SHR072 – Smart Ward Ethical Framework

Safehinge Primera Group

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ETHICAL ASSESSMENT OF THE SMART WARD SYSTEM

Proof of concept and initial testing considerations

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SHR072 – Smart Ward Ethical Framework

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Introduction

Smart Ward is a remote sensoring technology designed to keep people safe in in-patient, residential and secure environments. It locates the position of live bodies in a setting that is being monitored, for instance a service user bedroom. The technology includes zonal sensors that use radar to locate the body in space, coupled with a software application. The application generates alerts to staff when a one or more people is in a given zone for a period of time that suggests a service user may be at risk.

One of the primary uses for Smart Ward is in-patient mental health care. Self-harm is the most common incident in mental health services.[1] The most recent national report[2] records that in-patient deaths by suicide in the UK are occurring at a rate of 4.9 per 10,000 admissions. In 2020 94% of completed suicides that occurred on wards were at low-level. 63% people died in their ward bedroom, 28% in the ensuite bathroom, and the most common ligature points were doors (50%) or windows (9%). According to the most recent national data, 37% of suicides on in-patient wards took place while patients were under a medium or high level of observation.[3]

Smart Ward technology affords the capacity to continuously monitor patients' location within monitored zones with minimal intrusion, preserving their privacy and dignity.

The purpose of this ethical framework is to identify ethical considerations that may arise as this technology is developed at pre-deployment phases[4] for the purpose of monitoring vulnerable people in secure environments.

It incorporates ethical considerations elicited from the following sources:

- The Systems Engineering for Patient Safety (SEIPS) model.[5] This is one of the analytic models informing NHS England's Patient Safety Incident Response Framework.
- Guidance from the UK Government Central Digital and Data Office,[6] Dept for Health and Social Care,[7] the Health Research Authority[8] and Information Commissioners Office.[9]
- The 'Millan Principles' and the 'Wessely principles'. Millan's ten ethical principles underpin the Mental Health (Care and Treatment) (Scotland) Act 2003, while the 'Wessely principles' constitute four foundational ethical principles included in the 2018 final report of the

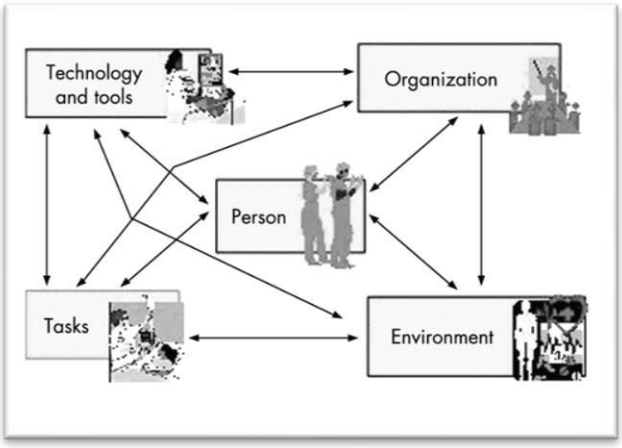
[1] It accounts for 27% of *all* reported patient safety events. However it is not what proportion of these are in in-patient wards. NHS Improvement. NRLS national patient safety incident reports: Commentary, September 2018. UK: NHS Improvement
[2] The National Confidential Inquiry into Suicide and Safety in Mental Health. Annual Report: UK patient and general population data, 2010-2020. 2023. University of Manchester.
[3] Ibid.
[4] As defined by HRA these are initial proof of concept, and then initial testing in the care environment.
[5] Carayon P et al. Work system design for patient safety: the SEIPS model. Qual Saf Health Care. 2006
[6] https://www.gov.uk/government/publications/data-ethics-framework/data-ethics-framework-2020
[7] https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology#introduction
[8] https://www.hra.nhs.uk/planning-and-improving-research/research-planning/how-were-supporting-data-driven-technology/
[9] https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/the-research-provisions/

independent review of the (English) Mental Health Act 1983.[10] Both draw on established principles of medical ethics.[11]

Testing Smart Ward in care environments: the SEIPS model.

The SEIPS model is based in Human Factors and Ergonomics (HFE) scholarship. It structures analysis around five elements in the health care 'work system' as seen in the diagram below. Each of these elements interacts with the others in care processes, leading to the outcomes that patients, their networks, and health care staff experience. SEIPS seeks to understand how people work with technologies and with each other within their particular environment and organisational culture.

