SC1-PHE-CORONAVIRUS-2B

ENVISION

Intelligent plug-and-play digital tool for real-time surveillance of COVID-19 patients and smart decision-making in Intensive Care Units

Project No. 101015930

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Deliverable Title	COVID-19 use cases and ICU scenarios
Work Package Number	3
Work Package Title	AI - driven data analytics and predictive modelling
Lead Participant	GUF
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Abstract – The ENVISION Project

Within only six months, over 7.4 million people have been diagnosed with SARS-CoV-2. In the most severely hit countries, more than 10% of infected patients have received treatment in intensive care units (ICUs). Insufficient data and limited knowledge on the disease, as well as the lack of tools to support the intensivist in making accurate, timely and informed decisions, has led to high mortality rates.

Continuous surveillance, the collection and intelligent analysis of data from many sources, including ventilators and electrical impedance tomography, would allow intensivists to decide on the best suitable treatment to accelerate the recovery of the often comorbid COVID-19 patients, while reducing the burden on clinical staff and healthcare costs. This information would also increase our understanding of the yet unknown course of disease, supporting other stakeholders in the quest for new therapies.

In ENVISION, our multidisciplinary public-private consortium will advance an innovative digital tool, Sandman.MD, a real-time and plug-and-play monitoring app, to an intelligent decision-support system for monitoring, prediction and treatment of COVID-19 patients in ICUs – the Sandman.IC – reaching Technology Readiness Level 9 and ready for CE marking by the end of the project. The app has been developed by our SME partner app@work and successfully introduced by several hospitals in Germany for use during the perioperative period. Sandman.IC will be integrated into an AI-driven data analytics suite with predictive modelling tools and enhanced with a smart alert functionality. The digital tool will be validated and demonstrated in 13 hospitals across Europe. Our health technology assessment expert partner will demonstrate the economic and societal value of Sandman.IC, while an experienced SME will manage the innovation process in view of an immediate market uptake. The rollout will be supported by the European Society of Anaesthesiology and Intensive Care (ESAIC).

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Partner short names

accelCH	accelopment Schweiz AG
accelDE	accelopment Deutschland GmbH
CCHT	Spitalul Clinic Judetan De Urgenta Pius Brinzeu Timisoara
CHUC	Centro Hospitalar e Universitario de Coimbra E.P.E.
DPT	Central Hospital of Southern Pest National Institute of Hematology and Infectious Disease
ESAIC	European Society of Anaesthesiology and Intensive Care
GUF	Johann Wolfgang Goethe Universität Frankfurt am Main
ICS-HUB	Institut Catala de la Salut – Bellvitge University Hospital
iDA	Intelligent Data Analytics GmbH & Co. KG
KC	Lietuvos Sveikatos Mokslu Universiteto Ligonine Kauno Klinikos
LMI	Löwenstein Medical Innovation GmbH & Co. KG
SE	Semmelweis Egyetem
TAU	Tampereen Korkeakoulusaatio SR
UCL	University College London
UHREG	Klinikum der Universitaet Regensburg
UMCG	Universitair Medisch Centrum Groningen
UMCL	Univerzitetni Klinicni Center Ljubljana
UMCM	Univerzitetni Klinicni Center Maribor
UMFCD	Universitatea de Medicina si Farmacie Carol Davila din Bucuresti
UNIPG	Università degli Studi di Perugia
UNITO	Università degli Studi di Torino

Revision history

Date	Authors	Revision
10.03.21	Benjamin Friedrichson (BD), Jan Kloka (JK)	Draft version
16.03.21	Antti Kallonen (TAU), Alpo Värri (TAU)	Revision 1
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Abbreviations

AI	Artificial intelligence
aPPT	Activated partial thromboplastin time
ARDS	Acute Respiratory Distress Syndrome
CPAP	Continuous positive airway pressure
CRP	c-rective potein
D	Deliverable
EC	European Commission
ECMO	Extracorporeal membrane oxygenation
E-selectin, ICAM1, VCAM1	Proinflammatory proteins
GCS	Glasgow Coma Score
GFR	Glomerular filtration rate
H2020	Horizon 2020
H1N1	Type of influenza virus
HIS	Hospital information system
ICU	Intensive care unit
IL-1, IL-2, IL-7, IL-10, GCSF, IP-10, MCP1, MIP1A, IL-6, IL-10, CRP, and IFN-γ	Immune response cytokines
M	Month
MS	Milestone
NMH	Low molecular weight heparin
pCO2	Carbon dioxide partial pressure
PEEP	Positive end-expiratory pressure
pH	pH value
pO2	Oxygen partial pressure
S2k	S2k guideline (consensus-based)
UFH	Unfractionated heparin
VTE	Venous thromboembolism
WP	Work Package

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Executive Summary

Within Deliverable 3.2, various use cases and scenarios are used to illustrate the perspective functional and evaluation possibilities of Sandman.IC (a digital app to be developed during the project ENVISION) and the artificial intelligence (AI) behind it. Based on the feedback collected from previous deliverables and meetings (e.g. web conferences on user requirements for Deliverable 2.1), ten unique use cases were created (see chapter 2).

