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Health Informatics - Telemedicine

Telemedicine

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Foreword

It is inevitable that there will be an even greater demand for healthcare in the future as a result of the ageing population, extended life expectancy and increased health problems. The shift from hospital-based care to extramural care, and shortened periods of hospitalization will intensify the ever-increasing pressure on primary, secondary and tertiary care systems. This increasing demand will not be accompanied by a corresponding growth in the number of healthcare practitioners. If policies remain unchanged, the gap between the demand and the supply of labour in the healthcare sector will soon widen.

Use of information and communication technologies (ICT) is currently undergoing significant growth within the healthcare sector. Originally, ICT was mainly used within institutions, but its use is now widespread throughout the healthcare sector and applications that make use of ICT facilities are now even finding their way into patients' and clients' homes. New forms of care provision will be needed if the demand for care is to be satisfied at an affordable price. Telemedicine is one example of such a new form of care provision. Situations in which telemedicine is being used are typically those in which actors at various locations actively cooperate in a particular process.

There are a growing number of telemedicine initiatives in the Netherlands, most of them small-scale. It is as yet unclear when the term telemedicine can rightly be used, because it is being described and interpreted in different ways and there is no unequivocal conceptual framework for the various forms. Normalization can contribute to the alignment and harmonization of telemedicine activities. For parties in the healthcare sector it is therefore important to define telemedicine more clearly. A widely accepted definition of telemedicine is also of importance for a safe, speedy and socially acceptable introduction of the phenomenon. The aim of this document is to improve communications between the various interested parties and to stimulate the application of telemedicine in the Dutch healthcare sector.

It is expected that telemedicine will lead to more efficient care, because of the improvement in communications between healthcare practitioners for example, which may itself lead to more patient-oriented referral policies. It is also expected that telemedicine will improve the quality of care, because healthcare practitioners will be better and more quickly informed about the patient, and they will have easier access to support from medical specialists. It can also be expected that the quality of life of the person needing care, the care consumer, will improve thanks to telemedicine; this might for example be brought about by the fact that the patient can be monitored in his own home, and receive advice without the need to travel to a healthcare practitioner or institution.

This normative document contains agreements about the concept of telemedicine. These agreements also concern the formulation of those quality aspects which are important for telemedicine. The document before you has the status of framework document; quality requirements can be further elaborated in follow-up documents.

Participants

This NTA has been drawn up by members of the Telemedicine Project Group. This group consisted of members representing:

— the Council of Healthcare Insurers (CVZ)

— CZ Healthcare Insurer

— De Friesland Healthcare Insurer

— H2W Partners

— ICTUS

— Intel Corporation

— inview

— Royal Netherlands Society for the Advancement of Pharmacology (KNMP)

— KSYOS TeleMedicine Centre

— Mextal

— Royal Haskoning

— Tunstall

— Vitaphone

— Vivici

— Wacomed

— ZuidZorg

— Mr J.G. Beun (in a private capacity)

The Project Group was chaired by Mr A.R. Bakker.

In addition to the Project Group, four "reading members" also followed the development and content of the NTA closely, these were: the national Health Care Inspectorate [*Inspectie voor de Gezondheidszorg*, IGZ], the Ministry of Public Health, Welfare and Sport [*Ministerie van Volksgezondheid Welzijn en Sport*, VWS], the National ICT Institute for Healthcare (NICTIZ) and Mr E. Kloosterman, an employee of the Norwegian Institute for Telemedicine.

A "response group" was also established and its members were given the opportunity to make non-binding comments and recommendations on the content of the NTA.

From the side of NEN, the NTA process was coordinated by Mrs F.M. Boomsma, a standardization consultant for NEN's Healthcare Division.

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Telemedicine

1 Subject matter and scope of application

Telemedicine is part of a much larger range of information and communications technology (ICT) applications within the healthcare sector known as e-health. Initially, ICT was mainly used within healthcare institutions such as hospitals. In more recent years, new forms of care have been introduced which - thanks to ICT - allow healthcare practitioners, irrespective of their location, to work together with other practitioners and with the care consumer. Some of these new forms of care are being referred to as telemedicine.

In the literature, however, we find many different definitions of telemedicine. This often leads to some confusion in discussions about telemedicine, and this is in turn a hindrance to the energetic introduction of new care forms and conducive policies. This NTA therefore pays specific attention to the demarcation of the concept of telemedicine and to the formulation of a widely supported definition.

