



Research article

Exception from informed consent for biomedical research in emergency settings: A study from Jordan

Samah F. Al-Shatnawi^{a,*}, Karem H. Alzoubi^a, Rawand A. Khasawneh^a, Omar F. Khabour^b, Basima A. Almomani^a^a Department of Clinical Pharmacy, Faculty of Pharmacy, Jordan University of Science and Technology, P.O. Box 3030, Irbid, 22110, Jordan^b Department of Medical Laboratory Sciences, Faculty of Applied Medical Sciences, Jordan University of Science and Technology, P.O. Box 3030, Irbid, 22110, Jordan

ARTICLE INFO

Keywords:

Emergency research
Informed consent
Exception
Jordan

ABSTRACT

Background: Research conduction in emergency settings is of paramount importance to promote knowledge and experiences related to treating acutely ill patients. However, the complexity of situations creates a considerable ethical challenge facing researchers who basically deal with emergent cases. This study aimed to determine attitudes of healthcare providers (HCPs) towards exception from informed consent (EFIC) and enrollment willingness in emergency research in Jordan.

Methods: A quantitative research with face-to-face questionnaire was conducted by an interviewer during 6-month period in 2019. Survey measures included items related to EFIC policy and overall willingness of HCPs to participate or support their family members' participation in emergency research.

Results: A total of 151 HCPs in the emergency departments (EDs) in Jordan was recruited. Positive attitude toward emergency research dominated among participants; about 21.9% of participants reported previous experience in the conduction of emergency research and 12.3% had related publications. Regarding EFIC policy, there was a general consensus of disagreement to most of the examined items. There was a trend for little support of EFIC policy when questioned about the enrollment of family members or public in emergency research, however, the application of EFIC was accepted for self-enrollment of respondents in emergency research. No significant differences ($P = 0.37$), among participants from different disciplines, were reported regarding the attitudes towards EFIC items or willingness to enroll in emergency research.

Conclusions: Generally, HCPs reported an overall positive support to emergency research despite a consensus of disagreement related to EFIC terms. Therefore, it is recommended to pursue future studies to compare well-informed subjects; recruited from well-developed institutions in regard to emergency research potentials; with the present basic attitudinal surveillance in order to dissipate the effect of such confounder and to get better insight of the actual attitudes related to emergency research and EFIC. In addition, efficient multidisciplinary communication channels between researchers and policy makers can lather the way to collaborative research with simultaneous innovative delivery of quality emergency care.

1. Introduction

Emergency medicine embraces the provision of immediate medical care to acutely ill patients across the whole age spectrum. Such care should be based on solid research evidence to ensure safe, and effective delivery of acute healthcare services (Dickert et al., 2016). Research conduction in the emergency settings is of paramount importance to promote knowledge and experiences related to treating acutely ill patients (CRASH Trial Management Group 2004; Brown, 2016). As aligned

by the FDA regulation 21 CFR Emergency Research is defined as "A planned clinical investigation that requires prior written FDA authorization to proceed and involves subject(s) who are in a life-threatening situation for which available treatments or in vitro diagnostic tests are unproven or unsatisfactory" (US Department of Health and Human Services 1996).

Emergency settings encompass highly vulnerable subjects, who are mostly incapable of consenting medical procedures or participation in research (Halperin et al., 2007; Feldman et al., 2019). The dynamic

* Corresponding author.

E-mail address: sfshatnawi@just.edu.jo (S.F. Al-Shatnawi).

nature of emergent conditions mandates immediate interventions; where healthcare providers (HCPs) are racing time to ensure the timely provision of effective and safe patient care (Kaiser 2014). At the other end of the spectrum, obtaining prompt informed consents from unstable patients or their legal representatives to provide pertinent interventions such as Cardio Pulmonary Resuscitation (CPR) might be challenging (Boulanger et al., 2018). Hence, the complexity of such situations creates a considerable ethical challenge facing HCPs and researchers who basically deal with emergent cases (Foex 2001; Feldman et al., 2019).

Worldwide, since the mid-70's and according to the Belmont report, researchers and healthcare practitioners must be cognizant about the utmost importance of subject's autonomy "respect for the patient's capacity of self-determination, and exercise of personal choice" (Luce 2003), represented by the principle of informed consent (The Belmont Report. Ethical principles and guidelines for the protection of human subjects of research 2014). However, the problem with emergency research stems from questionable feasibility of consenting patients who are unconscious, unable to communicate with HCPs or researchers, or suffering tremendous physical and/or psychological stressors (CRASH Trial Management Group 2004; Kompanje et al., 2005). Delays in providing imminent interventions or consenting patients (including proxy consent) in emergency settings, can lead to negative healthcare outcomes, including lower chance of survival (Rozynska and Czarkowski 2007). In accordance to that, the Federal Drug Administration (FDA) has established a policy in 1996 "Exception from Informed Consent (EFIC)" as an attempt to balance between human right of "Autonomy" and the progress of medical practices and research in emergency settings (US Department of Health and Human Services 1996). Additionally, the FDA set several protective measures to emphasize patients' autonomy (US Department of Health and Human Services 2013). To better control the use of EFIC, FDA articulated conditions for applying the policy. Such conditions include: unexpected case scenarios with life threatening states; like dealing with debilitated or incapacitated patients, lack of proven or satisfactory treatment options, availability of interventions that might achieve direct benefit to the health of patients, feasibility of offering treatments on timely manner (prior to obtaining proxy consent from legally authorized representatives), and community consultation. Such EFIC requirements, however, remain unclear to both emergency HCPs and researchers. Studies have revealed high levels of frustration among emergency researchers especially in scenarios where physicians are fully authorized to prescribe pharmaceuticals that have not been scientifically proven to be effective and safe for certain medical conditions regardless of obtaining an ethical approval (Foex 2001; Fost 1998; Margo 2001).

