STUDY PROTOCOL

Promoting assisted decision-making in acute care settings for care planning purposes: Study protocol [version 1; peer review: 2 approved]

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Abstract

**Background:** The Assisted Decision-Making (ADM) (Capacity) Act 2015 was enacted by Dáil Éireann in December 2015. The purpose of the act, as it applies to healthcare, is to promote the autonomy of persons in relation to their treatment choices, to enable them to be treated according to their will and preferences, and to provide healthcare professionals with important information about persons and their choices in relation to treatment. In practice, those patients with cognitive impairment, particularly dementia, and those with complex needs requiring composite decisions present the greatest challenge to healthcare professionals practicing in accordance with this legislation. Patients with complex needs requiring multifaceted decisions are often over 70 years of age and present in acute hospitals experiencing some form of cognitive impairment.

**Objectives:** The aim of this project is to develop an educational tool which will promote understanding of ADM among healthcare professionals working in acute care settings, and encourage their adoption of this understanding into their care planning with older people.

**Research design:** The study design for this project is mapped out over four consecutive work packages combining a multimethod approach including rapid realist review, qualitative exploration, participatory learning and action sets and intervention trialling and revision. This incremental and context sensitive approach to research design is appropriate for the exploration, development and evaluation of a complex behaviour change intervention.
**Conclusion:** The targeted beneficiaries of this project are healthcare professionals working within acute care settings as well as older people and their family carers who are interacting with the acute care system. The potential impact is improved communication between healthcare professionals and their patients in relation to assisted decision-making and care planning. This educational intervention will be embedded into the pedagogic strategies of the RCPI in their postgraduate education curricula as well as the continuous professional development scheme.

**Keywords**
Assisted decision-making, Community-based participatory research, Personal autonomy, Geriatrics, Professional-Patient relations

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Background and justifications
The Assisted Decision-Making (Capacity) Act 2015 was enacted by Dáil Éireann in December 2015. The Act gives effect to two international conventions: the UN Convention on the Rights of Persons with Disabilities (2006) and the Hague Convention on the International Protection of Adults (2000). It is a major piece of legislation providing reform of the law regarding adults (18+) who require, or who may require assistance in exercising their decision-making capacity. The fundamental principles of the Act state that it shall be presumed that a person has capacity in respect of a decision unless the contrary is shown in accordance with the provisions of the Act for evaluating decision-making capacity (Assisted Decision-Making (Capacity) Act, 2015). These provisions set out an understanding of capacity, which is functional and time-bound. According to the Act, a person’s capacity is to be assessed on the basis of the individual’s ability to understand, at the time that a decision is to be made, the nature and consequences of the decision to be made by him or her, in the context of the available choices at that time. This Act applies to everyone and has relevance for all health and social care services. The purpose of the Act as it applies to healthcare, is to promote the autonomy of persons in relation to their treatment choices, to enable them to be treated according to their will and preferences and to provide healthcare professionals with important information about persons and their choices in relation to treatment.

While the enactment of the Assisted Decision-Making Bill in 2015 is to be celebrated as facilitating Ireland in ratifying the UN Convention on the Rights of Persons with Disabilities, the commencement and implementation of the Act poses challenges to the health sector, and in particular the acute health sector. Codes of practice have yet to be implemented which will facilitate the adoption of the Act within healthcare practice. The Irish Hospice Foundation (2016) notes that there is professional uncertainty as to how to support and integrate assisted decision-making (ADM) into the care of all adults. It is anticipated that those patients with cognitive impairment, particularly dementia, and those with complex needs requiring composite decisions present the greatest challenge to healthcare professionals practicing in accordance with this legislation. Patients with complex needs requiring multifaceted decisions are most likely to present in acute hospitals; approximately 40% of all people aged over 70 years admitted to acute hospitals have dementia and/or delirium (Timmons et al., 2015). Education and training in relation to ADM along with codes of practice which will guide the responses of healthcare staff are necessary to ensure successful implementation of the Act within the acute care setting.

Internationally, the evidence points to a gap of best practice in supporting ADM within health and social care delivery (Dyrdstad et al., 2015; Smebye et al., 2012; Taghizadeh Larsson & Österholm, 2014). Research evidence has highlighted a disparity between physician support for the principles of ADM and the lack of impact this support has on actual clinical decision-making in practice (Bond & Lowton, 2011; Regnard & Louw, 2011). For example, in a study of geriatrician views of advance care decisions (an aspect of ADM), Bond & Lowton (2011) noted a disparity between doctors’ beneficence and patients’ autonomy, particularly where a patient’s decision conflicts with a physician’s understanding of best interests. Research has found that in Ireland assisted patient/client decision-making and the implementation of patient preferences into care plans are hindered by contextual barriers including limited resources, lack of training and education, interpersonal and family dynamics, as well as cultural assumptions and values regarding capacity (Donnelly et al., In Press; O’Donnell et al., 2015).

