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Exceptions to Informed Consent in Emergency Biomedical Research: Insights from a Jordanian Study

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ABSTRACT

Conducting research in emergency settings is crucial for advancing knowledge and improving the management of acutely ill patients. Nonetheless, the urgent and complex nature of these situations presents significant ethical challenges for researchers who handle emergent cases. This study sought to explore the attitudes of healthcare providers (HCPs) in Jordan regarding exceptions from informed consent (EFIC) and their willingness to enroll patients in emergency research. A quantitative study was carried out over a six-month period in 2019 using a face-to-face questionnaire administered by an interviewer. The survey assessed items related to the EFIC policy and evaluated healthcare providers' overall willingness to participate in emergency research or to support the participation of their family members. A total of 151 healthcare providers (HCPs) from emergency departments (EDs) in Jordan were recruited for the study. Participants generally expressed a positive attitude toward emergency research; 21.9% reported prior experience conducting such research, while 12.3% had related publications. Concerning the EFIC policy, most respondents disagreed with the majority of the items assessed. Limited support for EFIC was observed when participants were asked about enrolling family members or the general public in emergency research; however, respondents were generally willing to accept EFIC for their own participation. No significant differences (P = 0.37) were found among HCPs from different professional backgrounds regarding attitudes toward EFIC or willingness to participate in emergency research. Overall, healthcare providers expressed general support for emergency research, despite widespread disagreement with specific EFIC provisions. Consequently, future studies are recommended to compare the attitudes of well-informed participants from advanced institutions with the current baseline findings, in order to minimize confounding factors and gain a clearer understanding of perspectives on emergency research and EFIC. Moreover, establishing effective multidisciplinary communication channels between researchers and policymakers could facilitate collaborative research while promoting innovative and high-quality emergency care delivery.

Keywords: Jordan, Informed consent, Emergency research, Exception

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Introduction

Emergency medicine focuses on delivering rapid care to critically ill patients across all age groups. Ensuring this care is both safe and effective requires a foundation of rigorous research evidence [1]. Conducting research in emergency settings is crucial for advancing knowledge and refining approaches to acute patient management [2, 3]. According to the FDA, emergency research is defined as a "planned clinical investigation that requires prior written authorization and involves participants in life-threatening situations for which existing treatments or diagnostic tests are unproven or inadequate" [4].

Emergency patients are often highly vulnerable and may be unable to provide informed consent due to altered consciousness, severe illness, or stress [5, 6]. The urgency of these situations demands immediate interventions, leaving healthcare providers (HCPs) with limited time to balance patient care with research procedures [7].

Obtaining consent from patients or legal surrogates for interventions such as cardiopulmonary resuscitation (CPR) can therefore be logistically and ethically challenging [8].

Since the 1970s and the publication of the Belmont Report, respecting patient autonomy—specifically, the ability to make informed decisions—has been central to research ethics [9, 10]. Emergency research presents unique difficulties in this regard, as patients may be unconscious or unable to communicate, and delays in intervention to secure consent can adversely affect outcomes, including survival [2, 11, 12]. To address these challenges, the FDA introduced the Exception from Informed Consent (EFIC) policy in 1996, balancing patient autonomy with the need to advance research in critical care [4, 13]. EFIC stipulates several conditions, including life-threatening scenarios, absence of proven treatments, potential direct benefit to patients, timely administration before proxy consent, and consultation with the affected community. Despite these guidelines, EFIC remains poorly understood among HCPs and emergency researchers, often causing frustration when interventions must be administered without established efficacy [14-16].

In countries like Jordan, where emergency departments are often overcrowded and resources stretched [17, 18], regulations defining emergency research and ethical requirements are limited. The Jordanian Clinical Research Law of 2001, for example, does not explicitly address these issues [19, 20]. This study therefore aimed to explore HCPs' perceptions of emergency research and the ethical challenges associated with it, with a particular focus on their understanding of EFIC policy.

