# DELIVERABLE

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# D1.2 – Categorized and ranked clinical challenges and needs in patient journey phases

Revision: 1.0

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# Revision History, Status, Abstract, Keywords, Statement of Originality

**Revision History**

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| Abstract (for dissemination) | The objective of this report is to identify the most relevant clinical challenges and needs for each patient journey phases, concentrating on the most common and complex questions. These will be categorized in clinically relevant groups, which could benefit from similar data acquisition and handling tools. The different needs will be ranked by their clinical importance, considering current unmet needs and different journey phases. An accurate description will highlight uncertainties, open issues, as well as connections with potential benefits. |
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| | To this aim, in this work we propose a general methodology with the following components: 1) Identification stakeholder groups, types. 2) Formal definitions: What is an (un)met clinical need and challenge. 3) Bibliographic review of current (un)met clinical needs and challenges in the four different journey phases. 4) Review of existing methods to elicit user needs from the different involved stakeholders. 5) Elicitation methods for the Stakeholders. 6) Standard framework for understanding and studying health and health-related states, outcomes, determinants, and changes in health status and functioning: International Classification of Functioning Disability and Health (ICF). 7) Execution of unmet clinical needs and challenges elicitation methods for involved stakeholders in the ICF framework. 8) Results ranking by clinical importance, considering current unmet needs and different journey phases |
| Keywords | Clinical needs, challenges, focus groups, stakeholders, unmet needs |

**Statement of originality**

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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**Executive Summary**

The objective of this report is to identify the most relevant clinical challenges and needs for each patient journey phases, concentrating on the most common and complex questions. These will be categorized in clinically relevant groups, which could benefit from similar data acquisition and handling tools. The different needs will be ranked by their clinical importance, considering current unmet needs and different journey phases. An accurate description will highlight uncertainties, open issues, as well as connections with potential benefits.

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# 1      Scope and Purpose of this deliverable

The objective of this report is to identify the most relevant clinical challenges and needs for each patient journey phases, concentrating on the most common and complex questions. These will be categorized in clinically relevant groups, which could benefit from similar data acquisition and handling tools. The different needs will be ranked by their clinical importance, considering current unmet needs and different journey phases. An accurate description will highlight uncertainties, open issues, as well as connections with potential benefits.

To this aim, the proposed General Methodology is outlined below; the main components are described in the following sections.

## 1.1      General Methodology

This report has been elaborated gathering all the information obtained from the following sources:

1) Identification stakeholder groups, types...
2) Formal definitions: What is an (un)met clinical need and challenge.
3) Bibliographic review of current (un)met clinical needs and challenges in the four different journey phases.
4) Review of existing methods to elicit user needs from the different involved stakeholders.
5) Elicitation methods for the Stakeholders
6) Standard framework for understanding and studying health and health-related states, outcomes, determinants, and changes in health status and functioning: International Classification of Functioning Disability and Health (ICF).
7) Execution of unmet clinical needs and challenges elicitation methods for involved stakeholders in the ICF framework.
8) Results ranking by clinical importance, considering current unmet needs and different journey phases.

The information available in all the sources mentioned above has been analysed exhaustively by INSTITUT GUTTMANN and CHARITÉ teams and the conclusions of the present report have been obtained.

## 1.2      Patient journey phases

The main medical concept of PRECISE4Q is to target four different stages of stroke in the life trajectory in a novel precision medicine approach. Precision medicine is defined as a concept to tailor prevention, diagnostics and therapeutics individually to any given patient. Thus, we will develop a set of models for each of the four clinical stages of stroke - prevention, stroke therapy, stroke rehabilitation and stroke reintegration - and combine these in a digital stroke patient platform.

**Prevention.** One of the most promising approaches to reduce the effects of stroke on individual health and healthcare systems is to prevent stroke. More than 77% of stroke events are first time events. Former epidemiologic studies have identified major overarching causes of stroke such as hypertension, cigarette smoking, diabetes, dyslipidemia, atrial fibrillation and carotid stenosis. While general recommendations can be given to patients to treat these conditions, it is currently unknown how a given patient is individually affected by these risk factors. Importantly, most of the risk factors are currently undertreated in the population.

**Acute Treatment**. There have been advances in the therapy of ischemic stroke in the past decades. Overall therapy success, however, is still poor. For thromboembolic stroke, the most favourable current treatment paradigm is the time-based dissolution of the obstructing blood clot by a drug. Unfortunately, up to 20% of patients arrive with an unknown time from stroke onset, and most patients present too late in the hospital to receive treatment. However, the optimal treatment

strategy for an individual patient remains unknown. Additionally, what challenges the treatment of stroke patients is that the causes are highly heterogeneous. Thus, each patient suffering a stroke is an individual representation of the disease entity stroke. Current treatment paradigms, however, do not consider individual differences.

**Rehabilitation**. Multitude of different stroke rehabilitation concepts and methods has been developed to date. However, from an evidence-based perspective only very few general proven recommendations exist: a) Specialized rehabilitation is useful, b) early rehabilitation and mobilization is useful and c) higher intensities of therapy are useful. Beyond this, it is unclear which therapy options lead to better rehabilitation outcome, i.e. which therapies are best suited for the individual patient. Since the rehabilitation success can make the difference between the need for 24/7 care or independency, there is dire need to identify individual factors and therapy options to allow specifically tailored rehabilitation for optimal outcome after stroke.

