WCMC
Protocol Summary

Protocol Number: 1610017672

Status: Active - Open to Enrollment

Expiration Date: 03/06/2018

Last Approval Date:

Investigator: Carmel, Amanda S.

Protocol Description

Review Type: Initial Protocol (Full Board or Expedited or Exempt)

Application Date: 10/20/2016

Title: The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study

Required Summary: This is a randomized pilot study comparing the impact of the Patient Activated Learning System (PALS) on knowledge acquisition, recall, and decision making about antihypertensive medication compared to an established online health information system (WebMD). We will also compare the two systems with regard to user experience measures such as understandability and trust.

Performance Sites

Type	Site	Address
Performing Organization	Weill Medical College of Cornell University	Grants & Contracts 1300 York Avenue, Box 89 New York NY - 10021 USA

Investigators

Person Name	Primary Title	Directory Title	Units	Affiliate	Training Flag
Carmel, Amanda S.	Clinical Assistant Professor	M.D.	Medicine	PI - Responsible for Entire Protocol	N
Cornelius-Schecter, Anna	Temporary		Medicine	Conduct informed consent process,Screen subjects,Collect demographics,Evaluate Inclusion/Exclusion Criteria and Medical History,Perform other study specific interventions,Record Concomitant Medications,Review/Sign CRFs and/or DCFs,Protocol design,Data Analysis	N

Investigators

Person Name	Primary Title	Directory Title	Units	Affiliate	Training Flag
Frankel, Brittney Ariel			Medicine	Conduct informed consent process,Screen subjects,Collect demographics,Evaluate Inclusion/Exclusion Criteria and Medical History,Perform other study specific interventions,Review/Sign CRFs and/or DCFs,Protocol design,Data Analysis	N
Jannat-Khah, Deanna	Sr Research Data Analyst		Medicine	Protocol design,Supervision of study personnel,Data Analysis	N
Safford, Monika M.	Assistant Professor	M.D.	Medicine	Protocol design,Supervision of study personnel,Data Analysis	N

Administrative Contact

Type	Name	Comments
Administrator	Cornelius-Schecter, Anna	

Funding Source

Type	Name/Title
Department/Division	Medicine

Actions

Description	Comments	Action Date
Expedited Approval		03/09/2017
Submitted to IRB	Submit to IRB	03/06/2017
Modifications Required		02/21/2017
Administrative Correction	irb admin	02/14/2017
Submitted to IRB	Submit to IRB	01/27/2017
Protocol Created	Protocol Created	10/20/2016

Additional Form/s

Protocol Number: 1610017672 **Title:** The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study **Prinicipal Investigator:** Carmel, Amanda S.

Questionnaire Name: Subject population for Prod

Question:	Answer:
1. Will you be recruiting subjects to participate in this study? If you are obtaining tissue, examining medical records, or receiving data from another institution or database (e.g., WCMC will be acting as a coordinating center receiving data from subsites), then you must answer "yes" to this question.	Yes
2. How many subjects do you intend to enroll at WCMC (Please note, subjects are considered to be enrolled in the study once they have signed the consent form. The numbers below should include those subjects who will sign the consent form but may ultimately not participate in the study due to screen failure, not meeting inclusion/exclusion criteria, etc.)	120
3. How many subjects will be males? If male/female subjects will be enrolled regardless of gender, please indicate that here.	Subjects will be enrolled regardless of gender
4. How many subjects will be females? If male/female subjects will be enrolled regardless of gender, please indicate that here.	Subjects will be enrolled regardless of gender.
5. What is the age range for the subjects?	>18
6. What is the expected duration of study for individual subjects (days/months)? If this is a chart review or tissue procurement study, please indicate this here.	1 week
7. Please indicate the types of subjects you will be enrolling:	Outpatients
8. What is the subject's state of physical health? Please indicate of seriously or terminall ill.	Patients with hypertension may have a variety of medical problems. However, we will not be enrolling patients who are seriously or terminally ill.
9. Will you be targeting for enrollment of any of the following special groups: Minors, Pregnant Women/Fetuses, Neonates, Students and/or employees, Prisoners, Special racial or ethnic groups, Mentally/cognitively impaired (i.e. mentally ill, mentally retarded, emotionally disturbed, senile dementia, etc.).	No
10. Please select all of the recruitment methods for initially identifying potential subjects:	Medical records (request for HIPAA partial Waiver) Other (i.e. bedside, clinic interview, etc.)
	Demographic Information

