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Quality improvement tools to manage deceased organ donation processes: a scoping review

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ABSTRACT

Objective To collate and summarise the literature on the quality improvement tools that have been developed for deceased organ donation processes after circulatory determination of death and neurological determination of death.

Design Scoping review using the Joanna Briggs Institute framework.

Data sources We searched for published (MEDLINE, Embase, PsycINFO, CINAHL, Web of Science) and unpublished literature (organ donation organisation websites worldwide). The search was initially conducted on 17 July 2021 and updated on 1 June 2022. Included articles discussed the creation and/or use of quality improvement tools to manage deceased organ donation processes. Two independent reviewers screened the references, extracted and analysed the data.

Results 40 references were included in this review, and most records were written in English (n=38), originated in Canada (n=21), published between 2016 and 2022 (n=22), and were specific for donation after neurological determination of death (n=20). The tools identified included checklists, algorithms, flow charts, charts, pathways, decision tree maps and mobile apps. These tools were applied in the following phases of the organ donation process: (1) potential donor identification, (2) donor referral, (3) donor assessment and risk, (4) donor management, (5) withdrawal of life-sustaining measures, (6) death determination, (7) organ retrieval and (8) overall organ donation process.

Conclusions We conducted a thorough investigation of the available quality improvement tools for deceased organ donation processes. The existing evidence lacks details in the report of methods used for development, testing and impact of these tools, and we could not locate tools specific for some phases of the organ donation process. Lastly, by mapping existing tools, we aim to facilitate both clinician choices among available tools, as well as research work building on existing knowledge.

INTRODUCTION

Quality improvement (QI) tools are extensively used in healthcare settings and are included in nursing and medical school curricula.[1][2] Healthcare QI tools support

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This scoping review used a broad search process to summarise the international literature on how quality improvement tools can be used to support deceased organ donation management process.

⇒ This review brought forward evidence on how the existing tools can facilitate both clinician choices among available tools, as well as support research work building on existing knowledge.

⇒ Scoping reviews use a subjectivist epistemology and, therefore, our results can be limited for direct application into clinical settings.

clinicians and organisations in delivering high-quality care, optimising patient outcomes, improving patient safety and decreasing costs.[1][2] Further, organ donation has the potential for significant societal impact, with one donor able to save up to eight lives. The medical complexity and societal importance of organ donation has led to growing awareness of the need to standardise processes using QI.[3]

Deceased organ donation is a complex and multiphased process that starts with the identification of potential donors, and finishes with organ retrieval and return of the body to the donor's family.[4] Deceased organ donation can occur both after circulatory determination of death (DCD) and neurological determination of death (NDD). Both types of organ donation are medically complex, frequently lasting over 48 hours and involve multiple phases facilitated by distinct medical teams.[5][6] These processes take place in high-pressure environments such as emergency departments, intensive care units (ICUs) and operating rooms, where providers may be exposed to sleep deprivation, and physical and mental fatigue.[6] The complexity of cases, combined with the nature of the healthcare settings they take place in, can leave the

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organ donation process susceptible to adverse events and missed donation opportunities.

The complexity of each phase in NDD or DCD requires standardised approaches from both the bedside healthcare team (eg, ICU) and organ donation organisations (eg, organ donation coordinators), to facilitate successful donation and reduce errors. The use of QI tools to standardise healthcare practices is known to help to avoid inconsistencies and errors and optimise outcomes.[2 3] QI tools can be defined as standalone tools to enhance practices and reduce the risk of errors.[2] Healthcare QI tools support clinicians and organisations in delivering high-quality care, optimising patient outcomes, improving patient safety and decreasing costs.[1 2] Types of QI tools for healthcare settings include Plan-Do-Study-Act worksheets, as well as various forms of flowcharts, histograms, scatter diagrams, checklists, etc.[7] Despite the potential of QI tools in deceased organ donation, those tools have not been extensively described in the existing literature.

Objective

This study aimed to collate and summarise the literature on the QI tools that have been developed for deceased organ donation processes (both NDD and DCD). A comprehensive understanding of existing QI tools for both DCD and NDD processes can help guide the development, update and use of QI strategies in this field. Additionally, our overarching question was: What QI tools have been developed to enhance the quality of both DCD and NDD deceased organ donation processes worldwide?

