WHITE PAPER
On Deployment of Stratification Methods

Commission européenne

ASSEHS

ACTIVATION OF STRATIFICATION STRATEGIES AND RESULTS OF
INTERVENTIONS ON FRAIL PATIENTS OF HEALTHCARE SERVICES

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Foreword

The European project, Activation of Stratification Strategies and Results of the interventions on frail patients of Healthcare Services (ASSEHS), is an international attempt to bring together stratification-related professionals from Health Services, Academia and Research centres from European countries to study the current health risk stratification strategies and tools and to undertake the challenges involved in spreading their use and application on frail elderly patients. In this way, the ASSEHS European project intends to contribute to the innovation of care for the ageing population in Europe by generating knowledge on the use of stratification tools at the levels of policy making, healthcare management, clinical intervention and practice. Risk Stratification tools can help identify complex frail and high risk patients and maintain these patients monitored by the Health Services. It constitutes part of a broader area-level strategy on public health.

The ASSEHS project directly tackles the challenge of the deployment of stratification strategies across the EU, to change the way that medicine is used into proactive and targeted interventions adapted to the needs of patients.

The ASSEHS European project is fully aligned with the EIP on AHA and supports the implementation of its Action Plans, especially the B3 Group on «Integrated care». It will contribute to the identification of people at risk of frailty and the implementation of coordinated interventions to improve the quality of life of complex frail patients. The outputs of ASSEHS will pave the way for the development of personalized integrated care and fine tune interventions for frail patients.

ASSEHS has been made possible thanks to the joint efforts of many people. Special thanks must be given to the following: (i) the healthcare professionals, (ii) the patients that have participated in the processes of the different fields of care that have been studied (iii) the managers and policy makers that have been actively involved in providing their knowledge and experience, (iv) the Scientific Advisory Board members who have discussed and provided their insight during the Project lifetime, (v) all members of the Consortium Partners Research teams who have actively pursued the objectives and worked hard to meet deadlines and, last but not least, (vi) our Project Officer who has continuously supported our work.

Esteban de Manuel Keenoy
ASSEHS Project Coordinator
Kronikgune Director

Executive Summary

Chronic diseases and frailty are two hallmarks of ageing that must be considered when trying to improve health for older adults. Chronic diseases are highly heterogeneous, cluster into multi-morbidities and are intertwined with ageing. Frailty is not a disease, but a condition on a continuum that may be reversible, often medically, interlinked with the development and aggravation of some chronic diseases. Multi-morbid and/or frail patients consume up to 50 times more health care resources than non-chronic patients. This is partly due to the reactive and fragmented way in which care is nowadays delivered. It also relates to the particular needs of people with two or more conditions who may find themselves seeking advice from different specialists while also having a continuing relationship with a primary health care team.

European health systems were created to deal with acute health problems. A paradigm shift is needed to accommodate the changing demands for healthcare in our societies. These changes require an encompassing and holistic view, involving all actors and stakeholders in a common framework, creating synergies between providers and avoiding goal conflicts.

To face the challenge of active and healthy ageing (AHA), European Health Systems and services should move towards proactive, anticipatory and integrated care. Health care systems thus need to personalize services, put patients in the centre of care and provide services using the adequate resources. Population health risk management is emphasized through the use of tools to stratify people with chronic diseases according to their risk and offering support commensurate with this risk. Effective screening of frailty is key in optimizing care for frail populations at risk.

Risk Stratification (RS) tools can (i) help to identify complex frail and high-risk patients and maintain these patients on the radar of the Health Services (ii) ensure appropriate coverage of health risk prevention interventions. The systematic screening of groups of people at risk of suffering a disease constitutes part of a broader area-level strategy on public health.

The Activation of Stratification Strategies and Results of the interventions on frail patients of Healthcare Services (ASSEHS) EU project (N° 2013 12 04)i is an international effort to bring together stratification- related professionals from Health Services, Academia and Research in the EU to (i) study current existing health RS strategies and tools, (ii) spread their use and application on frail elderly patients, (iii) minimize deterioration of conditions and/or (iv) prevent emergency or hospital admissions. ASSEHS is in line with Area 4 of the B3 Action Plan of the EIP on AHA.

The ASSEHS consortium, lead by KRONIKGUNE, is enriched by the presence of stakeholders and regions in which the health system is organized in different ways, i.e. general practitioners as public salaried employees, general practitioners' cooperatives or health care models based on private care suppliers and with public and private hospitals providing secondary care. This gave the project a strong focus on European reality and with heterogeneity of input, which is beneficial for the design of patient RS tools that ought to be exportable to different regions and diverse health care models. The analysis of RS in different Health Systems generated conclusions and RS solutions transferable to a variety of regions.

A White Paper on Deployment of Stratification Methods was produced at the end of the ASSEHS project and the present paper represents the executive summary of the White Paper.

Risk stratification tools

Risk stratification tools are predictive models applied to predict future events at clinical and administrative levels in the healthcare domain. They are also used to stratify a population according to a selected metric, such as the likelihood of a future outcome, patient complexity, concurrent or future health care expenditure, etc. In general, predictive models are algorithms (e.g. statistical models, machine learning algorithms, etc.) which provide information about the relationship between a set of parameters, such as age, gender, clinical information, diagnosis, living conditions, district of residence, and the predicted outcome (e.g. readmission to hospital, death, healthcare expenditure, length of stay in hospital, etc.).

In order to facilitate critical and comprehensive comparisons among different RS models, the ASSEHS Appraisal Standard (AS) has been designed. This tool can help policy makers and health care managers for a broader integration of RS tools in European health care systems. A scoping review[1] collected the knowledge and identified the source of information used to design the AS. The web-based AS[2] dashboard allows the user to retrieve the data collected during the scoping review. The dashboard was designed using shinydashboard package within RStudio (RStudio, Inc. 2014).

Risk stratification models were compared in four EU regions (Basque country, Catalonia, Lombardia and Puglia).

Risk Stratification planning and deployment

In order to identify key RS feasibility elements, a scoping review was performed with a focus on barriers and facilitators at the macro, meso and micro levels of the care systems. The relevant elements were organized in a framework proposal which included dimensions and sub dimensions applicable to the feasibility of RS. Further refinement then took place based on the information regarding implementation experience. The scoping review[3] was carried out following five stages (1): (i) Identifying the research question (ii) Identifying relevant studies, (iii) Study selection, (iv) Charting the data, (v) Collating, summarizing, and reporting the results. Following Arksey et al.[4], a "Consultation" was carried out to refine the framework draft.

Planning, deployment and change management is composed of six sub-dimensions:
• The aim of the communication explaining the purpose and outcomes of RS.
• Training and mutual learning which is about the professional becoming competent in the use of RS.
• Multi-disciplinarity of the team leading RS deployment involving health professionals, managers, ICT professionals, epidemiologists and others.
• Professionals´ accountability, commitment and involvement and the ways to ensure that they are linked to the engagement of clinicians.
• The operational plan focusing on definition of action, quality and implementation.
• ICT-Information display and functionalities including the devices and applications used in RS, its support and visualization.

Care intervention has three sub-dimensions.
• Case finding is the selection, identification and enrolment of the target population.
• The pathway definition and implementation includes the intervention with patients and the follow up that should be done.
• Quality assessment and improvement process is related to the monitoring and assessment measures to be applied in the implementation process.

[1] De-Manuel-Keenoy E, David M, Mora J, Prieto L, Domingo C, Orueta J, et al. Activation of Stratification Strategies and Results of the interventions on frail patients of Healthcare Services (ASSEHS) DG Sanco Project No. 2013 12 04. Eur Geriatr Med. 2014;5(5):342-6..
[2] http://assehs.eu//upload/docpublicos/9/assehs_appraisal_standard_d5_wp4_v1.0.pdf
[3] Mora J, De Massari D, Pauws S, op den Buijs J, David M, Prieto L, et al. Selection of the method to appraise and compare health systems using risk stratification: the ASSEHS approach. Aging Clin Exp Res. 2015;27(6):767–74
[4] Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol. 2005;8(1):19–32.

During the implementation process, gaps can be identified and improvements put in place. These changes can affect the functionalities of RS. Understanding how RS is implemented in real practice can help to close the gap between knowledge and practice[5]. Implementation research analyses the adoption of clinical research findings using routine clinical practice in a systematic, widespread, sustainable and continued way[6]. ASSEHS has developed a framework to analyse RS feasibility to be implemented in health services.

A high-quality operational plan establishing the agenda and the strategic goals and objectives for the years to come is needed. Having trained people qualified in RS is necessary[7]. The clinicians' commitment is a sine qua non requirement. Since the clinical group consists of different profiles, a multidisciplinary team should lead the RS deployment[8]. Appropriate ICT is also crucial.

The main uses of RS include the identification of patients, workload distribution, planning and resource allocation. Despite RS functionalities, there are some limitations related to data availability and database lack of dynamism. Understanding barriers and facilitators is crucial for the implementation of improvements. The proposed framework is useful to analyse feasibility and identify improvement areas. For a successful implementation, leadership, internal communication and commitment on behalf of the clinicians are all relevant. At the same time, ICTs should enable clinicians to manage their own lists of stratified and target patients. Cost-effectiveness of the implementation process needs to be further measured.

Impact of Risk Stratification Tools

ASSEHS goals were focussed on three levels of impact: (i) healthcare structures (risk-adjusted resource allocation), (ii) health information systems and health professionals, (iii) processes (stratification of healthcare professionals, efficiency and resource utilisation and quality of care and health outcomes) and results. An analytical framework (the performance management framework) was developed. The analysis of impact was more qualitative than quantitative. A set of qualitative methods was designed to assess the degree of impact on each domain and subdomain identified in the ASSEHS framework. Interventions use RS, but its logic goes beyond predicting adverse events or identifying patients at risk that require collaborative and proactive care. In a nutshell, RS may be a necessary condition but it is not sufficient by itself to cause an impact on healthcare systems. Therefore, we designed a Performance Management Framework combining four different analytical frameworks: Donabedian's quality of care assessment[9], RE-AIM evaluation framework[10], the Triple Aim from the Institute of Healthcare Improvement[11] and Michael E. Porter's Outcome Measures Hierarchy[12].

Assessment for Regional Interventions using risk stratification

In order to generate the lessons learnt and identify improvement areas from ongoing Regional programmes using RS, the ASSEHS project has set up an Intervention Assessment Framework This is expected to assess all the different domains involved in RS: (i) the selection or development of an RS tool, (ii) the implementation plan for an RS tool, and (iii) the impact of the deployment of an RS tool.

The Intervention Assessment Framework (IAF) generated in the ASSEHS project is a heterogeneous set of tools, which can be used to assess Regional interventions based on RS tools. Each tool was targeting different profiles, from RS tool developers, to programme managers, to clinicians, to commissioners, to key informants, etc..

[5] McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, et al. The Quality of Health Care Delivered to Adults in the United States. N Engl J Med. 2003;348(26):2635–45.
[6] Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care. 2012;50(3):217–26.
[7] Johns Hopkins risk tool used in South [Internet]. [cited 2016 Apr 21]. Available from: http://www.digitalhealth.net/news/27490/johns-hopkins-risk-tool-used-in-south
[8] Hoult J, Matheson H. Long-term conditions. Spot future patients to find tomorrow's savings. Health Serv J. 123(6340):26, 28.
[9] Donabedian, A. The quality of care: How can it be assessed? JAMA (1988): 260(12), 1743-1748.
[10] Glasgow RE, Vogt TM, Boles SM. Evaluating the Public Health Impact of Health Promotion Interventions: the RE-AIM Framework. Am J Public Health Health 1999: 89(9)
[11] Berwick, DM., Thomas W. Nolan, and John Whittington. «The triple aim: care, health, and cost.» Health Affairs 2008;27: 759-769
[12] Porter, Michael E. «What is value in health care?» N Engl J Med 2010; 363: 2477-2481

Over 80 indicators were defined and the final list of tools (each of which might span through multiple domains) resulted in:
• 2 surveys (one on the selection/development of RS tools and one on the satisfaction of clinicians)
• 3 interviews (one on the selection/development of RS tools, one on implementation, and one on funding).
• 1 focus group (on barriers and facilitators for the implementation and deployment of RS tools)
• A data collection methodology from Regional Databases

These tools were applied in the four ASSEHS pilot Regions (Basque country, Catalonia, Lombardia and Puglia). The most important discoveries on the best practices and lessons learnt are reported.

Lessons learnt from the ASSEHS project

• Up-front 'buy or build' decision to be made when deploying RS: Building a proprietary solution in-house also requires maintaining and updating it, whenever needed. Buying comes down to license a commercial solution. However, one can learn from deploying a licensed model in a first exploratory phase before making a well-informed transition to an in-house solution. Evidently, this requires substantial professional and monetary resources.
• Lacklustre performance of available RS solutions on the market: Existing solutions are comparable in performance; there is no overall winner. Localization of methods is required for better performance. However, required performance can vary depending on the need at hand: low false positive rate is acceptable in the case of expensive interventions that are beneficial to a restricted sub-cohort of individuals.
• It is vital to bring disparate data sources together for deploying RS to all stakeholders: inpatient, outpatient, pharmacy, GP, claims and other sources.
• Identification of the need and scope of RS. Case finding, risk adjustment or resource planning are different needs that are most likely best served with different solutions. In addition, it is essential to properly choose the predictive model according to the objective of the clinical programme. The success of a clinical programme does not rely only on the performance of the risk model, instead it is based on a combination of the model's accuracy and the appropriateness and cost-effectiveness of the interventions. Identification of complex patients using a double process based on risk score and clinical assessment, as both are complementary and mutually supportive.
• Internal and external validation of RS solutions are crucial to create confidence in performance and generalizability across populations and settings. Communication and training are key elements in the implementation of RS solutions.
• The use of performance metrics allows benchmarking of RS solutions, though standardization on metrics is needed. Quality improvements and efficiency gains are difficult to demonstrate due to the multifactorial nature of healthcare interventions.
• The periodical update of an RS solution is required by monitoring estimated and actual outcomes in the population, demographical trends, prevailing public health issues or healthcare system changes. Monitoring comes down to a regular assessment on population changes (e.g. new people in the region not yet classified, people moving from one stratum to another, etc.). Updating comes down to re-calibrating parameters of the underlying RS model or re-generating a new model.

Ethical issues

Ethical issues may arise when deploying RS including (i) personalised medicine providing an equal access to care, (ii) the benefits and dangers of patient stratification and (iii) ethical considerations of personalized medicine in old age adults. Diverse solutions will be required to protect individual and societal interests but a balance could be reached through well deliberated healthcare policies. Wilson and Jungner[13] principles and criteria for disease screening may also apply for population RS. As an example, is there a recognized need for stratification, or is there beneficial intervention after stratification[14]?

[13] Wilson, J. & Jungner, Y., 1968. Principles and practice of screening for disease. World Health Organization, 65(4), pp.281–393.
[14] Lewis, G.H.. "Impactibility models": Identifying the subgroup of high-risk patients most amenable to hospital-avoidance programs. Milbank Quarterly, 2010; 88(2), pp.240–255

Conclusions

The goal of this White Paper is to spread knowledge about the use of RS tools at policy making, healthcare management and clinical practice levels. The White Paper describes in detail the main barriers which can be encountered when planning and deploying RS tools in a Regional intervention, as well as the facilitators that will help to overcome those barriers, as well as concrete examples of implementation from four pilot Regions participating in the ASSEHS project.

The best practices and lessons learnt from those pilots are supposed to serve as examples for the development of programmes for managing multi-morbidity among complex frail older citizens, and to help policy makers and stakeholders to design, plan, deploy and validate RS in other Regions.

The goal is that this White Paper will support other Regions and healthcare systems in the transformation towards new models of provisioning of proactive and targeted interventions according to the patients' needs.

The key general benefits of using stratification methods can be summarized as:
• A means to provide levels of care that are tailored to an entire population and individual patients, with the proposition to deliver better care to EU citizens with better outcomes and lower costs;
• A means to maximize population/patient benefit at a given level of resources;
• A means to cope with versatility in care delivery by addressing patients across all acuity levels (health risks), accounting for prevalence and progression of different long-term medical conditions and accounting for regional differences in patient case-mix;
• A means to inform policy makers, healthcare commissioners and medical specialists on expected outcome and expected (direct) costs on healthcare resource utilization for various intervention programmes for an entire population or an individual patient.
This White Paper aimed at the following outcomes:
• Increased predictability and reliability of the stratification tools in terms of population selection;
• Better selection of population groups thanks to fine-tuned stratification tools;
• Prevention / delay of onset of physical frailty thanks to customized/integrated interventions for each group of patients according to their specific needs;
• Improved outcomes of the interventions in order to reduce "avoidable emergency admissions" and readmissions and costs;
• Raised public and professional awareness on the use of stratification methods to address the management of multi-morbidity among elderly people;
• Increased capability of detecting physical frailty in older adults in any setting of the health system (community, primary care, hospital, long-term care or social facilities);
• Indicators of frailty that can be exported to other European Health Services.

1- **INTRODUCTION**
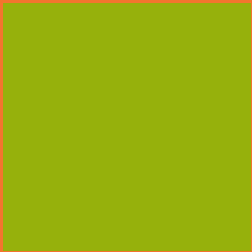
To face the challenge of active and healthy ageing (AHA), European Health Systems and services should move towards proactive, anticipatory and integrated care. Health care systems thus need to personalize services, put patients at the centre of care and provide services using adequate resources. Population health risk management is emphasized through the use of tools to stratify people with chronic diseases according to their level of risk. Effective screening of frailty is vital for optimizing the care of frail populations at risk. The aim of ASSEHS is (i) to study existing health risk stratification strategies and tools, (ii) to spread their use and application on frail elderly patients, (iii) to minimize the deterioration of conditions and/or (iv) to prevent emergency admissions or hospital admissions. The analysis of Risk Stratification in different Health Systems will generate conclusions and risk stratification solutions, which will be transferable to a variety of regions in the future. ASSEHS is in line with Area 4 of the B3 Action Plan of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA).

Problem analysis including evidence based data

Chronic diseases are highly heterogeneous, cluster into multi-morbidities, affect elderly patients in particular and are associated with frailty. Frailty can be defined as a reduced ability to bounce back from physical challenges and as being at greater risk of becoming disabled, dependent and dying earlier than expected. Frail patients show variable progression, poor response to treatment, high co-morbidity rate and represent 70% of health expenditure. Multi-morbid and/or frail patients consume up to 50 times more health care resources than non-chronic patients. This is partly due to the reactive and fragmented way in which care is nowadays delivered. It also relates to the particular needs of people with two or more conditions who may find themselves seeking advice from different specialists while also having a continuing relationship with a primary health care team. In these circumstances, there is a risk of care not being coordinated and of complications arising, for example, through drug interactions resulting from polypharmacy. Around 7 per cent of all hospital admissions have been attributed to, or associated with, adverse drug reactions, with up to two-thirds of these being preventable. Adverse reactions are particularly common among vulnerable groups, such as frail older patients in nursing homes. Evidence from the Commonwealth Fund's surveys underlines the reality of this risk, and the importance of overcoming professional, organizational and financial barriers to the integration of care.

Reviews of available literature on promising strategies for chronic illness management, many of which have derived from experience in European health care systems, highlight that the key elements in the care for chronic patients are: (i) the community, (ii) the health system, (iii) self-management support, (iv) delivery system design, (v) decision support and clinical information systems, with an emphasis on patient safety, care coordination and case management. These broad areas must be considered, but are not a specific set of interventions; rather, this is a framework in which improvement strategies can be tailored to local conditions.

Locally, the care of frail older people with complex conditions will improve only with deliberate intent and planning. Senior leaders should plan integrated pathways of care for older patients with complex needs and should specify them in detail and in advance, using ICTs as support tools in the decision making process and in their design. The care pathways should specify the number of staff and the qualifications and training they need to deliver high quality care for complex frail older people. The specification should be refreshed at regular intervals.

These approaches are especially relevant for frail and multi-morbid patients, since they can diminish or delay the occurrence of unwanted events and improve the patient´s wellbeing and system sustainability. Healthcare systems thus need to personalize their services, put patients in the centre of the system and provide appropriate services using the adequate resources. Population management is emphasized through the use of tools to stratify people with chronic diseases according to their risk and to offer support commensurate with this risk. Effective screening of frailty is a key element in optimizing care for the frail population.

Systematic screening of groups of people at risk of suffering a disease or a disease-related event, ensures secondary prevention forms and constitutes part of a broader area-level strategy in public health. Stratification tools identify complex frail patients that have a high risk of an undesired adverse event in the future. Once these patients have been identified, they can then be monitored. This helps to ensure appropriate coverage of key secondary prevention interventions and processes. Risk stratification also allows an increase in detection rates and the identification of practices where improvement is necessary. Stratifying populations or individuals who may benefit from a customized intervention is a prerequisite of care pathways.

Although various Risk Stratification (RS) tools have been developed, there is a lack of standardized and valid methods to screen for frailty. Current existing risk stratification strategies and tools have not been widely deployed and their ability to predict adverse events is unknown. As a result, very few physicians other than geriatricians routinely evaluate older patients for this condition. The challenge to spread their use not only includes the availability and use of tools, but also includes data requirements and accessibility, adaptation to real life services and clinical practice circumstances and whether or not clinicians accept healthcare structures and processes.

A Health System is an intricate network of health care structures with multiple levels of governance. Using population approaches is not easy due to the fact that each particular organization has specific structures, professional roles and governance schemes. Obtaining different data from a variety of sources for large numbers of patients can be troublesome. There is not a unique model for the screening and stratification of people at risk of suffering frailty. Furthermore, the different configuration of almost any Health System in the world creates even more alternatives.

The analysis of Stratification techniques in different Health Systems and the lessons learnt from the implementation intervention on the four intervention Health Services in ASSEHS (implemented in Basque Country, Lombardia, Catalonia and Puglia) will help generate useful conclusions and solutions transferable to a variety of regions in the future.

What is frailty?

Frailty is a chronic condition of increased vulnerability to the poor resolution of homoeostasis after a stressor event, which increases the risk of adverse outcomes, leading progressively to disability. Socio-demographic changes and the development of more effective therapeutic strategies are modifying disease patterns and increasing the population with chronic disease at risk of frailty.

Frailty is a progressive physiological decline in multiple organ systems marked by loss of function, loss of physiological reserve and increased vulnerability to disease. It is a prevalent and important geriatric syndrome associated with decreased survival. Frailty is considered as an early stage of disability which, unlike disability, is still amenable for preventive interventions and is reversible. Frail elderly persons increase their primary and hospital care utilization before the onset of disability. Frail older adults are vulnerable to poor health outcomes including an increased risk of disability, social isolation and institutionalization. The prevalence of frailty is high in most countries and is expected to increase. This renders frailty prevention and remediation efforts imperative for two complementary reasons: to promote healthier ageing and to reduce the burden on health systems.

Frailty appears to be secondary to multiple conditions using multiple pathways, leading to vulnerability when faced with a stressor. Biological (inflammation, loss of hormones), clinical (e.g. sarcopenia, osteoporosis), and social factors (isolation, financial situation) are involved in the vulnerability process. Many chronic diseases are associated with increasing frailty and functional decline in older people, with concomitant personal, social, and public health implications. Pre-frail subjects have more comorbidity and disability than non-frail subjects. This can be of particular value in eva-

luating non-disabled older persons with chronic diseases. Older people suffering from frailty often receive fragmented chronic care from multiple professionals.

There is an urgent need for the coordination of care and a multidimensional approach in developing interventions aimed at reducing frailty, especially in lower educated groups.

Numerous social factors, generally studied in isolation, have been associated with older adults' health. Social vulnerability has an important independent influence on older adults' health. Frailty is experienced by the homeless and other vulnerable populations. Multi-morbidity is one of the key causes of frailty and in this project we are using it as a proxy.

Risk Stratification tools can help to identify complex frail and high-risk patients and can maintain these their monitoring through the Health Services across the continuum of care. Risk Stratification helps to ensure an appropriate coverage of key secondary health risk prevention interventions, including managing disease stratification registers systematically by modelling expected versus actual prevalence and incidence, and thereby identifying practices where improvement is necessary. The systematic screening of groups of people at risk of suffering a disease constitutes a part of a broader area level strategy on public health.

What is ASSEHS?

As mentioned above, the Activation of Stratification Strategies and Results of the interventions on frail patients of Healthcare Services (ASSEHS) EU project (N° 2013 12 04) is an international effort to bring together stratification-related professionals from Health Services, Academia and Research in the EU to face the challenge of active and healthy ageing through proactive anticipatory and integrated care.

ASSEHS is in line with the B3 Integrated Care Action Plan of the European Innovation Partnership on Active and Healthy Ageing. Ultimately, ASSEHS will contribute to the innovation of care for the ageing population in Europe. It will generate knowledge on the use of stratification tools at policy making, healthcare management and clinical practice levels. But it will also increase knowledge on how to widen the use of stratification tools (methodologies and solutions to barriers) that will come as a consequence of the implementation of stratification tools and models. ASSEHS will directly tackle the challenge of the deployment of stratification strategies across the EU, in order to change the way of practicing medicine into proactive and targeted interventions according to the needs of those patients.

2- RISK STRATIFICATION TOOLS
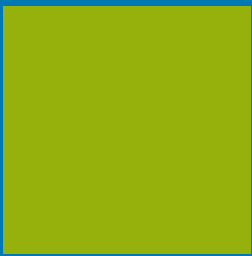
Key take-away messages

• The up-front 'buy or build' decision needs to be made when deploying risk stratification. Building a proprietary solution in-house also requires maintaining and updating it, whenever needed. Buying requires simply to purchase the license of a commercial solution. However, one can learn from deploying a licensed model in a first exploratory phase before making a well-informed transition to an in-house solution. Evidently, this requires substantial professional and monetary resources.

• Lacklustre performance of available RS solutions on the market. Existing solutions are comparable in performance; there is no overall winner. Localization of methods is required for better performance. However, required performance can vary depending on the need at hand: low false positive rate is acceptable in the case of expensive interventions that are beneficial to a restricted sub-cohort of individuals.

• Ethical issues may arise when deploying RS: equal access to care due to pitfalls in stratification, Wilson and Jungner[15] principles and criteria for disease screening may also apply for population risk stratification: for instance, is there a recognized need for stratification, or is there beneficial intervention after stratification[16]?

• It is vital to bring disparate data sources together for deploying RS: inpatient, outpatient, pharmacy, GP, claims and other sources.

• Identify the need and hence scope of risk stratification. Case finding, risk adjustment or resource planning are different needs that are most likely best served with different solutions. In addition, it is essential to properly choose the predictive model according to the objective of the clinical programme. The success of a clinical programme does not rely only on the performance of the risk model, instead it is based on a combination of the model's accuracy and the appropriateness and cost-effectiveness of the interventions.

• Internal and external validation of RS solutions are crucial to create confidence in performance and generalizability across populations and settings.

• The use of performance metrics allows benchmarking of RS solutions, though standardization on metrics is needed.

• The periodical update of a RS solution is required by monitoring estimated and actual outcomes in the population, demographical trends, prevailing public health issues or healthcare system changes. Monitoring comes down to a regular assessment (such as every six months) on population changes (e.g. new people in the region not yet classified, people moving from one stratum to another, etc.). Updating comes down to re-calibrating parameters of the underlying RS model or re-generating a new model.

Risk stratification tools - Why and How

Risk stratification tools are predictive models applied to predict future events at a clinical and administrative level in the healthcare domain. They are also used to stratify a population according to a selected metric, such as the likelihood of a future outcome, patient complexity, concurrent or future health care expenditure, etc. In general, predictive models are algorithms (e.g. statistical models, machine learning algorithms, etc.) which provide information about the relationship between a set of parameters, such as age, gender, clinical information, diagnosis, living conditions, district of residence, and the predicted outcome (e.g. readmission to hospital, death, healthcare expenditure, length of stay in hospital, etc.). The output of the RS can be a categorical variable (e.g. low, medium, high risk): i) the probability of an event occurring (e.g. the likelihood to be readmitted to hospital in the first 30 days after discharge), ii) a number indicating an amount of money, such as the expected healthcare expenditure for the following year, or iii) an amount of days, such as the expected number of days spent in hospital. According to the predicted outcome and its application, one might define different groups of RS. Models deployed for "case finding" aim at identifying top high-risk, high-need or high-cost patients, usually patients located above the 95th or 99th percentile. Those patients are then

[15] Wilson, J. & Jungner, Y., 1968. Principles and practice of screening for disease. World Health Organization, 65(4), pp.281–393.
[16] Lewis, G.H., 2010. "Impactibility models": Identifying the subgroup of high-risk patients most amenable to hospital-avoidance programs. Milbank Quarterly, 88(2), pp.240–255.

assigned to tailored programmes designed to prevent the adverse event predicted by the RS. An additional approach comprises the stratification of the entire population according to the outcome of the RS (e.g. risk of being readmitted/ or dying in the next 30 days / 1 year, expected length of stay in hospital, etc.). As a consequence, the healthcare organization can design a programme addressing each stratum of the population differently: for instance, low-risk patients can receive preventative instructions and medium-risk patients can be assigned with self-management programmes to increase their empowerment and disease awareness, whereas high-risk patients can receive targeted interventions. On the other hand, risk-adjuster tools are used to adapt insurance premiums, payment for healthcare plans, healthcare reimbursement, etc. and to reflect the health status of plan members[17]. "Risk-adjustment" methods aim at providing a data-driven method for a fair distribution of healthcare resources based on the clinical complexity of the patient. For instance, these tools prevent healthcare plans to avoid the enrolment of patients generating high healthcare costs, and allow healthcare providers to receive the necessary reimbursement. This reflects not only the number but also the "complexity" of the patients enrolled. Similarly, RS can be deployed for resource planning, guiding the distribution of healthcare resources according to the risks, needs or costs as estimated in the populations within a region. Finally, predictive models can be used to steer capital investments predicting the future needs of a population in terms of facilities (e.g. hospital beds), services and instruments (e.g. new MRI scanner) or for regional comparison.

