



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

D4.3 Updated Guidance for the Development of New Patient Pathways and Corresponding Care Plans

Work Package: WP4 Patient Pathway and Organisational Model Development & Change Management

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EXECUTIVE SUMMARY

Introduction

The C3-Cloud project, “A Federated Collaborative Care Cloud Architecture for Addressing the Needs of Multimorbidity and Managing Poly-pharmacy”, is establishing an ICT infrastructure enabling a collaborative care and cure cloud to enable continuous coordination of patient-centred care activities by a multidisciplinary care team and patients/informal care givers. A Personalised Care Plan Development Platform allows, for the first time, collaborative creation and execution of personalised care plans for multimorbid patients through systematic and semi-automatic reconciliation of clinical guidelines, with the help of Decision Support Modules for risk prediction and stratification, recommendation reconciliation, poly-pharmacy management and goal setting.

In the work package 4, “Patient Pathway and Organisational Model Development & Change Management”, the Task 4.1 “Exploration of New Patient Pathways and Corresponding Care Plans” addresses the challenges for patient-centred, integrated care pathways and corresponding personalised care plans that can facilitate multimorbid chronic disease management, supporting medicines optimisation and treatment adherence, and effectively handling poly-pharmacy complications. Based on a critical review of advantages and limitations of existing pathway approaches, the task outlines challenges for multimorbidity guidelines. It identifies key pathway components and lays the foundation for the further development of guidance for multimorbidity pathways and care plans, and how individual clinical guidelines can be reconciled for the automation of personalised care plan development.

This deliverable is an updated iteration of D4.1, which provided the original basis for structured discussion with the clinical representatives from OSAKIDETZA, SWFT and RJH. A *clinical reference group* of experts selected from the pilot sites was set up to support the upcoming work, advise on personalised care planning and help resolve overlaps and conflicts in clinical guidelines. The experience from this, was used to update this deliverable.

Outline of the deliverable

Chapter **Error! Unknown switch argument.** briefly states the way this deliverable handles updates to the original one. Chapter 2 summarises relevant definitions of the terms “care pathway” and “care plan” and evaluates existing approaches to integrated care pathways for multimorbid patients, in the literature and other European Union funded projects, with a focus on advantages and limitations.

Chapter **Error! Unknown switch argument.** introduces the challenges for guidance development for C3-Cloud care plans and pathways, including comorbidity & multimorbidity, and polypharmacy challenges.

Chapter 4 analyses patient-centred pathways and care plans for multimorbid patients, by identifying key components based on a literature review and information from the pilot sites. These components are transformed into a high-level integrated care pathway. In addition, chapter 40 elaborates on current medication reconciliation concepts and analyses the clinical guidelines and flowcharts in D7.1, with respect to the identified key components of patient-centred pathways and care plans for multimorbid patients. Key issues and steps providing a basis for reconciliation of clinical guidelines to support decision making in the management and treatment of multimorbid patients are outlined.

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1. UPDATES TO THE DELIVERABLE

As outlined in the description of work, this deliverable is an update to the previous iteration (D4.1), following the deployment of the C3-Cloud solution. It tries to capture adaptations to local needs and lessons learned, in order to inform the future development of integrated multi-morbidity care pathways and care plans. Updates to the original deliverable are visibly marked with headlines called “update” and are colour coded: (1) a green box reflects new insights gained from desk research, and (2) an orange box reflects insights gained from the project research and practical experience.

After the roll-out of the C3-Cloud solution, T4.3 conducted an internal review of the previous Deliverable 4.1 and identified sections that required an update. Furthermore, two sources of input have been taken into account for this update: (1) during the project, a reporting tool has been developed by WP9, collecting topics and issues around the deployment of C3-Cloud among the pilot sites, (2) following deployment, interviews with the pilot sites have been conducted to validate the generic care pathway that was developed in D4.1. Moreover, it was discussed how C3-Cloud changed management and care delivery at the pilot sites. Outcomes of these interviews are also reflected in the updates this D4.3 made to the original D4.1. The original chapter, on *Future Steps*, was removed from this deliverable as the content was updated accordingly.

2. APPROACHES TO CARE PATHWAYS AND CARE PLANS

2.1. Overview of definitions

The literature presents a rich variation of terms used (with differences in meaning) such as: care pathways; care paths; patient pathways; integrated care pathways; patient-centred pathways; clinical (care) pathways; case management plans; care maps, etc. The most relevant definitions of care pathways and care plans are summarised in Table 1 and Table 2.

Table 1: Definitions of pathways (selected examples)

Source	Term	Definition
Centre for Policy on Ageing ¹	Care pathway	<p>A way of setting out a process of best practice, to be followed in the treatment of a patient or client with a particular condition or with particular needs.</p> <p>Pathways are a distillation of the best available expert opinion on the care process and should be evidence based.</p> <p>Care pathways, which map out the care journey an individual can expect,</p> <ul style="list-style-type: none"> • should be multi-professional, • crossing organisational boundaries; • and can act as a prompt for care. <p>They can also create a consistent standard of documentation and provide the basis for ongoing audit.</p>

¹ Age UK. “The effectiveness of care pathways in health and social care. Centre for Policy on Ageing”. (2014). http://www.ageuk.org.uk/Documents/EN-GB/For-professionals/Research/CPA-Effectiveness_of_care_pathways.pdf?dtrk=true. Accessed 16-02-2017.

Source	Term	Definition
European Pathway Association ²	<i>Care pathway</i>	<p>The methodology for the mutual decision making and organisation of care for a well-defined group of patients during a well-defined period.</p> <ul style="list-style-type: none"> • An explicit statement of the goals and key elements of care based on evidence, best practice, and patient expectations; • Facilitation of the communication, coordination of roles, and sequencing the activities of the multidisciplinary care team, patients and their relatives; • Documentation, monitoring, and evaluation of variances and outcomes; and • Identification of the appropriate resources <p>The aim of a care pathway is to enhance the quality of care by improving patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources.</p>
ISO 13940:2015 ³	<i>Clinical pathway</i>	<p>Clinical pathways are designed to support healthcare administration and healthcare resource management.</p> <p>They provide detailed guidance for each stage in the management of a patient (treatments, interventions, etc.)</p>

Bleser et al.⁴ found that a definition of “pathway” was provided in 82 out of 263 eligible articles. Altogether, 84 different definitions were found. Each definition was rephrased by taking into consideration the following three features inherent to pathways:

- Naming word used (e.g., plan, document, algorithm, etc.);
- Characteristics and aims; and
- Outcomes.

“Care pathways” seem to aim to ‘level up’ care standards, so that individual patients and clients (in social care) all receive the best, evidence-based standard of care available.

As shown in Table 1, a “clinical pathway” is a method for the management of care for a well-defined group of patients, during a well-defined period of time. The aim is to improve the quality of care, reduce risks, increase patient satisfaction and increase the efficiency in the use of resources⁵. A clinical pathway explicitly states the goals and key elements of care based on Evidence Based Medicine (EBM) guidelines, best practice and patient expectations by facilitating the communication, coordinating roles and sequencing the activities of the multidisciplinary care team, patients and their relatives; by documenting, monitoring and evaluating variances; and by providing the necessary resources and outcomes.

² <http://e-p-a.org/care-pathways/>

³ ISO 13940:2015 Health informatics -- System of concepts to support continuity of care

⁴ Bleser et al. "Defining pathways." Journal of Nursing Management 14, no. 7 (2006): 553-63. doi:10.1111/j.1365-2934.2006.00702.x.

⁵ Ibid.

The C3-Cloud deliverable D3.1 also noted that a “clinical pathway” is defined as a “pathway for the healthcare activities informing the content of core care plans” (ISO 13940:2015). Clinical pathways are designed to support healthcare administration and healthcare resource management. They provide detailed guidance for each stage in the management of a patient (e.g., treatments, interventions, etc.).

Having reviewed all relevant definitions, the C3-Cloud project understands care pathways as a method for patient care management of a well-defined group of patients during a well-defined period of time. ***Care pathways illustrate a multimorbid patient's journey across the health system.***

UPDATE

Visser and Beech describe the care pathway of being one concept of Health Operation Management (HOM)⁶:

1. a care plan for each individual patient (patient planning and protocol);
2. the planning of care in care pathways (patient group planning and control);
3. the capacity planning of professionals, equipment and space (resource planning and control);
4. the planning of the number of patients to be treated and care activities to be carried out (patient volume planning and control), and
5. the long-term policy of the institution (strategic planning).

Because all five levels are connected, it is difficult to enforce changes in one of the levels without altering the others. As an example, introducing care pathways requires taking into account changes in scheduling systems for individual patients (level 1), or the capacity planning of the number of professionals and equipment (level 3). This deliverable considers levels 1 and 2 and, thus, offers guidance for designing new pathways for multimorbid patients on those. Since the delivery of care differs from location to location, from regional to national level etc., it is necessary to always also consider levels 3 to 5 of HOM when designing a pathway, a task that must be done while developing local pathways.

⁶ Visser and Beech cited in Schrijvers G, van Hoorn A, Huiskes N. The care pathway: concepts and theories: an introduction. *Int J Integr Care*. 2012;12(Spec Ed Integrated Care Pathways):e192. Published 2012 Sep 18. doi:10.5334/ijic.812

Table 2: Selected care plan definitions

Source	Term	Definition
ISO 13940:2015 ⁷	<i>Care plan</i>	<p>A dynamic, personalized plan including the identified needed healthcare activity, health objectives and healthcare goals, relating to one or more specified health issues in a healthcare process.</p> <ul style="list-style-type: none"> Recorded in one or more health records; Reviewed repeatedly during a healthcare process, each review based on a new healthcare needs assessment; The healthcare activities in a care plan follow a life cycle. Examples of statuses of such a life cycle are: ‘planned’, ‘performed’, ‘cancelled’, etc.; included in the care plan
	<i>Multi-professional care plan</i>	A care plan encompassing healthcare provider activities performed by healthcare professionals having different healthcare professional entitlements .
HL7 PCWG DAM ⁸	<i>Care Plan</i>	<p>A tool used by clinicians to plan and coordinate care for an individual patient.</p> <ul style="list-style-type: none"> Define the management action plans for the various conditions; Organize a care plan and check for completion by all individual professions and/or responsible parties (including the patient, caregiver or family) for decision making, communication, and continuity and coordination; Communicate explicitly by documenting and planning actions and goals; Permit the monitoring, flagging, evaluating and feedback of the status of goals, actions, and outcomes; Manage risk related to effectuating the care plan
IHE PCC PtCP ⁹	<i>Plan of care</i>	<p>A concept some clinicians use to focus on</p> <ul style="list-style-type: none"> discrete problems, the specific interventions to address the problem, and achieve a certain goal related to the problem.
	<i>Patient care plan</i>	<p>Describes the synthesis and reconciliation of the multiple Plans of Care produced by each provider to address specific health concerns of the patient.</p> <p>It is a content profile that defines a centralized patient care plan that will meet the needs of many stakeholders (providers and patients) and provide a method to reconcile and consolidate the many disparate</p>

⁷ ISO 13940:2015 Health informatics -- System of concepts to support continuity of care

⁸ http://wiki.hl7.org/images/1/1d/PCWG_Care_Plan_DAM_Specification_-_Part_1_-_Draft_2015-11-04.pdf

⁹ http://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_PtCP.pdf

Source	Term	Definition
		plans of care that can be attached to a patient. It provides the beginning of a framework for a centralized patient care plan.
NICE ¹⁰	<i>Individualised management plan</i>	An individualised management plan is a management plan covering clinical aspects of a person's care, such as the medicines they are taking and the services they are attending. It includes information about which areas of care are most important to the person and whether treatments have been stopped to reduce treatment burden.

As Table 2 illustrates, “Care Plans” are designed to target “health objectives” (a.k.a. intended outcome), which is defined as “desired ultimate achievement of a healthcare process addressing health needs”. A health objective can be expressed as one or several target conditions to be reached within a specified date and time. An intermediate step before reaching health objectives are “healthcare goals”. These are desired achievements of one or more “healthcare activities”, considered as an intermediate operational step to reach a specific “health objective”.

In ISO 13940:2015, the “care plan” is defined as “dynamic, personalized plan including identified needed healthcare activity, health objectives and healthcare goals, relating to one or more specified health issues in a healthcare process”. In ISO 13940:2015 representation, a “care plan” is usually based upon knowledge in “clinical guidelines” (including “protocols”).

Clinical guidelines are defined as “sets of systematically developed statements to assist the decisions made by healthcare actors about healthcare activities to be performed with regard to specified health issues”. Care plans implement “protocols” which are customised clinical guidelines, often presented in a formal manner with respect to the expected behaviours and roles of healthcare actors.

C3-Cloud has adopted the ISO 13940:2015 definition of a care plan as a dynamic, personalised plan including identified needed healthcare activity, health objectives and healthcare goals, relating to one or more specified health issues in a healthcare process. *A care plan refers to personalised care (according to the patient’s health and social status) of a single patient across the pathway.*

In summary, the following definitions for care pathway, care plan and core care plan are used within the scope of the C3-Cloud project (based on deliverables D3.1, D3.2 and T4.2):

Care Pathway: Method for the patient-care management of a well-defined group of patients during a well-defined period of time. Pathways illustrate a multimorbid patient's journey across the health system.

Care Plan: Dynamic, personalised plan including identified needed healthcare activity, health objectives and healthcare goals, relating to one or more specified health issues in a healthcare process.

A care plan refers to personalised care (according to the patient’s health and social status) of a single patient across the pathway.

Core Care Plan: Reusable content and structure for a potential care plan for a specified set of circumstances (sometimes also referred to as ‘Care Plan Template’). Core care plans will be created based on clinical decision support modules that process clinical guidelines to suggest treatment goals and interventions.

¹⁰ National Institute for Health and Care Excellence (NICE), ‘NICE guideline NG56: Multimorbidity: clinical assessment and management’, Sep-2016. [Online]. Available: <https://www.nice.org.uk/guidance/ng56>.

2.2. Integrated care pathways examples

The following section presents approaches to integrated care pathways developed in European Union funded projects on integrated care. The examples from SmartCare, BeyondSilos and CareWell¹¹ are included here, due to their high relevance to C3-Cloud. The C3-Cloud definitions fit well into the context of these example pathways.

2.2.1. SmartCare

The SmartCare project (wide deployment of integrated care services - 2013-2016) was funded by the ICT PSP-2012-6 Competitiveness and Innovation Programme (CIP). SmartCare dealt with the formalisation of integrated care pathways supported by ICT with the overall objective to facilitate

- Person-centred, co-ordinated care for individuals and their carers.
- Higher levels of self-care and self-management.
- Effective and efficient communication between all parties.
- Better use of resources and less duplication of effort.

The SmartCare approach has designed, delivered and deployed integrated care services following two care pathways for elderly people with complex needs:

1. **Integrated home support after a hospital discharge** focusing on integrating all the processes, services, information, and communication required to ensure an individual has a safe, timely and smooth transition from their hospital stay back to their home, and receive appropriate rehabilitation and independent living enablement services (Figure 1).
2. **Integrated long-term care support**, designed to provide integrated and coordinated services for people living at home and who have complex needs that require a flexible approach to both health and social care support (Figure 2).

¹¹ Adapted from C3-Cloud D3.1 (empirica was involved in all three projects)

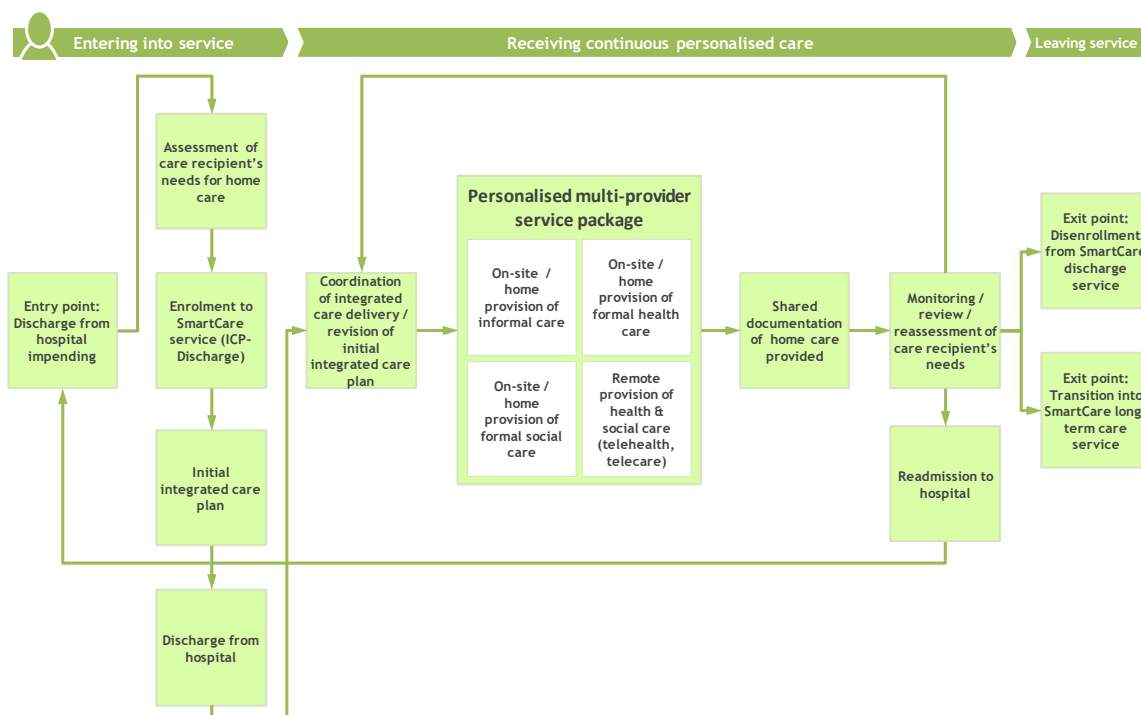


Figure 1: SmartCare care pathway for integrated home support after a hospital discharge

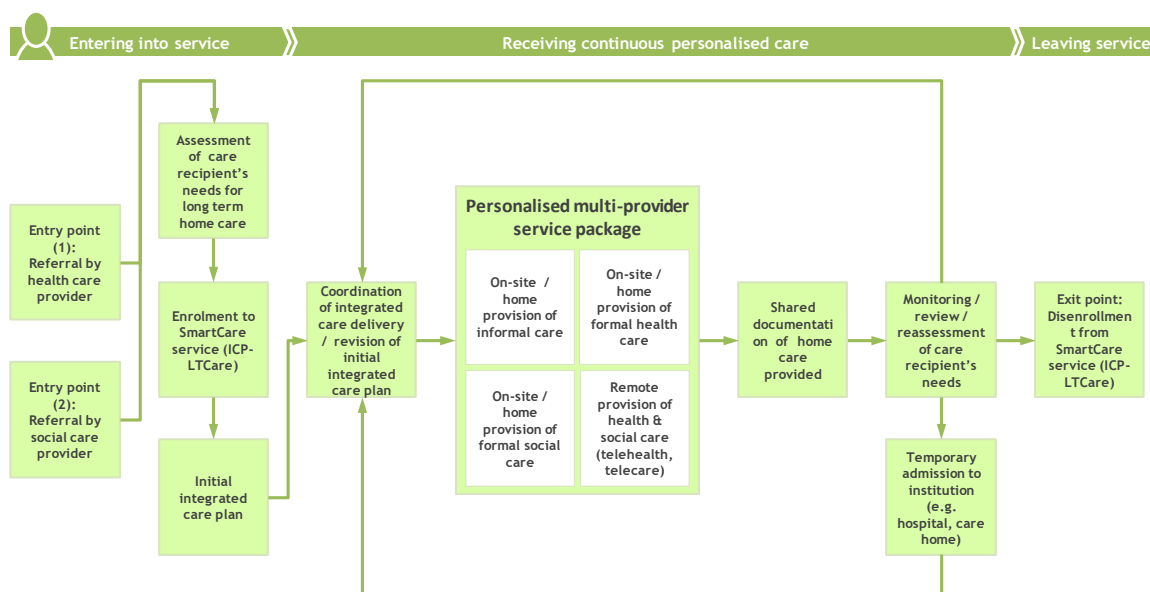


Figure 2: SmartCare care pathway for integrated long term care support

A formalised process model for the SmartCare pathways was developed (**Error! Unknown switch argument.**), describing the service flow including actors and their responsibilities, tasks and decision points as well as data/documents exchanged.

Full support to cooperative delivery of care, integrated with self-care and across organisational silos, was achieved through a comprehensive digital infrastructure that enabled effective care pathways, facilitating integrated care delivery across different care providers, including voluntary organisations, informal carers and self-care action.

ICT integration building blocks and workflow tools focused on the challenges of data-sharing, coordination and communication included:

- Integrated data access for care providers in different agencies and informal carers.
- Design and execution of pre-planned care pathways enabling temporal coordination between provision steps taken by care providers in different agencies, informal carers and cared for people.
- Access to the home: homebased systems (Tele-monitoring and/or Telecare TM/TC) by care providers in different agencies and informal carers.
- Real-time communication between care providers in different agencies and informal carers, e.g., support to case conferences, and older people.
- Joint response to ad hoc requests by care providers in different agencies and informal carers.

The SmartCare project, with its focus on formalisation of integrated, ICT supported care pathways specifically for the transition of hospital discharge to home support, is a valuable source and knowledge base for the further development of guidance in the context of D4.1.

2.2.2. BeyondSilos

BeyondSilos, also a CIP pilot (2014-2017), aligned its integrated care pathways with those of the SmartCare project:

- 1) Integrated short-term home support after an acute episode. This pathway was designed to support people who have experienced a significant ‘event’ such as stroke, MI, fractured neck of femur, or other injuries and illnesses, which impact adversely on the person’s ability to live independently. The activities in this pathway focus on delivering time-limited interventions (Figure 4).
- 2) Integrated long-term home care support. This pathway, on the contrary, was designed to support people living with complex needs whose joint care assessment indicates that ongoing health and social care services and wellbeing assistance is required (Figure 5).

The care pathways cut across organisational boundaries to activate and integrate all relevant actors to the patient’s care. Both in the long term and short term home care pathway, the service user will go through an assessment of their care needs when entering the service, followed by the elaboration of an initial integrated home care plan. The pathways follow similar courses, with the ongoing coordination of integrated care delivery and the revision of the initial care plan in order to establish a personalised multi-provider service package. The health and social care provided at home as well as remotely (telecare) feeds into documentation shared by multiple professionals who, based on this information, are able to review and reassess the service user’s needs and make the appropriate decisions in the context of a continuous personalised care process.

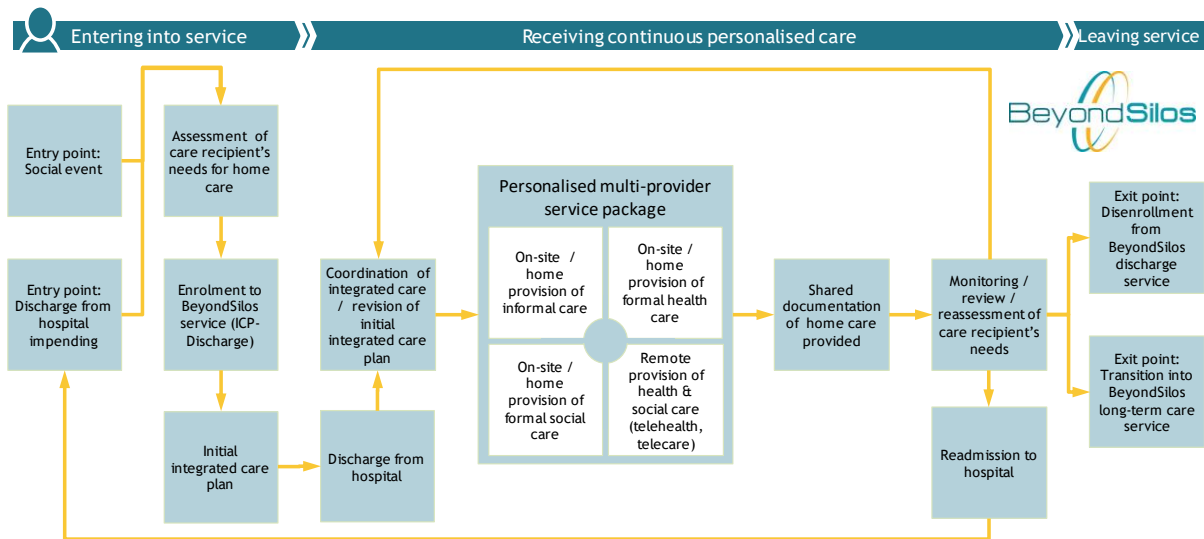


Figure 4: BeyondSilos care pathway for integrated short-term home care support

The coordinated transition of the patient from hospital or ER to home is supposed to be critical to their health and well-being. Patients, family caregivers and professional care providers all play roles in maintaining a patient's health after discharge. Coordinated discharge planning is seen as a significant step towards an integrated overall care plan. The exit point of the short term home care pathway is envisioned as a bridge the long term home care service. Hospital readmission may set the service user back at the short term home care pathway entry point.

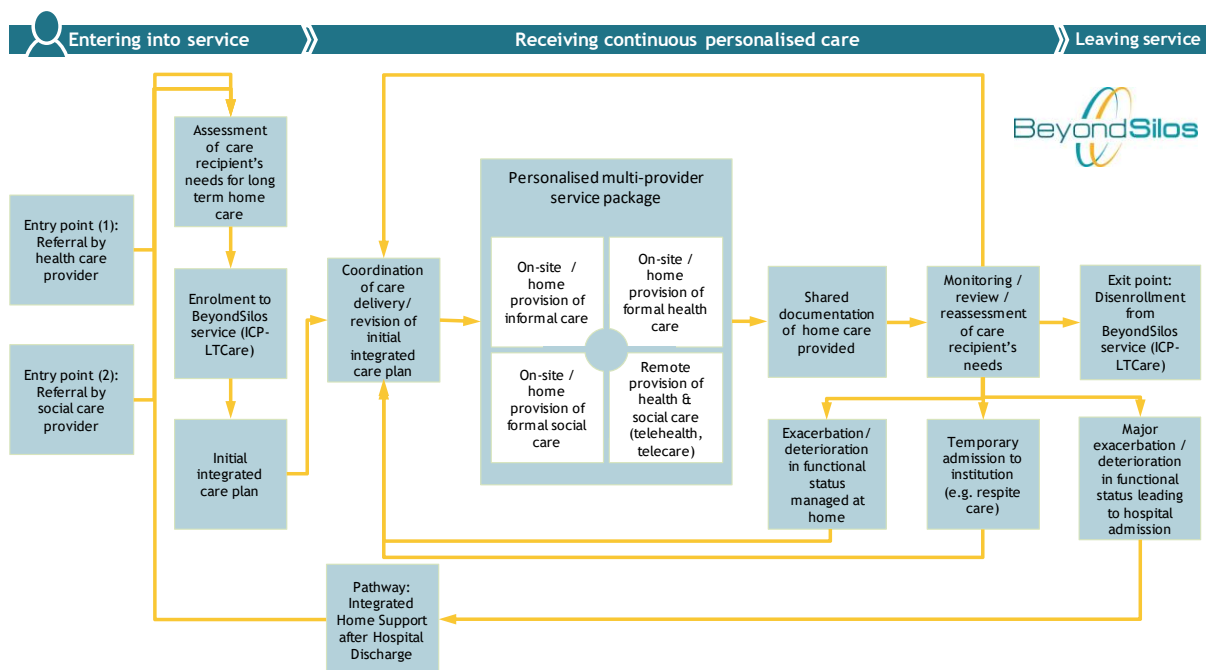


Figure 5: BeyondSilos care pathway for integrated long term home care support

Similarly, the integrated long term care pathway envisions an exit point which may lead back into the short term care pathway, in the event of a major exacerbation in functional status. An exacerbation or deterioration managed at home or a temporary admission to a care institution (e.g., a day care centre) would trigger a revision of the user's social and health care plan. The goal of both care pathways in

BeyondSilos is to keep the service user in their own home as long as possible, as this usually has a positive influence on their quality of life.