The aim of Deliverable 3.2 is to give the reader a perspective on what innovations and fields of activity are covered by Sandman.IC. The use cases range from AI-based medication and body positioning recommendations to ventilation guidance and trial inclusion suggestions.

The use cases presented in this document, however, constitute only possibilities for the implementation of Sandman.IC and are not guaranteed. In the course of this research project and with regard to the initial data collection and evaluation, the possibilities of Sandman.IC will become more and more granular, allowing more detailed statements and use cases to emerge (for more information on this, see chapter 3).

1 Introduction

1.1 Background

Since 2020, COVID-19 has presented nurses and physicians with a new situation - an unknown, potentially fatal disease with no clinical experience regarding pathogenesis, disease stages, and progression. It affects people worldwide and demands a viable therapy - in the shortest possible time. Of course, the efficacy and tolerability of such a therapy should be given. This is a challenge for clinicians and scientists. Numerous approaches are being pursued and some are being discarded. Within a year, an incredible amount of information has been exchanged between clinicians and researchers worldwide. To date, however, causal therapeutic approaches are still lacking. In the intensive care setting, the focus remains on optimising pharmacotherapy and symptom control. Coagulation management and inflammation control are the main pharmacological options for intensive care therapy.

Since the outbreak of the SARS-CoV-2 pandemic in 2019, more than 84.043.276 (01/01/2021) infected individuals have been registered worldwide, of which more than 1.828.893 cases ended fatally [1]. In the beginning of 2021, 8% of the patients hospitalised due to COVID-19 in Germany were in need of intensive treatment. Among patients requiring intensive care, mortality averaged approximately 26% [2]. In Germany, spring mortality was reported to be 53% among ventilated patients and up to 72% among patients who also needed dialysis [3].

Among the regions of the world hardest hit by the second wave is Europe. In parallel with the increasing number of cases, the experience of the treating nurses and physicians in particular is increasing, but the number of available therapeutic options remains limited.

This endothelial process provides an explanation for the clustered occurrence of thrombi in COVID-19 [4]. In a study of 184 COVID-19 patients requiring intensive treatment in spring 2020, thromboembolic events occurred in 31% of them. The incidence of deep vein thrombosis was 27% and in the case of arterial thrombosis, it amounted to 3.7%. The most common thrombotic complication was pulmonary embolism [5].

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Compared with pneumonia cases caused by the H1N1 influenza virus and control patients without an infection, post-mortem COVID-19 patients exhibited microthrombi in alveolar capillaries up to nine times more frequently, as well as marked thrombi and intussuscepted angiogenesis and occlusion of alveolar capillaries [6]. These microthrombi of alveolar capillaries lead to a disruption of the ventilation-perfusion relationship. Right heart strain with the appearance of cor pulmonale has also been reported. Endothelial damage and coagulation system activation appear to play an important role in the pathophysiology of severe COVID-19 cases. This is suggested by several observations and study results. Elevated D-dimer levels have been observed in patients with severe illness, which are associated with a worse prognosis [7]. In addition to the hemostaseological importance of the vascular endothelium, endothelial cells play a key role in the immune response and in the recruitment of immune cells. IL-1 and TNF induce the expression of proinflammatory proteins such as E-selectin, ICAM1, VCAM1, and chemokines, which promote adhesion and diapedesis of leukocytes to underlying tissues, particularly the lung in the case of COVID-19 [8].

A hyperinflammatory state is often observed in the middle and later phases of the disease. In a proportion of COVID-19 patients, the picture of a "cytokine storm" is reported and currently discussed in the context of possible superinfections in the literature. In general, a hyperinflammatory state develops due to a dysregulation of the immune response and is associated with elevated cytokine levels. This partly systemic hyperinflammation causes damage to various organs and may also result in multiorgan failure [9].

COVID-19 patients requiring intensive care show higher levels of IL-2, IL-7, IL-10, GCSF, IP-10, MCP1, MIP1A, and TNF than patients not requiring intensive care. Increased levels of IL-6, IL-10, CRP, and IFN-γ have also been observed. Furthermore, lymphopenia has been detected in 63% of COVID-19 patients [10]. Elevated levels of IL-6 and CRP appear to be independent risk factors of the severe course [11]. Another study of 1484 patients also shows that the levels of IL-6 and TNF are independent risk factors for a severe course and a fatal outcome [12].

The combination of a novel disease and an undefined, symptom-oriented dynamic treatment strategy poses major challenges for intensive care physicians. The use cases listed here are intended to demonstrate the supportive integration of AI into everyday clinical practice.

1.2 Goal of the ENVISION project and possible applications for Sandman.IC

The ENVISION project, launched within the H2020 project framework, is a research project aimed at improving the understanding and treatment options for SARS-CoV-2 (COVID-19) patients in Europe. This goal is pursued with the development of an intelligent tool, Sandman.IC, which is planned to enable real-time monitoring of various vital parameters and to support the medical staff in decision-making through an underlying AI.

The integration of artificial intelligence is a special feature that is still in its beginnings within the healthcare sector, not only in Europe but also worldwide. Accordingly, it is important to think about future functionalities and limitations of Sandman.IC at an early stage of the project.

