C3-Cloud

"A Federated Collaborative Care Cure Cloud Architecture for Addressing the Needs of Multimorbidity and Managing Poly-pharmacy"

PRIORITY Objective H2020-PHC-25-2015 - Advanced ICT systems and services for integrated care

D4.4 Guidelines for Management of Changes in the Models of Care Delivery

Work Package:	WP4 Patient Pathway and Organisational Model Development & Change Management
Due Date:	31 August 2020
Actual Submission Date:	26 August 2020
Project Dates:	Project Start Date: 01 May 2016
	Project End Date: 31 August 2020
	Project Duration: 52 months
Deliverable Leader:	EUROREC

Project funded by the European Commission within the Horizon 2020 Programme (2014-2020)		
Dissemination Level		
PU	Public	X
CO	Confidential, only for members of the consortium (including the Commission Services)	
EU-RES	Classified Information: RESTREINT UE (Commission Decision 2005/444/EC)	
EU-CON	Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC)	
EU-SEC	Classified Information: SECRET UE (Commission Decision 2005/444/EC)	

Document History:

Version	Date	Changes	From	Review
V0.1	20-05-2020	First complete version	EUROREC	By WP4 leader
V0.2	24-05-2020	Update following review feedback by Esteban	EUROREC	For WP4 review
V0.3	5-06-2020	Update with inputs from WP4: Marie Beach, Mikael, Malte	EUROREC	ALL
V0.41	19-06-2020	Updates from Gunnar, Marie Beach, Omar	EUROREC	For WP4 checking
V0.42	30-06-2020	Minor updates	EUROREC	INTERNAL REVIEWERS
V0.43	2-07-2020	Some additional literature in Section 1	EUROREC	(not circulated)
V0.44	17-07-2020	Incorporating feedback from Ana, Mustafa, Chris, Pete + 0.43 changes	EUROREC	WARWICK to external reviewer Tim Robbins (UHCW)
V0.5	5-08-2020	Incorporating feedback from Tim	EUROREC	WARWICK
V0.6	14-08-2020	Initial review from coordinator	WARWICK	WARWICK
V1.0	26-08-2020	Final checks, proof reading and editing by the Coordinating team	WARWICK	WARWICK

Contributors (Benef.)	George Despotou, Sarah N. Lim Choi Keung, Omar Khan, Theodoros N. Arvanitis, (WARWICK) Mustafa Yuksel, Gokce B. Laleci Erturkmen, Asuman Dogac (SRDC) Pontus Lindman, Tapio Jokinen (MEDIXINE) Marie-Christine Jaulent (INSERM) Mattias Fendukly, Rong Chen (CAMBIO) Dipak Kalra, Geert Thienpont, Pascal Coorevits (EUROREC) Malte von Tottleben (empirica) Marie Beach, Chris Marguerie, Danny Roberts (SWFT) Nicolas Gonzalez, Antonio de Blas (OSAKIDETZA) Gunnar Klein (ORU) Marie Sherman, Mikael Lilja, Göran Larsson (RJH) Ane Fullaondo Zabala, Lola Verdoy, Esteban de Manuel (KG)			
Responsible Author	Dipak Kalra		**Email**	dipak.kalra@eurorec.org
	Beneficiary	EUROREC		

EXECUTIVE SUMMARY

This deliverable explains the organisational changes and the culture changes that are needed in order to adopt and get most benefit from the C3-Cloud solutions for patients with multimorbidity and on multiple medications (polypharmacy).

These guidelines have been written in order to help a healthcare organisation, or a network of organisations offering integrated care services, to plan for a smooth and successful adoption of the C3-Cloud solution. Although the solution is mainly delivered as Information and Communication Technology (ICT) components, its beneficial use and impact on the care of patients with multimorbidity is both an organisational change programme and an ICT implementation.

These recommended adoption changes and practices have been collected through the process of designing, implementing, deploying and piloting the technology solutions and knowledge models in three C3-Cloud pilot sites, in the UK, Sweden and Spain. In order to develop them, an analysis was undertaken during the project of the deliverables and documents defining the requirements, solution components and the planning for their adoption at the pilot sites. These were distilled into a Standard Operating Procedure for the pilot sites to use themselves and was critiqued over by pilot site representatives. It was treated as adaptive, living material with the clauses updated during live deployment, evaluation stage and finalised through post-pilot reflection. They have been expressed here as recommended preparation and adoption measures for future health care provider organisation or regional health system considering adopting C3-Cloud as a key component of its strategy for the better management of patients with multiple long-term conditions.

This deliverable starts with an outline of the challenge of multimorbidity (and its accompanying risk of polypharmacy) and why a proactive strategy is needed, including good knowledge management, information management, clinical team collaboration and patient empowerment. The C3-Cloud project and its solution are briefly summarised, using materials from other project deliverables and the project website.

The adoption of a systematic and ICT enabled approach to the management of multimorbidity, as exemplified by the C3-Cloud solution, may require change in a number of areas within a healthcare organisation. The deployment and use of the C3-Cloud in an unprepared environment will not deliver its full potential. Some of the most important areas of preparation are in the culture of multidisciplinary team working, following evidence-based guidelines and engaging patients in understanding and contributing to their own condition self-management. These are discussed in Chapter 3. Our pilot sites have found that a culture supportive of patient engagement and of an empowering relationship between clinicians and patients is a critical success factor.

Other areas of good practice that are important relate to the quality of clinical documentation, so that tools like decision support services can reason on complete and well-structured clinical information. There is a certain level of ICT and Electronic Healthcare Record (EHR) maturity that is needed in order for the C3-Cloud solution to be appropriately populated and effectively used. This includes the ability to compile the main elements of a patient summary (such as health conditions, allergies, medication list and vital signs).

Multidisciplinary teams need to be trained before they use C3-Cloud, not only in how to use the application but in how to work in a care plan oriented way, how to use collaboration tools to work as a cohesive team, and how to educate and support patients in self-management.

It is hoped that this guide will be reviewed before and during internal consultations and decision-making about the adoption of C3-Cloud, so that organisations prepare themselves well to embrace better quality care for patients with multimorbidity.

TABLE OF CONTENTS

1. THE CASE FOR A PROACTIVE STRATEGY ON MULTIMORBIDITY

1.1. The challenges of multimorbidity

As people live longer, they are more likely to be living with different ongoing medical problems. When someone has two or more long-term health conditions, this is called "multimorbidity".

Health systems are challenged by increasing multimorbidity, due to our ageing population[1], and struggle with delivering their complex care management needs[2]**.** More than half of all older people have at least three chronic conditions, and a significant proportion has five or more[3]. Poorly managed multimorbidity may increase the risk of disease complications and vulnerability due to acute deteriorations, for example hospitalizations, falls and death[4]. It should be noted that multimorbidity is not only present in elderly patients: 35% of people aged 55–64 years and 55% of people aged 65–74 years have multimorbidity[5].

Finding the best way to support and treat people with multimorbidity can be challenging for patients, caregivers and clinicians. As the number and complexity of health conditions increase over time and episodes of acute illness are superimposed, the type and number of care providers contributing to the care of individuals also increases. It becomes significantly more difficult to align and coordinate care across care teams and care settings. This results in **specialty silos and fragmented care**, due to poor communication and information sharing. Without secure information exchange among the actors involved in health, social and informal care services and a process to reconcile potentially conflicting treatment plans, it is impossible to avoid redundant and potentially harmful interventions.

The clinical management of patients with multimorbidity is much more complex and time-consuming than those with single diseases. Currently those with chronic conditions and needing long-term care experience shortcomings and gaps in care provision. Promoting good quality integrated care remains a key challenge addressed by EC research call topics, twinning projects and conference sessions. It is resource intensive but there is **potentially avoidable effort and cost** for health systems, and avoidable

[1] Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. *Lancet*. 2012;380:37–43

[2] Vetrano DL, Calderón-Larrañaga A, Marengoni A, Onder G, Bauer JM, Cesari M, Ferrucci L, Fratiglioni L. An international perspective on chronic multimorbidity: approaching the elephant in the room. *Journals Gerontol Ser A*. 2018;73:1350–1356

[3] F. Luppi, F. Franco, B.B.L. Fabbri. Treatment of chronic obstructive pulmonary disease and its comorbidities. Proceedings of the American Thoracic society, vol. 5 (2008), p. 26

[4] Calderón-Larrañaga A, Vetrano DL, Ferrucci L, Mercer SW, Marengoni A, Onder G, Eriksdotter M, Fratiglioni L. Multimorbidity and functional impairment–bidirectional interplay, synergistic effects and common pathways. *J Intern Med*. 2019;285:255–271

[5] Jindai K, Nielson CM, Vorderstrasse BA, Quiñones AR. Multimorbidity and functional limitations among adults 65 or older, NHANES 2005–2012. Prev Chronic Dis. 2016; 13: E151

inconvenience - and even **preventable risk** - for patients if more co-ordinated and better informed multimorbidity care can be provided.

Clinical guidelines, which re-factor the best available published evidence on clinical effectiveness into decision trees and care pathways, and which are increasingly multi-professional and work across care providers, almost always focus on treating a single disease. **Clinical guidelines may clash** (e.g., due to incompatible treatment and monitoring regimes). Multimorbidity is especially challenging because clinical guidelines and the ways in which healthcare teams are organised are not designed for a combination of health problems. Different health conditions, and treatments for different health conditions may interfere with one another. Following more than one clinical guideline can, therefore, result in inefficiencies for the patient and for the health system due to duplicated and inconveniently scheduled investigations and clinic visits and, more importantly, treatments for one may exacerbate another condition. For example, a person with diabetes and renal disease might be advised by their healthcare professionals to follow two conflicting food diets; one focused on managing diabetes and another on managing kidney problems. There is a need to align the guidelines that are most likely to be used concurrently i.e. for conditions that are most likely to co-exist in patients with multimorbidity. There is increasing evidence of multimorbidity clusters: conditions that are likely to co-exist[6,7]. This makes the challenge a little more tractable, by enabling multimorbidity solutions to prioritise the alignment of single-disease guidelines into disease-cluster guidelines.

