Study Protocol
Hopewell Hospitalist: A Video Game Intervention to Increase Advance Care Planning by Hospitalists [Efficacy Trial]

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1. Introduction and Background

Advance Care Planning (ACP) is an integral part of the National Academy of Medicine's objective of ensuring that patients receive person-centered, family-oriented, and evidence-based care, particularly at the end-of-life. However, less than half of all people in the U.S. have documented advance care plans, such as an Advance Directive. Existing guidelines therefore advocate that physicians use the opportunity of hospitalization to initiate ACP conversations.

ACP involves discussion of goals, values, and preferences for health care with the patient, family members, or surrogates. Discussions may include hospice care, end-of-life care options, power of attorney for health care decisions, living wills, and physician orders for life-sustaining treatment (POLST).

Numerous barriers impede the initiation of ACP in the hospital. High-quality conversations require physicians to have both the willingness and the time necessary to engage in these emotionally complex interactions. As a result, physicians typically defer ACP for all except the most critically ill. In contrast, experts advocate that these conversations occur prior to discharge for every patient over the age of 65. How best to shift physicians' decisional thresholds – convincing them to engage in ACP conversations with all eligible patients – remains unclear.

In prior work, the PIs developed a customized video game to recalibrate physician heuristics (intuitive judgments) in trauma triage, drawing on research from other domains suggesting the potential effectiveness of using narrative engagement to change behavior. Narrative engagement interventions use messages designed to resonate with recipients in personally relevant and meaningful ways. The PIs found that physicians using the game made fewer diagnostic errors on a validated trauma triage simulation than those randomized to use a text-based educational program, a difference that persisted to six-month follow up. Given this success, this study hypothesizes that narrative engagement might also change physicians' decisional thresholds and adapted the video game to address the problem of ACP in the hospital.

This study is part of a larger project, "Physician Cognition, Inpatient Advance Care Planning, and Outcomes for Seriously Ill Older Adults," and uses a pragmatic, minimal risk behavioral intervention to test the effect of the intervention, compared to usual care quality improvement alone, on the likelihood of ACP discussions by hospitalists with hospitalized patients aged 65 and older. Hospitalists employed by Sound Physicians – a large national physician practice that employs more than 2000 acute care providers in hospital medicine at more than 200 hospitals in 38 states – are our study population. The primary outcome is billed ACP discussions.

The usual care quality improvement includes: 1) mandatory and voluntary CME-accredited e-learning, including modules on compliance with CMS billing codes 99497 (ACP first 30 mins) and 99498 (ACP additional 30 mins), templated ACP documentation, and training in serious illness communication; 2) compensation incentives rewarding quality and productivity performance, including $20/ACP conversation; and 3) handheld and desktop IT tools ("SoundConnect") that enable coding and billing and facilitate coordination and compliance with clinical pathways. The effect of these efforts will be treated as the baseline to which the effect of the game will be compared.

The planned study will test both the effect of the video game intervention on ACP billing practices as well as the impact of the distribution strategy in a hybrid efficacy-effectiveness clinical trial. We will use linked Sound-submitted claims data to quantify the influence of the intervention on ACP billing (available with a 3-month lag) and linked CMS-assembled claims data to quantify the influence of the intervention and any shifts in ACP behavior on secondary episode-based patient healthcare use and outcomes (available with a 2-year lag).

2. Objectives and Hypotheses

This study will test the efficacy of using a customized theory-based video game to increase rates of ACP for hospitalized older adults.

The primary outcome is physician billing for ACP (data available directly from Sound Physician-submitted claims with a 1 quarter lag). The primary hypothesis (H1) is that hospital ACP billing practices after distribution of the video game will increase (more than would be expected by secular trends alone). A priori post-hoc hypotheses include: (H2) The larger the proportion of hospital physicians who play the game, the greater the increase in ACP rates, and (H3) Differences in hospital billing practices before-and-after distribution of the video game will be positively associated with the proportion of physicians who have completed their organization's ACP e-curriculum.

The secondary outcomes are episode-based patient healthcare use and mortality (data available from CMS with a 2-year lag).

3. Study Design

Note: All aspects of this study design will need to be re-appraised in light of the evolving Covid-19 pandemic and the associated secular disruptions in hospital medicine staffing, medical decision-making processes, and mortality among older adults.