Below is a sketch (Figure 1) that metaphorically illustrates the various possibilities that AI can offer. The illustration shows a doctor who is "guiding" the patient on his/her "road to recovery" with the help of Sandman.IC. When in use, the tool is planned to offer suggestions and relevant data to the medical personnel. For example, Sandman.IC could be used to provide medical staff with a prediction of possible treatment outcomes, to highlight "what if" possibilities and to ensure a comprehensive view of the patient's vital condition.

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It is important to note that Sandman.IC is a tool used by medical staff to help them make "correct" decisions, but it can never replace the human element. This also includes considerations as to whether, and to what extent, the developers can review of the treatment proposals made by the AI in advance.

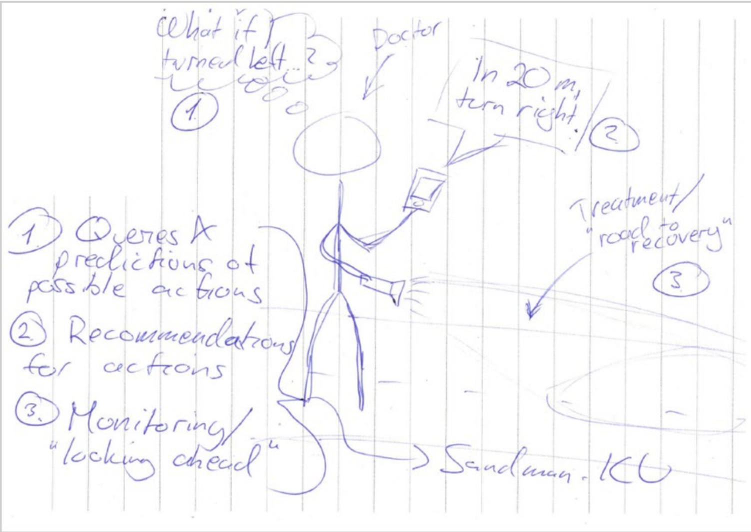

Figure 1: An illustration of the possibilities of the Sandman.IC.

1.3 Sandman.IC infrastructure

The planned local infrastructure in the clinics will consist of multiple (varying number depending on the clinic) iPads running the Sandman.IC app. One iPad will each be provided to a hospital bed in the ICU of a COVID-19 patient and connected to devices like a respiratory unit or a monitor. The app will automatically receive data from those connected devices and will also allow manual input from physicians for additional information such as used medication, activities, laboratory values and medical history of the patient. The local hospital information systems (HIS) will not be connected at the beginning of the project, but it may be considered at a later phase of the project, to provide additional data and to reduce the need of physicians recording some information twice.

The apps will be connected to a server to store the data and communicate with the underlying AI. The physicians can use the Sandman.IC app on the iPads to visualise and monitor the data as well as request recommendations such as medication or treatment suggestions, as specified in chapter 2. Figure 2 exemplifies the connection between the iPads and the connected devices.

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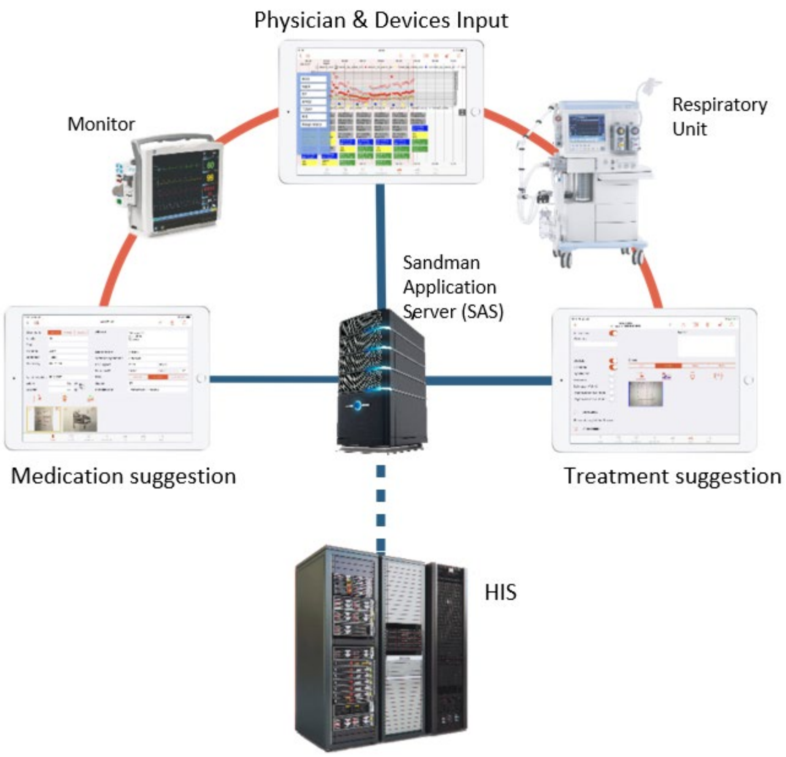

Figure 2: Sandman.IC infrastructure

1.4 Linking the Use cases with the artificial intelligence methods

Smart cohort building and supervised modelling using probabilistic machine learning

The use cases defined in this document will initially explore the collected data using state-of-the-art exploratory analysis methods using the tools defined in 3.1. Goal is to first identify distinctive subpopulations from the patient data that may have a specific complication profile or different treatment response. Figure 3 presents a clustering example where different population subsets are identifiable from the collected data. The results of the exploratory analysis are discussed and analysed in collaboration with the clinicians and data scientists in the project in order to identify clinically meaningful patient clusters and further refine the inputs to the use cases. The exploratory phase can be used as a smart cohort builder where patient selection is done using the identified subpopulations that may lead to better treatment responses in patients exhibiting specific phenotypes or enhanced response to some of the expert systems being developed in the deliverable 3.1.