Telemedicine is concerned with new healthcare processes or with existing processes in healthcare that have changed. The raison d'être for telemedicine is that the quality and efficiency of existing processes can be improved with the aid of technical resources (computers and telecommunications) and that it makes it possible to introduce new processes that contribute to improving the quality and efficiency of care.

This NTA was drawn up with the following users in mind:

— the care consumer and the person providing it, the most important actors in the actual care process supported by telemedicine;

— parties that are not directly involved in the telemedicine process but which do have an impact on it; such parties include industry, knowledge institutions, healthcare insurers, official supervising agencies, government, policy makers, professional bodies and trade associations, associations of patients, scientific associations and healthcare institutions.

2 Normative references

The following documents, which are referenced in the text, are indispensable to the application of this document. In the case of references stating a specific date, only that version is applicable. In other cases, undated, the latest version of the referenced document (including any amendment sheets) is applicable.

NEN 7510:2004	*Health informatics – Information security in the healthcare sector – General*
NEN 7511 -1:2005	*Health informatics – Information security in the healthcare sector - Specification for use of NEN 7510 in complex organizations*
NEN 7511 -2:2005	*Health informatics – Information security in the healthcare sector – Specification for use of NEN 7510 in cooperating practices*
NEN 7511-3:2005	*Health informatics – Information security in the healthcare sector – Specification for use of NEN 7510 in one-man practices*
NEN 7512:2005	*Health informatics – Information security in the healthcare sector – Basis for trust for exchange of data*
NEN-EN 13606-1:2007	*Health informatics – Electronic health record communication – Part 1: Reference model*
NEN-EN 13606-4:2007	*Health informatics – Electronic health record communication - Part 4: Security*

NEN-EN 13940-1:2007	*Health informatics – System of concepts to support continuity of care – Part 1: Basic concepts*
NEN-EN 50134 series	*Alarm systems – Social alarm systems*
NEN-EN-ISO 9000:2005	*Quality management systems – Fundamentals and vocabulary*
NEN-EN-ISO 9001:2000	*Quality management systems – Requirements*
NEN-ISO/IEC 17799:2005	*Information technology – Security techniques – Code of practice for information security management*
NPR-CEN/TS 15224:2005	*Health services – Quality management systems – Guide for the use of EN ISO 9001:2000*
NPR-ISO/TS 22600-2:2006	*Health informatics – Privilege management and access control – Part 2: Formal models*
ISO/IEC 9126-1:2001	*Software engineering – Product quality – Part 1: Quality model*
ISO/TR 16056-1:2004	*Health informatics – Interoperability of telehealth systems and networks - Part 1: Introduction and definitions*
ISO/TR 16056-2:2004	*Health informatics – Interoperability of telehealth systems and networks – Part 2: Real-time systems*
ISO/TS 16058:2004	*Health informatics – Interoperability of telelearning systems*
ISO/TS 18308:2004	*Health informatics – Requirements for an electronic health record architecture*

2.1 Legislation

Besides the above-mentioned standards, general legislation is of course also applicable, whether or not specific to the domain of healthcare and including but not limited to[1]:

— Exceptional Medical Expenses Act [*Algemene Wet Bijzondere Ziektekosten*, AWBZ];

— Quality of Healthcare Institutions Act [*Kwaliteitswet Zorginstellingen*];

— Personal Data Protection Act [*Wet Bescherming Persoonsgegevens*, WBP]

— Psychiatric Hospitals (Compulsory Admission) Act [*Wet Bijzondere Opnemingen in Psychiatrische Ziekenhuizen*, BOPZ];

— Municipal Database (Personal Files) Act [*Wet Gemeentelijke Basisadministratie Persoonsgegevens*, GBA];

— Medical Treatment Contract Act [*Wet Geneeskundige Behandelovereenkomst*, WGBO];

— Clients' Right of Complaint (Care Sector) Act [*Wet Klachtrecht Cliënten Zorginstellingen*, WKCZ];

1) This NTA mentions existing laws by name. At the time this NTA was published, a number of other laws were also being prepared which, although they are not listed, will doubtless have an impact on telemedicine. Example: the Use of the Citizen Service Number in the Healthcare sector Act [*Wet Gebruik Burgerservicenummer in de Zorg*], the Electronic Patient Record Act [*Wet op het Elektronisch Patiënten Dossier*], the Client and Quality of Care Act [*Wet Cliënt en Kwaliteit Zorg*] and the Electronic Child's Record Act [*Wet op het Elektronisch Kind Dossier*].

