Trials

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Views on consent approaches used in emergency and critical care research: a rapid, systematic review

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Abstract

Background Obtaining informed consent can be challenging in emergency and critical care research due to the acute and severe nature of the patient's condition. However, such research is urgently needed to inform practice and optimise patient outcomes. While alternative consent approaches have been commonly used, opinions may vary, particularly among diverse and underserved patient groups and in the context of the recent COVID-19 pandemic. The objective of this review was to assess views of alternative consent methods in emergency and critical care research.

Methods We conducted a rapid systematic review to understand diverse opinions of alternative consent models used in emergency and critical care research with searches of MEDLINE, EMBASE, PsycINFO, Web of Science and CENTRAL carried out to July 31, 2024. We included quantitative and qualitative studies and summarised findings using narrative synthesis. We specifically investigated underserved groups and consent in the pandemic setting.

Results From 9974 citations, we screened 289 full-text articles, and included 145 eligible studies from 26 countries. Consent methods included prospective informed consent, deferred consent, surrogate decision maker consent, healthcare professional consent and waived consent. Groups represented included previous trial participants, relatives of trial participants, patients, members of the general public, healthcare providers, researchers, site staff, and research ethics committees. It was recognised that prospective informed consent from the patient is not possible in all scenarios. In general, alternative consent models were acceptable, with emphasis on the inclusion of the patient and relatives in the decision-making process whenever possible. Acceptability of alternative consent models was influenced by previous research participation, experience of critical or emergency illness, perceived risk of participation, and invasiveness of the intervention. Study staff highlighted potential limitations of some alternative consent models, such as unavailability of relatives. Pandemic studies showed an increased need for alternative consent methods, and greater preparedness and engagement with ethics committees to facilitate implementation. Sub-analysis evaluating the views of underserved groups did not show consensus, and accommodations were largely not reported.

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Conclusion Alternative consent models used for emergency, critical care and pandemic research including deferred consent, relative/surrogate decision maker consent, and physician consent were generally acceptable.

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Keywords Emergency research, Critical care research, Intensive care, Consent, Surrogate decision maker, Pandemic research, Rapid review, Diversity, Inclusion

Background

Informed consent is central to research involving human participants to respect the rights and autonomy of participants [1, 2]. Due to the nature of emergency and critical care research, it can be difficult or impossible to fulfil the requirements of prospective first-party informed consent. Patients may be unconscious, sedated, or in too much pain and distress to understand information and communicate their wishes. In a study of 498 patients with critical illness, only 2.6% were able to give consent before randomisation and only approximately one third recovered sufficiently to provide consent [3]. Nonetheless, research related to emergency and critical care settings is essential to improve patient outcomes and facilitate evidence-based medicine.

To address this, alternative consent approaches to prospective written consent are used in this setting, including deferred, waived, surrogate decision maker (SDM) consent, usually by a patient's relative or other suitable person close to them, and independent healthcare professional (HCP) consent. There are limitations to these approaches, such as difficulties locating and approaching SDMs, lack of understanding between consent for treatment and consent for research (therapeutic misconception), variations in acceptability/legality across jurisdictions, and systematic exclusion of specific populations [4].

Our previous review focused on this topic (2015) found that patients, members of the public, SDMs, clinicians and research staff found alternative consent methods for research in emergency situations generally acceptable [5]. Subsequently, the COVID-19 pandemic highlighted the importance of health research, and emergency and critical care worldwide. Consent for emergency and critical care research is further complicated in a pandemic setting, where patients' SDMs may not be able to visit the hospital to provide consent due to infection control or visiting restrictions. We are now updating our previous systematic review on acceptability of consent approaches to include evidence from the last decade, as the previous review included only a single study related to pandemic research.

We also wish to investigate the views and opinions of traditionally underserved groups in clinical research. Attitudes towards consent processes used in emergency settings may differ among these patient groups, as has been previously noted to be the case among ethnic and racial minorities [6]. Underserved groups such as those with low literacy levels, communication barriers, and cognitive or physical impairments are some examples of groups who require additional considerations during the consent process to ensure appropriate understanding.

Exploring the perspectives of all interested parties affected by emergency and critical care research, including patients, the public, underserved populations, SDMs, research ethics committees (RECs), researchers, policymakers and funders, is needed to identify the most appropriate consent approaches that enable the conduct of research while protecting the rights and interests of participants. Our current review aims to summarise views and opinions on the various consent models for emergency and critical care, with a specific focus on pandemic research and underserved populations.

Methods

Selection criteria

We conducted a rapid review, which can be completed in a shorter timeframe to traditional systematic review methods, without major compromises in the quality of results [7]. Rapid reviews are increasingly used by policy makers and have been used in clinical decision-making [8–10]. Guidance released by the Cochrane Rapid Reviews Methods Group [7] was followed in this review and the protocol was pre-registered on the PROSPERO database (CRD42023408305). As such, our search was limited to the English language, reference lists were mined in included studies, 50% of citations were screened by a second researcher, a single researcher conducted data extraction and quality assessment, and evidence was synthesised narratively. The funders had no role in study design, data collection, analysis, or the decision to publish.

Types of studies and participants

We included research studies using any method, involving a spectrum of patients including adult, maternity, and paediatric research. Views of groups including previous study participants, previous patients or members of the public (with and without experience of emergency and critical care medicine, who have not participated in

a trial), their SDMs, healthcare professionals (HCPs), research ethics committee (REC) members, regulators and research staff, related to consent approaches used to enrol patients in emergency and critical care research were included. Definitions are provided in Table 1. We included studies published in English from 1996 onwards, as the international harmonisation of Good Clinical Practice including consent processes occurred in 1995. We excluded studies reporting on consent approaches for treatment, not research, as well as in the fields of neonatology, end-of-life care, organ donation and non-emergency or elective healthcare. We also excluded protocol papers, reviews and meta-analyses, opinion pieces, commentaries, editorials, unpublished articles, conference abstracts and book chapters.

Outcomes measures

The main outcome of interest was the views and opinions on consent models used in emergency or critical care research. We were intentional about capturing opinions on pandemic research, the views of groups which are traditionally underserved in clinical research, and the barriers and facilitators to research consent among those groups.

Search methods for identification of studies

We searched the following databases from until July 31 st 2024: MEDLINE (OvidSP), EMBASE, PsycINFO, Science Citation Index Expanded and Social Sciences Citation Index (SSCI) (Web of Science) and Cochrane Central Register of Controlled Trials (CENTRAL) including studies published from January 1 st 1996. We used the snowball method to mine references of included texts for further studies meeting the inclusion criteria. The search strategy was based on our previous review addressing this topic with additional terms related to COVID-19 [5]. This includes searches for informed consent, emergency care and pandemic research associated synonyms, along with an adapted filter to search for participant views including study design (e.g. qualitative, process evaluation) and outcomes (e.g. preferences, acceptability). The full search strategy is available in Additional file 1.