A special challenge in caring for the patients is that they often need to take **multiple medications**, the situation known as polypharmacy[8]. There is a risk that the side-effects of one medicine could exacerbate another condition which the patient has, and so special care is needed to manage multiple medications. It is essential that all of the clinical teams caring for multiple conditions of the patient are aware of each other's prescribing. As multimorbidity increases with age, estimated to range from 55% to 99%, medications (prescription, over the counter, and herbal preparations) are most likely to be used by the elderly, who are often the most vulnerable to side effects[9]. It is common for elderly patients to be taking nine or more medications concurrently[10]. These are often prescribed by multiple providers, at different times, for different reasons. A medication that results in an adverse drug event may be mistaken to be a separate diagnosis and treated with yet more medications.

Studies show that physicians provided with time and structured assessment instruments for medication review are able to identify and correct medication problems in a large percentage of their patients[11,12]. An important challenge in polypharmacy management is that health professionals may experience difficulties in performing medication reviews in daily practice. This is often due to not having easy to view information about how a patient is being managed across all of their diseases, or a lack of knowledge about how their own choices of treatment can be affected by other diseases and treatments.

---

[6] Prados-Torres A, Calderón-Larranaga A, Hancco-Saavedra J, Poblador-Plou B, van den Akker M. Multimorbidity patterns: a systematic review. *J Clin Epidemiol*. 2014;67:254–266

[7] Busija L, Lim K, Szoeke C, Sanders KM, McCabe MP. Do replicable profiles of multimorbidity exist? Systematic review and synthesis. *Eur J Epidemiol*. 2019;1–29

[8] Bushardt, R.L., Massey, E.B., Simpson, T.W., Ariail, J.C. & Simpson, K.N. Polypharmacy: misleading, but manageable. Clin. Interv. Aging 3, 383–389 (2008)

[9] Marengoni A, Angleman S, Melis R, Mangialasche F, Karp A, Garmen A, et al. Aging with multimorbidity: A systematic review of the literature. Ageing Res Rev 2011;10(4):430-39

[10] Rochon PA, Gurwitz JH. Drug therapy. Lancet. 1995; 346: 32-36

[11] Pit SW, Byles JE, Cockburn J. Medication review: patient selection and general practitioner's report of drug-related problems and actions taken in elderly Australians. J Am Geriatr Soc. Jun; 2007 55(6):927-934

[12] Drenth-van Maanen AC, van Marum RJ, Knol W, van der Linden CM, Jansen PA. Prescribing optimization method for improving prescribing in elderly patients receiving polypharmacy: results of application to case histories by general practitioners. Drugs Aging. 2009; 26(8):687-701

A further challenge with multimorbidity is that the complexity for patients of navigating multiple conditions, multiple care teams and their different (sometimes clashing) guidance can make it very difficult for patients to play an active role in their own self-management. However, without this, patients can feel disempowered, being less in control of their own health and its lifestyle impacts. Given the growing healthcare burden of chronic disease management, it is also not scalable for healthcare delivery to cut out the important role that patients and their informal caregivers can play.

1.2. The case for adopting a strategic approach

The healthcare cost for patients with multimorbidity is much higher than the average for patients. A large Swiss study, in 2013, showed that healthcare costs were 5.5 times higher in multimorbid patients[13]. Each additional chronic condition was associated with an increase of 3.2 consultations and increased costs of 33%. Multimorbid patients were 5.6 times more likely to be hospitalised.

Healthcare resource consumption is not only because of the accumulation of chronic health conditions but also because of interactions and synergies among health conditions present within an individual[14].

There is limited high-quality evidence available about some of the interventions currently being implemented to manage multimorbidity. However, despite considerable heterogeneity in interventions, patient populations, and processes and outcomes of care, integrated care programmes seemed to have positive effects on the quality of patient care [15]. Evidence that is available points to a positive impact of integrated care programmes on the quality of patient care and improved health or patient satisfaction outcomes, but uncertainty remains about the effectiveness of different approaches and their impacts on costs[16].

Gesundes Kinzigtal GmbH is a population-based integrated care approach that is accountable for the complete health care service budget for nearly half of the 69,000 inhabitants of the Kinzigtal region in southwestern Germany. Their first published results showed positive effects in all three European Triple Aim dimensions, improving the health of the population, improving the individual's experience of care, and at the same time reducing the per capita costs of care [17].

The introduction of more home care, patient education and multi-disciplinary team support for patients with advanced multimorbidity (including an oncology diagnosis) has been shown to reduce hospital admissions by 30% and cost of care by 26%[18].

Although there have been few formal quantitative evaluations of these personalised care innovations and interventions on health outcomes and healthcare costs, the emerging evidence indicates a positive impact on both.

[13] Bähler, C., Huber, C.A., Brüngger, B. *et al.* Multimorbidity, health care utilization and costs in an elderly community-dwelling population: a claims data based observational study. *BMC Health Serv Res* **15,** 23 (2015). https://doi.org/10.1186/s12913-015-0698-2

[14] Mercer S, Salisbury C, Fortin M. ABC of multimorbidity. New York: Wiley; 2014

[15] Ouwens M, Wollersheim H, Hermens M et al. Integrated care programmes for chronically ill patients: a review of systematic reviews. International Journal for Quality in Health Care 2005; (17) 2:141–146

[16] Nolte E, Pitchforth E. What is the evidence on the economic impacts of integrated care?. Copenhagen: World Health Organization; 2014. Available from: http://www.euro.who.int/__data/assets/pdf_file/0019/251434/What-is-the-evidence-on-the-economic-impacts-of-integrated-care.pdf

[17] Hildebrandt H, Schulte T, Stunder B. Triple Aim in Kinzigtal, Germany: improving population health, integrating health care, and reducing costs of care—lessons for the UK? Journal of Integrated Care. 2012;20(4):205–22

[18] Sweeney L et al. Patient-centered management of complex patients can reduce costs without shortening life. *Am J Manag Care. 2007;13:84-92*

The challenge for healthcare organisations and health regions is how to design and deliver successful integrated and patient engaged care to support management of multimorbidity. C3-Cloud has demonstrated a digitally enabled way of achieving this.

2. THE C3-CLOUD RESPONSE TO MULTIMORBIDITY

2.1. Introduction to the C3-Cloud solution

C3-Cloud, a European project that ran from 2016 to 2020, has designed, implemented, piloted and validated a portfolio of ICT innovations that offer healthcare professionals within multidisciplinary teams, patients and their caregivers, better access to integrated clinical information backed by well-aligned guidelines and decision support to improve the care and treatment decisions in cases of multimorbidity.

C3-Cloud has developed a modular ICT suite for clinicians and patients. It supports clinicians in reviewing, adjusting and reconciling the treatment plans of their patients with multiple conditions. It serves as a tool to facilitate clinical thinking and decision making. The integrated patient record repository ensures that the clinician can see all of the conditions and their (planned) treatments in one place. Decision support software provides guidance on the best non-clashing medication choice for any new proposed treatment, and the computerised multi-condition guidelines advise on the best aligned care plan for each patient. The care planning features allow the clinicians and patient to define goals and activities that, together with the medication reconciliation, constitute the personalised care plan for the individual multimorbid patient. This can be shared with patients and utilised by them directly using personal computers and mobile devices, the Patient Empowerment Platform.

These unified C3-Cloud solutions can be used by a multi-disciplinary team (MDT) during personalised care plan design and execution. C3-Cloud allows an MDT to automatically match each of the patient's conditions with his or her medications for detecting areas of mismatch, duplicate drugs in treatment regimens and contraindications across multiple treatment plans. Guideline reconciliation allows MDTs to also recognise conflicts in plans (e.g., in setting personalised goals for vital signs and laboratory results) in addition to medications. MDTs can become more confident that a patient is on the right medications and right dosage therapy.

The C3-Cloud solution is specified and illustrated in detail in other documents that can be accessed from https://c3-cloud.eu/project-overview-old/work-packages/deliverables/. This section provides a few of the main highlights of the clinical and patient value of the solutions.

2.2. Integrating and summarising clinical information

Clinical teams face the double information challenge that

- the complete health status and treatment planning of a patient with multimorbidity may be scattered across different ICT systems or modules, and is not easily brought together to enable safe decision making;
- if it is integrated, the information load may be overwhelming, and might require jumping across multiple screens to see what is relevant to a new care planning decision.

The C3-Cloud solution firstly creates a unified repository of relevant clinical data - the information needed to support care planning, but not necessarily all patient information. The full EHR is imported but only the relevant information is displayed on the care planning screen to avoid overloading the clinician (though this information can be viewed if requested).

The C3-Cloud Interoperability Middleware addresses technical, semantic and privacy/security interoperability challenges to seamlessly integrate with the existing health care, social care and home/community care information systems to enable patient-centric care coordination in an informed manner with the involvement of all stakeholders. It has three components:

- The **Security and Privacy Suite** has been developed, based on open and modern specifications for authentication and authorization of care team members and for ensuring encrypted and auditable data exchange across C3-Cloud software components.

- The **Technical Interoperability Suite** enables seamless data exchange between the local care systems and the C3-Cloud components. It provides a standard-based data exchange protocol, to enable information exchange between clinical sites and C3-Cloud components, such as C3DP (see below).
- The **Semantic Interoperability Suite** addresses the challenge of heterogeneous clinical data representation formats. It handles both structural mappings among different information models and resolves semantic mismatches due to the use of different terminology systems and different compositional aggregations, as used to represent the same clinical concept.

This harmonised information is stored in a repository that complies with the latest interoperability standards, HL7 FHIR®[19], so that it is easy for other companies to link their clinical systems to it. In C3-Cloud, the extensible and scalable open-source onFHIR.io Secure Repository[20] is used as the HL7 FHIR® Repository.

Clinical information is presented to clinicians through an application known as the **Coordinated Care & Cure Delivery Platform (C3DP)**, which is explained further in the upcoming sections. This presents the information most needed by clinicians to plan and revise care and medications.

