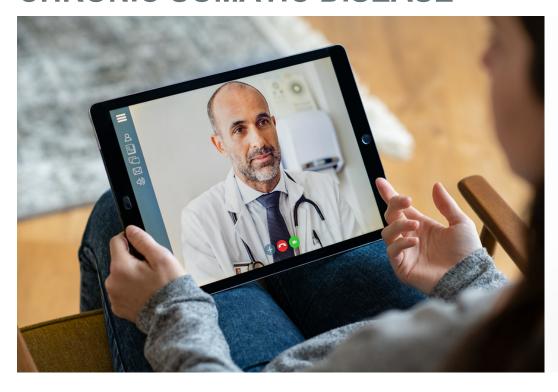


VIDEO CONSULTATIONS IN THE CARE FOR PATIENTS WITH A CHRONIC SOMATIC DISEASE





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VIDEO CONSULTATIONS IN THE CARE FOR PATIENTS WITH A CHRONIC SOMATIC DISEASE

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Ine Verhulst

Layout:

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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
ANS	Agence du Numérique en Santé
ARS	Agence Régionale de Santé
CNAM	Caisse nationale d'assurance maladie
CNIL	Commission nationale de l'informatique et des libertés
CNOM	Conseil national de l'ordre des médecins
CPAM	Caisse primaire d'assurance maladie
CPTS	Communauté professionnelle territoriale de santé
CS	Centres de santé
DBC	Diagnostic-treatment combination (diagnose-behandelcombinatie)
DGOS	Direction générale de l'offre de soins
DMP	Dossier Médical Partagé
EHPAD	Etablissement d'Hébergement pour Personnes Agées Dépendantes
ESP	Equipes de soins primaires
ETAPES	Expérimentations de télémédecine pour l'amélioration des parcours en santé
FES	Feuille de soins électronique
GCS	Groupements de Coopérations Sanitaires
GDPR	General Data Protection Regulation
GP	General Practitioner
HAS	Haute Autorité de Santé
HCP	Health care professional
IGJ	Dutch Health Care Inspectorate (Inspectie Gezondheidszorg en Jeugd)
LDD	Long duration disease



MSP Maisons de santé

NEN Nederlandse Normen

Nictiz Netherlands Institute for ICT in Healthcare (Nationaal ICT Instituut voor de Zorg)

NIVEL Netherlands Institute for Health Services Research (Nederlands Institut voor

Onderzoek van de Gezondheidszorg)

NSD No statistical difference

NZa Dutch Healthcare Authority (Nederlandse Zorgautoriteit)

RIVM Dutch National Institute for Public Health and Environment (Rijksinstituut voor

Volksgezondheid en Milieu)

TM Telemedicine

WHO World Health Organization



■ SCIENTIFIC REPORT

1 BACKGROUND AND AIM OF THE STUDY

In the past decades many technologies emerged that could be used for health care at a distance. These new developments received many names: telemedicine, telehealth, telemonitoring, tele-expertise, eHealth, mobile health, and many others ¹. These include a whole range of new appliances: e.g. administrative applications, electronic patient records, health monitoring wearables, video-communication between health care professionals for interprofessional consultation, video-communication between patients and health care professionals, robotic surgery, online psychotherapy, etc.

All of these new technologies have a lot of promising characteristics that could improve health care provision, but they also pose a lot of questions concerning feasibility, safety, privacy, effectivity, acceptability, reimbursement, and other and many of the questions are currently only partly answered. However, the trend of these developments cannot be stopped, and therefore it is needed to have more insight in how to integrate new technologies in the current health care system.

The World Health Organization ² defined in 2010 telemedicine as 'The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.' However, they also point out that there are many other definitions and that telemedicine is an open and constantly evolving field.

There are many forms of telemedicine. Categorizations may differ from source to source. As an example, the legislation of France ³ considers the following acts as telemedicine: teleconsultation, teleexpertise, medical telesurveillance, medical teleassistance, as well as distance-based medical support provided when emergency medical services are called. They define **Teleconsultation** as « La téléconsultation a pour objet de permettre à un

professionnel médical de donner une consultation à distance à un patient. Un professionnel de santé peut être présent auprès du patient et, le cas échéant, assister le professionnel médical au cours de la téléconsultation.»

Telemedicine received in the past few years much attention of international, European and Belgian^a health care authorities ^{2, 4-10}.

And in the middle of this project there was the COVID-19 crisis and this caused that care at a distance became daily front page news and it shed a whole other light on the study.

In this study, we focused on video consultation, defined as a synchronous two-way video and audio based interactive communication between (a) health care professional(s) and a patient concerning a health issue and replacing a regular face-to-face communication.

The term video consultation is applied as preferred term across the report, but sometimes it was needed to use other terms as well such as teleconsultation if the documents used that term without clearly explaining what was underlying it.

The aim of the study was to obtain insight in

- 1. the patient- (health) effects and effectivity of video consultations for patients with a chronic somatic disease
- 2. barriers/facilitators encountered by professionals and patients when implementing and using video consultations
- 3. how other countries implemented video consultations in their health care (insurance) system

in order to prepare policies to (further) implement video consultations and policies regarding reimbursement regulations and uptake in the national health insurance system in Belgium.

After concertation with RIZIV-INAMI and with UCL/CHU-Namur who submitted the research question, it was decided to limit the project to video consultations applied to patients with a chronic somatic disease and in the chronic follow-up phase (e.g. heart failure, stroke, kidney failure, diabetes, COPD, asthma, rheumatism). These choices were made because they saw the care for chronic somatic patients most suitable for using video consultation and thought this could be a good first step in the roll-out of telehealth in Belgium. We realize that video consultation is/could also be applied in patients with other conditions that have chronic care aspects, such as patients with cancer, or in patients with mental health problems, but due to time constraints (a fixed study period of five months), these patient categories were left out of scope.

Also video consultations applied in acute care situations and cross-border video consultations were out of scope.

Also other forms of telehealth such as telemonitoring^b, teleexpertise, etc. were out of scope for this study.

It is important to do this study since the status of evidence is unclear, as worded by Mallow et al. ¹¹ in 2016 "Although video conferencing has been studied for the past 15 years, evidence of effectiveness is limited by a low number of RCTs with large numbers of participants. Small samples and methodological weaknesses of the studies are major limiters to generalizability of the findings."

Also the Belgian National Institute for Health and Disability Insurance has an active policy for introducing telemedicine within the Belgian health care system: https://www.inami.fgov.be/nl/themas/kost-terugbetaling/door-ziekenfonds/Paginas/telegeneeskunde-mhealth-toepassingen.aspx

There is KCE study planned for second half of 2020 on telemonitoring: https://www.kce.fgov.be/nl/studie-2019-02-hta-telemonitoring-van-pati%C3%ABnten-met-ge%C3%AFmplanteerde-hartapparatuur



- 1. What are the patient-effects and effectivity of video consultations in patients with a chronic somatic disease?
- 2. What are effects, barriers and facilitators experienced by health care professionals and patients (and relatives) in implementing and using video consultations?
- 3. How did other countries handle the implementation of video consultations in their national health care insurance system?

And during the project, a fourth research question was added:

4. What was the effect of the COVID-19 outbreak on the video consultation landscape in Belgium, France and the Netherlands?

For research questions 1 and 2, we performed a rapid review of reviews and for research question 3 and 4 an international comparison with two countries was done.

Hereto we followed the guidance as described in KCE process notes ^{12, 13}.

There is an enormous amount of literature concerning effects/effectivity of telemedicine/telehealth, including primary research but also already many reviews (e.g. ¹⁴⁻²¹). Therefore, we performed a (rapid) <u>review of reviews</u> in which these aspects are described.

A review of reviews is a synthesis of systematic reviews on the same or a similar topic and/or intervention that have been derived through a systematic literature search and offer the opportunity of providing decision makers with a broader summary of the evidence and can contrast the findings of several reviews on the same topic. ²² A reason to perform a review of reviews is that they may be associated with time and resource savings, since the component systematic reviews have already been conducted. ²³

Rapid reviews are a form of knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a timely manner. ²⁴. These might be indicated when a request for evidence-based recommendations is urgent. ¹³

We also opted for this approach in light of the given time constraints of five months to do this project.

Based on the WHO Atlas of eHealth country profiles ¹⁰ and an initial screening in Google of potential relevant countries to be studied, learned that France and the Netherlands would be good candidates to select. Both countries already introduced legislation on video consultation ²⁵⁻²⁹.

In the international comparison we gathered information (a.o. on health insurance matters, privacy & safety regulations, barriers/facilitators in implementing video consultation) by internet searches and contacting relevant stakeholders. A topic list we used for the interviews and for the document analysis can be found in Appendix 1.

More detailed description of the applied methodology is presented at the beginning of each chapter.

In the final phase of the project, an online (Belgian) stakeholder consultation was organized in order to gather their opinion on the draft recommendations that were written based on the performed research. Draft recommendations are normally discussed with stakeholders in a physical meeting at KCE-offices at the end of a project, to check the stakeholder's opinion, the feasibility of the recommendations, the correct phrasing of the recommendations, and if something important has been missed. However, due to the COVID-19 crisis, such a meeting was not possible and therefore we opted for an online-survey. In line with normal KCE-procedures outcomes of such discussions with stakeholders are not part of the scientific report and only used to fine-tune the recommendations.



2 RAPID REVIEW OF REVIEWS ON VIDEO CONSULTATION FOR PATIENTS WITH A CHRONIC SOMATIC DISEASE

2.1 Key-findings

Results

- We included 20 reviews on patient effects, 3 reviews on providers effects, 12 reviews on barriers and facilitators (covering hundreds of primary studies). In addition we analysed 30 primary RCTs concerning patient effects and 10 reviews of reviews to compare our results with (covering > 100 reviews)
- All included reviews showed large heterogeneity in patient populations, interventions and control conditions, outcomes and study designs
- Although review authors cautiously conclude that telehealth in general and video consultations in specific may have a positive impact on patient health, the general conclusion is that there is no firm evidence that video consultations are equal or better than the control conditions. On the other hand there is no evidence that telehealth in general or video consultations in particular have negative patient effects. Also it seems that patients are satisfied with video consultations
- Review authors conclude that health care providers are rather reluctant to use telehealth/video consultations and it may increase their workload due to the setting up of the technology
- Review authors conclude that are many barriers in the implementation
 of video consultations and these are patient related (e.g. ICT-illiteracy),
 provider related (e.g. impossibility to do a physical exam), technology
 related (e.g. inadequate internet and Wi-Fi coverage) and health system
 related (e.g. no reimbursement regulations)

 Facilitators for implementation of video consultation are among others, well performing technology, reimbursement, ICT-skills and earlier experience both for patients and providers. Also there need to be a clear goal and well developed plan to implement successfully video consultations

Conclusion:

- Despite an enormous amount of studies, there is still no firm evidence that video consultations are equal or better than usual care, but on the other hand there is no evidence that video consultations have negative patient effects
- Our findings are in line with other reviews of reviews
- There is a need for further research in the comparable effectiveness of video consultations
- Many factors influence the implementation of video consultations at several levels. These should be handled together when further implementing video consultations

2.2 Methodology

There is an enormous amount of literature concerning implementation and effects/effectivity of telemedicine/telehealth, including primary research but also already many reviews (e.g. ¹⁴⁻²¹).

Therefore, we performed a (rapid) <u>review of reviews</u> in which these aspects are described. Guidance as described in KCE process notes ^{12, 13} was followed.

Furthermore we limited the review to recent articles (from 2014 on) and articles written in Dutch, French or English.



We retrieved literature from PubMed, Embase, CINAHL, EvidenceNHS and the Cochrane Library.

Based on other reviews ^{14, 15, 17, 30} an initial specific (mainly using Mesh-terms and with a review search filter^c) search strategy was developed for PubMed and adapted for the other databases (see Table 1).

Relevant outcomes on which data were extracted included quality of life, patient satisfaction, health status parameters, and health care use (e.g. hospital (re)admissions) (see Table 2).

Regarding the intervention, we focused on video consultation (as defined above) as main intervention; data about co-interventions (such as regular face to face consultations, telemonitoring, health apps, etc.) were extracted as far as possible.

Beside insight into patient-effects, it is also important to obtain more insight in effects for health care professionals, health care organisations and health care systems, as well as more insight in barriers and facilitators to implement teleconsultation and in to how the intervention works ³¹.

As mentioned above, there is an enormous amount of literature concerning telemedicine/telehealth, including primary research but also already many reviews. Some of these reviews also concern barriers in implementation, but many focus only on effects or effectivity. Therefore, for the aspect of barriers we studied the reviews obtained by the search strategy as described above, but in addition we also searched for primary qualitative research papers in which barriers might be described.

Hereto, we extended our strategy with a qualitative research filter^d.

The final search strategy for PubMed is depicted in Table 1.

Table 1 – PubMed search strategy

	Definition			Search terms
Patients:	Patients with a chronic somatic	Heart failure	1	"Heart Failure"[Mesh]
	disease in the follow-up/ counseling/ intervention phase of their disease	COPD	2	"Pulmonary Disease, Chronic Obstructive"[Mesh]
		Diabetes	3	"Diabetes Mellitus"[Mesh]
	_	Kidney failure	4	"Kidney Failure, Chronic"[Mesh]
	_	Asthma	5	"Asthma"[Mesh]
	_	Stroke	6	"Stroke"[Mesh]
		Chronic disease general	7	("Long-Term Care"[Mesh]) OR ("Chronic Disease"[Mesh] OR "Multiple Chronic Conditions"[Mesh])
	<u></u>	Rheuma	8	"Rheumatic Diseases"[Mesh]

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https://dal.ca.libguides.com/systematicreviews/searchfilters#s-lg-box-6303619

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	Definition			Search terms
	Combination	COMBINED 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8	9	"Heart Failure"[Mesh] OR "Pulmonary Disease, Chronic Obstructive"[Mesh] OR "Diabetes Mellitus"[Mesh] OR "Kidney Failure, Chronic"[Mesh] OR "Asthma"[Mesh] OR "Stroke"[Mesh] OR ("Long-Term Care"[Mesh]) OR ("Chronic Disease"[Mesh] OR "Multiple Chronic Conditions"[Mesh]) OR "Rheumatic Diseases"[Mesh]
Intervention	Teleconsultation: a synchronous interaction between a care professional (any type) and a patient by means of two-way internet-based videoconnection.	compilation, for a rapid assessment of the literature Based on search strategies in other reviews ^{14, 15, 30} and a little 'playing' with AND and NOT and OR	10	"Telemedicine" [Mesh] OR "Telenursing" [Mesh] OR "Remote Consultation" [Mesh] OR "Videoconferencing" [Mesh] OR telemedicine [tiab] OR telenursing [tiab] OR "remote consultation" [tiab] OR teleconsult* [tiab] OR telehealth [tiab] OR videoconsultation [tiab] OR telerehabilitation [tiab] OR telestroke [tiab] OR telerheumatology [tiab]
Comparison	Usual care			NOT IN SEARCH STRATEGY
Outcome				NOT IN SEARCH STRATEGY
Type of study	-review -qualitative study	a review search filter From: https://dal.ca.libguides.com/systematicreviews/searchfilters#s-lg-box-6303619	11	((((((((((((((((((((((((((((((((((((((



Definition			Search terms
	Qualitative research filter From: https://dal.ca.libguides.com/systematicreviews/searchfilters#s-lg-box-6303619	12	"interviews as topic" [Mesh:noexp] OR "focus groups" [Mesh:noexp] OR narration [Mesh:noexp] OR qualitative research [Mesh:noexp] OR ((("semi-structured" [TIAB] OR semistructured [TIAB] OR unstructured [TIAB] OR structured [TIAB] OR informal [TIAB] OR "indepth" [TIAB] OR indepth [TIAB] OR "face-toface" [TIAB] OR guide [TIAB] OR guides [TIAB]) AND (interview* [TIAB] OR discussion* [TIAB] OR questionnaire* [TIAB])) OR ("focus group" [TIAB] OR "focus groups" [TIAB] OR qualitative [TIAB] OR ethnograph* [TIAB] OR fieldwork [TIAB]))
Combination	11 OR 12	13	((((((((((((((((((((((((((((((((((((((



Definition		Search terms
		AND (interview*[TIAB] OR discussion*[TIAB] OR questionnaire*[TIAB])) OR ("focus group"[TIAB] OR "focus groups"[TIAB] OR qualitative[TIAB] OR ethnograph*[TIAB] OR fieldwork[TIAB] OR "field work"[TIAB] OR "key informant"[TIAB])))
OVERALL	9 AND 10 AND 13	(((((((((((("("Heart Failure"[Mesh]) OR "Pulmonary Disease, Chronic Obstructive"[Mesh]) OR "Diabetes Mellitus"[Mesh]) OR "Kidney Failure, Chronic"[Mesh]) OR "Asthma"[Mesh]) OR "Rheumatic Diseases"[Mesh] OR "Stroke"[Mesh]) OR ("Chronic Disease"[Mesh] OR "Multiple Chronic Conditions"[Mesh])))) AND ("Telemedicine"[Mesh] OR "Telenursing"[Mesh] OR "Remote Consultation"[Mesh] OR "Videoconferencing"[Mesh] OR telemedicine[tiab] OR telenursing[tiab] OR telenursing[tiab] OR telenursing[tiab] OR telenursing[tiab] OR telenursing[tiab] OR telerehabilitation[tiab] OR telestroke[tiab] OR telerehabilitation[tiab] OR telestroke[tiab] OR telerehabilitation[tiab] OR telestroke[tiab] OR telerehabilitation[tiab] OR telestroke[tiab] OR telerheumatology[tiab]) AND ((("interviews as topic"[Mesh:noexp] OR "focus groups"[Mesh:noexp] OR narration[Mesh:noexp] OR qualitative research[Mesh:noexp] OR ((("semi-structured"[TIAB] OR unstructured[TIAB] OR semistructured[TIAB] OR informal[TIAB] OR "indepth"[TIAB] OR guides[TIAB] OR semistructured[TIAB] OR informal[TIAB] OR "face-toface"[TIAB] OR guide[TIAB] OR guides[TIAB]) AND (interview*[TIAB] OR discussion*[TIAB] OR questionnaire*[TIAB] OR discussion*[TIAB] OR questionnaire*[TIAB] OR fieldwork[TIAB] OR "field work"[TIAB] OR "field work"[TIAB] OR "fieldwork[TIAB] OR "field work"[TIAB] OR "fieldwork[TIAB] OR "field work"[TIAB] OR "fieldwork"[TIAB] OR "field work"[TIAB] OR "fieldwork"[TIAB]))) OR meta analy*[tw]) OR m



Definition			Search terms
			Meta-Analysis[pt]) OR (((systematic AND (review* OR overview*)) AND tw))) OR "Review Literature as Topic"[Mesh])) OR ((((((((cochrane[tiab]) OR embase[tiab])) OR ((psychinfo OR psycinfo[tiab])))) OR (((cnahl OR cinhal[tiab])))) OR science citation index[tiab]) OR bids[tiab]) OR cancerlit[tiab])) OR ((((reference list*[tiab]) OR bibliograph*[tiab])) OR hand-search*[tiab]) OR relevant journals[tiab]) OR manual search*[tiab])) OR ((((selection criteria[tiab])) OR data extraction[tiab])) AND "Review"[pt]))) NOT (((("Comment"[pt])) OR "Letter"[pt])) OR "Editorial"[pt])) OR (("Animals"[Mesh]) NOT (("Animals"[Mesh]))))))))))) AND ("2014/01/01"[PDat]: "3000/12/31"[PDat]])))
	Limited to publication in the period 2014-2020	15	13 Filters: Publication date from 2014/01/01

After the initial searches, we subscribed to a daily alert from PubMed to check on new possible relevant reviews and was followed until the end of March 2020.

In addition, on 30 March 2020 a search was performed in PubMed to check for possible 'game-changing' e randomized trials in the past year, hereto we applied the above PubMed strategy on patients AND interventions, limited to randomized trials OR clinical trials and date-limit (past year).

The reviews of reviews we encountered were used as additional source for relevant reviews and to check our search strategy; also these reviews of reviews were used to compare our findings.

2.2.2 In/exclusion process and criteria

All search results were imported in Endnote, which was further used for deduplication of references.

Hereafter, references were sifted for relevance on title/abstract by a single reviewer.

After obtaining full-texts of possible relevant references, a single reviewer assessed them all on in- and exclusion criteria; in case of doubt a second reviewer did a second assessment.

The in- and exclusion criteria are listed in Table 2.

Game-changing trials are well-performed large studies that present conclusions that are in contrast with all previous published research



Table 2 - In- and exclusion criteria

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	INCLUSION	EXCLUSION
Patient	Adult patient with a chronic somatic disease and in chronic phase	Patients with mental disease Patients with dementia Patients with cancer, when in treatment phase Patients with chronic disease in diagnosis phase or initial acute treatment Children
Intervention	A form of video consultation (=a synchronous two-way video and audio based interactive communication between a health care professional and a patient concerning a health issue), either as stand-alone intervention or in combination with other types of telehealth, either as replacement of in addition to regular face-to-face consultation. Health care professional could be of any type (MD, RN,) Patients may be accompanied by someone else (either relative of other healthcare professional) The intervention may consist of a single teleconsultation or a series of teleconsultations	Tele-expertise (MD-specialist and MD-GP) Telemonitoring only Teleconsultation without video (e.g. telephone, sms WhatsApp,) Asynchronous teleconsultation Teleconsultation with solely diagnostic purposes
Control/comparison	Regular face-to-face consultation	
Outcome	For reviews: - At least a health status outcome at patient level - Or hospital (re)admission - Or quality of life measure - Or patient satisfaction For reviews and qualitative studies: - Patient effects - Effects in relatives - Barriers/facilitators in healthcare professionals - Barriers/facilitators in patients - Barriers/facilitators in relatives - Barriers/facilitators in technology - Barriers/facilitators in health care system organization	
Type of study	- Reviews (or review of reviews) of the literature concerning patient effects of teleconsultation OR barriers in implementing/using teleconsultation	Primary randomized controlled trialsEditorialsLetters to the editor

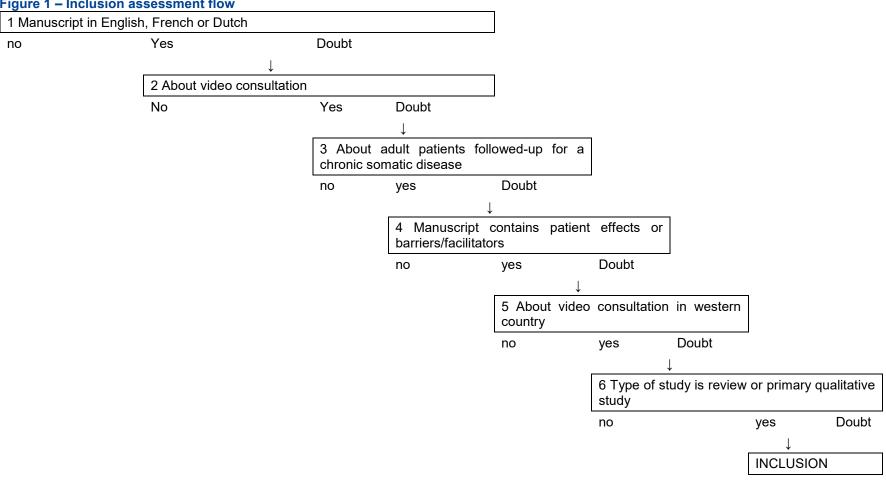


	INCLUSION	EXCLUSION
	 Primary research using qualitative methodology barriers/facilitators in implementing/using teleconsultation 	
Other	 Western country ((EU28/EEA, USA, Canada, Australia (see also https://www.gov.uk/eu-eea) Manuscript written in English, Dutch or French Manuscript published in 2014 or later 	a and New Zealand)

The sequence of applying the criteria, is depicted in Figure 1.









2.2.3 Data-extraction and synthesis

- Review characteristics:
 - Publication year
 - Study design
 - Methodological assessment : AMSTAR 2 https://amstar.ca/Amstar Checklist.php ³²
 - Number of studies
- Intervention characteristics:
 - Type of videoconferencing
 - Frequency/dosage
 - Duration
 - Other accompanying interventions
 - Type of healthcare professional(s)
- Patient characteristics
 - Type of disease
 - Phase of disease
 - Functional status
 - Age/gender
 - o ...
- Control characteristics
- Outcome characteristics
 - Instrument
 - Frequency
 - Timing

- Type of outcome (health status, readmission, adverse events, quality of life, satisfaction / barriers /feasibility/ acceptability/ costs, ...)
- Effect direction (in favor of TC, contra or equivocal...)
- Effect size
- o ..

All data-extraction was done with Excel by a single reviewer.

We intended to extract and synthesize in a first step all data from the reviews and in a second step to analyze the primary qualitative studies. However, due to sufficient amount of reviews, the second step was skipped.

Data were synthesized in a descriptive way only. No attempt was done to perform meta-analysis, due to the expected (and observed) heterogeneity.

2.3 Results

2.3.1 Search results

The initial databases searches resulted into a total of 1434 references (for results per database see Appendix 2) and to 1175 unique references after deduplicating. Additionally 7 references were added through the daily Pubmed alerts and 1 from the reference lists of the meta-reviews that were identified, leading to a total of 1183 unique references that were assessed on inclusion criteria.

After assessment of titles and abstracts, 331 references left for full-text assessment.

137 references fulfilled all inclusion criteria, of which 89 were reviews, 10 were reviews of reviews and 38 primary qualitative studies.

The reviews of reviews were used to track eventual additional reviews we did not identify and to compare and contrast their findings with ours.

The primary qualitative studies were kept aside and left from data-extraction, in contrast with the protocol, since there were already enough reviews with

qualitative data on barriers and facilitators and the primary studies were deemed not longer to be necessary.

Due to time constraints a further restriction was made to reviews that were focused on video consultation only or had a separate analysis of studies with video consultation, for as far they regarded effects on patients.

In consequence, 20 reviews ^{15, 33-51} were left for data-extraction with regard to patient and provider effects and 12 reviews 47,52-62 that focused on barriers and facilitators in implementing teleconsultation. And we kept 10 reviews of reviews ^{17, 63-71} to compare with our results.

Additionally, due to the large heterogeneity in interventions, outcomes and patient populations encountered in the included reviews, it was decided to have a closer look at randomized trials with video consultation in patients with a chronic somatic disease and in the chronic phase, that were included in one or more of the included reviews, in order to be more certain about the patient health effects. Thirty such RCT-studies 72-101 were included in one or more of the included reviews and subjected to further data-extraction.

The search for game-changing RCTs that was performed on 30 March 2020, resulted in 34 references 102-135 of which only one 123 was a (small scale) randomized trial in patients with a chronic somatic disease (i.c. heart failure) and with video consultation as intervention.

2.3.2 Effects of video consultation on patients

Key findings

- Large number of primary studies included in the reviews
- Large heterogeneity in patient populations, interventions, control conditions and outcomes, prohibiting to draw firm conclusions
- Review authors cautiously conclude in favor of video consultations
- No evidence of negative effects of video consultations on patient's health

Twenty reviews focused on video-consultation interventions or had a separate analysis on it; of these 19 reviews focused on patient effects or/and 3 on provider effects. Publication of the reviews dated from 2014 (2 39, 42), 2015 (3 15, 33, 40), 2016 (3 37, 44, 51), 2017 (2 38, 41), 2018 (7 34, 36, 46-50), and 2019 (3 ^{35, 43, 45}).

Methodological assessment of the 19 reviews with patient effects was performed with the AMSTAR-2 instrument; results of this are shown in Appendix 3. Four reviews were assessed as 'critical low quality', 7 as 'low quality', 6 as 'moderate quality' and 2 as 'high quality'.

The number of studies included in the reviews varied from 1 to 107, and between 1 and 41 included studies specific on video consultation and between 0 to 9 RCTs with video consultations in patients with a chronic somatic disease.

Table 3 shows the search period and number of included studies in the reviews with patient-effects.



Table 3 – Search period and number of studies included in the reviews

Review first author	date	search period	N studies included	N studies included specific on video consultation	N RCTs included with video consultation in patients with chronic somatic disease
Armfield, N. R. ³³	2015	2006-2014	27	27	3
Aronow WS 34	2018	inception-2018	58	2	2
Batsis JA ³⁵	2019	2012- mid 2018	17	17	6
Bauce K ³⁶	2018	inception-2016	11	11	6
Cottrell MA ³⁷	2016	inception-2015	13	13	0
Flodgren G ¹⁵	2015	inception-2013	93	36	9
Grona SL ³⁸	2017	2003-2016	17	17	2
Health Policy Advisory Committee on Technology ³⁹	2014	unclear	5	5	0
Inglis SC ⁴⁰	2015	2008-2015	41	41	2
Lee SWH ⁴¹	2017	inception-2016	107	8	1
Nordheim LV ⁴²	2014	1980-2014	1	1	0
Orlando JF ⁴³	2019	2013-2017	36	36	0
Ostherr K ⁴⁴	2016	1996-2014	38	2	0
Ovtcharenko N ⁴⁵	2019	unclear-2018	32	10	0
Pedrozo Campos Antunes T 46	2018	unclear-2017	18	4	0
Rush KL ⁴⁹	2018	2000-april 2018	8	8	1
Rush KL ⁴⁸	2018	2006-2017	16	3	1
Wagg AJ ⁵⁰	2018	unclear-2016	31	7	0
Zandbelt LC ⁵¹	2016	inception-2014	21	17	6

In Table 4 below the patient-inclusion and intervention-inclusion criteria, as worded in the reviews are listed. As can be seen, a whole variety of patients with a chronic somatic disease were considered in the reviews, varying from elderly in general or patients at the end of life to patients with heart failure or

diabetes; mostly it was not clear from the inclusion criteria what the phase of the disease was, when the intervention occurred.

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When the patient inclusion criteria of the reviews were compared with actual patient populations in the included studies, the myriad of several chronic diseases and phases were confirmed. This heterogeneity alone already prohibits to draw specific conclusions.

Next to this, the reviews considered several types of tele-health interventions, varying from the old-fashioned telephone talk, email or SMS to a simple Skype video-communication to complex multi-component telemonitoring interventions in which video-communication was part of it. When

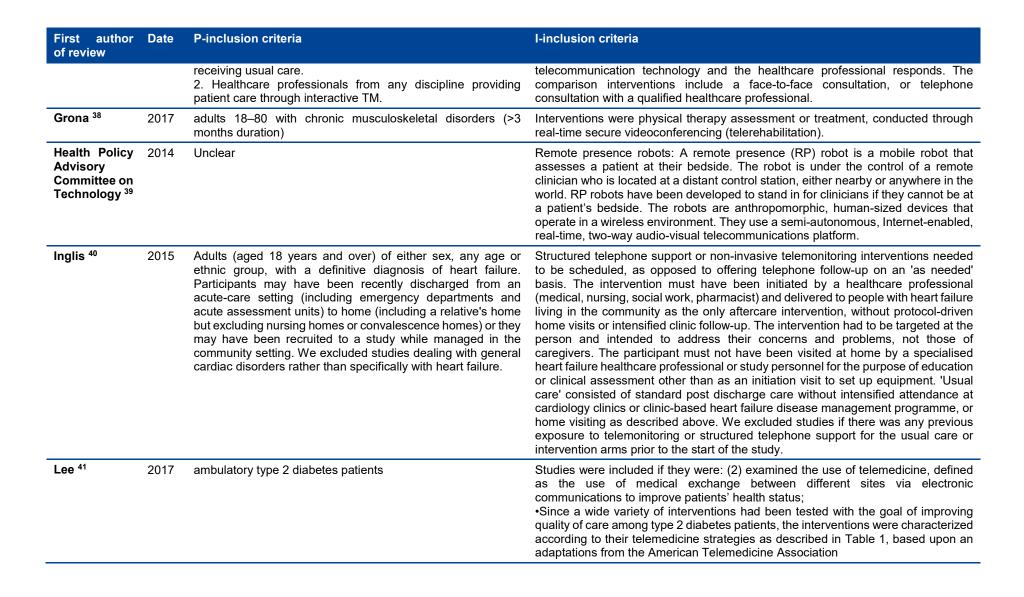
intervention inclusion criteria were compared to actual intervention description of the included studies, the heterogeneity in type, intensity, frequency of interventions and intervention providers was confirmed. Moreover, most reviews did not specify inclusion criteria for the control intervention and did not describe in detail the actual control conditions to which the telehealth interventions were compared with.

