



**EARLYDEL**

**HOSPITAL GENERAL UNIVERSITARIO  
GREGORIO MARAÑÓN**

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## EARLYDEL

### PITCH

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Predictive tool for early detection of delirium in hospitalized patients

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### ORGANISATION DESCRIPTION

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The Hospital General Universitario Gregorio Marañón (HGUGM) is a public hospital in Madrid, Spain. It is the largest hospital in the Community of Madrid and serves more than 2 million people. It has 8,000 employees and more than 1,200 beds. It is a teaching hospital, attached to the Complutense University of Madrid.

In the year 2021, the data on healthcare activity were: Total discharges 42.624, the average length of stay 7,61, total admissions 42.531, emergency admissions 26.691 total emergencies 239.076 and percentage of emergency admissions 11,34%. The incidence of delirium in patients over 65 years old ranges between 11,7% and 18,5%, depending on the type of hospitalization unit [1–3].

Since 2018, the Hospital has been equipped with an Electronic Health Record (EHR) that encompasses relevant information concerning the patient's acute clinical conditions, baseline medical history, functional and mental state, as well as socio-demographic and clinical variables.

The available Electronic Health Record (EHR) electronically stores a patient's medical information and care records. It enables healthcare professionals to access, review, and update patient information quickly and efficiently. Currently, with the EHR, it is possible to conduct a comprehensive review of a patient's medical data, including previous diagnoses, treatments, test results, prescribed medications, healthcare provider notes, and other relevant data for patient care. Additionally, it allows for the registration of comorbidity using the Charlson index[4] and assessment of pain with the relevant scale depending on the

cognitive level. Delirium is assessed upon admission and whenever there is a substantial change in the patient's condition through the Confusion Assessment Method (CAM)[5] The confusion assessment method (CAM) is a simple tool that can be used by physicians and nurses to integrate their observations and identify when delirium is the most likely diagnosis (Figure 1). In medical and surgical settings, CAM has a sensitivity of 94% to 100% and a specificity of 90% to 95%[5,6].

Feature	Assessment
1. Acute onset and fluctuating course	Usually obtained from a family member or nurse and shown by positive responses to the following questions: <ul style="list-style-type: none"> <li>▪ "Is there evidence of an acute change in mental status from the patient's baseline?"</li> <li>▪ "Did the abnormal behavior fluctuate during the day, that is, tend to come and go, or increase and decrease in severity?"</li> </ul>
2. Inattention	Shown by a positive response to the following: <ul style="list-style-type: none"> <li>▪ "Did the patient have difficulty focusing attention, for example, being easily distractible or having difficulty keeping track of what was being said?"</li> </ul>
3. Disorganized thinking	Shown by a positive response to the following: <ul style="list-style-type: none"> <li>▪ "Was the patient's thinking disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject?"</li> </ul>
4. Altered level of consciousness	Shown by any answer other than "alert" to the following: <ul style="list-style-type: none"> <li>▪ "Overall, how would you rate this patient's level of consciousness?"               <ul style="list-style-type: none"> <li>• Normal = alert</li> <li>• Hyperalert = vigilant</li> <li>• Drowsy, easily aroused = lethargic</li> <li>• Difficult to arouse = stupor</li> <li>• Unarousable = coma</li> </ul> </li> </ul>

\* The diagnosis of delirium requires the presence of features 1 AND 2 plus either 3 OR 4.

FIGURE 1: CONFUSION ASSESSMENT METHOD CAM FOR DIAGNOSIS OF DELIRIUM

Delirium is a potentially preventable complication, and several different interventions have been developed over the last decade to prevent and control it. Some of these interventions involve nursing staff, while others focus on treatment, and many attempt to prevent delirium after surgery through pharmacological interventions.

We believe that efforts should be made to improve the identification of patients at risk during admission in order to establish preventive interventions and avoid complications such as falls, increased average hospital stay, and unintentional removal of devices. The CAM has become a standard screening device in clinical studies of delirium conducted in multiple settings, including emergency departments and long-term care [7]. It takes five minutes to

administer and can be particularly useful when incorporated into routine bedside assessment, however current workloads and nursing shortages make it difficult to assess on a shift basis.