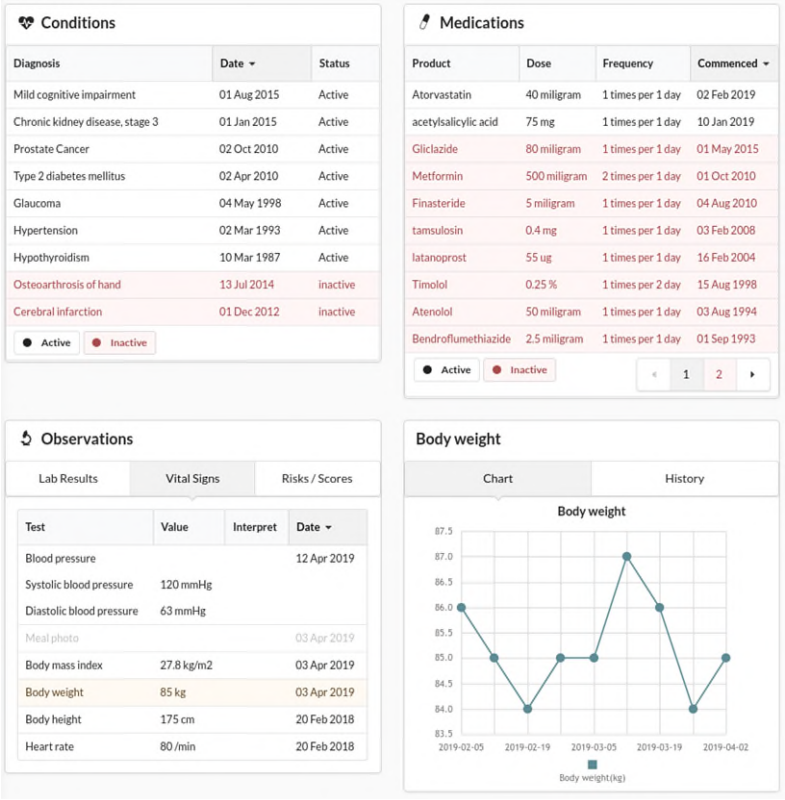

Figure 1: C3DP Medical Summary View:
Patient conditions, medications and observations, with weight chart

[19] The main standard adopted by the repository is the Fast Health Interoperability Resources (FHIR) standard published by Health Level Seven (HL7). Please see https://hl7.org/FHIR/ for more information about this standard.

[20] HL7 FHIR® Based Secure Data Repository, https://onfhir.io/

2.3. Clinical Decision Support

As discussed in the previous chapter, traditional clinical guidelines have been developed for single conditions. C3-Cloud identified four conditions that quite frequently occur in two or three condition combinations and are therefore commonly part of a multimorbidity picture. These are type 2 diabetes, heart failure, chronic kidney disease and depression. Before incorporating these guidelines within C3-Cloud it was therefore necessary for a clinical expert group, comprising domain experts from three European countries (our pilot site countries) to take four existing guidelines, published by the UK National institute for Health and Care Excellence (NICE)[21] and to create an aligned version of each so that the optimal clinical decisions could be made if any two or more were being used concurrently for the same patient.

The clinical guideline information was then represented computationally, and its connections to clinical information decision influencing points was mapped to the clinical concepts described via the Terminology Server sub-component of the Semantic Interoperability Suite. These computational representations of the guideline-based flowcharts and reconciliation rules were implemented as Clinical Decision Support (CDS) services, in order to assist the clinicians in taking the most suitable care decisions for the patient.

The C3-Cloud CDS Services are implemented as CDS Hooks API[22] compliant services, making use of the HL7 FHIR® resources, with decision logic encoded in the Guideline Definition Language v2 (GDL2) which is a part of the *openEHR official specification*. This means that the CDS Services are relatively easy to integrate into other systems if these also utilise health informatics standards. They can be either directly coupled with an EHR system, or as in the C3-Cloud solution be coupled with another user interface. Bearing the care market needs in mind – the CDS Services are flexible in terms of what kind of clinical decision it can support, in which context and for which user it is available. In general, CDS Services are and can be used as live alerting features, clinician-invoked applications or background calculation services inside an EHR.

In addition to the guideline-based services, a RESTful service is developed to manage drug-drug interactions. The drug interaction service provides warning of potential adverse interactions between drugs, as well as a list of side-effects. The service implements the interactions between drugs, as specified by the National Institute of Care Excellence's implementation of the British National Formulary (BNF)[23].

Applying CDS Services in a clinical setting can significantly improve patient care plans by facilitating clinicians' ability to make well-informed, guideline based, decisions.

The methodology adopted in the project for guideline alignment, for formalised representation using GDL2, and then their implementation in the CDS service by complying to the open CDS Hooks specification, are scalable to other clinical conditions and combinations.

2.4. Coordinated Care and Cure Delivery Platform

The Coordinated Care and Cure Delivery Platform (C3DP) is implemented within the scope of C3-Cloud as a Web application for collaborative and personalized care plan management by the members of a multidisciplinary team of care (MDT). All the patient data required for care planning are fetched from the C3-Cloud FHIR Repository, which is continuously updated with EHR data from the pilot sites with the help of the interoperability suite explained above. C3DP visualizes these data and helps the health professionals to easily manage the integrated care coordination process for multi-morbid elderly patients. C3DP implements the HL7 Care Plan Domain Analysis Model (DAM), and enables health

[21] Please see https://www.nice.org.uk

[22] CDS Hooks Specification, https://cds-hooks.hl7.org/1.0/

[23] British National Formulary (BNF), https://www.bnf.org/

professionals to design a care plan for a patient from scratch by selecting health concerns to be addressed from the EHR of the patient, and setting goals and activities to address the needs of this health concern. This process is formalized as a FHIR CarePlan resource, which consists of building blocks like Goal and different types of Activity resources.

To be able to intelligently propose individualized goals and activity suggestions for the addressed health concerns, C3DP is integrated with the C3-Cloud CDS services via CDS Hooks API. The relevant electronic health records of the patient retrieved from the C3-Cloud FHIR Repository are passed as input to CDS services after the semantic mapping of the local clinical concepts into the commonly defined ones are handled. Clinical guideline based CDS logic processing these patient specific diagnoses, lab results, medication data enables the selection of individualized goals and interventions for a specific patient. The CDS service response consists of textual recommendations communicated as information cards and computable recommendations communicated as suggestion cards in compliance with the CDS Hooks API. In suggestion cards, the recommended goals and activities are represented as FHIR resources (such as MedicationRequest, Goal, Appointment) which can readily be included into the care plan model.

C3DP offers a complete suite for integrated care planning with the following additional features: exchange of the care plan and patient provided data with the patient / informal care givers via standards-based integration with the Patient Empowerment Platform (PEP); discussions on individual care plan items among MDT members and patients / informal care givers; updating the progress of goals and activities; management of the multidisciplinary team of care (MDT) of a patient; safe messaging among all care team members, and also with the patients / informal care givers; a personalised activity calendar for the health and social care workers; real-time system notifications for any update on the care plan or availability of new data; and several management functions to the administrators such as for participating health professionals, patients, value sets, education materials.

C3DP is a generic and extensible care plan management solution. In C3-Cloud, it has been used for the management of four main conditions (type 2 diabetes, heart failure, chronic kidney disease and depression) and associated comorbidities; however it can easily be integrated with further CDS services for the management of other diseases via updating some configurations only.

2.5. Patient Empowerment Platform

The Patient Empowerment Platform (PEP) supports self-management that actively monitors a patient's symptoms: it enables the patient to see the goals set for him or her in the personalised care plan, the aimed time plan, and the list of treatment interventions and the patients' activities to achieve these goals. A patient can update his or her progress in achieving these goals. The PEP and supporting tools connect with the MDT through the Coordinated Care and Cure Delivery Platform for realising shared decision making and real time monitoring of the patient's status.

The objective of the **Patient Empowerment Platform** is to give the patient and their informal caregivers a voice in the management of their own care and ensure their active participation in the management of the multimorbid chronic conditions. Through the PEP patients, and any authorised informal caregivers such as family, have access to the current integrated care plan with the quantitative and qualitative outcome goals, the activities to help the patient achieve these goals and supporting educational training materials. The PEP can collect relevant data from patients and share this with the MDT. This includes data entered using patient questionnaires, data manually entered as observations (like measurements) and data collected from sensor devices such as weight scales or blood-pressure meters. Through the PEP the patient can also communicate with the MDT using messaging and video appointment communication tools.

3. SUCCESS FACTORS FOR ADOPTING A PROACTIVE APPROACH TO MULTIMORBIDITY

3.1. Acknowledging that preparation is needed

The adoption of a systematic and ICT enabled approach to the management of multimorbidity, as exemplified by the C3-Cloud solution, may require change in several areas within a healthcare organisation. The deployment and use of the C3-Cloud in an unprepared environment will not deliver its full potential. This chapter summarises the possible areas that may need organisational and/or cultural change. It is recommended that these are planned for in parallel to procuring, installing and configuring the C3-Cloud ICT components, so that the people and organisation are ready to work differently (better co-ordinated, more evidence based, more patient empowering) when it goes live.

Healthcare providers are progressively using formalised care planning tools, on paper or electronically, but exercise patient empowerment and patient self-management to a limited extent. They vary in the extent to which bilateral shared care communications take place between professionals, some providers having better established channels than others. In almost all cases there will be a need to strengthen and formalise the communications between healthcare organisations, especially between primary and secondary care, and better involve social care organisations. The adoption of C3-Cloud will give the opportunity for greater education and empowerment of patients, greater connection with informal caregivers, and perhaps for the first time the opportunity to co-create or adapt care plans with patients. C3-Cloud will scale up the quantity of self-management information and other patient generated feedback that clinical teams will be able to use to inform clinical decisions. Inevitably C3-Cloud introduces new applications, new collaboration tools for which training will be needed. Some of the changes may require new inter-organisational agreements.

Preparation in terms of the team-working culture, multi-disciplinary team workflows, electronic health record information management and the attitude to coaching patients are important success factors that need to be taken into consideration.

3.2. Care plans and team working

When configuring C3-Cloud in its care setting, multi-disciplinary teams will be able to design collaborative care plans that will potentially differ from their existing modes of delivering care. C3-Cloud will come with a portfolio of well aligned clinical guidelines that can be used in combination. However, there may be a need to fine tune these to a local environment, which may have specific team expertise, particular kinds of investigational equipment, a local formulary of drugs that are mainly to be used etc. Since greater patient involvement in self-management is intended, these new collaborative care plans also propose how the role of self-management and patient generated data are positioned within the decision-making logic.

An adopting site will not need to develop all this material, but an appropriately appointed multi-disciplinary core team needs to review the ones provided by C3-Cloud, endorse them and/or fine tune them if needed. This preparatory activity will need co-ordination and leadership, as it will require reviewing how the multiple single-condition care plans have been aligned by C3-Cloud, including the adjustments that have been made to avoid clashes and unnecessary duplications. A similar review process may be required periodically whenever clinical guidelines are updated, due to new evidence.