Despite the high pressure on emergency departments (EDs) services in developing countries, including Jordan (Obermeyer et al., 2015; Abujaber et al., 2016), there is a lack of regulations that demarcate emergency practices and research principles. As an example, there is an overall lack of demarcation of emergency research and ethical related issues in the Jordanian Clinical Research Law of 2001 (Ramahi and Silverman 2009; Alahmad et al., 2012). This research aimed to investigate perceptions of emergency research and associated ethical challenges among HCPs in emergency settings in Jordan. Examination of HCPs' understanding of EFIC policy permitting research of this kind was the main focus of the current search.

2. Method

2.1. Study instrument

Prior to study conduction the available literature was reviewed, comprehensively; and researchers failed to retrieve any regional guidelines governing emergency research practices. Therefore, survey items were developed based on EFIC guidelines and international studies related to emergency research (Feldman et al., 2019). A group of six HCPs (two physicians, one pharmacist and three nurses from different

EDs) and four researchers evaluated content and face validity of the applied instrument. Simple language related modifications were recommended on some items (2, 13, 23: from willingness scale) to improve the overall simplicity/clarity of the survey.

The instrument consisted of three main sections. The first part comprised 7 items that evaluated ethical issues related to the exclusion of informed consent within the emergency setting as aligned by EFIC policy. In this section, participants were asked to indicate their level of agreement (agree, disagree, or neutral) to different items (e.g Available treatments are unproven or unsatisfactory, and the research cannot otherwise be performed to determine whether the therapy is safe and effective). The second part embraced 25 items that aimed to assess the overall willingness of HCPs to participate or support their family members' participation in emergency research (e.g. (i) My participation in an emergency study would be a very good thing, (ii) More research that could benefit patients within emergency settings should be performed). A five-point Likert-scale of agreement (ranging from (1) strongly disagree to (5) strongly agree) was used to formulate responses to items in this section. Cumulative scores were calculated for both EFIC and willingness scales; with higher scores indicating higher levels of agreement. Finally, the last part consisted of items covering demographic information and experience in conducting research (e.g. (i) During your study and/or training, have you taken lectures or courses on research and research ethics, (ii) Number of your scientific publications).

2.2. Study design and setting

In this cross-sectional study, researchers targeted HCPs (physicians, pharmacists, and nurses) staffing EDs in Northern Jordan. Given the challenging nature of overcrowded and unexpected call for services in ED, a convenient sampling method was applied to recruit participants. Face-to-face interviews were conducted, by a pharmacist, throughout the study period of 6-month (between February 2019 and July 2019) during workdays and weekends. Preceding interviews, the definition, and criteria of EFIC were discussed with participants based on the criteria outlined in subpart B (Exception from informed consent requirements for emergency research) of the FDA regulation 21 CFR 50.24 (US Department of Health and Human Services 1996).

Participants were asked to fill out the study survey as aided by the pharmacist. Noteworthy, the pharmacist-in-charge of surveying participants was trained prior to study conduction and frequent meetings with study research team was held to ensure consistent interviewing and data collection.

2.3. Ethical approval

This study was approved by the Institutional Review Board (IRB) and Human Subjects Research Committee (reference number: 33/118/2018) at Jordan University of Science and Technology (JUST). Given the voluntary participation and anonymous nature of this study, a review process was expedited, and requirement of informed consent was waived. A cover page was included with the measurement tool to provide an overview of the study purpose and researchers' contact information to address any subsequently arisen inquiries.

2.4. Statistical analysis

Following data collection, collected information were entered into EXCEL sheet and imported into SPSS (version 23) for analysis. Descriptive statistics were used to summarize the data for the total sample using number (percentage) for categorical variables and mean, median (interquartile range) for continuous variables. The differences in EFIC scores between different disciplines were examined using an independent samples median test.

Worthy of mentioning, applied measures showed very good internal consistency, with reliability coefficients of 0.9 for EFIC scale and 0.89 for willingness scale.

