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Ethicists' Viewpoints on Face Transplant: A survey study to guide clinical practice

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OBJECTIVES/GOALS: Face transplant can offer functional and aesthetic restoration to patients who have exhausted reconstructive options. Ethical issues in face transplant still abound, including that of patient selection. The goal of this study was to assess ethicists' viewpoints on face transplant. METHODS/STUDY POPULATION: A large-scale online survey of attendees of the International Conference on Clinical Ethics Consultation (N = 401) was performed to assess ethicists' opinions on issues in face transplant. Questions were asked regarding the risk-benefit ratio of immunosuppression, permissibility of face transplant for more recipient subpopulations (including children and blind patients), donor-recipient age, gender, and ethnicity mismatches, and ethics committee makeup. RESULTS/ANTICIPATED RESULTS: Among 84 respondents, 84% agreed it is permissible to perform a face transplant on an adult with no medical contraindications. The majority of respondents agreed that it is permissible to perform a face transplant on a child or blind recipient. An issue of continued concern was risk of immunosuppression. Respondents had a high threshold of permissibility for ethnic mismatches between donor and recipient, and 43% reported it is permissible to have a gender mismatch. A 10 year age difference between donor and recipient was the most commonly accepted. Questions regarding the ideal composition of a face transplant ethics committee demonstrated consensus on the roles that should be represented. DISCUSSION/SIGNIFICANCE OF IMPACT: This study provides insight into ethicists' viewpoints on face transplant, which demonstrates a high level of permissibility towards the procedure. This may be due to the early success of face transplants and the shifting ethical issues in the field to practical aspects of the procedure. This research also provides guidance to programs regarding questions of donor and recipient selection, ethics committee composition, and offers insight into strengthening the ethical framework of the field.

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Examination of FDA Pediatric Regulations: Inclusion of Pediatric Populations in Clinical Trials, 2016 - 2018

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OBJECTIVES/GOALS: To assess whether FDA regulations aimed at the pediatric population following the Best Pharmaceuticals for Children Act (BPCA) of 2002 are effective, this study examines the inclusion of the pediatric population in recent clinical trials for drugs used by both adult and pediatric groups. METHODS/STUDY POPULATION: From the U.S. Food and Drug Administration (FDA) a list of drugs approved between 2016 and 2018 was compiled. A search of clinicaltrials.gov provided corresponding clinical trials for the approved drugs. Study information such as eligibility criteria and demographics was gathered from each trial. From studies that included both adult and pediatric populations, the percentage of pediatric and adult subjects was calculated, resulting in values expressing exclusively pediatric subjects or the pediatric subjects as part of a category that included both populations (i.e. 18 years old). RESULTS/ANTICIPATED RESULTS: Between 2016 and 2018, 26 drugs were approved under the BPCA. From an assessment of 220 total studies, a lack of standardization is evident in terms of which ages constitute a particular pediatric sub-population even though guidelines for these sub-populations already exist under the BPCA. This lack of standardization resulted in the separate examination of each drug for pediatric inclusion. For the majority of the trials evaluated, 1% of the pediatric population was represented in trials that were open to both adult and pediatric populations. DISCUSSION/SIGNIFICANCE OF IMPACT: There is a need for more effective regulations and incentives for the pharmaceutical industry to standardize data presentation and better incorporate the pediatric population in clinical trials, especially for drugs targeted for this group.

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Exposure to topical antimicrobials reduces inflammatory gene expression in keratinocytes

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OBJECTIVES/GOALS: Lupus lesional skin has elevated interferon expression, is highly colonized with *Staphylococcus aureus* (50%) and has no FDA-approved treatment options. We decided to investigate the effect of topical antibiotics on lupus lesional skin to determine whether it affects inflammatory gene expression. METHODS/STUDY POPULATION: Adult Systemic Lupus Erythematosus (SLE) patients with skin inflammation were recruited for this study from the Michigan Lupus cohort. All patients gave informed consent approved by the University of Michigan IRB. Lesions were swabbed for *S. aureus* colonization and then skin biopsies were collected from the affected area. Patients were then randomized for either mupirocin treatment or Vaseline™ as the control. Product was applied to the lesion thrice daily for 7 days and swab samples and biopsies were collected again. Biopsies were saved at −80 °C. RNA was isolated from the biopsies, checked for quality and RNA-sequencing was performed to determine transcriptomic changes. RESULTS/ANTICIPATED RESULTS: Our preliminary results indicate that a higher number of genes are differentially expressed (DEGs) following treatment with mupirocin (184) than Vaseline™ (133). Interestingly the DEGs from the two treatments were almost completely independent with only a few that were DE in both treatments when the data were fitted to a scatter plot. Functional enrichment analysis of the data showed significant downregulation of cytokine and chemokine pathways in the mupirocin but not the Vaseline™ treatment group. DISCUSSION/SIGNIFICANCE OF IMPACT: Our preliminary data suggests that inflammatory signaling can be reduced in lesional skin by reducing bacterial load by topical antibiotic treatment in lupus patients. This can be particularly helpful in patients who are recalcitrant to typical treatment protocols for skin inflammation. CONFLICT OF INTEREST DESCRIPTION: J.M.K. received research funding from Celgene and serves on advisory boards for AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, and Eli Lilly and J.E.G. received research funding from AbbVie, SunPharma, Celgene, and Genentech and serves on advisory boards for Novartis, AbbVie, and MiRagen. The other authors have no financial conflicts of interest.

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