Older people and their family carers, including those who are living with dementia, are a key demographic relevant to the implementation of the ADM legislation in Irish health and social care services. As in other jurisdictions Ireland’s population is ageing, with the number of people aged 65 and older standing at 19.1% of the overall population (CSO, 2017). Alongside this, the number of people living with dementia is expected to increase exponentially. Based on current population trends, it is predicted that the number of people living with dementia will rise from 55,000, to 94,042 people by 2031 and 152,157 by 2046 (Pierce et al., 2014). People with dementia are also high users of health and social care. For example, one in four acute hospital beds (Timmons et al., 2015) and 37% of all long-stay beds are occupied by someone with dementia (Smyth et al., 2017). Therefore, acute care planning with and for older people provides the focus of this protocol, however the project outputs will have applicability across the spectrum of the health and social care system.

Implementing any intervention in healthcare is complex and challenging. Complex interventions, such as assisted decision-making, operate across diverse health and social settings, professional boundaries and levels of care delivery. Multiple sources of contingency and a wide variety of confounding factors influence implementation such as organisational structures, culture, policy, economics, and individual and organisational behaviours (Damschroder et al., 2009; May, 2013). The realities are that even the strongest evidence can be mitigated by the conditions of the healthcare context (Rycroft-Malone et al., 2012). Research indicates that better implementation efforts are achieved when behavioural and contextual challenges are identified and supported using effective mechanisms of behaviour change (Grimshaw et al., 2012; Michie et al., 2011). Professional behavioural barriers to implementing new clinical guideline practices have been attributed to lack of knowledge and self-efficacy manifesting in behavioural resistance in performing new practices. The value of education and training interventions is emphasised as a key strategy to address these challenges (Fischer et al., 2016).

A review by Ricciardi & De Paolis (2014) concluded that healthcare staff who participated in serious games had better skill retention in comparison to staff who engaged in traditional learning processes. PlayDecide is a versatile open access serious game that has been proven to have good application to
potentially provocative, sensitive or controversial issues (Ward et al., 2017). The game initiates dialogue between healthcare professionals and patients in an informal safe environment. It is within this context that we designed the ‘Promoting Assisted Decision-Making within Acute Care Settings’ (PADMACs) project. This project is funded by the Irish Health Research Board Applied Partnership Awards (APA). The APA scheme supports applied research projects bringing academic researchers and knowledge users together to ensure that research findings have a direct impact on practice. The PADMACs project team brings together researchers and knowledge users from UCD School of Nursing, Midwifery and Health Systems, The Royal College of Physicians Ireland (RCPI), St Vincent’s University Hospital (SVUH) and The Mater Misericordiae Hospital (MMUH), as well as public and patient representative organisations Family Carers Ireland and the Alzheimer’s Society of Ireland. The engagement of RCPI as the knowledge lead, as well as hospital staff and clinical leaders as further knowledge users, will enable the development of highly relevant PlayDecide game which will have an immediate impact on knowledge user organisations.

Overall study aims and objectives
The aim of this project is to develop an educational tool which will promote understanding of ADM among healthcare professionals working in acute care settings, and encourage their adoption of this understanding into their care planning with older people. The project team will develop an open access serious game (based on PlayDecide methodology) via a participatory learning and action research method.

This project aim will be realised through five distinct objectives aligned to four consecutive work packages:

1. Undertake a rapid realist review of international literature and practice identifying and appraising mechanisms which enable healthcare professionals to engage and assist their patients in treatment decision-making during acute care planning.

2. Ascertain the practices and processes of interdisciplinary healthcare professionals within the Mater Misericordiae University Hospital (MMUH) and St Vincent’s University Hospital (SVUH) regarding treatment decision-making and care planning for older patients

3. Investigate patient and family caregiver perspectives on assisted decision-making and care planning

4. Develop (through a participatory learning and action framework approach) a prototype serious education game using the PlayDecide methodology

5. Scope the initial prototype game through trialling among health and social care professionals with public/patient involvement within the partner hospital sites with a view to developing an implementation process model.

Study design
The study design for this project is mapped out over four consecutive work packages combining a multimethod approach including rapid realist review, qualitative exploration, participatory learning and action sets, and intervention trialling and revision. Developmentally, the project can be located in the exploratory or modelling stages of complex intervention development and evaluation (Craig et al., 2008). Arguably, the design of a behaviour change intervention aimed at promoting ADM within acute care settings can be viewed as a context bound ‘complex intervention’.