Since the Hospital does not have an early detection system, we consider that incorporating a delirium algorithm into a third-party analytical solution owned by the hospital with a systematic approach would be an optimal solution for this problem.

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## CHALLENGE DESCRIPTION

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Delirium is an acute state of confusion characterized by an altered level of consciousness and impaired attention, resulting in cognitive and perceptual disturbances that cannot be explained by preexisting dementia. Its onset is rapid, typically occurring within a short timeframe of hours to days, and it tends to fluctuate throughout the day. Although some consider delirium to be a specific type of confusional state marked by heightened vigilance, increased psychomotor and autonomic activity, and symptoms such as agitation, tremors, and hallucinations. for the purposes of this project the terms "delirium" and "acute confusional state" are used interchangeably and encompass states characterized by decreased arousal, referred to as "hypoactive delirium." [8]

The management of delirium is primarily based on expert consensus and observational studies, as conducting controlled clinical trials with cognitively impaired patients poses significant challenges. The strongest evidence supports nonpharmacologic, multicomponent approaches for primary prevention of delirium in high-risk patients [9–11].

Detailed Explanation of Delirium Risk Evaluation in our Hospital:

### 1. Delirium Prevention:

1.1 Identifying patients at risk: Nursing professionals assess the risk of delirium within the first 24 hours (72 hours if admission occurs on a weekend). Patients at increased risk include the elderly, individuals with cognitive impairment, those with a history of delirium, or those undergoing specific medical procedures.

- 1.2 Managing medications: Reviewing and adjusting medications that may contribute to delirium, especially sedatives, anticholinergics, and medications affecting the central nervous system.
- 1.3 Ensuring adequate hydration and nutrition
- 1.4 Promoting good sleep hygiene
- 1.5 Encouraging early mobilization
2. Diagnosis of Delirium
  - 2.1 Nurses, physicians, and other healthcare providers regularly communicate with and observe patients for signs of delirium to ensure early detection. However, high workloads, staff shortages and turnover, and night shifts make it unfeasible to perform a shift-by-shift assessment. Currently, there is no early detection system available.
  - 2.2 The Confusion Assessment Method (CAM) is used as a widely used screening tool to identify delirium. It involves a series of questions and observations related to attention, disorganized thinking, and altered level of consciousness. The CAM is a test based on the presence of four criteria: acute onset and fluctuating course, inattention, disorganized thinking, and altered level of consciousness.
3. Management of Delirium:
  - 3.1 Identifying and treating underlying causes: Addressing the root causes of delirium, such as infections, electrolyte imbalances, pain, or adverse drug reactions.
  - 3.2 Providing supportive care
  - 3.3 Implementing non-pharmacological interventions
  - 3.4 Medication management: In some cases, medications may be prescribed to control severe agitation or distress, but they are used with caution due to the risk of exacerbating delirium.

The importance of having a predictive tool in the hospital is crucial especially in the context of nursing shortages and night shifts. The use of an early detection system for delirium

integrated with the EHR can be a valuable tool for the medical team, allowing for early detection and a more effective response to delirium, which enhances the quality of care and patient safety. The solver should provide the technological solution.

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## CHALLENGE MAIN OBJECTIVES

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Develop and validate a predictive algorithm or analytical model that enables doctors and nurses in hospital units to identify patients who are at a higher risk of developing delirium. This will aid in making informed decisions to prevent adverse events and unnecessary hospital stays.

Furthermore, the Challenger would like to understand the clinical parameters associated with the onset of delirium to optimize internal processes within the hospital units.

To explore everyday life experiences of patients with delirium during the hospital stay, from hospital discharge until 6 months follow-up, focusing on their health-related quality of life and cognitive function.

The secondary objective will be to facilitate systematic consideration of the barriers and implementation strategies needed to incorporate early detection systems for delirium prevention in wards.

