should begin as early as possible, which would support hospital discussions and allow additional time for hospitals to consider appropriate changes prior to commencing data collection. The feedback provided by all the hospitals was greatly appreciated and allowed for the implementation of a more tailored agreement relating to deceased individuals' records.

Methodological steps	What went well	Learning for national implementation
Information technology	There was direct engagement with participating hospital IT departments. A background technical document was prepared for local hospitals in order to support the implementation. This was found to be useful in supporting access for ODNMs. The electronic data collection tool was built quickly with excellent support and commitment from the developers. Hospital-level access was quickly ascertained. Prompt IT support was provided by developers.	A suitable device and location for data entry is required. Reliable Internet connectivity should be available at hospital level in order to improve access to the web-based tool. Access to Wi-Fi and mobile devices supports timely data collection. Future building of an electronic data collection tool should include change control process for system development even during the pilot design phase.
Testing of the PDA dataset and electronic IT tool	A thorough approach to testing of the dataset and information technology (IT) tool was undertaken. The dataset was refined through the testing process.	Prior to testing, further work on finalising specifications could be performed, and the test run against finalised specifications. The lack of real-world data meant that the system was not fully tested to its limits. A library of case studies should be developed for testing. A change management process should also be implemented for defining, testing and approving future changes to the dataset.
	Media engagement was conducted through the traditional health service and social media, as well as via health service conferences: • Social media posts included an informative video, patient testimonies, global organ donation news, and key stages of progression for the PDA. • Tweets were seen by more than 20,000 users. • Since its creation in late 2022, the PDA web page has been seen by more than 350 unique visitors, with approximately 10% of visitors coming from the NOCA Twitter account and the	It is important to maintain the positive momentum of the PDA. There is an opportunity for further communications with the publication of the development project report through social media, additional virtual presentations inviting all participating hospitals to attend, and publications in conference proceedings relating to critical care. Continuation of additional data collection using the PDA until the end of 2023 will ensure that the momentum of the development project is maintained in existing participating hospitals, will allow for testing the proposed changes to the dataset

Methodological steps	What went well	Learning for national implementation
	remainder coming from direct searches or referrals.	arising from the development project and allow for reporting on a full calendar year.
Pilot testing of the dataset and audit methodology	Commitment to the PDA was demonstrated through: • the timeliness of data entry • the level of attendance at training and support • data validation and accuracy. Commitment from INICUA audit coordinators in participating sites in order to ensure data quality was also evident.	• A robust data validation reporting process with a method of managing queries should be explored. • There is an opportunity to improve the approach to assessing data coverage in the PDA. Coverage reports were returned monthly by the ODNMs. INICUA was used to verify the number of admissions who died in a Unit in a given month. Where INICUA reports were not available during the timeline of the PDA, local ICU clinical information systems were used to identify all patients who died in that Unit in a given timeframe. • There was a systematic difference in PDA findings and INICUA findings due to the differences in inclusion criteria. In INICUA, patients are included by date of admission to ICU. In the PDA pilot study, patients were included by date of death in ICU. Including date of admission to ICU in the PDA and providing INICUA organ donation reports by date of death will facilitate greater ease of cross-referencing between datasets in the future. It will also provide clarity to data users in the expected differences in reporting metrics between the two datasets. • INICUA collects data retrospectively; thus, concurrent data were not available for all sites during the PDA pilot study. This was partially due to the residual impacts of the COVID-19 redeployment of personnel and the HSE cyberattack in 2020 and 2021, respectively, and is expected to be improved in 2023. • In the sites where it was not possible to use INICUA data (n=3), ICU clinical information systems (CIS) were used in lieu of INICUA to