Another crucial concept in the domain of RS is represented by the data fed into the RS. Not only must data be available during the design and development of the predictive model, but their availability must also be assured during the deployment of the RS. In other words, the selection of a RS highly depends on the data sources available and this aspect can considerably reduce the number of models on the market suitable for the selected scenario. That is why a great effort has been made in all four ASSEHS partner regions in order to either build a unified and centralized database or create a reliable linkage between the different available databases (e.g. prescription database, hospital electronic medical records, GP electronic records, etc.) where all the parameters needed by the RS are stored. Moreover, this activity facilitates future maintenance and updating tasks, such as recalibration, regeneration, reclassification, etc. of the RS.

All the issues described so far, along with other aspects (e.g. associated costs, licenses, training of personnel, etc.), have a great influence on the choice of the RS: one can either choose from the RSs already on the market, freely available or under license, or develop a new RS. In the latter case, higher predictive performances are expected but one has to assume that one has domain experts in the organization (as was the case in Puglia and Lombardia). On the other hand, one can think of another approach where first a proprietary model is purchased so that professionals can not only acquire knowledge in the field but can also focus more on administrative aspects (e.g. database linkage, ICT platform creation, integration of the RS output in the clinical workflow, etc.). In a second phase, all the lessons learnt in the previous step can be capitalized on and an in-house model can be designed which will be fully adapted to the present scenario. A clear example is offered by the Catalonia region which initially deployed Clinical Risk Groups (CRG) from 3M. In a more mature phase of its programmes, the region designed and developed its own morbidity grouper, Morbidity-Adjusted Groups (GMA in Catalan), achieving better predictive performances (see the section dedicated to the RS deployed in Catalonia).

An important aspect of RS models is represented by the predictive performance of how accurately the model predicts the outcome. A performance assessment not only allows a comparison between different models in terms of their predictive accuracy but it also allows one to compare the performance of the selected model in different scenarios. In the "case finding" scenario, one should assess how well the RS separates high- and low-risk patients, as high discrimination is needed to classify patients into two different subpopulations. The most popular metrics are areas under the curve (AUC), as well as sensitivity, specificity, and positive predicted value (PPV) at meaningful thresholds for case finding tools. In the case of continuous outcomes, like expected healthcare costs, one might be interested

[17] Winkelman R, Mehmud S. A comparative analysis of claims-based tools for health risk assessment. Society of Actuaries. 2007; 1-70.

in the model fit, that is how well the model explains the variance in the data. For this purpose, metrics such as R2 or adjusted-R2 are used to measure the discrepancy between the expected and predicted outcome. Finally, a RS can be evaluated in terms of the improvement it generates in the clinical decision process: does the RS allow for improved decision making by trading off potential harms such as false-negatives (i.e., patients erroneously classified as low-risk patients) and false-positives (i.e., patients erroneously classified as high-risk patients) from potential benefits? Does the RS allow for outcome improvement or cost savings or both (cost-effectiveness) when deployed in practice, triggering specific intervention programmes? Additionally, the validation of a RS should be performed not only internally but also externally using data collected in a different healthcare environment. These activities facilitate the transmission of RS and provide further insights concerning the generalizability of the model as well as ideas for prospective improvements. For instance, both the Catalonia and Puglia regions have already conducted an internal validation of their RS models and are planning to perform external validation. In the case of Catalonia, these activities have paved the way to the deployment of GMA in other Spanish regions.

Possible implication for the deployment of RS

Risk-adjuster models can be subject to manipulation by healthcare providers if specific inputs are used in the predicted model which allow a provider, for instance, to inflate the reimbursement for patients by altering the patients' clinical data[18]. This practice is called gaming and can be prevented by disregarding a particular model's inputs which makes the RS less prone to gaming but inevitably decreases its predictive performance. This issue is less prominent for "case finding" models and it suggests addressing "case finding" and "risk adjustment" by different RS . Moreover, the relationship between the healthcare expenses (studied by the risk adjuster) associated to a patient and the fact that she/he could benefit from a specific intervention (aim of "case finding") is not trivial and not captured by risk adjusters.

Inevitably the use of RS evokes equity issues. A bias must not be introduced in the RS design when used to identify patients eligible for specific intervention[19]. For instance, RS which relies on patients' past claims or clinical history cannot be used for patients with no prior data, hence their risk score cannot be determined. This is the case of new enrolees in managed programmes or patients with no, or intermittent, access to care. The same applies to RS based on pharmacy consumption which also includes purchased drugs as proxy for high risk, as patients with financial issues might be misclassified[19].

The use of RS outputs can have an impact not only on the health status of the population but also on the healthcare system. These changes need to be reflected in the design of the RS which has to be updated continuously in order to adapt to the new scenario.

The ASSEHS Appraisal Standard for Risk Stratification tools

In order to facilitate critical and comprehensive comparisons among different RS models, the ASSEHS Appraisal Standard (AS) has been designed. This tool is expected to provide meaningful insight to policy makers and health care managers and guide them towards a broader integration of RS tools in European health care systems.

A scoping review[20] has been carried out to collect the knowledge and to identify the source of information used to design the AS[21]. The latter is comprised of those features that help to unequivocally describe a RS model and the scenario where it has been deployed and tested. Therefore, not only the performance of the models is considered (e.g. discriminative power, predictive capacity, etc.) but also the implementation requirements (e.g. data and health

[18] Schone E, Brown R. Risk Adjustment: What Is the Current State of the Art and How Can it Be Improved? Mathematica Policy Research. 2013.
[19] Shadmi E, Freund T. Targeting patients for multimorbid care management interventions: the case for equity in high-risk patient identification, International Journal for Equity in Health 2013, 12:70.
[20] Mora J, et al. Selection of the method to appraise and compare health systems using risk stratification: the ASSEHS approach. Aging clinical and experimental research. 2015: 767-774.
[21] http://assehs.eu//upload/docpublicos/9/assehs_appraisal_standard_d5_wp4_v1.0.pdf

information system specifications) as well as the predictors used to derive the risk score (e.g. clinical, socio-demographic, pharmacy data, etc.). Moreover, the AS also considers the information regarding the study which introduced and tested the model, and the population's characteristics upon which the model was applied. Therefore, different dimensions have been identified to drive the appraisal of an RS model. For instance, the AS uses the classification of healthcare systems proposed by Böhm and colleagues[22]. The AS will support exhaustive reports on both existing and future stratification techniques for complete and transparent documenting. Undoubtedly, this tool will ease the comparison among different stratification methods and facilitate their broad deployment.

On the one hand, the scoping review facilitated the generation of the AS framework (i.e., the data model comprising all the dimensions and properties to unequivocally and comprehensively describe an RS model). On the other hand, it enabled the collection of the information related to the validation of stratification tools in different populations that have been published either in publically available reports or in peer-reviewed journal articles. This activity led to the generation of a knowledge base reporting the description of any RS encountered in the scoping review as well as an outline of the scenario in which those tools were evaluated in accordance to the AS framework. This information is accessible via the ASSEHS AS dashboard.

The ASSEHS Appraisal Standard dashboard

The AS dashboard[23] is a web-based dashboard which allows the user to retrieve the data collected during the scoping review. The dashboard has been designed using shinydashboard package within RStudio (RStudio, Inc. 2014). It contains different tabs, each allowing the user to refine the selection of the information from the knowledge base according to specific criteria. During the ASSEHS project, a workshop was organized to introduce the AS framework to the ASSEHS consortium and the members of the Stakeholder Advisory Board (SAB) as well as to collect those potential questions around RS to which the dashboard might give an answer. Each tab of the dashboard is dedicated to one or a combination of questions/issues as defined during the workshop.

Among other things, the dashboard was designed to provide:
• a suggestion to healthcare managers on the best-in-class RS for a specific setting;
• a useful tool for RS designers and researchers to benchmark their own tools;
• a source of information (e.g. a list of references) for healthcare professionals.

The current version of the dashboard allows the user to investigate and filter the RS tools appraised and stored in the knowledge base from three different perspectives: (i) the outcome predicted by the RS, (ii) the predictors set, required as input by the RS and (iii) the healthcare system category within which the RS has been evaluated. Each of these perspectives has a dedicated tab (see Figure 1) where the user can conduct the search and visualize the results. In addition, the dashboard is comprised of two tabs by which the user can have a more detailed overview of all the RSs appraised as well as the study settings in which they were evaluated.
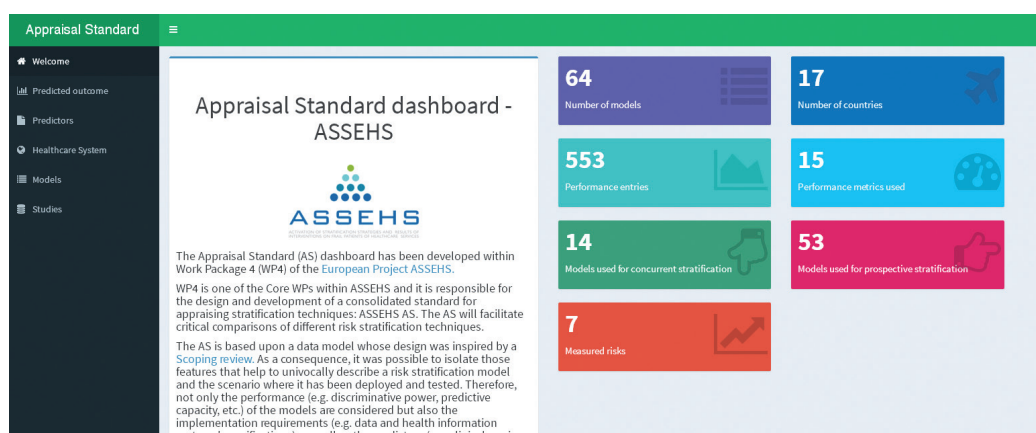

Figure 1:
Screenshot of the welcome page of ASSEHS Appraisal Standard dashboard.

[22] Böhm, K. et al., 2013. Five types of OECD healthcare systems: Empirical results of a deductive classification. Health Policy, 113(3), pp.258–269.
[23] http://assehs.eu:3845/appraisalstandard/

The risk stratification tool deployed in the Basque Country

Overview

Region name: Basque Country.

Health care system: National Health Service.

Size of target population: Approximately 2.000.000, all patients in the region are targeted by the risk stratification tool.

Aim: case finding for appropriate interventions and optimization of healthcare resources.

RS output: next year's healthcare costs.
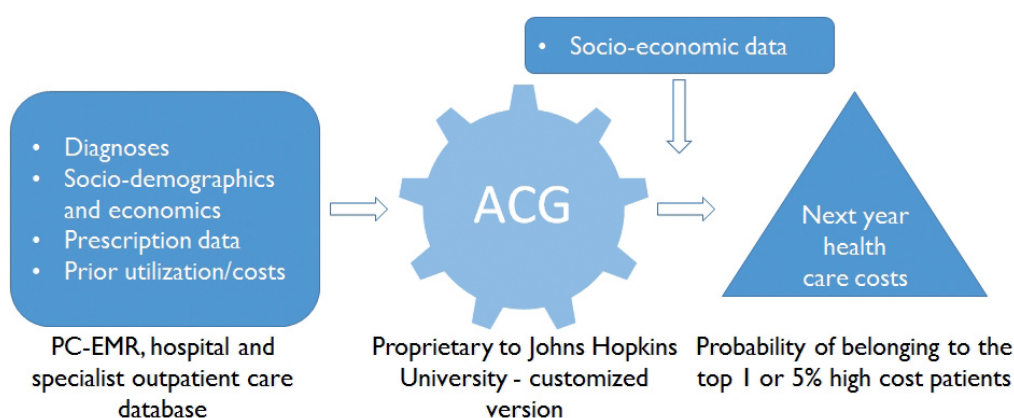
Figure 2: The diagram provides an overview of the data input, risk stratification model selected and model's outcome in the Basque Country.

The risk stratification model

Within the Basque Country healthcare system, a customized version of the Adjusted Clinical Groups Predictive Model (ACG-PM) has been in use since October 2015. The ACG case-mix system was developed at Johns Hopkins University and the Department of Health and Consumer Affairs of the Basque Government has purchased a license via IASIST. The above-mentioned RS is applied in all the districts of the Basque Country: namely, Álava (capital: Vitoria-Gasteiz), Biscay (capital: Bilbao) and Gipuzkoa (capital: Donostia-San Sebastián).

The implementation and successive deployment of a risk stratification in the Basque Country had two main aims:
• case finding
• risk adjustment and capitative payment.

Despite the fact that the RS has already been deployed for case finding purposes, some research activities are currently being performed in order to improve the final outcome of the procedure. The use of RS for risk adjustment and capitative payment has been investigated but not yet deployed.

The outcome (dependent variable) generated by the Basque Country RS is the predicted next year healthcare costs. Then population is classified in four groups according to the presence or not of a chronic disease, 95th percentile of healthcare costs is used and only for chronic population. Two different thresholds are being considered

for next year's healthcare expenditures which will involve dividing the population into low- and high-cost patients: 95th and 99th percentiles of healthcare costs. This was used only to assess the goodness of the tool, but actually only 95th percentile is used and only for chronic population. The RS is based on predictive modelling using regression techniques, and both the calibration and internal validation of the model have been performed using the data (standardized costs of admissions, visits and procedures provided to each patient) recorded in 2008 and 2009 from more than 2 million patients from the Basque Country. Additionally, the development, validation and related results are described in a peer-reviewed article[24].

Deployment and maintenance

The RS is deployed to stratify the entire population of the Basque Country with a special focus on the top 5% high-cost chronic patients with respect to next year's health costs. The risk score provided by the RS is meant to be deployed in emergency room visits, hospital admission and general practitioner visits.

The RS tool is deployed at a regional level where the entire population of the patients (approximately 2 million) is stratified every two years to identify the top 5% high-risk patients for appropriate programmes. Concurrently, the research team performs periodic evaluation and optimization of the RS model. In that respect, the model is recalibrated (i.e., the parameters of the predictive model are recalculated) and slight changes are introduced in the set of independent variables used as input to the RS model. Those activities are performed during refinement of the stratification strategy and associated programmes in the region.

ACG-PM software is employed to assign each patient to one of 34 mutually exclusive categories. The final logistic regression model, which receives as input the ACG category, previous cost, socio-economic and demographic variables, was developed and evaluated using SAS software (SAS Institute Inc., Cary, NC, USA) up to 2012 and, as from then, using SPSS software (SPSS Inc., Chicago, IL, USA). Currently, it is still undecided if the RS tool which was developed and validated in the Basque Country will be available to other healthcare organizations or institutions.

The implementation and deployment of a RS model in the Basque Country provided the basis for the design of interventions targeting the subpopulation identified by the RS model. Additionally, the linkage between different data sources (please see following section) not only increased the predictive performance of the model but also gave rise to other opportunities (e.g. epidemiological research, economic evaluation of programmes, etc.) within the healthcare system of the Basque Country.

Input data for the stratification tool

The RS in the Basque Country uses data retrieved from primary care electronic medical records (PC-EMR) as well as from hospital and specialist outpatient care databases. More specifically, the RS model is based on the following categories of data used at different levels in the risk generation process:
• diagnoses (from each contact with primary care, hospital admissions and day hospitals)
• socio-demographics (age, sex)
• pharmacy data (prescription data from PC-EMR)
• prior utilization obtained directly from PC-EMR, hospital admissions and specialist outpatient care information databases
• socio-economic data (census area of residence/deprivation index from MEDEA project).

[24] Orueta JF, Nuño-Solinis R, Mateos M, Vergara I, Grandes G, Esnaola S. Predictive risk modelling in the Spanish population: a cross-sectional study. BMC Health Serv Res. 2013 Jul 9;13:269.

The patients' data confidentiality is ensured via the use of an opaque identifier inside the Basque Country population stratification programme (PREST) database.

The following tasks and procedures are considered during the preparation of the data before being integrated into the model:
• Data pre-processing: automated
• Data lag: 3 months
• Data quality check: manual and automatic
• Missing data: not applicable
• Outliers: not applicable
• Data cost: no direct cost (only professionals' work load).

Performance of the model

The predictive performance of the model has been assessed using different metrics: namely, coefficient of determination (R^2), positive predictive value (PPV), negative predictive value (NPV), sensitivity, specificity and c-Statistic or area under the receiver operating characteristic (ROC) curve (AUC).

A peer-reviewed article reports the results for the RS model herein described and offers a comparison with other available classification systems (i.e. Diagnostic Cost Groups/Hierarchical Condition Categories and Clinical Risk Groups).

Figure 3 reports a summary of the results achieved by the RS model. In this scenario, R^2 refers to the amount of cost variability in the data which is explained by the model. The linear regression model was tested using different sets of input variables in order to evaluate their contribution to the overall predictive capability of the model. The highest R2 (0.260) was achieved when age, sex, diagnoses, prescriptions, previous costs and deprivation index were used as independent variables.
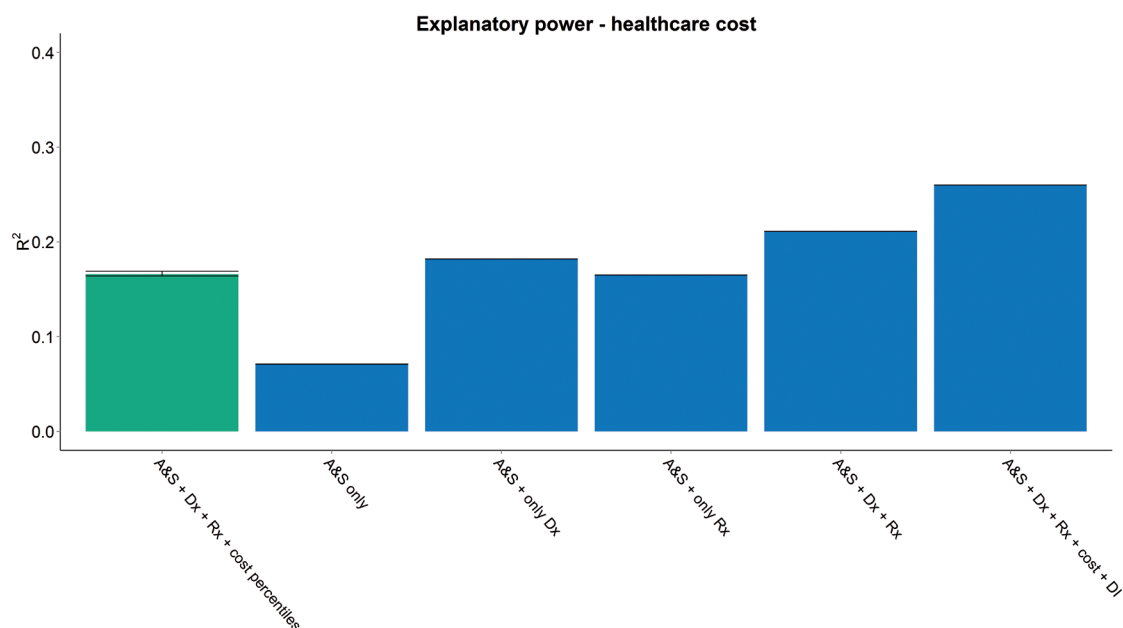
Figure 3: The graph reports a summary of the results achieved by the RS model in terms of cost variability explained. The green bar indicates the mean R2 achieved when the model was tested without a previous calibration on the local data (error bar spans over min-max range, only for green bar). The blue bars are used to report the results of the model with recalibrated parameters. A&S, Dx, Rx, cost and DI refer to age and sex, diagnoses, prescriptions, previous costs and deprivation index, respectively.

The RS tool developed in the Basque Country and deployed at a regional level aims at identifying patients that will incur high healthcare costs the following year. To this extent, a logistic regression model has been developed to classify patients into high- or low-cost patients. More specifically, two different thresholds were used to label high-cost patients: 95th percentile (5% of highest-consuming patients) and 99th percentile in terms of cost (1% of highest-consuming patients).

In this setting, the predictive ability of the model was measured in terms of area under the ROC curve. Figure 4 reports the AUC yielded when the logistic regression model was classifying patients as belonging to the 5% of highest-consuming patients or not. Different independent variable sets were evaluated with the most complete set (i.e., age, sex, diagnoses, prescriptions, previous costs and deprivation index) yielding the highest AUC (0.868).
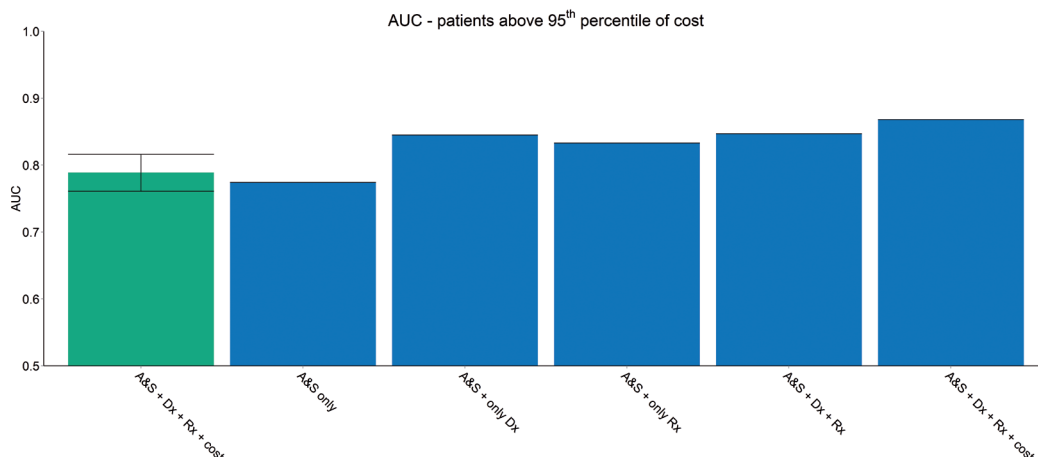
Figure 4: The graph reports a summary of the results achieved by the RS model in terms of ability to discriminate between high- (above 95th percentile) and low-cost patients. The green bar indicates the mean AUC achieved when the model was tested without a previous calibration on the local data (error bar spans over min-max range, only for green bar). The blue bars are used to report the results of the model with recalibrated parameters. A&S, Dx, Rx, cost and DI refer to age and sex, diagnoses, prescriptions, previous costs and deprivation index, respectively.

Figure 5 reports the AUC yielded when the logistic regression model was classifying a patient as belonging to the 1% of highest-consuming patients or not. Different independent variable sets were evaluated with the most complete set (i.e. age, sex, diagnoses, prescriptions, previous costs and deprivation index) yielding the highest AUC (0.897). We refer the reader to the peer-reviewed article9 for a complete overview of the performance and comparison assessment.
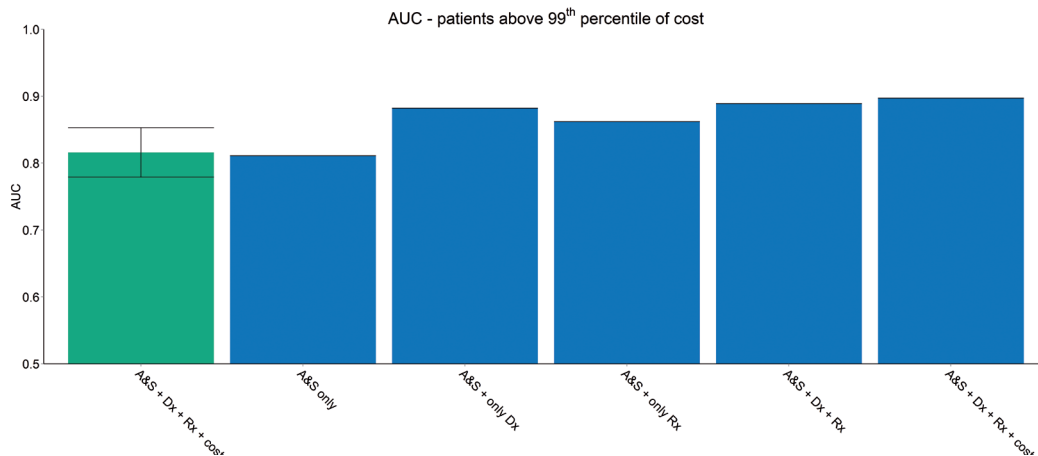
Figure 5: The graph reports a summary of the results achieved by the RS model in terms of ability to discriminate between high- (above 99th percentile) and low-cost patients. The green bar indicates the mean AUC achieved when the model was tested without a previous calibration on the local data (error bar spans over min-max range). The blue bars are used to report the results of the model with recalibrated parameters. A&S, Dx, Rx, cost and DI refer to age and sex, diagnoses, prescriptions, previous costs and deprivation index, respectively.

The risk stratification tool deployed in Catalonia

Overview

Region name: Catalonia.

Health care system: National Health Service.

Size of target population: approximately 7.500.000, the entire population in Catalonia region is stratified.

Aim: case finding for appropriate interventions, optimization of healthcare resources' allocation (e.g. including risk adjustment) and benchmarking.

RS output: expected cost of a given patient/average cost of the population, called Risk Prediction Index.
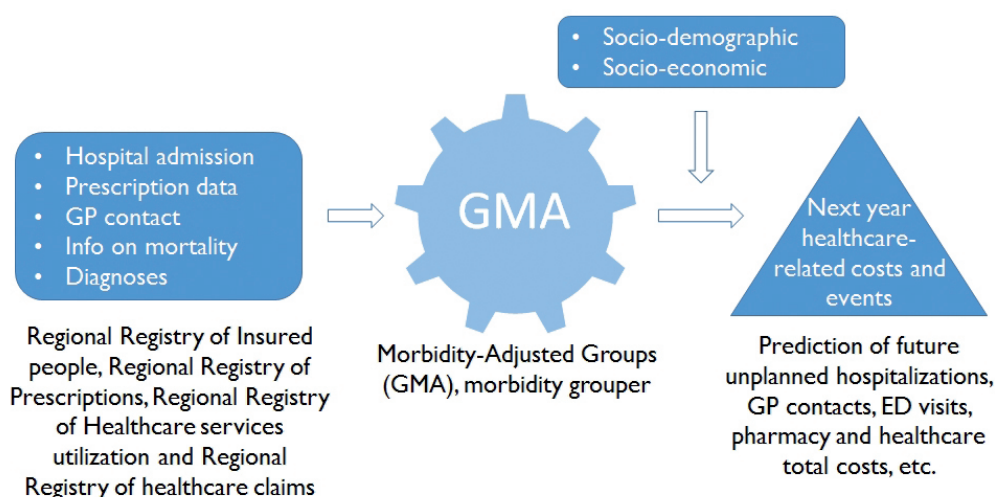
Figure 6: The diagram provides an overview of the data input, risk stratification model selected and model's outcome in Catalonia region.

The risk stratification model

Until the end of 2014, the risk stratification (RS) tool used by the Catalan Institute of Health (ICS, the main healthcare provider in Catalonia) was the CRG from 3M (a license has been purchased). Concurrently, another RS tool had been designed and implemented in the region in collaboration with CatSalut, the Catalan healthcare commissioner: named GMA.

In 2011, Catalonia initiated a new healthcare programme called PPAC (Prevention and Chronic Care Programme). Its aim was to improve the quality of care provided to complex chronic patients and to refine the provider payment mechanism in order for it to acknowledge the heterogeneity in the patient population in terms of clinical complexity. Its ultimate goal was to guide the health system towards better chronic care. RS was seen as a resourceful tool to achieve PPAC goals. Initially, CRG was deployed to stratify the population. It was used to identify complex chronic patients, who require a personalized intervention, and to define the risk-adjusted reimbursement in primary health-care contracts. In this respect, since early 2015, all primary care contracts have been issued based upon risk-stra-

tified populations. In the same period, GMA has been deployed to achieve those objectives. PIAISS represents the continuation of the PPAC programme and it investigates the use and recalibration of new independent variables in the RS model. PIAISS (Interdepartmental Plan on Health and Social Integration) and PPAC share the same RS tools.

The GMA morbidity grouper is based on statistical methods applied to mortality, hospital admissions, pharmaceutical use and GP contact information. It provides a quantitative assessment of the patient's disease complexity. The RS tools have been deployed in all the districts within Catalonia (Spain). In addition, GMA is currently being evaluated by the Spanish Ministry of Health (MoH) as a potential RS tool for the Spanish National Health System. A recent agreement led to the implementation of GMA RS tools in 13 out of 17 Spanish regions (92% of the Spanish population). Madrid is among these regions, having a population of 6 million people, and it was chosen as the pilot region to perform the pre-intervention test.