Materials and Methods

Study instrument

A thorough review of existing literature revealed a lack of regional guidelines governing emergency research. Consequently, survey items were developed based on EFIC regulations and international studies on emergency research [6]. A panel of six HCPs (two physicians, one pharmacist, and three nurses from different EDs) and four researchers assessed the content and face validity of the instrument. Minor revisions were made to enhance clarity, particularly for three survey items assessing willingness to participate.

The survey consisted of three sections. The first section (7 items) focused on ethical considerations when informed consent cannot be obtained, aligned with EFIC criteria. Participants indicated agreement or disagreement with statements such as the necessity of research when available treatments are unproven or unsatisfactory. The second section (25 items) assessed HCPs' willingness to participate in or support the participation of family members in emergency research, using a five-point Likert scale from "strongly disagree" to "strongly agree." Higher cumulative scores reflected greater agreement. The final section collected demographic information and prior research experience, including exposure to research ethics training and number of scientific publications.

Study design and setting

This cross-sectional study targeted physicians, pharmacists, and nurses working in EDs in Northern Jordan. Given the unpredictable nature of emergency care, a convenience sampling approach was employed. Face-to-face interviews were conducted over six months (February–July 2019) during both weekdays and weekends. Prior to survey completion, participants were provided a clear explanation of EFIC, based on FDA regulations (21 CFR 50.24).

A trained pharmacist conducted the interviews, ensuring consistency in delivery and clarification of survey items. Frequent meetings with the research team were held to maintain uniformity and address any procedural concerns during data collection.

Ethical approval

Ethical approval for this study was obtained from the Institutional Review Board (IRB) and Human Subjects Research Committee at Jordan University of Science and Technology (JUST), under reference number 33/118/2018. Because participation was voluntary and responses were collected anonymously, the review was expedited, and formal informed consent was not required. To inform participants, a cover sheet accompanied the questionnaire, outlining the study objectives and providing the researchers' contact details for any follow-up questions.

Statistical analysis

Once data collection was completed, the information was first entered into Excel and then imported into SPSS version 23 for statistical analysis. Descriptive statistics were applied to characterize the sample, with categorical variables expressed as frequencies and percentages, and continuous variables summarized using means and medians with interquartile ranges. Differences in EFIC scores among professional groups were evaluated using an independent-samples median test.

The measurement tools demonstrated high reliability, with internal consistency coefficients of 0.90 for the EFIC scale and 0.89 for the willingness scale, indicating strong reliability of the applied instruments.

Results and Discussion

Of the 305 healthcare providers invited from emergency departments, 151 consented to participate, resulting in a response rate of 49.5%. Participant demographics are presented in **Table 1**. The sample was predominantly male (61.6%) compared to female participants (35.8%). By profession, 57.6% were physicians, 36.4% were nurses, and 1.3% were pharmacists. The majority of participants worked in the public sector (63.6%), while 28.5% were affiliated with teaching institutions. Most participants (75.5%) were aged between 24 and 35 years.

In terms of professional experience, 28.5% had less than one year of practice, 21.9% had 1–3 years, 32.5% had 4–10 years, and 14.6% had more than ten years of experience. Notably, 71.5% of participants reported having received general education on research conduct, but only 34.4% had specific training in emergency research. Regarding research output, 78.1% and 88.7% of participants indicated no publications in general scientific research and emergency research, respectively. Meanwhile, 13.2% and 7.3% had 1–5 publications in general research and emergency research, respectively. Only a small number of participants reported more than five publications: four participants (2.6%) in general research and two participants (1.3%) in emergency research.

Table 1. Demographic characteristics of study participants.

