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A videogame intervention to increase advance care planning conversations by hospitalists with older adults: study protocol for a randomized clinical trial

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ABSTRACT

Introduction: Fewer than half of all people in the U.S. have a documented advance care plan (ACP), such as an advance directive, despite their importance in ensuring high-quality care at the end-of-life. Hospitalization offers an opportunity for physicians to initiate ACP conversations. Despite expert recommendations, hospital-based physicians do not routinely engage in these conversations, reserving them for the critically ill.

Methods and analysis: We developed *Hopewell Hospitalist*, a theory-based adventure video game, to modify physicians' attitudes towards ACP conversations, and to increase their motivation for engaging in them. Drawing on the theory of narrative engagement, players assume the persona of Andy Jordan, an emergency medicine physician who accepts a new job in a small town. Through a series of clinical encounters with seriously-ill patients over the age of 65, players experience the consequences of having (or not having) ACP conversations in a timely fashion. The planned study is a pragmatic stepped-wedge crossover phase III trial testing the efficacy of *Hopewell Hospitalist* for increasing ACP rates. Three design questions proved most challenging – the unit of randomization, the method of distributing the intervention, and the optimal outcome measures. We used a review of the literature and an iterative consensus process to inform design choices.

Ethics and dissemination: *Hopewell Hospitalist* will be made available on the iOS Application Store for download, free of cost, at the conclusion of the trial.

Key words: advance care planning; physician performance; serious games; narrative engagement

Trial registration: clinicaltrials.gov; NCT 04557930, 9/21/2020.

ARTICLE SUMMARY

- We developed a novel theoretically-based video game intervention designed to modify physician attitudes to advance care planning (ACP).
- We propose a pragmatic stepped wedge clinical trial, using billing patterns to assess physician behavior before and after exposure to the intervention.

Strengths and limitations of this study

- A strength of this study is the theoretical framework of the intervention, which draws on insights from the behavioral science literature.
- A second strength of this study is our plan to distribute the intervention through a partnership with a national staffing organization (Sound Physicians), which will increase the generalizability of our observations .
- A limitation of this study is our use of billing as a surrogate measure of physician behavior.

INTRODUCTION

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.[1] Unfortunately, fewer than half of all people in the U.S. have documented advance care plans, such as an advance directive.[1] Existing guidelines therefore advocate that physicians use hospitalization as an opportunity to initiate these conversations.[2]

Multiple barriers exist to the initiation of ACP in the hospital.[3-5] High quality conversations require physicians to have the motivation, skill, and time 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 all patients over the age of 65.[6] How best to ensure that physicians meet this standard remains unclear.[7-9]

We propose a novel intervention designed to modify physicians' knowledge of and attitudes towards ACP conversations, and increase their motivation for engaging in them. The central mechanism is *narrative engagement* (i.e. using storytelling to change behavior).[10] We built a theory-based, customized adventure video game that uses narrative engagement to educate players on the benefits of ACP planning for all patients age 65 and older. The planned study will test the effect of the video game intervention on ACP billing practices.

METHODS

Conceptual Framework

Our population of hospitalists employed by a national physician practice already receive best-practice ACP interventions designed to increase: 1) knowledge of ACP guidelines (through web-based didactic education); 2) identification of patients to prioritize for ACP (through decision support and reminders in the electronic medical record); 3) the influence of social norms (through audit and feedback regarding ACP billing rates compared to hospital peers); 4) and extrinsic motivation (through a small financial incentive of $20 for each documented ACP conversation that meets Medicare's criteria for reimbursement). Despite these efforts, ACP in the hospital remains below the standards set by a Delphi panel of experts, who recommend ACP conversations for all inpatients over the age of 65.[6,11] Formative work suggested positive attitudes could act as a facilitator of ACP; therefore, we chose hospitalists' attitudes towards ACP conversations as the primary intervention target.[11]

To intervene on this target, we refined an existing intervention based on the theory of narrative engagement.[12] The intervention – an adventure video game – had proven successful at improving physician decision making in trauma triage, without any identifiable adverse consequences. Strong conceptual reasons existed to believe it would have efficacy in this context.[14-18] Finally, in assessing potential harms and benefits associated with this intervention, we relied on a meta-analysis of interventions to increase ACP, which found positive outcomes for patients.[19]

Study overview

We developed the video game (*Hopewell Hospitalist*) in collaboration with Schell Games (Pittsburgh, PA) through an iterative process involving behavioral scientists, hospitalists, palliative care experts, intensivists, and game developers, with the intention of increasing physicians' frequency of ACP conversations with hospitalized patients. We plan to compare the

impact of *Hopewell Hospitalist* on billed ACP practices before-and-after intervention dissemination in a stepped-wedge cluster randomized trial [**Figure 1**].

A stepped-wedge crossover trial randomizes physician participants at the group level (e.g., hospital); each group 'crosses over' from control to intervention at a randomized timepoint and is followed through multiple 'time steps' of data collection.[20] This trial design is the best option to test the efficacy of the video game because: 1) physician-level randomization risks misclassifying patients, contaminating control physicians, and failing to address group-level attitudes to and practices of ACP; 2) a parallel cluster randomized design risks imbalance among groups, especially if relatively few hospitals participate in the study, because of the high intra-class correlation that exists for ACP billing practices at the hospital-level.

We will use a five wedge design (with each step lasting one month), and will compare difference in ACP billing of physicians enrolled in the trial in the time period before and after intervention dissemination. Drawing on more than three years of data, inclusive of the early stages of the COVID-19 pandemic (January 2017-June 2020), organization-wide ACP billing rates for patients 65 and older increased from 5% to 22%, corresponding to a 1.5% absolute quarterly increase. We hypothesize that physicians will have a 3.5% absolute increase in ACP billing in the quarter after dissemination of the intervention than would be expected based on secular trends alone (primary outcome).

Participants

Study Setting

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; 3) the organization seeks to further increase ACP rates.

Hospital Sampling

We will sample hospitals staffed by Sound Physicians using the following inclusion criteria: at least 4 quarters of engagement with Sound, a risk-adjusted ACP billing rate > 0% in the prior quarter, and availability of an onsite, Sound-employed, nurse liaison to distribute the iPads to participants and collect secondary outcome measures.

Once a hospital is sampled, we will recruit Sound-employed hospitalists at the hospital by distributing email invitations. Eligible hospitalists are those employed by Sound for at least 2 quarters. We will obtain electronic consent from interested physicians, collect baseline demographic and professional characteristic, as well as initial baseline measurements of attitudes towards ACP, then provide them with instructions on how to complete study tasks. A full list of the study sites will be published with the study results.

Randomization and Blinding

We will randomize sampled hospitals to the order in which they receive the video game. We will generate randomization schemas using R statistical software (R Core Team, Vienna, Austria), using random block sizes of 4, seeking to balance hospital risk-adjusted ACP rate, bundled payment care initiative (BPCI) participation, practice size (number of Sound-employed hospitalists) at the hospital, and region. Although we cannot blind study personnel and participants, we will mask the hospital's assignment during the analysis phase.

Study protocol

We will pre-load new iPads with the video game and mail them to nurse-liaisons at each site. The nurses will distribute the iPads and study instructions to consented hospitalists. We will ask participants to spend a minimum of two hours completing the intervention task, and then to complete a web-based questionnaire with items assessing a) the intervention's usability, b) fidelity of intervention delivery and receipt, and c) mediators of intervention receipt. Completing

the questionnaire will take approximately 20 minutes. Participants can complete the two portions of the study protocol at their convenience, within two weeks of enrollment. They will keep the iPad as an honorarium (approximate value $300). We will send reminder emails each week for the duration of the intervention period until study tasks have been completed. Participants will continue to receive all usual care ACP interventions, mandated by Sound Physicians, throughout the study period.

Intervention: Hopewell Hospitalist

Hopewell Hospitalist is a tap-and-click adventure video game designed to shift hospitalists' threshold for inpatient ACP conversations from only occurring when a patient is at high risk for clinical deterioration to occurring for all hospitalized patients over the age of 65, drawing on CMS policy, Sound policy, and ACP expert consensus.[6,21] We adapted the art and game mechanics from a previously-tested game,[14] identified key didactic principles based upon a review of the literature and the input of a multidisciplinary team of palliative care physicians, hospitalists, and critical care physicians, and iteratively piloted the game with a series of physician play-testers between June-August 2019. We summarize didactic principles, game content, and game mechanics of *Hopewell Hospitalist* in the **Box**.

In brief, players take on the persona of Andy Jordan, a young hospitalist who moves home after the disappearance of his estranged grandfather, Robert Jordan, and begins a job at a local community hospital. The player has two objectives: to diagnose and treat patients admitted to the hospital, and to solve the mystery of Robert's disappearance. [**Figure 2**]

Patient cases fall into two categories, 'teaching' and 'non-teaching.' Interactions with the 'teaching' patients are designed to communicate a didactic principle that instantiates the game objective of encouraging players to have ACP conversations with all patients over the age of 65 (see **Box**). These patients have a serious illness but are not at the very end-of-life. When players fail to engage in ACP conversations, the patient returns with complications that require

additional treatment. Players also receive feedback on their performance from in-game characters (e.g. peers, family members, or their supervisor). The feedback includes factual information about the probability of poor outcomes among patients over 65 who require hospitalization and a reminder about the value of early ACP conversations. In contrast, when players engage in ACP conversations, they subsequently receive an update about the patient's condition, describing how that ACP improved the care of the patient downstream, and a compliment on their decision-making and communication skills. Relevant patients also provide an opportunity for players to observe best practice principles of a high-quality serious illness conversation modeled on Ariadne Lab's Serious Illness Conversation Guide.[22] Specifically, when players choose to engage in ACP conversations, the interaction unfolds with Andy asking key questions from the guide and following other best practices (e.g. Andy Jordan pulls up a chair and sits for the conversation).

'Non-teaching' patients either have a critical, immediately life-threatening illness or a diagnostically challenging problem. These cases were designed to increase challenge levels and associated game-play enjoyment. Players do not receive in-game feedback on their treatment of 'non-teaching' patients. Instead, they receive a summary of their performance on all cases at the end of the game that summarizes decisions made on the teaching cases and the accuracy of their diagnoses for the non-teaching cases.

The mystery component of *Hopewell Hospitalist* occurs concurrently with the clinical challenges, and serves to facilitate players' identification with their character and interest in their task. Players must solve Robert's disappearance through interactions with other characters, including patients, and their physical environment. Andy Jordan's background and character are also revealed through these interactions, which are designed to make him and his decisions more appealing and sympathetic.

Data sources and management

Physician characteristics

Each participating physician will complete a baseline questionnaire with items related to: age, sex, race, ethnicity, educational background (board certification, years since completion of residency, location of medical school, location of residency/fellowship), and practice environment (number of patients evaluated/week of service, number of weeks on service/year), as well as an initial baseline measurement of attitudes towards ACP. Sound will provide information about physician completion of the organization's required continuing medical education (CME) about ACP. After playing the video game, physicians will complete a questionnaire with items related to usability, fidelity of intervention receipt, and mediators of intervention receipt (see Fidelity of intervention Receipt). See **Figure 1** for schedule of enrollment and data collection.

Hospital characteristics

We have crude and adjusted ACP billing rates for each the Sound-staffed hospitals and individual physicians between January 2017 to April 2020, as well as the number of hospitalists employed at each location as of January 2020, and the presence or absence of a clinical performance nurse. We will obtain additional information about the geographic and organizational characteristics of each of their hospitals using the 2018 Centers for Medicare and Medicaid Services (CMS) Healthcare Cost Report Information System (HCRIS). HCRIS contains facility-level characteristics of all non-federal hospitals, including geographic location (state and region), participation in a hospital network, total bed count, ICU bed count, ownership, and teaching status.

Patient characteristics

Sound will provide the study team with discharge abstracts for all the patients treated by its hospitalists during the study period. These abstracts include patient demographics, admission diagnoses, discharge diagnoses, and physician claims filed during the hospitalization. We will abstract information co-morbid conditions, illness severity, and organ failure from the ICD10-CM

(International Classification of Diseases 10 - Clinical Modification) diagnosis codes. We will link these data to patient-level CMS claims and Social Security Administration (SSA) records to collect post-discharge, episode-based outcomes.

Fidelity of intervention delivery (intervention dose)

The *Hopewell Hospitalist* application collects data on each player's behaviors and actions (e.g. total time spent in-game, number of game-play sessions, average number of minutes per session, cases completed, decisions made, feedback reviewed) during game-play. These data will be summarized using Google Analytics and then downloaded to a secure server hosted by Dartmouth.

Fidelity of intervention receipt

We will measure the fidelity of intervention receipt by capturing physicians' attitudes towards ACP before and after completion of the game using items adapted from published studies.[6,23] Additionally, we will measure narrative engagement, the proposed mediator of the intervention, using the Narrative Engagement Scale.[24] Finally, we will assess the game's usability both qualitatively and quantitatively.[25]

Fidelity of intervention enactment (outcome assessment)

We summarize our outcomes in the **Table 1**.