Both the GMA and the CRG were tested as morbidity groupers during the validation of the RS model in the Catalonia region. Their predictive power was evaluated together with other covariates (i.e. age, sex and socioeconomic status) to predict different healthcare outcomes: mortality, unplanned admissions, emergency department consultations, total healthcare expenditure, pharmacy cost, cost related to drugs strictly dispensed by hospitals (e.g. AIDS treatment, oncology treatments, etc.), contacts with GPs and number of outpatient consultations. To achieve this aim, different multiple linear regression models were designed and tested. The data from the entire population of the patients from Catalonia (approximately 7.5 million patients) were used during the validation. In addition to the statistical validation of the tool, a clinical validation was performed through a pilot test which comprised a survey administered to GPs.

Deployment and maintenance

In the Catalonia region, the RS tool has been deployed to stratify the entire patient population. The risk score provided by the tool is used mainly during GP visits for case finding purposes. Although the GMA tool is already being deployed at a regional level and will soon be deployed at a national level, numerous activities are being carried out towards the further development and optimization of the tool. In this context, new independent variables (e.g. social data, functional autonomy, risk of being readmitted to a nursing home, etc.) were and will be tested in terms of their predictive power. These regeneration activities are performed without any precise schedule. Whereas the recalibration of the GMA tool is planned to take place every six months, this schedule might change to align with the MoH's strategy once the GMA is deployed at a national level.

As already stated above, the GMA tool has been transferred to other regions in Spain but could also be used by regions outside Spain providing it is under license. A dedicated software has already been implemented and training is provided to external institutions/organizations willing to adopt GMA within their healthcare environment. In Catalonia, healthcare professionals have access to the risk score generated by the RS model in the ICS electronic health record and HC3 (the Catalan shared electronic health record) of a specific patient. Indeed, while both CRG and GMA models provide information on the complexity/severity per group of patients, only GMA has been validated to generate an individualized risk score of hospitalization in the next 12 months. This risk score is listed in the selected patient's electronic health record.

Input data for the stratification tool
As mentioned above, the CRG and GMA were adopted as morbidity groupers and used with other independent variables within the RS models. In contrast to CRG, GMA is based on statistical information derived from the target population without relying on the knowledge of specific experts.

The categories of data used by the RS tool in Catalonia are the following:
• socio-demographic (i.e. age and sex)
• socio-economic (e.g. information regarding income and accessibility of healthcare services for the patient's district of residence)
• the use of healthcare resources
• information on mortality
• prescription data.

This information has been used in the different phases of the design of the RS tool. In particular, data on mortality, hospital admissions, pharmaceutical use and GP contacts have been the input for the morbidity grouper: CRG (until the end of 2014) and GMA (since the beginning of 2015).

The above-mentioned information is retrieved from different data sources:
• Regional Registry of Insured people (Registro Central de Asegurados, RCA)
• Regional Registry of Prescriptions (Registro de Actividad de Farmacia, RAF)
• Regional Registry of Healthcare services utilization (Conjunto Mínimo Básico de Datos, CMBD)
• Regional Registry of healthcare claims (Facturación de servicios sanitarios, FSS).

The personal identification code (Código de identificación personal, CIP) is used to perform the data linkage at the patient's level and to create a unique database: the Multi-morbidity Unified Database.

The following tasks and procedures are considered during the preparation of the data before being integrated into the model:
• Data pre-processing: automated
• Data lag: 3-4 months
• Data quality check: automated
• Missing data: not applicable
• Outliers: not applicable
• Data cost: none.

Performance of the model

Up to now, there have been no peer-reviewed articles revealing the results of the validation of CRG and GMA in the Catalonia region. Nevertheless, a validation was performed and reported internally within ASSEHS. The predictive performances of the two morbidity groupers were assessed together with other independent variables in terms of Akaike's Information Criterion (AIC) and R^2. Only the latter results were available to the authors of this document and they are reported below. Three different models were tested to predict eight different outcomes (Figure 7): a model based on Age and Sex, a second one based on Age, Sex and CRG as a morbidity grouper, and a third one based on Age, Sex and GMA as a morbidity grouper. The inclusion of a morbidity grouper, either CRG or GMA, improved the predictive performance of the RS model for all eight scenarios. The inclusion of GMA rather than CRG yielded better results in terms of R2 in all cases except when general and hospital pharmacy costs and total healthcare costs were the dependent variables.

Figure 7: The graph reports the results of the RS models validated in Catalonia in terms of R2. Specifically, three different models were tested to predict eight different outcomes: a model based on Age (A) and Sex (S), a second one based on A, S and CRG as a morbidity grouper, and a third one based on A, S and GMA as a grouper.

In addition, the inclusion of socio-economic status information in the models has been assessed (Figure 8) for four different outcomes: mortality, hospital admissions, emergency admissions and healthcare total cost. The inclusion of variables based on morbidity groupers yielded a substantial improvement in the predictive performance of the models in all four scenarios in terms of R^2. Additionally, this assessment identified GMA as being more informative than CRG when used together with socio-demographic and economic factors in predicting the outcomes of interest in the Catalonia region.
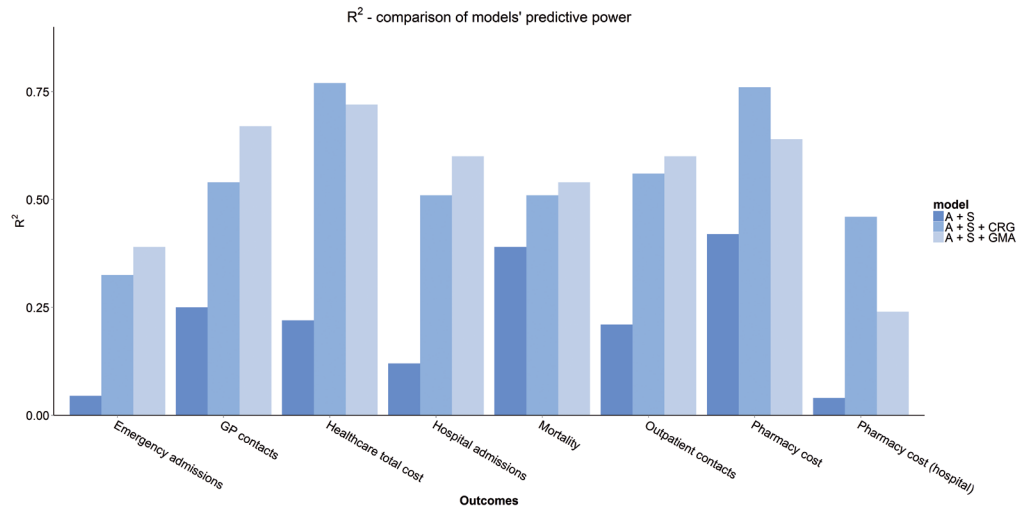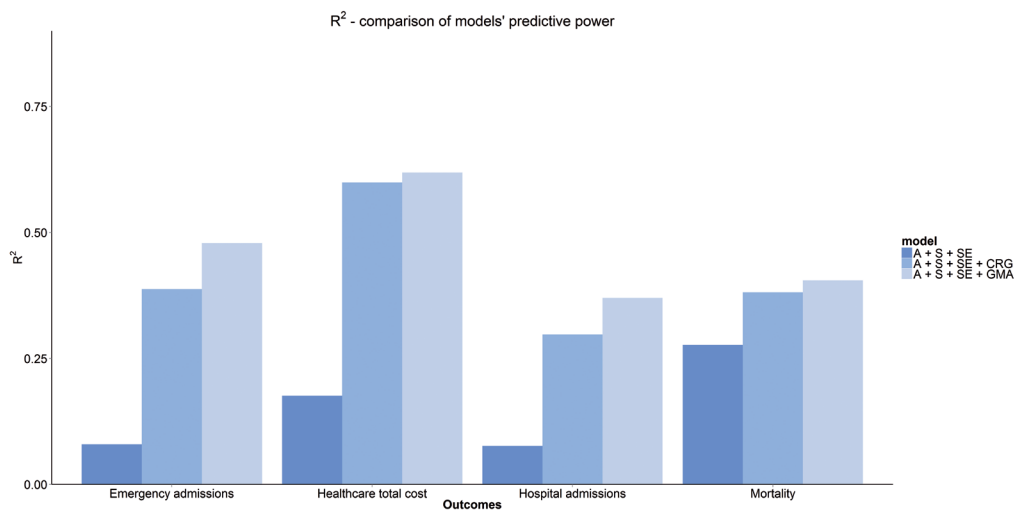

Figure 8: The graph reports the results of the RS models validated in Catalonia in terms of R2. Specifically, three different models were tested to predict eight different outcomes: a model based on Age (A), Sex (S) and socioeconomic status (SE), a second one based on A, S, SE and CRG as a morbidity grouper, and a third one based on A, S, SE and GMA as a grouper.

The risk stratification tool deployed in Lombardia

Region name: Lombardy.

Health care system: National Health Insurance.

Size of target population: approximately 10.000.000 people.

Aim: case finding for appropriate interventions and risk adjustment for healthcare resources' allocation.

RS output: each patient is assigned to a class according to clinical complexity and associated costs.
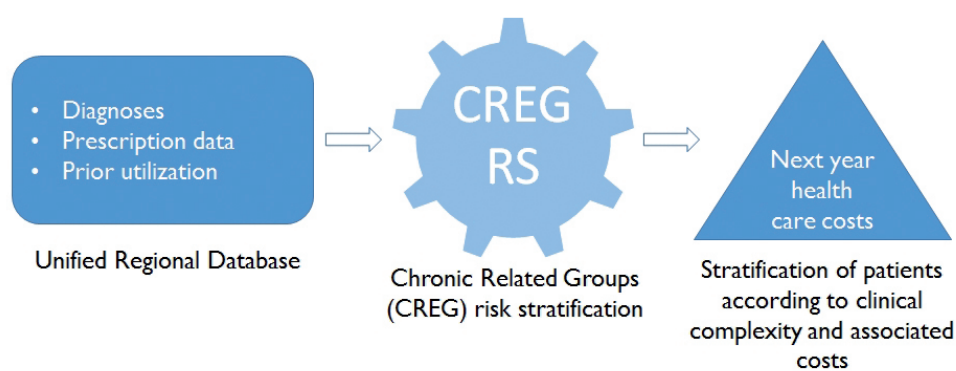
Figure 9: The diagram provides an overview of the data input, risk stratification model and model's outcome in Lombardy region.

The risk stratification model

In the Lombardy region, a proprietary model, named Chronic Related Groups (CREG), has been developed and is deployed in five local health authorities within Lombardy (Italy): Milano, Milano2, Lecco, Como and Bergamo. The scope of the CREG model was to stratify the patient population according to the clinical complexity and associated costs used to estimate the consumption for the upcoming year, enabling case finding for appropriate interventions and risk adjustment for healthcare resources allocation. This risk stratification (RS) model is an essential part of the CREG programme. The latter promotes continuity of care for patients with non-communicable diseases with comorbidities. It also aims at delegating care coordination for chronic diseases to primary care instead of to secondary/episodic care. The CREG model is mainly an administrative tool and lacks clinical validation as well as the inclusion of social data.

The RS tool of the Lombardy region is currently being deployed in a controlled environment at a regional level. Data belonging to the entire population (approximately 10 million people), including healthy people, were used during the design of the model. The CREG model provides an estimation of the patient's healthcare expenditure in the next year. This patient profile is then given to the GP to generate a care plan accordingly. The GREG model is based on threshold modelling using inclusion/exclusion criteria and if-then rules. It assigns the patients to one of the 150+ classes. Each class is meant to cluster patients with similar healthcare needs and potential consumption of resources. During the construction of the CREG model, pathologies were coded and ranked according to their economic relevance, and predefined resources were assigned to each CREG class, based on historical consumptions. Each patient was assigned to one of the 150 CREG classes using information on the "most expensive" pathology, the difference

with respect to ranking position between the "most expensive" and second "most expensive" pathologies and the total number of pathologies. The CREG RS was validated and the possibility to use its output to estimate next year's healthcare costs was investigated using the data acquired over two consecutive years. The results of the validation are not publicly available.

Deployment and maintenance

The CREG model was designed to improve the healthcare resource allocation in order to ensure coordinated care to chronic patients. Its development was based on the data of approximately 10 million people. A script in SAS language (SAS Institute, Cary, NC) was coded to run the stratification based on healthcare cost risk. The use of the RS model by other institutions/organizations has not yet been discussed by the Region as no request in this respect has arisen. The stratification was deployed for the first time in 2010 and the provided classification of patients was supposed to remain unaltered for three years. Internal discussions and research provided the evidence to suggest a change in the deployment timeline and the stratification of the population is now performed annually. The possibility of including new independent variables in the RS model (e.g. pathology severity) and of refining the predefined resources assigned to each CREG class whenever a new version of the CREG model is implemented was also discussed.

The output of the CREG model, namely the CREG class which the patient belongs to, is used at an administrative level to define the reimbursement to which the healthcare provider is entitled. This includes outpatient visits, drug consumption (including oxygen provisioning), prosthetics, medical disposables, integrated home care, all the healthcare services included in the CREG plan (excluding hospitalizations) and other activities (e.g. transport for patients undergoing dialysis).

Input data for the stratification tool

In order to characterize the pathology of a patient, the CREG model uses different information:
• co-payment exemption codes
• hospitalization codes
• drug consumption
• outpatient specialist visits.

This set of data is retrieved from an administrative database: the Unified Regional Database which provides clinical resource utilization profiles based on administrative data.
Whether any security and/or protection measures for the patients' data are taken is unknown to the authors of this document.

The following tasks and procedures are considered during the preparation of the data before being integrated into the model:
• Data pre-processing: automated
• Data lag: 3 months; there is a lag of 3 months for the data from the service providers (e.g. hospitals, pharmacies, etc.) to be available in the central system
• Data quality check: not applicable
• Missing data: not applicable
• Outliers: not applicable
• Data cost: none.

Performance of the model

The results obtained during the validation of the CREG model are not available.

The risk stratification tool designed in Puglia

Overview

Region name: Puglia (Italy).

Health care system: National Health Insurance.

Size of target population: approximately 2.000.000 people. All inhabitants aged 40 years or older alive on 01/01/2004 were targeted by the risk stratification tool (RS) during the development and validation phase.

Aim: case finding for appropriate interventions (main aim) as well as optimization of healthcare resources and provision of a case-mix measure to compare the performances of different healthcare districts.

RS outcome: prediction of short- and long-term mortality and time-to-first unplanned hospital admission and readmission.
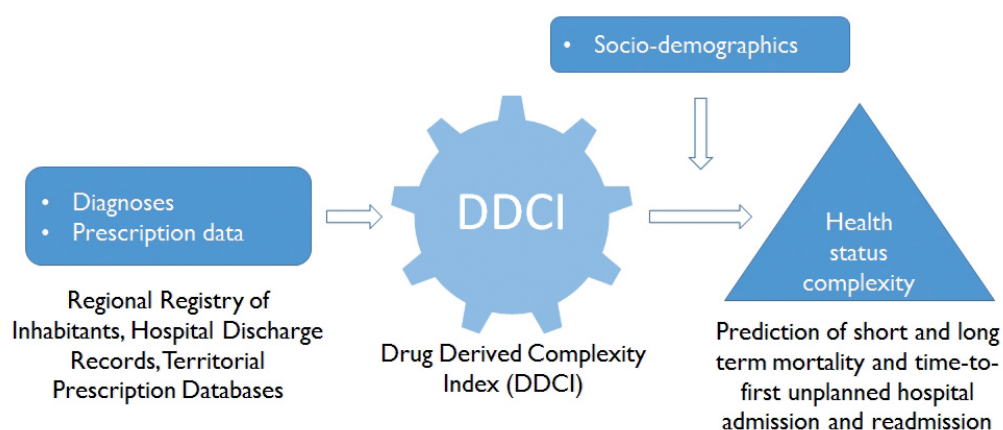
Figure 10: The diagram provides an overview of the data input, risk stratification model and model's outcome in Puglia region.

The risk stratification model

In the Puglia region, a predictive model derived from drug prescriptions, named Drug Derived Complexity Index (DDCI), has been developed and validated. Although other risk stratification (RS) models have been used in the Puglia region, such as Clinical Risk Groups (CRGs) and the Charlson Comorbidity Index (CCI), the current document focuses solely on the novel DDCI. The RS has been implemented at a regional level to better understand variability components in healthcare expenditure and in patients' usage of health services. It was decided to achieve these aims through the design of a model which could stratify the patient population according to their clinical risk and to find the high-risk cases. This activity was aligned with the main scope of the health plans within which the RS could have been eventually deployed: to allocate resources among healthcare districts according to the case-mix of patients and to develop healthcare pathways tailored to patients' clinical profiles. Despite the results achieved by the model in providing clinical risk stratification, research activities are foreseen to improve the RS model: for instance, the inclusion of socio-economic and self-sufficiency variables as well as the evaluation of the RS model's impact on clinical practice.

The RS tool has been applied in all Local Health Authority of Puglia (Italy): Bari, Barletta-Andria-Trani (BAT), Brindisi, Foggia, Lecce and Taranto.

The DDCI has been designed and validated to stratify the open population with respect to short- (1 year) and long-term mortality as well as time-to-first unplanned hospital admission and readmission. The DDCI is based on a multivariate Cox proportional hazard regression model and its design, calibration and validation are described in a scientific article[25] using data recorded between 2003 and 2010 from approximately 2 million patients from the Puglia region. Additionally, the above-mentioned article outlines the comparison of DDCI with the CCI in terms of discrimination and reclassification.

Deployment and maintenance

The DDCI was developed to stratify the adult population (above 40 years old) in the entire region of Puglia (approximately 2 million patients) with a special focus on prescription data and its ability to provide a proxy of chronic diseases and the complexity of the patient's healthcare needs. Additionally, the DDCI output was designed to be used both at planning level and in the out-patient setting. Indeed, it can be deployed for case finding for appropriate interventions, optimization of allocation of healthcare resources and as a case-mix measure to compare the performances of different healthcare districts.

The RS model in Puglia is subjected to continuous evaluation and optimization. In this context, the inclusion of new variables in the DDCI model (i.e. regeneration of the model), such as socio-economic and self-sufficiency variables, highly depends on future collaborations between the research team who designed the RS model and some of the other stakeholders involved (e.g. general practitioners, clinicians, etc.). The recalibration of the model is expected to occur every three years, while the classification of the patient population is performed each year in May. The described activities rely on the maintenance and availability of the data sources (please see next section) upon which the DDCI is based.

The RS model was designed and its predictive performances evaluated using SAS Software Release 9.3 (SAS Institute, Cary, NC). Although a dedicated software has not yet been implemented (currently under development), the DDCI model is available to other healthcare organizations/institutions along with specific training.

Input data for the stratification tool

The DDCI model uses data from different sources:
• Regional Registry of Inhabitants (RRI)
• Hospital Discharge Records (HDR)
• Territorial Prescription Databases (TPD)
• Death Registry (DR).

The independent variables comprised in the RS model are:
• socio-demographic data (e.g. age, sex, life status, etc.) from RRI;
• pharmacy data (prescription data) from TPD;
• diagnoses for computation of CCI (HDR).

During the validation phase, other information was needed for the comparison between the predicted and recorded outcomes:
• unscheduled admissions, early readmissions from HDR;
• date of death from DR.

[25] Robusto F, Lepore V, D'Ettorre A, Lucisano G, De Berardis G, Bisceglia L, et al. (2016) The Drug Derived Complexity Index (DDCI) Predicts Mortality, Unplanned Hospitalization and Hospital Readmissions at the Population Level. PLoS ONE 11 (2): e0149203. doi:10.1371/journal.pone.0149203

All security and protection measures for patients' data comply with the Italian national law.

The following tasks and procedures are considered during the preparation of the data before being integrated into the model:
• Data pre-processing: automated
• Data lag: the linked database is updated annually and available immediately after
• Data quality check: automated
• Missing data: not applicable
• Outliers: remove entry or truncation (e.g. age above 110 years)
• Data cost: no recurring cost.

Performance of the model

The performance of DDCI has been evaluated[26] through the survival concordance index (C-Index) and net reclassification improvement (NRI). Table 1, Table 2 and Table 3 show the results for 1-year mortality, overall mortality and 1st unplanned hospitalization, respectively. CI was used to assess the discrimination power of the Cox regression model. Specifically, the DDCI provided higher CI values in comparison to the performance achieved by the reference model (i.e., a model based only on sex and age) for both short- and long-term mortality. Conversely, the reference model slightly outperformed the model incorporating the DDCI score in predicting time-to-first unplanned hospitalization. The ability of a model to discriminate between a binary outcome (e.g. experience or not an unplanned hospitalization in the following year, survive or die in the next year, etc.) and the improvement provided by adding additional input information in the model can be assessed via the NRI. Table 1,Table 2 and Table 3 report the gain in classification accuracy achieved by the DDCI using the model based solely on age and sex as the reference model for the three scenarios. In accordance with the CI results, the NRI (DDCI versus reference model) is more prominent when the model is predicting either long- or short-term mortality than when the DDCI model predicts time-to-first unplanned hospitalization.

Table 1: 1-year mortality

1-YEAR-MORTALITY				
Model	Survival C-Index (CI)	NRI (CI)	Proportion of events correctly reclassified	Proportion ofnon-events correctly reclassified
Age, sex*	0.815 (0.809-0.820)	-	-	-
Age, sex, DDCI	0.851 (0.846-0.856)	0.698 (0.673-0.725)	0.1634	0.5349

Table 2: overall mortality

OVERALL-MORTALITY				
Model	Survival C-Index (CI)	NRI	Proportion of events correctly reclassified	Proportion of non-events correctly reclassified
Age, sex*	0.815 (0.813-0.817)	-	-	-
Age, sex, DDCI	0.835 (0.833-0.837)	0.586 (0.571-0.600)	-0.07	0.6563

Table 3: unplanned hospitalization

1st-UNPLANNED-HOSPITALIZATION				
Model	Survival C-Index (CI)	NRI (CI)	Proportion of events correctly reclassified	Proportion of non-events correctly reclassified
Age, sex*	0.585 (0.583-0.587)	-	-	-
Age, sex, DDCI	0.584 (0.582-0.586)	0.301 (0.290-0.310)	-0.2341	0.5351

[26] Robusto F, Lepore V, D'Ettorre A, Lucisano G, De Berardis G, Bisceglia L, et al. (2016) The Drug Derived Complexity Index (DDCI) Predicts Mortality, Unplanned Hospitalization and Hospital Readmissions at the Population Level. PLoS ONE 11 (2): e0149203. doi:10.1371/journal.pone.0149203

3-RISK STRATIFICATION PLANNING AND DEPLOYMENT
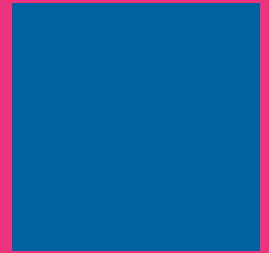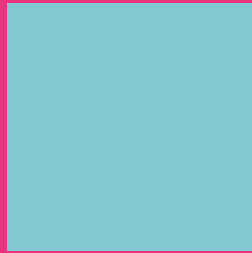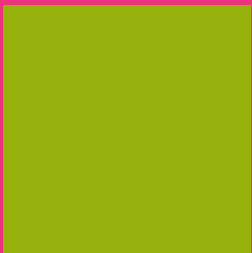
Key take-away messages

Shortcomings
- Not enough communication about stratification.
- Lack of formal and direct training.
- Some professionals do not rely at all on mathematical algorithms to support the identification of complex patients.
- Time lapse between the stratification process and its implementation.
- Mismatch and /or errors in diagnosis codes in different registries.
- Economic incentives may lead to undesired behaviours.
- Changes take a long time.

Assets
- Promotes a more proactive way of working.
- Clinician's involvement in the process.
- Training tailored to local situation.
- Useful instrument for regional health care planning.
- Automatic data management reduces time and cost.
- Stratification process results available in the EHR.
- Association of the development of care pathways, the redefinition of roles and improved coordination.

Recommendations
- Implementation process should take into account the dimensions of the Feasibility Framework.
- Appropriate learning time should be taken into account.
- Invest in data quality and ICT functionalities.
- RS results /risk score, patients list... should be displayed in the EHR.
- Time between stratification and implementation should be shorter.
- Complementarity of RS and clinical assessment.
- Allows a proactive action using pathways to manage targeted population.
- RS implementation requires the acknowledgement of the political level and the acceptance of the clinicians.
- RS implementation requires further research and evaluation.

Feasibility framework

In order to identify key RS feasibility elements, a scoping review was performed. Focus was put on barriers and facilitators at the macro, meso and micro levels of the care systems. The relevant elements were organized in a framework proposal which included dimensions and sub dimensions applicable to the feasibility of risk stratification. Further refinement then took place based on the information regarding implementation experience.

A scoping review[27] was carried out following five stages (1): (i) Identifying the research question (ii) Identifying relevant studies, (iii) Study selection, (iv) Charting the data, (v) Collating, summarizing, and reporting the results.

Documents describing the experiences of Risk Stratification implementation or those addressing key aspects of this process were the only ones eligible. The scoping review was conducted during the month of May 2014 with the aim of identifying the relevant scientific evidence. Research was carried out by a documentalist.

[27] Mora J, De Massari D, Pauws S, op den Buijs J, David M, Prieto L, et al. Selection of the method to appraise and compare health systems using risk stratification: the ASSEHS approach. Aging Clin Exp Res. 2015 Dec;27(6):767–74

Search strategy

The description of risk stratification strategies is frequently found in classic scientific research papers. This is why a scoping review was conducted with the aim of identifying the relevant scientific evidence. The search questions that were defined aimed to (i) identify interventions in Europe where risk stratification approaches have been used, (ii) describe the implementation process and (iii) collect information on barriers and facilitators. Among others, the main databases consulted were MEDLINE (Pubmed), EMBASE.com and The Cochrane Library (Wiley platform) following the process defined in Figure 11 (Scoping Review Process Workflow). Further information can be found in the article on the selection of the method to appraise and compare health systems using risk stratification[28].
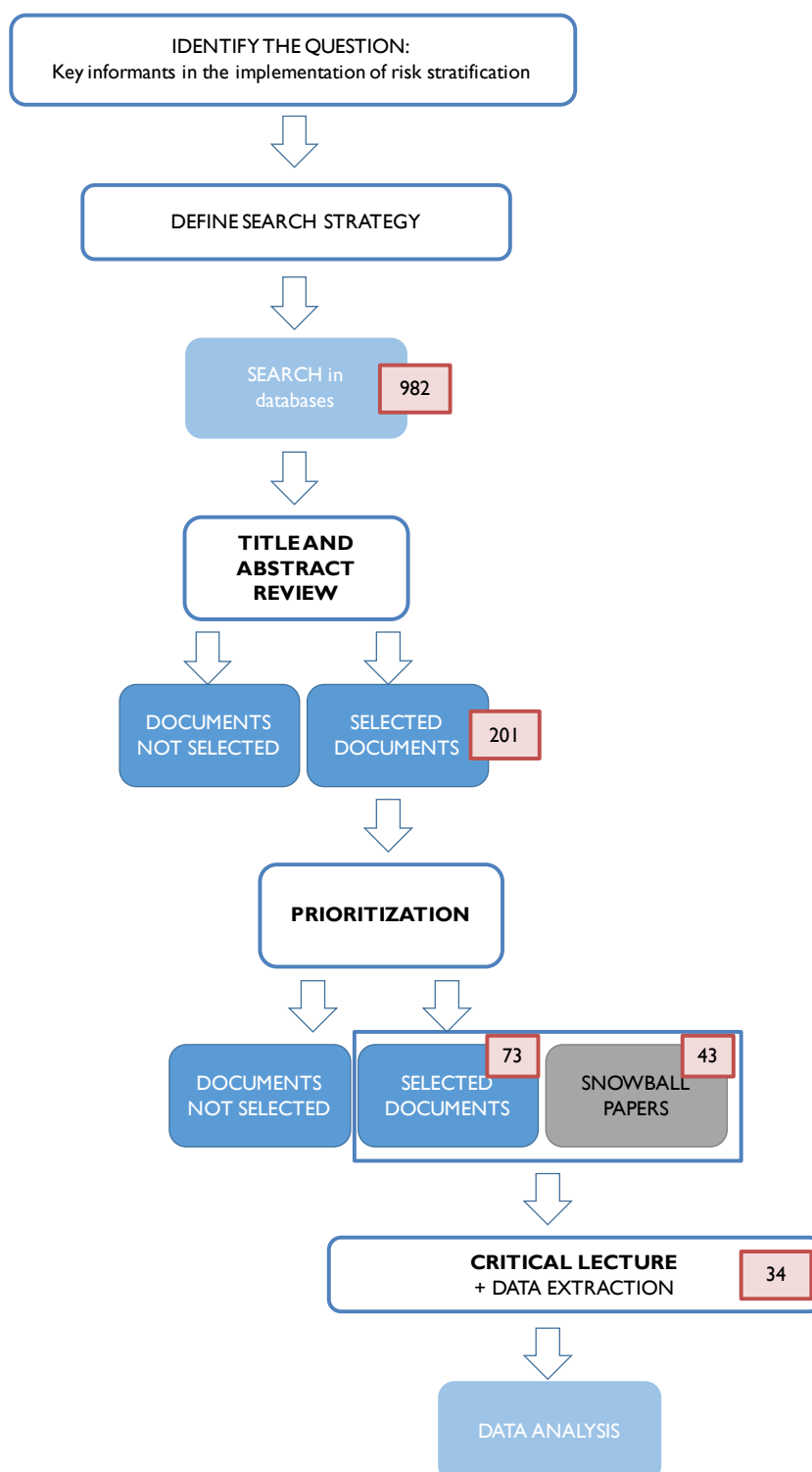
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┌─────────────────────────────────────────────────────┐
│ IDENTIFY THE QUESTION:                                │
│ Key informants in the implementation of risk         │
│ stratification                                        │
└─────────────────────────────────────────────────────┘
                         ↓
┌─────────────────────────────────────────────────────┐
│ DEFINE SEARCH STRATEGY                                │
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│ SEARCH in databases  │  │ 982 │
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│ TITLE AND ABSTRACT   │
│ REVIEW               │
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│ DOCUMENTS        │  │ SELECTED     │ │ 73  │  │ SNOWBALL     │ │ 43  │
│ NOT SELECTED     │  │ DOCUMENTS    │ └─────┘  │ PAPERS       │ └─────┘
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                │ + DATA EXTRACTION    │ └─────┘
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                    │ DATA ANALYSIS    │
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Figure 11:
Scoping Review
Process Workflow

[28] Mora J, De Massari D, Pauws S, op den Buijs J, David M, Prieto L, et al. Selection of the method to appraise and compare health systems using risk stratification: the ASSEHS approach. Aging Clin Exp Res. 2015 Dec;27(6):767–74

Further to a thorough critical review, 34 topics were identified. Not all of the topics were related to feasibility, some pertaining to incomes, outcomes, tools, characteristics of the organization, etc... After the first grouping, these topics were structured into a framework draft with 23 sub-dimensions and 7 dimensions, such as cost, ethics, funding and resource allocation, key aspects of care intervention, planning, deployment and change management, risk stratification information and others.