**Reintegration**. Reintegration is the long-term outcome after stroke. After acute treatment and rehabilitation, reintegration success is measured by the patients' reintegration into their family, communities and workplaces. Self-esteem, depressive symptoms, social support satisfaction and other parameters are important. Such psycho-social parameters – together with functional rehab outcome – comprise long-term stroke outcome picture complete, e.g. by determining social integration, return to the work force (RTW) and work performance. However, this field is affected – up until now – by a lack of data, and it is no wonder that no guidelines for interventions exist that predict return to work force.

# 2      Identification of stakeholders

Stakeholders are those who may be affected by or have an effect on an effort.  They may also include people who have a strong interest in the effort for academic, philosophical, or political reasons, even though they and their families, friends, and associates are not directly affected by it.

## 2.1      Sectorial Community: Potential clients, facilitators, influencers:

**Sectorial Community: potential clients, facilitators, influencers**

**Internal to PRECISE4Q project**
Project team: clinical, socio-economic impact assessment, industry liaison, medical informatics, data aggregation and harmonization, ethical factors, data evaluation, insurances.

**External to PRECISE4Q project**
Associations of Patients
Private Healthcare professionals
Medical centers (private and public)
Private IT healthcare companies in any of the 4 journey phases

## 2.2      Scientific and education community

**Scientific and education Community**

Universities and applied research centers
Development of IT solutions in 4 phases
Academic and Scientific associations
Stroke, neurology, in-silico modeling, machine learning, data mining technologies, health informatics

## 2.3    Policy makers

**Policy Makers**

**Public Administrations**
Regional and National entities, regulatory authorities, ministries, counseling, platforms, related to competitive calls, funding, innovation management in healthcare sector, at local, regional, national and European level
**European platforms and international initiatives**
in the well-being field such as "European Innovation Partnership for Active and Healthy Aging" or "Knowledge Innovation Community".

## 2.4    Society:

**Society**

**General media** non-specific to the field
**Specialized media** related to any of the 4 journey phases
**Public** general population
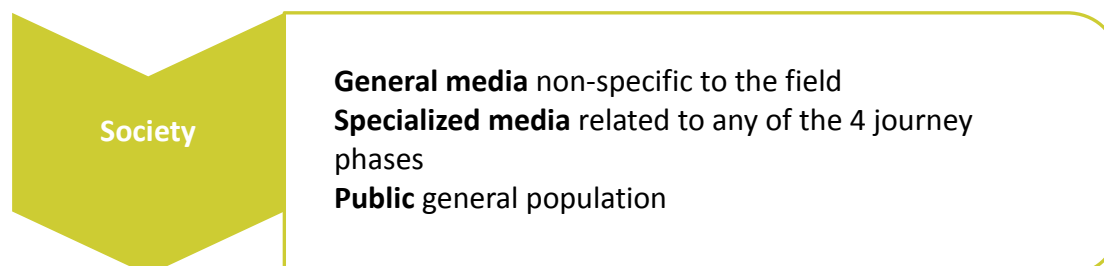
# 3 Formal definitions

While there is no universal consensus, outcomes are principally defined as "benefits or changes for intended beneficiaries" (Wainwright, 2003). This is in contrast to needs, considered in healthcare to be the "capacity to benefit from healthcare services" (Asadi-Lari, Tamburini, & Gray, 2004) and unmet needs, defined as the "difference between health services deemed necessary to deal with a particular health problem and the actual services received" and which thus reflects shortcomings in the provision of care (Herr et al, 2014).

## 3.1 Quality of Life

The concept of quality of life first appeared in medical science in the 70s of the previous century (Sheridan C. L., Radmacher S. A., 1998). New methods of treatment, advances in medicine and the huge costs of treatment did not seem to directly translate into effects noticeable to the patient. This called for a change of approach – giving priority to non-material values.

Accordingly, medicine's interest in quality of life has been observed to relate in particular to the examination of medical and non-medical consequences of illness, as well as the assessment of medical and non-medical effects of health-care and treatment on the patient's well-being in such branches of medicine as oncology, cardiology, rheumatology, psychiatry or gerontology.

Attempts at delimiting the concept of quality of life led by Schipper ( Schipper, 1999) to the formulation of the concept of ''health-related quality of life'' (HRQOL), which defines quality of life as a functional effect of illness and its treatment as perceived by the patient. HRQOL is a multidimensional concept embracing physical, emotional and social components relating to illness and its treatment.

According to the experts of WHO, the concept of quality of life ought to comprise an individual's mode of perception of their material and subjective resources, information about their functioning, its assessment and the level of satisfaction with it (WHOQOL, 1998). Quality of life has been defined as the perception by an individual of their position in life in the context of value and culture systems they live in, and in relation to the culture's expectations, standards and interests. It includes the following elements:

- physical condition,
- mental condition,
- self-reliance,
- social relationships,
- environment,
- religion, beliefs, convictions and views.