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## SOLUTION FUNCTIONAL REQUIREMENTS

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### Compulsory functional requirements

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#### *Compulsory functional requirements for an early delirium detection system*

- The Solvers will use the analytical intake of the hospital, and the solution they provide should have the capability to predict and alert delirium or agitation episodes. This means that the solution will analyze the data available in the hospital's analytical intake, such as patient records, vital signs, behavioural patterns, and other relevant information, to identify potential signs of delirium or agitation in patients. When the

solution detects such episodes, it will generate alerts to inform healthcare professionals promptly, enabling them to provide timely and appropriate care to the affected patients.

- The validation of the predictive model should be carried out within a period of 10 months, and this includes both retrospective analysis and algorithm testing.
- In the 24 hours following admission, provided that all information recorded by nurses and doctors in the electronic medical record associated with the predictive algorithm is available. After admission, the patient's situation may change, and factors may be modified. Therefore, ideally, the solution should work in real-time or within 12 hours to allow preventive measures to be implemented if the patient's situation changes.
- **Data Security and Privacy:** The system should adhere to strict data security and privacy protocols to protect patient information and ensure compliance with relevant regulations, such Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
- In every step, data, security and privacy must be followed with the highest standard.

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## Desirable functional requirements

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- **Trend Analysis:** The system should analyse patient data over time to identify patterns and trends associated with delirium development, enabling proactive interventions and prevention strategies.
- **Decision support:** Incorporating a hospital delirium decision support system into clinical workflows, healthcare teams can improve patient outcomes, reduce complications, and enhance the overall quality of care for individuals at risk of or experiencing delirium during their hospital stay. This decision support system utilizes data from patients' medical records, assessments, and other relevant information to

provide evidence-based recommendations and guidance for managing delirium effective.

- In the future, the delirium alert will be integrated with the hospital's Command Center platform.

## PILOT SCOPE

### Type and number of targeted end-users

End-user type	Role	Number
<b>Nurses or physicians</b>	<i>They have to provide requirements, recruit patients, use and validate the solution.</i>	30
<b>Patients</b>	<i>Validate the solution.</i>	150
<b>Nurses or physicians</b>	<i>Use the solution</i>	<b>50</b>

TABLE 1. TARGETED END-USERS

### Language

The technological solution must be available in Spanish.

### Other aspects

- The delirium algorithm should be seamlessly incorporated into the hospital's third-party analytics solution, improving patient care and providing valuable information to healthcare professionals.
- Training sessions will be required for healthcare professionals who will be using the analytics solution, ensuring that they understand the algorithm's capabilities, its limitations, and how to interpret its results.



- Mechanisms will be designed to monitor the performance of the delirium algorithm within the analytical solution. Any issues should be addressed promptly, and regular updates must be carried out.

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## PILOT SET-UP CONDITIONS

### **Ethical, legal or regulatory**

The project will be led from the Nursing Department by the Nursing Research Support Unit and the IISGM's (Instituto de Investigación Sanitaria Gregorio Marañón) Innovation Support Unit, and the Hospital IT Department

#### Privacy Policy

Since May 2018, Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 (General Data Protection Regulation, GDPR) has been fully applicable in Spain. This regulation applies to any total or partially automated processing of personal data, as well as non-automated processing of personal data contained or intended to be included in a file.

Additionally, in December 2018, Organic Law 3/2018 of December 5, on the Protection of Personal Data and the Guarantee of Digital Rights (LOPDDD) came into force. The Seventeenth Additional Provision (DA17<sup>a</sup>) includes specific provisions, applicable in Spain and complementary to the GDPR, regarding the processing of health data.

Regarding data processing subject to personal data protection regulations, once data capture is completed, the data will be pseudonymized from the sources of information, and structured data files will be provided to the researchers/solvers. The hospital acts as the data processing controller, with no data processor or joint controller involved.

In addition to the legal bases indicated, Article 9(2)(j) of the GDPR specifies one of the exceptions to the general prohibition of processing health data: that the processing is necessary for scientific research or statistical purposes.

The processing of health data included in EarlyDel is for scientific research purposes, whether in-house research or conducted by other researchers in the healthcare field. To do so, the conditions established in Article 89(1) of the GDPR and the requirements indicated in paragraph 2(d) of the Seventeenth Additional Provision of the LOPDDD must be met, as the GDPR itself states that these conditions must be established based on the laws of the European Union or the Member States.