This ethical assessment is concerned with 'who should do what to whom' in circumstances of testing Smart Ward with service users in care setting. It is important to note that it is the *interactions* between people, and between people and the other four elements of the SEIPS model, that will ultimately determine the ethical quality of Smart Ward activities. This analysis is therefore informed both by SEIPS and the ethical principles referenced in the introduction.



Section One: Interacting with technology and tools in care settings

1.1 Smart Ward hardware

Smart Ward hardware consists of sensors that use radar technology to indicate the presence or movement of a body in spatial zones. The sensor does not use a camera. It does not capture, nor does it generate, a likeness of the person whose position is being monitored. It can detect where in the room a person is, if a person is on the floor, and when another person enters the room. It can also detect sensor tampering.

[10] The review was chaired by Sir Simon Wessely
[11] https://www.mhtscotland.gov.uk/mhts/files/Millan_Report_New_Directions.pdf

The system also includes an above the bed sensor, providing information about sleeping patterns. In future it is anticipated that vital signs could also be monitored but this capability is not yet included and is not assessed here.

1.2 Smart Ward software

The software application informs staff of where one or more people are located in the spatial zones, and the time that they have been there. It does not include a visual image of any person, only their location.

The application functions to alert staff to risky situations:

a) Excessive time spent in known high risk areas (e.g. bathroom or doorway)[12]
b) A person on the floor (a possible low level strangulation attempt or a fall)
c) Multiple occupancy (risk of abusive behaviour)
d) Sensor tampering (avoidance of monitoring)

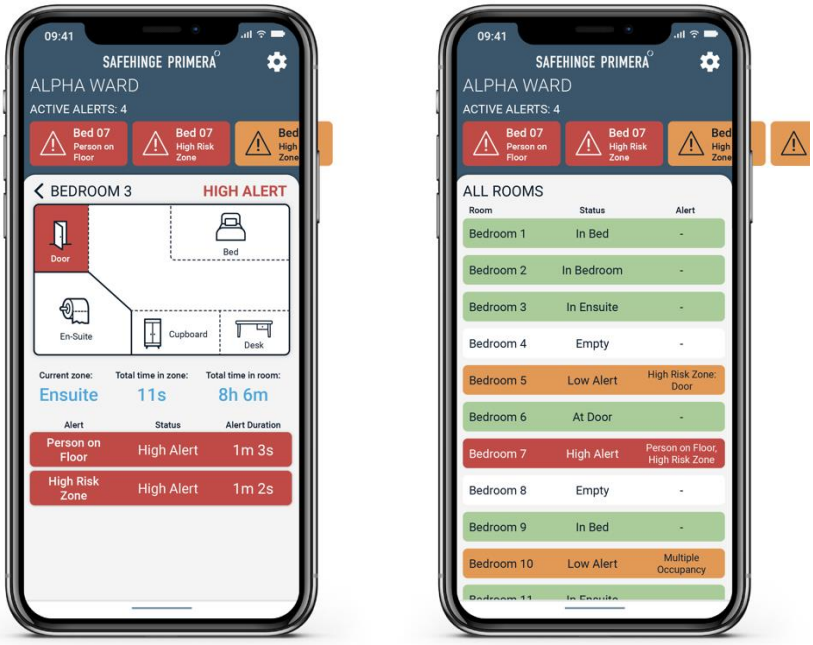
1.2.i What members of the health care team will see

The images below are two examples of the monitoring information as presented on handheld devices. It should be noted that monitoring data and alerts do not provide patient identifiable information. In both these images the information is pseudonymised.[13] Names and identities are not presented by the application, but will be known to staff and are potentially discoverable to third parties from other information.

[12] Data show that patients attempting suicide may spend some time in proximity to the door, which is the most common ligature point

[13] https://www.hra.nhs.uk/planning-and-improving-research/research-planning/how-were-supporting-data-driven-technology/overview-legal-requirements-using-health-and-care-data-development-and-deployment-data-driven-technologies/5-definitions-alphabetical/

SHR072 – Smart Ward Ethical Framework



1.3 Proving the concept

Preventing harm and self-harm is a principal goal in caring for people in crisis. Data indicate that a vulnerable person is at greatest risk of harm or self-harm in a private space, including a bathroom. At the lower levels of face-to-face observation[14] visualisation of the service user is intermittent. Service users are unobserved for periods of 10-15 minutes and unobserved while in the bathroom. As death from strangulation can occur within 5 minutes it has long been recognised that intermittent observation cannot keep patients safe.[15] Even intermittent general observation can feel intrusive, and higher levels of observation involve more severe incursions on privacy and dignity.