The above definition views quality of life from the perspective of the individual. Previously, research on quality of life focused on the objective aspect, tending to ignore the subjective one. The former includes, among other things, the state of health and socio-economic status of an individual (occupation, family income, and spare time); the latter stresses the level of contentment with life, satisfaction of one's needs and participation in social structures.

The assessment of health-related quality of life commonly takes into consideration the following three elements:

1) The functional capability of an individual, i.e. the ability to satisfy their everyday needs, to take up or continue in social roles; intellectual and emotional efficiency.
2) The way an individual perceives his/her situation in life; the level of satisfaction and contentment with life.
3) Symptoms of an illness, and the general level of fitness following on the illness and age.

The evaluation of quality of life must address both particular aspects of the individual's life as well as their life as a whole. It is significant that the concept of quality itself carries positive connotations, as does the notion of health. Health has an absolute value, but it also has an instrumental value, i.e. it enables the individual to achieve his/her goals, most importantly, a better quality of life.

Health, on the one hand, is treated as a general predisposition to and capability for all-round development, the ability to perform social roles and to adapt to the ever-changing environment. On the other hand, it is a process of seeking and maintaining an equilibrium continually disturbed by the pressures of the internal and external environment. Health thus conceived is the most valuable resource of the individual; therefore, its role in the shaping of quality of life cannot be overestimated The holistic approach to health is based on five dimensions:

1) physical,
2) psychological (mental and emotional),
3) social,
4) public,
5) spiritual.

In comparison with the most frequently cited definition of health included in the WHO charter defining health as a physical, mental and social well-being, and not merely a lack of disease or ailment, the newer definition supplements the concept of health with public and spiritual dimensions (WHOQOL, 1998).

# 4      Standard framework for structuring results: ICF

The International Classification of Functioning, Disability and Health (ICF) is a framework for describing and organising information on functioning and disability. It provides a standard language and a conceptual basis for the definition and measurement of health and disability (Stucki, Cieza and Melvin, 2007).

The ICF conceptualises a person's level of functioning as a dynamic interaction between her or his health conditions, environmental factors, and personal factors. It is a biopsychosocial model of disability, based on an integration of the social and medical models of disability.
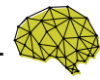
As illustrated in Figure 1, disability is multidimensional and interactive. All components of disability are important and any one may interact with another. Environmental factors must be taken into consideration as they affect everything and may need to be changed (Cieza and Stucki, 2008).

**Figure 1 – Interactions between the components of ICF**
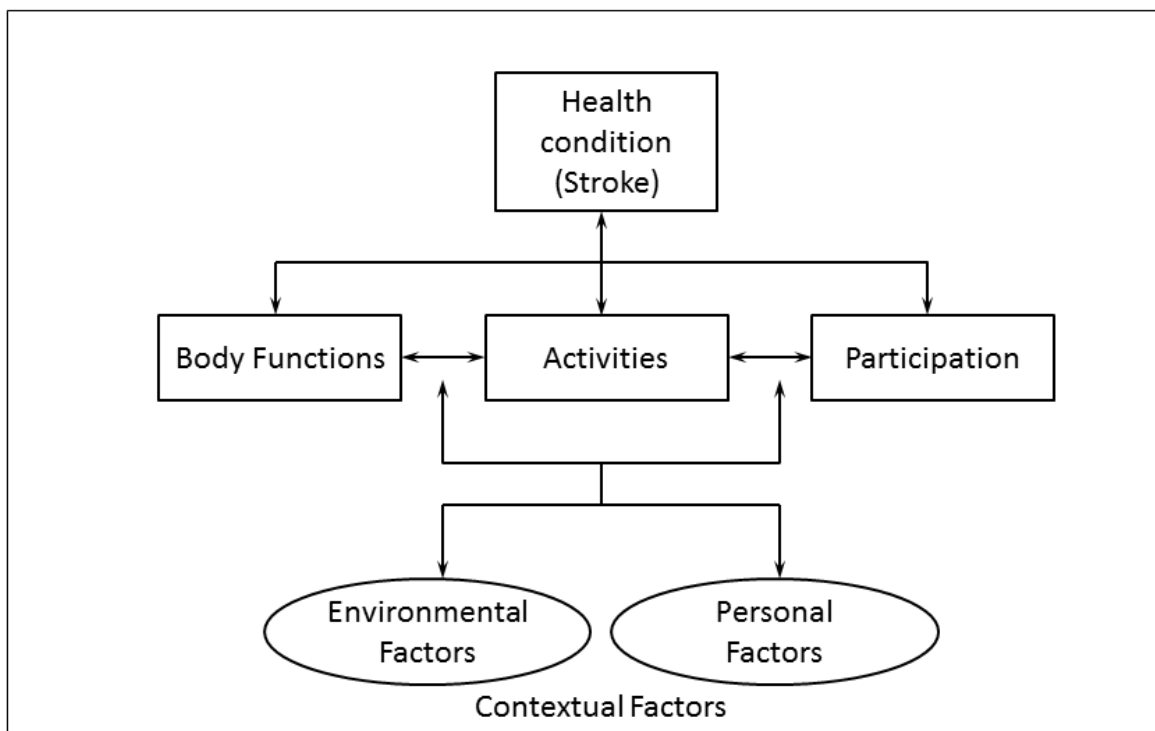


Two major conceptual models of disability have been proposed. The medical model views disability as a feature of the person, directly caused by disease, trauma or other health condition, which requires medical care provided in the form of individual treatment by professionals. Disability, on this model, calls for medical or other treatment or intervention, to 'correct' the problem with the individual. The social model of disability, on the other hand, sees disability as a socially created problem and not at all an attribute of an individual (Cieza and Stucki, 2008).