11. Please specify what Protected Health Information (PHI) will be used and disclosed without immediate authorization from subjects.	Medication information Other Information
12. Additional Information (if any) on Protected Health Information (PHI) used and disclosed without immediate authorization from subjects.	None
13. Please specify what is being reviewed (i.e. Electronic Medical Record, appointment logs, etc.)	The medical record and upcoming appointments will be reviewed.
14. What is the plan to protect identifiers from improper use and disclosure?	Data is only recorded electronically Data will be coded Data will be kept on a password-protected computer Data will be saved on a secure server
15. What is the plan to destroy identifiers?	At the completion of the study
16. Additional Information (if any) on plan to protect identifiers from improper use and disclosure.	NA
17. With respect to the HIPAA partial waiver, will the PHI be reused or disclosed to any other person or entity? Please note, if you answer yes to this question, the study does not qualify for a HIPAA partial waiver.	No
18. Will the use or disclosure of PHI involve more than a minimal risk to privacy? If the answer to this question is Yes, then you do not qualify for a HIPAA partial waiver of Authorization. Please click on Start Over link to restart this form from the beginning.	No
19. Additional Information (if any) on plan to destroy identifiers.	NA
20. Is it feasible to conduct the research without access to and use of PHI? If the answer to this question is Yes, then you do not qualify for a HIPAA partial waiver of Authorization. Please click on Start Over link to restart this form from the beginning.	No
21. We need to access to the PHI to check eligibility of potential subjects before we seek an authorization. Please note, if you will be requesting a waiver of HIPAA authorization in the confidentiality section, the answer to this question should be no.	Yes
22. Please confirm that the screening of medical records for recruitment purposes involves no more than minimal risk to potential subjects.	Yes
23. Please confirm that the screening of medical records for recruitment purpose will not adversely affect the rights and welfare of the potential subjects.	Yes
24. Please confirm that the screening of medical records for recruitment purpose could not practicably be carried out without the waiver of immediate HIPAA Authorization.	Yes

25. Please provide justification for why the screening of medical records for recruitment purpose could not practicably be carried out without the waiver of immediate HIPAA Authorization.	There are a very large number of patients and visits at WCIMA. There is no way to know which patients might meet criteria for this study and it would not be feasible to obtain authorization from all patients who visit the clinic.
26. Please explain Other methods (i.e. bedside, clinic interview, etc.; if you will be approaching potential subjects in the clinic or at the bedside, please indicate how potential subjects will be approached, who will introduce the study to potential subjects, and who will obtain informed consent; This information should be the same in the informed consent section)	If potential subjects are not reachable prior to their clinic visit, they may be approached by the research assistant while they are waiting for their scheduled WCIMA visit. Patients will be approached in the waiting room with a very brief introduction by the RA. If they are interested, the RA will arrange a time after their WCIMA visit or at another visit for the patient to learn more about and potentially participate in the study.
27. If there is more than one active trial being run by the PI or in the department/division (if known), please provide an algorithm/schema or information on how it will determined which study the subject(s) will be offered. If none, state not applicable.	NA
28. Will subjects receive any compensation before or after study?	Yes
29. Please explain how much, at what rate, and in what form (i.e. cash, taxi fare, medical care, meals, gifts, etc.).	Patients will receive $25 in the form of a ClinCard

Additional Form/s

Protocol Number: 1610017672 **Title:** The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study **Prinicipal Investigator:** Carmel, Amanda S.

Questionnaire Name: Risk Level for production

Question:	Answer:
1. What is the risk level of the proposed research study?	Minimal Risk
2. Does your study qualify for exempt review in any of the categories detailed in the More section (Please click More on the right for a list of the categories)?	No
3. Does your study qualify for expedited review in any of the categories detailed in the More section (Please click More on the right for a list of the categories)?	Yes
4. Does your study qualify for expedited review under the category: Category 1 - Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.	No
5. Does your study qualify for expedited review under the category: Category 2 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.	No
6. Does your study qualify for expedited review under the category: Category 3 - Prospective collection of biological specimens for research purposes by noninvasive means. Examples include: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery;	No