A reliable system that can supply more consistent monitoring will potentially support discharge of the public sector's obligations under Art. 2 of the Human Rights Act (the right to life), as well as fundamental health goals. Where a system can do so without undermining therapeutic relationships, and without infringing service users' privacy and confidentiality, it is highly likely to produce more benefit than harm.

Proof of concept testing should therefore be designed to establish both the system's reliability and also its impact on clinical work and outcomes.

1.4 Establishing clinical safety in initial testing

Health information technologies bring substantial benefits but also the risk of technology-induced errors. These can be caused by faulty design or customization of technology, inadequate work

[14] Levels 1&2 in England, in accordance with NICE Guidance, Level 1 in Scotland and Northern Ireland
[15] National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH). In-patient Suicide Under Observation. Manchester: University of Manchester 2015.

process design in response to technological prompts, and unintended disruption of established work processes by new demands.

1.4.i Testing to provide technical assurance.

For service user safety the system must be reliable in practice settings. Proof of concept testing should be consistent with the guidance for developing data-driven technologies set out in the UK Government Data Ethics Framework.[16] This aims to secure transparency, accountability and fairness and is the starting point in DHSC guidance for innovators developing applications for the NHS market.

DHSC Guidance advises that developers consider the following tests for technical assurance:[17]

a) validation testing – that the design of the product serves the intended purpose. This can include end-user testing and acceptance
b) verification testing (functional correctness): checking that the requirements of the product have been appropriately implemented
c) load testing: that it performs reliably under continued stress and load
d) performance: that it maintains responsiveness under various loading conditions
e) regression testing: to prove that the product still performs as expected following a change or update
f) security, for example penetration testing
g) integration testing
h) unit and system testing
i) bias testing/monitoring

1.4.ii Testing to explore clinical work systems & evidence of technology benefit and risk

Validation testing is in part about establishing how a technical system interacts with clinical work systems to produce a range of benefits as well as unintended consequences resulting in risk. The DHSC guidance supplies important information for developers on steps required to evidence clinical safety.[18]

To mitigate alert fatigue, the alerts generated by the application must be relevant to service user need. Alert thresholds (i.e. alerts based on risk calculation) should be calibrated as part of initial testing of the system.

Work processes in response to alerts should be co-designed with the provider. They should specify what action must be taken in response to an alert, by whom (including substitutes) and how this is entered in a service user's record.

[16] https://www.gov.uk/government/publications/data-ethics-framework/data-ethics-framework-2020
[17] https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology#generate-evidence-that-the-product-achieves-clinical-social-economic-or-behavioural-benefits
[18] https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology#clinical-safety

SHR072 – Smart Ward Ethical Framework

Work process design should take into account data indicating that in-patient suicide attempts are more likely to succeed when staff are distracted by other events on the ward, during busy periods (e.g. 7-9am), when there are staff shortages, when shifts are reliant on bank or agency staff, and when ward design impedes direct observation.[19] Testing should also review the impact of alerts on other established work processes to determine any emergent risks (e.g. from disruption during medication administration)

Section Two – Task design and development activities in mental health settings

The SEIPS model prompts consideration of how tasks and activities that are carried out in the work system interact with the other elements including technologies (above) and a range of different people (below). This section sets out ethical considerations relating to testing Smart Ward in a mental health ward work system, and how testing can assess potential benefits.

2.1 Work systems in mental health & testing the ethical effects of Smart Ward.

Independent reviews of mental health law and care in all four UK countries have emphasised the importance of patient autonomy, choice, and participation in decisions about how they are cared for. The Millan review formulated the principle of participation as to "be fully involved, to the extent permitted by their individual capacity, in all aspects of their assessment, care, treatment and support [and] provided with all the information necessary to enable them to participate fully".

This subsection considers aspects of the work system in mental health that could be affected by use of Smart Ward. Evidence for potential benefits and risks in these aspects of the work system should be sought during development.

2.1.i Maintaining safety through supportive observation and engagement.

Observations on in-patient wards are not done solely to prevent harm, but also to engage patients and build therapeutic relationships. Research indicates that patients in crisis on mental health in-patient wards feel safe when they experience connection, protection and sense of control.[20] Non-intrusive remote monitoring of service users who are at risk of harm can offer a sense of protection, but axiomatically not a sense of connection.