Refinement of the framework

Following Arksey et al.[29], a "Consultation" was carried out to refine the framework draft. Key experts on implementation experiences were interviewed. Experts that had been actively involved in the design and/or implementation of risk stratification were identified for this purpose. The interviews were conducted as a representative sample. Practical information was collected. This information was generated through the implementation process of risk stratification strategies in the four ASSESHS Regions. The relevant concepts related to facilitators and barriers were identified, taking into account the frequency of appearance.

The first draft of the framework was reviewed, tanking the relevance given by the experts into consideration. A final version with a reduced number of dimensions and sub-dimensions was then produced. On the one hand, the sub-dimensions of the framework are related to planning, deployment and change management; on the other hand, they are related to the key aspects of care intervention.

Planning, deployment and change management is composed of six sub-dimensions.
• The aim of the communication explaining the purpose and outcomes of risk stratification.
• Training and mutual learning which is about the professional becoming competent in the use of risk stratification.
• Multidisciplinarity of the team leading risk stratification deployment involving health professionals, managers, ICT professionals, epidemiologists and others.
• Professionals´ accountability, commitment and involvement and the ways to ensure that they are linked to the engagement of clinicians.
• The operational plan focusing on definition of action, quality and implementation.
• ICT-Information display and functionalities including the devices and applications used in risk stratification, its support and visualization.

Care intervention has three sub-dimensions.
• Case finding is the selection, identification and enrolment of target population.
•The pathway definition and implementation includes the intervention with patients and the follow up that should be done.
•Quality assessment and improvement process are related to the monitoring and assessment measures to be applied in the implementation process.

Table 4: Dimensions and sub-dimensions for risk stratification implementation

DIMENSIONS	SUB-DIMENSIONS
Planning, deployment and change management	Communication
	Training and mutual learning
	Multidisciplinarity of the team leading RS deployment
	Clinicians' engagement
	Operational plan
	ICT - Information display and functionalities
Care intervention	Case finding /Selection of the target population
	Pathway definition and implementation
	Quality assessment and improvement process

[29] Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol. 2005 Feb 1;8(1):19–32.

The framework was used to design the Feasibility and Impact Questionnaire as well as the semi-structured interviews and focus groups. This all leads to the Intervention Assessment Framework (IAF).

A first draft of the questionnaire and a proposal for its deployment protocol was developed, based on open interviews with key informants and on the dimensions and subdimensions identified in the scoping review. Before deployment, its face-validity was checked to ensure that the language used and the translation of concepts were understandable for the target respondents. The questionnaire was translated into Italian, Spanish and Catalan.

The sample included at least one person from each of the professional profiles involved in implementation. The total number of key informants by profile was weighted according to the number of people involved in the actual implementation process. They all belonged to different settings: primary care, specialized care, social care, prevention and the planning service. Several professional profiles were targeted: clinicians, healthcare managers, healthcare planners, commissioners, developer-subcontractors, operators involved in the management, processing and evaluation of the data and technology providers. Finally, it was distributed to thirty people that had been actively involved in the design and/or implementation of the risk stratification strategies and/or tools.

Twenty-six people completed and returned the questionnaire. The results were grouped according to the dimensions obtained from the scoping review. A descriptive analysis was made and open questions were summarized taking into account the frequency of repeated ideas.

Baseline feasibility analysis

Risk stratification (RS) is a tool for healthcare planning; it enables a more precise alignment of regional policies. The current uses given to RS in each ASSEHS region are relevant in order to understand the implementation process and the main plan underpinning the introduction of risk stratification.

RS in healthcare systems is not as mature a strategy as others already implemented[30]. The main aim for using RS may vary as the system gains knowledge from the implementation process and as initial gaps are covered and improvements put in place. These improvements and changes in the process can affect the functionalities of RS strategies.

Figure 12 shows that the top utility in ASSEHS regions for RS is the identification of patients according to their risk of suffering an adverse event. RS is also used for planning interventions for target populations. Workload distribution and resource allocation are less frequent in ASSEHS Regions.

[30] Goldfield N. The evolution of diagnosis-related groups (DRGs): from its beginnings in case-mix and resource use theory, to its implementation for payment and now for its current utilization for quality within and outside the hospital. Qual Manag Health Care. 2010 Mar;19(1):3–16.
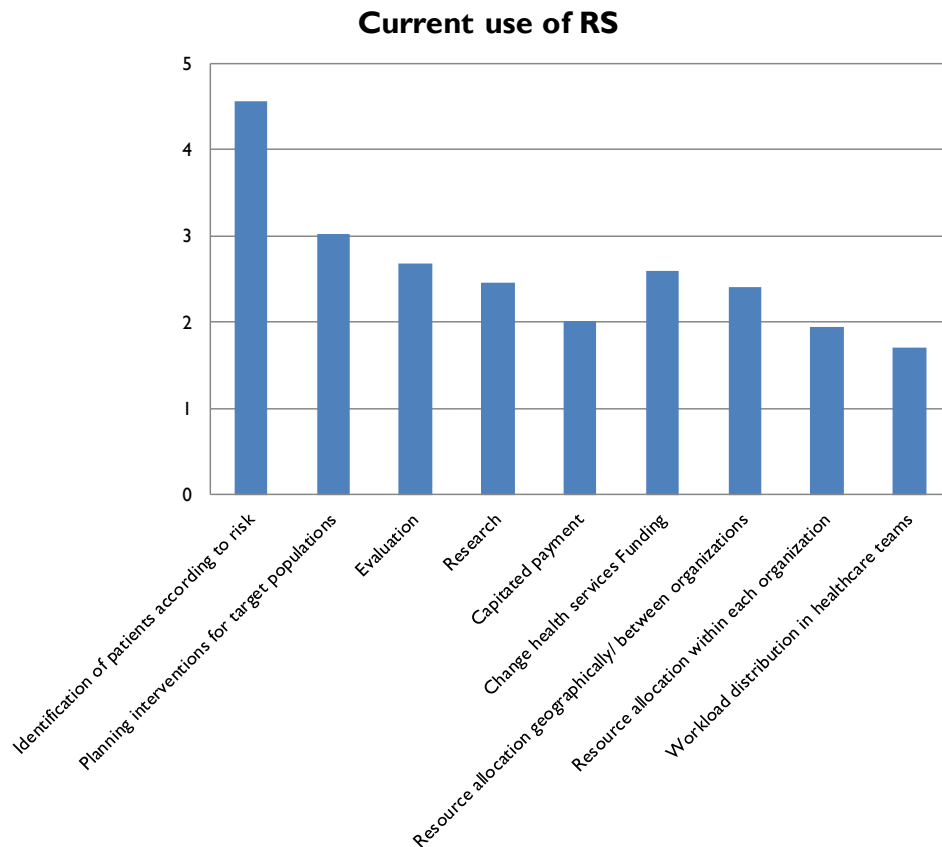
Current use of RS

Respondents consider that the identification of patients according to their risk will continue to be applied in the near future in ASSEHS regions. Workload distribution, planning and resource allocation will also be more frequently used (Figure 13).
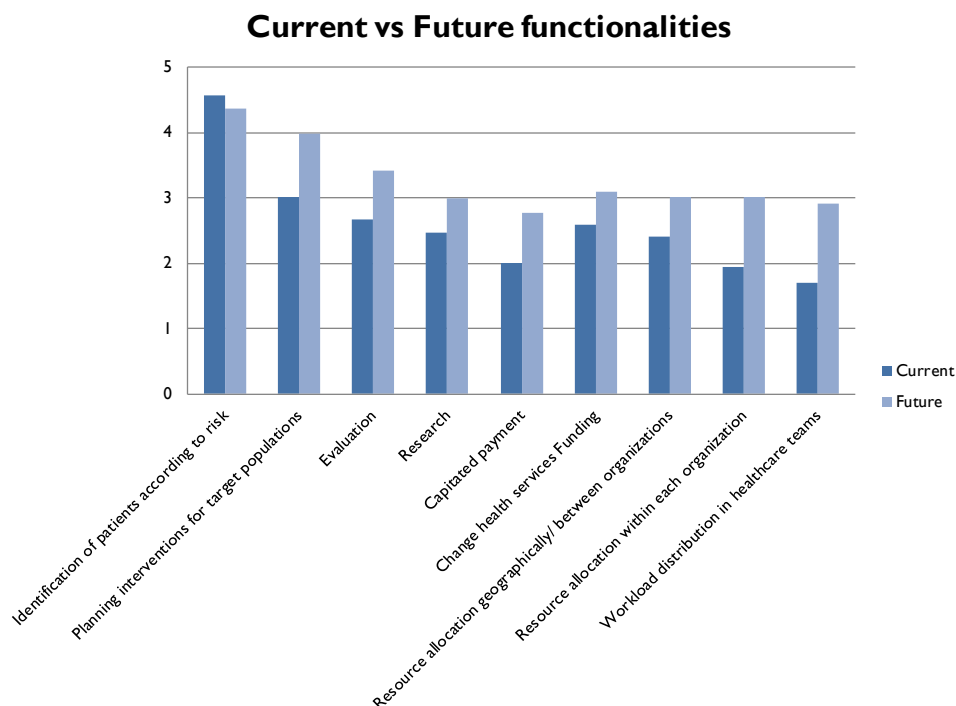
Current vs Future functionalities

Several aspects have been identified as advantages amongst key informants, i.e., the provision of information about the whole population, the possibility of identifying groups of patients with similar levels of risk and care needs and the provision of proactive care and design of pathways in a more efficient way (Figure 14).

Frequency of concept citation

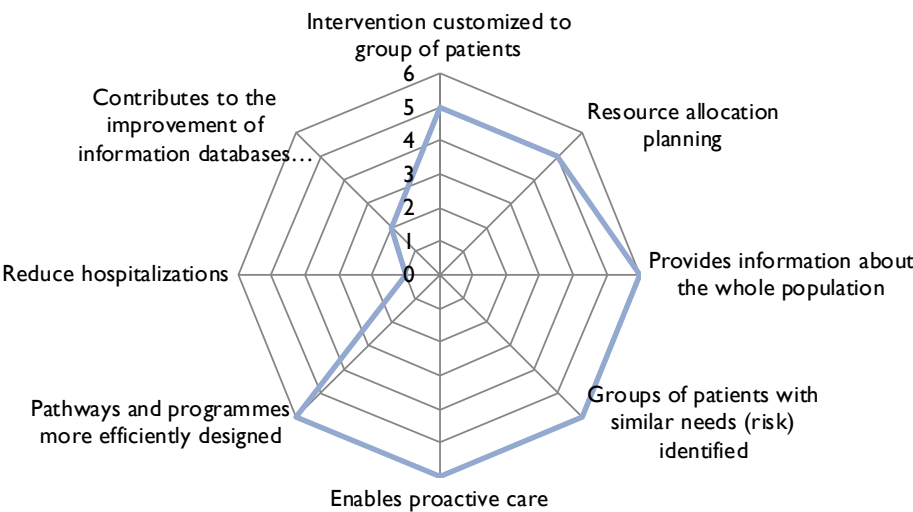When questioned about the disadvantages, many respondents pointed out the ICT and data provision-related aspects, such as the difficulties and limitations of the databases used and the lack of dynamism and user friendliness (see Figure 15).
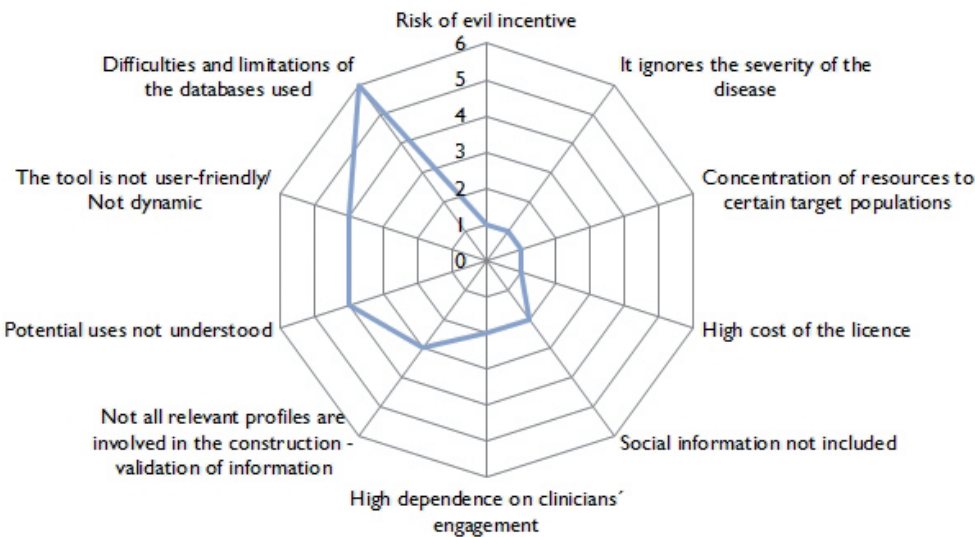
Frequency of concept citation

Planning, deployment and change management

The baseline status of each region influences the implementation and scope of risk stratification. For example, the maturity of the information systems, which comprise issues such as the availability of online clinical information, its integration with administrative data or the level to which clinicians can interact with ICT tools in order to manage their patients through RS, has important implications for RS strategies. Information systems are based on the construction and sharing of information. The area more frequently addressed was the integration of the tool with the information systems. The provision of training for involved professionals was not often dealt with (Figure 16).

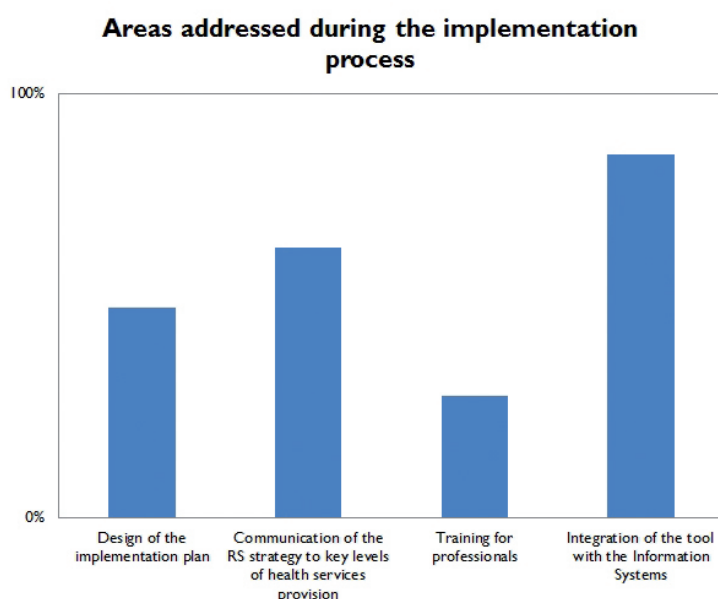### Areas addressed during the implementation process

Figure 16: Areas covered during the Implementation of RS in ASSEHS regions (0% = Nobody considers the item as addressed, 100% = Everybody consider the item as addressed).

An early detection and understanding of barriers and facilitators can help to implement improvements in place while enabling a proactive follow-up. Leadership has been identified as an important barrier and facilitator through interviews of key informants in the ASSEHS Regions. Organizational context is perceived as an important facilitator in the process. Internal communication and clinicians' engagement are both pointed out as relevant barriers for the implementation of RS in their regions (Figure 17).

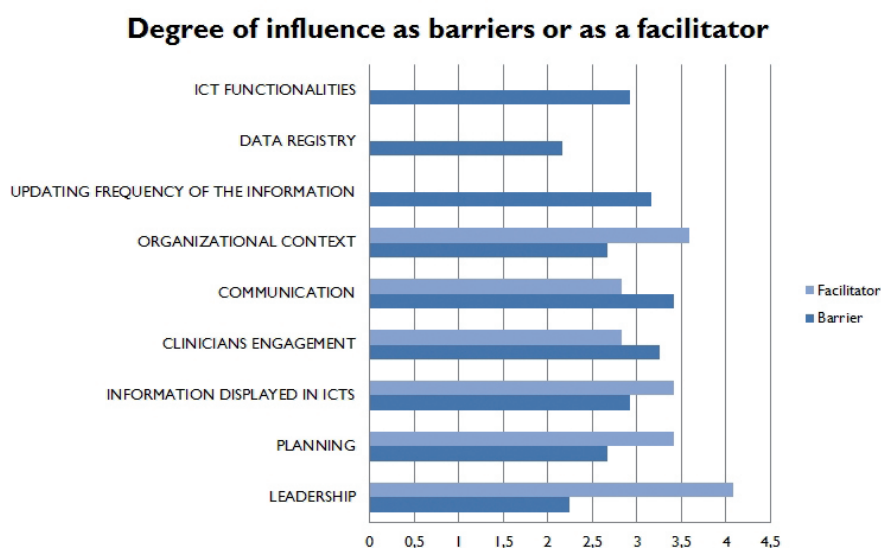### Degree of influence as barriers or as a facilitator

Figure 17: Degree of influence as barriers or as a facilitator (for facilitators: 0 = not a facilitator, 5 = great facilitator; for barriers: 0 = not a barrier, 5 = important barrier)

Communication is carried out to disseminate the information on Risk Stratification within each organization. It comprises topics such as the explanation of Risk Stratification Strategy, its potential benefits or the main objective underpinning the implementation of risk stratification in a given setting. Communication activities are targeted to the different organizational levels and professional profiles. Specific actions, time-schedules and contents were defined for each group.

Training is deployed to ensure that all agents involved understand the technical information that enables the professionals to perform their activities throughout the process. Communication and training activities have been targeted mainly to managers, but also to a selected group of primary care clinicians in each region (Figure 18)

Audience of the communications and training activities
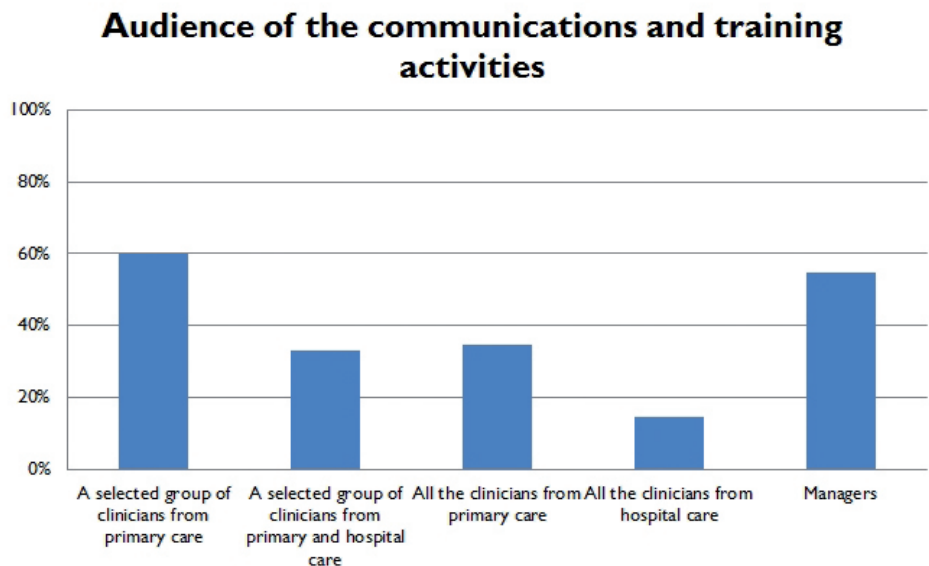
Figure 18: Audience of the communications and training activities (0% = Nobody considers this has been targeted; 100% = Everybody consider that has been targeted)

Multidisciplinarity addresses the active participation of all relevant agents and professional profiles in the team leading the interventions. It includes medical directors and managers, clinical leaders, ICT experts and/or tool designers.

Clinicians are the final users of risk stratification information. They are often involved in the risk score given to each patient. They play a key role in the implementation of risk stratification strategies. Therefore, their engagement is crucial. Nevertheless, not many activities have been carried out to achieve this purpose (see Figure 19).

Specific actions carried out to engage clinicians

Figure 19: Specific Action carried out to engage clinicians (0 =nobody mentions the action, 4 = everybody mentions the action)

The operational plan should cover all relevant issues within the implementation and should include mechanisms to tackle the challenges that may arise during the process.
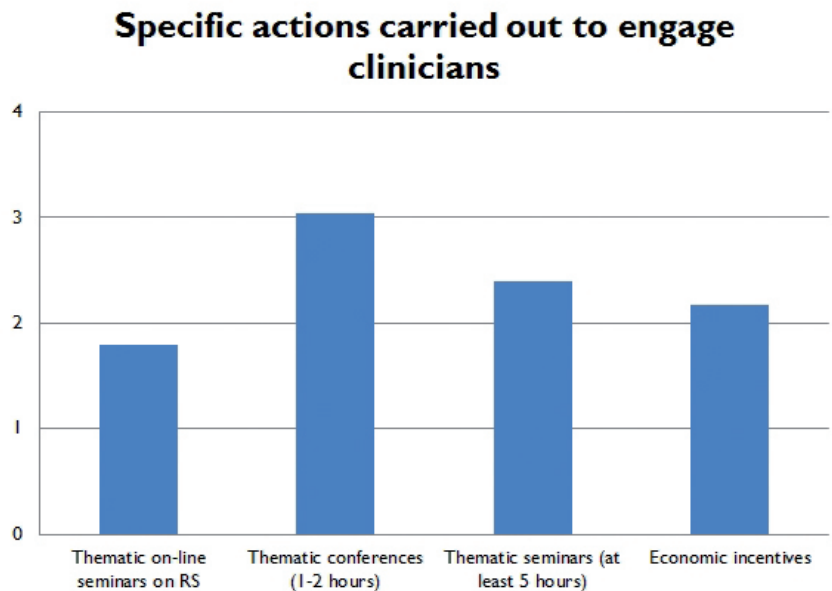
Displaying RS information linked to clinical and administrative data of the patient in an ICT tool can help to manage information regarding the patient. The patient's electronic health record (EHR) is the ICT in which this information is what is most frequently made available to clinicians (Figure 20). These functionalities define the level to which the ICT tool interacts with the user and enables him/her to manage risk stratification information.

Information displayed in ICT
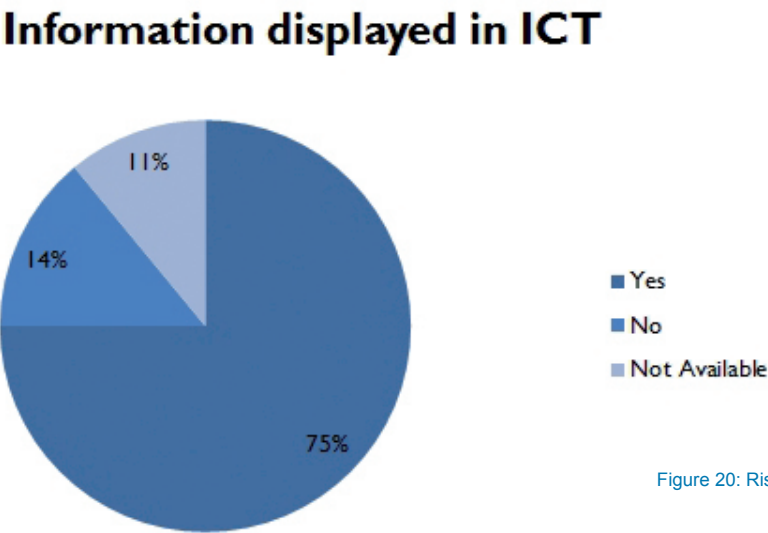
Figure 20: Risk Stratification displayed in ICTs

ICTs can be functional and enable clinicians to manage their own lists of stratified and target-specific patients. For example, they can allow queries and lists. ICTs influence the process of changing from pathology-centred care provision to patient-centred care provision, enhancing the ability for case management. They also affect the usability of the ICT tool and the satisfaction of the professionals involved. The main functionality provided by the ICTs is the display of stratification values and the risk score of each patient in their EHR. On the other hand, data mining is not frequently provided as a functionality for clinicians (Figure 21).