The fundamental innovation of BeyondSilos integrated care pathways was the integration of the components listed below with one another in a shared care platform that enables the various formal and informal care providers who play a role in the support of the older people selected for the deployment of BeyondSilos to act in a coordinated way. This helped eliminate gaps and duplications in the continuum of care that older people living independently require. The services available within the shared platform include: collection and transmission of measurements and alarms coming from the medical devices; panic button; reminders; emergency calls; falls detector, daily scheduler, etc.

The integrated care pathways for home support developed in BeyondSilos offer a coherent approach to the problem posed by the lack of care coordination, taking into account unexpected health outcomes and the need for health and social care practitioners to jointly review and readjust integrated care plans and involve informal carers.

The knowledge obtained from the BeyondSilos project can feed directly into C3-Cloud's development of a complex workflow mechanism, based on several decision support modules, which treat social and informal care services as elements essential to innovative integrated care approaches.

2.2.3. CareWell

The CareWell Project (CIP-ICT Policy Support Programme 2013-2017), funded by the European Commission, aimed to design and implement new and cost-effective organizational models of Integrated Care for multi morbid patients. CareWell care pathways included two main approaches:

- 1) Integrated care coordination pathway to improve communication, coordination and information sharing between health care professionals
- 2) Patient empowerment and home support pathways focused on keeping the patients at home maintaining, or even improving their health.

The main innovation of CareWell project lies in combining a number of evidence-based components together to deliver a comprehensive, coordinated integrated care service. These components fall into the following broad areas:

- organizational models and care pathways underlining the importance of integrated care and how it can improve the patient experience, health outcomes and efficiency of care,
- ICT tools focused on facilitating more timely communication and sharing information between the patient and healthcare professionals,
- ICT tools ensuring the tracking and follow-up together with effective support for self-care and self-management of patients,
- multidisciplinary organizational care service delivery models coordinated through the respective care pathways.

The CareWell project not only incorporates technological components, but also fosters the organizational and cultural changes needed for the provision of the integrated care.

A closer look at the CareWell pathways for patient empowerment and integrated care coordination is provided in section 4.2 of this report, which uses the Basque Country pilot site as an example. The CareWell pathways address the complexity of elderly multimorbid patients' needs in particular and outline their journey through the healthcare system, covering stable out-of-hospital care, unstable out of hospital care, in hospital care and hospital discharge preparation. The CareWell pathways specifically follow the steps of identification, baseline comprehensive assessment, therapeutic plan definition, programmed follow-up, stabilisation at home, integrated care during hospitalisation and coordinated hospital discharge.

The care pathways implemented in the CareWell project are useful for the C3-Cloud care pathway development, in that the transition from hospital to home care was one important element, similarly to

the C3-Cloud project. The work conducted in the Basque Country is also particularly relevant, as the Basque Country is one of the sites where the C3-Cloud solution will be deployed.

2.3. Review of advantages and limitations of pathway approaches

Due to the nature of care plans and their origin in manufacturing, pathways work best in linear settings. For this reason, pathways are most effective in contexts where the trajectory of care is predictable¹². Multimorbidity proves a challenge to this structural approach¹³: as patients become older and their health problems more frequent; immobility and volatile health concerns affect the number of variables that need consideration. Unlike in product manufacturing, patients cannot be treated as mere “widgets”, and clinicians may dislike “cookbook-medicine”.

The installation of a pathway, thus, requires not only a buy-in but also comes with problems of introducing new technology in general. Not only will standardisation of workflow not eliminate human or technical errors, but it can also increase the workload for new documentation, audits, and action plans. Such work plan standardisation can create a “tunnel vision”, implying that responses to health deterioration may be inadequate.

Two additional concerns should be noted about multimorbid patients:

- Polypharmacy, and
- patient’s adherence to treatment regimen.

Polypharmacy and multimorbidity increase the workload of healthcare providers as they need to collaborate to optimize their skill-mix¹⁴ - this needs to be taken into account when designing a pathway for multimorbid patients. Furthermore, many multimorbid patients have trouble in following their treatment regimen, reinforcing patient’s self-management issues. According to the WHO, adherence to long-term therapy for chronic illnesses averages 50%¹⁵. Thus, monitoring the self-management process, or tools that do the like, need to be established.

While care pathway effects generally indicate positive impact on clinical outcomes, cost reduction, patient satisfaction, teamwork and process outcomes, these positive findings are not universal¹⁶. Care pathways have a significant impact on the organisation of care processes, yet the pathway methodology does not necessarily have such an impact on patient-focused organisation, communication with patients and family or collaboration with primary care¹⁷. Therefore, it is important to raise awareness for such limitations when creating a pathway for patients with multimorbidity.

A review of the Liverpool Care Pathway for the dying patient (LCP)¹⁸ demonstrates these issues quite well. The Liverpool Care Pathway is defined as a multidisciplinary management tool based on evidence-based practice for a specific group of patients, with a predictable clinical course, in which the different tasks (interventions) by the professionals involved in the patient care are defined, optimized and sequenced either by hour (Emergency Department), day (acute care) or visit (homecare). End-of-

¹² Allen, Gillen and Rixson (2009), The effectiveness of integrated care pathways for adults and children in health care settings: a systematic review

¹³ Arora, Rakesh C.. Development and Implementation of Clinical Pathways in the CTICU. AATS/STS Cardiothoracic Critical Care Symposium. May 5th, 2013.

¹⁴ Salisbury, C., Johnson, L., Purdy, S., Valderas, J. M., & Montgomery, A. A. (2011). Epidemiology and impact of multimorbidity in primary care: a retrospective cohort study. *The British Journal of General Practice*, 61(582), e12–e21. <http://doi.org/10.3399/bjgp11X548929>

¹⁵ Sabaté E. Adherence to long-term therapies. Evidence for action. Geneva: World Health Organization 2003.

¹⁶ Age UK. The effectiveness of care pathways in health and social care. Centre for Policy on Ageing. (2014). http://www.ageuk.org.uk/Documents/EN-GB/For-professionals/Research/CPA-Effectiveness_of_care_pathways.pdf?dtrk=true. Accessed 16-02-2017.

¹⁷ Ibid.

¹⁸ Neuberger et al (2013), More care, less pathway: a review of the Liverpool care pathway

life care however is a special situation with important patient outcomes that may not easily be incorporated into a care pathway. The implementation of the Liverpool Care Pathway, while having the good intention of setting end-of-life care standards has, on too many occasions, led to a withdrawal or reduction of care, a ‘tick-box’ mentality and actions that would appear to hasten the death of the patient. The review concluded that there was often **too much pathway and too little care**¹⁹.

Schrijvers, Van Hoorn, and Huiskes²⁰ provide an overview of the history, application, advantages and disadvantages of care pathways.

Originating from the (defence-) industry, various path methods were developed to increase parallelism and activity in production, and decrease duration and costs. Ultimately, the concept of care pathways has its roots in the following theories: Critical Path Method, Lean Six Sigma, Business Process Redesign and the Theory of Constraints.

The perceived advantages and disadvantages of pathways for patients and health professionals as summarised by Schrijvers, Van Hoorn, and Huiskes are the following:

Perceived advantages of care pathways:

- Shortening the duration of the production process by parallelization of sub-processes can imply that patients benefit from faster diagnosis.
- Increased coherence: Patients benefit from consistency of care between different professionals, reducing the risk of opposing opinions and therapies.
- Reduced risk of errors: Patients naturally benefit from a reduced risk for errors in diagnosis and treatment.
- Reduction of costs: Patients benefit from standardization, waiting times, and avoidance of duplication (e.g., duplicated testing). Shortening hospitalization and reducing outpatient visits reduces costs.
- Increased job satisfaction = A well-defined job description, framework and work protocol lead to higher coordination between groups and increasing job autonomy. Patients benefit from more dedicated, passionate health professionals.
- Improved patient experience: Patients benefit from an improved overall experience when being provided with health care.

Perceived disadvantages of care pathways:

- Dehumanization of work: The Relationship between health professional and patient is less personal and the care plan reduces patients’ choices; time constraints can compromise the quality of care.
- Increase in cost: Checking for errors and defects is costly; risk avoidance can lead to exclusion of patients with poor physical condition.
- Reduction of job satisfaction: Time constraints and little variation can lead to job frustration, poor communication between health professional and patient, and ultimately poor diagnosis and treatment.

¹⁹ Ibid.

²⁰ Schrijvers, Guus, Arjan Van Hoorn, and Nicolette Huiskes. "The Care Pathway Concept: concepts and theories: an introduction." *International Journal of Integrated Care* 12, no. 6 (2012). doi:10.5334/ijic.812.

Improvement areas of Integrated Care Pathway approaches identified by CHRODIS²¹:

- Patient-centeredness,
- Coordination of care,
- Improvement of collaboration and communication and
- Outcome orientation.

The overall findings on advantages of Integrated Care Pathways vary in several studies. Findings on reduced in-hospital complications, improvements in documentation and significant reduction in length of stay and hospital costs stand against no evidence of differences in readmission to hospital or in-hospital mortality²².

Further, ICPs (Integrated Care Pathways) are **most effective in contexts in which patient care trajectories are easily predictable**. In settings in which recovery pathways are more variable, their benefit is obscured.

Behavioural changes like improvements in documentation, communication and service quality can be recorded. However, their value in contexts where inter-professional working is well established is less certain²³. Unless health care professionals agree to work with clinical pathways, no effect can be achieved. Thus, standardised implementation and continuous monitoring processes are needed²⁴.

In summary, it can be reported, that clinical pathways are likely to improve clinical outcomes, reduce costs and improve patient satisfaction, however not in all cases.

Furthermore, it should be noted that the concepts of patient satisfaction or patient experience should not be deemed equivalent to improvements in health conditions.

UPDATE

The material outlined in this chapter remains unchanged as the practical experience of the projects indicates that its content remains valid. While the project outcomes will be evaluated separately, thus far pilot sites have stated that C3-Cloud now enables them to easier and more frequently develop individualised care plans. At the same time, these care plans are now based on a decision support system that reduces errors and issues in care which previously stemmed from using individual single disease guidelines. Further, the pilot sites state, that the C3-Cloud solution increase the patient centeredness, and improve the coordination of care, collaboration and communication between care team members.

²¹ CHRODIS http://chrodis.eu/wp-content/uploads/2017/02/deliverable-7-02-of-joint-action-chrodis_final.pdf

²² Rotter et al. (2010) Clinical pathways: effects on professional practice, patient outcomes, length of stay and hospital costs, Cochrane Database of Systematic Reviews Reviews 2010 (3)

²³ Allen D. A., Gillen E. and Rixson L. J. (2009) Systematic review of the effectiveness of integrated care pathways: what works, for whom, in what circumstances?, International Journal of Evidence-based Healthcare 7 (2) : 61-74

²⁴ Mad, P., Johansson, T., Guba, B. und Wild, C. (2008): Klinische Pfade: Systematischer Review zur Ergebnismessung der Wirksamkeit [Clinical Pathways: Systematic review of outcome parameters and effectiveness; German with English summary]. HTA-Projektbericht 16.

3. CHALLENGES FOR C3-CLOUD PATHWAYS AND CARE PLANS

3.1. Multimorbidity and co-morbidity challenges

This section focuses on defining multimorbidity and outlines key challenges for the management of multimorbid patients.

NICE definition of multimorbidity

Multimorbidity in its broadest sense has been defined as

- the combination of 1 chronic disease,
- with at least 1 other disease (acute or chronic),
- or biopsychosocial (biological, psychological or social) factor (associated or not),
- or somatic (related to or affected by the body) risk factor.

It is often defined more simply as **the co-existence of 2 or more long term conditions**.²⁵

Generalist and multiagency care is particularly relevant to people with multimorbidity, while specialist care is usually organised around care for a single condition. Multimorbidity increases markedly with age, but it is also found in younger people, especially in socially deprived areas where the co-existence of physical and mental health problems is particularly common.

Multimorbidity is associated with poor quality of life, disability, psychological problems and increased mortality. Multimorbidity is also associated with increased frequency of health service use including emergency hospital admission, adverse drug events, polypharmacy, duplicate testing and poor care co-ordination.

Polypharmacy is often significantly driven by the introduction of multiple drugs intended to prevent future morbidity and mortality, but the case for using such drugs weakens as life expectancy reduces. The absolute difference made by each additional drug may also reduce when people are taking multiple preventative medicines.

According to NICE, “multimorbidity refers to the presence of 2 or more long-term health conditions, which can include:

- Defined physical and mental health conditions such as diabetes or schizophrenia.
- Ongoing conditions such as learning disability.
- Symptom complexes such as frailty or chronic pain.
- Sensory impairment such as sight or hearing loss.
- Alcohol and substance misuse”.

An approach to care that takes account of multimorbidity should be considered if any of the following apply:

- Difficulty in managing treatments or day-to-day activities.
- Receiving care and support from multiple services and need additional services.
- Having both long-term physical and mental health conditions.
- Having frailty or falls.

²⁵ National Institute for Health and Care Excellence (NICE). Multimorbidity: the assessment, prioritisation and management of care for people with commonly occurring multimorbidity. Final scope. [Online]. Available: <https://www.nice.org.uk/guidance/NG56/documents/multimorbidity-final-scope2> [Accessed: 17-May-2017].

- Frequently seeking unplanned or emergency care.
- Prescribed multiple regular medicines.

The European General Practice Research Network (EGPRN)²⁶ has elaborated a similarly comprehensive definition of multimorbidity. It differs from the WHO definition²⁷ (“people being affected by two or more chronic conditions”) and reflects the holistic approach of Family Medicine. The definition intends to be both understandable and usable to Family Medicine researchers as well as practicing GPs:

“Multimorbidity is defined as any combination of chronic disease with at least one other disease (acute or chronic) or biopsychosocial factor (associated or not) or somatic risk factor. Any biopsychosocial factor, any risk factor, the social network, the burden of diseases, the health care consumption, and the patient’s coping strategies may function as modifiers (of the effects of multimorbidity). Multimorbidity may modify the health outcomes and lead to an increased disability or a decreased quality of life or frailty.”

EGPRN specifies that the term multimorbidity emerged in 1970s German research as “an addition to the concept of comorbidity [...] defined as any disease or risk factors that could interact with one main disease with the effect of making it worse”. The interchangeable use of the two terms is common, however co-morbidity “refers more specifically to conditions that occur as a consequence of one leading (“index”) condition such as diabetes”²⁸.

The EGPRN definition of multimorbidity enables a “functional” view useful to long-term care as opposed to a “diseases-centred” one, and at the same time shifts the focus on its possible outcomes: health outcomes, disability, impact on quality of life and frailty).

Clinical Decision Support and multimorbidity

C3-Cloud deliverable D3.1, “*Survey of the State of the Art – Research, Technologies and Architectures*”, has reviewed the current state of development of Clinical Decision Support (CDS) modules that take into account the complexity of multimorbidity issues. The WP3 review has found only a modest number of relevant articles addressing CDS and multimorbidity.

We refer to a 2015 systematic review²⁹ on the matter which revealed that multimorbidity is improperly addressed in CDS, despite its clinical importance and the urgency of the challenge. The main areas of improvement identified in the review consist in:

- The shift from disease-centred care towards **patient-centred approaches** in CDS, which considers the patient’s psychological and physiological needs on a case-by-case basis, through the introduction of integrated care services. Multimorbidity should no longer be regarded in terms of an index condition and comorbid diseases or only as an element relevant to the process of medicinal prescribing.

²⁶ Le Reste et al. (2013). The European General Practice Research Network Presents a Comprehensive Definition of Multimorbidity in Family Medicine and Long Term Care, Following a Systematic Review of Relevant Literature. *Journal of the American Medical Directors Association*, 14(5), 319-325. doi:10.1016/j.jamda.2013.01.001

²⁷ Multimorbidity: Technical Series on Safer Primary Care. Geneva: World Health Organization; 2016. Licence: CC BY-NC-SA 3.0 IGO.

²⁸ Nolte, E., & McKee, M. (2008). *Caring for people with chronic conditions: a health system perspective*. Maidenhead: Open University Press.

²⁹ Fraccaro, P., Castelerio, M. A., Ainsworth, J., & Buchan, I. (2015). Adoption of Clinical Decision Support in Multimorbidity: A Systematic Review. *JMIR Medical Informatics*, 3(1). doi:10.2196/medinform.3503

- **Combining several (2 or more) clinical practice guidelines** and their application in a non-harmful way, taking into account the health care practitioners' direct experience and their knowledge exchanges with their peers. Clinical practice guidelines are currently too narrowly focused and do not consider interactions between different diseases or between treatments.
- The **continuity of care** across several different clinical settings, in a way which allows for professionals to work together on ensuring the safety of the patient's treatment.
- Introducing **self-management interventions**, particularly through mobile technologies.
- Broadening the methodological approaches to CDS in order to include not only knowledge-based systems, but also **data-driven methods**.
- Enabling **interoperability** through international standards in order for systems to deliver the relevant support and information when dealing with the interacting variables of multimorbidity.
- The necessity for **rigorous evaluations of systems' usability and effectiveness** before and after their deployment.

The challenge of guidelines for multimorbidity

Challenges in creating a pathway for multimorbid patients and corresponding care plans emerge from the underlying medical / clinical guidelines. The following Figure 6 is based on the NICE guideline on multimorbidity: clinical assessment and management NG56.³⁰

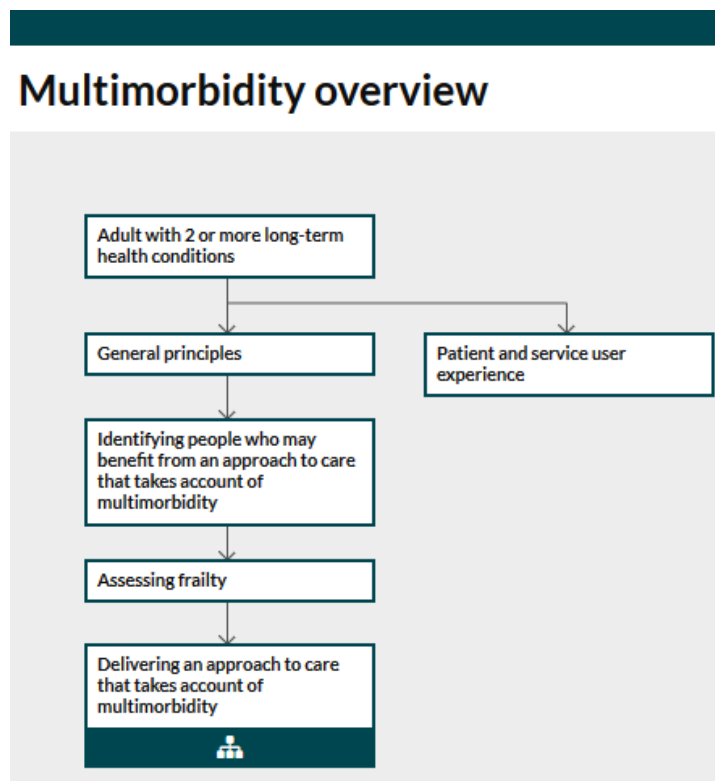


Figure 6: NICE Multimorbidity overview

³⁰ National Institute for Health and Care Excellence (NICE), 'NICE guideline NG56: Multimorbidity: clinical assessment and management', Sep-2016. [Online]. Available: <https://www.nice.org.uk/guidance/ng56>. [Accessed: 29-Dec-2016].

The objective of this guideline is to optimise care for adults with multimorbidity (multiple long-term conditions), by reducing treatment burden (polypharmacy and multiple appointments) and unplanned or uncoordinated care.

Possible approaches to optimising treatment and care for patients with multimorbidity

NICE has listed the following possible approaches³¹:

- Maximising benefit from existing treatments.
- Considering treatments that could be stopped because of limited benefit.
- Reviewing medicines with a higher risk of adverse events.
- Introducing non-pharmacological treatments as possible alternatives to some medicines.
- Reviewing treatments and follow-up arrangements with a high burden.
- Making alternative arrangements for follow-up to coordinate or optimise the number of appointments, prioritising healthcare appointments.
- Assigning responsibility for coordination of care and ensuring this is communicated to other healthcare professionals and services.

The challenge of drug-disease and drug-drug interactions

Clinical guidelines, such as the widely used NICE guidelines, usually deal with single conditions despite the growing number of patients with multimorbidity. The multimorbidity overview provided by NICE, does not depict the issue of overlapping medical guidelines for multiple chronic diseases. The application of recommendations from multiple single disease guidelines in people with several conditions can result in complex multiple drug regimens and thus potentially harmful combinations of drugs^{32,33,34}. Therefore, when designing an integrated care pathway or care plan, drug-disease and drug-drug interaction have to be taken into account.

In a 2015 examination of 12 UK national clinical guidelines³⁵, the NICE clinical guidelines for type 2 diabetes, heart failure, and depression were examined for drug-disease and drug-drug interactions. The findings demonstrate potentially serious interactions (Figure 7).

“There were 32 potentially serious drug-disease interactions between drugs recommended in the guideline for type 2 diabetes and the 11 other conditions compared with six for drugs recommended in the guideline for depression and 10 for drugs recommended in the guideline for heart failure.

Of these drug-disease interactions, 27 (84%) in the type 2 diabetes guideline and all of those in the two other guidelines were between the recommended drug and chronic kidney disease.

More, potentially serious drug-drug interactions were identified between drugs recommended by guidelines, for each of the three index conditions and drugs recommended by the guidelines for the 11 other conditions: 133 drug-drug interactions for drugs recommended in the type 2 diabetes guideline,

³¹ Ibid.

³² Guthrie B, McCowan C, Davey P, Simpson CR, Dreischulte T, Barnett K. High risk prescribing in primary care patients particularly vulnerable to adverse drug events: cross sectional population database analysis in Scottish general practice. *BMJ* 2011;342:d3514.

³³ Bourgeois FT, Shannon MW, Valim C, Mandl KD. Adverse drug events in the outpatient setting: an 11-year national analysis. *Pharmacoepidemiol Drug Safety* 2010;19:901–10.

³⁴ Boyd C, Darer J, Boult C, Fried L, Boult L, Wu A. Clinical practice guidelines and quality of care for older patients with multiple comorbid diseases implications for pay for performance. *JAMA* 2005;294:716–24.

³⁵ Dumbreck et al (2015). Drug-disease and drug-drug interactions: systematic examination of recommendations in 12 UK national clinical guidelines. *BMJ* 2015; 350. doi:10.1136/bmj.h949

89 for depression, and 111 for heart failure. Few of these drug-disease or drug-drug interactions were highlighted in the guidelines for the three index conditions.”

This should raise concern in regards to the creation of an ICP. Such potential drug-disease and drug-drug interactions need to be taken into account by the care plan and any sort of underlying software.

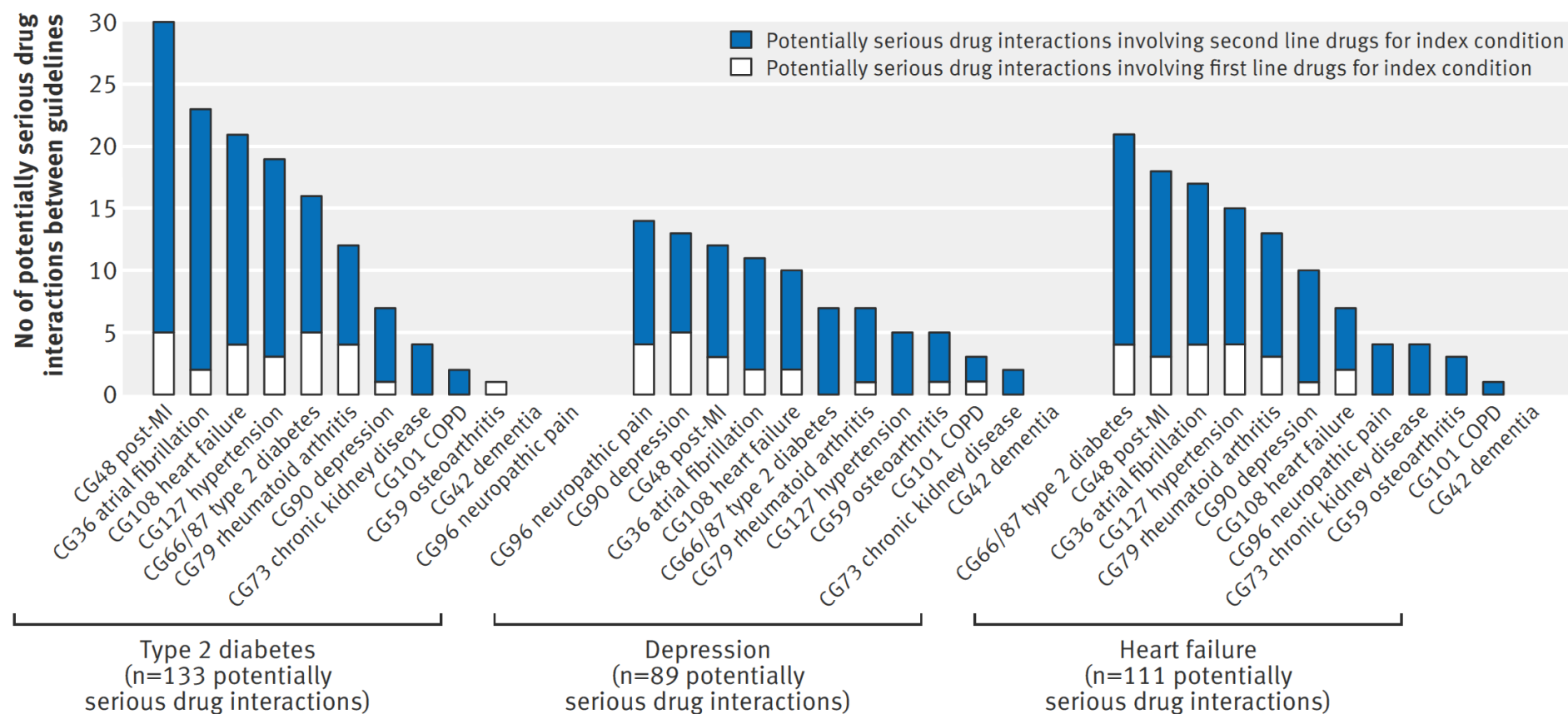


Figure 7: Potentially serious drug-drug interactions between drugs recommended by clinical guidelines for three index conditions and drugs recommended by 11 other guidelines (Dumbreck; 2015)

UPDATE

As of 2019, an international consensus of the definition and measurement of multimorbidity is still lacking. The definition by Le Reste (EGPRN)³⁶ is most likely to capture the complexity of multimorbidity but the multi-faceted nature of the definition makes it difficult to operationalize in practice.³⁷ The most common approach is to rely on the NICE guidelines. However, the existing NICE guidelines on multimorbidity have not been updated since 2016³⁸.

In an updated 2018 review³⁹ addressing the use of clinical guidelines and clinical decision support systems to manage multimorbidity, the following areas of improvement have been identified:

- **Shortcomings of clinical practice guidelines:** Single disease clinical guidelines, despite offering substantial benefits for the healthcare system and patients, are not solely sufficient for developing personalised care plans for multimorbid patients. For that, multiple guidelines have to be reconciled together with clinical knowledge and patient data.
- **Complexity of managing temporal constraints between actions in CPGs:** Correct timing of guideline actions plays a significant role upon achieving safe therapy implementation. Multiple treatments need to be sequenced, arranged and processed (in a parallel manner).
- **Conflicting actions affecting care:** Guidelines do not adequately address polypharmacy issues that can be induced by multimorbidity, including drug-drug, drug-disease, drug-patient interactions.
- **Issue of care non-adherence:** With an increase of the condition's complexity, often patient adherence decreases due to a significant amount of medical information and medication increase. Shared decision-making with the patient and caregiver are key.
- **Guideline reconciliation is key** for the identification of adverse interactions induced by contradicting targets of the guideline actions, the medication conflicts offered by different guidelines or inappropriate timing of medical processes.

The project addressed (in D7.2) the challenge of drug-disease and drug-drug interactions, in the clinical decision support module (CDSM) by considering the perspective of the CDSM as a support for the reconciliation of care plans and solve interactions in multimorbid patients. Four elements of the care plan personalisation have been recommended:

- Risk assessment;
- Goals;
- Activities;
- Pharmacotherapy.