A new multimorbidity care plan may introduce possible changes to currently recommended treatments, possible changes to current practice for monitoring intervals and other areas of change. These will need to be agreed across all relevant actors within the adopting healthcare ecosystem, including working through any legal and professional implications (for no longer adhering to a previous standard of care) and possibly cost implications if the changes are more expensive. There may be a reallocation of costs between players in a healthcare ecosystem due to reallocation of roles and responsibilities.

In almost all cases there will be changes to inter-professional communication, sometimes the introduction of new professional expertise within a team and new shared care inter-dependencies.

These new care plans will become personalised by interacting with the patient and their companion caregivers. There will be a need to educate almost all professionals about how to explain care plans to patients, how to discuss and agree personalisation, and how to educate patients to use the care planning tools (the PEP) to which they will have access. It is not envisaged that patients will be able to modify care plans themselves, so the education process will need to include advising patients on how they can request changes to their plan.

Apart from formalising the development of personalised care plans, there will be a need to formalise the tracking of progress along a care plan, partly from a care delivery orchestration perspective (ensuring that the data, decisions, resources and actors are ready for the next steps to be executed in a timely way) and from a health outcomes perspective (monitoring if the current care plan is leading to the expected health benefits for each patient). Ideally the care plan itself will include criteria for its own revision (for example, care escalation criteria and channels), but some interdisciplinary agreements may be required about how changes to a care plan will be agreed if they impact on the activities to be performed by multiple professionals.

There will be a need for all classes of user to learn to use new applications to develop and revise care plans (the C3-Cloud C3DP and PEP).

3.3. Using shared electronic health records

It is intended, through the C3-Cloud architecture and its ability to connect across multiple healthcare provider systems, to offer care teams with access to richer, multi-provider EHR data including clinical, social care and patient self-management information. This will provide support to all MDT members, giving them better clinical insights across the multiple conditions being treated for each patient. This richer information will help enable better tracking of care pathway progression across care provider sites. However, recognition of, and action on, some potential challenges will be necessary, such as information overload, and reconciling differences in the information coming from multiple sites, what constitutes the current medication list, allergy list etc. There are significant information governance issues as well between information sharing between different EHRs.

Most clinicians today recognise the need to author clinical documentation in a way that is easily understood by other local professionals. C3-Cloud provides real-time decision support, real-time care pathway alerts and notifications, and timely messages to patients. To be successful all of the clinicians involved in an MDT must document their patient encounters promptly and fully, using structured and coded data entry where these data are used computationally (e.g., for decision support). For some healthcare providers this might mean reinforcing existing good practice in structuring and coding, but it may in places require introducing important quality changes in documentation practice.

Each of the healthcare provider organisations deploying C3-Cloud solutions will have existing information systems used to capture and present clinical documentation (EHRs or equivalent). The C3-Cloud adoption manuals and training include clear guidance on what care and documentation functions C3-Cloud applications and tools support, and when and how MDT staff should continue to use their existing information systems. It must be recognised that some patients will be cared for partly by C3-Cloud MDT users and partly by other professional staff (e.g., caring for other health conditions of the patient).

It is generally good practice that all members of an MDT can see all of the information entered by their colleagues, so that everybody's practice is as complete as possible, and therefore safe. However, the introduction of C3-Cloud solutions may require some preparation of user roles and access controls, so that these can be included as part of the initial configuration. For each healthcare provider deploying and using C3-Cloud, somebody needs to be nominated to maintain the role-based access control list, so that new team members can be added and outgoing team members can be removed when appropriate.

3.4. Care collaboration and co-ordination, professional accountability

By strengthening the collaborations between MDT members and with patients and their caregivers, the introduction of C3-Cloud will inevitably increase the level of communication. Some communications

might be mediated exclusively through the platform and tools, such as the delivery of electronic messages and notifications. There may be a need for less frequent multidisciplinary team meetings because planning decisions are taken in real time on a patient specific basis through shared information and electronic messages.

The new care pathways might introduce changes to roles and responsibilities within multi-professional care teams and across sites. For example, it will need to be clear which actors are responsible for educating and equipping a patient to manage elements of their condition autonomously, and to which actors a patient should report difficulties or concerns with self-management. If new streams of patient monitoring data are being introduced, it will need to be clear which actors are responsible for routinely monitoring such data and to which other actors any issues and alerts should be escalated.

Lines of responsibility, oversight and governance, and escalation need to be formalised and documented in situations where multiple teams are working in new collaborations.

There are potentially new training, legal and accountability issues to be examined when introducing virtual consultations with patients, unless these are already taking place in the adopting healthcare environment.

3.5. Delivering care differently

Although focusing on the challenge of multimorbidity, C3-Cloud solutions introduce a formalisation to clinical workflows, to decision-making and to collaboration that are equally applicable to practising evidence-based care for single conditions, since computerised care pathway solutions are not widely used today. It serves as a tool to facilitate clinical thinking and decision making. There are several potential areas of beneficial impact which might be introduced through adopting the solutions, which are not exclusively to do with multimorbidity, but are in any case clinical practice changes that might sometimes require professional buy-in and organisational change support. These include:

- impacts on the workflow and workload of individual professionals;
- changed relationships with patients, families, caregivers;
- potentially new or more detailed formalised patient assessments;
- reinforcing shared decision making on how to achieve agreed future goals, bringing the time dimension to centre stage;
- the opportunity to plan for the achievement of specific health outcomes, promoting their weight in clinical decision making;
- greater emphasis on, and so potentially an increased workload in delivering, lifestyle education (health coaching);
- potentially greater emphasis and workload around rehabilitation, social needs, family needs and impacts;
- opportunity to monitor patients at home through patient-generated data;
- opportunity to track care plan progress and deviations;
- opportunity to monitor medication adherence and tolerance;
- opportunity to monitor health outcomes;
- potential to positively impact on the other conditions and care pathways, not covered by C3-Cloud;
- opportunity to monitor the extent to which care plan goals are achieved.

These impacts may vary, considerably, across healthcare sites and care pathways. The adoption of C3-Cloud may serve as a catalyst for reviewing, improving and streamlining the way in which MDT members co-ordinate and collaborate in delivering person-centred, more efficient and more effective care.

3.6. Patient empowerment

Patient empowerment is an explicit goal of the C3-Cloud services. This concept is complex and includes a number of important viewpoints from the patient perspective.

Our framework[24] includes the core characteristics of the empowerment concept (control, psychological coping, self-efficacy, understanding, legitimacy and support) as well as a set of empowerment consequences: expressed patient perceptions, behaviour, clinical outcomes and health systems effects.

The framework for designing interventions includes strategies to achieve empowerment goals using different ICT services.

C3-Cloud offers greater engagement of patients and their informal caregivers through the Patient Empowerment Platform which should contribute positively to the ability of patient understanding, self-efficacy and control. Patients will have access to new patient tailored applications, to new educational resources about their condition and its self-management, plus lifestyle guidance. Through the PEP platform they will receive reminders to carry out monitoring, treatment or lifestyle actions.

The PEP will offer the opportunity for change to patients and their informal caregivers, if they elect to use it. They may need reassurance that their involvement in self-management and their uptake of lifestyle guidance will not adversely affect, or diminish, the care that they receive from their healthcare professionals. They should be reassured that the PEP is intended to improve both their self-efficacy and the ability of their healthcare professionals to deliver the best possible care. As with patients, PEP will need all healthcare professionals to embrace fully the importance of patient empowerment. This may require a change in personal attitudes and organisational culture. Involved healthcare professionals will need to understand and be able to demonstrate to patients the tools within the PEP. They will need to be able to answer patients' questions and concerns regarding the PEP. Healthcare professionals will need to appreciate potential importance of patient generated observations, delivered through the PEP from home monitoring devices, and the ability of these observations to reflect treatment effects e.g., changes in blood pressure following the introduction of a new antihypertensive.

Professionals will need themselves to review and be aware of the educational resources their patients are going to access. Time needs to be allocated to this, perhaps via education sessions for professionals.

3.7. Organisational accountability and agreements

If the distribution of care responsibilities between organisations changes as a result of the new care pathways, there may be complementary organisational governance adaptations that need to be actioned. For example, richer care collaboration may require the better definition of risk sharing and risk management, and more formalised mechanisms for traceability.

There might be a need for formalised (legal) data sharing agreements between care organisations, such as between social care and health care entities, in order for their health and care records to be shared.

3.8. Reimbursement and reporting

If care activities are transferred between care organisations because of new models of collaboration, such as shifting some additional hospital activities to primary care, then this may impact on the health care costs incurred by each healthcare provider organisation. This might in turn require shifts in budget allocation and reimbursement.

Apart from the financial aspects, different models of care may impact on performance and management reporting by each healthcare organisation, which may also impact the organisations financially and non-financially.

[24] Framework for ICT-based Interventions Targeting Patient Empowerment. Karni, Memedi, Dalal, Kalra and Klein. JMIR in Press 2020

3.9. Preparing for change

The purpose of this chapter has been to draw attention to the cultural and organisational changes that are needed in order to provide better and more empowering care to patients with multimorbidity. Not all organisations will need to implement changes in the way they plan and deliver care. For some organisations that do not already work with clinical guidelines, use their electronic health record systems to manage personalised care planning, do not have well-coordinated MDTs or do not engage patients well in self-care, then the adoption of C3-Cloud must not be seen as a technology adoption process but a healthcare quality improvement programme that is technology enabled.

Members of the C3-Cloud project and community have experience of implementing such quality improvement programmes holistically. Their advice might be available via the C3-Cloud service provider to those organisations who are unsure about how to design and orchestrate this kind of improvement programme.

4. C3-CLOUD ADOPTION GUIDELINES

4.1. Introduction to these guidelines

This chapter, the heart of this document, presents adoption guidelines for the C3-Cloud solution.

These guidelines have been written to help a healthcare organisation, or a network of organisations offering integrated care services, to plan for a smooth and successful adoption of the C3-Cloud solution. Although the solution is mainly delivered as ICT components, its beneficial use and impact on the care of patients with multimorbidity, depends as much on an organisational change programme as the implementation of the ICT programme.