30 hospitals (conditional on the response rate) will be randomized into an order for a stepped wedge cluster randomized trial. The stepped wedge trial randomizes hospitalist participants at the group level (i.e., hospital) rather than the individual level (i.e. hospitalist). We will use a stepped-wedge trial design for two reasons: 1) individual-level randomization risks misclassifying patients, contaminating unexposed physicians, and failing to address group-level attitudes to and practices of ACP; 2) a parallel cluster randomized design risks imbalance among groups because of the high intra-class correlation coefficient that exists for billing practices at the hospital-level. Each group 'crosses over' from control to intervention at a randomized timepoint and multiple 'time steps' of data collection occur. All the Sound-affiliated hospitalists at each hospital will be invited to use the video game intervention. If a participant accepts, the participant will receive an iPad with the video game pre-loaded. The iPad will be mailed to either a participant's home address or the hospital site where it will be distributed by the clinical performance nurse or nurse liaison. We will contact and consent a small sample of 20-30 physicians who completed the efficacy portion of the trial for a semi-structured interview via Zoom to discuss their experiences playing the game. These semi-structured interviews will be recorded and transcribed, and participants will be compensated with a $50 Amazon gift card for

participating in the interview. All data will be collected through the game itself with Google Analytics and Qualtrics. This data will be linked with Sound data and with Medicare claims that is regularly and continually collected by those external parties. Finally, we will ask Sound to abstract the charts of a random sample of 200-300 patients treated by trial physicians, so that we can test the validity of our outcome measures.

4. Analysis

Please see the Statistical Analysis Plan

5. Study Progress Monitoring

This study will be overseen by a Data Safety and Monitoring Board. The DSMB has been empaneled. It will be approved and the first meeting will be held before the start of the trial. In the process of establishing the DSMB charter, DSMB members will provide guidance on safety surveillance and reporting requirements.

As determined by NIH, the DSMB will "1) periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy, and 2) make recommendations to NIDCR concerning the continuation, modification, or termination of the trial. The DSMB considers study-specific data as well as relevant background knowledge about the disease, test agent, or patient population under study."

As described by NIH, "The DSMB is responsible for defining its deliberative processes, including: event triggers that would call for an unscheduled review, stopping procedures that are consistent with the protocol, unmasking (unblinding), and voting procedures. The DSMB is also responsible for maintaining the confidentiality of its internal discussions and activities as well as the contents of reports provided to it.

The DSMB should review each protocol for any major concern prior to implementation. During the trial, the DSMB should review cumulative study data to evaluate safety, study conduct, and scientific validity and integrity of the trial. As part of this responsibility, DSMB members must be satisfied that the timeliness, completeness, and accuracy of the data submitted to them for review are sufficient for evaluation of the safety and welfare of study participants. The DSMB should also assess the performance of overall study operations and any other relevant issues, as necessary."

All eligible participants will be contacted at the start of the trial and receive the interventions as described under Section 3. The trial will run for a total of 6 months.

6. Risks & Benefits

Note: Risks may be physical, psychological, social, legal, economic, to reputation, or others.

a. Describe any potential risks, their likelihood and seriousness:

There are two categories of participants in this pragmatic trial: 1) Consented research participants (hospitalists); and 2) Unconsented research participants (patients of participating hospitalists).

The consented research participants are the hospitalists employed by Sound Physicians. *A key consideration in this study that the participants' employer is a partner in conducting the trial.* The primary outcome is the hospitalists' behavior; specifically, the frequency with which hospitalists bill for ACP conversations with patients 65 and older.

The unconsented research participants are the patients of participating hospitalists. Since the trial seeks to influence hospitalist ACP behavior during patient encounters, hospitalists' patients will be indirectly affected. *A key consideration is that this study randomizes participation at the level of the hospital, and consent at the physician level, with the intent to improve the quality and patient-centeredness of patient care. However, neither the hospitals nor the physicians will obtain consent from their patients*

Consented research participants (hospitalists):

Potential Risks: There are no health risks to consented research participants (hospitalists). The three major potential risks are lack of voluntariness (coercion), impact on employability, and loss of confidentiality.

Lack of voluntariness (i.e., undue influence). A central tenet of clinical research is that participation is voluntary. This study will make it very explicit that research participation is not a condition of employment by Sound. However, there may yet be a perception of lack of voluntariness. This study cannot completely separate research participation from employer purview. Study implementation requires the disclosure of study participation to members of the Sound study team who are responsible for programming the information technology (IT) platforms that will be used to deliver the intervention(s).