This other type of heterogeneity added to the difficulty to draw conclusions across the reviews.

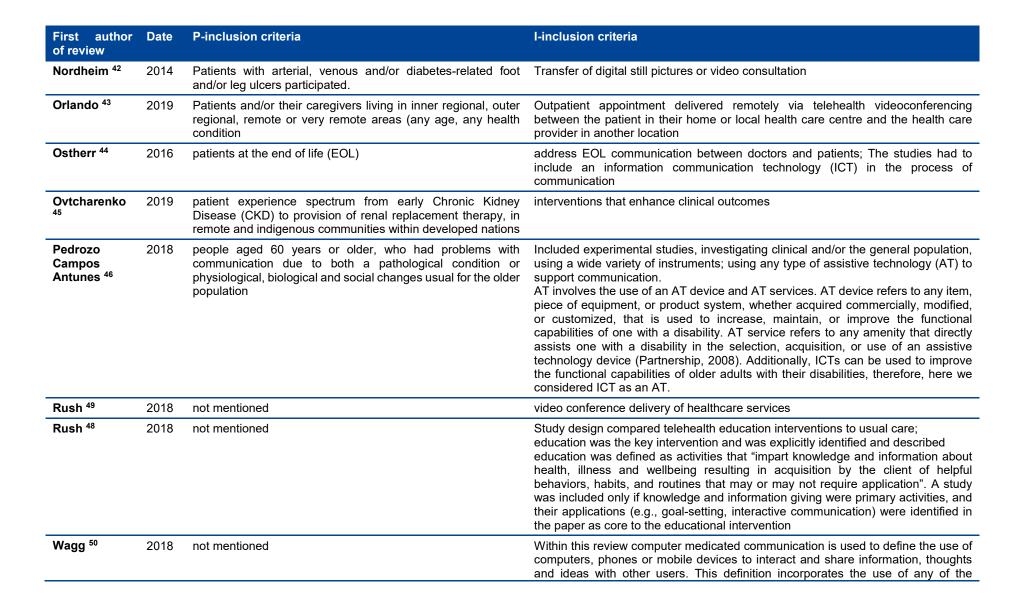
Table 4 – Patient and intervention inclusion criteria in reviews

First author of review	Date	P-inclusion criteria	I-inclusion criteria
Armfield ³³	2015	All	Papers were included if they reported the use of video calls by Skype for patient care or clinical education, in any clinical application area.
Aronow ³⁴	2018	Adults With Chronic Congestive Heart Failure	Non-invasive information technologies that were eligible for the review included telemonitoring; structured telephone support; and use of personal digital assistants, videophone and conferencing, or interactive voice
Batsis ³⁵	2019	Patients aged 65 years, in home or in an assisted living or long-term care setting; and with a comorbid physical or mental health conditions	Ambulatory Telemedicine care delivered either in home or in an assisted living or long-term care setting on the receiving end of the intervention. Interventions were considered only if telemedicine was defined as live, real-time, synchronous, two-way videoconferencing on both the receiving and delivery end. and with focus on patient care with a healthcare provider or trained staff (ie, physicians, associate providers [advanced practice registered nurses or physician's assistants], physical/occupational therapists, psychologists, social workers, or dietitians) on one end and a patient on the receiving end. We also included peer-to-peer therapy for medical conditions, as it ultimately resulted in delivering patient care.
Bauce ³⁶	2018	adult patients with heart failure in the home environment	Telemedicine interventions that include videoconferencing (VC)
Cottrell ³⁷	2016	Adults (≥ 18 years) presenting with any diagnosed primary musculoskeletal condition, including post-operatively for surgical procedures as a result of a primary musculoskeletal condition.	Any treatment intervention provided via a real-time telerehabilitation medium, either in conjunction with, or in isolation of, other treatment interventions were included.
Flodgren ¹⁵	2015	Patients receiving interactive Telemedicine (TM) from any qualified healthcare practitioner, compared with those	Telemedicine used in direct patient care, in which the patient is at a different location to the healthcare professional and transmits clinical information via a

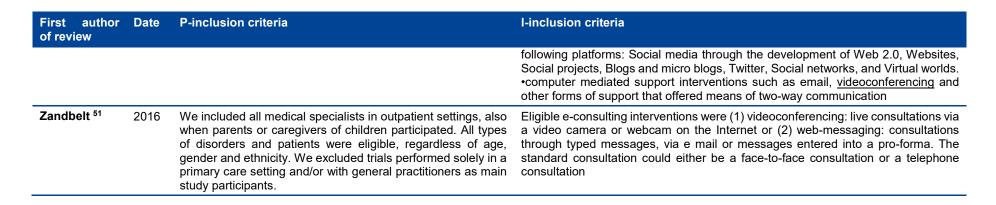
Video consultation for chronic somatic disease











When looking at the applied inclusion criteria concerning type of outcome or type of research design, the same pattern of heterogeneity appeared. These varied from very specific clinical parameters such HBa1c –levels, to health care use measures (e.g. readmissions), to generic or disease specific quality of life instruments, mortality and patient satisfaction. When looked at the actual outcomes that were measured in the studies included in the reviews, the heterogeneity even increased due to plethora of different instruments used to measure outcomes, the different time frames and frequencies in which outcomes were measured, and the different periods of follow-up.

Nevertheless, and despite all types of heterogeneity, most review authors conclude cautiously that telehealth-intervention in general or video

consultation specifically might lead to equal or slightly better effects than the control condition.

Next to this, none of the reviews found evidence that telehealth or video consultation led to negative patient health effects. Caveat, no evidence of negative effects does not mean the same as evidence of no negative effects.

However, all review authors point to the large heterogeneity in patients, intervention and outcome characteristics and to the weak study designs and warn that this precludes firm conclusions regarding effects of tele/video-consultations. Review authors in fact state that there is insufficient evidence and stress the need for more research.

Conclusions of the review authors are listed in Table 5.

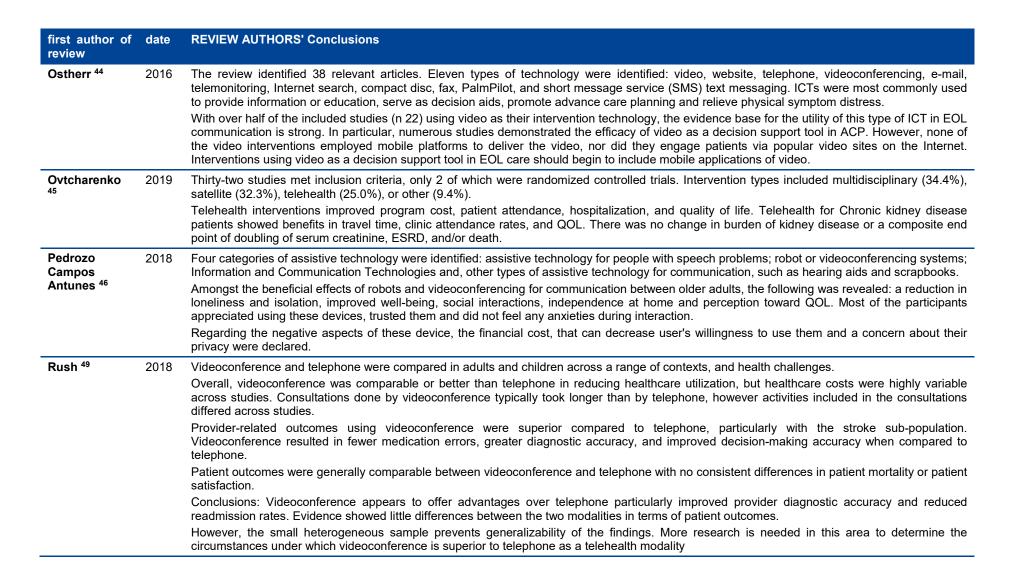


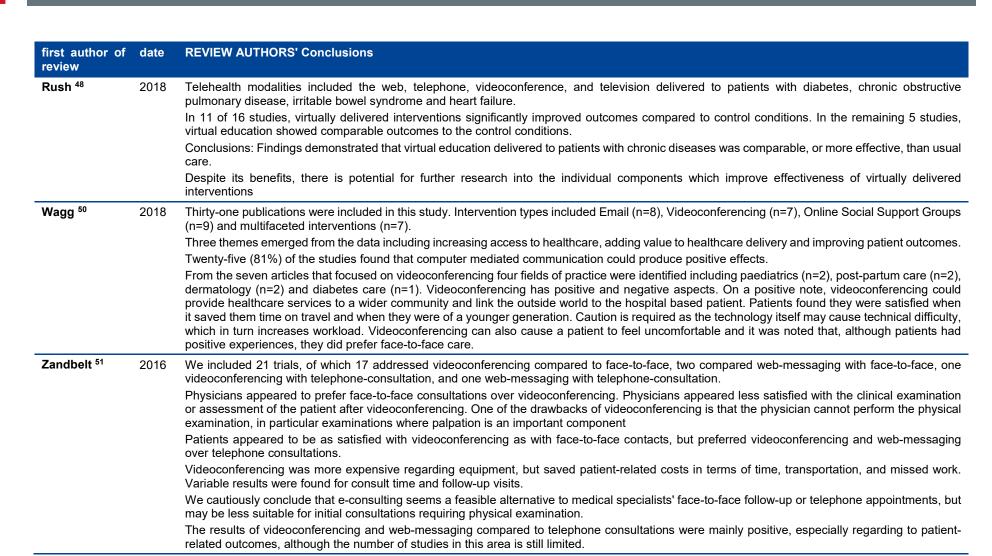
Table 5 - Review authors' conclusions

first author of review	date	REVIEW AUTHORS' Conclusions
Armfield ³³	2015	The use of Skype was most prevalent in the management of chronic diseases such as cardiovascular diseases and diabetes, followed by educational and speech and language pathology applications. In all but one case, Skype was reported by the authors to be feasible and to have benefit. However, while Skype may be a pragmatic approach to providing telemedicine services, in the absence of formal studies, the clinical and economic benefits remain unclear.
Aronow 34	2018	Videophone or interactive voice is not better than usual care in improving patient outcomes.
Batsis 35	2019	Telemedicine is feasible and acceptable in delivering care to older adults.
Bauce ³⁶	2018	The use of videoconferencing combined with remote physiological monitoring yielded promising results. Many studies demonstrated reduced hospital services use and increased Quality of Life.
		However, these findings should be interpreted cautiously due to the methodological limitations described.
Cottrell ³⁷ 2016	2016	Real-time telerehabilitation appears to be effective and comparable to conventional methods of healthcare delivery for the improvement of physical function and pain in a variety of musculoskeletal conditions.
		Studies that utilised telephone as the telerehabilitation medium showed a moderate-large effect favouring telerehabilitation, whilst videoconferencing software yielded a small effect in favour of the same cohort.
		Telerehabilitation via videoconferencing software is comparable, and not inferior, to standard face-to-face physiotherapy treatment following total knee arthroplasty
Flodgren ¹⁵	2015	Telemedicine provided remote monitoring (55 studies), or real-time video-conferencing (38 studies), which was used either alone or in combination. The findings in our review indicate that the use of telemedicine in the management of heart failure appears to lead to similar health outcomes as face-to-face or telephone delivery of care.
		There is evidence that telemedicine can improve the control of blood glucose in those with diabetes.
		The cost to a health service, and acceptability by patients and healthcare professionals, is not clear due to limited data reported for these outcomes. The effectiveness of telemedicine may depend on a number of different factors, including those related to the study population e.g. the severity of the condition and the disease trajectory of the participants, the function of the intervention e.g., if it is used for monitoring a chronic condition, or to provide access to diagnostic services, as well as the healthcare provider and healthcare system involved in delivering the intervention.
Grona 38	2017	Intervention studies were of moderate quality, and found positive impact on health outcomes and satisfaction.
		Two studies evaluated costs, with evidence of cost savings in one study.
		More robust research is required to evaluate long-term effects of telerehabilitation for physical therapy management of musculoskeletal disorders, including cost-benefit analyses.
Health Policy Advisory Committee on Technology ³⁹	2014	One small randomised controlled trial and four non-randomised comparative studies were identified on the RP-7 remote presence robot. Study designs were variable, as were the outcomes tracked. With respect to efficacy, good to excellent performance and high rates of satisfaction for physicians, nurses and patients were noted. Several studies reported decreased length of stay (LOS) for patients assessed by remote presence devices, primarily due to an increased presence and timely patient assessment (e.g. evening rounds following surgery). However, in one study it is



first author of review	date	REVIEW AUTHORS' Conclusions
		not clear whether the reduced LOS was due to the remote presence robot or the fact that the patients in this treatment group had additional visits compared with the control group. Adverse events attributable to remote presence devices were not reported.
Inglis ⁴⁰	2015	For people with heart failure, structured telephone support and non-invasive home telemonitoring reduce the risk of all-cause mortality and heart failure-related hospitalisations; these interventions also demonstrated improvements in health-related quality of life and heart failure knowledge and self-care behaviours. Studies also demonstrated participant satisfaction with the majority of the interventions which assessed this outcome. Although some technologies appeared inferior, such as the videophone and IVR, tests for heterogeneity were unable to confirm differences.
		Technology categories that did not individually demonstrate statistically significant effects on all-cause mortality in people with heart failure included videophone
		Technology categories that did not individually demonstrate statistically significant reductions in all-cause hospitalisation in people with heart failure included videophone
		The only two videophone studies in this review both had low satisfaction and statistically non-significant satisfaction ratings
Lee ⁴¹	2017	Studies were classified according to the following telemedicine strategies: teleeducation, telemonitoring, telecase-management, telementoring and teleconsultation. Network meta-analysis showed that all telemedicine strategies were effective in reducing HbA1c significantly compared to usual care except for telecase-management and telementoring.
		Ranking indicated that teleconsultation was the most effective telemedicine strategy, followed by telecase-management plus telemonitoring, and finally teleeducation plus telecase-management. The review indicates that most telemedicine strategies can be useful, either as an adjunct or to replace usual care, leading to clinically meaningful reduction in HbA1c.
Nordheim ⁴²	2014	Only one non-randomized study was included. The study (n = 140) measured the effect of real-time interactive video consultation compared with face-to-face follow-up on healing time, adjusted healing ratio and the number of ulcers at 12 weeks among patients with neuropathic forefoot ulcerations. There were no statistically significant differences in results of the different outcomes between patients receiving telemedicine and traditional follow-up. We assessed the study to have a high risk of bias.
		Conclusions: There is insufficient evidence available to unambiguously determine whether telemedicine consultation of leg and foot ulcers is as effective as traditional follow-up.
Orlando ⁴³	2019	Thirty-six studies of varying study design and quality met the inclusion criteria. The outcomes of satisfaction with telehealth were categorised into system experience, information sharing, consumer focus and overall satisfaction.
		There were high levels of satisfaction across all these dimensions.
		Despite these positive findings, the current evidence base lacks clarity in terms of how satisfaction is defined and measured. People living in rural and remote areas are generally satisfied with telehealth as a mode of service delivery as it may improve access to health care and avoid the inconvenience of travel.







Due to these very general conclusions of the reviews, it was decided to have a closer look in the included reviews at the primary studies they included and that used a randomized control design with a specific video consultation intervention in patients with a chronic somatic disease in a chronic phase, since these give a better and a methodologically stronger picture of real patient effects. Thirty primary studies 72-101 fulfilled this pattern and are listed

below in Table 6; some studies were included in more than 1 review. In some studies video-communication was part of a multicomponent telehealth intervention.

Below in Table 6 the effects of the video consultation in the RCTs are listed, as worded by the review authors.

Table 6 - Characteristics of RCTs included in the reviews

First Author of primary study	year	type of patients	N exp	N control	risk of bias according to review authors	teleconsult mode according to review authors	effect according to review no significant difference Better for video-intervention Better for control condition
Ishani ⁸⁴	2016	chronic kidney disease	451	150	high risk of bias	live, real-time, synchronous, two-way videoconferencing on both the receiving and delivery end	No significant difference (NSD) between groups for any component of the primary outcome
Pronovost 92	2009	chronic pain	26	26	high risk of bias	videoconferencing + telemonitoring	Patient-related outcomes: • patient satisfaction with format of the consultation: better for TM; • pain score: day of consultation: NSD; • pain score day after consultation: NSD; •pain score first week: NSD; •quality of life: IIRS score: NSD •Cost outcomes: total patient cost: better for TM
Dichman ⁷⁹	2016	COPD	132	134	low risk of bias	live, real-time, synchronous, two-way videoconferencing on both the receiving and delivery end (Computer with web camera and microphone and peripherals)	No difference in number of hospital readmissions
Mark ⁸⁹	2013	COPD	11	12	low risk of bias	skype	(not specified)effects favor SKYPE
Nield ⁹⁰	2012	COPD	9	7	low risk of bias	skype	(not specified)effects favor SKYPE
Tsai ⁹⁸	2017	COPD	19	17	high risk of bias	live, real-time, synchronous, two-way videoconferencing on both the receiving and delivery end (Laptop	Improvement in Endurance exercise capacity test ESWT (P < .001)



First Author of primary study	year	type of patients	N exp	N control	risk of bias according to review authors	teleconsult mode according to review authors	effect according to review no significant difference Better for video-intervention Better for control condition
						computer with built-in camera and peripherals)	
Davis ⁷⁷	2010	diabetes	85	80	high risk of bias	video-conferencing	 +HbA1c at median 9 months follow-up: slightly better for TM. LDL-cholesterol at median 6 months follow-up: better for TM Systolic blood pressure at median 9 months follow-up: better for TM
Esmatjes ⁸¹	2014	diabetes	78	76	high risk of bias	videoconferencing + telemonitoring	Patient-related outcomes: (change between first and last visit) Hypoglycemia: HbA1c: NSD No of severe and mild hypoglycemic episodes: NSD quality of life (EuroQol): NSD diabetes quality of life (DQoL): satisfaction: better for control impact: NSD Social wory: NSD Diabetes Worry; better for control diabetes self-management: blood glucose testing frequency/week: NSD diabetes knowledge (DKQ2): NSD, adherence to self-care: NSD, hypoglycaemia perception: NSD Cost outcomes: patient time costs: mean estimated cost of visits for patient: better for TM Diabetes team costs: better for TM
Izquierdo ⁸⁵	2003	diabetes	24	22	high risk of bias	video-conferencing/ education	 HbA1c at median 9 months follow-up: NSD No difference in blood pressure or BMI between groups.

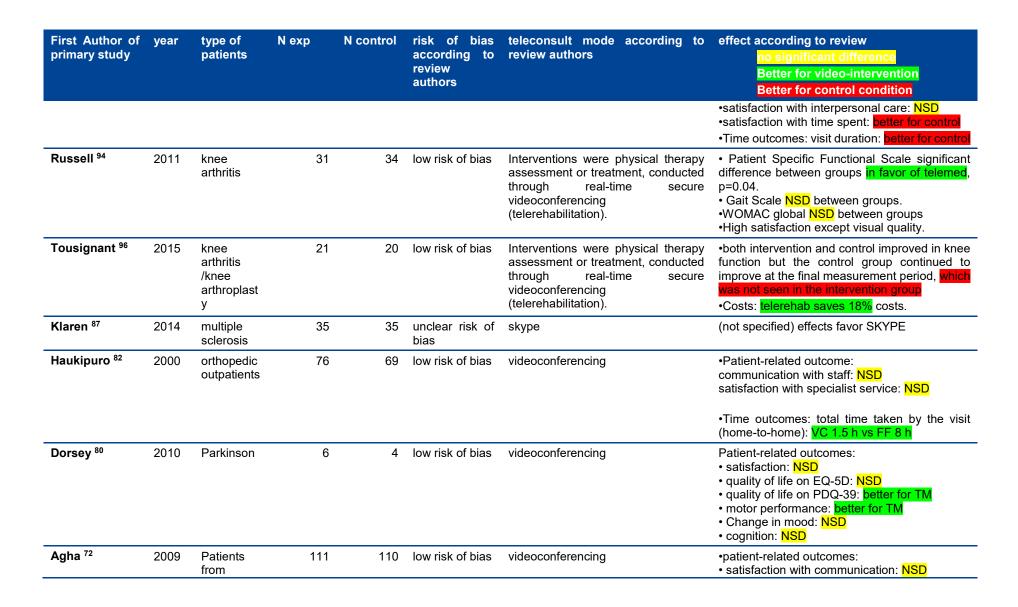
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First Author of primary study	year	type of patients	N exp	N control	risk of bias according to review authors	teleconsult mode according to review authors	effect according to review no significant difference Better for video-intervention Better for control condition
Rasmussen ⁹³	2015	diabetes	20	20	unclear risk of bias	Home treatment by physicians via video consultation	unclear
Shea ⁹⁵	2006	diabetes	144	104	low risk of bias	Video-conferencing (over plain old telephone service) allowing patients to interact with nurse case managers	lower HbA1c levels in people allocated to telemedicine than in controls LDL-cholesterol at median 6 months follow-up: better in TM Systolic blood pressure at median 9 months follow-up: better in TM Diastolic blood pressure at median 9 months follow-up: better in TM
Trief ⁹⁷	2013	diabetes	844	821	unclear risk of bias	live, real-time, synchronous, two-way videoconferencing on both the receiving and delivery end (Webenabled computer with camera and peripherals)	Self-reported adherence improved for intervention compared to control (P < .001)
Whitlock 100	2000	diabetes	15	13	high risk of bias	video-conferencing; and monitoring	• QOL: no differences
Burns ⁷⁴	2017	head & neck cancer	43	39	low risk of bias	live, real-time, synchronous, two-way videoconferencing on both the receiving and delivery end, (Videoconferencing unit with pan-tilt-zoom camera and handheld medical camera system)	Significant reduction in number (P = .004) and duration (P = .024) of contact events required to manage cases by telepractice
Bowles ⁷³	2011	heart failure	101	116	high risk of bias	remote monitoring + video- conferencing (partly substituting usual home care)	 mortality NSD ED visits NSD LOS NSD higher satisfaction with care in the TM group
Comin-Colet ⁷⁵	2016	heart failure	81	97	low risk of bias	live, real-time, synchronous, two-way videoconferencing on both the receiving and delivery end (touchscreen computer, 3G access with videocall ability)	Significant decrease in nonfatal HF events (P < .001) with lower readmission rates (P = .007), among telehealth group



First Author of primary study	year	type of patients	N exp	N control	risk of bias according to review authors	teleconsult mode according to review authors	effect according to review no significant difference Better for video-intervention Better for control condition
Dansky ⁷⁶	2008	heart failure	45	139	high risk of bias	Telemedicine interventions that include videoconferencing combined with remote physiological monitoring	•significant reductions in hospital admissions and/or ED visits •Videoconferencing was less effective than asynchronous monitoring for improving patients' self-assessment of symptoms related to diet and medication
De Lusignan ⁷⁸	2001	heart failure	10	10	high risk of bias	Telemedicine interventions that include videoconferencing combined with remote physiological monitoring	 self-care improved but not statistically significant VC significantly improved clinical outcomes related to participants' blood pressure and weight at 60 days and 120 days
Idris ⁸³	2015	heart failure	14	14	high risk of bias	Telemedicine interventions that include videoconferencing combined with remote physiological monitoring	• significant reductions in hospital admissions
Jerant ⁸⁶	2003	heart failure	13	24	high risk of bias	Telemedicine interventions that include videoconferencing combined with remote physiological monitoring	• significant reductions in Emergency department visits
Pekmezaris ⁹¹	2012	heart failure	84	84	high risk of bias	Telemedicine interventions that include videoconferencing combined with remote physiological monitoring	unclear
Wakefield ⁹⁹	2008	heart failure	52	96	high risk of bias	Telemedicine interventions that include videoconferencing combined with remote physiological monitoring	• improvement in overall disease-specific QOL
Woodend ¹⁰¹	2008	heart failure	62	59	high risk of bias	Telemedicine interventions that include videoconferencing combined with remote physiological monitoring	improvement at various data points in some aspect of quality, such as physical functioning, physical role, bodily pain, vitality, and mental health
Krousel-Wood	2001	hypertensi on	107	107	high risk of bias	videoconferencing + telemonitoring	 Patient-related outcomes: satisfaction with technical quality: better for control







First Author of year primary study	type of patients	N exp	N control	risk of bias according to review authors		according	to	effect according to review no significant difference Better for video-intervention Better for control condition
	pulmonary, endocrine, and rheumatolo gy clinics							 satisfaction with clinical competence: NSD satisfaction with interpersonal skills: NSD; satisfaction with convenience of care: better for TM
	gy omilos							• Time outcomes: visit length (reported as covariate): VC 23.2 min vs FF 28.8 min (p = 0.002): better for TM

As can be seen, most trials were done in patients with heart failure. The sizes of the research population were below 100 total in 14 of the 30 studies and as such probably having not enough statistical power to demonstrate real differences. Moreover, only 11 of the 30 RCTs were considered as having a low risk of bias according to the review authors. These factors combined already preclude to draw firm conclusions on patient effects.

Some of these trials show (slight) positive patient effects for video consultation, while some other show (slight) negative patient effects and that most RCTs found no statistical differences between groups. However, many trials had small research populations and there was heterogeneity in interventions (dose, frequency, providers), type of outcomes and when these were measured. Also effect sizes are not clear.

So, no overall conclusions can be drawn if video consultations are as good or better than the control condition. On the other hand, it could also be stated that there is no evidence of negative effects.

In summary, all included reviews concluded cautiously in favor of telehealth, despite lack of firm evidence; a closer look at included RCTs confirmed the lack of firm evidence. Nevertheless there are no firm indications that video consultation lead to negative patient effects.

2.3.3 Provider effects

Key-findings:

 effects for health care providers are rather negatively perceived and they don't seem to see many advantages of video consultation compared to face-to-face consults

Three reviews ^{47, 49, 51} focused as well on effects of telehealth/video consultation for health care providers. The characteristics and conclusions are shown in Table 7.

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Table 7 - Review authors' conclusions on provider effects

first author of review	date	N studies included in the review	type of providers	Review author's conclusion regarding provider effects/outcomes
Penny ⁴⁷	2018	9	nurses & midwives	While videoconferencing offers benefits, it comes with personal, organisational and professional consequences for nurses and midwives. Understanding potential benefits and limitations, training and support required and addressing potential professional implications all influence adoption and ongoing use of videoconferencing.
Rush ⁴⁹	2018	8	physicians	Consultations done by videoconference typically took longer than by telephone, however activities included in the consultations differed across studies. Provider-related outcomes using videoconference were superior compared to telephone, particularly with the stroke sub-population
Zandbelt ⁵¹	2016	21	physicians	Physicians appeared to prefer face-to-face consultations over videoconferencing Physicians appeared less satisfied with the clinical examination or assessment of the patient after VC. One of the drawbacks of videoconferencing is that the physician cannot perform the physical examination, in particular examinations where palpation is an important component. This may be related to the finding that physicians ordered more follow-up consultations or investigations in the VC-group. In some cases, the specialist may rely on the examination by another health-care professional, e.g. a general practitioner or nurse present with the patient. Although attention from two healthcare professionals is related to higher total costs, it may also promote patient confidence [35] and general practitioners' confidence in managing patients as a result of learning benefits during the VC. Based on the available evidence we can conclude that physicians are not satisfied with videoconferencing compared to face-to-face consultations, which is probably related to the inability to perform physical examination. This may make follow-up consultations more suitable for videoconferencing than initial consultations. The results of videoconferencing and webmessaging compared to telephone consultations were mainly positive, especially regarding to patient-related outcomes, although the number of studies in this area is still limited.

From these reviews it can be concluded, that effects for health care providers are rather negatively perceived and they don't seem to see many advantages of video consultation compared to face-to-face consults.



2.3.4 Barriers and facilitators in the implementation of video consultations

Key-findings:

- Large number of primary studies included in the reviews
- Many barriers and facilitators exist and are related to patients, health care providers, technology and health system organization
- It is not clear what the effect (size) of a single barrier or facilitator is and how they are interrelated
- It is not clear if barriers and facilitators are related to video consultations specifically or rather to telehealth applications in more general.

We identified twelve reviews ^{47, 52-62} focusing on barriers and facilitators in implementing video consultation (or telehealth including video consultations). The number of studies included in these reviews are shown in Table 8.

Table 8 – Reviews on barriers and facilitators: N of studies included

First author of review	year	N studies included	N studies included on chronic somatic patients
Almathami 52	2020	45	28
Alvarado ⁵³	2017	41	41
Brewster 54	2014	10	10
Brunton 55	2015	7	7
Foster ⁵⁶	2014	14	14
Gaveikaite ⁵⁷	2020	17	??

-			
Gorst ⁵⁸	2014	37	37
Koivunen ⁵⁹	2018	25	14
Macdonald ⁶⁰	2018	48	48
Penny ⁴⁷	2018	9	3
Sinclair ⁶¹	2015	13	13
Vassilev ⁶²	2015	15	15

2.3.4.1 Barriers

All reviews used another type of categorization of factors, making it difficult to synthesize the information; we tried to put all factors into 1 scheme, based on the one proposed by Alvarado et al. ⁵³, and extended it a bit (see italic).

After each barrier, reviews are cited that mentioned that barrier.

Patient Barriers

- P1 Low formal education 53
- o P2 Technology illiteracy (uncomfortable with technology) 53, 55, 57, 62
- P3 Medication nonadherence 53
- P4 Patients desire in-person contact with provider (perceived lack of confidence and comfort) ^{52, 53, 58}
- o P5 Low perceived value or effectiveness 53, 55, 57, 58, 62
- o P6 Health illiteracy 53
- o P7 Other
 - Low income ⁵³
 - Hard to express emotions 52, 53
 - Lack of bodily language ^{52, 53}
 - Patient's lack of seriousness 52,53
 - Patient's environment obstruction 52, 53



- Patients may feel overburdened due to increased own input in the communication ⁵⁵
- Difficulty in handling equipment ^{56, 58}
- Anxiety to use technology ⁵⁸
- Patient health conditions and need for assistance 52, 53, 56, 59, 60

Technology barriers

- Technnology functioning barriers
 - No or difficult or slow or unstable connection 52, 54, 59, 61
 - poor audio quality ^{47, 52}
 - poor video quality ^{47, 52}
 - technology under development 52
 - difficult to use system /user unfriendliness 52, 54-56, 58, 62
 - device size and weight ^{47, 52, 56}
- Technology access barriers
 - T1 Patient does not have required technology ⁵³
 - T2 Technology is cost prohibitive to the patient (not affordable)
 53, 59
 - T3 Limited internet access in the area 52, 53, 60
 - T4 Other

Design barriers

- D1 Lack of customization to patient preferences and needs 53,60
- D2 Lack of accuracy or reliability (patient or provider) ^{53, 55}
- o D3 Content not engaging or relevant 53
- D4 Timing of patient-provider interactions ^{47, 53}

- D5 Decisions of content and frequency of interventions 53, 55
- D6 Patients not incorporated into the design needs 53
- D7 No analysis on impact with comorbidities 53
- D8 Labor- and time-intensive for providers ⁵³3^{47, 54, 55, 57, 59, 61, 62}
- o D9 Other ⁵³

Health provider barriers

- Pv1 Data accessibility to patient logs (access to patient logs) ⁵³
- Pv2 Low integration into provider work flow 47, 52, 53, 59
- o Pv3 Other 53
- Low communication skills 52
- Low technology skills 59
- o Inadequate support 59{Penny, 2018 #1543}
- Insufficient experience with technology 59
- Resistance to technology 52, 55, 57, 59
- Negative impact of service change/implementation^{54, 59}
- Negative impact on staff-patient relationship 47, 54, 59
- o concern about creating dependence on the technology and/or practitioner support,⁵⁵
- Low expectations of outcomes/need 54
- Negative impact on staff autonomy/credibility 54, 55, 57, 59
- Technophobia/lack of confidence in technology ^{54, 55, 59}
- Patient safety concerns 54, 55, 57
- o Poor change management 54
- Communication issues 54



Lack of training ^{47, 54, 59}

System barriers

- S1 Limitations on scalability 53
- S2 Lack of program reimbursement by insurance 52, 53, 59
- S3 High cost of intervention 52, 53, 59
- o S4 Other 53
- Lack of synchronization with other systems 52
- Security and privacy concerns 52, 54, 59
- o Policy and law/ legislations issues 52, 57

From the reviews, it could not be distilled what the exact size of the barrier was and neither how barriers are interrelated. Also, it was not clear if barriers related to video consultations specifically or rather to telehealth applications in more general.