Selection of studies

All titles and abstracts were reviewed for inclusion and exclusion by at least a single reviewer (NM/EC) and 50% were reviewed by a second reviewer (NM/EC) with conflicts resolved by consensus.

Table 1 Summary of consent model definitions

Term	Definition
Emergency, critical and intensive care research	Research which includes participants who are in a serious or life- threatening condition, requiring immediate or time-sensitive intervention
Prospective informed consent	The provision of written, signed, informed consent to participate in research by the patient prior to enrolment, after receiving detailed explanation of the study activities according to local requirements. This may include witnessed oral consent in cases where the patient cannot sign for themselves
Surrogate decision maker (SDM) Consent	Informed consent provided by an appropriate relative, friend, or other person close to the patient who represents the wishes of the patient to be enrolled/excluded. This is carried out prior to randomisation, and consent to continue is usually provided by the patient if/when they regain capacity. In some jurisdictions, there is a legal element to who is delegated to act as an SDM
Healthcare professional (HCP) consent	Informed consent provided by a healthcare professional, who is ideally independent of the patients care, prior to enrolment. Consent will usually then be obtained from an SDM or the patient when appropriate, explaining that they were previously enrolled under HCP consent
Deferred consent	Informed consent from the patient or SDM takes place after a patient has been enrolled in a trial, when appropriate
Waived consent	A full informed consent procedure does not take place at any point, before or after enrolment to a study. Use of this method was most commonly reported from the USA, where a community consultation of acceptability may take place prior to initiation
Opt-out/in consent	Participants are not formally approached to take part in a study at the time of enrolment, but are offered the opportunity to opt in/out before or after. For example, a trial may advertise the opportunity to be added to an 'opt-out' list in the community in which the trial is being conducted, so a potential participant who has joined the 'opt-out' list will not be enrolled if they have the condition being studied
Verbal assent	Patients/SDMs are provided with (usually) abridged information about the trial at the time of enrolment, so they can give a verbal yes/no decision on enrolment, and complete the full informed consent procedure when their condition has stabilised post-enrolment

Data extraction and analysis

Data extraction and management

A single researcher (NM) extracted data including the general study characteristics and methodology, consent model, respondent group, evidence of acceptability and inclusion of underserved groups. We used a pre-developed and tested form for data extraction [11] (provided in Additional file 1) and no assumptions were made for missing or unclear information.

Assessment of quality of included studies

A single researcher (NM) carried out quality assessment for each paper included, using the CROSS checklist for survey studies [12] and the CASP checklist for qualitative research [13]. In accordance with PRISMA 2020, methodological appraisal was used to identify study limitations and potential sources of bias, rather than to generate quantitative risk-of-bias estimates or stratify results by study quality.

Grouping of studies for analysis and narrative synthesis

We used narrative synthesis to summarise results in accordance with ESRC Methods guidelines [14]. We grouped studies for synthesis by consent model and study population and classified as waived consent if a specific requirement for informed consent to be obtained when the patient had regained capacity was not detailed. We analysed studies with results not directly related to any of the identified standard consent models separately. Efforts were made to address the results of all included studies in the narrative synthesis, with emphasis on findings that offered particularly valuable insights in the context of the evidence base. Percentage agreement/disagreement with consent model use and associated confidence intervals (CI) were reported where available. We provided a specific focus on pandemic studies and those that specifically enrolled patients that are traditionally underserved in emergency and critical care research. For such studies, we extracted any accommodations made to consent processes, and if acceptability of alternative consent models differed in underserved populations. Identified barriers and implemented accommodations were collected as part of this review.

Results

Study selection

A total of 9974 results were returned from the searches with 645 removed as duplicates. The remaining 9329 titles and abstracts were screened leading to the identification of 289 potentially relevant articles for full-text screening, of which 132 were suitable for inclusion. A further 13 publications were identified from mining of reference lists for a total of 145 included studies. Reasons for study exclusion are summarised in the PRISMA diagram (Fig. 1).

Study characteristics

The characteristics of the included studies are outlined in Supplementary Tables S1–S8 (Additional files 2–9). The included studies consisted of 25 mixed methods studies, 66 quantitative studies and 54 qualitative studies across 26 countries. Participant numbers varied widely (10–74 participants and 20–23,832 participants for qualitative and quantitative studies, respectively). 28 studies discussed prospective informed consent, 40 surrogate decision maker consent, 30 deferred consent, 46 waived consent, 19 healthcare professional consent. 24 studies were paediatric studies, 12 were pandemic-related (6 COVID-19, 2 general concept of epi-/pandemic research, 4 other specific epidemics) and 10 included other alternative designs. The majority of studies focusing on waived consent were conducted in the USA (73%), but there was a relatively wide spread of countries across all other consent categories. Areas of research included critical care, myocardial infarction, stroke, trauma, and obstetrics.

Quality assessments

The vast majority of reports had clear statements of aims or objectives (91%) and disclosed conflicts of interest (82%), lower numbers provided details of the roles of funders (45%).

Quantitative studies

Non-response bias was deemed high in 26% of studies, low in 49% and unclear in 25%. Incomplete outcome bias was deemed high in 6% of studies, low in 54% and unclear in 40%. Surveys/questionnaires were provided in full for the majority of reports (74%). Statistical analysis methods and software were widely provided (84%). The survey/questionnaire was pretested in the population of interested in 48% of reports. Details of a sample size calculation were presented in a minority of studies (14%), however as many of the studies were classified as exploratory studies this was not necessary in all cases. The demographics of the sample that completed the study were compared to the demographics of the general population of interest for representativeness in 30% of studies. 10% of studies provided details on rates of missing data or how missing data was dealt with in analysis. Non-response rate was provided in 48% of studies and non-response error was not addressed in any analyses.

Qualitative studies

Using the CASP checklist for qualitative research [13], qualitative methods were generally appropriately used

