I-CARE4OLD

INDIVIDUALISED CARE FOR OLDER PERSONS WITH COMPLEX CHRONIC CONDITIONS AT HOME & IN NURSING HOMES

Ethical and Legal Considerations of AI-Based Clinical Decision Support: Insights from a Multinational iCARE-Tool Pilot Study with Healthcare Professionals

EHMA conference 2025

4.6.2025

The ICARE4OLD project has received funding from the European Union's Horizon 2020 Research and Innovation programme, under the Grant Agreement number 965341

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CONFLICT OF INTEREST DISCLOSURE

I have no potential conflict of interest to disclose

Grants from European Union H2020 & Horizon

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Agenda

1. Study background and setting
2. Descriptive results
3. Initial analysis of ethical and legal considerations expressed by the healthcare professionals
4. Discussion and conclusions
5. Publications

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Study background and setting

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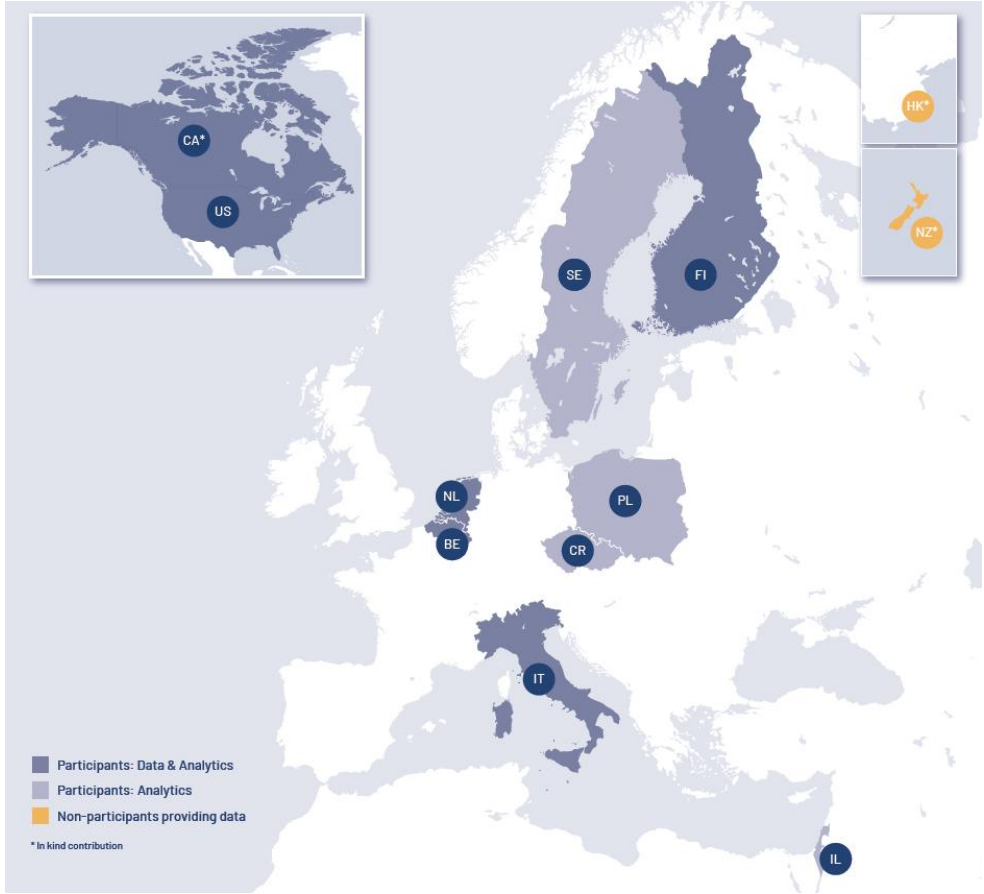
I-CARE4OLD is a multinational EU research project focused on improving the care of older adults with complex health needs, based on interRAI assessments.