2.3.4.2 Facilitators

For the facilitators we started from the list from Almathami et al. ⁵² and brought some categorization in it and extended it with facilitators elsewhere found.

• Telehealth characteristics and effects

- Saving costs 52
- Reducing waiting time 52
- o Reducing travel time 52
- o Easy to use 47, 52, 54-56, 58, 60, 62
- Ease of instruction to patients 59
- o Convenience 52, 56, 58
- High audio and video quality 59

- o Fast Internet speed 52
- Utilizing low tech platforms ⁵⁶
- Developed with health care expert 52, 54
- Systems that are designed to provide solutions to clinical and behavioral problems that specific patient populations identify as priorities, ⁶⁰
- End users being consulted in the design process wherever possible
- Integrated in daily practice 54
- o Technology fits with patients' needs, skills, and daily life 62
- Personalized and patient feedback ^{54, 56}
- Maintaining quality of staff–patient interactions ⁵⁴
- Enabling connections and contact, notably between patients and professionals ⁶²
- Telehealth gives opportunities to provide flexible services 59
- o Affordable 59, 60
- Reliable system 60
- As automated as possible 60

Patient characteristics

- Familiarity with the system ^{52, 62}
- Trust in technology ^{52, 55, 58}
- o Involvement of family 52
- Patients' (young) ages and (better) health condition 52,59
- o Patients' training 52, 62
- Intrinsic motivation to use the technology 57

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- Previous (positively experienced) use of the technology ^{55, 57}
- Patients' familiarity with staff and past experience 52
- Perceived usefulness of the system 60, 62
- Feeling that using the system gave them more autonomy 55, 58
- Feeling that using the system sense of reassurance in having someone 'watching over them ⁵⁵
- Feeling that the system increased contact and level of continuity 55,
- Feeling that system increased their knowledge 58
- Positive appreciation of telehealth nurses, 58

Clinician characteristics

- Clinicians' training and skills 52
- Motivation and engagement 52, 57
- Provided support: emotional, technical, and organizational 52, 54
- Trust in technology ^{54, 59}
- o perceived value of the technology 47, 57
- o positive previous experience with technology 47, 57, 59
- o regular use of the technology 57
- adequate skills to use the technology ⁵⁹
- feeling that felt that the use of telehealth increases the job satisfaction ⁵⁹
- feeling that felt that the use of telehealth decreases the workload 59
- o involved in technology development and implementation 59

System characteristics

- Availability of guidelines and tools and support to use technology
 47, 57, 59, 61
- Champion presence 57
- Training to use the equipment, and training to adapt to the different context of care provision 47
- o Internet or phone availability 52
- Flexible and responsive working places 54
- Strong leadership and local champion 54
- Insurance coverage ⁵²
- Security ⁵²
- Risk and safety assessment 54
- Privacy 52
- o Better management 52
- System approach to improve patients' compliance 52
- Improved accessibility to care 52

Also here, it could not be distilled from the reviews what the extent is of the influence of individual facilitators, neither how they inter-act. Also, it was not clear if facilitators related to video consultations specifically or rather to telehealth applications in more general.

However, it looks that main facilitators are that telehealth interventions need to solve a perceived problem, must be easy to use, must be reliable, must be affordable; and it helps when patients and health care providers are trained enough to obtain needed skills.



2.3.5 Our findings compared to other reviews of reviews

Key-findings:

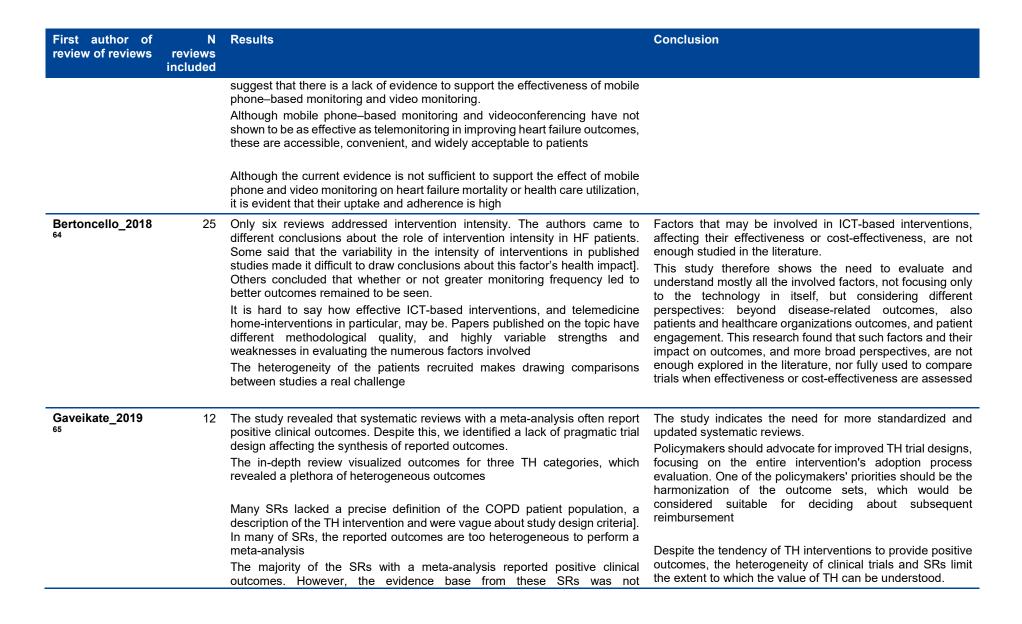
- Each review of reviews included a large number of reviews
- All reviews of reviews conclude that there is large heterogeneity in several aspects, preventing to draw firm conclusions
- Nevertheless, all review of reviews state that the included reviews conclude cautiously in favour of telehealth interventions
- All reviews of reviews state that there is need for further research on the effects of telehealth interventions and on the implementation of them

We identified 10 reviews of reviews ^{17, 63-71} that had quite similar objectives as our review and are therefore good sources to compare to.

Results and conclusions are presented in Table 9.

Table 9 - Results from other reviews of reviews

First author of reviews	N reviews included	Results	Conclusion
Bashi_2017 ⁶³	19	Reviews consisted of remote patient monitoring (RPM) with diverse interventions such as telemonitoring, home telehealth, mobile phone—based monitoring, and videoconferencing. All-cause mortality and heart failure mortality were the most frequently reported outcomes, but others such as quality of life, rehospitalization, emergency department visits, and length of stay were also reported. Self-care and knowledge were less commonly identified.	Telemonitoring and home telehealth appear generally effective in reducing heart failure rehospitalization and mortality. Other interventions, including the use of mobile phone—based monitoring and videoconferencing, require further investigation.
		Despite recent advances in telecommunications technology that have facilitated clinical use of videoconferencing, the results of this overview	Lack of sufficient information in the current evidence indicates a clear need for further high-quality research on mobile phone–based and videoconferencing interventions



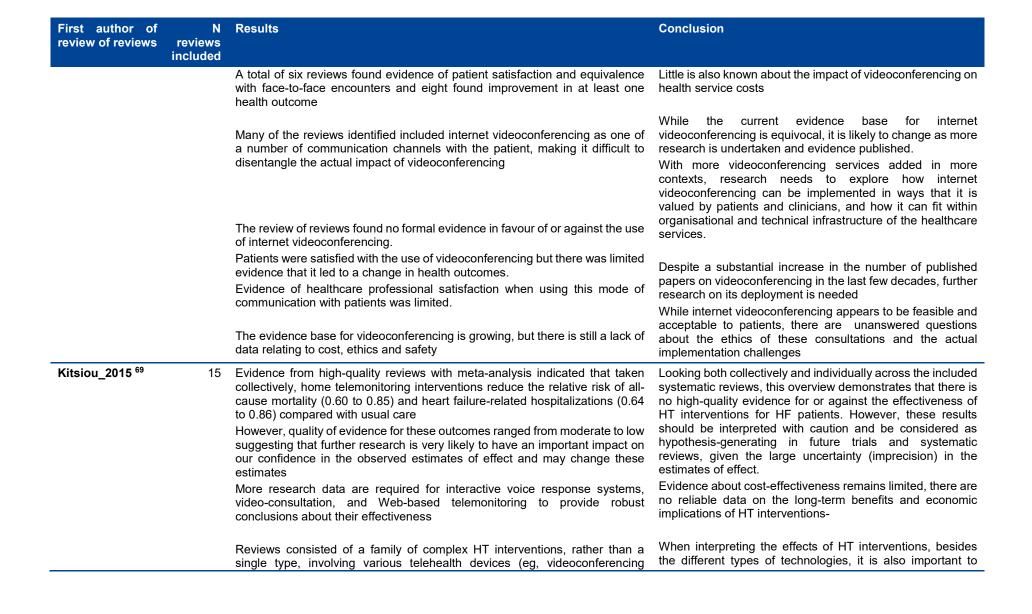
First author of reviews	N reviews included	Results	Conclusion
		comprehensive enough to be directly used to suggest TH implementation into clinical practice for many different reasons., such as trial design, limited compliance, complex interventions where TH connects with other intervention types, limited follow-up and sample size, and an absence of blinding to healthcare providers.	
Greenhalg_2017	>30 Including 7 reviews of reviews	The question is why so many trials and secondary analyses have produced so few clear recommendations for practice and policy. The single most striking feature of experimental trials of telehealth in heart failure is their heterogeneity. As the above-referenced reviews have noted, different trials included widely differing patient samples in terms of demographic variables (especially age cut-offs), severity and stability of disease (especially the cut-off value for HFREF and whether patients with HFPEF are included), exclusion criteria (especially co-morbidities), and recruitment route (outpatient clinic, post-acute hospital admission, primary care); they collected different kinds of data using different devices combined with different packages of human support in different organisational settings; they compared these interventions with different control arms (especially, different definitions of 'usual care'); and they applied different primary and secondary outcome measures (total or heart failure-specific hospital admission, all-cause or cardiac-specific mortality, and quality of life). Published trials of telehealth in heart failure appear to be positively skewed by publication bias Recruitment of participants to trials of telehealth for heart failure is usually poor and sometimes abysmal. In one trial of telehealth that included but was not limited to heart failure, 80% of approached patients refused to participate; the most common reason was preferring a home visit from a nurse. In a review of heart failure telehealth studies that reported recruitment data, on average, two thirds of eligible participants agreed to try telehealth and of those, a fifth withdrew during trials (most commonly because they were unable to use the device or did not wish to)	The limited adoption of telehealth for heart failure has complex clinical, professional and institutional causes, which are unlikely to be elucidated by adding more randomised trials of technology-on versus technology off to an already-crowded literature
		Despite frequent acknowledgement of these factors in the literature, empirical research into telehealth has tended to be narrowly focused on describing and	



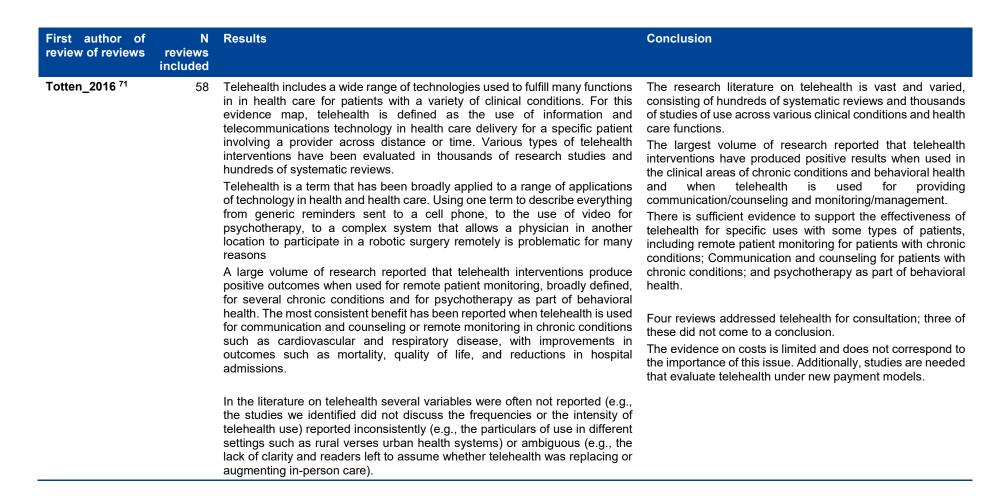


First author of reviews	N reviews included	Results	Conclusion
		trialing particular technologies in experimental designs without systematically studying the personal, professional, organisational, financial and regulatory context affecting their acceptance and routinisation	
		The literature is muddied by poor-quality, underpowered trials with weakly positive results, synthesised (sometimes) in misleading meta-analyses that overlook publication bias and lump different denominator populations, devices and service models together inappropriately.	
		Low recruitment to telehealth trials raises questions about the external validity of results.	
		The literature on implementation of telehealth in heart failure can be summarised in a long and perhaps unsurprising list of barriers to (and conversely, facilitators of) success, of which clinician resistance appears to be particularly significant.	
Greenwood_2017	25	There was extreme heterogeneity of the interventions and methodologies given this rapidly evolving field. However, this review of review demonstrates clear evidence that technology-enabled diabetes self-management education and support is effective in reducing A1c in the context of a complete feedback loop.	Technology-enabled diabetes self-management solutions significantly improve A1c. The most effective interventions incorporated all the components of a technology-enabled self-management feedback loop that connected people with diabetes and their health care team using 2-way communication, analyzed patient-generated health data, tailored education, and individualized feedback
Hanlon_2017 ⁶⁸	53	All of the interventions in the included systematic reviews were complex interventions with multiple components. Reporting of the details of the components of interventions was highly variable While it was clear that most telehealth interventions were complex multicomponent interventions, most of the included reviews either provided limited description of the interventions or did not specifically analyze the impact of individual components on the efficacy of the intervention as a whole While the intensity of the interventions included in many of the reviews varied widely between the included RCTs , few reviews specifically analyzed the relationship between the intensity (in terms of either contact with health care professionals or the complexity or number of components in the intervention) and outcomes	While telehealth-mediated self-management was not consistently superior to usual care, none of the reviews reported any negative effects, suggesting that telehealth is a safe option for delivery of self-management support, particularly in conditions such as heart failure and type 2 diabetes, where the evidence base is more developed. Larger-scale trials of telehealth-supported self-management, based on explicit self-management theory, are needed before the extent to which telehealth technologies may be harnessed to support self-management can be established.

First author of reviews	N reviews included	Results	Conclusion
		The highest-quality evidence for heart failure showed an overall improvement in mortality in meta-analyses of telemonitoring and telephone support. In contrast, none of the reviews assessing mortality in COPD showed any significant improvement with telehealth. None of the reviews, however, reported a negative impact of interventions employing telehealth for any condition. This should be treated with some caution, however, as few reviews specifically considered or assessed for publication bias and, of those that did, some found evidence to suggest bias	
		The highest-weighted reviews showed that blood glucose telemonitoring with feedback and some educational and lifestyle interventions improved glycemic control in type 2, but not type 1, diabetes, and that telemonitoring and telephone interventions reduced mortality and hospital admissions in heart failure, but these findings were not consistent in all reviews.	
		Results for the other conditions were mixed, although no reviews showed evidence of harm.	
		Analysis of the mediating role of self-management, and of components of successful interventions, was limited and inconclusive.	
		More intensive and multifaceted interventions were associated with greater improvements in diabetes, heart failure, and asthma.	
Ignatowciz_2019	35	The included reviews covered a wide range of long term conditions, including: heart failure, depression, schizophrenia, stroke, asthma, spinal cord injury, and chronic pain.	In the home setting, for patients with long-term conditions, the review of reviews indicates that there is no formal evidence in favour of or against the use of internet
		Of 35 articles included in this review, 25 were reviews or systematic reviews. Overall, eight looked at internet videoconferencing exclusively with the remainder examining a range of telehealth interventions including videoconferencing.	videoconferencing. Evidence for its impact on health outcomes suggests it mostly has equivalence with face-to-face communication.
		Among the videoconferencing exclusive reviews, there were five that included more than 25 studies in their review. In 24 of the included reviews, forms of internet videoconferencing were compared with a face-to-face consultation or usual care.	Videoconferencing seems to be an acceptable mode of care delivery for patients with long-term conditions. Research indicates that patients who have experienced videoconferencing with clinicians, like it. There is limited evidence about healthcare professionals'



First author of reviews	N reviews included	Results	Conclusion
		equipment, automated telemonitoring stations, mobile phones, and interactive voice or symptom response systems), technological approaches for data collection and transmission (eg, modem, broadband, or mobile phone transmission; Web-based or telephone touch-pad data entry), as well as other chronic disease management strategies (eg, education and home visits). However, reporting of the active ingredients of these interventions was often poor in the included reviews Virtually all reviews treated HT as a "black box" making no attempts to investigate whether technological differences between HT interventions are associated with different effects. One of the frequently discussed challenges in the reviews was that in most primary studies the control group was not clearly described Uncertainties remain around the determinants of successful HT programs Given that the evidence base consists mainly of small trials that usually are not adequately powered to detect meaningful differences in outcomes, several meta-analyses included in this overview did not meet the optimal information size criterion] required to establish a high level of confidence and therefore, lacked precision.	consider the technological advances that have occurred over the years (eg, in analytics, user-interfaces, and devices) and the different generations of HT technologies that have been developed. Overall, there is a great need to shift our research focus from the basic evaluation question of "is HT effective?" to "what features or components of HT are effective, which patients benefit more from these interventions, under what circumstances, for how long, and why?
Quireos_2018 ⁷⁰	51	The retrieved reviews synthesize evidence related to the use of several monitoring devices to measure a wide range of physiological outcomes, including: vital signs (e.g., body temperature, blood pressure, heart rate, respiratory rate, and pulse oximetry), glucose level, weight, physical activity (e.g., pedometers), and foot skin temperature. Independently of the outcomes being measured, the retrieved systematic reviews show that the usage of remote care technology has positive effects with moderate to large improvements in different outcomes when compared with conventional practices One of the problems that emerged from the study reported in the present article is related to the outcomes being considered. Besides their diversity, it is important to consider that different measurement methods were being applied.	Remote care technology has positive effects in various health-related outcomes, but further research is required to allow its use in clinical practice Despite the huge research effort related to remote care technology, there is an insufficient number of successful interventions that have been translated beyond the research setting and broadly adopted.





One of the reviews of reviews ⁶⁶ gives an overview of factors that influence the implementation of telehealth interventions: this list is to a large extent comparable with the ones we retrieved from reviews as described in previous section.

Barriers, according to meta-review of Greenhald 2017 et al. 66:

Patient factors:

- Low motivation perhaps due to belief that the technology will have no benefit over existing approaches to care ("relative advantage")
- Preference for a face to face encounter
- Inability to use the technology (including limitations of health impairments)
- Inability or unwillingness to take action in response to data or remote instructions
- Lack of confidence in own ability to use the technology or the service (self-efficacy)
- Fear that engaging with telehealth will lead to exclusion from a valued traditional service

Staff factors:

- Absence of champions
- Dislike of new clinical routines (including increased workload)
- Dislike of new clinical interaction (i.e. prefers face-to-face encounters)
- Belief that relationships and therapeutic interactions will be compromised
- · Perception that their clinical expertise is being marginalised
- Perception that there is no value for them in the new way of working
- Inability to use the technology (including inability to remember password)

Technology factors:

- Technology unreliable (including too slow, or interrupted)
- Technology too difficult to use
- Technology doesn't fit / gets in the way in patient's home
- Technology (and/or the routines for using it) too inflexible
- Inadequate IT infrastructure including absence of high bandwidth connectivity
- Inter-operability problems (especially with electronic patient record)
- Inadequate helpdesk or technician support

Team/service factors:

- Lack of clarity about who will interpret and act on remote monitoring data
- Poor integration of the telehealth support role with wider team and service roles
- Poor working relationships between providers
- Insufficient staff
- Absent, inadequate or delayed staff training
- Lack of guidance on which patients/conditions are suitable for telehealth consultations
- Lack of a clear and integrated referral pathway
- Lack of (or inadequate) participation of staff in the implementation process
- Lack of timely feedback on the success of the service
- Programme dependent on a single individual with inadequate succession planning



Governance and regulatory factors

- Concerns about data protection and privacy
- Inadequate supporting policy and legislation
- Opposition (or lack of active support) from professional bodies or defence societies

Financial/business factors:

- Lack of a plausible business case
- Lack of clear strategy
- Unrealistic financial reimbursement
- Unsupportive policy context

Our findings are in line with other reviews of reviews. Key findings as limited firm evidence, large heterogeneity etc are confirmed.

2.4 Conclusion and discussion

Key-findings:

- A large number of primary studies, reviews and reviews of reviews exist
- There is unclarity in terminology used throughout the publications
- Video-consultation is used and has been studied in patients with chronic somatic disease. We could include 20 reviews covering hundreds of primary studies.
- Large heterogeneity in patient populations, interventions, control conditions and outcomes, prohibits to draw firm conclusions

- Despite, this enormous amount of research, no firm conclusions can be drawn to what extent video consultations are equal, better or worse than face-to-face- consultations.
- Review authors cautiously conclude in favor of video consultations
- No firm evidence of negative effects of video consultations on patient's health was available
- Patients seem mostly satisfied with video consultations
- Health care providers seem rather reluctant towards video consultation/telehealth
- The implementation of telehealth interventions is influenced by a large number of factors, but is unclear what the influence of each or a combination of factors is

One of the challenges in this review, was the **confusing terminology** used in the literature. Many terms as telemedicine, telehealth, teleconsultations, remote consultations, e-consultations, consultations at a distance are used (and sometimes interchangeable) and frequently without a clear definition or a good description what the interventions entailed.

This has several consequences for this review. We have certainly missed relevant publications (e.g. ^{11, 136}) since we have not searched sensitively enough or we excluded erroneously relevant publications when unclear terms were used in titles or abstracts.

Also during the data-extraction it was often unclear if a result related to video consultations specifically or to telehealth interventions more generally.

The problem of unclear terminology has already been mentioned frequently in the literature and calls (e.g. ^{137, 138} were made to have a clear taxonomy in this rapid evolving field.



Next big problem that we encountered was the **large heterogeneity** of several aspects in the reviews we included. Often, different patient populations, different interventions (content, dose, frequency, provider) and different outcomes (instrument, time of measurement) were used in a single review. The heterogeneity existed within the included primary studies of the reviews but also between the reviews we analyzed. This may cause that effects that are existing in reality were not observed or misinterpreted.

Also good descriptions of intervention and control conditions were lacking, prohibiting to see what was actually compared.

On the other hand, all the reviews of reviews we discussed come to similar conclusions as we do.

Several caveats need to be mentioned. The field of telemedicine and technology is rapidly evolving and it may be questioned to what extent research findings from 5 to 10 years ago still apply to current technology and current ICT-literacy of patients and health care providers.

Next to this, the slightly positive results that were encountered in the studies, may have to do with selection bias: only patients and/or providers that were already positive towards teleconsultation agreed to participate in the studies or continued during the experiments.

Also there is a chance for **publication bias** in the sense that only successful projects were published and not the negative ones.

The fact that we found that there is no evidence of negative effects, does not mean that there doesn't exist negative effects. E.g. Ossebaard et al. 139 did a review focused on negative effects of eHealth applications and conclude that there might be risks related to the use of e-health applications, and that more attention should be paid to this. Also OECD 140 warns that 'telemedicine is a tool that can be well used or misused; it can have benefits but has the potential to also cause harm. The information collected for this report suggests that telemedicine is not beneficial or harmful in itself, and that under a best use scenario, it can lead to gains in effectiveness, efficiency and equity'.

And inherent to a review of reviews is the fact that it is difficult to get grip on details and on what really happened in the primary studies; in a review of reviews, one is dependent on the methodological qualities and judgement of the reviewers that sought, selected and analyzed the primary studies.

This is a general disadvantage of the chosen method for this review: reviews of reviews don't give good insight in the actual primary studies ^{22-24, 141}. A systematic review of primary studies would certainly have given more details but would have taken much more time to complete.

On top of this it has to be mentioned that many reviews on which we relied regarding patient health effects were of suboptimal methodological quality when judged by the AMSTAR-2 instrument; only two were assessed as 'high quality'.

A general conclusion of this review is that video-consultations are used and have been studied in patients with chronic somatic disease. We could include 20 reviews covering hundreds of primary studies. However, despite this enormous amount of research, **no firm conclusions** could be drawn to what extent video consultations are equal, better or worse than face-to-face consultations. But on the other hand, in this enormous amount of research there are neither clear signs that video consultations lead to negative patient effects.

An interesting finding across several reviews, is that **patients are in general positive** towards using video consultations and are satisfied with the use of it, while **health care providers seem to be more reluctant** and are not as satisfied. This is in line with a recent systematic review ¹⁴² on older adults view on eHealth services in general and with a recent umbrella review ¹⁴⁰ on telemedicine in general.

It is also come clear from this review that there are many factors (barriers and facilitators) influencing successful implementation of video consultations in health care. Video consultations can be regarded as complex interventions (although it might looks like a simple communication tool) and implementation should well be thought and planned beforehand; otherwise there is great chance for disillusion in patients, health care providers and health systems .In this study we considered



reviews (and primary studies) from across the world and therefore it appears that the identified barriers and facilitators apply in several countries. This is in line with the findings of other reviews of reviews concerning the implementation of telemedicine: e.g. Enam et al. 143 conclude 'that the development of more robust and comprehensive evaluation of eHealth studies or an improved validation of evaluation methods could ease the transferability of results among similar studies'; Varsi et al. 144 points to the lack of eHealth studies that report implementation strategies in a comprehensive way and highlights the need to design robust studies focusing on implementation strategies in the future; Otto et al. 145 state that 'implementation of telemedicine has been proven to be hampered worldwide, regardless of the political system, legal framework or development status. With reviews focusing on a wide range of diseases, e.g. diabetes mellitus, hearing loss or psychological disorders, we could also show that barriers do not solely originate from the treatment requirements of a particular disease (only four of the 98 identified barriers were unambiguously disease related). Furthermore, as the barriers are highly interrelated, a holistic approach in overcoming the barriers is necessary.' And a OECD-report 140, based on questionnaires in several countries and a umbrella-review, states that 'important barriers to wider use of telemedicine remain, with providers and patients facing regulatory uncertainty, patchy financing and reimbursement, and vague governance'; also they state that a lack of funding and clear reimbursement mechanisms is the single biggest hurdle to wider development of telemedicine interventions. This is confirmed in the WHO 2019 guideline 'Recommendations on digital interventions for health system strengthening'

This is also in line with a systematic review ¹⁴⁷ on barriers and facilitators in the implementation of asynchronous e-consultations, in which they found in general the same barriers and facilitators, pointing out that several e-health interventions face the same factors for implementation.

3 VIDEO CONSULTATIONS IN BELGIAN HEALTH CARE

3.1 Key findings

- Prior to the COVID-19 pandemic:
 - Many different terms are used for video consultation and often, video consultation is not considered separately from telemedicine or telemonitoring.
 - Video consultation in Belgium was limited to pilot projects, some well worked-out private initiatives, and a preliminary interest by official government bodies shaped by balanced and cautious advices of the Order of Physicians. No specific legislation or reimbursement existed. Most more general eHealth initiatives considered telemedicine and telemonitoring rather than video consultation.
- The COVID-19 pandemic sparked off numerous official and private initiatives from March 2020 onwards to respond to an acute need for care at a distance required by the official measures to limit as much as possible the further spread of SARS-COV-2.
 - RIZIV-INAMI opened up temporary reimbursement of video consultation during the COVID-19 pandemic measures for many health care providers, as replacement for face-to-face consultations. We found several different ways reimbursement is adapted:
 - New reimbursement codes with a corresponding reimbursement, usually without out-of-pocket payments for the patient.
 - Existing reimbursement codes following the usual reimbursement rules.



Existing reimbursement codes following the usual reimbursement rules but additionally, a special code for care at a distance (792433) must be declared as well.

3.2 Methodology

All information used in this chapter was collected using a grey literature search and interviews. 12 The following sources of information were looked at: laws and regulations in the official Belgian legislative index database and the consolidated legislation database; websites of official government institutions including but not limited to RIZIV-INAMI and Federal Public Service of Health, Food Chain Safety and Environment; websites of governing bodies; and websites of professional and scientific associations. Additionally, general purpose search engines were used to search for the following Dutch terms: teleconsult, teleconsultatie, videoconsult, videoconsultatie, beeldbellen, zorg op afstand; as well as their equivalent in French: téléconsultation, vidéoconsultation, consultation numérique, consultation à distance. The search strategy consisted of searching for each term individually and subsequently for each combination of the above search terms combined by 'OR' in google.be and in duckduckgo.com with region set to Belgium (NL) or Belgium (FR) depending on the language searched in.

Based on the documents found, we searched for references contained in these documents and we tried to identify key informants to contact for further information. Based on our need for further information, we scheduled semi-structured interviews using the topics and questions described in Appendix 1 and we have included the information subsequently obtained.

3.3 Terminology

For Belgium, we encountered numerous ways to describe the synchronous communication with video and sound that is the topic of this report. In this chapter, we use video consultation to refer to a consultation between a health care provider and a patient by means of synchronous communication with video and sound, independent of the technological solution chosen.

This term will be used unless the terminology in the retrieved information does not correspond more or less to this definition. In that case, the English equivalent of the term used in the original source will be used and a definition will be provided if needed.

3.4 Legislation

This section details the current legal aspects specific to video consultation definition and use on top of more general (European) legislation as put forward by different parties in the recent past, both prior to and as a response to the COVID-19 pandemic. We looked at official advices from the Belgian Order of Physicians and on a legal assessment requested by the RIZIV–INAMI. Where applicable, we described the measures taken as a response to the COVID-19 pandemic and added them in the relevant section.

3.4.1 Applicability

3.4.1.1 Order of Physicians

The Belgian Order of Physicians, established by law, has a number of disciplinary competencies among which the enforcement of medical ethics for the medical profession. To that end, they publish and maintain a 'Code of medical deontology', comprising the principles and rules of conduct to be followed by physicians in exercising their profession. They are also competent to advice on issues related to medical practice and medical ethics. Membership is compulsory for each physician willing to practice medicine in Belgium. Both the code of medical deontology and the advices are to be respected and followed by physicians, but due to the absence of a Ministerial decree implementing article 15 §1 second paragraph of the Royal Decree 79 on the Order of Physicians, neither can currently be legally enforced. The second paragraph of the Royal Decree 149.

In the past ten years, several advices on different aspects of eHealth or video consultation were provided. Table 10 lists a summary. We kept in this summary as much as possible the terminology used in the advices.