Functionalities provided by ICT tools
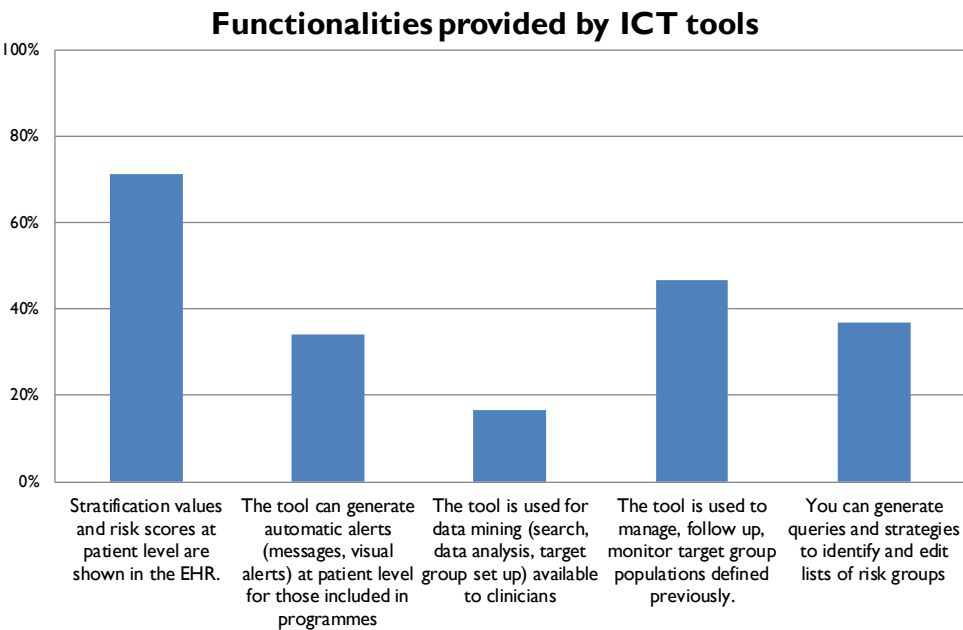
Figure 21: Functionalities provided by ICT tools (0% = Nobody considers this functionality has been provided, 100% = Everyone considers this functionality has been provided)

The most frequently used ICT tool to display information to clinicians is the patients' EHR. The risk score or tag given to a patient is integrated in the online record of each patient's clinical background (Figure 22).
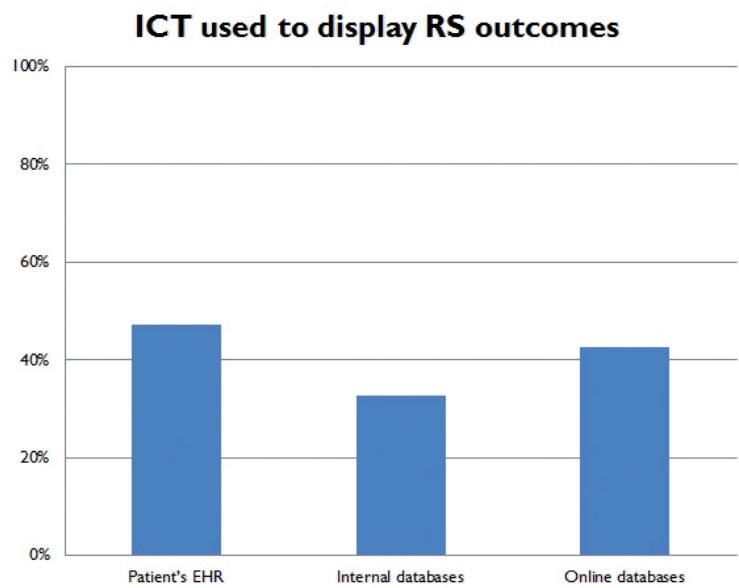
Figure 22: ICTs used to display Risk Stratification Outcomes (0% = nobody considers this use, 100% = everyone considers this use)

Key aspects of Care Interventions

Quality assessment monitors identify problems and propose improvements in the implementation process, including economic ones. Cost-effectiveness of the implementation process has not been measured in most of the regions (Figure 23).
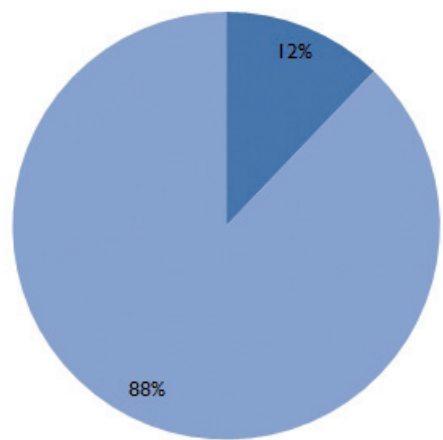
Figure 23: Risk Stratification Implementation for the measurement of Cost-effectiveness

Risk stratification is used for case finding/selection of the target population. This means identifying patients who may benefit from interventions to prevent unwanted events. Risk stratification information is also used to quantify the needs of a certain group of patients according to the risk profile of each individual (see Figure 24).
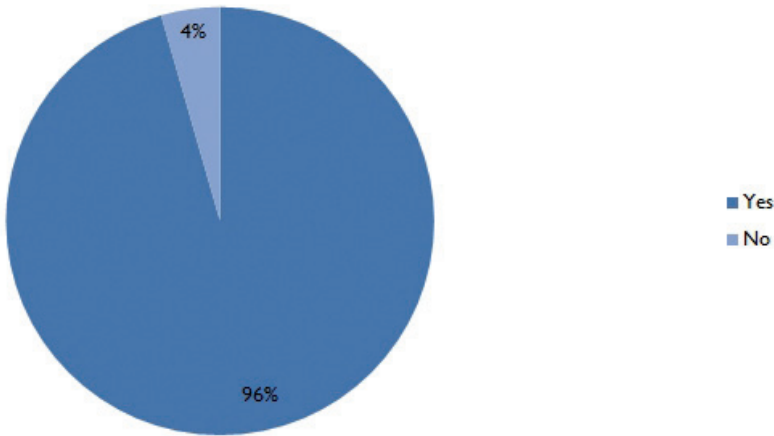
Figure 24: Use of Risk Stratification Information for Case Finding/Selection of the target population

Managers and commissioners are often the main people responsible for the selection of the target population to be included in the programmes (see Figure 25).
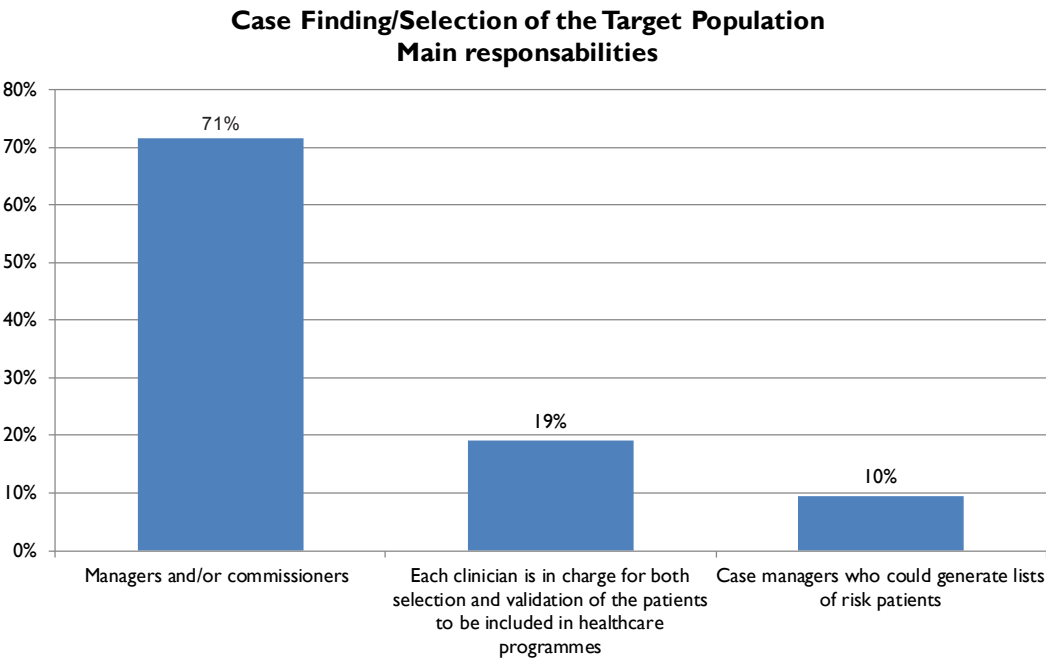
Figure 25: Use of Risk Stratification Information for Case Finding/Main person in charge

The assessment of Risk Stratification information made by clinicians refers to the process through which clinicians review it once the risk information has been provided by the tool. Furthermore, based on recently added data regarding the patient, it assesses the clinical validity of the risk information (see Figure 26).

Case Finding/Selection of the Target Population
Main criterion considered

- Clinical criterion
- RS and clinical criterion equally considered
- RS criterion

Figure 26: Use of Risk Stratification Information for Case Finding/Selection of the target population

RS impacts the pathway definition and its implementation. It refers to the adjustment of existing care pathways or the definition of new ones adapting them to the needs of the at-risk groups.

Conclusions

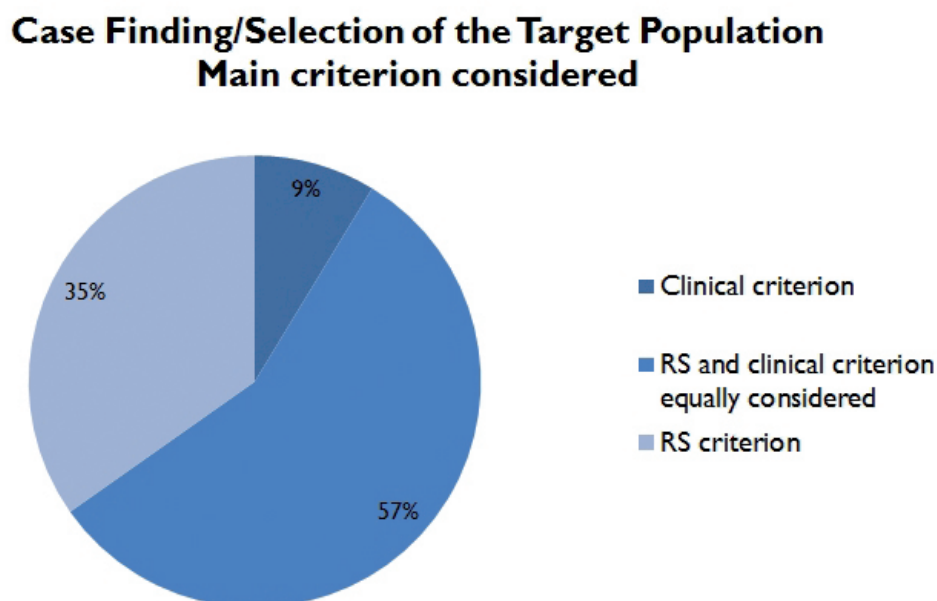Risk stratification (RS) is a tool for healthcare planning at macro, meso and micro levels. However, its implementation is not yet mature. During the implementation process, gaps can be identified and improvements put in place. These changes can affect the functionalities of RS. Understanding how RS is implemented in real practice can benefit from a formal research approach to close the gap between knowledge and practice[31]. Implementation research analyses the adoption of clinical research findings using routine clinical practice in a systematic, widespread, sustainable and continued way[32]. ASSEHS has developed a framework to analyse RS feasibility to be implemented in health services.

The framework identifies two dimensions and nine sub-dimensions. A high-quality operational plan establishing the agenda and the strategic goals and objectives for the years to come is needed. Having trained people qualified in RS is necessary[33]. The clinicians' commitment is a sine qua non requirement. If we can assure the commitment of innovators and early adopters (Rogers 1995), the remaining organizations will follow in their steps. The communication, not only of RS, but also of what it is aiming for, is a key element of its feasibility[34]. If the clinicians do not see the point of RS, it would be really difficult to implement. Since the clinical group consists of different profiles, it is vital to have a multidisciplinary team leading the RS deployment[35]: each and every one of the professional profiles involved is important. Besides, having appropriate ICT has been identified as crucial.

[31] McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, et al. The Quality of Health Care Delivered to Adults in the United States. N Engl J Med. 2003 Jun 26;348(26):2635–45.
[32] Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care. 2012 Mar;50(3):217–26.
[33] Johns Hopkins risk tool used in South [Internet]. [cited 2016 Apr 21]. Available from: http://www.digitalhealth.net/news/27490/johns-hopkins-risk-tool-used-in-south
[34] Yi C. Developing decision trees to classify patients suited for similar interventions by combining clinical judgments with Leeds Risk Stratification Tool. London, UK: London School of Economics and Political Science.; 2012.
[35] Hoult J, Matheson H. Long-term conditions. Spot future patients to find tomorrow's savings. Health Serv J. 123(6340):26, 28.

Case finding and selecting the target population allows one to focus efforts on the people that can make the best of the programmes designed for chronic patients. A process of continuous improvement that, on the one hand, includes the quality assessment and improvement process and, on the other hand, the pathway definition and implementation, always helps to produce feasible interventions.

It may be concluded that the main uses of RS include the identification of patients, workload distribution, planning and resource allocation. Despite RS functionalities, there are some limitations related to data availability and database lack of dynamism. Understanding barriers and facilitators is crucial for the implementation of improvements. The proposed framework is useful to analyse feasibility and identify improvement areas. For a successful implementation leadership, internal communication and commitment on behalf of the clinicians are relevant. At the same time, ICTs should enable clinicians to manage their own lists of stratified and target patients. Cost-effectiveness of the implementation process needs to be further measured.

4-IMPACT OF RISK STRATIFICATION TOOLS

Impact is a broad term that can be applied in many different dimensions. Our goal is to focus on three levels of impact: healthcare structures, processes and results.

In accordance to the aim of the ASSEHS project, an analytical framework called the performance management framework was developed, which approached the different levels of impact. A set of qualitative methods was designed to explore and appraise the existence and degree of impact on each domain and subdomain identified in our framework. The analysis of impact is more qualitative than quantitative due to the difficulties of establishing a direct correlation between the use of risk stratification tools and the observed changes in healthcare systems which are more likely to be motivated by the intervention programmes deployed in each territory that stratifies its population. Interventions use risk stratification but its logic goes beyond predicting adverse events or identifying patients at risk that require collaborative and proactive care. In a nutshell, risk stratification may be a necessary condition but is not sufficient by itself to cause an impact on healthcare systems. Therefore, we designed our Performance Management Framework combining four different analytical frameworks: Donabedian's quality of care assessment[36], RE-AIM evaluation framework[37], the Triple Aim from the Institute of Healthcare Improvement[38] and Michael E. Porter's Outcome Measures Hierarchy[39].

Scoping review on the impact of risk stratification

The goal of the impact analysis of risk stratification use is to seize the scope and degree of impact in healthcare services. The method of the scoping review was chosen to perform literature reviews prior to in-site knowledge retrieval and discovery by qualitative methods.

The search strategy was performed between August and October 2014 in the following sources: PubMed, Embase, Cochrane, CINAHL, PsycInfo and CRD. Searches were carried out from 1989 to August 2014 and included articles which focused on studies describing the impact of risk stratification tools. Impact was defined as the effect of the use of risk stratification on budget allocation, funding, information systems, organizational configurations, resource utilization and impactibility models. A total of 473 articles were scanned and a final set of 29 works were analysed covering different sub-dimensions such as cost of healthcare, organizational models, information systems and reimbursement practices.
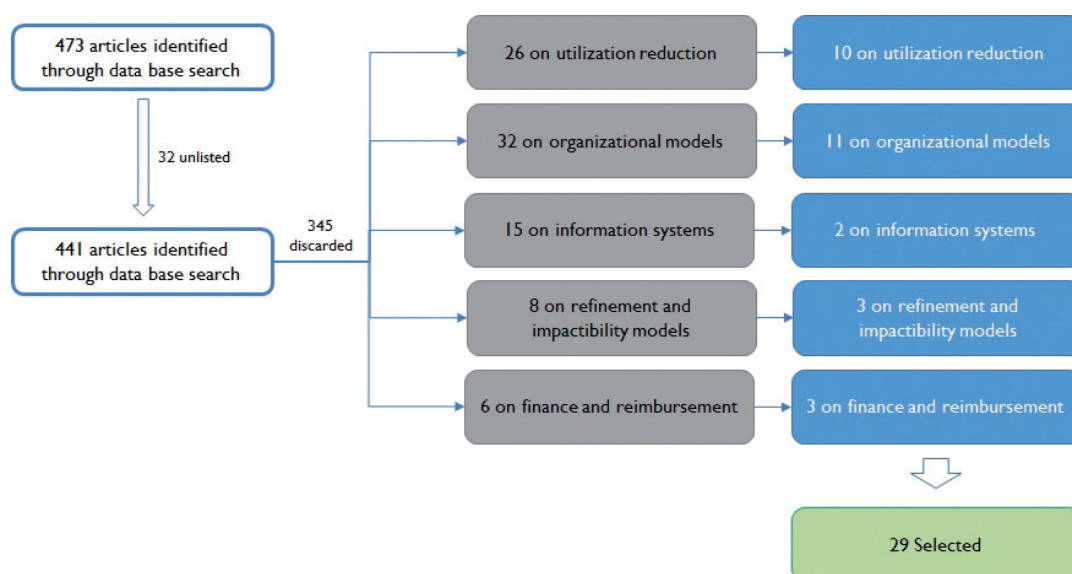
Figure 27: Scoping review process

[36] Donabedian, A. The quality of care: How can it be assessed? JAMA (1988): 260(12), 1743-1748.
[37] Glasgow RE, Vogt TM, Boles SM. Evaluating the Public Health Impact of Health Promotion Interventions: the RE-AIM Framework. American Journal of Public Health 1999: 89(9)
[38] Berwick, Donald M., Thomas W. Nolan, and John Whittington. «The triple aim: care, health, and cost.» Health Affairs 27.3 (2008): 759-769
[39] Porter, Michael E. «What is value in health care?» New England Journal of Medicine 363.26 (2010): 2477-2481

Most of the articles selected belong to descriptive works (14 in total) while comparative studies account for two cases. There are also reviews and systematic reviews but only one randomized clinical trial. Therefore, most studies reviewed in the scoping review are in a lower position in the evidence GRADE scale, suggesting difficulties in carrying out studies that yield a high level of scientific evidence.

Readmission is the main area of impact studied by this selection of work as well as emergency admissions and different sorts of transitional care after discharge using patient-at-risk identification to enrol patients in care management processes.

Impact is measured by the level of service utilization and focuses mainly on hospital readmissions due to new financial incentives introduced in Medicare programmes which strive to avoid readmissions before 30 days of discharge (readmission policy) and thus incentivize new models of care in connection with the community. Despite the intense focus on hospital to community transitions, no other quality measures, such as mortality or complication indexes or institutionalization degree, are present in this selection. In consonance, there is a lack of analysis on other dimensions of impact, such as professional satisfaction or ICT developments.

In regard to the type of population covered, there is a high presence of complex multi-morbidity patients that may well belong to the classification of frail patients, particularly those with conditions of heart failure.

As most of the studies focus on hospital readmission, the main source of the data is hospital minimum basic data sets which are enhanced by information collected through qualitative methodologies such as structured telephone interviews or assessment processes[40],[41]. There is a constant lack of ambulatory and primary healthcare data sources including mental health, long term care and social information.

Impact on Healthcare Structures

The first domain of focus is the impact on healthcare structures. It includes risk-adjusted resource allocation, health information systems and health professionals involved in risk stratification interventions. All three elements are in some way a representation of production factors. Capital (resources) and labour (human resources) are the classical production factors of the industrial age, and knowledge (information systems) is the post-industrial age factor, also applicable to the healthcare sector.

Risk-adjusted resource allocation

Resource allocation is by all means the structural aspect most covered in the literature, mainly due to the readmission policy implemented under Medicare programmes and its extension to other health systems. Public reporting and financial penalties for hospitals with high 30-day readmission rates are spurring organizations to innovate and implement quality improvement programmes in the US context[42].

At system and organizational levels, budget allocation and reimbursement are affected by penalties linked to target compliance on hospital readmission rates[43],[44],[45],[46],[47],[48],[49]. At a clinical level, the reallocation of workload among care

[40] Lewis, G. H. (2010). "Impactibility models": identifying the subgroup of high-risk patients most amenable to hospital-avoidance programs. Milbank Q, 88(2), 240–255. doi:10.1111/j.1468-0009.2010.00597.x
[41] Iloabuchi, T. C., Mi, D., Tu, W., & Counsell, S. R. (2014). Risk factors for early hospital readmission in low-income elderly adults. J Am Geriatr Soc. doi:http://dx.doi.org/10.1111/jgs.12688
[42] Kansagara, D., Englander, H., Salanitro, A., Kagen, D., Theobald, C., Freeman, M., & Kripalani, S. (2011). Risk prediction models for hospital readmission: a systematic review. Jama, 306(15), 1688–1698. doi:10.1001/jama.2011.1515
[43] Snyderman, D., Salzman, B., Mills, G., Hersh, L., & Parks, S. (2014). Strategies to help reduce hospital readmissions. Journal of Family Practice, 63(8), 430–438. Retrieved from http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L373839316
[44] Banerjee, D. D., Thompson, C., Kell, C., Shetty, R., & Vetteth, Y. (2014). Reducing heart failure readmissions: A clinical business analytics approach. J Card Fail, 20(8), S109. Retrieved from http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L71587564
[45] Tuso, P., Huynh, D. N., Garofalo, L., Lindsay, G., Watson, H. L., Lenaburg, D. L., … Kanter, M. H. (2013). The readmission reduction program of Kaiser Permanente Southern California-knowledge transfer and performance improvement. Perm J, 17(3), 58–63. doi:10.7812/tpp/12-141
[46] Kripalani, S., Theobald, C. N., Anctil, B., & Vasilevskis, E. E. (2014). Reducing hospital readmission rates: Current strategies and future directions. Retrieved from http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L373185114
[47] Iloabuchi, T. C., Mi, D., Tu, W., & Counsell, S. R. (2014). Risk factors for early hospital readmission in low-income elderly adults. J Am Geriatr Soc. doi:http://dx.doi.org/10.1111/jgs.12688
[48] Hayward, A., Rastogi, R., Hillstrom, T. J., & Barnes, C. A. (2012). Transitions bundle: Ensuring smoother transitions at hospital discharge. J Am Geriatr Soc, 60, S173. Retrieved from http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L70737908
[49] Morgan, L. L., Stevens, A. B., & McGhee, H. R. (2013). Strategies to identify high-risk patients for the care transitions intervention (registered trademark) (CTI) in an integrated healthcare system. J Am Geriatr Soc, 61, S58. Retrieved from http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L71038143

and case managers, nurse practitioners and social workers is documented in Bielaszka-DuVernay[50] and Freund[51].

In the interview on funding, carried out during the ASSHES project to commissioners, all the participating regions pointed out that risk stratification does play a role in budget distribution. Its intensity is variable among respondents in terms of the proportion of the budget and scope in their care systems (primary, specialized, regional and capitation resource allocation). However, this consensus does not apply with respect to the adjustment of the terms of the contract in the negotiation process between commissioners and healthcare providers. For instance, Puglia declares that adjusting the terms of the contract according to risk stratification strategies is not yet in place, even if stratification is used to evaluate the past allocation of resources.

Risk stratification is also involved in the definition or composition of the Pay for Performance (P4P) programmes in some of the regions' contracts (emergency units, complex service delivery, chronic care management) as well as in the micro level and within healthcare organizations, where certain healthcare professionals may have part of their contract or salary based on goal achievement. None of the regions adjust workloads or patient lists by any sort of complexity measurement that recognizes case-mix complexity, although debate is ongoing in Catalonia, the Basque Country and Puglia.

Part of the survey conducted in the four ASSEHS Regions focuses on resource allocation reviews and includes information on the needs, frequency and economic circumstances of the reviews. Some of the causes motivating the need to review initial resource allocation relate to the modification of the epidemiological context or population structure, changes in the health service portfolio, health planning objectives or contract model, increased or decreased capacity and goal compliance. Due to this, there are annual reviews in all regions.

During years of growth as well as periods of crisis, budget allocation may be reviewed and is accordingly increased or decreased; for instance, the allocation of extra-funding to increase capacity or the need to downshift healthcare services. When reviews are initially motivated by the economic cycle, respondent regions declare that RS is not used to adjust the new resource allocation or disinvestment.

Health information systems ■ ■ ■ ■

A second domain of structural impact is related to the definition and development of health information systems. Here we are interested in scoping the availability of risk stratification and prediction information nested in health information systems accessible to clinicians. The way is displayed in clinical workstations, in the development of filtering and query capabilities for clinicians (end-users) and the availability of alerts and warnings for patients at risk.

Risk stratification and prediction information were common place in most of the studies and were a main source for clinical teams to proactively organize healthcare, particularly to avoid readmissions through transitional care models. In the literature, filtering and query capabilities were found only in work by Morgan et al.[52], whereas alerts and warnings for patients at risk were more prevalent[53,54,55] in the shape of automated alerts and workflows.

The level of satisfaction of clinicians and healthcare managers concerning the way data is displayed, shared and managed in the health information systems used in the ASSEHS pilot regions leads us to think that risk stratification has reached the core of the business, as all regions with RS information available to clinicians scored on the positive satisfaction range.

[50] Bielaszka-DuVernay, C. (2011). Innovation profile: The "GRACE" model: In-home assessments lead to better care for dual eligibles. Health Affairs. doi:10.1377/hlthaff.2011.0043
[51] Freund, T., Gondan, M., Rochon, J., Peters-Klimm, F., Campbell, S., Wensing, M., & Szecsenyi, J. (2013). Comparison of physician referral and insurance claims data-based risk prediction as approaches to identify patients for care management in primary care: an observational study. BMC Fam Pract, 14, 157. doi:10.1186/1471-2296-14-157
[52] KMorgan, L. L., Stevens, A. B., & McGhee, H. R. (2013). Strategies to identify high-risk patients for the care transitions intervention (registered trademark) (CTI) in an integrated healthcare system. J Am Geriatr Soc, 61, S58. Retrieved from http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L71038143
[53] Morgan, L. L., Stevens, A. B., & McGhee, H. R. (2013). Strategies to identify high-risk patients for the care transitions intervention (registered trademark) (CTI) in an integrated healthcare system. J Am Geriatr Soc, 61, S58. Retrieved from http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L71038143
[54] Banerjee, D. D., Thompson, C., Kell, C., Shetty, R., & Vetteth, Y. (2014). Reducing heart failure readmissions: A clinical business analytics approach. J Card Fail, 20(8), S109. Retrieved from http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L71587564
[55] Tuso, P., Huynh, D. N., Garofalo, L., Lindsay, G., Watson, H. L., Lenaburg, D. L., ... Kanter, M. H. (2013). The readmission reduction program of Kaiser Permanente Southern California-knowledge transfer and performance improvement. Perm J, 17(3), 58–63. doi:10.7812/tpp/12-141

The description of health information system features related to risk stratification, specifically embedded in electronic health records, as well as its connection with the level of use and health professional satisfaction, is an underexplored area that deserves further research.

Health professionals ■ ■ ■ ■

The third structural layer deals with the enhanced or changing role of health professionals. Most of the studies show an active role in different health professional categories including social workers and nurse practitioners that have an important role in care transitions. The emergence of new professions, such as care and case managers, liaison nurses and community matrons, is one of the clearest consequences of the introduction of risk stratification information. Nevertheless, only a small role is left to informal caregivers, and its activation in the reduction of hospital readmissions and in-home assessments following the GRACE model is covered only by Snyderman[56] and Bielaszka-DuVernay[57].

The results from the scoping review were echoed in the results of the focus groups on implementation. In Catalonia, risk stratification has helped in the creation of new roles and the modification of traditional roles in the interface between primary care, hospital care and long term care. In primary care, some family doctors have started to specialize in chronic diseases and have become referents in their primary care teams. Primary care nurses with a solid training in the management of chronic diseases have also emerged in primary care teams, as well as link nurses from hospital care. In the Basque Country, advanced practice nurses and case managers in primary care have evolved with new roles in hospitals, like referral internists. In Lombardia and Puglia, family doctors have seen their work towards chronic patients emphasized by patient classifications, and agree to the potential changing role of nurses.

New roles require new skills, particularly non-technical ones, such as those regarding coordination and communication.

■ ■ ■ ■ Impact on Healthcare Processes

The central domain of our Performance Management Framework deals with four subdomains: healthcare organizational strategies (from system level to organization and clinical level), the quality of care process, the redesign of healthcare delivery through innovative models of care and impactibility models.

To complete the process section, we have the impactibility models, also known as further refinement of stratification information, to improve prediction power and healthcare effectiveness.

Healthcare organizational strategies ■ ■ ■ ■

An organizational impact may be possible at a system level, an organizational level and a clinical level. Sometimes it is difficult to trace a clear cut to split levels and this is actually what the literature showed. All of the studies analysed are related to impact on system, organizational and clinical levels, as all three levels are involved in new healthcare interventions to reduce hospital readmissions or to find new models of care transition.

For instance, one way of reducing emergency admissions is to identify people at higher risk. They can then be prioritized for an intervention, such as case management[58]. Also, predictive model information triggers a transitional

[56] Snyderman, D., Salzman, B., Mills, G., Hersh, L., & Parks, S. (2014). Strategies to help reduce hospital readmissions. Journal of Family Practice, 63(8), 430–438. Retrieved from http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L373839316
[57] Bielaszka-DuVernay, C. (2011). Innovation profile: The "GRACE" model: In-home assessments lead to better care for dual eligibles. Health Affairs. doi:10.1377/hlthaff.2011.0043
[58] Wallace, E., Stuart, E., Vaughan, N., Bennett, K., Fahey, T., & Smith, S. M. (2014). Risk prediction models to predict emergency hospital admission in community-dwelling adults: a systematic review. Med Care, 52(8), 751–765. doi:10.1097/mlr.0000000000000171

care intervention, many of which involve discharge planning, as seen in the systematic review on hospital readmissions[59]. At a clinical level, multifaceted interventions were also identified by Kripalani et al[60].

In the focus group on implementation results, Catalonia, Lombardia and the Basque Country shared the observation of improving care around the patient due to the development of new care pathways in coordination with local actors and the leadership of primary care services. At organizational and clinical levels, risk stratification information is helping managers and clinicians to rethink the way they deliver services and start to experiment with new configurations, like virtual words and case managers. As mentioned before, the role of the nurse is that of being one of the drivers involved in order to change practice towards proactive care and chronic care of patients at risk.

Service delivery redesign ■ ■ ■ ■

Under innovative models of care, we may find delivery redesigns, such as virtual wards or care pathways. The emergence of new professional roles observed in the structure section applies here as an element of process redesign. New models of care based on transitional care from hospitals to the community, particularly after discharge, were observed in most of the selected works. Probably the most outstanding experience is reported by Tuso et al.[61] during the description of the South California Kaiser Permanente intervention to reduce hospital readmissions.

In the ASSEHS regions, risk stratification information helped to shape new care pathways. In Catalonia, the process of the creation of new care pathways rolled out independently of the risk stratification information availability. In the Basque Country, when a top-down strategy took place, a brand new care pathway emerged, aiming at multi-morbidity patients. In Lombardy, specific care pathways for specific diseases and integrated pathways for multi-morbid patients were created by GP cooperatives.

Impact on Healthcare Results

The Performance Management Framework also covers the end-point impact on healthcare results. This is a difficult field where the multifactorial nature of healthcare makes it difficult to connect cause and effect in a straightforward way. Our framework sees results in three subdomains: satisfaction of principals, efficiency in resource utilization and quality of care and health outcomes.

Satisfaction of healthcare professionals ■ ■ ■ ■

Surprisingly, satisfaction of healthcare professionals is the subdomain result the least covered in the literature. Only one work focuses on professional satisfaction, and is only concerned with the use of clinical decision support systems. To improve the knowledge in this domain, a specific survey on satisfaction was designed and deployed in Catalonia, the Basque Country, Lombardia and Puglia.

A quantitative analysis based on Likert scales ranging from 1 to 6 was carried out jointly with a qualitative analysis of open questions. Scores of over 3.5 are considered in the positive impact and satisfaction range, while those under 3.5 are identified as weaknesses. Table 5 displays the results at a regional level.

