Study Title: Evaluating the Change in Knowledge, Clinical Practice, and Behavior Outcomes of a Community Hospital’s Enduring Continuing Medical Education Activity on the Topic of Genetically Modified Organisms.

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Introduction

An enduring continuing medical education (CME) activity entitled Genetically Modified Organisms: Good, Bad, or Both? has been created in partnership by the CME Coordinator and CME Committee as part of a doctoral action research study affiliated with Capella University in the School of Public Service Leadership. The Researcher is employed by Flagler Hospital as the Manager, CPPD/CME. If the professional association causes you discomfort you may decline expressing an interest in this study.

If you have any questions or do not understand something in the slides, you should ask the researcher. Do not agree to participate in the study unless the researcher has answered your questions and you decide that you want to be a part of this study. You are welcomed to complete the CME activity on GMO and earn CME/CEU credit even if you elect not to be a participant within the action research study.

What is this study about?
The researcher wants to learn about the changes in knowledge, clinical practice and behavior of physicians, physicians’ assistants, nurse practitioners, and hospital employees that complete the continuing medical education activity.

Why am I being asked to be in the study?
*You are a physician (MD, DO, DDS, DMD, or DPM)
*You are a physician’s assistant or advanced registered nurse practitioner that has hospital privileges
*You are an interested clinical or non-clinical hospital employee

How many people will be in this study?
As many credentialed physicians, physicians’ assistants, nurse practitioners and other allied health practitioners, nurses and clinical and non-clinical hospital employees that participate in the enduring CME activity within a three month study period.

Who is paying for this study?
The Researcher is not being paid to conduct this study.

Will it cost anything to be in the study?
You do not have to pay to be in the study.

How long will I be in the study?
*Approximately 1.25 hours to complete pre-test to determine knowledge of GMO, CME activity, post-test to determine knowledge gained and potential changes in behavior resulting from CME activity through activity evaluation;
*Approximately 20 minutes to complete post-test and activity evaluation about personal and professional behavior changes, and
* Approximately 20 minutes to complete sustained knowledge test and post-post activity evaluation provided three weeks after activity completion.

What will happen during the study?
If you decide to be in this study, you will do the following things:
*complete the pre-test questions prior to the CME activity topic by accessing the SurveyMonkey® link provided within this CME activity.
CME Activity Genetically Modified Organisms: Good, Bad, or Both?
Action Research Informed Study Consent Form

*complete the continuing medical education activity and review the patient hand-out available on the CME website.
*provide demographic information that includes your name, degree, and Florida state license number for continuing education credit reporting, answer post-test questions to evaluate the change in knowledge about the activity topic, and answer the continuing medical education evaluation questions about the activity content, effectiveness of activity, reported change in your knowledge, competence, practice, or patient outcomes as a result of completing the CME activity by accessing the SurveyMonkey® link provided within this enduring CME activity.
*answer the post-continuing medical education sustained knowledge and change in your practice or behavior evaluation questions. The SurveyMonkey® link will be e-mailed to you approximately three weeks after completing the CME activity.

If you decide not to participate in the study you will do the following things:
*answer no to the consent question included within the CME activity pre-test questions by accessing the SurveyMonkey® link provided prior to the start of the CME activity.
*complete the continuing medical education activity and review the patient hand-out attached to this enduring CME activity.
*provide demographic information that includes your name, degree, and Florida state license number for continuing education credit reporting, answer post-test questions to evaluate the change in knowledge about the activity topic, and answer the continuing medical education evaluation questions about the activity content, effectiveness of activity, reported change in your knowledge, competence, practice, or patient outcomes as a result of completing the CME activity by accessing the SurveyMonkey® link provided at the end of the CME activity.

What is the CME activity about?
Genetically modified organisms (GMO) have been a controversial topic for approximately 20 years. According to the United States Department of Agriculture, over 90% of the corn, soybean, and cotton grown within the United States are genetically modified. The Grocery Manufacturing Association estimate that approximately 70%–80% of foods eaten daily contain genetically modified ingredients. Numerous news articles report the approval of new genetically modified plants, animals, and pharmaceutical products; or they hear about the corporate announcements of newly approved herbicide and/or pesticide compounds available for farmers to use on the new GMO plants, which raise questions for patients and healthcare providers alike, resulting in the need for additional education.