Primary

Our primary outcome will be physician ACP billing for their patients over the age of 65 in the three months before and after dissemination of the video game intervention. We will screen Sound discharge abstracts for the presence/absence of ACP charges (billing codes 99497 and 99498) during the hospitalization and will categorize each patient as having had (or not had) an ACP conversation. The rationale for using ACP billing as the primary outcome is: 1) it can be obtained administratively for all physicians' patients; and 2) it is a less sensitive but more specific measure of a comprehensive ACP conversation than the Merit-based Incentive

Payment System (MIPS) self-report measure of ACP because it is a time-based billing code requiring an ACP conversation of at least 16 minutes in length.

Secondary

Secondary measures of physician ACP practices will include a self-report measure and a chart-abstraction based measure. We will collect each physicians' self-report MIPS ACP quality measure (the proportion of patients who have an ACP or surrogate decision maker documented in the medical record [or declined to participate in the process] of all patients 65 years and older treated by the physician). Additionally, Sound nurse-liaisons will provide a 20% random sample of the charts of eligible patients. We will abstract these charts for documentation of a conversation about ACP, which we will evaluate using natural language processing to assess the content of those conversations. This will allow estimation of the sensitivity and specificity of claims-based and MIPS-based measurement of ACP relative to chart-review.

Secondary measures of patient outcomes (i.e. downstream consequences of intervention enactment) will include: disposition status, in-hospital mortality, 90-day mortality, and resource utilization during the index hospitalization. Index hospital outcomes will be drawn from Sound data; post-discharge 90-day episode based outcomes will be drawn from linked CMS and SSA data.

Analyses

We will summarize sample hospital and consented physician characteristics using means (standard deviations) for continuous variables and proportions for categorical variables, and will compare the distribution of characteristics between the five ‘steps’ in the trial using chi-square and F tests as appropriate. We will summarize and compare patient characteristics between ‘steps’ of the trial similarly.

Participation rate

We will calculate an enrollment (cooperation) rate for the trial as the proportion of physicians at randomized hospitals who agree to participate in the trial, and a completion (response) rate as the proportion of physicians who agree to participate and complete all the study tasks .

Usability

For physicians who use the video game, we will categorize quantitative and qualitative feedback as positive or negative and will assess opinions about the usability of the interventions.

Fidelity of intervention delivery

We will summarize the length of time that physicians spend playing the game and their self-report of game play. We will compare participation at hospitals in different wedges of the trial using chi-square tests, and the duration of exposure using chi-square tests and F-tests. Information about fidelity of intervention delivery will provide insight into the usability of the game and will also allow for secondary analyses into the mechanism of the intervention's success or failure.

Fidelity of intervention receipt

We will compare physician attitudes towards ACP before and after use of the intervention using a vignette-based instrument and questionnaire, as well as narrative engagement and user experience questionnaires after completion of the intervention.

Fidelity of intervention enactment

We plan to conduct intention-to-treat analyses with two-tailed significance testing at an alpha of 0.05 for the primary outcome, excluding only those participants who choose to withdraw from the trial. We will account for multiple comparisons when reporting analyses of secondary outcomes. We list our hypotheses in **Table 2** and describe our analytic plan in more detail in the **Appendix.**

We will begin by calculating ACP billing practices among participating physicians at each randomized hospital, defined as the proportion of patients they treated who had an ACP conversation billed during their hospitalization, during the quarter before and after distribution of the video game intervention. To test the efficacy of the video game, we will first compare billing practices before and after distribution among physicians enrolled in the efficacy trial using a Student's t-test. Next, we will fit a mixed effects patient-level logistic regression model for patients treated by physicians enrolled in the trial, with presence of ACP billing during the hospitalization as the dependent variable.

In secondary analyses we will test the association between the effect of the intervention on secondary outcome measures, and the effect of mediators and moderators on the effect of the intervention.

Human subjects and power calculation

We arrived at our sample size using a combination of feasibility (cost) and assumptions regarding effect size, absent any pilot data. We plan to recruit 120 physicians at between 20 to 40 hospitals (conditional on willingness to participate). If fewer physicians per hospital agree to participate, we will plan to increase the number of hospitals allocated to the trial. Assuming a baseline ACP rate of 22% (rising by 1.5%/quarter), a hospital intra-class correlation (ICC) coefficient of 0.008-0.115, and 160 evaluable patients per physician-quarter, with 120 physicians willing to participate in the study, we can detect a 3.5% difference between ACP practices before and after the distribution of the intervention with an alpha for a two-sided test of 0.05 and 80% power.

Security, ethics, and dissemination

Data Security

On enrollment in the trial, participants will receive a unique identifier. They will use that identifier to login to *Hopewell Hospitalist* and to the website that hosts the questionnaire. Only the study team will have access to the linkage file connecting the identifier to the physician's name and contact information. This file will be encrypted and stored on a secure server at Dartmouth-Hitchcock.

Ethics

The Dartmouth Committee for the Protection of Human Subjects has approved this study (STUDY00031980). The Data and Safety Monitoring Board convened by the funding agency, the National Institute on Aging, reviewed and approved the protocol and the data and safety monitoring plan. We do not plan any interim analyses and, therefore, have not included any stopping guidelines. However, the PI will ask participants to communicate any adverse events or unintended effects of participation via email, which she will in turn relay to the review boards. Physicians may opt to withdraw from the trial at any point. We have registered the trial on clinicaltrials.gov (NCT04557930). Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Dissemination of results

Results from the study will be reported to the public through manuscripts and oral presentations at national meetings. We will provide an abstract of the findings to all participants. Access to the de-identified dataset will be made available upon written request to the study team.

DISCUSSION

This protocol paper outlines a phase III clinical trial to test the efficacy of the video game at increasing ACP conversations among hospitalized patients.[26] *Hopewell Hospitalist* uses stories designed to immerse participants in playing the role of a physician concurrently solving both clinical and personal problems.[27] Research indicates the power of stories to facilitate behavioral change.[10] Stories facilitate processing and retaining new data.[14-16] In our context, the stories are meant to help physicians integrate their simulated experience into the mental models evoked in normal clinical practice. Stories also can engage players cognitively and emotionally in ways that transcend traditional forms of education.[10,17,18] Additionally, video game and simulation-based environments allow learners to practice desired behaviors in a safe environment, which supports the development of self-efficacy.[28,29] We designed the video game to achieve the intervention goal (simplifying the decision for ACP [to any patient 65 and older]) by influencing a specific target (attitudes to ACP [positive, valuable for patient well-being, and role-aligned]).[30] This design combined research insights regarding human behavior from the psychological literature and clinical insights regarding both descriptive and normative assessments of ACP for hospitalized older adults.[31,32]

We designed the protocol for a phase III clinical trial of video game efficacy to complement best practices in system-level quality improvement initiatives. We struggled with three design challenges, which we resolved both by reviewing the existing literature and through iterative consensus when data did not exist. First, we debated the unit of randomization. We considered and then rejected physician-level randomization for both conceptual and pragmatic reasons. Conceptually, shift-based hospital physicians practice collaboratively, so that the work flow of one individual can have important implications for colleagues' role responsibilities. As we considered peer-effects, we imagined that, on one end of the spectrum, unexposed physicians might also shift their practice patterns, and, on the other hand, exposed physicians might be pulled back to conform to group norms. Either scenario risks biasing results towards the null if

physicians are the unit of randomization. Pragmatically, patients (particularly the sickest ones) may have contact with multiple physicians during the course of one hospitalization. Consequently, physician-level randomization risks the misclassification of patients. In contrast, hospital-level randomization alleviates these concerns, although it decreases power (due to increasing within-cluster correlation) and increases the complexity of ensuring adherence to the intervention.

Second, we debated the problem of intervention delivery. We decided to deliver the intervention using the platform of a video game to encourage utilization and to harness the power of narrative engagement to stimulate behavior change. Although potentially more enjoyable than standard didactic text-based continuing medical education, it does not rise to the level of entertainment. To further incentivize participation and engagement, we decided to deliver the game pre-loaded on a new iPad. In prior work, we found providing a fixed material honorarium (i.e. an iPad) produced adherence rates of up to 80%.[33] We therefore considered, but rejected, alternative strategies of distributing the intervention, including requesting that physicians download the game onto personal devices or using re-furbished iPads. Providing an honorarium to promote adherence restricts the use of the intervention to the research setting, but maximizes the fidelity of the intervention delivery and receipt across participants.

Third, we debated the problem of how to assess the impact of the intervention. Direct observation has the greatest validity but limited feasibility. Review of charts or electronic health records provide an alternative. Although dependent on the quality of physician documentation, this method does allow for the evaluation of a larger number of physicians. However, the resources and time required to abstract charts would limit our ability to detect small (albeit clinically significant) effect sizes. We therefore have opted to use billing practices as our primary outcome measure. In 2016, CMS rolled out a time-based billing code for ACP conversations held in the hospital. We anticipate that use of billing codes will bias our results towards the null,

and plan to perform secondary analyses using alternative methods of measuring ACP practices to test the validity of our primary analyses.

Advances in technology hold the potential to transform the means by which behavioral and social science interventions are delivered. They ensure treatment fidelity and can extend treatment duration, thus improving behavioral maintenance. We have developed one such behavioral intervention to encourage hospital-based physicians to initiate ACP conversations for hospitalized older adults, and plan to test its efficacy. We intend that results of this trial will contribute to the literature on physician quality improvement and the efficacy of video games as behavioral interventions.

TRIAL STATUS: Not yet recruiting

ABBREVIATIONS

ACP - Advance Care Planning
BCPI - Bundled payment care initiative
ICU - Intensive Care Unit
CME - Continuing Medical Education
CMS - Centers for Medicare and Medicaid Services
HCRIS - Healthcare Cost Report Information System
ICD10-CM - International Classification of Diseases 10th Revision - Clinical Modification
SSA - Social Security Administration
Merit-based Incentive Payment System (MIPS)

DECLARATIONS

Ethics approval and consent to participate

The Dartmouth Committee for the Protection of Human Subjects has approved this study (STUDY00031980). Given our recruitment strategy (email letters soliciting participation), we obtained permission to waive written consent for participation. The study team will obtain electronic consent and will explain the study protocol to all physicians who agree to participate in the trial.

Consent for publication

Not applicable

Availability of data and material

Access to the de-identified dataset will be made available upon written request to the senior author.

Competing interests

The authors have no financial conflicts to disclose.

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LM012339 Mohan). The funding agencies reviewed the study but played no role in its design; and will play no role in the collection, analysis or interpretation of data.

Authors' contributions

Study concept and design: AEB, DM, JC, JOM, MR, MM, MM

Drafting of the manuscript: DM, JC, AEB, JOM

Critical revision of the manuscript for important intellectual content: AEB, DM, JC, JOM, MR, MM, MM

All authors read and approved the final manuscript.

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REFERENCES

1. Institute of Medicine 2015. Dying in America: improving quality and honoring individual preferences near the end of life. Washington, DC: The National Academies Press.
2. Anderson WG, Berlinger N, Ragland J et al. Hospital-based prognosis and goals of care discussions with seriously ill patients: a pathway to integrate a key primary palliative care process into the workflow of hospitalist physicians and their teams. Society of Hospital Medicine and The Hastings Center, 2017.
3. Howard M, Bernard C, Klein D et al. Barriers to and enablers of advance care planning with patients in primary care. *Canadian Family Physician* 2018; 64: e190-8.
4. Lund S, Richardson A, and May C. Barriers to Advance Care Planning at the end of life: an explanatory systematic review of implementation studies. *PLoS One* 2015; 10: e0116629.
5. Heyland DK, Barwich D, Pichora D et al. Failure to engage hospitalized elderly patients and their families in Advance Care Planning. *JAMA Intern Med* 2013; 173: 778-787.
6. Mohan D, Sacks OA, O'Malley J et al. A new standard for advance care planning conversations in the hospital: results from a delphi panel. *J Gen Intern Med* 2020. Online ahead of print.
7. Milkman KL, Chugh D, Bazerman MH. How Can Decision Making Be Improved? *Perspectives on Psychological Science* 2009; 4:379–83.
8. Hunt DL, Haynes RB, Hanna SE, *et al.* Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review. *JAMA* 1998; 280:1339–46.
9. Graber ML, Kissam S, Payne VL, *et al.* Cognitive interventions to reduce diagnostic error: a narrative review. *BMJ Qual Saf* 2012;**21**:535–57. doi:10.1136/bmjqs-2011-000149
10. Miller-Day M, Hecht ML. Narrative Means to Preventative Ends: A Narrative Engagement Framework for Designing Prevention Interventions. *Health Communication* 2013;**28**:657–70. doi:10.1080/10410236.2012.762861

11. Barnato AE, O'Malley AJ, Skinner JS et al. Use of advance care planning billing codes for hospitalized older adults at high risk of dying: a national observational study. *J Hosp Med* 2019; 14: 229-231.