- Funded by the European Union, active from 2021 to 2025
- Carried out by an international, multidisciplinary team of healthcare and AI experts
- Aims to improve care for older adults with complex health conditions
- Develops machine learning models to predict adverse health and well-being outcomes
- Delivers a digital decision-support platform for healthcare professionals



Amsterdam UMC University Medical Centers · VU Vrije Universiteit Amsterdam · Università Cattolica del Sacro Cuore · Marcus Institute for Aging Research Hebrew SeniorLife · Harvard Medical School Affiliate · PROFILITY · Karolinska Institutet · thl · Uniwersytet Jagielloński Collegium Medicum w Krakowie · KU LEUVEN LUCAS · EuGMS European Geriatric Medicine Society · Nordic Healthcare Group · Univerzita Karlova · University of Waterloo Faculty of Health School of Public Health Sciences

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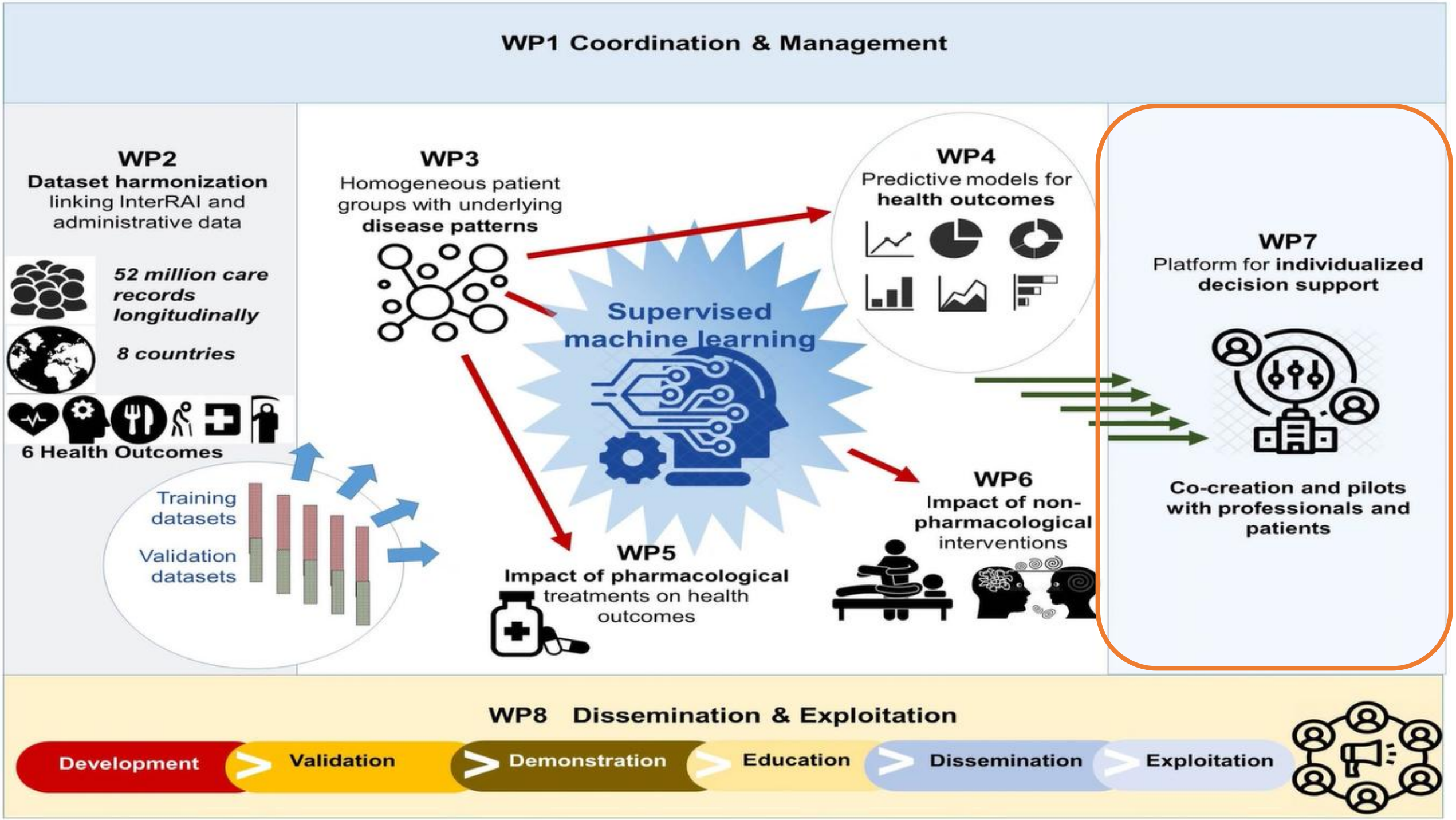
WP1 Coordination & Management
WP2
Dataset harmonization
linking InterRAI and
administrative data
52 million care
records
longitudinally
8 countries
6 Health Outcomes
Training
datasets
Validation
datasets
WP3
Homogeneous patient
groups with underlying
disease patterns
Supervised
machine learning
WP4
Predictive models for
health outcomes
WP5
Impact of pharmacological
treatments on health
outcomes
WP6
Impact of non-
pharmacological
interventions
WP7
Platform for individualized
decision support
Co-creation and pilots
with professionals and
patients
WP8 Dissemination & Exploitation
Development
Validation
Demonstration
Education
Dissemination
Exploitation