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.	
7. Does your study qualify for expedited review under the category: Category 4 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.	No
8. Does your study qualify for expedited review under the category: Category 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). PLEASE NOTE: If extra tissue is being taken during a routine clinical procedure (i.e. additional tissue that is not being taken for diagnostic purposes), you do not qualify for expedited review under this category.	Yes
9. Is this a medical record/chart/appointment log review?	Yes
10. What are the inclusive dates of the charts you will be reviewing (mm/yyyy format)?	02/1/2017-1/31/18
11. Does your study qualify for expedited review under the category: Category 6 - Collection of data from voice, video, digital, or image recordings made for research purposes.	No
12. Does your study qualify for expedited review under the category: Category 7 - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.	Yes
13. This study is minimal risk but does not qualify for initial exempt or expedited review.	No

Additional Form/s

Protocol Number: 1610017672 **Title:** The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study **Prinicipal Investigator:** Carmel, Amanda S.

Questionnaire Name: Confidentiality of Data and Privacy of Subjects

Question:	Answer:
1. Will you be collecting identifiable PHI, either from the Medical Record or during the course of the study, where the data, either directly or through a code, can be linked back to an individual?	Yes
2. Are you requesting a complete HIPAA Waiver of Authorization? If you require a waiver of HIPAA authorization for some, but not all subjects, please answer no to this question and indicate in an open text field in this section which subjects you are requesting a waiver of HIPAA authorization from (e.g., you will be obtaining authorization from some subjects, but others are lost to follow-up)(Please note, the request for the HIPAA partial waiver to confirm subject eligibility is requested in the subject population section)	Yes
3. Please specify what Protected Health Information (PHI) will be used and disclosed without immediate authorization from subjects. Demographic Information, medication information, blood test results, urine test results, CT Scan results, MRI results, X-Ray results, PET Scan results, Physical Examination Information, Neurological Examination information, Psychological information, alcohol and substance use information, pathology results, HIV testing information, genetic testing results, cardiology results	Demographic information (age, name, phone contact information, race/ethnicity, zipcode)
4. Additional Information	NA
5. Please specify what is being reviewed (i.e. Electronic Medical Record, appointment logs, etc.)	Electronic medical record and appointment logs
6. What is the plan to protect identifiers from improper use and disclosure?	Data is only recorded electronically Data will be coded Data will be kept in the Pis locked office Data will be kept on a password-protected computer Data will be saved on a secure server
7. Additional Information	Patient's contact information will be collected and stored along with the patient's name on a secure computer/server, only until they have been contacted for the follow up call. Once they have completed the follow up call this information will be destroyed and, no name or contact information will be kept or linked to the patient's survey responses. We will record part of the semi structured interviews to keep track of responses accurately. Patients' identifying information will not be on the recording.

	They will be tracked by study ID only. The recording device will be stored in a locked desk in a locked office.
8. What is the plan to destroy identifiers?	Electronic identifiers will be deleted from the database Immediately when a patient chooses not to participate in the study
9. Additional Information	NA
10. Will the PHI be reused or disclosed to any other person or entity?	No
11. Will the use or disclosure of PHI involve more than a minimal risk to privacy? If the answer to this question is Yes, then you do not qualify for a HIPAA waiver of Authorization.	No
12. Is it feasible to conduct the research without the complete waiver of authorization? If the answer to this question is Yes, then you do not qualify for a HIPAA waiver of Authorization.	No
13. Please explain why it is not feasible to conduct the research without the waiver.	We are hoping to minimize the risk of breech of confidentiality for our subjects. For patients to sign a HIPPA waiver this would be a document linking them.
14. Is it feasible to conduct the research without access to and use of PHI? If the answer to this question is Yes, then you do not qualify for a HIPAA waiver of Authorization.	No
15. Please explain why it is not feasible to conduct the research without the access to specified PHI.	We need PHI to contact patients for the follow up call. This identifying data will be destroyed as soon as the patient has been contacted. It will not be linked to any survey responses or other research data.
16. Are you obtaining written HIPAA authorization from subjects by incorporating the appropriate HIPAA language into the informed consent form?	No
17. What specific safeguards will be employed to protect confidentiality of data?	Data is only recorded electronically Data will be coded Data will be kept on a password-protected computer Data will be saved on a secure server
18. Additional Information (if any) on specific safeguards employed to protect confidentiality of data when data is recorded electronically.	NA
19. How will samples be coded, who will have access to the code, and where will the code be kept?	Samples will be coded by number. Only the PI and the statistician will have access to the code. The code will be kept on a password protected computer. The code will be destroyed at the end of the study.
20. Additional Information (if any) on specific safeguards employed to protect confidentiality of data when data is kept on a password-protected computer.	NA