On the social model, disability demands a political response, since the problem is created by an unaccommodating physical environment brought about by attitudes and other features of the social environment. On their own, neither model is adequate, although both are partially valid. Disability is a complex phenomena that is both a problem at the level of a person's body, and a complex and primarily social phenomena. Disability is always an interaction between features of the person and features of the overall context in which the person lives, but some aspects of disability are almost

entirely internal to the person, while another aspect is almost entirely external (Stucki and Grimby, 2004).

In other words, both medical and social responses are appropriate to the problems associated with disability; we cannot wholly reject either kind of intervention. A better model of disability, in short, is one that synthesizes what is true in the medical and social models, without making the mistake each makes in reducing the whole, complex notion of disability to one of its aspects (Cieza and Stucki, 2008).

This more useful model of disability might be called the biopsychosocial model. ICF is based on this model, an integration of medical and social. ICF provides, by this synthesis, a coherent view of different perspectives of health: biological, individual and social.

## 4.1    Concepts of functioning and disability

As Figure 1 indicates, in ICF disability and functioning are viewed as outcomes of interactions between health conditions (diseases, disorders and injuries) and contextual factors. Among contextual factors are external environmental factors (for example, social attitudes, architectural characteristics, legal and social structures, as well as climate, terrain and so forth); and internal personal factors, which include gender, age, coping styles, social background, education, profession, past and current experience, overall behaviour pattern, character and other factors that influence how disability is experienced by the individual.

Figure 1 identifies the three levels of human functioning classified by ICF: functioning at the level of body or body part, the whole person, and the whole person in a social context. Disability therefore involves dysfunctioning at one or more of these same levels: impairments, activity limitations and participation restrictions. The formal definitions of these components of ICF are provided in the box below (Cieza and Stucki, 2008).

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**Body Functions** are physiological functions of body systems (including psychological functions).

**Body Structures** are anatomical parts of the body such as organs, limbs and their components.

**Impairments** are problems in body function or structure such as a significant deviation or loss.

**Activity** is the execution of a task or action by an individual.

**Participation** is involvement in a life situation.

**Activity Limitations** are difficulties an individual may have in executing activities.

**Participation Restrictions** are problems an individual may experience in involvement in life situations.

**Environmental Factors** make up the physical, social and attitudinal environment in which people live and conduct their lives.

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- ICF offers an international, scientific tool for the paradigm shift from the purely medical model to an integrated biopsychosocial model of human functioning and disability. It is a valuable tool in research into disability, in all its dimensions -- impairments at the body and body part level, person level activity limitations, and societal level restrictions of participation.

- ICF also provides the conceptual model and classification required for instruments to assess the social and built environment. ICF will be an essential basis for the standardization of data concerning all aspects of human functioning and disability around the world.

- ICF will be used by persons with disabilities and professionals alike to evaluate health care settings that deal with chronic illness and disability, such as rehabilitation centres, nursing homes, psychiatric institutions, and community services.

- ICF will be useful for persons with all forms of disabilities, not only for identifying their health care and rehabilitative needs, but also in identifying and measuring the effect of the physical and social environment on the disadvantages that they experience in their lives.

- From the viewpoint of health economics, ICF will help monitor and explain health care and other disability costs. Measuring functioning and disabilities will make it possible to quantify the productivity loss and its impact on the lives of the people in each society. The classification will also be of great use in the evaluation of intervention programmes.

- In some of the developed countries, ICF and its model of disability have been introduced into legislation and social policy, across sectors. It is expected that ICF will become the world standard for disability data and social policy modelling and will be introduced in the legislation of many more countries around the globe.

- In sum, ICF is WHO's framework for health and disability. It is the conceptual basis for the definition, measurement and policy formulations for health and disability. It is a universal classification of disability and health for use in health and health-related sectors (Stucki, Cieza and Melvin, 2007). .

# 5 Bibliographic review of current clinical needs and challenges.

In this section we summarize results from fifty-two qualitative, ten quantitative survey, and four mixed-methods studies from 11 countries (Krishnan, 2017). The data synthesis produced the following three ICF metathemes: (a) body functional needs, including psychological function, physical function, cognitive function, and uncertainty related to function; (b) activity and participatory needs, including healthy lifestyle, physical activities, speech, independence, cognitive activities, and uncertainty related to activities and participation; and (c) environmental needs, encompassing support, services, safety, accommodation and accessibility, and uncertainty related to environmental factors.