³⁶ Le Reste et al. (2013). The European General Practice Research Network Presents a Comprehensive Definition of Multimorbidity in Family Medicine and Long Term Care, Following a Systematic Review of Relevant Literature. *Journal of the American Medical Directors Association*, 14(5), 319-325. doi:10.1016/j.jamda.2013.01.001

³⁷ Johnston, M. C., Crilly, M., Black, C., Prescott, G. J., & Mercer, S. W. (2019). Defining and measuring multimorbidity: a systematic review of systematic reviews. *European Journal of Public Health*, 29(1), 182-189.

³⁸ National Institute for Health and Care Excellence (NICE). Multimorbidity: clinical assessment and management. NICE guideline [NG56] [online] Available: <https://www.nice.org.uk/guidance/ng56> [Accessed 30-March-2020].

³⁹ Bilici, E., Despotou, G., & Arvanitis, T. N. (2018). The use of computer-interpretable clinical guidelines to manage care complexities of patients with multimorbid conditions: A review. *Digital health*, 4, 2055207618804927. <https://doi.org/10.1177/2055207618804927>

The reconciliation of evidence based clinical guidelines included resolving the interactions between them on the four components selected. They were classified as follows:

Table 3: Types of interactions

Disease Disease

The presence of a disease is a risk factor to develop comorbidity or when it is already, it worsens its prognosis (i.e. RF increases the risk of developing HF but if both are present, HF has a worse prognosis) or both diseases overlap their symptoms (Asthenia as a symptom in a person with heart and renal failure) or may interfere with the diagnosis by altering lab tests results.

Disease to Drug / Drug to disease

The presence of a second disease (i.e. nephropathy) determines some type of contraindication, interaction or dose adjustment in people who need pharmacological treatment (Drug) derived from their index disease (i.e. diabetes) or its complications (i.e. complications Micro / macro of diabetes). Pharmacological treatment of comorbidity (i.e. nephropathy) conditions the evolution of the index disease (i.e. diabetes)

Drug Drug

The use of a drug for the treatment of a disease determines some type of risk with the use of another drug to treat the comorbidity. i.e.: ACE-inhibitors may increase the side effects of metformin.

3.2. The polypharmacy challenge

The question of how to tackle multimorbidity in Europe needs to include the challenges posed by the use of multiple medications by one individual, also referred to as polypharmacy. Polypharmacy status determinants include co-morbidity, age, functional and cognitive status.⁴⁰ Chronic multimorbid patients, especially those over 65 years of age, are often prescribed multiple drugs in order to treat co-existing conditions. The term “polypharmacy” is usually applied to situations where a person takes more than four or five medication items.⁴¹ The primary concerns associated with polypharmacy are that it increases the complexity of care and the risk of adverse effects and drug-drug interactions, also lowering the chances of treatment adherence and patient empowerment. Simply following disease-based guidelines in the case of multimorbid elderly patients can give rise to potentially harmful polypharmacy, as many of standard guidelines are based on evidence from clinical trials which only included middle-aged subjects suffering from few conditions and not taking a large number of additional medications. Negative associations (decline in physical and instrumental activities of daily living, increased mortality risk) have led to polypharmacy in elderly patients being approached as a practice to be avoided.⁴² More recently, a distinction between appropriate and problematic or inappropriate polypharmacy has been made.⁴³

Inappropriate or problematic polypharmacy occurs when there is a lack of evidence-based indication, the indication is no longer valid or the dose is unnecessarily high, one or more medicines do not achieve their therapeutic objectives, one or more medicines cause unacceptable adverse drug reactions or put the patient at risk of unacceptable adverse drug reactions, and the patient is not willing or able to take

⁴⁰ Onder, G., et al. (2012) “Polypharmacy in nursing home in Europe: results from the SHELTER study.” *J Gerontol A Biol Sci Med Sci*. Jun;67(6):698-704. doi: 10.1093/gerona/qlr233.

⁴¹ Ibid.

⁴² Woodruff. K. (2015) “Preventing polypharmacy in older adults”. *Am Nurs Today*. 2010;5(10)

⁴³ Wilson, M., Mair, A., Dreischulte, T., & Witham, M. (2015). Prescribing to fit the needs of older people – the NHS Scotland Polypharmacy Guidance, 2nd edition. *Journal of the Royal College of Physicians of Edinburgh*, 45(2), 108-113. doi:10.4997/jrcpe.2015.204

one or more medicines as intended.⁴⁴ An additional problematic effect of polypharmacy can be a “prescribing cascade”, a situation which occurs when an adverse drug reaction is not recognized as such and further medication is prescribed to treat iatrogenic symptoms. Furthermore, asymptomatic patients are often prescribed complex preventive drug regimens which increase risk.⁴⁵

Appropriate polypharmacy can be achieved in conditions of evidence-based optimised medicines use. The therapeutic objectives of each medicine must be discussed with the patient, therapeutic objectives need to be realistic and observable, the risk of adverse drug reactions should be considered, and measures should be taken for minimising it. The patient needs to be motivated to follow the therapeutic plan as intended. Appropriate polypharmacy can improve life expectancy and the quality of life.⁴⁶ Cases of under-prescribing in order to avoid a potentially problematic polypharmacy regimen for elderly patients are an additional concern.⁴⁷

Carefully crafted holistic polypharmacy management programmes are needed in order to ensure that polypharmacy occurs appropriately, especially with regards to its increased prevalence due to the challenge of the ageing society.⁴⁸

D3.1 has reviewed the relevance for C3-Cloud of the European FP7 project PRIMA-eDS – “Reduction of inappropriate medication and adverse drug events in elderly populations by Electronic Decision Support”.⁴⁹ The project gathers the best available evidence to develop recommendations to optimise treatment of multimorbid elderly. An electronic decision support tool has been developed to incorporate these recommendations to be applied in primary care. The PRIMA-eDS tool analyses the patient’s diagnoses, current medication, symptoms, biometric measurements and laboratory results and performs an electronic comprehensive medication review. It then returns recommendations for drug discontinuation or modification based on the European list of inappropriate medications for older people, 45 rules and recommendations based on systematic reviews and guidelines, 95 rules and recommendations from the Evidence-Based Medicine electronic Decision Support (EBMeDS) database⁵⁰ and several other databases.

From the PRIMA-eDS trial we can learn that incomplete electronic health records are a particular challenge for primary care professionals, who may not know all medications prescribed by specialists. When the PRIMA-eDS results are published, they can serve as additional input for polypharmacy management with a focus on primary care.

UPDATE

A qualitative study⁵¹, which included 21 GPs using the PRIMA-eDS tool was carried out in North Rhine-Westphalia, Germany. According to the study, GPs found the patient data entry into electronic

⁴⁴ Ibid.

⁴⁵ Duerden, M., Avery, T., & Payne, R. (2013). *Polypharmacy and medicines optimisation: making it safe and sound*. London: The King's Fund.

⁴⁶ Wilson, M., Mair, A., Dreischulte, T., & Witham, M. (2015).

⁴⁷ Duerden, M., Avery, T., & Payne, R. (2013).

⁴⁸ SYMPATHY Project. Stimulating Innovation Management of Polypharmacy and Adherence in the Elderly <http://www.sympathy.eu/>

⁴⁹ Renom-Guiteras, Anna, Gabriele Meyer, and Petra A. Thürmann. 2015. ‘The EU(7)-PIM List: A List of Potentially Inappropriate Medications for Older People Consented by Experts from Seven European Countries’. *European Journal of Clinical Pharmacology* 71 (7): 861–75. doi:10.1007/s00228-015-1860-9.

⁵⁰ Evidence-Based Medicine electronic Decision Support Database (EBMeDS). <http://www.ebmeds.org/web/guest/home>

⁵¹ Rieckert, A., Sommerauer, C., Krumeich, A., & Sönnichsen, A. (2018). Reduction of inappropriate medication in older populations by electronic decision support (the PRIMA-eDS study): a qualitative study of practical implementation in primary care. *BMC family practice*, 19(1), 110.

case report form to be inconvenient and time-consuming. The Comprehensive Medication Review (CMR) was conducted often outside practice hours and without the patient present. GPs found that the PRISMA-eDS CMR provided relevant information for, and had several positive effects on, the care process.

- Treatment: Due to the CMR, the GPs became aware of risks and got a better sense of them.
- Communication: The recommendations supported the GPs in the dialogue with other medical specialists and patients as the GPs became more confident and better at explaining the results.

However, they encountered several barriers when wanting to change medication. Among these barriers:

- Prescriber factors: GPs prioritised differently certain medications compared to the PRIMA-eDS CMR or regarded the medication as necessary. Furthermore, they had been prescribing the same medication for years and lacked motivation to reconsider it. They also found sometimes the new recommendations not comprehensible or considered them not applicable to their individual patient.
- Patient factors: GPs reported that sporadically, patients postponed implementing medication changes, or they were willing to take fewer drugs, but had little willingness to change lifestyle.
- External factors: GPs were reluctant to discontinue medication prescribed by other medical specialists without contacting them or feared that it would be difficult to reach a consensus as the specialists often have different viewpoints.
- Infrastructural factors: the CMR was sometimes conducted without the patient being present in the practice and thus medication changes could have been delayed or even forgotten.

The study concluded that it is unlikely that the PRIMA-eDS CMR will be used in the future as it is now as patient data entry is too time-consuming. Given the positive attitude towards the CMR, a new way of entering patient data into the PRIMA-eDS tool to create the CMR needs to be developed.

In another instance, the use of PRIMA-eDS⁵² was investigated regarding the experience of GPs with the tool in all 5 participating study centres. According to the study results, The PRIMA-eDS tool was found to be useful (69%) and the recommendations were found to help to increase awareness (86%). Common to the 2018 study, one of the most common barriers identified to implementing deprescribing recommendations was the perceived necessity of the medication (69%). Time was considered to be the most important factor for future implementation; thus, further development should focus on how the PRIMA-eDS tool could become more time efficient. Despite the difficulties in de-prescribing, most respondents (65%) would use the electronic medication check in routine practice if it was part of the electronic health record.

A 2020 review of the Scottish polypharmacy guidance on realistic prescribing and the EU SIMPATHY project resulted in the following conclusions⁵³:

Polypharmacy is still increasing globally along with increasing multimorbidity. Inappropriate polypharmacy is responsible for up to 11% of hospital admissions, of which 50% are deemed preventable. This is estimated to cost \$18 billion annually. There is a lack of evidence on the effects of polypharmacy on patient-centered and clinical outcomes. Current guidance on polypharmacy is based predominantly on consensus rather than evidence. For example, to improve decision-making by patients

⁵² Rieckert, A., Teichmann, A. L., Drewelow, E., Kriechmayr, C., Piccoliori, G., Woodham, A., & Sönnichsen, A. (2019). Reduction of inappropriate medication in older populations by electronic decision support (the PRIMA-eDS project): a survey of general practitioners' experiences. *Journal of the American Medical Informatics Association*, 26(11), 1323-1332.

⁵³ Mair, A., Wilson, M., & Dreischulte, T. (2020). Addressing the Challenge of Polypharmacy. *Annual review of pharmacology and toxicology*, 60, 661-681.

and providers, more research is required to better understand the risks of drug–drug interactions involving more than two drugs.

As a result of the current guidance, work is being undertaken to develop a series of measures that monitor the impact of the guidance and supplementary initiatives on patient outcomes. Research on the impact of a patient-centered approach to adherence and persistence with multiple treatments and on patients' views about shared decision-making in this context would help ensure that treatment can be optimized to improve patient outcomes while minimizing harm. Although, SIMPATHY identified key change-management tools for implementation, ongoing work will be needed to evaluate implementation in different countries. There is also a need to develop the patient's role and measure patient-reported outcomes from these reviews and from their views as shared decision makers.

The authors have identified six key recommendations to implement programs to improve medication safety, of which polypharmacy is an essential element:

- Use a systems approach that has multidisciplinary clinical and policy leadership.
- Nurture a culture that encourages and prioritizes the safety and quality of prescribing.
- Ensure that patients are integral to the decisions made about their medicines and are empowered and supported to do so.
- Use data to drive change and measure outcome.
- Adopt an evidence-based approach with a bias toward action.
- Utilize, develop, and share tools to support implementation.

The International Group for Reducing Inappropriate Medication Use & Polypharmacy (IGRIMUP) issued a *Position Statement and 10 Recommendations for Action*⁵⁴.

The cornerstone of this position statement is that without evidence of definite and relevant benefit, when prescribing for many older patients 'less is more'. The approach differs from standard guidance as the focus here is on what, when, and how to stop, rather than on when to start medications/interventions. The scope can be extended beyond frailty to include many subpopulations with multimorbidity, dis-ability, or limited life expectancy. It extends beyond the list-based approach of any explicit tool.

Recommendations on Individual and System Approaches to Inappropriate Medication Use and Polypharmacy:

1. Review the medications of all older adults with an eye to de-prescribing, particularly those who are vulnerable to the adverse effects of medication.
2. Before initiating a potentially 'appropriate' medication, consider the validity of the evidence based on patient characteristics and preferences.
3. Consider each medication for potential withdrawal, extending beyond standardized lists.
4. Employ mixed implicit and explicit approaches to polypharmacy.
5. Address the underrepresentation of older patients in clinical trials.
6. Acknowledge and address commercial influences on polypharmacy: trial results should not be implemented in older adults unless access to all available patient-level data is provided. Appropriate outcome measures should be required before licensing indications that include older populations.
7. Medical education needs a stronger focus on IMUP and its potential negative impact. Education about generalist approaches to multimorbidity should teach prioritization skills and aim to improve the clinician's understanding of the strengths and weaknesses of evidence and how best to apply standard models of care to vulnerable older adults with multimorbidity.

⁵⁴ Mangin, D., Bahat, G., Golomb, B. A., Mallery, L. H., Moorhouse, P., Onder, G., ... & Garfinkel, D. (2018). International Group for Reducing Inappropriate Medication Use & Polypharmacy (IGRIMUP): position statement and 10 recommendations for action. *Drugs & aging*, 35(7), 575-587.

8. Medical training should review methods to stop treatments and provide equal attention to drug side effects and benefits.
9. When patients have multimorbidity, the single disease model (and its incentivization) should be spurned.
10. Decisions in older complex patients should routinely consider expected survival and quality of life, giving the highest priority to patient/family preferences.

The C3-Cloud project developed a drug interaction advisory service (DIAS) for clinical decision support⁵⁵. DIAS is based on the NICE implementation of the British National Formulary (BNF), a pharmaceutical reference book used by the NHS⁵⁶. The information provided by the service, includes potential adverse interaction between substances, the effects of the interaction, the severity of the interaction, as well as the evidence basis of interaction. It was tested with random sampling covering 50 substances. The current database contains over 50,000 interacting pairs of substances for over 1,000 substances. Future work will extend DIAS to include advisory on probability of side-effects.

4. ANALYSIS OF PATIENT-CENTRED PATHWAYS AND RESPECTIVE CARE PLANS

C3-Cloud is dealing with several co-morbidities including diabetes 2, hypertension / chronic heart failure (CHF), chronic kidney disease (CKD) / renal failure. In this section we provide an overview of approaches towards establishing patient pathways and care plans for such complex patients.

4.1. Disease specific pathways

Pathways have a significant impact on the organisation of care processes; however, the pathway methodology does not have a significant impact on patient-focused organisation, communication with patients and family or collaboration with primary care⁵⁷.

Currently, *NICE pathways* exist for a whole variety of medical issues and are disease specific. Approaches to create integrated care pathways for multimorbid patients are still limited. The NHS House of Care⁵⁸ lists a number of issues that hamper integrated care: single condition services, lack of care coordination, emotional and psychological support, fragmented care, lack of informational continuity, reactive services, not predictive services, lack of care planning consultation. In addition, a qualitative study by Bayliss, Edwards, Steiner and Main⁵⁹ presents the processes of care desired by elderly patients with multimorbidities. These include: convenient access to providers; clear communication of individualized care plans; support from a single coordinator of care; and providers who would listen to and acknowledge their unique and fluctuating needs, as well as a caring attitude.

A patient centred integrated care pathway needs to demonstrate the route patients take, by displaying the different possibilities, options, and alternatives for a group of patients with similar chronic diseases,

⁵⁵ Despotou G, Yuksel M, Sarigul B, Arvanitis TN. Drug Interaction Advisory Service for Clinical Decision Support of Multimorbidity Patient Centric Care Plans in the C3-Cloud System. *Studies in Health Technology and Informatics*. Volume 262, pp 388-391 (2019). Published July 2019. DOI 10.3233/SHTI190100

⁵⁶ <https://www.nice.org.uk/bnf-uk-only>

⁵⁷ Age UK. The effectiveness of care pathways in health and social care. *Centre for Policy on Ageing*. (2014). http://www.ageuk.org.uk/Documents/EN-GB/For-professionals/Research/CPA-Effectiveness_of_care_pathways.pdf?dtrk=true. Accessed 16-02-2017.

⁵⁸ NHS. House of Care. <https://www.england.nhs.uk/ourwork/ltc-op-eolc/ltc-eolc/house-of-care/>. Accessed 23-02-2017

⁵⁹ Bayliss, Edwards, Steiner, and Main. Processes of care desired by elderly patients with multimorbidities. *Family Practice* 25, no. 4 (2008): 287-93. doi:10.1093/fampra/cmn040.

and thus is different from disease specific care pathways. Embedded in a timeframe, it should demonstrate the various steps the patient and other actors (GP, Nurse, Specialist, etc.) take, e.g., under what circumstances a referral to a specialist is recommended, ways of communication, information and decision making power. The pathway provides a management tool, ensuring who is taking care, when and under what circumstances. At the centre of the pathway exists the care plan: the individual treatment, goals and means of patient care.

Our literature review has resulted in several different approaches towards establishing patient pathways, of which some will be quickly depicted below, highlighting their shortcomings with respect to the integration of these care pathways. Figure 8 below presents the type 2 diabetes care pathway of the Barnsley Hospital in Yorkshire, UK. The pathway differentiates between **five milestones in diabetes care**, namely

1. Diagnostic phase;
2. Educative phase;
3. Treatment management phase;
4. Complication/risk management, and;
5. Maintenance phase.

It elaborates in more detail for each milestone (i.e. phase) with specific guidance for care management but does not allow for differentiation of care pathways for different patient subgroups (e.g. co-morbidities) as the following Figure demonstrates.

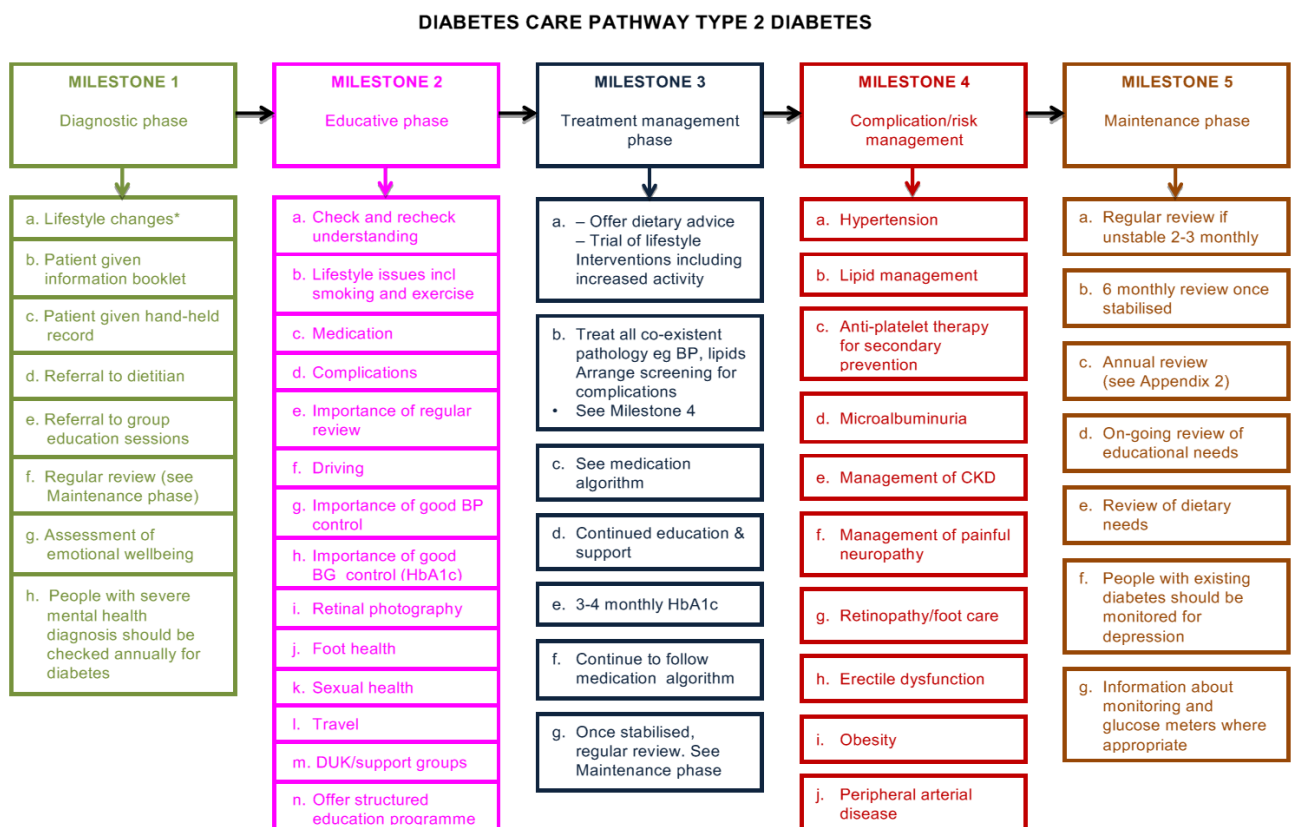


Figure 8: Diabetes Care Pathway, Barnsley Hospital, NHS, 2014

These five milestones have to be taken into account in the development of integrated care pathways.

Another useful example is the BAYNAV management of Type 2 Diabetes⁶⁰, presented in Figure 9. It includes patient background information, screening and diagnostic activities, and places the patients' empowerment as a key factor in the diabetes management. It further includes investigations, self-management and splits up into five categories of patient management: retinal screening, medication, complications, lifestyle advice and CVD risk management. Information resources for patients, pathway update information as well as information and recommendations for referrals are also included in our high-level integrated care pathway.

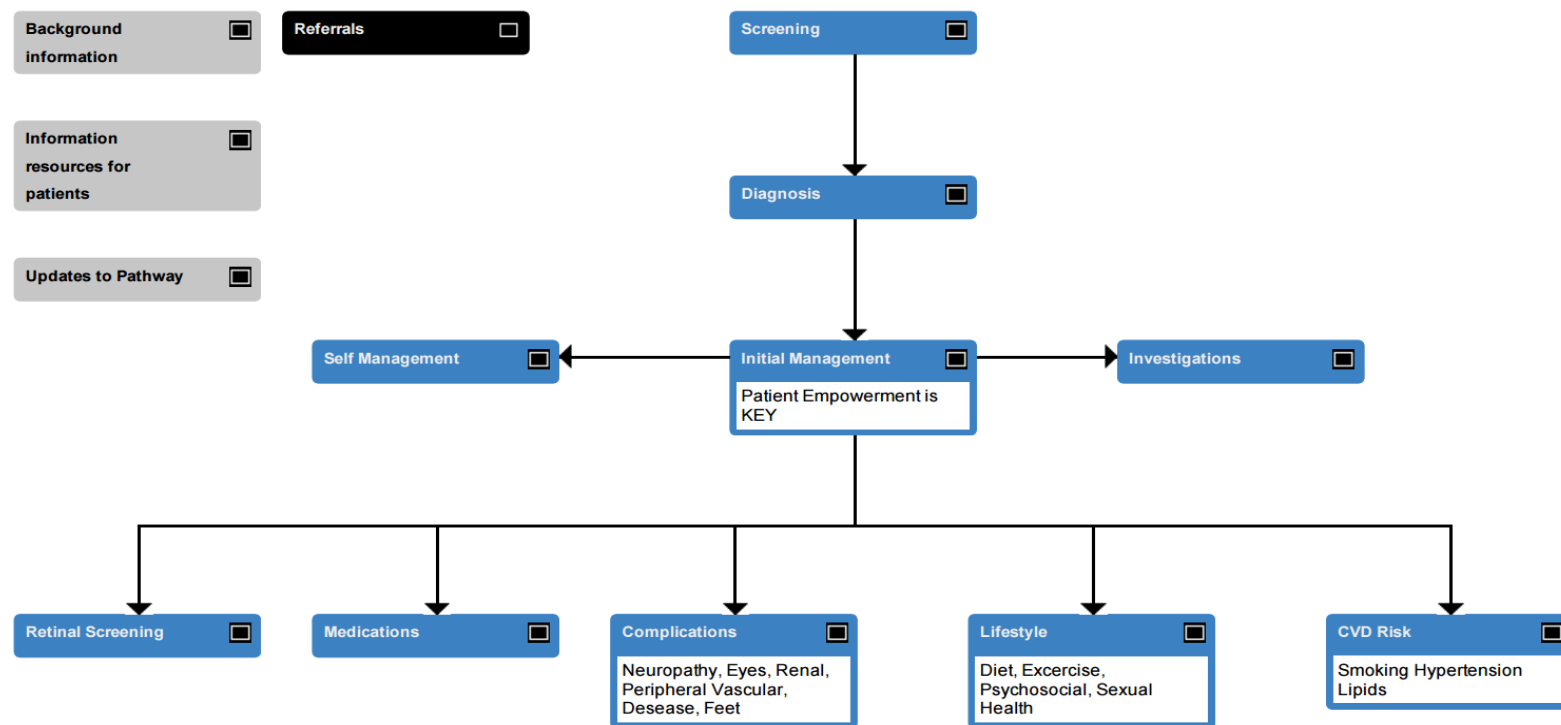


Figure 9: BAYNAV Management of Type 2 Diabetes

⁶⁰ <http://baynav.bopdhb.govt.nz/diabetes/typetwodiabetes/?pathways>

Finally, a pathway model for heart failure patients from the NHS Foundation Trust South Warwickshire is presented in **Error! Unknown switch argument.** below.

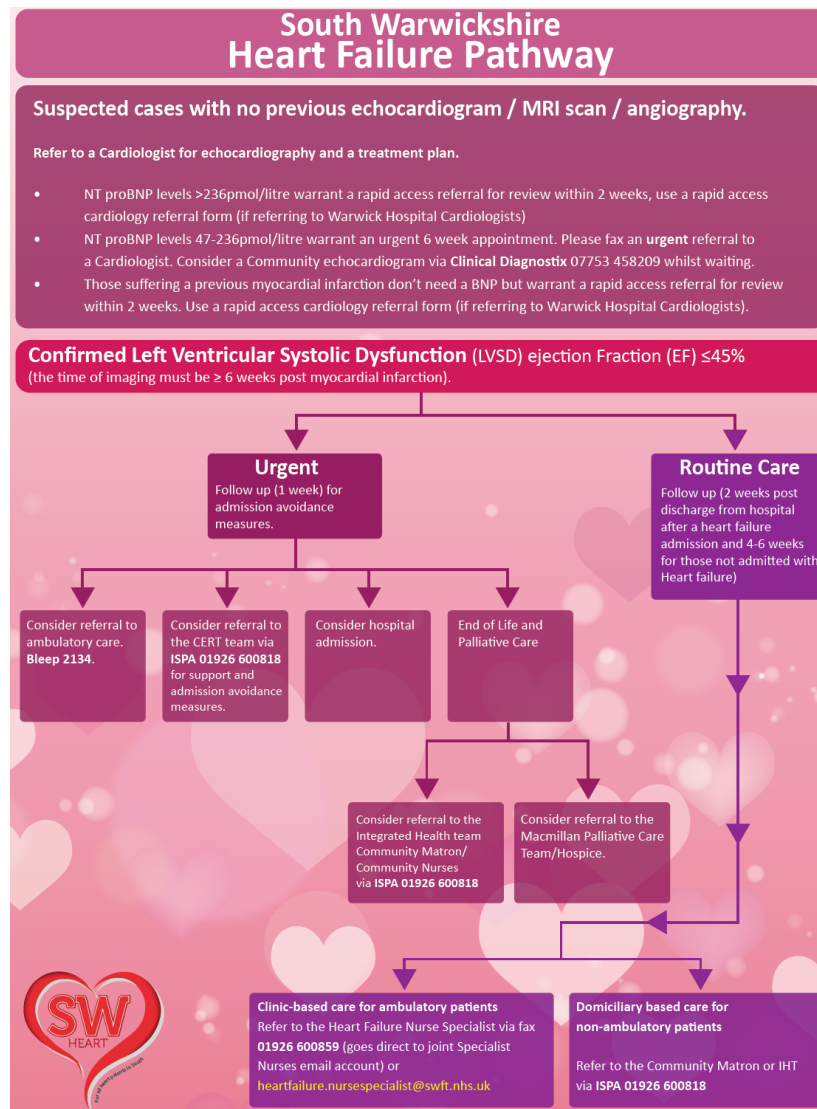


Figure 10: Heart Failure Pathway, NHS, South Warwickshire

The pathway is largely based on clinical parameters and referrals to certain health professionals in case of exacerbations of the health condition.