METHODS

This scoping review was conducted following JBI methodology.[8] The title of this review was registered at JBI collection,[9] and the protocol was published elsewhere.[10]

Inclusion and exclusion criteria

We considered studies that included deceased organ donors, both DCD and NDD, in any country. For the concept, we considered studies, reports or documents that investigated the creation and/or use of tools to optimise deceased organ donation and/or promote patient quality in organ donation processes worldwide. For the context, we considered hospital settings where potential donors are managed, organ donation/procurement organisations, clinics and other healthcare settings involved in organ donation processes in any country. We also included studies of any design, but abstracts were only included if we could find an associated full text. Literature reviews were screened for the inclusion of potential articles. The reference lists of all included resources were also searched for additional sources.

Search strategy

A search strategy was developed to locate both published and unpublished reports. The search strategy was designed and executed by an experienced information specialist, verified by content experts and reviewed by a second information specialist using Peer Review of Electronic Search Strategies.[11] The full search strategy used for each source can be found in online supplemental table S1. To locate published literature, we searched the following electronic databases: MEDLINE Ovid, Embase Ovid, PsycINFO Ovid, CINAHL via EBSCOhost, Web of Science—Science Citation Index and Social Science Citation Index via Clarivate and Academic Search Complete via EBSCOhost. To locate grey and unpublished literature, we searched Google and screened the first five pages of relevancy-ranked results (100 records), as well as searched for various institutional protocols and QI tools on organ donation organisation websites worldwide. The search was initially conducted on 17 July 2021, and updated on 1 June 2022.

Evidence selection, extraction and analysis

After the search process was completed, reports were uploaded into Covidence and duplicates were removed. Following an initial pilot screening, all unique references were screened by title and abstract, and then through full text by at least two independent reviewers (AS, AR, LG, ML and EJ) for assessment against the inclusion criteria; conflicts were solved by a third reviewer (VSeS). All included references had the tool publicly available at the time of the data extraction process. The data from all included reports were extracted using a data extraction tool developed by the authors for this study. Data were collected on the participants, concept, context, methods and key findings relevant to our review questions. The data of all reports were extracted by the lead author (AS) and checked by a second reviewer (AR). Where needed, authors of the reports were contacted to request additional data (reports were only included if we could locate the QI tool). The data extracted from the resources was assembled and summarised quantitatively (tabular form) and qualitatively (narrative summary) in response to the review questions. The qualitative narrative summaries were organised using a deductive content analysis approach in accordance with the steps of the organ donation process described by Silva e Silva (2020)[4] (online supplemental table S2).

Quality appraisal

The quality appraisal of references is not mandatory for scoping reviews, but we conducted a quality appraisal of the included references to ensure rigour and provide comprehensive information for readers. To critically appraise the quality of the studies in terms of QI intervention publication, we used the Quality Improvement Minimum Quality Criteria Set (QI-MQCS) tool.[12] The QI-MQCS tool consists of 16 items that evaluate minimum standards of the publications report related to: (1) organisational motivation, (2) intervention rationale, (3) intervention description, (4) organisational characteristics, (5) implementation, (6) study design, (7) comparator, (8) data source, (9) timing, (10) adherence/fidelity, (11)
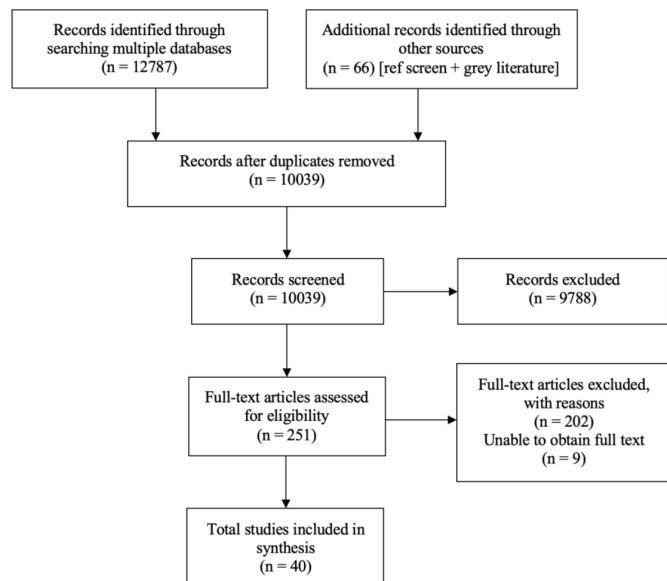
Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping reviews flow chart.

health outcomes, (12) organisational readiness, (13) penetration/research, (14) sustainability, (15) spread and (16) limitations.