The studies included were original peer-reviewed articles in English, addressing needs of stroke survivors throughout the survivors' recovery process in 3 settings (acute, post-acute or rehabilitation and community) as perceived by the caregiver. The focus of this review was to explore needs of stroke survivors as perceived by the caregivers; hence, all studies included were those that explored this perspective. Studies excluded were those with only stroke survivors' perspectives, did not distinguish caregivers' perspectives from those of other stakeholders, did not distinguish stroke from other conditions, and focused only on perspectives for a program/intervention evaluation. Although some studies included caregivers own needs or other stakeholders' perspectives, the data extraction for this review only focused on the needs of stroke survivors perceived by their caregivers. Case studies, dissertation theses, editorials, reviews, and commentaries were also excluded.

## 5.1 Body Functional needs

Caregivers in 41 studies (62%) revealed the need for body functional needs after stroke. The most common body functional needs included psychosocial function (n = 26, 39%), followed by physical function (n = 15, 23%), cognitive function (n = 10, 15%), and uncertainty related to functional impairments (n = 9, 14%; Table 2). Under the psychosocial function subtheme, ten articles mentioned the need to improve the mood of the survivor, and nine studies heighted the changes in behaviour including anger, agitation, etc. Caregivers in seven studies highlighted the importance of dealing with depression. The need to motivate and encourage the stroke survivor was emphasized in ten studies. Under the physical function subtheme, six articles highlighted that the caregivers were concerned for the overall physical function, and caregiver in one study specified the need to improve limb function. Caregivers in six studies also identified the importance of managing pain and fatigue. In addition, two studies emphasized the need for visual and hearing function, and four studies revealed the need to improve the voice functions. Under the cognitive function subtheme, ten articles revealed the need to improve the stroke survivors' cognitive function including, comprehension, memory, orientation, etc. Under the uncertainty related to functional impairments subtheme, caregivers in nine studies were uncertain of the stroke recovery process because of functional changes in the stroke survivor's body.

## 5.2 Activity and Participatory needs

Caregivers in 43 studies (65%) highlighted the activity and participatory needs for stroke survivors. The most common activity and participatory need included healthy lifestyle (n = 26, 39%), followed by physical activities and independence (n = 15, 23% each), speech (n = 11, 17%), and cognitive activities and uncertainty related to limitations in activity and participation (n = 2, 3%each, Table 3). Under the healthy lifestyle subtheme, the caregivers in 11 studies valued stroke survivors' social and leisure activities. Seven studies indicated the need to improve nutrition among stroke survivors. Caregivers were concerned with the overall health, including spiritual health of the stroke survivor in four studies, and they highlighted the need to prevent future strokes in 13 studies. Under the
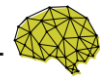
physical activities subtheme, ten studies indicated the caregivers' perspectives related to self-care needs. Caregivers wanted to improve the mobility of the stroke survivors and wanted them to walk, transfer independently, improve their balance and posture, increase physical activity, and independently climb stairs. Under the independence subtheme, 11 articles identified the need for the stroke survivor to return to normalcy and prestroke activities. Most of the caregivers wanted to preserve the survivor's autonomy and wanted them to go back to work and be able to drive. Under the speech subtheme, in 11 studies, the caregivers highlighted the need for the stroke survivor to communicate, express, and speak efficiently. Under the cognitive activities subtheme, caregivers in two studies wanted to improve the stroke survivor's decision making and judgment. In addition, caregivers in two studies expressed uncertainty to plan for the future because of the survivor's limitations in activities.

## 5.3     Environmental needs

In most of the studies (62 studies, 92% of the studies), the caregivers stressed the importance of some form of environmental need. The most common environmental needs included support (n = 50, 76%), followed by services (n = 44, 67%), safety (n = 17, 26%), accessibility and accommodation (n = 14, 21%), and uncertainty related to environmental factors (n = 11, 17%, Table 4). Under the support subtheme, 33 articles indicated a need for communication with HCPs and 27 studies highlighted the importance of support from family and friends. Nineteen studies indicated that the caregivers had difficulty paying for the survivors' medical bills, rehabilitation services, and other household expenditures, and four studies highlighted the need for support groups. Some supportive needs would benefit both stroke survivors and caregivers, but in some of the original texts, it was not possible to distinguish between needs of survivors and caregivers. Under the services subtheme, 22 articles indicated the need for rehabilitation services. The details on specifics of rehabilitation needs are listed in Table 4. Thirty two studies revealed the need for information on various aspects for the stroke survivor. The specific information needs are listed in Table 4. Fifteen studies highlighted the importance of other supportive services including but not limited to having paid caregivers, meals, etc. Under the safety subtheme, caregivers ensured survivors' safety to prevent falls in 12 studies because of impaired cognition, 43 restricted mobility, 58 lacks of sleep, 4 inadequate support, 4 etc. In nine studies, caregivers were worried about leaving the survivor alone, and in three studies, the caregivers wanted to safely administer these medications to avoid any mistakes. Under the accessibility and accommodation subtheme, six studies highlighted the need for accessibility at public toilets, travel, and transportation. In addition, six studies revealed the need for equipment and other assistive devices for stroke survivors such as wheelchairs, walking frames, and augmented or alternative communications, and four studies highlighted the need for home and vehicle accommodation. Under the uncertainty related to environmental factors subtheme, the caregivers in 11 studies were unable to anticipate the stroke survivor's needs at home and community post-discharge.