12. Sacks OA, Knutzen KE, Rudolph MA, Mohan D, Barnato AE. Advance care planning and professional satisfaction from 'doing the right thing:' interviews with hospitalist chiefs. *J Pain Symptom Manage* 2020; 9: S0885-3924(20)30565.

13. Mohan D, Farris C, Fischhoff B et al. Efficacy of educational video game versus traditional educational apps at improving physician decision making in trauma triage: randomized controlled trial. *BMJ* 2017; 359: j5416.

14. Moyer Gusé E, Nabi RL. Explaining the Effects of Narrative in an Entertainment Television Program: Overcoming Resistance to Persuasion. *Human Communication Research* 2010;**36**:26–52. doi:10.1111/j.1468-2958.2009.01367.x

15. Thorndyke PW. Cognitive structures in comprehension and memory of narrative discourse. *Cognitive Psychology* 1977; 9: 77-110

16. Bower GH and Morrow DG. Mental models in narrative comprehension. *Science* 1990; 247: 44-48.

17. Nabi RL, Green MC. The Role of a Narrative's Emotional Flow in Promoting Persuasive Outcomes. *Media Psychology* 2014;**18**:137–62. doi:10.1080/15213269.2014.912585

18. Zillmann D. (1991). Empathy: affect from bearing witness to the emotions of others. In J. Bryant and D Zillman (Eds.), *Communication*. *Responding to the screen: reception and reaction processes* (pp. 135-167). New York: Routledge.

19. Weathers E, O'Caoimh Ronan, Cornally N et al. Advance care planning: a systematic review of randomized clinical trials conducted with older adults. *Maturitas* 2016; 91: 101-109.

20. Hemming K. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ* 2015; 350: h391.

21. Centers for Medicare and Medicaid Services (2019). Quality Measures Fact Sheet: Advance Care Plan (ACP) (NQF #0326) https://innovation.cms.gov/files/fact-sheet/bpciadvanced-fs-nqf0326.pdf

22. Ariadne Labs. (2015). Serious Illness Conversation Guide. Retrieved from https://www.ariadnelabs.org/wp-content/uploads/sites/2/2017/05/SI-CG-2017-04-21_FINAL.pdf.

23. Zhou Guiyan, Stoltzfus JC, Houldin AD et al. Knowledge, attitudes, and practice behaviors of oncology advanced practice nurses regarding advanced care planning for patients with cancer. (2010). *College of Nursing Faculty Papers & Presentations*. Paper 31. https://jdc.jefferson.edu/nursfp/31.

24. Busselle R and Bilandzic H. Measuring narrative engagement. *Media Psychology*. 2009; 12: 321-347.

25. O'Brien HL, Cairns P, and Hall M. A practical approach to measuring user engagement with the refined user engagement scale (UES) and the new UES short form. International Journal of Human-Computer Studies. 2018; 112: 28-39

26. Gitlin LN. Introducing a new intervention: an overview of research phases and common challenges. *American Journal of Occupational Therapy.* 2013; 67: 177-184.

27. Perski O, Blandford A, West R et al. Conceptualizing engagement with digital behavior change interventions: a systematic review using principles from critical interpretive synthesis. *TBM* 2017; 7: 254-267.

28. Primack BA, Carroll MV, McNamara M, et al. Role of video games in improving health-related outcomes. Am J Prev Med 2012; 42(6): 630-638.

29. McGaghie WC, Issenberg SB, Cohen ER et al. Does simulation-based medical education with deliberate practice yield better results than traditional clinical education? A meta-analytic comparative review of the evidence. Acad Med 2011; 86: 706-711.

30. Michie S, van Stralen M, and West R. The behavior change wheel: a new method for characterising and designing behaviour change interventions. *Implementation Science*. 2011; 6: 42.

31. Ryan RM and Deci ED. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American Psychologist* 2000; 55: 68-78.

32. Hartzband P and Groopman J. Physician burnout, interrupted. *NEJM* 2020; 382: 2485-2487.

33. Mohan D, Rosengart MR, Fischhoff B, et al. Using incentives to recruit physicians into behavioral trials: lessons learned from four studies. BMC Res Notes. 2017; 10:776

ADDITIONAL FILES

Figure 1

File format: pdf
Title of data: Schedule of enrollment, interventions, and assessments.
Description of data: Description of enrolment, interventions, and assessments based on SPIRIT guidelines.

Figure 2

File format: .pdf
Title of data: Screen shots of trailer to *Hopewell Hospitalist*
Description of data: We show the trailer to the game. We provided players with two explicit objectives in order to heighten narrative engagement, while simultaneously providing a vehicle for physician education.

Box 1

Description of *Hopewell Hospitalist*

Duration: Three hours of gameplay possible.

Objective: To increase ACP conversations

Theory-based intervention targets: Attitudes to ACP [positive, valuable for patient well-being, and role-aligned]

Theory-based intervention goal: Simplifying the decision for ACP [to any patient 65 and older]

Theory-based intervention delivery strategy: Provide personally-relevant and emotionally-compelling feedback through storytelling that increases retention of the message (theory of narrative engagement)

Didactic principles: All hospitalized patients who are 65 years or older should have an ACP conversation. Each of the 5 teaching cases (see below) embeds supporting didactic principles in the feedback.

- Older adults who require ICU care for mechanical ventilation have ≥70% risk of death or disability at one year, and pre-admission frailty is associated with even higher risk of death or disability after ICU-level care. Assessing goals for treatment can help hospitalists support goal-concordant treatment decision making when/if medical decompensation occurs.
- Patients with severe co-morbidities (e.g., cancer, end-stage renal disease) are at high risk of medical decompensation requiring decisions about ICU-level care, yet ≤10% have had documented ACP conversations with their specialists or primary care providers prior to admission. Hospital admission is a fruitful time for ACP conversations and can be an opportunity to discuss hospice eligibility and introduce hospice services.
- Patients hospitalized with even a minor clinical problem have a 30% risk of dying within 3 years. Hospitalization can therefore be an opportunity to think generally about values and goals, and therefore attend to 'life completion' tasks.
- Having an ACP conversation early reduces the emotional distress and decisional conflict experienced by surrogates and patients when/if medical decompensation occurs.
- Race should not influence physician decisions to engage in ACP conversations because individual goals and values, not race, affect patient preferences for end-of-life treatment.

Game concept: The player takes on the role of Andy Jordan, a young emergency medicine physician, who moves home after his grandfather's disappearance and accepts a job at a local community hospital covering night shifts.

Game content

Medical: Physicians interview patients who present to Hopewell Hospital, and have the option of investigating further, having an ACP conversation with the patient/surrogate, or completing the daily documentation. The patients include:

- 5 "teaching" cases of patients with serious illness, adapted from clinical practice. These patients are 65 years or older and require hospitalization for assorted complaints (e.g. heart failure, peptic ulcer disease). If players engage in ACP conversations, they later receive updates on the positive outcomes experienced by these patients. If players do not engage in ACP conversations, these patients return with complications of their initial complaint. Players also receive feedback from in-game characters (e.g. their supervisor, consultants, family members) about the impact that timely advanced care plans can have on the trajectories of patients' care.
- 5 "non-teaching" cases of patients with diagnostically challenging problems, adapted from the

clinical case records of the Massachusetts General Hospital as presented in the *New England Journal of Medicine*. These patients are designed to facilitate player engagement in the clinical task.

- 2 "non-teaching" cases of patients with life-threatening illnesses, adapted from clinical practice. These patients serve as a management challenge to facilitate player engagement in the clinical task.

Non-medical: Robert Jordan, Andy's estranged grandfather, has disappeared. The prologue hints that his disappearance may or may not have occurred voluntarily. The player must solve the mystery by uncovering clues revealed through conversation with in-game characters and by exploring the environment.

Game mechanics

1. Connect the dots: clues (medical and non-medical) appear on a notepad on the screen. The player can draw connections between clues to uncover information and to unlock additional dialogue options.
2. Tap to act: the player can tap on the screen to move through the world and interact with other characters. This mechanic also allows the player to perform key patient-care actions, including procedures like lumbar punctures and intubations.
3. Points: players receive points for uncovering non-medical clues, which unlock in-game lore. Specifically, they can access letters written by Andy and his grandfather, which should provide additional insight into their characters and motivations.

Table 1. List of Outcomes Measures

Type of measure	Measure target	Description of measure
Fidelity of intervention enactment		
Primary	ACP performance	ACP billing rates
Secondary	ACP performance	Self-report MiPS ACP quality measure
		ACP conversations assessed using chart abstraction of a random 20% of patients.
	Patient outcomes	Disposition status
		In hospital mortality
		90-day mortality
		Resource utilization (length of stay, admission to ICU, mechanical ventilation, placement of tracheostomy, insertion of gastric feeding tube, new onset dialysis, palliative care consults, 90-day spending)
Fidelity of intervention receipt		
Secondary	Physician attitudes	Physician attitudes towards ACP conversations

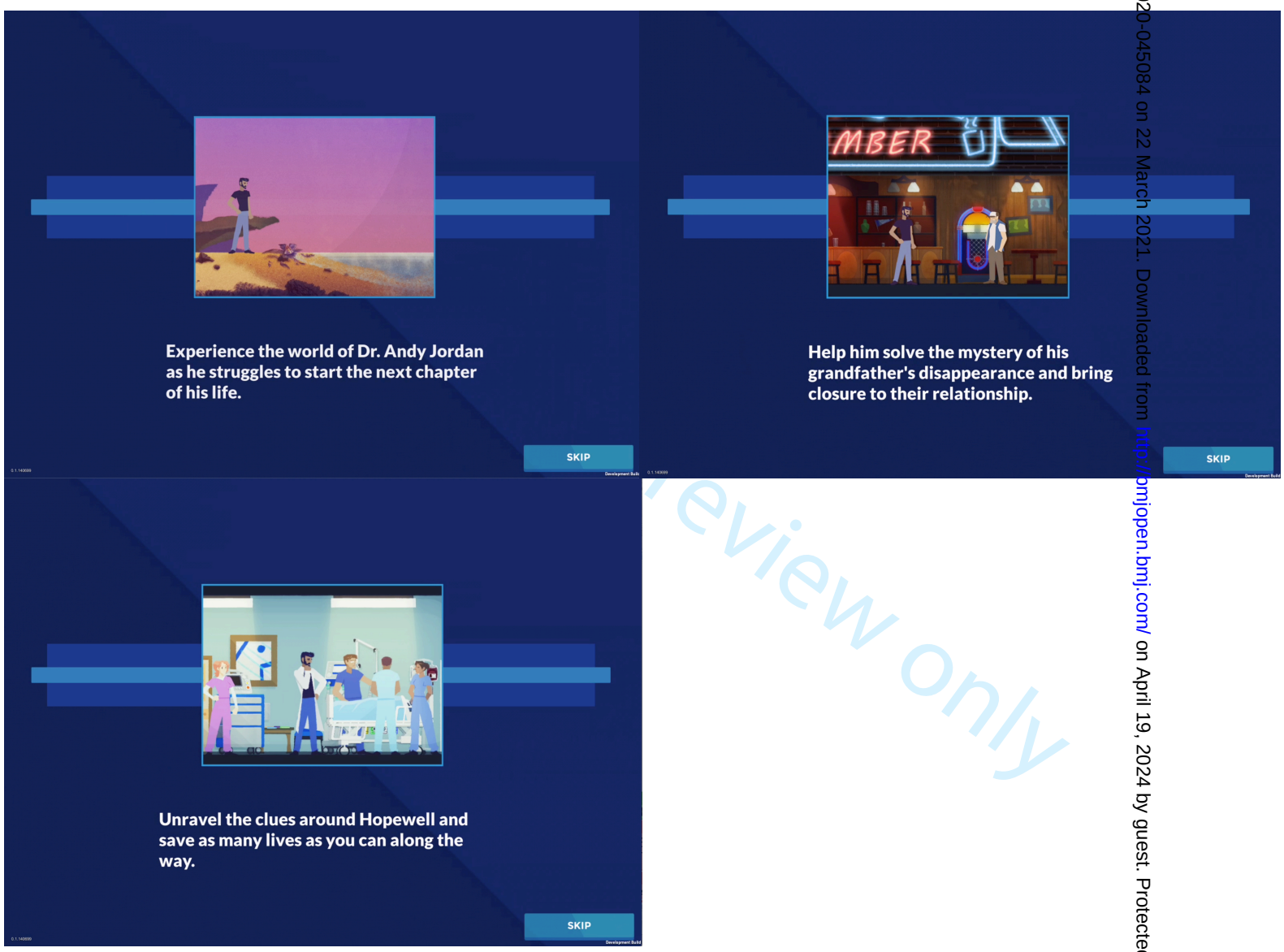
Table 2. Hypotheses to be tested

Hypotheses	
Fidelity of intervention enactment	
Primary	Physicians will have a 3.5% greater increase in ACP billing in the quarter after dissemination of the intervention than would be expected based on secular trends alone.
Secondary	Physicians will have an increase in MiPS self-report of ACP and chart-abstracted ACP documentation after dissemination of the intervention.
	The difference in physician billing practices after dissemination of the intervention will be correlated with participants' minutes of game play; narrative engagement scores, and changes in ACP attitudes (mediators).
	The difference in physician billing practices before-and-after distribution of the intervention will be positively associated with the proportion of physicians who have completed Sound's e-curriculum (baseline knowledge - moderator).
	The difference in physician billing practices before-and-after distribution of the intervention will be positively associated with the proportion of physicians at each hospital who use the game (peer effects - moderator).
	The difference in billing practices before-and-after the distribution of the intervention will be associated with differences in patient-level outcomes, including resource utilization and disposition during the index hospitalization and during the 90-day illness episode (patient care outcomes)
Exploratory	Billing for ACP conversations (at the hospital level) will correlate positively with documentation of ACP conversations in patients' charts and with MiPS self-report of ACP.
Fidelity of intervention receipt	
Secondary	An increased proportion of physicians will describe ACP as part of their role responsibility, measured before-and-after the distribution of the intervention.

