The Role of the Researcher
in Making Serious Games for Health

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ABSTRACT

There has been increasing focus on serious games for health, however, there is very little evidence for the effectiveness of these games and the existing research often lacks scientific rigor. The aim of this chapter is to demystify the process of collaborating with researchers and outline how a researcher can contribute to making more effective games and start the process of evaluating it scientifically. Researchers should be engaged BEFORE serious games for health are developed in order to place serious games for health in the best position to have a measurable impact on health outcomes. The chapter covers issues of working with researchers to agree on problems to address, applying behavioral and learning theories to solve them, and finding optimal research designs to validate the serious game. Issues of safety and ethics in health research are also given considerable attention.

INTRODUCTION

There has been an exponential growth and interest in the area of serious games for health. This has resulted in a striking increase in the number of conferences, funding opportunities, research journals and articles specifically focused on serious games for health. Despite this, we still do not have adequate knowledge about the efficacy of games to improve health (De Freitas & Oliver, 2006; Kato, 2010; Peng & Liu, 2009). A handful of scientifically rigorous studies have been conducted and they have shown that patients who play the games under study show increased health-related knowledge, greater self-efficacy to engage in health-related behaviors, and improved adherence to medical recommendations and regimes. These cognitive and behavioral changes have been shown to be related to actual health outcomes. Research on serious games to train medical professionals have shown improvements in skills in emergency situations and there is even a suggestion that playing video games improves fine motor skills related to surgical operations among physicians (see Kato, 2010 for a review). While the findings are promising, there are far more games for health that HAVE NOT been evaluated scientifically than those that have. The guidelines described in this paper are an attempt to close this gap by providing knowledge about how to develop more effective games and how to conduct research on them.

In this chapter, we will discuss some barriers to pursuing validation research on serious games for health, describe some guidelines for engaging researchers in serious-game-for-health projects, and present a possible structure for engaging a researcher to evaluate the efficacy of a serious game for health to have an impact on health and well-

being. This chapter has a bias to present the approach that a psychologist would take, focusing on the evaluation of cognitions and behaviors because that is their specialty. The approach is basic enough so that researchers and specialists in other disciplines such as communication scientists, anthropologists, and medical educators will find similarities. This approach should not be taken as a prescriptive approach because individual serious-game-for-health projects will differ widely in their scope, resources and goals. It should however provide some guidance to people interested in making serious games for health who may not have experience working with researchers. Finally, the focus of this chapter is on the importance of collaborating with researchers in order to validate the efficacy of a serious game for health to impact outcomes.

BACKGROUND

Validation research on a serious game for health is an attempt to evaluate whether or not the game intervention is able to have a measurable impact on an outcome. With a serious game for health, this outcome is assumed to be related to health. It is not about how satisfied the user is with the serious game for health, how much fun he or she has playing it, or whether or not the person understands how to use the game software and navigate it successfully. This type of research is usually considered to be usability research. Validation research is also not about how many copies of the game are distributed or bought although this certainly plays a part in how much of an impact the game can have on outcomes. Game usability and sales may have play a role in the ability of a serious game for health to impact health outcomes, but they do not represent validation research as we are using it here.

Addressing the current research gap regarding the efficacy of serious games for health would benefit a number of key stakeholders. Researchers who conduct sound research studies on the efficacy of serious games for health will be providing a significant contribution to the field of serious games and also health interventions. Game developers who are involved in the process of developing games that will be scientifically validated will develop unique expertise and knowledge about how to develop a game that "works" and thereby benefit from the interest and enthusiasm that their games garner. Funding agencies and investors will benefit from research on the efficacy of serious games because the knowledge will enhance their ability to make more informed decisions about where to focus their resources for the greatest financial and societal returns on their investment. Medical educators will be interested in serious games for health that have been shown to be efficacious in helping them reach their educational and training goals. Medical professionals who practice evidence-based medicine will appreciate scientifically valid research on tools that can uniquely address the problems they are trying to solve with their patients. These professionals will prefer to "prescribe" or recommend serious games for health that have been scientifically evaluated for their efficacy. Ultimately, patients will benefit from the research because it will help them be informed consumers of serious games for health.

The time is now to start doing excellent research on what our serious games for health can do. The current wave of interest and investment in serious games for health will inevitably wane if there is only scant evidence for the value of serious games for health to ultimately improve health outcomes. We may be missing a big opportunity if indeed serious games have a significant effect on well-being and health outcomes that

heretofore have been difficult to address with existing tools and technologies. We may also be missing opportunities to focus on approaches and outcomes that serious games for health are particularly adept at addressing and avoiding those that they appear not to address well. If we are truly interested in improving health outcomes, our research should point us in the direction we should take to improve health outcomes effectively and efficiently whether it be with serious games for health or not.

Why some people may not pursue research

Tension between technology and research.