Activity Objectives: At the conclusion of this presentation, participants will be able to:
1. Define genetically modified organisms (GMO) and the various types of genetic modifications utilized in plants and animals.
2. Consider the historical and future impact of GMO on the food and pharmaceutical supply.
3. Discuss the controversial benefits, health risks and conflicts of interest associated with GMO products.
4. Summarize the various positions and viewpoints of medical and governmental organizations, scientists, and consumers.

Will I be recorded?
The information you provide by answering the pre/post test questions, demographic information, and evaluations will be recorded within SurveyMonkey® for analysis. Only aggregated results will be published.

Will being in the study help me?
You may not be helped by this study.
Are there risks to me if I am in the study?
No study is completely risk-free. However, it is not anticipated that you will be harmed or distressed during this study. You may stop being in the study at any time if you become uncomfortable.

Will I get paid?
You will not be paid a monetary value to complete the study. If you are qualified to earn continuing education credit, you may complete the CME activity and the accompanying pre/post test questions and activity evaluation to earn one (1) AMA PRA Category 1 Credit™ or one (1) CE/U credit.

Do I have to be in this study?
Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study by not completing the components of the enduring CME activity, which include the pre/post tests and activity evaluation.

The researcher can remove you from the study at any time. This could happen if:
* the researcher believes it is best for you to stop being in the study.
* you do not follow the directions about the study.
* you no longer meet the inclusion criteria to participate.

Who will use and share the information about my being in this study?
Any information you provide in this study that could identify you such as your name, demographics, or license number will be kept confidential within the confines of the CME Committee’s SurveyMonkey® password protected account accessible only by the Continuing Medical Education (CME) personnel. Since the non-researchers (CME personnel or CME Committee members) do have access to the CME Committee’s SurveyMonkey® account, your name, demographics, and license number has the potential risk of being revealed as a participant of the CME activity and/or study.

All printed documentation from the CME Committee’s SurveyMonkey® account will be maintained in a locked file drawer within the CME Coordinator’s office located in the hospital on a closed floor accessible by badge only. The provided personal information will only be used to report continuing medical education credits to the state of Florida. Your name, demographics or license number will not be revealed in any written reports or publication; only aggregated information will be utilized.

The researcher will keep the information you provide in a password protected hospital network folder for seven years and the researcher, researcher’s supervisor, dissertation committee, CME personnel and CME committee will have access to the study data. Additionally, Capella University’s IRB, the Research Compliance Committee (RCC), or its designee may review the research records.

Even if you leave the study early by not answering the SurveyMonkey® post-continuing medical education sustained knowledge question and evaluation e-mailed to you approximately three weeks after completing the CME activity, the researcher may still be able to use the data provided during the pre/post tests and activity evaluation.

Who can I talk to about this study?
You can ask questions about the study at any time. You can contact the researcher if you have any concerns or complaints. You should either e-mail or call the researcher at the e-mail address or phone number listed on page 1 of this form if you have questions about the study procedures, study costs (if any), study payment (if any), or if you get hurt or sick during the study.

Capella University’s Institutional Review Board (IRB) has been established to protect the rights and welfare of human research participants. Please contact us at 1-888-227-3552, extension 6313, for any of the following reasons:
You may contact the IRB without giving us your name. We may need to reveal information you provide in order to follow up if you report a problem or concern.

**Do you want to be in this study?**

I have read this form, and I have been able to ask questions about this study. The researcher has talked with me about this study. The researcher has answered all my questions. I voluntarily agree to be in this study. I agree to allow the use and sharing of my study-related records as described above.

By signing this form, I have not given up any of my legal rights as a research participant. I will get a signed copy of this consent form for my records.

______________________________
Printed Name of Participant

______________________________  __________________
Signature of Participant Date

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

______________________________
Printed Name of Researcher

______________________________  __________________
Signature of Researcher Date

Please return this signed consent form to Celina Makowski, Manager, CPPD/CME in the Medical Staff Library via inter-office mail, e-mail to celina.makowski@flaglerhospital.org or fax to 904-819-5290.