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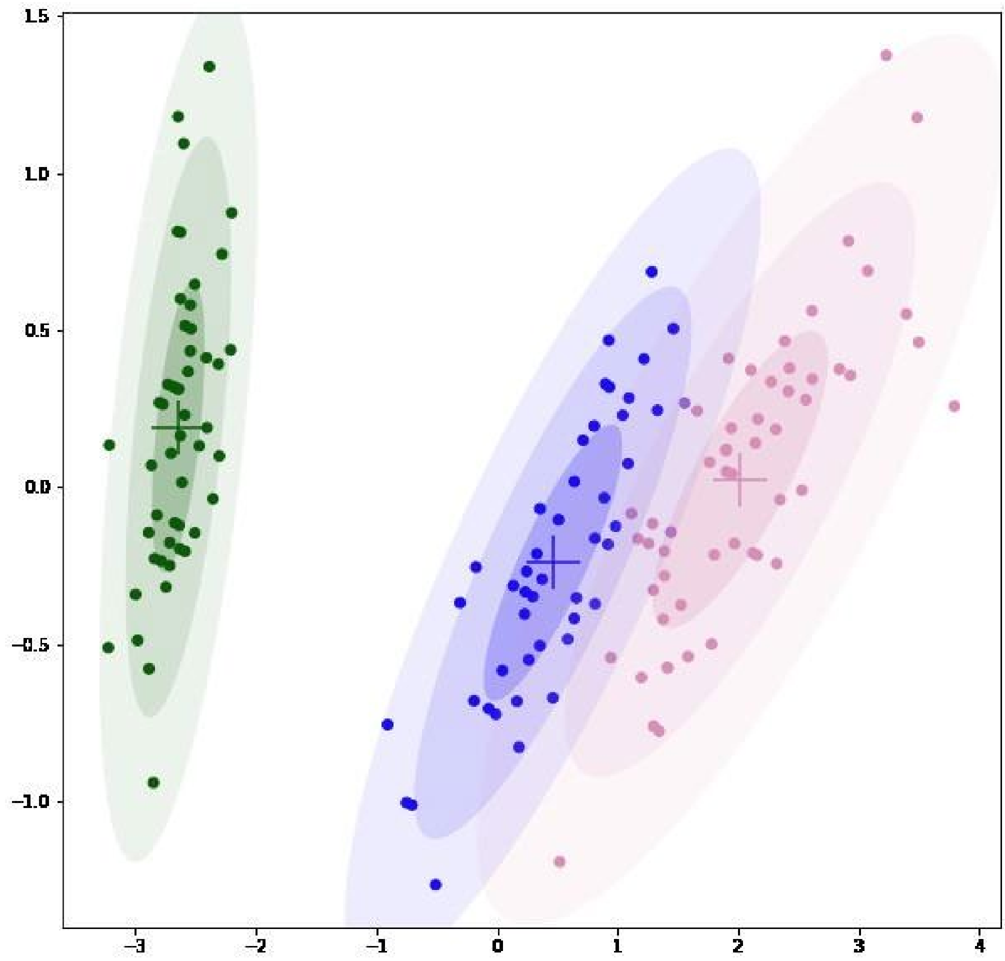

Figure 3: Extraction of different patient phenotypes from the collected data using Gaussian mixture modelling. X- and Y-axes present a different combination of vital signs, such as oxygen saturation and blood pressure. The different colours highlight the discovered patient subpopulations that may have a different treatment response.

Each of the implemented use cases is divided in three categories: 1) Supervised modelling. 2) Expert system and 3) Combination of a supervised model and expert system based on feasibility estimate on the initial batch of collected data. An automated alert indicator is implemented if the use case and collected data favour an automated approach where supervised machine learning methods can provide clinically useful early warning or decision support potential. If the collected data is insufficient in addressing the use case, an expert system approach with manual input from the Sandman.IC is selected. In some special cases the data quality and quantity may not be enough for a fully autonomous approach, but may be used to supplement an expert system to bring additional support for the intensivist.

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2 AI use cases

In the following, eight different use cases with corresponding scenarios are presented. Each use case starts with a short scenario introducing the patient, his condition and the possible use of the Sandman.IC. Following this, a diagram is presented that summarises the above scenario in a concise way and shows possible uses of the Sandman.IC.