Theory-based interventions are critical to the effective design of behaviour change programmes (Craig et al., 2008; Grimshaw et al., 2012; Michie et al., 2014). The Behaviour Change Wheel (BCW) is a synthesis model of several behavioural change theories, and has made significant contribution to the field of Implementation Science and behaviour change intervention design. The inner core of the BCW maps a concept of Behaviour (B) into three interdependent component elements: Capability (C), Opportunity (O) and Motivation (M). This COM-B model acknowledges that to instigate behaviour change requires individuals or groups to have sufficient capability (physical and psychological) alongside opportunity (social and physical) and motivation (reflective and automatic). The COM-B behavioural analysis guides the choice of intervention functions to those most likely to achieve desired behavioural change. The taxonomy of Behavioural Change Techniques (BCTTv1) provides for a more granular detailed intervention design on the underlying mechanisms and ‘active ingredients’ which can support behaviour change. The framework strengths include: its multidisciplinary origin lending itself to a broad frame to evaluate behavioural change that is particularly valuable for interventions related to implementing evidence into practice (Michie et al., 2005). The COM-B, BCW and BCTTv1 will provide an evidence informed design framework for the PlayDecide intervention resulting from this project.

The PADMACS study will identify mechanisms which enable healthcare professionals to adopt ADM behaviour and engage their patients in treatment decision-making during acute care planning through a rapid realist review of international literature (WP1). Current practice with regard to care planning for older people will be captured through exploratory qualitative analysis, with multi-disciplinary healthcare professionals from two acute hospitals, as well as family carers and older people with recent experience of acute care (WP2). The nuanced data collected from both the rapid realist review as well as the qualitative exploratory stages of this research will inform the next phase of the project design; participatory learning and action workshops (WP 3) and the development of a prototype PlayDecide game. The final phase (WP 4) of the game will involve a series of iterative trials in order to adapt the prototype emerging from the workshops and refine it to develop an implementation process model for transferability.
to the knowledge user organization (RCPI). Figure 1 illustrates the key elements of each work package and demonstrates the work flow in the study design.

Work package one: Identifying the mechanisms which encourage healthcare staff to adopt ADM in their practice within the acute setting

For those working within an applied clinical setting, a rapid realist review (RRR) is an approach that enables the unpacking of the complexities of contexts and interrelated mechanisms underlying implementation activities (Khangura et al., 2014; Lavis et al., 2012; Rycroft-Malone et al., 2012). The benefits of engaging diverse stakeholders in the co-production of the literature review process include increased clarity and awareness of the transferability of the review findings (Saul et al., 2013). Whilst a full realist review engages in a much longer exploration of the literature and a period of ‘testing’, the RRR, assists in a speedier transition from research to practice (Shé et al., 2018). RRRs are best suited during the initial phase of a multiphase project to enable the findings to be rapidly adapted for the
next stage. The basic question of a RRR is ‘what is it about this intervention that works in this context and why?’

This RRR will identify and appraise mechanisms which enable healthcare professionals to engage and assist their patients in treatment decision-making during acute care planning. There is a growing recognition in the literature that interventions are implemented through a process of transforming mechanisms which speak to the deliberative and autonomic behaviour of the relevant personnel or collectives (Lacouture et al., 2015). However, these mechanisms are often not recognized in the reporting literature, except in reference to general barriers and facilitators to implementation (May et al., 2016; Wilson et al., 2017). While the focus of this RRR will be on mechanisms, the realist elements of context and resources will be pertinent in as far as they interplay with the operationalizing of mechanisms. Context in this study refers to the commencement of the recent ADM legislation in Ireland as well as the particular complexities of acute care planning for older patients. Resources are also relevant as they interplay with the reasoning of healthcare professionals as to what is possible as well as desirable in their care planning practice. This RRR seeks to identify and appraise initiatives which encourage behavioural change among healthcare professionals in relation to the engagement and assistance of patients in care decision-making. These initiatives will include those which target cognitive reasoning as well as more autonomic responses reflecting emotion based reactions and the dynamic behavioural interplay between systems factors.