— Social Support Act [*Wet Maatschappelijke Ondersteuning*, WMO];

— Healthcare Market Regulation Act [*Wet Marktordening Gezondheidszorg*, WMG];

— Participation (Clients of Care Institutions) Act [*Wet Medezeggenschap Cliënten Zorginstellingen*, WMCZ];

— Individual Healthcare Professions Act [*Wet Beroepen in de individuele Gezondheidszorg*, BIG];

— Youth Care Act [*Wet op de Jeugdzorg*];

— Healthcare Insurance Act [*Zorgverzekeringswet*, Zvw].

3 Terms and definitions

3.1
actor
any individual natural person who has a significant impact on the decision-making process

NOTE	This definition is based on: www.actor.nl.

3.2
quality
the degree to which all the properties and characteristics of a product, process or service satisfy the requirements which ensue from the purpose for which that product, process or service is to be used

[ISO 9001]

3.3
healthcare provider
healthcare practitioner or healthcare institution that actively and directly provides health services

NOTE	This definition is based on: NEN 7510

3.4
healthcare institution
an organizational entity that engages in the provision of healthcare

[Quality of Healthcare Institutions Act]

3.5
care process
interrelated or integrated activities in the healthcare sector

3.6
healthcare practitioner
a natural person who provides, has provided or will provide healthcare services to a care consumer

NOTE	A distinction can be made between the care provided by accredited healthcare practitioners (registered under the BIG ACT) and the care provided via non-accredited sources (such as informal care services provided by friends and family)

3.7
care consumer
the natural person who is, has been or will be the recipient of care services

4 Telemedicine

4.1 Definition of telemedicine

Telemedicine is a care process or the whole of the care processes which satisfies both of the following criteria:

— the effect of distance is reduced by the use of information technology and telecommunications;

— there are at least two actors involved, at least one of whom must himself be an accredited healthcare practitioner (in the definition of the Individual Healthcare Professions Act [BIG Act]) or must be acting under the responsibility of an accredited healthcare practitioner.

4.2 Elucidation of the definition of telemedicine

4.2.1 Care processes

Telemedicine is concerned with care processes aimed at improving:

— the quality of life;

— the quality of care;

— the quality of services.

Care processes are aimed at achieving outcomes in the domain of health, self-reliance, social functioning and/or self-determination.

4.2.2 Care processes involving at least two actors

Telemedicine is concerned with processes and subprocesses in which at least two actors are actively involved.

At least one of these actors belongs to a legally accredited professional group or is acting under the supervision of a person who belongs to such a group (see Appendix A). One of the other actors can be the care consumer.

It is possible for one of the actors to be the supervisor of a technical application, as in the case of a remote operation, or a digital analysis system.

4.2.3 Processes involving the transfer of data from/on care consumers

Telemedicine involves the transfer of digital data from or about care consumers. This could be an image, the results of a test, a document in which patient information has been recorded (such as observations, case history, diagnosis), a "real-time" consultation by means of video conferencing, the transfer of physiological parameters or communication with remote treatment equipment.

4.2.4 Processes that bridge distance

Telemedicine often leads to a reduction in the need for actors to physically move from place to place. Telemedicine can also facilitate meetings and discussions between actors at different locations. This can also be the case within the walls of one and the same institution.

EXAMPLE 1 This can reduce the number of visits that a care consumer needs to make to a medical specialist.

EXAMPLE 2 Teleconferencing between radiotherapy and X-ray department, whereby digital images are available to the actors at their own work stations.

Telemedicine also makes it possible to communicate at a moment that may suit one or both actors. This is possible because the data and information necessary for telemedicine can be exchanged or made available by the "store-and-forward" method or by direct real-time communication.

4.2.5 Applications that make use of information and communication technology (ICT)

The concept of telemedicine came about once computers started to be used in combination with telecommunications. The use of ICT is essential to the definition of the term telemedicine.

