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Passion for Participatory Research on the Menstrual Cycle

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Abstract

A two-day symposium entitled “The Menstrual Cycle and Adolescent Health” was held in Potomac, Maryland in mid October 2007. Groups sponsoring the meeting included the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), the National Institute of Child Health and Human Development, the American Society for Reproductive Medicine, the NIH Office of Research on Women's Health, the NIH Office of Rare Diseases, the US Food and Drug Administration Office of Women's Health, the DHHS Office of Women's Health, and Rachel's Well, Inc. Attendees included patients, patient advocates, and experts from a variety of fields and disciplines. The effort identified areas in which there are only sparse data from which to create evidence-based recommendations for management of menstrual issues in young adolescents. In a final session of the meeting, which is the subject of this report, participants worked together to develop a manifesto regarding research on the menstrual cycle in adolescents. The group reached two major conclusions. First, there is need for a new research model that integrates grass roots community passion for participatory research in the research planning and regulatory oversight. Secondly, there is a need for a coordinated research effort on the menstrual cycle and its disorders in adolescents. This could initially take the form of a Study of Puberty Across the Nation (SPAN), similar to the Study of Women Across the Nation (SWAN) that addressed the normal menopausal process.

Keywords

adolescents; menstrual cycle; research models

Introduction

The purpose of this report, written jointly by a team of patients and clinical investigators, is to propose a new model by which to conduct research on the menstrual cycle in adolescents. This new research model involves an injection of passion. The word “passion” comes from the Latin “passus,” a form of “pati,” meaning “to suffer.”¹ This same root gives rise to the English word “patient.” Research without injected passion lacks the animating life force provided by the human conscience.² Research efforts that include patients and their representatives in the planning and regulatory process can add back this animating life force. As stated by Frederick Wilhelm Nietzsche, “Oh, my friends, that your self be in your deed as the mother is in her child – let that be your word concerning virtue.”(ref) Research on the menstrual cycle that is a partnership involving adolescent patients, their parents, and investigators is the model we propose.

Menarche and the establishment of regular ovulatory menstrual cycles involve complex and delicate interactive physiologic mechanisms that are poorly defined. Most importantly, there are significant benefits associated with understanding the mechanisms underlying menarche, the establishment of regular menstrual cycles, and the mechanisms underlying disorders of the menstrual cycle. These efforts would be expected to lead to better preventative health care, the earlier diagnosis of adult health problems such as osteoporosis or insulin resistance, and early initiation of specific therapies which could, in their own right, represent preventative measures. The menstrual cycle deserves more respect as a clinical concern and topic worthy of research.^{3–5}

Menstruation is denigrated in our society.⁶ There are pharmaceutical efforts to suppress the cycle, to make it go away, and there is often a delay in the evaluation of amenorrhea by women and their clinicians.⁷ Young adolescent girls have no power, few advocates, and their health concerns are frequently hijacked by issues surrounding contraception and abortion. There is a need for a coordinated research effort on the menstrual cycle and its disorders in adolescents.

There are challenging obstacles that make it difficult to conduct research on the menstrual cycle in adolescents. There are few community activists pushing for this research. There are few clinical investigators devoted to this area. In addition, there exists an increasingly obstructive regulatory process that clinical investigators have to navigate before research can be conducted. This obstructive regulatory process likely discourages young scientists who might otherwise become clinical investigators in this field.

An injection of passion for participatory research on the menstrual cycle could help alleviate some of these barriers. Passion from community activists could coalesce around specific yet diverse genetic disorders that adversely effect the menstrual cycle. The patients and families who are affected by the *FMRI* premutation, galactosemia, and congenital adrenal hyperplasia are specific examples of groups who could form communities that could rally around this effort. Also, families who have children that experience amenorrhea related to cancer chemotherapy would have interest in this area. This could be a nidus for the formation of a consortium that brings together diverse expertise. Passionate community

partners would help by bringing visibility to the area, helping to define the clinical dilemmas in need of work, and assisting in the recruitment of patients for protocols. A consortium of passionate community activists interested in the menstrual cycle could play the role as a “governmental conscience” around this issue and direct more funding of research to be initiated through partnerships between patient advocates and investigators. As shown in Figure 1 this research model would seek appropriate balance of funding for investigator initiated research and community initiated research. By the same token an injection of passion for participatory research from the community might inspire a growing cadre of committed translational investigators to work with the menstrual cycle consortium.

As discussed previously (Chapter __), Fuller Albright, often referred to as the “father of modern endocrinology,” exemplified this type of passion for investigation that greatly benefited science and ultimately, clinical care. Talented and altruistic investigators need to be identified early in their careers, possibly with support via employment by the US Public Health Service. Funding agencies might make long-term commitments to outstanding young scientists interested in the field, as well as facilitate the development of programs that support research in these areas. Equally important, established seasoned investigators need encouragement and support so that they are able to continue their commitment to research on the menstrual cycle and train the next generation of investigators.

An injection of passion into the governmental regulatory environment, aimed at articulating the specific the needs of patients, would energize research on the menstrual cycle. Balance could be added by placing patient advocates on institutional review boards. Additional balance to the regulatory environment could occur by placing patient advocates on federal committees that set research agendas. Mechanisms that encourage patient advocacy groups and community groups to collaborate by providing a “community principal investigator” on grant proposals would ensure that patient and community interests are well represented. Finally, a chapter of this monograph carefully addresses changes in governmental regulations that would benefit investigators and ultimately patients (Chapter __). The present regulatory environment includes numerous roadblocks that delay the initiation of protocols and discourage clinical investigators as they attempt to carry out their work.

Meeting participants concluded that working together to develop a “Study of Puberty Across the Nation (SPAN)” should be initial goal. Similar to the Study of Women Across the Nation (SWAN),⁸ this effort would provide impetus for the formation of a research consortium organized by partnerships inspired by the passion of community activists. SPAN would be a multi-site longitudinal, epidemiologic study designed to examine the health of adolescent girls and boys during the pubertal transition. The study would examine the physical, biological, psychological and social changes during this transitional period. The goal of SPAN would be to help scientists, health care providers, adolescents and parents learn how pubertal experiences affect health and quality of life as adults.

Conclusions

Research efforts that include patients and their representatives in the planning and regulatory process can add back an animating life force that governmental beauracracies have difficulty

providing. Patients and their families can provide insights from a grass roots level that can help formulate a “governmental conscience” regarding research priorities and research regulation. This monograph has identified several areas of research priority and importance related to the initiation of menarche and regulation of the menstrual cycle. The current model for research on the menstrual cycle is in need of improvement. Patients and their families need to fuel the passion for research in this area by working closely with investigators. This will direct efforts to probe the most clinically relevant questions and attract the needed support. A consortium involving diverse expertise from academia, industry, nongovernmental organizations, and government would bring together the needed resources to support “team science.” This would facilitate the development of multi-site protocols capable of using state-of-the-art assessment tools. There is much talk about health care reform. Equally important is discussion about reform of health research, and the adolescent menstrual cycle represents an important area in need of both recognition and investigation. We hope that the meeting in October 2007 and this monograph will represent an important initial step towards achieving goals of a “health research reform” as related to the menstrual cycle and adolescent health.

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Figure 1.
Models for community initiated and investigator initiated research.