3. Results

Out of the 305 HCPs invited to participate from EDs, 151 agreed to participate in the study yielding a response rate of 49.5%. Demographics of study participants are listed in Table 1. Study results indicate predominance of participating males (61.6%) vs. females (35.8%). Regarding study participants' profession, 57.6% were physicians, 36.4% were nurses, and only 1.3% were pharmacists. A total of 96 (63.6%)

participants were from the public sector, and 43 (28.5%) participants were from a teaching institution. Almost two thirds (75.5%) of participants' ages ranged between 24 to 35 years. Regarding number of years in practice, 28.5% reported an experience of less than one year; 21.9% had an experience of 1–3 years; 32.5% had an experience of 4–10 years; and 14.6% had an experience of more than ten years. Noteworthy, 108 of participating emergency practitioners (71.5%) received education about the general conduct of research. However, only 52 of them (34.4%) have received specific education in emergency research. Interestingly, 78.1% and 88.7% of participants reported lack of published research in the general scientific field and in emergency research, respectively, while, 13.2% and 7.3% reported to have 1–5 publications in general scientific research and emergency research, respectively. On the other hand, only four participants (2.6%) have indicated more than five scientific publications in general, and two participants (1.3%) have indicated more than five publications in emergency research.

The majority of respondents (70.2%) have agreed on the need for more medical research, and 80% of them have indicated their support to conduct emergency research. Approximately 85% of participants generally agreed on the importance of emergency research. However, when asked about their enrollment in emergency research, 76.2% of participants preferred their family members to consent on their behalf. In cases where family members were not available to consent, 49.7% and 29.8% of them have selected HCPs and emergency physicians to provide consent on their behalf, respectively.

Regarding responses to the items related to the EFIC policy as pertained to emergency research, there was a general sense of disagreement regarding the exception of informed consent in emergency settings (Table 2). As depicted in Figure 1, EFIC scores ranged between (7–21) and the mean score was 9.5 ± 3.9 (SD), with both median and mode scores of 7. Independent samples median test revealed no difference in EFIC scores among participating physicians and nurses ($p = 0.37$). Differences between the HCP as related to EFIC policy are summarized in Table 2.

As demonstrated in Table 3, enrollment in emergency research without prospective consent was not supported. When the risks and benefits of the experimental procedure/treatment are reasonable compared to those associated with the subject's medical condition and

Table 1. Demographic characteristics of study participants.

Characteristics	n (%)
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 (years):	
<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)

Table 2. EFIC comparison according to participants main positions (Physicians vs. Nurses).

	Disagree n (%)	Neutral n (%)	Agree n (%)	P-value
EFIC 1				0.054
Physicians	73 (83.9)	6 (6.9)	8 (9.2)	
Nurses	45 (81.8)	5 (9.1)	5 (9.1)	
EFIC 2				0.810
Physicians	70 (80.5)	8 (9.2)	9 (10.3)	
Nurses	42 (76.4)	5 (9.1)	8 (14.5)	
EFIC 3				0.870
Physicians	66 (75.9)	10 (11.5)	11 (12.6)	
Nurses	45 (81.8)	4 (7.3)	6 (10.9)	
EFIC 4				0.710
Physicians	68 (78.2)	10 (11.5)	9 (10.3)	
Nurses	48 (87.3)	3 (5.5)	4 (7.3)	
EFIC 5				0.930
Physicians	67 (77.0)	5 (5.7)	15 (17.2)	
Nurses	44 (80.0)	2 (3.6)	9 (16.4)	
EFIC 6				0.770
Physicians	62 (71.3)	15 (17.2)	10 (11.5)	
Nurses	44 (80.0)	6 (10.9)	5 (9.1)	
EFIC 7				0.940
Physicians	65 (74.7)	11 (12.6)	11 (12.6)	
Nurses	44 (80.0)	6 (10.9)	5 (9.1)	

EFIC: Exception From Informed Consent.

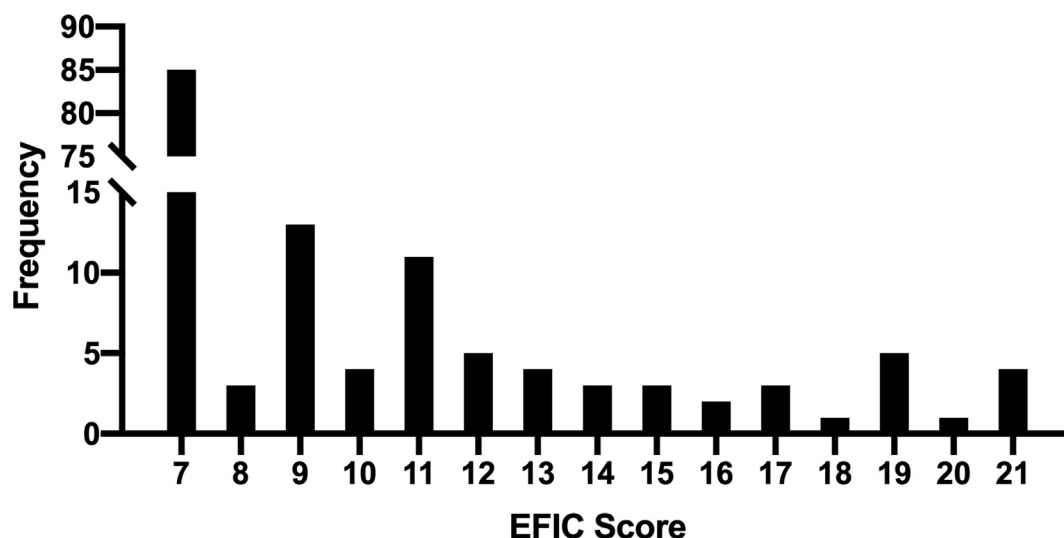


Figure 1. EFIC scores range and frequency. EFIC: Exception From Informed Consent.