Characteristic	Category / Response	Frequency (n)	Percentage (%)
Clinical Position	Physician	87	57.6
	Nurse	55	36.4
	Pharmacist	4	2.7
	Others	5	3.3
Gender	Male	93	61.6
	Female	54	35.8
	Missing	4	2.6
Age Groups (years)	<24	15	9.9
	24–35	114	75.5
	36–45	14	9.3
	46–55	4	2.6
	Missing	4	2.6
Years of Experience	<1	43	28.5
	1–3	33	21.9
	4–10	49	32.5
	>10	22	14.6
	Missing	4	2.6
Education on Research	Yes	108	71.5
	No	34	22.5
	Not Sure	5	3.3
	Missing	4	2.6
Education on Emergency Research	Yes	52	34.4
	No	79	52.3
	Not Sure	15	9.9
	Missing	5	3.3

Number of Scientific Publications	None	118	78.1
	1–5	20	13.2
	>5	4	2.6
	Missing	9	6.0
Number of Publications in Emergency Research	None	134	88.7
	1–5	11	7.3
	>5	2	1.3
	Missing	4	2.6
Type of Practice / Experience	Public Hospitals	96	63.6
	Private Hospitals	2	1.3
	Teaching Hospitals	43	28.5
	Other	5	3.3
	Missing	5	3.3

Most respondents (70.2%) expressed agreement on the need for increased medical research, and 80% supported the conduct of emergency research specifically. Around 85% of participants acknowledged the general importance of emergency research. However, regarding personal enrollment in such studies, 76.2% preferred that consent be provided by a family member. In situations where no family member was available, 49.7% indicated that healthcare providers and 29.8% indicated that emergency physicians could provide consent on their behalf.

Responses to EFIC-related items demonstrated an overall tendency to disagree with the use of exceptions from informed consent in emergency research **(Table 2)**. As shown in **Figure 1**, EFIC scores ranged from 7 to 21, with a mean of 9.5 ± 3.9 (SD), and both the median and mode were 7. Analysis using the independent samples median test revealed no significant differences in EFIC scores between physicians and nurses (p = 0.37). Detailed comparisons of EFIC responses across different healthcare provider groups are presented in **Table 2**.

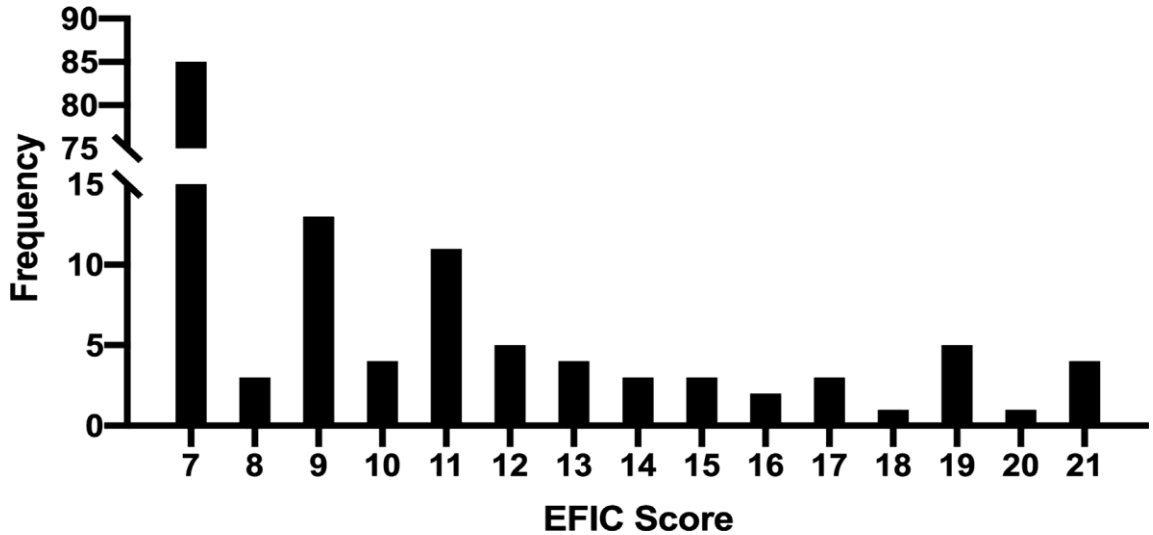

Figure 1. Distribution and range of EFIC scores. EFIC: Exception from Informed Consent.