While this care pathway model integrates several stakeholders, it is limited to a single health event (left ventricular systolic dysfunction) and does not visibly outline a holistic approach including patient empowerment or the involvement of the patient in care plan creation and setting of goals.

4.2. The care pathway for multimorbid patients in the Basque Country

Partner KG has developed, in the CareWell project, an integrated care pathway which has been piloted in Basque Country, Spain. The pathway has already proven its usability in that it is already implemented and currently used in six of the thirteen Health Care Organizations (OSIs) of Osakidetza in the Basque Country.

The integrated care pathway includes:

- Identification of frail elderly patients.
- Baseline comprehensive assessment.
- Therapeutic plan definition.
- Programmed patient's follow-up.
- Patient stabilisation at home.
- Integrated care during hospitalisation.
- Coordinated hospital discharge.

Initially, a GP identifies potential candidates by reviewing electronic health records. After patient identification, the GP proceeds to schedule a consultation with the patient, either in the health centre or at home, depending on the patient's mobility. During this visit, the GP performs a comprehensive assessment, defines the therapeutic plan and provides patient with educational material in order to increase his/her self-management capability. In addition, the need for extra resources (inclusion in specific empowerment programmes, social care activation, health advice by eHealth Centre, or tele-monitoring / telecare programme) is assessed. Irrespective of the activation of additional resources, the primary care nurse schedules a face-to-face follow-up plan depending on the patient's needs. During this face-to-face consultation, the primary care nurse analyses the patient's therapeutic plan and his/her adherence to treatment, reinforces patient's self-management capacity, revises laboratory tests and performs medical examinations according to the patients' pathologies. If no health deterioration is detected during these consultations, the patient will have routine check-ups approximately every three months. However, if any instability sign is identified, the patient is referred to see the GP in order to re-assess his/her clinical situation. If the patient can benefit from home care, a variety of resources can be activated: home hospitalisation, home visits of highly skilled nurses or reinforcement calls or health advice by an eHealth Centre. If the patient cannot be treated at home, or his/her health status impairment continues, the patient will be admitted to hospital. During the hospitalisation, the reference internist is in charge of assessing the patient's clinical situation, defining corresponding treatment, and managing medical interventions to stabilise the patient. During this process, the internist will coordinate all activities and liaise with different specialists as necessary. In parallel, the hospital nurse will use specific questionnaires to assess the social integration of the patient, and determine if any social care resource is required.

Once the patient is stable, the reference internist will consider if the patient requires additional interventions such as home-hospitalisation, admission to a sub-acute hospital, social care, or special coordination with primary care. If applicable, the reference internist is responsible for arranging for the intervention needed. At hospital discharge, the reference internist writes the discharge letter, contacts the GP to ensure continuity of care and resolves any queries that may arise. The hospital nurse (called hospital liaison nurse) draws up the patient's follow-up plan, and schedules a face-to-face appointment for the patient with the GP nurse from the health centre. The visit with the GP nurse is the starting point of the integrated care pathway, from where the patient can be referred to periodic follow-up consultations with GP nurse, to the GP or the hospital, depending on his/her health status.

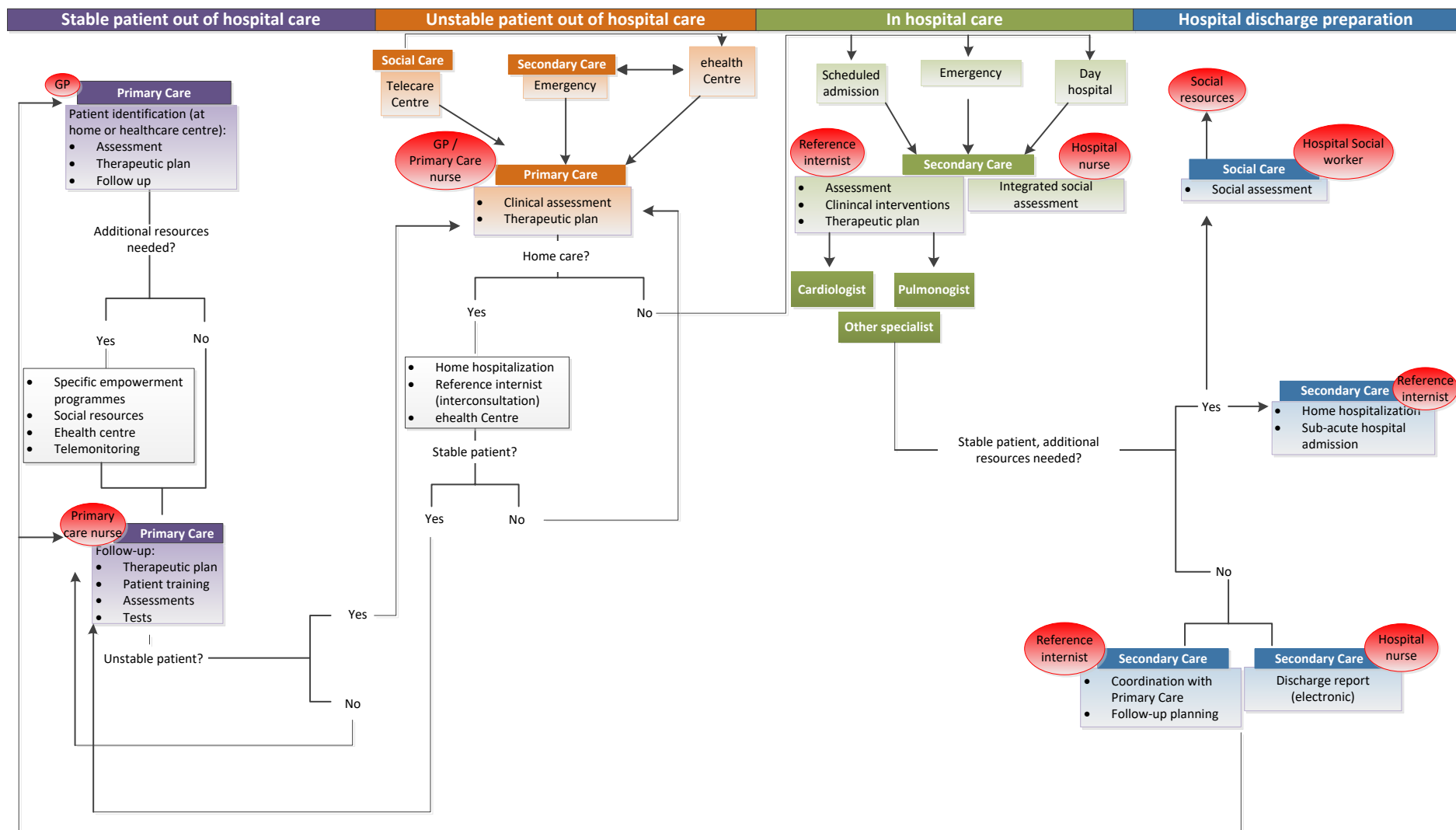


Figure 11: The integrated care pathway for multimorbid patients in the Basque Country (from the CareWell project)

Our analysis shows that the adopted four stages characterise well the patient status and transition stages of management of multimorbid patients:

1. Stable patient out of hospital care.
2. Unstable patient out of hospital care.
3. Patient in hospital care.
4. Hospital discharge preparation.

UPDATE

CareWell intervention included, besides EHR or e-prescription, a large range of new elements: patient stratification, the establishment of new roles, such as the care manager and the reference internist, and the multidisciplinary working team sharing explicit decision making criteria, such as assessment tools and scales, communication protocols and care plans, patient and care givers training and skills development, among others

The CareWell project has suggested that technology-enabled integrated care must be recognised as a complex service innovation and can be fully effective, including impact on budgets, through change strategies that influence, educate, train and enable transformation in the way care professionals work and how they engage effectively with patients and carers.^{61, 62} CareWell has shown that ICT applications may provide new and effective tools to promote information gathering and communication, but the effectiveness of inter-professional collaboration will always depend more on social relationships and on the context of the organization within which they are placed.⁶³

The implementation of the CareWell project has improved the integration in the Basque health system. Around 6200 patients benefited from the proposed integrated care pathway; it has been adapted and scaled up by the ACT@SCALE project.⁶⁴ Furthermore, the comprehensive patient empowerment programme KronikON, developed specifically for CareWell, is now available to patients and their informal carers through the Electronic Health Folder and the Osakidetza web portal.⁶⁵

This exemplary *CareWell* integrated care pathway from the Basque Country (Spain) can be adapted for use by the other piloting organisations in the C3-Cloud project.

⁶¹ Goodwin N. Tomorrow's World: Is Digital Health the Disruptive Innovation that will Drive the Adoption of Integrated Care Systems?. *International Journal of Integrated Care* 2018, 18(4): 14.

⁶² Soto-Gordoa M, Arrospe A, Merino HM, Mora AJ, Fullaondo ZA, Larranaga I et al.: Incorporating Budget Impact Analysis in the Implementation of Complex Interventions: A Case of an Integrated Intervention for Multimorbid Patients within the Carewell Study. *Value Health* 2017, 20: 100-106.

⁶³ Goodwin, N. How important is information and communication technology in enabling interprofessional collaboration? *Journal of Health Services Research and Policy* 2017, 22(4): 202–203.

⁶⁴ Schonenberg H, Nielsen E, Syse T, Bescos C. Experiences on scaling Care Coordination and Telehealth Best Practices. ACT@SCALE Handbook. 2019. https://www.act-at-scale.eu/wp-content/uploads/2019/03/ACT@Scale_Handbook.pdf

⁶⁵ KronikOn Programa. Paciente Crónico Complejo. Osakidetza, Departamento de Salud del País Vasco. <https://www.osakidetza.euskadi.eus/kronik-on-programa-paciente-cronico-complejo/ab84-oescon/es/>





4.3. Drafting a generic, high level care pathway

Based on the key components and elements discussed in the previous sections, we have drafted a provisional, generic care pathway illustrating the care journey of a complex patient at a high level - see Figure 12. The pathway serves as a high level illustration of an integrated care pathway and provides a basis for discussion with the three pilot sites on potential amendments according to local requirements.

Flowcharts Symbols

The following symbols are used in the modelling process (based on Modelio⁶⁶ freeware modelling tool) –

Table 4: Keys for symbols used in Error! Unknown switch argument. (table adapted from D7.1)

Name	Flowchart Symbol	Usage
Start point		Indicates the starting of a process.
Process		Represents a process, action, or function.
Decision		Indicates a point where the outcome of a decision dictates the next step. There can be multiple outcomes.
Flow arrow		Indicates the flowcharting path.

Error! Unknown switch argument. provides a high-level view of a pathway of a patient with multimorbidities (two or more chronic conditions). The patient undergoes an initial assessment and receives the new diagnosis that classifies the status as multimorbid. Subsequently, goals are set up to feed into the care plan creation. The care plan creation involves other stakeholders and may include referral to specialists. In addition, it may imply to consolidate an envisaged care plan with a previously existing care plan. When the care plan is set up, treatment planning is carried out by the MDT and is continuously monitored. If the patient's health status is stable, patient empowerment and self-management programs are initiated, including patient reminders to check for all drugs they take. Subsequently the care plan will be reviewed and the patient enters a new loop with new goals, a care plan revision and so forth.

If, however, the patient's health status is not stable, additional diagnostic measures will be started, potentially including other secondary care stakeholders. This is followed by the additional treatment and a monitoring phase. This "unstable condition"-loop ends with the question, if a stable condition was reached.

The third possible loop starts, when a patient is classified as "unstable", undergoes additional diagnosis and an admission to a hospital for further treatment is involved. Again, the treatment is carried out and the patient is discharged from the hospital. The hospital discharge is another important transition point. The question is raised again, if the patient's condition is stable or unstable and the patient pathway enters the respective loop.

There are several critical decision points for which guidance for all actors involved needs to be developed. This includes transition points such as referral, hospital admission, hospital discharge, etc.

⁶⁶ <https://www.modelio.org/>

Particularly challenging is the medication reconciliation (see NICE guideline on medicines optimisation⁶⁷ and also “medication reconciliation upon discharge” process map after redesign (MATCH toolkit - Medications at Transitions and clinical handoffs)).

NICE has formulated recommendations for patients transitioning from hospital settings back into their communities.⁶⁸ In order for patients to be properly supported, they need to receive person-centred care. Person centred care treats everyone involved in the care process, including patients and, with the patient’s consent, their family, as equally important to the decision making process. It thus empowers patients to make informed choices about their own care while communication and information exchange between the patient, informal carers and all involved health professionals is envisaged. Furthermore, facilitating communication and information sharing between all those involved in the transition process is another instrumental step. Patients are entitled to receive information about their diagnoses, treatment and prescription regimen when being transferred between hospital to home or home care. With the patient’s consent, this extends to their family members or other (informal) carers.

⁶⁷ <https://www.nice.org.uk/guidance/ng5/chapter/1-Recommendations#medicines-reconciliation>

⁶⁸ <https://www.nice.org.uk/guidance/ng27/chapter/Recommendations#discharge-from-hospital>

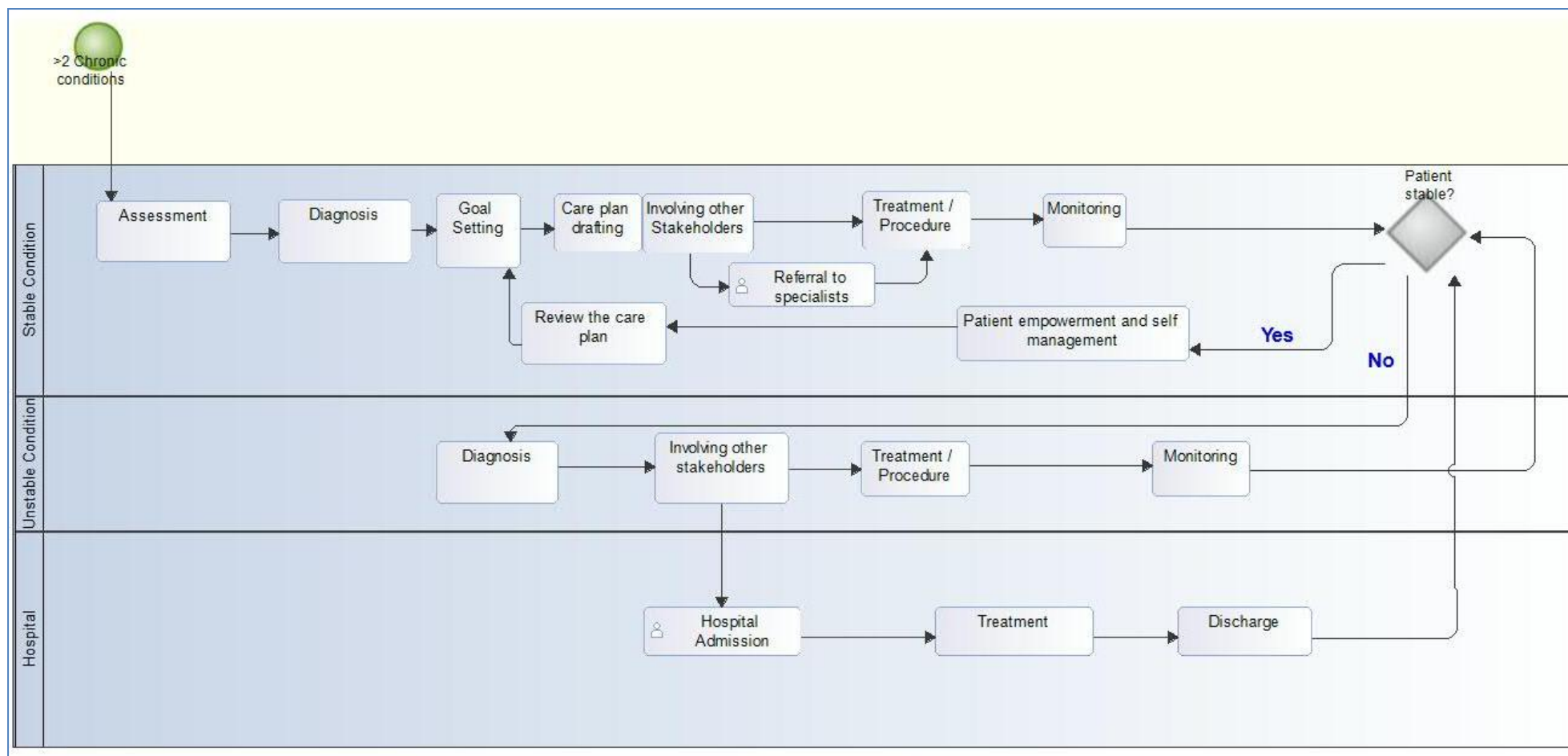


Figure 12: Generic, high-level care pathway for multimorbid patients

UPDATE

During the interviews with the pilot sites, partners criticised the classification of “stable” and “unstable” as misleading. In the practitioners’ points of view, a stable patient can also have a critical condition. As a means of correction, the generic care pathway for multimorbid patients now refers to “controlled” and “uncontrolled” conditions. An identification as to it being a “dynamic system that strives for stability and continuously reassesses the goals was missed.

In response to the question of “stable” and “unstable” patients, an approach was followed, recognising the “heterogeneity of treatment effects”, the response to a medical treatment, which can be different among patients.

Heterogeneity of treatment effects depends on:

- methodologic issues (quality and rigor of design and conduct of clinical research),
- clinical settings in which studies were conducted,
- individual patient characteristics which can include:
 - initial severity of disease (risk of a poor outcome independent of treatment);
 - responsiveness to treatment (for physiologic, behavioral, or genetic reasons);
 - vulnerability to side effects or adverse events;
 - adherence;
 - patient preferences and risk perceptions;
 - presence of multiple comorbid conditions and their treatments⁶⁹.

Thus, the following was adopted to the pathway: “**controlled**” refers to the proportion of patients **responsive to treatment**, **no adverse effects** are present, and they are **stable** in term of management of other persistent diseases, and “**uncontrolled**” refers to the proportion of patients **not responsive to treatment**, could **present adverse effects** or are **unstable** in term of management of other persistent disease.⁷⁰

Furthermore, in the more detailed stages of the pathway, it was pointed out that there was a lack of integrated care which was addressed by adding the social assessment and diagnosis as well as the involvement of the informal caregiver to the goal setting, monitoring and self-management.

Two of three pilot sites did not have a pre-existing multimorbidity pathway in place, decisions were based on individual clinical guidelines and the ad hoc decision making of healthcare professionals. C3-Cloud addressed these by undertaking guideline reconciliation and implementing this through the CDS. (This implementation was limited to the four disease areas of this project.)

Except for Basque country, the pilot sites followed individual clinical guidelines and single disease pathways were applicable, resulting in less personalised care and a large variation of pathways prone to individual errors. Multimorbidity pathways were either ad-hoc decision-making based on medical staff experience or handled via a “one size fits all” manner. Care plan development before C3-Cloud was time consuming and only done manually for few patients.

⁶⁹ Sherrie H.K., John B, Dara H.S Quyen Ngo-Metzger and Sheldon Greenfield, *Who Can Respond to Treatment? Identifying Patient Characteristics Related to Heterogeneity of Treatment Effects*, Med Care. 2010 Jun; 48(6 Suppl): S9–16. doi: 10.1097/MLR.0b013e3181d99161

⁷⁰ Pivonello R, Arnaldi G, Scaroni C, Giordano C, Cannavò S, Iacuniello D, Trementino L, Zilio M, Guarnotta V, Albani A, Cozzolino A, Michetti G, Boscaro M, Colao A., *The medical treatment with pasireotide in Cushing’s disease: an Italian multicentre experience based on “real-world evidence”*, Endocrine. 2019 Jun;64(3):657-672. doi: 10.1007/s12020-018-1818-7.

Following the definition of care pathway – *a method for the patient-care management of a well-defined group of patients during a well-defined period of time; pathways illustrate a multimorbid patient's journey across the health system* – the project achieved to address main elements:

- Introduction of a multidisciplinary approach to care.
- Improvement of communication, coordination, and sequencing of activities.
- Guideline reconciliation for four disease areas.
- Care plan creation and monitoring.

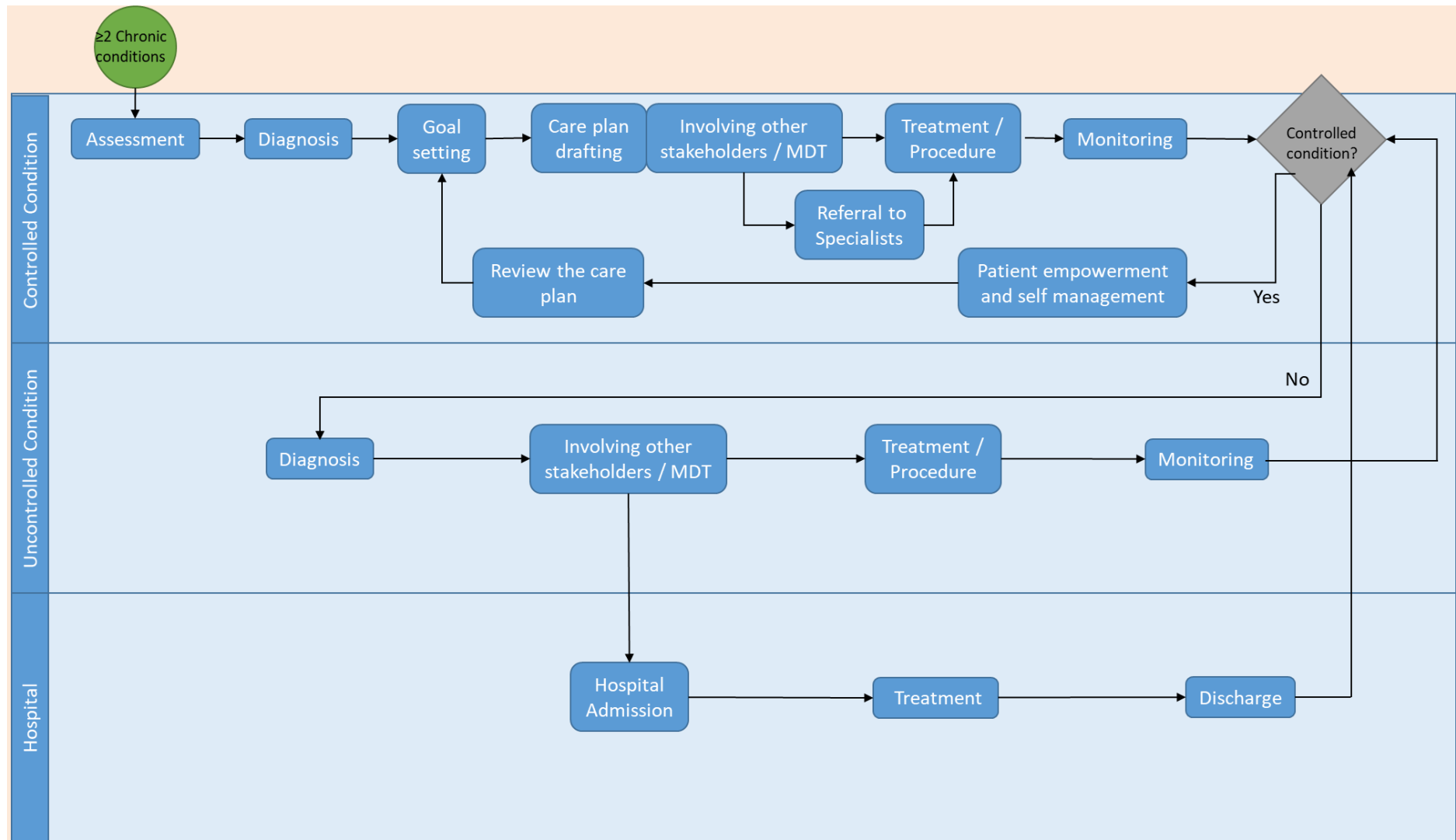
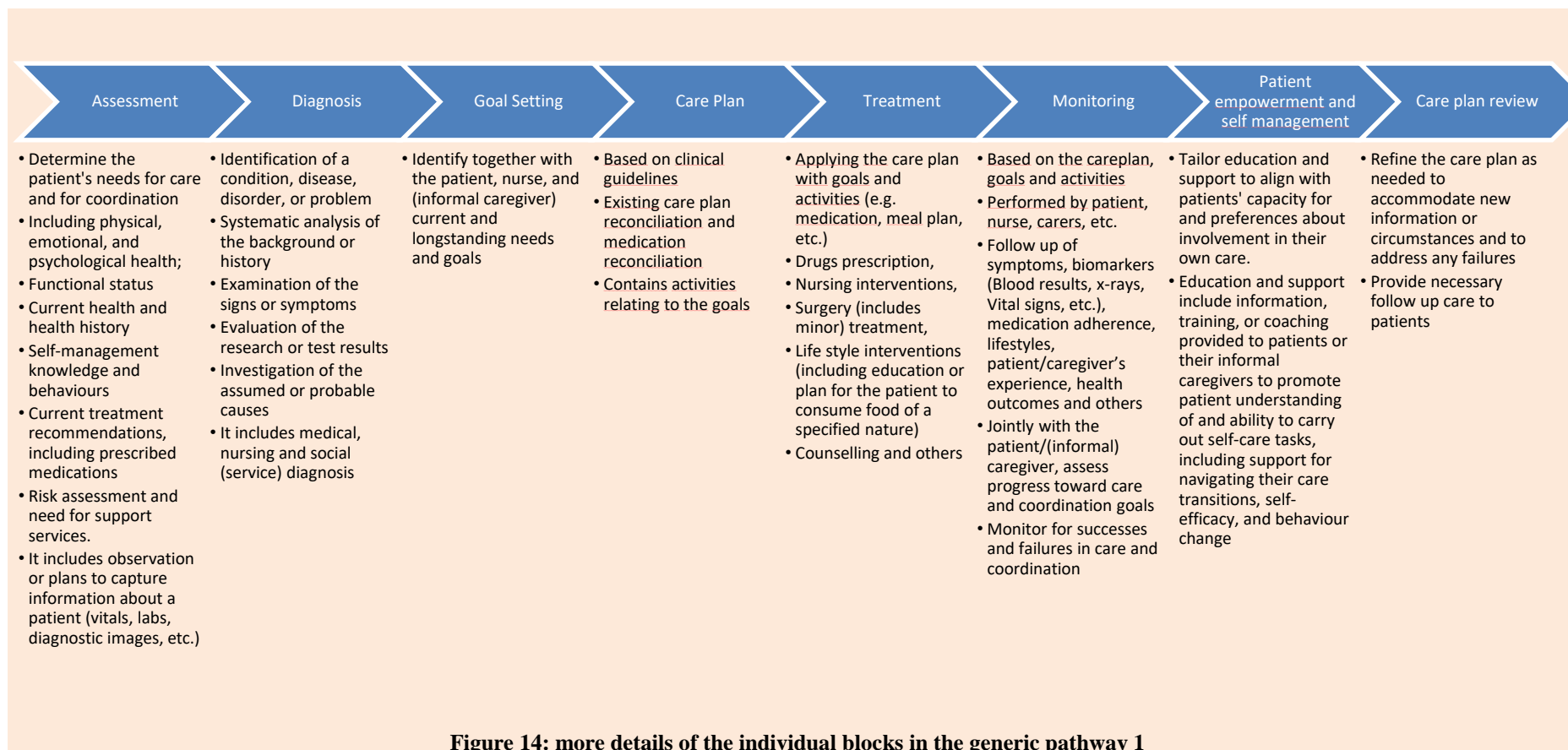