Patient and public involvement

For the conduction of this review, we engaged with key stakeholders in the area of deceased organ donation for the entire conduction of the review. This engagement included, but was not limited to, review of the search terms used by clinicians in the field, consultation during the data analysis process and review of final results. These stakeholders included healthcare professionals with clinical and/or research background in deceased organ donation and/or QI strategies. Still, as the concept of interest in this review was specific to healthcare process, we did not include patient involvement in the development of searching processes and manuscript development.

RESULTS

The search process yielded 12 787 reports, of which 10 039 were unique and were screened by title and abstract. From these, 251 eligible articles were screened by full-text. A total of 40 reports were included in this review. For details regarding the search process and study selection, please refer to the Preferred Reporting Items for Systematic Reviews and Meta-analyses Extension for Scoping Reviews flow chart in figure 1.

From the 40 reports included in this review, most were published in English (n=38), followed by Portuguese (n=1) and Spanish (n=1). Included reports were from Canada (n=21), USA (n=4), Brazil (n=3), Australia (n=3), Switzerland (n=2), Italy (n=1), The Netherlands (n=1), UK (n=1), Iran (n=1), Ireland (n=1) and The United Arab Emirates (n=1). The majority of publications were from 2016 to 2022 (n=22), followed by 2008–2015 (n=16) and 2000–2007 (n=1). One report did not

identify a publication date. Lastly, most references were specific to NDD (n=20), followed by DCD (n=19), both NDD and DCD (n=6) and unspecified (n=5). Details related to the main findings and characteristics of the included studies can be found in online supplemental table S3.

Following a deductive content analysis approach, we grouped our findings into eight categories to address the research question of this review: (1) potential donor identification, (2) donor referral, (3) donor assessment and risk; (4) donor management; (5) withdrawal of life-sustaining measures (WLSM), (6) death determination, (7) organ retrieval and (8) Overall organ donation process. The tools identified in our search process and their division according to the organ donation process can be found in figure 2.

Potential donor identification

The initial identification of potential organ donors is an essential step of the organ donation process that is usually performed by the ICU healthcare team (eg, nurses and physicians). Patients who are identified as potential donors for NDD or DCD (controlled) usually include those with a Glasgow Coma Scale (GCS) of 3, serious brain injury and/or diagnosis of neurological death, as well as patients with an end-of-life care plan that includes WLSM.[13] We identified two reports from a Canadian organ donation organisation (Trillium Gift of Life Network (TGLN)) that described an algorithm for referral consistent with these criteria, for both adult and paediatric populations.[14 15] Specifically, this algorithm reported four characteristics, using the acronym GIFT, to identify a potential organ donor: (G) Grave prognosis or GSC=3; (I) Injured brain or non-recoverable injury/ illness; (F) Family initiated discussion of WLSM; (T) Therapy-limited, WLSM or de-escalation of care plan in place. In cases where any of these criteria are met, the ICU team or other healthcare professional responsible should contact the organ donation organisation for further evaluation of the patient as a potential donor. Testing for the tool was not reported on.