Table 10 – Advice on eHealth and video consultation by the Order of Phy

Year	Title	Advice
2013 ¹⁵⁰	Communication by videoconference in health care	A specific advice on a question posed to the Order on the use of videoconference between a chronic patient and voluntary care providers in a home care setting:
		Sees an advantage in reducing patients' isolation.
		 Stresses the importance of a sufficiently secured connection and the possibility for the patient to leave the project without consequences.
2015 151	Physicians and digital media	A guidance for physicians on the different aspects of the digital transformation of health care:
		 Stresses the importance of keeping in mind the general privacy rules that govern the treatment of data related to health and that are covered by professional secret.
		 Specifically on the use of videoconferencing, the current advice repeats the 2013 advice described above.
2017 152	Deontological and medical-	A general reflection on the use of e-health and m-health (mobile health solutions) in health care:
	ethical reflection on the use of	• Ecourages the use of a well-secured platform for information exchange and the advantages of e-health and m-health.
	e-health and m-health within the health care system.	Points in particular to the importance of obtaining informed consent of patients and respecting their privacy.
	the health care system.	Repeats the importance of the personal contact between patient and physician.
		Stresses the need to develop protocols for using e-health and m-health.
2019 ¹⁵³	Teleconsultation with a view to making a diagnosis and proposing a treatment	A deontological guidance with respect to the use of teleconsultation in diagnosing a patient and proposing a treatment:
		• Teleconsultation is defined as a consultation in which a doctor has a consultation with a patient at the a distance and simultaneously, through the use of information and communication technology (ICT)
		 Teleconsultation is considered a justifiable medical act, subject to the same rules as other medical acts, when beneficial to the patient.
		• Teleconsultation should only be considered after a risk-benefit analysis and respond to a medical need rather than a commercial need. User-friendliness is insufficient justification if not accompanied by a health benefit. The technology should finds it place within the care relationship.
		• The physician should follow scientifically validated protocols for medical reasoning adapted to the context of teleconsultation. The advice refers to protocols for medical reasoning as e.g. already used in triage for emergencies or severe cases. The physician should be aware of the risks related to physical absence of the patient.
		 The technology used should be adequate given the skills of the patient and physician. The physician remains responsible for the appropriateness of (continuing) a teleconsultation. The physician should ensure the use of technology that comes with guarantees on quality and privacy. The physician's professional liability insurance should cover teleconsultation.
		• Face-to-face contact remains the preferred way of working. Teleconsultation does not provide the safety and accuracy level of a face-to-face contact for diagnosis and treatment. It should be used only if the situation warrants it:
		To improve accessibility of care (although the advice questions if there is a problem of accessibility in Belgium).

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Year	Title	Advice
		The physician must check the motivation of the patient and inform him or her of the inherent risks. Considering quality and safety of care, using teleconsultation for diagnosis and treatment requires that the physician knows the patient, has access to his or her medical file, and can guarantee continuity of care. The pathology should be compatible with care at a distance.
2019 154	Platform ViVidoctor.com ^f – Online teleconsultations	 A specific advice on a question posed to the Order on the platform ViVidoctor.com: Reiterates that diagnosing a patient without personal contact is potentially dangerous and that follow-up consultations with a known patient are useful only in exceptional cases. Restates that user-friendliness of teleconsultation does not outweigh the safety and accuracy of a face-to-face consultation.
2020 155	Exceptional measures in first- line medicine due to COVID- 19 pandemic	 A specific advice on consulting a physician without personal contact: Reiterates that diagnosing a patient without personal contact is potentially dangerous and that follow-up consultations with a known patient are useful only in exceptional cases. Considers the COVID-19 pandemic an exceptional situation in which the movement of (potential) COVID-19 patients should be limited as much as possible to reduce further spread. A number of conditions should be met before considering care at a distance: The physician knows the patient and his antecedents. In the COVID-19 pandemic circumstances, this could be met by consultation of the up-to-date electronic medical file accessible through the regional exchange platforms (the system of hubs, meta-hubs, and electronic vaults). The physician has access to the medical file of the patient. The physician can guarantee the continuity of care. It is up to the physician to carefully balance the risks for the patient and society prior to deciding to have a teleconsultation.
2020 156	COVID-19 - Press release - Teleconsultations via video in times of pandemic	 A specific advice on teleconsultations via video: Reiterates conditions specified in the previous advice when considering care at a distance (see previous row in this table). Points to guidelines by the <u>Task Force 'Data & Technology against Corona'</u> and <u>RIZIV-INAMI</u> to take into consideration when contemplating the use of teleconsultations via video.

 $(\underline{\text{https://kbopub.economie.fgov.be/kbopub/toonondernemingps.html?} lang = en \& ondernemingsnummer = 675755052})$

A bankruptcy procedure was opened for ViViDoctor in November 2019.



As the previous advices show, the Order considers the video consultation, given certain limitations, as similar to the medical act of a regular consultation. The applicable laws on practicing the medical profession do not exclude the possible use of video consultation: article 31 of the law of 2015^g on the practice of health care professions gives the physician the freedom to choose any means necessary for his or her profession ¹⁵⁷, controlled by the Order of Physicians. To this extent, the rules laid out in the 'Code of medical deontology' apply for video consultation as well.

3.4.1.2 RIZIV-INAMI

In 2019, RIZIV-INAMI organised a workshop^h and stakeholder consultation on legislation and reimbursement aspects of telemedicine (including video consultation) and mHealth applications (see section 3.10.1 for more details). Specifically for this workshop, a report was prepared by a law firm on the legal and administrative aspects on incorporating telemedicine in regular reimbursement.^{8, 158}

The report points out that there currently isn't a common or legal definition of teleconsultation and proposes to define it as "an application of telemedicine where the health care professional by means of video technology, has a consultation with a patient, at a distance and synchronously", which corresponds closely to the definition of video consultation we use for this chapter (see section 3.3 on terminology).

On the research question if an additional legal framework is necessary to insure the safety of mobile applications (CE marking), the analysis in the report excludes video consultation as it cannot be considered as a medical device and as such is not subject to the relevant European legislation.

In 2020, in the wake of the COVID-19 pandemic, RIZIV-INAMI published a comprehensive approach to providing health care at a distance for multiple health care professions, as a response to the measures taken and ratified by a Ministerial Decree. ^{159, 160} The guidelines provide general conditions for providing health care at a distance:

- Patient consent is required prior to starting health care at a distance.
- Video communication requires a tool with end-to-end encryption.
- The patient is physically and mentally able to work with a PC.
- The duration of the service should remain realistic.
- The service should be provided for the continuity of care (with a possible exception for urgent interventions).
- The number of sessions per care provider are limited to assure the quality of care.
- The service will be reimbursed by a flat rate.
- Reimbursement through third party payer is possible or can be mandatory in some cases.

Some of the guidelines concern privacy and security and are discussed in section 3.4.4 on privacy and security.

3.4.2 Liability

There is no specific legislation for video consultation in Belgium on top of more general or health care specific liability laws. The report prepared for the RIZIV-INAMI workshop on telemedicine concludes that no additional legislation on liability is necessary as all aspects are covered by existing legislation on contractual liability, general liability, and product liability.^{8, 158} A possible extension of the product liability legislation could be envisioned for software, but this largely surpasses telemedicine and requires a debate on its own. One aspect to keep in mind is the case a patient has a video consultation with a health care provider residing outside of Belgium, the Belgian (and European) liability legislation is not necessarily applicable.¹⁶¹

h riziv workshop 210619

^g Article 4 in the new law on a qualitative practice applicable from 2021¹⁴⁰



3.4.3 Privacy and security

Prior to the COVID-19 pandemic, no specific legislation for video consultation existed in Belgium on top of more general or health care specific privacy and information security legislation, such as the GDPR ¹⁶² and the Belgian law on the protection of natural persons related to processing of personal data. ¹⁶³

The report prepared for the RIZIV-INAMI workshop on telemedicine researched if additional Belgian legislation specifically for video consultation is needed.⁸ The report concluded that the existing GPDR and ePrivacy¹⁶⁴ legislation are sufficient and additional legislation carries the risk of making current legislation unworkable. The report highlighted points of attention regarding the privacy aspects of the use video consultation:

The patient needs to explicitly consent with the use of video consultation just as with other proposed treatment aspects.¹⁶¹

An issue particularly important towards respecting and being able to maintain all privacy required measures pertains to the difficulty of authentication at a distance: unless both physician and patient know each other well, correct authentication is not always easy but primordial in making sure only authorised parties have access to the personal data generated by a video consultation.

A distinction needs to be made between non-healthcare personal data processed by the video consultation solution for basic operation (e.g. email, account info, user agreement...) and the personal data related to health generated by the actual consultation with a health care provider. In particular the latter type of data is subject to additional requirements in terms of lawfullness of processing according to GDPR:

• It's prohibited to process personal data related to health except when the patient consents or another legal base applies (article 6, 1) of which for video consultation the performance of a contract seems the only other applicable base. Additionally, the processing is only allowed for specific purposes (article 9, 2) of which article 9, 2 (h) seems the only applicable for video consultation: "processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, *medical diagnosis*, the *provision* of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3" (emphasis added).

 It's not necessary to request consent for each subsequent video consultation under routine care.

As a recommendation, the report proposes to have the sector providing video consultation solutions to draft and submit a code of conduct as provided for by GPDR article 40, 2. to the Belgian Data Protection Authority. Such a code of conduct clarifies the practical application of the GDPR and how video consultation solutions in particular and digital health care applications in general implement and conform to the GDPR.

The Belgian Data Protection Authority issued an advice in response to the many applications that are developed related to the COVID-19 pandemic. 165 Although the advice is not specific to video consultations services, the advice brings forward important principles in processing personal data related to health:

- If the processing can use anonymous data, it should. Data are only (sufficiently) anonymous if they can no longer lead to re-identification in combination with other data (also from other parties).
- Data processed within an existing care relation should only be processed for the purposes of assuring quality and continuity of care by the treating health care providers. This should be clearly communicated to the patient preferably by the health care provider.
- If the above doesn't apply, then the usual precautions and conditions of informed consent as specified by the GDPR apply.

The COVID-19 pandemic also caused the formation of a task force on data and technology, composed of representatives of the Ministers of Public Health and Digital Agenda and Privacy, of the FPS Public Health, of Sciensano, of the eHealth-platform and of the President of the Belgian Data



Protection Authority. ¹⁶⁶ The task force has a coordinating and directive role in assessing privacy, security, efficiency and scientific underpinnings of applications or platforms developed in health care to alleviate the COVID-19 pandemic. Its recommendations and decisions do not constitute a formal certification. Among other guidelines, the task force published a good practice guideline ¹⁶⁷ for platforms geared towards health care at a distance. It prescribes the following minimal conditions:

- Patient consent.
- Video communication via a tool with end-to-end encryption.
- Video or audio communication is not stored on the platform used.
- If, in addition to the possibility of video or audio communication, the tool provides other functions, these are offered in such a way as to enable users to comply with the rules of use (see below).
- Documents containing personal data can only be exchanged via a system with end-to-end encryption and with a reliable system of authentication of the identity of the users; the two-factor authentication tools (possession and knowledge) integrated in the Federal Authentication Service (FAS), such as the electronic identity card, Itsme or, for patients, the authentication generated within the framework of the Helena platform, are already regarded as reliable systems of authentication of the identity of the users.
- Patient is physically and mentally able to work with a PC.

Additionally, the following rules of use are formulated:

 Video or audio communication is not stored by the participants in the communication.

- Medication prescriptions are created electronically on Recip-e, and can be consulted by the patient via the Personal Health Viewer; the unique number of the electronic prescription (the so-called RID), which does not contain any personal data, can be transferred to the patient.
- Documents that the healthcare provider and/or the patient can consult via the eHealth portal or the Personal Health Viewer should be consulted there.

The task forceⁱ maintains a webpage with an assessment and recommendation of video consultation solutions. 168

3.4.4 Certification

There are no official bodies of certification or certification for video consultation in Belgium.

3.5 Funding

Outside of the specific government budget foreseen under the section on remuneration, there is no specific government budget for video consultation. For general physicians as well as for other health care providers, there exists a subsidy for ICT in general. Likewise, hospitals receive a budget for ICT as part of their financing (Budget of Financial Means). But no specific part of this funding is attributable to video consultation.

Any use of video consultation currently is either financed entirely by private means (either by provider or by the patient) or is part of a more general budget not specially geared towards video consultation. The COVID-19 pandemic has prompted RIZIV-INAMI to provide reimbursement for the actual use of video consultation in particular cases (see next section), but not for e.g. the other costs associated with acquiring and maintaining a video consultation solution.

This task force was erected at the end of March 2020, but disbanded already in mid May 2020 (https://www.ehealth.fgov.be/nl/egezondheid/task-force-data-technology-against-corona)



3.6 Remuneration

In Belgium, the remuneration of health care providers is largely through RIZIV-INAMI nomenclature, defining what health care acts are reimbursed by the compulsory health insurance, as well as by out-of-pocket payments of patients. For some health care domains, federated entities are responsible for the financing, like residential care for the elderly and prevention. If relevant and specific to video consultation, the distinction will be highlighted in the sections below.

3.7 Reimbursement

Until the 14th of March 2020, a video consultation was not reimbursed by the compulsory health insurance. The RIZIV-INAMI nomenclature specifies that consultations require the physical presence of both the health care professional as well as the patient. 169

In the light of the COVID-19 pandemic, and after a further advice of the Order of physicians (see above), the Minister of Social Affairs ordained a reimbursement for advice at a distance by means of a Royal Decree. ¹⁷⁰ RIZIV-INAMI has progressively introduced new measures to accommodate the fast changing needs of health care providers and institutions during the COVID-19 pandemic in 2020. All initiatives are temporarily until the Minister of Social Affairs ends the measures taken for the COVID-19 pandemic and revokes the Royal Decree.

In the sections below, we summarise the new conditions and reimbursements related to care at a distance by health care provider profession, updated up to the 28th of April 2020. We use the conditions as described in the last available version for the specific measures at the time of writing. In the sections below, all RIZIV-INAMI conditions for video consultations described in section 3.4.1.2 must be respected and we will not always repeat them in the description of individual measures.

3.7.1 Physicians

Initially, reimbursement is created for phone consultations: specific for COVID-19 assessment at a distance by phone for non-hospitalised patients, two nomenclature codes are created, one regular and one for guard duty. A third nomenclature code (101135), allows the physician to advice at a distance in the light of continuity of care. The use of these phone consultations is conditional on following the advices of the Order of Physicians (see above). The physician receives 20 € for the nomenclature code for advice at a distance in the light of continuity of care during the COVID-19 pandemic. There is no out-of-pocket payment for the patient: neither a co-payment nor a supplement. Non-conventioned physicians cannot charge a supplement. It cannot be cumulated with another consultation, visit or advice on the same day.

Although the general texts on these nomenclature codes do not mentioned it, the frequently asked questions section does confirm these codes can be used for individual video consultation as well, provided the physician can motivate he cannot see the patient in person due to the measures taken for the COVID-19 pandemic (question 12).¹⁷¹

In psychiatric hospitals, there is the possibility to offer ambulatory follow-up treatment after discharge. To uphold the possibility of these sessions, a temporary nomenclature code (762996) is created that reimburses individual video consultations on the following conditions:

- Individual video consultation with an and-to-end encrypted solution.
- The consultations are conducted by the therapeutic team of the hospital.
- Each patient can receive a maximum of one 45 minutes session per calendar day, with a maximum of three per calendar week.

The code is reimbursed at 40 € without out-of-pocket payment for the patient: neither a co-payment nor a supplement is allowed and use of the third party payer regulation is compulsory.

Also in psychiatric hospitals and psychiatric wards in general hospitals, video consultation is now allowed as support for patients in the system of



partial hospitalisation.¹⁷³ Normally patients in partial hospitalisation receive treatment by coming in at the hospital either during the day or at night. Hospitals can now continue this treatment system at home by combining phone support, video consultation or house visits. This "partial hospitalisation at home" is compulsory for patients aged 65 years or older but not for younger patients. Reimbursement for these patients remains the same as if they were in regular partial hospitalisation.

For ambulatory treatment and follow-up by psychiatrists (both for adults and children), four types of sessions at a distance and two types of concertation at a distance are introduced.¹⁷⁴ Most relevant to our topic are the four session types and these are shown in Table 11. Again, these codes are conditional on following the advices of the Order of Physicians (see above).

Table 11 - Psychiatric sessions at a distance nomenclature

	r systillative sessions at a distance nominional		
Code	Description	Conditions	Reimbursement
101894	Session with a minimum duration of 30 minutes, without physical presence, for the purpose of a psychiatric diagnosis or psychotherapeutic treatment.	Diagnosis or start of treatment by video consultation	45€
		 Continuation of treatment by video consultation or phone 	
101916	Session with a minimum duration of 45 minutes, without physical presence, for the purpose of continuing the psychotherapeutic treatment started prior to the government measures.	By video consultation	70€
101931	A session of at least 60 minutes for mediation therapy for a child or adolescent under 18 years of age with the participation of one or more the adults providing education and daily supervision, without physical presence.	By video consultation with the presence of the child for at least 30 minutes and of the adult of at least 60 minutes	96€
101975	Session with a minimum duration of 120 minutes for a comprehensive and individual psychiatric evaluation of a child or adolescent under 18 years of age for the purpose of diagnosis or follow-up, without physical presence, on prescription of the treating physician, with record keeping and reporting.	By video consultation	200€

For patients with neurodevelopmental disorders or intellectual disabilities, an adapted session for follow-up at a distance is created for neuropaediatricians (code 101791) reimbursed at 50 € without out-of-pocket payment for the patient.¹⁷⁵

3.7.2 Other healthcare professions

Dieticians can for patients in a care trajectory for chronic renal insufficiency (code 794010) or follow-up of diabetes type 2 (771131) replace two face-to-face sessions by video consultation or by phone. ¹⁷⁶ The usual conditions for these sessions remain valid, including reimbursement rules, but additionally:

an end-to-end encrypted solution should be used;

- 3
- an additional nomenclature code (792433) identifying care at a distance must be declared;
- the patient should be contacted and briefed beforehand and agree to the care at a distance.

These video consultations cannot be used for dietetic interventions in children with overweight or obesity.

For diabetes educators, dieticians, pharmacists or nurses providing diabetes education within the care trajectory for diabetes, two sessions can be replaced by phone or video consultation, but not the group sessions. The the sessions provided by diabetes educators, dieticians or nurses, the regular nomenclature codes should be used, in addition to the code identifying care at a distance (792433). Similar conditions as above apply for these sessions. Additionally, in the case of follow-up of diabetes type 2, only one of the health care providers can use phone or video consultation.

For alternative care forms for the elderly (Protocol 3 agreement), the following types of sessions can be replaced by phone, video communication or video consultation sessions: case management, psychological follow-up, and occupational therapy. Two sessions of occupational therapy can be replaced by video consultation as well for patients already under treatment.

Occupational therapists can replace two sessions of information, advice and training on the use of environmental adaptations, orthoses, prostheses and functional aids (code 784335), by video consultation for patients for which an observation report has been realised. The usual reimbursement rules apply but additionally, the code for care at a distance needs to be declared (792433).

Physiotherapists can use video consultation as well for non-hospitalised patients that do not need a hands-on treatment. ¹⁸⁰ A lump sum (code 518011) is reimbursed at 40 € per week without out-of-pocket payment for the patient. The lump sum covers anamnestic evaluation, drawing up and adjusting an individual exercise program and timing of ADL activities, two contacts per week supporting the patient through video consultation, and reporting.

The first-line psychological care by clinical psychologists and remedial educationalists can replace face-to-face sessions by video consultations both for new and patients already under treatment. The usual reimbursement rules apply, but different codes need to be declared for video consultations (789972 for 45 minute sessions and 789950 for 60 minute sessions).

Speech therapists can replace their regular sessions by video consultation under the usual reimbursement rules and by declaring the code for care at a distance needs (792433).¹⁸²

Midwifes can replace their regular consultations by video consultation under the usual reimbursement rules and by declaring the code for care at a distance needs (792433).¹⁸³ Of course, video consultation for services in which the physical presence of the midwife is indispensable are not allowed (e.g. injections, supervision and assistance to the patient during labour, deliveries, postnatal surveillance on the day of delivery...).

For a number of health care professions, no specific measures are taken to allow video consultation: home nurses (except for the above noted specific cases of diabetes and alternative care forms for the elderly), opticians, orthopaedists, podiatrists, dentists, audiologists, and bandagers. Although other supportive measures for these health care professions are generally implemented.

3.8 Technology

The COVID-19 pandemic has seen the number of available tools grow rapidly. Therefore we do not include here a list of available tools because it becomes outdated by the time this report is published. However, Table 12 shows a non-exhaustive list of Belgian organisations maintaining a list of available solutions. All these tools can be categorised into one of three categories:

 General purpose video call solutions targeted at consumers like FaceTime, WhatsApp, Snapchat, Signal, ...

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- General purpose video call solutions targeted at professional use like Zoom, Skype, Google Hangouts Meet, Webex, TeamViewer, GoToMeeting, ... Some of these professional solutions also provide a more limited free tier aimed at consumers or professionals with limited videoconferencing needs.
- Dedicated software solutions targeted at health care (see e.g. the section 3.10.1 on SIMBA below for pointers to examples). Prior to the 2020 COVID-19 pandemic most of these providers were foreign companies. However, the accelerated use of video consultations caused by the measures taken, spawned a number of new providers, either using their own solution, or using another tool as backend. In most evaluations, only this category is usually deemed sufficiently private and safe for use in health care (see also section 3.4.4 on privacy and security).

Table 12 – Lists of available video consultation solutions (last updated on 2020-04-27)

011 2020-04-27)		
Link		
https://elearning- onlinehulp.be/simba/courses/professionele-beeldbeltools/		
https://www.ehealth.fgov.be/nl/egezondheid/task-force-data-technology-against-corona/nuttige-platformen-voor-een-raadpleging-zonder-fysiek-contact		
https://www.onlinehulp-vlaanderen.be/online-in- coronacrisis/		

3.9 Effects

To our knowledge, no evaluation was performed in Belgium on the effects of video consultations on the health of patients, health system, its possible benefits, costs or problems.

3.10 History/implementation

At the time of writing, a number of initiatives were implementing video consultation in various stages of completion: from exploration over pilots to fully implemented. In the section below, we describe a number of these initiatives without trying to be exhaustive.

3.10.1 RIZIV-INAMI workshop on telemedicine

As previously mentioned, RIZIV-INAMI organised in 2019 a workshop^j on a Belgian framework for telemedicine and mobile health applications in Belgium.^{184, 185} The workshop presented a report on several research questions related to the legal and administrative aspects of telemedicine, including video consultation of which several have already been discussed in previous sections.^{8, 158}

In addition to the report, several stakeholders expressed their vision on telemedicine in Belgium. Most visions and point of views related to telemedicine and telemonitoring rather than video consultation. All stakeholders stress the importance of solutions that respect the privacy and provide adequate security.

Table 13 summarises the vision of these stakeholders on aspects of video consultation only, to the extent they are available in the documents published on the workshop webpage.¹⁸⁴

https://www.riziv.fgov.be/nl/themas/kost-terugbetaling/door-ziekenfonds/Paginas/telegeneeskunde-mhealth-toepassingen.aspx

Table 13 - RIZIV-INAMI workshop on telemedicine - summary of vision of stakeholders with respect to video consultation (in the publishing order on the workshop webpage)

Stakeholder	Summary points on video consultation
Health care professionals – Alliantie Artsenbelang ¹⁸⁶	No specific information on video consultation mentioned in the available documentation.
Health care professionals – Kartel (ASGB, MODES, GBO) ¹⁸⁷	No specific information on video consultation mentioned in the available documentation.
Health care professionals – ABSyM-BVAS ¹⁸⁸	Sees a role for video consultation ("virtual visits") in care integration through digital transformation: it's one of the tools that have the possibility to simplify care for patients.
Health care professionals – VVL - UPLF ¹⁸⁹	Sees a clear role for video consultation in speech therapy for both diagnostics and therapy for reasons of accessibility for the patient, self-therapy and for therapy effect measurement; given appropriate conditions.
Sickness Funds ¹⁹⁰	 Proposes a government developed generic GDPR compliant platform for telemedicine (including video consultation), using the services of the eHealth-platform, that integrates all aspects of use (e.g. authentication, validation of use, invoicing, electronic health record linking).
	 Proposes teleconsultation with advising physician or paramedical professions as a pilot as it doesn't require RIZIV-INAMI nomenclature changes.
Patient organisations ¹⁹¹	No specific information on video consultation mentioned in the available documentation.
Industry – Agoria and beMedTech ¹⁹²	Request to initiate as soon as possible administrative and legal processes to make video consultation possible.
Government ¹⁹³	Video consultation: need to clearly define the target population and for what purpose.

3.10.2 SIMBA

SIMBA is an acronym for "successfully implementing video calls in ambulatory help and care"k. SIMBA isn't a video consultation solution as such, but a framework for organisations that want to implement video consultation in their workflows. SIMBA is a collaboration of private, government and semi-government partners led by two research teams. The SIMBA project does not focus specifically on the medical sector but at the health and care sector in general, including for example the welfare sector.

Eleven e-learning modules and corresponding documents were developed to assist organisations in the preparation and execution of integrating video consultation (see Table 14 for a description of the modules).

Succesvol IMplementeren van Beeldbellen in Ambulante hulp en zorg



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Table 1	4 - 3	ועווכ	DA	шоо	luies

Module	Description	Accompanying documents
Implementing video consultation	The module provides an overview of the steps needed and aspects to be considered in implementing video consultation that will be discussed in the other 10 modules.	Quickscan to assess the readiness of the organisation to implement video consultation.
Added value of video consultation	The module provides guidance and tools to explore possible added value of video consultation within the organisation from different perspectives (organisation, organisational user, clients).	Checklist to survey possible added value from three perspectives "Client trip": method to survey video consultation from the perspective of the client. Template to determine organisational vision on video consultation.
Professional video consultation tools	The module provides a comparison of video consultation solutions on a number of dimensions like administrative tools, privacy, technology, user friendliness,	Comparison of existing tools Decision aid
Clients and video consultation	The module provides guidance and tools to assess the client perspective, to engage the client and to identify eligible groups of clients.	
Video consultation methodology	The module provides practical guidance on actually using video consultation: from preparation over rules to conducting a video consultation and administrative aspects.	Practical guideline
Organisational user trust	The module provides guidance on surveying and engaging organisational users in setting up video consultation in their workflow.	
Privacy and ethical aspects	The module provides guidance on GPDR aspects of video consultation.	
Communication on the use of video consultation	The module provides guidance on communicating the use of video consultation within and outside of the organisation.	
Costs and benefits of video consultation	The module provides guidance on calculating the costs and the benefits of video consultation, both budget wise as well as more soft returns on investment.	Detailed excel files on possible costs and benefits Tool to map soft returns
Partners in video consultation	The module provides guidance on implying other organisations in implementing video consultation.	
Step by step implementation	The module provides a systematic approach to implement video consultation in both small and larger organisations.	Step by step guide



The modules are currently available in Dutch after creating an account (without charge).

Although all modules are quite important in implementing video consultation in an organisational workflow, we like to discuss two modules in more detail. The first concerns the assessment of a technical solution for video calls. The SIMBA projects maintains a list of software solutions and assesses them according to a list of criteria. 194 These criteria are shown in Table 15.

Table 15 – SIMBA criteria for the assessment of video consultation solutions (adapted from SIMBA comparison¹⁹⁴).

Topic	Criterium	Description
Integration	Part of platform	Is the video consultation part of a more general solution for digital care (e.g. client portal, electronic health record, secure exchange of documents, secure messaging,)?
	Standalone use	Can the video call solution be used independently if also integrated in a platform?
	Supported operating systems	What client and host operating systems are supported? Is it a browser solution and what browsers are supported?
	Link to other systems	Is there a link possible with other registration systems, e.g. electronic health record? Is integration possible in the own website?
	User management	Does the application allow to manage hosts and users by central administration?
Usability and functions	Client application	Does a separate client software needs to be installed?
	Client account	Does the client needs create an account?
	Number of participants	How many concurrent participants are allowed?
	Waiting room	Are participants put in a virtual waiting room or are they immediately connected to the video consultation?
	In session tools	Can the software share the host's screen? Can files be shared? Is there a chat function? Can clients dial in by phone? Can the host remote control the client for support?
	Language	Is the client tool available in multiple languages?
Privacy and security	GDPR compliant	Does the software application conform to the GDPR rules on the treatment of personal data? This should be covered by a contract explicitly stating the conformity to GDPR and the measures taken by the provider.



1 TO TIME! Support	Technical help with	boos the provider have a herpaesk and what are the opening hours:
Provider support	Helpdesk	Does the provider have a helpdesk and what are the opening hours?
	Server location	Are the servers of the provider located in the European Union? Does all communication stays in the European Union or does part of the data can be communicated outside of the European Union (e.g when the provider uses a third party solution)?
	Logging by provider	To what extent contain the log files at the provider personal data like IP address? What are the security measures and retention times?
	Recording of conversations	Can the software record conversations and under what conditions?
	Secured connection	Is the connection secured in a known and tested way: e.g. currently preferably 256 bit AES ^I end-to end encryption ^m ?

Video consultation for chronic somatic disease

Advanced Encryption Standard¹⁹⁵

KCE Report 328

End-to-end encryption ensures data is encrypted when being passed through a network and intermediate servers, like from a provider, cannot decrypt the data, only the device of the end user can. This reduces the number of parties that can access the data.



3.10.3 AXA Doctors Online

Private insurer AXA launched a <u>service to teleconsult</u> with a GP in November 2019 for clients with an AXA hospitalisation insurance. ^{196, 197} The service allows for clients to call by phone and schedule an appointment with a GP contracted by AXA. A nurse triages during the call to spot medical urgencies or other reasons to refer to other services. Otherwise, the client receives an appointment for a video consultation with a GP. The service is aimed at acute pathologies, on top of regular care but not as a replacement of contacts with the regular GP, e.g. for follow-up in chronic care. Consultations resemble face-to-face consultations in terms of usual care practices (e.g. assessment, medical file, SumEHRⁿ, ...). The client is not charged separately for the video consultation as its part of the hospitalisation insurance.

AXA uses an external partner for the technical solution.

At the time of writing, no usage statistics for Belgium were available, but AXA indicated that preliminary data seemed to follow the same trend as in France where the service exists since June 2017. In France, about 70% is accepted for a video consultation after triage, while about 20% is referred to their regular GP and about 10% are referred to emergency services. ¹⁹⁸ About 6% of video consultations are from patients temporarily abroad from France.

At the end of March 2020, AXA opened up the Doctors Online service for patients not insured with AXA that have COVID-19 complaints and have difficulty reaching their regular GP. ¹⁹⁹

3.10.4 Wit-Gele Kruis West-Vlaanderen

Wit-Gele Kruis is a federation for home nursing organised as five autonomous non-profit organisations in each Flemish province. The branches in West-Vlaanderen and Vlaams-Brabant participated at the SIMBA project described above.

Wit-Gele Kruis West-Vlaanderen has since started a project implementing video consultation in their daily workflow. A rigorous project plan identifying all steps needed to assess the added value and the integration in the daily workflow was drafted. An overview of the plan is shown in Figure 2. In March 2020, the plan was ready for a phased roll-out.

The starting point for the project was that video consultation by video call would only be considered for cases with a clear added value compared to contact by phone. Wit-Gele Kruis West-Vlaanderen categorised multiple types of care offer into three categories: planned care, unplanned care, and peer consultation. They identified added value for video consultation in a first implementation in particular in planned care and in peer consultation. As a first pilot, the follow-up of diabetes patients is chosen: replacing one or more visits by a video consultation if the patient agrees. In peer consultation, they see added value in second opinions by a more specialised nurse, e.g. in wound care.

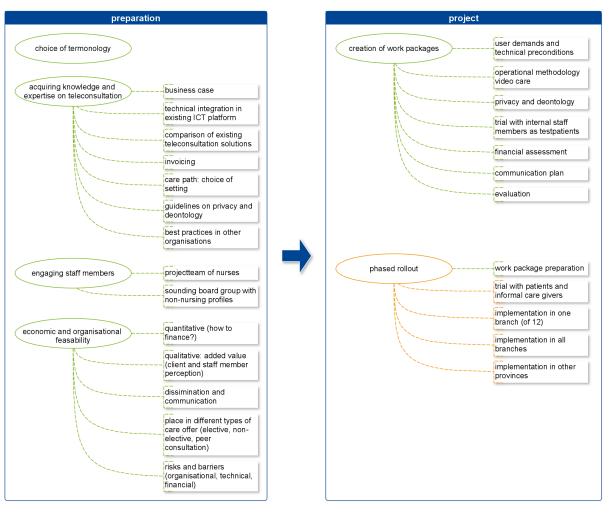
At the time of writing, all preparatory work and the evaluation of an internal trial without actual patients was finished and the project was preparing to start a real pilot with patients and care givers°.