Methodological steps	What went well	Learning for national implementation
		identify all patients who died in a given Unit in a given timeframe, providing assurance on data quality. ODNMs were able to work locally with IT teams to develop automatic discharge reports from the CIS, indicating the patients who were discharged as deceased. This was particularly helpful in identifying deceased patients who the ODNMs might not have been aware of (for example, during periods of leave). • Data were very occasionally misclassified on the CIS. This shows an opportunity for the PDA to be used as a cross-check for the CIS, improving data quality in both.
Developing reporting from audit development	This national clinical audit provides real-time preliminary information to data users. There was a robust, QI-focused approach to developing the PDA reporting metrics.	There were some preliminary reports in the PDA pilot project and in the data collection tool. Real-time reports for all reporting metrics are required in order to drive improvement in all organ donation processes. The specification of which preliminary information is required, and in what format, should be agreed and tested as a part of the testing of the data collection tool. What will be presented through the tool and what will be presented through a NOCA dashboard should be agreed as part of that specification.
Findings	The findings focused on areas amenable to improvement (i.e. clinical and operational organ donation processes). There was unambiguous presentation of the findings, which is accessible to relevant data users and is suitable for national and some international benchmarking. Multiple methods of presentation – patient flow diagram, tables and figures.	As the PDA accrues more data, future presentation of findings will have an improvement focus (e.g. run charts).

Methodological steps	What went well	Learning for national implementation
Evolving relationships	A strong, supportive relationship was nurtured with staff at National Health Service Blood and Transplant (NHSBT), who shared their learning and expertise from more than 20 years of Potential Donor Audit implementation. This included an invitation for the ODNMs to join the NHSBT national shared practice sessions, which ODNMs reported as a positive experience. Expert advice was received from Professor Michael O'Leary, Intensive Care Specialist at the Royal Prince Alfred Hospital and Co-State Medical Director of the New South Wales Organ and Tissue Donation Service in Australia. There were consultations with transplant centres around an agreed list of contraindications for the PDA, and opportunities for shared learning.	Continuous engagement with international colleagues with well-established potential donor audits should be maintained in order to ensure learning from their wealth of experience. In engaging with international colleagues, it was identified that in other regions, organ donation personnel and transplant centres meet to review cases where organ donation did not proceed. During the process of carrying out the PDA pilot project, it became apparent that decision-making is not always obvious, particularly around the determination of contraindications. Feedback on this decision-making can provide ICUs with valuable learning, upon which improvement can be made. A QI forum can identify these practices and either mainstream them or change them for future implementation. A collaborative QI-focused relationship between organ donation and transplant personnel should be nurtured in conjunction with Organ Donation Transplant Ireland (ODTI). This forms the basis of a recommendation four in Chapter 7, p.51.

CHAPTER 7
RECOMMENDATIONS

CHAPTER 7 RECOMMENDATIONS

The PDA Development Project demonstrated a robust approach to national clinical audit development, with excellent data quality demonstrated using the Health Information and Quality Authority (HIQA) dimensions of data quality (HIQA, 2018). It demonstrated the feasibility of collecting the required data elements for the PDA in participating ICUs. This NOCA national clinical audit provided preliminary information to data users in real time. This report recommends implementing a continuous PDA nationally in all acute hospitals with ICUs and/or EDs. Commissioning and funding should be approved without delay. Tables 7.1-7.4 details each recommendations, the rationale for the recommendation, the evidence base for its implementation, the beneficiaries, owners and suggested actions for implementation and when the recommendation should be implemented.

TABLE 7.1: RECOMMENDATION 1

Implement the PDA nationally in all acute hospitals with ICUs and/or EDs.	
Rationale for this recommendation	The rationale for the need for a PDA was outlined in the *Potential Donor Audit Feasibility Study Report* (NOCA, 2022). **What the PDA Development Project adds** The 3-month pilot project demonstrated some potential missed opportunities for organ donation and areas for improvement in six Irish hospitals. As these opportunities are so few, every opportunity must be maximised. If the pilot project were to be replicated for a full year and across the entire country, 24 more donors could possibly be realised (3 additional donors per quarter × 4 quarters × rest of the country [×2] = 24 [See reference p.22]), which equates to 4.8 per million population (PMP). This could have a considerable impact on donor families and transplant recipients. The true value of the PDA is expected to lie in regional hospitals outside the six large hospitals in which ODNMs are primarily based. This is a conservative estimate and may increase gradually over time. This *Potential Donor Audit Development Project Report*: • quantifies the potential for organ donation in six ICUs where there is a long-established culture of organ donation (in order to estimate the true potential donor pool, the PDA must be implemented in all acute hospitals with an ICU and/or ED) • acknowledges the work of ICU personnel in participating hospitals and specialist ODP who are largely embedded in the participating hospitals • demonstrates the variability and opportunities for improvement across a number of areas, and precisely where in the patient journey these opportunities occur • identifies reasons for a non-donation outcome • systematically assesses the degree to which best practice standards in organ donation are being met • demonstrates the feasibility of collecting the required data elements for the PDA in participating ICUs • demonstrates the value and necessity of specialist ODP in promoting a culture and practice which highlights the potential for organ donation, in educating