The methodology adopted for this RRR will be informed by Ní Shé and colleagues (2018) and will take as its starting point the establishment of expert and reference panels. Data will be extracted over 8–10 weeks, and weekly data sessions will be held to critically appraise, analyse and synthesise the data. The search for evidence is iterative and will be progressively extended and refocused based on the identified sources as the review evolves. Following agreement of the expert/reference panels the RRR will identify mechanisms (individual or collective) that were observed across different interventions leading to successful implementation. The results of the synthesis will be written up according to the ‘Realist and Meta-Review Evidence Synthesis: Evolving Standards’ (RAMESES) standard for reporting realist reviews (Wong et al., 2013). A modified version of the template for Intervention Description and Replication (TIDieR) checklist will be used for data extraction (Cotterill et al., 2018).

Work package two: Exploring experiences and perceptions of ADM in acute settings and scoping existing practices and processes

The overall aim of this work package is to ascertain key stakeholder experiences of existing practices and processes relating to ADM. This aim will be realized through exploration of the experiences of healthcare professionals (component 1) as well as representatives of patients and family carers (component 2) using an exploratory qualitative methodology. A combination of semi-structured individual interviews and focus groups will be used to collect the qualitative data in this work package. The semi-structured interviews will focus on individual experience and perception of ADM in the acute care of older people. The focus group discussions will be held either within disciplines (component 1) or among representatives of patients and their family carers (component 2). The purpose of these focus groups is to ascertain the cultural and value contexts which influence ADM. Case studies and debates sourced from the Essex Autonomy Project as well as a podcast from a BBC Radio 4 documentary series ‘Inside the Ethics Committee’ will be used in these focus group sessions to generate debate and discussion on the complex issues associated with ADM, patient autonomy and care planning.

The first component of this work package will focus on two sites, SVUH and MMUH, and will be undertaken in the day hospital as well as the geriatric wards. These settings have been selected as they are likely to produce decision scenarios with a certain degree of complexity while circumventing palliative and emergency decision scenarios. We propose to collect data via semi-structured interview from a total of 8 physicians (2 physicians per setting and site) as well as undertaking a focus group interview with multidisciplinary staff (n=20) within each of the four settings.

The second component of this work package will be to explore the experiences and perceptions of ADM, influencing clinical decision-making and care planning among representatives of patients and family carers. The project sub-team responsible for delivering this component will include members from the collaborator public/patient representative organisations who will assist in participant recruitment and participation. Two focus groups will be held, one with representatives of older patients and one with representatives of family carers of older people. Furthermore 10 semi-structured qualitative interviews will be undertaken with patients and family carers recruited via a combination of purposive and snowball sampling. A key aspect of this component will be to explore patient experiences of journeying through acute care in order to identify key decision-making points along these pathways and ascertain opportunities for ADM.

The topic guides and themes to be addressed within these interviews will be developed following completion of the RRR (WW1) and in consultation with the project team members with experience of acute care planning with/for older people in the relevant healthcare settings (component 1). Similarly, the project team members with experience of representing family carers and patients living with dementia will be consulted in the development of the interview material for component 2 of this work package.

All interviews and focus groups will be audio recorded (with consent) and transcribed. The data collected and analysed for this research will be anonymised and stored securely under password protection. It will be held for a period of five years after the completion of the project. At such time it will be destroyed. The Data Protection Act 1998 and the Data Protection (Amendment) Act 2003 will be adhered to at all times in order to protect the data and confidentiality of participants for this
research. Data will be analysed by the project sub-teams using thematic framework analysis (Ritchie & Lewis, 2003). The rapid realist review findings will provide an initial structure for the framework applied to the interview data (based on its programme theory for assisted decisions -linking WP1 and WP2). Data will be coded in line with this framework and sub-codes iteratively developed as part of the constant comparative coding process (i.e. comparing coding within and between respondent types and data sources (individual interviews/focus groups). As part of the familiarisation process with the collected data, two independent analysts will read interview transcripts and further refine the thematic coding framework on the basis of the inductive process of data analysis. ‘Deviant cases’ describes experiences or reports that demonstrate a degree of inconsistency with the patterns emerging in the dataset. In order to understand these cases or situations better, we will examine these scenarios carefully and report them separately in relation to the framework. Data analysis will be facilitated by using software package NVivo N10.

Work package three: Co-production of PlayDecide game using a participatory action and learning strategy

The purpose of the third work-package is to design the PlayDecide game. This will involve the establishment of interdisciplinary workshops which will follow a participatory and learning action (PLA) research method (Reason & Bradbury, 2008). PLA is a practical, adaptive research strategy that enables diverse groups and individuals to learn, work and act together in a co-operative manner, to focus on issues of joint concern, identify challenges and generate positive responses in a collaborative and democratic manner (de Brún et al., 2016). The workshops will be composed of representatives from the health and social work professionals allied to the care of older people in acute settings as well as public and patient representatives. Three workshops will be run in each of the hospital sites (MMUH and SVUH). There will be a maximum of 10 participants in each session and these will be drawn from across the relevant healthcare disciplines with at least two representatives from the medical profession and two representatives of patients and family carers in each workshop.