Donor referral

After appropriate identification of potential organ donors, a referral to an organ donation organisation should be completed as early as possible to ensure appropriate approach with family members and adequate donor management.[4] A donor referral checklist from a Canadian organ donation organisation (Transplant Manitoba Gift of Life) was identified to help forward potential donors' information to the responsible organ donation organisation. Only the tool was available, and no testing for its implementation was presented. The checklist included information such as donor characteristics (eg, age, admission date, weight), history of current illness and medical information (eg, vital signs, drugs in use, lab values).
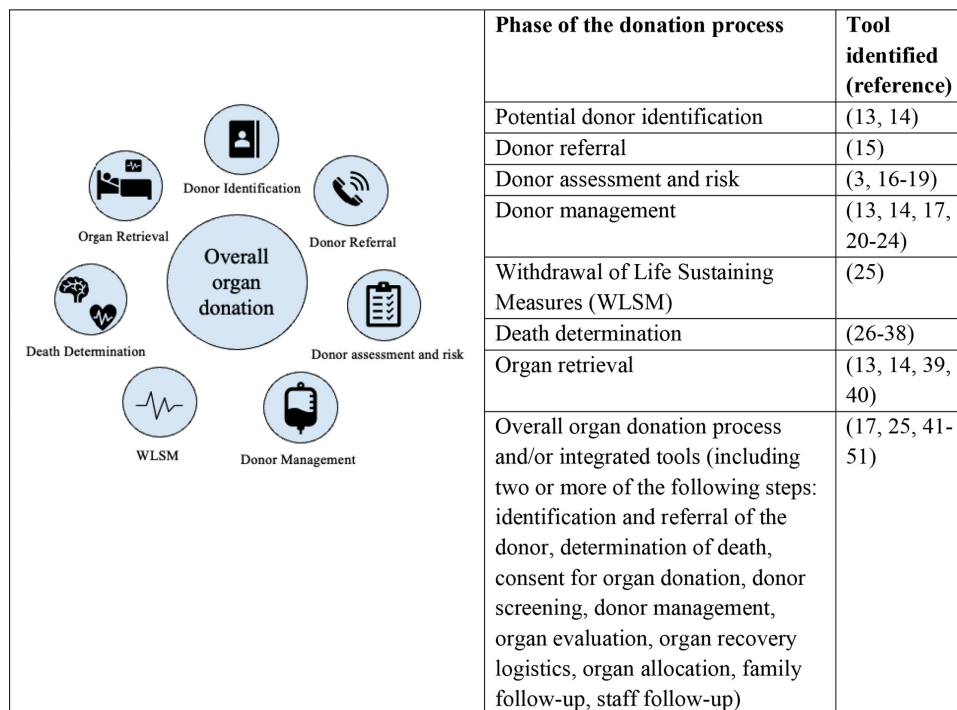
Phase of the donation process	Tool identified (reference)
Potential donor identification	(13, 14)
Donor referral	(15)
Donor assessment and risk	(3, 16-19)
Donor management	(13, 14, 17, 20-24)
Withdrawal of Life Sustaining Measures (WLSM)	(25)
Death determination	(26-38)
Organ retrieval	(13, 14, 39, 40)
Overall organ donation process and/or integrated tools (including two or more of the following steps: identification and referral of the donor, determination of death, consent for organ donation, donor screening, donor management, organ evaluation, organ recovery logistics, organ allocation, family follow-up, staff follow-up)	(17, 25, 41-51)

Figure 2 Phases of the organ donation process for which tools were identified. *Some refereces are repeated as they included toolsfor more than one phaseof the organ donation process.

Donor assessment and risk

Patients who are considered potential donors are screened through a series of clinical, physical and health history inquiries to determine the suitability of organs for transplant. This assessment includes clinical history, pre-existing diseases, current clinical status and others. Screening starts after donor referral and can last through the entire organ donation process.[13] The risk assessment allows healthcare professionals to screen potential clinical conditions that can impact the organ allocation process, as well as safety of potential transplant recipients.[4] A total of six tools were identified for the assessment and risk of potential organ donors.[3 16-19]

Loor et al[3] developed a checklist to improve processes related to thoracic donor assessment, including assessing organ compatibility and quality, with tasks such as checking arterial blood gases, tomography, ECG, mechanical ventilation parameters, etc. The tool was refined through five review and feedback cycles performed by a panel of expert procurement surgeons. Also, Cavallin et al[16] developed an application for iOS devices for donor screening, including aspects such as donor information (eg, sex, age), exclusion criteria (eg, HIV), donation type (NDD or DCD), testing and documentation needed. The application was developed based on a needs assessment from organ donation coordinators. Although the authors did not include information on testing the app, they mentioned that the pilot test was successful.

National Health Service provided a 10-point checklist to guide healthcare professionals during the screening and planning of potential paediatric organ donors but testing of the checklist was not included in the manual,[17] while the clinical guidelines from the Transplantation Society of Australia and New Zealand had four different flow charts to support screening for pre-existing conditions (hepatitis, skin cancer and gastrointestinal stromal tumour).[18]

Clinical guidelines from the Transplantation Society of Australia and New Zealand included a diagram for liver allocation, targeting both adults and paediatric donors. The purpose of the diagram is to support the decision-making process of organ allocation, through further risk-assessment screening around paediatric and adult donors' risk assessment (eg, HBC, HCV, skin cancer, gastrointestinal stromal tumour), as well as whether the organs should be allocated.[18] Additionally, in their manual on increased risk donors for organ transplantation, TGLN offers an HCV Donor Algorithm for how organs should be allocated.[19] Testing of these tools was not presented.