2.1 Early ECMO vs. late ECMO (rescue)

Introduction

The Early Extracorporeal Membrane Oxygenation (ECMO) Prediction Model is a pivotal use case within the Sandman.IC system, aimed at revolutionising the decision-making process for initiating ECMO therapy in COVID-19 patients. By leveraging routinely collected patient parameters using Sandman.IC and harnessing the power of AI-driven models trained on retrospective patient data from participating hospitals, this use case seeks to enhance critical care outcomes.

Scenario

Let's delve into the case of Sigrid Schwarzwaelder (Figure 4), a 26-year-old woman who found herself in the grips of COVID-19's devastating impact. Sigrid's health had been relatively stable for over a week following her admission to the hospital, but a sudden shortness of breath heralded a critical turn. Swiftly, intensive medical intervention was deemed essential. Her respiratory parameters deteriorated at an alarming pace, prompting the intensive care team to make the tough decision to intubate her. The inflammation-driven assault on Sigrid's lungs was unrelenting, and it was determined that only the application of an extracorporeal membrane oxygenator (ECMO) could adequately manage her oxygenation and decarboxylation.

Sigrid's journey through ECMO therapy proved successful, marking a turning point in her battle against the virus. As her ventilation parameters stabilised, the ECMO support was gradually phased out, and she eventually made the transition from the intensive care unit to the regular ward. Reflecting on this experience, the lead intensivist wondered whether ECMO therapy could have been a viable option at an earlier stage, thereby possibly mitigating the severity of Sigrid's condition. This is where Sandman.IC's AI intervention could have made a substantial difference, offering insights into the potential benefits of ECMO therapy during the critical phases of intensive care.

Leveraging Sandman.IC Data

The intrinsic capacity of the Sandman.IC system to consistently gather and retain patient data forms the cornerstone of the Early ECMO Prediction Model. By routinely aggregating data on respiratory rate, heart rate and blood oxygen saturation, Sandman.IC creates a comprehensive foundation for predictive analytics. Moreover, the historical patient data necessary for training the AI model is sourced from collaborating hospitals, ensuring the broad representation required for accurate predictions.

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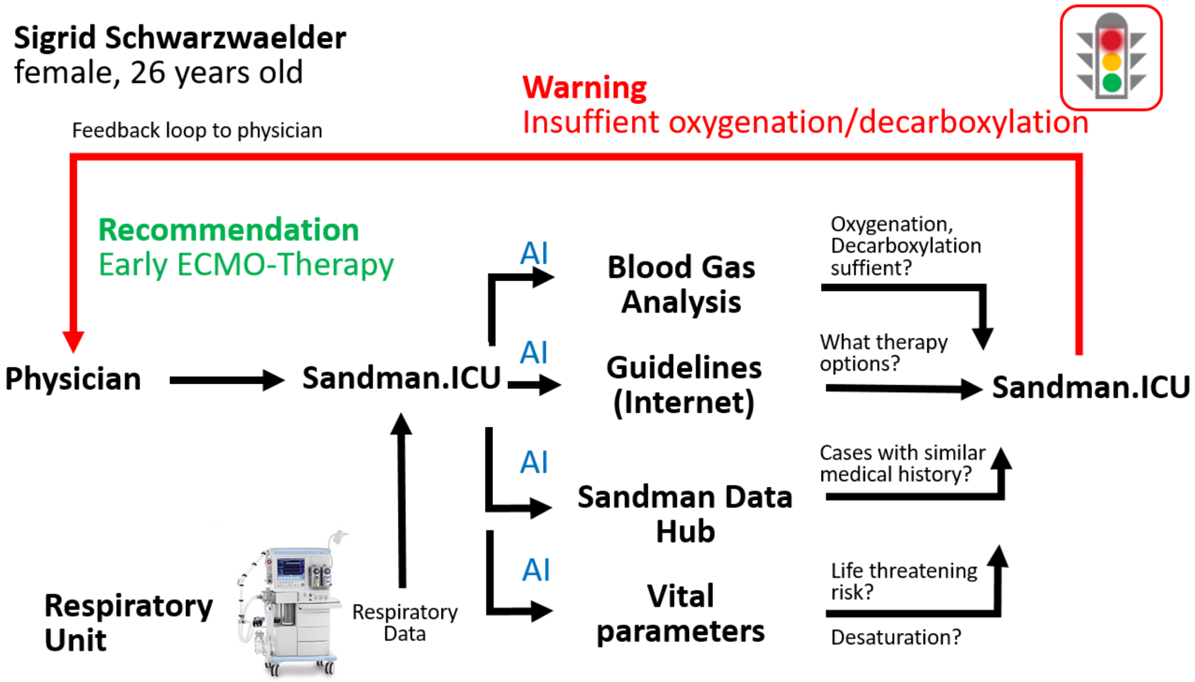

Figure 4: The treating physician wonders when the optimal timing of extracorporeal membrane oxygenation is indicated. Sandman.IC can support this decision and provide a recommendation for action. For this purpose, data from various sources are analysed and a recommendation for action is derived by AI (artificial intelligence). In addition to the ventilation parameters, the current blood gas values (pO2, pCO2, pH, etc.) are also taken into account. But also the current recommendations for action in the form of guidelines, the current vital parameters (blood pressure, heart rate, etc.) and comparison data from Sandman.IC database is taken into account. Since this is a decision with a potentially fatal outcome for the patient, Sandman.IC reflects the need for action in the form of a red traffic light to ensure the attention of medical staff.