Table 3. Summary of participants' agreement with EFIC requirements for emergency research.

Items	Agree n (%)	Neutral n (%)	Disagree n (%)
1. Available treatments are unproven or unsatisfactory.	16 (10.6%)	11 (7.3%)	120 (79.5%)
2. The research cannot otherwise be performed to determine whether the therapy is safe and effective.	20 (13.2%)	13 (8.6%)	114 (75.5%)
3. It is not feasible to obtain informed consent from the subject or the subject's legal representative, and there is no reasonable way to identify potential subjects prospectively.	20 (13.2%)	14 (9.3%)	113 (74.8%)
4. Participation in the research holds out the prospect of direct benefit to the subjects.	16 (10.6%)	14 (9.3%)	117 (77.5%)
5. The risks and benefits of the experimental procedure/treatment are reasonable compared with those associated with the subject's medical condition and standard therapy.	26 (17.2%)	8 (5.3%)	113 (74.8%)
6. The research proposal has been reviewed and approved by the IRB.	18 (11.9%)	22 (14.6%)	107 (70.9%)
7. Subjects may receive the experimental therapy without consent only if all of the conditions are met	18 (11.9%)	17 (11.3%)	112 (74.2%)

EFIC: Exception From Informed Consent.

standard therapy, only 17.2% of respondents agreed that it is acceptable to enroll patients in emergency research without consent. Disagreement was dominant despite informing participants that the proposed EFIC research was reviewed and approved by the IRB of participating institutions (70.9%).

The mean willingness score for enrollment in emergency research was 76.4 (SD: 12.87) with a range of (38–108). There was some variation in emergency HCPs' willingness to be enrolled or to enroll their family members in emergency research settings. In fact, their strong beliefs about the importance of emergency research and its beneficial outcomes to the community were positively influencing their willingness to be enrolled in such studies (64%). In general, participating HCPs in emergency settings (43.7%) indicated that emergent situations, such as injuries related to violence or accidents, are serious concerns in our community. Thus, they were generally willing to be enrolled in emergency research without providing a consent (49.7%), especially if the research offered a direct benefit or might help future patients without direct benefit. However, participants were generally less willing to agree with the enrollment of their family members and community members in emergency research without an obtained consent (19.2% and 13.2%, respectively).

4. Discussion

Emergency research is essentially important to promote public health related outcomes. In the Middle East and North Africa (MENA) region, EDs have high occupancy rates and are usually crowded with acutely ill patients (Al Ghobain et al., 2017). Therefore, it is of paramount

importance to highlight the need to apply evidence-based principles and practices in treating such vulnerable subset of patients. In this aspect, the conduction of emergency research sounds to be a viable option. However, scientific medical research and associated ethical issues within emergency settings in the MENA region has been overlooked.

Considering the wealth of literature on emergency research and related ethical issues in many developed countries (Feldman et al., 2019), there was an evident lack of emergency research in the MENA region along with some sporadic information in such aspect. Pertinent regional studies, related to ED research, originated from Jordan (Abbadi et al., 1997; Ahmad M Abdallat and Abbadi 2007; A. M. Abdallat et al., 2000; Halasa 2013; Jerius et al., 2010; Hani Shakhathreh and Al-Issa 2009; H Shakhathreh et al., 2003; Sabbagh et al., 2015), Turkey (Topacoglu et al., 2004; Yildirim et al., 2005; Pekdemir et al., 2010; Oktay et al., 2003; Karabocuoglu et al., 1995; Eroglu et al., 2012; Cevik et al., 2001; Cander et al., 2006; Bresnahan and Fowler 1995), Yemen (Naser and Saleem 2018), Egypt (Montaser 2013; Abou-ElWafa et al., 2015; Saleh et al., 2018; Abdo et al., 2015; El-Shafei et al., 2018), Iran (Jafari-Rouhi et al., 2013; Jalili et al., 2013; Soleimanpour et al., 2011), Lebanon (Moucharafieh and Bu-Haka 1996; El-Khatib et al., 2014; El Sayed and Bayram 2013; El Zahran et al., 2018; El Majzoub et al., 2018), Saudi Arabia (Alhajjaj and Aldamigh 2017; Mehmood et al., 2017; Alamri 2017; Alquraini et al., 2015; Alghamdi et al., 2014; Rhine 2000), and United Arab Emirates (Partridge et al., 2009; Fares et al., 2014). Surprisingly, emergency research and related ethical issues were marginalized among all of those regional studies; all studies were not designed to investigate emergency research at any depth, but to describe some aspects of available emergency interventions and offered practices and/or services.