Smart Ward is therefore only likely to be of overall benefit to service users when it is implemented alongside appropriate levels of therapeutic observation and engagement. Smart Ward's non-invasive monitoring should therefore be viewed as an adjunct to therapeutic observation, and not as an alternative. Relying upon Smart Ward to replace observations and engagement could jeopardise the benefits that service users receive from empathetic human interaction .

[19] National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH). In-patient Suicide Under Observation. Manchester: University of Manchester 2015.
[20] Berg, S.H., Rørtveit, K. and Aase, K., Suicidal patients' experiences regarding their safety during psychiatric in-patient care: a systematic review of qualitative studies. BMC health services research, 17(1), pp.1-13. 2017.

2.1.ii Providing service users with the least restrictive option.

All relevant national law and guidance emphasises the importance of selecting the least restrictive option for care. Scottish guidance summarises the general principle as "observation should be set at the least restrictive level, for the least amount of time within the least restrictive setting".[21] Zonal monitoring and face to face observation are different actions. However, zonal monitoring is also a form of oversight of a person's movements that requires justification.

For patients who require observation, this system offers continuous monitoring of room occupancy and movement as a supplement to therapeutic observation. The system design means that supplementary monitoring can take place without infringing privacy and dignity in the way that additional direct observation of the person would do.

To support personalised care and patient autonomy, it should be possible to switch off the system in individual rooms when monitoring is assessed as unnecessary. Professional judgment of suicide risk may, however, be that a residual risk will always remain because of the well-established limitations of suicide risk assessment. (In a study of 76 patients who committed suicide while in the hospital or immediately after discharge, 78% denied suicidal ideation when last asked.)[22] Remote non-invasive monitoring in apparently low risk circumstances may be viewed by professionals as the least restrictive option.

2.1.iii Giving information about Smart Ward

NICE Guidance on both violence reduction and patient experience reflects the Millan ethical principle of participation, and emphasises the importance of providing information about care facilities consistent with service users' ability to understand it at the time.[23] Whilst zonal monitoring using Smart Ward is not as intrusive as other ways of maintaining awareness of service users' activity in their rooms, it is nevertheless an aspect of the care and support people will receive.

Service users should therefore be provided with relevant information about Smart Ward at an appropriate time in their admission and their views on this sought in the development phase.

2.1.iv Considering privacy and dignity.

Care settings frequently prioritise harm prevention over the privacy and dignity of patients. There is potential for Smart Ward to enhance service users' feelings of privacy and dignity, and the availability of remote monitoring may support ward teams to feel more confident about avoiding blanket restrictions.

The software supplies information only to ward teams and without generating a likeness of the person. This makes Smart Ward more conducive of privacy than other arrangements for monitoring

[21] Scottish Government Observation of People with Mental Health Problems s3.1.4
https://www.gov.scot/publications/observation-people-mental-health-problems/pages/4/
[22] Busch KA, Fawcett J, Jacobs DG. Clinical correlates of inpatient suicide. J Clin Psychiatry. 2003;64:14-19.
[23] NICE NG10 Violence and aggression s.1.4.15 and NICE CG136 Service user experience in adult mental health
https://www.nice.org.uk/guidance/ng10/chapter/1-Recommendations
https://www.nice.org.uk/guidance/CG136/chapter/1-Guidance#hospital-care

(e.g. CCTV). It is gender neutral, reducing the frequency of male staff observing female patients and vice versa. Intrusion is minimised by data being shared via a smartphone application, unlike CCTV which when used in health facilities may be seen by others outside the health team such as security staff.

2.1.v Considering Smart Ward's contribution to sexual safety.

The system is able to alert staff to the presence of multiple occupants in a room, including staff members. It may thus afford an additional layer of protection against sexual exploitation or abuse on in-patient wards by either patients or staff.

2.1.vi Considering Smart Ward's impact on violence and aggression towards staff.

Observation can be a source of patient distress and agitation, which is sometimes expressed in abusive behaviour towards staff.[24] A system of constant non-invasive monitoring may help to reduce the rate of such incidents.