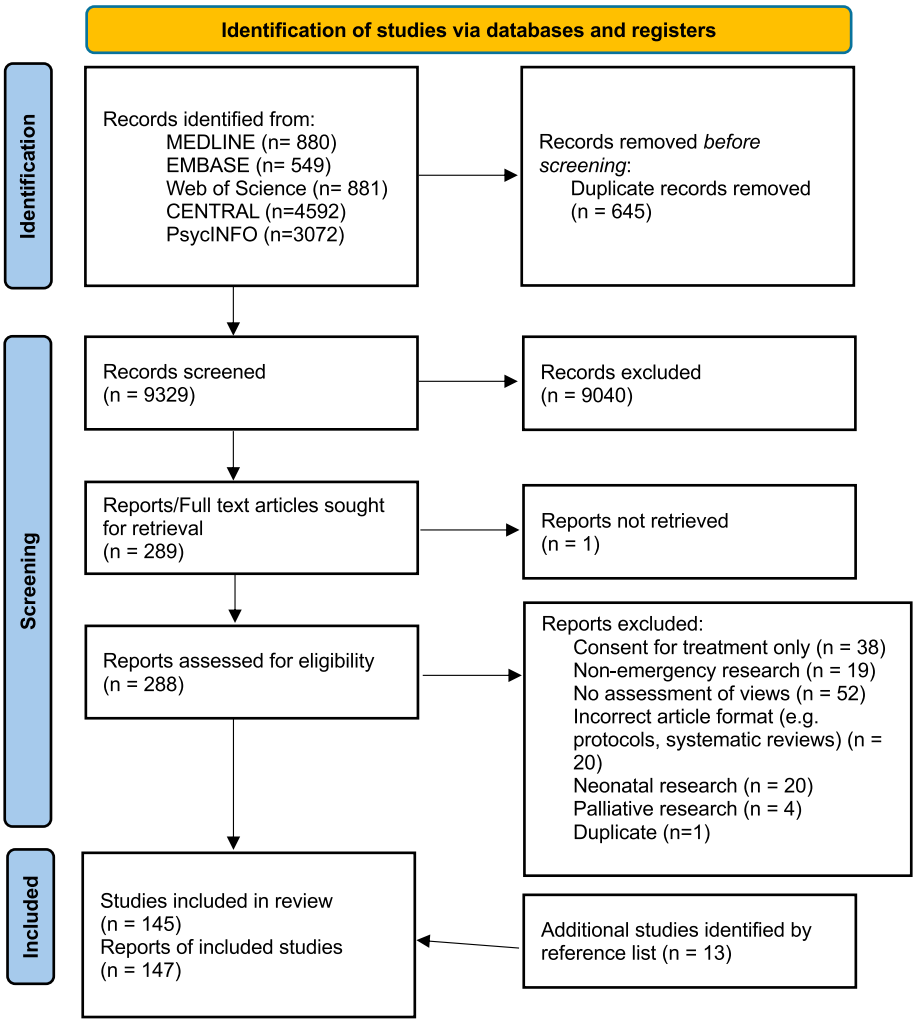

Fig. 1 PRIMSA flow diagram of systematic review process. Template obtained from Page MJ, et al. BMJ 2021;372:n71. https://doi.org/10.1136/bmj.n71. Two identified studies were mapped to 2 reports each, resulting in 145 included studies from 147 identified reports

with reasonable recruitment strategies (85% appropriate, 14% insufficient details). The majority of studies did not adequately consider the relationship between the participants and the researcher and its potential for influence in the report (71%). Data collection/analysis methods were deemed appropriate in 90% of cases and there was insufficient detail in 4%. Non-response bias was deemed high in 25%, low in 40% and unclear in 35%.

Consent model opinions

Prospective informed consent

Prospective informed consent was considered in 28 studies. 17 of these included those who had previously been approached for participation in an emergency or critical care research trial, 4 included those who had previous experience of an emergency medical situation as a patient, 6 included researchers/site staff, 2 included HCPs, and 1 included members of the public.

Previous research participants Opinions from previous myocardial infarction and stroke trial participants on whether they should be approached for prospective informed consent and self-assessed capacity were mixed, with some previous participants finding enrolment decisions difficult to make [15–17], and others reporting positive views on their prior consultation [18, 19]. Among participants of a stroke trial, 28% of the patients felt they had been capable of making an adequate decision [16]. In qualitative studies of participants involved in obstetric trials, most participants noted that they were too exhausted or overwhelmed to read and retain even short trial materials and were approached in a very vulnerable moment [20–23]. Poor understanding and recall of study

details from the participants was consistently reflected in the included studies [16, 17, 19, 22, 24–27].

Previous patients/members of the public Those who had experience of an emergency medical situation were asked for their opinions on providing consent had they been asked to participate in a trial (hypothetical scenario). Previous patients acknowledged that they would not have been in a position to make such a decision during critical illness [28], acute brain injury [29], stroke [30], or post-partum haemorrhage [31] with inconclusive views for general emergency research [32]. Others expressed a desire to be involved in the consent process if possible, but did acknowledge that there were limitations to this [33, 34]. Obstetric patients expressed a desire to be approached for research when their clinical situation had stabilised instead of during the emergency [35]. Among the general public in the USA, 51.1% chose prospective written consent as their preference for a myocardial infarction trial, with 45.8% selecting notification after enrolment as their preference [36].

Research staff and HCPs Concerns about adequate understanding in an emergency setting were reflected in the opinions of both research and clinical staff. Study staff and researchers participating in recruitment cited challenges with obtaining prospective informed consent [37, 38] including determining whether severely ill patients were competent [27, 39] and worrying about approaching them at a vulnerable time [40, 41]. Staff also noted pain and distress as barriers to participants' ability to concentrate on the consent procedure in a peri-partum trial [20, 21]. Along with participants, staff expressed the benefits of giving verbal information at this point and providing full written information sheets later. Additionally, paramedics expressed concerns about obtaining prospective written consent prior to hospital arrival [42, 43] with the potential of a delay in emergency transportation [44].

Surrogate decision maker consent

There were 40 studies identified which considered consent by a SDM. Seven of these included previous participants of emergency trials, 13 included those patients with experience of emergency or acute medical situations, 18 included SDMs, 6 included researchers/site staff, 2 included members of RECs, 6 included HCPs, and 7 included members of the public.

Previous research participants/SDMs Those who had been previously enrolled in a trial through SDM consent from a relative were generally positive about the process, as were the relatives who had provided consent [16, 45–48]. Capacity was questioned by participants of a post-partum haemorrhage trial, with some noting their partner would also be compromised by the emergency situation post-birth [22]. Timing remains an important factor. One study of SDMs who were approached to provide consent on behalf of a critically ill family member found that 29% of those who declined consent would have agreed if they were approached at a later time and 67% said they were too worried to consider a research study at that time [49].

Previous patients/members of the public Similar results were found for those who had experience of emergency care but not in research participation. Consent by an SDM was selected as the main preferred option if the participant could not consent for themselves [34, 50–53] and there was widespread acceptance of SDM consent [28–30, 54–64]. One study observed only 26% agreement with relative consent while 55% of responses were neutral [65]. Distress was seen to be a factor [66, 67], which was reduced if relatives had received an update on the patient's condition prior [28, 38, 60]. The risk of the proposed intervention was also identified as a factor in acceptability of SDM consent [28, 54, 55, 60, 66]. However, increasing the risk of harm did not change patient preference for SDM consent over deferred or waived consent [50]. Among those who had experienced a post-partum haemorrhage, asking their partners for consent at this time evoked mixed views and most felt this approach was not acceptable as many partners said the burden would be too great for them at that time [31]. Limitations of this consent approach when an SDM is not available were acknowledged [68].

Research staff, HCPs and ethics boards Among researchers, staff, and RECs, views were again generally accepting of the use of SDM consent [28, 42, 68–70], but also highlighted some potential issues. Researchers noted that most critical care research was time-sensitive and therefore often did not coincide with an appropriate time to consult with SDMs [38, 41, 43, 70]. HCPs also questioned whether SDMs had capacity to make an informed decision during this time of distress [48, 70]. There were potential difficulties in identifying which relative should act as the SDM for the patient, particularly in cases where there were disagreements between the views of relatives [38].