A summary of the clinical dossier using a standard format and uploaded into a virtual vault to one of the digital platforms (<u>Vitalink</u>, <u>RSW</u>, or <u>Abrumet</u>)

o https://www.focus-wtv.be/nieuws/wit-gele-kruis-geeft-diabeteseducatie-beeldbellen

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Figure 2 – Schematic overview of the implementation plan for video consultation of Wit-Gele Kruis West-Vlaanderen (green = finished in March 2020; orange = ongoing in March 2020)



Source: adaptation of documents provided by Wit-Gele Kruis West-Vlaanderen (personal communication).

3.10.5 l'Observatoire de la Santé de la Province de Luxembourg

l'Observatoire de la Santé de la Province de Luxembourg (Observatory for health of the province of Luxembourg in Belgium) initiated a project on remote consultations in a nursing home or prison.²⁰⁰

The project was born on recurrent problems for nursing home residents and prison residents to have a timely consultation with their GP when having an acute health care problem. Because of this, residents were often unnecessary transported to the emergency room. Other problems the remote consultation tries to solve is the relatively large distance GP's have to travel to the nursing home or prison for a single visit. Remote consultations would here increase the availability of the GP.

Additionally, nurses from the nursing home could use the remote consultation to prepare an actual visit of the GP at a later date, or if

necessary, transport the resident to the emergency room, but for medical and not organisational reasons.

Given that the project was run before the COVID-19 pandemic, the remote consultation was not meant as a replacement for an actual visit by the GP but as an organisational aid, in line with the advices of the Order of Physicians (see also section 1.1.1).

The pilot project was run in two practices of general practitioners with patients in nearby nursing homes or in prison. It consisted of providing a stethoscope and a camera connected to a tablet allowing to conduct a remote consultation by video with the clear objective of judging the medical urgency or planning a visit at a later date. The physician can consult with the patient and listen remotely through the stethoscope. The patient is assisted by a nurse. A bird's eye view on the project plan is shown in Table 16.

Table 16 – Overview of phases in the videoconferencing project of l'Observatoire de la Santé de la Province de Luxembourg (adapted from 200)

Phase	Description		
0: objectivation of need	Consultation of the nurses in the participating nursing homes and the general practitioners to take stock of the needs.		
1: definition and choice of equipment	 Availability of the eHealth-box at the nursing home to safely exchange patient information. Availability of a separate network with Wi-Fi for the patient connection. Selection of stethoscope, camera, tablet and software solution that: guarantee a high level of security; is GPDR compliant; adaptable to future needs; interoperable with other systems like patient electronic health record, the eHealth-platform infrastructure, and the Résau Santé Wallon (the Walloon region platform for the safe exchange of health care information between patients and health care providers and between health care providers mutually); 		
2: training - protocol	 Material testing and simulation. Drafting of the pre-consultation protocol as part of the procedure of a pre-consultation followed by a consultation. Training of the whole team at the nursing home, in particular for the nurses to correctly apply the stethoscope. Training of the participating physicians. 		
3: project kick off	Planned real life testing of the remote consultations.		
4: evaluation	Planned evaluation of the project.		



At the time of writing, the project was in test phase with fictitious consultations. Preliminary results were inconclusive on the use of the stethoscope and raised some practical issue for both the nurses and the GP that well need to be dealt with.

4 VIDEO CONSULTATIONS IN FRENCH HEALTH CARE

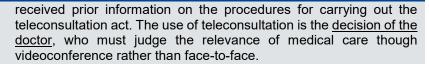
4.1 Key points

Implementation

- Initially, telemedicine was implemented in France through pilot projects, financed by the government, and supervised locally by the Regional Health Agencies between 2014 and 2018. Since then, telemedicine acts have been well defined in the law and teleconsultation is now reimbursed by the Health Insurance at the same price as face-to-face consultations (under certain conditions).
- However, the uptake of teleconsultations has been slower than expected by the French government. Between September 2018 and September 2019, only a small proportion of doctors have used teleconsultation and it is in Île-de-France that there were the most teleconsultations billed. Similarly, patients who benefited from teleconsultation are unequally distributed over the territory.
- Surveys suggest that French adults are in favour of teleconsultation although they reported reluctance regarding the reliability compared to a face-to-face consultation as well as several technical problems.

Reimbursement

- While teleconsultation acts reimbursed by the Health Insurance can be done by <u>any medical doctor</u>, recently concluded conventional texts aim to encourage the participation of other health professionals (i.e. pharmacists and nurses) in the realization of these consultations. Teleconsultation acts are remunerated under the same conditions as "face-to-face" consultations.
- Reimbursement of teleconsultation acts is possible for <u>any patient</u>, regardless of their place of residence, as soon as the teleconsulting doctor offers it and the patient gives his/her consent after having



- A teleconsultation is billed by the teleconsultant doctor at the <u>same</u> <u>price as a face-to-face consultation</u>, and the reimbursement rules are the same as for a face-to-face consultation.
- However, reimbursement of teleconsultation is subject to some general (being integrated within the <u>coordinated care pathway</u> and the <u>patient already being known</u> by the teleconsulting doctor) and <u>technical requirements</u> (being conducted by video-transmission and use of a secure connection).
- The territorial organisation of care and the respect of the coordinated care pathway of the patient are central in the teleconsultation use as agreed in the convention. While some exceptions have been defined (for patients who have no GP or the GP is not available) to allow those patients to have access to a reimbursed teleconsultation, this framework still seems too restrictive with regard to the wide dispersion of health professionals over the French territory. Next to this, the obligation to use video transmission restrict the use of teleconsultation to patient having access to (and knowing how use) several technical equipment (computer...), adding a technological barrier to health care access.

Technology

- Any teleconsultation, whether invoiced or not, must take into account the security aspects of personal health data. Those are related to the Interpersonal communication and the exchanges of health documents containing personal data.
- The offer of teleconsultation services is generally done though a package of technical tools and supports (video transmission software, smartphone application...). They can be scheduled (part of

- the care pathway, the doctor offers them to his own patients) or immediate (offered to insurer's members for example).
- There are many providers of teleconsultation solutions, and doctors have many possibilities. The offer of teleconsultation solutions is shared between regional institutions and private actors (Market place and BtoBtoC providers).
- The French National Authority for Health (HAS) established several recommendations to support the deployment of teleconsultations on the national territory and to ensure the quality and safety of teleconsultation acts.

Privacy and ethics

- Teleconsultation and teleexpertise meet the same requirements as face-to-face medical practice (laws and regulations applicable to the conditions of practice, ethical rules and standards of clinical practice).
- In addition, the regulation in France includes some <u>specific</u> requirements for the practice of telemedicine (regarding the informed consent, conditions of performance of acts, patient record, professional training, and compliance with personal health data hosting).

Evaluation

- While many experimental projects were carried out to implement telemedicine in France during the last decade, it seems that no proper post-evaluation was made.
- An advanced evaluation of telemedicine practices is needed to assess the impact of these kind of innovations on patients and the health system, but no such evaluation has been performed so far.



4.2 Methodology

The information used in this chapter was collected using a grey literature search and interviews. The following sources of information were looked at: laws and regulations, websites of official government institutions, websites of governing bodies, websites of professional and scientific associations, and websites of teleconsultation solutions providers.

Based on the documents found, we tried to identify key informants to ask for further information sources. Additionally, we sent a questionnaire developed at KCE to collect further information regarding implementation, barriers and facilitators, laws and regulators as well as technical aspects. This questionnaire was completed by representatives of the HAS (Haute Autorité de Santé) and the French Health Insurance (see below). One scheduled interview (by phone) was conducted with the President of the association "Les Entreprises de Télémédecine". We have included the information subsequently obtained.

4.3 History/implementation

4.3.1 History

When was telemedicine started?

Telemedicine was progressively developed in France since the 1980s, date of the first pilot projects. At the end of 2010 telemedicine was regulated by a Decree, defining telemedicine acts and setting their conditions of implementation (see section 4.4.1). This allowed to extend the pilots at the regional and national level^p, though the Regional Health Agencies (Agences Régionales de Santé, ARS), which are autonomous public institutions

For example, ETAPES project (Expérimentations de télémédecine pour l'amélioration des parcours en santé. More information on ETAPES can be found here: Ministère des Solidarités et de la Santé, ETAPES: Expérimentations de Télémédecine pour l'Amélioration des Parcours En Santé (mise à jour: 27/11/19). Available from: https://solidarites-sante.gouv.fr/soins-et-maladies/prises-en-charge-

responsible for the implementation of health policy under the supervision of the Ministry of Health^q. They fostered these pilot projects by providing funds and regional platforms for the exercise of telemedicine (see section 4.9).²⁰¹

How was teleconsultation implemented?

In 2018, teleconsultation and teleexpertise were integrated into the structural (and no longer experimental) funding by the compulsory Health Insurance (see section 4.4.1). This regulatory evolution has allowed the entry on the market of a multitude of private actors offering telemedicine platforms and services (see section 4.8.2).²⁰¹

4.3.2 What barriers/facilitators were encountered during implementation?

This section is derived from a specific questionnaire developed at KCE and send to a Medical Advisor of the DDGOS unit at the Health Insurance and to a Project Manager at the "Haute Autorité de Santé" (HAS) in February 2020.

During the experimentation phase, the scaling up of pilot projects was mainly hospital-centred. The main barriers reported in the questionnaires were related to several needs:

- The implementation of an adequate regulatory framework;
- Ensure the permanence of funding (initially obtained though research credits);
- Contractualization between the various actors and agreements with the regional health agencies;

<u>specialisees/telemedecine/article/etapes-experimentations-detelemedecine-pour-l-amelioration-des-parcours-en</u>

More information on Regional Health Agencies can be found here: Qu'est-ce qu'une agence régionale de santé (mise à jour: 7/5/2019). Available from: https://www.ars.sante.fr/quest-ce-quune-agence-regionale-de-sante



• The existence of a **personal electronic medical** file easily accessible to any health care provider.

When teleconsultation was enshrined in the French Law, several factors could have slow down the use of teleconsultation. Some of them are listed below:

- Underestimation of the time needed for the information of patients;
- Underestimation of the time of information, training and appropriation of health professionals;
- Barriers encountered by the health professionals: technical (instability, breakdowns, security, confidentiality...), administrative (billing management...), practical use (which clinical situations, which patients, medical risks, dehumanization, lack of training), lack of knowledge;
- Barriers described by the patients: technical equipment (internet access, ...), dehumanization, lack of knowledge;
- Frame: respect of the patient care pathway (orientation by the GP to a specialist), prior knowledge of the patient by the doctor carrying out the teleconsultation (at least one face-to-face consultation in the preceding year), territorial organisation.

These factors together can explain the overestimation of teleconsultation use in the forecasts made initially (see below).

4.3.3 How were barriers in implementation solved?

According to the information collected via the questionnaires, several adapted strategies have been implemented following the many barriers identified:

- Multichannel **communication** by health insurance to healthcare professionals and patients;
- Recommendations developed by the HAS to support the deployment of telemedicine by informing professionals and patients and to

- guarantee that telemedicine acts are performed under the same quality and safety conditions as face-to-face acts;
- Studies and communications published by other health agencies or other organizations have helped inform users and professionals;
- Training of health professionals via the Continuous Professional Development (Développement Professionnel Continu, DPC), by placing telemedicine practices as a priority. For example, SFSD (Société Française de Santé Digitale) offers training to all kinds of healthcare professionals in their learning process of telemedicine. Similar training courses are available in most EU countries but their prices are often prohibitive.⁷
- Simplified technological requirements: only compliance with security requirements is necessary for i) health data (use of text messages or a secure connection) and ii) medical practice (compulsory use of video transmission);
- Funding: reimbursement of teleconsultation acts at the same price as face-to-face consultation and equipment assistance for doctors (including subscription to technical solution services and connected medical devices);
- Gradual opening of the reimbursement framework for the intervention of other health professionals: nurses, pharmacists, health centres, allowing additional access to teleconsultation by expanding the offer;
- Project of amendment to the conventional agreement: modification
 of the framework (respect for the regular GP's orientation and prior
 knowledge of the patient by the doctor carrying out the teleconsultation
 to take into account relevant clinical situations (elderly patients in
 institutions for example));
- Registration of a compulsory teleconsultation development mission within the framework of the deployment of professional territorial health communities (communautés professionnelles territoriales de santé, CPTS).



4.3.4 Which institutions are responsible for the deployment of teleconsultation in France?

In France, the deployment of telemedicine is currently driven and supervised by several national (i.e. Ministry of Health, CNAM, and HAS) and regional (ARS) institutions, but there is a lack of clear definition and distinction of their specific roles and missions. This may represent a brake on its development, or at least constitute a development coherence issue.²⁰¹ Next to this, several health agencies and scientific societies support the deployment of telemedicine acts by conducting plenty of studies, surveys, informative documents ...

The main institutions playing a role in the deployment of teleconsultations are:

- The Ministry of Health DGOS (direction générale de l'offre de soins): regulator/legislator
 - provides guidelines for negotiations between professionals and health insurance, via its central departments and regional health agencies,
 - is responsible for providing information and instructions for those involved in the deployment of teleconsultation,
 - o publish the necessary legal and regulatory documents.
- The Health Insurance (Caisse nationale d'assurance maladie, CNAM)
 - negotiates agreements with doctors' unions and ensures their implementation
 - financier, via the reimbursement of teleconsultation acts
- The Regional Health Agencies (agences régionales de santé, ARS)
 - o regional regulators (supports actors in the field)
- Other health agencies
 - Haute Autorité de Santé (HAS): supports the deployment of telemedicine in France, developed a good practice guide for health

- professionals, conducted medico-economic studies, published patient information sheets ...²⁰²
- Agence du numérique en santé (ANS- ex ASIP): commissioned by the Ministry of Health to draw up an inventory of telemedicine, describe use cases, guarantee the security of exchanges, analyse the development of telemedicine internationally, and publish a section of the ci-sis content²⁰³
- Agence nationale d'appui à la performance (ANAP): supports the project initiator (in particular hospitals) and the regional health agencies, the dissemination of good practices, and gives assistance in project design²⁰⁴
- The National French Order of Physicians (Conseil National de l'Ordre des médecins, CNOM)
 - gives opinions on the regulation and ethical conditions for the implementation of teleconsultation
- Scientific societies
 - Société Française de Santé Digitale (SFSD): promotes a humanist and responsible use of telemedicine and promotes innovation in digital health through the mobilization and training of stakeholders by experts in the field^{205, 206}
 - Institut de recherche et documentation en économie de la santé (IRDES): produced a literature review on the experience of patients and health professionals in the field of telemedicine,²⁰⁷ and carried out a medico-economic evaluation of telemedicine²⁰⁸

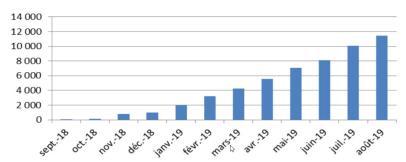
4.3.5 What is current scale of teleconsultation?

The number of teleconsultations billed each month has been constantly increasing since the implementation of the reimbursement, in September 2018. In January 2019, there were 2000 teleconsultations, while the number reached 7000 in May 2019 and exceeded 10 000 monthly teleconsultations since the summer of 2019 (**Figure 3**). From September 2019, the number of teleconsultations is around 3,300 per week.²⁰⁹



However, this remains far from the forecasts of the government which, in its 2018 budget, counted on 500 000 acts in 2019, one million in 2020, and 1.3 million in 2021.

Figure 3 – Monthly evolution of the number of teleconsultations billed in France between September 15th 2018 and September 15th 2019



Available from:

https://www.ameli.fr/fileadmin/user_upload/documents/DP_1er_anniversaire_du_remboursement de la teleconsultation sept 2019.pdf

How many health care professionals are using teleconsultation?

Proportion of doctors using teleconsultation

While the exact proportion of doctors using teleconsultation among all practicing doctor in France is difficult to measure, the Health Insurance reported that since the reimbursement, 1647 self-employed doctors or health institutions have invoiced teleconsultations.²⁰⁹

According to the survey conducted in November 2019 by the "Agence du Numérique en Santé" (ANS, ex-asip) on 3012 representative French people and 522 health professionals, 9% of health professionals and 13% of doctors have already used teleconsultation at least once.^{203, 210} On average, teleconsulting doctors have done 22 teleconsultations (from November 13 to 25, 2019), although there was a substantial variation between doctors.

Characteristics of teleconsulting doctors

Among all teleconsultations billed between September 2018 and September 2019, 85% were billed by liberal doctors, 8% by health centres, 5% by hospital doctors during their outpatient consultations and 2% by health institutions. Among the self-employed, it is general practitioners (GPs) who practice teleconsultation the most with 65% of acts, while specialists represent 35% of acts invoiced (mostly, psychiatrists, gynaecologists, and paediatricians).²⁰⁹

While the proportion of men and women doctors practicing teleconsultation is similar than among those currently practicing (i.e. 62% men and 38% women), the "teleconsulting" GPs are generally younger; half of them are under 50, while this age group constitutes only 37% of the total self-employed GPs.

The use of teleconsultation is unequally distributed over the territory since some departments concentrate the vast majority of teleconsultations. It is in Île-de-France that there were the most teleconsultations billed (44% of all teleconsultations).

How many patients are seen by teleconsultation?

While 6% of the participants to the ANS's survey declared using teleconsultation, ²⁰³ the proportion of consultations performed though videoconference is not known, as well as the type of pathology of teleconsulting patients.

However, according to the Health Insurance, about 30 000 patients have benefited from a teleconsultation in France between the launch in September 2018 and September 2019. Two-thirds (64%) of teleconsultations were carried out with a woman.²⁰⁹

Regarding the age of patients, a third of those who benefited from a teleconsultation are less than 30 years old and 56% are less than 40 years old; 12% of teleconsultations however concern patients aged 70 and over. Patients with long duration disease (LDD) also use it, with 27% of teleconsultations billed to this category of patients.

It is also interesting to note that patients who practice teleconsultation for the first time with their regular GP are more likely to use this mode of



consultation a second time, as shown by the average of 1.4 procedures per patient.

As for "teleconsulting" GPs, patients who benefited from teleconsultation are unequally distributed over the territory.

Predictions

According to the Health Insurance, teleconsultation should spread more widely in the next months and years, in particular thanks to the recently concluded conventional texts which aim to encourage the participation of other health professionals (i.e. pharmacists and nurses) in the realization of these consultations (see section 4.4.1).

Moreover, the level of equipment will increase, as doctor's organization will continue to evolve towards more pooled exercise (health homes, territorial health professional communities, etc.), which divides the financial weight of the equipment. The doctors are still quite few to be equipped with the necessary equipment for teleconsultation.²⁰⁹

Next to this, teleconsultation will become more acceptable for all types of patients. For now, not all patients are completely comfortable with this new way to see a doctor, especially older people (see below).²¹¹

Surveys

According to a survey realised at the beginning of 2019 on 1018 individuals aged 18 and over, representative of the French population (quota method-sex, age, occupation, region) for the teleconsultation platform *Livi*, 63% of French adults are in favour of teleconsultation and 52% might consider using teleconsultation, especially in the following situations: to seek medical advice (72%), renew a prescription (71%), while traveling (67%), in the absence or unavailability of their regular GP (66%), for a health problem that seems not urgent (66%), request a medical certificate (63%), or get an emergency consultation (60%). Factors that could dissuade a patient from consulting at a distance were: the impossibility to be examined directly by the doctor (50%), the need to have a direct contact (36% and up to 41% for

65 years old and over), the feeling of being less well taken care of (29%) or the fact of not choosing the doctor teleconsulted (22%).^{211, 212}

Another survey conducted on a sample of 1003 representative French people (using the quota method) in September 2019 for the teleconsultation platform *Medaviz* showed that 79% of them believe that "teleconsultation remains less reliable than a physical appointment with a doctor". ^{213, 214} Teleconsultation remains marginal since only 9% of respondents declare using it, which is far less than the number of patients who go to the doctor's office without an appointment (39%) or to the emergencies (27%). This demonstrates the caution patients have regarding this new practice.

Finally, in a survey conducted in November 2019 by the "Agence du Numérique en Santé" (ANS, ex-asip) on 3012 representative French people and 522 health professionals, several technical problems were reported by the participants. In particular, patients were unsatisfied with the quality of the image (21%) and of the sound (14%) and had technical problems with the connexion (17%). Among health professionals, these proportions were of 33% for each of the 3 technical problems (image, sound, and connexion).²⁰³



4.4 Legislation

4.4.1 Applicability

Telemedicine was first defined in Article 78 of the law n° 2009-879 of July 21, 2009^r as a form of distant medical practice using information and communication technologies.²¹⁵

The definition of telemedicine acts and their conditions of implementation were then set by the Decree n° 2010-1229 of October 19, 2010.³ The different acts considered as telemedicine are teleconsultation, teleexpertise, medical telesurveillance, medical teleassistance, as well as distance-based medical support provided when emergency medical services are called.

Teleconsultation was defined as follows: « La téléconsultation a pour objet de permettre à un professionnel médical de donner une consultation à distance à un patient. Un professionnel de santé peut être présent auprès du patient et, le cas échéant, assister le professionnel médical au cours de la téléconsultation. § »

This definition led to the setting up of an experimental framework for telemedicine from 2014 (in 9 pilot territories) to 2018 (nationwide). In August 2018, a decree approving the amendment 6 of the national convention organizing the relationship between the liberal doctors and the health insurance^t, has brought certain acts of telemedicine into the structural **reimbursement by health insurance**. The agreement formalized and framed the two acts of telemedicine that are reimbursed:

- teleconsultation, from September 2018: open to all insured persons, whatever their place of residence, and to any doctor, whatever their specialty;²¹⁷
- teleexpertise, from February 2019: currently reserved for certain patients (suffering from long duration diseases or rare diseases, living in sparsely populated areas, EHPAD (Etablissement d'Hébergement pour Personnes Agées Dépendantes), medico-social structures or prisons). The schedule for deploying tele-expertise for the benefit of all patients will be defined before the end of 2020.²¹⁸

Teleconsultation must, however, be part of a strict framework that respects the patient's care pathway so that the patient can claim reimbursement (see section 4.7).

For the other dimensions of telemedicine not yet entered in the structural reimbursement scheme, the financing is still done by subsidy of experimentation. In particular, telesurveillance will remain experimental for a period of 4 years from January 1st 2018.²¹⁹

Which health care professionals?

Teleconsultation acts reimbursed by the Health Insurance can be done by:

- any liberal doctor, regardless of his or her medical specialty,
- salaried doctors of health institutions, in the context of outpatient consultations,
- salaried doctors of health centres.

https://www.legifrance.gouv.fr/affichCodeArticle.do:jsessionid=A8640C7359 E677BCFA57C50062648AFD.tplgfr22s 1?cidTexte=LEGITEXT000006072 665&idArticle=LEGIARTI000020891702&dateTexte=20191218&categorieLien=id#LEGIARTI000020891702

Now corresponds to the « Article L. 6313-1 du Code de la Santé Publique », Available from :

Les psychologues mentionnés à l'article 44 de la loi n° 85-772 du 25 juillet 1985 portant diverses dispositions d'ordre social, peuvent également être présents auprès du patient.

More information on the French Health Insurance named Ameli can be found here: https://www.ameli.fr/

 Consultant opinion (art 18 of the "Nomenclature Générale des Actes Professionnels", NGAP²²³): advice given by a specialist at the explicit request of the GP. The specialist, requested for his medical opinion, sends his conclusions and therapeutic proposals to the GP;

 The specific consultation by a doctor specialized in cardiovascular pathology or in cardiology and medicine of vascular diseases, which implies a physical examination of the patient (art 15.1 of the NGAP).

The underlying reasons for these exclusions are based on the concern to offer a quality service to the patient. These consultations usually require a long time, a thorough clinical examination, potential additional tests (e.g. ultrasound or ECG), and sometimes difficult announcements on the diagnosis or prognosis. All these elements appeared to be not compatible with the framework of a teleconsultation and led conventional partners to exclude them from the framework of reimbursable teleconsultation. These situations cannot thus led to the invoice and reimbursement of a teleconsultation. Patients can benefit from reimbursement within the framework defined by the convention.

4.4.2 COVID-19

Following the COVID-19 health crisis and the increasing use of teleconsultation in all the French territory, the ministry published a decree (Decree n $^{\circ}$ 2020-227 on March 9, 2020 and valid until April 30, 2020) adapting the conditions giving access to the reimbursement of teleconsultation acts for people exposed to covid-19.

While several producers of software for liberal doctors (Doctolib, Consulib...) made their teleconsultation tool available for free to respond to the spread of Covid-19, these temporary more flexible conditions for carrying out teleconsultation worried specialists of the health data protection, and in particular the CNIL (Commission nationale de l'informatique et des libertés).²²⁵

In addition, new agreements are gradually opening access to telemedicine activities to new medical professions (i.e. pharmacists) and new acts (i.e. telecare). Indeed, since the decree of September 2nd 2019,²²⁰ pharmacists can offer services to help their customers to teleconsult within their pharmacy thanks to individual booths made available to the patient. Moreover, since January 2020, the 6th amendment to the national convention of liberal nurses allowed nurses to assist patients at home to consult online.²²¹

Patients can also count on local territorial organizations, such as health centres, primary care teams, and professional territorial health communities (see below Territorial organization, section 4.7.1), who can offer the use of teleconsultation procedures for certain patients who encounter difficulties accessing care (because they have no regular GP or he/she is not available within a period compatible with their health state).²⁰⁹

Which patients?

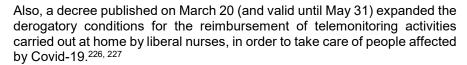
Reimbursement of teleconsultation acts is possible for any patient, regardless of their place of residence, as soon as the teleconsulting doctor offers it and the patient gives his/her consent after having received prior information on the procedures for carrying out the teleconsultation act.

Which situations?

All medical situations could potentially be concerned by teleconsultation. The use of teleconsultation is **the decision of the doctor**, who must judge the relevance of medical care though videoconference rather than face-to-face.

However, the following situations are **excluded** from the reimbursement of teleconsultation acts:

 Complex or very complex consultations (Article 28.3 of the medical convention²²²), because they cannot be done without a physical examination of the patient;



In April, other decrees followed to widen the access to teleconsultation to other health professionals (midwives, speech therapists, occupational therapists and psychometricians ...). 228, 229

In this context, the ministry published a list of all teleconsultation tools for doctors and nurses with, for each, the proposed functionalities and the level of security, in order to support professionals in their choice of digital tool.²³⁰

4.4.3 Liability

See specific requirements for the practice of telemedicine (Haute Autorité de santé. Téléconsultation et téléexpertise. Mise en œuvre. 2019).²⁶

4.4.4 Certification

See recommendations from the French National Authority for Health (section 4.8.3).

4.4.5 Privacy and ethics

Safety regulations applicable to teleconsultation

See Exchange modalities, section 4.8.1.

Informed consent

As recommended by the HAS, the patient's information and the collection of his consent must be made before the teleconsultation.²⁶

The information of the patient relates, in particular, to the practical modalities of this distant act (use of technical tools...), possible alternatives, the possibility of being accompanied, the confidentiality of the exchanges, the data processing of personal data, the protection and data security, cost and co-payment. An information notice may also be given to the patient. The

collection of the free and informed consent of the patient or, where appropriate, of his legal representative is included in the patient's file.

Legal base

Teleconsultation and teleexpertise meet the same requirements as face-toface medical practice (laws and regulations applicable to the conditions of practice, ethical rules and standards of clinical practice). In addition, the regulation in France includes some specific requirements for the practice of telemedicine.

These regulations, specific to the activity of telemedicine, are described below.²⁶

Definition of telemedicine acts

The Article R. 6316-1, introduced by the Decree n° 2010-1229 in October 19th, 2010 (see section 1.2.1) gives the definition of the telemedicine acts.

Informed consent

As stated in the French law, Article R. 6316-2, the acts of telemedicine are carried out with the **free and informed consent** of the person, in application of articles L. 1111-2 and L. 1111-4.

Conditions of performance of acts

As stated in the French law, Article R. 6316-3, each act of telemedicine is performed under conditions guaranteeing:

- 1) a) Authentication of health professionals involved in the act;
 - b) The identification of the patient,
 - c) The access of health professionals to the patient's medical data necessary for the realization of the act;
- 2) When the situation requires so, the training or preparation of the patient for the use of telemedicine device.



Patient record

As stated in the French law, Article R. 6316-4, the patient's record kept by each medical professional involved in the act of telemedicine (and in the observation form mentioned in Article R. 4127-45) is recorded in the patient file:

- 1) the report of the execution of the act;
- medical acts and prescriptions performed as part of the telemedicine act;
- 3) the identity of the health professionals involved in the act;
- 4) the date and time of the act;
- 5) where applicable, technical incidents that occurred during the act.

Professional's training and skills

As stated in the French law, Article R. 6316-9, liberal health organizations and professionals who organize a telemedicine activity ensure that health professionals and psychologists participating in telemedicine activities have the training and technical skills required to use the corresponding devices.

Compliance with personal health data hosting

As stated in the French law, Article R. 6316-10, organizations and healthcare professionals using information and communication technologies for the practice of telemedicine ensure that the use of these technologies complies with the interoperability and safety standards mentioned in Article L. 1110-4-1.

4.4.6 Ethical aspects

No information found.

^u See https://entreprise.axa.fr/protection-salaries/teleconsultation-medicale.html

4.5 Funding

In France, since 2012, the government, through the Fonds d'Intervention Régional (FIR), has invested €40 million each year in actions and experiments validated by the regional health agencies (ARS) in order to stimulate telemedicine projects and foster innovation. Yet less than 50% of this annual budget has been effectively dedicated to telemedicine, the regional health agencies using the "fungibility principle" to allocate these resources to other projects.²³¹ Moreover, since the structural reimbursement of teleconsultation, this source of funding is no longer used for teleconsultation, although it remains for other telemedicine acts (such as telesurveillance).

However, more recently, in its 2018 budget, the government counted on 500 000 teleconsultation acts in 2019, one million in 2020, and 1.3 million in 2021.²³²

Next to the funding by the government, the funding of teleconsultation in France is assured by the Health Insurance, which reimbursed the acts within the framework defined by the convention (see section 1.2.1). Similarly to face-to-face consultations, complementary private health insurances can reimburse the co-payment part, which is otherwise charged to the patient.

Moreover, some insurances propose to their members a free access to teleconsultation (i.e. AXA^u).



4.6 Remuneration

Consultations

The convention stipulates that teleconsultation acts are remunerated under the same conditions as "face-to-face" consultations. The doctor's supplements associated with these consultations also apply under the same conditions.²²²

Moreover, teleconsulting doctors using BtoC type platforms (see section 4.9) are generally salaried and remunerated by those.

Technical equipment

Assistance for **doctors' equipment** is offered by the Health Insurance for liberal doctors via the structure package²³³ (a financial assistance for doctors in their medical practice) starting in 2019:²³⁴

- € 350 for video-transmission equipment, update computer equipment, and telemedicine platforms subscription to ensure teleconsultation in secure conditions;
- € 175 for connected medical devices equipment.

In addition, doctors will continue to be supported by public authorities (in particular regional health agencies) in their telemedicine projects.

Next to this, the State offers a grant of € 1,225 the first year and then € 350 the following years to pharmacists to purchase equipment. Another lump sum is offered for the working time allocated to the organization of the teleconsultation and to the assistance provided to the doctor and to the patient during the teleconsultation, varying according to the number of teleconsultations carried out (€ 200 from 1 to 20 teleconsultations; € 300 from 21 to 30; € 400 for more than 30). 220

More information on the coordinated care pathway can be found here: Ameli : Le dispositif du médecin traitant (mise à jour : 14/11/19). Available on:

4.7 Reimbursement

In 2018, following a national convention between Health Insurance and doctors' unions, the amendment 6 included a structural reimbursement of teleconsultation and teleexpertise acts. This chapter is mainly based on the decree approving the amendment 6 of the national convention²¹⁶ and the circular (and annexes) published by the Health Insurance²³⁵.