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## Technological

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The predictive tool will aim to use advanced data analytics, machine learning algorithms, and clinical patient data to identify early signs and risk factors associated with delirium. By analyzing various patient parameters, such as age, medical history, medications, vital signs, laboratory results, and cognitive assessments, the tool can proactively predict the likelihood that a patient will develop delirium during their hospitalization.

Dedalus HCIS is the software used in the hospital for the management of clinical information. The hospital utilizes HCIS, a comprehensive Electronic Health Record (EHR) platform implemented in 100% of healthcare processes. They leverage open standards like HL7 FHIR to ensure interoperability of data and clinical pathways across the care continuum. This facilitates collaboration for healthcare organizations, allowing them to work seamlessly with the patient as the primary focus.

The hospital uses Power BI for Machine Learning, and it would be ideal for the solver to also utilize it. The solver will have access to whatever they need. The hospital has a Balanced Scorecard (BSC) created using Power BI healthcare dashboards. This is a specialized tool used to represent and evaluate the hospital's overall activity. Its main objective is to translate the key aspects that constitute the organization's strategy and mission into a set of performance indicators. These indicators are part of a strategic management and measurement system that allows organizations to calibrate and monitor the strategies and actions implemented to improve performance.

Unlike a conventional scorecard, the BSC covers all aspects related to the strategic plan. In the scorecard, activity and performance indicators, as well as KPIs, are represented. The Information Technology (IT) department is involved in the project team and will collaborate on the implementation of the technology solution

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## Data access

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The hospital will provide retrospective historical data available from 2019. We have a record of over 2,500 patients from the geriatric unit, which includes the following information:

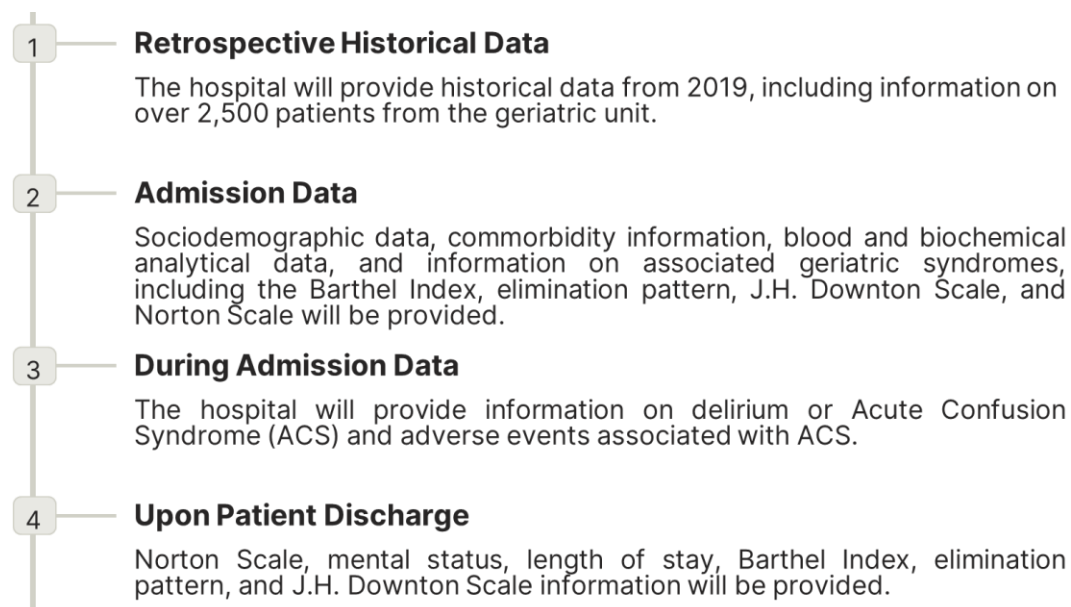


FIGURE 2: DATA ACCESS

### Admission data

- Sociodemographic data: Age, Gender, Marital status, Occupation, Place of residence, etc.
- Comorbidities: Hypertension, dyslipidemia, diabetes mellitus, heart failure, COPD, Cancer, thyroid disorder, dementia, ischemic heart disease, stroke/CVA, chronic kidney disease, anemia, and osteoarthritis.
- Blood and biochemical analytical parameters and vital signs (temperature, heart rate, and blood pressure).