Workflow

The Early Extracorporeal Membrane Oxygenation (ECMO) Prediction Model within Sandman.IC utilises the data collected on a routine basis in real-time. The model allows predictions concerning the right time for initiating ECMO therapy in COVID-19 patients followingly:

- Data Collection
  - Sandman.IC collects live patient data from various sources.
- AI Model
  - The AI model analyses the real-time data stream for patterns.
  - It suggests when to start ECMO therapy.
- Recommendation
  - The AI recommendation is shared with medical teams.
- Clinical Decision
  - Doctors may use the AI suggestion to decide on ECMO timing based on their clinical experience.

AI Model Development

The AI model's development is grounded in the synergy between real-time data collected through Sandman.IC and the wealth of historical patient information. This intricate interplay allows the model to identify intricate patterns, relationships, and trends, equipping it to make informed predictions about the optimal timing for initiating ECMO therapy.

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Empowering Clinical Decision-Making

In the context of Sigrid's case, her real-time data would have been input into the Early ECMO Prediction Model as her respiratory parameters progressively deteriorated. The model would meticulously scrutinise her parameters, comparing them against the patterns unearthed from the retrospective patient data. With these analyses at its core, the model would then generate a recommendation for Sigrid's medical team, shedding light on the potential benefits and the optimal timing for ECMO initiation.

Advantages and Challenges

While offering promising prospects, the Early ECMO Prediction Model is not without its challenges. Ensuring the quality and diversity of the training dataset is crucial to avoid biases and maintain predictive accuracy. Additionally, the model's performance should be validated across diverse clinical scenarios to guarantee its robustness.

Conclusion

The Early ECMO Prediction Model showcases the transformative potential of AI-guided decision support within Sandman.IC. The model empowers healthcare professionals to make informed decisions regarding ECMO therapy initiation by synergising routinely collected patient data and historical information from collaborating hospitals. This use case epitomises the system's commitment to melding cutting-edge AI technologies with clinical practice, ultimately fostering better patient outcomes and bolstering healthcare efficacy.

2.2 COVID-19 and bacterial superinfection

Scenario

In the midst of the battle against COVID-19, a medical thriller unfolds in the ICU. Meet Rose Green (Figure 5), an 81-year-old female patient who has been bravely fighting the virus for the past week. Just as the medical team thought she was turning the corner, a new challenge emerged. Her heart rate starts racing, her blood pressure becomes erratic, and her once-steady breathing takes on a worrisome rhythm. Dr. Sofia Reyes, an experienced intensivist, senses that something more sinister might be afoot.

Use Case Description

Dr. Reyes has a hunch that Rose's sudden deterioration might be more than just COVID-19 complications. She turns to the Sandman.IC platform, not as a crystal ball, but as a medical detective tool. The platform is designed to analyse patient data like a skilled detective examines clues. It pulls in Rose's vital signs, laboratory results, medical history, and treatment records, forming a comprehensive canvas of her health journey. All this information will be fed into the Early Sepsis Prediction Model on board the Sandman.IC software.

The AI engine in Sandman.IC starts connecting the dots. It knows that bacterial superinfections can stealthily infiltrate even the most resilient patients during their battle with COVID-19. The platform compares Rose's current state to a database of cases extracted from retrospective patient data, drawing on its knowledge of how early sepsis signs can masquerade as mere fluctuations.

As the AI algorithm scrutinises Rose's data, it spots subtle patterns – a spike in inflammatory markers, a history of antibiotic use, and the telltale signs of a possible infection lurking beneath the surface. The platform doesn't just present raw numbers; it tells a story of potential danger.

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Dr. Reyes receives an alert from Sandman.IC. It points out the worrisome signs and hints at the possibility of bacterial superinfection. Dr. Reyes knows she must act quickly. She orders specific diagnostic tests to confirm her suspicions. The platform provides her with a checklist of potential interventions, guiding her with evidence-based suggestions tailored to Rose's unique situation.

As the test results trickle in, the pieces of the puzzle start to come together. The data-driven suspicions are confirmed: Rose is indeed grappling with a bacterial superinfection that, if left unchecked, could escalate into sepsis. Dr. Reyes and her team spring into action, using targeted antibiotics and closely monitoring Rose's response.

In this medical detective story, Sandman.IC isn't a crystal ball, but it's the partner Dr. Reyes needs to uncover the hidden threat and intervene in the nick of time. By using routine patient data, AI analysis, and its ability to spot patterns that escape the human eye, Sandman.IC assists medical teams in staying one step ahead of a formidable foe – early sepsis.