Serious games in general are often based on technologies that have a limited lifespan. Operating systems are replaced by new ones and hardware becomes outdated and obsolete over time. Conducting research on serious games for health can be particularly time consuming if the target group of patients is relatively small or if the health outcome needs to be tracked over a long period of time to show the effects of the serious game for health. The length of time it takes to do research is particularly problematic if it is critical to do an evaluation of a serious game for health before making it available to the targeted users. There is a risk that the technology and hardware used on the game will become outdated during this time. Even if the research can be conducted relatively quickly, it may take one or more years before the research is eventually published. The technology may be "old" by the time the world knows that your serious game for health is actually highly effective at improving health outcomes!

Insufficient resources to do an intervention.

Research on serious games for health may also not be carried out because the resources to do them are inadequate. Some evaluations can be very costly and time consuming depending on the problem that needs to be addressed and the power of the serious game to address it. Because the game development process itself can also be costly and time consuming, many people would prefer to simply see if their game will be accepted and used without having to conduct a costly and time consuming research study as well.

Conflict of interest.

A person has a conflict of interest if they are in a situation where financial or personal considerations have the potential to compromise their professional judgment or bias their objectivity (American Association of Universities Task Force on Research Accountability, 2001). This can take a variety of forms but a situation likely to occur with serious games for health is when the researcher is paid as a contractor by a commercial, for-profit organization that intends to make a profit related to sales or other activities related to the success of the serious game for health.

The medical community is actually quite frequently faced with conflict of interest issues because of their frequent involvement in medical device and drug trials sponsored by pharmaceutical companies. Meta-analyses and literature review studies have shown that investigators of biomedical treatments and devices who report a conflict of interest are significantly more likely to evaluate those treatments and devices favorably (Bekelman, Li, & Gross, 2003; Wang, McCoy, Murad, & Montori, 2010). Although it is premature to evaluate issues of conflict of interest with serious games for health given the

paucity of studies, a review of the efficacy of computerized clinical decision support

systems, a health care software application, showed that when the makers of the software

were also authors of the study, the programs were significantly more likely to be rated

positively than if none of authors of the study were involved in the making of the

software (Garg et al., 2005). Researchers should be prepared to be aware of these issues

and address them when dealing with serious games for health in the domain of health

care.

A scientific researcher's job is to objectively evaluate whether or not a serious

game for health has an impact on an outcome. They are obliged to report what outcomes

the serious game for health impacts and also the outcomes the serious game for health

does not impact. They are also obliged to report any findings that may indicate that the

serious game for health is related to adverse outcomes among users. Researchers who

partner with industry may feel a conflict between their obligations as a scientist to be

objective and their obligations to their industry partner as a consultant to help their

product be successful. Conflicts of interest issues are even more concerning if a

researcher has ownership or is a stakeholder of a company that stands to benefit

financially if the serious game for health is successful. The concern in these situations is

that the researcher him/herself may be tempted to suppress or falsify findings as they

attempt to fulfill two potentially conflicting roles of being a scientist pursuing objectivity

and a business person pursuing financial gain.

A conflict of interest exists because of the situation one is in and does not

necessarily mean that science or professionalism has been or will be compromised. The

key in situations of conflicts of interest is open disclosure (Friedman, 2002). A researcher

who has a conflict of interest can still be involved in the evaluation of research but the conflict of interest must be openly disclosed so that others can consider the possibility that some of the findings my be biased. These types of relationships must be disclosed to ethics review boards, during conference presentations and also to journals to which research on the serious game for health will be submitted. Objectivity is the essence of scientific inquiry and open disclosure is a first step in allowing others to evaluate the extent or potential for scientific or professional compromise. As early as possible, the team working on a serious game for health can decide for themselves how they can avoid conflicts of interest. For example, a researcher can be involved in guiding the development of a serious game for health to be effective and an evaluation of the outcomes can be conducted by researchers completely independent of the university where the serious-game-for-health research was conducted and the industry organization that sponsored the development of the game. The researcher can also be involved in the evaluation but arrange responsibilities so that data collection, analysis and interpretation are handled by a party without a conflict of interest.

For more on conflicts of interest in research, the Columbia Center for New Media Teaching & Learning (CCNMTL) in collaboration with the Columbia University Office for Responsible Conduct of Research has an excellent free online course on the subject (Vasgird, 2004). (Note: In the interest of open disclosure, I have no financial ties with the Columbia Center for New Media Teaching and Learning nor do I stand to benefit financially from making this suggestion to you.) It is important to investigate conflict of interest issues at the start of projects because the presence of such conflicts can have a negative impact on the eventual publication of research results and even professional

standing in the scientific community and in the public eye if they are not handled appropriately.

Lack of knowledge.