- Associated geriatric syndromes: Acute coronary syndrome, chronic pain, polypharmacy, urinary incontinence, falls, dementia, ulcers, constipation, immobility, dysphagia.
- Barthel Index (BI). The BI is a generic measure that assesses the patient's level of independence in performing some basic activities of daily living (ADLs).
- Elimination pattern: continent, urinary incontinence, fecal incontinence, constipation.
- J.H. Downton Scale, allows assessing the risk of falls in individuals, commonly used in older adults. The scale has five dimensions, which are: Previous falls, Medications, Sensory deficits, Mental status, and Ambulation.
- Norton Scale, allows assessing the risk of developing pressure ulcers. The scale has five dimensions, which are: Physical condition, Mental status, activity, mobility, and incontinence.
- Cognitive/emotional pattern at admission: No alteration, Cognitive impairment, behavior alteration, depression, anxiety, insomnia.
- Mental status: oriented/disoriented.
- Sensory deficit: Hearing impairment and/or Visual deficit.
- Nutritional pattern: Weight loss, preserved appetite, dysphagia, dehydration, denture wearer.
- Nutritional screening: Mini Nutritional Assessment (MNA) is a scale for nutritional status evaluation.
- Pharmacological treatment upon admission.

### During the admission

- Delirium OR Acute Confusion Syndrome (ACS) during admission: Yes/No.
- Adverse event associated with ACS.

### Upon patient discharge

- Length of stay.

- Mental status: oriented/disoriented.
- Barthel Index (BI). The BI is a generic measure that assesses the patient's level of independence in performing some basic activities of daily living (ADLs).
- Elimination pattern: continent, urinary incontinence, fecal incontinence, constipation.
- J.H. Downton Scale, allows assessing the risk of falls in individuals, commonly used in older adults. The scale has five dimensions, which are previous falls, Medications, Sensory deficits, Mental status, and Ambulation.
- Norton Scale allows assessing the risk of developing pressure ulcers. The scale has five dimensions, which are physical condition, Mental status, activity, mobility, and incontinence.

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## EXPECTED IMPACTS AND KPIS

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The success of the pilot will be determined by the effectiveness of the predictive algorithm in identifying patients at risk of delirium as well as complications that can be avoided.

**Delirium Detection Rate = (Number of Delirium Cases Detected / Total Number of Patients at Risk or Screened) x 100**

This KPI calculates the percentage of delirium cases that were successfully identified through screening or assessment among the total number of patients who were at risk of delirium or underwent screening for delirium. The goal is to achieve a high detection rate, indicating that a significant proportion of delirium cases has been accurately identified. A higher delirium detection rate can lead to timely management, reducing complications and improving patient outcomes.

- Unit of measurement. % percentage
- Person responsible for the measure: Nursing Supervisor.
- Threshold : >70%
- Frequency: monthly

**Delirium Adverse Event Rate = (Number of Adverse Events in Delirium Patients / Total Number of Delirium Patients) x 100**

This KPI calculates the percentage of delirium patients who experience adverse events during their hospital stay. Adverse events in delirium patients may include falls, injuries, pressure ulcers, medication errors, prolonged hospital stays, and other complications related to delirium. The goal is to reduce the rate of adverse events in delirium patients over time, indicating successful efforts in improving patient safety and minimizing the impact of delirium on patient outcomes.

- Unit of measurement. % percentage
- Person responsible for the measure: Nursing Supervisor.
- Threshold : < 5%
- Frequency: monthly

**Unintentional removal of device Removal of Device Rate = (Number of Cases of Involuntary Device Removal in Delirium Patients / Total Number of Delirium Patients) x 100**

Unintentional removal of device removal of devices may include instances where patients unintentionally remove or displace devices, such as IV lines, urinary catheters, or ventilator tubes.