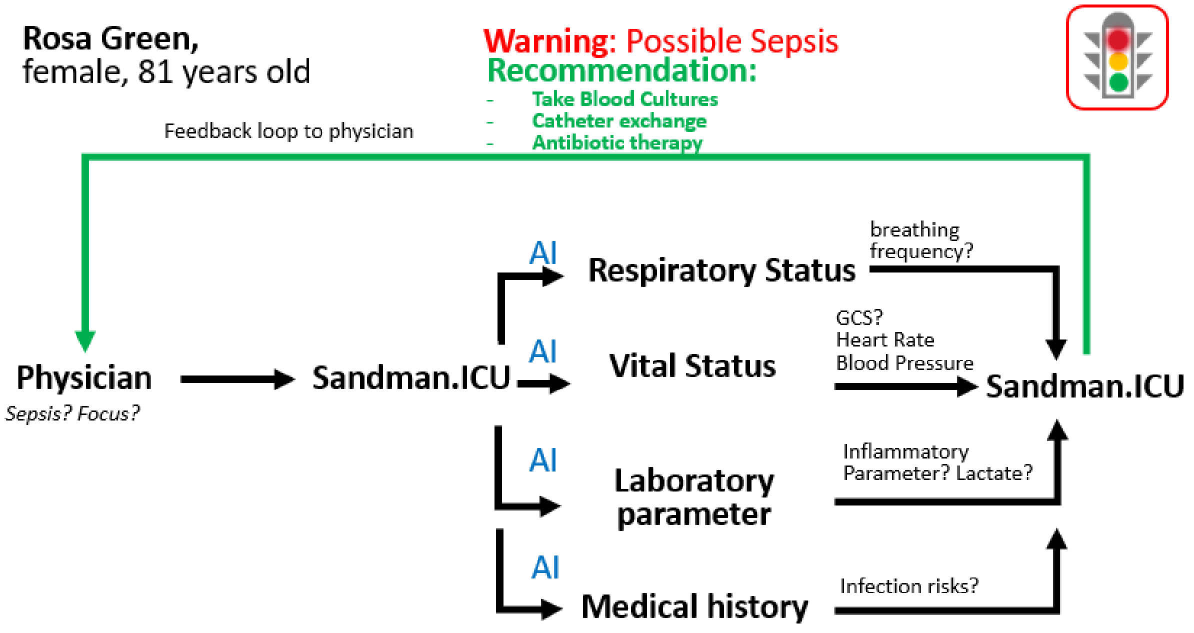

Figure 5: Clinical deterioration of patients is often due to secondary infections (superinfections). In the worst case, these secondary infections lead to sepsis. In such cases, it has been shown that patients benefit from therapy at the earliest possible stage. Sandman.IC can support this process. During the treatment process, the artificial intelligence (AI) analyses the respiratory parameters (respiratory rate), the vital signs (heart rate, blood pressure, Glasgow Coma Scale, etc.) and laboratory values (especially inflammation parameter, lactate, etc.) in the background. However, factors favouring infections such as immunosuppression or previous antibiotic treatments are also evaluated. Since sepsis is a serious illness, the physician is alerted to the need for intervention.

Leveraging Sandman.IC Data

The capacity of the Sandman.IC system for collecting and analysing real-time patient data forms the cornerstone of the Early Sepsis Prediction Model. The model combines 25 different medical parameters, including diastolic and systolic blood pressures, laboratory values such as blood albumin, leukocyte and platelet concentrations for use in the prediction. The Early Sepsis Prediction Model was trained on combined ICU data from GUF, UCLH and University Hospital of Regensburg.

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Benefits

The early sepsis detection use case within Sandman.IC transforms medical mystery into action. By weaving together patient data, AI insights, and the art of medical detective work, the platform empowers clinicians like Dr. Reyes to detect and address bacterial superinfections early. This timely intervention can mean the difference between a dangerous escalation and a triumphant recovery, showcasing how cutting-edge technology and medical expertise can combine forces for the good of patients like Rose Green.

2.3 Guideline-based ventilation

Scenario

Amid the challenges posed by COVID-19, maintaining optimal lung function becomes a critical concern. To ensure adequate oxygenation and mitigate further harm, adherence to carefully designed ventilator protocols is paramount. Extensive research has underscored the benefits of lung-protective ventilation, particularly for patients with Acute Respiratory Distress Syndrome (ARDS).

Patient Case - Jimmy Blue

In the battle against COVID-19, Jimmy Blue (Figure 6) finds himself in need of medical attention. Recognising the urgency, Sandman.IC steps in as a proactive ally to the attending physicians. By harnessing a sophisticated expert system, the platform delivers personalised recommendations for lung-protective ventilation. These recommendations are based on a comprehensive analysis of Jimmy's vital signs, prevailing guideline directives, unique pre-existing conditions, and insights from comparable cases in the Sandman.IC Data Hub.

Implementation Steps

- Expert Model Integration: The first phase involves the seamless integration of an expert model within Sandman.IC's framework. This model operates in accordance with established guidelines for lung-protective ventilation. In real-time, Jimmy's patient data and ventilator settings are meticulously evaluated against the current guidelines. Any deviations or discrepancies are promptly highlighted, ensuring vigilant adherence.
- Advanced Treatment Insights: Beyond conventional guideline adherence, the expert system harnesses a wealth of additional patient data. This includes historical medical records, vital parameters, and specialised measurements like those obtained from techniques such as Electrical Impedance Tomography (EIT) or oesophageal pressure measurements.