Confidentiality. Participant data will be collected and stored with physician identifiers (e.g., names and UPIN numbers linked to unique study IDs). Strict confidentiality and privacy procedures have been put in place to protect against any potential public disclosure of individual provider performance data. All physician-level data will be de-identified for analysis and reporting. A compromise of security of survey, interview, intervention adherence, and ACP performance data outside of the study would result in a breach of confidentiality and violation of privacy.

Sound and TDI each have detailed policies and procedures in place for the physical and electronic security of the SoundConnect and Medicare claims data.

Employability. Study participation is not a condition of employment. Sound collects and reports multiple measures of hospitalist performance. These are conditions of employment. Hospitalists already receive data on their own ACP performance monthly, which is reported to their direct hospital supervisors in comparison with all of the hospital's other hospitalists' performance. There is no central Sound policy regarding how hospital supervisors use any

performance data, including ACP performance. This study will not change these reporting procedures. Therefore, responses should not influence employability. Indeed, if the intervention(s) are effective, participants randomized to active treatment will improve their performance. A theoretical concern is if increased attention to ACP crowded out hospitalists' focus on other quality targets. While this was not originally a secondary outcome proposed in the original protocol, the administrative and statistical feasibility of adding this safety measure will be assessed (see below).

Unconsented research participants (patients of hospitalists):

The three main risks to unconsented research participants (patients of participating hospitalists) are violation of rights due to non-consent and lack of voluntariness, breach of confidentiality, and shortened survival time associated with preference-concordant treatment associated with modifying code status to "do not resuscitate" or completing ACP documents such as physician orders for life-sustaining treatment (POLST) as well as potential medical undertreatment associated these orders.

ACP meets the minimal risk standard as defined at 45 C.F.R. § 46.102(i), "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." ACP involves discussion about goals, values, and treatment preferences with the patient, family members, or surrogates. Discussions may include hospice care, end-of-life care options, power of attorney for health care decisions, living wills, and physician orders for life-sustaining treatment (POLST). Engagement in comprehensive ACP conversations are not strictly required and practices vary widely. Specifically, while the Joint Commission requires that patients be asked whether they have a pre-existing advance directive at the time of acute care admission and that code status be documented. Comprehensive ACP conversations are not currently a Joint Commission requirement. Medicare encourages comprehensive ACP conversations by paying for these services, but their policy states that the services are "voluntary," meaning that if a provider broaches an ACP conversation with a patient, they must provide an opportunity to decline the services and documented in the record. Therefore, having or not having a comprehensive ACP conversation during an acute care admission are both currently medically recognized standards of care.

Lack of voluntariness (i.e., non-consent). As outlined above, patients of consented and randomized hospitalist will not be provided with a choice regarding whether they are treated by an intervention or control hospitalist. This situation is common to cluster randomized studies designed to improve adherence with clinical practice guidelines.

Confidentiality. The source of patient-level data for clinical trial outcomes is administrative billing data. This includes data collected by Sound Physicians for the purposes of billing the Centers for Medicare and Medicaid Services (CMS) and other payers for physician services during the index hospitalization (primary outcome: ACP billing) and additional claims data from CMS for data on predictors/risk-adjusters and secondary outcomes.

The main procedures to protect against risks (lack of voluntariness, confidentiality, employability) to participation by the consented research participants (hospitalist physicians) involve separating research- and operations-related elements of the study. Specifically,

Dartmouth team members, not Sound Physician team members, will complete key research-related activities such as recruitment, informed consent, primary data collection, data analysis and storage.

To protect against lack of voluntariness, confidentiality, and threats to employability, no Sound Physician employee will participate in the recruitment and informed consent process beyond introducing the study and Dartmouth investigators to potential research participants. Any reports regarding undue influence will be treated as a SAE. No member of the study team will disclose study participation to Sound leadership (including co-investigator Birkmeyer) or to the hospitalists' direct supervisors.

Data elements will be entered directly by the research coordinator; these files are backed-up daily and archived weekly. All study subjects will be assigned unique study identifiers that will appear on all data collection instruments, documents, and files used in the statistical analysis and manuscript preparation. Limited team members will have access to identifiers needed for tracking and informed consent. We will follow TDI data security procedures to protect the confidentiality of physician research participant data along with Medicare beneficiary billing claims data (see below).