Healthcare professional (HCP) consent

Nineteen studies discussed HCP consent for emergency research. 3 of these included previous emergency trial participants, 8 included those with experience of an emergency medical situation, 10 included SDMs,

4 included researchers/site staff, 4 included HCPs, 2 included REC members and 2 included members of the public.

Previous research participants There was a lack of studies including participants enrolled under this consent approach, potentially reflecting the current limited use of this consent option globally. Among previous participants of an ICU-based trial, 16.8% listed 'the intensive care doctor looking after me' as their preferred option for someone who could consent on their behalf, while 5.4% listed their general practitioner [45]. Some previous participants of an acute myocardial infarction trial noted that they wanted advice from a doctor, but did not want the doctor to make the enrolment decision for them [15].

Previous patients/members of the public A high proportion of those who had experience of emergency situations were supportive of physician consent (74–92%) [17, 30, 56, 61] in addition to members of the public (72–74%) [56, 64]. Acceptance was higher when patients had no known/contactable relatives to act as SDMs to provide consent [28, 29, 68]. SDM consent was preferred over physician consent for unconscious patients, except in cases where the patient did not have an available SDM [34, 52]. There were mixed views from those who had experienced a post-partum haemorrhage [31]. Participants were less accepting of enrolment by emergency medical technicians for an out-of-hospital trial [29].

Research staff, HCPs and ethics boards Acceptance from HCPs and research staff was dependent on the scenario, again with higher acceptance when an incapacitated patient had no contactable relatives [28, 38, 69], with a preference for deferred consent [71]. RECs were much less comfortable with this approach [68, 69]. Paramedics were generally happy to provide consent, followed by deferred SDM consent when they reach the hospital, but noted multiple issues including conflicting priorities [42–44].

Deferred consent

Thirty studies investigated deferred consent. Thirteen studies included previous participants of emergency trials, 5 included those with prior experience of an emergency medical situation, 11 included SDMs, 9 included researchers/site staff, 6 included HCPs, 2 included members of RECs, and 4 included members of the public.

Previous research participants Among those who had been enrolled under deferred consent and those acting as SDMs, there were high levels of acceptability (61–100%) [22, 23, 45, 48, 72–76] with one notable exception where there were high rates of disagreement to its use in a stroke trial [77]. Acceptability has been seen to vary based on whether the included participant had a 'good' versus 'bad' outcome in the course of their illness [75, 78]. Similarly, disclosure of positive study outcomes led to more positive views of participant inclusion and disclosure of negative study outcomes led to more negative views [79]. In some cases, poor understanding and recall of the consent discussion were noted, potentially due to being approached for consent before they had fully stabilised [22, 40, 75, 76]. There was no consensus on when in their recovery participants wished to be approached [40, 78] but providing some information early on helped participants to make sense of the study when they were approached for deferred consent at a later stage [80].

Previous patients/members of the public Deferred consent was again broadly acceptable among those who had not previously participated in a trial but had experience of a critical illness [30, 50, 52] and the general public [53, 81]. Views were more mixed in a survey of stable emergency department patients [82]. Related to the timing of deferred consent, a large majority of respondents indicated that they would prefer to be informed immediately or as soon as possible [81, 83]. Participants also stated that their feelings towards deferred consent would depend on what health state they were in when they regained capacity [32].

Research staff, HCPs and ethics boards Research staff reported high levels of acceptability towards deferred consent and rarely encountered anyone who declined to continue in a trial [39, 71, 72]. As with previous participants, deferred consent was not the preferred option if an SDM was available to provide consent prior to their enrolment [69]. In addition, there were some concerns from REC members and HCPs about the legal status of deferred consent and the potential for this process to be abused [68]. Research staff described being under pressure to obtain consent to continue before the participant was discharged [39, 40]. Similarly, there were concerns over ICU memory deficits and lack of recall when taking deferred consent [84]. Experience was found to be a facilitator for research staff in obtaining deferred consent as they are more comfortable with deciding on an appropriate time to approach the patient/SDM [37].

When a patient dies before consent is obtained A major difficulty with the use of deferred consent is that in many emergency or critical care research studies, the mortality rate can be as high as 60% and death often occurs before

consent to continue has been obtained from the participant or an SDM [3]. Views on all aspects of this situation were mixed [68]. Researchers had conflicted views on if and how to disclose study enrolment to families when a relative dies prior to consent being obtained and felt further guidance was needed in this area [38]. There was no consensus from survivors of critical illness and their families on whether consent should be obtained from relatives following a death [28, 38, 55, 78, 83] and if so when they should be approached [28, 78, 85]. HCPs and REC members also highlighted the bias introduced by excluding these participants from research [68].

Waived consent

A total of 46 studies discussed waived consent or exception from informed consent. Eight of these included previous emergency trial participants, 12 included those with prior experience of an emergency medical situation, 2 included researchers/site staff, 3 included members of RECs, 7 included HCPs, 12 included SDMs, and 18 included members of the public. A community consultation is a requirement for some studies conducted under exception from informed consent (EFIC) in the US, and therefore there were many studies published as the result of these community consultations.

Previous research participants Views from previous research participants were mixed, with the majority of those who took part in a stroke trial disagreeing with automatic enrolment [77], a majority agreeing with EFIC in a pre-hospital status epilepticus trial [86] and a pre-hospital cardiac arrest trial [48]. It was noted that SDMs should be involved if available [86]. Higher acceptance levels were seen among participants who had been enrolled in a traumatic brain injury (TBI) trial conducted with EFIC than in the prior community consultation (78% and 72%, respectively) [87]. Again, the level of study risk is a factor in acceptance [78, 88]. One study in the USA where whole buildings participated in a trial with community residents trained as lay responders to cardiac arrest was conducted under EFIC. When residents were asked about waived consent they were often strongly opposed, despite strongly supporting the cardiac arrest trial they were involved in which used a waiver [46].

Previous patients/members of the public Some studies saw a clear disagreement with research conducted under waived consent [33, 34, 50, 63, 85, 89, 90] whereas others saw acceptability rates of around 50–60% [61, 62, 83, 91–95]. Some found support for waived consent/EFIC research [29, 79, 96–101]. Acceptability for their own enrolment in EFIC studies was higher, compared to the general idea of EFIC research [62, 63, 83, 89–91, 101]. The associated risk of the study was again seen to be associated with acceptance, with waived consent being more acceptable for observational and low risk studies [57, 82, 89, 102]. There was a strong preference for providing information about the trial to patients and families and giving them the option to opt-out at a later stage [100]. Among members of the public who requested an opt-out bracelet for a cardiac arrest trial conducted under EFIC, 87% objected to all research using EFIC, citing reasons such as disagreement with research conducted without consent, prior negative experience with medical research and unwillingness to be involved in any medical research [103].

