

Basic principles

Release 1.0

The below translation is based on the MedMij Framework (=MedMij Afsprakenstelsel) release 1.0. For the latest and official framework, we refer to the Dutch version which can be found on the [MedMij Afsprakenstelsel webpage](#).

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The basic principles provide the foundation on which the appointments are detailed in the framework.

First, the environment of the framework and 'requests' to this framework are outlined. The section Background describes the background, scope and objective of the framework. It also explains the decision to develop a voluntary and decentralised framework with service providers. The Criteria specify the parameters (conditions) that the framework has to comply with, and the factors that will be used to measure the success of the framework (goals).

The most important design decisions are then listed, which the framework uses to respond to requests submitted. The Principles provide an overview of the guiding design decisions. The Structural Overview of the framework explains how data is exchanged by listing the roles involved, their respective responsibilities and the interactions between roles.

Finally, the list of Terms and definitions provides the official definitions for the terms used to describe the framework.

Background

Growth model

The Background also describes the way in which the framework is ultimately intended to work. Release 1.0 of the framework will not yet provide all the functionalities. The Release description for Release 1.0 provides a summary of the content of Release 1.0 of the framework.

Purpose

The Background describes the problems that the framework has to solve/resolve and gives the reasons why the framework was opted for as the chosen solution.

The MedMij program aims to give personal health environments a prominent place in the Dutch healthcare system. By 2020, a critical mass will have to have been achieved in respect of the demand (usage) and supply of personal health environments amongst care providers, patients or individuals in general and suppliers of the technical solutions.

The personal health environment gives you the option of managing your own health and healthcare and managing the sharing of your data. It offers peace of mind, confidence and insights, because it creates a clear and accurate picture of how an individual's personal health is developing and about what this individual can do to improve it. Using a personal health environment can also help the professional to deliver the right (and best) care and support. It also provides options for making more effective use of the time spent by both the professional and the individual in question. The whole is made more personal by using a personal health environment. In addition, professionals are given easier access to the relevant information that is shared by the individual. People become better informed themselves too. This facilitates collaboration and communication between professionals and the individual: they increasingly become 'partners in health'.

The program facilitates increased use of personal health environments through the targeted removal of obstacles that stand in the way of the development and usage and by setting criteria for quality and legitimacy. At the current time, the potential offered by personal health environments is underutilised. Individuals and care providers do not yet have enough confidence in the digital exchange of data and have been unable to gain much experience in using this concept. Suppliers of ICT solutions are in their turn cautious about making investments as long as individuals and care providers fail to articulate what they want; in addition, there are issues relating to interoperability and authentication. The program uses a framework for which it has launched the label 'MedMij'.

The personal health environment

The Dutch Patients' Association uses the following definition for a personal health environment:

Definition of a personal health environment

A personal medical file (PGB):

- Is a universally accessible, user-friendly life-long tool that laypeople can understand that can be used to gather, administer and share relevant health information, and can be used to manage health and care and to support self-
- Management by means of digital care services.
- Is managed and/or shared by the patient or his or her legal representative.
- Is protected in such a way that the confidentiality of the health data and the user's privacy are protected.
- Is not a legal health record unless it is defined as such, in which case it is subject to legal restrictions.

Source: Bierma, L. & Heldoorn, M. (2013), *Het persoonlijk gezondheidsdossier - De visie van patiëntenfederatie NPCF ('The personal medical file - the views of the NPCF patients' association)*.

In other words, a personal health environment is a digital environment that enables you to view clearly and securely all your relevant health data that is stored in various locations at professionals, care institutions and authorities, to supplement this data with your own measurements and to share it with whomever you wish. Content-related functionalities, including in the form of digital care services, are optional and will differ for each individual depending on their personal needs and situation. In doing so, an individual must be able to choose a single personal health environment and must not be forced to keep updating multiple environments. Suppliers of personal health environments utilise information from care providers' underlying systems and can use their personal health environments to add value to this data with the help of digital care services. There will also be providers of individual functionalities such as mobile apps that can exchange data via the MedMij Framework.

The ability to keep control of your own health data and to access digital functionality enable you to work on your own health - and to have your care process supported - in the way you choose.