		STUDY PERIOD							
	Enrolment	Allocation	Post-allocation						Close-out
TIMEPOINT**	$-t_1$	0	t_1 ***Month 1***	t_2 ***Month 2***	t_3 ***Month 3***	t_4 ***Month 4***	t_5 ***Month 5***	t_6 ***Month 6***	t_6 ***Months 7-9***
ENROLMENT:									
Eligibility screen	X								
Informed consent*				X	X	X	X	X	
Allocation		X							
INTERVENTIONS:									
Hopewell Hospitalist: Wedge 1				X	X	X	X	X	
Hopewell Hospitalist: Wedge 2					X	X	X	X	
Hopewell Hospitalist: Wedge 3						X	X	X	
Hopewell Hospitalist: Wedge 4							X	X	
Hopewell Hospitalist: Wedge 5								X	
ASSESSMENTS:									
Hospital: Number of hospitalists, ACP billing rates, presence of Sound-employed, nurse liaison.	X								
Physicians: demographics, educational background, practice environment, baseline attitudes to ACP, completion of organization's CME course				X	X	X	X	X	
Physicians: intervention dose (collected by application)				X	X	X	X	X	

***Physicians*:** questionnaire with items relating to intervention usability, fidelity of intervention receipt, mediators of fidelity of intervention receipt (self-report)				X	X	X	X	X	
***Patients*:** claims based data from CMS and SSA**			X	X	X	X	X	X	X

* Consent will be obtained immediately preceding roll-out of the intervention at hospitals in the wedge to limit erosion of participant adherence to the intervention.
**Data will be collected for all sites for the three months following the trial.



APPENDIX

Statistical Plan

Here we provide additional information about our analytic plan.

Primary Analysis

Let Y_{ijt} denote the binary outcome variable (coded as 1 if an ACP conversation occurred and 0 otherwise) for patient *i* seen at hospital *j* at time *t*; $Game_{jt}$ a binary variable indicating whether hospital j has received the Game by time t ($Game_{jt} = 1$ if received and 0 otherwise), x_{ijt} a vector of patient-level covariates, z_j a vector of hospital-level covariates and θ_j a random effect for hospital. The mathematical specification of the statistical model is given as $Y_{ijt}|\theta_i \sim Bernoulli(\pi_{ijt})$, where

$$logit(\pi_{ijt}) = log\left(\frac{\pi_{ijt}}{1-\pi_{ijt}}\right) = \beta_0 + \beta_{1t} + \beta_2 Game_{jt} + \beta_3 x_{ijt} + \beta_4 z_j + \theta_j$$

where $\theta_j \sim Normal(0,\tau^2)$ is the distribution of the hospital-level random effects to account for the fact that the statistical significance of inferences about the effect of the game are likely to be reduced by the clustering of patients in hospitals. The model includes fixed-effects for time-period, β_{1t}, to allow for an unstructured trend across calendar time, which makes the effect of the game (the primary target of inference) to be estimated net of any time-trend. The key coefficient of interest is β_2, which captures the structural shift in the outcome of patients of physicians who were enrolled in the study that occurs when the hospital receives the iPads, net of general trends across time and other covariates. Because this is a cluster-randomized study, there is a risk that the hospitals in each step are not perfectly balanced, despite attempts to balance these during randomization by forming blocks, and that the distributions of patient characteristics of patients treated by a given hospital may vary across time. To mitigate these concerns, we will adjust for judiciously selected patient and hospital covariates that we hypothesize are reasonably likely to be associated with the outcome and, in the case of

patients, that vary over time will be prioritized for inclusion in the model. We do not plan to adjust for time-varying hospital-level covariates but we will adjust for whether the hospital was in other programs (e.g., the bundled payment care initiative (BPCI) program) that might influence the culture of the hospital towards ACP; an advantage of adjusting for BPCI participation is that we may obtain more precise inferences.

Secondary analyses

In secondary analyses, we will also explore whether there is evidence on an interaction effect between BPCI participation and the impact of the game on the adjusted odds that a patient has an ACP billed. We will also estimate the effect of the intervention on ACP practices, using both the chart review and the MiPS measures to estimate the sensitivity and specificity of the different methods of measuring ACP. Finally, we will test the effect of mediators on the effect of the intervention on practice patterns, including the dose of a patient's exposure to the intervention, physicians' self-reported engagement with the intervention, and physicians' prior training. These factors are potential mediators of the effect of the game being employed at a hospital on patient outcomes as they are on the causal pathway of the hospital-level intervention to patient outcomes; if no physicians who indicated their willingness to participate in the study end up playing the game it is difficult to imagine how the game could then impact their patients' outcomes. Likewise, the hypothesis that a patient who encounters multiple physicians who played the game will have outcomes that are more pronounced than a patient who encountered only a single physicians or even no physicians who played the game a priori appears to be plausible.

In a potential extended analyses we will adapt statistical methods for incorporating the sensitivity and specificity of the measurement of the occurrence of an ACP conversation, which is informed by the agreement between chart-review and insurance-claim (or MiPS) measurement, into the analysis. The resulting analysis can be viewed as a calibration analysis that combines the standard cluster-randomized stepped-wedge design with a bivariate outcome

(a more expensive measurement in the form of chart-review and a less expensive measurement in the form of insurance-claim or MiPS) in order to evaluate the impact of the deployment of the game at a hospital on chart-based measurement of ACP occurrence. The statistical model entwining the outcomes will allow the missing values of chart-based measurement for those observations where charts are not reviewed to be learned from observations for which multiple forms of ACP measurement are made and automatically allow for uncertainty in the missing values of chart-review measurements to permeate through the analysis. A Bayesian statistical model and Bayesian computational methods may provide the least burdensome pathway to successfully implementing this analysis.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym *Page 1*
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry *Page 14*
	2b	All items from the World Health Organization Trial Registration Data Set *Available at clinicaltrials.gov*
Protocol version	3	Date and version identifier *Page 1*
Funding	4	Sources and types of financial, material, and other support *Page 18*
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors *Page 18*
	5b	Name and contact information for the trial sponsor *N/A - no trial sponsor*
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities *Page 18 - description of funders' responsibilities only (no trial sponsor)*
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) *Page 14*
Introduction		

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention. *Page 3-4*
	6b	Explanation for choice of comparators *Page 4*
Objectives	7	Specific objectives or hypotheses *Page 5 and Table 2*
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) *Page 5*
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained. *Page 6*
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists). *Page 6*
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered. *Page 7-9*
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease). *Page 14*
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) *Page 7*
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial *Page 7*

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended *Page 11 and Table 1*
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) *Figure 2*
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations *Page 12*
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size *Page 12*

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions *Page 6*
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned *Page 6*
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions *Page 6*
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how *Page 6*

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial *Not applicable - we will mask assignment during data analysis, but will not blind participants (and therefore have not addressed a process for circumstances under which unblinding is permissible).*
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol *Page 9-12*
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols *Page 7, 13*
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol *Page 14*
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol *Page 12, 13, Appendix*
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) *Appendix*
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) *Appendix*
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial *Page 14*
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct *Page 14*
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor *Page 14*

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval *Page 14*
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) *Page 14*
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) *Page 19*
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable *N/A - no additional consent provisions planned.*
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial *Page 14*
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site *Page 19*
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators *Page 19*

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation. *Not applicable - based on experience with use of the intervention in other contexts, no adverse consequences are anticipated and therefore no provision has been made for compensation or post-trial care for participants.*
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions *Page 14*
	31b	Authorship eligibility guidelines and any intended use of professional writers *Page 19*
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code *Page 19*
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates *N/A - we have received a waiver of written consent from the Institutional Review Board.*
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable *N/A - no biological specimens will be collected during the trial.*

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

A videogame intervention to increase advance care planning conversations by hospitalists with older adults: study protocol for a stepped wedge clinical trial

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A videogame intervention to increase advance care planning conversations by hospitalists with older adults: study protocol for a stepped wedge clinical trial

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ABSTRACT

Introduction: Fewer than half of all people in the U.S. have a documented advance care plan. Hospitalization offers an opportunity for physicians to initiate advance care planning (ACP) conversations. Despite expert recommendations, hospital-based physicians (hospitalists) do not routinely engage in these conversations, reserving them for the critically ill.
The objective of this study is to test the effect of a novel behavioral intervention on the incidence of ACP conversations by hospitalists practicing at a stratified random sample of hospitals drawn from 220 US acute care hospitals staffed by a large, nationwide acute care physician practice with an ongoing ACP quality improvement initiative.

Methods and analysis: We developed *Hopewell Hospitalist*, a theory-based adventure video game, to modify physicians' attitudes towards ACP conversations, and to increase their motivation for engaging in them. The planned study is a pragmatic stepped-wedge crossover phase III trial, testing the efficacy of *Hopewell Hospitalist* for increasing ACP conversations. We will randomize 40 hospitals to the month (step) in which they receive the intervention. We aim to recruit 30 hospitalists from up to 8 hospitals each step to complete the intervention, playing Hopewell Hospitalist for at least 2 hours. The primary outcome is ACP billing for patients age 65 and older managed by participating hospitalists. We hypothesize that the intervention will increase ACP billing in the quarter after dissemination, and have 80% power to detect a 1% absolute increase and 99% power to detect a 3.5% absolute increase.

Ethics and dissemination: Dartmouth's Committee for the Protection of Human Subjects has approved the study protocol, which is registered on clinicaltrials.gov. We will disseminate the results through manuscripts and the trials website. *Hopewell Hospitalist* will be made available on the iOS Application Store for download, free of cost, at the conclusion of the trial.

Key words: advance care planning; physician performance; serious games; narrative engagement

Trial registration: clinicaltrials.gov; NCT 04557930, 9/21/2020.

ARTICLE SUMMARY

Strengths and limitations of this study

- A strength of this study is the theoretical framework of the intervention, which draws on insights from the psychological and behavioral science literature.
- A second strength of this study is our plan to distribute the intervention through a partnership with a national acute care physician staffing organization, which will increase the generalizability of our observations .
- A limitation of this study is our use of billing as a surrogate measure of physician behavior.

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.[1] ACP improves the quality of end of life care, while reducing unwanted resource utilization.[2] Unfortunately, fewer than half of all people in the U.S. have documented advance care plans, such as an advance directive.[1] Existing guidelines therefore advocate that physicians use hospitalization as an opportunity to initiate these conversations.[3]

Multiple barriers exist to the initiation of ACP in the hospital.[4-6] High quality conversations require physicians to have the motivation, skill, and time 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 all patients over the age of 65.[7] Efforts to facilitate ACP through text-based education, reminders, incentives, and outreach by opinion leaders have had variable success.[8,9] How best to ensure that physicians meet this standard therefore remains unclear.[10-12]

We propose a novel intervention to modify physicians' knowledge of and attitudes towards ACP conversations, and increase their motivation for engaging in them. The central mechanism is *narrative engagement* (i.e. using storytelling to change behavior).[13] Stories deliver memorable messages that resonate with recipients in personally-relevant and meaningful ways.[13] Programs using stories to transmit best-practice decision principles have reduced drug use among middle school students, reduced sexually transmitted diseases among high school students, and increased the rates of mammogram acquisition among low-income minority groups.[13-15] We built a customized adventure video game that uses narrative engagement to educate physicians about the benefits of ACP for all patients age 65 and older.

The objective of the planned study is to test the effect of the video game intervention on ACP rates, measured by billing, among a convenience sample of 150 hospitalists recruited from up to 40 US hospitals staffed by a large, nationwide acute care physician practice with an ongoing ACP quality improvement initiative. We hypothesize that the intervention will increase

ACP billing in the quarter after dissemination, and have 80% power to detect a 1% absolute increase and 99% power to detect a 3.5% absolute increase.