The development of the PlayDecide intervention resulting from the PLA process will be guided by behavioural change theory specifically the COM –B Model of Behaviour, Behavioural Change Wheel (BCW) and Behavioural Change Techniques (BCTS) (Michie et al., 2014). The PlayDecide game design will follow the eight step method outlined by the BCW developers (Michie et al., 2014). Behavioural diagnosis will identify what the intended intervention functions will be and this in turn will guide the selection of the game content. PLA workshop participants, trained in BCW, will be guided to synthesis and interpret the findings from the realist review (WP1) as well as the qualitative data (WP2) in order to identify key content to be included in the information, issue and story sections of the PlayDecide Game. The content of the game will be carefully designed to ensure behaviour change techniques are incorporated as these are considered the ‘active ingredients’ and critical mechanisms that create the conditions for behaviour change. This structured approach to the intervention design will facilitate implementation, evaluation and replication.

Through their engagement in the PLA process the workshop participants will have acquired an appreciation of the values and principles underpinning the Assisted Decision-making Act (2015) as well as the nuances and complexities involved in contextualizing these principles within concrete case stories based on practice experience. They will become familiar with the legislation and any guidance documents or codes of practice issuing from the HSE. They will discuss examples of international best practice in relation to implementation of ADM in acute care settings and they will be immersed in the nuanced and complex data issuing from the qualitative phase of the project. As such, these workshop participants, sourced from each of the study hospital sites as well as from public and patient representation, will be identified as ADM champions poised to facilitate the implementation of ADM mechanisms within their own practice settings, thereby influencing the practice of their peers. The project champions will be integral to instigating a meaningful and sustained shift in the culture and values which inform acute practice in relation to ADM.

Work package four: Trialling and scoping of the game with iterative adaptation towards an implementation process model

The purpose of the final work package is trialling of the PlayDecide game within the two partner hospital sites (MMUH and SVUH) among interdisciplinary groups including public and patient involvement. A minimum of 5 sessions in each of the sites will be held and the project team have secured access to the hospital libraries as venues for the game playing sessions. Recruitment of game players will be facilitated by co-applicants and collaborators for the project who are clinical staff as well as the public patient representative organisations. A maximum of 8 players will be recruited for each game session and these will include a minimum of two medical staff and two public patient representatives. The game sessions will be facilitated by a member of the project sub-theme responsible for this work package.

The focus of the trialling phase will be to evaluate the validity and integrity of the PlayDecide game, ensuring it is appropriate for the acute care setting and for the RCPI postgraduate training programmes of medical professionals. The sessions will be rolled out on an iterative basis whereby adaptation to the game, based on ongoing evaluation, will be made after each session. The content will be recorded in one session and the data will be analysed to ensure it is sufficiently rich to stimulate dialogue and to undertake a behavioural diagnosis. Formative evaluation will be conducted with the participants and any adjustments required will be completed. After final editorial work on the game it will be published on the PlayDecide database under a creative commons license in order to facilitate its potential transferability to other acute care settings and patient population groups.
Ethical approval and consent

The research team has extensive experience in conducting research to a high ethical standard, and team members will ensure that ethical guidelines will be adhered to. The research team are currently preparing submissions for ethical approval for each phase of this programme of research to the relevant ethics boards including UCD Human Research Ethics Committee as well as the research ethics committees of SVUH and MMUH.

UCD Code of Good Practice in research will guide the research team in ensuring ethical and good practice in relation to obtaining informed consent for study participation and the publication and dissemination of the study results and outputs. The team will ensure that patient care is not compromised at any time due to participation in this study. The strict criteria of ethical review committees in relation to research with potentially vulnerable adults will be adhered to at all times. The research participants may include those with some degree of frailty including mild cognitive or physical impairment. The project team includes consultant geriatricians who have experience of delivering care and working with frail older people. The research team also includes those with extensive experience of conducting research, including co-design and action research, with vulnerable sections of the population including survivors of elder abuse, older people living with dementia and those living with other intellectual and physical disabilities. The team will be guided by best practice, as underpinned by the Assisted Decision-making Act (2015) in ensuring that accommodations are made which will maximise the capacity of all potential participants to provide informed consent to participate in the study and to fully engage with the action research activities.