21. Additional Information (if any) on specific safeguards employed to protect confidentiality of data when data is saved on a secure server.	Only investigators involved in the study will have access to the data on the server.
22. Will data that identifies individual subjects be published or in any way disclosed to third parties other than project personnel or the study sponsor?	No
23. Will subjects have access to their research records while they are enrolled in the study? PLEASE NOTE: the HIPAA authorization form must include this information.	Yes

Additional Form/s

Protocol Number:	1610017672	**Title:**	The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study	**Prinicipal Investigator:**	Carmel, Amanda S.

Questionnaire Name: Human Tissue for Prod

Question:	**Answer:**
1. Tissue Submission Policy: Human tissue removed during a diagnostic or therapeutic procedure must be submitted to Pathology intact and may not be incised, opened, or damaged in any way, with the exception of surgical waste (defined below). Peripheral blood is not considered tissue. Surgical waste is specifically defined by the Medical Board as: 1. Subcutaneous tissue removed to facilitate wound closure and/or 2. Tissues significantly altered or diluted by the procedure such as lens phakoemulsifications, vitrectomy specimens or liposuction specimens. Other than the surgical waste noted above, ALL tissue must go FIRST to Pathology unless an exception to the tissue submission policy is requested. 1. Is human tissue from patients at this institution (WCMC) being used in this study based on the WCMC tissue policy described above? If yes, please complete the human tissue request form, found on our website at http://weill.cornell.edu/research/forms_and_policies/irb_forms/index.html and submit to submit2pathology@med.cornell.edu. Please note, if you answer yes to this question, IRB approval will not be released until the IRB office receives confirmation of approval from Pathology.:	No

Additional Form/s

Protocol Number:	1610017672	**Title:**	The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study	**Prinicipal Investigator:**	Carmel, Amanda S.

Questionnaire Name: Data and Safety Monitoring Plan for Prod

Question:	**Answer:**
1. Does this study qualify for exempt or initial expedited review?	Yes

Additional Form/s

Protocol Number:	1610017672	**Title:**	The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study	**Prinicipal Investigator:**	Carmel, Amanda S.

Questionnaire Name: Use of Drugs or Biological Agents

Question:	Answer:
1. Does this study involve the administration of an FDA regulated product, Nutritional supplement or a biological product?	No

Additional Form/s

Protocol Number: 1610017672 **Title:** The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study **Prinicipal Investigator:** Carmel, Amanda S.

Questionnaire Name: Non-Technical Research Plan Prod

Question:	Answer:
1. What is the expected end date of the study? Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	06/30/2018
2. Will there be student investigators (must be older than 18 years of age)? Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	Yes
3. List the student names. Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	Brittney Frankel
4. What are their responsibilities in the project? Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	Brittney Frankel is a 4th year medical student at Weill Cornell. She will be responsible for some content development of the PALS site and will participate in study design. She will also be responsible for screening charts for subject eligibility, contacting and enrolling patients in the study, informed consent, study procedures, and data collection. She will also be involved in data analysis and manuscript preparation.
5. Please list the investigator(s) who will be supervising the students. Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	Carmel, Amanda S.
6. Study Design: Include information on the hypothesis, research question, standard vs. experimental procedures (interventions happening as part of clinical care vs. those that are occurring only because the subject is part of the study), the use special or unusual equipment or procedures.Include specifics on all study interventions and their frequency and the treatment plan (For example, the dosage of a drug to be given and the frequency). For randomized studies, list the study groups and under each describe the categories of procedures. List together in a group all procedures that are part of standard of care treatment,and list together in a group all procedures that are investigative, separating and labeling the two groups. Tables and/or charts are helpful and encouraged and should be uploaded in the attachments section as a continuation of the study design. Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	Primary research question: 1)Do hypertensive patients who learn about hypertension medication with PALS (intervention) have higher immediate and 1 week knowledge assessment scores than patients randomized to learn the same information via WebMD (control)? We hypothesize that patients in the PALS group will have higher immediate and one week assessment scores. Secondary research questions: 1)Do patients in the PALS group feel more informed to make hypothetical decisions about taking medications compared to patients in the WebMD group? We hypothesize that patients in the PALS group will be more likely to indicate that they have sufficient information to make hypothetical decisions about taking medications than patients in the WebMD group. 2)Do patients in the