Research staff, HCPs and ethics boards The majority of REC members from US Institutions believed that the EFIC regulations were protecting human subjects if followed adequately [104]. Acceptance was much lower among Canadian RECs [69] and difficulties in obtaining ethical approval for this consent approach were anticipated in the UK if it were to be introduced [38]. Investigators and researchers indicated a preference for requesting SDM or deferred consent, rather than waiving the requirement [70, 71]. A survey of 23,832 EMS providers found that only 30.9% (99% CI: 30.1–31.6) agreed that there are situations where it is acceptable to enrol patients without consent [105]. Another study found a higher rate of acceptance, at 52.4% with 20.9% being neutral [106]. There was also concern surrounding being liable for any harm caused by the research protocol [107].

Paediatric

Prospective SDM informed consent As with SDM consent for adult participants, there are limitations in emergency trials due to distress and worry. Many parents did not feel that meaningful informed consent was possible while attending the emergency department with a seriously ill child [108, 109], specifically if the child was undergoing major surgery [110] or within 30 min after resuscitation for paediatric cardiac arrest trials [111]. A critical care trial which used prospective informed consent saw high levels of acceptability and understanding among parents who had given consent; however, 25% of those approached for the study declined participation [112]. In paediatric intensive care, signed prospective informed consent was the option favoured by the highest proportion of parents, waived consent was the lowest, with 74% (95% CI 60–84%) accepting of an alternative consent approach for minimal risk observational study (opt-out, physician consent, broad authorisation, waived) [113]. Timing of consent was again identified as

important in cases where guardians declined [114] while hesitancy for one parent to provide written consent without the other present was noted [115].

Additionally, some HCPs were concerned about parents' ability to give prospective informed consent in an emergency, as it may be an additional burden and their understanding may be poor due to stress [116, 117]. Several included studies supported this concern, as levels of understanding and recall were found to be poor [115, 117, 118].

Deferred consent Deferred consent was generally supported by parents [108, 109, 112, 114, 119–123]. They described how the consent conversation should take place when their child's condition had stabilised [109, 115, 119, 122, 123]. HCPs were again accepting of deferred consent [116, 124, 125]. One study of the opinions of children aged 7–15 years who had experience of an emergency setting saw high acceptance and willingness to be involved in the deferred consent discussion [126]. As noted above, there were concerns about the level of parental understanding of the trial, even when consent was deferred [121]. In one study which obtained initial verbal consent at enrolment, followed by a full informed consent later, staff questioned the validity of the initial prospective consent as many parents could not remember it [124]. The majority of bereaved parents stated that they would like to be told about the trial [119, 122, 123]. They did, however, acknowledge the associated complexities, with no consensus on the right time and format. Among those who had not experienced the death of a child, views were inconclusive [85, 123]. Most staff supported a waiver of signed consent in the case that the included child died following parental verbal assent [124].

An EFIC community consultation for a paediatric study found that 70% of those included supported children being enrolled in an anti-seizure trial without prior consent [127].

Epi-/Pandemics

There was acknowledgement from the research community that alternative consent models are required in a pandemic setting [39, 128–132]. In a study carried out after the 2009 H1N1 pandemic, 74.4% of research coordinators agreed that alternative consent models were needed in a pandemic setting [128]. Those experienced in working for an international humanitarian medical organisation during the 2013–2016 Ebola virus outbreak described informed consent procedures for clinical trials as areas for improvement, and stressed the importance of vulnerable patients being consented in a culturally appropriate manner [133].

This is reflected in the views of the general public where our group previously investigated the public's views on consent in a hypothetical influenza-like pandemic through European focus groups [134] and an international public survey [135]. Focus groups questioned the validity of prospective informed consent when they or their family members were unwell or distressed [134]. They viewed pandemics as 'exceptional circumstances' where 'different rules or thresholds' for research should apply with simplified and alternative consent approaches suggested. In the multinational survey ($n=6800$, 8 countries), 74.8% of respondents believed that special rules should apply to make pandemic-related research feasible [135]. For those willing to participate in ICU research, SDM consent (35.3%), deferred consent by a HCP (28.1%) or a relative (20.0%) were the most preferred consent options with waived consent the least favoured (12.4%).

COVID-19 Informed consent was identified by RECs in South Africa and Germany as a key challenge in the COVID-19 pandemic, particularly where patients and SDMs required isolation [132, 136, 137]. In South Africa, there were divergent views on when deferred or waived consent was appropriate [137] and RECs said they were insufficiently prepared to deal with alternative consent models, with difficulties classifying who would be restricted from providing consent. Among the literature, suggested solutions to address consent challenges during COVID-19 included deferred consent, telephone/video consent, electronic signatures and researchers and patients signing separate forms to avoid contamination [39, 129, 130, 136], while oral consent was considered challenging to prove and not widely used in European countries [130]. There were concerns raised about disadvantaging participants with lower technology literacy or access when using electronic methods [129].

Research staff highlighted the need for adaptive consent strategies [39] with the pandemic described by some as enabling and driving long-awaited changes including remote forms of consent. Physicians were more comfortable with the use of deferred consent for a randomised trial of a medication of unknown efficacy or safety in a pandemic setting compared to a non-pandemic setting [131]. In a study repeated before and after the COVID-19 pandemic, more respondents in the post-pandemic cohort preferred study-specific consent to broad consent (45% vs 38%, respectively), though some form of consent was still felt to be important to respect individual preferences [138]. Opt-out approaches were acknowledged to

be relevant for researchers, but opt-in approaches were still often preferred [138]. There was emphasis on implementing consent strategies for those who cannot provide consent in advance of a future pandemic [132].

Other

There were some additional alternative consent approaches, or adaptions to these approaches, discussed in the included studies.

Verbal consent Verbal consent or assent (where full written consent will be provided later), in lieu of a full signed informed consent procedure was supported by participants during emergency situations where the patient remains conscious [17, 18, 20, 21, 36, 111, 139] and understanding of the study was seen to be comparable to written consent [140]. This was also supported by researchers for the pre-hospital setting [42]. However, study staff had concerns around participants and SDMs not remembering the consent discussion and a potential lack of opportunity to get the form signed retrospectively [20, 21]. Participants of an obstetric trial detailed feeling it would be inappropriate to discuss research during a traumatic time [23]. Participants that gave verbal consent at the time of ICU admission did not object when approached for written consent at a later date [74]. Despite this, in paediatric study, staff questioned the validity of the assent provided as many parents could not remember this initial assent process when written consent was sought at a later time [124].

Opt-in, opt-out, and consent prior to eligibility In some cases, participants were supportive of an opt-in or opt-out system, where for example wearing a bracelet or carrying a card to indicate their preference [51, 97]. However, study staff were quick to question feasibility, with excessive cost and staff burden [42]. Two studies which did have opt-out procedures and advertised them in the community [79] or study hospital [141] saw a lack of awareness of this option, with some participants stating they would have chosen to opt out if they had known [79, 141]. A different approach, where patients were given a short summary by EMS personnel and given the opportunity to opt-out, was seen to be acceptable and effective [142].