2.2 Proof of concept testing – developing Smart Ward as a service innovation

It has been argued that health organisations have an ethical obligation to carry out service development projects.[25] Service development activities are excluded from Research Ethics Review under NHS Health Research Authority (HRA) provisions so the responsibility for ethical appraisal sits with the host Trust and professional staff. This relative freedom can enable some limited proof of concept testing, but this would fall short of the robust evidence gathering required to satisfy NHS and MHRA regulatory and procurement processes.[26]

The HRA differentiates service development from research by defining service development as a study that 'seeks to find out what improvement can be achieved within that service only. It may involve a new intervention or service, or one that is new to that context, but there should be no randomisation and the choice of treatment, care or services is that of the care professional and patient/service user…' (The definition of research can be found is below)

2.2.i Ethical governance of service development.

As governance of service development is managed by NHS Trusts' own Research & Development (R&D) offices the approach to ethical appraisal will depend on the organisation's own policies. In general terms however, an ethically sound approach[27] should ensure that:

[24] National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH). In-patient Suicide Under Observation. Manchester: University of Manchester 2015

[25] Dixon, N., Guide to managing ethical issues in quality improvement or clinical audit projects. *London, UK: Healthcare Quality Improvement Partnership*. 2017

[26] See e.g. https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology#clinical-safety

[27] Hunt et al have written a very thorough guide to managing ethical considerations in QI projects in mental health. Hunt, et al, Ethical considerations in quality improvement: key questions and a practical guide. *BMJ open quality*, *10*(3). 2021

a) Service users' self-determination (their autonomy and wish to participate) is respected. They should give a voluntary and informed consent to participating in service development and may withdraw from this at any time.
b) Professionals should have a reasonable belief that the innovation will afford a benefit to existing or future service users that outweighs potential risks.
c) The testing process should not expose service users to unwarranted harm.
d) Where service users may lack capacity to consent to their participation, service development activities should include appropriate safeguards that are equivalent to those required by ethical research.
e) Service users' privacy and confidentiality must be preserved
f) Service development considers the needs of diverse groups and those with protected characteristics. [28]

2.2.ii Data protection

Complex provisions apply to managing service users' data depending upon the nature of the research / testing design, whether it is confidential patient information or other personal data, how it is processed (e.g. pseudonymised, anonymised) and by whom.

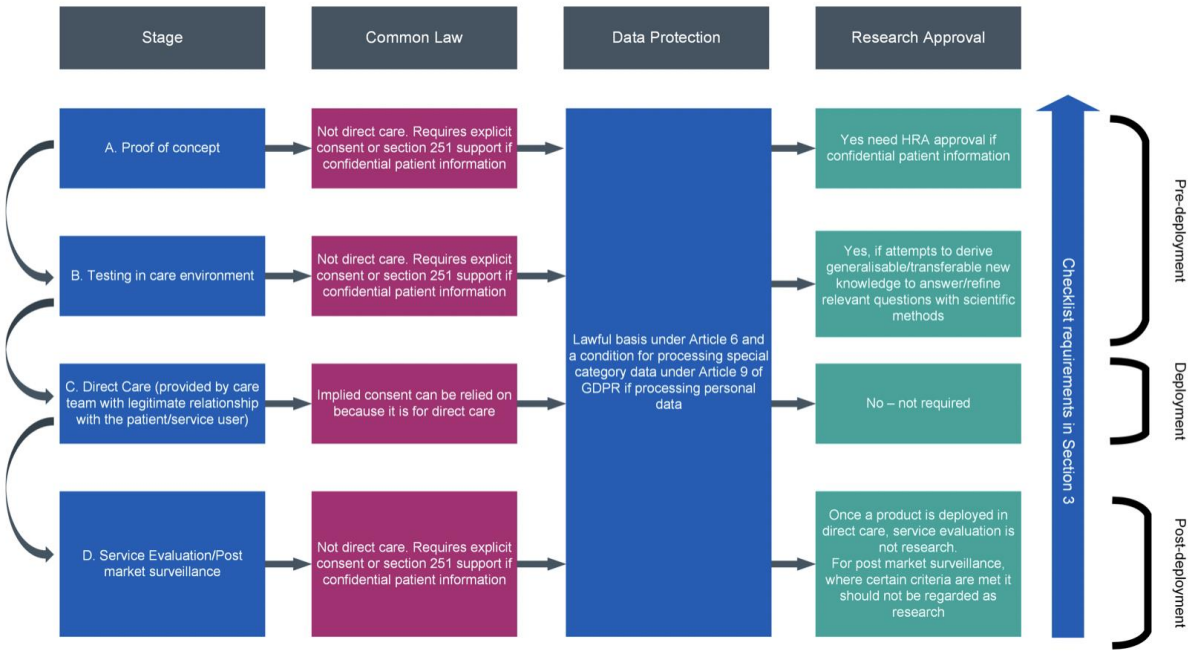
The flow chart below summarises the data protection considerations for both proof-of-concept testing through service innovation (stage A) and more formal research for purposes of full evidence gathering (stage B).[29]

Where proof of concept testing is to be carried out in partnership with providers in a care setting, it should be possible to seek explicit consent from services users for use of their data alongside seeking consent to be involved in the proof-of-concept test. It might also be feasible to have patient data processed by the data controller (i.e. the Trust) to remove identifiers and render it either pseudonymous or anonymous.