NOTE Some applications that are considered to be "telemedicine" applications would also, in principle, be possible by other means, sometimes of a technical nature. As long as the application fulfils the criteria, it is considered to be telemedicine.

4.3 Objectives of telemedicine

Telemedicine can have various objectives, including:

a) quality of service:

- improved health situation;
- changes in the behaviour of care consumers and their informal carers so as to promote better health in the future;
- a better fit with the wishes, needs and expectations of care consumers and informal carers;
- improvement of the quality of information provision in the healthcare sector;
- improvement in the cohesion between care processes;
- enhancement of the knowledge of actors who can influence care processes;

b) quality of life:

- increased and extended independence;
- increased and extended self-reliance;
- improved participation in society and social life;
- improved self-determination (autonomy through freedom of choice) for the care consumer and his environment;

c) quality of care:

- improved productivity / efficiency;
- speedier response thanks to rapid communication facilities and remote intervention options;
- preventive measures to avoid exacerbation;
- improved therapy compliance.

The points listed above under c) can lead to an increase in the effectiveness of care.

NOTE Telemedicine can bring about changes to the current care process and to the roles that the actors involved play in it.

4.4 Other aspects

4.4.1 Telemedicine and prevention

Telemedicine can play an important role in prevention. The answer to the question whether a preventive ICT application can be considered to be Telemedicine depends on whether the application satisfies the defining criteria.

EXPLANATION The aim of primary prevention is to prevent illness. Secondary prevention seeks to detect illness at an early stage so that treatment can be started sooner with a view to restoring health or avoiding a further worsening of the illness. Tertiary prevention is aimed at individuals who have already been diagnosed with an illness but for whom, thanks to preventive measures, further hindrances in their health situation and/or self-reliance can be eliminated, reduced and/or compensated.

Some of the ways in which telemedicine can contribute to prevention:

— by taking advantage of improved knowledge and motivation to promote healthy behaviour and a healthy lifestyle, and by preventing further deterioration for those who already have health problems;

— by avoiding the need for an individual patient to be visited by a healthcare practitioner;

— by ensuring that an individual does not receive care from an actor who is unnecessarily high on the care ladder;

— by avoiding lengthy and frequent periods of hospitalization;

— by improving the therapy compliance of the care consumer.

4.4.2 Telelearning and telemedicine

ICT can play a significant role in remote training, refresher and educational courses for the healthcare sector. According to some definitions, telelearning even falls under the umbrella of telemedicine. But this is not really the case, because telelearning does not directly support the care process.

5 Quality aspects

5.1 Introduction

A good description of the process and organizational structure for both the healthcare aspects and the information provision are necessary to ensure that the quality is safeguarded and assured. In the case of telemedicine it is also necessary that all actors are constantly aware of legislation (see 2.1) and regulations for the acquisition, collection, processing, distribution, etc. of information. This section considers the various quality aspects at the level of the process of care provision, at the level of information provision and at the level of business processes. Quality assurance and verifiability will also be reviewed.

NOTE The formulation of quality **requirements** does not fall within the scope of this NTA, but since quality cannot be totally disregarded in the application of telemedicine, this NTA will consider a number of **aspects** of quality.

5.2 Quality at the level of care provision

5.2.1 Patient orientation

The Quality of Healthcare Institutions Act [*Kwaliteitswet Zorginstellingen*] is applicable to telemedicine. This law says: "The healthcare provider offers proper care. Proper care should be taken to mean care at the correct level, that is at least effective, functional and patient oriented, and that is in line with the realistic needs of the patient." (Quality of Healthcare Institutions Act, article 2)

5.2.2 Effectiveness and efficiency of care

Just like the normal care process, telemedicine is aimed at improving the health, the self-determination, the self-reliance and/or social functioning of the care consumer. Questions to be asked in assessing quality aspects at the level of care provision are at least:

— is the care consumer receiving proper care;

— does the care consumer receive this care in good time;

— does the care consumer receive care at the best location;

— is the care consumer receiving care from the proper actor;

— to what extent have the intended results been achieved and have there been any unintentional side-effects;

— is the care consumer receiving care where efficient use is being made of the available material and financial resources;

— to what extent are the persons concerned satisfied.