PALS group rate it higher on user experience measures such as trust, usefulness, comprehensibility, and adequacy of the information, attractiveness of the site, and level of engagement, than those in the WebMD group? We hypothesize ratings on these measures will be higher in the PALS group compared to the WebMD group. 3)Which questions about antihypertensives do patients consider most important and are the 5 most highly rated questions more likely to be addressed on PALS vs. WebMD? We hypothesize that PALS will address more questions that patients rate as important compared to WebMD. Patients with hypertension, who have been prescribed any antihypertensive medicine except chlorthalidone will be recruited from the Weill Cornell Internal Medicine Associates (WCIMA) practice. Potentially eligible patients who have an upcoming appointment at WCIMA will be identified via a review of the electronic medical record. In cases where the patient's eligibility is unclear, RA's will contact the patient's PMD to confirm eligibility. Potentially eligible patients will be contacted via the telephone to assess their interest in participating and to schedule a study visit for those interested. Verbal consent will be obtained either on the phone or at the study visit. Potentially eligible patients may also be recruited from the waiting room at WCIMA if we were unable to contact them by phone prior to their WCIMA visit. Eligible patients who agree to participate will be randomized to view information about the antihypertensive, chlorthalidone, via the PALS or WebMD. The study procedures will be identical for both the PALS and WebMD groups. Chlorthalidone was chosen because, despite its efficacy, it is not prescribed as often as other antihypertensives. This will allow us to select a sample of patients who are less likely to have baseline knowledge of the information we are testing. To assess knowledge acquisition and recall, patients will be shown up to 10 pre-specified webpages within their site of randomization that contain information that answers up to 10 discrete questions about chlorthalidone. We administer up to 10 corresponding assessment questions to be answered immediately after viewing the information. The knowledge score will be the percentage of correct responses. We will evaluate knowledge retention by asking the same assessment questions over the phone one week later. User experience, trust, and patient decision-making will be assessed through a patient survey and through a short semi structured interview. We will also collect information on health literacy via the REALM-SF health literacy questionnaire as well as demographic information including age, level of education, race/ethnicity, prior Internet use, and access to the Internet. To assess question prioritization/availability on PALS/WebMD, we will show patients a

list of up to 40 questions and ask them to chose those most important to them. We will search for the answers to the highest prioritized questions to determine availability on PALS/WebMD. Surveys and knowledge scores will be administered via Qualtrics. Subjects will be compensated with a $25 ClinCard after completing the study visit.

7. Rationale and Justification for the study: for example, historical background, investigator's personal experience, pertinent medical literature. Please include any information regarding studies in animals that are pertinent to the proposed study. If this study involves an investigational drug, an FDA approved drug being used off label or that is being given according to label but for research purposes only, please indicate what are the effects of the drug for its intended use (dosage range and efficacy, data in humans plus animal studies, when appropriate. Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.

For patients to participate as partners in shared decision-making, and to adhere to physician recommendations, they need to have access to easily understood, reliable information that they can remember. Despite physicians¿ efforts, patients often retain little information, or remember incorrectly. According to one review patients remember only 40-80% of what physicians discuss. Further, people with lower health literacy are less likely to remember health information. Many patients use the Internet as a means of educating themselves about their conditions and treatments. However, delivering effective eHealth information has many of the same challenges as other modes of delivering patient education. Using strategies shown to enhance adult learning may maximize the utility and benefit of eHealth sources. In the educational literature, it has been shown that people generally learn better from audiovisual (AV) compared to written materials (the modality effect). Further people learn better when shown information in a conversational versus formal narration style (the personalization effect). In 2015, Bol et al. showed that AV vs. written modality increased recall of information in both younger and older adults (P=.04). Further, there was a statistically significant synergistic effect between modality and narration style: combining AV with conversational style increased recall compared to combining written information with formal style (P=.01), and to written information with conversational style (P=.045). Structuring information also appears to improve recall. Langewitz et al. randomly assigned subjects to ¿structured¿ video education (content divided into ¿chapters¿) or unstructured video education. Subjects in the structured group recalled statistically significantly more items than those in the non-structured group and rated the information significantly easier to understand. Structuring information in ¿reusable knowledge objects¿ has been used in the learning technology industry as a strategy to facilitate learning. Finally, lowering the reading level of written health information is another strategy that may enhance eHealth learning. As noted, many in the US have low health literacy. According to the 2003 national assessment of adult health literacy report, only 12% of adults had proficient health literacy, 53% had intermediate health literacy, 36% had basic or below health literacy. The