Current situation

The supply and usage of personal health environments is only getting off the ground slowly. The benefits of personal health environments, as resources that enable the individual to manage his (or her) own care process and to apply self-management, have been little utilised so far. The target for the MedMij program, namely to achieve critical mass by the year 2020, will not be achieved without intervention.

The development of personal health environments is being hindered by a number of obstacles that relate to individuals, care providers and the suppliers of personal health environments. We will now list the most important such obstacles.

Individuals - who may or may not already be a patient - do not always have enough confidence to share sensitive information about their health with parties other than the care provider itself, such as with the suppliers of personal health environments. The existing legislation and regulations that lay down requirements for handling personal data are still based on the principle of health records that are managed by care providers that have a duty of professional confidentiality about medical data, and are not based on personal health environments where individuals weigh up for themselves whether to use a personal health environment or not. Adequate safeguards that are needed to protect their relatively vulnerable position are still not in place; for example, there is no principle of patient confidentiality that corresponds to the duty of professional confidentiality about medical data that care providers

have.

In many cases, care providers likewise experience caution on the part of other ICT suppliers and organisations when it comes to sharing data about patients via personal health environments. It is precisely because they are bound by their duty of professional confidentiality on medical matters that they want to be sure that the data only ends up with the patient himself (or with the latter's authorised representative). They also want to be certain about the extent to which they can be held liable in the event of medical injury that is the result of information from personal health environments. Furthermore, the technical and organisational complexity of many of the initiatives relating to digital health records do not make it any easier to be confident that data is being protected. What's more, care providers are uncertain about which solution they should choose for their interaction with personal health environments; there are a number of possible non-standardised solutions, with concerns about investing in the wrong solution leading to a conservative approach to investment and to solutions being chosen that in many cases do not go beyond a digital health environment that is linked to the care provider itself. Finally, there is a lack of clarity about the financing of functionalities and prerequisite services that relate to personal health environments. It is also unclear how investments made by care providers will be recouped, because information services are either paid for separately or as part of the funding for care products.

In addition, suppliers of personal health environments are just as concerned about the uncertainty regarding interoperability. In the event of a lack of standardisation, many investment decisions are risky, even though the differences between the personal health environments are not something that the patient will notice. It is much more about choices of the type 'should we drive on the left or right side of the road?'. This is because the more parties 'drive on the same side of the road', the greater the effect an investment in the standardised option will have. In terms of personal health environments, this means that it has to be possible to access as much care information as possible with one and the same solution. Suppliers of care information systems actually see interoperability as a threat to their existing market share, instead of as an opportunity to increase it. In addition to issues of interoperability, there is also uncertainty about the options for complying with the legal requirements relating to privacy. For instead, there are hardly any generic authentication facilities available that are sufficiently powerful to protect environments that contain personal health information. Finally, suppliers are unclear about who the funder is and who the client is when it comes to personal health environment-related services.

It is true for all parties that the lack of standardisation is not limited to technical agreements or to ICT alone. The many different types of agreements made (and even the lack of them) regarding privacy, security, management, supervision, enforcement, financing, communication and suchlike is a hindrance. The 'many to many' characteristic of the intended data exchange, where many people exchange data with a multiplicity of care providers with the help of a multiplicity of suppliers, requires robust standardisation, because otherwise it would be almost impossible to get a system of data exchange off the ground that is practicable and socially affordable for both individuals and care providers.

The obstacles related to individuals, care providers and suppliers have a blocking effect on each other, as if the demand is lacking then the supply will not get off the ground either, and vice versa. The current situation is that there is an almost non-existent bilateral 'market' that will not get going until a significant first step is taken by one of the players. The key to the situation lies in influencing the supply factors, as solving this problem would also overcome the obstacles faced by providers (care providers and software suppliers) and individuals.

What needs to be done to overcome these obstacles?

Individuals will start trusting personal health environments when they can be certain about the confidentiality of their data. Transparency (which in this case means seeing that standards are being complied with) and real-world liability (namely accessible recovery options, if injury does in fact result) are of crucial importance in this respect. This combination ensures that standards enshrined in paper documents are actually complied with in practice.