Implement the PDA nationally in all acute hospitals with ICUs and/or EDs.	
	staff and supporting the families and loved ones of organ donors, and in coordinating a PDA • demonstrates a robust approach to national clinical audit development with excellent data quality as a result of applying the HIQA dimensions of data quality (HIQA, 2018); this is the first NOCA national clinical audit to provide preliminary information to data users in real time.
Evidence base for implementation of this recommendation	According to the International Registry in Organ Donation and Transplantation (IRODaT), Ireland's deceased organ donation rate in 2022 was 16.78 PMP (IRODaT, 2023). The strong international evidence base demonstrating improvement following the national implementation of a continuous potential donor audit was demonstrated in the *Potential Donor Audit Feasibility Study Report* (NOCA, 2022). For example, Spain commenced its Quality Assurance Programme for Deceased Donation in 1998. In 2000, the rate of organ donation was 33.90 PMP, which increased to 46.03 PMP in 2022 (IRODaT, 2023), making Spain one of the world leaders in organ donation. **What the PDA Development Project adds (examples of improvement)** As a direct result of this PDA Development Project, ODNMs have engaged with NHSBT during its monthly national shared practice sessions. Shared learning from these experiences has been positive. For the first time, ODP and transplant centre personnel have consulted on creating a jointly held list of absolute medical contraindications to support the data collection for the PDA. Over time, agreeing this list may support the development of national guidelines for the operational delivery of donation and transplant services nationally.
Who benefits from the recommendation?	Patients, families, healthcare service providers, legislators, and the public at large, who will be assured that all potential donors will be given the opportunity to donate their organs, where this is appropriate and where this is their wish.
Suggested owner(s)	ODTI and NOCA will submit a proposal to the HSE commissioning process for a new national clinical audit.
Suggested actions	• Submit this *Potential Donor Audit Development Project Report* and a proposed implementation plan to the HSE National Centre for Clinical Audit and the Department of Health for prioritisation. • The implementation plan should be phased and align with the workforce planning for the specialist hospital-based ODP. This will support a PDA and the development of a positive hospital-based organ donation culture. • The implementation plan should include all ICUs. A strategic plan should be developed to extend the PDA to all EDs. • A collaborative approach between NOCA and ODTI should continue throughout the implementation of this national clinical audit.
When should this be implemented	January 2024 **Urgency** The Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill 2022 is currently passing through the Dáil and Seanad and is expected to be enacted by the end of 2023. The PDA will support this legislation by aiming to ensure that every person who is approaching the end of life in ICU and ED is offered the possibility of becoming an organ donor, where this is appropriate. Dáil debates have consistently highlighted the public demand for data on organ donation processes.