4.7.1 Conditions

Under what conditions is teleconsultation reimbursed to patients?

Reimbursement of teleconsultation is subject to some general requirements and technical conditions (see below).

The general requirements are:236

- being integrated within the coordinated care pathway^v. The patient must therefore be initially referred by his regular GP when the teleconsultation is not carried out by him, to guarantee quality of care;
- and the patient already being known by the teleconsulting doctor, meaning he had a face-to-face appointment with him in the 12 months preceding the teleconsultation so that the doctor can have the information he needs to carry out a good medical follow-up.

Similarly to the face-to-face consultations, the following situations make it possible not to follow the coordinated care pathway:

- Patients under 16 years old;
- Consultations of certain specialists (gynaecology, ophthalmology, stomatology, oral surgery or maxillofacial surgery, psychiatry or neuropsychiatry and paediatrics);

https://www.ameli.fr/medecin/exercice-liberal/remuneration/dispositif-medecin-traitant/dispositif-medecin-traitant

c somatic disease

 Emergency situations, i.e. « la situation non prévue plus de 8 heures auparavant et qui concerne une affection, ou la suspicion d'une affection, mettant en jeu la vie du patient ou l'intégrité de son organisme et entraînant la mobilisation rapide du médecin » (Article R160-6 of the Social Security Code);

Moreover, some additional exceptions have been made for patients using teleconsultation:

- The patient has no regular GP;
- The regular GP is not available for an appointment within a period compatible with the patient's health state

In these two situations, the general requirements for reimbursement (i.e. the initial orientation by the regular GP and the patient being known by the teleconsulting physician) do not apply. The use of teleconsultations is then ensured within the framework of what is called a "coordinated territorial organization" (nursing home, health centre, CPTS) (see below).

Territorial organization

According to the convention, teleconsultation is based on a territorial organization composed exclusively of practitioners performing physical consultations and can only be given in parallel with face-to-face consultations. Thus, when a patient has no GP or the GP is not available within a period compatible with his health state, the patient must contact a "coordinated territorial organization" to have access to teleconsultation with a doctor, outside the care pathway.

Territorial organizations must allow patients: to be taken care quickly, according to their care needs; to have access to a doctor, in particular through teleconsultation, given their distance from healthcare providers; and then to designate a GP for their long-term follow-up and their reintegration into the care pathway.

These territorial organizations which offer a coordinated response in telemedicine can be:

- Professional territorial health communities (communauté professionnelle territoriale de santé, CPTS),²³⁷ gathering health professionals in order to ensure a better coordination of their actions, though a common medical(-social) project. A contract is organized with the ARS. They can include: persons who provide primary and secondary care (general practitioners and specialists, nurses, pharmacists ... working alone, in group, in MSP or in primary care teams); hospitals (public and private); the medico-social and social sector (EHPAD...).
- Primary care teams (équipes de soins primaires, ESP),²³⁸ gathering primary care doctors. They contribute to the structuring of the patient's care pathway, particularly for those suffering from chronic diseases, autonomy loss, and social insecurity.
- Nursing homes (maisons de santé, MSP),²³⁹ multi-professional structures gathering medical professionals, medical assistants or pharmacists. They must develop a coordinated health project and conclude a multi-year contract with the regional health agency (ARS).
- Health centres (centres de santé, CS), have a social mission of access to healthcare for all. They are mainly located in deprived urban areas, and almost systematically play the role of third-party payer and apply conventional rates.

To meet their objectives, territorial organizations must rely on volunteer doctors from the territory and must be easily identifiable by patients and health professionals in the same territory. Information on these organizations is usually available from health insurance, ARS and professionals in this territory.

However, in practice, telemedicine implementation is generally not a major priority for territorial organizations. And territorial organizations gathering doctors who propose this kind of offers are still rare. This creates some issues when a private company creates a cluster of doctors backed by a virtual health centre to do teleconsultation. In that case, reimbursement should not be possible since it is contradictory with the amendment 6. This had to be clarified in some situations.



For example, *Livi*'s organization is based on a set of part-time salaried doctors, spread all over the country, who are mobilized only for teleconsultations. The health centre^w that was created has the vocation to deliver teleconsultations throughout the national territory, which is clearly not the extension of a physical activity of practitioners within an identified territory, and therefore does not meet the objectives and limits that result from the decree.²¹⁶ This conducted the director of the Health Insurance, in January 2019, to refuse the reimbursement of teleconsultations carried out by *Livi*'s health center in Créteil (Val-de-Marne). The association DigiSanté and the "centre de santé de CNP et Téléconsultations" then send a request to the "Conseil d'état" requesting the suspension of the decision and 3,500 euros to the Health Insurance, which was rejected by the administrative judge.^{240, 241}

Next to this, some teleconsultation providers have been pinned at the beginning of 2019 by the French Order of Physicians for advertisements on teleconsultation offers, with the possibility of reimbursement. The Order then asked the Health Insurance for a "clarification" on the reimbursement or not of the act.²⁴² For example, in October 2019, he sent a notice to the *Qare* teleconsultation company to "stop the publication of advertising inserts relating to telemedicine".^{243, 244}

Technical requirements

The access to the reimbursement of teleconsultation acts is also conditioned by two technical requirements:

- being conducted by video-transmission;
- the use of a secure connection.

These conditions are necessary to guarantee the quality of the consultation and the confidentiality and security of the exchanges.

Generally, it is the teleconsulting doctor (whether is it the regular GP of the patient or not) who decides how the teleconsultation is organized: choice of equipment, the patient need to be accompanied or not, etc.

Doctors must check with their software publisher or their telemedicine solution provider that the security criteria are well respected for the exchange of personal health data (that means that the tools used are in accordance with the general security policy for health information systems and the legal framework for health data hosting, and that the global risk analyses integrating the impacts on private life are respected) (see section 1.6).²⁴⁵

What is covered by the reimbursement for patients?

If the teleconsultation meets the legal conditions (prior knowledge of the patient by the healthcare professional, initial orientation by the regular GP, consultation by video), the reimbursement rules are **the same as for a face-to-face consultation**: 70% coverage by the compulsory Health Insurance or more if, for example, the teleconsultation relates to a long-term condition as part of a care protocol, as part of a pregnancy ... The remaining 30% (co-payment) can be covered by a complementary private health insurance, with the exception of the fixed contribution of 1 euro.²⁴⁶

For more details, see section 4.7.2.

4.7.2 Price

At what price is teleconsultation covered by the reimbursement?

Two teleconsultation acts ("TCG" and "TC") have been created in the Nomenclature of acts (nomenclature générale des actes professionnels, NGAP) to bill teleconsultation acts. A teleconsultation is billed by the teleconsultant physician at **the same price as a face-to-face consultation**, i.e. between € 23 and € 58.50 depending on the doctor's specialty and sector

DigiSanté is the manager of the health centre in Créteil, using the Livi platform as a technology provider: https://www.livi.fr/centre-sante-livi/



of practice (sector 1^x or sector 2^y). The same billing rules apply to teleconsultations (including the 20% increase in acts in the Overseas Departments). For example, for general practitioners of sector 1 or 2 respecting the rates of the Health Insurance, it is reimbursed on the basis of \leq 25 in metropolis and \leq 29.60 in the Overseas Departments. Eventual coordination surcharges may also be billed. Page 246

Thus, for a teleconsultation with a registered general practitioner from sector 1:

- The cost of the consultation which serves as a basis for reimbursement is 25 €.
- Of this amount, Health Insurance reimburses 70%, or € 17.50.
- The amount of the co-payment is 30%, or € 7.50.
- However, the patient will have to pay € 1 for the fixed fee.
- The remaining total charge is therefore € 7.50 + € 1, or € 8.50.

As for any consultation, the "third-party payment system" is applied entirely for:

- patients with long-term illness,
- pregnant women,
- patients receiving complementary universal health coverage (CMU-C) or assistance with the acquisition of complementary health insurance (ACS).

For other consultations, such as liberal doctors practicing in sector 2, it is possible to have an excess of fees under the usual conditions.

Payment method

When the patient is not 100% reimbursed, when the co-payment is not covered by the sickness fund or when the doctor practices extra fees, the doctor must have a "cashing/payment" system.

The payment methods remain the same as for face-to-face consultations. The doctor tells the patient how to pay for his consultation:²³⁴

- bank transfer.
- sending a check,
- online payment if the doctor proposes this solution,
- third-party payment system.

The patient will be able to find this invoice information under the label "Teleconsultation" in its "ameli" account (secure personal account).

In practice, the doctor creates a treatment sheet. Until the recognition of the vital card at a distance (already technically operational on certain services) by the GIE Sesam Vitale and the Health Insurance, it is necessary to carry out either an electronic care sheet (feuille de soins électronique, FSE) in degraded mode or a treatment sheet sent by post or email (which the patient must then send to his primary health insurance fund (caisse primaire d'assurance maladie, CPAM)).²⁴⁷



4.8 Technology

4.8.1 Exchange modalities

Any teleconsultation, whether invoiced or not, must take into account the security aspects of personal health data.

First of all, teleconsultation acts are characterized by two exchange modalities (Figure 4):

- Direct interpersonal communication (voice or video) between the teleconsulting doctor and the patient;
- Health documents containing personal data exchanged before (making an appointment, sending documents, etc.), during (exchange of document images, etc.) and after the teleconsultation act (medical report, prescription). These materials are not necessarily produced during the teleconsultation act. Data exchanges can be bidirectional.²⁴⁸

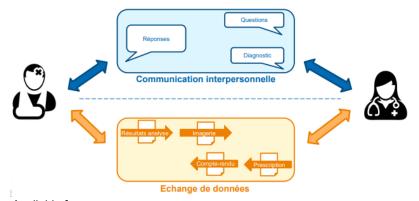
Interpersonal communication with the teleconsultation doctor (whether by video or only by voice), uses communication services on the Internet, the services of telecommunications operators or operators "over the top" (OTT) as well. These are framed, in terms of confidentiality by the General Data Protection Regulation (Règlement général sur la protection des données, RGPD) and the European directive 2018/1972. Traditional electronic communication operators and OTT actors are required to ensure:

- · the security of their networks and services;
- the confidentiality of the exchanges: prohibition for anyone other than the users concerned to listen, intercept, or store communications;
- the protection of personal data: according to the ePrivacy regulation.²⁴⁸

Exchanges of health documents containing personal data carried out before, during or after teleconsultation are also subject to various regulations: PSSI MCAS (Politique de sécurité des systèmes d'information du Ministère chargé des affaires sociales), PGSSI-S (Politique générale de sécurité des systèmes d'information en santé), HDS (Hébergement des données de santé), etc. This concerns:

- Discussions with the patient himself. These cannot be carried out with secure health messaging (for the moment not yet open to the patient), nor with interpersonal communication tools of the "general public" type that do not comply with the regulations in force for this type of exchange. They must be carried out via teleconsultation solutions integrating the functionality of secure exchange of personal data with the patient. Risk analysis and security are the responsibility of the solution person in charge;
- Communication between health professionals can be carried out via secure health messaging or any other device in accordance with the regulations (in particular for sending reports);
- Sharing with other health actors via the DMP (Dossier médical partagé).²⁴⁸

Figure 4 – Exchange modalities for teleconsultation



Available from:

https://esante.gouv.fr/sites/default/files/media_entity/documents/20191202_R%C3 %A9flexions%20s%C3%A9curit%C3%A9%20et%20t%C3%A9l%C3%A9consultation_VF2.pdf



For instance, if the Health Insurance considers that the current video communication tools, such as Skype or FaceTime, are sufficiently secure for a video exchange, they do not meet the security conditions for the exchange of medical documents (photos, prescription, etc.).

In practice, before the teleconsultation, the practitioner sends the patient a link to a secure site or application. On the day and at the time of the appointment, the patient clicks on the link via a computer or tablet equipped with a webcam.

At the end of the teleconsultation, the doctor may be required to establish a medical prescription (drugs, analyses, examinations, etc.) which will be sent by email via secure messaging or by post. He also writes a medical report, archives it in his files and in the patient's shared medical file (DMP) if the patient has one opened. The teleconsulting doctor **must imperatively transmit the report, by secure messaging, to the patient's regular GP**.

As mentioned above, according to the law, only acts of teleconsultation **using videotransmission** give access to reimbursement of the act of teleconsultation by health insurance.²¹⁶

4.8.2 Teleconsultation solutions

The offer of teleconsultation services is generally done though a package of technical tools and supports (video transmission software, smartphone application...). They allow the delivery of teleconsultation services, sending documents electronically, paying online, etc. There are many providers of teleconsultation solutions, and doctors have many possibilities.

Certain private companies, led by doctors, offer teleconsultation solutions that are well suited to users. Public telemedicine platforms, managed by the GCS (Groupements de Coopérations Sanitaires) or GRADeS (Regional Support Group for e-Health development funded by ARS), also make teleconsultation offers with subscriptions.²⁴⁹

There are several models of teleconsultation solutions:²⁵⁰

- Scheduled teleconsultation solutions managed by regional eHealth GCS. These public organizations have organized teleconsultations scheduled within health establishments since 2013, in particular within EHPAD (Etablissement d'Hébergement pour Personnes Agées Dépendantes). However, they were gradually replaced by the solutions proposed by the private actors arrived on the market.
- Scheduled teleconsultation solutions, carried out by liberal doctors and engineers, where the medical time spent in teleconsultation is only devoted to the doctor's own patients. These videotransmission teleconsultations are scheduled by an electronic agenda associated with the solution. They are then part of the care pathway and the doctor offers them to his own patients, especially those suffering from chronic diseases. Face-to-face consultations in the medical office are alternated with teleconsultations using the digital solution the GP has chosen and to which he subscribes. The patient gives or not his consent to use this solution with his doctor. This model best fits the vision of the Health Insurance.
- Immediate teleconsultation solutions whose organizers (sickness funds, insurers, etc.) contract with the ARS in order to comply with the regulations. The service is offered to members. These platforms employ medical doctors who agree to devote part of their liberal or hospital medical time to these solutions.

4.8.3 Recommendations from the French National Authority for Health

The French National Authority for Health (HAS, Haute Autorité de Santé), an independent public scientific advisory body, established in May 2019 several recommendations to support the deployment of teleconsultations on the national territory and to ensure the quality and safety of teleconsultation acts. ^{26, 202} The recommendations proposed concern all teleconsultation acts (regardless of their location), including acts not eligible for reimbursement by Health Insurance. They are listed below.



Before the teleconsultation

- · Material and equipment
- Have communication tools for teleconsultation (videotransmission)
- Have computer tools for the exchange, sharing and storage of data:
 - secure health messaging and / or access to a secure exchange solution;
 - o accredited or certified health data host in case of data outsourcing.
- Documentation
- Have procedures for the use, the verification, and the equipment maintenance
- Provide work modalities in a degraded mode (e.g. hardware malfunction, internet connection break, need for urgent patient care, etc.)
- Establish contracts with his/her service providers / suppliers (e.g. ensure that the supplier of technical solution ensures the protection of data in accordance with the regulations, establish a maintenance, define the response time in case of failure, etc.).

Protection and security of personal data

- Put in place the security measures relating to the protection of health data in accordance with the General Data Protection Regulation (GDPR) and the general system security policy health information system (PGSSI-S).
- Use a communicating information system, which allows sending the report of the acts of telemedicine in the patient's shared medical record

(Dossier medical partagé, DMP); in accordance with the interoperability framework of health information systems (CI-SIS).

- Use an accredited or certified health data host.
- The security measures also concern the protection of the access to the premises, the security of the computer (automatic locking, password), the management of authorizations, the traceability of the accesses, the incident management.

During teleconsultation

The patient must be identified and his identity verified aa

- Patient identification makes sure:
 - that the identity of the patient who benefits from the teleconsultation is the correct one;
 - o that health data is referenced in the correct patient record.
- Data identifying the patient include: birth name, first name (s), date and place of birth, sex.
- The medical professional must also know the exact location of the patient at the time of the procedure and his telephone (in case of need to organize emergency care or to recontact the patient if the teleconsultation is interrupted).

The medical professional must authenticate

 There are different possible authentication devices (password, smart card, etc.). At least two must be combined (strong authentication device).

See https://esante.gouv.fr/labels-certifications/hebergement-des-donnees-de-sante

In many teleconsultation solutions the authentication of the patient before the teleconsultation is assured by the doctor thanks to the patient's identity card.



4.9 Actors

Telemedicine was initially developed around a mainly public offer and funded by the Regional Health Agencies (ARS) in an experimental setting. But telemedicine in France has taken a new step forward when teleconsultation acts were included in the reimbursement scheme. This allowed new manufacturers (start-ups mainly) to find an economic model for a "BtoC" offer (see below). Thus, an unprecedented situation of cohabitation and / or competition between public and private platforms is emerging and should be an important issue for the coming years.

Nowadays, the teleconsultation offer is shared between 2 types of actors:

- Public regional telemedicine platforms: Pioneers in the development of telemedicine in France, the regional platforms constitute a territorial offer of telemedicine, proposed by the ARS through their regional support groups for the development of eHealth (groupements régionaux d'appui au développement de la e-santé, GRADeS). There are about twenty telemedicine platforms (corresponding to the territorial division before the 2016 reform), since each region had at least one telemedicine platform, or even several when specialized on a given type of act. However, since the law defining the acts of telemedicine (i.e. teleconsultation and teleexpertise) and the multiple new private actors on the market, the model of these regional platforms and their perimeter of intervention is questioned. Indeed, they mainly invested in implementing digital medical equipment (for imaging...) in the hospitals of the region and need the presence of two health professionals (at each side of the machine).
- Private actors: Following the law on the reimbursement of telemedicine
 acts, a BtoC ("business to consumer" between the patient and his
 practitioner, or even between the patient and the start-up offering the
 telemedicine solution) type of offer has emerged in France to directly
 connect the patient and his doctor (without going through a platform
 maintained by a GRADeS). Many actors have positioned themselves in
 this sector. Some provide a nationwide teleconsultation offer while
 others are restricted to a specific region.

While today teleconsultation solutions are mainly offered by private actors, we can distinguish two kinds of offer:

- a Market place offer: the company (e.g. Hellocare, Livi, Qare, Medaviz...) who developed the technical tool sells the license for its use to professionals (who have to subscribe) and patients, the company is an intermediary service provider between the patient and the healthcare provider:
- a BtoBtoC offer (business to business to consumer): the company (e.g. MedecinDirect, BonjourDocteur...) buys medical time to doctors (who are salaried and remunerated) and sells medical time to companies or insurances (like AXA). This way the members have a free access to teleconsultation, using a digital tool (= a teleconsultation solution). While several factors (welcome by a nurse, medical report, medical history, and teleconsultation with a doctor on the phone) allow a good patient care, this system is outside the patient's coordinated care pathway.

The main differences between these two systems are described in Table 17.



Table 17 – Two types of private teleconsultation solution providers

	Market Place	BtoBtoC
Definition	Name given to a commercial web application providing, via third parties, goods or services	Business to business to consumer: sells to companies that resell to the individual customer
Sells what?	License to a digital tool (e.g. WhatsApp or in this case, a teleconsultation solution)	Medical time (using a teleconsultation solution)
To who?bb	Health professionals (who generally have to subscribe)	Companies and insurance (e.g. AXA)
Cost for doctors	Huge variability	Doctors are remunerated
Cost for patients ^{cc}	For most of them, same price as face-to-face consultations, and reimbursed by the Health Insurance if the convention's conditions are fulfilled	Free for partner's members (cover all or part of the costs of the insured, sometimes for a few appointments per year, sometimes without any limit)
Relation with teleconsultation solutions	Developer and owner	Partner
Type of solutions (see section 1.6.1)	Scheduled and immediate teleconsultation solutions	Immediate teleconsultation solutions
Responsibility for private data	Only holds user data (ip address, connection information, etc.) Patient's health data are held by the health care provider	The company holds all user and health data of the patient
Respect of the coordinated care pathway	Only if the teleconsultation is performed with the patient's regular GP	No

Private teleconsultation companies have generally developed a pool of doctors spread across France and available at certain times to do teleconsultation. The exemptions mentioned in the convention (for patients who do not have a GP or whose GP is unavailable within a period compatible with their state of health) have become the rule for certain actors in the market. So it became common for a patient living in Nice to "teleconsult" a

doctor in Lille, far from the geographic proximity required by the Health Insurance.

In this context, there is a divergence of points of view between the Health Insurance and the government on the one hand (for which a "proximity" link must be kept within the framework of telemedicine) and some private actors

Can also be as part of a contract with the competent regional health agency.

While the teleconsultation service is in most cases provided to the patient free of charge, the equipment (smartphone, internet connection, etc.) allowing access to and use of the teleconsultation platform are the exclusive responsibility of the patient.



as well as elected local politicians from medical deserts on the other hand, for which telemedicine must above all be a solution for those who no longer have an easy access to face-to-face medical consultations. They denounce the too weak coverage of these consultations by the Health Insurance.²⁵¹

4.10 Policy

Initially, the implementation of telemedicine in France was part of a program named ETAPES, financed by the ministry, and supervised locally by the Regional Health Agencies (see section 4.3.1). Since then, teleconsultation has been well defined in the law and is reimbursed by the Health Insurance (under certain conditions) (see section 4.4). Currently there is a new amendment to the medical convention in project by the Health Insurance, giving more flexibility on teleconsultation use.²⁵²

4.11 Effects

While many experimental projects were carried out to implement telemedicine in France between 2014 and 2018, it seems that **no proper post-evaluation was made**. More recently, since the reimbursement of teleconsultation acts by the Heath Insurance (September 2018), some statistics have been published by the Health Insurance and several surveys have been conducted (see section 4.3). The HAS also proposed to evaluate the implementation of teleconsultation using the "méthode du patient traceur" dd, among others. ²⁵³

However, the implementation of teleconsultation should be accompanied by a more advanced evaluation of telemedicine practices on health services to assess the impact of these kind of innovations on patients and the health system. But no such evaluation has been performed so far.

5 VIDEO CONSULTATIONS IN DUTCH HEALTH CARE

5.1 Key findings

Definitions

 Different terms and different definitions are used by authorities and other stakeholders. Definitions also evolved during the years.
 Consequently, terminology might be confusing between official legislation, grey literature, scientific articles etc.

Implementation

- The Netherlands have a long history of experimenting with health technology, including telemedicine and telecare.
- eHealth is actively supported by the government in policy documents and by several important financial injections.
- The authorities also progressively waived all barriers in the legislation on declarable health care provisions in order to promote the use of video consultation.
- Despite these investments and efforts, the use of video consultation remains very limited.
- Remaining barriers are mainly related to the reluctance of health care
 professionals and patients. The health care professionals often see
 more disadvantages than advantages in using video consultation
 (time consuming, extra effort to guarantee the quality of care,...) and
 lack of confidence (unreliable tool, uncertainties regarding the data,

practices to benchmark practices and then implementing improvement actions. The analysis is carried out using interview guides.

This methods aims to improve the quality and safety of care. It consists in retrospectively analysing a patient's care pathway by comparing actual

- etc.). In addition patients, especially in the elderly care sector, often prefer a face-to-face contact.
- Implementation of eHealth technology including video consultation is watched by yearly eHealth monitors (surveys) since 2013. In 2019 a decrease in the use of video consultatation was reported in the specialized care sector where phone calls and emails seem to have increased slightly
- The exact number of video consultation reimbursed by the insurers remain however unknown because no comprehensive list of the number of video consultations billed each month seems to be available for each sector.

Legislation

- Video consultation is allowed in the Netherlands, under certain conditions, in all care sectors, for all patients and for all health care provision performed by any health care professional regardless of the setting. The position consistently defended by the authorities is that care can be reimbursed in an eHealth form within the boundaries of the already insured care (declarable care), provided that this new means do not change the composition and effectiveness of the declarable care.
- This means that the healthcare provider must in both cases equally comply with the applicable legal rules, standards, guidelines and protocols of the profession and that the health care insurer who reimburses this care shall ensure that it is of good quality. In particular, all requirements applicable to the therapeutic relationship (regarding patient's consent and information, personal data collection and use, etc.) have to be complied with and if necessary adapted to the digital context.
- A therapeutic relationship (but not necessarily a priori face-to-face contact) between the patient and the health care provider is in principle required prior to all video consultations.

Funding and reimbursement

- Dutch Healthcare Authority treats e-consults and face-to-face consultations equally, so insurers may reimburse at the same rate as the face-to-face. The reimbursement of video consultation (health care provision itself) depends on the negotiations between the health care providers and the health insurers.
- To a large extent, support for the necessary investments (hardware, subscription to platforms etc.) also depends on agreements with private insurers. However, public authorities (national or local) also provide subsidies for these expenses.
- Massive public funding is invested in eHealth including in video consultation projects.

Technology

- An large number of specialized private operators (mainly platforms offering multiples ICT services for HCP) offer services allowing health professionals to connect with their patients via video. Some platforms are specially dedicated to certain HCP (e.g; hospitals, mental healt, GP's etc.).
- These services are usually paid for.
- Lists of reliable providers are established by many professional associations, but the authorities do not certify these solutions themselves.
- Specialized platforms are generally preferred to non-specialized technical solutions such as Skype etc., and offer services that allow health professionals to connect with their patients via video.
- To ensure the safety and reliability of the technology different certification norms are applicable. The NEN7510 concern the safety of medical information exchanges and is mandatory. The NEN 8028 is recommended and concerns the quality of telemedecine.



- Insurance companies and health care professionals are the main actors in the implementation of video consultation. They negotiate the quality of the care they offer, including the use of health technology.
- The authorities regulate, enact general quality norms and when necessary, they allow a temporary funding.
- Professional and sectoral associations play an important role in developing specific quality norms, professional standards etc. The authorities use these standards in their controlling procedures.

Privacy and ethics

- Data protection rules are applicable to protect the patient privacy (AVG).
- In the Netherlands professional standards are not only ethical or deontological rules most of them are really part of the self regulation and are therefore recognized used by insurers and authorities

Effects

 Latest monitor of 2019 shows that healthcare providers are predominantly enthusiastic about eHealth. Nevertheless, the use of videoconsulation remains low. This seems to be explained by reluctance of HCPs and patients to use video consultation, for quality reasons but also because other less time and cost consuming possibilities exist (mail and phone).

Corona pandemic

- Since the COVID19 pandemic new providers are popping up in addition to the already very broad offer of specialized platforms offering video consultation services. Some existing platforms opened their services to all free of charge during the crisis.
- Several lists of applications, stepplans and guides are issued to help health care providers to organize video consultations.

- We observed an exponential increase of video consultations in all sectors (including hospitals).
- Additional budget was made available by the government to speed up eHealth/video consultations.

5.2 Methodology

The WHO Atlas of eHealth country profiles ¹⁰ and an initial screening in Google of potential relevant countries to be studied learned that France and the Netherlands would be good candidates to select. Both countries already introduced legislation on teleconsultation ²⁵⁻²⁹.

Information was gathered among others on health insurance matters, privacy & safety regulations, barriers/facilitators in implementing video consultation.

We searched the internet by means of google advanced and using 'teleconsultation AND reimbursement' OR 'teleconsultation AND 'health insurance' OR 'teleconsultatie AND 'vergoeding' OR 'teleconsultatie' OR 'telegeneeskunde' OR 'telemedicine' OR 'telehealth' OR 'telecare' OR 'telezorg' OR 'beeldzorg' OR 'beeldbel' OR 'zorg op afstand'. In a second step, websites of the relevant identified organisations were consulted. And we applied snowball-technique with the identified relevant documents.

The sources of information were particularly looked at: laws and regulations, websites of official government institutions, websites of governing bodies, and websites of professional and scientific associations.

In addition we contacted with competent authorities (Ministry of Health, Welfare and Sport (VWS)), the Nederlandse Zorgautoriteit (NZa) and Rijksinstituut voor Volksgezondheid en Milieu (RIVM) to discuss our findings and asked for further information sources. A videoconference was held with Bernard Creutzberg (NZa) and Antony Heil (NZa) and another one with Gelle Klein Ikkink (VWS), Nienke Zwennes (VWS) and Myrah Wouters (RIVM, previous Nictiz).



5.3 Characteristics of the Dutch health system

The Dutch health care system is based on universal health insurance coverage operated by a (regulated) private market ²⁵⁴.

The 3 central actors of this market are citizens/patients, insurers and health care providers. The government only acts as supervisor and facilitator of the relationships between these actors:

- **Citizens/patients** may freely choose and change (yearly) their (private) health insurer and their health care providers^{ee}.
- Health care insurers are obliged to offer the coverage of health care
 provisions included in the basic health insurance package defined by
 the authorities and extend this with other insurance possibilities. They
 have an obligation to accept applicants and are prohibited to apply
 premium differentiation. At all times insurers must fulfil their duty to offer
 adequate care.

In order to be able to compete on the price of policies and the quality of care offered, insurers negotiate price and quality of health care provisions with **health care providers**^{ff}.

• The **Ministry of Health, Sports and Welfare** (advised by Zorginstituut Nederland⁹⁹) defines the content and composition of the basic health insurance package which all private insurers have to offer to citizens^{hh}. In addition, the **Nederlandse Zorgautoriteit** (NZa) describes the health care provisions that can be "declared" by health care providers to their patient's insurers. For certain health care provisions, the NZa establishes maximum prices.

The **gatekeeping** is another feature of the Dutch system: specialized care (except emergency care) is only accessible upon referral from the GP or other directly accessible HCP'sⁱⁱ. Everyone has to be registered with a GP.

Care pathways exist mainly in the specialized care and in the chronic care sectors. Care pathways are defined in nationally agreed protocols or "care standards". Patients are free to participate in integrated care or to organize the necessary care themselves.

In addition, specific assessment and authorization procedures apply in order to allow patient to have access to long term care^{jj}.

healthcare. The first €385 must be paid out of pocket by the patients, except for GP consultations, maternity care, home nursing care and care for children under the age of 18. Care that is not covered under the basic package can be insured via complementary voluntary health insurance, such as glasses and dental care. Insurers can freely define the content and conditions of their complementary voluntary health insurance package (https://www.rijksoverheid.nl/onderwerpen/zorgverzekering/zorgverzekering sstelsel-in-nederland).

- Other HCP's who are directly accessible are medical specialist for elderly care and occupational physicians.
- ji https://www.ciz.nl/client/wat-is-de-wlz.

However, in their policies, health insurers may impose restrictions on the patients' free choice of provider. Usually they offer a lower premium if the patient agrees to choose amongst the health care providers who contracted with the insurance company, or they limit their coverage to an average medical fee for the care provided by health care providers who did not contract with them.

Megotiation on price and quality on the healthcare purchasing market is regulated by the public authorities.

https://www.zorginstituutnederland.nl/over-ons/taken/adviseren-over-enverduidelijken-van-het-basispakket-aan-zorg/adviseren-over-de-inhoud-vanhet-basispakket.

The basic health insurance package includes GP care, maternity care, hospital care, home nursing care, pharmaceutical care and mental

en



5.4 Terminology

During the past years, several terms and definitions were used in Dutch documents and legislations to describe digital care in general and video consultations specifically.

In 2019, Lettow et al. ²⁵⁵ performed a study on terminology and based on this they proposed as **definition of eHealth**:

"eHealth is de toepassing van zowel digitale informatie als communicatie om de gezondheid en gezondheidszorg te ondersteunen en/of te verbeteren"

This definition is now also used in recent documents from governmental agencies (e.g. Nederlandse Zorgautoriteit ²⁵⁶, Inspectie Gezondheidszorg en Jeugd ²⁵⁷). However, they coined the term 'digitale zorg' as synonym of eHealth. Also the Dutch Patientenfederation^{kk} is using the term 'digitale zorg' to describe several kinds of care that use a type of digital modus.