Table 2. Comparison of EFIC scores by primary professional role (Physicians vs. Nurses).

EFIC Item	Profession	Disagree n (%)	Neutral n (%)	Agree n (%)	P-value
EFIC 1	Physicians	73 (83.9)	6 (6.9)	8 (9.2)	0.054
	Nurses	45 (81.8)	5 (9.1)	5 (9.1)	
EFIC 2	Physicians	70 (80.5)	8 (9.2)	9 (10.3)	0.810
	Nurses	42 (76.4)	5 (9.1)	8 (14.5)	
EFIC 3	Physicians	66 (75.9)	10 (11.5)	11 (12.6)	0.870
	Nurses	45 (81.8)	4 (7.3)	6 (10.9)	

EFIC 4	Physicians	68 (78.2)	10 (11.5)	9 (10.3)	0.710
	Nurses	48 (87.3)	3 (5.5)	4 (7.3)	
EFIC 5	Physicians	67 (77.0)	5 (5.7)	15 (17.2)	0.930
	Nurses	44 (80.0)	2 (3.6)	9 (16.4)	
EFIC 6	Physicians	62 (71.3)	15 (17.2)	10 (11.5)	0.770
	Nurses	44 (80.0)	6 (10.9)	5 (9.1)	
EFIC 7	Physicians	65 (74.7)	11 (12.6)	11 (12.6)	0.940
	Nurses	44 (80.0)	6 (10.9)	5 (9.1)	

EFIC: Exception From Informed Consent.

Table 3 illustrates that most participants were reluctant to endorse enrollment in emergency research without prior consent. Only 17.2% of respondents considered it acceptable to include patients without consent when the experimental intervention's risks and benefits were judged reasonable in relation to the patient's condition and standard care. The majority (70.9%) remained opposed, even after being informed that the proposed EFIC study had been reviewed and approved by the IRB of the participating institutions.

Table 3. Overview of participants' responses regarding EFIC criteria in emergency research.

EFIC Requirement	Agree n (%)	Neutral n (%)	Disagree n (%)
1. Available treatments are unproven or unsatisfactory.	16 (10.6)	11 (7.3)	120 (79.5)
2. Research cannot be conducted otherwise to assess the therapy's safety and effectiveness.	20 (13.2)	13 (8.6)	114 (75.5)
3. Obtaining informed consent from the patient or their legal representative is not feasible, and potential subjects cannot be identified prospectively.	20 (13.2)	14 (9.3)	113 (74.8)
4. Participation in the study offers the prospect of direct benefit to the participants.	16 (10.6)	14 (9.3)	117 (77.5)
5. The risks and benefits of the experimental procedure are reasonable relative to the patient's condition and standard therapy.	26 (17.2)	8 (5.3)	113 (74.8)
6. The research protocol has received IRB approval.	18 (11.9)	22 (14.6)	107 (70.9)
7. Experimental therapy may be administered without consent only if all EFIC conditions are satisfied.	18 (11.9)	17 (11.3)	112 (74.2)

EFIC: Exception From Informed Consent.

The average willingness score for participation in emergency research among respondents was 76.4 (SD = 12.87), with individual scores ranging from 38 to 108. Variability was observed in healthcare providers' readiness to enroll themselves or their relatives in such studies. Approximately 64% indicated that their recognition of the value of emergency research and its potential community benefits positively influenced their willingness to participate. Nearly 44% of participants identified emergency scenarios, such as trauma from accidents or violence, as pressing issues in the community. As a result, nearly half of the respondents (49.7%) were open to personal enrollment in emergency research without prior consent, particularly if the study could offer direct benefit or improve outcomes for future patients. In contrast, willingness to allow family members (19.2%) or broader community members (13.2%) to participate without consent was substantially lower.