4.2. Methodology for developing these guidelines

The starting point for this guideline has been

- an analysis of the scope and potential impact of tackling multimorbidity through the planned C3-Cloud interventions: MDT co-ordination, better information, CDS, patient empowerment;
- the overall design of the C3-Cloud solution, as documented in several early deliverables;
- the plans for piloting C3-Cloud at three European healthcare sites, as documented in later deliverables and working documents detailing the piloting methodology.

The three pilot sites were:

- South Warwickshire NHS Foundation Trust and the Rother House Medical Centre in Stratford upon Avon. 16 healthcare professionals were recruited from these organisations, including GPs, practice nurses, diabetes specialists, heart specialists, dieticians and district nurses.
- In Osakidetza, the public healthcare service of the Basque Country, C3-Cloud was piloted at five Integrated Care Organizations (OSIs): OSI Araba, OSI Barrualde-Galdakao, OSI Donostialdea, OSI Ezkerraldea Enkarterri Cruces and OSI Tolosaldea. 34 healthcare professionals (GPs and Primary Care Nurses) from 8 health care centers were actively participating in the pilot.
- In Region Jämtland Härjedalen, C3-Cloud was piloted at eight healthcare centres, in urban Östersund as well as in rural parts of the region, up to 160 km from the city. At all healthcare centres doctors (mostly specialists in family medicine) and nurses, including diabetic nurses were involved along with nurses in municipality care in three municipalities, a total number of about 25 healthcare personnel.

More information about the pilot sites can be found in several deliverables from project work packages 4, 8, 9 (which are summarised here https://c3-cloud.eu/project-overview-old/work-packages). A detailed profile of each, and their starting position in relation to multimorbidity care, is documented in Deliverable 4.2.

In September 2017 an analysis of the potential areas of change (organisational, professional, workflow, reimbursement etc.) that might be required to obtain maximum value from C3-Cloud enabled high quality multimorbidity care was compiled into an initial consultation paper, after examining the following deliverables, which can be accessed here https://c3-cloud.eu/project-overview-old/work-packages/deliverables:

D1.7 Data Protection Plan

D2.2-Business and Exploitation Plan

D3.1 Survey of the State of the Art

D3.2 Requirements Specification of the C3-Cloud Architecture

D3.3 Conceptual Design of the C3-Cloud Architecture

D4.1 Guidance for the Development of New Patient Pathways and Corresponding Care Plans

D4.2 New Organisational Models

D5.1 Self-Management Training Materials for Increasing Patient Adherence

D5.2 Data Collection and Feedback Mechanism

D5.3 Patient Empowerment Platform

D7.1 Evidence based clinical guideline definitions

D8.1 Use Cases and Requirements Specifications of the Pilot Application

D8.2 Design of the implementation of the pilot application scenarios

D9.1 Functional and Non-Functional Testing Criteria for C3-Cloud Components

D10.1 Audit of the security measures

Deliverable 4.2 was especially relevant since this already examines and reports on the main areas of change that each of the three pilot sites anticipated.

Following initial exchanges with three pilot sites, a more comprehensive framework was developed for a standard operating procedure (SOP) in December 2017. Through frequent remote and in-person meetings with pilot site representatives over the following several months this SOP was enriched, and later adapted into a series of checklist tables (June 2017) so that the sites could monitor their progress in developing local methodologies to define and implement the necessary organisational measures, training programmes and ICT departmental interactions.

In collaboration with other partners, the content of the eventual SOP was transferred in September 2018 into a tracking tool spreadsheet, with macros and colour coding so that the progression of compliance or issues could be monitored. Where relevant, more technical members of the consortium were invited to join some of the calls in order to help explain some of the design features of the solution and how sites needed to prepare for adoption.

The tracking tool eventually enabled the pilot sites to complete all of the preparations needed for live use by autumn 2019, which paved the way for the operational pilot studies.

Once the pilot phase had completed, the tracking tool information and the original SOP clauses were synthesised in April-May 2020 into the following guideline sections. A further round of interaction with the pilot sites in June 2020 has validated that these guidance points might indeed be applicable to a downstream adopting healthcare organisation. This also provided a final opportunity to capture *post hoc* good practice suggestions from the pilot sites, for any future healthcare provider adopting C3-Cloud solution.

4.3. Approvals and governance

4.3.1. Required approval and agreement types

The C3-Cloud multimorbidity programme will almost always involve introducing patient care pathway changes. The scope of these may be limited to a single healthcare provider organisation, which is the one adopting and hosting the C3-Cloud solution. However, patients with multimorbidity are often under the care of more than one healthcare provider, and changes in the care pathway might therefore have implications for the relationships between healthcare provider organisations.

Some deployment environments may be collaborative, covering multiple healthcare provider organisations who share care for a population of multi morbidity patients.

The adopting healthcare organisation(s) therefore need to work out carefully which approvals and formalised agreements will be required in order for the use of C3-Cloud to be acceptable across all organisations and perspectives. This section can therefore only provide a suggestion of possible areas of approval and governance that might be required.

As discussed in Chapter 3, new collaborative multimorbidity care pathways may alter the balance of care delivery services that are provided by different organisations within an integrated care environment. This may have implications for the contractual relationships that healthcare provider organisations have with a healthcare payer such as a regional health authority, a health insurer, a care commissioning organisation or a national health ministry. Approvals may be needed from any of these bodies in order to authorise transfers of care between healthcare provider organisations for novel aspects of a care pathway.

Depending upon how healthcare services are reimbursed, prior permission may be required for changes in the configuration of healthcare services. Reimbursement fees may need to be renegotiated for packages of care that include additional services that were previously provided by a different healthcare provider in the network or exclude certain services which will now be delivered by a different healthcare provider organisation.

If more than one healthcare provider organisation's EHR system is going to be connected to the C3-Cloud infrastructure, then data sharing agreements may be required between the organisations in the care network.

It is likely that approval from the hosting organisation's Data Protection Officer will be required, and possibly similar approval from any other healthcare organisations that are part of the C3-Cloud network. This topic is discussed in more detail in section 4.3.2.

Since the C3-Cloud solution will be installed as a set of locally hosted data repositories and services, and includes connectivity with patients, it is important that the ICT department and information security lead be consulted before making decisions about deploying C3-Cloud. The hosting healthcare provider organisation might also wish to consult with its medical director, clinical governance lead and patient safety lead. Since this is an innovation increasing patient engagement and empowerment, consultation with patient representatives may also be advisable. If C3-Cloud will be accessed by multiple healthcare provider organisations, then parallel consultations may be appropriate across all of the involved healthcare organisations.

Research Ethics Committee approval is very unlikely to be required because the C3-Cloud solution will be used as part of operational healthcare delivery. However, if any supplementary evaluations are being undertaken, these studies might require ethics committee approval.

The PEP might link to externally hosted information resources, for education or background information, for which an agreement with those organisations might be needed.

Agreements that will be needed with the C3-Cloud service provider and its technical staff are discussed in section 4.3.3.

4.3.2. Information Governance and data protection

In most cases the C3-Cloud solution will not alter the existing practices on the disclosure and use of personal health data, except in expanding the electronic channels for sharing data between health professionals involved in care delivery, and in engaging patients more explicity. The legal basis for collecting and processing data will be unchanged, since the data will only be used for direct patient care, and any usual organisational practices for quality and safety monitoring. The C3-Cloud solution by default is hosted within the healthcare organisation's infrastructure so no patient data will be transferred to the C3-Cloud service providers or third parties.

Patients and their authorised caregivers using the PEP will have access to a shared care plan and some of their electronic health record information. The healthcare organisation's Data Protection Officer should verify that patient educational materials provide a full and clear explanation about information that will be collected by them, why, how and by whom it will be accessed and used. The normal rights of a data subject under GDPR, such as the right to access their own personal data, the right of data portability etc. need to be explained and be capable of being implemented. Patients must be clear that caregivers they have authorised to use the PEP will have access to the same clinical data as the patient.

It is recommended that the hosting organisation, its Data Protection Officer (DPO) and ICT department specify how, in their view, the intended deployment of the C3-Cloud solution complies with local information governance policies (including GDPR compliance). This should also stipulate the circumstances under which the C3-Cloud service provider may access locally hosted resources, remotely or on site, for maintenance and troubleshooting purposes, and reference the Service Level Agreement and Data Processing Agreement signed by the C3-Cloud service provider (see section 4.3.3).

4.3.3. SLA with the C3-Cloud service provider

A Service Level Agreement should be signed with the C3-Cloud service provider, to specify at minimum what components are being supplied, in what form and with what configuration and installation support. It should specify the scenarios for which technical support will be provided, how it may be invoked, how it will be provided, if there are any limits or staged fees for certain kinds of support.

A separate Data Processing Agreement may also be required in order to permit the C3-Cloud service providers technical team to access the deployed components, repositories, hardware and data in order to test, troubleshoot and rectify any technical issues. This or an additional agreement should set out liabilities and responsibilities with respect to patient safety and data protection.

These agreements will probably be fairly standard, mirroring other health ICT vendor agreements.

4.4. Preparing and training MDT staff

Chapter 3 of this document has explained some of the cultural and clinical workflow implications of adopting a proactive, evidence based and co-ordinated strategy for managing multimorbidity. These organisational and team changes are not specific to C3-Cloud and are not really introduced by C3-Cloud. They reflect good practice, but C3-Cloud can help with implementing this good practice.

MDT staff training for C3-Cloud should not primarily be considered ICT training, although staff will need to be introduced to the applications and how to use them. It will be organisational change training. The Coordinated Care and Cure Delivery Platform (C3DP) has user manuals and training videos that can be used to supplement or reinforce in-person ICT training. It is recommended that training logs are maintained to ensure that all involved MDT members have received adequate training before they use the system.

MDT staff education may be needed in the content of the chosen clinical guidelines, understanding how they have been aligned and how they are delivered in a structured and computerised form.

They may also need education in how to identify and tag patients who are suitable to include in the programme.

Staff may need to understand if their role within the C3-Cloud programme introduces new responsibilities or care activities, such as educating and supporting patients with self-management.

The following specific areas of training may be considered, depending upon the current extent of MDT experience.