- Unit of measurement. % percentage
- Person responsible for the measure: Nursing Supervisor.
- Threshold : < 10%
- Frequency: monthly

**Delirium Patient Fall Rate = (Number of Falls in Delirium Patients / Total Number of Delirium Patients) x 100**

This KPI calculates the percentage of delirium patients who experience falls during their hospital stay. Falls in delirium patients can result from altered mental status, reduced mobility, and other factors associated with delirium. The goal is to reduce the rate of

patient falls in delirium patients over time, indicating successful efforts in improving patient safety and reducing the risk of injuries or complications associated with falls.

- Unit of measurement. % percentage
- Person responsible for the measure: Nursing Supervisor.
- Threshold : < 1%
- Frequency: quarterly

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## BUSINESS OPPORTUNITY

### Market size

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Delirium is an acute state of confusion characterized by an altered level of consciousness and impaired attention, resulting in cognitive and perceptual disturbances that cannot be explained by preexisting dementia. Its onset is rapid, typically occurring within a short timeframe of hours to days, and it tends to fluctuate throughout the day. Underlying medical conditions, substance intoxication, or medication side effects are commonly responsible for delirium[12,13].

Delirium affects between 12.5% and 30% of patients over 65 years of age, but is often not detected early or adequately treated. It is associated with an increased risk of falls, a longer hospital stay, and higher morbidity and mortality rates. It is a scary and unpleasant experience for both patients and their families. Delirium results in (adjusted) increased costs ranging from \$1,532 to \$22,269, depending on the cost categories included, country, and type of hospital department[14–17]

This system can be extended as standard with the same technology to other healthcare resources: home hospitalisation, nursing homes, geriatric hospitals, psychiatric units and critical care units within and outside the Challenger organisation, with great potential for growth. The literature describes that delirium results in (adjusted) increased costs ranging from \$1,532 to \$22,269, depending on the cost categories included, country, and type of hospital department[18]. The increase in hospital stay for patients with delirium ranged from

2.5 to 10.4 days and contributed to the overall direct incremental costs [19]. Changes in Health-Related Quality of Life (HRQoL) due to delirium are not well demonstrated and further research is needed to determine the effect of delirium on HRQoL. The ineffective management of delirium in hospitals can have significant economic, social, environmental, and liability impacts.

- **Economic impact:** Delirium can lead to longer hospital stays, increased use of healthcare resources, and higher healthcare costs. The additional testing, interventions, and consultations required for patients with delirium can contribute to increased healthcare expenses, which can be a financial burden for patients and their families, as well as for healthcare systems. According to Globe Newswire, the global delirium management market is expected to value at USD 352.6 million in 2021 and is expected to grow at a CAGR of 5.6% during the forecast period [20]. The economic cost of delirium has been evaluated by Kinchin et al. in a systematic review and quality assessment of published research. The economic cost of delirium was reported from a variety of sources, and the estimated incremental cost ranged from \$806 to \$24,509 (in 2019 dollars). The lowest incremental cost was observed in Spain (\$806) and the highest in Switzerland (\$24,509), both in the hospital setting. The economic cost of delirium in the hospital setting ranged from \$806 to \$24,509, in the intensive care unit from \$1,529 to \$14,462, and among community residents from \$1,045 to \$12,452. [18]
- **Social impact:** Delirium can have a significant impact on patients' well-being and quality of life, as well as that of their caregivers. Patients with delirium may experience confusion, disorientation, and agitation, leading to increased stress and anxiety. Family members and caregivers may also experience increased stress and burden in caring for patients with delirium, which can have negative effects on their own health and well-being. [9,10,21–23] Delirium affects between 12.5% and 30% of patients over 65 years of age, but is often not detected early or adequately treated.



It is associated with an increased risk of falls, a longer hospital stay, and higher morbidity and mortality rates. It is a scary and unpleasant experience for both patients and their families[17],

- **Environmental impact:** Ineffective management of delirium can lead to longer hospital stays and increased use of healthcare resources, which can contribute to the environmental impact of healthcare systems. This includes increased energy use, waste generation, and greenhouse gas emissions associated with healthcare activities, which can have negative environmental impacts. Additionally, demographic trends indicate that the population over 65 is experiencing significant growth. This shift in population structure suggests that, in the future, there will be an increasing demand for specific services to meet the needs of this age group. Aspects such as specialized medical care, home care programs, long-term care services, and other initiatives related to the health and well-being of older adults will become increasingly important to ensure an adequate quality of life for this segment of the population. The planning and provision of these services become key elements in addressing demographic challenges and ensuring a healthy and sustainable ageing process.