It will be necessary to determine whether the proof-of-concept activity falls within the Trust or Safehinge's existing Data Protection Impact Assessments or whether these will require modification.

[28] Dixon, N., Guide to managing ethical issues in quality improvement or clinical audit projects. *London, UK: Healthcare Quality Improvement Partnership*. 2017
[29] https://www.hra.nhs.uk/planning-and-improving-research/research-planning/how-were-supporting-data-driven-technology/overview-legal-requirements-using-health-and-care-data-development-and-deployment-data-driven-technologies/3-development-deployment-and-monitoring-data-driven-technologies/

SHR072 – Smart Ward Ethical Framework



2.3 *Research beyond initial proof of concept*

The Health Research Authority defines research as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods.[30] Inquiry of this nature will be required to address the evidentiary requirements of NHS clinical safety procedures and procurement.

Research involving patients in NHS settings and led from England or Wales[31] requires approval by a Health Research Authority Research Ethics Committee (REC) and compliance with the R&D governance arrangements at each participating NHS site. Once secured, HRA approval can be used support multi-centre cross border studies across all four countries of the UK. This process can be time consuming although HRA RECs aim to respond within 60 calendar days of the receipt of a valid application.

2.3.i HRA Approval and REC review

Application HRA Approval and REC review[32] entails a comprehensive ethical assessment of both the intervention and the study design and a clear strategy for data management. Research ethics derive from two fundamental principles: avoidance of harm and participant consent to participation. These principles are reflected in the principles of good service development outlined above, so compliance with those ethical considerations as the proof-of-concept stage will provide a strong foundation for developing the application for ethical review.

[30] HRA UK policy framework for health and social care research https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
[31] If the research is led from NI or Scotland applications are initiated to the equivalent bodies in those countries.
[32] HRA approval obviates the need to seek R&D consent from each individual provider in multi-site studies

a) Researchers must work from a position of 'equipoise', believing that the benefits of an intervention outweigh any potential harms.
b) Service users with capacity must give informed consent to their participation in research. They may withdraw their consent at any time.
c) Where service users over the age of 16 lack capacity, research must comply with ss.30-33 of the Mental Capacity Act 2005. These clauses apply to research that, if done to people with capacity, would require their consent. The provisions stipulate that the research involving people lacking capacity must be related to the treatment of their condition; must have the potential to benefit them without imposing disproportionate burdens; and may proceed only with consent from a consultee acting in their best interests. They must be withdrawn from research if they object in any way.
d) Service users' privacy and confidentiality must be preserved
e) Research involving adult offenders in a forensic setting is expected to have a particularly robust ethical assessment, as there have been long-standing concerns about whether their participation and consent can be truly voluntary.[33] .
f) Research involving children is discussed below.

Section Three – People considerations

Previous sections have taken adult service users and their interests as the focus for discussion. This section considers three further groups: children, service users' support networks, and staff.

3.1 Children

Children here refers to those who have not yet reached the age of full legal capacity. This is 18 in England and Wales (children over 16 may consent to medical treatment), and 16 in Scotland.[34] Children below this age may consent to care and treatment according to their 'Gillick competence', which rests upon assessment of the child's understanding of what is being proposed. Respecting children's rights and interests entails acknowledging their vulnerability, the unequal power relationship with adults, and their developing competence to make decisions for themselves.

3.1.i Assessing potential benefit, harm and vulnerability

The balance of potential benefits and harms could tip even more strongly towards a net benefit when Smart Ward comes to be used in settings where children are especially vulnerable to harm or self-harm. Children's vulnerabilities supply the underlying rationale for several articles in the UN Convention on the Rights of the Child. Appropriate deployment of Smart Ward's zonal monitoring system could support the state's obligation under Articles 3 (prioritizing the best interests of the child) 6 (right to life), 19 (protection from violence, abuse and neglect), and 34 (protection from sexual exploitation).