Study objectives

1

Development of a platform implementing tools to assess individual risk for patients with multiple chronic conditions, to propose treatment options and estimate their modification of individual risks on specified outcomes

2

Demonstrate the feasibility and end user value through pilot testing the platform and develop an understanding on how the decision support tool changes the professionals' decision making

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Study protocol published in BMJ Open in April 2025

Open access Protocol

BMJ Open

Protocol of the pilot study to test and evaluate the iCARE tool: a machine learning-based e-platform tool to make health prognoses and support decision-making for the care of older persons with complex chronic conditions

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ABSTRACT

Introduction The provision of optimal care for older adults with complex chronic conditions (CCCs) poses significant challenges due to the interplay of multiple medical, pharmacological, functional and psychosocial factors. To address these challenges, the I-CARE4OLD project, funded by the EU-Horizon 2020 programme, developed an advanced clinical decision support tool—the iCARE tool—leveraging large longitudinal data from millions of home care and nursing home recipients across eight countries. The tool uses machine learning techniques applied to data from interRAI assessments, enriched with registry data, to predict health trajectories and evaluate pharmacological and non-pharmacological interventions. This study aims to pilot the iCARE tool and assess its feasibility, usability and impact on clinical decision-making among healthcare professionals.

Methods and analysis A minimum of 20 participants from each of the seven countries (Italy, Belgium, the Netherlands, Poland, Finland, Czechia and the USA) participated in the study. Participants were general practitioners, geriatricians and other medical specialists, nurses, physiotherapists and other healthcare providers involved in the care of older adults with CCC. The study design involved pre-surveys and post-surveys, tool testing with hypothetical patient cases and evaluations of predictions and treatment recommendations. Two pilot modalities—decision loop and non-decision loop—were implemented to assess the effect of the iCARE tool on clinical decisions. Descriptive statistics and bivariate and multivariate analysis will be conducted. All notes and text field data will be translated into English, and a thematic analysis will be performed. The pilot testing started in September 2024, and data collection ended in January 2025. At the time this protocol was submitted for publication, data collection was complete but data analysis had not yet begun.