[59] Kansagara, D., Englander, H., Salanitro, A., Kagen, D., Theobald, C., Freeman, M., & Kripalani, S. (2011). Risk prediction models for hospital readmission: a systematic review. Jama, 306(15), 1688–1698. doi:10.1001/jama.2011.1515
[60] Kripalani, S., Theobald, C. N., Anctil, B., & Vasilevskis, E. E. (2014). Reducing hospital readmission rates: Current strategies and future directions. Retrieved from http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L373185114
[61] Tuso, P., Huynh, D. N., Garofalo, L., Lindsay, G., Watson, H. L., Lenaburg, D. L., ... Kanter, M. H. (2013). The readmission reduction program of Kaiser Permanente Southern California-knowledge transfer and performance improvement. Perm J, 17(3), 58–63. doi:10.7812/tpp/12-141

Impact questions	CAT	BC	LOM	PUG
Use of RS information	4,03	3,44	4,36	4,46
Impact on Coordination	3,77	3,59	4,36	2,54
Usefulness in daily practice	4,19	4,07	4,64	4,56
Use for new interventions	3,98	3,34	4,45	3,96
Overall healthcare Impact	3,53	3,49	4,18	3,23
Clinical coherence	3,88	4,21	4,09	4,46
Satisfaction questions	CAT	BC	LOM	PUG
Communication	3,56	3,36	NA	4,04
Training	3,40	3,41	NA	4,04
Information visualization	3,47	3,59	NA	3,87
Data sharing	3,15	3,44	NA	3,86
Data management	3,37	3,32	NA	4,06

Table 5: Impact and satisfaction of RS by region (CAT: Catalunya; BC: Basque Country; LOM: Lombardia; PUG: Puglia)

Results vary significantly from region to region. This is expected, as the four ASSEHS Regions had completely different intervention programmes in very different contexts. In Catalonia, impact questions score higher than satisfaction. Among impact, usefulness and level of use score at the positive range, while overall healthcare impact is controversial. Regarding satisfaction of end-users, data sharing is the area to improve, while clinicians are satisfied with the communication received and the information displayed in the EHR. In the Basque Country, clinical coherence has the highest impact, while the level of use to design new interventions is below centrality. Basque clinicians and managers are satisfied with data visualization and dissatisfied with data management features. In Lombardia, only impact questions applied to the intervention, because the stratification information was not provided directly in the patients' healthcare records and thus many questions on how stratification information was perceived are not applicable. All impact related questions are in the positive range, highlighting the level of usefulness. Finally, in Puglia, usefulness, use and clinical coherence have a higher impact and clinicians claim to be satisfied with communication, training and data management.

Efficiency and resource utilization ■ ■ ■ ■

Efficiency seems to be the driving force behind most interventions in search for a better sustainability balance of modern healthcare systems threatened by the epidemiological transition. From a healthcare provider's perspective, avoiding financial penalties or achieving set targets on hospital readmissions and transitional care programmes are the important variables of risk stratification information use found in the literature reviewed. Other sorts of service utilization reduction, such as avoidable admissions (following Ambulatory Care Sensitive Conditions criteria) and avoidable emergencies, were found in addition to hospital readmission reduction in almost all selected studies. Similarly, the cost of healthcare services as a logical consequence of service utilization reduction was found in the literature.

The interview on funding tackled the consequences of the introduction of risk stratification in the resource allocation system on the behaviour of healthcare providers and professionals. With respect to the efficiency of the providers, the predictive power of risk stratification strategies is very valuable in order to reach health objectives. It facilitates the identification of targets, the redistribution of workloads and the sensitizing of health professionals towards care pathways, collaboration between providers, alternatives to hospital admissions, telephone contact, long-term care

and shared individual intervention plans. In this sense, there is a clear alignment towards chronic care strategies and programmes.

Quality of care and health outcomes ■ ■ ■ ■

The quality of care and health outcomes, including measures of patient quality of life, reversal of frailty, increased autonomy or patient quality of life, are the last subdomain of the impact on results.

Equity is also included as an element of health outcomes and results. There is an increasing concern about the equity consequences in the use of risk stratification tools and predictive modelling. Inequity relies on the reduced accessibility for vulnerable patients if they are excluded in advanced impactibility models (use of socioeconomic status as proxy for non-compliance). As Shadmi[62] notes, there is a trade-off between improving impact and achieving equity that will increase as more personal data become available.

Among the studies related to MEDICARE readmission policy, a special focus in specific diseases such as heart failure is dominant due to its importance in terms of exacerbations and non-planned emergency admissions in acute hospitals, causing higher costs.

During the interview on funding, and in terms of the quality of care, respondents highlighted that risk stratification strategies more specifically affect those working in chronic care programmes with comorbidities, while other interviewees still see it as being far off. It was also stressed that there is an increased awareness on data gathering and that changes might be more relevant to healthcare managers rather than to clinicians.

Finally, we identified a lack of focus on the use of variables related to the quality of life like "self-perception". Some authors are demonstrating a positive relationship between self-perception and hard indicators like mortality and emergency admissions that should lead to a systematic collection of patient-reported outcome measures[63].

■ ■ ■ ■ Considerations about the Impact of Risk Stratification

Measuring the impact of multifactorial phenomena, such as the art and science of healthcare, is a difficult endeavour. In the ASSEHS work plan, the first milestone was to charter the measuring of impact in a systematic and practical way. This work ended with the configuration of the Performance Management Framework that has been revealed as a thorough reference to assess the impact of the introduction of risk stratification tools, information and strategies in healthcare systems. As part of the framework, the PMF provided a practical classification of elements that need to be studied with different methodologies.

We may conclude from the scoping review that most of the works were produced in the last five years and predominantly in the US context. The readmission policy, introduced by Medicare to penalise those hospitals with a higher rate of hospital readmission before 30 days, has triggered the introduction and use of risk stratification tools and information. Moreover, programmes and interventions, tailored to patients identified at risk, have proliferated to avoid readmissions and to explore new models of care.

A lack of studies on the use of risk stratification tools in ambulatory care or primary care setting was detected, as

[62] Shadmi, E., & Freund, T. (2013). Targeting patients for multimorbid care management interventions: the case for equity in high-risk patient identification. Int J Equity Health, 12, 70. doi:10.1186/1475-9276-12-70
[63] Hibbard, J. H., Greene, J., Sacks, R., Overton, V., & Parrotta, C. D. (2016). Adding A Measure Of Patient Self-Management Capability To Risk Assessment Can Improve Prediction Of High Costs. Health Affairs, 35(3), 489-494.

well as a lack of use of data sources other than those found in hospital data. The combination of information from social data sources and mental health, long term care and primary care would significantly improve the richness of risk stratification and prediction models.

At a structural level, resource allocation is the "king of the class" due to the incentive programmes introduced by health authorities which are able to mobilize the whole industry. In terms of health information systems, the literature illustrates that this is an evolving field, although the level of adoption is high enough. Improving the filtering and query capabilities of the different information suites turned out to be the main area of improvement. In the last element on structure, health professionals have shown how risk stratification tools have been able to shape a brand new set of health professionals, converting their roles (like nurses becoming case managers, liaison nurses or advanced practice nurses) or gaining a new space within the health professions (like social workers to collaborate in transitions of care).

Healthcare processes have also been impacted by risk stratification tools. The development of care management, case management, transitions of care or virtual wards are only a small sample of the new ways of providing healthcare that risk stratification tools are able to induce. The power of identifying patients at risk and the capacity of the health system to proactively deal with these patients is a powerful combination to improve quality and efficiency at the health system level.

Impactibility models and their consequences in terms of equity and access are probably the most exciting and emerging themes in the risk stratification landscape. The consequence over vulnerable populations of refinement in the prediction models may bring more power in predicting, but may also bring secondary effects in terms of accessibility. The improvement in refining social, mental and primary care data was also highlighted in different works.

At the result dimension, it seems that readmission focus is the predominant outcome to be predicted, especially in US and English articles where penalties are being introduced as a policy to decrease the number of 30-day readmission rates related to exacerbation of chronic conditions.

There are not many studies assessing the satisfaction of professionals with stratification. This identified niche, yet to be researched was addressed in a specific survey for all four ASSEHS regions. Further to our analysis, we may conclude that front line clinicians and managers, particularly in primary care, are quite satisfied with the use of risk stratification information for daily practice and for innovations, its usefulness, its clinical coherence in the identification of patients at risk, the impact on coordination and the overall healthcare impact. Slight differences were observed by regions, but they have to be tackled carefully as they cannot be compared in a linear way due to the contextual difference of each health system. Each region has a different tradition and experience in risk stratification use and deployment, and further analysis has to be developed in each context.

In the case of professional satisfaction regarding the risk stratification communication process, training, information visualization, data sharing and data management, there was concordance among regions in that the area with a high potential for improvement as an easy target to achieve was the training of healthcare professionals. This was therefore spotted as part of the intervention in each region.

Finally, risk stratification tools and information may also cause effects on health outcomes, both in the quality and on the results. Cost reduction and efficiency gains were reported largely in the literature, whereas quality improvements were more difficult to demonstrate due to the mentioned multifactorial nature of healthcare.

To conclude, we would like to point out under-covered areas that require further exploration. This is the role of social care information. The prediction of social care events, such as admissions to nursing homes, a higher intensity of home care services or the probability of a higher loss of autonomy, are non-desirable events that could be avoided or at least delayed.

5-ASSESSMENT FOR REGIONAL INTERVENTIONS USING STRATIFICATION
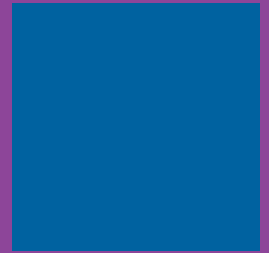
Introduction about Intervention Assessment Framework

In order to generate the lessons learnt and identify improvement areas from ongoing Regional programmes using risk stratification, the ASSEHS project has set up an Intervention Assessment Framework This is expected to assess all the different domains involved in risk stratification: a) the selection or development of a risk stratification tool, b) the implementation plan for a risk stratification tool, and c) the impact of the deployment of a risk stratification tool. The Intervention Assessment Framework (IAF) generated in the ASSEHS project is a heterogeneous set of tools, which can be used to assess Regional interventions based on risk stratification tools. Each tool was targeting different profiles, from risk stratification tool developers, to programme managers, to clinicians, to commissioners, to key informants, etc.

The whole framework can be found in the ASSEHS Internal Deliverable called "ID10 - Intervention Assessment Framework". For the moment, it is sufficient for the reader to know that the framework was divided into the three main domains as described in the first paragraph, that more than 80 indicators were defined and that the final list of tools (each of which might span through multiple domains) resulted in:
- 2 surveys (one on the selection/development of risk stratification tools and one on the satisfaction of clinicians)
- 3 interviews (one on the selection/development of risk stratification tools, one on implementation, and one on funding)
- 1 focus group (on barriers and facilitators for the implementation and deployment of risk stratification tools)
- A data collection methodology from Regional Databases
These tools were applied in the four ASSEHS pilot Regions. The most important discoveries on the best practices and lessons learnt are reported in the section below.

Lombardy Intervention Assessment

Description of the region and programme

In 2015, 10,006,727 people lived in Lombardy. About 19.7% of its population were above 65 years of age and about 27.5% were diagnosed with a chronic condition. Lombardy is divided into 12 administrative provinces. In 1997, it was the first Italian region to have set up a so-called quasi-market model in its local health care system, introducing competition to improve quality and control expenditures. As a consequence, the four main principles of the Lombardy health care system are: 1) universal coverage (solidarity), 2) the separation between health care purchasers and providers, 3) competition between public and private accredited providers in the presence of a third-party payer and 4) the possibility for patients to freely choose among providers. The health system is financed by general taxation and by citizens' co-payment. The National Government assigns the financial resources to the Regions on a capitation system which is adjusted for different indicators (age, chronic diseases, geomorphology, etc.).

The Lombardy Region receives and manages funds for health care, plans activities in cooperation with so-called Local Health Authorities (LHA or ATS) and monitors the delivery of minimum levels as defined by the central Italian Government. LHAs (of which there were 15 until 2015, when they were merged into 8 Agencies) manage health care in a geographic region within Lombardy and manages contracts with service providers. Providers – either public, non-profit-making or privately accredited - compete in production following the same rules. LHAs are paid by Lombardy through weighted capitation using previous expenses, demographics and geographical criteria. On the other hand, providers are financed by LHAs on a fee-for-service basis: prospective DRG (Diagnosis Related Group) payment for hospital discharges, and tariffs for outpatient services. In short, Lombardy acts as an autonomous region having insurance and funding functions, the LHAs have programming and purchasing power, while

production is carried out by providers.

The Chronic Related Groups (CREG) is an innovative model of mono-pathological and multi-morbid chronic patients care coordination with a built-in economic model. The initiative started in 2011 in the Lombardy Region, and it is still ongoing. Five Local Health Authorities (LHA) were selected to test the new model, with the idea of scaling it up to the entire Region in the event of positive results. In 2015, the pilot was enlarged to 10 LHAs. A tutoring system was set up from the original 5 LHAs in order to initiate the 5 new LHAs, corresponding to 6 Agencies (ATS) out of 8, following a 2015 health system reform.

From a structural point of view, the CREG model is based on three pillars: 1) the technological infrastructure which allows the identification and stratification of chronic patients; 2) the care plans (CP) and medical guidelines; 3) a new reimbursement system, which allows the creation of new actors in the management of chronic patients. In particular, these new actors, called CREG Providers, were formalized as being Cooperatives of General Practitioners.

One of the main issues for the Lombardy Region is being able to correctly identify chronic patients (including all the possible disease and co-morbidities they have, and the severity of each disease) starting from data generated from administrative processes and hence improving the appropriateness of their care. Chronic patients should follow a care pathway in order to control the diseases and prevent exacerbations.

What happens in reality is that some patients are under-consumers, do not follow a care plan and - besides the possible onset of complications and disease worsening - are therefore a potential cause for higher costs in the healthcare system. On the other hand, others are over-consumers and cost more than expected. However, the majority of patients are appropriate consumers and stay in the middle of a quasi-Gaussian curve.

To overcome the complexity in the management of the patients, the Lombardy Region has adopted a unique database (BDA – Banca Dati Assistito) which, thanks to the citizens smart card, collects all the relevant health information for each patient's consumption (in particular hospitalizations, drug consumptions, outpatient visits, etc.). This information, merged with the information from the co-payment exemption system, was not only able to provide (through appropriate algorithms) the pathology by which the patient was affected, but also the severity level. This severity level is not to be considered in a "clinical" sense: it is more a judgment on the complexity of the clinical pathway, the care needs and the potential consumption of resources.

Intervention Assessment ■ ■ ■ ■

The stratification in Lombardy is mostly an economic stratification, even if, of course, it contains implicit and explicit clinical information. The differences between clinical assessment and risk stratification information might be very different, mainly because the risk stratification is calculated using administrative data, which might be incomplete, not present (e.g. for patients relying only on private not-accredited Service Providers), or not updated (e.g. for events happening after the stratification, delays in data flows, etc.). However, this is not a major concern, as they have different purposes: risk stratification is made for population management and for the estimation of the individual expenses, while clinical assessment is made for single case management.

One of the main issues, while creating a stratification model linked to an economic tariff, is the determination of the actual tariff for each strata of the population. This is a very complex issue, due to the following difficulties: (i) getting updated and synchronized data flows (e.g. drug consumptions, hospitalizations, ER access, etc.), (ii) correctly mapping pathologies with patients, (iii) monitoring the evolution of complex multi-morbid patients, which might change radically over the period of a year. The definition of the tariffs changed during the years of the pilot, both in terms of the reimbursement

model (originally only paid on the difference between the individual consumptions forecast and actual consumptions, then changed to a pro-capita payment for each patient enrolled, and finally to a mixed system), and in terms of economic amounts (starting from a forecasting approach and arriving at a retrospective approach).

The fact that the programme is strongly linked to an economic payment is a double-edged weapon: on the one hand, it is possible that some bad practices arise due to opportunism, but on the other hand, it ensures a strong commitment from GPs.

Overall, stratification was not introduced alone in Lombardy. It was strongly linked to a new care model which had delegated a new role to primary care, with respect to multi-morbid and frail chronic patients. This change was first of all cultural and it required General Practitioners to re-think the way they usually provided care.

Through the IAF, a study comparing different outcome variables was conducted on the population. The data analysed was from the first year of the programme, when most of the enrolment took place. Amongst the 103.986 patients, 79.700 were randomly selected, and were classed in the non-eligible population, matching them with the intervention group using the following variables: gender, age, Local Health Trust, risk class, number of hospitalizations in the previous year, number of ER admissions in the previous year, number of pathologies, and defined daily dose (DDD) in the previous year.

Figure 28 shows the numbers of the population involved in the study:
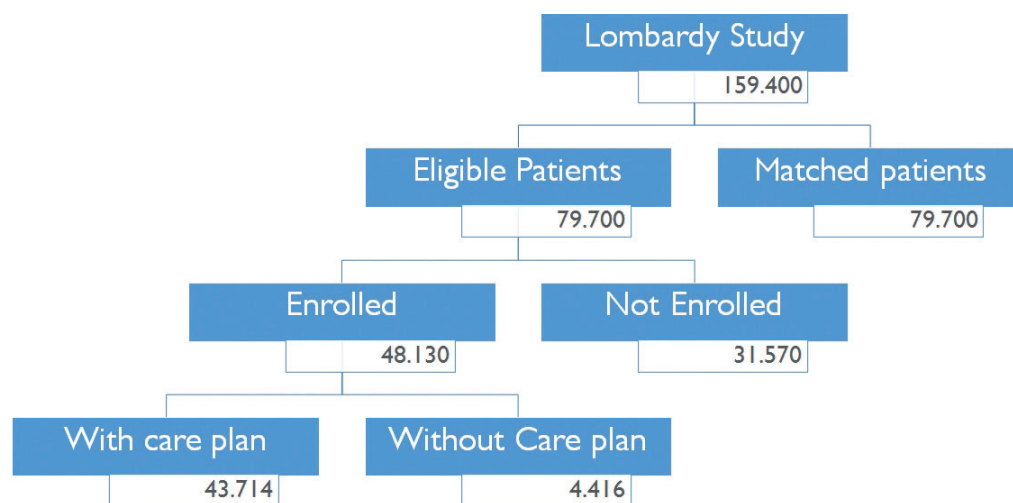
Figure 28: Lombardy population studied with the IAF

Given that being enrolled in a programme without a care plan has the same effect as not being enrolled at all, we will from now on refer to the patients enrolled and prescribed with a care plan as the Intervention Group. We will use the Control Group of the matched patients as a reference.

The following table and figures summarize the differences in percentage of the Intervention Group, with respect to the Control Group (all p values are <0.001):

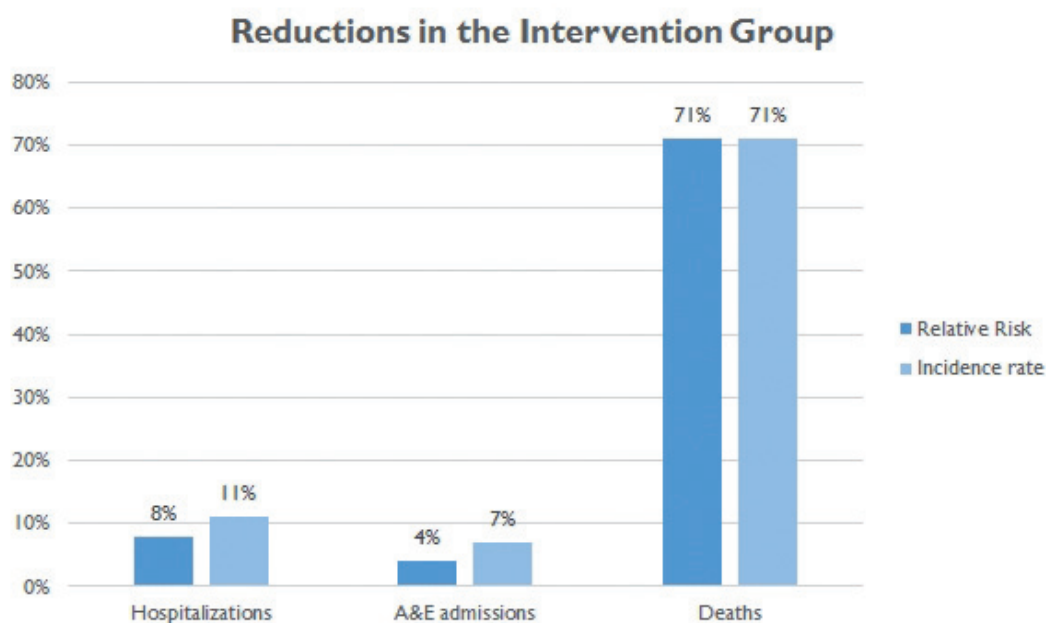|	Relative Risk	Incidence rate
Hospitalizations	-8%	-11%
A&E admissions	-4%	-7%
Deaths	-71%	-71%

Figure 29: Reductions in the Intervention Groups in percentage with respect to the Control Group

Even if it is true that an effect on these outcomes is expected from the programme, the data related to mortality lead us to believe that there are other impacting factors which have not been considered in this analysis, as the reduction in the mortality rate is definitely too high. A hypothesis might be an enrolment bias: if a less critical part of the population was enrolled, this would explain the numbers. Another possible explanation is that in 2013, terminally-ill patients were excluded from the programme by the Region. Whatever, the programme is expected to improve these outcomes, and it is interesting to see that at least the results do not contradict this expectation.

A further analysis was conducted on the difference of the DDD and costs, by taking the delta difference between 2012-2013 DDD and costs, compared with the difference between 2010-2011 DDD and costs. In other words, the analysis checked if DDD and costs increased or decreased more during the program than before. Again, data are reported below and all p values are < 0.001:

	Mean difference	95% C.I.
Delta costs	-154.85€	-222.15€, -87.19€
Delta DDD	31.98	25.80, 38.15

Table 7: Comparison in changes in DDD and costs. Delta calculated for years 2010-2011 (before the program) and 2012-2013 (after two years of the program)

It is interesting to note that while the DDD has increased, overall, the costs have significantly reduced. This can be interpreted in many different ways, one of them being that patients treated appropriately (with more drugs) generated less cost in the healthcare system (e.g. less hospitalizations, etc.). However, in this case, there can be other confounding factors not tracked by this study which might also have had an impact (e.g. the expiration of some patents on certain drugs, becoming then available at lower costs, or the availability of equivalent drugs, or the reimbursement of a new drug, etc.).

The presence of many confounding factors in the studies is not surprising: these are not randomized control trials in controlled environments, but studies on the whole population, where controlling the number of confounding variable is almost impossible.

Good Practices ■ ■ ■ ■

The main peculiarity with respect to similar initiatives in Italy and in Europe with the CREG programme is the introduction of an economic tariff associated to the care management of multi-morbid and frail chronic patients. This was the first and main important good practice, as it ensured a strong participation and adherence of GPs and consequently a large enrolment of eligible patients. The way to measure the compliance of GPs with the chronic care programme is to observe the percentage of enrolled patients with an active care plan. Figure 30 reports data from the BuongiornoCREG initiative, an implementation of the CREG Programme which uses the same technology platform provided by Telbios. It is used by four cooperatives of GPs and involves approximately 60% of the GPs in the programme. In this figure, it is possible to observe that most of the patients (approx. 93% of them) have an active care plan, while only a small percentage has an expired care plan or no care plan at all. This shows a very good compliance of the GPs within the CREG Programme.
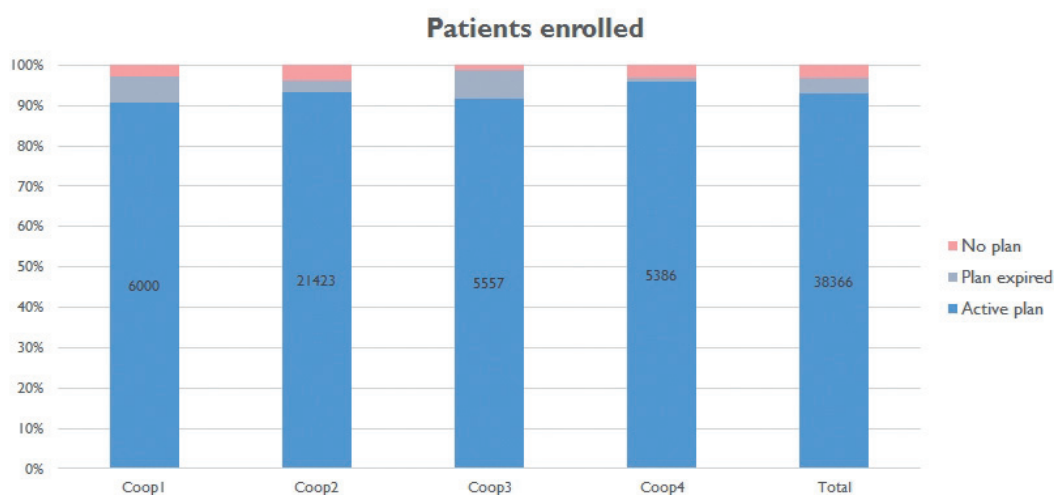

Figure 30: Lombardy GPs' compliance with the programme (data updated in May 2016)

A second important good practice is related to the creation of the team: as the creation of an appropriate stratification of the population is a very complex issue. Very different profiles have to be involved in the planning and monitoring of the programme. In Lombardy several professionals were involved, including medical doctors (both from primary care and specialists), epidemiologists, statisticians, data managers, analysts and developers with IT background, health economists, etc. The heterogeneity of the team is crucial for the success and acceptance of the stratification.

A third good practice which is worth mentioning is related to the training of GPs. Even if not organized directly by the Region, the training activities were a mandatory requirement to become accredited CREG Providers. The training covered several aspects (from clinical governance, to auditing, to the use of the ICT tools, etc.). However, most importantly, it demonstrated the importance of peer-learning and peer-support, as in the end GPs helped each other to become active participants in the programme.

Improvement Areas ■ ■ ■ ■

The CREG Programme has improved and evolved a lot since its original formulation. The same applies to the stratification tool, strategy, and reimbursement model. The evolution is continuous and hopefully it will never end. However, some important improvement areas can be highlighted, as a lesson learnt and to be shared with a broader community.

a) One of the main goals that was not achieved was the full enrolment of the eligible population. The reasons are yet to be investigated, but the original idea when introducing the stratification was to identify over-consumers and un-der-consumers in the population for each stratum, in order to assign a constant set of economic resources. However, if there is no shift from over to under-consuming, the tariff will always be lower than the actual costs, and this would be the case if the GPs did not enrol all their patients. Sometimes only patients with the most convenient tariff were enrolled and sometimes only the most critical ones were (for example, in general, younger and non-consumer patients were not enrolled). Another hypothesis is that the administrative costs to manage a patient (mostly in terms of time and bureaucracy) are so high that they might become overwhelming in the daily clinical practice of a GP. Furthermore, there is also a risk that the older and more severe part of the population is not enrolled at all, due to hospitalisation, or living in retirement homes, or maybe due to them being managed directly by the specialist and not by the GP.

b) Another problem was the separation between clinical and administrative information. As the risk stratification is designed for population management and not for clinical assessment, it doesn't really include (at least not explicitly) all the information needed for a GP to make informed decisions. The Lombardy Region provided an administrative tool to manage patients, but it was mostly unused because GPs were already using another clinical tool in their daily practice. The existence of two separate tools (one for clinical management and one for administrative management) should be avoided in the future. Some CREG Providers used an integrated system provided by Telbios[64], which had information and functionalities from both an administrative and clinical point of view.

c) To simplify the creation of the population classes, only the two most expensive pathologies were explicitly descri-bed in the CREG class assigned to a patient, while all the other pathologies were grouped and provided collectively with a number of other diseases. Furthermore, severity level was not taken into account (because not present in administrative databases), so for example heart failure patients were all grouped together independently from their NYHA class, making "in general" the heart failure pathology very expensive. These two factors combined caused some pathologies to appear as more expensive and made them hide other ones which might otherwise have been quite important from a clinical point of view, sometimes causing the risk information to be quite far from the actual clinical assessment.

d) Another problem in the creation of the tariff associated to the stratification information was the heterogeneity from a geographical point of view. In different local situations there are different healthcare services offered, which somewhat influence the expenses. For example, in big metropolitan areas there is a trend towards over-consuming, whereas in rural areas, the trend is to under-consume. Stratification information should also include (at least in the tariff calculation) the geographical area and the possibility to access healthcare services.

Puglia Intervention Assessment

Description of the region and programme ◼ ◼ ◼ ◼

Puglia is a region in Southern Italy. Its southernmost part, known as Salento, forms the high heel of Italy's «boot». The surface area of the region is 19,345 km2, and its population is about 4.1 million. The capital of the Region is Bari, situated on the coast.

Puglia is divided into 6 local health authorities (LHAs) with an overall population of 4,090,105 inhabitants (2015). The population aged 65 years and above is 835,139 (20.4%) and more than 50% showed at least one chronic condition. Puglia's healthcare system provides universal coverage to all citizens and immigrants in its territory through public and accredited private providers. The health system is financed by general taxation and by the citizens' co-payment. Inhabitants can access the healthcare system through a free choice among providers. The National Government allocates resources to the Regions through the use of a sharing system adjusted for geomorphology and clinics-demographical factors. The Puglia Region plans activities and allocates resources in cooperation with LHAs in order to ensure the minimum level of healthcare to its population, as defined by the central Italian Government. LHAs manage health care in a geographic region within Puglia, define the supply of healthcare services and manage contracts and modality of reimbursement with the providers. The distribution of resources to LHAs is defined by the Region through weighted capitation adjusted by demographical and geographical criteria. Healthcare spending is managed using a system of competition among providers – either publicly or privately accredited.