The current study found that the vast majority of participating HCPs (85%) in emergency settings agreed on the importance of emergency research. However, less than 20% of them agreed with enrolling their family and/or community members in emergency research without consent. This difference is comparable to the findings reported by Portland, where 98% of emergency medicine providers agreed that emergency research is important, but 31% agreed with enrolling patients without consent (Jasti et al., 2016). Such findings might indicate that HCPs in emergency settings are with limited experience in scientific research that preclude consenting process, thus they might be less confident about facilitating and/or conducting emergency research.

Another important finding is that only 64% of participants agreed to be personally enrolled in research without consent suggesting an issue of concern surrounding the implementation of EFIC policy. Lack of sufficient knowledge about the emergency research in general and related terms such as EFIC, in particular, can be argued as a potential confounder in the reported disagreement regarding EFIC items. This finding highlights the needs to educate and train HCPs within emergency settings about emergency research and EFIC concepts before conducting emergency-based trials.

Noteworthy, lack of support from HCPs in emergency settings would negatively affect the conduct and outcomes of emergency research. Reluctance to enroll patients in ED research without waived consent may stem from logistics related to the ED environment where HCPs race time to provide emergent care that saves patients' lives without consideration of consenting; rendering emergency research neglected. Thus, researchers should spend time and efforts tackling the concerns of HCPs within emergency settings regarding the conduct of research and the application of EFIC terms. Given the dynamic environment and variety of cases within emergency settings, HCPs might encounter several hurdles and challenges in conducting research. Therefore, future research should highlight HCPs' discomfort and target to identify potential strategies that guide the conduct of emergency research.

As part of suggested solutions to overcome barriers limiting emergency research, it is prudent to have accessible, ED-IRB committee that is readily available to discuss evolving research proposals that can arise upon caring for acutely ill patients in ED. Such stand-by ED IRB committee is inspired by the approach initially suggested in 2011 by National Preparedness and Research Science Board (NPRSB) ([Forum on Medical and Public Health Preparedness for Catastrophic Events 2015](#)). Part of the recommendations aligned by NPRSB called for the establishment of so-called Public Health Emergency Research Review Board (PHERRB) which is responsible for immediate assembly to assess research protocols in disasters while maintaining the rights of involved human subjects ([Forum on Medical and Public Health Preparedness for Catastrophic Events 2015](#)). Additionally, it is also advised that future research explores issues related to emergency research as perceived by IRB committees in the MENA region.

To the best of our knowledge, this study was the first of its kind that was designed as prospective, cross-sectional study focusing on exploring ethical issues related to the principle of informed consent within an emergency setting in Jordan. In addition, the availability of a well-trained interviewer helped in obtaining consistent responses to applied research measures, regardless of their disciplines and previous research experience. Similarly, obtaining 50% response rate in this study is considered very good, considering the unexpected nature of ED's environment. Some respondents had to suddenly leave the interview after receiving urgent calls. Likewise, study limitations should be acknowledged. Firstly, the current study did not evaluate the dominant hurdles that prevent the application of high-quality practices in emergency settings. Furthermore, the insights of HCPs were surveyed in one geographical region; thus, results may not be generalizable to other regions. In addition, this study assessed opinions about the conduct of emergency research and EFIC policy in general. Future emergency research should sufficiently address such limitations, by addressing the main challenges facing the application of evidence-based practices using large and representative samples of HCPs. In addition to exploring HCPs' perspectives, future studies may assess such perspectives

from the general population's point of view as related to specific ED based procedures or interventions.

The current study findings could be of great value to the overlooked field of emergency research in our region. These results would help decision makers and stakeholders from different healthcare disciplines to better understanding the importance of medical and emergency research within emergency settings. The lack of research experience among HCPs within EDs worth highlighting, in order to stimulate more efforts that focus on facilitating the conduct of medical and emergency research, with careful ethical considerations.

5. Conclusions

Surveillance of HCPs in the emergency setting in Northern Jordan revealed suboptimal knowledge about emergency research and related ethical considerations including EFIC policy. Unexpectedly, most of research participants indicated minimum or nil research experience. Positive support toward emergency research was evident, however, willingness to enroll family members and community individuals in emergency research without consent was descent. More efforts focusing on emergency settings and related ethical considerations are highly needed. In order to ensure the success of EFIC-based research, vigilant discussions with emergency staff are recommended to clarify respective researchers' perceptions regarding patient enrollment and to address pertinent concerns to HCPs within EDs. At the current stage, the involvement of decision-makers and healthcare stakeholders is highly needed to stimulate, facilitate, and regulate the conduct of emergency research. Therefore, it is highly recommended to conduct more research that explore in detail the main challenges encountering decision-makers as well as research ethics committee members, while processing the approvals of research conduct in complex settings such as emergency departments.