National Institutes of Health recommends that patient education materials be at a 6-7th grade reading level. However, many health information resources such as WebMD are written at a higher level. Given the growth of eHealth and its potential shortcomings, there is a crucial gap in our understanding of how best to deliver health information to improve outcomes. To address this gap, we are developing a Patient Activated Learning System (PALS). The long-term goal of the PALS is to improve health outcomes through improved medical literacy and medical adherence. PALS uses best practices in adult education to improve patient education. The PALS is based on combining several core features: 1) content is organized according to patient¿s questions, 2) information is delivered through audiovisual (as well as written) content in an engaging, conversational style, 3) content is organized into concise, discrete segments that cover a single learning objective, and 4) the writing is at 6-7th grade reading level. To date studies have not addressed the impact of combining several of these best practice approaches to eHealth information on knowledge acquisition, recall, or website user experience. We aim to understand if the PALS approach to eHealth delivery improves patient learning and provides an enhanced user experience over the current leading eHealth source, WebMD. This study will also generate pilot feasibility data for a larger project testing the effect of using PALS as part of an intervention to enhance medication adherence.

8. Primary Objective: Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.

Determine if 60 hypertensive patients who learn about hypertension medication with PALS (intervention) have higher immediate and 1 week knowledge assessment scores than 60 hypertensive patients randomized to learn the same information via WebMD (control).

9. Secondary Objective: Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.

1) Compare differences in patient¿s responses to hypothetical questions about antihypertensive medicine-related decision making between those who viewed information via PALS and those who viewed information via WebMD. 2) Describe differences in patients¿ user experience with PALS vs. WebMD. We will compare usefulness, comprehensibility, and adequacy of the information as well as attractiveness of the site, level of engagement, and trustworthiness of the materials between the two sites. 3) To determine which questions about antihypertensives patients consider most important and whether or not the 5 most highly rated questions are more likely to be addressed on PALS vs. WebMD.

10. Statistical Considerations (e.g. justification for sample size or "n". Please include the total number of subjects to be recruited at

Preliminary analyses and data summaries: All analyses will begin by examining

WCMC, the total number of subjects at all site (if a multisite study), expected total screening failures/dropouts at WCMC (if applicable), How the data will be analyzed, etc: Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.

characteristics and potential differences between the control and intervention groups. Particular attention will be paid to assessing normality among the knowledge retention scores. Assessment of outlying observations will also be examined. We will use distribution-appropriate bivariate tests for pair wise and overall differences between and among study groups in baseline characteristics. Descriptive statistics, such as frequencies, means, ranges and standard deviations (SD) will also be calculated for participant demographics. General analytic approach: This Randomized Control Trial (RCT) has adequate statistical power for detecting main effects between study groups for retention of knowledge scores. As an RCT, main hypothesis tests will be conducted between groups first without adjustment then with adjustment for covariates as the unit of analysis. Additional analyses will assess differences between groups adjusting for demographic characteristics associated with knowledge retention. Testing the main hypotheses. The main analyses will test for differences in the mean knowledge scores between control vs. PALS immediately following and one week after visiting the website of randomization. The main hypothesis is that there will be significant differences in the mean knowledge scores between the participants who visit the control and PALS website. If the outcomes are approximately normally distributed, we will use two-sided unpaired t-tests for the main hypotheses, and Wilcoxon tests if non-normality is a concern. Further analyses. We will conduct additional analyses for secondary outcomes. Chi-square tests will be used to compare categorical responses between the two study groups. Two sample t-tests will be used to assess differences between continuous variables. Unless otherwise specified, all statistical tests will be two-sided, and p<0.05 will be considered to be significant. Sample size. We plan to recruit 120 participants. Sixty will be randomized to the control (WebMD) arm and 60 to the PALS arm. We conservatively estimate patient attrition at 20%, resulting in an effective sample of 100. For various mean knowledge scores in the control group, we calculated the mean score needed to detect statistical significance in the PALS group for standard deviations of 5, 10, and 15. Our sample size of 120 will be sufficient to detect a clinically meaningful difference in the knowledge retention scores. Power and Detectable Difference. All detectable difference calculations are based on two-sided tests with an alpha of 0.05 and 80% power. The primary outcome analyses will be t-tests or Wilcoxon tests, if non-parametric, for assessing differences between the two groups in mean knowledge retention scores. Since the knowledge score will be created for this study and standard deviations (SD) are not known,