It may be the case that one has the resources, time and willingness to do a research evaluation but the team lacks knowledge on how to conduct one. The aim of this chapter is to help the reader learn more about how to conduct research on a serious game. As will be discussed in the next section, an evaluation of a serious game for health should be led by someone who is experienced in doing evaluations and has expertise in the problem that will be addressed in the game. Practical guidelines should serve as a basic start for researchers who may be working on developing content or evaluating the software performance of serious games but have never been involved in evaluation of a serious game for health to impact outcomes.

The content of this chapter is based in part on research findings but also on my own personal experiences making serious games and doing research on them. The information presented is based not only on what I have done that has led to success, but also what I have learned from my own mistakes and failures. There is a focus on what a research can do BEFORE the game is released because it is my belief that the researcher's role during this phase is the most important but often overlooked and misunderstood. The particular knowledge provided in this chapter is not often shared or documented in one place.

The Solution

  Before the game is designed.

  Engage research experts. Even though actual research on the efficacy of a serious game for health will happen after the game is complete, the time to prepare for doing research on your game should begin BEFORE you start designing your game. If you DO NOT engage a researcher at the beginning of the project, you may fail to find an effect of your serious game for health simply because you may have chosen to focus on a problem that is very difficult to measure. For example, you may have chosen to develop a game to reduce symptoms of depression among young people with cancer, a very worthwhile endeavor. If you do an evaluation of your serious game for health, you may find that your evaluation of its impact on depression is minimal. You may find to your surprise that the rate of depression and severity of depression among your research sample of young patients with cancer was not very high in the first place. While this may be a surprise you, if you had engaged a researcher before you started designing your game, they would hopefully have done their homework by investigating past studies documenting the rates of depression among young people with cancer and the severity of the problem. Their background research would have led them to find that while depression as a reaction to having cancer as a young person is an issue that deserves to be addressed, most well-designed studies comparing depression rates and severity between children with cancer and their healthy counterparts find no differences in rates or severity with only rare exceptions (Bennett, 1994; Massie, 2004). Some researchers have been able to explain this finding through the patient's use of repression as a coping style (Canning, Canning, & Boyce, 1992). Even given this, a researcher involved at the beginning of a project

would likely recommend that the serious game for health 1) focus more on other more widespread and severe problems that young children with cancer face or 2) target another group of patients with cancer that show higher and more severe rates of depression which are more easily detected and influenced through a serious game for health. For example, these groups might be survivors of childhood cancer or older adults coping with a diagnosis of terminal cancer.

Research may also fail to validate your serious game for health if you fail to engage a researcher at the beginning of your project because you may have designed and developed your serious game for health with behavior change approaches or pedagogical styles that are not driven by theories that have empirical support. It is common for non-specialists to take an intuitive approach to interventions. For example, many people assume that scare tactics and information about the detrimental consequences of a behavior will deter that behavior. One may aim to scare smokers into stopping that behavior with pictures of a black lung or information about what it is like to for patient to have lung cancer. These tactics are not consistently effective (Witte & Allen, 2000) and may have unintended consequences of increasing anxiety among target groups (Hastings, Stead, & Webb, 2004). Clearly a researcher could help the design and development team navigate the complexities of delivering an effective intervention based on a knowledge of the existing literature on the topic. We will address this issue in more detail later in the chapter when we describe what a researcher would do during game design and development.

Finally, and perhaps most importantly, if you wait until your game is finished to find a researcher to scientifically evaluate it, you may find that very few qualified

researchers are interested in conducting the study. They may not be interested because the

approach used in the serious game for health to solving the problem they are expert in

may not be compatible with their current research focus or direction. It may also be that

the approach in the serious game for health is outdated and not cutting-edge in terms of

most recent research in the field. While serious games as a medium may be innovative

tools to improve health, the training and education techniques implemented in the game

should be cutting-edge as well. Even though evaluation is a research activity, most

researchers want to be involved in researching the problem and coming up with

hypotheses about how to solve the problem. If you hand a researcher a completed game

to evaluate, you are asking them to test out someone else's hypotheses in which they may

or may not have expertise. Perhaps more commonly, most researchers are trained to be

objective scientists. If you make your game and then ask a researcher to evaluate it, they

may get the overt or implicit message that you are hiring them because you want the

game to work. They may feel that this places undue pressure on them to relinquish their

objectivity as scientists to please a customer. As discussed previously, this places them in

a situation where there is a conflict of interest. This combined with the above stated

reasons make this approach less than attractive for most researchers.

The remaining guidelines that appear in this chapter will be based on the

assumption that a researcher is involved during the development of the game and this

same researcher will conduct the research on it.

Agree on the problem to solve.

There are many different problems that a serious game for health could be

designed to solve. A game can be designed to help elderly stroke patients rehabilitate and

regain motor control (Burke et al., 2009), to promote exercise among children (Daley, 2009), to increase pain tolerance and reduce disruptive pain related behaviors during painful medical procedures (Hoffman et al., 2008), to improve the rates at which young people with a serious chronic illness take their medication as instructed (Kato, Cole, Bradlyn, & Pollock, 2008), or to train medical first responders in applying a specific procedure in stressful situations (van der Spek, Wouters, & van Oostendorp, 2011).