- Personalised care plan management for multimorbid patients within an MDT environment
- Guideline alignment and reconciliation in a computerised format
- The utilisation of clinical decision support services implementing clinical guidelines
- How drug interaction databases work
- How to personalise a care plan, and how to engage patients in co-creating it
- How to initialise the PEP for each patient

- How to educate and support a family or informal caregiver in self-management and in using the PEP
- The materials such as information sheets and videos that can be provided to patients and caregivers to explain the C3-Cloud system and the PEP
- Dealing with exceptional patients who are part of the target population, that have entered the programme but for whom the multimorbidity care plan becomes inappropriate during the programme
- How team communications, messages, alerts etc. will take place via the C3-Cloud collaboration platform, potentially including videoconferencing if this is installed
- The concurrent use of existing EHR and C3-Cloud applications, including the need to continue current documentation practices, and what their documentation workflow might now look like. (The C3-Cloud tools do not prevent shared care plans from being transferred back to local EHR systems, and the C3-Cloud service provider will support activities to enable 2-way communication between the C3-Cloud solution and existing systems where this is allowed by local site governance and security procedures.)
- About the existence and governance of audit trails
- Reviewing and responding to patient communications including readings from home monitoring devices or urgent queries and concerns
- How staff queries about C3-Cloud will be handled, including the main contact points for different kinds of query (see section 4.7.1)

C3-Cloud has developed training materials that were used during its research and evaluation stages, which might be useful as a basis for local customisation, and translation if needed. These are included in C3-Cloud deliverable 9.4 https://c3-cloud.eu/wp-content/uploads/2019/09/D9.4.pdf.

4.5. Setting up and running the C3-Cloud multimorbidity programme

4.5.1. Initiating patients within the C3-Cloud programme

Patient involvement, to explore who is suitable for using the C3-Cloud multimorbidity programme, and the main aspects of informing and equipping patients and caregivers, are described in section 4.6.1. These target population criteria may include having two or more of the C3-Cloud managed conditions, possibly excluding those with advanced disease, possible setting an age range for inclusion, having sufficient digital literacy etc.

A method needs to be defined for tagging a selected patient within the healthcare provider EHR system as being in the C3-Cloud multimorbidity programme so that their health data are transferred to C3-Cloud and regularly updated. Once a patient is registered in C3-Cloud, the solution allows the site to set up regular updates to keep the C3-Cloud system in sync with the EHR, without manual intervention.

Once a patient has been set up in C3-Cloud, a nominated member of the MDT (or perhaps one expert per disease that the patient has) will need to initiate personalised care planning for the patient.

This personalisation may include specifying which members of a complete MDT have care responsibilities for this patient. Personalised activities and goals will be assigned to care team members, as well as to the patient and informal caregiver, both via suggestions provided by the CDS services automating evidence-based clinical guidelines and manually by the MDT members based on their experience.

An initial visit should be arranged with the patient (and optionally their caregiver) to introduce C3-Cloud and to talk though the care plan, so that any personalisation of it is jointly discussed and agreed.

This should take place after initial training has taken place (e.g., how to use the PEP) or might be undertaken as part of this initial patient and caregiver training.

Putting the patient on a well-aligned multimorbidity care plan might suggest immediate changes to existing care, and to monitoring activities. If these are clinically accepted, then there will be a need to explain these to the patient and teach them about any new aspects of home monitoring. Sufficient time will need to be allocated for this initial visit, so that the patient is well-equipped to play their active and empowered role in his or her care.

A member of the MDT should also determine if any clinical staff who care for other aspects of a patient's health, such as conditions not included in the C3-Cloud disease portfolio, or who undertake prevention activities, need to be informed that this patient is now part of the C3-Cloud programme.

4.5.2. Following up patients through C3-Cloud

Routine follow up care for patients should follow the recommendations of the personalised care plan a patient is on. This will include how frequently a patient should be followed up and what monitoring assessments should be undertaken.

MDTs should have clear lines of responsibility for monitoring patient generated data through the PEP, as discussed in section 4.6.2. Patients should also be clear about who to contact directly if they need urgent or non-urgent clinical guidance, as discussed in section 4.6.3.

As would be expected within any MDT, there should be well defined policies for managing escalations of care: how to handle any deterioration of the patient that radically changes their care plan, and how to deal with significant health or life events that take the patient out of the care plan (e.g., how to communicate this across the MDT). The C3-Cloud collaboration platform could help with this.

The healthcare provider should consider if a documented process is needed for unscheduled care events for patients with a C3-Cloud care plan, especially how to inform other clinicians that the patient is following a multimorbidity care plan and if this might influence their treatment decisions or clinical documentation practices. However, through integration with local EHR systems, the C3-Cloud system will always be kept up to date with the latest data available for a patient including any decisions made outside the C3-Cloud platform as long as these are recorded in the EHR system.

4.5.3. Clinical information access

The use of C3-Cloud offers MDT staff a well-designed and comprehensive summary view of each patient, across their multimorbidity diseases, linked to a personalised care plan and patient provided data via the PEP. It is populated from healthcare provider EHR data and offers a way to capture new care planning decisions.

MDT staff must be informed about which EHR or other systems will be synchronised with C3-Cloud, and how frequently. They must also be advised if information entered via C3-Cloud applications will be synchronised back to their local EHR, or not.

MDT staff must have an easy way of knowing which of their patients have been included within the C3-Cloud programme, through which they may find integrated patient information and care plans on those patients.

MDT staff need to have explained to them that, in order to avoid information overload and to facilitate clinical decision-making, the C3-Cloud C3DP does not display all of a patient's clinical data integrated across multiple EHR systems. It offers a carefully designed summary that presents the information that our clinical experts have felt to be most relevant to assessing the progress of a patient along a multimorbidity care pathway. Staff therefore need to be aware that there might be details or incidental

clinical information that the C3-Cloud system does not display, unless it is part of a standard heading such as a problem list, allergy list or medication list.

MDT staff must be able to easily tell which of their team colleagues are included within the access control list for a given patient within C3-Cloud, so that they are aware who else can view and contribute to a shared care plan, but who might not be able to access it.

MDT staff and patients/caregivers should be assured that the PEP is automatically updated whenever changes are made by an MDT member to the patient's care plan using the C3-Cloud C3DP.

MDT staff should know if patient-provided data from the PEP can be accessed in any locally deployed systems apart from the C3-Cloud system.

4.5.4. Clinical documentation practices

In order for clinicians to safely understand what data they are viewing through C3-Cloud, and to ensure that they maintain their organisational EHR correctly, it is recommended that a simple clinical documentation protocol be developed and promoted.

In order to retain integrity with the operational EHR at every healthcare provider, MDT members are still required to perform their usual clinical documentation practices in their usual EHR system. In order to minimise a double data entry burden, C3-Cloud itself needs very little data entry: it is more of a tool to facilitate clinical thinking and decision making which is then documented in the normal EHR. However, it may prove helpful to specify the intended new documentation workflow: which information should be entered into which systems. C3-Cloud will itself be refreshed with that EHR data at the next synchronization cycle automatically or by a manual trigger by the MDT members.

MDT staff must therefore be informed about which systems (screens) to enter particular kinds of new clinical data into, and which data (if any) from C3-Cloud goes back to local systems. For example, it must be clear where a change in medication dose must be entered in order to be reflected in the future prescriptions and communicated to a hospital pharmacy department. Currently, the C3-Cloud solution saves new medication prescriptions made within the platform inside the FHIR repository which can be queried or transferred back into local prescription systems / EHR systems (if supported at the site). If this is not supported, either due to legal or technical issues, these medication updates will only appear as recommendations within C3-Cloud and will need to be made directly on the local EHR system in order to be actioned.

4.5.5. Multi-Disciplinary Team interactions

The C3-Cloud solution enables MDT members to collaborate electronically. It is not mandatory to use this, and it may be seen as a supplementary channel for one-to-one or team collaborations, in addition to those methods already used such as face-to-face meetings.

There must be guidance to MDT members on how to use the collaboration platform.

It may be helpful to discuss the use of this collaboration platform within the team and arrive at a consensus on the initial situations and when it will be used most commonly, until more experience is gained, and collaboration patterns evolve.

As with most other collaboration channels, it is recommended that the outcome of an MDT interaction via C3-Cloud is documented within the patient's record, possibly as a change to their care plan.

4.5.6. Interacting with non-C3-Cloud healthcare staff

Healthcare providers that deploy C3-Cloud need to recognise that some patients will have a condition amongst their multimorbidity profile that is not covered by the C3-Cloud solution, and/or they might at

times need healthcare that is not delivered by their C3-Cloud empowered multimorbidity MDT, such as in an emergency.

It is suggested that healthcare providers consider having a strategy, which might be light touch, for the following scenarios:

- non-local unplanned healthcare encounters: who and how to notify in order that records and care plans are kept up to date;
- incidentally involved healthcare staff, since one cannot guarantee that the C3-Cloud MDT members will be the only ones dealing with the patient for their multimorbidity conditions;
- keeping other clinicians informed and getting information from other clinicians who manage other conditions that the patients may have, e.g., cancer.

It may be helpful to inform a wider range of neighbouring healthcare professionals about the adoption of C3-Cloud and which kind of patients are likely to be included.

As C3-Cloud supports the deployment of computer executable clinical guidelines written using an industry standard format, there is the potential to extend the C3-Cloud system to support conditions above those provided with the base offering. This could potentially allow a larger set of specialties to be involved in the C3-Cloud MDT and shared care planning. Efforts to extend C3-Cloud coverage can be supported by the C3-Cloud organisation.

4.6. Engaging patients

4.6.1. Patient selection, empowerment and training

Nominated MDT members need to agree on the target population of patients to be managed through the C3-Cloud multimorbidity solution. These target population criteria may include having two or more of the C3-Cloud managed conditions, possibly excluding those with advanced disease, possibly setting an age range for inclusion, having sufficient digital literacy etc. An illustrative set of criteria, for the four conditions that were included during the C3-Cloud project itself, are included in Appendix 1 as an example from which the specific criteria could be developed. These criteria should be well documented and publicised across the care organisation so that all staff are aware of who might be eligible to include and are able to tag the patient in an agreed way, ideally within the EHR system, so that the patient can be considered for inclusion.

When developing each personalised care plan for the patient-specific combination of diseases, the responsible MDT member should agree with the patient (and possibly with their caregiver) areas of self-management, care adaptation and prevention that will be undertaken. The goals of this activity are to enable better quality care planning and greater patient empowerment (self-management and shared decision making).