Consent in advance of study eligibility among those who are at risk of the disease was considered. In a study of patients at risk of healthcare-associated pneumonia, patients and caregivers expressed little concern about being approached for study participation before developing the condition and were unsurprised about their increased risk [143]. REC members and physicians also did not object to this strategy. In contrast, problems were identified with this approach in a paediatric cardiac arrest trial and an obstetric trial, as it may cause unnecessary emotional burden among those who are not of specific additional risk of developing the condition [23, 111]. In this case, parents therefore suggested distributing brochures with study information and having posters around the hospital instead.

Telephone and E-consent methods In some non-pandemic studies, there were concerns regarding telephone consent, with it being found to be potentially more impersonal and overwhelming, along with difficulties processing trial information without being physically present [78, 144, 145]. A total of 64% of ICU patients, 76% of their relatives and 59% of HCPs considered it acceptable to conduct SDM consent over the phone [28]. In qualitative discussions, HCPs criticised this approach as they could not gauge body language to tailor their approach. Participants said that telephone consent was 'better than nothing' but should only be used for time-sensitive studies. Telephone consent was found to have similar levels of understanding to face-to-face consent [146]. An acute care stroke trial which investigated using an e-consent process with SDMs found that 91% rated the experience as 'excellent' or 'good', with 22% preferring paper consent [147].

Underserved populations

Ethnic minorities Consent opinions among minority ethnicities varied across included studies, with the majority of studies which investigated these factors being EFIC community consultations in the US. There was no association between race and acceptability of EFIC in some studies [57, 62, 97, 99, 101], but others found lower acceptance in Black [127] and Hispanic communities (~23% compared to 58%) [94], Black, Asian, and other ethnicities [127, 148], and non-White participants [86, 89]. In one study, there was no difference in acceptability between Black and White respondents but significantly lower EFIC acceptance among 'other' races [62]. In addition, more Black participants in an epilepsy trial disagreed with enrolment without their prospective consent (36%; 95% CI 28–44%) compared to White (23%; 95% CI 16–31%) and other race (14%; 95% CI 0–29%) counterparts [73].

Educational status There was no consensus on an effect of educational status on acceptance of alternative consent. Some studies found no association [62, 87, 89, 94, 97, 100, 101, 127], while others found an association between higher education level and EFIC willingness

[63, 99]. In contrast, one study found that SDMs with a university level education were more likely to believe that informed consent should be obtained from the patient [58]. Similarly, lower educational level was associated with increased willingness for SDM consent if they were unable to decide for themselves [57], and a preference for paper over e-consent methods [147]. For pandemic research, no difference was observed with educational level, but experience of critical care and greater trust in the government increased acceptability of alternative models, while a lower level of pandemic knowledge was associated with less willingness to participate overall [135].

Religion There was no effect of religion on consent preferences in the following studies [65, 89, 97, 100]. In one EFIC trial, Catholic religion was associated with decreased willingness to participate [91].

Low- and middle-income countries There were a few studies on emergency consent processes conducted in low- and middle-income countries (LMIC) which are broadly underserved in clinical research. In two studies in Uganda, qualitative results were similar to that of other countries, with difficulties in understanding the consent process in an acute situation highlighted [35, 139]. In two studies conducted in Malawi, participants expressed that getting SDM consent was important to respect established social structures, but were also supportive of HCP consent [68, 117]. Fears surrounding blood draws for research purposes were identified as affecting consent agreement [117]. In LMICs, visual aids were suggested to help those with low literacy levels. In studies in Kenya, Uganda, and Malawi study staff mentioned that for paediatric studies, some mothers may not want to give a definitive decision on their child's inclusion without their husband present [124], and a study in South Africa found deferred consent acceptable [83].

Accommodations for inclusion in alternative consent models The majority of studies only included English-speaking participants and/or did not include information about the availability of translators/interpreters. There were a few exceptions identified, where translators/interpreters were noted to be made available [19, 26, 40, 149]. Some studies provided multiple local language options [35, 83, 93, 114, 118, 124, 144], including multiple studies carried out in the USA which provided surveys in Spanish in addition to English [46, 73, 89, 91, 98, 101, 127, 141, 148, 150]. Two studies allowed consent in English or a local language for the parent trial, but only included local language speakers in the consent sub-study [25, 72]. The majority of studies did not report on the number of potential participants excluded due to language, but those that did showed an exclusion rate of 3–14% [34, 45, 50, 118]. In qualitative comments, research staff cited difficulties in obtaining consent from parents of patients when English was not their primary language [151] and in locating an interpreter in time to recruit eligible participants [40]. SDMs who reported English as their first language were 7.25 times more likely to agree to study participation [49].

There was a widespread absence of information on any accommodations for those with low literacy levels, deaf, blind, or cognitively impaired participants. The vast majority of studies indicated that there was a discussion around providing consent for the study, rather than participants/SDMs solely being given a form to read. This would provide opportunities for those with lower literacy levels or sight impairments to have the consent information read and explained to them, but set procedures for this were not mentioned in any study. Some studies explicitly stated that they had excluded such groups, including those with a cognitive deficit/impairment or developmental delay [45, 55, 61, 72, 152], and those with written and/or spoken communication barriers [24, 27, 61, 76].

Discussion

We systematically reviewed the views and the acceptability of different consent approaches used in emergency and critical care research in order to plan future acute care research, particularly during pandemics. All groups were supportive of the conduct of such research and recognised that alternative consent processes are necessary in certain circumstances. These diverse groups were broadly accepting of the alternative approaches used, with a preference for a relative to provide consent for unconscious participants if possible. Interestingly, views were mixed on obtaining prospective informed consent from conscious patients in the emergency and critical care research field, indicating that it may not be the right option for all patients and alternative approaches may still be required. If there were no contactable relatives/SDMs, consent by an independent HCP was seen to broadly be acceptable. Pain/distress limiting the ability to comprehend information was highlighted with research staff expressing concerns over decision-making capacity, along with increased potential for therapeutic misconception due to the emergency situation. Participants preferred other discussed methods over waived consent, with deferred consent having higher levels of acceptability. RECs were generally accepting of alternative approaches, but did raise some potential concerns such as lack of acceptability in approaching SDMs shortly after