Empowering ICU Decision-Making

Sandman.IC's expert system revolutionises ventilation management within the context of COVID-19. By orchestrating a sophisticated interplay between real-time patient data, established protocols, and patient-specific intricacies, the system generates finely tailored ventilation recommendations. These recommendations not only align with best practices but are also attuned to Jimmy's distinct medical history and present condition.

Key Advantages

- Tailored Care: The expert system delivers care that is finely attuned to the unique attributes of each patient, ensuring precision in treatment.
- Rule-Based Precision: Operating on predefined rules and algorithms, the system offers strategic decision-making support to the medical team.

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- **Enhanced Outcomes:** By following the expert system's guidance, healthcare practitioners can potentially enhance lung protection and contribute to favourable patient outcomes.

Conclusion

The utilisation of an expert system for guideline-based ventilation marks a pivotal convergence of medical acumen and cutting-edge technology. This synergy equips medical professionals with the tools needed to make informed decisions, guided by evidence-based protocols and the individual nuances of each patient. In the evolving landscape of healthcare, Sandman.IC's expert system stands as a testament to the potent impact of advanced technology on patient care, exemplified in cases like Jimmy Blue's.

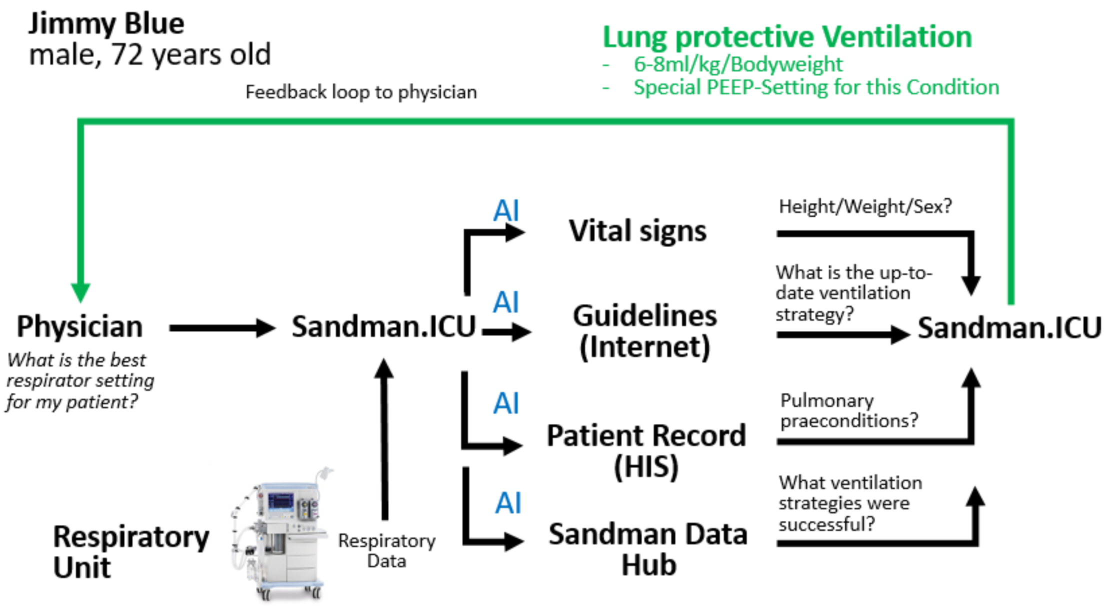

Figure 6: Patients benefit from lung-protecting ventilation. However, this ventilation strategy differs for many clinical syndromes and is significantly influenced by the patients' diseases. Sandman.IC combines data from a wide variety of sources and gives the treating intensivist an AI (artificial intelligence) analysed treatment option. For this use case, patient characteristics in the form of weight, height and gender play a role in addition to ventilation parameters (pressure levels, tidal volume, etc.). The current guidelines, the patient's pre-existing conditions and comparative cases from Sandman.IC database is also included in the recommendation.

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3 Additional Information, limitations and outlook

This document has presented several use cases for which AI could be applicable. All these use cases were created before the data collection from ICUs started. For this reason, it is not clear at this point how much data will be available by the time the ENVISION project is approaching its end and the AI models can be tested. Depending on the amount of data, some use cases may not be implemented, implemented only partially or in a modified form. On the other hand, new use cases can be created at any time depending on clinical needs.

The most successful AI systems rely on the availability of massive amounts of data. A large amount of data enables the generalisations in the AI models and the testing of the methods in a statistically sound manner. For a better understanding of the evaluation of machine learning algorithms for health care applications, reference is made to a recent article co-authored by Mr Mark van Gils from Tampereen Korkeakoulusaatio SR in Finland, one of the parties in ENVISION [14].

For practical reasons, the amount of data will not be massive in the ENVISION project. Simultaneously, the number of variables to be considered is relatively large. This poses the risk that the models cannot always be tuned so well that the results from the AI system are statistically acceptable. To address this risk, an expert system approach is attempted in the use cases that are feasible. In these use cases, efforts are being made in parallel to create rule-based systems based on international and national guidelines and to implement them in the Sandman.IC.

As the AI system is supposed to work in a life-critical environment, the regulatory requirements for its reliable operation are high. For this reason, the use cases with the highest potential to receive regulatory acceptance are preferred in the development work in ENVISION.

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