Care providers have to be able to reliably authenticate individuals online, so that trust is created that the data is being provided to the correct person. In this regard, providers of personal health environments also need there to be generic authentication options available; this relates to solutions that are not dependent on the specific ICT party or care provider but that can provide the desired high degree of security at low cost.

Interoperability is of great importance to both care providers and ICT suppliers in order to reduce the investment risks and to create a favourable network effect with as many individuals, ICT solutions and care providers being

connected to each other as possible. This increases the options for higher-quality, more secure care provision.

However, the data exchange needs to be secure and protect the privacy of those involved. Uncertainty about the financing can be resolved by using a financing structure that makes it clear which parties are willing to pay for what (services etc.).

What options are there for overcoming these obstacles?

An intervention is needed to overcome the aforementioned obstacles. There are four options for the form that this intervention should take:

1. In many cases, legislation is used as a way of safeguarding collective interests and of setting requirements for the conduct of the parties in the marketplace. In the area of personal health environments too, there is already a great deal of generic legislation in force, which legislation is expected to be tightened up further in the foreseeable future, including by the European General Data Protection Regulation. When it comes to the additional interventions that specifically relate to personal health environments, such as the aforementioned issues relating to the lack of 'patient confidentiality' and issues regarding liability, the desirability of possible legislation and regulations can be explored. However, we have had little experience so far with a successful market for personal health environments, which means that for the time being, it makes sense to be cautious about implementing legislation and regulations, so as to ensure that there continues to be sufficient flexibility. Legislation has the disadvantage that the turnaround time is long, which means that this instrument is especially suitable once the desired direction to take has already become clear.
2. Such parties as care providers and possibly care insurers can boost the market too by using their purchasing power. In some cases, doctors are already requiring apps for this too. Once there are sufficient buyers in the marketplace that use the same framework, this will encourage the other parties to start using their norms too. This model requires the buying parties to formulate their wishes clearly and to be willing to make significant investments. At the current time, however, the parameters for a personal health environment are not yet clear enough, and care providers are still encountering obstacles to data exchange, these including legal issues and the other issues mentioned above.
3. One model that was used a lot in the past was that of the centralised provision of facilities. With this model, the authorities or other dominant parties such as care insurers provided an infrastructure, which means that many decisions are taken at a collective level, with participants automatically conforming to the collective norms. However, when it comes to personal health environments, this model is a less obvious choice. The concept of personal health environments is still a new one, and if a clear choice is made for a specifically prerequisite solution then this could get in the way of innovation. When it comes to getting care providers to join, there are already a number of decentralised solutions available for this. This means a decentralised model is a good 'fit' with the experiences that the sector has had in recent years with the accessing of health information and also means that institutions and investments are re-used. Another factor is that the care sector appears to have little interest in a system of centralised provision, in part due to political viewpoints. For this reason alone, there would be little support for a system of centralised provision, quite apart from the fact that such a solution would introduce a 'single point of failure'.
4. We are left with the option that is a system of voluntary agreements. These agreements would quickly take the form of a framework, because different types of agreements would be needed between the different types of actors. It is a feature of voluntary agreements that parties can join and leave them voluntarily (subject to certain conditions). If a framework is to be effective then it will have to be both standard-setting - and able to overcome the obstacles - and attractive enough for the parties to want to conform to its standards.

What are the features of a good framework?

In order to arrive at a good framework for the exchange of data with personal health environments, it pays to look at examples from other sectors where agreements have been made about removing obstacles relating to trust and interoperability whilst still safeguarding collective interests. The different agreements have varying degrees of voluntariness; in many cases, agreements were initially voluntary in nature, only becoming mandatory later on. In such areas as case law, the financial system and digital identity, a great deal of experience has been gained with systems of related agreements. A number of common features can be seen in all these sectors that can serve as a starting point for the MedMij Framework.

The parties to the agreements are almost always professional parties that in many cases act as intermediaries who act on behalf of citizens or consumers. This means that the citizens are relieved of most of their tasks in this regard. In many cases, there are professional parties that facilitate the interaction between two parties. A debtor and a creditor, a defendant and a plaintiff, or a webshop and a customer, make use of service providers that make the complicated execution of the desired interaction possible. Transferring money is relatively easy for both the payer and the recipient, with banks handling and settling the complicated payment transactions for their customers. This also applies to the initiation of legal proceedings, where lawyers and other players within the legal system deploy complex procedures that aim to achieve their respective clients' goals. In these sectors, we find commercial service provision by professional parties that are involved in a game with each other, which game is different to the one that those they represent are involved in. In the case of personal health environments too, such a model could well happen; after all, it is providers of ICT solutions, not the individual and the care provider themselves, that handle the actual information exchange.