Ethics and dissemination Ethical approvals were granted in each participating country before the start of the pilot. All participants gave informed consent to participate in the study. The results of the study will be published in peer-reviewed journals and disseminated during national and international scientific and professional conferences and meetings. Stakeholders will also be informed via the project website and social media, and through targeted methods such as webinars, factsheets and (feedback) workshops. The I-CARE4OLD consortium will strive to publish as much as possible open access, including analytical scripts. Databases will not become publicly available, but the data sets used and/or analysed as part of the project can be made available on reasonable request and with the permission of the I-CARE4OLD consortium.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Although the sample size is not large, the pilot includes participants with several clinical backgrounds and from different countries, increasing representativeness and reliability in the findings.
⇒ The mixed-methods design provides the opportunity to gather comprehensive insights and make a thorough exploration of complex issues.
⇒ The main limitation of the study is the early status of the iCARE tool, which does not yet contain a broad range of features and predictions.
⇒ As this is the first evaluation of the tool, feedback will be used to further improve its usability and enhance its predictions.

INTRODUCTION

Optimal care for older patients with complex chronic conditions (CCCs) is challenging.[1–4] Not only do older patients with CCC present with multiple conditions and functional

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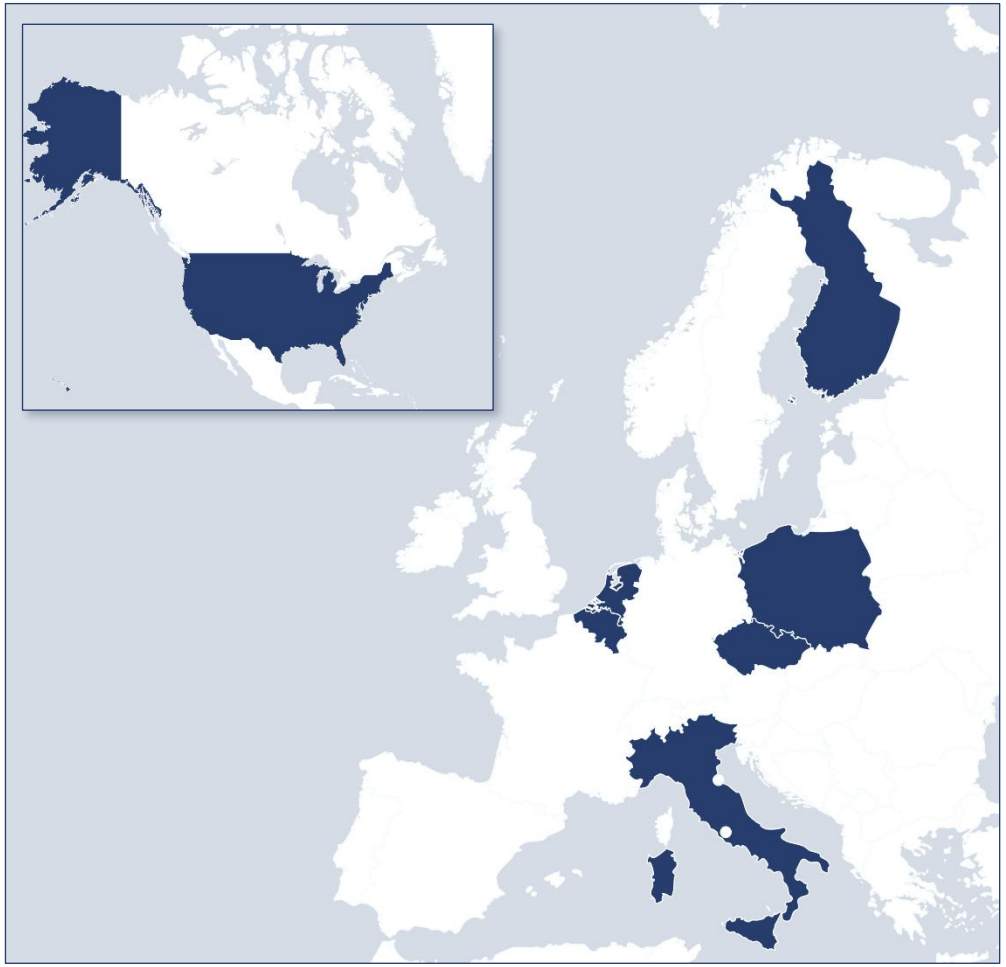
Participating countries