MDT members should be provided with a portfolio of multimorbidity self-management and C3-Cloud PEP training materials, in their patients' languages and also supporting different levels of literacy, from which to select the relevant ones for each patient.

The PEP displays the data to be shared with the patient via the care plan (including goals, activities and assigned training materials). It can collect home monitoring data. The PEP can also be used to collect data from the patient using health assessment questionnaires, providing updates on how they are progressing against the goals and activities in their care plan. The details of what data this includes can be determined and set individually by each MDT, which should be agreed at a generic level by the MDT during C3-Cloud configuration and only needing to be fine-tuned per patient.

Patients need to be guided about which features of the PEP will be relevant to their personal health management, how the guidance resources can be accessed and what data they should enter into the application. They should also be coached in how to use, appropriately but not excessively,

communication channels within the PEP to their MDT. They should also be reassured that they do not need to use all of the functions that the PEP is capable of, if they are not comfortable with taking autonomy in some aspects of their health and care.

Patients need to be appropriately reminded about access by caregivers they have previously authorised, such as family members, in their care planning. The inclusion of caregivers needs to be on the basis of informed consent. Patients should understand the risks and the benefits, and this should be tailored to the individual and to the consent laws and practices of each country / region. Explanation should include the data that the caregiver will be given access to and the channels of communication to clinical staff that the caregiver will be able to leverage. Informal caregivers will be able to access personal information when logged into the PEP, when managing the care plan and providing monitoring or health status information. Patient information leaflets that explain this need to be approved locally, including by the healthcare provider's Data Protection Officer, to make sure that the patient has given well-informed consent to the involvement of specified caregivers.

Information must be provided to patients and to authorised caregivers about what data will be collected about them, how it will be used and by who it will be used/accessed, and any other GDPR compliance information. The data collected will not exceed that volunteered by the participant themselves, will not be transferred out of the healthcare organisation(s), and will not be used for any purpose other than direct care and patient safety monitoring etc.

Patients and their caregivers also need to be advised on what personally owned devices, such as smartphones and home computers, are suitable to run the PEP or if a new device needs to be purchased, or if one can be issued by the healthcare provider organisation to the patient. If a suitable device will be provided by the healthcare organisation, then guidance needs to be provided about its use, technical support and the return of the equipment at a later stage.

It is recommended that nominated staff are specifically trained and given protected time in educating patients about the use of the PEP, and about taking autonomous responsibility for some elements of their own care plan. The contact points for different kinds of query, as outlined in section 4.6.3, should be explained.

A formal training programme for patients and caregivers should be developed. C3-Cloud has some videos that might be useful to incorporate. These are hosted on YouTube: https://www.youtube.com/channel/UCsS6z-YA4TET5iDZSejUGiQ/videos. These include:

- a video for patients (English) - overview: https://youtu.be/sXaTXYkayLA
- a video for patients (English) – tutorial: https://youtu.be/x3XwF_kQVp4
- a video for patients (Swedish): https://youtu.be/CnIDlTqjo_U

MDT staff will need training and possibly peer mentoring in how they can best guide patients in these different areas. Because this direct patient engagement and empowerment will be new to many MDT staff, healthcare provider organisation should consider setting up a peer mentoring group to facilitate common learning and the sharing of experiences including how to handle issues and areas of uncertainty. Participation in such a mentoring group might extend beyond the MDT members who will directly utilise the C3-Cloud solutions, since the learning and skills are probably beneficial to a wider group of MDT members. C3DP training videos are accessible here:

- for HCPs (English): https://youtu.be/wV5I8Mj8LmQ
- for HCPs (Swedish): https://youtu.be/KcJLRVLM7bI

It should be remembered that a small number of patients may prefer exclusively to engage with their clinicians face-to-face, and not be interested in using remote connections or applications such as the PEP.

4.6.2. Monitoring PEP use

MDTs will need to define a protocol for how incoming patient data via the PEP will be reviewed, by whom, and how frequently.

This protocol needs to specify how the reviewer should handle urgent queries, unusual readings, exceptional readings and intervals with no incoming data.

It should specify to whom, how and how urgently, different kinds of escalation should be actioned. It should also specify the circumstances and with what objectives patients should be contacted via the PEP or by direct contact, e.g., by phone.

It should be noted that only C3-Cloud MDT users will have access to this patient-generated data, unless a real time feed from the C3-Cloud repository to the healthcare provider's EHR system has been added.

It should also be noted that both in the C3-Cloud repository and in the C3DP, patient provided data is explicitly marked as 'the patient provided data' and they are not mixed with the original clinical data coming from underlying EHR systems. The source of any data is always known and tagged appropriately.

4.6.3. Handling patient and informal caregiver queries

Patients and their caregivers should be given clear instructions and details for direct contact for the following scenarios, some of which may point to the same contact person:

- concerns about their health or the results of any home monitoring, requiring clinical guidance;
- feedback on their progress in managing their health situation, advice on measures they can take to better optimise their health trajectory or to deal with deviations from their intended care plan;
- questions about how to use PEP technology they have been issued with;
- technical support issues when the PEP or their device appears not to be working properly, if they have made an error with entering data or have issues with their login.

Suitably skilled and trained staff within the healthcare provider organisation need to be equipped and given sufficient protected time to respond to possible enquiries from patients, some of which may be urgent.

These staff may themselves need escalation guidelines in case they are not able to respond adequately to a patient or caregiver concern, especially if it may require urgent intervention.

Staff need to be guided on how they should document their interactions with patients and caregivers, so that there is a permanent record of their handling of an issue and of any advice given, especially if it is clinical advice.

4.7. ICT support for multimorbidity care using C3-Cloud

The ICT department of a healthcare provider organisation, especially the one that is acting as the hosting environment for the deployed C3-Cloud solutions, primarily needs to be responsible for making available the appropriate technical infrastructure for installation and operation, for setting up the clinical and demographic data feeding pipelines that will populate the C3-Cloud data repository and access control systems, and providing day-to-day support services to MDT staff, patients and caregivers using the C3-Cloud solutions. At the minimum, this includes servers with the appropriate specifications to host the C3-Cloud components, e.g., RAM, CPU, OS, etc., and network infrastructure to allow users to connect to front-end components, C3DP, PEP, etc.

APIs allow the C3-Cloud solution to query and retrieve patient data from the local EHR (common to most large EHR vendors), or data extracts where this is not provided.

Unless the EHR system product has already been integrated with C3-Cloud, an integration project is needed to ensure this data flow even if the use of international standards such as HL7 FHIR® will facilitate this. This might include the need to derive data for the C3-Cloud repository from multiple existing healthcare provider subsystems. These data mappings and terminology mapping might need to be updated whenever there are significant changes to the healthcare provider EHR system or APIs it provides.

It is important to note that the language support available from the EU project includes English, Spanish and Swedish and adoption to other languages for user interface and clinical data will require a non-trivial project activity.

4.7.1. C3-Cloud system installation, support & maintenance

The hosting ICT department should ensure that it has nominated suitable individuals who will learn about the C3-Cloud system, its components, services, interfaces and the pipelines that need to feed it with clinical, demographic and operational data.

The ICT department should ensure it has procured and/or provided an ICT deployment infrastructure for C3-Cloud that will meet its performance, resilience, protection and accessibility needs. This includes appropriate positioning within a firewall and other protection measures that will enable full MDT access and patient access via the PEP. It should be noted that the C3-Cloud service provider's ICT team may need remote support capability, but no MDT clinician-facing ICT services require remote or cloud hosting.

The ICT department should ensure it has secured permission (e.g., from the DPO, if appropriate) for the deployment of the C3-Cloud solution. This may include confirming that inter-organisational agreements such as data sharing agreements are in place.

Deployment should include a period of local testing of the installed C3-Cloud services, repositories, security measures and access controls, data interchange interfaces and communication with the PEP. Clinician validation of the integrity and completeness of sample patient records should be obtained.

Backup strategies should be defined, e.g., method, frequency, criteria and authorisation for roll-back, disaster recovery. Ideally this should align with the ICT department policies and infrastructure for the backup of other clinical operations systems.

The contact details of nominated individuals within the ICT department and/or of a helpdesk should be disseminated to C3-Cloud MDT members so that they can report any issues with accessing or using the C3-Cloud systems, or with data integrity concerns.

A protocol should be defined and disseminated for reporting, assessing, escalating and resolving faults once identified. This includes how remote and on-site support will be facilitated by the ICT department to support its users, and by C3-Cloud technical staff to support the ICT department.

The SLA, Data Processing Agreements and/or specific ICT support service agreements should make clear that C3-Cloud only requires access to the deployed systems and its data in order to respond to a support request. Access will not be continually available, and can be audited by the healthcare organisation. Real patient identifiable data will not be copied outside the healthcare organisation. Where error checking of data is needed that cannot be performed within the healthcare organisation's deployed C3-Cloud architecture, data will be suitably anonymised before taken for analysis. Agreements should require that any data copied for error checking will be deleted as rapidly as possible.

4.7.2. EHR data sources

The healthcare provider organisation or organisations whose MDT users and patients will be using the C3-Cloud solution need to agree which of their EHR systems and specialist clinical subsystems will act as data sources to populate the C3-Cloud clinical data repository. In making this decision care should

be taken to include all of the data sources that contain information about the clinical conditions and their treatments which are within the scope of the multimorbidity disease portfolio being deployed.

A single nominated source (in case there are multiple healthcare providers contributing to the C3-Cloud) of patient demographic details and health system identifiers needs to be agreed, and a data feed pipeline implemented.

In the case of a multi-provider network of EHR data sources, all clinical staff (not just the MDT users nominated to use C3-Cloud) should be advised that the data will be used in this way, stressing the importance of timely and complete updating of clinical data such as medications, allergies, new diagnoses and the progression of each of the diseases in scope.

It is likely that only selected patients who fulfil the set of agreed multimorbidity inclusion criteria will be included within the C3-Cloud system, and staff need to be advised on appropriate tags (such as diagnostic codes) that would enable the appropriate patients to be accurately identified.

(The requirements for data mapping, terminology alignment, the frequency of updates and how these are to be orchestrated are the subject of other C3-Cloud technical documentation.)