Declarations

Author contribution statement

Samah F. Al-Shatnawi: Conceived and designed the experiments; Analyzed and interpreted the data; Wrote the paper.

Karem H. Al-Zoubi: Conceived and designed the experiments; Analyzed and interpreted the data; Wrote the paper.

Rawand A. Khasawneh: Analyzed and interpreted the data; Wrote the paper.

Omar F. Khabour: Conceived and designed the experiments; Analyzed and interpreted the data; Wrote the paper.

Basima A. Almomani: Analyzed and interpreted the data; Wrote the paper.

Funding statement

This work was supported by the Fogarty International Center of the U.S. National Institutes of Health on behalf 29 of the Research Ethics Program in Jordan (# 5R25TW010026-02).

Data availability statement

Data included in article/supplementary material/referenced in article.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

References

- Abbad, S., Abdallah, A.K., Holliman, C.J., 1997. Emergency medicine in Jordan. *Ann. Emerg. Med.* 30 (3), 319–321.
- Abdallat, A.M., Abbad, M.D., 2007. Frequent attenders to the emergency department at prince Rashed BIN AL-Hassan hospital. *JRMS* 14 (3), 67–69.
- Abdallat, A.M., al-Smadi, I., Abbad, M.D., 2000. Who uses the emergency room services? *East. Mediterr. Health J.* 6 (5-6), 1126–1129.
- Abdo, S.A.M., El-Sallamy, R.M., El-Sherbiny, A.A.M., Kabbash, I.A., 2015. Burnout among physicians and nursing staff working in the emergency hospital of Tanta university, Egypt. *East. Mediterr. Health J.* 21 (12), 906–915.
- Abou-ElWafa, H.S., El-Gilany, A.-H., Abd-El-Raouf, S.E., Abd-Elmouty, S.M., El-Sayed Hassan El-Sayed, R., 2015. Workplace violence against emergency versus non-emergency nurses in Mansoura university hospitals, Egypt. *J. Interpers. Violence* 30 (5), 857–872.
- Abujaber, S., Chang, C.Y., Reynolds, T.A., Mowafi, H., Obermeyer, Z., 2016. Developing metrics for emergency care research in low-and middle-income countries. *Afr. J. Emerg. Med.* 6 (3), 116–124.
- Al Ghobain, M., Aldrees, T., Alenezi, A., Alqaryan, S., Aldabeeb, D., Alotaibi, N., et al., 2017. Perception and attitude of emergency room resident physicians toward Middle East respiratory syndrome outbreak. *Emerg. Med. Int.* 2017, 6978256.
- Alahmad, G., Al-Jumrah, M., Dierickx, K., 2012. Review of national research ethics regulations and guidelines in Middle Eastern Arab countries. *BMC Med. Ethics* 13, 34.
- Alamri, Y., 2017. Emergency medical technician education in Saudi Arabia: history and challenges. *Prehosp. Disaster Med.* 32 (6), 699.
- Alghamdi, K., Alburaih, A., Wagner, M.J., 2014. A comparison between emergency medicine residency training programs in the United States and Saudi Arabia from the residents' perception. *Emerg. Med. Int.* 2014, 362624.
- Alhajjaj, F.S., Aldamigh, A.S., 2017. Assessment of readiness of academic emergency departments in the central region of Saudi Arabia to receive a sick child. *Int. J. Health Sci.* 11 (3), 4–8.
- Alquraini, M., Awad, E., Hijazi, R., 2015. Reliability of Canadian emergency department triage and acuity scale (CTAS) in Saudi Arabia. *Int. J. Emerg. Med.* 8 (1), 80.
- Boulanger, J.M., Lindsay, M.P., Gubitz, G., Smith, E.E., Stotts, G., Foley, N., et al., 2018. Canadian stroke best practice recommendations for acute stroke management: prehospital, emergency department, and acute inpatient stroke care. *Int. J. Stroke*, 6th Edition, Update 2018. 1747493018786616.
- Bresnahan, K.A., Fowler, J., 1995. Emergency medical care in Turkey: current status and future directions. *Ann. Emerg. Med.* 26 (3), 357–360.
- Brown, J., 2016. National Institutes of health support for clinical emergency care research, 2011 to 2014. *Ann. Emerg. Med.* 68 (2), 164–171.
- Cander, B., Kalkan, E., Girisgin, S., Gul, M., Coskun, F., 2006. Emergency operation indications in emergency medicine clinic (model of emergency medicine in Turkey). *Adv. Ther.* 23 (2), 359–363.
- Cevik, A.A., Rodoplu, U., Holliman, C.J., 2001. Update on the development of emergency medicine as a specialty in Turkey. *Eur. J. Emerg. Med.* 8 (2), 123–129.
- CRASH Trial Management Group, 2004. Research in emergency situations: with or without relatives consent. *Emerg. Med. J.* 21 (6), 703.
- Dickert, N.W., Brown, J., Cairns, C.B., Eaves-Leanos, A., Goldkind, S.F., Kim, S.Y., et al., 2016. Confronting ethical and regulatory challenges of emergency care research with conscious patients. *Ann. Emerg. Med.* 67 (4), 538–545.
- El Majzoub, I., El Khuri, C., Hajjar, K., Bou Chebl, R., Talih, F., Makki, M., et al., 2018. Characteristics of patients presenting post-suicide attempt to an academic medical center emergency department in Lebanon. *Ann. Gen. Psychiatr.* 17, 21.
- El Sayed, M.J., Bayram, J.D., 2013. Prehospital emergency medical services in Lebanon: overview and prospects. *Prehosp. Disaster Med.* 28 (2), 163–165.
- El Zahran, T., El Warea, M., Bachir, R., Hitti, E., 2018. The pediatric disease spectrum in an emergency department at a tertiary care center in Beirut, Lebanon. *Pediatr. Emerg. Care.*
- El-Khatib, M.F., Kazzi, A.N., Zeineldine, S.M., Bou-Khalil, P.K., Ayoub, C.M., Kanazi, G.E., 2014. Use of noninvasive positive pressure ventilation in emergency departments of public and private hospitals in Lebanon. *Eur. J. Emerg. Med.* 21 (3), 230–232.
- El-Shafei, D.A., Abdelsalam, A.E., Hammam, R.A.M., Elgohary, H., 2018. Professional quality of life, wellness education, and coping strategies among emergency physicians. *Environ. Sci. Pollut. Contr. Ser.* 25 (9), 9040–9050.
- Eroglu, S.E., Toprak, S.N., Urgan, O., Onur, O.E., Denizbasi, A., Akoglu, H., et al., 2012. Evaluation of non-urgent visits to a busy urban emergency department. *Saudi Med. J.* 33 (9), 967–972.
- Fares, S., Irfan, F.B., Corder, R.F., Al Marzouqi, M.A., Al Zaabi, A.H., Idrees, M.M., et al., 2014. Emergency medicine in the United Arab Emirates. *Int. J. Emerg. Med.* 7 (1), 4.
- Feldman, W.B., Hey, S.P., Franklin, J.M., Kesselheim, A.S., 2019. Public approval of exception from informed consent in emergency clinical trials: a systematic review of community consultation surveys. *JAMA Network Open* 2 (7) e197591-e197591.
- Foex, B.A., 2001. The problem of informed consent in emergency medicine research. *Emerg. Med. J.* 18 (3), 198–204.
- Forum on Medical and Public Health Preparedness for Catastrophic Events, 2015 Apr 6. Board on Health Sciences Policy; Institute of Medicine. Enabling Rapid and Sustainable Public Health Research during Disasters: Summary of a Joint Workshop by the Institute of Medicine and the U.S. Department of Health and Human Services, Washington (DC). National Academies Press (US). PMID: 25411682.
- Fost, N., 1998. Waived consent for emergency research. *Am. J. Law Med.* 24 (2-3), 163–183.
- Halasa, W., 2013. Family medicine in the emergency department, Jordan. *Br. J. Gen. Pract.* 63 (614), 462.
- Halperin, H., Paradis, N., Mosesso Jr., V., Nichol, G., Sayre, M., Ornato, J.P., et al., 2007. Recommendations for implementation of community consultation and public disclosure under the food and Drug administration's "exception from informed consent requirements for emergency research": a special report from the American heart association emergency cardiovascular care committee and council on cardiopulmonary, perioperative and critical care: endorsed by the American college of emergency physicians and the society for academic emergency medicine. *Circulation* 116 (16), 1855–1863.
- Jafari-Rouhi, A.H., Sardashti, S., Taghizadieh, A., Soleimanpour, H., Barzegar, M., 2013. The emergency severity index, version 4, for pediatric triage: a reliability study in Tabriz children's hospital, Tabriz, Iran. *Int. J. Emerg. Med.* 6 (1), 36.
- Jallili, M., Shirani, F., Hosseininejad, M., Asl-e-Soleimani, H., 2013. Emergency department nonurgent visits in Iran: prevalence and associated factors. *Am. J. Manag. Care* 19 (1), e1–8.
- Jasti, J., Fernandez, A.R., Schmidt, T.A., Lerner, E.B., 2016. EMS provider attitudes and perceptions of enrolling patients without consent in prehospital emergency research. *Prehosp. Emerg. Care* 20 (1), 22–27.
- Jerius, M., El-Salim, A., Tarawneh, M.G., Habashneh, M., 2010. Inappropriate utilization of emergency medical services at prince Ali Military hospital. *J. Royal Med. Serv.* 17, 32–35.
- Kaiser, R., 2014. Emergency settings: be prepared to vaccinate persons aged 15 and over against measles. *J. Infect. Dis.* 210 (12), 1857–1859.
- Karabucoglu, M., Kartoglu, U., Molzan, J., Ugur, S., Uzel, N., Neyzi, O., 1995. Analysis of patients admitted to the emergency unit of a university children's hospital in Turkey. *Turk. J. Pediatr.* 37 (3), 209–216.