TABLE 7.2: RECOMMENDATION 2

Provide an agreed list of contraindications that can be operationalised for clinical practice in order to support the PDA.	
Rationale for this recommendation	An agreed list of absolute medical contraindications is the key pillar by which the success of the PDA will be determined. In the absence of this agreement, the PDA may systematically overestimate or underestimate the true number of eligible donors. Furthermore, there is a risk of uncertainty among ICU personnel of what is acceptable as an absolute medical contraindication to organ donation if the process for the PDA is different from the process used in clinical practice. Without an agreed list of absolute medical contraindications, data collection would be overly burdensome, would undermine the findings of the PDA, and would render the PDA inoperable. This work was commenced during the PDA Development Project and is complex. This recommendation seeks to finalise this work prior to national implementation of a PDA.
Evidence base for implementation of this recommendation	In countries with established potential donor audits where improvement has been realised (e.g. DonateLife in Australia, and NHSBT in the United Kingdom), an agreed list of absolute medical contraindications exists. There is also a change management process to manage modifications to the list over time.
Who benefits from the recommendation?	• Hospital Group ODP, who can focus their improvement endeavours where there is true potential for organ donation • transplant centres, which will receive referrals for patients with true potential for organ donation • family members, ICU personnel and other hospital staff, who, in liaising with Hospital Group ODP, will have a clear, responsive process for caring for patients at the end of their lives • all stakeholders of the PDA, who will be assured of an internationally aligned, transparent process ensuring that every person who is approaching the end of life in ICU or ED is offered the possibility of becoming an organ donor, where this is appropriate.
Suggested owner(s)	ODTI
Suggested actions	• Agree a list of absolute contraindications – in consultation with ICU and transplant centre personnel – that is suitable for both clinical practice and clinical audit. • Agree a process whereby absolute medical contraindications can be managed at ICU level by Hospital Group ODP. • Furnish NOCA with the agreed list for use in the PDA. • Include the agreed list in the SNOMED-CT Ireland reference set for potential organ donation. • Establish a process to review the agreed list every 2 years.
When should this be implemented	The list should be finalised by the end of 2023.

TABLE 7.3: RECOMMENDATION 3

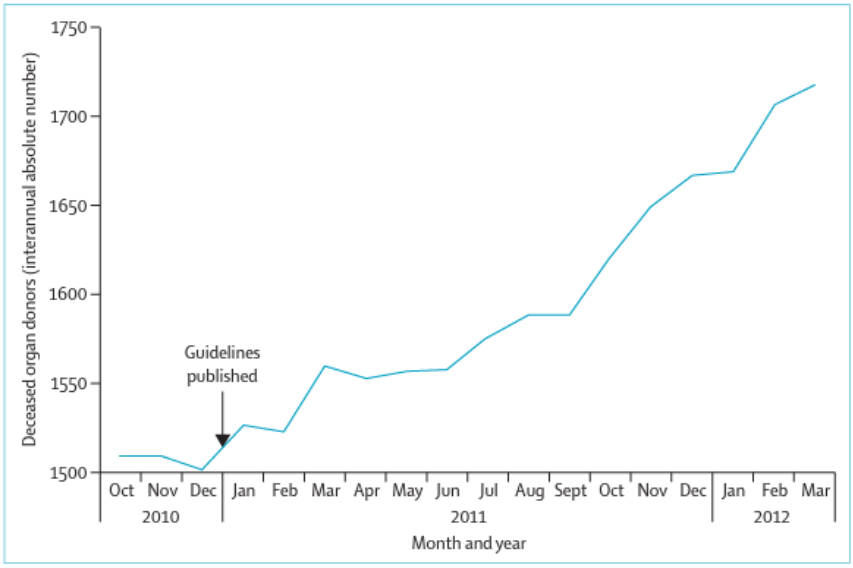
Use the findings from the PDA Development Project to inform a set of national guidelines for organ donation.	
Rationale for this recommendation	The rationale for the need for national guidelines was outlined in the *Potential Donor Audit Feasibility Study Report* (NOCA, 2022).
Evidence base for implementation of this recommendation	There is strong evidence of improvement in donation rates as a result of the implementation of guidelines as demonstrated in Figure 7.1 (Matesanz *et al.*, 2012).  Figure 7.1: Monthly evolution of inter-annual absolute number of deceased organ donors in Spain after implementation of good practice guidelines The inter-annual absolute number of deceased organ donors is equal to the number of deceased organ donors within the past 12 months on a given date (Matesanz *et al.*, 2012).
Who benefits from the recommendation?	Healthcare professionals providing end-of-life care in Irish hospitals will have clarity around organ donation processes so that they can offer it as an option for patients at the end of life.
Suggested owner(s)	ICSI, in consultation with stakeholders.
Suggested actions	• Review the findings of the PDA pilot study. • Establish a steering committee of relevant stakeholders. • Develop a system-wide communications strategy. • Review the effectiveness of the guidelines using the PDA.
When should this be implemented?	January 2024