Agreements that are made within systems with intermediary service providers are usually made at two different levels. First of all, rules are set for the relationship between the representative (the service provider) and the party represented. These are fairly static agreements that focus on ensuring that the representative can adequately serve the interests of the represented party. They relate to such matters as transparency, the prevention of conflicts of interest, compliance with professional norms, options for submitting complaints and recovering monies, the reasonableness of commercial provisions, confidentiality, and the ability to switch over to competitors. These agreements help to create confidence on the part of the ultimate user, which offsets the greater expertise of the professional service provider. This also reduces the transaction costs and helps to create healthy competition.

In addition, there is a domain of agreements that exists between the service providers themselves. These are much more dynamic agreements that primarily relate to work procedures; this is why such agreements are not technology-neutral. The professional agreements relate to such matters as procedures, obligations to provide information, the content of professional quality standards, certification, technical and organisational admission requirements, and reciprocal warranties. These agreements too focus on reducing the transaction costs, and on stimulating competition, and ultimately serve to increase an individual's confidence in the system. However, it is difficult for the buyer of the services to assess the content of the agreements, as this is a mutual discourse amongst peers.

It is true for every framework that proper control thereof is a prerequisite for the set-up, continued development, management and checking of the agreements. One aspect of this is that clear representation of the parties involved must be regulated, and that the contribution and decision-making process must be both transparent and openly accessible. If the stakeholders are to trust the system then its supervision must be clearly defined. The authorities can play various roles in, and exercise varying degrees of influence on, this control and supervision.

Why would a party join an framework?

If the norms are created in a voluntary system then the professional parties (service providers and any care-givers) can decide for themselves whether to take part or not. Of course, it is desirable that sufficient professional players participate in the framework, because only then will a functioning market for personal health environments be created and will the framework not be dominated by a handful of parties. Participating parties must exert influence on the agreements, so that the parties can feel confident that the agreements made are appropriate and that continued development is progressing at the right tempo. The quality and continuity of the agreements has an important role to play in this regard too. Participation must also offer sufficient benefits for those who put a lot of effort into it; these benefits may take the form of opportunities in marketing, privileged information or operational efficiency. Those parties that do not participate in the system (free-riders) can benefit from the creation of a single market too; However, for professional players it has to remain more attractive to participate in MedMij than just to benefit from the work undertaken by others.

In order to encourage parties to participate, it is both necessary to gear the nature of the agreements made to the potential participants and to organise the governance in such a way that the interests of participants are properly safeguarded at all times, so that both predictability and confidence can be created.

Purpose and scope of the MedMij Framework

The MedMij Framework helps to ensure that personal, sensitive and confidential information can be exchanged in a user-friendly and secure way between personal health environments on the one hand and care providers (initially) and the authorities and other parties that possess relevant health data (subsequently) on the other. The exchange takes place in two directions, as persons can both retrieve and share data.

MedMij aims to achieve interoperability for the exchanging of personal health data between individuals and care providers. To this end, a framework will be agreed that will consist of agreements in respect of legal, organisational, financial, communication, semantic and technical matters, so that individuals and care providers can exchange data securely. Parties that participate in the MedMij Framework commit themselves to the agreements and can offer services based on the agreements already concluded.

The framework is based on centralised trust and decentralised operation. The framework is a consciously created collection of institutions that provide safeguards for the interests of the various stakeholders being dealt with fairly. However, the exchange of data on the MedMij network proceeds on the basis of decentralised technical facilities.

The value of the MedMij Framework for the individual and for his or her personal health environment

By using a personal health environment that bears the MedMij 'hallmark', an individual can be sure that this personal health environment is part of the MedMij network and that he/she can exchange data securely with care providers. Conditions imposed by the MedMij Framework ensure that a personal health environment that bears the MedMij hallmark will handle data securely. This may mean that there are some apps or environments that cannot, or that are not permitted to, work with the MedMij Framework.