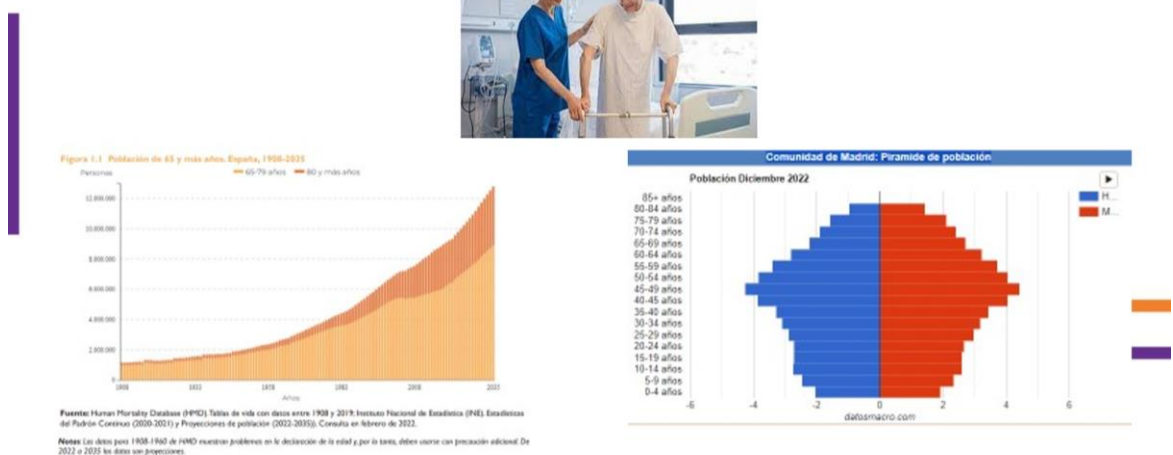


FIGURE 3: DEMOGRAPHIC TRENDS IN SPAIN

- **Liability impact:** Ineffective management of delirium can also lead to legal and liability issues for healthcare providers. Failure to recognize and manage delirium can lead to adverse outcomes, including falls, medication errors, and other adverse events, which can result in liability claims and lawsuits against healthcare providers

This system can be extended as standard with the same technology to other healthcare resources: home hospitalisation, nursing homes, geriatric hospitals, psychiatric units and critical care units within and outside the Challenger organisation, with great potential for growth.



#### Extendable Solution

Our system can be extended to other healthcare resources, such as home hospitalization, nursing homes, geriatric hospitals, and critical care units.



#### Digital Health Innovation Centre

- In Madrid ten hospitals have the same electronic medical records .
- The Community of Madrid launched the first digital health innovation Centre located in Zenda .

FIGURE 4: BUSINESS OPPORTUNITY

In addition, the Gregorio Marañón General University Hospital has been selected as the winner of the Best Digital Intelligence Project of 2022 at the CIO 100 Awards. This award highlighted the complete technological integration of its new Surgical Center, which, thanks to interconnected data flows and the application of artificial intelligence and machine learning, has managed to optimize the management of its facilities and resources.

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## Adoption plans

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The Hospital management, in collaboration with the procurement department, is fully committed to purchasing a co-created solution by engaging with the appropriate stakeholders. They recognize the value of leveraging collective expertise and are dedicated to supporting the development and implementation of a solution that caters to the specific needs of the hospital. This commitment ensures that the jointly created solution will be seriously considered for adoption and acquisition within the organization.

The Regional Ministry of Health of the Community of Madrid, through the Directorate General for Research, Teaching, and Innovation, is responsible for promoting and fostering innovation activities in the health sector. Public Procurement of Innovation (PPI) is the tool through which a public purchaser acquires a solution that is not yet available on the market.