TABLE 7.4: RECOMMENDATION 4

Develop a clinically led quality improvement forum dedicated to improving organ donation and transplantation. Improvement activities may include, but are not limited to: • Reviewing cases that did not proceed to organ donation • Sharing examples of best practice and improvement activities • Developing quality improvement plans.	
Rationale for this recommendation	The PDA Development Project provided information on reasons why organ donation does not occur within the ICU. It also identified potential donors who were deemed ineligible for donation by the transplant centres. Learning from the PDA Development Project suggests that there is value in bringing together organ donation personnel and transplant centre personnel in order to deepen their understanding of decision-making practices, learn together about where things went well, and learn from issues where improvement potential exists. Currently there are few mechanisms through which ICU and transplant centre personnel can work and learn together to improve organ donation practices in Ireland.
Evidence base for implementation of this recommendation	QI-focused fora exist in countries that lead the world in organ donation, such as Spain and Australia. Both countries have demonstrated improvement over time with the implementation of a potential donor audit and related improvement activities. A professional collaborative approach between ICUs and transplant centres may help to redefine and expand the eligible donor pool. A Cochrane Review of 140 trials evaluating the effectiveness of clinical audit indicates that the effects of clinical audit can be significantly augmented by adjunct activities, such as feedback given by a supervisor or colleague that is provided more than once, delivered in different formats, and includes QI plans with explicit targets (Ivers *et al.*, 2012). The QI forum can provide a mechanism through which to discuss feedback and develop improvement plans. There is some evidence, theory and expert opinion supporting the mechanism for improvement from this recommendation. Group discussion of audit results in a safe environment between organisations involved in care, may lead to greater improvement (Brown *et al.*, 2019; Colquhoun *et al.*, 2021). Undertaking work (in this case, the healthcare record review) to identify the behaviours that could be changed, and subsequently identifying and addressing barriers to and facilitators of change, may lead to a more effective audit response (Colquhoun *et al.*, 2021; Sykes *et al.*, 2022). Identifying influences on practice and selecting improvement actions to address these is known as 'tailoring', and there is some evidence that tailored interventions may be effective (Baker *et al.*, 2015).
Who benefits from the recommendation?	• Healthcare staff, who will have a better understanding of where exactly the process of organ donation can be improved and will learn from peers in a dedicated, supportive learning environment. • Family members of potential donors, as well as healthcare staff, who will have a more transparent approach to decision-making.
Suggested owner(s)	ODTI and NOCA
Suggested actions	• Define the report specification that NOCA provided to ODTI.

Develop a clinically led quality improvement forum dedicated to improving organ donation and transplantation. Improvement activities may include, but are not limited to: • Reviewing cases that did not proceed to organ donation • Sharing examples of best practice and improvement activities • Developing quality improvement plans.	
	• ODNMs, in collaboration with National Organ Procurement Service personnel, should populate reasons why potential donors do not proceed to organ donation at the level of the transplant centre in the PDA as part of the audit. • NOCA should amend the existing data sharing agreement for the purpose of developing the QI forum. • ODTI should establish a structure to govern a biannual meeting. • ODTI should roll out the QI forum as a key quality improvement initiative. • ODTI should share the outcome of the forum with NOCA. • NOCA should evaluate the impact of this recommendation (i.e. how is the QI forum enacted and does it lead to improvement?).
When should this be implemented?	Once the report specification and data sharing agreements are in place for participating hospitals.

CHAPTER 8
CONCLUSION

CHAPTER 8 CONCLUSION OF THE PDA PILOT PROJECT

The PDA Development Project, led by NOCA in conjunction with ODTI, demonstrated a robust, end-to-end approach to audit development. This provided a baseline methodology for the development of other future national clinical audits, which can evolve over time. Important learnings from the PDA Development Project will be reflected in the future national implementation of the PDA.

The findings of the PDA pilot project provide the necessary information to frontline ODP to drive improvement in participating hospitals, ensuring that every person who is approaching the end of life in ICU or ED can be offered the possibility of becoming an organ donor, where this is appropriate. The final recommendations are the pillars of improvement from which donor families may find some solace and lives can be saved.