Figure 13: updated generic, high-level care pathway for multimorbid patients



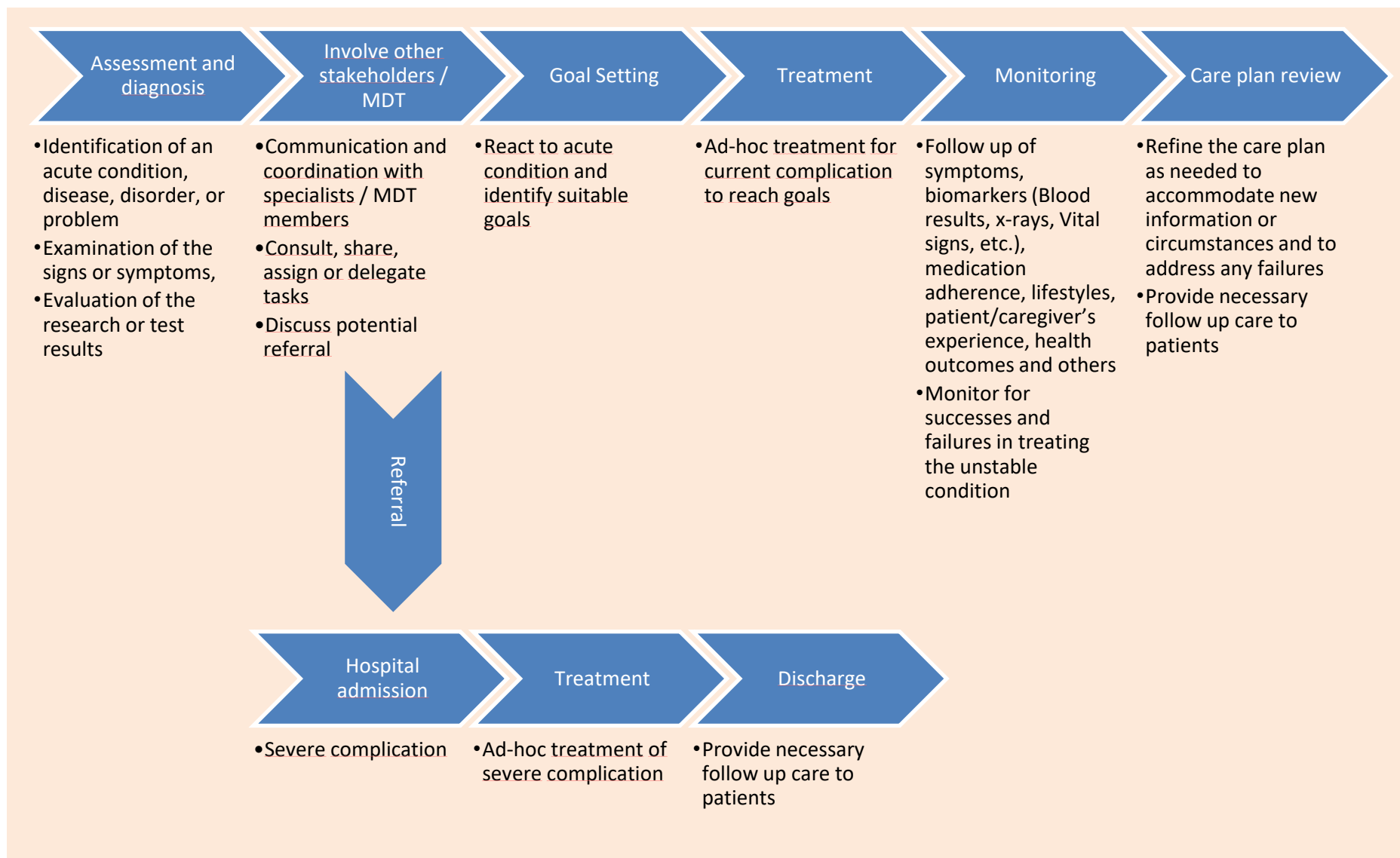


Figure 15: more details of the individual blocks in the generic pathway 2

Figure 13 is an updated version of the original generic high-level pathway. The two out of hospital stages have been renamed according to the feedback from the pilot sites and additional literature review into stable and unstable condition, the decision point has been renamed to controlled condition and the starting point was changed from >2 to ≥ 2 conditions. Figures 14 and 15 provide more details of the individual steps in the pathways. Part of localising this generic pathway lies within the identification of actors and locations of the steps mentioned. In order to adapt the generic pathway for multimorbid patients to local circumstances or the integration in existing pathways, it is necessary that health care sites need to individually assess their organisational models (D4.2) by focusing on:

- Principal characteristics of the health and social care systems: the structure of the health care system, legislation, funding, policy developments on integrated care, key players and variations.
- Target groups of integrated care, such as the elderly or chronically ill.
- Integrated care providers and services, which includes various care sectors, providers, and provincial or local authorities.
- Coordination mechanisms, like case management, care teams, or clinical pathways.
- Promoting and inhibiting factors at the system level.
- Coordinated care actors, activities and interpersonal communication
- With the help of this undertaking, individual structures can be identified that help to adapt the generic pathway for multimorbid patients to different localities.

4.4. Currently used (single morbidity) care plans and assessment forms

In this section, we briefly review care plans and assessment forms currently used by the pilot sites. A learning example is also provided, the so called TrueBlue Care Plan (see section 4.5.1), which is used in a study with multimorbid patients. It may provide useful ideas for the development of care plan templates that take account of multiple conditions.

At RJH. Care Plans are usually produced at discharge from hospital and used for communication with the municipality nurse. Figure 16 presents a screenshot of the care planning communication tool. The patient receives the care plan on paper only. The paper care plan the patient receives compiles information on post-discharge needs and information compiled by different actors:

- Emergency Care (doctor, nurse, occupational therapist, physiotherapist);
- the Municipality (district nurse, assistants / social workers, occupational therapist, physiotherapist), and;
- Primary Care (GP).

Figure 16: RJH screenshot of care planning communication tool

The presented (Core) Care Plans and Assessment Forms made available by NHS Warwickshire, partner SWFT (Figure 17, Figure 18 and Figure 19) illustrate two main issues in currently used care plans and care pathways that need consideration:

Firstly, there exist multitudes of plans that are disease specific, not adapted for multimorbid patients. *Secondly*, the same holds true for assessment forms, having various disease specific forms.

Currently, care plans are not widely used in SWFT, and are not shared across health professionals and sectors. They tend to be documents which are not updated as the patient's treatment/disease progresses or changes.

Warwickshire Community Health

NHS
Warwickshire

Name of Patient	_____
Date of Birth	_____
NHS Number	_____
Use White Patient ID Label if available	

Core Care Plan for Insulin Therapy Care Plan Number _____

Date / Time	Problem	Goal Planning	Treatment Plan	Review Date	Signature/Print Name
	Mr / Mrs / Miss / Other Requires insulin therapy due to Type 1 / Type 2 Diabetes and is unable to <ul style="list-style-type: none"> Self administer injections* Monitor own blood glucose levels* 	Mr / Mrs / Miss / Other will receive their medication as prescribed Blood glucose levels will be maintained within the patients normal range – to be determined with GP Patient / carer will be able to explain the underlying cause of the problem and the reasons for treatment	Monitor blood sugars twice weekly on Monday/Tuesday/Wednesday/Thursday/ Friday /Saturday/Sunday * (delete as appropriate) Increase frequency if necessary totimes a week if concerned that condition is deteriorating Give medication as prescribed Advise relatives and carer of specific signs and symptoms of hypoglycaemia and hyperglycaemia and who to inform if they are concerned Monitor and record weight monthly Liaise with Community Matron /Virtual Ward/ Diabetes Nurse Specialist or GP if concerned Encourage exercises within own abilities		

Figure 17: Core Care Plan for insulin therapy (NHS Warwickshire)

Warwickshire Community Health



Name of Patient	_____
Date of Birth	_____
NHS Number	_____
Use White Patient ID Label if available	

Care Plan for Heart Failure – Care Plan Number _____

Date / Time	Problem	Goal Planning	Treatment Plan	Review Date	Signature/Print Name
	Mr/ Mrs / Miss / Ms / Other Has heart failure and is at risk of exacerbation of their condition which could lead to a hospital admission for management	Minimise the risks of acute exacerbation Minimise the risks of hospitalisation and associated risks Maximise quality of life	Heart Failure Specialist Nurse (HFSN) / Community Matron / Community Nurse to visit with patient's consent Monitoring visits to take place regularly to observe and provide early intervention at the first sign of deterioration Record weight on Weight Chart _____ (frequency) Record Blood Pressure on Physiological Observations Chart _____ (frequency)		
Date / Time	Problem	Goal Planning	Treatment Plan	Review Date	Signature/Print Name
		Continued from previous page	Observe breathlessness / cough / sputum and record findings Observe exercise tolerance Observe for limb oedema/ abdominal ascites and document changes Ensure that medication is taken as prescribed and liaise with GP/HFSP re optimisation of heart failure medication Monitor renal function as agreed with GP and record results on Haematology /Biochemistry Results Sheet Liaise promptly with GP regarding concerns/changes in condition		

Figure 18: Care Plan for Heart Failure (NHS Warwickshire)

A distinction between developing a care plan for people with diabetes and collaborative care planning needs to be made. Evidence from the United Kingdom illustrates this distinction well. The development of a care plan is undertaken by a multidisciplinary determines the care to be delivered to a patient, with input from the patient who discusses this with a practice nurse. However, collaborative care planning is based on ongoing communication between people with diabetes and their health care professionals. Patients are given a questionnaire at their annual review appointment which will help determine and

consider their care priorities. Patients are also being given the time to reflect on their answers and discuss the elaboration of a care plan directly with their clinician.⁷¹

South Warwickshire NHS Foundation Trust Heart Failure Assessment Form	
Date and Time of Assessment	
Consultant Cardiologist	
Patient Concerns	
Symptoms	
Exercise Tolerance	Ask the patient - "At what distance on the flat do they become breathless and / angina)
Orthopnoea (Breathlessness lying flat)	Number of pillows required ____
Paroxysmal Nocturnal Dyspnoea (PND)	Ask the patient - "Do you wake up in the night breathless?"
Dizziness	
Palpitations	
Chest Pain	
Fluid Intake (1.5/2L per day, please state)	
Appetite	
Weight Trend ↑ ↓	
Mood	

Examination	
Blood Pressure – Sitting	
Blood Pressure – Standing	
Pulse /Apex - Regular / Irregular	
ECG QRS Duration	
Respiratory Rate	
Weight today	
Chest Auscultation	
Peripheral Oedema	
NYHA Score (See Below)	
Blood results	
Hb	eGFR
Creatinine	Potassium
Sodium	Urea
Other – (please state)	
Sample Sent Today Yes * / No*	
Other Relevant Signs/Symptoms Problems	
NYHA Score: Functional Classification of Heart Failure	
NYHA Score: Functional Classification of Heart Failure The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. 9th ed. Boston, Mass: Little, Brown & Co; 1994:253-256	
<ul style="list-style-type: none"> Class I Cardiac disease that does not limit normal physical activity. (Normal physical exertion is not associated with undue fatigue, dyspnoea, or angina pain.) Class II Patients with cardiac disease causing slight limitation of physical activity. (Comfortable at rest, ordinary physical activity results in fatigue, palpitation, SOB or angina) Class III Patients with cardiac disease causing marked limitation of their physical activity. (Comfortable at rest, < ordinary physical activity causes fatigue, palpitation, SOB, or angina). Class IV Patients with cardiac disease that prevents them carrying out any physical activity without discomfort and onset of symptoms. (Symptoms may be present at rest (angina, SOB). Symptoms increase with any physical activity) 	

⁷¹ Diabetes UK. *Improving the Delivery of Adult Diabetes Care through Integration*. 2014. <https://www.diabetes.org.uk/integrated-diabetes-care>

Heart Failure Medication				
Group	Name	Current Dose	Target Dose	Contraindicated or Previous Problems
ACE / ARB				
Beta Blocker				
Aldosterone Antagonist				
Digoxin				
Ivabradine				
Loop Diuretic				
Metolazone				
Hydralazine				
Nitrate				
Other Prescribed Medication				
Drug Name	Frequency	Start Date	Finish Date	
Over the Counter Medicines				
Takes medication without any problems	Yes / No			
Difficulty remembering to take medication	Yes / No			
Blister Pack/dosette box in house	Yes / No	Blister Pack/Dosette		
If yes who prompts medication?				
If yes who fills blister pack/dosette box				
Any problems with compliance with medication?				

Outcome of Today's Visit

	<input type="checkbox"/>
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	<input type="checkbox"/>

Date and Time of Next Appointment	
Date and Time of Assessment	
Signature of Assessor	
PIN No	

Figure 19: Heart Failure Assessment Form (NHS South Warwickshire)

4.5. Care plans for multimorbid patients

This section presents first the Population Intervention Plan for the management of multimorbid patients in the Basque Country. The following section 4.5.2 provides an interesting example of a care plan for multimorbid patients from the TrueBlue study. Section 4.5.3 presents the results of a literature review on care plans and section 4.5.4 reflects the key care coordination components identified in D4.2. These sections will provide the basis for developing further guidance for core care plan development for multimorbid patients in the three C3-Cloud pilot regions.

4.5.1. The Population Intervention Plan in Basque Country

In the Basque Country, OSI ARABA, one of the Healthcare Integrated Organizations (named OSIs) is using the so-called “Population Intervention Plan” (Plan de Intervención Poblacional – PIP) for the management of multimorbid patients and disease management (diabetes, COPD and Heart Failure).⁷²

The PIP lays out a strategy for risk stratification and case management of multimorbid patient population. It focuses on disease management for diabetes, COPD and Heart Failure in Comarca Araba through integrated and patient centred care. It addresses both patients and their carers, and involves cross-sectoral multidisciplinary teams (primary care, hospital care, social services and other organisations). It contains tables compiling intervention plans for both Primary Care and Hospital Care including:

- the activities,

⁷² Plan de Intervención Poblacional (2012). Gestión de Caso: Paciente Pluripatológico Gestión de Enfermedad: Diabetes – EPOC - Insuficiencia Cardíaca. Protocolo de Intervención. Área Integrada de Salud Araba, 6 de Noviembre de 2012.

- the professionals involved,
- the methodology followed, and
- the proper documentation.

It covers also a checklist to be carried out in the hospital. For each activity, it incorporates a scheduling of interventions to perform and to operate according to the PIP.

For example, the Population Intervention Plan has defined the functions of the Care Managing Nurses in primary care and in the hospital – see section 4.5.3.

Figure 20 illustrates care plan elements, embedded in a timeframe of 12 months. In this scenario, diabetes patients follow timed pattern in primary care. It is divided into performances during the initial month, following three, four, six, nine, ten months, and annual. It contains anamnesis, including physical, and psychological assessment, tests such as urine and blood checks, eye revision and EKG during initial and annual revision. Hypertension and chronic foot problems are reviewed regularly, while dietary education, advice on alcohol diet, physical activity, and medication adherence are also part of the regular review and information gathering. The review in months four and ten is performed via telephone appointment.

CONSULTAS PROGRAMADAS CONSULTA / DOMICILIO	INICIAL O MESES	SUCESIVA 3 MESES (SI MAL CONTROL FACTORES RIESGO)	TELEFÓNICA 4 MESES (EXCEPTO LOS VISTOS A LOS 3 MESES)	SUCESIVA 6 MESES	SUCESIVA 9 MESES (SI MAL CONTROL FACTORES RIESGO)	TELEFÓNICA 10 MESES (EXCEPTO LOS VISTOS A LOS 9 MESES)	ANUAL 12 MESES
ANAMNESIS	X			Si precisa			X
EXPLORACIÓN FÍSICA	X						X
VALORACIÓN FUNCIONAL (BARTHEL) -PSICOAFECTIVA - SOCIOFAMILIAR	Annual y según plan de seguimiento						
ANALÍTICA SANGRE Y ORINA	X			Si precisa			X
REVISIÓN OPTALMOLÓGICA	c/3 años sin retinopatía						
RCV (Regicor) *Excepto pacientes con enf. cardiovascular por ser de alto riesgo	X			X			X
EKG	Annual: En caso de cardiopatía						
TENSIÓN ARTERIAL Y FC (toma/registro de AMPA)	X	X		X	X		X
PESO - TALLA- IMC - PESO PACTADO	X	X		X	X		X
TABACO	X			X			X
DERIVACIÓN A DESHABITUACIÓN TABÁQUICA SI PROCEDE	X			X			X
ALCOHOL	X			X			X
DIETA	X	X	X	X	X	X	X
ACTIVIDAD FÍSICA	X	X	X	X	X	X	X
CONSEJO HIPOGLUCEMIA	X	X	X	X	X	X	X
EDUCACIÓN AUTOCUIDADOS	X	X		X	X		X
ADHESIÓN TTO - EFECTOS SECUNDARIOS	X	X		X	X		X
PIE DIABÉTICO - EDUCACIÓN	X	Si riesgo alto		Si riesgo alto o aumentado	Si riesgo alto		X
VACUNACIÓN ANTIGRIPIAL							X
PLAN DE CUIDADOS	Annual y según plan de seguimiento						
CONCERTAR PRÓXIMA CITA	X	X		X	X		X

Figure 20: Primary care treatment of patients with diabetes in Basque Country

4.5.2. An example from the literature review

We have selected a learning example of a care plan for multimorbid patients from the Australian TrueBlue study⁷³. The study was designed to demonstrate the impact of a multimorbid care plan for patients with diabetes and heart disease; it also served as a tool for easier detection of patients with depression. A care plan was designed around *diabetes, coronary heart disease, and depression management* guidelines to prompt implementation of best practices and to provide a single document for information from multiple sources. This care plan template is handed to the patient to help better

⁷³ Schlicht et al. "Safety and acceptability of practice-nurse-managed care of depression in patients with diabetes or heart disease in the Australian TrueBlue study." *BMJ Open* 3, no. 4 (2013). doi:10.1136/bmjopen-2012-002195.

understand diabetes and heart disease. With the organisational help of a nurse, patients set their goals and activities and have an overview of their current health status.

The *TrueBlue* example demonstrates the necessity of

- (1) a reconciled care plan template to be developed from multiple disease guidelines,
- (2) the importance of a care manager / practice nurse to enter information and coordinate the patient care, and
- (3) the GP's clinical judgment to determine which targets should be followed.

TrueBlue recommendations or lessons for the creation of a care plan include the following:

- Multiple guidelines need to be formulated into a single care plan in which practice nurses enter and collate patient information. GPs will need to use clinical judgement to determine which targets should be followed.
- Patient priorities need to be determined and SMART (Specific, Measurable, Attainable, Realistic, and Time-bound) goals developed and written into the care plan to assist GPs making appropriate clinical decisions. This requires that nurses be trained in effective goal setting and problem solving.
- Patient goals and priorities need to be reviewed and updated in the next appointment and the care plan needs to be updated accordingly.
- The care plan should automatically plan recall visits to ensure ongoing continuity of chronic disease management.
- The care plan should assist with case-management tasks by documenting referrals to other healthcare specialists, acting as a communication tool between the healthcare teams, and allowing referrals to be monitored over time.
- The care plan should provide a succinct summary of healthcare information, management targets, and personal goals to enable patients to proactively self-manage their care, while simultaneously providing important information useful for emergency hospital visits or for visits to external health providers.
- The care plan should contain automatic prompts so that all recommended checks are performed and data entered into the clinic's medical records.

The care-plan template used by *TrueBlue*

The *TrueBlue* care plan template can be adapted to include other guidelines and relevant local information as required. Items in double-angle brackets were populated automatically from each practice's electronic medical record and from data entered during the consultations.

<<Practice Name>>

<<Practice Telephone>>

<<TRUEBLUE Care-plan/Review>> (<<Diagnosis>>)

This plan should help you to better understand diabetes and heart disease. It should help plan your preventative care. Leaflets about diabetes, diet, exercise, foot care, and heart disease can be attached to this record.

Patient's Name: <<Patient Full Name>>

Date of Birth: <<Patient DOB>>

Goals to help minimise my risk factors, with help from the practice nurse and my GP: << Guideline based clinical and lifestyle targets>>

Patient goals for the next three months:

Goal – what change do I want to achieve and why?	Barriers – what will make it difficult?	Enablers – what will help?
<<Goal 1>>	<<What makes it difficult 1>>	<<What will help 1>>
<<Goal 2>>	<<What makes it difficult 2>>	<<What will help 2>>

<<Goal 3>>	<<What makes it difficult 3>>	<<What will help 3>>
------------	-------------------------------	----------------------

Three-month review:

Previous goal 1	<<Previous goal 1? Met/partially met/renegotiated>>
Previous goal 2	<<Previous goal 2? Met/partially met/renegotiated>>
Previous goal 3	<<Previous goal 3? Met/partially met/renegotiated>>

Measures	Last Recorded	Previous result -Comments
Weight	<<Current Weight>> kg	
Waist	<<Waist size>> cm	Target <94 (men), <80 (women)
BP	<<Current BP>> mmHg	Target less than 130/80
HbA1c	<<Current HbA1c>>%	Target less than 7.0
Total cholesterol	<<Total cholesterol>> mmol/L	Target less than 4.0
LDL	<<LDL>> mmol/L	Target less than 2.0
HDL	<<HDL>> mmol/L	Target more than 1.0
Triglycerides	<<Triglycerides>> mmol/L	Target less than 2.0
Urine microalbuminuria	<< Normal/raised>>	
Last ECG		
Last professional eye exam	<<Last professional eye test>>	
Doppler checks of circulation in feet	L <<Doppler left Yes/No>>	
	R <<Doppler right Yes/No>>	
Foot exam (pulses, fine touch, skin and nails)	<<Date of foot exam by podiatrist, nurse or doctor>>	
Exercising	<<Exercise at/above guideline>>	Target 30 min per day, 5 days pw

Depression

Depression can be hard to detect in people with long-term medical conditions, but it can have a big impact on their diabetes and heart disease. The Patient-Health Questionnaire (PHQ-9) score helps identify those who might be at risk.

PHQ-9 score for depression	<<PHQ-9 Score>>
Previous episode of depression or anxiety	<<Previous depression/anxiety? Yes/No>>
If there were previous episodes how were they treated?	<<Treatment? None/medication/therapy/both>>
Currently taking anti-depression medication?	<<Taking anti-depression medication? Yes/No>>
Currently seeing a mental health worker?	<<Attending mental health worker? Yes/No>>

MEDICAL HISTORY	<< Medical history>>
MEDICATIONS	<<Current Medications>>
Other medications	<<Over-the-counter medications>>
ALLERGIES	<<Clinical details: allergies>>
ALCOHOL	<<Clinical details: alcohol>>
SMOKING STATUS	<<Clinical details: smoking>>
REVIEW DATE:	<<Proposed review date>>
REFERRALS:	<<List of referrals and area of expertise>>
Doctor signature	
Doctor name:	<<Doctor Name>>
Date:	<<GPMP date>>

C3-Cloud development of guidance for multimorbid patient care plans can benefit from the TrueBlue study recommendations for two main reasons: first, the focus on reconciling several clinical guidelines for multimorbid patients; and second, two of the diseases considered in the TrueBlue (diabetes type II and heart disease) are also studied by C3-Cloud.

UPDATE

The health care professional facing application of C3-Cloud displays all relevant patient information, including conditions and diagnoses, current and past medications, allergies, immunisations, procedures, encounters, care barriers, and observations including lab results, vital signs, and risk scores.

Setting up a new care plan always starts with the patient summary and which condition to address, and which existing medication to import. In the care plan management, the HCP can set goals and corresponding activities and include educational material if needed. The activities can then be filtered according to responsibility, e.g. patient, HCP, care team members.

Create New Care Plan

Title

Title

Diseases

Diabetes Heart Failure Renal Failure Depression

Addressed Conditions

Patient doesn't have registered conditions

Care Team

☐ Assign existing care team

Create New Care Team

Add New Member

Q Search

Anna Svensson, Practitioner

Role Organization Manager

Code Q Search ☒ Set as manager

Create & Continue

Figure 21 Care Plan Initiation Screen


C3-CLOUD

[Home](#)
[My Patients](#)
[Activities](#)
[Messages](#)

1

GB

Logout



Sven Karlsson

Patient

Age: 76 (16 Aug 1942)

Gender: male

E-mail: svenkarlsson@example.com

Phone: (360) 555 1212

Address: Sollidenvägen 29
Östersund 831 43 (home)

Medical Summary

Chronic Disease Profile

Care Plan

Care Team

Previous Care Plans

Clinical Docs

Notifications

Safe Message

All

Lipid Management

Diet & Lifestyle

Patient Education

Complication Management

BP Management

Glucose Management

Goals

+ Add New Goal

Display Inactive Goals

	Title	Status	Category	Start Date
📌	Eye Disease Screening	Sustaining	Safety	21 Jul 2009
📌	Avoid Microangiopathy	Sustaining	Safety	21 Jul 2009
📌	Decrease Non-HDL Cholesterol	Sustaining	Safety	21 Jul 2009
📌	Keep blood pressure under control	Sustaining	Safety	21 Jul 2009
📌	Keep HbA1c under 6.5% mmol/l	Sustaining	Safety	21 Jul 2009
📌	Comply with dietary restrictions	Sustaining	Dietary	13 Aug 1999

Activities

+ Add New Activity

Display Inactive Activities

Assigned To: Anyone Me Care Team Patient

	Title	Start Date	Actions
👤	Annual Control visit with Dr. Anna Svensson	20 Jul 2010	📅 🗨️
👤	6 monthly Control visit with Dr. Anna Svensson	20 Jan 2010	📅 🗨️
👤	3 monthly Control visit with Dr. Anna Svensson	20 Oct 2009	📅 🗨️
👤	Diabetes Education Encounter with Diabetes Nurse Erik Larsson	30 Jul 2009	📅 🗨️

Figure 22 Care Plan Screen

Goals

Title

● Stop Smoking

● Comply with the dietary restrictions. Evaluate every 6 months

● Increase physical activity

● Reduce weight

Activities

Filter By Assignee

Anyone

Title

● Structured assessment of the patients who is self-monitoring blood

● Mediterranean diet with reduced sodium level (salt intake)

● Carer Education

● Dietician

● Sulfonylurea for blood glucose lowering

● HbA1c Test

● Self-measurement of blood pressure

● Submit photo for dietary intake assessment

● Diabetes and Diet Questionnaire

● Metformin 500mg tablets

Education Materials

Title

● Eating Well

Figure 23: Detailed view of the care plan management (example)

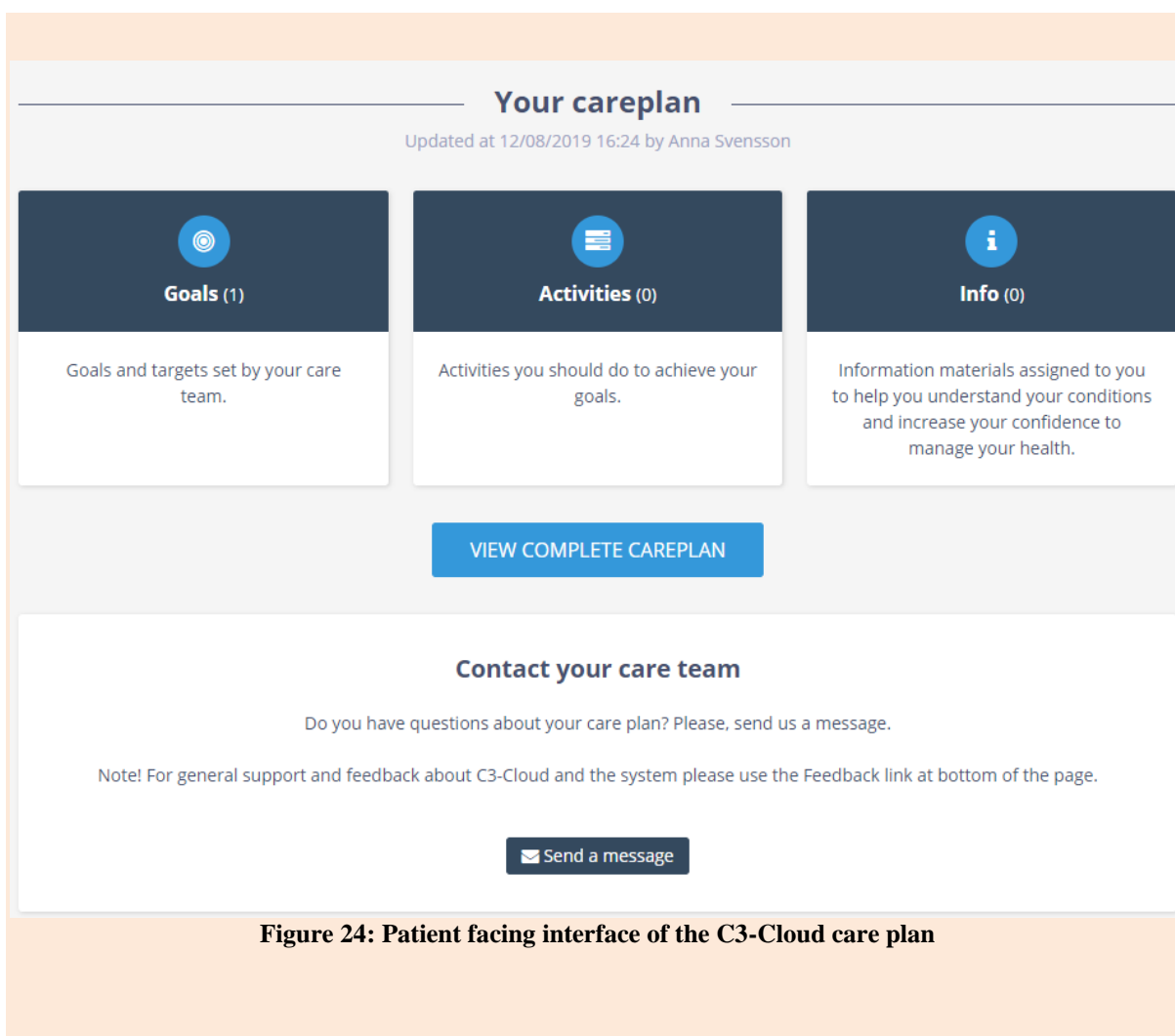


Figure 24: Patient facing interface of the C3-Cloud care plan

4.5.3. Key care plan and pathway elements

In the following, we list selected care plan elements, synthesised from example care plans and a literature review.

