|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ethical Risk Identified | Severity Risk score  (1-5) | Likelihood Risk Score (1-5) | Overall Risk Score  Severity\*Likelihood | Proposed solution(s) |
| Human dignity – access to education.  Uphold the common good - probably?  Students will be denied education material that the government will not otherwise provide. | 3 | 4 | 12 | Allow the Consortium scheme to go ahead but try to have more open source software included. |
| Does it preserve autonomy – no?  Student data used for commercial purposes. | 2 | 5 | 10 | Try and agree restrictions to sign up to programme for students. (‘Right to be forgotten’). |
| Is processing necessary – no?  Exploiting student data. | 2 | 5 | 10 | Try and agree restrictions to sign up to programme for students. (‘Right to be forgotten’). |
|  |  |  |  |  |

Table

Description automatically generated

A screenshot of a computer

Description automatically generated with medium confidence

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ethical/Privacy Risks Identified | Severity Risk score  (1-5) | Likelihood Risk Score (1-5) | Overall Risk Score  Severity\*Likelihood | Proposed solution(s) |
| **Does it preserve or enhance human dignity?**  Early intervention to either an emergency condition, or a more gradual deterioration in health, by Medic Sensors, and the data decisions within the TriCARE/MLHealth system, can improve the longer-term well-being of a patient. It can be argued that this is exactly why patients sign up to TriCARE in the first place – they wish to extend quality of life for themselves, if possible. | 3 | 3 | 9 | The ‘risk’ in this instance is that not joining the Project Predict programme will prevent early detection of serious illness. Therefore once the client has given explicit, written consent to join Project Predict then it is expected that their medical data becomes part of this data ecosystem. |
| **Does it preserve or enhance human dignity?**  The MLHealth ML models offer the potential of faster triage response to patient health issues. However, the models are built on a relatively small survey of data, and one that we believe lacks certain elements of diversity. An automated triage decision must not generate a TriCARE response that is potentially inaccurate, and distressing to a patient. | 4 | 3 | 12 | The DPIA flagged concerns with the spread of diversity in the 500 members of the Project predict sample population.  It is strongly recommended that artificial data ‘profiles’ are added to the modelling data so that triage recommendations are not skewed towards an elderly white male class. |
| **Does it preserve the autonomy of the human?**  Patients are consenting to membership of Project Predict, but they are expecting MLHealth and TriCARE to be responsible custodians of their sensitive medical information. | 5 | 1 | 5 | All MLHealth and TriCARE company directors will be required to make a declaration that the understand their data responsibilities under GDPR/Irish Data Protection legislation.  It must also be clear that as Joint Data Controllers they are aware of the legal sanctions that would apply in the event of data breaches.  (The is a core assumption in the establishment of Project Predict, hence the likelihood of an issue is considered ‘remote’. |
| **Does it preserve the autonomy of the human?**  Every individual competent adult is entitled to determine how they interpret and react to medical advice. Project Predict should not force triage decisions on a patient or refer this information to an external medical agency (hospital, etc.) without a patient’s consent. | 4 | 2 | 8 | Most patients, by virtue of signing up to the Project Predict programme, are probably willing to accept medically recommended triage decisions.  However, there must be an ‘opt-out’ decision that can be captured after the TriCARE Triage team has assessed the recommendation from the nurse/ML model. Triage information must not leave the Project Predict data perimeter unless explicitly agreed by the patient.  If the patient is unable to provide this triage consent, due to a very serious medical condition, the TriCARE employees should be empowered to act on the patient’s behalf. |
| **Does it preserve the autonomy of the human?**  A number of patients involved in the Project Predict lifecycle will be elderly and may be uncertain about their data rights, in terms of access and removal. | 4 | 4 | 16 | Project Predict must provide patients with access to an individual (not a website or a chat-bot) who will explain, in straightforward terms, their data rights.  This must cover data access rights throughout the four years of the project and include specific reference to the Year 3 survey. |
| **Is processing necessary and proportionate?**  There is a constant recoding of daily patient data, which is then supplemented by the Year 3 Trial survey information. This means that patient data will have to be identifiable at all stages in the Project Predict process. Is it clear who has access to these identifiers and how they are used? | 4 | 2 | 8 | It is expected that DigiHealth will implement a system that linking PII to a specific individual will only be available to a minority of MLHealth and TriCARE staff.  Access will only be available for specific purposes and access will be tracked in an audit log for later scrutiny should any data breach occur. |
| **Is processing necessary and proportionate?**  TriCARE is clearly an organisation that has connections with the broader Healthcare industry. Project Predict data could be a valuable commodity for other players in the sector. How can this be addressed? | 5 | 2 | 10 | Given the legal implications of providing PII to external entities for unauthorised use, it is unlikely that MLHealth and/or TriCARE employees would be guilty of such a breach.  However, data management protocols should be a feature of regular staff training throughout the four year Project Predict lifecycle. |
| **Is processing necessary and proportionate?**  Certain patients may be agreeable to the use of automated Medic sensors but reluctant to take part in the Year 3 trial. Will participation in the survey, and providing that supplementary data, be a pre-requisite to joining Project Predict? | 3 | 2 | 6 | Survey. The trial interview sessions are intended to take place either at patient’s home address, or over the phone. Ideally, patients will be briefed well in advance on the purpose of this survey and be willing to get involved.  A patient may be uncomfortable disclosing information to an unknown researcher. An alternate would be to allow the option of completing the survey online, or by post.  The researcher should also ideally be an identified medical professional, who would be qualified to interpret survey responses, if required. |
| **Does it uphold the common good?**  The USP of the Project Predict services is that it promises a quicker (automated) response when medical sensor data detects a dangerous deterioration in a patient’s health. Project Predict offers a potentially repeatable solution that can market better healthcare for sections of society. | 1 | 5 | 5 | It is a strong belief that initiatives like Project Predict can use data management to delivery societal benefit in early health care issue detection. |
| **Does it uphold the common good?**  The Medic sensors are also calibrated to build an ongoing daily history for a patient. This can have the benefit of highlighting emerging conditions and recommending treatment early. This is beneficial to both the patient and to the broader health service by avoiding later (and costly) emergency intervention. | 1 | 5 | 5 | Project Predict operates outside of a hospital or doctor’s surgery setting. This avoids expense for both the individual and the health care service in general. |
| **Does it uphold the common good?**  If a patient is unwilling to share identifiable personal medical data, they will be excluded from Project Predict. Does this set a precedent for future similar systems? Is PII always an essential ingredient for such systems? |  |  |  |  |