Finland
Netherlands
Belgium
Italy
Poland
Czech Republic
USA

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Research population

INCLUSION CRITERIA

- ✓ Qualified healthcare professionals who are in charge of making or preparing therapeutic decisions (e.g., nurse, physician, physiotherapist)
- ✓ Involved in the care process of patients >=65 years old (with CCCs) in home care or nursing homes
- ✓ Capability to interpret interRAI assessments
- ✓ Experience with utilizing or willingness to utilize interRAI assessments

EXCLUSION CRITERIA

- Unwilling to give informed consent

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Decision loop flow: Finland, Italy, Netherlands, Poland, Czechia

CLINICIAN + RESEARCH FACILITATOR

1. Respond to the pre-questionnaire

The clinician responds to a pre-questionnaire and views e-training material before the pilot

30 min

2. Select one patient case

Clinician selects one patient case at a time

3. Evaluate the case and answer multiple choice questionnaire

The clinician answers multiple-choice questionnaire of patient care

4. View predictions

The clinician views predictions

5. Re-evaluate the case and answer multiple choice questionnaire

The clinician answers same multiple-choice questionnaire of patient care than in phase 3.

45-60 min

6. Respond to the post-questionnaire

Questionnaire will be answered right after the pilot.

20 min

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Study flow without decision loop: Belgium, USA

CLINICIAN	CLINICIAN + RESEARCH FACILITATOR				
1. Respond to the pre-questionnaire	2. Select one patient case	3. Evaluate the case and answer multiple-choice questionnaire	4. View predictions	5. Re-evaluate the case and answer multiple-choice questionnaire	6. Respond to the post-questionnaire
The clinician responds to a pre-questionnaire and views e-training material before the pilot	Clinician selects one patient case at a time	The clinician answers multiple-choice questionnaire of patient care	The clinician views predictions	The clinician answers same multiple-choice questionnaire of patient care than in phase 3.	Questionnaire will be answered right after the pilot.
30 min	30-45 min				20 min

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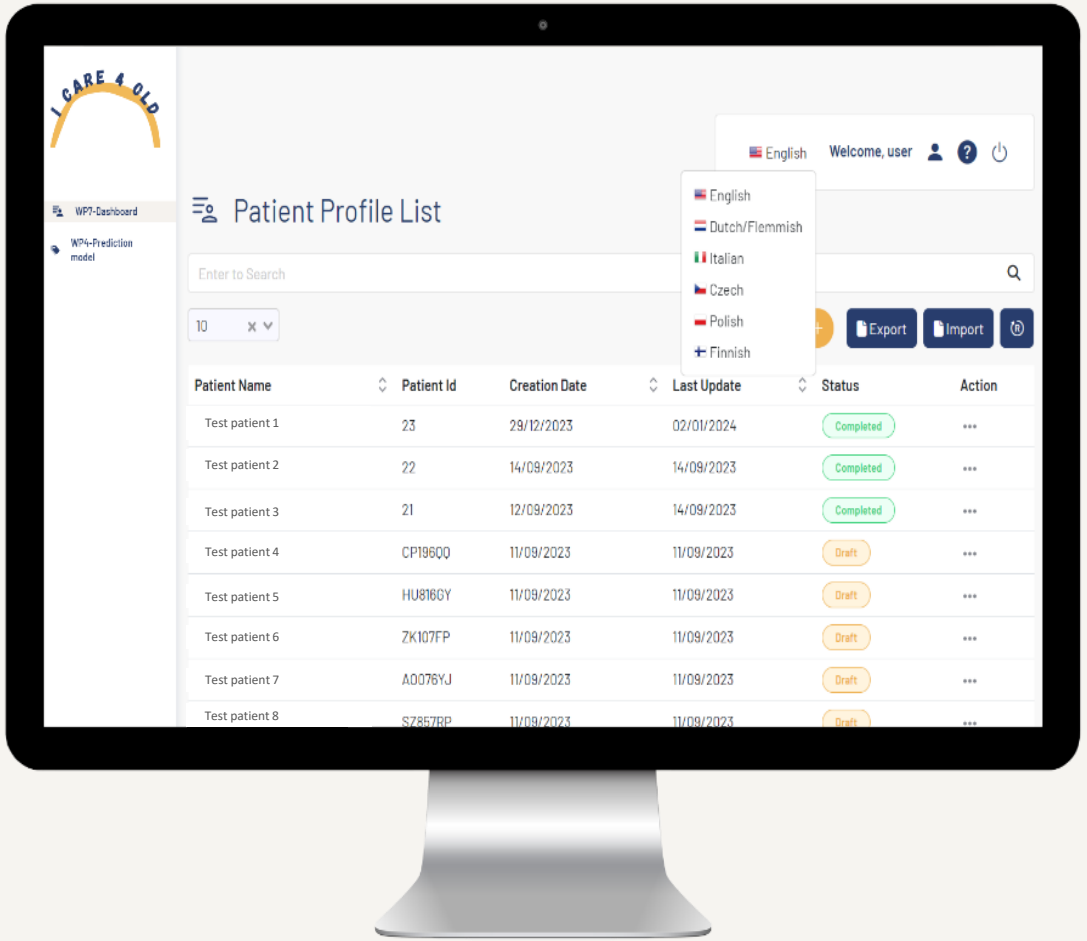
UI of the tested platform