Drafting guidance for the improvement and building of new care plans for multimorbid patients requires further detailed analysis of the literature and the actual local pathways in order to define the core components and areas for improvement. Firstly, integrated care requires the involvement of several stakeholders, including a care coordinator / care manager as well as the patient (also social and informal carers), coordination of activities and interpersonal communication, planning of monitoring and follow up, etc.

- **Coordination of activities by a Care Manager**

Usually, a specially trained nurse supporting and coordinating the care across all providers – see for example “Functions of Care Managing Nurses” in Basque Country, at the end of this section.

- **Assessment of multiple conditions by a Multi-Disciplinary Team (MDT)**

Many useful examples from the literature exist regarding MDTs. Guidance and concrete information on the local set up of the MDT will be taken from D4.2 and elaborated together with OSAKIDETZA, SWIFT and RJH representatives.

- **Goal setting⁷⁴**

As described in C3-Cloud deliverables D3.1 and D3.2, a goal is a defined outcome or condition to be achieved in the process of patient care. Goals include patient-defined overarching goals (e.g. alleviation of health concerns, desired/intended positive outcomes from interventions, longevity, function, symptom management, comfort) as well as health concern-specific or intervention-specific goals to achieve desired outcomes.

- Highest commitment when the goal is important and achievable.
- Goals affect the direction, effort, and persistence of care.
- Use SMART goals: Specific, Measurable, Attainable, Realistic, and Time-bound⁷⁵.

It is particularly important for care plan personalisation that the goals are

- elaborated together with the patient;
- taking into account the patient's personal values and beliefs;
- appropriately balancing clinical evidence of benefit and harm, and individual preferences.

- **Self-management guidance & home support**

- Educational material, Self-care plan.
- Health coaching.
- Affected by:
 - The illness.
 - Personal attributes.
 - Attributes of health providers.
 - Cultural and social factors.
- Self-management skills need to be assessed before the right intervention is offered⁷⁶

- **Requirements for self-management support (health professionals)⁷⁷**

- Assist, Inform.
- Person centred skills.
- Behaviour change skills.
- Organizational / system skills.
- (Nurses) need to be trained in effective goal setting and problem solving⁵.

- **Treatment consolidation⁷⁸**

- Client defined problems.

⁷⁴ Battersby, Malcolm. Care Planning and Goal setting in Diabetes management. How can we provide self-management support to people with chronic conditions? Flinders Human Behaviour and Health Research Unit. Flinders University

⁷⁵ Morgan, Coates, and Dunbar. Using care plans to better manage multimorbidity. *The Australasian Medical Journal* 8.6 (2015): 208-215. doi:10.4066/AMJ.2015.2377.

⁷⁶ Battersby, Malcolm. Care Planning and Goal setting in Diabetes management. How can we provide self-management support to people with chronic conditions? Flinders Human Behaviour and Health Research Unit. Flinders University

⁷⁷ Ibid.

⁷⁸ Ibid.

- Client defined goals.
- Medical needs / management aims according to evidence based guidelines.
- A prioritised action plan.
- Community education or resources.
- Community services.
- Planned review and follow-up.
- Agreed upon with the GP and other health professionals.
- Planned appointments, tests, medication lists, etc.
- **Care management consolidation**
- **Activities by the Patient / GP / Care Manager (at home, GP office, or other location)**
 - Treatment.
 - Monitoring.
 - Life style.
 - Communication, reminders, appointments and tests, alarms, etc.
- **Evaluation of outcomes**

In addition to the above, regular updates of a care plan, ensuring (reading) access for the patient (short and non-technical) as well as required ICT support required must be ensured.

The most prominent stakeholders involved in care plans include the GP, Nurse, Specialists and the Multidisciplinary Team (MDT). Within this consortium, a Care Manager (CM) should be assigned. The care manager can either be the GP or one of the specialists the patient tends to address most frequently. The care manager could further be a specialised nurse, trained in assessing the patient's situation, leading the communication, educating the patient and helping to monitor the patient's status.

According to NICE social care guideline NG27, the members of the so called **community-based multidisciplinary team** could include⁷⁹:

- GP;
- Community nurse;
- Community mental health practitioner;
- Social worker;
- Housing officer;
- Voluntary sector practitioners;
- Community pharmacist;
- Therapists;
- Registered manager.

In the Population Intervention Plans (PIP) from the Basque Country (OSI Araba) the following functions of the Care Managing Nurses in primary care and in the hospital have been defined:

1. Case Management Nurse

Support to the Primary Care team in the care and planning of care for the patient and caregiver.

- Comprehensive valuation.
- Care planning.

⁷⁹ <https://www.nice.org.uk/guidance/ng27/chapter/Recommendations#terms-used-in-this-guideline>

Planning, coordination and activation of resources

- Notification to the Primary Care team of the patient's contacts with the health services according to care pathways I and III.
- Resource management: appointments, materials and social resources.
- Continuity of Care Management.
- Coordination with other professionals, levels and areas of care of information and communication circuits.

Support and facilitation

- Updated directories of resources and contacts.
- Registration of the activities and interventions carried out.

Participation

- Interdisciplinary working groups.
- Elaboration of guides, protocols, joint circuits.
- Clinical sessions.

Training

- Clinical sessions and training activities for professionals.

Research

- Development and participation in research studies.
- Data collection and analysis of results.

Evaluation

- Elaboration of improvement proposals.
- Follow-up of Population Intervention Plan (PIP).
- Evaluation of PIP structure, process and results.
- Registration and incident management.

2. Hospital Liaison Manager [Nurse]

Support to the personnel of the care unit, the patient and caregiver.

- Comprehensive assessment at admission and discharge (functional, cognitive, affective and social) using validated scales.

Planning, coordination and activation of resources

- Coordination with EGC of patient contacts stratified in case management and disease management with the hospital.
- Coordination with all other professionals involved in the process.
- Participation in the nursing report at discharge and care planning.

Support and facilitation

- Resource information for professionals and professionals.
- Management of hospital consultations and at discharge.
- Non-face-to-face consultations, via telephone or e-mail, with users, professionals and internals (primary care, subacute, acute hospital).

Participation

- Interdisciplinary working groups.
- Elaboration of guides, protocols.
- Clinical sessions.

Training

- Clinical sessions and paraprofessional training activities.

Research

- Development of and participation in research studies.
- Data collection and analysis of results.

Evaluation

- Elaboration of improvement proposals.
- Follow-up of the Population Intervention Plan (PIP).
- Evaluation of the structure, process and results of the PIP.
- Registration and incident management.

Regardless of the specific actor, the pathway for a patient with co- or multimorbidity has to be clear. To achieve such a flow, as a first action, the necessary activities need to be defined.

A useful tool in this sense is the NICE “Baseline assessment tool for Transition between inpatient hospital settings and community or care home settings for adults with social care needs”, NICE social care guideline NG27⁸⁰. In particular, regarding, discharge from hospital, it formulates the following action plan:

- Discharge coordinator.
- Communication and information sharing.
- Discharge planning.
- Early supported discharge.
- People at risk of hospital readmission.
- Involving carers.
- Support and training for carers.
- After transfer from hospital.

UPDATE

The effects of integrated care: a systematic review⁸¹ of UK and international evidence

There are inherent challenges when defining models of integrated care, given the lack of agreed definition and clear boundaries to the term. Most of the included models of integrated care were complex and multi-element interventions. Many models incorporated multiple elements, and it was often challenging to elucidate the form and components due to limited reporting. The elements contained within them could be divided into four main categories:

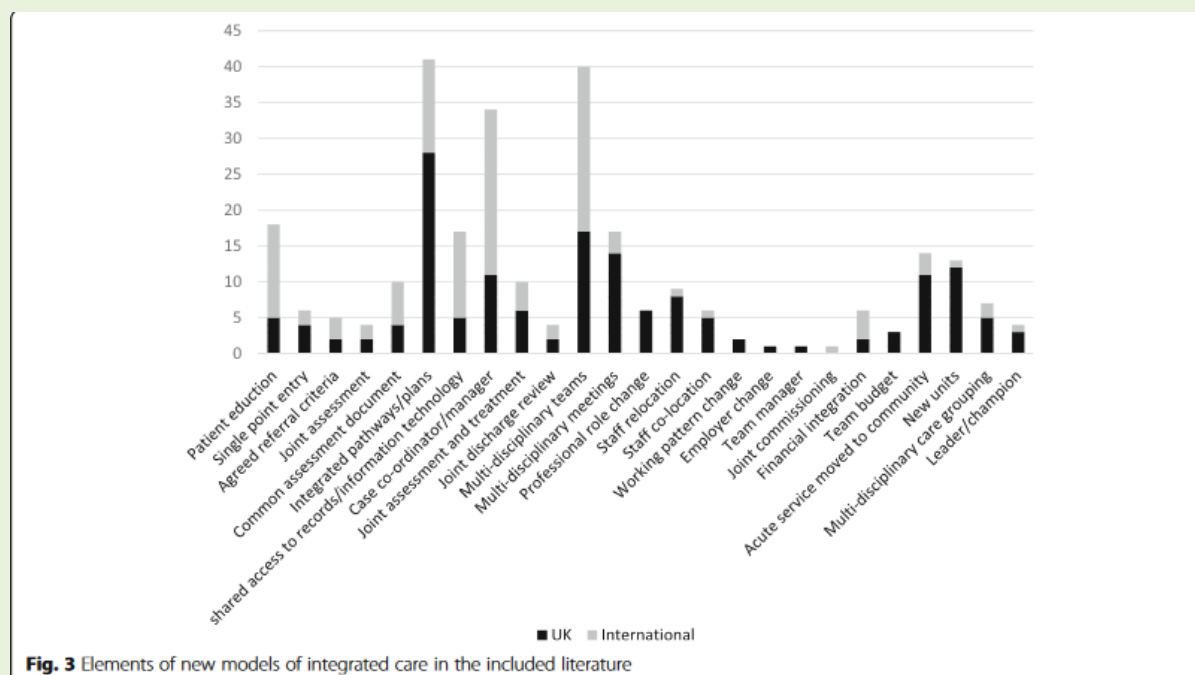
- with a focus on improving patient care directly;
- focused on making changes to organisations and systems;
- focused on changing staff employment or working practices;
- addressing financial or governance aspects of integration.

The greatest number of elements identified in a single intervention was nine, which compared with other integrated care initiatives containing a single element. Typically, models contained four to six

⁸⁰ Baseline assessment tool for Transition between inpatient hospital settings and community or care home settings for adults with social care needs (NICE social care guideline NG27), <https://www.nice.org.uk/guidance/ng27/resources/baseline-assessment-tool-excel-2186962381>

⁸¹ Baxter, S., Johnson, M., Chambers, D., Sutton, A., Goyder, E., & Booth, A. (2018). The effects of integrated care: a systematic review of UK and international evidence. *BMC health services research*, 18(1), 350.

elements. The following figure summarises elements of new models of integrated care in the included studies.



As a summary, the review found that integrated care leads to:

- an increase in patient satisfaction;
- increased perceived quality of care (staff perception in the UK studies, staff and patient perceptions in the non-UK studies);
- can lead to increased/improved patient access;
- reduction in waiting times and out-patient appointments in UK (international literature as a whole was more inconclusive);
- increased satisfaction amongst older, acute and paediatric patient populations following service integration, case management and patient-centred medical home interventions;
- staff perceptions of increased quality of care following service re-design, case management or integrated pathway interventions in hospital or primary care for older adults, general caseloads or patients with C-difficile infection;
- a positive effect on quality of care in terms of staff or patient perception.

Evidence regarding the following outcomes was rated as inconsistent:

- number of clinician contacts (five indicated a reduction, and three an increase);
- number of GP appointments;
- length of stay (24 studies reported a reduction, two studies found an increase, and 11 no effect);
- unscheduled admissions (10 studies found a reduction, two an increase, and nine no effect);
- number of admissions (24 studies found a reduction, five reported an increase, and nine no effect) although considered alone the systematic reviews provided stronger evidence of a reduction;

- re-admissions (nine studies, with eight from the same authors reported no effect, two studies found an increase and two a reduction);
- attendance at accident and emergency (nine studies found a reduction, two an increase and eight no effect);
- quality of care standards (two studies reported an increase and one no difference);
- staff work experience (two reviews of UK studies indicated improved experience, and one international study indicated no difference).

The reviewers identified little evidence regarding the impact of integrated care models on patient experiences of services, beyond measures of reported patient satisfaction. There seems a need for further attention to how reconfiguration impacts on patients and carers, including whether service users perceive any change, or have greater knowledge of or involvement in services.

4.5.4. Care coordination components identified in D4.2

In this section, we draw on the AHRQ⁸² and the FHIR⁸³ classification described in *D8.1* and use cases from *D3.2*, for care plan development, in order to further adding details to the components identified in the previous section. The following descriptions are largely based on *D4.2 “New Organisational Models for Improved Delivery of Integrated Care”*.

Actors/roles: An actor is an autonomous and intelligent being that is able to perceive and act, i.e. to interpret, determine goals, reason and decide, either independently or in dialogue, negotiation and cooperation with other actors. They include:

- Patient, Care Manager, Care Team health professionals (general practitioners, primary care and hospital nurses, specialists and other professionals), Social workers, Family, Caregivers, other Support Individuals, etc.).

Assessment: Determine the patient's needs for care and for coordination,

- Including physical, emotional, and psychological health;
- Functional status;
- Current health and health history;
- Self-management knowledge and behaviours;
- Current treatment recommendations, including prescribed medications;
- Risk assessment and need for support services;
- It includes observation or plans to capture information about a patient (vitals, labs, diagnostic images, etc.).

Diagnosis: Identification of a condition, disease, disorder, or problem by

- Systematic analysis of the background or history;
- Examination of the signs or symptoms;
- Evaluation of the research or test results;
- And investigation of the assumed or probable causes;⁸⁴
- It includes medical, nursing and social diagnosis.

Treatment or procedure: Plan to modify the patient in some way including

- Drugs prescription;

⁸² <https://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/atlas2014/section3.html>

⁸³ <https://www.hl7.org/fhir/valueset-care-plan-activity.html>

⁸⁴ <http://www.businessdictionary.com/definition/diagnosis.html>

- Nursing interventions;
- Surgery (includes minor) treatment;
- Life style interventions (including education or plan for the patient to consume food of a specified nature);
- Counselling and others;
- Reconciling discrepancies in medication use in order to avoid adverse drug events associated with transitions in care.

Involving other stakeholders:

- Referrals;
- Consult (discuss with, confer with others);
- Share, delegate, assign or entrust tasks;
- Including negotiate responsibility for a particular aspect of that care and facilitate transitions to ensure timely and complete transmission of information or accountability;
- It is key in setting a stable MDT.

Monitoring and review:

- Follow up of symptoms, biomarkers (Blood results, x-rays, Vital signs, etc.), medication adherence, lifestyles, patient/caregiver's experience, health Outcomes and others.
- Jointly with the patient/caregiver, assess progress toward care and coordination goals.
- Monitor for successes and failures in care and coordination.
- Refine the care plan as needed to accommodate new information or circumstances and to address any failures.
- Provide necessary follow up care to patients.

Patient empowerment and self-supported management:

- Tailor education and support to align with patients' capacity for and preferences about involvement in their own care.
- Education and support include information, training, or coaching provided to patients or their informal caregivers to promote patient understanding of and ability to carry out self-care tasks, including support for navigating their care transitions, self-efficacy, and behaviour change.

Care plan drafting:

- Establish and maintain a personalised plan of care, jointly created and managed by the patient/formal and informal caregivers and health care team, which outlines the patient's current and longstanding needs and goals for care and/or identifies coordination gaps.
- The personalised plan is designed to fill gaps in coordination, establish patient goals for care and, in some cases, set goals for the patient's providers.
- Ideally, the care plan anticipates routine needs and tracks current progress toward patient goals.
- It includes: create a new care plan, review and reconcile multiple plans, update existing care plan, discard care plan and share care plan.
- It includes encounter or plans to meet or communicate with the patient (in-patient, out-patient, phone call, etc.).

Interpersonal communication: Describing information and communication channels amongst actors. Examples include:

- Face-to-face interactions, telephone conversations, email, and letters.

- Health IT-enabled coordination consists of using tools, such as electronic health records (EHR), patient portals, or databases, to communicate information about patients and their care between health care entities (health care professionals, care teams, or health care organizations) or to maintain information over time.

4.6. Interlinking care pathways, care plans and clinical guidelines

The previous sections described current care plans and care pathways in practice, as well as developed initial guidance for the development of integrated care pathways and personalised care plans for multimorbid patients. Some of the key elements that characterise integrated, collaborative care pathways and care plans can be summarised as follows:

- ✓ **Coordination of care activities by a Care Manager**
 - e.g., Care Managing Nurse, GP in a community based team, etc.
- ✓ **Assessment by MDT**
 - Team assesses physical, emotional and psychological health.
 - In-depth interview of current health and health history.
- ✓ **Diagnosis by MDT**
- ✓ **Goal setting**
 - Patient and HCP defined goals.
 - Identification of treatment value.
 - Long term motivation.
- ✓ **Treatment and procedures**
 - Medication reconciliation with MDT as required.
- ✓ **Support to self-management:**
 - Lifestyle and dietary advice.
 - Behavioural skill change.
 - Support organisational skill change.
 - Organised discharge and home support.
- ✓ **Monitor progress**
 - Follow up of symptoms and test results.
 - Assess progress towards goal achievement.
- ✓ **Regular review by Care Manager.**
- ✓ **Care coordination for transition**
 - e.g., hospital discharge coordinated by a Hospital Liaison Nurse or similar (Discharge Coordinator).

It is particularly important for care plan personalisation that the goals are

- elaborated together with the patient;
- taking into account the patient's personal values and beliefs;
- appropriately balancing clinical evidence of benefit and harm, and individual preferences.

These care pathways and care plans make use of clinical guidelines for different chronic conditions.

The reconciliation of clinical guidelines is further elaborated in section 4.8 based on the C3-Cloud deliverable D7.1 and section 4.9.

Figure 25, below, illustrates how integrated care pathways, care plans and clinical guidelines interlink on a high level. The clinical guidelines for several chronic conditions (e.g., kidney disease, chronic heart failure, diabetes type II and depression) feed into the care plans and potential conflicts are subject to reconciliation. The NICE multimorbidity guideline also feeds into the ICT supported creation of an individualised care plan for the multimorbid patient, which is shared across and allows access for the multi-disciplinary team. The patients themselves have access to their personal care plan ("My care plan") which provides summarised and understandable information for a layperson.

The analysis has shown that the adopted four stages in an integrated care pathway characterise best the patient status and transitions of care for multimorbid patients: (1) stable patient out of hospital care; (2) unstable patient out of hospital care; (3) patient in hospital care and (4) hospital discharge preparation. The shared care plan is thus carried out along the integrated care pathway stages.

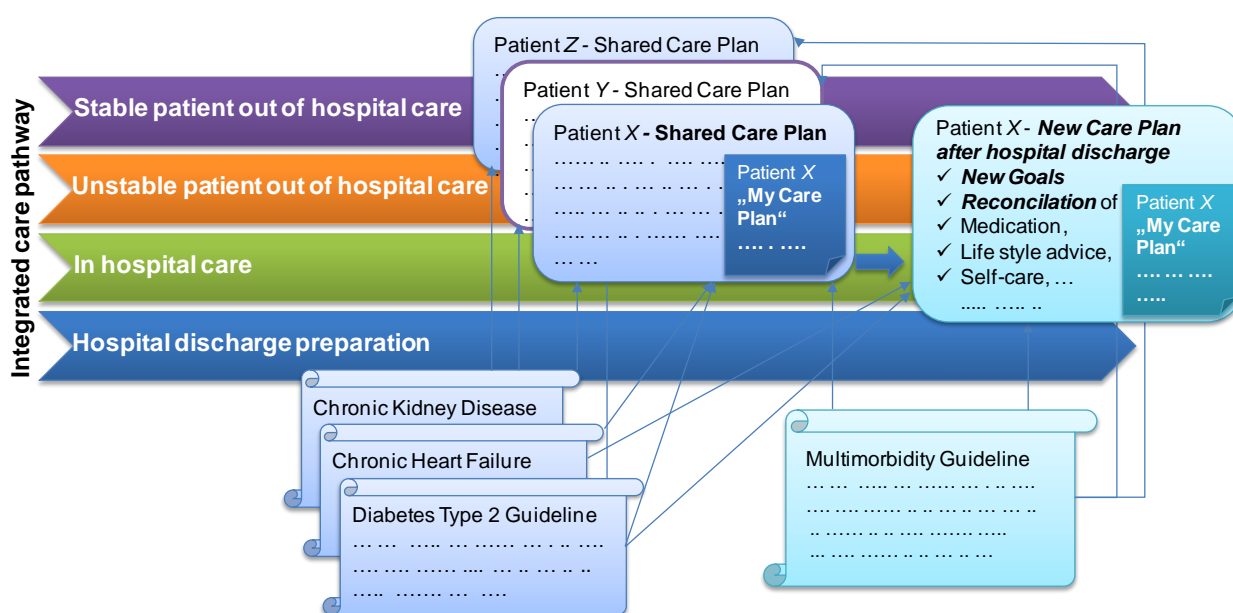


Figure 25: Relation between integrated care pathways, care plans and clinical guidelines

UPDATE

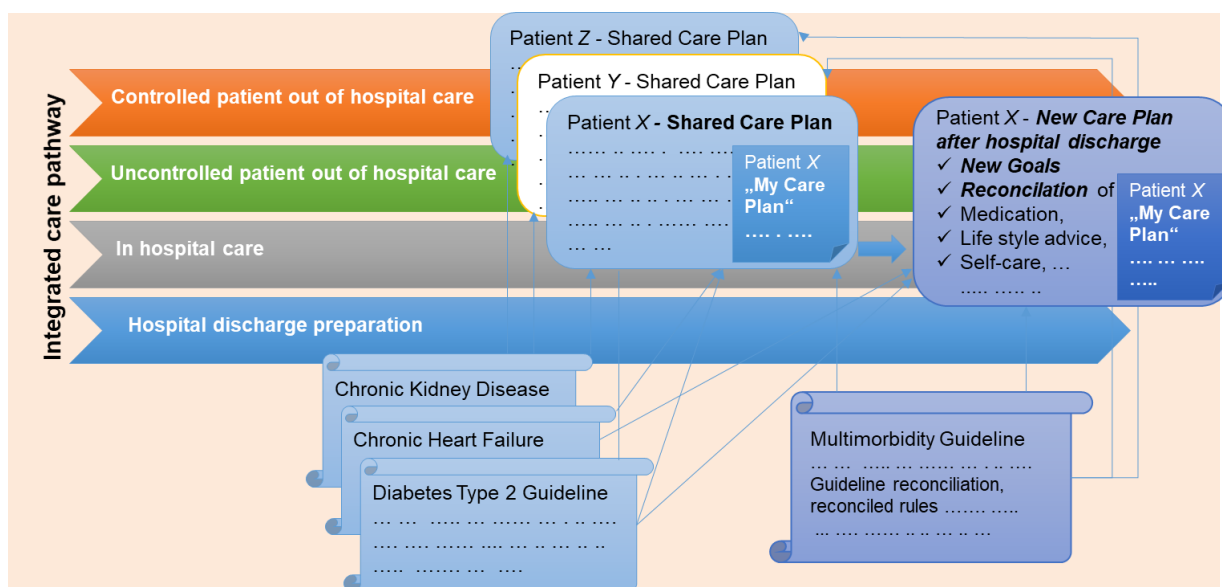


Figure 26: Relation between integrated care pathways, care plans and clinical guidelines (updated)

The previous figure has been updated, changing “stable” and “unstable” to “controlled” and “uncontrolled” (see also section 4.3). The basis in literature and interviews with the pilot sites reveal that currently no multimorbidity guideline exists and thus in most cases no pathway for multimorbid patients. As mentioned above, **care pathway** is different from a patient's **care plan**, **although interlinked**. A **care pathway** represents the ideal way to manage a patient population with a specific problem or long-term condition. A **care plan** is for an individual. The **care pathway** provides recommendations which should be included **and** enacted within a **care plan**. Care plans promote self-

management by encouraging patients to take an active role in their own care. Care plans are useful in educating patients about their condition, and include their individual clinical circumstances, their risk-factors, co-morbidities and management, as recommended by the care pathway. The patient's care plan will change as their risks change and complications occur, as opposed to the pathway which is a rigid overview of recommendations and only changes with the evidence.⁸⁵ Guidelines are tools used to improve the quality of healthcare by recommending a recognised best practice approach at a certain stage of a disease or condition, i.e. in a care plan or care pathway process.

The C3-Cloud project achieved a major part towards the creation of a true multimorbidity pathway, by identifying the local resources, reconciling clinical guidelines, and creating a system used in daily practice. All pilot sites stated that the main benefit of C3-Cloud is a much-improved communication between HCPs but also with the patient, easier access to information, and the strengthening of patients' self-care.

⁸⁵ Care pathways for long-term conditions: Using type 2 diabetes as an example. BPJ: 47, October 2012.