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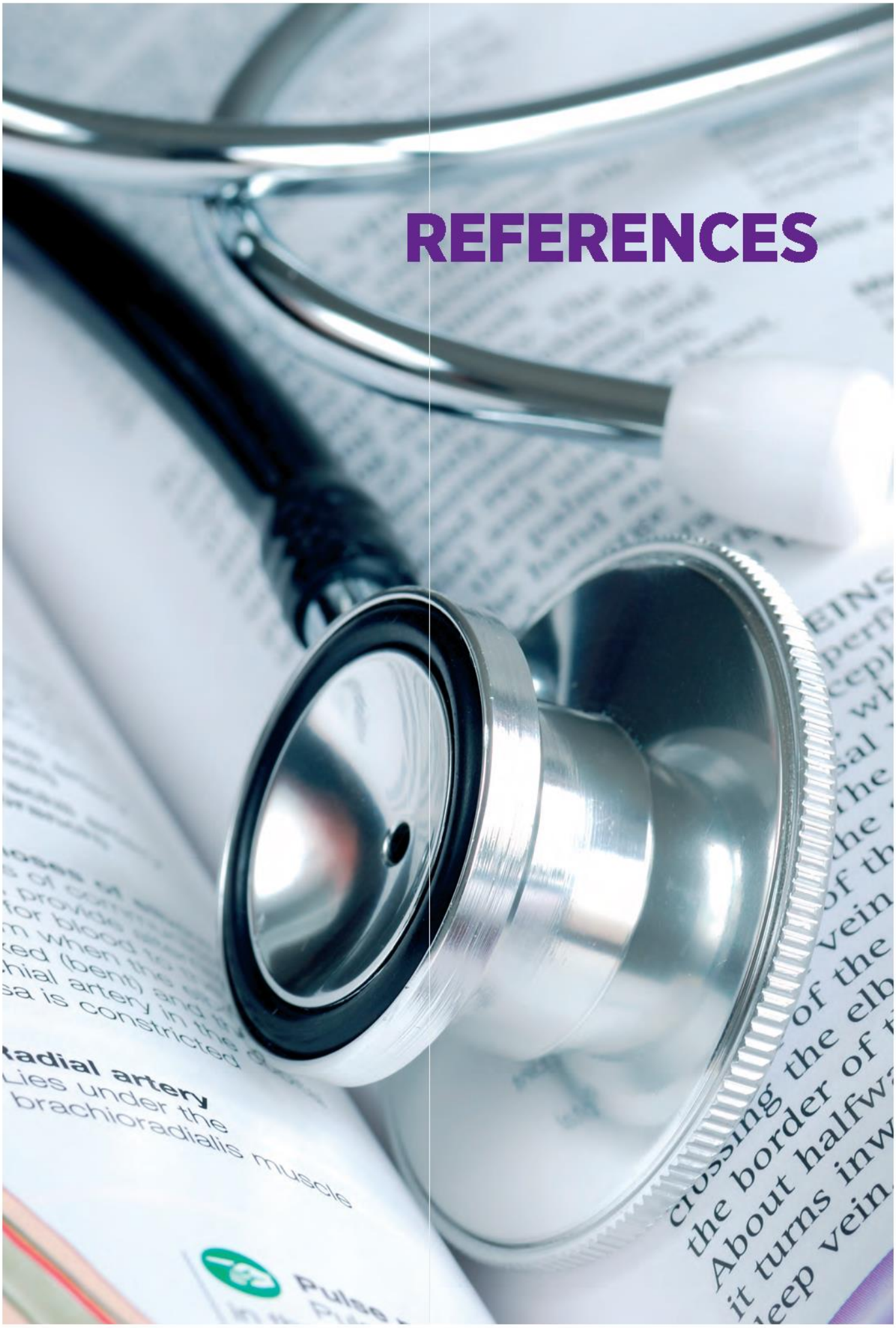
Radial artery
Lies under the
brachioradialis muscle
Pulse