An ideal evaluation of an intervention specifies one primary endpoint from the start (Hanson, 2008). Teams should agree on the problem they want to solve through the game. It may be necessary to evaluate multiple endpoints in an evaluative study. Recommendations are available in the literature for how to deal with this situation (Turk et al., 2008).

It is a good idea to be VERY SPECIFIC about the problem you want to solve in making a serious game. First, this focus will help you make a more effective intervention. The more problems you try to solve in one intervention, the less focus you will have to do a good job in solving any of them. Sometimes you have to sacrifice some worthwhile goals in pursuing your target goal. For example, if you want to help improve patient adherence to medication and increase their physical activity level, you may need to give up focusing on increasing physical activity if increased medication adherence is related to restrictions on mobility. Most effective interventions have very targeted goals that focus their resources on solving a really big problem that is very specific. For example, if you want to make a game to cure world hunger, your team will have a harder time deciding on game mechanics, the target audience, the local language of your game, marketing strategy, distribution channels, etc. than if you say you want to develop a serious game to

reduce Vitamin A deficiency among pre-school age children in Nepal. By agreeing on a

common goal, diverse teams of researchers, developers and even business people can

more effectively work together in the complex process of making a serious game.

Second, this specificity will help you focus your evaluation efforts on doing a

good job of measuring specific outcomes in many ways rather than measuring many

outcomes in limited ways. Focused prevention efforts tend to be more successful (Gunter,

Kenny, & Vick, 2006) and a focused approach is recommended as an approach for

serious game development (Tate, Haritatos, & Cole, 2009).

The problem that you agree on should also be of sufficient scope and magnitude

that your serious game has a chance of making a measurable impact on it. In doing

research on which problems to solve, your researcher should be looking in the existing

literature to see which specific problems related to your target group or issue are large

enough so that even a small to medium improvement in the problem can be detected

statistically. Your researcher should also be thinking about doing some power estimates

to see how many people may need to ultimately be included in a research trial in order to

detect these changes (Cohen, 1992a, 1992b). Finally, the researcher will evaluate whether

or not it will be feasible to recruit the target number of participants in the trial needed to

conduct the trial on that problem and cycle through this process again if the answer is

"no."

Agree on a theory or theories of how to solve it.

A characteristic of successful prevention programs is that they are theory driven

(Nation et al., 2003). The theories chosen for the serious game intervention may be

grounded in the causes of the problem to be addressed, whether they are factors that

increase the risk or severity of the problem or protect against it (Kumpfer, 1997). Your

researcher should be working on finding appropriate theories to guide game approaches

to addressing the problem you intend to solve. The specific goal chosen for your game

and the theory or theories used to guide the design of the game should be associated with

a game type that your team agrees (based on empirical work or intuition) will be the most

successful for putting the theories into practice and reaching the agreed upon goals. This

should be done as a collaborative effort between the research and production teams.

Games are often highly complex, because they will not only have to include the

instruction pertaining to possible learning goals, but players have to spatially navigate

virtual characters through a world that is most likely new to them, with an input device

that is new as well, therefore it is best not to lose yourself in multiplayer or elaborate

virtual worlds unless it is absolutely necessary (Wouters, van der Spek, & van

Oostendorp, 2009).

Your researcher should also be working with the team to familiarize them with

how the theory works. Researchers are used to sharing information through research

articles, so do not be surprised if your researcher hands you a few articles to read and

abide by in your work. But please be impressed if your researcher sits down with your

team and talks with them about the theory and how it might be implemented in the game.

Be further impressed if your researcher fields questions and queries from the

development team on an ongoing basis and is willing to be flexible in order to see the

theory realized and implemented in the game. You should also be incredibly pleased if

you have a team that is willing to think about these research theories and how to

implement them in the game. The art of collaborating to make a serious game is very

difficult to successfully manage and will be continually negotiated through most of the project. Begin by agreeing that your team will find solutions to disagreements and misunderstandings without giving up.

Find candidate measures.

The researcher should make sure you are be able to measure what you want to achieve with your game. No measure is perfect. How much do you weigh? You can measure someone's weight through self-report. But given that some people may be hesitant to tell you exactly how much they weigh or may not weigh themselves on a regular basis or at the same time each day, it would be helpful to gather this information from one or more other measures. As an observer, you could also make a subjective estimate of how much a person weighs. Again, do we really want to trust that? We might then ask the subject to stand on a bathroom scale or even a medical scale. There is measurement error on any scale. Reliability between scales may differ so that the weight that one scale shows might be a pound or two different from another scale. There are also validity issues in using your bathroom scale to assess weight. If you weigh a lot for your height and fall into the obese range on the body mass index (BMI), are you REALLY obese? Many athletes with high muscle mass are categorized as obese on the BMI even though the percentage of fat on their body is low. The ideal measurement of an outcome is multimodal and ideally includes objective measurements in addition to self-report (Adams, Soumerai, Lomas, & Ross-Degnan, 1999). It is thus ideal to measure obesity by evaluating self-reports of height and weight along with direct measures of those indices as well as waist circumference, and body fat percentage (Gelber et al., 2008; Gorber, Tremblay, Moher, & Gorber, 2007; Seidell & Flegal, 1997).