METHODS

Conceptual Framework

Our population of hospitalists employed by a national physician practice already receive best-practice ACP interventions designed to increase: 1) knowledge of ACP guidelines (through web-based didactic education); 2) identification of patients to prioritize for ACP (through decision support and reminders in the electronic medical record); 3) the influence of social norms (through audit and feedback regarding ACP billing rates compared to hospital peers); 4) extrinsic motivation (through a financial incentive of $20 for each billed ACP conversation). These efforts have increased ACP substantially over the last three years, but rates remain below the standards set by a Delphi panel of experts, who recommend ACP conversations for all inpatients over the age of 65.[7,16] Formative work, consistent with behavioral theory, suggested positive attitudes could facilitate ACP; therefore, we chose hospitalists' attitudes towards ACP conversations as the primary intervention target.[17]

To intervene on this target, we refined an existing intervention based on the theory of narrative engagement.[18] The intervention – an adventure video game – had proven successful at improving physician decision making in trauma triage, without any identifiable adverse consequences.[18] Strong conceptual reasons existed to believe it would have efficacy in this context.[19-23] Finally, in assessing potential harms and benefits associated with this intervention, we relied on a meta-analysis of interventions to increase ACP, which found positive outcomes for patients.[2]

Study overview

We developed the video game (*Hopewell Hospitalist*) in collaboration with Schell Games (Pittsburgh, PA) through an iterative process involving behavioral scientists, hospitalists, palliative care experts, intensivists, and game developers, with the intention of increasing physicians' frequency of ACP conversations with hospitalized patients. We plan to compare the impact of *Hopewell Hospitalist* on ACP practices before-and-after intervention dissemination in a stepped-wedge cluster randomized trial [**Figure 1**].

A stepped-wedge trial randomizes physician participants (and the patients they collectively care for) at the group level (e.g., hospital); each group 'crosses over' from control to intervention at a randomized timepoint and is followed through multiple 'time steps' of data collection.[24] This trial design is the best option to test the efficacy of the video game because: 1) physician-level randomization risks misclassifying patients, contaminating control physicians, and failing to address group-level attitudes to and practices of ACP; 2) a two-group parallel cluster randomized design risks imbalance among groups, especially if relatively few hospitals participate in the study, because of the high intra-class correlation that exists for ACP billing at the hospital-level; 3) there are logistical challenges to rolling out the intervention simultaneously at all hospitals.

We will use a stepped-wedge design with five-steps (with each step lasting one month), and will compare the difference in ACP billing of physicians enrolled in the trial in the time period before and after intervention dissemination. A pre-period of three-months duration will yield retrospectively measured observations that augment the analysis data. Drawing on more than three years of data, inclusive of the early stages of the COVID-19 pandemic (January 2017-June 2020), organization-wide ACP billing rates for patients 65 and older increased from 5% to 22%, corresponding to a 1.5% absolute quarterly increase. We hypothesize that physicians will have a 5% absolute increase (a 3.5% net increase) in ACP billing in the quarter after dissemination of the intervention (primary outcome).

Participants

Study Setting

We partnered with a national physician practice that employs acute care providers in hospital medicine, emergency medicine and critical care. This physician practice: 1) staffs over 200 hospitals with a wide variety of geographic and organizational characteristics, increasing the generalizability of our observations; 2) has already implemented best-practice quality improvement efforts to improve ACP practices at its hospitals, making our comparator enhanced-usual care; 3) seeks to further increase ACP rates, increasing organizational buy-in.

Hospital Sampling

We will sample hospitals staffed by the physician practice using the following inclusion criteria: at least 2 quarters of contracting with the practice, a risk-adjusted ACP billing rate > 0% in Q2 of 2020, agreement of physician leaders within the hospital to participate, and availability of an onsite, practice-employed, nurse liaison to collect secondary outcome measures.

Once a hospital is sampled, we will recruit hospitalists at the hospital by distributing email invitations. Eligible hospitalists are those employed by the practice for at least 2 quarters. We will obtain consent from interested physicians, collect baseline demographic and professional characteristics, as well as initial baseline measurements of attitudes towards ACP, then provide them with instructions on how to complete study tasks. A full list of the study sites will be published with the study results.

Randomization and Blinding

We will randomize sampled hospitals to the order in which they receive the video game. We will generate randomization schemas using R statistical software (R Core Team, Vienna, Austria), using random block sizes of 8, seeking to balance hospital risk-adjusted ACP rate, change in ACP rate between Quarter 2 2019 and Quarter 1 2020, practice size (number of practice-employed hospitalists) at the hospital, and region. Although we cannot blind study personnel and participants, we will mask the hospital's assignment during the analysis phase.

Study protocol

We will pre-load new iPads with the video game and mail them to hospitalist participants. We will ask participants to spend a minimum of two hours completing the intervention task, and then complete a web-based questionnaire with items assessing a) the intervention's usability, b) fidelity of intervention delivery and receipt, and c) mediators of intervention receipt. Completing the questionnaire will take approximately 15 minutes. Participants should complete the two portions of the study protocol within two weeks of receipt of the iPad. They will keep the iPad as an honorarium (approximate value $300). Reminders will include three email letters and a phone call, made by the study PI. Participants will continue to receive all usual-care ACP interventions, mandated by the practice, throughout the study period.

Intervention: Hopewell Hospitalist

Hopewell Hospitalist is an adventure video game designed to shift hospitalists' threshold for selecting patients with whom to have inpatient ACP conversations from patients at high risk for clinical deterioration to all hospitalized patients over the age of 65, drawing on CMS policy, the physician practice quality improvement (QI) targets, and ACP expert consensus.[7,25] We adapted the art and game mechanics from a previously-tested game,[18] after identifying key didactic principles based upon a review of the literature and the input of a multidisciplinary team of palliative care physicians, hospitalists, and intensivists.[26] We iteratively piloted the game with a series of play-testers between June-August 2019. We summarize didactic principles, game content, and game mechanics of *Hopewell Hospitalist* in the **Box** and in **Figure 2**.

Data sources and management

Physician characteristics

Each participating physician will complete a baseline questionnaire with items related to: age, gender, race/ethnicity, use of ACP billing codes, educational background, professional

characteristics (years spent as hospitalist, nocturnist, years spent as a hospitalist), and an initial baseline measurement of attitudes towards ACP.[27] The practice will provide information about physician completion of the organization's required continuing medical education (CME) about ACP. After playing the video game, physicians will complete a questionnaire with items related to usability, fidelity of intervention receipt, and mediators of intervention receipt (see Fidelity of Intervention Receipt). See **Figure 1** for schedule of enrollment and data collection.

Hospital characteristics

We have crude and adjusted ACP billing proportions for each candidate hospitals between January 2017 to June 2020, the number of hospitalists employed at each location as of January 2020, the presence or absence of a nurse liaison, and the hospital's geographic location . We will obtain additional information about the organizational characteristics of each hospital using the 2018 Centers for Medicare and Medicaid Services (CMS) Healthcare Cost Report Information System (HCRIS). HCRIS contains facility-level characteristics of all non-federal hospitals, including geographic location (state and region), participation in a hospital network, total bed count, ICU bed count, ownership, and teaching status.

Patient characteristics

The practice will provide the study team with discharge abstracts for all the patients treated by its hospitalists during the study period. These abstracts include patient demographics, admission diagnoses, discharge diagnoses, and physician claims filed during the hospitalization. We will abstract information about co-morbid conditions from the ICD10-CM (International Classification of Diseases 10 - Clinical Modification) diagnosis codes. We will link these data to patient-level CMS claims and Social Security Administration (SSA) records to collect post-discharge, episode-based outcomes.

Fidelity of intervention delivery (intervention dose)

The *Hopewell Hospitalist* application collects data on each player's behaviors and actions (e.g. total time spent in-game, number of game-play sessions, average number of minutes per

session, cases completed, decisions made, feedback reviewed) during game-play. These data will be reported and stored in Google Analytics. Additionally, participants are asked to self-report their play time and details of the most memorable case they encountered.

Fidelity of intervention receipt

We will measure the fidelity of intervention receipt by capturing physicians' attitudes towards ACP before and after completion of the game using items adapted from published studies.[7,27] Additionally, we will measure narrative engagement, the proposed mediator of the intervention, using the Narrative Engagement Scale.[28] Finally, we will assess the game's usability, using a validated instrument and open-ended questions.[29]

Fidelity of intervention enactment (outcome assessment)

We summarize our outcomes in the **Table 1**.

Primary

Our primary outcome will be the patient-level binary variable indicating whether an ACP bill occurred during their hospitalization. The study sample will be restricted to patients over the age of 65 before-and-after dissemination of the video game intervention: each hospital will contribute a minimum of three months and a maximum of eight months of data to each time period depending on their step (see Figure 1). We will screen the practice's discharge abstracts for the presence/absence of ACP charges (billing codes 99497 and 99498) and will categorize each patient as having had (or not had) an ACP conversation during their hospitalization. The rationale for using ACP billing as the primary outcome is: 1) it can be obtained administratively for all patients; and 2) it is a less sensitive but more specific measure of a comprehensive ACP conversation than the Merit-based Incentive Payment System (MIPS) self-report measure of ACP because it is a time-based billing code requiring an ACP conversation of at least 16 minutes in length.

Secondary

Secondary measures of physician ACP behavior will include a self-report measure and a chart-abstraction based measure. We will collect each physicians' self-report MIPS ACP quality measure (the proportion of patients who have an ACP or surrogate decision maker documented in the medical record [or declined to participate in the process] of all patients 65 years and older treated by the physician). Additionally, practice nurse liaisons will provide a 20% random sample of the charts of eligible patients. We will review these charts for documentation of a conversation about ACP. This will allow estimation of the sensitivity and specificity of claims-based and MIPS-based measurement of ACP relative to chart-review.

Secondary measures of patient outcomes (i.e. downstream consequences of intervention enactment) will include: disposition status, in-hospital mortality, 90-day mortality, and resource utilization during the index hospitalization. Index hospital outcomes will be drawn from the practice's data; post-discharge 90-day episode based outcomes will be drawn from linked CMS and SSA data.

Analyses

We will summarize sample hospital and consented physician characteristics using means (standard deviations) for continuous variables and proportions for categorical variables, and will compare the distribution of characteristics between the five ‘steps’ in the trial using chi-square and F tests as appropriate. We will summarize and compare patient characteristics between ‘steps’ of the trial similarly.

Participation

We will calculate an enrollment (cooperation) frequency for the trial as the proportion of physicians at randomized hospitals who agree to participate in the trial, and a completion (response) frequency as the proportion of physicians who agree to participate and complete all the study tasks.

Usability

For physicians who use the video game, we will summarize responses to free-text response questions to assess usability, and will categorize this qualitative, open-ended feedback as positive or negative.

Fidelity of intervention delivery

We will summarize the length of time that physicians spend playing the game as captured by the application and reported by the participant in the post-intervention questionnaire. We will also summarize additional characteristics of game play (e.g. number of cases completed). We will compare participation at hospitals in different steps of the trial using chi-square tests, and the duration of exposure using chi-square tests and F-tests. This information will allow for secondary analyses into the mechanism of the intervention's success or failure.

Fidelity of intervention receipt

We will compare physician attitudes towards ACP before and after use of the intervention using a vignette-based instrument and questionnaire, as well as narrative engagement and user experience questionnaires after completion of the intervention.

Fidelity of intervention enactment

We plan to conduct intention-to-treat analyses of all patients treated at a hospital during the time period of the study who received care from at least one consenting hospitalist who received an iPad during the intervention period for that hospital, regardless of whether they actually played the game. All statistical tests will be performed with two-tailed significance testing at an alpha of 0.05 for the primary outcome. We list our hypotheses in **Table 2** and describe our analytic plan in detail in the **Appendix.**

In unadjusted descriptive analyses, we will begin by calculating ACP billing proportions among participating physicians at each randomized hospital in the pre-intervention and post-intervention periods. The minimum length of each period is 3 months (one quarter).

$$\text{Physician ACP billing proportion} = \frac{\text{Number of treated patients} \geq 65 \text{ years with an ACP charge}}{\text{Number of treated patients} \geq 65 \text{ years}} \quad [1]$$

Next, we will compare ACP billing proportions for the period before and after intervention distribution among enrolled physicians using a Student's t-test.

To test the efficacy of the intervention, we will fit a mixed effects patient-level logistic regression model for patients treated by physicians enrolled in the trial (i.e., physicians who were sent an iPad with the game during the intervention period), with presence of ACP billing during the hospitalization as the dependent variable. Since the linkage of a patient to a specific physician is inexact, we do not involve physician attribution in our primary outcome analysis. Instead the key predictor will be a time-varying variable indicating whether the patient received care – as measured by daily billing – by a hospitalist who consented to receive the intervention before (0) or after (1) the hospital was randomized to intervention roll-out. The model includes dummy variables for time-period to absorb trends across time and random-effects for hospital to account for the clustering of observations within hospitals. In addition, we will adjust for patient and hospital covariates hypothesized to influence the likelihood of an ACP conversation (e.g. cancer diagnosis).