[33] Magyar, M.S. et al Examining attitudes about and influences on research participation among forensic psychiatric inpatients. *Behavioral sciences & the law*, *30*(1), pp.69-86. 2012.
[34] Family Law Reform Act 1969 and Age of Legal Capacity (Scotland) Act 1991 s2(4)

3.1.ii Taking into account unequal power, and respecting children's views.

Unequal power between adults and children, and a desire to protect vulnerable children, can lead to paternalistic or authoritarian behaviour in which children are treated as objects of concern and not people in their own right.[35] The manner in which Smart Ward comes to be deployed with children should take into account Article 12 of the UN Convention, respect for the views of the child. This implies that where the child is competent to understand it, information about the system should be given to children when appropriate for their care (as would be the case for adults).

3.1.iii Gauging children's emerging competence to make decisions.

Children's capacity for self-determination rests upon their maturity as well as their mental health status. The principle of 'Gillick competence' in law means children should be assessed for their ability to make decisions about aspects of care for themselves.

a) Where a child is assessed as Gillick competent (in this case, able to understand their need for protection and how Smart Ward works), Smart Ward may be used in their care following the same steps as are appropriate for adults.
b) Where the child is assessed as not Gillick competent to make decision about their care, such decisions are based on their best interests and may be made for them by parents or others with legal responsibility for them. In these cases, it is in the child's interests and best practice to seek the child's assent (agreement) to aspects of their care, but assent is not imperative.
c) For purposes of Smart Ward development or research, steps taken to secure children's involvement should be consistent with principles of research ethics. In the absence of law relating specifically to research with children, it is generally assumed that decisions about children's involvement in research are associated with their 'Gillick competence'. Where they are assessed as competent, they may give their own informed consent. Where they are not competent, parents or others with legal responsibility for them may give consent and the child's assent should be sought.

3.2 Respect for service users' support networks

The Millan principles emphasise the importance of respect for carers. Where appropriate information about Smart Ward should be given to service users' support networks, and their views sought during development. It is proposed that understanding how Smart Ward can help keep service users safe, without infringing on their privacy and dignity, could give those close to the service user greater trust and confidence in their care.

3.3 Assessment of potential benefits/risks for staff

Smart Ward potentially affords several benefits for staff and raises only minimal risks.

[35] This phrase originated in the report of the Cleveland child sexual abuse inquiry in 1988.

3.3.i Reducing violence, aggression and injury to staff.

It has already been noted that Smart Ward may contribute to reductions in violence and aggression where this is associated with frequent observation. Additionally, zonal monitoring has the benefit to staff of being able to locate people in a monitored room in the event of a fight or barricade situation.

3.3.ii Reducing moral distress

Client suicides have a profound effect upon both individuals and multi-disciplinary teams. It is estimated that mental health clinicians will experience between 1 and 4 patients dying by suicide during their professional life and client suicide can be followed by significant attrition in mental health teams. [36] Whilst it is clearly in service users' interests to keep them as safe as possible without undue restrictions, it is equally in the interests of professionals and organisations.

3.3.iii Monitoring ward team activity.

Smart Ward affords the functionality of identifying staff movement in monitored zones, and can provide a record of movement in the monitored areas for audit purposes. Monitoring of staff movement provides an additional safeguard against abuse or sexual exploitation of service users by staff, or inappropriate relationships.

Audit of staff movements or responses to alerts provides for an enhanced level of supervision and oversight. This is of value in managing work settings that may be culturally and socially closed off from much external scrutiny, as is the case with a variety of secure provision. While some staff may be uncomfortable with their activity being subject to greater scrutiny via zonal monitoring, it is less intrusive than body worn cameras and no more intrusive than day to day management oversight in more open environments.

Section Four - Organization

This element of the SEIPS model refers to matters such as teamwork and organizational climate.

4.1 Potential benefits and risks in teamwork

Smart Ward is potentially supportive of interdisciplinary teamwork. The application enables more than one member of a team to be aware of and alerted to patients at risk in monitored zones. This is an important consideration in light of the proportion of in-patient suicides that take place while under observation.[37] Additionally it may facilitate visualisation of handover information.

However, effective teamwork depends on effective task design so the observations made above (section 1.4.ii) on testing for alert validity, and the need to co-produce effective work processes are relevant here.

[36] Gibbons R, et al "Effects of patient suicide on psychiatrists: Survey of experiences and support required". BJPsych 43(5): 236–41. 2019
[37] Ibid.