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Descriptive results

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Descriptive results

Item name	All	US	FI	NL	IT	BE	CZ	PL
Participants, n	139	20	20	21	20	19	19	20
Age, mean (std)	46.33 (11.14)	51.55 (10.28)	45.0 (9.03)	38.81 (9.24)	48.45 (6.91)	47.84 (10.4)	46.68 (15.84)	46.45 (11.66)
Gender female, n (%)	101 (72.66%)	19 (95.0%)	19 (95.0%)	14 (66.67%)	9 (45.0%)	15 (78.95%)	8 (42.11%)	17 (85.0%)
Home care, n (%)	63 (45.32%)	10 (50.0%)	11 (55.0%)	11 (52.38%)	10 (50.0%)	10 (52.63%)	1 (5.26%)	10 (50.0%)
Long term care, n (%)	76 (54.68%)	10 (50.0%)	9 (45.0%)	10 (47.62%)	10 (50.0%)	9 (47.37%)	18 (94.74%)	10 (50.0%)
Position - nurse, n (%)	52 (37.41%)	16 (80.0%)	15 (75.0%)	4 (19.05%)	0 (0.0%)	10 (52.63%)	0 (0.0%)	7 (35.0%)
Position - phycisian, n (%)	76 (54.68%)	2 (10.0%)	2 (10.0%)	17 (80.95%)	20 (100.0%)	5 (26.32%)	18 (94.74%)	12 (60.0%)
Position - other, n (%)	11 (7.91%)	2 (10.0%)	3 (15.0%)	0 (0.0%)	0 (0.0%)	4 (21.05%)	1 (5.26%)	1 (5.0%)
Years in clinical practice, mean (std)	18.78 (11.92)	24.65 (13.0)	15.7 (8.35)	12.29 (9.07)	18.2 (6.33)	20.74 (11.71)	23.21 (17.44)	17.3 (11.35)
Years of experience with older adults, mean (std)	16.49 (10.69)	23.1 (14.89)	14.2 (8.95)	11.48 (8.47)	18.3 (6.61)	18.11 (10.22)	13.05 (10.04)	17.35 (10.79)
Have used DSS in work, n (%)	71 (51.08%)	9 (45.0%)	18 (90.0%)	12 (57.14%)	3 (15.0%)	6 (31.58%)	14 (73.68%)	9 (45.0%)
Have used predictions, n (%)	32 (23.02%)	6 (30.0%)	3 (15.0%)	10 (47.62%)	4 (20.0%)	2 (10.53%)	6 (31.58%)	1 (5.0%)