<https://bpac.org.nz/BPJ/2012/October/carepathways.aspx> Accessed 15/04/2020

4.7. Medication reconciliation concepts

This section provides a brief review of the literature on medication reconciliation, focusing on key concepts relevant to C3-Cloud. Medication reconciliation is a formal process for creating the most complete and accurate list possible of a patient's current medications and comparing the list to those in the patient record or medication orders⁸⁶, including the name, dosage, formulation, frequency, timings and route⁸⁷. The intent is to avoid errors of omission, duplication, incorrect doses or timing, and adverse drug-drug or drug-disease interactions. Medication reconciliation enables the respective personnel (GP, Specialist, Hospital, etc.) to make the most appropriate decision for describing. According to the Medication Guidelines of the College and Association of Registered Nurses of Alberta, it involves⁸⁸:

- | |
|---|
| ✓ A systematic and comprehensive review of all medication a client is taking including complementary and alternative medications; it is also known as a best possible medication history (BPMH) |
| ✓ Compiling an accurate and current medication list utilizing two sources of information (e.g. client and the electronic health record) |
| ✓ Using the medication list at all transitions of care to create medication orders or compare orders to what the client should be taking |
| ✓ Identifying any discrepancies and bringing them to the attention of the health-care team and client |
| ✓ Resolving all discrepancies |
| ✓ Documenting and communicating any resulting changes and the reasons why |

The following is a list of sources that may be used to obtain an accurate medication history, identified by the NHS Grampian Medicines Reconciliation Protocol⁸⁹:

- | |
|---|
| ✓ Patient Interview |
| ✓ Carer / Relative Interview |
| ✓ Patient's Own Drugs |
| ✓ GP Letter |
| ✓ GP Practice patient admission summary |
| ✓ Emergency Care Summary (ECS) or Key Information Summary (KIS) printout from trackcare/web - it is important to check the date of last upload for ECS/KIS at the top of the sheet as there are occasional system disruptions and possible delays in the upload of information to ECS/KIS. Note that not all medications will be on the ECS/KIS information if they are hospital/out-patient-prescribed medications, trial or over-the-counter medication |
| ✓ Medicine Administration Record Sheet (MAR sheet) – used in care homes and for level 3 medication management patients |
| ✓ GP repeat prescription slip (right hand side of script) |
| ✓ GP phone call |
| ✓ Community pharmacy |

⁸⁶ Barnsteiner, Jane H. Chapter 38. Medication Reconciliation. In *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*, 459-72. Vol. 2. (2008) AHRQ.

⁸⁷ NHS Grampian Medicines Reconciliation Protocol (2017).
http://foi.nhsgrampian.org/globalassets/foidocument/dispublicdocuments---all-documents/Med_Rec_711_0115.pdf

⁸⁸ Medication Guidelines. College and Association of Registered Nurses of Alberta (2015)
http://www.nurses.ab.ca/content/dam/carna/pdfs/DocumentList/Guidelines/MedicationGuidelines_Mar2015.pdf

⁸⁹ NHS Grampian Medicines Reconciliation Protocol (2017).
http://foi.nhsgrampian.org/globalassets/foidocument/dispublicdocuments---all-documents/Med_Rec_711_0115.pdf

✓	Nursing home phone call
✓	Case notes/previous discharge prescription/eIDL if recent
✓	Community Nurse
✓	Hospital pharmacy records
✓	Recent patient-held compliance chart
✓	Hospital clinic letters – used as guide only, not as single information source

The following provides an overview on existing concerns of medical reconciliation: discharge and evaluation of clinical guidelines.

A high number of medication discrepancies occur at discharge affecting a substantial proportion of patients, with omissions in medications representing the most common type of discrepancy noted at discharge. It is a patient safety activity that would seem to demand a high degree of multidisciplinary cooperation or collaboration to maximize the impact from the effort⁹⁰. In a 2001 publication, Rozich and Resar quantified discrepancies during key transition points such as hospital admission, intra-hospital transfer, and discharge⁹¹. Variances between medications patients were taking prior to admission and their admission orders ranged from 30 percent to 70 percent in two literature reviews^{92,93}. Further, Gleason KM, McDaniel MR, Feinglass J, et al. note that 36 percent of patients had errors in their admission medication orders with the majority of these occurring during the medication history gathering phase⁹⁴. Three main sources of information are consulted to reconcile medications at discharge and create the Best Possible Medication Discharge Plan (BPMDP)⁹⁵:

✓	Best Possible Medication History (BPMH) of medications taken prior to admission
✓	Medication administration record (MAR) from the last 24 hours (or most current medication profile) of medications taken during hospitalization
✓	Discharge medication orders for new medications to be taken post-discharge

A 2014 study states that despite having multiple guidelines for the treatment of hypertension, the guidelines agree in almost all cases⁹⁶. Additionally, when comparing the tools to identify potentially inappropriate medication (PIM), i.e. the Beers Criteria and STOPP/START criteria, it was found that 1) the Beers and STOPP Criteria can be used complementary to increase sensitivity to detect adverse outcomes and 2) future updates to the individual Criteria should learn from each other to broaden and

⁹⁰ Canadian Agency for Drugs and Technologies in health. 2012. Medication Reconciliation at Discharge: A Review of the Clinical Evidence and Guidelines. *Rapid Response Report: summary with critical appraisal*. <https://www.cadth.ca/media/pdf/htis/april-2012/RC0339%20-%20Medication%20Reconciliation%20Final.pdf>

⁹¹ Rozich JD, Resar RK. Medication safety: one organization's approach to the challenge. *J Clin Outcomes Manage*. 2001;8(10):27–34.

⁹² Cornish PL, Knowles SR, Marchesano R, et al. Unintended medication discrepancies at the time of hospital admission. *Arch Intern Med*. 2005;165(4):424–9.

⁹³ Gleason KM, Groszek JM, Sullivan C, et al. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. *Am J Health Syst Pharm*. 2004;61(16):1689–95.

⁹⁴ Gleason KM, McDaniel MR, Feinglass J, et al. Results of the Medications At Transitions and Clinical Handoffs (MATCH) Study: an analysis of medication reconciliation errors and risk factors at hospital admission. *J Gen Intern Med*. 2010;25(5):441–7.

⁹⁵ Medication reconciliation in acute care getting started kit. Edmonton: Canadian Patient Safety Institute; 2011

⁹⁶ Marissa Salvo, and C. Michael White. Reconciling Multiple Hypertension Guidelines to Promote Effective Clinical Practice. *Annals of Pharmacotherapy* 2014 (2014), Vol. 48(9) 1242–1248
DOI:10.1177/1060028014540452

strengthen the evidence-based PIM criteria⁹⁷. Systematic reviews and published evidence suggest some common drug groups associated with preventable drug related admissions especially in the elderly^{98,99}. It becomes apparent that using CDS (clinical decision support) tools, such as STOPP/START, is highly recommended¹⁰⁰.

As the above demonstrates, medication reconciliation should focus on the best possible documentation (i.e. medication history, patient EHR, pharmacy records, clinical discharge records) and an enhanced role of communication between the respective parties (GP, Nurses, Specialist, Pharmacist, Hospital). Consequentially, in the C3-Cloud set-up, an underlying CDS tool such as STOPP / START needs to be considered to help making the most appropriate decisions for describing. As patients with multiple prescribed chronic medications are at higher risk for unintentional discontinuation following hospital discharge, and intensive care unit (ICU) stay during hospitalization, this increases the risk of medication discontinuation even further¹⁰¹. Hence, due to the architecture of the C3-Cloud, documentation and communication should improve significantly: The software should be able to compile a most accurate medication history, potentially set reminders for GPs, Nurses or other personnel to remind the patients of their descriptions and, taking into account possible monitoring data from home monitoring or regular patient review visits, risks of adverse drug reactions should decrease. Additionally, with the help of the MDT, reconciliation should also improve.

The AHRQ Medications at Transitions and Clinical Handoffs (MATCH) Toolkit for Medication Reconciliation¹⁰² illustrates the path in changing current medication reconciliation processes upon admission and discharge before. AHRQ has defined essential principles to design the medication reconciliation process:

✓	Develop a single medication list (“One Source of Truth”), shared by all disciplines for documenting the patient’s current medications.
✓	Clearly define roles and responsibilities for each discipline involved in medication reconciliation.
✓	Standardize and simplify the medication reconciliation process throughout the organization, and eliminate unnecessary redundancies (the flowchart of the current process can help you identify these redundancies).
✓	Make the right thing to do the easiest thing to do within the patterns of normal practice.
✓	Develop effective prompts or reminders for consistent behaviour if true forcing functions (i.e., required reconciliation step presented to the physician during admission order entry within an EHR are not possible).
✓	Educate patients and their families or caregivers on medication reconciliation and the important role they play in the process.
✓	Ensure process design meets all pertinent local laws or regulatory requirements. Linking medication reconciliation to other strategic goals (e.g., heart failure publicly reported process

⁹⁷ Brown JD, Hutchison LC, Martin BC (2016) Comparing the Tools to Identify Potentially Inappropriate Medications in the Elderly and Future Research Directions. *J Gerontol Geriatr Res* 5: 321. doi:10.4172/2167-7182.1000321

⁹⁸ Howard R et al. Which drugs cause preventable admissions to hospital? A systematic review. *Br J Clin Pharmacol* (2006); 63:2; 136-147

⁹⁹ Pirmohamed M et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. *BMJ* (2004); 329; 15-17

¹⁰⁰ NICE Guidance – Medicines Optimisation: the safe and effective use of medicines to enable the best possible outcomes, published March 2015

¹⁰¹ Institute of Medicine of the National Academies. Preventing Medication Errors: Quality Chasm Series. 2006. <http://iom.edu/Reports/2006/Preventing-Medication-Errors-Quality-Chasm-Series.aspx>. Accessed December 1, 2011.

¹⁰² Medications at Transitions and Clinical Handoffs (MATCH) Toolkit for Medication Reconciliation. AHRQ Publication No. 11(12)-0059, Revised August 2012

of care measures related to discharge instructions on medications) and/or other initiatives (e.g., a hospital project working on improving patient satisfaction related to pain

Figure 27, below, displays the state of medication reconciliation upon admission before the redesign. During this initial admission process, the patient's medication history is obtained by multiple professionals who do not communicate with one another. It is, documented in different ways, leading to ordering decisions based on the list of the patient's medication prior to admission and patient's clinical status, result in discrepancies in ordering decisions. Further, due to the lack of a standardised process for reconciliation, an increased time is spent on identifying and verifying the correct medication.

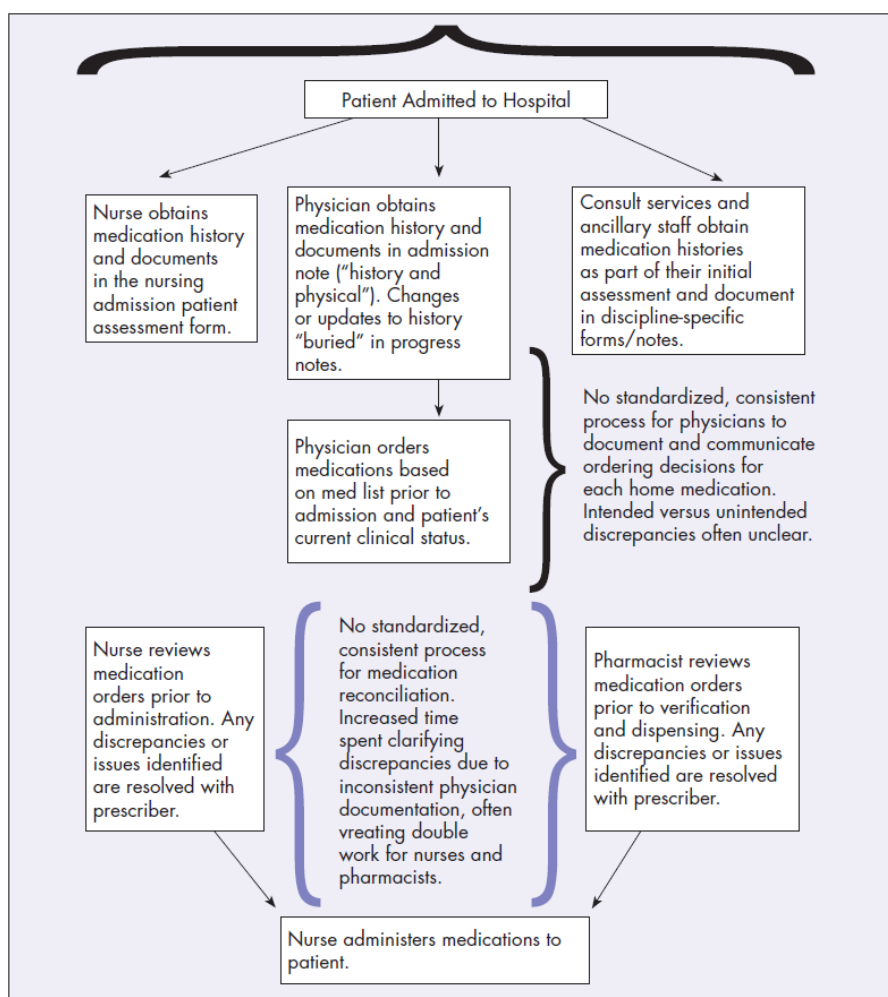


Figure 27: Medication reconciliation upon admission: high-level process map before redesign, AHRQ 2012

Figure 28, below, illustrates the hospital admission scenario after redesign of the process. A “Med Profile” (or “One Source of Truth”) is established and it is central to a working medication reconciliation process. It provides a single location for documenting and confirming home medications, shared by all disciplines. This document becomes the sources for review and reconciliation of inpatient and outpatient medications, while changes and updates to home medications become clearly accessible and up-to-date for future admission.

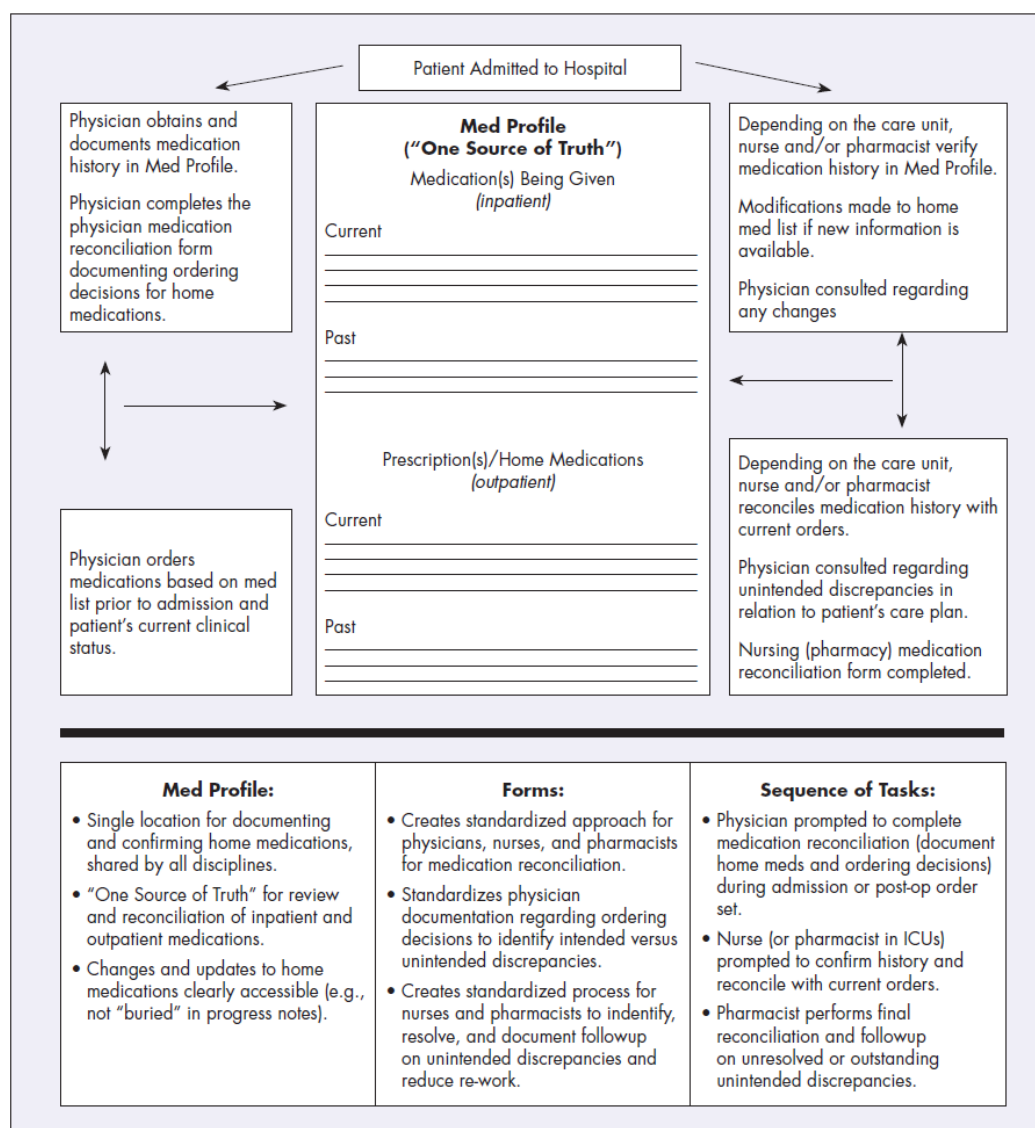


Figure 28: Medication reconciliation upon admission: high-level process map after redesign, AHRQ 2012

Similarly, the medication reconciliation upon discharge, Figure 29, below, shows the same issues as the admission process before redesign: inconsistent and non-standardized documentation and practice to perform medication reconciliation. The patient is discharged in no consistent manner.

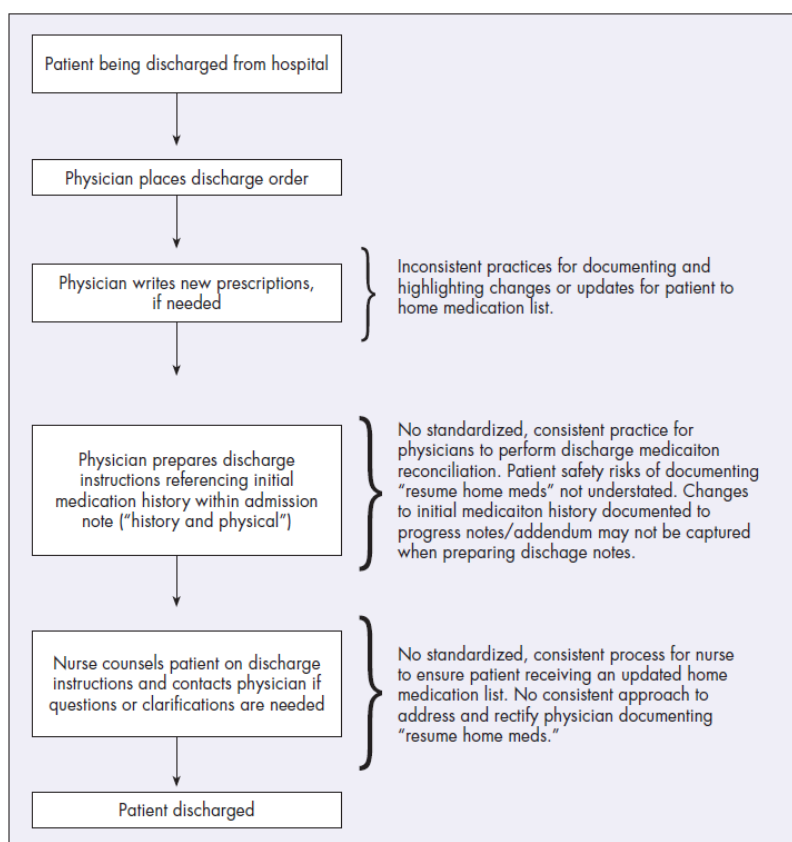


Figure 29: Medication reconciliation upon discharge high-level process map before redesign, AHRQ 2012

After redesign, the “Med Profile” (or “One Source of Truth”), where the medication is documented before, during and after admission, is used also for medication reconciliation upon discharge. Clear tasks are assigned to physicians, nurses and pharmacists, and the sequence of tasks is specified.

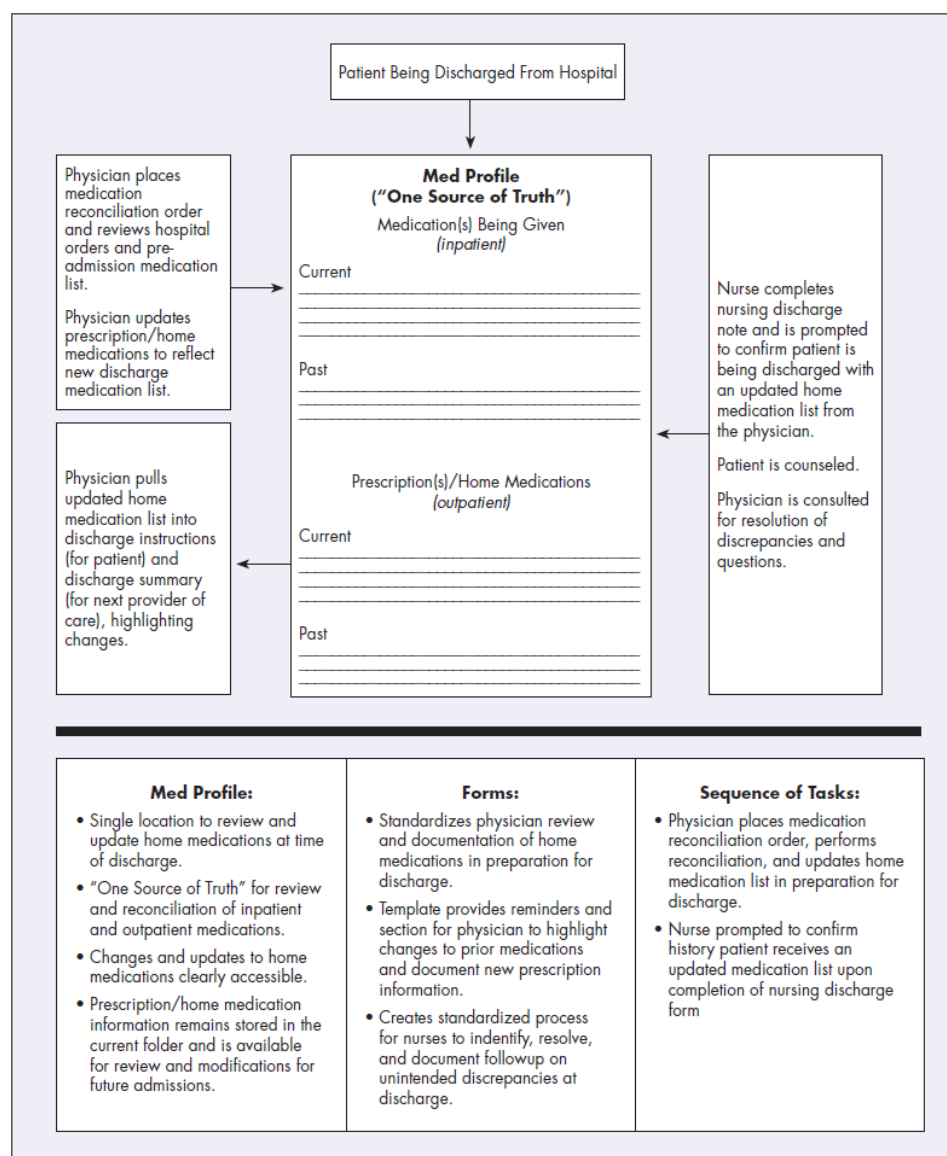


Figure 30: Reconciliation upon discharge: high-level process map after redesign, AHRQ 2012

Figure 31 below presents the medicines optimisation overview from the NICE guidelines¹⁰³:

Medicines optimisation overview

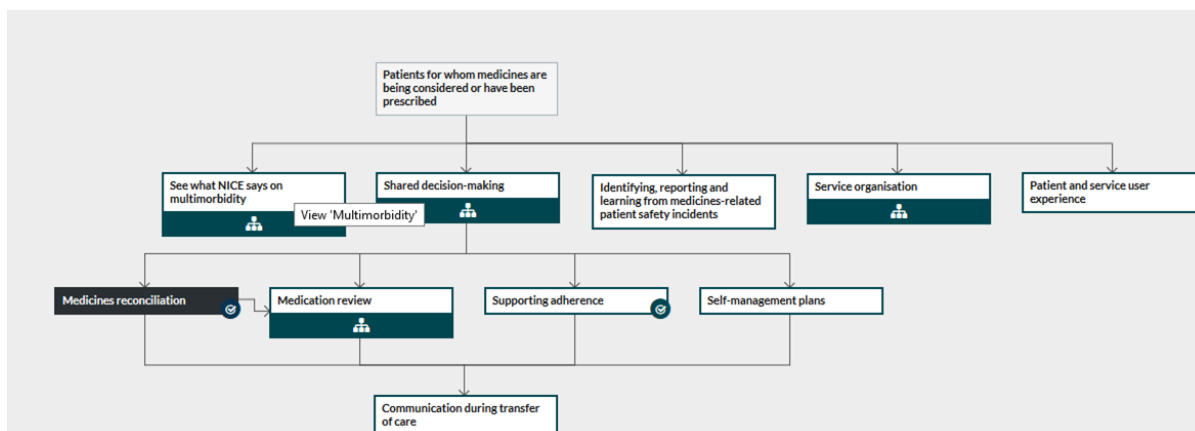


Figure 31: Medicines optimisation overview, NICE

Regarding medicines reconciliation, NICE recommends to:

- ✓ Accurately list all of the person's medicines (including prescribed, over-the-counter and complementary medicines)
- ✓ Carry out medicines reconciliation within 24 hours or sooner if clinically necessary, when the **person moves from one care setting to another** – for example, if they are admitted to hospital
- ✓ Recognise that medicines reconciliation may need to be carried out on more than one occasion during a hospital stay – for example, **when the person is admitted, transferred between wards or discharged**
- ✓ In primary care, carry out medicines reconciliation for all people who have been discharged from hospital or another care setting
- ✓ This should happen as soon as is practically possible, before a prescription or new supply of medicines is issued and within 1 week of the GP practice receiving the information
- ✓ **Involve patients and their family members or carers**, where appropriate, in the medicines reconciliation process

NICE recommends further a multidisciplinary team approach to improve outcomes for people who have long-term conditions and take multiple medicines (polypharmacy). Furthermore, organisations should “involve a pharmacist with relevant clinical knowledge and skills when making strategic decisions about medicines use”.

¹⁰³ NICE Guidance – Medicines Optimisation: the safe and effective use of medicines to enable the best possible outcomes, published March 2015, Available at: <https://pathways.nice.org.uk/pathways/medicines-optimisation#content=view-index>

4.8. Mapping to clinical guidelines in D7.1

D7.1, “Evidence Based Clinical Guideline Definitions and Flowcharts for Individual Chronic Conditions”, provides evidence-based information and guidance covering four types of chronic diseases: Diabetes, CHF, Chronic Kidney Disease and Depression. It has also created numerous flowcharts based on the NICE guidelines for the four conditions. We have analysed D7.1 from the perspective of key integrated care pathway components such as patient information and education, lifestyle (and dietary) advice, self-management, assessment/evaluation, monitoring/review, (drug) treatment, referral, MDT/ coordinated care organisation & communication, side effects and interactions. The following table presents the results of the mapping. The *Italic quotes* indicate that the respective information was not found in D7.1 and was provided by a specialist (from SWFT).