Provide a structure for reaching research goals.

In order to help create a mutual understanding of the processes towards goals that would ideally be incorporated into a serious game for health, researchers should provide a preliminary set of rules and guidelines for the development team. If the serious-game-for-health project is innovative, the team should expect the rules and guidelines to be updated on a regular basis during the development of the serious game for health. These rules should be negotiated and agreed upon in collaboration with other members of the serious-game-for-health team.

Some general rules and guidelines that the researcher may create in collaboration with the serious-game-for-health team will most likely reflect the answers to these basic questions:

1. Who is our target audience?

It will be very important to explicitly describe the target players of the game in terms of their demographics (e.g., age, sex, ethnicity, race, income, education, job type). For any game intervention, it is often helpful to make clear whether or not the game will be aimed to please avid gamers or tailored to try to engage as many non-gamers as possible. This is particularly important if a commercial development team is involved in the project since commercial games are often targeted to the high standards of avid gamers. Games designed to engage people who normally do not play games or may even be very hesitant about playing games will often require different design approaches to maximize interest and engagement. For serious games for health that address patient groups, it will also be important to specify disease status (specific diagnosis, on- or off-treatment, etc.). The process of specifying the target audience should also include a

description of individuals who ARE NOT in the target audience. For example, many

teams go through a process of deciding whether or not they want to exclude the general

public as part of the target audience for their game.

2. What is the primary research goal of the game?

Even though the serious game for health may have many effects, it is wise in

terms of doing research to focus efforts on one single outcome. As mentioned before, the

researcher should have investigated which problem to solve in terms of how common it

is, how much room there is for an intervention to have a measurable impact on it, and

how well the impact can be measured and interpreted. The more the primary research

goal can be specified, the better. For example, if one wants to develop a serious game for

health to improve physical fitness outcomes, one can specify that the game must aim to

improve physical fitness outcomes among the target population by demonstrating at least

a 60% improvement in aerobic capacity.

3. How can we go about reaching those goals through gameplay?

The answer to this question will be based on the theory or approach that the

researcher and the team have agreed on to solve the problem. Researchers should be

aware of their own cultural bias as researchers to assume that if they hand papers or other

written materials to other people, that they will read, understand it, and carry it out in

their work on the game. That is what happens in the research world. It is not a common

practice in the world of creative media, especially video games. Researchers who practice

this will hopefully quickly learn that this is an inefficient and culturally insensitive

approach to propagating learning in a diverse group. In fact, if researchers truly believe in

the premise that visual and interactive contexts promote learning, they will put down their

research articles and written summaries and stop lecturing to their teammates and turn to

a more visual and interactive process with their technical and creative teammates. At a

very basic level, this means having an ongoing back-and-forth discussion of practical

gameplay mechanics and how they could embody basic tenets of the target theory being

carried out and tested in the serious game for health. This back and forth process

acknowledges current thinking in instructional design in digital game based learning

(Hirumi, Appelman, Rieber, & Van Eck, 2010).

      Game team members should also be aware of their own cultural bias to assume

that if they are making a game, especially if it is a fantasy game and a major goal is that it

is entertaining and fun, that they can sit in a room and come up with the game based on

their own creative genius and that the concept and design phase of the project can be

relatively quick. The design phase of the serious game project will be much longer than

what they are used to. It may also feel very frustrating as a result because it will involve

intense interactions with the researcher (hopefully) over time to resolve issues of

blending fun and entertainment with serious goals.

      Start thinking about the research design.

      As mentioned in the introduction, good scientific evidence provides the basis of

decision-making. At least, it should be the basis. Unfortunately the field is filled with

poorly designed research studies from which it is virtually impossible to conclude what

causal effect a serious game had on outcomes (O'Neil, Wainess, & Baker, 2005). There is

great value in conducting qualitative research, non-experimental designs, case studies,

etc. They play an important role in understanding many aspects of an intervention under

study (Audrey, 2011). They cannot however compete with the value of conducting a

randomized-controlled trial when it comes to determining the causal effect your game has on outcomes. While randomized trials are not perfect, they are the gold standard for evidence-based medicine (Jaillon, 2007).