## 5.4     Clinical Practice implications

An increased rate of post-stroke disability interferes with the individual's ability to perform activities of daily living. Because older stroke survivors have higher levels of inactivity, 94 caregivers in this review wished to improve stroke survivors' independence under the activity and participatory needs theme. The caregivers were also concerned with stroke survivors' speech. Stroke survivors with aphasia usually have difficulty interacting with their caregivers and their clinicians effectively, which puts them at risk of receiving inadequate health care.88 In addition to motor and sensory activities, the clinicians should encourage the survivors to participate in social and leisure activities. The caregivers also valued the importance of stroke survivors' social and leisure activities under the activity and participatory needs theme, because the stroke survivors are at a higher risk of inactivity and feel isolated.

# 6 Methods to elicit users' needs

Needs analysis should involve real users. Only real users can provide the understanding of real needs that is necessary for system development. It is important to address those people who will provide results that can be generalized to the whole group, since the researcher will be able to talk with a relatively small number of people (Adams and Cox, 2008).

## 6.1 Surveys and Questionnaires

Survey and questionnaires belong to the scientific methods category; they produce results, which are replicable and generalizable to a broader population. These results can be used to predict future actions and can be transferred to other researchers so they can reproduce the process. It is important to consider that people may lie or misunderstand the question or even give incorrect information to please the interviewer. Surveys should be used to understand what, how often and to what extent a person could be interested in using a new product, to get information from many people and to test a new idea. Indeed surveys allow the involvement of large numbers with low effort, and they can cover many topics, also ensuring anonymity and confidentiality. However the survey construction is a tricky process that the researcher should carry out with great attention, and he has to consider that the opportunity to provide further explanation of each question is limited; the possibility of a low response rate should also be considered.

## 6.2 Structured interviews

Structured interviews are systematic methods; their results are less replicable and generalizable than that of scientific methods. The interview must be planned before data collection and it must be focused on the purpose of the study. The collected results must be interpreted and summarized. The structured interviews allow researchers to go deep into a particular subject, give the chance to hear the stories and metaphors that the subjects use as they describe their tasks and environment and avoid the problem of having people intimidated by the presence of other users. Structured interviews can be used to get feedback on a new idea and to contextualize survey findings, however they require a skilled interviewer; the interview should be recorded and transcribed and sometimes recruitment of participants could be difficult.

## 6.3 Focus Groups

Focus Groups belong to impressionistic methods and range from simple brainstorming to group discussions combined with sorting, surveying and other tasks to elicit individual opinions in a more controlled manner. During a Focus Group, a group of people is asked about their perceptions, opinions, beliefs, and attitudes towards a product, service, concept, advertisement, idea, or packaging. Questions are asked in an interactive group setting where participants are free to talk with other group members. Results are not generalizable or replicable, but they give researcher the chance to hear the words and phrases used by members of the user group of interest. Researchers can improve system usability by using this language when designing the system and when introducing it to users. An additional advantage is that more diverse groups may produce more and better ideas, heterogeneous groups can arise new and unexpected topics and information due to the synergies between different users' classes.

Focus Groups should be used to get feedback on a new idea, to contextualize survey findings and to gather a wide range of responses and diverse views on a topic.

| Method | Why | When |
|---|---|---|
| Survey | Large groups for low cost<br>Cover many topics<br>Anonymity and confidentiality | To understand what, how often, to what extent<br>To get information from many people<br>To test a new idea |
| Interview | Provides rich, in-depth info<br>Allows for follow-up questions<br>Stories & quotes | To understand how and why<br>To get feedback on a new idea<br>To get in-depth information<br>To contextualize survey findings |
| Focus Group | Ideas build<br>Diverse views on a topic<br>Collect info in a short time | To understand how and why<br>To get feedback on a new idea<br>To contextualize survey findings<br>To gather a wide range of responses |

| Method | Survey | Focus Group |
|---|---|---|
| Sectorial Community | Internal to PRECISE4Q project | Internal to PRECISE4Q project<br>External |
| Scientific and education Community | Universities and applied research centres | Academic and Scientific associations |
| Policy Makers | | European platforms and international initiatives |
| Society | Public | |

### 6.3.1   Focus Groups Guidelines

Commonly, users have been interviewed about their needs and expectations by adopting different methods (questionnaires, well-validated scales, interviews) when it suffers new situation such as the stroke. Here we preferred the Focus Group instrument because, with respect to other methods, it allows obtaining a larger amount of data of excellent quality and facilitates the interaction between different actors. Further, though it is usually planned and structured in advance, it is still flexible and allows deepening the topics discussed.

One of the aims of the PRECISE4Q project is to capture different stakeholders (Sectorial community, scientific and education community, policy makers and society) needs, in this regard the group discussion, involving different classes of users, and facilitating the expression of different point of view. Moreover, the heterogeneity of the group would allow capturing different type of needs in the

different phases. We planned to carry out Focus Groups in two regions (Spain and Germany) based on the clinical expertise of the partners and the facilitators to contact with the different stakeholders.