A range of dependent variables are analyzed in the secondary analyses. In analyses that involve physician variables, the mixed-effects generalized linear model will be extended from a two-level model to a three-level model (see **Appendix** for details) for ACP billing. We will also test the efficacy of the intervention on secondary outcome measures, and the effect of mediators and moderators on the effect of the intervention. We will account for multiple comparisons when reporting analyses of secondary outcomes.

Human subjects and power calculation

We arrived at our sample size using a combination of feasibility (cost) and assumptions regarding effect size, absent any pilot data about the latter. For each step, we plan to recruit 25 to 30 physicians from 4 to 8 hospitals. Assuming a baseline ACP rate of 22% (rising by 1.5 percentage points per quarter), a hospital intra-class correlation (ICC) coefficient of 0.01-0.10,

and 160 evaluable patients per physician-quarter, we can detect between a 1-percentage-point absolute difference with a power of 80% and a 3.5 percentage-point absolute difference with power of 99% using a two-sided test at the 0.05-level between ACP billing rates before and after the distribution of the intervention.

The method of computing power for this stepped-wedge design follows the commonly used strategy for cluster randomized trials of first determining the design-effect, which can be thought of as a measure of the inefficiency of the given design in comparison to a completely randomized design that is expressed in terms of a ratio of the sample-sizes needed to obtain equally precise estimates, and then applying conventional power calculations (see **Appendix**).[30,31]

Security, ethics, and dissemination

Data Security

On enrollment in the trial, participants will receive a unique identifier. They will use that identifier to login to *Hopewell Hospitalist* and to the website that hosts the questionnaire. Only the study team will have access to the linkage file connecting the identifier to the physician's name and contact information. This file will be encrypted and stored on a secure server at Dartmouth-Hitchcock.

Ethics

The Dartmouth Committee for the Protection of Human Subjects has approved this study (STUDY00031980). The Data and Safety Monitoring Board convened by the funding agency, the National Institute on Aging, reviewed and approved the protocol and the data and safety monitoring plan. We do not plan any interim analyses and, therefore, have not included any stopping guidelines. However, the PI will ask participants to communicate any adverse events or unintended effects of participation via email, which she will in turn relay to the review boards.

Physicians may opt to withdraw from the trial at any point, at which point we will exclude all self-reported data from analysis. We have registered the trial on clinicaltrials.gov (NCT04557930). Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Dissemination of results

Results from the study will be reported to the public through manuscripts and oral presentations at national meetings. Access to the de-identified dataset will be made available upon written request to the study team.

DISCUSSION

This protocol paper outlines a clinical trial to test the efficacy of the video game at increasing ACP conversations among hospitalized patients.[32] *Hopewell Hospitalist* uses stories designed to immerse participants in playing the role of a physician concurrently solving both clinical and personal problems.[33] Research indicates the power of stories to facilitate behavioral change.[13] Stories facilitate processing and retaining new data.[19-23] Stories also can engage players cognitively and emotionally in ways that transcend traditional education.[13,32,34] Additionally, video game and simulation-based environments allow learners to practice desired behaviors in a safe environment, which supports the development of self-efficacy.[35,36] We designed the video game to achieve the intervention goal (simplifying the decision for ACP [to any patient 65 and older]) by influencing a specific target (attitudes to ACP [positive, valuable for patient well-being, and role-aligned]).[37] This design combined research insights regarding human behavior from the psychological literature and clinical insights regarding both descriptive and normative assessments of ACP for hospitalized older adults.[36-38]

We designed the protocol to complement best practices in system-level quality improvement initiatives. We struggled with three design challenges, which we resolved both by reviewing the existing literature and through iterative consensus when data did not exist. First, we debated the unit of randomization. We considered and then rejected physician-level randomization for both conceptual and pragmatic reasons. Conceptually, shift-based hospital physicians practice collaboratively, so that the work flow of one individual can have important implications for colleagues' role responsibilities. As we considered peer-effects, we imagined that, on one end of the spectrum, unexposed physicians might also shift their practice patterns, and, on the other hand, exposed physicians might be pulled back to conform to group norms. Either scenario risks biasing results towards the null if physicians are the unit of randomization. Pragmatically, patients (particularly the sickest ones) may have contact with multiple physicians during the course of one hospitalization. Consequently, physician-level randomization risks the

misclassification of patients. In contrast, hospital-level randomization alleviates these concerns, although it decreases power (due to increasing within-cluster correlation) and increases the complexity of ensuring adherence to the intervention.

Second, we debated how to deliver the intervention. We decided to deliver the intervention using the platform of a video game to encourage utilization and to harness the power of narrative engagement to stimulate behavior change. Although potentially more enjoyable than standard didactic text-based continuing medical education, it does not rise to the level of entertainment. To further incentivize participation and engagement, we decided to deliver the game pre-loaded on a new iPad. In prior work, we found providing a fixed material honorarium (i.e. an iPad) produced adherence rates of up to 80%.[39] We considered, but rejected, alternative strategies of distributing the intervention, including requesting that physicians download the game onto personal devices or using re-furbished iPads. Providing an honorarium to promote adherence restricts the use of the intervention to the research setting, but maximizes the fidelity of the intervention delivery and receipt across participants.

Third, we debated how to assess the impact of the intervention. Direct observation has the greatest validity but limited feasibility. Review of charts or electronic health records provide an alternative. Although dependent on the quality of physician documentation, this method allows for the evaluation of a larger number of physicians. However, the resources and time required to abstract charts would limit our ability to detect small (albeit significant) effect sizes. We therefore opted to use billing proportions as our primary outcome measure. In 2016, CMS rolled out a time-based billing code for ACP conversations held in the hospital. We anticipate that use of billing codes will bias our results towards the null, and plan to perform secondary analyses using alternative methods of measuring ACP practices to test the validity of our primary analyses.

Advances in technology hold the potential to transform the means by which behavioral and social science interventions are delivered. They ensure treatment fidelity and can extend treatment duration, thus improving behavioral maintenance. We have developed one such

behavioral intervention to encourage hospital-based physicians to initiate ACP conversations for hospitalized older adults, and plan to test its efficacy. We intend that results of this trial will contribute to the literature on physician quality improvement and the efficacy of video games as behavioral interventions.

TRIAL STATUS: Recruiting

ABBREVIATIONS

ACP - Advance Care Planning
BCPI - Bundled payment care initiative
ICU - Intensive Care Unit
CME - Continuing Medical Education
CMS - Centers for Medicare and Medicaid Services
HCRIS - Healthcare Cost Report Information System
ICD10-CM - International Classification of Diseases 10th Revision - Clinical Modification
SSA - Social Security Administration
MiPS - Merit-based Incentive Payment System
QI - quality improvement

DECLARATIONS

Ethics approval and consent to participate

The Dartmouth Committee for the Protection of Human Subjects has approved this study (STUDY00031980). Given our recruitment strategy (email letters soliciting participation), we obtained permission to waive written consent for participation. The study team will obtain electronic consent and will explain the study protocol to all physicians who agree to participate in the trial.

Consent for publication

Not applicable

Availability of data and material

Access to the de-identified dataset will be made available upon written request to the senior author.

Competing interests

The authors have no financial conflicts to disclose.

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LM012339 Mohan). The funding agencies reviewed the study but played no role in its design; and will play no role in the collection, analysis or interpretation of data.

Authors' contributions

Study concept and design: AEB, DM, JC, JOM, MR, MM, MM

Drafting of the manuscript: DM, JC, AEB, JOM

Critical revision of the manuscript for important intellectual content: AEB, DM, JC, JOM, MR, MM, MM

All authors read and approved the final manuscript.

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REFERENCES

1. Institute of Medicine 2015. Dying in America: improving quality and honoring individual preferences near the end of life. Washington, DC: The National Academies Press.
2. Weathers E, O'Caoimh Ronan, Cornally N et al. Advance care planning: a systematic review of randomized clinical trials conducted with older adults. *Maturitas* 2016; 91: 101-109.
3. Anderson WG, Berlinger N, Ragland J et al. Hospital-based prognosis and goals of care discussions with seriously ill patients: a pathway to integrate a key primary palliative care process into the workflow of hospitalist physicians and their teams. Society of Hospital Medicine and The Hastings Center, 2017.
4. Howard M, Bernard C, Klein D et al. Barriers to and enablers of advance care planning with patients in primary care. *Canadian Family Physician* 2018; 64: e190-8.
5. Lund S, Richardson A, and May C. Barriers to Advance Care Planning at the end of life: an explanatory systematic review of implementation studies. *PLoS One* 2015; 10: e0116629.
6. Heyland DK, Barwich D, Pichora D et al. Failure to engage hospitalized elderly patients and their families in Advance Care Planning. *JAMA Intern Med* 2013; 173: 778-787.
7. Mohan D, Sacks OA, O'Malley J et al. A new standard for advance care planning conversations in the hospital: results from a Delphi panel. *J Gen Intern Med* 2020. Online ahead of print.
8. Houben CHM, Spruit MA, Groenen MTJ et al. Efficacy of Advance Care Planning: a systematic review and meta-analysis. *JAMDA* 2014; 15: 477-489.
9. Bryant J, Turon H, Waller A et al. Effectiveness of interventions to increase participation in advance care planning for people with a diagnosis of dementia: a systematic review. *Palliative Medicine* 2019; 33: 262-273.
10. Milkman KL, Chugh D, Bazerman MH. How Can Decision Making Be Improved? *Perspectives on Psychological Science* 2009; 4:379–83.

11. Hunt DL, Haynes RB, Hanna SE, *et al.* Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review. *JAMA* 1998; 280:1339–46.
12. Graber ML, Kissam S, Payne VL, *et al.* Cognitive interventions to reduce diagnostic error: a narrative review. *BMJ Qual Saf* 2012;**21**:535–57. doi:10.1136/bmjqs-2011-000149
13. Miller-Day M, Hecht ML. Narrative Means to Preventative Ends: A Narrative Engagement Framework for Designing Prevention Interventions. *Health Communication* 2013;**28**:657–70. doi:10.1080/10410236.2012.762861
14. Murphy ST, Frank LB, Chatterjee JS, et al. Narrative v. non-narrative: the role of identification, transportation, and emotion in reducing health disparities. J Commun. 2013: 63: doi: 10.1111/jcom.12007.
15. Hinyard LJ and Kreuter MW. Using narrative communication as a tool for health behavior change: a conceptual, theoretical, and empirical overview. Health Educ Behav 2007; 34: 777.
16. Barnato AE, O'Malley AJ, Skinner JS et al. Use of advance care planning billing codes for hospitalized older adults at high risk of dying: a national observational study. *J Hosp Med* 2019; 14: 229-231.
17. Sacks OA, Knutzen KE, Rudolph MA, Mohan D, Barnato AE. Advance care planning and professional satisfaction from 'doing the right thing:' interviews with hospitalist chiefs. *J Pain Symptom Manage* 2020; 9: S0885-3924(20)30565.
18. Mohan D, Farris C, Fischhoff B et al. Efficacy of educational video game versus traditional educational apps at improving physician decision making in trauma triage: randomized controlled trial. *BMJ* 2017; 359: j5416.
19. Moyer Gusé E, Nabi RL. Explaining the Effects of Narrative in an Entertainment Television Program: Overcoming Resistance to Persuasion. *Human Communication Research*

2010;**36**:26–52. doi:10.1111/j.1468-2958.2009.01367.x

20. Thorndyke PW. Cognitive structures in comprehension and memory of narrative discourse. *Cognitive Psychology* 1977; 9: 77-110
21. Bower GH and Morrow DG. Mental models in narrative comprehension. *Science* 1990; 247: 44-48.
22. Nabi RL, Green MC. The Role of a Narrative's Emotional Flow in Promoting Persuasive Outcomes. *Media Psychology* 2014;**18**:137–62. doi:10.1080/15213269.2014.912585
23. Zillmann D. (1991). Empathy: affect from bearing witness to the emotions of others. In J. Bryant and D Zillman (Eds.), *Communication*. *Responding to the screen: reception and reaction processes* (pp. 135-167). New York: Routledge.
24. Hemming K. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ* 2015; 350: h391.
25. Centers for Medicare and Medicaid Services (2019). Quality Measures Fact Sheet: Advance Care Plan (ACP) (NQF #0326) https://innovation.cms.gov/files/fact-sheet/bpciadvanced-fs-nqf0326.pdf
26. Ariadne Labs. (2015). Serious Illness Conversation Guide. Retrieved from https://www.ariadnelabs.org/wp-content/uploads/sites/2/2017/05/SI-CG-2017-04-21_FINAL.pdf.
27. Zhou Guiyan, Stoltzfus JC, Houldin AD et al. Knowledge, attitudes, and practice behaviors of oncology advanced practice nurses regarding advanced care planning for patients with cancer. (2010). *College of Nursing Faculty Papers & Presentations*. Paper 31. https://jdc.jefferson.edu/nursfp/31.
28. Busselle R and Bilandzic H. Measuring narrative engagement. *Media Psychology*. 2009; 12: 321-347.