5.3 Quality at the level of information provision

There is always a risk that the use of ICT could cause information to be distorted or distributed, either intentionally or inadvertently. Actors must therefore make sure that adequate security measures have been taken to protect both information and information streams. The following aspects play a role in this context:

— confidentiality. Data must only be accessible to authorized persons;

— integrity. Information must have integrity, i.e. it must be reliable. Data must not be distorted or otherwise damaged by the information system;

— availability. Data must be available to the user at the right place and at the right time, throughout the statutory retention period. The fact that technology can never be 100% reliable makes it necessary to pay attention to the issue of continuity in the event of any failure or disruption;

— non-repudiation and accountability. It must be clear who has entered or accessed which data;

— usability. The data must be usable for the purpose for which it is intended;

— interpretability and analysability. The data must be unambiguous;

— selectivity. The data are selected and consequently suitable and accurate for the appropriate purpose.

Quality demands on the user equipment and peripheral equipment used for telemedicine, information security at the workstation and the secure transport and storage of data, all form part of the overall security and safety of telemedicine (see also NEN 7510, NEN 7511, NEN 7512 and NEN 17799).

5.3.1 Control of data

The care consumer has ultimate control over his own data. The care consumer decides who, in which functional capacity within the care process, may access which data at which level (reading) and may process it in some way: making additions, changes or possibly deleting (writing). On request, the healthcare provider must allow the care consumer access to his own data as quickly as possible and/or provide a copy of (part of) the record (as set out in the Medical Treatment Contract Act). It is therefore essential that the process is designed on the basis of any statutory requirements for the allocation and registration of the roles, rights and obligations of all actors concerned.

5.3.2 Interoperability: standardization and connectivity

Telemedicine bridges distance and links actors at different locations who have different roles and responsibilities. This calls for interoperational systems whereby the actors and the systems themselves can communicate with each other. This requires standardization (NEN-EN 13606, ISO/TR 16056, ISO/TS 16058) and connectivity.

5.3.3 User convenience

The nature of telemedicine is such that it should preferably be capable of being seamlessly incorporated into the process in use by the user (whether healthcare provider or care consumer). The process and the basic functions must be adapted so as to be readily comprehensible to the user, after instruction and/or support where necessary.

5.3.4 Quality aspects of an information system

The quality aspects of information systems can be divided into a number of categories and this has already been done in ISO/IEC 9126. The principal characteristics of the quality of information systems are as follows:

— functionality;

— reliability;

— usability;

— efficiency;

— maintainability;

— portability.

5.4 Quality at the level of business processes

Various aspects of legislation and regulation are applicable to business processes, e.g. facilitating business process security, the arrangement of the roles, the rights and the obligations of actors, the aim for interoperability between systems and the arrangement of certification for both processes and administrative organizations.

This NTA focuses on those aspects of quality that are of particular importance for the business processes of telemedicine.

5.4.1 Process description and organizational structure

An accurate description of the processes of care and the permanent availability of that description is essential. The description must take account of the definition of a “care process”. According to various ISO standards (ISO 9000, ISO 9001, ISO 9004), processes must be defined on the basis of the function that they perform in the achievement of the resulting situation (output) from the starting situation (input). Output is taken to mean the desired final situation, i.e. the situation that fulfils the needs or requirements of the parties involved. This description must cover all processes and subprocesses that are necessary to achieve that desired situation. It should also set out the relationships between the processes and subprocesses, in terms of sequentiality and interaction; the output of one subprocess serves as input for a following subprocess.

It is preferable that coordination and execution of the process should progress in accordance with predefined agreements and procedures. In order to assure both quality and transparency, the roles and rights of the actors involved must be known and be clear, namely: what can be done, how and when (role), and who may do what and when that may be done (right).

At least the following aspects play a role in this context:

— have procedures and protocols been written up and made known?

— has supervision been organized?

— besides being suitably competent, is the person processing the data (in the terms of the Personal Data Protection Act) also authorized to do so?