General guidelines on how to prepare and carry out Focus Groups were delivered. Each focus group involved 5-7 participants with different stakeholders to cover the different phases (prevention, treatment, rehabilitation, and reintegration). One week before the scheduled session each focus group leader sent the information material (see section 8.2) to participants. For each Focus Group we defined a set of questions according to the questioning route method. The latter consists of a structured program of articulated and detailed questions, formulated according to the purpose of the research and organized as follows:

• Opening question: it requires a quick response and is intended to create a comfortable environment;

• Introductory question: introduces the topic of research and allows participants to start thinking about it. Generally, participants are asked to give a definition or an example;

• Question of transition: it anticipates the main questions and connects the topic with the purpose of the research. Inquires about the experience of the participant with the topic.

• Main Question(s): it allows collecting the information needed. Usually there are 2-5 main questions.

• Closing question: closes the session and allows participants to reflect on what was said during the discussion and to identify the most important point of the discussion.

To conclude the focus group the moderator summarized the issues raised, and asked participants to confirm the appropriateness of the synthesis of their views, ranked the needs in importance order, and he asked if they had something else to mention (Zammuner, 2003; Stewart et al., 2006; Liamputtong, 2011). Focus group discussions were video/audio recorded. The main identified conceptual categories were summarized according to the needs of the focus group and organized as follows:

• Participants' background and previous experience with stroke;

• Users' Opinion;

• Ethical issues, Social aspects and long-term risks;

• Requirements;

• Conclusion and main results.

Information material

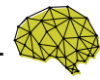One week before the scheduled focus group participants received a document including:

• An introduction about the PRECISE4Q Horizon 2020 project.

• The aim of the focus group, description of the functioning (i.e. collect feedback from users, no details about the questions to be discussed).

• Information about how data extracted from the focus group will be used in the project and where it will be stored.
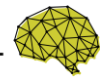
# 7    Results

The findings of the bibliographic review suggest that the caregivers wished for increased support and services.

- Effective communication with the patients helps the HCPs arrive at an accurate diagnosis, develop optimal treatment plans, and encourage participation in rehabilitation, which enhances patients' and families' satisfaction with overall care. In addition, lack of support from family and friends is known to be associated with poorer health outcomes among stroke survivors.

- Being involved in support groups and services and having additional assistance from paid caregivers are known to reduce stroke survivors' institutionalization. This additional support makes the caregivers return to their caregiving duties with enthusiasm.

- Health care professionals must educate the stroke survivors and their caregivers on the locally and regionally available community services. In addition, the provision of community-based services would help facilitate access to supportive services to address the long-term post-stroke needs of stroke survivors and their caregivers.

- The caregivers face increasing financial and economic burden post-stroke that may be due to the direct costs of medical expenditures and the indirect costs of loss of productivity.

- Identifying cost-effective interventions tailored to the individual stroke survivor and their caregivers can yield positive outcomes. In this review under the service needs subtheme, the caregivers identified the importance of information and education focused on stroke survivors' disease process, prognosis, interventions, and recovery.

- To maximize the stroke survivors' rehabilitation process, the caregivers must be informed on the various aspects of recovery, the disease process, and prevention of secondary complications.

- Lack of education on the stroke recovery process is known to be associated with increased anxiety, stress, fear, and uncertainty about the future. Conversely, educating caregivers on the management of stroke improves health outcomes. Providing stroke education may be one way to eliminate caregivers' feelings of uncertainty post-stroke.

- When communicating with stroke survivors and their families, clinicians should set realistic expectations and provide encouragement in working together on patient recovery.

- Maintaining a routine and incorporating the caregivers' preferences can enhance stroke survivors' outcomes. The HCPs must educate the caregivers that the survivors' future may not be predictable and work with them as a team through the recovery process. In this review under the environmental needs theme, the caregivers were concerned with stroke survivors' safety and wanted to prevent falls and administer medications appropriately.

- Caregivers were concerned with the stroke survivors' medication administration, fearing the adverse consequences of improper administration. Engaging the caregivers during the stroke survivors' recovery process, educating them on the intrinsic as well as the extrinsic factors related to falls, and the adverse side effects of medications can improve the survivors' outcomes because their caregivers learn to manage these problems effectively.

- The caregivers in this review also identified the importance of accessibility, accommodations, and assistive devices under the environmental needs subtheme. The increasing need for accommodation after deficits post-stroke includes a necessity for mobility devices such as canes, walkers, wheelchairs, and safety devices. The use of assistive devices and appropriate accommodations are known to decrease caregiver burden and maximize the survivors' independence.

- Most stroke survivors do not have adequate access to assistive devices and accommodations despite the associated benefits. The HCPs must prescribe assistive technology when appropriate.