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Initial analysis of ethical and legal considerations expressed by the healthcare professionals

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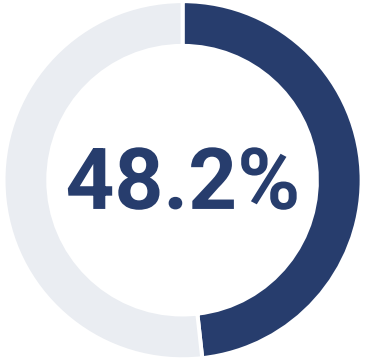
Participants' ethical and legal considerations of the tested tool



of participants (N=67) perceived no ethical or legal concerns regarding the tool's clinical use.

- Czech participants were the most likely to hold this view, while Dutch and Italian participants were the most reserved.
- Participants from other countries fell between these two positions.

Among those who did not perceive ethical or legal concerns, the primary justification was that clinical decisions should always remain the responsibility of healthcare professionals, with the tool serving strictly as a supportive aid.

- Some participants also emphasized the importance of patient and family consent, compliance with medical device regulations, and adherence to information security standards.

Among those who identified ethical or legal concerns, key issues included data security, reliance on AI, prediction reliability, responsibility allocation, patient involvement, and the need for a holistic care approach, which they felt was not fully realized in this pilot.

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Discussion and conclusions

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Discussion and conclusions – preliminary results

We received a good number of participants (N=139), and the participants were evenly distributed across countries.

The participants were evenly distributed between home care and assisted living services experts.

A surprisingly high number – 48.2% of participants – did not see any potential ethical or legal concerns in the tool.

- This was partly explained by the fact that respondents believed clinical decisions should be made by professionals, not computers. They viewed the tool mainly as an aid.

Some participants had concerns about the risk of the approach narrowing from a holistic perspective to focusing solely on individual numbers. In this regard, tool developers and commercializers play a key role in ensuring that employees feel the tools support the broader care process.

CONCLUSION

Preliminary analysis already provides valuable insights and raises critical follow-up questions. Addressing these will be essential before tools like this can be used safely and meaningfully in real-world clinical practice. In particular, a lack of ethical caution in implementation raises serious societal concerns that warrant further investigation—also beyond the health and social care context, for instance through interdisciplinary research in the social sciences.

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Publications

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Publications

	Forum of the publication	Theme of the publication	Authors	Form of the publication	Status of the publication
1	Health and Technology	Systematic review of the performance evaluation of clinicians with or without the aid of machine learning clinical decision support system	Mikko Nuutinen & Riikka-Leena Leskelä	Journal article	Published
2	EuGMS 2024	Pre-pilot and stakeholder engagement	Anna-Maria Hiltunen, Mikko Nuutinen, Mari Lahelma, et al.	Conference	
3	EHMA 2025	Evaluating the Ethical and Legal Considerations of AI-Based Clinical Decision Support: Insights from a Multinational iCARE-Tool Pilot Study with Healthcare Professionals	Anna-Maria Hiltunen, Ira Haavisto, Anna Salminen, et al.		
4	BMJ Open	Protocol of the pilot study to test and evaluate the iCARE tool: a machine learning-based e-platform tool to make health prognoses and support decision-making for the care of older persons with complex chronic conditions	Anna-Maria Hiltunen, Ira Haavisto Mikko Nuutinen, et al.	Journal article	
5	TBC	The impact of healthcare professionals' characteristics on the evaluation of clinical decision support systems: insights from a cross-country usability and feasibility study of the iCARE tool	Mikko Nuutinen, Anna-Maria Hiltunen, Riikka-Leena Leskelä et al.		Manuscript submitted
6	TBD	Feasibility & usability results	Mikko Nuutinen & Anna-Maria Hiltunen, et al.		Analysis in progress
7	TBD	DSS used by healthcare professionals in older aldults care in the context of CCC	Johanna Mello, Collin Exmann et al.		Manuscript in preparation

THANK YOU

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