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APPENDICES

APPENDICES

APPENDIX 1 POTENTIAL DONOR AUDIT DEVELOPMENT PROJECT STEERING COMMITTEE AND MEETING ATTENDANCE

Representative organisation	Role(s)	Name	Meeting			
			1	2	3[a]	4
Health Service Executive (HSE)	National Director for Strategy and Research	Dr Philip Crowley (Chair)	X	√	√	√
National Office of Clinical Audit (NOCA)	Potential Donor Audit (PDA) Development Project Lead	Dr Maria Kehoe, PhD	√	√	X	X
RCSI group CLOD	Clinical Lead of the PDA Development Project; Clinical Lead in Organ Donation (CLOD), RCSI Hospital Group; Consultant Intensivist, Beaumont Hospital	Dr Alan Gaffney	√	√	√	√
RCSI group ODNM	Organ Donation Nurse Manager (ODNM), RCSI Hospital Group	Karen Healy	√	√	√	√
Organ Donation Transplant Ireland (ODTI)	Chief Operations Officer	John Walsh	√	√	√	√
ODTI	Director of ODTI; Consultant Lung Transplant Physician	Prof. Jim Egan	√	√	X	X
HSE National Quality and Patient Safety Directorate	Assistant National Director (Deputy Chair)	Maria Lordan Dunphy	√	√	X	√
HSE Acute Operations	Clinical Lead of the National Renal Office/Consultant Nephrologist	Prof. George Mellotte	√	√	X	√
Intensive Care Society of Ireland	President	Dr Colman O'Loughlin	√	X	√	√
Irish Association of Critical Care Nurses	Intensive Care Unit (ICU) Nurse	Breda Doyle	√	√	√	√
Public and patient interest	Public and Patient Interest Representative	Louise Galvin	X	X	X	X
Strange Boat Donor Foundation	Public and Patient Interest Representative	Martina Goggin	√	√	√	√
Irish National ICU Audit (INICUA)	INICUA Audit Manager	Mary O'Dwyer Baggot	√	√	√	X
National Organ Procurement Service	Donor Coordinator	Emma Corrigan	X	√	√	√
Irish Association for Emergency Medicine	Consultant in Emergency Medicine; CLOD, South/South West Hospital Group	Professor Adrian Murphy	X	X	X	√
Children's Health Ireland	Consultant Paediatric Intensivist, Children's Health Ireland at Crumlin	Dr Suzanne Crowe	X	X	X	√
Transplant Centre	Consultant Liver Transplant Surgeon; Responsible Person, National Liver Transplant Programme, St Vincent's University Hospital	Professor Emir Hoti	X	√	X	X
Ireland East Hospital Group Chief Executive Officers (CEOs)	CEO, Ireland East Hospital Group	Declan Lyons	√	√	√	√
NOCA	Head of Quality and Development	Marina Cronin	√	√	√	√

[a]Fionnuala Treanor, National ICU Bed Information System Manager and Brid Moran, NOCA Information Manager attended meeting 3.

APPENDIX 2 INDICATIVE COST MODEL FOR IMPLEMENTATION OF A POTENTIAL DONOR AUDIT

PDA costings: Implementation, Estimate at May 2023						
Cost type	Cost category	Year 1 implementation	Year 2 implementation	Year 3 implementation	Year 4 Steady State	Year 5 steady state, review data collection
NOCA Costs						
NOCA human resource subtotal cost	Audit manager, analyst, developer and information governance lead	220,500	158,406	143,427	124,112	125,849
Overheads and pass throughs	For example; licenses, events, edit and design of report, travel, NOCA overhead	60,800	64,700	84,700	82,850	81,850
		-	-	-	-	-
Annual total NOCA costs		281,300	223,106	228,127	206,962	207,699

Estimates may vary depending on the final solution.
Costs are exclusive of VAT and include 2% cost increase per annum.
Costs of National Clinical Lead (circa €20,000 pa) and Organ Donation Personnel at site are separate to NOCA costs.
Organ Donation Personnel will be funded through the Organ Donation Transplant Ireland as part of their annual workforce plan.

Readers of the print format of this report can access additional Potential Donor Audit resources using this QR code: