



Patient Perspectives on Emergency Research Informed Consent for Patients with Opioid Use Disorder Requiring Emergency Cesarean Delivery

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Introduction	Results		Conclusion
<p>Maternal opioid use disorder (OUD) affects 6.5 of every 1000 births in the US.¹ Cesarean deliveries account for 32% of annual births, with emergent cesareans accounting for 18% of annual births.² Pregnant women with OUD undergoing emergent cesarean have the highest risk for morbidity and poor outcomes related to opioid exposure and are under-represented in research due to practical barriers for enrollment. This study aimed to glean patient perspectives on consent procedures for research on pain management, specifically during emergency cesarean among pregnant women with OUD.</p>	Main Themes	Qualitative Themes Extracted from Focus Group	<ul style="list-style-type: none">• Women want greater involvement in pain management decision making• Pregnant people with OUD desire engagement with research• Research information preferred during prenatal visits• Women with OUD history are open to research opportunities during emergencies.• Specific actions to improve engagement for research in emergency settings were identified.
	FEAR AND STIGMATIZATION Barriers To Prenatal Care <div>“...Education... for physicians to attend to, like, really provide education to diminish stigma is like incredibly important”</div>	Women express fear and stigma associated with OUD lead to: <ul style="list-style-type: none">• Lack of open conversation with providers early on in pregnancy and during prenatal care• Limited prenatal care due to stigmatization• Limited prenatal contact with clinicians for fear of children-youth services referrals• Fear of opioid re-exposure during hospital stay and discharge	
	Improvement in Bi-directional COMMUNICATION <div>“...As early in the game as possible to identify any issues that may come up and to build trust”</div>	Lack of communication between clinical care teams and patients <ul style="list-style-type: none">• Need for specialized birth plans for people with OUD• Need for provider education when caring for patients with OUD Lack of counseling <ul style="list-style-type: none">• Interventions for neonatal substance withdrawal• Delivery procedures and possible outcomes• Pain management education after hospital discharge Recovery clinic early engagement with pregnant women needed to establish prenatal care	
	EDUCATION On Pain Management Alternatives To Opioids	Patients would prefer non-opioid pain management options <ul style="list-style-type: none">• Belief that there are limited pain management options for people with OUD	
Methods	Future Considerations		
<p>Semi-structured Focus Group to evaluate acceptability of consent procedures for research during emergency cesarean.</p> <ul style="list-style-type: none">• Six women (5 patients, 1 community leader, 1 anesthesiologist).• Participants were non-Hispanic, white females, aged 29-41 years <p>Community leaders engaged in peer recovery programs and other maternal-neonatal safety programs identified participants.</p> <ul style="list-style-type: none">• Women with OUD who were pregnant• Women with OUD who recently experienced an emergent delivery <p>Discussions focused on:</p> <ul style="list-style-type: none">• patient perspectives of postpartum pain management• acceptability of consent procedures for emergent cesarean• barriers to research consent during emergencies• acceptability “<i>exception from informed consent</i>” procedures in emergency cesarean settings <p>Transcription and Theme analysis determined using ATLAS.ti.</p> <ul style="list-style-type: none">• During initial coding analysis, three independent coders assigned codes to the focus group transcript• The team met and compared independent coding and made a universal code book of extracted themes	CONSENT For Research During Emergency Deliveries	Consent for research during an emergent cesarean delivery REQUIRES infographic consent schematics	<p>Areas to improve research consent processes in emergencies were identified:</p> <ol style="list-style-type: none">1. Patients with OUD perceive pain management options are limited and research would be valuable;2. Addressing barriers in patient-clinician relationships are essential;3. Informed consent for research should preferentially be obtained before the emergency;4. Treatments or devices lacking broad approvals would be a perceived barrier to research participation;5. Use of visual aids and obtaining verbal consent for research rather than written consent would be acceptable during an emergency
	FDA Approved Pain Reduction Methods, Not Experimental Pain Management	Best approach: Early engagement of informed consent for <i>possible</i> emergency cesarean delivery	
		Greater acceptance of research when an FDA approved treatment is being used	
		Alternative pain management studies could benefit women with OUD	
			References
			<p>1. O'Connor A et al. (2022) <i>Substance Abuse: Research and Treatment</i>. 16, 1-6.</p> <p>2.CDC. National Vital Statistics Report. 70(17), 6.</p>
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