The reimbursement to providers is defined by LHAs through a system of fee for service. The DRG (Diagnosis Related Group) system is used to define the payment for hospital discharge and tariffs for outpatient services (diagnosis and procedures are codified through ICD9-CM coding), while the cost for the reimbursement of drugs is defined with the help of a regional rate table. In short, although Puglia receives national funding, the organization and management of its healthcare system is autonomous; the LHA have programming, purchasing and control functions, while public and private accredited providers act in the production of healthcare services.

During the involvement in the ASSEHS project, the Regional Healthcare Agency of Puglia (A.Re.S.) developed and validated a risk stratification model able to define the case-mix of the regional population.

This model uses administrative databases to define the clinical risk profile of the whole adult population. In particular, the Charlson Comorbidity Index (CCI) was calculated on the diagnosis contained in Hospital Discharge Records. Furthermore, a new tool - called Drug Derived Complexity Index (DDCI) - was developed and validated through the use of territorial drug prescriptions. The DDCI has been designed and validated to stratify the population (40 years and above) with respect to short (1 year) and long-term mortality as well as time-to-first unplanned hospital admission and readmission. This model was deployed in 2014 as a potential predictor of the level of complexity of the case-mix to allocate healthcare resources among LHAs. This initiative is still ongoing at the time of writing this White Paper. Despite the results achieved by applying the Puglia Risk Stratification model, research activities are ongoing in order to improve the RS model, for instance:

a) In the ongoing analysis on healthcare impact of Puglia Care (the Chronic Care Model of Puglia), DDCI was used to match subjects included in Puglia Care with controls with same clinical characteristics;

b) In a different population from Apulia, DDCI was recently applied on a cohort of 90,000 subjects followed by 100 general practitioners in the Veneto region;

c) A pilot ongoing experimentation with 40 GPs in Puglia is evaluating the correlation between the DDCI score and the clinical judgment of GPs.

If the results of these experimentations are positive, then, starting from 2016, the DDCI score will probably be used as inclusion criteria to involve patients in the regional CCM.

The routinely structured use of administrative databases in the planning of healthcare intervention requires an IT framework able to record any contact that patients make with the healthcare system and to aggregate patient data. To ensure these complex needs, Puglia has adopted a unique IT platform (BDA - Banca Dati Assistito) which collects all the healthcare data (hospitalizations, drug consumptions, outpatient visits, payment exemption for pathology or income, recourse to A&E department, etc.) of every inhabitant of Puglia. This information not only allows one to define the pathologies that affect the Apulian population but also provides an aggregated degree of complexity level. This stratification of the population is not only clinical but also predicts the consumption of healthcare resources.

The stratification of the population allowed a better allocation of the healthcare resources. It thus avoided over-consumption or under-consumption with potential inappropriate use of the regional emergency system. Moreover, the definition of specific healthcare pathways related to the clinical risk profile could afford a more appropriated planning for chronic patients in order to have secondary prevention and to delay the exacerbation of the disease.

Finally, the pilot study of the DDCI comparison with the GPs' clinical assessments will enable the introduction of clinical, social and anthropometric variables - not contained in administrative databases - in the forthcoming stratification tool. This will allow better performances in the prediction of clinical or economical end-points.

Intervention Assessment

The experience of using risk stratification tools in Puglia is less mature than in the other ASSEHS pilot Regions, but it is not less interesting. In fact, the development of the stratification of the population is almost as advanced as in the other Regions. The only real difference is that, with the exception of small pilots, there is not a main Regional programme or initiative strongly tied to the stratification.

The main goal of the application of the risk stratification tool is to describe population case mix at a macro level for use by the Region's top management. For this reason, in its first implementation, risk stratification tools were only implemented at a macro level. Only pilot studies are carried out at micro level. In particular, the tool was used to make a retrospective study on the resources consumption. As already described, the proposed tool was the Drug Derived Complexity Index (DDCI). In particular, the Region evaluated whether DDCI was able to stratify the general population according to the risk of death, unplanned hospital admission and readmission, and it was compared with the Charlson Comorbidity Index in terms of discrimination and reclassification.

As the introduction of the risk stratification tool was not meant to be used by GPs (at least not in the first design), there has not been any introduction of new care pathways associated to the different levels of risk, even if the Region recognizes that it would be beneficial to use risk stratification tools in order to support their definition. Of course, in case new organizational models of advanced health care pathways are defined, new professionals and new skills (case manager, care giver, care manger, etc.) will be needed, as well as new professional networks. At the moment there are only small scale experimentations going on. These are expected to create the foundation for the use of risk stratification at a more systematic level.

In the small scale pilots, appropriate training was provided to most of the GPs involved. The training sessions regarded the construction of the risk stratification tool, the main findings of its application on the population, and potential users. Moreover, some information about the use of the web-based platform (created to facilitate the project participation) was provided. Feedback was received from GPs about the methodology of validation of the stratification tool, the aims of the stratification programme, the implications on the healthcare organization and the

modality of access to web-based platforms created to support the programme. No training was provided to the meso-level, and this was perceived as a potential weakness for the success of a potential introduction of risk stratification methodologies.

The Region developed a web-based platform in which GPs were not only able to record the data of frail patients, but also the clinical judgement about the risk information. Systems are not yet integrated into the regional web-platform, but data are linkable through the use of the same anonymization criteria. So far, patients cannot access their own data, but electronic medical records are shared between healthcare professionals.

The team that worked on the introduction of the risk stratification in Puglia was rather heterogeneous and included all levels of professionals in the Region: healthcare agency directors and managers, local health authority directors, hospital trust directors, health district directors, policy makers, epidemiologists and general practitioners. There is a monitoring process performed by the Regional Healthcare Agency staff, with a periodical analysis of the strategy used at a population level.

In Puglia, the stratification of patients is performed yearly. The current deployment of the tool has taken approximately three months from the decision to use risk stratification. As administrative databases were used to stratify the clinical risk profile of the population, a clinical assessment is fundamental to validate and/or improve the risk stratification tool.

Finally, through the IAF, we performed a population-based study on healthcare outcomes. Since 2012, AReS Puglia has developed and deployed a Chronic Care Model for the integrated care of the frail population called Care Puglia. This programme provides the inclusion of frail or at risk of frailty subjects on the advice of GPs. A Case Manager has been designated for the coordination of the healthcare and provides screening and monitoring actions, support for therapeutic compliance, improvement of dietary, physical activity and voluptuary habits, and coordination in the recourse to regional healthcare supply. Currently, 311 GPs have included the data of 3413 frail patients who are under the care of 50 Case Managers. From the electronic medical records (EMRs) of patients included in Puglia care, a cohort of 1074 subjects aged 40 and above were selected and included in the intervention programmes in the period 2012-2013 with a minimum follow-up period of 12 months. A cluster analysis was used to include 2 subjects - when possible - for each subject of the intervention group. These subjects had to be in usual care and present the same clinic-demographic characteristics (age, sex, local health authority, DDCI class, number of urgent hospital admissions, absence of neoplasm).

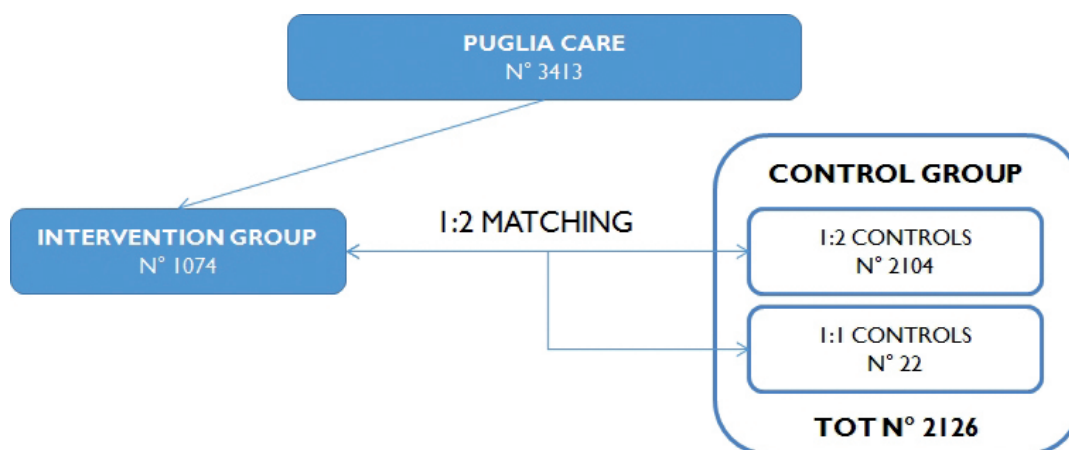This following picture shows the population in the study:

Figure 31: Puglia population studied with the IAF

The recourse to healthcare services has been compared in the intervention and control group, evaluating the following end-points: number and days of hospitalization (total and unplanned), number of early readmissions (within 30 and 60 days) and healthcare costs. We calculated the average number of events per 100 persons/year in intervention and control groups during the follow-up period. Incidence Rate Ratio (IRR) was used to compare the results.

The following table and figures summarize the main results:

	Intervention Group	Control Group	IRR (CI)
N° of unplanned hospitalizations	10.3 (9.1-11.7)	13.1 (12.1-14.1)	0.79 (0.68-0.91)*
Days of unplanned hospitalizations	92.6 (88.8-96.6)	115.9 (113.0-118.9)	0.80 (0.76-0.84)*
Costs for unplanned hospitalizations	39572 (39491-39653)	49622 (49562-49683)	0.80 (0.80-0.80)*

*p<0.001

Table 8: Mean number of events per 100 persons/year and Incidence Rate Ratio with Confidence Interval in intervention and control group during follow-up.
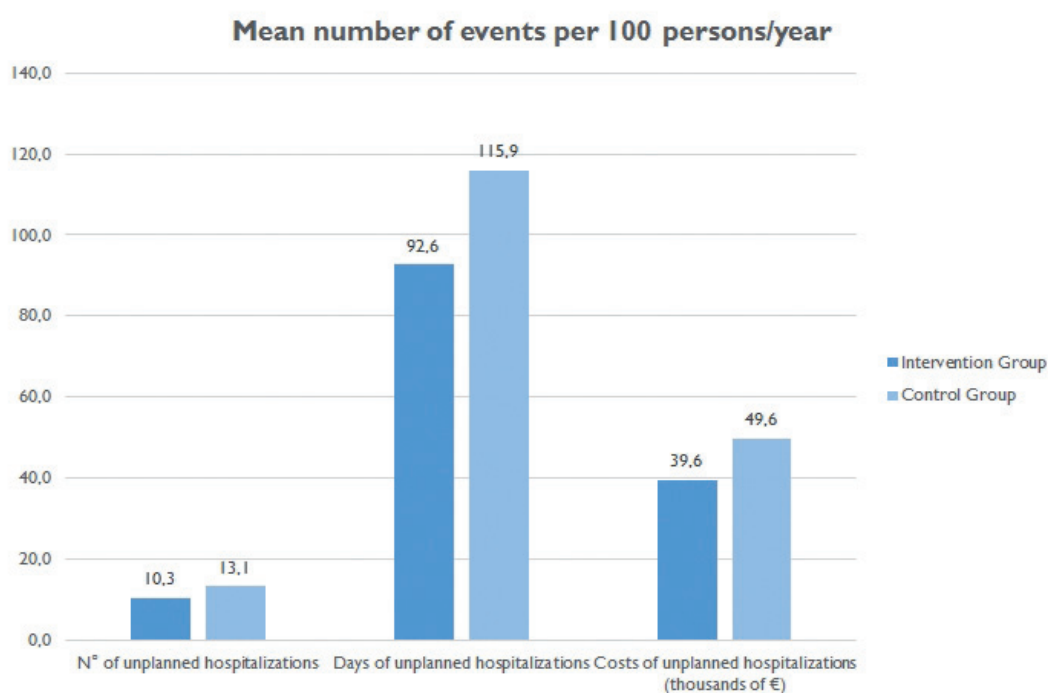

Figure 32: Mean number of events per 100 persons/years in intervention and control group during follow-up

During the follow-up, there is a significant reduction both in the number and days of unplanned hospitalisation (-21% and -20% respectively) in intervention groups. The minor recourse to emergency services is also testified by the reduction of healthcare expenditure due to unplanned hospitalisation (-20%). Moreover, healthcare savings due to the minor recourse to emergency systems could be higher with the acquisition of data of recourse to the A&E department and the out-patient emergency system.

Although this study is not a randomized control trial in a controlled environment, and it is impossible to constrain the number of variables, the findings of this population-based study, in which case and controls are matched by the

major clinic-demographical variables, have an important epidemiological significance as already attested by other scientific publications that apply the same method.

Good Practices ▪ ▪ ▪ ▪

Formal data from an ongoing regional programme are still missing in Puglia at the time of writing this White Paper. However, through some preliminary studies, the Puglia Region developed and validated a prognostic index derived from prescription data, able to stratify the entire population into homogeneous risk groups. For this reason, the first good practice that is interesting to share is related to the developed index. The DDCI can represent a useful tool for risk adjustment and for policy planning, as well as an instrument for the identification of patients needing a tailored approach in everyday practice. Its use foresees the improvement of the quality of care and the optimization of the allocation of resources. The major strength of the DDCI score is its reliance on a single source of administrative data based on the ATC coding system, widely used in many countries. For this reason, the DDCI can be applied in all the healthcare contexts in which there is a lack of clinical data; it can be easily applicable at a population level, requiring only the availability of data on drug prescriptions.

The second good practice is related to the creation of a network of professionals: in the small pilot carried out within the Care Puglia initiative, it was observed that professionals started working better as a team, and they found it easier to share clinical assessments of patients with a network of professionals. Of course the new organization of work (in networks) needs to undergo an evaluation of healthcare outcomes, but the results are promising.

Finally, a third good practice is the development of a web-based platform to facilitate the involvement of GPs. This platform also acts as a consultation system to get feedback. The software is able to automatically calculate the score of complexity of each patient, thus reducing dramatically reclassification timings and costs. In its current development, the stratification scores (Charlson, DDCI, and CREG) are available in the main Regional database (BDA), but not yet available to the GPs, who can however calculate DDCI quite easily thanks to provided tools.

Improvement Areas ▪ ▪ ▪ ▪

As the actual application of the stratification tool in a regional programme is still under development, there is room for improvement in the Puglia experience.

The first main point which was identified through the application of the IAF in Puglia was the absence of a pay-for-results retribution for GPs and the absence of any economic incentives, which, together with an added workload for professionals, generated some resistance in the adoption and use of the tool. Some GPs considered the use of a risk stratification tool useless, and in general, professionals don't like to undergo continuous assessment procedures, the consequence being that this can increase conflicts between professionals and policy makers. Therefore, the area that needs to be improved is the involvement and training of general practitioners.

The second area that needs to be improved is related to the validation of the stratification tool. DDCI was not externally validated, but the random split into two equally large datasets (training and validation set) of a whole regional population of approximately 2 million people represents a reliable methodology for the validation. Anyway, further studies are needed to evaluate the performance of DDCI compared to other stratification tools on an external population of outpatients. Furthermore, some GPs have found it somewhat difficult to identify patients with social frailty, which might suggest that the tool needs to be improved in order to include social conditions.

A final improvement area, which is more of a shared concern provided by the IAF interviews and focus groups, is that the use of a risk stratification tool could stiffen the healthcare system. It could put the equity of access to care at risk (it is possible that not all complex patients get intercepted by the tool, which could worsen the access to treatment and to adequate delivery of care to patients), and might introduce other bad practices from the clinicians. Clinicians could choose their patients among those that are less complex (discrimination), or vice versa they could end up choosing complex patients if incentive systems were activated. GPs could also be misled on the assessment of the patients if they consider only the risk stratification information, etc.

These points should be clearly and carefully addressed in the design of a Regional intervention which uses stratification tools.

Catalonia Intervention Assessment

Description of the region and programme

The Catalan Health System covers the health needs of more than 7.4 million citizens and it faces new challenges with an in-depth population ageing process compared with other European countries. In 2050, over 30% and 12% of the population will be over 65 and 80 years old, respectively. As a consequence, an increasing number of people with chronic conditions will increase very intensively. Currently, 17% and 4.4% of the population are over 65 and 80 years old, respectively.

In the past, Catalonia has developed a very good network of primary care centres and long-term care facilities, providing very good care in the community as an alternative to acute hospital care. The split between commissioning and provision roles has been incorporated in our model, establishing new contracts and a new commissioning process incorporating cross-cutting targets related to different providers like primary, hospital, mental health and long-term care facilities.

Within this context, the Ministry of Health of the Government of Catalonia created a Chronicity Prevention and Care Programme at the end of 2011. Within this programme, there was an integrated care vision within the new Health Plan. It was under Government management and was explicitly entrusted by legislators to develop the programme and make it operational, in conjunction with the Ministry of Social Welfare and Family. The task of removing organizational silos is difficult and more emphasis on integrated care has been a great opportunity to improve performance[65].

Some interesting key factors have been identified as high inspiring points that should be incorporated into our model: i) chronic and integrated care policy-driven orientation, ii) the introduction of stratification, iii) the commitment of clinical leadership involved in the design and implementation of local integrated care pathways (ICPs), iv) shared ICT between clinicians and between patients and professionals, v) the overcoming of financial barriers introducing new joint cross-cutting targets among primary and secondary care, vi) community care orientation promoting more care at home thus avoiding unnecessary emergency admissions and institutionalizations and vii) self-management policies.

In addition, the Chronicity Prevention and Care Programme has set out different actions for an increasing number of populations with concurrent health and social needs, especially complex chronic patients (CCP) with multi-morbidity, complexity or advanced chronic disease (ACD) and social needs or dependence.

[65] Contel JC, Ledesma A, Blay C, Mestre AG, Cabezas C, Puigdollers M, Zara C, Amil P, Sarquella E, Constante C. . Chronic and integrated care in Catalonia. Int J Integr Care. 2015 Jun 29;15:e025
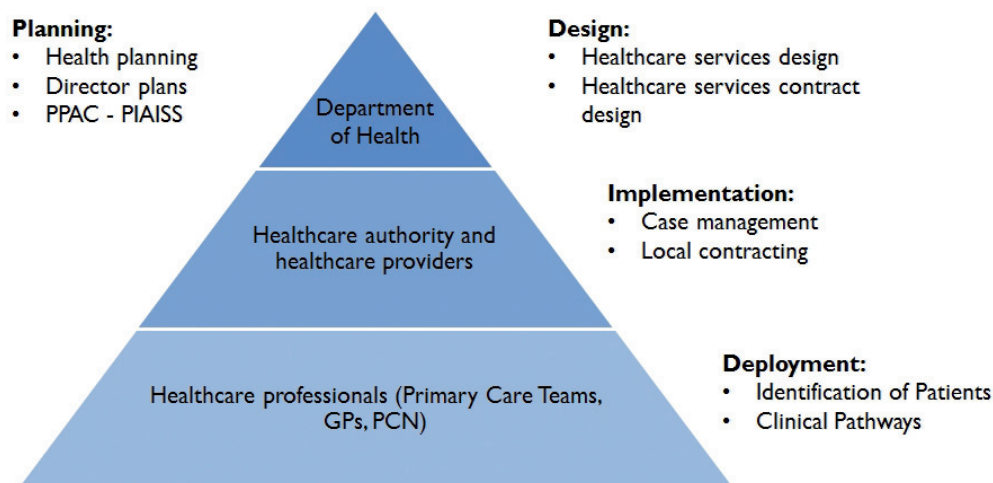
Figure 33: Roles in the Health Plan 2011 – 2015 and the Chronic Care Program

Risk stratification (RS) has become a cornerstone in the making of the new Health Plan 2011-2015 and has been a lever of healthcare transformation towards a more chronic and proactive oriented care. It has introduced a population stratification using clinical risk groups (CRGs) by 3M enterprise in order to support clinicians to identify people who could be at risk of hospitalization, readmission or death. Analytical Services at the Catalan Ministry of Health are offering stratification at a central level for all providers and it is published in the national EHR so that it can be shared by all organizations, providers and clinicians. The entire Catalan population is classified in a different and exclusive morbidity group. A 'score risk' is set out showing patients that are likely to be admitted to hospital in the next 12 months. This work was able to have been performed by the availability of all aggregated minimum data sets related to primary health care, hospitals, nursing homes, mental health and pharmacy.

Catalonia deployed social services and health care facilities working with a more integrated care approach, and developing adequate comprehensive systems for providing care for chronic and dependent patients. As a consequence, a new integrated health and social care plan in Catalonia was launched in March 2014. Real integrated care between health and social services is expected. The chronic care approach requires an updated vision incorporating social care contribution to achieve better care for people with complex health and social care needs. This new Plan has created great expectations to overcome some of the barriers we have identified in the Chronicity Prevention and Care Programme.

The possibility of uploading a newly launched and ad-hoc 'complex chronic condition' and 'advanced chronic disease' mark or label to the EHR has been set up. This will be available to all providers and professionals who work and act in order to care for these patients. This mark has an attached individual minimum risk score such as the key information summary with critical and summarized information of the patient-like diagnosis, pharmacy, services used and 'what to do recommendations' in case of a 'crisis or exacerbation' and 'advanced care planning' directives. After 3 years of development, we currently have almost 200,000 patients marked with this condition - more than 2% of the general Catalan population.
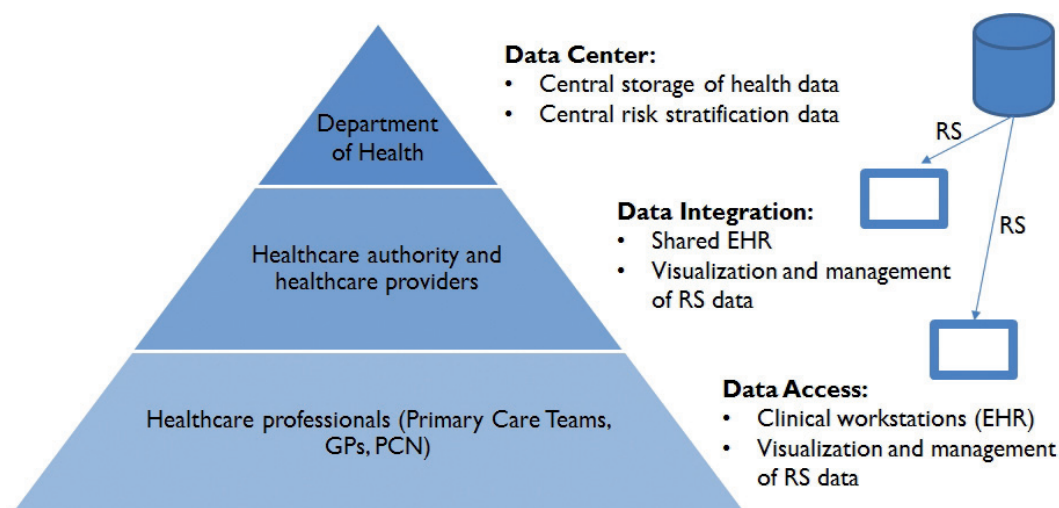
Figure 34: Data sources and displays for risk stratification information

Intervention Assessment ■ ■ ■ ■

The Catalan evolution from CRG to GMA is a very interesting case of how to approach population risk stratification. One of the main reasons was the impossibility of the CRG to capture the patient's complexity from a social point of view. The GMA introduced social care data and social determinants which helped to shape the concept of "complexity". However, the complexity condition goes beyond the classification offered by a multi-morbidity grouper (CRG or GMA), and it needs the incorporation of new clinical and social care variables. Before switching to GMA, a clinical validation activity was conducted. This activity involved 40 clinicians. The result was that most of the clinicians think that GMA better supports the identification of complex patients. The switch from CRG to GMA had initial development costs, but generated a saving afterwards as GMA is a home-made system for Catalonia and is free.

The main purpose of the risk stratification in Catalonia is to provide a tool which enables clinicians and professionals to identify people at risk (potential or real need) more easily. However, there is a clear distinction between risk stratification and clinical assessment and needs assessment. For this reason, the clinical pathways design and implementation did not follow the definition of risk classes. In other words, risk stratification could be a support for the definition of clinical pathways, but risk stratification is not mandatory for this definition.

Even if it is not directly used by the Region for payment, risk stratification information is used by many organizations as a criterion for the evaluation of goal achievements. A percentage of the additional budget is dedicated to goal achievements. For this reason, we can indirectly claim that risk stratification is important from an economical point of view. Furthermore, there are some pilots of a new model of primary care which include risk stratification in the budget calculation. A lot of work is still required, but the main goal would be to be able to allocate a territorial/population based budget, according to the risk stratification of the population.

According to information gathered by the IAF, it would appear that Regional representatives are concerned about the potential misuse of the risk stratification information by the clinicians, if a proper clinical validation and needs assessment is not performed. The other important concern is related to how carefully risk stratification information is used, to avoid the perception of risk or stigma in patients. In order to do this, a training and communication strategy should be incorporated in the implementation process.

In 2015, video-tutorials were created to disseminate risk stratification concepts and to train clinicians all over the Region. These video-materials have been designed and presented by clinical leaders and the risk stratification tool

designers. Its format allows multiple uses such as being part of intranet, dissemination blogs or just off-the-shelf video training.

At a meso-level, special training sessions have been organized and led by the EHR referent in each territory. For programme managers, chronic care plan referents have performed communication and training activities on risk stratification availability and its use to primary care teams during their clinical sessions in each territory.

In Catalonia, risk stratification is seen mostly as a support tool for clinicians. The clinician is the last responsible person to diagnose and register in the EHR "complexity" condition, which might be very different from the stratification tool result. There is no direct and real relation between stratification and enrolment in programmes. Risk stratification is a support tool available to clinicians and professionals. It performs a needs assessment to determine if a person is in a complex condition and should thereby be marked in EHR as "complex". After labelling, the patient is immediately incorporated to a case management programme or directly case managed by a reference GP or community nurse, depending on the internal organization model within every Primary Health Care Team. In other words, needs assessment is the most important determinant and not the risk stratification information.

The risk stratification tool is embedded in the EHR and in local clinical workstations, and it also allows clinicians to query their population based on risk and other clinical variables in order to organise proactive care to fragile populations. Functionalities inside the EHR allow clinicians and case managers to edit lists with different combined risks using tool variables and other data (specific diagnoses, pharmacy, home care inclusion, etc.).

After being tested and deployed all over Catalonia, the system has been scaled up to other regions in Spain and is being used by the Spanish Ministry of Health as part of their chronic care strategy. A recent agreement led to the implementation of GMA in 13 out of 17 Spanish regions. This means that more than 90% (38 million) of the Spanish population is currently stratified with GMAs.

Good practices ■ ■ ■ ■

There are various good practices to highlight from the experience of the Catalan Health System with the use of the risk stratification information.
A first good practice is related to how the risk stratification information has been incorporated into the different health information systems and electronic health records. Currently, risk stratification is an information source for:

a) Electronic Health Records at Primary Care workstations: risk stratification information is published in patients' records showing individual morbidity group classifications and 'risk scores' related to a future potential risk of hospitalizations and death, all very important for identifying Chronic Care Patients and advanced chronic patients (ACD) respectively.

b) Healthcare providers' health information systems: risk stratified information is returned to the different healthcare providers so they can incorporate this information into their systems and manage it in the different local HIS and so deliver to front-line clinicians and professionals.

c) Risk stratification information is also available to be queried by clinicians in order to focus on identifying and selecting people at higher risk to be case managed.

A second good practice of risk stratification information is related to its use in adjusting the capital payment system of primary healthcare providers. In 2015, CatSalut introduced the first adjustment based on risk stratification information. Previously, capita was calculated only taking into consideration the ageing population (patients over 65), the socioeconomic level and the geographical dispersion. Since 2015, morbidity is a new adjuster that accounts for

20% of the new capita system and the remaining 80% maintains previous criteria. This innovation should address the inverse care law and would make healthcare resource distribution more equitable and sensitive to health needs.

A third good practice and a cornerstone is the design and development of a "home-made" risk stratification tool. Off-the-shelf patient classification systems such as Adjusted Clinical Groups or Clinical Risk Groups are a quick win in the beginning of the risk stratification journey. They are easy to adopt and deliver value to health commissioners and health providers without developing costs. However, the cost of licenses and the fact that the classification algorithm has been developed with data from a completely different healthcare context, both in epidemiological, economic and political terms caused debate about the appropriateness and sustainability of using these "prêt-à-porter" tools.

A taskforce of health data analysts from the Department of Health (CatSalut and the Catalan Health Institute) explored the possibility of developing a system that would better fit our healthcare context, would have a better cost-effectiveness balance and would capture the complexity of comorbidity in a more sensitive way. This effort brought us the design of GMA (Adjusted Morbidity Grouper). The GMA morbidity grouper is based on statistical methods applied to diagnoses, mortality, hospital admissions, pharmaceutical use and GP contact information and provides a quantitative assessment of the patient's disease complexity.