A personal health environment that bears the MedMij hallmark is a guarantee that you can both trust and control your health data. This provides an individual with added value. In other words, MedMij says something about the data's integrity, validity and up-to-dateness, as well as about interoperability, but not about the content-related functionality. The use of additional functionality enables people to live more healthily and to make a more active contribution to a treatment.

The layout of a personal health environment will be just as personalised with additional functionalities as a smartphone is with apps. People will use the functionalities and apps themselves and deploy the ones they think are good quality. In this way, market forces are used to capitalise on a person's needs. For these reasons, MedMij sets no criteria for the content-related functionality and apps. This may change when further agreements are made between the individual, care providers, the authorities and suppliers about that which must be guaranteed in the pre-competitive phase and/or as standard for the individual in the MedMij Framework.

Criteria



Purpose

Criteria show the yardsticks that can be used to measure the success of the framework. Criteria consist of goals (factors where the highest possible score is aimed for, albeit with possible weighings-up between the different goals) and prerequisites (non-negotiable requirements). The creation of the system (i.e. its design process and management process) and the content of the agreements are intertwined; this means that goals can relate to both aspects.

Goals

Nr.	Title
D1	The creation of trust in individuals and care providers in respect of data exchange
D1a	Confidentiality of personal data
D1b	Clarity about liability for data processing
D1c	Transparency about compliance with norms
D1d	Reliable, secure authentication
D1e	Clarity about supervision and enforcement
D1f	Clarity about the role of the authorities
D2	The interoperability of data exchange
D2a	Availability of generic authentication solutions
D2b	Clarity about the prescribed standards
D2c	Completeness of the prescribed standards
D2d	Ease of implementing the prescribed standards
D2e	Adaptability of prescribed standards in the future
D2f	Ease of implementing amendments in the future
D3	Creation of a bilateral market with the right encouragement of innovation and quality, along with sufficient options
D3a	Real-world market forces for service provision in the individual's domain
D3b	Real-world market forces for service provision in the care providers' domain
D3c	Confidence in the future-proof nature of the framework
D3d	Clarity about business models
D4	User-friendly

D4a	Understandability and speed of the interactions relating to data exchange
D4b	Understandability and speed for the individual for his/her first-time usage of MedMij
D5	Speed of implementation by service providers
D6	Future-proof nature of the solution
D6a	Strategic flexibility of the exchange with new domains
D6b	Strategic flexibility for the use of new information standards
D6c	Clarity about the longer-term governance
D6d	Scalability for large numbers of users
D6e	Scalability for large data volumes
D6f	Scalability for high-frequency exchanges
D6g	Scalability for large numbers of participants
D7	Support for as many of a personal health environment's functions as possible
D8	Affordability

Prerequisites

Nr.	Title	Clarification
R1	Compliance with current legislation and regulations	At all times, the agreements must be implemented in accordance with the Dutch legislation and regulations.
R1a	Compliance with the AVG (the European General Data Protection Regulation)	The AVG will come into force on 25 May 2018, i.e. shortly after the MedMij network becomes operational. This is why the framework's design is already directly based on the AVG.
R1b	Compliance with care legislation	The framework's set-up must comply with health laws.
R1c	Compliance with competition legislation	The framework's set-up must not be in conflict with competition legislation. Amongst other things, this means that participants' access must be non-discriminatory.
R1d	Compliance with other legislation and regulations	The framework's set-up must comply with the other relevant legislation and regulations.
R2	Rapid delivery of the first working version of the framework and of the MedMij network	There is a great need to make data exchange between individuals and care providers possible. If the framework takes too long to be up and running even though it would deliver benefits, there is a risk that the parties will look for alternative solutions, which could lead to fragmentation and that part of the envisaged benefits would fail to materialise.

