C02 Ethics - Human/Animal Research and Clinical Practice

(244) Parental knowledge of genetic research in pediatric pain

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There is a paucity of peer-reviewed clinical research investigating healthy infants donating DNA for minimal risk genetic research. The inclusion of healthy infants in genetic pain studies has been hindered by parental lack of knowledge and misinformation about the association between genetics and pain. To determine parental knowledge of genetic research in pediatric pain we conducted 30 semi-structured interviews with mothers or mother-father dyads 24-48 hours after the birth of their healthy, full-term infant. Parents were interviewed in their private rooms. Audio recording and field notes were collected. Data driven content analysis using selected principles of grounded theory was performed. Parental knowledge of genetic research in pediatric pain emerged as a process involving three interacting components, parent's overall knowledge of genetics, parent's knowledge of someone involved in genetic testing, and parent's belief in the value of the research embedded within the context of personal benefit to the child. Sixty-six percent (n=18) of parents had no knowledge of genetics or genetic testing. Parents that expressed an understanding of genetics or genetic testing (n=11) received their information from personal prenatal care (n=6) or television (n=5). Ten percent (n=3) of parents received their knowledge of genetics from someone who experienced genetic testing. Thirteen percent (n=4) of parents felt there may be an association between genetics and pediatric pain and believed research to advance that understanding was worthwhile. Parents originally refusing to participate in genetic research in pediatric pain stated they might change their minds if there were direct benefits to their child (n=7). This research identified significant gaps in parental knowledge of genetic research in pediatric pain. Removing potential parental educational barriers is essential for supporting ethically sound, prospective, cohort studies of gene/environment interactions and for developing evidence-based pain therapies for this vulnerable population. Support: Sigma Theta Tau International Honor Society of Nursing #5971.

(245) Predictors of placebo treatment acceptability: participant demographics, perceived knowledge, and efficacy

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There is significant debate among healthcare providers, researchers, and ethicists concerning the ethics and acceptability of using placebo treatments to alleviate clinical pain. Although a contested issue, empirical evidence demonstrates that placebo analgesia effects can be large and clinically meaningful, with well-defined psychological and neurobiological mechanisms. Recent evidence suggests that there may be ethically permissible placebo clinical applications, as studies have demonstrated that patients may be open to placebo interventions under certain contexts. The aim of the present study was to expand upon the current placebo ethics literature by examining potential predictors of placebo acceptability. This investigation represented a secondary data analysis of variables used in a web-based placebo survey. Participants (n = 100) provided visual analogue scale ratings of the following: placebo analgesia perceived knowledge, treatment acceptability, treatment efficacy, and willingness to participate in placebo analgesia randomized controlled trials (RCTs). Placebo acceptability significantly correlated with treatment efficacy and willingness to participate in RCTs. Regression analyses illustrated that placebo effectiveness ratings accounted for nearly 25% of the variance in placebo acceptability ($p < .001$). None of the demographic variables (e.g., participant age, income, education, race/ethnicity) were significant predictors of placebo acceptability. Perceived knowledge was not a significant predictor of either placebo treatment effectiveness or acceptability ($p > .05$). Both placebo analgesia acceptability and efficacy significantly predicted willingness to participate in an analgesic placebo RCT. Findings from this secondary analysis of a published placebo survey (Kisaalita, J Pain 2012) suggest that, while perceptions of placebo efficacy may greatly impact impressions of treatment acceptability, lay individuals likely have uninformed understandings of placebo mechanisms. Future studies are needed to determine whether explicit, mechanism-based education about placebo can beneficially influence perceptions of placebo treatment acceptability.

(246) Blinding data collectors in investigations of experimental pain: let's get real

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Clinical trials often state investigators were blinded without describing or testing the blinding procedures. Here we examined the blinding of data collectors to participants' assigned condition within a crossover investigation of sex differences in exercise-induced hypoalgesia and conditioned pain modulation. Participants (N = 33; 52% women; 23 years old (SD = 5.01)) were assigned to a random order of three conditions: (1) control - quiet rest and trapezius isotonic saline injections; (2) algesic injections - quiet rest and trapezius hypertonic saline injections; and (3) exercise - quadriceps exercise and trapezius isotonic injections. Data collectors recorded participants' pressure and heat pain thresholds and pain ratings before and after a condition was administered by different personnel, but they did not observe the experimental condition. Thus, each session required multiple research personnel. At the end of each session, data collectors recorded their beliefs regarding the injection and exercise condition, their confidence level in their beliefs (0-100% scale), and the reason/s for their beliefs. Seven participants (21.2% of sample; 57.1% women) had vasovagal reactions to the injections, which caused missing data. Of the remaining participant sessions, investigators correctly identified isotonic and hypertonic injections 90% and 73% of the time, respectively, and quiet rest and exercise 94% and 69% of the time, respectively. Accordingly, substantial agreement was detected between the data collectors' beliefs and the actually administered condition for both the injections (Kappa = 0.65, $p < .001$) and exercise (Kappa = 0.67, $p < .001$). The average confidence of the data collectors in their beliefs was 60.17% (SD = 34.54) for injections and 62.19% (SD = 34.95) for exercise. Participants' pain responses were the primary reason for data collectors' beliefs, but the multitude of reasons reported supports the challenges of successful blinding. Researchers should consider the impact and probability of success of blinding procedures.

C04 Impediments to Opioid Use

(247) Differential access to pain medications: comparing metropolitan, micropolitan, small town, and rural pharmacies in Michigan

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Rural areas rank poorly on a number of health indicators. Adequacy of pain medication supply at local pharmacies has been an indicator of racial and ethnic disparities in health care. However, the role of these factors in rural disparities is unknown. A cross-sectional survey study combined 2010 census data and data from Michigan community retail pharmacists to explore potential disparities in pain medication availability. Pain medication availability was assessed for change since 2005; sufficient availability was defined as stocking at least one long-acting, short-acting, and combination opioid analgesic. Sufficient pain medication was then defined as stocking at least one medication in any of 14 classes related to treating chronic pain conditions: opioid analgesics, opioid analgesic combinations, opioid agonist-antagonist analgesics, oxycodone hydrochloride, agents for migraine, benzodiazepines, anticonvulsants, sulfonamides, nonsteroidal anti-inflammatory agents, selective cox-2 inhibitors, bupropion, selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, and tricyclic antidepressants. For the 140 pharmacies contained in zip codes with >70% white residents; availability increased from 86.9% to 96.24% ($p<.05$). Pharmacies located in rural, small town, micropolitan, and urban zip codes as defined by the census tract-based classification scheme, Rural-Urban Commuting Areas, were randomly selected (response rate, 82.2%). Of the 144 pharmacies surveyed, rural pharmacies were more likely than small town (odds ratio, 3.97) and micropolitan pharmacies (odds ratio, 4.47) to have insufficient pain medication supply ($p\leq .005$). Because of the high correlation between sufficient supplies in every class and sufficient opioid agonist-antagonist analgesics ($r=.856$, $n=144$, $p<.001$) a second regression was run. After accounting for median household income, pharmacies in rural zip codes were more likely than small town (odds ratio, 4.33) and micropolitan pharmacies (odds ratio, 4.47) to have insufficient opioid agonist-antagonist analgesics ($p < .01$). This study demonstrates disparities and barriers to rural pain care while having significant public health and policy implications.