Status of study

The study commenced in December 2017 and the first work package is currently underway including preparation of submissions to the hospital research ethics committees in SVUH and MMUH and UCD. The rationale for the rapid realist review has been agreed by the project team and the expert and reference panels have been appointed. The first meeting of the expert panel is scheduled for early March 2018 in order to agree the programme theory which will decide the initial search strategy for the review of literature.

Public involvement in research

In line with the guidance from Involve UK the involvement of public and patients has been incorporated into this project from the point of funding application and proposal development through to the dissemination of research outputs. Meaningful public and patient involvement in this project will not only ensure the research quality and relevance, but also will ensure the research is informed by broader democratic principles and the values of accountability and transparency which are fundamental to the principles of the Assisted Decision-Making Act (2015). A panel of PPI representatives called the Older People’s Empowerment Network were consulted throughout the period of project proposal development. Furthermore, two public/patient representative organisations; Family Carers Ireland and Alzheimer’s Society Ireland have nominated a staff member to represent their membership as collaborators on this project. Consultation with these collaborators was undertaken in preparation for this grant proposal in order to obtain their input in shaping the research design and strategy; this PPI collaboration will continue throughout the lifetime of the project.

The project team members have experience of facilitating the active involvement of patient/public representatives alongside representatives of health and social care professionals in participatory research projects and in the co-design of healthcare interventions. The recruitment of PPI representatives to the project steering group, to the qualitative data collection (WP2) as well as to the PLA workshops (WP3) will be facilitated by the project PPI collaborators. These third sector advocates will act as gatekeepers and as a link person for PPI members to the study. Each PLA workshop will be co-facilitated by an academic team member with experience of facilitating interdisciplinary workshops as well as by a third sector advocate. This will ensure that each workshop is being chaired by a public/patient advocate who is familiar to the PPI participant. Furthermore, a critical mass of PPI members (N>2) will be recruited for each workshop. Finally, the team propose to offer a capacity development session before the commencement of the PLA workshops in which public/patient representatives will be given the opportunity to meet with each other as well as with the project team in a relaxed, informal setting and to obtain some information about the project.

Dissemination of results

The serious game which results from this project will be embedded into the pedagogic strategies of the RCPI in its physician postgraduate education curricula as well as the continuous professional development scheme. The project will result in multi-disciplinary local champions within the hospital settings who have knowledge and understanding of the legislation and who are prepared to steer its successful implementation into acute care practice. Under a creative commons licence, the project team will facilitate access to the PlayDecide open source materials through a range of websites including UCD research repository and the PlayDecide dissemination platform. The findings from this study will also be disseminated to the research community through publications in international peer-reviewed open access journals and presentations at national and international conferences. Patient advocacy groups and our PPI collaborator organisations, will also disseminate the findings to patients, their families and the public through their websites, patient newsletters and information evenings.

Conclusion

The targeted beneficiaries of this project are healthcare professionals working within acute care settings as well as older people and their family carers who are interacting with the acute care system. The potential impact is improved communication between healthcare professionals and their patients in relation to assisted decision-making (ADM) and care planning. We expect that through involvement in the programme of research that there will be an impact upon the behaviours of the participating healthcare staff in both partner hospital settings (MMUH
and SVUH). In particular, local ADM champions will be identified in each of the hospital sites. Through their engagement in the Participatory Learning and Action (PLA) workshops (WP 3) these champions will develop knowledge of the legislation and ensuing guidelines as well as the complexities and nuances associated with implementing ADM in clinical practice. Following their participation in the project they will be poised facilitate the successful implementation of the provisions of the 2015 Act within their settings and through their influence on their peers will be integral to instilling a meaningful and sustained shift in the culture and values which inform acute care practice in relation to ADM.

We expect that the outputs from this project will impact the behaviour of healthcare professionals in relation to engaging patients in treatment decision-making and healthcare planning. This intervention addresses the cultural and social contexts in which behaviour occurs as well as the individual motivational factors, therefore it is expected it will promote ADM within acute care settings. This is integral to the successful adoption of the provisions of the 2015 Act into healthcare settings. The ultimate beneficiary of this project therefore are the patients and family carers who are communicating their care preferences and decisions to healthcare professionals. They will benefit from interacting with professionals who understand the issues involved, are prepared to have these conversations and are doing so in a supportive and open environment. The study also has implications for the training of physicians and it is intended that this educational intervention will be embedded into the pedagogic strategies of the RCPI in their postgraduate education curricula as well as the continuous professional development scheme. This translation of the research output into practice will be facilitated by the game methodology employed in the project; it does not require a trained facilitator but can be facilitated by any member of the team and it is an open source tool available under a creative commons licence.