Research conducted in emergency care is vital for improving health outcomes, yet it remains underdeveloped in many parts of the Middle East and North Africa (MENA). Emergency departments (EDs) in this region frequently operate at high capacity, often managing critically ill patients in overcrowded conditions [21]. Within such environments, the integration of evidence-based practices is crucial, but the ethical and operational complexities of emergency research are often overlooked. Despite extensive research on emergency care ethics in developed countries [16], studies examining these issues in the MENA region are scarce. Existing reports, originating from Jordan [22-25], Turkey [26-28], Egypt [29, 30], Iran [31, 32], Lebanon [33, 34], Saudi Arabia [35, 36], and UAE [37, 38], primarily focus on describing emergency services, with minimal attention to the ethical or practical aspects of conducting research in these high-pressure settings.

In our study, a significant majority of healthcare providers (85%) acknowledged the importance of emergency research, yet fewer than 20% supported enrolling patients, family members, or community participants without prior consent. This discrepancy mirrors observations in other settings; for example, Portland-based emergency providers reported a high recognition of research importance (98%), but only 31% were comfortable enrolling patients without consent [39]. Such findings suggest that limited exposure to research practices in EDs may reduce confidence in managing consent processes, particularly under EFIC (Exception From Informed Consent) protocols.

Interestingly, only 64% of respondents were willing to participate themselves in research without consent, highlighting a potential barrier for EFIC implementation. A likely contributing factor is insufficient familiarity with emergency research methodologies and regulatory frameworks. These results underscore the necessity for targeted training and educational initiatives to enhance understanding and confidence among ED personnel prior to conducting EFIC-based studies.

The reluctance to enroll patients without consent may also reflect the logistical realities of emergency care. ED clinicians prioritize rapid intervention and life-saving procedures, often leaving little time to navigate research-related consent, which can delay or limit participation in studies. Addressing this challenge requires structured engagement strategies, including education and dialogue, to clarify ethical responsibilities and procedural expectations for HCPs.

One potential approach to streamline ethical oversight is the establishment of an ED-focused Institutional Review Board (ED-IRB), capable of rapid assessment of emergent research proposals. This concept aligns with recommendations from the National Preparedness and Research Science Board (NPRSB), which proposed the creation of Public Health Emergency Research Review Boards (PHERRBs) to expedite review during emergencies while maintaining participant protections [40]. Future research should also explore how IRBs in MENA perceive emergency research, including the application of EFIC, to identify potential gaps and facilitate smoother implementation.

To our knowledge, this study represents the first prospective, cross-sectional investigation in Jordan aimed at examining ethical challenges, particularly informed consent, in emergency care research. The use of trained interviewers helped ensure consistent data collection across disciplines, despite variable research experience among participants. Achieving a 50% response rate is notable, given the unpredictable and fast-paced nature of ED workflows, which occasionally required participants to leave mid-interview.

However, the study has limitations. It did not explore the primary systemic or operational barriers preventing high-quality emergency research, and its focus on a single geographical area limits generalizability. Additionally, the research captured HCP perceptions about EFIC and emergency research broadly, without examining specific procedures or interventions. Future studies should address these gaps by engaging larger, more diverse populations and by evaluating both HCP and community perspectives regarding emergency research in high-pressure clinical environments.

Overall, these findings provide important insights into the underexplored area of emergency research in MENA EDs. They highlight the critical need to enhance research literacy, ethical awareness, and engagement among HCPs to promote safe and effective implementation of emergency studies.

Conclusion

This study reveals that healthcare providers in Northern Jordan's EDs possess limited knowledge and experience regarding emergency research and related ethical issues, including EFIC. While general support for research was high, willingness to enroll patients or community members without consent was restricted. These findings emphasize the importance of education and structured engagement with ED staff to improve understanding of research protocols and ethical obligations. Stakeholder involvement and policy-level support are essential to foster, guide, and regulate emergency research effectively. Future work should investigate operational and ethical barriers from both HCP and IRB perspectives to strengthen the feasibility and ethical conduct of studies in fast-paced emergency care environments.

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Conflict of Interest: None

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Ethics Statement: None

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