Table 5: Mapping of clinical guidelines

	Diabetes	Chronic heart failure	Chronic kidney disease	Depression
Patient information and education	<ul style="list-style-type: none"> - At diagnosis and annual reinforcement - Insulin therapy <ul style="list-style-type: none"> • Injection delivery advice • Devices and needles • Provide containers for used needles - Discuss neuropathic pain - Erectile dysfunction 	<i>“In practice we would direct the patient to web based information (e.g., provide a link to Patient.Info) or give them a paper Patient Information Leaflet (PIL)”</i>	<ul style="list-style-type: none"> - Enable patients to fully understand and make informed choices - Information individually tailored according to severity - Focus on self-management issues - Education provided by well-trained and experienced professionals - Psychological, social, and coping aspects - Information on causes and treatment option 	<i>“The guideline talks about giving patients and their families information about depression and sleep hygiene”</i>
Lifestyle (and dietary) advice	<ul style="list-style-type: none"> - Dietary advice from healthcare professionals with expertise in nutrition - High-fibre diet - Low-glycaemic-index sources of carbohydrates - Low-fat dairy products and oily fish - Controlled intake of saturated and trans fatty acids - Individualised intake of carbohydrates and alcohol - Discourage the use of specifically marketed food for people with diabetes 	Lifestyle advice, offer stop smoking, assistance and alcohol advice as needed	<ul style="list-style-type: none"> - Encourage to take exercise, achieve a healthy weight, and stop smoking - Provide dietary information - Do not recommend low-protein diet - Advice on potassium salt, calorie, phosphate intake 	<i>“It would be common practice to give advice about alcohol and its effect on mood, having a healthy diet and exercising regularly”</i>

	Diabetes	Chronic heart failure	Chronic kidney disease	Depression
Self management	<ul style="list-style-type: none"> - Insulin injection - Self monitoring of blood glucose - Management of hyperglycaemia - Fitness and exercise 	<ul style="list-style-type: none"> - Provide access to EHR/ medical data to facilitate self management - Enable people with CCF to share in decision-making about their care - Provide information about: condition & prognosis, management options, available support, active participation - Empower patients to make decisions about management by provision of patient data 	<ul style="list-style-type: none"> - Access to medical data (diagnosis, co-morbidities, tests) - Enable people with CKD to participate in decision-making about their care - Support of self-management (includes providing information about blood pressure, smoking cessation, exercise, diet and medicines) 	<i>See above</i>
Measure / evaluate / assess	<ul style="list-style-type: none"> - Blood pressure - QRISK 2 - Liver transaminases - Total cholesterol - HbA1c and glucose - eGFR - Diabetic foot problem - Eye disease 	<ul style="list-style-type: none"> - Blood tests: U+ES, eGFR, FBC - Drug review - Functional capacity: ADLs, Exercise + Tolerance - Physical examination (pulse, fluids) - Assess depression (severity) 	<ul style="list-style-type: none"> - Blood pressure - Serum potassium (K) and estimate Glomerular Filtration Rate (GFR) 	<ul style="list-style-type: none"> - Severity: <ul style="list-style-type: none"> • mild to moderate • moderate and severe • severe and complex

QRISK2: Cardiovascular Disease Risk Calculator 2

HbA1c: Glycated Hemoglobin A1c

eGFR: Estimated Glomerular Filtration Rate

ADLs: Activities Of Daily Living

	Diabetes	Chronic heart failure	Chronic kidney disease	Depression
Monitoring / review	<ul style="list-style-type: none"> - Blood pressure: 1-2 months / 4-6 months / annually - Lipid lowering: annual follow-up - Lipid modification: liver transaminases within 3 months, 12 months / annual review; cholesterol at 3 months / annual review - Check insulin injection sites annually - Regular clinical reviews of neuropathic pain treatment - Diabetic foot problem: <ul style="list-style-type: none"> • Low risk: annual foot assessment • Moderate: 3-6 months • High risk: 1-2 months or arrange visit at foot protection service - Eye disease: <ul style="list-style-type: none"> • Screening no later than three months after referral • Annual screening/review 	<ul style="list-style-type: none"> - Review state (stable/unstable) - Stable: <ul style="list-style-type: none"> • 6 months • 3 months if co-morbidities - Mild to moderate (unstable) CHF: GP/specialist nurse – review every 7 to 14 days until stable - Follow up on depression treatment – GP/specialist nurse 	<ul style="list-style-type: none"> - Non-RASA treatment: <ul style="list-style-type: none"> • Blood pressure after two weeks 	<ul style="list-style-type: none"> - Check response to SSRI

RASA: Renin-Angiotensin System Antagonist
SSRI: Selective Serotonin Reuptake Inhibitor

	Diabetes	Chronic heart failure	Chronic kidney disease	Depression
(Drug) Treatment	<ul style="list-style-type: none"> - Blood pressure: <ul style="list-style-type: none"> • ACE inhibitor • A II blocker • Calcium blocker or diuretic • Alpha blocker • Beta blocker • Potassium-sparing diuretic - Lipid lowering: <ul style="list-style-type: none"> • Atorvastatin - Lipid modification: <ul style="list-style-type: none"> • Statin - Insulin (short acting/NPH/levemir) or Sulfonylurea, or combination with SGLT-2 - Metformin - DDP-4 or pioglitazone or sulfonylurea - Titration - Neuropathic pain: <ul style="list-style-type: none"> • Tramadol (only if acute rescue medication is needed) • Capsaicin • Amitriptyline, duloxetine, gabapentin, pregabalin - Erectile dysfunction: phosphodiesterase-5 inhibitor 	<ul style="list-style-type: none"> - ACEi or BB - ARB - Spironolactone + or digoxin - Exercise rehab - Fluid overload: <ul style="list-style-type: none"> • Diuretic 	<ul style="list-style-type: none"> - Blood pressure without diabetes: <ul style="list-style-type: none"> • ACR >70 → target: syst 120-130 or diast <90 → BP > target → RASA indication - Blood pressure with diabetes: <ul style="list-style-type: none"> • target: syst 120-139 or diast < 80 → ACR > 3mg/mmol / BP > target → RASA indication - non-RASA treatment: <ul style="list-style-type: none"> • Calcium channel Blocker CCB • Thiazide diuretic • Beta-blocker - CVD prevention and treatment: <ul style="list-style-type: none"> • Antiplatelet • Anticoagulant • Consider apixaban over warfarin 	<ul style="list-style-type: none"> - Mild to moderate depression: <ul style="list-style-type: none"> • Low intensity psychosocial interventions • CBT • IPT • Group based CBT • Antidepressant treatment - Moderate and severe depression: <ul style="list-style-type: none"> • High intensity psychological interventions: CBT, IPT, behavioural activation, behavioural couple therapy • Optimise antidepressant treatment • Combining psychological and drug treatment - Complex and severe depressions (risk of suicide, self-harm or self-neglect): <ul style="list-style-type: none"> • Medication, high intensity psychological interventions • electroconvulsive therapy • crisis service • combined treatment • multi-professional • inpatient care - SSRI Treatment

SSRI: Selective Serotonin Reuptake Inhibitor
 ACE: Angiotensin Converting Enzyme Inhibitor
 A II: Angiotensin Receptor II
 ARB: Anatomical Therapeutic Chemical
 BB: Blood Blocker
 CBT: Cognitive Behavioural Therapy
 IPT: Interpersonal Therapy
 SGLT-2: Sodium/Glucose Cotransporter 2
 DDP-4: Dipeptidylpeptidase-4

	Diabetes	Chronic heart failure	Chronic kidney disease	Depression
Referral	<ul style="list-style-type: none"> - Consider referral to specialist if in doubt of differential diagnosis or if persistent severe vomiting (in case of gastroparesis) - Consider referring patients with severe pain or if pain significantly limits lifestyle and daily activities - Eye disease: referral to ophthalmologist if pathologic finding - Erectile dysfunction: discuss referral for medical, surgical, or psychological management 	<ul style="list-style-type: none"> - Refer to cardiologist for consideration of treatment with Hydralazine + Nitrate when ACEi/ARB + BB intolerant - Refer to cardiologist for consideration of treatment with Sacubitril + Valsartan (ENTRESTO) of insertion of biventricular pacemaker (Patients with ejection fraction <35%) - Refer to specialist: <ul style="list-style-type: none"> • Treatment failure after 1st and 2nd line treatments • Severe (NYHA IV) failure - Severe CHF: consider admission to hospital or palliative care - Mild/ moderate depression: refer CBT - Severe depression: mental health team 	<ul style="list-style-type: none"> - Referral or consultation with renal specialist if: <ul style="list-style-type: none"> • GFR <30 ml/min/1.73m² (GFR category G4 or G5) • ACR ≥= 30mg/mmol (ACR category A3) AND haematuria • ACR ≥= 70mg/mmol AND not caused by diabetes • (↓GFR ≥= 25% AND change in GFR category) OR (↓GFR ≥= 15ml/min/1.73m² within 12 months) • Poorly controlled hypertension despite the use of at least 4 antihypertensive drugs at therapeutic doses • Known or suspected rare or genetic causes of CKD • Suspected renal artery stenosis - Referral to urological services: <ul style="list-style-type: none"> • Renal outflow obstruction • Haematuria 	<ul style="list-style-type: none"> - If no response to combined psychological and drug treatment refer to specialist

HbA1c: Glycated Hemoglobin A1c

ACEi: Angiotensin Converting Enzyme Inhibitor

ARB: Angiotensin Receptor Blocker

BB: BetaBlocker

NYHA IV: New York Heart Association Classification Class IV

CBT: Cognitive Behavioural Therapy

GFR: Glomerular Filtration Rate

ACR Albumin Creatinine Ratio

	Diabetes	Chronic heart failure	Chronic kidney disease	Depression
MDT, coordinated care organisation / communication	<ul style="list-style-type: none"> - Atorvastatin dose increase with renal specialist - Advice from specialists in diabetes or clinical biochemistry - Assistance from a carer to inject insulin - Discuss non-pharmacologic treatments of neuropathic pain, e.g. physical and psychological therapies - Multidisciplinary foot care team */ foot protection service** 	<ul style="list-style-type: none"> - For diagnosis review refer to specialist - Mild to moderate CHF: GP/specialist nurse - Mild to severe depression: Mental health team 	<ul style="list-style-type: none"> - Education provided by well-trained and experienced professionals - Renal specialist - Urological services 	<ul style="list-style-type: none"> - If physical health problem, work closely with physical health service - Mild to moderate depression: <ul style="list-style-type: none"> • Primary care • MH specialist - Moderate and severe depression: <ul style="list-style-type: none"> • MH specialist - Severe depression: <ul style="list-style-type: none"> • MH specialist • Multi-professional • Crisis service • Hospital
Side effects / interactions	<ul style="list-style-type: none"> - CKD, CVD, Hypertension, microvascular and/or macrovascular - Gastroparesis - Neuropathic pain - Autonomic neuropathy - Diabetic food problem - Erectile dysfunction - Kidney problems - Eye disease 	<ul style="list-style-type: none"> - Consider depression and other co-morbidities 	<ul style="list-style-type: none"> - Blood pressure - Hypertension - CVD 	<ul style="list-style-type: none"> - Potential drug interactions

*led by healthcare professional and consists of specialists with skills in diabetology, podiatry, diabetes specialist, specialist nursing, vascular surgery, microbiology, orthopaedic surgery, biomechanics and orthoses, interventional radiology, casting, and wound care

**led by a podiatrist with specialist training in diabetic foot problems and with skills in diabetology, biomechanics and orthoses and wound care

GP: General Practitioner

MH: Mental Health

For goal setting, additional information needs to be gathered, in particular for different combinations of comorbidities. Due to limited evidence, this will require judgement by clinicians.

4.9. Developing guidance for reconciliation of clinical guidelines for multimorbidity

An uncritical combination of clinical guidelines for separate diseases, when treating multimorbid patients, would inevitably increase risk and in some cases even result in unfeasible treatment. The accumulation of disease recommendations often results in harmful polypharmacy, which is considered the most problematic aspect of supporting a clinical decision based on more than one guideline. A 2012 BMJ article identifies several measures to be taken in this sense¹⁰⁴:

- Cross referencing guidelines using electronic systems

In order for clinical guidelines to be more useful to clinicians treating multimorbid patients, their delivery format needs to reconcile relevant recommendations for different chronic conditions by identifying the synergies, cautions and contradictions. Such a reconciliation of clinical guidelines could be facilitated by ICT, through the development of “electronic formats that present different recommendations depending on demographic and clinical information provided through screening questions (if web based) or coded data (if embedded in Electronic Health Records)”.

- Guidance about treatments most likely to benefit and least likely to harm

Systematic and appropriate ICT-based cross-referencing support would also enable decision making which balances clinical evidence of benefit and harms but it also needs to take into account the patient’s preferences. Such a system would then also facilitate providing the multimorbid patients more readily with comparative data on the likely benefit and harm, which is a step towards making the patient a part of the decision-making process.

- Better use of existing evidence

Examining the effectiveness of interventions in multimorbid patients should be integrated in the improvement of current clinical guidelines.

We have identified the following key issues and steps providing a basis for reconciliation of clinical guidelines supporting decision making in the management and treatment of multimorbid patients (this requires detailed modelling work):

1. Develop patient-centred pathways for each patient condition / each comorbidity, following the respective clinical guidelines (cf. *D7.1*) for each disease (a hypothetical) patient has.
2. Define **clear goals**
 - for each condition/comorbidity separately;
 - taking into account the patient’s personal values and beliefs;
 - appropriately balancing clinical evidence of benefit and harm, and individual preferences.
3. Develop each separate pathway as a **time-based executable workflow of activities** towards achieving the respective goals.
 - ⇒ Model time-based sub-pathways for each identified goal within the pathway.
4. Specify all **tasks and activities** for all stages of the integrated care pathway separately (stable patient, **transitions (critical decision points)** such as hospital discharge, etc., including:
 - Concrete **timeline** with **timestamps** for each activity;
 - Location (home, hospital, GP office, community care, etc.);
 - Responsible actors (from *D4.2*).

¹⁰⁴ Guthrie, B, et al. (2012) Adapting clinical guidelines to take account of multimorbidity. BMJ 345, no. Oct04 1 2012. doi:10.1136/bmj.e6341.

5. Identify patterns with **conflicts overlaps, contradictions, constraints, outliers, inconsistencies within pairs of pathways.**
6. **Focus on a few conflicts/constraints:**
 - **Expose these to clinicians;**
 - Find solutions with the clinicians taking into account the patient specific goals.
7. **Examples of conflicts** include:
 - **Overlaps (medication, tasks, etc.);**
 - **Wrong sequence of activities**
Detected based on the timestamps for each activity.
 - Solution – change / reverse the sequence (to be decided / confirmed by clinician).
 - **Medication interactions**
 - Check drug interactions database (requires connection of the decision support modules to the DB).
 - Find solutions with the clinician taking into account the patient specific goals.
 - **Location inconsistencies**
(e.g., home hospitalisation vs. hospital admission).

Some of these key considerations are listed in the simplified **Error! Unknown switch argument.**:

Table 6: Key considerations for the reconciliation of clinical guidelines in the case of multimorbidity

Condition	Patient's Goals	HCP Goals	Activities to achieve the goals	Responsible Actor(s)	Timeline	Location
<i>To be specified for all integrated care pathway stages and critical transition points</i>						
<i>Develop as an executable workflow a detailed timeline with activities required to achieve the set goals</i>						
Diabetes Type 2						
<i>Conflict identification & resolution / reconciliation of guidelines</i>						
Hypertension						
<i>Conflict identification & resolution / reconciliation of guidelines</i>						
Heart Failure						
<i>Conflict identification & resolution / reconciliation of guidelines</i>						
Chronic Kidney Disease						
<i>Conflict identification & resolution / reconciliation of guidelines</i>						
Depression						
<i>Etc.</i>						

UPDATE

Routine care treats common chronic conditions following standardised procedures known as clinical guidelines. These clinical guidelines usually apply to single conditions, yet for patients suffering from two or more chronic conditions (multimorbidity), several guidelines have to be applied simultaneously, which may lead to severe adverse effects when the combined recommendations and prescribed medications are inconsistent or incomplete. One of the problems arising from treating multimorbid patients is the management of treatment plans based on single disease guidelines as contradictions may arise when combining several guidelines. Conflicts may correspond to polypharmacy, adverse reactions, and inconsistencies in health recommendations. There is still little information on how to handle conflicts when they arise, or what alternatives to suggest instead.¹⁰⁵

In the past, it has been suggested to identify steps in different clinical guidelines that cause problems if carried out together (e.g., two drugs prescribed for different conditions may interact, food may interact with a drug, health recommendations may contradict each other) whilst at the same time find preferred alternatives according to certain criteria (e.g., drug efficacy, prevalent disease, patient allergies, preferences, etc.). It was envisioned that a future integration of such techniques in practice can lead to the development of clinical decision support systems to manage treatments for patients with complex needs and multimorbidities.¹⁰⁶

During the C3-Cloud project, several of those points were also raised by the original D4.1 and were addressed by D7.1 and D7.2, i.e. presenting logical flowcharts based on the NICE clinical guidelines of the individual diseases and their reconciliation. D7.1 presents logical flowcharts, described in an algorithmic way, for the NICE clinical guidelines targeting the individual diseases of the project. D7.1 algorithms provide information for the target single disease care plans. The project's work cumulated in the development of such a clinical decision support system envisioned in the past. The project's work lays the foundation for future reconciliation of clinical guidelines beyond the four target diseases of the project. A systematic approach is necessary to combine more guidelines beyond the scope of the project, and to capture more facets of multimorbidity.

Using the generic pathway (Section 4.3) as a starting point, it should work as a pre-defined structure of how to behave in the health process: to whom does the GP send the patient? When does the GP refer the patient? What happens if ..., and so on. One way of creating a patient centred pathway for multimorbid patients is to merge existing separate comorbidity pathways as time-based executable workflows (sub-pathway) of activities towards achieving the respective goals. It should include sharing amongst the MDT explicit decision-making criteria such as assessment tools and scales, communication protocols and care plans, patient and care givers training and skills development. The sub-pathways then must include all specified goals and activities including a concrete timeline with timestamps for each activity, location and responsible actor.

The approach followed by the project was to translate clinical guidelines into flowcharts (T7.1) which then were used to create a decision support system (D7.2), which reconciles clinical guidelines for individual diseases, detects and proposes resolutions for guideline clashes; detects duplicate, unnecessary or contraindicating medications; and monitors and detects deviations from the outcome goals set in a patient's care plan. Figure 32 demonstrates such an approach. "Pathway 1, Disease1" and "Pathway 2, Disease 2" can merge into an overarching multimorbidity pathway. In order to achieve such a general multimorbidity pathway, the single disease/comorbidity pathways need to be revised according to their conflicts. The methodological approach is to work backwards, starting at a more detailed "zoom-in" into the different elements of the pathway (see sections 4.6 – 4.9). The localisation

¹⁰⁵ J. Bowles, M.B. Caminati, S. Cha, J. Mendoza (2019). A framework for automated conflict detection and resolution in medical guidelines. *Science of Computer Programming*. Volume 182. Pages 42-63. <https://doi.org/10.1016/j.scico.2019.07.002>.

¹⁰⁶ Hughes L., McMurdo M.E.T., Guthrie B. (2013). Guidelines for people not for diseases: the challenges of applying UK clinical guidelines to people with multimorbidity. *Age Ageing* 42:62–69.

of pathways is connected to level 3 and 4 of the health operation management, as resources, actors and roles need to be identified.

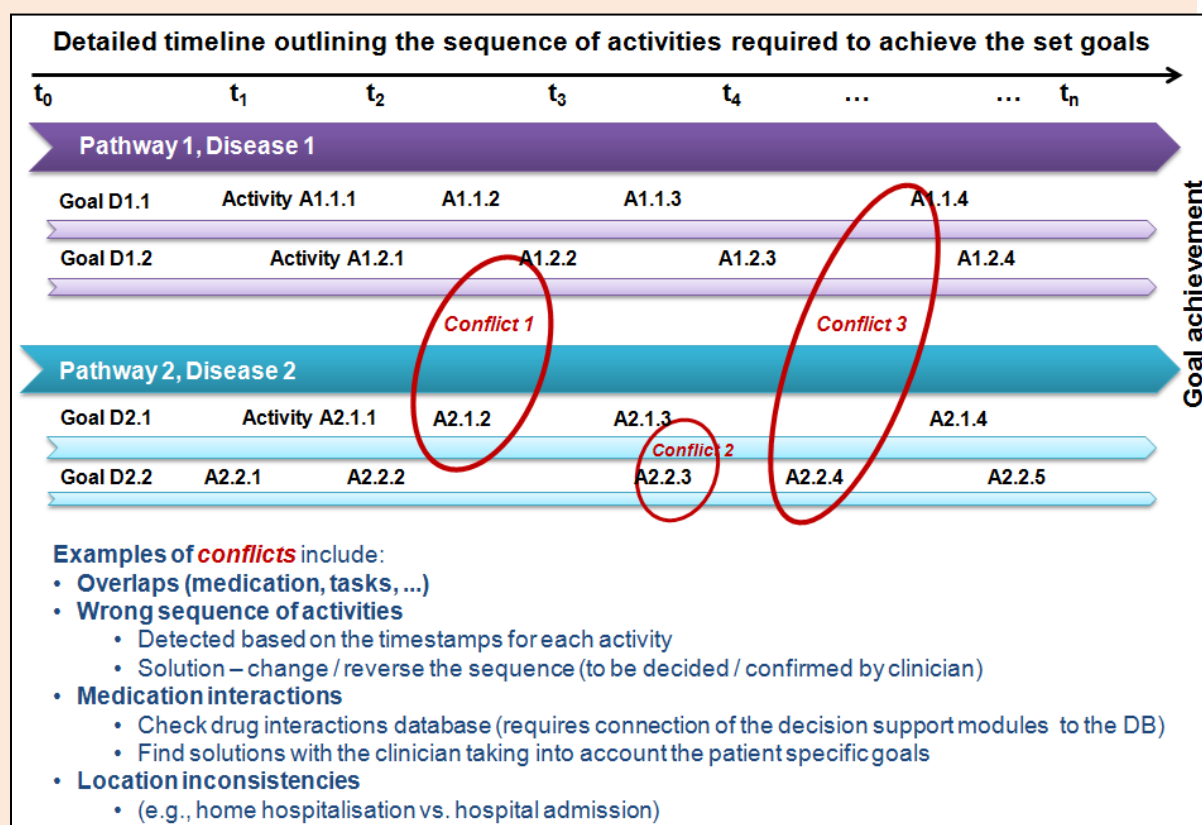


Figure 32: Identifying conflicts in overlapping pathways and care plans

By developing the clinical decision support system for C3-Cloud, D7.2 addressed the reconciliation of care plans by identifying the information on risk assessment, goals, activities, and pharmacotherapy for numerous co-morbidities based on their individual clinical guidelines. The reconciliation of evidence based clinical guidelines includes resolving the interactions between them on the four components selected. The reconciliation exercise aims to analyze the Disease-Disease, Disease-Drug and Drug-Disease interactions between comorbidities. The aim is to identify synergies, cautions and contradictions within the individual conditions and guidelines. To address drug-drug interactions, it is recommended to use polypharmacy criteria such as STOPP-START.

Table 7: D7.2 Comorbidity patterns: 15 different patterns (4 of one single disease) + (6 of two-disease combinations) + (4 of three-disease combinations) + (1 of four-disease combinations).

Single disease	Diabetes Mellitus Type 2 (DM2)	Renal Failure (RF)	Heart Failure (HF)	Depression (DP)		
Two disease combination	DM2, RF	DM2, DP	DM2, HF	RF, HF	DP, RF	DP, HF
Three disease combination	DM2, RF, HF	DM2, RF, DP	RF, HF, DP	DM, HF, DP		
Four disease combination	DM2, RF, HF, DP					

In D7.2 a methodological approach was used to identify interactions between individual guideline recommendations that include the risk of the patient, setting goals, defining different activities for the care plan or identifying pharmacological treatment. Potential conflicts were identified: repetition,

wrong sequence or overlaps of activities, contradictory goals, location inconsistencies alternative options, constraints, potential treatment synergies (either beneficial or harmful), outliers, and inconsistencies within pairs of pathways. In a few more steps, it was tried to mitigate the conflict between guideline recommendations by modifying them according to clinical knowledge and then peer reviewed considering local issues. For the detailed methodological approach see D7.2.

The project has demonstrated that after the deployment of the C3-Cloud solution, the original insights of D4.1 remain valid, yet it is necessary to once more state the importance of guideline reconciliation of individual guidelines in lack of a true multimorbidity guideline. This does not only include the algorithmic reconciliation but also the resolving of conflicts and adaption to local guidelines and local populations. The target conditions in this project were four disease combinations of DM2, RF, HF and DP, and other combinations exist, e.g. approximately 60.4% of Rheumatoid arthritis (RA) and 37.2% of non-RA controls had ≥ 3 comorbidities, and 23.5% of RA and 12.0% of non-RA controls had ≥ 5 comorbidities¹⁰⁷. Multimorbidity has been estimated to affect up to 95% of the primary care population aged 65 years and older¹⁰⁸. Future work in this field must not only address multiple combinations of guidelines but also the creation of an evidence-based pathway creation.

¹⁰⁷ An, J., Nyarko, E. & Hamad, M.A. Prevalence of comorbidities and their associations with health-related quality of life and healthcare expenditures in patients with rheumatoid arthritis. *Clin Rheumatol* **38**, 2717–2726 (2019). <https://doi.org/10.1007/s10067-019-04613-2>

¹⁰⁸ Violan C, Foguet-Boreu Q, Flores-Mateo G, Salisbury C, Blom J, et al. (2014) Prevalence, Determinants and Patterns of Multimorbidity in Primary Care: A Systematic Review of Observational Studies. *PLOS ONE* 9(7): e102149. <https://doi.org/10.1371/journal.pone.0102149>

5. CONCLUSION

The aim of this deliverable was to critically review and highlight the shortcomings and limitations of current care pathways and care plans for multimorbid patients and to develop guidance for respective clinical guideline reconciliation and care plan creation. There is no definition of care pathways and care plans, yet the definitions commonly provide principles of managing a patient group, ideally by a multidisciplinary team, during a defined period. They also provide a personalised care plan, including health assessment, patient needs, goals and activities.

Single disease care pathways offer many advantages towards care without standardized pathways. These include the standardisation and thus shortening of processes, increased treatment coherence, reduced risk of errors and reduction of costs. They tend to work well in linear care settings as they are often built on medical guidelines for single diseases. However, multimorbidity is not linear and as the name suggests, it is a combination of multiple health conditions. In addition, according to the present state of knowledge, no single comprehensive multimorbidity guideline exists. Furthermore, multimorbid patients require polypharmacy treatment which not only increases the workload of the healthcare professional but also increases the healthcare risks due to drug-drug, drug-disease or disease-disease interactions.

Thus, C3-Cloud delivered a blueprint for the development of local care pathways for multimorbid conditions. At the heart of that blueprint are the individual steps that a care pathway should include: assessment, diagnosis, goal setting, care plan, treatment, monitoring, patient empowerment and self-management, care plan review, and when necessary, the involvement of the multidisciplinary care team. Key care plan elements include the goal setting, self-management and home support, treatment, and monitoring. These elements need to be adopted to local circumstances and roles of individuals in the health system.

The major work of developing a guideline for a true multimorbid pathway and care plan was the underlying guideline reconciliation of single disease guidelines into a decision support with the inclusion of a polypharmacy. Only by doing so, it was possible to address the challenges and shortcomings of conventional, single-disease approaches. Yet the work should not be finished here. As more and more people suffer from multiple conditions and as polypharmacy is increasing, it is even more important than before to continue the work of guideline reconciliation and to finally develop an evidence based multimorbidity guideline which then can be translated into care plans and local pathways.

6. ANNEX

In the following, functionalities identified in D8.1 have been reviewed - all are considered very relevant for C3-Cloud care planning.

C3-Cloud functionalities for personalised care plan creation, execution and monitoring

- Core care plans (i.e. unpersonalised template care plans) based on clinical guidelines should be available.
- Machine processable representation of personalised care plans detailing the agreed goals, an ordered list of treatment interventions, clear roles for all of the care actors including the patient.
- Possibility to set goal and outcome indicators.
- Possibility to involve patients in the care plan creation process.
- Systematic and semi-automatic reconciliation of digitally represented clinical guidelines for individual chronic conditions.
- Possibility to monitor care plan progression and amendments.
- It should support care managers through updates of care plans during the transition of care among care providers.
- Utilisation of clinical decision support services (e.g., poly-pharmacy management, avoiding contraindications) during creation and execution of personalised care plans.
- Communication among care team members (asynchronous messaging, tele-conference) supporting the collaborative creation and update of personalised care plan.
- Alerting MDT members to communicate any changes leading to care plan interventions to team members that are not present during the care plan development.
- Supporting regular face-to-face and virtual case review meetings for review and update of care plans by multidisciplinary care team.

C3-Cloud functionalities for clinical decision support

- Providing decision support for managing poly-pharmacy.
- Providing decision support for scanning available recorded data for indications and contraindications to a treatment proposed for the personalized care plan.
- Providing decision support for reconciling all the different conditions of the patient and possible goal conflicts.
- Providing decision support for proposing goals and interventions based on clinical guidelines.
- Providing decision support for calculating risk factors based on the current conditions of the patient.
- Providing decision support for reconciling multiple treatment plans.

C3-Cloud functionalities for patient empowerment

- Collecting real-time data from off-the-shelf wireless medical sensors.
- Monitoring the most recent status of the patients through the recorded activities.
- Monitoring possible risk factors through online patient-reported outcome measures (PROM) questionnaires based on integrated risk assessment.
- Sharing the most recent context and feedback of the patient with the care plan execution platform.
- Presenting the targeted goals of the care plan, listing and reminding the action items to the patients regularly (like medications, exercises, diet, rehabilitation therapies).
- Enabling patients to flag treatment interventions and corresponding goals, as “achieved” and “not achieved”.
- Supporting self-management training following international and national disease self-management programs.
- Providing educational intervention / training materials / tools supporting self-management.