The principal means of protecting against violation of patient rights and harming welfare of unconsented research participants (patients of participating hospitalists) for pragmatic trials like ours is thoughtful review by multiple experts in human subjects research ethics and regulation, including NIH staff, an independent DSMB, and the Dartmouth Institutional Review Board. The physician-directed behavioral interventions proposed in the current study augment a suite of non-randomized quality improvement interventions already deployed by Sound Physicians to increase ACP by hospitalists which are not subject to such review or to rigorous safety or efficacy evaluation.

The PIs will audit a purposive sample of ACP conversations during the trial to assess quality. They will follow TDI data security procedures to protect the confidentiality of Medicare beneficiary billing claims data (see below).

Data Security Procedures:

TDI has a long and flawless history in maintaining and using extremely large confidential databases. The mission of the Data Analytic Core (DAC) at The Dartmouth Institute for Health Policy and Clinical Practice (TDI) is to provide support to research that contributes to the effectiveness, quality, equity, and efficiency of health care within the United States, which is complemented by its promise to respect personal privacy, safeguard the confidentiality of data and to provide a secure environment for the databases under its management. The DAC functions as the Data Coordinating Center for TDI. As detailed in the DAC Policies and Standards Manual (PSP), the DAC meets this commitment by ensuring data anonymity; maintaining principles and policies for the protection 55of health care data including strict policies which limit access to data and heightened security measures (organizational, technological, and physical) according to both FISMA (Federal Information Security Management Act) and HIPAA (Health Information Portability and Accountability Act) requirements; reviewing and approving research proposals requesting use of the data sets controlled by the DAC; assuring that appropriate and current data use agreements, institutional reviews and other approvals are in

place for research projects; an active IT Security Committee, at the working and governance levels; annual staff training to keep health information protection matters a constant priority; requiring that ALL TDI and the Data and Analytic Core (DAC) users sign a TDI DAC Policies, Standards, and Procedures Information Security Acknowledgement and Agreement; regularly reviewing the DAC policies to ensure they are in line with current health information legislation and protection practices.

Additionally, the DAC must adhere to both FISMA and HIPAA requirements as well as CMS requirements to ensure the security of protected health information (PHI). PHI is the terminology used in HIPAA legislation and by the Centers for Medicare and Medicaid Services (CMS). Under HIPAA, PHI consists of any "individually identifiable data such as SSN, birth date, admission date, discharge date or zip code". The claims data used for research within the DAC at TDI contain files with PHI. The safeguards vary depending on the amount, distribution, format of the information, and the method of storage.

Description of Security Measures

The methods of protection in place for both the claims data and the physician level data as outlined above include:

1. Physical measures; e.g., locked facility with tracked key access, locked filing cabinets, and restricted access to offices;
2. Organizational measures; e.g., strict employee confidentiality agreements (with restrictive actions as a sanction) and limiting access on a "need-to-use" basis;
3. Technological measures; e.g., the use of firewalls, "moating" of administrative data making it inaccessible externally, passwords, and encryption of data; use of VPN terminals and networks; and,
4. Anonymity of data by stripping off conventional identifiers for data provided to users (when conventional identifiers are not necessary for research).

As a condition of employment, all staff (full-and part-time) must sign the DAC Policies, Standards, and Procedures Information Security Acknowledgement and Agreement prior to working with the data. Staff includes TDI faculty, adjunct faculty, fellows, research analysts, programmers, students, and other approved researcher staff seeking access to or utilizing the DAC.

All DAC servers, data storage, switches, and other peripherals are stored in isolated rack cages with DAC-dedicated key locks limiting access to only the DAC Network Systems Administrator. All DAC servers, are maintained by Dartmouth computing. All data traffic for the project is contained within a private, dedicated DAC VLAN network. All network traffic to the servers must pass through the Dartmouth hardware firewall. The only access to the servers is via SSH and requires 2-factor authentication (NetId/password and DUO). All networks located on switches are segmented and behind Dartmouth firewalls where the DAC data resides.

Derivative data variable definitions and labeling will be confidential and described as per data type and use. Labeling will not include any PHI.

b. Describe why all the risks to subjects are reasonable in relation to both anticipated benefits and the knowledge expected to be gained from the study:

There are no direct benefits to the study participants. Knowledge gained from the study will contribute to the academic literature on physician quality improvement and the efficacy of video games as behavioral interventions. This knowledge will inform how advances in technology may transform the means by which behavioral and social science interventions are delivered. These technologies ensure treatment fidelity and can extend treatment duration, thereby improving behavioral maintenance.