SHR072 – Smart Ward Ethical Framework

4.2 Smart Ward in the context of ward climate

It was noted above (section 2.1.i) that Smart Ward is potentially protective of suicidal service users when it is used as a supplement to care that offers human connection. Studies indicate that patients' sense of connection with health care professionals arises when they meet someone who seems to care, when they feel understood, and when they feel respected and trusted by being acknowledged as a human being.[38] The need for a sense of connection highlights the importance of ward climate, and that deployment of Smart Ward should not be a substitute for knowledgeable and caring staff nor therapeutic time. Its greatest benefit will accrue from enabling staff to focus on therapeutic engagement as well as physical safety.

Section Five - Physical environment

Ligature is the primary means of death by suicide in in-patient units.[39] This can be exacerbated by poor ward design

5.1 Ligature reduction

Whilst Smart Ward is able to alert staff to risky behaviour, death from strangulation can occur within 5 minutes. Providers should maintain a continuing focus on eliminating ligature potential from the environment, as well as recognising that this is not always possible and may be at variance with providing personalised care.

Smart Ward should be viewed as an adjunct to reduction of ligature opportunity in the physical environment, not an alternative.

[38] Berg, S.H. et al Suicidal patients' experiences regarding their safety during psychiatric in-patient care: a systematic review of qualitative studies. *BMC health services research*, *17*(1), pp.1-13. 2017

[39] The National Confidential Inquiry into Suicide and Safety in Mental Health. Annual Report: UK patient and general population data, 2010-2020. University of Manchester2023.

SHR072 – Smart Ward Ethical Framework

Summary of actions to meet ethical considerations

Element	Actions	See section
Tools and technology		
Smart Ward system	Proof of concept testing should establish both reliability and impact on clinical work processes and outcomes	1.3
Technical assurance	Technical assurance should be consistent with guidance set out in the UK Gov Data Ethics Framework and DHSC Code of Conduct for data driven health and care technology	1.4.i
Interactions with clinical work systems	• Alert thresholds should be calculated to minimise alert fatigue • Work process in response to alerts should be co-designed with the in-patient health provider • Work process design should take into account known associations between in-patient suicide attempts and clinical work systems	1.4.ii
Tasks and activities		
Supportive observation and engagement	Smart Ward should be viewed as an additional safety system not a substitute for therapeutic engagement	2.1.i
Providing least restrictive option	Smart Ward provides a less restrictive option than other forms of monitoring. However, where professional judgement is that monitoring is not justified the system should be deactivated in that area.	2.1.ii
Participation in care decisions	Service users should be given information about Smart Ward when it is in use	2.1.iii
Promoting privacy and dignity	In testing, consider the impact of Smart Ward on service user feelings of privacy and whether it supports avoidance of blanket restrictions	2.1.iv
Promoting sexual safety	In testing, consider multiple occupancy alerts and their impact	2.1.v
Reducing violence and aggression	In testing, consider association between reduction / increase in incidents of violence and aggression towards staff and use of Smart Ward	2.1.vi
Proof of concept testing - service innovation study	• Study design should comply with best practice in service innovation, including service user consent.	2.2.i

SHR072 – Smart Ward Ethical Framework

	• Subject to provider policies, testing in service innovation should be consistent with HRA research requirements.	
Initial use testing – research study	Study design should build on findings from proof-of-concept testing and have HRA approval.	2.3
Data protection	Data processing and storage should comply with GDPR and ICO best practice.	2.2.ii
People		
Children	• Where a child is competent to understand it, they should be given information about the system when appropriate in their care • When testing Smart Ward with children, consent for participation depends upon assessment of their 'Gillick competence'. If Gillick competent they can give consent. If not Gillick competent a parent or person with legal responsibility can give consent. • If another person gives consent on their behalf the child should be invited to assent to participation.	3.1.ii 3.1.iii
Service users' support networks	• Service users' support networks should be given information about Smart Ward as appropriate. • If possible, the support network's views should be sought during testing	3.2
Staff	• Where possible, test studies should gauge the appropriateness of supervisors using Smart Ward to monitor ward team activity	3..3.iii
Organisation		
Teamwork	• Where possible, test studies should assess how interdisciplinary teams work with Smart Ward • Where possible, test studies should examine the use of Smart Ward to support handover.	4.1
Physical environment		
Ligature risk	Providers should continue to reduce ligature points in the environment and not rely on Smart Ward to compensate for removable risks.	5.1