Donor management

To ensure the quality of organs for transplantation, optimal management of potential donors is essential. Optimal donor management prevents deterioration of the potential donor's clinical condition and preserves overall organ function. Donor management ensures that potential donors' physiological parameters (such as respiratory, haemodynamic and endocrine functions) are maintained as stable and close to the normal reference values as possible.[13] We located eight QI tools supporting donor management that were specific to either or both DCD and NDD, and the tools included algorithms, checklists and flow charts.[14 15 17 20-24] Overall, the tools were focused on supporting the respiratory, cardiovascular,

endocrine and renal systems of potential donors, and included specific interventions, such as laboratory investigations, nutrition, intravenous fluids, glycaemic control, fluids, infection prevention and treatment, and mechanical ventilation/lung optimisation. Still, none of the authors presented testing of the tools.

Withdrawal of life-sustaining measures

WLSM is performed by the hospital healthcare team and allows for controlled organ donation following DCD. WLSM involves the discontinuation of medical interventions (eg, mechanical ventilation, vasopressors) ultimately resulting in the patient's death.[25] One report from Healey et al[26] was identified discussing this phase of the donation process. The authors offer a series of tools to support improving the quality of WLSM in organ donation: standardised WLSM order set (including preparation, pharmaceutical management of distress and withdrawal of support); WLSM checklist (including decision making and documentation, preparing for WLSM, consultative supports, family and interview, withdrawal and DCD); WLSM documentation tool template (to register the parameters and data from withdrawal); and a WLSM system and case audit tools. Although testing of the tools' implementation was not mentioned, the tools were reviewed by the forum participants and modified based on feedback received.

Death determination

For approach of a potential organ donor, a discussion with family members should be held by the physician responsible to discuss prognosis. In NDD, organ donation conversation usually happens after confirmation of brain death diagnosis, while for controlled DCD, conversations are held beforehand as the death following WLSM is the final step prior to organ retrieval.[13] We identified a total of 13 QI tools in the literature for death diagnosis, where 12[27–38] were specific for NDD and one for both NDD and DCD.[39] Not all tools were specific to the organ donation process as some focused on death determination but not for donation purposes. An included report from the WHO provided a flow chart for the clinical DCD using circulatory and neurologic criteria, with clinical criteria and confirmatory/instrumental tests for the determination.[39] The other reports were all specific to NDD. The tools for NDD included a mix of algorithms, checklists, flow charts and decision trees; some were specific to paediatric and/or adult donors.[27–38] Overall, the focus of the tools for NDD were to establish clinical criteria (eg, GCS=3 and absent brain stem reflexes), apnoea testing, ancillary tests, possible confounders (eg, drugs, hypothermia), death declaration, standard end of life care and/or organ donation, and documentation needed based on local guidelines.[27–38] Lastly, none of the authors presented testing for the implementation of the tools.

Organ retrieval

The organ retrieval step involves the planning and execution of procedures related to donor preparation, family support and organ retrieval surgery in the operating room. This step requires organisation and planning to ensure that all needed resources (material and personnel) are in place in a timely manner for the retrieval procedure.[13] We identified four tools that aimed to support the organ retrieval process.[14 15 40 41] The adult and paediatric donation resource manual from TGLN reported on the same organ recovery equipment checklist to support organisation of the operating room in regard to the equipment, drugs and sutures needed for the procedure, as well as the quantity of each item.[14 15] Negreiros et al[41] proposed a flow chart using a clinical protocol model to support nurses during liver retrieval procedures on the activities needed for organisation of material, retrieval in the hospital and delivery of the liver. Also, Shemie et al[40] proposed an overview of current DCD protocols for heart donation using a flowchart to highlight the main procedures that precede heart donation. None of the authors presented testing for the implementation of the tools.

Overall organ donation process

Besides all QI tools identified that were specific for each phase of the organ donation process, we also identified 13 QI tools that were not specific for only one step of the process.[17 26 42–52] The tools for the whole organ donation process included a mix of checklists and flowcharts; and some were specific to paediatric and/or adult donors, as well as NDD and/or DCD cases. Overall, the focus of these tools included at least two of the following phases: identification and referral of the donor, DCD, consent for organ donation, donor screening, donor management, organ evaluation, organ recovery logistics (eg, operating room preparation), organ allocation, family follow-up, staff follow-up. Still, none of the authors presented testing for the implementation of the tools.