	we calculated the detectable difference for SD of 5, 10, and 15, which would give us detectable differences in mean scores ranging from 2.8-8.5. The primary outcome, knowledge retention, is a 0-100 score. We will be able to detect a 10-point difference in control-intervention scores. We will also be able to detect clinically important differences in user experience scores (2.8-8.5) across a range of SDs.
11. Inclusion Criteria: Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	-Weill Cornell Internal Medicine Associates (WCIMA) patients with hypertension who have been prescribed any antihypertensive medicine except chlorthalidone. -Patients who meet the criteria above and are English speaking and without cognitive impairment or other medical condition that would impair or preclude their ability to participate (such as a serious medical condition).
12. Exclusion Criteria: Any information that is written in this space prior to CSEC approval will be overwritten by the CSEC upon approval.	-WCIMA patients without hypertension -WCIMA patients with hypertension who have not been prescribed antihypertensive medicine -Patients who are non-English speaking -Patients with cognitive impairment or other medical condition that would impair or preclude their ability to participate (such as a serious medical condition).
13. Will you be collecting as a part of this research study any of the following: tissue from surgical pathology, blood, urine, bone marrow aspirate or other biological samples?	No
14. Does the research planned in this project involve any form of invasive procedure (minimally invasive or greater, including venipuncture)?	No
15. Does the research planned in this project involve any major changes in diet or exercise?	No
16. Does the research planned in this project involve any administration of physical stimuli other than auditory and visual stimuli associated with normal classroom situations?	No
17. Does the research planned in this project involve any deprivation of physiological requirements such as nutrition or sleep, manipulation of psychological and/or social variables (i.e. sensory deprivation, social isolation, psychological stress, etc.?	No
18. Does the research planned in this project involve any use of deceptive techniques without the knowledge of the subect?	No
19. Does the research planned in this project involve any probing of information which might be considered personal or sensitive, including the examination of the medical record?	Yes
20. Please explain in detail.	We will review the medical record of potential subjects to identify eligible patients to contact about possible participation in the study.

21. Does the research planned in this project involve any presentation to the subject of any materials which they might find to be be offensive, threatening or degrading?	No

Additional Form/s

Protocol Number:	1610017672	**Title:**	The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study	**Prinicipal Investigator:**	Carmel, Amanda S.

Questionnaire Name: Radiation Safety for Prod

Question:	Answer:
1. Will this study involve in vivo imaging or image guided interventions (e.g., CT, US, MRI, x-ray, fluoroscopy, etc.)?	No
2. Will this study involve the use of radioisotopes or other sources of ionizing radiation (i.e., diagnostic and/or therapeutic radiation, e.g. xray machines, CT, cardiac catheterization, radioisotopes, radiation therapy, etc.) for purposes other than standard of care either entirely or in part? (i.e., subjects would not be having these procedures in the manner described in the protocol and informed consent if they were not enrolled in the study; or subjects might have some of these procedures for standard of care and some of these procedures outside of normal standard of care)? If so, please obtain review and approval from the Radiation Safety Committee and attach the approval documentation to the eIRB application prior to submission. You must receive approval from the Radiation Safety Committee (RSC) before IRB approval can be released. Contact the RSC Chair, Stanley Goldsmith, M.D. at 212-746-4588 or sjg2002@med.cornell.edu for more information. Please contact Peter Capitelli (pec2008@med.cornell.edu) the Radiation Safety Officer, for assistance in calculating the dosimetry prior to submitting the protocol to the IRB or Radiology for review.	No

Additional Form/s

Protocol Number:	1610017672	**Title:**	The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study	**Prinicipal Investigator:**	Carmel, Amanda S.