4.7.3. Data integrity

If there are frequency limitations in the updating of the C3-Cloud clinical data repository from source systems, MDT staff need to be advised that, from certain EHR data sources, there may be a lag in the currency of the information they are able to see via the C3-Cloud applications. However, the C3-Cloud system itself can be configured to update at any frequency the healthcare organisation deems appropriate.

MDT staff need to be advised to report any omission in clinical data content within the C3-Cloud applications that cannot be explained due to a time lag, in case there is a data mapping error or if one of the pipelines communicating data has failed.

The ICT department of the main deploying healthcare provider organisation needs to establish a process for regularly checking message logs and error logs in relation to the implemented pipelines feeding the C3-Cloud clinical data repository. C3-Cloud is currently configured to use a ‘fetch’ approach to querying and retrieving data from local systems so errors in pipelines should only ever occur if the source system itself is down or the API to access it has been taken offline. Additionally, every effort will be taken during the installation and configuration phase to reliably map source data formats and terminologies to the FHIR standard and standardised terminologies, although errors due to issues with data quality at source cannot be completely eliminated.

Appropriate expertise and a procedure should be defined for how error messages or data transfer inconsistencies are investigated, within the ICT department as well as in collaboration with C3-Cloud technical experts.

Through standardised HL7 FHIR conformant APIs, data entered by clinicians via the C3DP application or transferred into the C3-Cloud repository from the PEP can be pushed to any other clinical data repository or EHR system nominated by the hosting healthcare provider organisation. The healthcare provider organisation, in consultation with its MDTs, need to determine if and which push interfaces should be implemented.

Whether for backup and business continuity purposes, or for data reuse purposes, a strategy for regularly exporting data from the C3-Cloud clinical data repository should be considered, and a target repository under the direct management of the hosting ICT department should be nominated to hold a copy of the data. All components will be hosted within the healthcare provider infrastructure and will be managed by the local ICT department unless issues arise which require intervention from the C3-Cloud service provider.

4.7.4. Business Continuity & Disaster Recovery

The healthcare provider organisation should integrate the C3-Cloud clinical data repository and its repository of care pathways within its normal ICT backup schedules and infrastructure (both are saved within the same FHIR repository instance).

However, it should be noted that all of the clinical data about patients (apart from PEP data) should be a copy of data within the EHR system, and so there should be no patient safety risk should there be a failure of the C3-Cloud system. Data on the shared care plan will be lost so any goals and activities only recorded within C3-Cloud will be lost unless this is transferred back to the EHR or otherwise recorded.

As with all deployed ICT systems and subsystems, a Business Continuity Plan should be defined before live use, irrespective of the availability of the original EHR data, to support MDTs in continued collaboration, care planning and support of patients managing elements of their own care.

The Service Level Agreement made with C3-Cloud service provider needs to detail what technical support will be available, through what channels and with response time, in the event of a technical problem or system failure, or a wider organisational ICT issue such as a computer virus attack.

4.7.5. System Security & User Access

Procedures

The deploying healthcare provider will probably have standard procedures for approving, granting & revoking access rights across its EHR and other specialist ICT systems. C3-Cloud system, specifically the Security and Privacy Suite (SPS) component, is connected to healthcare provider's Single Sign On procedures when these are established and accessible (e.g., in the case of Region Jamtland Harjedalen via OpenID Connect and in Basque Country via JWT tokens). On the other hand, because C3-Cloud might be used by MDT members across multiple provider organisations (e.g., a hospital and its local GP practices), SPS also maintains a separate directory of user profiles and access controls for those users whose business accounts cannot be linked to C3-Cloud.

The organisation needs to plan for populating C3-Cloud with the agreed user credentials. Procedures for approving, granting & revoking access to the system for patients, caregivers and MDT members must therefore be defined.

Ideally a nominated administrator should have responsibility for the maintenance of personnel records about which patients, caregivers and MDT staff were provided with authorisation credentials and when, and if/when they were revoked due to personnel changes or other life events. The administrators must be trained in how to perform these tasks either in their native Identity Provider (IdP) systems or in C3-Cloud IdP.

Managing users and roles

C3-Cloud adopts an industry standard approach to role-based access control, user identification and authentication. The healthcare provider will need to determine which MDT members should be able to:

- read clinical data
- write clinical data
- read care plans
- write care plans

It is recommended that the mapping of MDT users to the C3-Cloud access control framework should be compatible with their usual functional roles and access to EHR data. This will ensure that their access to patient lists and EHR data is not different between C3-Cloud and their usual EHR system. This has been implemented similarly in the C3-Cloud pilot sites.

If the C3-Cloud deployment integrates data from more than one healthcare provider organisation and/or EHR system, MDT users might have access to clinical data from providers they do not normally access.

They may also have access to patients not under their direct care. Any access of patient data is logged so unauthorised access to patient data can be monitored and acted upon in the same way as with local EHR systems. This should be explained to them, since this may result in an inconsistency between their view of a patient summary in C3-Cloud and their view in their normal EHR system (for example, a problem list might contain additional problems that have been documented by a different healthcare provider).

Separate provision needs to be made for creating user profiles for patients and their care givers. A plan needs to be defined for how the usernames and passwords will be provided to them.

As is normal information security practice, MDT staff, patients and caregivers should be reminded not to share their C3-Cloud credentials, which needs to be clear in the training and in any guidance materials.

Managing passwords

MDT staff should be advised if the usernames and passwords that are issued to healthcare professionals will be specific to the C3-Cloud solution and so may be different from the credentials they use for accessing their local systems and networks (unless the feature to link C3-Cloud to the healthcare provider's authorisation services has been implemented).

Staff and patients should also be advised of the following regarding their passwords.

- Users can change their own passwords when they wish. Passwords must have a minimum of 6 characters, with one uppercase and one lowercase character and at least one number.
- Passwords are not displayed in clear text on the screen when being entered. There is no indication as to which part of the login details is incorrect if user logon fails. There is a limit to the allowed number of unsuccessful logon attempts.
- C3-Cloud passwords are stored separately from application system data. Passwords are stored and transmitted in a hashed form, including from the PEP.

Patients and MDT staff need to have explained to them how they can recover forgotten passwords or have them reset. C3-Cloud has an email-based mechanism for password resetting that follows information security good practice.

4.7.6. Managing audit trails

The C3-Cloud data repository is tightly coupled to an audit trail of creation and access to data via C3-Cloud applications and services.

The healthcare provider needs to specify, before live use, who will access these audit trails, on what grounds, with what safeguards.

4.7.7. Decommissioning the C3-Cloud system

Should it prove necessary to decommission the deployed C3-Cloud solution, for example if a healthcare provider migrates to a new EHR system that provides duplicating functions, it will be important for the organisation to migrate patient level clinical data and to extract patient specific care plans. The C3-Cloud service provider has created a closure plan for this purpose covering all assets and processes relating to the C3-Cloud components.

Since the clinical data entered by clinicians and by patients is consolidated within the C3-Cloud FHIR-conformant repository, any future EHR system vendor will be able to access and extract the data in a standard format. However, it will be necessary for the healthcare provider organisation to ensure that its new procurement contract includes this data migration, or that its own ICT staff are able to undertake

this. The C3-Cloud repository implements HL7 FHIR (RESTful) APIs for this purpose. Alternatively, raw JSON exports can be parsed or imported into any application which supports the FHIR standard.

C3-Cloud promotes the entry of clinical findings and actions in the healthcare provider's usual EHR system, so this data should already be in the EHR and not need migrating except as a backup. However, patient generated data via the PEP will need to be exported, as well as shared care plan decisions not reflected in the EHR. Each healthcare organisation will need to make a decision about long-term storage of the data in its original form, if it is bound by legal or policy obligations to retain records of health, care and service provision.

MDT users will need to be trained in how to use any replacement EHR system for multimorbidity care planning and team collaboration. A replacement solution for patient empowerment will also be required and configured to enable continuity of their engagement in self-management.

Once clinical data and care plans have been extracted, the C3-Cloud systems can be safely decommissioned, and any copies of data and user profiles held in the systems can be erased.

Patients and caregivers will need to be informed that the PEP will no longer be supported and should no longer be used. The PEP can itself be used to supply a notification message to this effect.

Other health professionals who might be interacting with patients who have been included in the C3-Cloud programme should also be informed that the program has been discontinued, in case they have been relying on certain features of it for the holistic care of their patients.

Even when applications are no longer to be used for new data collection, an interval should be agreed during which time the historic records in the C3DP and PEP are still accessible, to enable a graceful clinical transition to the replacement systems. After this time, user accounts should be deactivated, as well as retained access to the applications and systems be removed from user portals and menus.

If there is no plan to migrate the data, then healthcare providers are advised to generate the same extracts of data and care plans, even though they might wish to maintain the C3-Cloud repository as their primary source of the data.

5. APPENDIX 1: C3-CLOUD PROJECT INCLUSION CRITERIA FOR PATIENTS

Inclusion criteria

Aged 55 or older[25]

Multimorbid patients that have at least two or more of the following four conditions in various disease combinations (two conditions set as the minimum threshold):

- Type II Diabetes.
- Renal Failure with eGFR/GFR 30 – 59 (measured or estimated glomerular filtration rate).
- Heart Failure in compliance with NYHA I-II (New York Heart Association classification of heart failure).
- Mild or moderate depression.

They or, if relevant, their informal caregiver have access to and some familiarity with the use of ICT.

They, or if relevant, their informal caregiver, have stable access to the internet and at least one of the following devices readily available to use the C3-Cloud components: Computer; Notebook; Smartphone; Tablet. This includes the use of Internet Browsers to open the C3-Cloud patient dashboards online.

It should be noted that the C3-Cloud project tested the solutions with patients with mild or moderate conditions. Different guidance might be relevant for patients with more advanced conditions.

Exclusion criteria

Having any of the following conditions:

- Severe Renal Failure with eGFR/GFR <30.
- Severe Heart Failure in compliance with NYHA III-IV.
- Severe depression.

Having other debilitating conditions that impair their decision-making capability or their life expectancy (e.g., end-of-life patients or cancer patients). However, patients with further chronic diseases and other co-morbidities or symptoms, for example frailty, sleeping problems, malnourishment or anxiety, will not be excluded from recruitment.

They or their informal caregivers do not have access to suitable IT devices and do not have some familiarity with the use of ICT.

[25] This age limit was set for practical (study recruitment) reasons in the project, but need not be applied to a healthcare environment adopting the C3-Cloud solution