Data availability
All data underlying the results are available as part of the article and no additional source data are required

Competing interests
No competing interests were disclosed.

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 Shaun T. O’Keeffe  
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This is a very ambitious and well written project. I have a number of suggestions and comments.

1. As the authors will know, the Act has a number of components including particularly:
   - The underlying principles, including presumption of capacity and time- and decision-specific assessment of capacity
   - The hierarchy of specific interventions
   - Advance healthcare directives

   Is it proposed to cover all of these aspects or just the general principles of assisting decision making?

2. It is increasingly looking as though the actual ‘roll-out’ will not occur until 2019. What is the time frame for all of the work programmes?

3. One problem is that a number of essential components to successful implementation of the Act are currently missing.

   a. The Codes of Practice covering the specific provisions haven’t been written or finalised: it will be almost impossible to provide guidance on how to use these aids to assisted decision making in their absence.
   b. The ‘Deprivation of Liberty safeguards’ are also missing. I suspect that interviews with healthcare professionals in ‘Work package two: Exploring experiences and perceptions of ADM in acute settings and scoping existing practices and processes’ will reveal a big focus on the difficulties regarding place of discharge decisions and ‘residence capacity’.

4. ‘The focus group discussions will be held ... among representatives of patients and their (my emphasis) family carers (component 2)’ suggests that patient-carer dyads will be involved, while later ‘one with representatives of older patients and one with representatives of family carers of older people’ seems more ambiguous.

5. The argument should be made as to why family carers are being recruited? – I appreciate the reality of current decision making but the Act won’t privilege family carers.
6. 'The ultimate beneficiary of this project therefore are the patients and family carers who are communicating their care preferences and decisions to healthcare professionals'. This may be misleading: it is only the preferences and decisions of patients (or of their or a court’s appointees if judged to lack capacity) that count under the Act.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

**Competing Interests:** No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

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Author Response 12 Apr 2018

**Deirdre O’Donnell**, University College Dublin, Dublin, Ireland

The authors wish to thank Dr O’Keeffe for this very thoughtful and considered review of the protocol paper which prompted dynamic team discussions and increased clarity for our vision for the project. Our response to his review comments are as follows:

**Point One**

As the authors will know, the Act has a number of components including particularly:

- The underlying principles, including presumption of capacity and time- and decision-specific assessment of capacity
- The hierarchy of specific interventions
- Advance healthcare directives

Is it proposed to cover all of these aspects or just the general principles of assisting decision making?

Implementation of the principles of assisted decision-making into practice will need to address the interrelated components of knowledge and skills as well as behaviours and attitude. Arguably, knowledge and skills of the principles of ADM can be readily addressed through well scoped codes of practice, clinical guidelines, educational curricula and Continuous Professional Development (CPD). However, knowledge based educational programmes, while vital to the implementation of the legislation, will also need to give careful consideration to the behavioural and attitudinal components which influence how a culturally embedded individual adopts knowledge and skills into their practice. Therefore, the focus of this project is on the attitudes of individuals towards the principles of ADM outlined in the legislation and their existing behaviours in relation to supporting patients to make decisions about their health care. The game players will include healthcare
professionals as well as patients and family. Case stories as well as factual information about ADM from the legislation (including reference to a functional understanding of capacity, the hierarchy of intervention as well as AHCDs) will prompt the players to reflect upon their own values, beliefs and attitudes as well as their existing behaviours.

Point Two
It is increasingly looking as though the actual ‘roll-out’ will not occur until 2019. What is the time frame for all of the work programmes?
This is a two year project beginning in December 2017. It is envisaged the game will be ready for implementation by January 2020.

Point Three
One problem is that a number of essential components to successful implementation of the Act are currently missing.

1. The Codes of Practice covering the specific provisions haven’t been written or finalised: it will be almost impossible to provide guidance on how to use these aids to assisted decision making in their absence.
2. The ‘Deprivation of Liberty safeguards’ are also missing. I suspect that interviews with healthcare professionals in ‘Work package two: Exploring experiences and perceptions of ADM in acute settings and scoping existing practices and processes’ will reveal a big focus on the difficulties regarding place of discharge decisions and ‘residence capacity’.