Improvement areas ■ ■ ■ ■

The experience accumulated during these years has facilitated new improvements in the strategy of RS implementation:

The transition from the CRG to the GMA grouper facilitates the introduction of new and key variables to explain "complexity". CRG is a commercial solution which does not allow the introduction of social care data and social determinants which explain "complexity". Therefore, we have a new and promising innovative instrument which could incorporate new variables related to areas of special interest regarding high risk population with complex health and social care needs.

As there has been a lack of good RS understanding among clinician and professional communities, a well-extended strategy of spreading educational material is being implemented incorporating videotape materials produced by TICSalut and the Department of Health where RS and its utilization and usefulness in complexity strategy is explained. Seven videos have been produced and are being edited and distributed among clinicians

The Catalan Region is convinced about the importance of social care data and extended clinical variables. It is a long journey in which the incorporation of those variables is progressive and welcome, increasing the potential capacity to identify people with current or potential complex health and social care needs. There are new require-ments related to challenging issues like social care diagnosis standardization because there is not an international consensus in a standardized minimum dataset related to social care problems. The next step in improving GMAs is the incorporation of new "social care data" in the stratification model to facilitate a better comprehension of complex patients. Current stratification does not completely explain complexity and it should be ensured that "complex condition" diagnostics must always be validated by clinicians and professionals who must have the last say in this decision.

Basque Country Intervention Assessment

The Basque Autonomous Community, Euskadi, is configured by three constituent provinces. The Basque Ministry for Health controls policy planning, financing and contracting of health services. The Ministry for Employment and Social Affairs defines the social policies, whilst the contracting of social services is done by the Provincial Councils and municipalities. The Public Basque Health System is a Beveridge type of system working to improve the health status of the population. It is funded by taxes, and healthcare professionals are public employees. It governs and funds the public Healthcare provider (Osakidetza), other organizations in charge of biomedical research and innovation (BIOEF) as well as health services research in chronicity (Kronikgune). The process of commissioning and funding of the Ministry of Health, defines the type and volume of activity and the founders of the care providers. This relationship is expressed in Law 8, 26 June 1997 on Health Regulation in the Basque Country and is articulated through the Framework Contract with the public provider, Osakidetza. A minor part of the activity (elective surgery mainly) is outsourced to private providers.

Osakidetza was created by the Health Department of the Basque Government in 1983. It is composed of 13 Integrated Care Organizations (OSIs) and includes 324 primary care centres, 11 acute hospitals (4,100 beds), 4 sub-acute hospitals (500 beds), 4 psychiatric hospitals (777 beds) and 2 contracted long-term mental health hospitals. Activity indicators (2015) are: 15053861 primary care and 4199534 specialized care consultations, 253579 hospital admissions, and 118049 surgical interventions per year.

There are 2.2 million inhabitants in the Basque Country, of which the over 65s represent 20.8%. The Health and Care expenditure in 2015 was 3400M€, and it is estimated that 80% was used for chronic patients. It is projected that in 20 years, 26% of the Basque population will be older than 65 years. This epidemiological pattern requires the improvement of the management of chronic diseases. In order to address the challenge of chronicity, ageing and dependency, the Basque Country (BC) has deployed a global approach in which all key stakeholders play a significant role.

The Basque Government has a clear strategic vision towards the challenge of ageing, chronicity and dependency. It has provided explicit support, distributed leadership and created capacities in the organizations to transform the health and social care system. In fact, an explicit Strategy on Chronicity was already approved in 2010 and designed to create an all-round patient-centred model capable of providing continuity of care on both health and social levels. The Strategic Guidelines 2013-2016 of the Healthcare service, Osakidetza, reinforced and extended an integrated approach. The Basque Healthcare model aims to enhance patient centred and seamless care by improving the coordination and continuity of care between service levels and by adapting care to patient needs.

The prospective stratification of all the population assigned to Osakidetza was performed for the first time in 2010 using the Johns Hopkins Adjusted Clinical Groups predictive model (ACG-PM). The stratification process in the Basque Country classifies more than two million citizens according to the resources that they will require during the following twelve months. The data come from Osakidetza and the Department of Health, based on the previous use of health resources, demographic, socioeconomic and clinical variables. The expected use of health resources, the "output", is a proxy of patient morbidity and severity with different needs of care. The aim of stratifying is to identify and select target groups that may benefit from specific programmes of action. Consequently, Integrated Intervention Programmes for multi-morbid and specific diseases patient groups (e.g. for diabetes, COPD, etc.) have been deployed. The objective is to provide anticipatory care and coordinated care to all patients identified through the risk stratification tool.
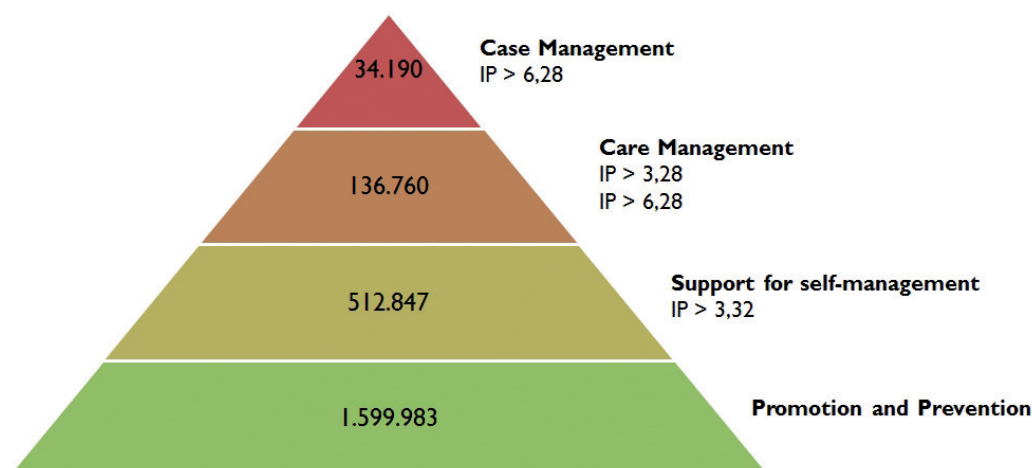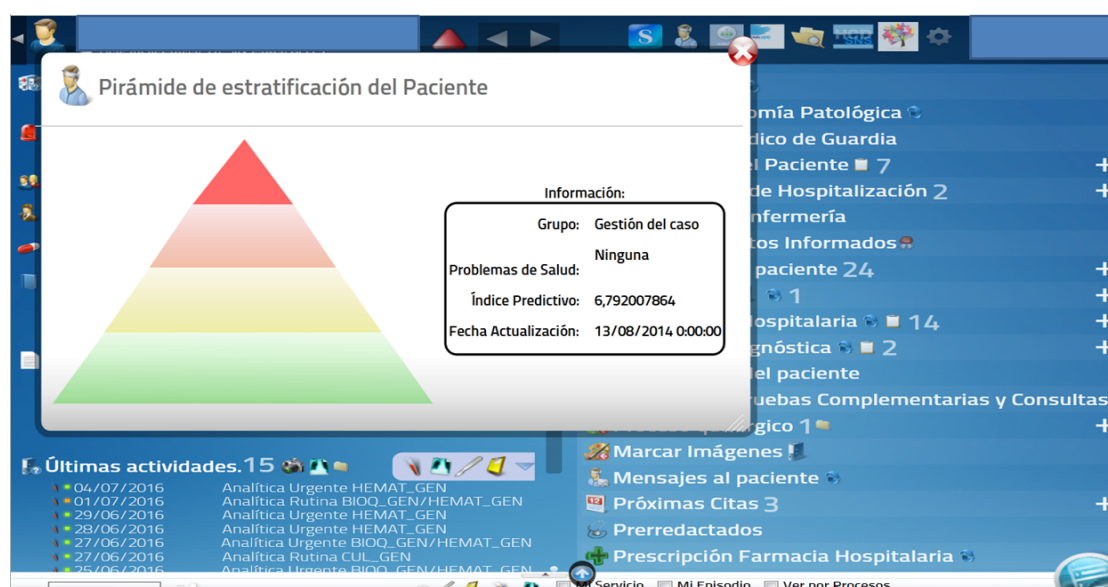
Figure 35: Risk stratification in 2014

Figure 36: Risk score display in the EHR

This Integrated Intervention Programme for multi-morbid patients has been designed by managers and clinicians of the Hospitals and Primary Care Centres involved. The population risk stratification process identified 683797 chronic patients in 2014 as the target population. A clear design methodology of the new care pathway has been used: the analysis of current models, the detection of improvement areas, and the prioritization and definition of actions. The perspectives of all the stakeholders have been taken into account.

The new service model has improved "care as usual" in a number of ways: wider deployment of the reference internist and hospital liaison nurse into other hospitals in the region; follow-up phone calls by the GP practice nurse on a monthly basis to monitor the patient's health status; the use of eHealth Centre professionals in the care pathways; provision of symptom management questionnaires in the Personal Health Folder to further support self-management; rolling out the electronic prescription to additional healthcare professionals including pharmacists; the development of a structured and standard empowerment programme for frail elderly patients and caregivers and provision of self-care and self-management educational material through the Personal Health Folder and Osakidetza web portal.

Intervention Assessment

The introduction of stratification was made in the Basque Country in conjunction with the creation of new care pathways for multi-morbid chronic patients. Integrated Intervention Plans for population groups identified according to their risk, with clinical pathways that include all levels of care, disciplines and actions, are needed to implement the best clinic practice for multi-morbid patients, patients with Diabetes Mellitus, heart failure and Chronic Obstructive Pulmonary Disease. This made significant progress in the co-ordination between primary and specialized care, creating a new way of working, especially in Primary Care. Furthermore, new specific roles have been created to improve the co-ordination and communication of new care pathways. For example: the liaison nurse, the advanced practice nurse (APN) or the referral internist.

The Basque Country is the only example among the ASSEHS Regions that has analysed the intervention of the usage of a commercial tool, the John Hopkins' ACG stratification tool, contrary to all the other Regions which developed their own tools (sooner or later during the programme lifetime).

Several issues arise. There is a time lapse between when the data are collected and when the tool is used: for example, the 2015 Electronic Health Records feature the results of stratification carried out on the basis of 2013 data. The updating frequency can widen the lapse between the coding and the actual use of the data. The quality and reliability of the data sources used for stratification need continuous improvement. There can be different ICD codes for the same patient in Primary Care or Specialized Care. Coding is very laborious and it is important to have the knowledge and training required. However, risk tool implementation has boosted patient coding improvement, even if there is still room for more and there are still certain challenges to overcome. The use of an international system like ACG seems to help to solve problems like under-recording patients' data in medical records.

Another issue is the correct interpretation of risk information. The Risk Stratification Score is a prospective value based on population data. Not all clinicians read it as the current status of the individual patient. This leads to misunderstanding as the prospective score might not match the clinical judgement on the patient current health status. More training and education of the front line staff is needed to use the information correctly.

One of the first improvement areas that was rapidly identified, thanks to the ASSEHS project, was the lack of proper training in the stratification process. For this reason, in 2016, the Region introduced an appropriate training for risk stratification, especially targeting the clinical staff (nurses and GPs). Training was mainly based on concepts such as: stratification, management of multiple co-morbidity patients, predictive index, as well as the Population Intervention Plan with the functions and tool development required to implement stratification. Despite a certain resistance to change and different unfolding efforts that had to be made to ensure correct implementation, the professionals who have taken part in the training are perceived as being very involved. They responded well to the tasks allocated and communication was fluid and ongoing. Like in other regions, the number of experts in stratification is really small, while the training in how to use the stratification tool and information is broader. A risk stratification full-day workshop was held within the ASSEHS project, targeting managers (meso level). It focused on ACG, risk stratification information systems, the implementation of stratification in clinical practice and the deployment of Integrated Intervention Plans in the BC.

From a financial point of view, stratification has implied changes in resource re-allocation and care intervention plans, but not in professional behaviour or in savings. The use of stratification to adjust funding is currently being tested. Changes are not yet expected in the attitude of professionals.

Good Practices ▪ ▪ ▪ ▪

Several good practices can be observed through the experience of the use of stratification tools in the Basque Country:

a) First of all, the stratification of the entire population. 100% of the Basque population has been stratified since 2010, gathering data from Osakidetza and the Department of Health, based on the previous use of health resources, demographic information, aggregated socioeconomic data, and clinical variables.

b) Population Integrated Intervention Programmes have been deployed to provide anticipatory care and coordinated care to all patients identified through the risk stratification tool. At micro-level or through bottom-up approaches, more pathways emerged. The creation of new pathways is very important to improve care coordination among all the levels (from primary care to hospital practice). Furthermore, it demands the creation of new roles, most of time attributed to skilled nurses. The creation, training and definition of roles for these profiles must be properly addressed in the design of the programme.

c) A third good practice is related to communication channels, which were created between care levels. A common opinion among interviewees in several surveys and interviews conducted by ASSEHS highlighted that communication and co-ordination among professionals has improved a great deal. Communication between Primary Care and Specialized Care has been reinforced, thanks indirectly to the introduction of stratification, and directly to the programme using stratification. Understanding and co-ordination among professionals have improved a great deal; trust has increased, as everyone knows each other much better now and everyone is perfectly aware of the role played by each person to focus care on the patient.

d) As a result of the improvement areas early identified in the ASSEHS project, a training programme was created in 2016, with an on-line training platform developed to provide the basic skills in risk stratification to clinicians. Despite some resistance to change, trained professionals resulted in being very active and involved, responding well to the tasks allocated to them.

Improvement Areas ▪ ▪ ▪ ▪

One of the main improvement areas was already mentioned before and is related to the improvement of the stratification tool. In particular, a first aspect is related to the inclusion of individual social data (it is currently aggregated for the local population managed by the GP) in the algorithm. Another important factor is related to the increase of the updating frequency of the risk stratification information. Outdated information causes objections to stratification, because it is perceived as a very static system. Furthermore, the difference between risk stratification information and clinical assessment may arise from the difference between the actual diagnosis of the patient and the diagnosis coding featured in an electronic medical record.

A second improvement area (which, as previously mentioned, is already progressing in the Basque Country) is related to an increase in the commitment of the professionals. More training and communication activities allow better interrelation between clinical assessment and risk scoring. Training activities worked very well and the Region is now thinking of expanding the training to more professional profiles and stakeholders. Furthermore, current training is being improved thanks to feedback received during the activities.

A third improvement area can be seen the increase of the use of risk stratification in personalized pathway development and evaluation. Even if Population Intervention Programmes were developed, there would be room for improvement in the personalization of the interventions and pathways, thanks to the use of stratification information. Furthermore, stratification can also be used to evaluate the new clinical pathways, both at an individual and a population level.

6-ETHICAL ISSUES
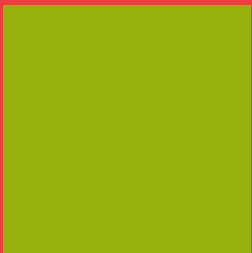
When we think about risk stratification tools offering higher quality healthcare services for frail patients, it might seem trivial to also think about the risks associated with the implementation of strategies which aim to improve the service. However, when vulnerable patients are involved, some additional precautionary measures might be necessary to make sure that the provided healthcare services meet the patients' needs.

Healthcare professionals are expected to provide patient care that is filled with empathy and compassion, respect to dignity and individual autonomy while carefully weighing up the benefits and harms certain interventions might bring. Patient stratification can be a powerful tool for improving service delivery, foreseeing what care will be needed and delivering it at the right time so that unexpected illness and emergency hospital admissions are reduced to a minimum. Meanwhile, even if stratified and placed in a group, each patient is still an individual with a history, a cultural and socio-economic context and with unique relationships and views on life.

Therefore, ethics is a multi-levelled and multi-layered concept. In the process of creating a tool for risk stratification, more focus might be put on the optimal use of available resources and efficient service delivery on a national, continental or even global level. Meanwhile, the regional and local healthcare service providers might have to adjust the tool to their existing infrastructures. Moreover, it might be left to individual healthcare service providers to make a final judgment to whether applying particular stratification methodology serves the best interest of an individual patient.

Ethical issues surrounding personalized medicine

Personalized, or precision, medicine remains a vague term in healthcare. Its definition is still open to interpretation and could depend on the interests and preferences of various stakeholders. However, there have been explicit attempts to review the literature and offer a more consolidated definition. Therefore, it is suggested that personalized medicine seeks to improve patient stratification and timing of healthcare by using biological information and biomarkers on the level of molecular disease pathways[66]. Individual risk assessments could be used to target interventions such as screening, treatment and health education.

Benefits of patient stratification

Some reports suggest that stratification in medicine offers new incentives for innovation, alters the drug and diagnostic development process, improves clinical outcomes by allowing payers to spend less on ineffective treatment and hence allowing manufacturers to continue developing new products[67]. Therefore, one of the major benefits expected from patient and disease stratification on a societal level is economic, as it allows the resources to be used in the most efficient way. Meanwhile, on an individual level, it would offer each patient the most effective treatment or preventive intervention with a minimum of side-effects and the shortest time possible spent in hospital. Risk stratification could help to make therapies safer, improve diagnostic accuracy, reduce the number of medical errors, and promote the efficient use of resources[68], all of which have a high potential for improving public health and promoting social welfare.

Dangers related to patient stratification

One of the key elements of patient stratification is that specific interventions should be given to those who are the strongest responders and are the most likely to benefit from the intervention, especially if its availability is publicly funded[69]. However, sometimes it might be difficult to draw a line between strong, moderate and marginal responders,

[67] Mesko, B., Zahuczky, G., & Nagy, L. (2012). The triad of success in personalised medicine: Pharmacogenomics, biotechnology and regulatory issues from a Central European perspective. New Biotechnology, 29(6), 741–750. http://doi.org/10.1016/j.nbt.2012.02.004
[68] Braithwaite, R. S., Stevens, E. R., & Caplan, A. (2016). Is risk stratification ever the same as "profiling"? Journal of Medical Ethics, 42(5), 325–329. http://doi.org/10.1136/medethics-2015-103047
[69] Fleck, L. M. (2012). Pharmacogenomics and personalized medicine: Wicked problems, ragged edges and ethical precipices. New Biotechnology, 29(6), 757–768. http://doi.org/10.1016/j.nbt.2012.03.002

which could lead to denying access to treatment to those from disadvantaged backgrounds. Therefore, socio-cultural and economic barriers could prevent certain patients from qualifying as eligible for specific interventions[70], while others might qualify. Having said this, in order to access personalized treatment, patients would need to travel to specialized centre which might not always be a feasible option for those living in remote areas. Furthermore, patient and disease stratification could lead to the creation of new forms of differences among patients and new forms of injustice based on these divisions[71].

In addition, medical risk stratification could lead to social stratification, including economic risks faced by pharmaceutical and insurance companies[72] as well as individuals.

Furthermore, stratification use in medicine is changing the ways in which health and diseases are defined. One of the major goals when stratifying patients is to offer personalized care, and such an approach mainly focuses on fighting the disease rather than maintaining health[73]. The latter is subject to numerous pitfalls. Focusing on the disease could lead to various biases, such as giving preference to patients whose care is reimbursed more, or over-diagnosing or under-diagnosing those who do not fit the stratification standards.

Ethical challenges when implementing patient stratification among older populations

Timing could be one of the key elements in efficient and effective patient stratification, as health conditions in elderly people appear to be changing rapidly. Therefore, risk stratification tools should take into account the fact that health conditions are heterogeneous and require adequate adjustments in the system in order to remain relevant in the course of time.

Informed consent is considered an ethical standard in clinical practice[74]. There are three core pillars constituting this concept: voluntariness, capacity, and information[75]. An extra effort may be necessary when acquiring consent to stratification itself and stratification-based interventions from individuals constituting older populations. Currently, it would appear that the pressure to implement risk-stratified screening programmes will increase. If this happens, a new enquiry must be made questioning the roles of individual patients, healthcare providers and the state in organizing and mandating such programmes[76].

Available solutions

Some advocate for a democratic deliberative process in order to find solutions in morally problematic situations[77]. This would require public discussion, provision of information, and educational events aimed at the general public as well as a collaboration between researchers, healthcare professionals, patient organizations, academic institutions and public activists.Diverse solutions will be required to protect individual and societal interests but a balance could

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be reached through well deliberated healthcare policies. Empirical research findings reflecting the views of those directly affected by the implementation of tools for risk stratification in healthcare should be taken into account when developing evaluative and normative frameworks[78].

It would be important to consider:

1) What the profiling information will be used for
Is it only going to be used for stratification at the level of local healthcare systems? If not, will such data be given to a third party (academic and industrial researchers, banks, insurers, etc.)?
However, policies and guidelines are usually aimed at big groups of patients. Therefore, enrolling individual patients in stratification programmes might raise new questions. In such situations, help could be outsourced from institutional ethics committees, ethics support groups and similar bodies[79].

Some patients might require attentive and sensitive counselling in order to understand the nature and purpose of being enrolled in a risk stratification programme. This could also include a brief discussion on the patient's preferences concerning his or her ways of seeing and understanding life, good living and death[80].

2) Guiding ethical principles
One of the major ethical principles in a European context is solidarity, which requires sharing the resources and preventing the fall-outs from the stratification system. It relates closely to justice, which is a leading principle for personalized medicine[81] and biomedical ethics in general[82]. It is especially relevant to both individual and societal decision-making levels, when ensuring individual access to the most effective healthcare interventions and maintaining the most cost-effective public expenditure.

Respect for patient autonomy and privacy are essential in modern biomedical ethics in order to allow patients to make informed decisions about their clinical care[83] without inflicting harm[84]. It is very important to note that harm is never limited solely to health and can extend to exclusion, segregation, stigmatization in healthcare and within the community. Moreover, the risk stratification scheme leading to fewer deaths in society overall might increase deaths among certain vulnerable groups or impede autonomy by compromising the patient's personal values[85].

Accountability for reasonableness[86] is an ethical requirement to be followed, when making stratification decisions and creating healthcare policies on a societal level.

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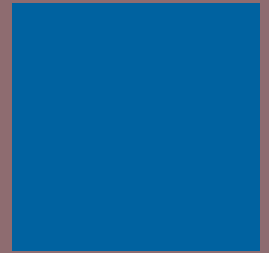[83] Braithwaite, R. S., Stevens, E. R., & Caplan, A. (2016). Is risk stratification ever the same as "profiling"? Journal of Medical Ethics, 42(5), 325–329. http://doi.org/10.1136/medethics-2015-103047
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7-CONCLUSIONS

Recommendations and Guidelines

Domain	Sub-domain	Recommendations	Target
The quality of Risk Stratification Tools	**Selection and/ or development of Tools**	- Check the alignment between predicted outcomes and the objective of the clinical programme/intervention triggered by the stratification. - Before purchase, verify affordability of tools (price of the license, maintenance costs, etc.) - Evaluate carefully the presence of an ICT tool supporting the risk stratification. In particular, those with querying mechanisms should be preferred. - In case of purchase, verify model accuracy and check how it was validated. In case of development, plan an appropriate validation before full deployment.	Healthcare planners
		- Differentiate utilizations of stratification: managerial and clinical.	Healthcare commissioners
	Risk stratifica-tion information	- Check data availability: existence of the data feeding the model selected/developed, accessibility of this data, updating frequency, etc. - Include information from other care sectors (i.e. social care) - Discuss with clinicians the potential explanatory variables related to stratification supporting the identification of a complex patient.	Healthcare planners
RS Tools and the deployment of programmes	**Planning and deployment**	- Create a team with multi-disciplinary competences for the design of the interventions. Useful profiles include programme managers, statisticians, epidemiologist, health economists, clinicians, local health authorities, etc. - Do not give a restricted "managerial" use of stratification. It could help everyone, especially clinicians.	Healthcare commissioners
		- Communicate and straightforwardly teach stratification tools and their use to GPs. - Educate clinicians to correctly understand stratification as a predictive value of the citizen with respect to the whole population, rather than a precise clinical assessment. - Introduce stratification as a support tool in clinical management. Identification of complex patients using a double process based on risk score and clinical assessment, as both are complementary and mutually supportive. Use the potential of IT tools to show and give functionalities to clinicians to proactively select targeted populations at risk. - Identify and encourage positive "facilitators" (or early adopters) of stratification: case managers, local managers of chronic care units, etc. - Prepare and train personnel for the new responsibilities and new roles (e.g. case management), to gain efficiency in managing these high risk populations that will be managed by them.	Healthcare providers
		- Design quality assessment and improvement processes. - Make sure that frequent reclassifications are a structural part of the programme, as outdated risk stratification information might generate resistance from clinicians in its use or adoption.	Healthcare planners

RS Tools and the deployment of programmes	**Pathways definition**	- RS can favour the definition/redefinition of pathways. Targeted pathways can be defined for very specific population segments.	Healthcare planners
	Funding and allocation of resources	- The structure of incentives should not be underestimated in implementation. - RS can support commissioning and contractual mechanisms. - Proper care quality monitoring mechanisms have to be established (especially in cases of payment-for-performance models) to avoid undesired bad practices.	Healthcare commissioners
	Ethics	- Make sure that there are no socio-cultural and econo-mic barriers which could prevent certain patients from qualifying as eligible for specific interventions. - Include informed consent in the interventions, as this is considered an ethical standard in clinical practice. - Carefully monitor who can access patients' data, especially when third parties are involved in the management of the programme (e.g. in managing ICT infrastructure).	Healthcare planners
Evaluation of the impact of stratifi-cation tools and programmes	**Health outcomes**	- The evaluation framework should be based on the improvement of Triple Aim vision (better outcomes, adequate use of services and better experience of care)	Healthcare commissioners
		- Design clear and measurable endpoints during the planning phase, and constantly monitor them during the intervention development.	Healthcare planners
	Communication Results	- Generate evidence of stratification and disseminate the best practices of good use	Healthcare planners

Gaps in knowledge and limitations

This White Paper originated from the ASSEHS project, which is a project with limited duration and resources, therefore suffering certain limitations in the analysis.

One of these limitations is the strong focus of the participating ASSEHS Regions in the European Mediterranean area (Italy and Spain). The project did of course have other partners in central Europe and was supported by the work of a Scientific Advisory Board, with representatives from Anglo-Saxon countries. Furthermore, the scoping and literature review were not limited to such Latin countries, but they included worldwide references and publications. However, it is clear that most of the lessons learnt have generated from specific Regions with specific healthcare system models.

Another limitation is that the interventions using RS analysis are population-wide interventions, usually with long durations and in unconstrained environments. Unlike randomized control trials and more rigorous studies, it is clear that the strength of the conclusions that can be derived is lower, as the number of unconstrained and confounding variables is very high.

Another limitation, which was a more deliberate choice when designing the ASSEHS project, was to exclude insurance companies from the analysis, which are however in many cases a very rich source of information.

Finally, another bias source is that the project investigated only population-based stratification interventions, while individual-based stratification was considered out of scope.

Final conclusions

The goal of this White Paper is to spread knowledge about the use of stratification tools at policy making, healthcare management and clinical practice levels. The White Paper gives a detailed description of the main barriers that can be encountered when planning and deploying RS tools in a Regional intervention, as well as giving details about the facilitators that will help to overcome those barriers, and concrete examples of implementations from four pilot Regions, participating in the ASSEHS project.

The best practices and lessons learnt from those pilots are supposed to serve as examples for the development of programmes for managing multi-morbidity among complex frail older citizens, and to help policy makers and stakeholders to design, plan, deploy and validate risk stratification in other Regions.

The goal of this White Paper is to support other Regions and healthcare systems in the transformation towards new models of the provisioning of proactive and targeted interventions according to patients' needs.

The key general benefits of using stratification methods can be summarized as:
- A means to provide levels of care that are tailored to an entire population and individual patients, with a proposition to deliver better care to EU citizens;
- A means to maximize population/patient benefit with a given level of resources, allowing proactive care, as case finding and selecting the target population and focusing the efforts on the people that can make the best of the programmes designed.
- A means to cope with versatility in care delivery by addressing patients across all acuity levels (health risks), accounting for the prevalence and progression of different long-term medical conditions and accounting for regional differences in patient case-mix;
- A means to inform policy makers, healthcare commissioners and medical specialists on expected outcome and expected (direct) costs on healthcare resource utilization for various intervention programmes for an entire population or an individual patient.
- A means to adjust indicators for monitoring and evaluation.
- A means to identify patients, workload distribution and planning and resource allocation.

This White Paper aimed at the following outcomes:

- Increased predictability and reliability of the stratification tools in terms of population selection;
- Better selection of population groups thanks to fine-tuned stratification tools;
- Prevention / delay onset of physical frailty thanks to customized/integrated interventions for each group of patients according to their specific needs;
- Improved outcomes of the interventions in order to reduce "avoidable emergency admissions" and readmissions and costs;
- Raised public and professional awareness on the use of stratification methods to address the management of multi-morbidity among elderly people;
- Increased capability of detecting physical frailty in older adults in any setting of the health system (community, primary care, hospital, long-term care or social facilities);
- Indicators of frailty that can be exported to other European Health Services.

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ASSEHS
ACTIVATION OF STRATIFICATION STRATEGIES AND RESULTS OF
INTERVENTIONS ON FRAIL PATIENTS OF HEALTHCARE SERVICES