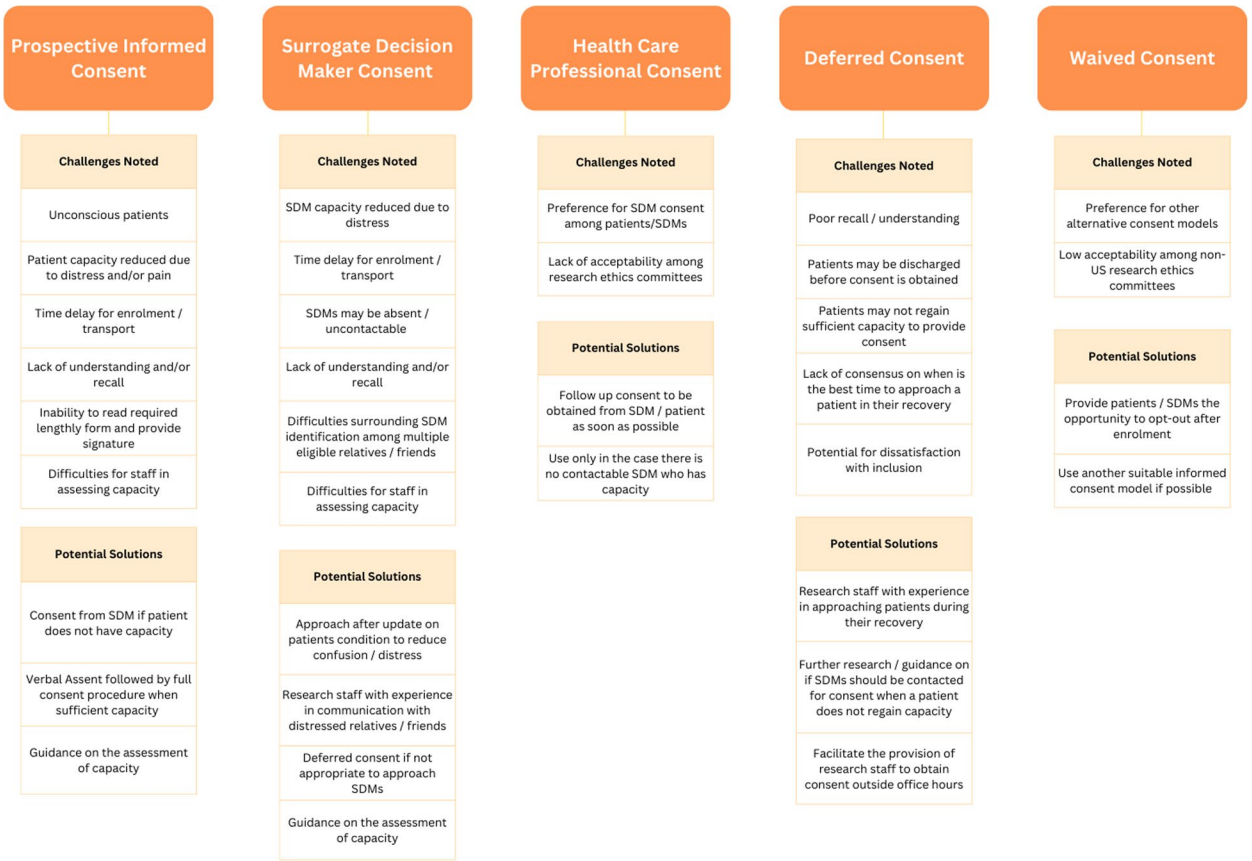

Fig. 2 Summary of challenges and potential solutions identified for each consent model discussed. *SDM-surrogate decision maker*

the acute event and were less accepting of HCP consent compared to other models, potentially due to regulatory constraints. Results are summarised in Fig. 2.

There were many factors influencing acceptability. It was dependent on the framing of the question, which varied widely across included studies, likely contributing to the heterogenous results. As previously identified, the actual or perceived risk of the described study had an influence over acceptability. Most studies found participants were less accepting of alternative consent models for higher-risk studies (e.g. novel medicinal product), with some SDMs less willing to make a decision for such studies. Acceptance was found to be higher both when individual participants had a favourable outcome from their illness or injury, and when the study was disclosed to have had a positive result. Some less widely used approaches such as verbal consent, opt-in, opt-out and consent prior to meeting eligibility criteria have drawbacks, but may be appropriate in some situations. Telephone consent, which increased in use during the COVID-19 pandemic, has remained a widely used option when deferred consent is not possible and SDMs are not physically present, with E-consent methods also acceptable in some cases [153]. These results lead us to believe that the consent approach should have flexibility, and move away from a once-off incident of signing a form and towards maintaining continuous contact to ensure sufficient understanding and acceptability [115, 124]. Paediatric and maternity research had similar results, with mixed views on prospective consent in an emergency and general support for deferred consent, even though implementation may be limited by regulatory requirements. Previous systematic reviews of paediatric emergency consent processes have shown similar results to that seen in adults [154]. Results reported here also have parallels with studies of non-emergency research consent acceptance, including concerns from research staff about understanding and comprehension, and the importance of timing [155].

Obtaining prospective consent in emergency studies where interventions are time-sensitive can cause delays in starting interventions, potentially influencing the benefit to the patient and the study results. One emergency trial testing one such treatment saw that sites which did not operate under a waiver of consent and required written SDM consent prior to enrolment

had an average treatment delay of 1.2 h that would not occur in normal clinical practice, which then corresponded to an increased mortality risk [156]. For these reasons, it can be argued that the use of appropriate acceptable alternative consent models may allow the study sample to be more representative of the population of interest and give the greatest possible benefit to the participants, particularly for interventions that are low-risk or have an established safety profile. Ethics committees, regulators, and individual investigators should consider the individual needs of the patient and the study and what would be most acceptable in the particular context, rather than a blanket approach for all emergency and critical care research. [157] have developed a thorough guidance document for obtaining consent for critical care research, including a decision-making flowchart to aid researchers, based on the views of over 1400 stakeholders [157]. The recommendations of this guideline are widely aligned with this systematic review, although implementation of some aspects may not be possible at this time in all jurisdictions (e.g. healthcare professional consent) [157].

In light of recent pandemics emphasising the need for alternative consent models, included studies found participants and the public are understanding and accepting of the greater need for accommodations for pandemic-related research. While there were more pandemic-related studies in recent years, there was still a relatively small number of studies ($n=12$). There was some evidence of a lack of preparedness of RECs and investigators to manage such alternatives in the recent COVID-19 pandemic, as consent was identified as a key challenge [132, 136, 137]. Plans should therefore be put in place in advance of the next health emergency given the likelihood of future pandemics and other health threats, including ethical and regulatory frameworks. Further qualitative and quantitative assessment of patients' and the public's views on emergency and critical care research and alternative consent approaches post-pandemic are required.

Current consent models used in emergency research may lead to bias in the study population. In a stroke trial, patients enrolled through SDM consent were older, with more severe stroke and more frequent aphasia than those included with capacity to give personal consent [158–160]. These patients also had worse functional and cognitive prognosis and significantly higher mortality [159, 160]. In a trial of antibiotics in the critically ill, those who were included in the trial had a lower disease severity score, incidence of septic shock, need for mechanical ventilation, mean length of ICU stay and mortality rates [161]. This was due to strict exclusion criteria including consent, meaning that only 13% of patients in clinical practice were eligible, indicating the study sample was not representative. Exclusion of patients who died before deferred consent was obtained was seen to introduce selection bias, make randomisation asymmetrical and decrease external validity [162]. In a systematic review of cardiac arrest trials, notifying relatives after the inclusion of non-surviving patients did not result in any negative responses [163]. In addition, SDM unavailability can account for the large majority of eligible patients who are not approached for inclusion [4]. Discrepancies in inclusion decisions made by SDMs and patients were seen to occur in 16–42% of cases in hypothetical critical care research, indicating that SDMs may not always accurately represent the views of patients [164, 165].