R3	Linking up multiple domains	<p>Health and health data relate to all aspects of life and are not just about being healthy or ill. Health is also about making living a life of (total) awareness, about obtaining help, about self-management, and about informal care, long-term care and support as you get older, and about living with a handicap.</p> <p>Accordingly, the collection of relevant health data means more for a personal health environment than just collecting data from the professional curative care sector.</p> <p>The framework does not need to link up multiple domains right from the start, but the fundamental decisions taken do have to make it possible to support multiple domains in the future.</p>
R4	Open and transparent decision-making process for the development (and continued development)	<p>It is true for both users, participants and other stakeholders that their confidence in the framework is increased if the progress made in the development process is transparent and it is clear how important considerations have been weighed up.</p>

Principles

Purpose

Principles are guiding pronouncements about design-related decisions in the framework. They are about the way in which the goals can be achieved to the greatest extent possible and about the way in which the prerequisites are best served. The principles set out on this page are general pronouncements. Where principles relate to a specific aspect (such as legal or architectural), they can be found by the relevant management products. Principles are given a rationale that sets out the most important design-related considerations.

P1 – The MedMij network is as data-neutral as possible

The service providers make up a mutual network for the exchanging of data between the individual's domain and the care providers' domain. This network consists of all service providers that participate in the framework. A service provider in one domain can be used to contact all the service providers in the other domain. A service provider who is a network participant is obliged to interact with other service providers when the user asks it to do so. This means that potentially a user can use a service provider to gain access to all the users in the other domain. The MedMij network regulates the realisation of data exchanges, including the process of addressing and authentication, as well as the actual transfer of the data between the service providers. The network's set-up is as neutral as possible in respect of the structure and the content of the data itself. This core group of agreements is independent of the data service in question. In addition, specific agreements may be in force that apply to a particular data service or group of data services.

P2 - Service providers provide transparency about the data services

The service providers provide clear information to each other and to users about the data services that they can provide to the MedMij network on their users' behalf. MedMij defines which data services can be offered across the MedMij network and offers a facility that provides clear information on the service providers' range of products and services.

P3 - Service providers compete on their functionalities

The service providers provide their users with functionality in the form of a personal health environment, along with gateways to care information systems, apps, and so on. The service providers are free to shape this provision as they wish and to compete with each other for the user's favour. The way in which the MedMij network is set up means that a single user can have multiple service providers and can place the same data with multiple service providers and keep it up-to-date there.

P4 - Service providers are accountable to the user

Service providers can offer functionalities themselves or else make available the data that they have received on an individual's behalf to other parties that deliver functionality in the individual's domain, doing so at this individual's request. In addition, service providers in both domains can opt to outsource the data logistics-related service provision to other parties. However, at all times the MedMij service provider remains accountable to the user for handling personal data correctly and for the quality of the interaction provided via the MedMij network.

P5 – Individuals exchange data with the care provider

Individuals exchange health data with care providers. Much of this data is either registered or used by care-givers. However, in many cases the data is updated in an information system at the level of the organisation. This may be a GP (general practitioner's) practice or a hospital that maintains digital health

records of patients, with multiple care-givers updating and consulting the health record. In more and more cases, health records are also maintained by multiple specialities, with the development of a core health record file being a good example of this. MedMij may also contain care-related administrative data (such as appointments) that is maintained by parties other than the care provider itself. With regard to data exchange, this makes it appropriate to call it an interaction between the individual and the care provider, whereby the care provider is an organisation that is made up of one or more actual care-givers. If we were to describe the framework on the basis of the care-giver then this description would become unnecessarily complicated, because in many cases the care-giver has a relationship with other care-givers or with non-medical employees or organisations. The care provider is a logical party to make agreements with the service provider in the MedMij network when it comes to the entire set of activities needed for the exchange of health data with the patient on the care-givers' behalf.

P6 – MedMij only makes an agreement about what needs to be agreed

Those matters that are already regulated in legislation and regulations or that de facto do not constitute an obstacle are not included in the framework. Instead, the system concentrates on agreements that are needed to overcome obstacles and does not strive for completeness. In this way, the power of the existing norms is also utilised as much as possible and improves the maintainability of MedMij. Changes to legislation or regulations, or generic technical innovations (provided that they do not affect the other options in the framework) can be followed up on or monitored by participants without a need to amend the official agreements.

P7 – The individual and the care provider each choose their own service provider

The individual and the care provider each choose their own service provider(s) that will represent them in the data exchange process. It is not possible to work with a single service provider throughout the entire system, because then there would be no freedom of choice and because then de facto a central facility would be created instead of a system of agreements.