Further, this study will inform how these technologies may be used in the context of ACP, as well as broadly because ACP is an extension of the game's original use-case of trauma triage. This study will provide information about how hospital-based physicians initiate ACP conversations for patients admitted acutely and if the decision to initiate a conversation can be improved with a customized theory-based video game.

7. Unexpected Events or Incidental Findings

Note: It may be important to consider the potential for certain unanticipated events to occur, for example:

- finding an anomaly in a MRI
- discovering child abuse
- causing distress in interviews of a sensitive nature

Describe potential events and provide a plan of action:

Unexpected events may include: unexpectedly high rates of advance care planning billing that raise concerns regarding Medicare billing fraud, or systematic biases or disparities in advance care planning conversations. No action will be taken regarding unexpectedly high advance care planning billing rates. Systemic biases will be reported back to the hospital without any identifying information.

8. Deception

Does any part of this study involve deception or withholding of information from participants?

☐ **Yes** ☒ **No**

If Yes, provide an explanation which addresses the following:

- A description of the deception being used
- Why the deception is necessary
- A plan for debriefing, or providing subjects with the pertinent information after participation

9. Equitable Participant Selection

a. Estimated number of participants at Dartmouth CPHS reviewed sites:

Sound Physicians is a national physician practice that employs acute care providers in hospital medicine, emergency medicine and critical care. We selected this physician practice as a partner in our efforts to test the effect of the video game for three reasons: 1) it staffs over 200 hospitals with a wide variety of geographic and organizational characteristics, increasing the generalizability of our observations; 2) it has already implemented best-practice quality improvement efforts to improve ACP practices at its hospitals, including providing employees with web-based didactic education on the importance of ACP in the hospital and a small financial incentive ($20) for each documented ACP conversation that meets Medicare's criteria for reimbursement; 3) billing practices remain lower than desired.

We will selectively sample 30-40 hospitals that contract with Sound Physicians, and will randomize them to the step in which they receive the intervention. We will stratify randomization based on hospitals' baseline characteristics (e.g., number of providers, region, baseline ACP billing rate). We will generate randomization schemas using Stata 13.0 (Statacorp, College Station, TX, USA) statistical software, using random block sizes of 4. Although we cannot blind study personnel and participants, we will mask the arm and group assignment during the analysis phase.

b. Provide a justification of the proposed sample size

For the **Efficacy condition**, we plan to recruit 120 physicians at 30 hospitals (conditional on willingness to participate) and will expose them sequentially to the video game intervention. If fewer physicians per hospital agree to participate, we will plan to increase the number of hospitals allocated to the efficacy trial.

Assuming a baseline ACP rate of 14% (rising by 1.25%/quarter), a hospital intra-class correlation coefficient of 0.008-0.115, and 160 patients/physician/quarter, with 120 physicians, we can detect a 3% difference between ACP practices before and after the distribution of the intervention with an alpha of 0.05 and 80% power.

For the **Effectiveness condition**, we will recruit 170 hospitals. This represents the remainder of the Sound hospitals. As part of our agreement with the funding agency, we are to deliver the intervention to all Sound hospitalists. The effectiveness study, therefore, is not specifically powered.

c. Define the target population:

The target population is physicians whose job responsibilities include ACP. In this study, all inpatient hospitalist physicians who have worked for Sound Physicians at a study hospital for at least one quarter are eligible to participate. There are approximately 200 hospitals across the US providing a total of approximately 2000 eligible hospitalists. The study aims to balance the sample in the following characteristics:

- A hospital's ACP billing rate.
- Number of hospitalists at a hospital.
- If the hospital is an academic medical center.
- Availability of Clinical Performance Nurse to pull charts.

Additionally, the inclusion criteria are: a hospitalist must have worked for Sound for at least 6 months, report use of ACP billing codes, provide contact information that matches a contact in our list of eligible physicians (i.e. full name match or partial name match and employer-based email match), and receive a working iPad. If participants do not meet any of these criteria, they will be informed that they are ineligible, but that they may play the video game intervention voluntarily and without compensation for their time. They will receive instructions on how to download and play the game, as well as complete the post-game questionnaire. Communications with eligible and ineligible participants may be modified if a participant contacts the study team directly with specific questions or concerns. The response will be modified to address the participant's needs.

d. Vulnerable populations

Note: Certain populations are considered vulnerable to coercion and undue influence and are provided with additional protections when participating in a research study.

Identify any of the below populations which you plan to recruit for this study. In addition, complete the form(s) linked with each population as necessary and upload on the 'Supporting Documents' page in Rapport.