The project team is liaising with the HSE quality improvement division and the working groups for the development of codes of practice in relation to Advance Healthcare Directives as well ADM guidance and documentation and training and education. The expert panel for the Rapid Realist Review includes HSE staff from the quality improvement division working on these educational aspects of the legislation implementation. It is envisaged that the game which emerges from this project will complement the roll-out of the codes of practice upon commencement of the legislation in 2019/20. It should be noted that a functional understanding of capacity, is already commenced in terms of common law and is embedded within the National Consent Policy (HSE, 2013) and therefore should be already operationalised in healthcare settings. As noted in response to review point one, the focus of this project is less on the specific knowledge required for implementation but more on promoting environmental receptivity for the roll out of codes. The educational target is the attitudes and behaviours of individuals which facilitate the implementation of knowledge and skills. That said, contextual factors which are specific to the implementation of ADM (including the deprivation of liberty provisions to be included in the Act) in acute settings such as difficulties regarding ‘place of discharge’ will doubtless inform the discussions during the game. It is intended that these discussions will in themselves reveal some of the practical constraints and barriers to implementing ADM in practice behaviour. We look forward to the game prompting these important discussions and highlighting these contextual realities as areas for quality improvement in terms of legislation implementation.

Point 4
The focus group discussions will be held ... among representatives of patients and their (my emphasis) family carers (component 2)’ suggests that patient-carer dyads will be involved, while later ‘one with representatives of older patients and one with representatives of family carers of older people’ seems more ambiguous.

Thank you for highlighting this ambiguity in the protocol which will be revised. The intention is to
ascertain the perspectives of patients separate to the perspectives family carers through distinct and separate focus group sessions. We do not intend to include patient/carer dyads. We wish to understand the issues specific to each group which will be captured through within group dynamic discussion and interactions.

Point 5
The argument should be made as to why family carers are being recruited? – I appreciate the reality of current decision making but the Act won’t privilege family carers.

It should be noted, that for the purposes of this project the term ‘family carer’ includes any person (family, friend or neighbour) who provides unpaid care to the relevant person and who a patient may include in their decision-making processes. It is acknowledged that the person-centred focus of the 2015 Act places the ‘relevant individual’ at the heart of the legislation and does not specifically reference family carers. However, as mentioned, the reality of current decision-making in many healthcare settings includes, at the very least, consideration of the dynamics of the relationships around the ‘relevant person’. This reality quite often involves decisions which, in their implementation, are directly dependent upon those relationships. For example the availability and dynamics of family care and/or support are often critical to discharge decisions in acute care settings. Furthermore, the decision support mechanisms outlined in the legislation, specifically the role of decision-making assistants, co-decision makers and decision-making representatives will, in many cases, involve the appointment of a family carer.

As this project aims to target the actual behaviour and attitudes of the game players it is important that the discussions prompted through the game reflect the ‘real world’ complexities in which the legislation will be commenced and all the relevant characters who may be implicated by the legislation. The project team includes healthcare providers working in acute care settings to develop and implement care plans with older people. Furthermore, the expert panel for the rapid realist review includes healthcare providers from across the disciplinary spectrum of geriatric and older person’s care. These team members and consultations have indicated that the quality of family relationships, the nature of family structures as well as the relationship circumstances of the relevant individual/patient are critical every day factors encountered by professionals planning and delivering care to older people in acute care settings. Therefore it will be important that this perspective is included in the development of the content of the game. It will also be critical that family carers are included as game players. This will provide a stimulus to elicit rich dialogue and discussion which will reflect the everyday realities and contexts in which ADM behaviour is conducted and attitudes formed. This in turn, will assist with the identification of the learning needs of professionals and context resource deficits for successful implementation of ADM in acute care settings.

Point 6
“The ultimate beneficiary of this project therefore are the patients and family carers who are communicating their care preferences and decisions to healthcare professionals.”
This may be misleading: it is only the preferences and decisions of patients (or of their or a court’s appointees if judged to lack capacity) that count under the Act.

This is an excellent point very well made. Reference to family carers as an ultimate beneficiary of the project will be removed so that this line will read: ‘the ultimate beneficiaries of the project are the patients who are communicating their care preferences to healthcare professionals.’

Competing Interests: No competing interests were disclosed.
Brendan D. Kelly
Department of Psychiatry, Trinity Centre for Health Sciences, Tallaght Hospital, Trinity College Dublin, Dublin, Ireland

This is an interesting study protocol, looking at promoting assisted decision-making in acute care settings for care planning purposes.

There is not a vast literature on this topic.

Most published papers are theoretical, and there is a real deficit in the literature about how to make this work in practice, especially in busy medical settings where time is a scarce resource.

I have no corrections or changes to suggest to the protocol just to congratulate the authors on their project and their vision with this.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Deirdre O'Donnell, University College Dublin, Dublin, Ireland

Thank you for taking the time to review this study protocol and for your positive feedback. We hope that this study will contribute to developing a body of knowledge on implementing ADM in practice.
**Competing Interests:** No competing interests were disclosed.