P8 – Different requirements are laid down for the Individual's and for the Care Provider's Service Provider

The individual and the care provider are in an unequal relationship with each other. For instance, it is the individual who takes the initiative for data exchanges, with the care provider following him or her in this. The individual is a non-professional party who deserves some degree of protection in respect of the professional care provider. Legislation usually imposes requirements on the care provider but only does so to a limited extent on the individual, although the legislation is geared towards protecting the individual. It follows from the different positions of the individual and the care provider that it also has to be possible to impose requirements on the Individual's Service Provider that differ from those imposed on the Care Provider's Service Provider. This relates to both the commercial and the professional agreements.

P9 – The service providers are participants in the framework

The framework leads to agreements between the service providers. Users do not participate in the system directly, because we want to relieve them of as much of this work as possible. The service providers are participants in the framework and commit themselves voluntarily and under private law to comply with the entirety of the agreements.

P10 – It is only the service providers who exert control over personal data during the exchange

The service providers exchange personal data between the domains. Service providers are allowed to use third parties to perform the tasks but remain fully responsible for and accountable for the performance of the agreements. Those parties for whom a service provider is not fully responsible must not be allowed to exercise control over the personal data. These parties may include telecom providers that provide

connectivity between the service providers; they can fulfil a role in the transfer of the data but only if they cannot access the content of the exchange in any way at all. This principle ensures that it is always clear who potentially has access to personal data, without this creating a 'find-the-hidden-information puzzle' for users or supervisory authorities. A decentralised solution for data exchange without having third parties between the service providers is certainly a possible solution in both a technical and legal sense. From a simplicity perspective, this is why it is not necessary to introduce parties into the system that are not the responsibility of service providers.

P11 – System roles will be assigned from the start

The functioning of both the MedMij network and the framework depends in part on the degree to which the system as a whole is able to respond to developments (both favourable and unfavourable) in the environment or in the operations. Amongst other things, this means assigning roles that focus on the interests of the system, not on a specific participant or on a specific relationship between two participants in it. After all, there are issues (such as continued development, the settlement of disputes or the response to a security incident) that go beyond the interests of one or two participants. The most important system roles, these including at least development, supervision and enforcement, will be assigned right from the start of the framework. The scope of these roles and the organisation(s) that fulfil(s) these roles may change over the course of time.

P12 – The framework is a growth model

In order to quickly create an initial version of the framework and to be able to learn from early experiences, the framework has been set up as a growth model. The greatest obstacles to those exchanges that have the greatest potential benefit have been tackled first. A criterion here has also been the feasibility of realisation, this including tying in with the current developments in the marketplace. A growth track can be agreed where clarity is needed in those agreements that will not come into force until later but that are not yet achievable.

The framework starts with the exchange between the individual and the care provider. The system has however been set up in such a way that an exchange between the individual and third parties will be possible over time.

P13 – Development takes place using a semi-open process with various stakeholders

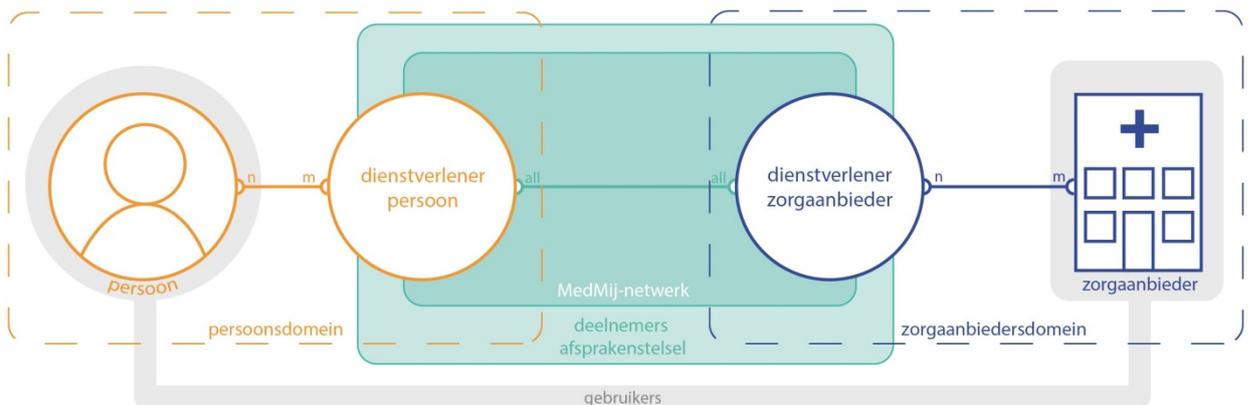
The framework is being developed in collaboration with the most important stakeholders, these including representatives of the participants, the users and the parties who have an interest in the system functioning properly. This ensures that development and usage benefit from each other as much as possible, that implementation is accelerated, and that the customers for the development process support this. Development takes place using a semi-open process, due to the speed required and to the linking-up with other centrally-directed initiatives. Any party can participate that can provide sufficient added value; however, the parameters for and the rhythms of the design process will initially be set by the MedMij program.