Randomized trials are designed to reduce bias. In a randomized controlled trial, participants will be randomly assigned to an experimental group where they play your game or to a control group where they either engage in treatment as usual with or without a control game. Because participants will be randomly assigned, we can be assured that people who really wanted to game to work didn't somehow put certain people who could benefit the most from the game in the treatment group and all of the people who could never be helped by your game in the control group. Randomization helps remove bias about who goes to what group and it also equals out any differences that may exist between groups. For example, if a certain percentage of your sample has some kind of characteristic like color blindness that may be an artifact indicating that your game does not work, randomization makes it equally likely that people with color blindness would be in the experimental or control condition.

Because randomized trials are so good at removing bias from evaluations, they are key to determining a causal link between playing your game and the outcomes observed in the study. This is why clinicians and policymakers rely heavily on the results from clinical trials when choosing and recommending treatments for patients. This is also why anybody who wants to evaluate the efficacy of their serious game for health should strive to conduct a randomized trial on it.

The reality of conducting randomized trials is that despite their theoretical elegance, in a practical sense, they can be very costly and time consuming to conduct. If

you are working with a skilled researcher, they should have investigated what other types

of research designs might be more practical with an awareness of the pros and cons of

pursuing other more feasible research designs. For example, if your serious game

represents a type of treatment for a mental health issue, your researcher should be

familiar with the Chambless criteria for identifying effective psychological treatments for

specific populations (Chambless et al., 1998). There are also alternatives to randomized

controlled trials (RCTs) if your serious game for health is part of a public health

information (Bonell et al., 2011). If your serious game represents a treatment that a

physician might recommend to a patient, your researcher should be familiar with the

general criteria that physicians use in practicing evidence-based medicine (Gray, 1996).

During game design and development

Engage the target group.

As has been emphasized previously (Tate, Haritatos, & Cole, 2009), it is very

important to involve your target group during the process of making your game. Even if

everybody on the team once was an adolescent, if you are making a game targeted at

adolescents, individuals who are currently adolescents should be providing feedback and

input on your game. This is not only good for product development but it will also help

increase the likelihood that your game is acceptable and credible as a game and as an

intervention for your target group.

Consider issues of safety.

We want to know what our games do and do not do. What we also might want to

know is if the serious games we develop are harmful in any way. This may be a particular

issue for serious games for health. The general public has a tendency to think of video games in general and not differentiate among the diversity of games. There has been a particular focus in the media on violence in video games. Because the public may make similar implicit assumptions about negative consequences of serious games, serious-game-for-health teams should consider these concerns and scientific studies on serious games for health should track and address these concerns.

There is also a concern in the general public about video game addiction. There does seem to be evidence that a subgroup of people who play games and may have a predisposition to addictions, show signs of excessive gameplay that interferes with positive functioning in other aspects of their lives (Gorber, et al., 2007). As a responsible researcher or person delivering a form of training or educational tool, a good evaluation of your tool should allow for measures that might detect addictive use of the game or any other possible negative side effects related to the use of the serious game for health so that this can be reported and addressed appropriately.

It is a requirement of any randomized trial that is supported by government (e.g., National Institutes of Health) funding in the US that it has a Data and Safety Monitoring Board (DSMB) in place. These boards monitor the progress and scientific quality of research trials while they are being conducted. They also monitor the safety of the people participating in the trial to ensure that they are not being harmed as a result of participating in the research trial. DSMBs are a standard fixture in medical trials and as serious games encroach on this area as therapeutic tools, there will be a strict focus on the quality and safety of games for health even if the interventions are behavioral in nature

(Czaja, et al., 2006). Researchers should consult with their own specific guidelines for the need to set up a DSMB for their particular research study and if so, how to go about it.

Before the Game is Completed

Finalize design issues and research protocol.

Consider first doing a dosing study to make sure that you are giving enough of the intervention to have the desired effect. A characteristic of prevention programs that are effective is that the programs are provided in doses that are adequate for most people to show a benefit (Nation, et al., 2003). Professionals in health care are well aware that providing patients with the appropriate dose of a drug is critical to drug safety, efficacy and even cost effectiveness. Typically it is virtually unheard of for a "dosing" study to be done in the field of education, much less serious games. Who has ever asked the question, "How many weeks does the average person need to attend a class in order to have a working knowledge of the subject under study?" Typically, courses are designed without an evaluation of the maximum tolerable "dose" of a course of study nor an investigation of which "dose" of a course provides the maximum effectiveness (and safety) in the most efficient way.

Dosing studies for your serious game for health are particularly helpful as part of the process of planning to do a scientifically rigorous outcome study on the effects of the game. Research protocols will require participants to "play" the game for a certain amount of time and evaluate changes observed over time and ideally compared to a control group. If participants are not playing your game long enough, or at an inadequate dosing level, your study may show that your serious game for health is ineffective when in fact, it was only ineffective at that dosing level. If participants are playing your game

over and above the level of maximum effectiveness, one may be wasting precious

resources relating to time to complete the study. In addition, safety issues may also arise

if the game dose required in a study is too high. Players may become fatigued or even

feel psychologically frustrated if the requirements surpass their ability to meet them due

to time or ability constraints. Thus, information on proper dosing of serious games for

health will be helpful in conducting outcomes evaluations that are efficient and avoid

false negatives. Dosing information is also helpful so that one can provide information

about the "safety" of your game.