29. O'Brien HL, Cairns P, and Hall M. A practical approach to measuring user engagement with the refined user engagement scale (UES) and the new UES short form. International Journal of Human-Computer Studies. 2018; 112: 28-39
30. Hemming. K. Sample size calculations for stepped wedge trials using design effects are only approximate in some circumstances. Trials 2016; 17:234.
31. Woertman W, de Hoop E, Moerbeek M, Zuidema SU, Gerritsen DL, Teerenstra S. Stepped wedge designs could reduce the required sample size in cluster randomized trials. J Clin Epidemiol. 2013; 66:752–8.
32. Gitlin LN. Introducing a new intervention: an overview of research phases and common challenges. *American Journal of Occupational Therapy.* 2013; 67: 177-184.
33. Perski O, Blandford A, West R et al. Conceptualizing engagement with digital behavior change interventions: a systematic review using principles from critical interpretive synthesis. *TBM* 2017; 7: 254-267.
34. Primack BA, Carroll MV, McNamara M, et al. Role of video games in improving health-related outcomes. Am J Prev Med 2012; 42(6): 630-638.
35. McGaghie WC, Issenberg SB, Cohen ER et al. Does simulation-based medical education with deliberate practice yield better results than traditional clinical education? A meta-analytic comparative review of the evidence. Acad Med 2011; 86: 706-711.
36. Michie S, van Stralen M, and West R. The behavior change wheel: a new method for characterising and designing behaviour change interventions. *Implementation Science*. 2011; 6: 42.
37. Ryan RM and Deci ED. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American Psychologist* 2000; 55: 68-78.
38. Hartzband P and Groopman J. Physician burnout, interrupted. *NEJM* 2020; 382: 2485-2487.
39. Mohan D, Rosengart MR, Fischhoff B, et al. Using incentives to recruit physicians into behavioral trials: lessons learned from four studies. BMC Res Notes. 2017; 10:776

ADDITIONAL FILES

Figure 1

File format: pdf
Title of data: Schedule of enrollment, interventions, and assessments.
Description of data: Description of enrolment, interventions, and assessments based on SPIRIT guidelines.

Figure 2

File format: .pdf
Title of data: Screen shots of trailer to *Hopewell Hospitalist*
Description of data: We show the trailer to the game. We provided players with two explicit objectives in order to heighten narrative engagement, while simultaneously providing a vehicle for physician education.

Box 1

Description of *Hopewell Hospitalist*

Duration: Three hours of gameplay possible.

Objective: To increase ACP conversations

Theory-based intervention targets: Attitudes to ACP [positive, valuable for patient well-being, and role-aligned]

Theory-based intervention goal: Simplifying the decision for ACP [to any patient 65 and older]

Theory-based intervention delivery strategy: Provide personally-relevant and emotionally-compelling feedback through storytelling that increases retention of the message (theory of narrative engagement)

Didactic principles: All hospitalized patients who are 65 years or older should have an ACP conversation. Each of the 5 teaching cases (see below) embeds supporting didactic principles in the feedback.

- Older adults who require ICU care for mechanical ventilation have ≥70% risk of death or disability at one year, and pre-admission frailty is associated with even higher risk of death or disability after ICU-level care. Assessing goals for treatment can help hospitalists support goal-concordant treatment decision making when/if medical decompensation occurs.
- Patients with severe co-morbidities (e.g., cancer, end-stage renal disease) are at high risk of medical decompensation requiring decisions about ICU-level care, yet ≤10% have had documented ACP conversations with their specialists or primary care providers prior to admission. Hospital admission is a fruitful time for ACP conversations and can be an opportunity to discuss hospice eligibility and introduce hospice services.
- Patients hospitalized with even a minor clinical problem have a 30% risk of dying within 3 years. Hospitalization can therefore be an opportunity to think generally about values and goals, and therefore attend to 'life completion' tasks.
- Having an ACP conversation early reduces the emotional distress and decisional conflict experienced by surrogates and patients when/if medical decompensation occurs.
- Race should not influence physician decisions to engage in ACP conversations because individual goals and values, not race, affect patient preferences for end-of-life treatment.

Game concept: The player takes on the role of Andy Jordan, a young emergency medicine physician, who moves home after his grandfather's disappearance and accepts a job at a local community hospital covering night shifts.

Game content

Medical: Physicians interview patients who present to Hopewell Hospital, and have the option of investigating further, having an ACP conversation with the patient/surrogate, or completing the daily documentation. The patients include:

- 5 "teaching" cases of patients with serious illness, adapted from clinical practice. These patients are 65 years or older and require hospitalization for assorted complaints (e.g. heart failure, peptic ulcer disease). If players engage in ACP conversations, they later receive updates on the positive outcomes experienced by these patients. If players do not engage in ACP conversations, these patients return with complications of their initial complaint. Players also receive feedback from in-game characters (e.g. their supervisor, consultants, family members) about the impact that timely advanced care plans can have on the trajectories of patients' care.
- 5 "non-teaching" cases of patients with diagnostically challenging problems, adapted

from the clinical case records of the Massachusetts General Hospital as presented in the *New England Journal of Medicine*. These patients are designed to facilitate player engagement in the clinical task.

- 2 “non-teaching” cases of patients with life-threatening illnesses, adapted from clinical practice. These patients serve as a management challenge to facilitate player engagement in the clinical task.

Non-medical: Robert Jordan, Andy’s estranged grandfather, has disappeared. The prologue hints that his disappearance may or may not have occurred voluntarily. The player must solve the mystery by uncovering clues revealed through conversation with in-game characters and by exploring the environment.

Game mechanics

1. Connect the dots: clues (medical and non-medical) appear on a notepad on the screen. The player can draw connections between clues to uncover information and to unlock additional dialogue options.
2. Tap to act: the player can tap on the screen to move through the world and interact with other characters. This mechanic also allows the player to perform key patient-care actions, including procedures like lumbar punctures and intubations.
3. Points: players receive points for uncovering non-medical clues, which unlock in-game lore. Specifically, they can access letters written by Andy and his grandfather, which should provide additional insight into their characters and motivations.

Table 1. List of Outcomes Measures

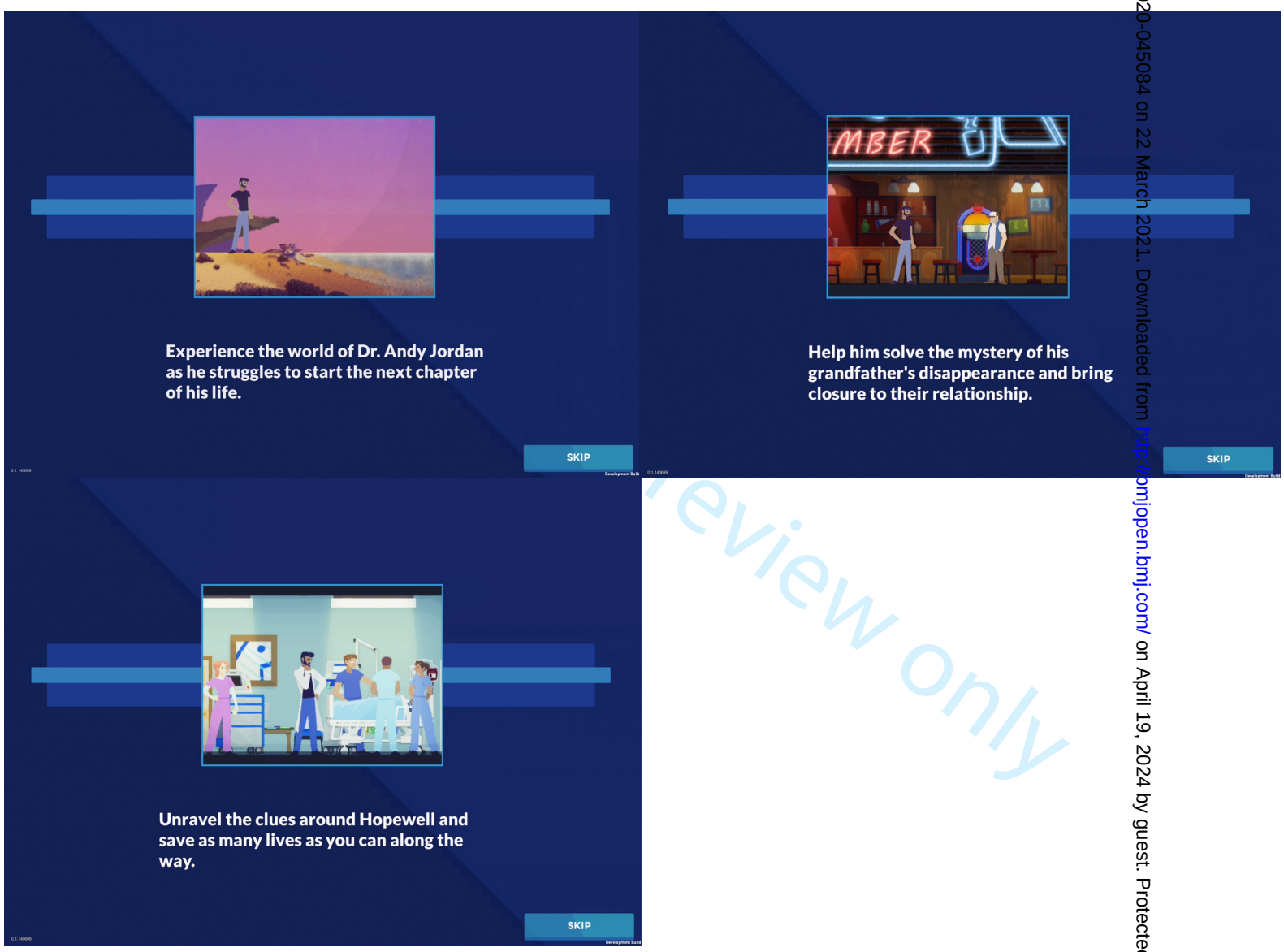
Type of measure	Measure target	Description of measure
Fidelity of intervention enactment		
Primary	ACP performance	ACP billing proportion
Secondary	ACP performance	Self-report MiPS ACP quality measure
		ACP conversations assessed using chart abstraction of a random 20% of patients.
	Patient outcomes	Disposition status
		In hospital mortality
		90-day mortality
		Resource utilization (length of stay, admission to ICU, mechanical ventilation, placement of tracheostomy, insertion of gastric feeding tube, new onset dialysis, palliative care consults, 90-day spending)
		Length of stay
		90-day episode based spending
Fidelity of intervention receipt		
Secondary	Physician attitudes	Physician attitudes towards ACP conversations (vignette-based)
		Physician attitudes towards ACP conversations (questionnaire-based)

Table 2. Hypotheses to be tested

Hypotheses	
Fidelity of intervention enactment	
Primary	Physicians will have a 3.5% greater increase in ACP billing in the quarter after dissemination of the intervention than would be expected based on secular trends alone.
Secondary	Physicians will have an increase in MiPS self-report of ACP and chart-abstracted ACP documentation after dissemination of the intervention.
	The difference in physician billing proportion after dissemination of the intervention will be correlated with participants' minutes of game play; narrative engagement scores, and changes in ACP attitudes (mediators).
	The difference in physician billing proportion before-and-after distribution of the intervention will be positively associated with the proportion of physicians who have completed the practice's e-curriculum (baseline knowledge - moderator).
	The difference in physician billing proportion before-and-after distribution of the intervention will be positively associated with the proportion of physicians at each hospital who use the game (peer effects - moderator).
	The difference in billing proportion before-and-after the distribution of the intervention will be associated with differences in patient-level outcomes, including reduction of resource utilization during the index hospitalization and during the 90-day illness episode (patient care outcomes)
Exploratory	Billing for ACP conversations (at the hospital level) will correlate positively with documentation of ACP conversations in patients' charts and with MiPS self-report of ACP.
Fidelity of intervention receipt	
Secondary	An increased proportion of physicians will describe ACP as part of their role responsibility, measured before-and-after the distribution of the intervention.