Groups who are considered underserved by research are often systematically excluded from clinical research despite the fact that they can usually participate with simple accommodations and often have a higher burden of disease [166]. This was highlighted in the COVID-19 pandemic, where underserved populations were significantly more affected, but were under-represented in trials [167, 168]. A review of EFIC community study consultations noted that in two-way communications, concerns were often voiced about minority patients carrying an unfair burden of EFIC research participation [169]. For example, trauma and TBI has been seen to occur disproportionately among racial and ethnic minorities in the studies' catchment areas [170]. A previous review exploring minority populations' views on deferred consent reported lower levels of acceptability [6], which may be due to experiences of systemic racism and discrimination when seeking healthcare and historical abuse of rights in clinical trials [171]. However, other studies have shown that minority ethnic populations in the USA are as likely as those who are White to provide consent to a clinical trial when asked [172, 173]. Our sub-analyses of quantitative studies to investigate an effect of ethnicity found mixed results, with a similar number of studies finding an association and not. This is likely due to the heterogeneity in classification of participants across studies, with groups such as 'non-White' participants used, rather than specific ethnic groups, a previously noted issue with these studies [6]. The majority of these studies were EFIC community consultations, possibly as only these studies had enough participants to run such sub-analyses. There was also limited qualitative data related to the experiences of minority ethnic groups found in this systematic review.

Lack of appropriate accommodations to allow for the inclusion of underserved populations into clinical trials remains a concern. In this review, very limited evidence of accommodations was identified for those with language barriers, low literacy, visual or speech difficulties.

As a consequence, there are limited published accounts of the views of those who require these accommodations for consent in emergency and critical care research, and how they can be best adapted. Reporting of diversity, the availability of translators and the exclusion of potential participants based on language requirements should be made clear at publication. In a recent ED-based observational study in Germany, of 35% of those who could not provide consent to participate, the reason was due to language barriers, emphasising the potential exclusion of a large percentage of the population [174]. Fortunately, there are now many initiatives focused on increasing representation in clinical trials such as INCLUDE (NIHR) [175], Trial Forge (University of Aberdeen) [176], and ACCESS (University of Sheffield) [177].

Strengths and limitations

The search strategy utilised in this review was comprehensive with a large number of studies identified, including a wide range of methodologies, quantitative and qualitative evidence, and diverse illnesses and settings. This has provided thorough and up-to-date insight into opinions on the full spectrum of consent approaches across many different groups (patients, public, SDMs, parents, communities, RECs, HCPs, research staff) and contexts within emergency and critical care research. This also included an increased number of pandemic-related studies, less commonly used methods and allowed us to assess underserved groups as a sub-analysis.

Although the review followed a set methodology with a pre-registered study protocol and two independent reviewers, as a rapid review it has limitations. Grey literature, unpublished studies and non-English language studies were not searched which may have provided additional perspectives from underserved groups, publication bias could not be assessed, and increased risk of human error, selection and framing bias (heterogeneity in how the question of acceptability was asked) exist. A narrative synthesis was performed, in lieu of a meta-analysis or other quantitative evidence synthesis, which does not provide as much detail or certainty and may introduce bias. There was generally good consistency of results across qualitative and quantitative studies. Heterogeneity was however observed across included studies, likely reflecting the wide range of methods, scenarios, and populations included in this synthesis. This was reflected in the results on diversity, which found little consistency across populations. Although quality assessments were carried out and presented for all included studies, no studies were excluded based on lower quality assessments and results were not stratified by quality for comparison. We included studies over a large time period (1996–2024) to capture all available evidence but acknowledge that opinions may have changed over time, which was not analysed here. Results were, however, consistent with the 2015 review [5].

Conclusions

Consent for emergency and critical care research studies are complicated by the nature of acute illness, where challenges are posed by the lack of patient capacity, stress and trauma for relatives, and an urgent need for interventions to commence quickly. This means alternatives to the traditional prospective procedures are required and approaches need to be streamlined and flexible while maintaining research integrity. Interested parties including patients, the public, previous research participants, their families, clinicians, research staff, and research ethics boards are highly accepting of a variety of consent approaches including surrogate decision maker and deferred consent. Which exact model is used will be highly dependent on the situation, with participants emphasising a need for flexibility while still respecting the rights and autonomy of research participants. The recent COVID-19 pandemic brought emergency and critical care research to the forefront worldwide, with participants agreeing that further accommodations to facilitate research during a pandemic are acceptable and should be implemented in advance. RECs and regulators should consider these accommodations prior to the onset of future health emergencies to allow research to commence as soon as possible. Further clarity is needed related to timing of consent during the patient's recovery and the use of integrated consent, which was not covered by included studies. Research should continue to solicit views on alternative consent models to add to this evidence base, particularly related to views among diverse groups, cultural contexts and countries, as the majority of the identified studies were conducted in high-income countries. Consent models should also strive to be as inclusive as possible, implementing procedures to overcome identified barriers to underserved and diverse groups.

Abbreviations

ED	Emergency department
EFIC	Exception from informed consent
EMS	Emergency medical service
HCP	Healthcare professional
ICU	Intensive care unit
LMIC	Low-middle-income country
RCT	Randomised controlled trial
REC	Research Ethics Committee
SDM	Surrogate decision maker
TBI	Traumatic brain injury

Supplementary Information

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Additional file 1. "Rapid review search strategies for each database", containing systematic review search strategy.

Additional file 2. Table S1 - Prospective Informed Consent", containing study characteristics which investigate prospective informed consent.

Additional file 3. "Table S2 - SDM Consent", containing study characteristics which investigate SDM consent.

Additional file 4. "Table S3 – Deferred Consent", containing study characteristics which investigate deferred consent.

Additional file 5. "Table S4 - Waived Consent", containing study characteristics which investigate waived consent.

Additional file 6. Table S5 - HCP Consent", containing study characteristics which investigate HCP consent.

Additional file 7. "Table S6 – Pandemic Research", containing study characteristics which investigate pandemic research.

Additional file 8. "Table S7 – Paediatric Research", containing study characteristics which investigate paediatric research.

Additional file 9. "Table S8 – Other", containing study characteristics of remaining studies.

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Authors' contributions
NM, LH, KA, AN, and DFM designed the study, NM and EC conducted the search, and NM extracted and analysed the data, and drafted the manuscript. LH and AN developed the manuscript. AB, ACG, CW, DH, DP, EG, FT, HS, JM, JS, NG, SW and TT provided expertise on analysis and reporting, and provided input on the draft manuscript. AN and DFM leads the research team, participated in study design, and provided clinical expertise in the reporting of findings. All authors reviewed and approved the final manuscript.

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Declarations

Ethics approval and consent to participate
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Consent for publication
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Competing interests
The authors declare that they have no competing interests.

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