"Digitale zorg is een soort verzamelnaam. Het omvat alle digitale mogelijkheden die u in kunt zetten om uw gezondheid te verbeteren of te ondersteunen"

Consequently, eHealth or 'digitale zorg' covers a broad range of services such as e-diagnosis, e-consultation, e-therapy, e-monitoring, online support or e-prevention interventions.

Another term covering the same scope is "telemedicine". This term is not used in the Dutch legislation but can be found in some, non-mandatory, certification rules used in the Netherlands such as the NEN8028 or NEN7510 standards for telemedicine^{mm}. Once embedded in a law, field norms such as NEN may become mandatory and become 'ISO standards'. According to these standards, telemedicine covers care process or group of

care processes using both information technology (ICT) and telecommunications and involving a care seeker, a care provider and/or a care institution and a manufacturer or supplier offering telemedicine services.

More accurate terms, related to the scope of video consultation of this report, that are used in the Netherlands are listed below.

Remote care ('Zorg-op-afstand')

'Zorg op afstand' is the most used term in the Netherlands and is referred to in a multitude of documents (e.g. 258-268) and in sectoral legal rules describing the health care provisions that can be declared to insurers (see infra section 1.6.2.2). NZa describes 'zorg op afstand' as:

"Een deel van de zorg kan op afstand plaatsvinden in plaats van in de behandelkamer, spreekkamer of op locatie van de zorginstelling. De patiënt, cliënt of burger kan met zijn zorgverlener (beeld)bellen, emailen, chatten, of het zorgcontact kan verlopen via een patiënten portaal."

Remote care is also an umbrella term encompassing several digital modalities to communicate, including telephone, email, sms, video consultation etc.

- Remote consultations ('consult op afstand') are specific types of remote care which can cover:
 - o Consultation by telephone ('telefonisch consult')
 - Screen-to-screen consultation ('video-consult' also referred to as 'beeldbellen' 'beeldschermzorg' of 'videobellen')
 - E-mail consultation ('schriftelijk consult')

https://www.digitalezorggids.nl/ https://www.patientenfederatie.nl/themas/digitale-zorg/wat-hoe.

https://www.nza.nl/documenten/publicaties/2020/01/28/wegwijzer-bekostiging-digitale-zorg-2020. and https://www.digitalezorggids.nl/

NEN, Stichting Koninklijk Nederlands Normalisatie Instituut, https://www.nen.nl/ is a private institute issuing certification norms. https://www.nictiz.nl/standaarden/nen-8028-telemedicine/.

nn https://puc.overheid.nl/nza/doc/PUC 304668 22/1/.



In the Netherlands, remote consultations can be used either between the patient and his/her HCP or between professionals (meekijkconsult).

Beeldbellen

More specific terms used in the Netherlands for the concept of video consultation as we understand it for the purpose of this study are: "beeldbellen" (e.g. ^{27, 28, 222, 256, 266-286}, 'beeldschermzorg' ²⁸⁷⁻²⁸⁹ or 'videoconsultatie' ²⁹⁰⁻²⁹³, 'e-consult' ²⁹⁴⁻²⁹⁸ and "screen-to-screen consult" ^{273, 298, 299}).

The amount of different terms used in Dutch documents made it sometimes difficult to disentangle what was really meant and to see for instance the number of real video consultations or to see what factors were specific related to the implementation of video consultation or to other eHealth interventions.

5.5 History / implementation of teleconsultation/video consultation

5.5.1 History

The Netherlands have a long history of experimenting with health technology, including telemedicine and telecare. It is impossible to list all the initiatives in this sector. However, some projects and care sectors seem to be frequently cited. For example, in the nineties several projects with technology at home were conducted and het Kwaliteitsinsitituut voor Technologie in de Thuiszorg (KITTZ) started projects with digital support (including videoconferencing) for patients and an informal caregivers ^{160, 300-303}. The RIVM report ³⁰³ concluded that there were large possibilities for 'televisites' in the area of patients with a chronic somatic disease (see **Figure 5** below).

Figure 5 - Televisites 303

3.2.6 Televisites

Een aanzienlijk deel van de tijd van thuiszorgmedewerkers wordt besteed aan reistijd tussen opeenvolgende huisbezoeken. Dit geldt in dunbevolkte gebieden, maar in Nederland kan verkeerscongestie ook leiden tot verlies van werktijd. 'Elektronisch huisbezoek' zou mogelijk kostenbesparend kunnen zijn. Dit kan per telefoon, maar videoconferencing is wellicht effectiever en zal door patiënten wellicht meer als een echt bezoek worden opgevat. Bovendien geeft de camera ook visuele indrukken aan de zorgverlener. Videoconferencing kan slechts voor een deel visites ter plaatse vervangen, regelmatig bezoek aan huis blijft toch noodzakelijk om het contact te ondersteunen. Bovendien zijn veel van de werkzaamheden in

3.3.6 Televisites

Werkzaamheden in de thuiszorg bestaan voor een groot deel uit verzorging van patiënten, huishoudelijke zorg, begeleiding en sociaal contact. Met name de verzorging van patiënten en de huishoudelijke zorg zijn moeilijk op afstand te leveren, omdat het hierbij gaat om fysieke handelingen. Desalniettemin zal in de periode 2005-2010 de toepassing van televisites toenemen, met name met gebruik van video als medium. Door een grotere bandbreedte van de communicatienetwerken in de toekomst zal de beeldkwaliteit hoog zijn, waardoor ook bruikbare beelden voor telemedicine gerealiseerd kunnen worden, bijvoorbeeld voor wondbehandeling. De aanwezigheid van een videocamera en een spraakverbinding maken het mogelijk dat de zorgverlener zich richt op de patiënt als geheel, en mogelijk ook op personen in de directe omgeving van de patiënt.

Since the beginning of the 2000's, the number of studies and pilot projects regarding eHealth increased drastically, also due to very active governmental support.

Main drivers for the government to put efforts into eHealth projects were an increasing ageing (and less mobile) population, a decreasing number of health care professionals and high expectations of new technologies.

Together with the active supportive role of the government, they initiated already very soon a permanent yearly monitoring of the eHealth and remote care projects ^{262, 266, 267, 304} ^{28, 222, 268, 271, 272, 275-277, 282, 305} and continued to do so up to now.



The RIVM ³⁰⁶ estimated that beginning 2007 there were already more than a hundred 'telecare' projects in the Netherlands.

The scaling up of pilot projects was mainly observed in the home care and elder care sectors.

Without being exhaustive, a chronologic list of important projects and publications is listed below:

2001-2002:

- Foundation EPN-Platform voor de informatiesamenleving 301
- RVZ study' eHealth in zicht' 302
- Report Stoom 'ICT in de thuiszorg' 307
- Report Stichting Toekomstbeeld der Techniek 'Zorgtechnologie. Kansen voor innovatie en gebruik' 300
- RIVM report 'Telemedicine en Telecare in de thuiszorg: historische ontwikkelingen en toekomstverwachtingen' 303
- Foundation of Nictiz in 2002
- Letter from the minister of health to parliament concerning eHealth

• 2004

Publication KNMG guideline 'Richtlijn online arts-patiënt contact' 308, detailing for which health care provision a doctor may use online contact and which conditions he/she should comply with. This guideline has become a prerequisite for the reimbursement and has recently (2020) been included in the recent KNMG-richtlijn 'Omgaan met medische gegevens' 309

2005

Start monitor zorg op afstand/ monitor videonetwerken ^{262, 266, 267, 267, 304}

2007'

 Oprichting Netwerk zorg op afstand, later 'platform zorg en technologie' (Zie voor leerpunten uit dit project ³¹⁰)

2009

- Algemene Rekenkamer report 'Zorg op afstand. Een innovatie in de langdurige zorg' ²⁵⁸
- Vilans report 'Zorg op afstand, literatuurstudie naar internationale ontwikkelingen en kennis over effecten' ²⁶¹
- o The Zorg Op Afstand project: This project started in January 2009 and was carried out by Nictiz in cooperation with the NPCF, ActiZ, VGN, GGZ Nederland and V&VN. It consists in a large preliminary study, in which the existing situation of e-care was inventoried and the needs of the field were mapped out. In the context of this project, the authorities allowed the HCP's involved in the project (approximately 30) to temporarily (between 2009 and 2012) declare a specific health care provision 'zorg op afstand'.

2010

- Development 'Meetinstrument zorg op afstand' ²⁶⁴
- Development 'Juridisch kader zorg op afstand'²⁶⁵

• 2012

The Nederlandse Patiënten en Consumenten Federatie (NPCF), de Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst (KNMG) en Zorgverzekeraars Nederland (ZN) took the initiative to work together to promote the development and use of eHealth. They agreed upon a **National Implementation Agenda for eHealth** ³¹¹, starting from the observation that there were plenty of promising applications, but that already developed applications were rarely widely implemented. To improve this situation, the Agenda identified as one of the central priorities for the years 2012 - 2015, the scaling up of telemonitoring in patients with diabetes mellitus and in patients with chronic heart failure, and



the development of teleconsultation, starting with teledermatology. The parties also agreed to ask and fund the Nictiz^{oo} association to organize and facilitate the standardization process for health care technologies.

RIVM report on risks of eHealth technologies ¹³⁹

2013:

- the National Implementation Agenda partners have joined forces with Nictiz, the Netherlands Healthcare Institute and the Association of Healthcare Providers for Care Communication (VZVZ) and agreed on a eHealth Covenant to remove obstacles regarding financing, standardization, familiarity and management:
- Start of the eHealth monitor in 2013 ^{28, 222, 268, 271, 272, 275-277, 282, 305}. The methodology for the eHealth Monitor is mainly based on surveys among care users (Consumer Panel Health Care) and care providers (KNMG members panel and nursing and care panel). When necessary, desk research, focus group discussions or interviews are also carried out.

However, scale of use remained low: e.g. Peeters et al. ²⁶⁹ concluded in 2013 that 'Veel vormen van technologie in de zorg bevinden zich nog in het pilotstadium, veelal als aanvulling op bestaande zorg. Zo lopen er pilotprojecten van zorg op afstand in de zorg thuis maar verschillende onderzoeken laten zien dat het met de opschaling en verspreiding ervan niet zo'n vaart wil lopen'. Similarly, van Raalte et al. ²⁷⁴ concluded in 2015 that 'eHealth komt moeizaam en veelal kleinschalig van de grond. Tekorten in strategie, evidence, bekostiging, connectiviteit, veiligheid, privacy, kunde en acceptatie zijn bekende oorzaken'. Also there was uncertainty about legal rules, financing and reimbursement of remote care ^{258, 312}.

Therefore, in 2014, the government of the Netherlands developed its strategy (2014-2019) to speed up and support the development of eHealth and remote care, in particular for chronically ill persons. In a letter to Parliament ²⁷⁰ they presented **a strategic plan 'Informatie- en Communicatietechnologie (ICT) in de Zorg'**, with clear aims:

- "1. Binnen 5 jaar heeft 80% van de chronisch zieken direct toegang tot bepaalde medische gegevens, waaronder medicatie-informatie, vitale functies en testuitslagen, en kan deze desgewenst gebruiken in mobiele apps of internetapplicaties. Van de overige Nederlanders betreft dit 40%. Dit heeft tot effect dat mensen bewuster zijn van hun eigen gezondheid en dat fouten in dossiers bij zorgverleners sneller gedetecteerd kunnen worden.
- 2. Van de chronisch zieken (diabetes, COPD) en kwetsbare ouderen kan 75%, die dit wil en hiertoe in staat is, binnen 5 jaar zelfstandig metingen uitvoeren, veelal in combinatie met gegevensmonitoring op afstand door de zorgverlener.
- Zij kunnen zo de voortgang van hun ziektebeeld volgen en krijgen door de regelmatige feedback inzicht in het effect van hun gedrag op hun ziekte. Dit zal het voor mensen makkelijker en aantrekkelijker maken trouw te zijn aan hun therapie.
- 3. Binnen vijf jaar heeft iedereen die zorg en ondersteuning thuis ontvangt de mogelijkheid om desgewenst via een beeldscherm 24 uur per dag met een zorgverlener te communiceren. Naast beeldschermzorg wordt hierbij ook domotica ingezet. Dit draagt eraan bij dat mensen langer veilig thuis kunnen wonen."

and together with parties in the healthcare sector. Nictiz identifies and advises parties in the healthcare sector on information exchange and (future) national and international developments. https://www.nictiz.nl/over-nictiz/

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Nictiz is a national, independent knowledge organisation dedicated to digital information exchange in healthcare. Nictiz does this by, among other things, developing and managing user-oriented information standards on behalf of

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To achieve these objectives, the government decided:

- On the one hand, to remove barriers by improving knowledge, access (including financial) and confidence of HCPs in new technologies, and by improving the interoperability of these new technologies with the ICT system used by the authorities (generic approach).
- On the other hand, to define specific long term actions to promote the use of eHealth for people with a chronic disorder or disability, starting in the field of diabetes and home care (**specific approach**).

In order to achieve the goals presented to the Parliament in 2014, the government is mainly focussing on the following actions:

1. Informing on eHealth solutions

The Ministry of Health, Welfare and Sport wants to make existing innovations in healthcare more widely known. They provide general information about smart care solutions and organize the national eHealth week (https://ehealthweek.net/) and set-up the website and organization 'zorg van nu'.

2. Funding innovations

Via ZonMw the government offers the possibility to apply for research/innovation grants in this sector^{pp} ^{313, 314}. In addition, the government is allocating €20 million until 2020 for direct support to entrepreneurs in the development of innovative products. The authorities also provide useful information for entrepreneurs via the website www.Zorgvoorinnoveren.nl .

Facilitating efficient and safe collection, exchange and use of medical data

The national government participates in the **Healthcare Information Council** (Informatieberaad zorg^{qq}). This administrative collaboration (with trade associations, physicians' associations, hospitals, pharmacies, home care organisations, nursing homes, care insurers and patients) works on a voluntary bass and aims to develop procedures to ensure a safe and reliable exchange and use medical data.

In addition, the government funds the specific program 'MedMij' supervised by the Patiëntenfederatie Nederland (Dutch Patients' Association) developing specific standards and a label confirming that health data can be exchanged in a safe and reliable way and that MedMij's high standards are met^{rr}.

The NEN7510 standard (see infra section 5.6.4) helps to ensure that the confidentiality, integrity and availability of patient and client data is technically and organizationally well organized. The MedMij label complement this NEN standard in the form of a standards framework for information security. By means of a supplementary audit statement of the NEN7510 with a substantiated report, it can be demonstrated that the MedMij standards framework is being complied with.

In addition, MedMij provides complementary norms to the General Data Protection Regulation (AVG). This consists of specific requirements for healthcare providers arising from the articles of the AVG.

PP https://www.zonmw.nl/nl/over-zonmw/innovatie-in-de-zorg/financiering-van-innovaties/.

https://www.zorginstituutnederland.nl/over-ons/programmas-ensamenwerkingsverbanden/informatieberaad-zorg.

https://www.medmij.nl/wat-is-medmij/. See also the list of validated services https://www.medmij.nl/wp-content/uploads/2020/04/Overzicht-kandidaat-deelnemers-gekwalificeerde-gegevensdiensten-6-april-2020-.pdf.



4. Monitoring the eHealth availability and use (eHealth Monitor)

As mentioned above, since 2013 the Ministry of Health, Welfare and Sport (VWS) asked the Netherlands Institute for Health Services Research (NIVEL) and the Netherlands Institute for ICT in Healthcare (Nictiz) to annually monitor the actual availability and use of eHealth in practice.

After 2014, expectations of remote care remained high ²⁸⁸ and the list of projects, studies and initiatives continued to grow. For instance, the initiative was taken to set up an online knowledge center for the implementation of e-Health (https://www.kennisbankehealth.nl/) and a research institute 'National eHealth Living Lab' (https://www.kennisbankehealth.nl/) and a research institute 'National eHealth Living Lab' (https://nell.eu/over-nell). Several organizations developed guidelines concerning using eHealth and remote care (e.g. de 'digitale zorggids' https://www.digitalezorggids.nl/, ³¹⁵ ^{296, 298, 298, 316}). Also a framework for to control the sue of eHealth was developed ^{257, 278}. And more funding opportunities were created such as 'Stimuleringsregeling E-health Thuis' ³¹⁷. And the NZa sketched how to they could contribute to enhance ehealth initiatives ³¹⁸.

More specifically related to video consultations, several places/institutions across the country started/continued to use video consultation, in home nursing care^{ss} ³¹⁹⁻³²¹, in nursing home care³¹⁹, care for people with a handicap³²², in speech therapy^{tt}, in GP-care^{uu} ^{296, 323, 324}, in specialized hospital care^{vv} ³²⁵⁻³³⁰. More examples are listed by Zorgverzekeraars Nederland ^{ww}.

Despite all efforts, several studies showed the implementation of eHealth, remote care and video consultations **continued to be difficult and slowly adopted**:

- In 2016, **the e-Health Monitor** ^{275, 276} observed that only 5 percent of people receiving care at home could make visual contact with a nurse or caregiver directly from home via the computer, telephone, tablet or television screen. The main obstacle was at the time that not all elderly and chronically ill people have internet, or want to or can work with it. One in six people did not have a computer or internet and three quarters of this group did not know whether they can access their own medical data, according to the report.
- According to the e-Health Monitor 2017 ²⁷⁷, in 62% of the general practitioners' practices it is possible to do an e-consultation. However, the actual use of the e-consult is not high^{xx}.
- The **e-Health Monitor 2019** ²⁸shows that the increase in the offer and use of 'beeldbellen', which was visible in previous years, has not continued in 2019 and that use of it remained low and even decreasing. However, there is an increase in the use of alternative applications that can contribute to longer safety independent living at home, such as surveillance mechanisms (toezichthoudende) and care robots. Also the offer of consultation via app and email contact is rising.

Figure 6 from the eHealth Monitor 2019 ²⁸, clearly illustrates this decline in 2019:

https://www.sensire.nl/zorgzoeker/zorg-op-afstand/, last accessed 22/04/20.

And https://www.google.com/

tt <u>https://www.rivas.nl/over-rivas/nieuws/primeur-clienten-kunnen-via-app-beterdichtbij-beeldbellen-met-hun-logopedist/</u>

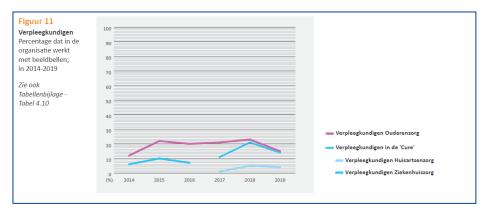
https://www.icthealth.nl/nieuws/beeldbellen-alternatief-voor-gebrek-aan-huisartsen/, last accessed 07/02/20.

https://www.icthealth.nl/nieuws/martini-ziekenhuis-zet-videoconsult-in-bij-diabetespatient/, last accessed 13/02/20.

ww https://www.zn.nl/zoekresultaten?query=beeldbellen

 $[\]frac{\text{https://www.nhg.org/actueel/nieuws/e-consult-biedt-meerwaarde-voorhuisarts-en-patient}}.$

Figure 6 – Percentage of nurses that work with video consultations 2014-2019



- The Netherlands Zorginstituut ³³¹ wrote a discussion paper in which they state eHealth is still immature and that there remains a lack of proof that eHealth is effective and that this forms a barrier to persuade health care professionals to use it.
- Barsom et al ²⁹¹ performed a survey among 968 patients (mainly with a chronic somatic disease) of the University Medical Center in Amsterdam and only 1.7% of the patients ever had a video consultation with a hospital care provider; they also checked data from an insurance company and this showed that in the period 2016-2018 only 30 Dutch hospitals registered one or more video consultation: in total 135, 166 and 83 video consultations from a hospital were registered in respectively 2016, 2017 and 2018 (compared to for instance 113 917 telephone consultations in 2018).

- In 2018, the NZa ²⁶³ conducted a study on the use of **e-consults** by specialists^{yy}. The objectives of this study was to screen the use of remote consultation by medical specialists and to analyse whether these remote consultations actually replace a physical outpatient clinic visit. Since 2018 there are 3 new remote consultations that medical specialists can use in their practice: the screen-to-screen consultation, the call consultation and the written consultation
 - o The study showed that phone **call consultation** in particular was used a lot in 2018 (about 200,000 times a month in total).
 - The share of **remote consultations** in the total number of consultations varies greatly and is between 0 and 30%, with peaks of 40%.
 - This percentage also differs per specialty: in clinical genetics it was the highest and in psychiatry the lowest.
 - In addition, the study observed that the number of physical consultations did not decrease in the same proportions asncrease in the number of remote consultations (by phone, mail or video call). This may mean that care has been added instead of being replaced. But this finding must be confirmed in further studies because the method of registration has changed. The content of the care may also have changed.
- Verest et al. 332 observed in 2019 that care providers (verpleegkundigen, verzorgenden, begeleiders en praktijkondersteuners) consider the skill "communication with clients and/or their relatives via the electronic way" as less relevant than other required competences. Almost half (44%) of health care providers consider this electronic communication irrelevant and more than half (55%) does not master this competence. One in five caregivers indicate that they want to be educated on this area. Nevertheless, the use of



eHealth applications by nurses and caregivers raised in 2017 but decreased in 2019 ²⁸. In 2018, a third of employers invested in new technologies (including eHealth) focused on contact with clients.

5.5.2 What barriers were encountered during implementation of video consultation?

Many Dutch documents 28, 139, 222, 258, 260-262, 265-269, 271-277, 279-283, 285-288, 290, 294, 295, 297, 302, 304, 305, 307, 311, 326, 331-342 talk about barriers and facilitators in the implementation of eHealth in general, and some pay specific attention to the implementation of remote care or video consultations specifically. It may be assumed that factors that foster or impede implementation of eHealth interventions in general also apply to the implementation of video consultations but the magnitude may differ.

Barriers can be classified into 5 main categories: patient related, provider related, technology related, financially related and legislation related.

1. patient related factors

- o insufficient ICT-literacy
- o no previous experience with technology
- o unwillingness/lack of interest to use eHealth/video consultations
- inability to use technology
- o unavailability of technology
- o insufficient financial means

2. provider (health care professional/organization) related

- o insufficient ICT-literacy
- o unwillingness/lack of interest to use ehealth/video consultations
- o fear of increase in workload
- o fear to lose personal contact
- o lack of knowledge concerning technological possibilities

- o not persuaded of technology effectiveness
- lack of confidence in technology
- inability to use technology
- unavailability of technology
- o guidelines of associations are contra
- too much innovations at the same time

3. technology related

- not performant/ not stable
- no internet /no Wi-Fi
- o too difficult to handle
- too costly
- too difficult to install
- o insufficient integration into other digital systems
- insufficient evidence of effectiveness and lack of risks/adverse events

4. financial factors

- o no remunerations to use it
- no reimbursement
- too high investment costs to buy technology

5. legislation

- o ethical concerns, such dehumanisation of care, privacy intrusive
- privacy
- lack of quality standards
- o too many standards to fulfil



6. health system related

- o insufficient central coordination
- o insufficient (financial) incentives
- o insufficient promoting ehealth
- o fear of increasing health care costs
- o insufficient investments in research and development

However, it is not clear from the documents what the effect size of each factor is and how they interrelate.

A publication from van Duijvendijk et al. ²⁸⁷ focused on barriers and facilitators in implementing video consultations; their list of success factors is presented below in Table 18. They conclude that all dimensions are equal important to address.

Table 18 – Success factors in implementation of video consultations ²⁸⁷

Dimensie	Factor	Positief/
		negatief
Project en organisatie	Constante begeleiding om betrokkenheid te stimuleren	++
	Beginnen met bepaalde groep cliënten	+
	Klein beginnen	+
	Meerwaarde duidelijk maken op enthousiaste manier	+
	Houd rekening met doelgroep	+
	Bied beeldschermzorg aan als reguliere zorg en niet als 'optie'	+
	Ontbreken van draagvlak	
	Leeftijd en persoonlijkheid cliënt en medewerker-	-
	Kennistekort bij zorgverlener	-
	Weerstand bij zorgverlener	-
	Beeldschermzorg blijven evalueren	++
Technische dimensie	Keuze leverancier met veilige verbinding	++
	Goede ondersteuning door leverancier	++
	Communicatie over veiligheid en privacy	+
	Slechte internet verbinding	
	Gebruiksongemak hardware	-
	Kwetsbare cliënten	-
	Invloed van familie	-
	Gebruiksgemak van iPad en bijbehorende apps	++
Financiële dimensie	Onduidelijkheid bekostiging beeldschermzorg	
	Budget cliënten	-
	Garantie bekostiging beeldschermzorg	+



Resultaat	Contact hetzelfde of verbeterd	++
	Meerdere toepassingen van de iPad voor zorg	++
	Meedoen in de maatschappij en zelfredzaamheid	++
	Effectiviteit van zorg verhoogd	+
	Weinig informatie over effect toepassing	
	+ positieve factor, - negatieve factor, ++/ kritische factor	

5.5.3 How were barriers in implementation solved?

In the initial development phase of teleconsultation, barriers were mainly related to uncertainties regarding legislation and financing and the absence of common ICT and quality standards ³⁰⁵. Today, the remaining barriers do not seem to lay in legislation or regulation, but rather in failing technology or the lack of trust in this technology. In addition, the eHealth application is not always well embedded in current practice and may lead to increased workload ²⁸.

Anyhow, joined forces of the government and stakeholders in the past twenty years have already helped to remove, at least partially, some of these barriers. As presented above, the development of quality procedures and technical standards is ongoing and already well advanced. In addition, teleconsultation services have been authorised for many years within the declarable health care provisions. HCP's and insurers enjoy a wide margin to negotiate the reimbursement of e-care, including video consultations. Also a clear informative document ²⁵⁶ was developed on the financing, remuneration and reimbursement of digital care activities in which all financial barriers to use digital care were removed. Additionally, a framework to control eHealth applications was developed ^{257, 278}.

Also as stated previously, the government invested a lot in research and innovation program through ZonMw. Also several professional associations and care organizations developed guidelines on the use of remote care applications. Universities developed courses to increase ICT-skills of healthcare professionals.

5.6 Legislation

Different type of remote care, including video consultation is allowed in the Netherlands, under certain conditions, in all care sectors, for all patients and by all health care providers regardless of the setting.

5.6.1 List of legislations

The regulation regarding eHealth is complex and extensive and include different kind of rules:

- The **Dutch legislation** contains rather broadly formulated requirements.
- The interpretation of these requirements are left to healthcare providers who translate scientific knowledge into professional practice guidelines or quality rules. These self-regulations are called standards, guidelines, recommendations, convenants or codes of conduct and play a major role in health regulation in the Netherlands. They are extremely numerous and include for example, professional standards for home nursing care, professional standards for the management of chronic illnesses by general practitioners or nurses, professional standards concerning mental health care in certain circumstances, etc. (e.g. 298, 309, 343).
- In addition public and private bodies develop certification norms or label regarding technical aspects of eHealth.



 Finally, next to Dutch legislation, also European legislation applies to eHealth sector such as 'Algemene Europese verordening gegevensbescherming' (AVG).

Of particular importance regarding the regulation of video consultation are the rules applicable to the **organization of health insurance and health services** and describing under which conditions (remote) health care provision can be offered by HCPs and declared to the patient's insurers. These rules are mainly included in the following texts:

- Wet marktordening gezondheidszorg (Wmg)^{zz}
- Wet langdurige zorg (WIz)^{aaa}
- Regeling medisch-specialistische zorg NR/REG-2001a
- Beleidsregel huisartsenzorg en multidisciplinaire zorg 2020 BR/REG-20133^{bbb}
- KNMG-richtlijn 'Omgaan met medische gegevens' 309

In addition, specific **rules regarding the quality of the delivered care** apply. For eHealth applications, including video consultation, the IGZ listed the following relevant rules^{257, 278}:

- Wet kwaliteit, klachten en geschillen zorg (Wkkgz)
- Uitvoeringsbesluit Wkkgz
- Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg
- Governancecode zorg
- · Kader toezicht op goed bestuur
- Kwaliteitskader verpleeghuiszorg

- Handreiking verantwoordelijkheidsverdeling bij samenwerking in de zorg
- Prestatie-indicatoren kwaliteitsborging medische systemen
- Leidraad overdracht van medicatie gegevens in de keten
- Richtlijn elektronisch voorschrijven
- Convenant medische technologie
- Leidraad nieuwe interventies in de medische praktijk
- Handreiking toezichthoudende domotica
- NEN 7510 Medische informatica informatiebeveiliging in de zorg
- NEN 7512 Vertrouwensbasis voor gegevensuitwisseling
- NEN 8009 Veiligheidsmanagementsysteem voor ziekenhuizen en instellingen die ziekenhuiszorg verlenen
- NEN 8028 Medische informatica Kwaliteitseisen telemedicine
- NEN-EN-ISO 22301 Maatschappelijke veiligheid Managementsystemen voor bedrijfscontinuïteit

This chapter concerning the Netherlands does not detail the whole of the aforementioned legal framework applicable to eHealth but focuses on the specific rules governing the use of video consultation.

https://wetten.overheid.nl/BWBR0020078/2020-01-01#Hoofdstuk4. In particular, articles 35, 36, 37 en 38 en 50.

https://wetten.overheid.nl/BWBR0035917/2020-03-19.

https://puc.overheid.nl/nza/doc/PUC 274340 22/1/.



5.6.2 Applicability

Video consultation is allowed in the Netherlands, under certain conditions, in all care sectors, for all patients and for all health care provision performed by any health care professional regardless of the setting. The position consistently defended by the authorities is that care can be delivered in an eHealth form within the boundaries of the already insured care (declarable care), provided that this new means does not change the composition and effectiveness of the declarable care.

Consequently, all medical situations could potentially be concerned by video consultation. The use of teleconsultation **depends on the negotiations between the health care provider and the insurer,** who must judge the quality, feasibility and relevance of remote health care rather than face-to-face.

Most of the time, the existing declarable health care provisions offers sufficient room for teleconsultation.

For digital care that does not fit in with existing declarable care, providers can invoke a specific policy rule called 'Innovation for small-scale experiments'ccc. This policy rule makes it possible (during three years and in some cases five years) to declare care provision that are not already listed in the context of a small-scale experiment concerning an innovative form of care. The request for an experiment must be sent to the NZa and it must be a joint proposal from a care provider and insurer or 'zorgkantoor' ddd together. During the experiment other care providers and health insurers or care offices can join and ask for the same exception. Before the end of the experiment, they can submit an application to the NZa to be allowed to declare the care. The NZa will then investigate whether the care can be included in the regular funding.

General requirements apply to all type of video consultations. In addition, as mentioned above, video consultations have to comply with **specific requirements** depending on the care sector. Additional requirements can be added in the contracts between insurers and HCP's. Those are however not public and could not be studied in the context of this study.

5.6.2.1 General requirements

- Exactly as in face-to-face contacts, the HCPs providing video consultation must observe all applicable legislations and behave like a good healthcare provider in accordance with all professional standards, guidelines and protocols of his/her profession.
- 2. Moreover, the **composition and effectiveness of the care cannot not substantially be changed** compared to the face-to-face care. This also implies an assessment of the added value of using teleconsultation in the care process.
- 3. Other general conditions are described in the KNMG "Richtlijnen online arts-patient contact" which has recently (2020) been included in the new KNMG-richtlijn 'Omgaan met medische gegevens' 309. Under the 'Beleidsregel huisartsenzorg en multidisciplinaire zorg 2020 BR/REG-2013', compliance with this guideline is mandatory to declare remote health care to insurance companies. In other care sector, it appears that these guidelines are also applied by insurers and HCP's as guidelines of good care in the digital context.

In this guideline, the KNMG advises that, in principle, an e-consultation is only permitted in the case of an **existing therapeutic relationship and care a distance should not be used for the initial assessment of a condition**. This can only be waived if the quality of care is sufficiently guaranteed if 2 cumulative conditions are met:

Zorgkantoor is a specific intermediary organizing the care in the field of long term care for those who are entitled to receive such care.