Questionnaire Name: Test Articles and Bioavailability/Bioequivalence S

Question:	**Answer:**
1. Will this study involve the use of test articles and/or is a bioavailability/bioequivalence study?	No

Additional Form/s

Protocol Number: 1610017672 **Title:** The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study **Prinicipal Investigator:** Carmel, Amanda S.

Questionnaire Name: Additional Information for prod

Question:	Answer:
1. Will this study take place in WCMC/NYP?	Yes
2. Please provide information on where in WCMC/NYP this study will take place (i.e., WCMC or NYP specific clinics or laboratory space or CBIC, etc.)	The study will take place at Weill Cornell Internal Medicine Associates.
3. Will this study take place in a private office or another location outside of WCMC/NYP?	No
4. Please indicate the number of externally funded research and/or sponsored projects that this IRB protocol falls under. If this protocol is funded internally please enter 0. Externally funded research and/or sponsored projects include the following. Please click "More" for definitions of these terms. A) Grant/Contract/Subaward/Clinical Trial Grant B) Clinical Trial Agreement (Investigator Initiated) C) Clinical Trial Agreement (Industry Initiated) D) Sponsored Research Agreement (Investigator Initiated) E) Sponsored Research Agreement (Industry Initiated) F) Material Transfer Agreement (Recipient Initiated) G) Material Transfer Agreement (Provider Initiated) H) Other (i.e. Data Use Agreement, Registry)	0

Additional Form/s

Protocol Number: 1610017672 **Title:** The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study **Prinicipal Investigator:** Carmel, Amanda S.

Questionnaire Name: Potential Benefits for Prod

Question:	Answer:
1. Please assess potential benefits to subjects and to society which may accrue as a result of this research, analyzing the risk/benefit ratio and why the risks are justified by the potential benefits.	Direct benefits to subjects may include increased knowledge about hypertension and hypertension medicines. Information gleaned from this study may help them and patients like them in the future obtain better health information and thus be better informed for medical decision making and medication adherence. We believe these benefits outweigh the minor risks of participation.

Additional Form/s

Protocol Number:	1610017672	**Title:**	The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study	**Prinicipal Investigator:**	Carmel, Amanda S.

Questionnaire Name: Institutional Biosafety Committee for Prod

Question:	Answer:
1. Is this study a human gene transfer trial?	No
2. Does this study involve the use of non-FDA approved Biological agents in human subjects (i.e. non-fDA approved viruses, bactertia or other etiological agents that are used as investigational new drugs/vaccines in human subjects	No

Additional Form/s

Protocol Number:	1610017672	**Title:**	The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study	**Prinicipal Investigator:**	Carmel, Amanda S.

Questionnaire Name: Clinical Translational Science Center for Prod

Question:	Answer:
1. Will the clinical Translational Science Center be used? (This would include the use of the RedCap data base program)	No

Additional Form/s

Protocol Number:	1610017672	**Title:**	The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study	**Prinicipal Investigator:**	Carmel, Amanda S.

Questionnaire Name: Informed Consent for Prod

Question:	Answer:
1. Are you requesting a waiver of informed consent, either written or oral? If you require a waiver of informed consent for some, but not all subjects, please answer no to this question and indicate in the open text field which subjects you are requesting a waiver of informed consent from (e.g., you will be obtaining consent from some subjects, but others are lost to follow-up).	No
2. Are you obtaining written consent?	No
3. Are you obtaining oral consent?	Yes
4. Are you obtaining oral consent because the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.	Yes
5. Are you obtaining oral consent because the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.	Yes

Additional Form/s

Protocol Number:	1610017672	**Title:**	The Impact of the Patient Activated Learning System (PALS) on Knowledge Acquisition, Recall, and Decision Making about Antihypertensive Medication: A pilot Study	**Prinicipal Investigator:**	Carmel, Amanda S.

Questionnaire Name: Medical Devices Questionnaire

Question:	**Answer:**
1. Will any medical devices as defined by FDA regulations be used in this protocol?	No