The onus on serious games to provide information on the dosing or recommended

time to play or content to focus on is higher than it is for traditional educational

approaches. As a practical matter, it will also be important to inform teachers and other

people who might be responsible for delivering your game to users about how much of

game could be played by a user. In general, a teacher can estimate how much a student

can be asked to read outside of class using pages of text as a proxy measure. However,

serious games for health will be diverse in their levels of replayability and game time. It

will be important for teachers to be provided with information about how much they

should be asking their students to play the game. This information should be balanced

with the amount of time needed for students or patients to play the game in order to see

targeted learning or behavioral outcomes intended through the use of your serious game

for health.

Submit for ethics approval.

Before you start your research study, your responsible research partner will have

investigated the necessity for ethics approval for your study. There are differing rules and

regulations for ethics approval between different universities and countries. The

Declaration of Helsinki provides guidelines for research in health care internationally

(World Medical Association, 2002 revision). The Council for International Organizations

of Medical Sciences created more specific ethical guidelines to address issues of

conducting medical research in developing countries (Council for International

Organizations of Medical Sciences [CIOMS], 2002). More specific guidelines are also set

forth by individual countries such as the Belmont Report in the United States (National

Commission for the Protection of Human Subjects of Biomedical and Behavioral

Research, 1978) and often individual institutions and professional societies set forth their

own code of ethics. It is very helpful to be familiar with these guidelines and understand

the intent of their directives. It helps make the process of applying for ethics approval

more meaningful rather than a seemingly petty administrative task. It will also help you

anticipate and address any concerns raised by the committees about your work.

   The intent of these boards is to make sure that research participants are treated

with respect, beneficence and justice (Department of Health, 1979). This means that they

are particularly interested in making sure that vulnerable populations (children,

incarcerated individuals, and patients) are protected and therefore treated with respect in

your research studies. They also review your research project to make sure that

participants are not harmed and that any harm that occurs is dealt with appropriately.

They also look at the short- and long-term benefits that may result from the research

keeping in mind any risks that may also arise in the conduct of the study or investigation.

Finally, they look for a sense of justice or equality. In research this often means that they

want to make sure for example that your sample is representative of the people who will

benefit and if certain subgroups will not be represented, that there are compelling reasons for this situation.

Research on serious games for health may need to address some relatively unique ethical issues. For example, many game engines, the software programs that underlie functioning games, automatically collect player data. Because an advantage of serious games is that they can be tailored to the users, some programs may collect personal and health related data that could be accessibly by those not directly involved with the project. This poses risks for violating the research participants' confidentiality as a result of playing the serious game for health and being a part of a study (Petrovic & Brand, 2009). For example, could someone access their data of a player of your HIV-related serious game for health and discover personal information, health-related or otherwise, thereby violating their privacy and possibly even leading to discrimination against that individual on a personal or even institutional level? Issues of privacy and confidentiality of player data, especially if the data is health-related, should be anticipated during the serious-game-for-health design process (encrypting data, protecting files, leaving out this function entirely, etc.) so that they can easily be addressed for the ethics board as well as in the future when the game is distributed. Many countries have very strict rules and regulations about how health information is stored and transferred. The United States implemented the Health Insurance Portability and Accountability Act in 1996. The act is intended to protect the health insurance status of individuals who change or lose their jobs and it has a particular focus on protecting the privacy and confidentiality of health information of individuals. The act was in large part a response to the growing amount of health data that were available electronically so they could be easily and quickly

transferred compared to paper medical records and office files. This information was

often not secured adequately and was getting into the hands of insurance companies and

was used in a discriminatory way. The act provided guidelines as well as legal sanctions

and criminal penalties for those who do not comply with the laws set forth in the act

(Health Insurance Portability and Accountability Act of 1996, 1996). An ethics board will

thus work hard to make sure that any individual's private and confidential data that are

captured electronically (and otherwise) in your game and as part of your research study

are secured. It is furthermore the responsibility of makers of serious games for health to

be aware of the implications of collecting personal health information through serious

games for health and research studies according to local and national laws.

On the practical side, the overall serious-game-for-health project plan should

consider issues of timing in gaining ethics review for a particular study. The review

process can be as short as a few weeks and can be months long depending on an

institution's internal processes and the number of revisions they may require of

applicants. Thus, if one would like to assess the impact of a serious game for health on

outcomes as soon as the product is finished, it will be wise to have the research planned

and submitted for ethics review well before the release date of the serious game for

health. By talking with other researchers at that institution and even directly calling the

Ethics Board, you can get a good idea of how long the ethics approval process will take

from submission to approval. As a general rule of thumb, it is always a good idea to

submit your application for ethics approval early so that it is approved a couple for

months before the actual anticipated start of the study. Because ethics approval is needed

well before the actual start of the study, serious-games-for-health teams who are working

with a researcher from the start of their project should be in a good position to see timely

start of their research evaluation efforts once the serious game for health is ready for

evaluation.