Set-up



Purpose

The set-up of the framework provides an overview at the highest possible level of the roles in the data exchange performed via the MedMij network, and of their interrelationships, the interactions between these roles and the most important terms associated with the roles and parties.



We distinguish between the Individual's Domain and the Care Provider's Domain. These terms help us to distinguish between the events that take place within the Individual's sphere of control (either undertaken by himself (or herself) or by his Individual's Service Provider acting on his behalf) and those which take place within the Care Provider's sphere of control (either undertaken by the Care Provider itself or by the Care Provider's Service Provider acting on its behalf). Different legislation applies to the two different domains, and in both domains the relationship between the Service Provider and the User may differ.

The Individual's Domain is made up of the Individual and the Individual's Service Provider chosen by him. An Individual can use one or more Individual's Service Providers. An Individual's Service Provider may work for one or more Individuals. The above figure shows this as a n:m relationship.

The Care Provider's Domain consists of the Care Provider and the Service Provider he has chosen. The Care Provider chooses one or more Care Provider's Service Providers. A Care Provider's Service Provider can work for one or more Care Providers. The above figure shows this as a n:m relationship.

The Individual and the Care Provider are both Users of MedMij. The Individual's Service Provider and the Care Provider's Service Provider are Participants in the framework. Together, all Individual's Service Providers and all Care Provider's Service Providers form the MedMij network. Each Individual's Service Provider must be able to contact each Care Provider's Service Provider, and vice versa. This is why an 'all-to-all' relationship is included in the figure above.

When it comes to the interaction carried out via the MedMij network, the Service Providers are obliged to comply with a set of agreements about the desired and permitted conduct on the network. The framework contains agreements about the interactions performed via the network, as well as a number of additional agreements that the Service Provider must comply with in respect of protecting the User. In addition, the Service Providers provide the User with services for which no agreements have been made under the framework.

Interactions between the roles

The table below describes at the highest level the data exchanges between the users of the MedMij network. It also states where the key responsibilities held by the various roles in the framework lie. This summary of the interactions does not look at the way in which this is achieved (as this is shown in the technical and legal elaboration, for instance), or the prerequisite interactions or at the data exchanges between the parties (such as the connecting to the MedMij network).

	Nr. Intended outcome	Interactions
1	The Individual has received the health data he or she requested, which the Care Provider has made available to him or her digitally.	The Individual asks the Individual's Service Provider to ask the Care Provider's Service Provider on the Individual's behalf to send to the Individual's Service Provider the requested data that the Care Provider has at its disposal.
2	The Individual has provided the Care Provider with data about the Individual's health.	<p>The Individual asks the Individual's Service Provider to send the Care Provider's Service Provider on the Individual's behalf a data set that the Individual has made available to the Individual's Service Provider.</p> <p>The Care Provider's Service Provider informs the Care Provider about the new data.</p>
3	The Individual has received new data from the Care Provider as soon as this became available at the Care Provider, with this relating to types of data that the Individual had stated previously that he wished to receive from the Care Provider as soon as they became available.	This will be elaborated on in future releases.



Growth model

In Release 1.0, Interaction 1 has been worked out in detail. Interactions 2 and 3 will be supported in later releases.