- Kompanje, E.J., Maas, A.I., Hilhorst, M.T., Sliker, F.J., Teasdale, G.M., 2005. Ethical considerations on consent procedures for emergency research in severe and moderate traumatic brain injury. *Acta Neurochir. (Wien)* 147 (6), 633–639 discussion 639–640.
- Luce, J.M., 2003. Is the concept of informed consent applicable to clinical research involving critically ill patients? *Crit. Care Med.* 31 (3 Suppl), S153–160.
- Margo, C.E., 2001. When is surgery research? Towards an operational definition of human research. *J. Med. Ethics* 27 (1), 40–43.
- Mehmood, T., Al Shehrani, M.S., Ahmad, M., 2017. Acute coronary syndrome risk prediction of rapid emergency medicine scoring system in acute chest pain. An observational study of patients presenting with chest pain in the emergency department in Central Saudi Arabia. *Saudi Med. J.* 38 (9), 900–904.
- Montaser, T., 2013. Emergency medicine in Egypt: current situation and future prospects. *Afr. J. Emerg. Med.* 3 (4), S20–S21.
- Moucharafieh, R., Bu-Haka, R., 1996. Development of emergency medicine in Lebanon. *Ann. Emerg. Med.* 28 (1), 82–86.
- Naser, W.N., Saleem, H.B., 2018. Emergency and disaster management training: knowledge and attitude of Yemeni health professionals- a cross-sectional study. *BMC Emerg. Med.* 18 (1), 23.
- Obermeyer, Z., Abujaber, S., Makar, M., Stoll, S., Kayden, S.R., Wallis, L.A., et al., 2015. Emergency care in 59 low- and middle-income countries: a systematic review. *Bull. World Health Organ.* 93 (8), 577–586.
- Oktyay, C., Cete, Y., Eray, O., Pekdemir, M., Gunerli, A., 2003. Appropriateness of emergency department visits in a Turkish university hospital. *Croat. Med. J.* 44 (5), 585–591.
- Partridge, R., Abbo, M., Virk, A., 2009. Emergency medicine in Dubai, UAE. *Int. J. Emerg. Med.* 2 (3), 135–139.
- Pekdemir, M., Ersel, M., Yilmaz, S., Uygun, M., 2010. No significant alteration in admissions to emergency departments during Ramadan. *J. Emerg. Med.* 38 (2), 253–256.
- Ramahi, I., Silverman, H., 2009. Clinical research law in Jordan: an ethical analysis. *Develop. World Bioeth.* 9 (1), 26–33.
- Rhine, D.J., 2000. Emergency medicine in Saudi Arabia: an expatriate's perspective. *Cjem* 2 (2), 125–128.
- Rozynska, J., Czarkowski, M., 2007. Emergency research without consent under Polish law. *Sci. Eng. Ethics* 13 (3), 337–350.
- Sabbagh, C., Chaddad, M., El Rassy, E., 2015. Experience of morning reports in the emergency department. *Intern. Med. J.* 45 (7), 780–783.
- Saleh, H.M., ElSabagh, A.E., Elewa, M.G., Fawzy, A.A., Hassan, O.M., Comer, A.C., et al., 2018. Admission delays' magnitude of traumatized patients in the emergency department of a hospital in Egypt: a cross-sectional study. *Eur. J. Trauma Emerg. Surg.* 44 (2), 225–230.
- Shakhatreh, H., Al-Issa, A., 2009. Patient satisfaction in emergency department at King Hussein medical center. *JRMS* 16 (2), 26–30.
- Shakhatreh, H., Karim, A., Al-Durgam, M., Jerius, M., Khalifah, N., 2003. Use and misuse of accident and emergency services at queen Alia Military hospital. *J. Royal Med. Serv.* 10, 44–47.
- Soleimanpour, H., Gholipouri, C., Salarilak, S., Raoufi, P., Vahidi, R.G., Rouhi, A.J., et al., 2011. Emergency department patient satisfaction survey in Imam Reza hospital, Tabriz, Iran. *Int. J. Emerg. Med.* 4, 2.
- The Belmont Report, 2014. Ethical principles and guidelines for the protection of human subjects of research. *J. Am. Coll. Dent.* 81 (3), 4–13.
- Topacoglu, H., Karcioğlu, O., Ozucelik, N., Ozsarac, M., Degerli, V., Sarikaya, S., et al., 2004. Analysis of factors affecting satisfaction in the emergency department: a survey of 1019 patients. *Adv. Ther.* 21 (6), 380–388.
- US Department of Health and Human Services, 1996. Code of federal regulations, protection of human subjects; informed consent and waiver of informed consent requirements in certain emergency research: final rules 21 CFR Part 50.24 and 45 CFR Part 46.101. *Fed. Regist.* 61 (192), 51497–51531.
- US Department of Health and Human Services, 2013. Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research, 2013.
- Yildirim, C., Kocoglu, H., Goksu, S., Gunay, N., Savas, H., 2005. Patient satisfaction in a university hospital emergency department in Turkey. *Acta Med. (Hradec Kralove)* 48 (1), 59–62.