EXPLANATION Under Article 1 (d) of the Personal Data Protection Act, the controller of the data is: "the natural or legal person or the administrative body which, alone or in conjunction with others, determines the purpose of and means for processing personal data." It is this controller who therefore determines the purpose of such processing and decides on the use of the personal data, the provision to third parties, the data retention period, etc. According to Article 1 (e) of the Personal Data Protection Act, the processor is the person or body which - on behalf of the controller, but not necessarily directly subject to his authority - processes the personal data in some way. The processor therefore processes data on behalf of the controller, i.e. in accordance with his instructions and under his responsibility, whether express or implied. The determining factor in the definition is the relationship with the entity responsible for data processing (the controller) and the degree to which the processing of personal data is accompanied by participation/control on the part of the processor.
(http://www.cbpweb.nl/downloads_uit/z2002-0362.pdf?refer=true&theme=purple)

5.4.2 Responsibility and administrative management

Telemedicine can involve various actors, sometimes a large number, and they can be at different locations. It is therefore important to have a clear description of who is responsible for what process, or aspect of the process. Parties should be aware that the necessity to assure quality implies that minimum demands must be imposed on other actors in the care process. Those others sometimes stand outside the direct sphere of influence of the actors more immediately involved. It is therefore important that all parties recognize that potential risk and work together to reduce it to an acceptable level. The responsibilities of the various parties involved in telemedicine can be set out in contracts or agreements.

EXPLANATION Specific risks are involved when one of the parties is a care consumer (in communication between the patient and the healthcare practitioner for example). The client or patient will often be in a domestic situation. The quality of the client/patient's activities is not guaranteed by legislation, whereas the healthcare practitioner does need to depend on the quality of those activities. Example: the care consumer provides information about the condition of his health and himself carries out measurements such as blood pressure. Specific supplementary criteria then become necessary, such as regular checks of the equipment and of the care consumer's connection; attention must also be paid to correct use of the equipment and the devices used by the care consumer to take measurements.

Telemedicine requires that one or more administrative organizations take responsibility for the process or its component parts.

NOTE In some cases, telemedicine can make use of devices, products and even services that were not designed specifically for use in the context of telemedicine. The weighing up of any possible additional risks that could arise in connection with the use of such devices, products and services outside their "intended use" should be carried out by the controller in a responsible manner (risk analysis).

5.5 Quality assurance

5.5.1 Internal quality system

Any healthcare provider must monitor, manage and where necessary improve the quality of his service in a cyclical and ongoing process. This can best be done by developing a quality management system based on indicators and criteria for quality. The starting point for any improvement of quality must be determined on the basis of the needs of the parties involved.

With the aid of quality indicators in relation to the telemedicine process, and the outcomes of that process, the administrative organization can monitor the effectiveness and efficiency of both the care-related and the logistic process and report on the effects achieved. The monitoring and evaluation of quality indicators also provides information for users (healthcare practitioners and care consumers), healthcare providers, policy makers and healthcare insurers.

5.5.2 External auditability of the process

The quality of the care-related aspects of telemedicine can be assured by auditing systems, spot checks by professional bodies or by certification, all based on the quality requirements formulated by the parties involved.

To ensure auditability and to facilitate reconstruction of the process, it is important that an audit trail is maintained throughout all the various phases of the telemedicine process. Such an audit trail for the process makes it possible to determine at which moment, by which actor and in which capacity data input is effected. The same also holds for any changes effected to the data.

Appendix A
(informative)

Registers of accredited professions in the Dutch healthcare sector

In the definition and elucidation it is stated that healthcare practitioners can use telemedicine applications in the process of caring for a patient. The list of practitioners to whom this applies is set out in Article 3 and Article 34 of the Individual Healthcare Professions Act [*Wet Beroepen in de individuele Gezondheidszorg Wet*, or BIG Act].

The professions defined in Article 3 are those of pharmacist, physician, physiotherapist, healthcare psychologist, psychotherapist, dentist, obstetrician and nurse.

The professions defined in Article 34 are the paramedical professions. These are also mentioned in the BIG Act, although they are listed in a different register which can be found at http://www.kwaliteitsregisterparamedici.nl/. Registration is carried out by the Central Agency for Information on Healthcare Professions (CIBG) under instructions from the Quality Register for Paramedics [*Kwaliteitsregister paramedici*]. This register covers the following professions: pharmacy technician, dietician, occupational therapist, speech therapist, dental hygienist, Cesar and Mensendieck exercise therapists, remedial orthoptist, optometrist, podo- or posture therapist, radiodiagnostic technician, radiotherapeutic technician, dental prosthetician, and care workers providing healthcare in an individual setting (known in Dutch as VIG-ers).