Quality appraisal

Out of the 40 references included in this review, 31 did not include aspects related to tool's development, from which 17 references were solely the tool, 7 guidelines, 4 manuals, 1 toolkit and 2 original researchers. Since these references did not report on methods, we could not assess the quality of those references (as they would not meet any of the standards due to the lack of report in the methods used). Additionally, nine studies reported detailed information related to the methods used to elaborate the QI tools for the deceased organ donation process, and these references were critically appraised using the QI-MQCS tool by two reviewers (EJ and SP) and the lead author (AS) took the final decisions to reach consensus. All 9 references reached a high score of either 15 or 16 out of 16. Details related to the quality appraisal performed can be found in online supplemental table S4.

DISCUSSION

In this scoping review, we identified, organised and synthesised the QI tools, through a systematic searching process, that were used to help manage the various steps of the deceased organ donation process. The QI tools identified were focused on multiple phases of the organ donation process and according to the existing literature, the use of QI tools can support the practice of healthcare professionals involved directly and indirectly in organ donation cases. However, the current evidence is limited in terms of evidence of testing and actual impact of those tools on the quality of deceased organ donation.

Even though we identified multiple tools for the various steps of the organ donation process, little was reported on the actual testing of the tools for their effectiveness in increasing the quality of the donation process. Loor et al[3] developed a checklist for thoracic donor assessment, the tool was reviewed by experts but no testing was mentioned. Similarly, to the study from Healey et al,[26] where tools were reviewed by the forum participants and modified based on feedback received. Also, Cavallin et al[16] developed an application for iOS devices for donor screening, and the they mentioned that the pilot test was successful, but without further details. None of the studies from this review reported on actual outcomes that could indicate the effectiveness of QI tools to improve the quality of the process approached.

The development of effective QI tools and strategies in healthcare settings requires the use evidence-based information. Still, the reports included in this review lacked details regarding the methods and theoretical evidence used in the development of QI tools for deceased organ donation, and from the 40 references included, only 9 presented this information. This lack of information on whether adequate methods to develop the tools had been used can negatively impact the implementation process of QI tools, as well as reduce its transferability to other settings. Authors from a systematic review[53] on the effectiveness of QI strategies highlighted that although QI is important for healthcare practices, the current evidence on its effectiveness is uncertain, which is due to poor quality of evaluations and the complexity of healthcare services.

Various types of QI tools are used to manage deceased organ donation processes, and included checklists, algorithms, flow charts, charts, pathways, decision tree maps and mobile apps. Due to the lack of reports on actual measurements related to the implementation of the QI tools from this review, it was not possible to evaluate which tools are associated with improvements in deceased organ donation processes. Nonetheless, there is evidence that aspects influencing the effectiveness of such interventions, regardless the choice of tool, include the use of evidence-based information to develop protocols/tools, and team meetings to discuss interventions and frequency of those meetings.[53 54] To better understand whether QI tools can improve the deceased organ donation process and provide solutions for the current issues faced by the donation and transplantation system, more studies investigating the development and use of QI tools is currently needed.

This scoping review brought important information that can be used to guide improvements in healthcare practices, including enhance the quality of organ donation processes and reduce missed opportunities. Still, there are still some limitations of this review that are worth noting. We believe that other QI tools that would be relevant to this study exist but have not been published or been made publicly available because many such tools are often created as part of local QI initiatives within organ donation organisations and hospitals. Also, scoping reviews use a subjectivist epistemology and, therefore, our results can be limited for direct application into clinical settings.

CONCLUSIONS

In this study, we mapped the existing international QI tools used to support the deceased organ donation process in its different phases. The information summarised in this document will allow healthcare professionals to easily locate the existing tools for each step of the donation process to be adapted to clinical practice. In addition, this work offers a unique contribution to the literature as clinicians and researchers planning to develop, implement and test QI tools and strategies in the healthcare field, particularly in the organ donation community, now have a thorough summary of the existing tools in the field.

This review also highlighted that there is a lack of description of the methods used in the development of existing QI tools, which can negatively impact the applicability. Additionally, most of the tools in this review were identified through searching in grey and/or unpublished literature, showing a lack of publication from organisations of their QI strategies. What is more, only one study mentioned testing of the tools and two mentioned reviewing the tools, still, none of them presented actual outcomes, so this review cannot claim or quantify the actual efficiency and/or impact of QI tools in the quality of deceased organ donation processes.

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