		STUDY PERIOD							
	Enrolment	Allocation	Post-allocation						Close-out
TIMEPOINT**	*Month 0*	*Month 0*	*Months -2-0*	*Month 1*	*Month 2*	*Month 3*	*Month 4*	*Month 5*	*Months 6-8*
ENROLMENT:									
Eligibility screen	X								
Informed consent*				X	X	X	X	X	
Allocation		X							
INTERVENTIONS:									
Hopewell Hospitalist: Step 1				X	X	X	X	X	
Hopewell Hospitalist: Step 2					X	X	X	X	
Hopewell Hospitalist: Step 3						X	X	X	
Hopewell Hospitalist: Step 4							X	X	
Hopewell Hospitalist: Step 5								X	
ASSESSMENTS:									
Hospital: Number of hospitalists, ACP billing, presence of practice-employed, nurse liaison.	X								
Physicians: demographics, educational background, practice environment, baseline attitudes to ACP, completion of organization's CME course				X	X	X	X	X	
***Physicians*:** intervention dose (self-report, application)				X	X	X	X	X	
***Physicians*:** questionnaire with items relating to intervention usability, fidelity of intervention receipt, mediators of fidelity of intervention receipt (self-report)				X	X	X	X	X	
***Patients*:** claims based data from practice, CMS and SSA**			X	X	X	X	X	X	X

* Consent will be obtained immediately preceding roll-out of the intervention at hospitals in the step to limit erosion of participant adherence to the intervention.
**Data will be collected for all sites for the three months preceding and following the trial.



APPENDIX

Description of Intervention

Players take on the persona of Andy Jordan, a young hospitalist who moves home after the disappearance of his estranged grandfather, Robert Jordan, and begins a job at a local community hospital. The player has two objectives: to diagnose and treat patients admitted to the hospital, and to solve the mystery of Robert's disappearance.

Patient cases fall into two categories, 'teaching' and 'non-teaching.' Interactions with the 'teaching' patients are designed to communicate a didactic principle that instantiates the game objective of encouraging players to have ACP conversations with all patients over the age of 65 (see **Box**). These patients have a serious illness but are not at the very end-of-life. When players fail to engage in ACP conversations, the patient returns with complications that require additional treatment. Players also receive feedback on their performance from in-game characters (e.g. peers, family members, or their supervisor). The feedback includes factual information about the probability of poor outcomes among patients over 65 who require hospitalization and a reminder about the value of early ACP conversations. In contrast, when players engage in ACP conversations, they subsequently receive an update about the patient's condition, describing how that ACP improved the care of the patient downstream, and a compliment on their decision-making and communication skills. Relevant patients also provide an opportunity for players to observe best practice principles of a high-quality serious illness conversation modeled on Ariadne Lab's Serious Illness Conversation Guide.[26] Specifically, when players choose to engage in ACP conversations, the interaction unfolds with Andy asking key questions from the guide and following other best practices (e.g. Andy Jordan pulls up a chair and sits for the conversation).

'Non-teaching' patients either have a critical, immediately life-threatening illness or a diagnostically challenging problem. These cases were designed to increase challenge levels

and associated game-play enjoyment. Players do not receive in-game feedback on their treatment of 'non-teaching' patients. Instead, they receive a summary of their performance on all cases at the end of the game that summarizes decisions made on the teaching cases and the accuracy of their diagnoses for the non-teaching cases.

The mystery component of *Hopewell Hospitalist* occurs concurrently with the clinical challenges, and serves to facilitate players' identification with their character and interest in their task. Players must solve Robert's disappearance through interactions with other characters, including patients, and their physical environment. Andy Jordan's background and character are also revealed through these interactions, which are designed to make him and his decisions more appealing and sympathetic.

Statistical Plan

Here we provide additional information about our analytic plan.

Primary Analysis

Let Y_{ijt} denote the binary outcome variable (coded as 1 if an ACP conversation occurred and 0 otherwise) for patient *i* seen at hospital *j* at time *t*; $Game_{jt}$ a binary variable indicating whether hospital j has received the Game during period t ($Game_{jt} = 1$ if received by hospital j before or during period t and 0 otherwise), x_{ijt} a vector of patient-level covariates, z_j a vector of hospital-level covariates and θ_j a random effect for hospital. The mathematical specification of the statistical model is given as $Y_{ijt}|\theta_i \sim Bernoulli(\pi_{ijt})$, where

$$logit(\pi_{ijt}) = log\left(\frac{\pi_{ijt}}{1-\pi_{ijt}}\right) = \beta_0 + \beta_{1t} + \beta_2 Game_{jt} + \beta_3 x_{ijt} + \beta_4 z_j + \theta_j$$

where $\theta_j \sim Normal(0, \tau^2)$ is the distribution of the hospital-level random effects to account for the fact that the statistical significance of inferences about the effect of the game are likely to be reduced by the clustering of patients in hospitals. The model includes fixed-effects for time-

period, β_{1t}, to allow for an unstructured trend across calendar time, which makes the effect of the game (the primary target of inference) to be estimated net of any time-trend. The key coefficient of interest is β_2, which captures the structural shift in the outcome of patients who were enrolled in the study when the hospital receives the iPads, net of general trends across time and other covariates. Because this is a cluster-randomized study, there is a risk that the hospitals in each step are not perfectly balanced, despite attempts to balance these during randomization by forming blocks, and that the distributions of patient characteristics of patients treated by a given hospital may vary across time. To mitigate these concerns, we will adjust for judiciously selected patient and hospital covariates that we hypothesize are reasonably likely to be associated with the outcome. We do not plan to adjust for time-varying hospital-level covariates but we will adjust for whether the hospital was in other programs (e.g., the bundled payment care initiative (BPCI) program) that might influence the culture of the hospital towards ACP; an advantage of adjusting for BPCI participation is that we may obtain more precise inferences.

The reason why physician is excluded from the above model is that a patient may receive care from multiple physicians during their hospital stay. This makes it difficult to designate a single physician as being responsible for the patient's care and thus whether or not they receive an ACP conversation. In our primary analysis we hold the hospital as a collective unit as being responsible for the patient and, therefore, exclude any involvement of physician factors or identifiers in relation to the likelihood of the patient having an ACP conversation. However, based on analyses of preliminary data, we anticipate that for 80% of hospitalizations a single physician will dominate the care of the patient. Therefore, in a sensitivity analysis, we will add a physician layer to the above model and perform a physician-level analysis. Where more than one physician treats a patient, we will assign the patient to the discharging physician, as per the practice of the staffing organization. The resulting statistical model with be a three-level model with physician as the second level (between patient and hospital) to allow patients to be

nested within physicians that are in turn nested within hospitals. Because patients are not randomized to physician, we will consider adjusting for physician covariates, emulating some of the secondary analyses described below.

Secondary analyses

In secondary analyses, we will also explore whether there is evidence on an interaction effect between BPCI participation and the impact of the game on the adjusted odds that a patient has an ACP billed. We will also estimate the effect of the intervention on ACP practices, using both the chart review and the MiPS measures to estimate the sensitivity and specificity of the different methods of measuring ACP. Finally, we will test the effect of mediators on the effect of the intervention on practice patterns, including the dose of a patient's exposure to the intervention, physicians' self-reported engagement with the intervention, and physicians' prior training. A natural game exposure-dose is the number of physicians, encountered by the patient, who had played the game by the time they cared for the patient. The game-exposure measure will replace the hospital-level indicator of game intervention status as the key predictor in these analyses. In analyses in which a single physician is attributed to the patient, the indicator of whether or not that physician has played the game will become the primary predictor of interest, although we may still include other exposure variables in order to extract the independent effect of each source of exposure.

The above factors are potential mediators of the effect of the game being employed at a hospital on patient outcomes as they are on the causal pathway of the hospital-level intervention to patient outcomes; if no physicians who indicated their willingness to participate in the study end up playing the game it is difficult to imagine how the game could then impact their patients' outcomes. Likewise, the hypothesis that a patient who encounters multiple physicians who played the game will have outcomes that are more pronounced than a patient who encountered

only a single physician or even no physicians who played the game a priori appears to be plausible.

In a potential extended analysis, we will adapt statistical methods for incorporating the sensitivity and specificity of the measurement of the occurrence of an ACP conversation, which is informed by the agreement between chart-review and insurance-claim (or MiPS) measurement, into the analysis. The resulting analysis can be viewed as a calibration analysis that combines the standard cluster-randomized stepped-wedge design with a bivariate outcome (a more expensive measurement in the form of chart-review and a less expensive measurement in the form of insurance-claim or MiPS) in order to evaluate the impact of the deployment of the game at a hospital on chart-based measurement of ACP occurrence. The statistical model entwining the outcomes will allow the missing values of chart-based measurement for those observations where charts are not reviewed to be learned from observations for which multiple forms of ACP measurement are made and automatically allow for uncertainty in the missing values of chart-review measurements to permeate through the analysis. A Bayesian statistical model and Bayesian computational methods may provide the least burdensome pathway to successfully implementing this analysis.

Power calculation

We arrived at our sample size using a combination of feasibility (cost) and assumptions regarding effect size, absent any pilot data about the latter. For each step, we plan to recruit between 25 to 30 physicians from each of 4 to 8 hospitals. Assuming a baseline ACP rate of 22% (rising by 1.5 percentage-points per-quarter), a hospital intra-class correlation (ICC) coefficient of 0.01-0.10, and 160 evaluable patients per physician-quarter, we can detect a 3.5 percentage-point difference between ACP practices before and after the distribution of the intervention using a two-sided test at the 0.05-level with power in excess of 99%, even under the most conservative sample-size assumptions. If we invert the problem to find the smallest

effect-size at which our study has 80% power, we find that in the most conservative scenario (76,800 total patients) we can detect a 1.5 percentage-point difference and in the most optimistic scenario (192,000 total patients), we can detect a 1 percentage-point increase.

The method of computing power for this stepped-wedge design follows the commonly used strategy for cluster randomized trials of first determining the design-effect, which can be thought of as a measure of the inefficiency of the given design in comparison to a completely randomized design that is expressed in terms of a ratio of the sample-sizes needed to obtain equally precise estimates, and then applying conventional power calculations. The latter computes power for a two-population comparison using the effective-sample-sizes determined from the design-effect. We estimate the design-effect using the expression in Woertman et al (2013), that was clarified and illustrated in Hemming (2016). Because hospitals may induce correlations in the outcomes of patients who receive care from them, we perform illustrative power calculations that account for the net impact of clustering at the hospital-level. Based on our own prior research and published results of others, we decided that the ICC of hospital is highly likely to be in the range 0.01 to 0.10. The design-effects across the optimistic and pessimistic scenarios ranged between 2.88 and 3.14, implying that for all considered scenarios the stepped-wedge design is about 33% as efficient as a patient-level completely randomized design. The effective sample-sizes (ESS) per group ranged from 30,603 to 12,388 patients per group over the study period (the 5 steps and a baseline period).

The second part of the calculation is to determine the power of a two-group comparison of a binary outcome in the absence of clustering when the total sample-size per group equals the above values for the ESS. Because the sample-sizes are still reasonably large, an asymptotic normal approximation is well justified, especially at a baseline ACP rate of 22%. Because we generally err on the side of making conservative estimates about the level of information available (e.g., we may extend the baseline period in which can retrospectively

acquire data to 3-months), Therefore, this approximate two-step calculation yields trustworthy estimates of power that, if anything, are expected to err on the side of being conservative.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym *Page 1*
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry *Page 14*
	2b	All items from the World Health Organization Trial Registration Data Set *Available at clinicaltrials.gov*
Protocol version	3	Date and version identifier *Page 1*
Funding	4	Sources and types of financial, material, and other support *Page 18-19*
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors *Page 19*
	5b	Name and contact information for the trial sponsor *N/A - no trial sponsor*
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities *Page 18-19 - description of funders' responsibilities only (no trial sponsor)*
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) *Page 14*
Introduction		

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention. *Page 4-5*
	6b	Explanation for choice of comparators *Page 4*
Objectives	7	Specific objectives or hypotheses *Page 5 and Table 2*
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) *Page 6*
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained. *Page 6*
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists). *Page 6*
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered. *Page 7-9 and Appendix*
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease). *Page 14*
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) *Page 7*
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial *Page 7*

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended *Page 12 and Table 1*
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) *Figure 1*
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations *Page 13-14 and Appendix*
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size *Page 7*

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions *Page 6*
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned *Page 6*
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions *Page 6*
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how *Page 6*

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial *Not applicable - we will mask assignment during data analysis, but will not blind participants (and therefore have not addressed a process for circumstances under which unblinding is permissible).*
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol *Page 8-11*
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols *Page 7, 14*
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol *Page 14*
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol *Page 12, 13, Appendix*
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) *Appendix*
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) *Appendix*
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed *Page 14*

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial *Page 14*
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct *Page 14*
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor *Page 14*

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval *Page 14*
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) *Page 14*
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) *Page 19*
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable *N/A - no additional consent provisions planned.*
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial *Page 14*
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site *Page 19*
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators *Page 19*

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation. *Not applicable - based on experience with use of the intervention in other contexts, no adverse consequences are anticipated and therefore no provision has been made for compensation or post-trial care for participants.*
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions *Page 15*
	31b	Authorship eligibility guidelines and any intended use of professional writers *Page 19*
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code *Page 19*
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates *N/A - we have received a waiver of written consent from the Institutional Review Board.*
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable *N/A - no biological specimens will be collected during the trial.*

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.