As an aside, it is worth noting that a commitment to address issues of player

privacy and confidentiality not only promotes the ethical treatment of research

participants but it also can potentially help the researcher collect higher quality data.

People who perceive that their personal information is not confidential or private are

likely to either not participate at all in research studies, to falsify the data they provide, or

fail to provide certain data (Anderson & Agarwal, 2011). Protecting privacy and

confidentiality of data that may be collected by the serious game for health also has

implications for its acceptance among users. Patients who feel they can trust the

technologies to protect their privacy and confidentiality are more likely to use it and rate

their satisfaction with it more highly (Iachello & Hong, 2007). Similarly, medical doctors

are more open to adopting new technologies if they feel they adequately address their

own concerns about the privacy of patient data (Ludwick & Doucette, 2009). Thus,

addressing issues of ethics has broad implications for success of a high quality serious

game for health endeavor.

After the Game is Finished

Once the game is finished, you have hopefully carefully planned your study and

obtained ethics approval in order to carry it out and engaged a Data Safety and

Monitoring Board to oversee it if applicable. Your study is conducted with minimal

problems and you have analyzed your data and submitted it for publication. If you did

you planning and homework well, your study provides you with a nice picture of what

your game has a measurable impact on and also other factors your game failed to effect. You have submitted your research to an appropriate journal and they have finally published the results. If they are interesting results the media might be hungry to focus on your story. In the end, through planning, hard work, and collaboration, you have closed the loop and contributed knowledge to this growing field of serious games for health and you are seeing the benefits of your hard work.

FUTURE RESEARCH DIRECTIONS

This chapter has provided a template for engaging researchers early on in the process of making serious games for health in order to develop more effective games and prepare the way for high quality research to be conducted on them. There are some limitations to the approach and assumptions presented in this chapter. The approach proposed is merely one that is based on my training and experience. Serious games for health are diverse in their technologies, game genres employed, target audiences, and health goals. Thus, many other approaches are possible. Future research should try to document and qualify a wide variety of approaches to making successful and unsuccessful serious games for health.

In addition, the approach presented in this chapter is obviously biased towards presenting the researcher's perspective. Future investigations should also document the perspective of the developers, business people, artists, quality assurance managers and others in making serious games for health, especially their view on collaborations with researchers and specialists in other disciplines.

CONCLUSION

In this chapter I discuss the need for more high quality research on the impact of serious games for health on actual health outcomes. I then present some reasons why this research is not being conducted. A lack of knowledge about research is suggested as one of the reasons and the remainder of the chapter focuses on addressing this problem. The solution presented includes advice on when to engage a researcher in the project and a description of what the researcher with the serious-game-for-health team would do before the game is designed, during game design and development, and before the game is completed. A brief description of the actual research activities that would take place after the game is complete and ready for evaluation is presented.

In sum, if we want our serious games for health to be taken seriously by the healthcare field, then we need to create the best possible game and hold those games up to the highest scientific standards of evaluation. Serious research on serious games for health is needed and researchers should play a critical role.

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KEY TERMS AND DEFINITIONS

Evidence-based medicine: the practice of actively seeking out the most recent studies and

summaries of multiple studies over the years to form a scientific basis for making

clinical decisions about the care of individual patients

Efficacy: the ability of an intervention to produce the desired therapeutic effect as

evaluated in the controlled conditions of a research trial

Effectiveness: the ability of an intervention to produce the desired therapeutic effects in

the "real world" given the ability of patients to take it as directed, the ability of

doctors to prescribe it appropriately, the actual cost of the intervention, etc.

Endpoint: drug studies typically focus on improving endpoints such as survival or

symptom improvement. Quality of life is typically not a primary endpoint of a

drug study but most drug studies assess quality of life along with the primary

endpoint to assess whether or not prolonging life or improving symptoms are at the

cost of quality of life. Endpoints targeted in serious games research will typically be more broad to include health-related behaviors and cognitions.

Power estimates: involves balancing information about the magnitude of a problem, how much that problem varies in a population (e.g., around the average score, across time, as a result of interventions), how much of an effect one would like to see an intervention have (e.g., a 20% improvement in symptoms), the level of confidence one would like to have that an intervention works is "true" (typically 95%), and how many people are needed to show that effect at that level of confidence if indeed the intervention "works"

Validation studies: research conducted to determine whether or not the software meets the requirement of its intended use, especially to improve a direct health or health-related outcome when applied to serious games for health

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