## 7.1    Concepts emerging from bibliographic review

Meaningful concepts extracted from each interview topic questions and responses/discussions with end-users and healthcare professionals are listed in Table 1

| Interview Topic | Main concepts |
|---|---|
| Demographic characteristics | Age, gender, type/time of stroke, side of weakness, dominant side, speech and language skills, vision, stiffness, weakness, sensation, pain, cognitive problems, mood, and employment |
| Therapy and exercises | Duration of exercises, intensity of exercises, walking, upper limb specific exercises, time since stroke, National Health Services (NHS) resources, daily activities, quality of life, and personal goals |
| Home exercises | Home setting, private therapy, fine hand skills, stretching exercises, strengthening exercises, endurance exercises, sensitization exercises, balance, compliance, motivation, and cognitive problems |
| Functional activity goals | Use of affected arm, writing, daily activities, combing hair, washing, dressing, cooking, eating, swimming, and driving |
| Home technology | Playing games, engagement, intensity of therapy, personal choice, and leisure interests |
| IT skills and computer games | Computer use, owning a computer, playing games, cognitive skills, gender, vision, interest, and experience |
| Individual perception | Concentration, thinking, coordination, fine skills, time since stroke, purpose in life, competition, motivation, social life, age, and community resources |
| Comparison between technology and hands-on physiotherapy | Therapy principles, cognitive skills, independence, supervision by professionals, cost, and maintenance |
| Expectations from home-based device | External look of device, expectations of users/professionals/friends/family carers, motivation, assistance, safety, hygiene, engagement, and meaningful exercises |

## 7.2    Preliminary clinical needs emerging from interviews

For prevention two main clinical needs have been so far identified

1) To be able to predict the stroke risk in a certain time period
   a. Clinicians can quantify stroke risk
   b. Clinicians can give patients quantified and not only qualified assessment of their risk

2) To be able to quantify the importance of certain predictors on stroke risk for the development interventions
   a. Clinicians can develop individualized stroke risk lowering intervention plans

In the acute phase these clinical needs have been identified so far

1) To be able to predict stroke outcome
    a. Clinicians can better stratify patients to treatment

2) To be able to predict the influence of different treatments on stroke outcome
    a. Clinicians can choose the best treatment based on objective evidence

3) To identify risk factors for bad outcome and especially death as they might allow the development of interventions around treatment to increase the chance for good outcome
    a. A potential novel way to improve stroke outcome by modification of para-treatment parameters

In the Cognitive Rehabilitation phase two main clinical needs have been identified:

1. Be able to predict performance in rehabilitation activities

    • Clinicians prescribe activities that should be actually executed (predict overall level of compliance)
    • Clinicians prescribe activities targeting different functions (predict performance per function)
    • Clinicians prescribe activities at different difficulty levels (predict individual performance in them)

2.  Be able to predict **deficit reduction** due to performed activities

    • Clinicians evaluate functionality pre- post treatment to assess individual global response (predict pre-post)
    • Clinicians evaluate functionality pre- post treatment to assess individual per function response (predict pre-post for each targeted function)

Input to Cognitive Rehabilitation phase:

    • Level of disability: functional profile by means of standardized assessment (i.e. STROOP, TMT, WCST, TMT, TAS, BOSTON...)
    • Assignation of resources (i.e. professional's dedication, number of sessions, interviews, group sessions,)
    • Intervention monitoring (i.e. number of tasks executions per function, obtained results, level of difficulty per task, …).

Regarding Reintegration phase main clinical needs:

1. Predict maintenance of achieved functionality level measured at different dimensions of Quality of Life (as introduced in Section 3.1 in this document)
    • Psychological (measured by standardized tests: PHQ-9, IBP, SWLS, HAD, COPE, BDI...)
    • Social (measured by standardized tests: CIQ, EVSF, ESS,...)
    • Environmental Factors (measured by standardized tests: EFA, ESIG...)

2. Be able to predict cost benefit results
   • Structured data (predict pre-post evolution and transitions from one state to another)
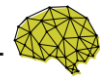   • Unstructured data (predict evolution through notations)

Data representation:
   • To make such predictions possible it is an important precondition for data to be represented by means of standardized framework for measuring health and disability at both individual and population levels such as WHO-ICF framework introduced in Section 4 in this document )
   • Provide a data representation system that takes as input standardized assessment tools (e.g. STROOP, TMT, TAS, WCST, PHQ-9, IBP, SWLS, HAD, COPE, BDI…) and outputs:
   - Their respective WHO-ICF representation
   - Their respective WHO-ICF qualifiers

# 8    Conclusions

The objective of this report is to identify the most relevant clinical challenges and needs for each patient journey phases, concentrating on the most common and complex questions. These will be categorized in clinically relevant groups, which could benefit from similar data acquisition and handling tools. The different needs will be ranked by their clinical importance, considering current unmet needs and different journey phases. An accurate description will highlight uncertainties, open issues, as well as connections with potential benefits.

To this aim, in this work we propose a general methodology with the following components: 1) Identification stakeholder groups, types. 2) Formal definitions: What is an (un)met clinical need and challenge. 3) Bibliographic review of current (un)met clinical needs and challenges in the four different journey phases. 4) Review of existing methods to elicit user needs from the different involved stakeholders. 5) Elicitation methods for the Stakeholders. 6) Standard framework for understanding and studying health and health-related states, outcomes, determinants, and changes in health status and functioning: International Classification of Functioning Disability and Health (ICF). 7) Execution of unmet clinical needs and challenges elicitation methods for involved stakeholders in the ICF framework. In this version of this report we included in Section 7.2 a set of preliminary unmet clinical needs emerging from interviews with involved professionals 8) Results ranking by clinical importance, considering current unmet needs and different journey phases.

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