☐ Pregnant Women, Fetuses and Neonates
☐ Children
☐ People with impaired decision-making capacity

The following populations may also be considered vulnerable to coercion or other undue influence:

- Prisoners
- People who are economically disadvantaged
- The elderly
- People who are illiterate or do not speak English
- Students and employees

Describe any other potentially vulnerable population(s) and the additional protections provided to them:

Employees. See section 6.

10. Recruitment

Describe method(s) of recruitment. Associated advertisements and other materials to be used for recruitment should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport.

All participants will be offered the opportunity to "opt in" to participate.

Those who engage with the study procedures are provided with consent information at each step of engagement; including an agreement to proceed with pre- and post-game survey questionnaire completion on the face page of the Qualtrics surveys (efficacy); and information about the data captured by game use at the time of downloading the game App (effectiveness condition).

Recruitment and "Opt-In" Consent Process: Game Use. All Sound hospitalist participants in the efficacy condition will provide "opt-in" consent for active participation (e.g., use of the game and provision of personal information). Sound Physician leadership will introduce the research study to regional and hospital team leaders at the annual leadership conference and to all eligible hospitals via e-mail, with a web-based link to a Qualtrics survey to opt-in to study participation. We seek a waiver of documentation from the Dartmouth IRB to use electronic consent documentation.

Claims analysis. Sound hospitalist participants and their patients will not provide consent for use of their billing data. We have relevant data use agreements with Sound Physicians and CMS. We seek a waiver of informed consent from the Dartmouth IRB.

11. Informed Consent, Assent, and Authorization

All forms discussed in this section should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport

a. Please describe the consent and/or assent process, addressing the following:

- Who will obtain consent/assent from participants
- Where the consent/assent process will take place
- The timeframe for providing information potential participants about a study, having the consent form signed, and beginning study activities
- Any precautions taken to minimize the possibility of coercion or undue influence
- The forms which will be used as well as any aids used to simplify scientific or technical information
- How comprehension will be ensured

Those who engage with the study procedures are provided with consent information at each step of engagement; including an agreement to proceed with pre- and post-game survey completion on the face page of the Qualtrics surveys (electronic research consent, efficacy consent); and information about the data captured by game use at the time of downloading the game App (electronic "terms of use" agreement, effectiveness condition).

b. Waiver(s) or alteration(s) may be requested for research that involves no more than minimal risk.

Indicate requested waiver(s) or alteration(s) below. In addition, complete the corresponding section of the Waivers and Alterations Request Form and upload it to the 'Consent Forms and Recruitment Materials' page in Rapport.

☐ For the informed consent *process*

☒ **For the *documentation* of informed consent**

☐ For the HIPAA Authorization to use and/or disclose PHI
☐ For a waiver of the requirement for medical record documentation

12. Compensation or Gifts

Please describe any payments, gifts or reimbursements participants will receive for taking part in the study:

All participants in the Efficacy condition will be compensated for their time. These participants will keep the iPads provided during the study. Participants from the efficacy condition who complete a semi-structured interview will be compensated with a $50 Amazon gift card for participating in the interview.

All participants in the Effectiveness condition who are sent the game URL only will receive up to 2 AMA PRA Category 1 Credit(s) ™ if they complete the continuing medical education (CME) evaluation form.

13. Privacy of Participants

Note: Methods used to obtain information about participants may have an effect on privacy. For example:

- Consent discussions or interviews held in public which concern sensitive subjects or behaviors
- Observations of behavior, especially illicit behavior, in quasi-public settings

Describe any activities or interactions which could lead to a breach of privacy and provide a plan to protect participant privacy:

See section 6.

14. Confidentiality of Data

Note: Any person engaged in research collecting information that could cause financial, social or legal harm to participants may apply for a Certificate of Confidentiality. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They are intended to allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

a. If disclosed, could any of the data collected be considered sensitive, with the potential to damage financial standing, employability, insurability, or reputation?

☐ **No** ☒ **Yes**

If Yes, describe the data or information, the rationale for their collection, and whether a Certificate of Confidentiality will be obtained:

See Section 6.

b. Describe the safeguards employed to secure, share, and maintain data during the study, addressing any of the following which may apply:

- Administrative, ie. coding of participant data
- Physical, ie. use of locked file cabinets
- Technical, ie. encrypted data systems

See Section 6.

c. Describe the plan for storage or destruction of data upon study completion:

See Section 6.