 $[\]textbf{See} \ \underline{\textbf{https://www.informatielangdurigezorg.nl/soorten-zorg/zorgkantoor}.$

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- the chance of adverse consequences is sufficiently reduced
- the care provided benefits the patient

In addition, an online consultation in which an individual medical advice is given is only permitted if the following cumulative conditions are met:

- The doctor has informed the patient sufficiently about the procedure and conditions for online contact:
- The doctor has received sufficient relevant and reliable (medical)
 data from the patient and/or already has sufficient data (e.g. a reliable
 and relevant medical history) to be able to give a medically sound
 individual advice:
- The professional rules on quality and safety of care and the rights of the patient are observed;
- The identity of the patient is sufficiently established. The doctor should also check that the patient is capable and major (16 years of age or older). Also the physician has to identify himself to the patient. To this end, he mentions his BIG registration number on his website eee. Only if there are other safeguards to give advice to unknown patients.
- The doctor clearly indicates that the advice is based on the data presented by the patient, and possibly the available recorded data. In addition, the doctor states that in the event of aggravation of the symptoms, if there is reason to do so, or in the event of uncertainty, the patient should seek contact with the adviser or another doctor;

If the doctor is not the patient's (general) physician, he will inform the
patient's own GP about the advice given to the patient. The patient
may object to this provision of data. In that case, the patient is expressly
advised to inform the GP himself/herself.

If medication is also prescribed during an online consultation, the following additional (to the above mentioned conditions) conditions must be met (see also art. 67 of the Medicines Actff):

- The prescribing physician must have met the patient face-to-face at least once;
- The prescribing physician must know the patient (the doctor at least knows what the current health status of the patient);
- The prescribing physician must have the patient's medication history available; the prescribing physician must know the patient's medication history. This means that the physician has the patient's current medication history available at the time of prescription. For this purpose, the general practitioner's observation data or pharmacists' medication overviews, for example, can be consulted via the LSP. Within an existing treatment relationship, a doctor will often have the following information at his disposal on sufficient medication data because this results from the legal filing obligation. The doctor must also be aware of the patient possible self-medication.
- There is sufficient reliable and relevant information available to rule out any contraindications for the intended medication and to decide to prescribe the medication on that basis;

de zorgverlening, alsmede over de bereikbaarheid en waarneming in geval van spoed te vermelden.

Artikel 67 Geneesmiddelenwet: "Het is een ieder verboden via internet geneesmiddelen voor te schrijven aan personen die de voorschrijver nog nooit persoonlijk heeft ontmoet, of die de voorschrijver niet kent of van wie de voorschrijver de medicatiehistorie niet beschikbaar heeft."

Op grond van artikel 3:15d BW is degene die 'een dienst van de informatiemaatschappij verleent' verplicht om onder andere de volgende gegevens toegankelijk te maken voor de afnemers van die (online) dienst: naam, emailadres, postadres, bezoekadres; BIG-titel en BIG-registratienummer; de beroepsvereniging waar men bij is aangesloten; verwijzing naar deze en andere relevante richtlijnen; de tarieven. Geadviseerd wordt om ook informatie over de gehanteerde procedure voor

- 3
- On the basis of the available information and with a view to the medication to be used, there is no reason to carry out a (supplementary) physical or other examination;
- The patient is adequately informed about the use of the prescribed medication and any side effects thereof and it is sufficiently plausible that the patient understands the instructions accompanying the medication, follows them and, if necessary, completes the course of treatment.

Moreover, in case of repeat prescriptions, three additional conditions apply:

- The doctor has, or receives, sufficient relevant information to assess whether a repeat prescription is necessary and/or desirable;
- No additional (physical) examination is required for the provision of a repeat prescription;
- The patient is alerted to the possibility of reporting any side effects
 to the doctor since the last issue of the prescription or changes in the
 state of health.

With regard to the **safety of online communication**, the KNMG advices that a doctor should use a computer equipped with an **up-to-date virus scanner**, **firewall** and recent patches for the software being used. When exchanging data online, sufficient measures must be taken to safeguard the patient's privacy. For example, data should at least be sent in encrypted form. However, 'Secure e-mail' solutions and/or a 'secure' connection (encrypted server) are preferable.

In principle, e-mails from patients should not be stored in the e-mail program itself, in order to prevent computer viruses from getting hold of the confidential data. A printed, paper version of these e-mails will be included in the file or stored in the electronic medical record.

The access to the doctor's computer must also be secure, for example by means of a password, or even better, by means of biometric identification. In addition, the physician's computer should be equipped with a password-protected screen saver, so that access to the data on the computer is also restricted at the time the physician is logged in but is not present at his (work) place.

5.6.2.2 Specific declaration rules in each sector

In the primary care sector, in paramedical care sector (except speech therapy), for pharmaceutical care and for basic and specialized mental health, it does not matter whether a consultation takes place digitally, by telephone or physically, provided that it complies with general requirements described above.

Teleconsultation in primary and multidisciplinary care

The declaration rules regarding teleconsultations by GP's⁹⁹⁹ are described in the 'Beleidsregel huisartsenzorg en multidisciplinaire zorg 2020 - BR/REG-20133' ³⁴⁴

The financing of primary care and multidisciplinary care is based on three sectors or "segments". In each of these sectors, teleconsultation is possible.

 Segment 1 covers basic primary care, including consultations with the general practitioner, a 'praktijkondersteuner huisartsen voor geestelijke gezondheidszorg' (poh-ggz^{hhh}), a GP assistant or a nurse. In this segment maximum rates apply.

Since January 2019, the Dutch Healthcare Authority treats **e-consults** and face-to-face consultations equally: not the form (electronic, telephone, video or face-to-face) but the duration of the consultation determines its reimbursement rate. GP consultations (face-to-face, by

In the Netherland, primary care is often provided by a group of care workers and not only by GP's. For example, consultations with the general practitioner or poh-ggz

hhh The POH GGZ is someone with knowledge of and experience in mental health care.

email, telephone or video) can be of different durations (shorter than 5 minutes, from 5 minutes up to 20 minutes or 20 minutes and longer).

Remote consults can however only be declared if they replace a consultation, in which the care provided is comparable to the care provided in a face-to-face consultation, both in terms of care content and time expenditure.

Additionally, consultations without direct physical face-to-face contact must comply with the conditions laid down by the health care professionals in the KNMG guideline online doctor-patient contact 308. This guideline states, among other things, that in the case of online care, there must be an existing treatment relationship between the doctor and the patient and that care via Internet should not be used for the initial assessment of a condition. In the absence of such a treatment relationship, online contact can only take place when the associated risks are minimised and for the benefit of the patient.

- Segment 2 covers care for chronically ill people. In this sector free rates apply and the care pathways are broadly described. This enables care providers to provide parts of their care provisions remotely, or to offer self-management programmes. The level of reimbursement will depend on what is agreed between the HCP and the insurer.
- **Segment 3** covers the renewal of the care provided in segments 1 and 2. The general practitioner can only charge these care in this segment if he or she has an agreement on this with the health insurer. The provision's rates in this segment are free.

In this segment, health insurers and healthcare providers can make additional agreements to pay for eHealth applications that they consider to be of value to the patient. For example, via the declarable provision 'Zorgvernieuwing eHealth', they can make agreements about the reimbursement or remuneration for deployment of eHealth within the care provided for digital tools for self-management by the patient and digital forms of treatment.

The general practitioner can also use the declarable provision "Resultaatbeloning service en bereikbaarheid". This includes arrangements between the GP and the insurer regarding the payment of health care provisions improving the quality or accessibility of the provided care such as the reimbursement of possibilities for patients to make digital appointments with the general practitioner or to request digital renewal prescriptions or to access a GP at all time by telephone.

Moreover, the general practitioner can also declare a **review consultation** (meekijkconsult). This type of consultation is intended to call on the expertise of other healthcare providers, such as medical specialists or other experts, to determine treatment policy. This consultation can take place either face-to-face or remotely. The purpose of the consultation is to prevent referrals or, if necessary, to be able to make targeted referrals. In addition, a specific declarable provision exists for GP using teledermatology. This provision allows the general practitioner to share images of his patient's skin with a dermatologist to obtain his advice and then discuss the results with his patient. The dermatologist who assesses the skin is paid for by a performance from the second line (other care product).

Teleconsultation in specialized care

The declaration rules regarding teleconsultations by specialists are described in the 'Regeling medisch-specialistische zorg - NR/REG-2001a' 345. For the large majority of specialized care, nothing in these rule limit the possibility to replace a face-to-face care by remote care. For consultations some specific rules apply since 2018.

Three different forms of remote consultations are possible:

- a screen-to-screen consultation replacing an outpatient clinic visit (een polikliniekbezoek) (190161)
- a phone call consultation replacing a repeat outpatient clinic visit (een herhaal-polikliniekbezoek) (190162)
- a written consultation (includes contact by e-mail or other digital forms of contact such as chatting) replacing a repeat outpatient clinic visit (herhaal-polikliniekbezoek) (190163)

The phone **call consultations** and **written consultations** can only be registered if they are comparable to the care provided in a regular (physical) **repeat visit** in terms of both content and time. This implies that a prior face-to-face contact is required (the first visit).

If the care provider provides the first consultation at a distance, the care provider can register the care activity "screen-to-screen consultation". A condition is that the consultation at a distance is comparable to the care provided in a **regular first clinic** visit in terms of both content and time.

For the care delivered in the context of a care pathway, health care providers and health insurers consider it important that the coordinating caregiver has physically seen the patient at least once to ensure the quality of care. The face-to-face contact was therefore still mandatory in 2019 on the basis of Article 5 of the Regulation on specialised medical care. This obligation led to several bottlenecks and administrative burden. Because the patient contact via other means is guaranteed, it has been decided to end the face-to-face obligation in this article since 2020 ²⁵⁶.

Teleconsultation in paramedical care

Paramedical care includes occupational therapy, extramural dietetics, physiotherapy, speech therapy (logopedie), exercise therapy and podotherapy ³⁴⁶.

In this sector, the NZa has determined which services can be charged but the paramedical care works with free prices.

Within the existing declarable health care provisions (e.g. the regular session), paramedical care providers are free to change their care process by, for example, partially replacing face-to-face contact with digital care at a distance, or to offer digital care as a supplement to treatment. This is possible without having to change the existing health care provision.

Currently, for remote speech therapy (telelogopedie), a separate provision has to be declared. This will be abolished in 2021, and it will be charged via the regular services.

Teleconsultation for personal care, assistance and nursing (Verpleging en verzorging WIz and Zvw)

From 2020, a single performance description will apply to all digital forms of care or supervision at a distance (BR/REG-20123, https://puc.overheid.nl/nza/doc/PUC-277680-22/2/). This performance has been defined more generally, so that all forms of care or supervision at a distance with digital support can be included from 2020. Examples are pharmaceutical telecare, care at a distance, personal alarm and Googleglass application iii. A maximum of 6.5 hours per month per client for home care technology at the agreed rate for nursing, personal care or counselling can be declared. Exclusively in the home care sector WIz, supervision may also be included.

5.6.3 Liability

The main approach regarding liabilities implies that the party with whom a treatment agreement has been concluded is liable for errors and problems if in the performance of the treatment agreement has failed imputably. The other aspects can be addressed through self-regulation ²⁶⁵

However, it is important to take into account that several liabilities may be at stage regarding the contact between clients and HCP via video consultation kkk.

For instance, if the client/ patient has his own tablet or smartphone and uses it to make video calls to relatives. Care workers can help and support this. The device is the property of the client and therefore no additional security

Wegwijzer 2020. See also artikel 5.7 van de Regeling verpleging en verzorging.

https://puc.overheid.nl/nza/doc/PUC 304668 22/1/.

https://www.actiz.nl/nieuws/digitaal-werken-en-corona.

requirements apply to the mode of video calling and consumer applications such as WhatsApp can be used (choice of client/relative).

If the organisation organises a daily visual call hour between the client and a relative with a tablet or smartphone of the healthcare organisation, the healthcare organization is responsible for ensuring that this is done safely; the same requirements apply as for video calling between clients and healthcare workers.

In all cases, the contracts must clearly indicate how responsibilities are to be allocated and the Inspectorate Health Care (IGJ) will control whether the allocation of responsibilities is sufficiently clear 257, 278.

5.6.4 Certification

Safe image calling applications must comply with the GDPR (AVG: Algemene Verordening Gegevensbescherming). European providers fall under the AVG, non-European providers do not and will therefore often not meet the requirements.

New codes of conduct GPPR proof are to be approved by the authorities.

In addition, all actors involved in teleconsultation are obliged to comply with the 'NEN 7510 - Medische informatica - informatiebeveiliging in de zorg' and the standards that follow from it, such as the NEN 7513^{mmm}. The NEN 7510 is a standard/certification rule on information security in healthcareⁿⁿⁿ. Since January 2018, working according to and complying with these three NEN standards has been made mandatory in the 'Besluit Elektronische Gegevensverwerking Zorgaanbieders' (Decree on Electronic Data Processing for Healthcare Providers).

The certification norms contains rules regarding:

- organisational security (concerns security awareness);
- procedural security (e.g. the establishment of working methods and processes);
- **technical security** (covering the infrastructure and workplace security).

The NEN 7510 was updated in 2017 and made compatible with the European General Data Protection Regulation (AVG) and the international security standard ISO/IEC 27001. The NEN 7510 provides guidelines and principles for determining, setting up and enforcing measures that an organization in the healthcare sector must take to secure the provision of information. The purpose is to maintain the confidentiality, availability and integrity (including authenticity, accountability and verifiability) of information.

The controlling authority of the health care sector (IGJ) ^{257, 278} also refers to the standards of NEN8028 - Quality requirements for telemedicine oo

The NEN 8028 is a standard for the entire chain from manufacturer to supplier, care company, care provider and caretaker. It mainly concerns the patient safety and good transmission of information between the different parties. The NEN 8028 has no legal value but is recommended by the Dutch Patients and Consumer Federation (NPCF).

The quality requirements in NEN 8028 describe the criteria that a provider of telemedicine services or applications must meet to ensure that this service from is of sufficient quality. The purpose of these quality requirements is to reduce the risks of remote care.

https://autoriteitpersoonsgegevens.nl/nl/zelf-doen/avg-gedragscode.

NEN 7510 is a general standard; NEN 7512 and NEN 7513 further elaborate this standard for a specific area.

NEN (https://www.nen.nl/) is the Foundation of the Royal Dutch Standardization Institute (Stichting Koninklijk Nederlands Normalisatie

Instituut) does not certify itself, but acts as an independent platform to set up and manage certification schemes (standards and guidelines).

This NEN norm served as basis of the ISO-richtlijn Telehealth (13131).



The quality requirements described in NEN 8028 focus on three aspects:

- 1. The quality management of the health care institution.
- 2. The care processes around the patient.
- The processes relating to the manufacture and supply of resources for telemedicine.

In the quality management around telemedicine, the care institution sets targets for the telemedicine services offered and describes the processes, responsibilities and powers around the use of telemedicine. In addition, a healthcare institution establishes what risks are involved and what specific quality requirements are relevant in that case.

Within the care processes around the patient, three sub-processes are distinguished, namely orientation, intake and care ³⁴⁷.

For each subprocess NEN 8028 contains quality requirements regarding, among other things, freedom of choice, transparency, continuity and timeliness of care and privacy. For example, a health care institution must have procedures in place that ensure the continuity of telemedicine and the privacy regulations must explicitly address the risks that telemedicine can pose to patient privacy.

The manufacturing and delivery processes are subject to quality requirements regarding effectiveness, safety and user-friendliness. An example of a requirement is that the manufacturer has demonstrably established that the means used are safe and effective.

5.6.5 Privacy and ethics

5.6.5.1 Protection of personal data

As already mentioned, exchange of medical data in the context of video consultation has to comply with the General Data Protection Regulation (AVG).

5.6.5.2 Technical and organisational standards are described in the mandatory certification rules NEN7510 for health care providers and ICT platforms. In addition, the voluntary MedMij label provides complementary norms for healthcare providers. Ethical aspects

Each health profession usually has its own organization, association, college or society to advocate for professional interests as well as to contribute to scientific development and quality. Their number amounts to more than a hundred. Besides defending material interests, these organizations develop guidelines on professional and ethical aspects. The only professional association specifically addressing ethical/professional aspects of video consultation is the KNMG.

5.7 Funding

5.7.1 Budget of the private insurers

As described above the budget allocated for the reimbursement of the health provisions themselves (medical acts) is, when the provision is included in the list of declarable care, paid by the insurers. However, there seems to be no official record of the number of video consultations billed each month for each sector and reimbursed by health insurers.

5.7.2 Subsidies granted by the public authorities

The Dutch government invests massively in health technologies either indirectly through the funding of a very large number of research and supporting organisations, or directly via subsidies. It is impossible to describe all the funding possibilities. The main interlocutor for direct or indirect grants is Zon Mw organisation (https://www.zonmw.nl/nl/). 'Zorg voor Innoveren' (https://www.zorgvoorinnoveren.nl/) is also an important support for the implementation of remote care: it is single point of contact for questions regarding the implementation of innovations, including eHealth.

Below, we have listed some of the most frequently mentioned funding programs for video consultation.



1. Stimuleringsregeling E-Health Thuis (SET)

This specific scheme is intended for to promote the structural embedding and sustainable funding of existing eHealth applications that facilitate support or care at home. The targeted population are elderly people and people with a (risk of) chronic illness or disability can live longer at home with a higher quality of life. Budget for this projects is € 28.000.000. In the context of this program, HCPs can apply for further scaling up of digital applications in care at a distance^{ppp}.

2. Promising care

In order to bring innovative care to the patient more quickly, the Zorginstituut Nederland has been running the subsidy scheme since the beginning of 2019. Through this scheme it is possible to obtain a subsidy for treatments that seem promising but are not yet reimbursed in the basic package. With this scheme, the Ministry of Health, Welfare and Sport makes a maximum of € 69 million available annually^{qqq}.

- 3. There are currently various pilot projects aiming at the inscription of a new declarable health care provision. These initiatives are described here: https://puc.overheid.nl/nza/doc/PUC_288047_22/1/.
- 4. In the context of the Corona pandemic, extra grant options were opened.

5.8 Remuneration

Recipients

Video consultations are remunerated under the conditions negotiated between the health insurers and the health care professionals (individuals or institutions). This means that the cost linked to teleconsultation will be paid either to the health care professional or to the institution or association for which a HCP works.

There are no out-of-pocket payment or supplement for the basic insurance package: For all citizens of 18 years or above, a mandatory deductible is in place: the first €385 (2016) of healthcare costs in a certain year has to be paid out of pocket (except for GP-consultations, maternity care and home nursing care). After having spent that amount (plus any voluntary deductibles), insurance takes over.

What is covered by the remuneration (time, hardware, software, connection, ...)?

Digital care is part of the primary care of the patient. The hardware, software, or supporting material are therefore usually not considered as healthcare in themselves. This means that healthcare providers usually cannot claim the costs they incur for these digital care applications separately from the care provided.

When fixed maximum rates apply, the NZa takes as much as possible into account the costs of digital healthcare applications that are reasonably necessary and unavoidable due to the close relationship with the provision of care. When free rates apply, insurers and health care professionals can of course negotiate the price with health insurers.

PPP https://www.rvo.nl/subsidie-en-financieringswijzer/stimuleringsregelingehealth-thuis-set.

Wegwijzer 2020.



5.9 Reimbursement

The CVZ position paper 'When is eHealth insured care' ³⁴⁸ states: "As a general rule, if existing, already insured care is offered in an e-health form, that care remains insured care if its composition and effectiveness does not substantially change compared to the original care. The reverse also applies: care that was not insured care in its original form will not be insured care if it is offered in the form of e-health".

Concretely, this position means that it is not prohibited for insurers to reimburse pain management as part of a DBC with virtual reality glasses for instance without much evidence of its effectiveness. In somes cases innovations will not be tested against the criteria for science and practice but will be investigated in this way.

The pragmatic position of the NZA is that e-health applications are usually, only another form (presentation) of pre-existing care. In other words it is a variant of the same care. The authorities consider that it is up to the health insurers to assess whether specific e-health interventions are indeed just another form of presentation or should be declared separatly as specific type of care. Consequently, the CVZ assumes that the care continues to meet the set conditions for declaration and will not reasses it in advance.

The NZA usually only assesses care if there are clear indications (e.g. complain from health insurers or care providers) that the content of the declarable care is at stake.

When they can be declared, teleconsultations are reimbursed at the same price than face to face consultations.

As mentioned above, public authorities set maximum prices in some care sectors while prices are free in others. The real price will depend on the commercial negotiations with the insurance companies. It is therefore not possible to give the exact price of a teleconsultation.

- The price invoiced by the health care providers can be lower, but may not exceed that maximum. Free rates apply in a number of other sectors: in the entire paramedical care, most of the specialised care and part of the general practitioner care.
- Health care provisions in the specialized care sector can be declared via "diagnose-behandelcombinatie" (DBC). A DBC is a reimbursable health care provision (identified via a decisional three) that is part of a care sub pathway. The Nederlandse Zorgautoriteit (NZa) defines the DBCs.

5.10 Technology

The current market for platforms is only made up of private operators offering various services such as chat, document sharing, remote consultation etc. between providers or between providers and their patients.

There is no public operator for this type of services and these platforms are not grouped together. There is currently no coordination between these private actors.

The **Dutch patient association** also made an overview of all available video-consult providers in the Netherlands, and patient themselves can rate the products^{rrr}. The Nederlands Huisartsgenootschap also did^{sss}. Other professional associations^{ttt} or private actors^{uuu} listed certain applications that are likely to comply with minimal quality rules. See for instance:

https://www.smarthealth.nl/beeldbellen-zorg

[&]quot; https://www.digitalezorggids.nl/product/zoekresultaten?facet theme%5B%5D=Videoconsult.

https://www.nhg.org/sites/default/files/content/nhg_org/uploads/ 20200327_keuzetabel_beeldbelapplicaties_v1_0.xlsx

https://www.lhv.nl/actueel/nieuws/lhv-advies-voor-inzet-beeldbellen_en-videoconsult_entry.
https://mxi.nl/uploads/files/publication/beeldbeldoverzicht.pdf.

uuu https://www.smarthealth.nl/beeldbellen-zorg



https://airtable.com/embed/shrsJNfRJq6Te4M0x/tblWCaPtkLniNU 9pZ?viewControls=on&blocks=hide

https://www.digitalezorggids.nl/product/zoekresultaten?facet_them e%5B%5D=Videoconsult

5.11 Effects

5.11.1 The eHealth Monitor

The e-Health Monitor 2019 28 shows that the increase in the offer and use of video consultation which was visible in previous years, has not continued in 2019 and that use of it remains low and even decreasing. However, there is an increase in the use of alternative applications that can contribute to longer safety independent living at home, such as surveillance mechanisms (toezichthoudende) and care robots. Also the offer of consultation via app and email contact is rising.

5.11.2 The ZonMW study

Health care is under pressure and calls for the right care, at the right time, in the right place and by the right person. To provide quality care now and in the future, at an affordable price and with fewer people, a change in thinking and doing is needed. The use of technology can contribute to this. making it possible to use ICT to provide care at a distance, to monitor, to promote healthy behaviour and to intensify support for clients in the home situation. The application of both digital information and communication to support and/or improve health and healthcare is called eHealth. Despite the increasing use of eHealth applications in healthcare, eHealth is hardly part of the structural healthcare infrastructure or healthcare processes.

The ZonMw organisation currently commissioned a study on the type, nature and severity of various bottlenecks regarding the use of eHealth in order to target the application of eHealth and to accelerate the embedding of eHealth in healthcare. The results of this study are expected in May 2020

5.11.3 The NZa study on teleconsultation in the specialized care

To monitor the introduction, in 2018, of 3 new remote care activities in specialized care (see supra), the NZa examined ²⁶³ whether care providers applied these care activities in 2018 and whether there were differences between types of providers and specialisms. When these new activities were introduced in the declarable health care provisions, the parties agreed that expenditure on specialist medical care would not increase as a result of the introduction of the new care activities. Therefore, the NZa also examined whether there was a link between the use of the new care activities and the average 'weight' of outpatient care products. They looked at this connection because they expected visible effects on expenditure. There was indeed a risk that consultations at a distance would be simply 'added' and that the number of physical consultations would not decrease to the same extent.

However, whether or not expenditure increases is also related to the price of care products that include remote consultations and any additional agreements made by health insurers and care providers in this regard. This falls outside the scope of this overview. The analyses are based on national declaration data of Vektis (https://www.vektis.nl/) for 2018. For 2019 there was not yet sufficient data available to use.

https://www.zonmw.nl/nl/onderzoek-resultaten/kwaliteit-vanzorg/programmas/project-detail/kwaliteit-van-zorg-ontwikkeling-



Number of remote consultations in 2018

The healthcare activity 'screen-to-screen consultation' was registered 400 to 500 times a month in 2018. For the care activity 'written consultation' the number fluctuated between 600 and 1500 per month. The numbers are considerably higher for the care activity 'telephone consultation'. This care activity was registered around 200,000 times a month nationwide in 2018. In January 2018 this was approximately 170,000, up to 225,000 in October. There was a slight increase during the year.

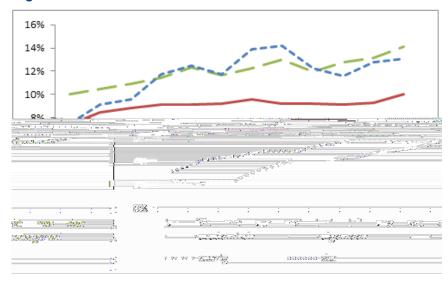
Percentage of remote consultations in total number of outpatient and first aid visits

In 2018, the proportion of call consultations in the total number of outpatient and first aid visits per care provider varied between 0 and 30%. The proportion of remote consultations in the total also varies between 0 and 30% per provider, with peaks of up to approximately 40%.

Differences between types of care providers

A difference in the application of remote consultations was observed between types of care providers (see Figure 8). In 2018, the share of remote consultations was lower for university hospitals and 'zelfstandige behandelcentra' and higher for categorical hospitals and other healthcare providers (such as centres for radiotherapy, clinical genetics and sports medical advice).

Figure 7 – Number of remote consultations per type of health care organisation 2018



Differences between medical specialities

The percentage in relation to the total number of consultations in clinical genetics was on average 23%. In gastroenterology and anaesthesiology the percentage is slightly lower, 19% and 18% respectively. Relative use is lowest in the specialisms of psychiatry (1%) and ophthalmology and cardio-pulmonary surgery (both 2%). This is the average percentage for the entire year 2018.



Number of physical consultations did not decrease at the same time as the number of remote consultations increased.

A slightly positive correlation between the proportion of remote consultations (in the total number of outpatient and first aid visits) in 2018 and the change in the weight of outpatient care products between 2017 and 2018 was observed. This indicates that more consultations are performed remotely. but that the number of physical consultations is not decreasing equally. This correlation remained after correction for a number of factors, such as the specialism and the care institution. It is therefore possible that care has been added instead of being replaced. However, there are also other possible explanations for this positive relationship. It may be that the way in which consultations are held has not so much changed, but that is mainly an effect of registering differently (because the consultations at a distance now count alongside the other consultations in the registration).

5.12 COVID-19 pandemic

In order to further promote and facilitate the use of care at a distance, including teleconsultation, several initiatives were taken by both the public and the private sectors.

5.12.1 Governmental measures

Extension of the declaration rules

As outlined in the previous sections it was already largely possible for HCP's to declare consultations at a distance (phone, mail or video) replacing a face-to-face consultation prior to the COVID-19 pandemic. The main restrictions in the declaration rules applied in the specialized medical care sector and in the nursing care sector (both in care settings and at home). In the context of the COVID-19 pandemic, the NZa decided to, temporarily, waive these restrictions www xxx.

- The Dutch Healthcare Authority (NZa) has temporarily extended declaration rules to allow hospitals (specialized medical care) to conduct the initial patient consultation by telephone or otherwise remotely in the case of regular care. Normally, the first contact should be face-to-face to be eligible for remuneration. As regular consultations are now shifted to telephone consultations, this is important to ensure financing of regular care^{yyy}.
- The first contact for **speech therapy** can take place at a distance instead of in a treatment room. This extension also applies to group treatments, for example combined lifestyle intervention.

The NZa also asked health insurers to suspend possible obstacles in contracts with care providers in this area (e.g. mandatory minimum size of face-to-face contact) during this period (see next section on insurer's initiatives).

Guidance to help on the choice of technical solutions

The Dutch authority on personal data (Autoriteit persoonsgegevens) looked at the most important privacy aspects of 13 frequently used video call apps and issued a guidance to help HCP to compare different video call apps. This comparison was made in the context of the urgency of the pandemic and is not based on in depth technical researches but relies on the declaration of companies themselves, for example in their privacy statements^{ZZZ}.

https://www.nza.nl/actueel/nieuws/2020/03/17/nza-brengt-extra-verruimingaan-voor-zorg-op-afstand.

https://puc.overheid.nl/nza/doc/PUC 274340 22/1/

ууу https://www.nza.nl/actueel/nieuws/2020/03/13/nza-past-regelgeving-aanvanwege-coronavirus.

ZZZ https://autoriteitpersoonsgegevens.nl/nl/nieuws/keuzehulp-privacy-bijvideobel-apps



Emergency budget for the implementation of screen to screen care for vulnerable elders aaaa

The Ministry of Health, Welfare and Sport released money for additional digital applications for remote support and care for vulnerable elderly people living at home and people with a chronic illness or disability. Within the national program called "Stimuleringsregeling E-health Thuis (SET)", a special emergency scheme has been set up: SET Covid-19. The scheme is intended for care and welfare organisations that want to invest extra in digital care at a distance. This concerns, for example, **proximity nursing organisations, mental healthcare providers and hospitals**. The scheme makes € 50,000 available per application.

The Ministry of Health, Welfare and Sport has asked suppliers of devices for screen to screen care to reserve sufficient stock for care at a distance. They have indicated that they will give priority to the healthcare sector in the global allocation. In order to help healthcare organisations implement screen to screen care as quickly as possible, the regulation offers a 'Fasttrack screen to screen care'. This provides healthcare organizations with practical and direct support in making the right choices.

Per application € 50,000 is available. The subsidy is primarily used to pay project costs for the implementation of the digital applications. Help with the implementation may be hired. In addition, up to 50 percent of the amount can be spent on technology such as the purchase of licenses or devices. The total budget for the whole scheme is 23 million euros.

5.12.2 Privates initiatives

Health insurers also took measures to help insured persons and care providers to receive and provide safe and timely care that is reimbursed under the basic and supplementary health insurances. More details are available via the insurer platform https://www.zn.nl/corona/coronavirus.

The insurers reached a common position regarding the **nursing indication assessment** during corona crisis. Although the starting point for **indication assessment** is that the assessment interview takes place in the client's own environment, in view of the special circumstances it is now up to the healthcare professional to assess whether care at a distance (through, for example, image calling) is preferable to a home visit. It remains of undiminished importance for healthcare professionals to assess the indication set at a distance and record it in the care file.

Various professional associations also issued toolkits and list of reliable providers to support HCP's in the fast implementation of video consultation bbbb.

Covid-19 crisis caused also a popping up of a whole number of video-consultations providers. E.g,. the Dutch GP-association NHG listed 14 providers

(https://airtable.com/shrjeMWX9tNrRiPxP/tblWCaPtkLniNU9pZ/viwyBbhzTNd0epo43?backgroundColor=blue&blocks=hide); and the Knowledge platform for digital health 'smarthealth' (https://www.smarthealth.nl/beeldbellen-zorg/) lists 35 providers and the Dutch patient federation listed in April 2020 over 40 providers (https://www.digitalezorggids.nl/digitale-dienst/videoconsult/producten).

bbbb See https://www.actiz.nl/informatisering/zorgtechnologie/digitaal-werken-encorona.

https://www.rijksoverheid.nl/actueel/nieuws/2020/03/24/noodregeling-maakt-direct-meer-digitale-zorg-thuis-mogelijk.



6 GENERAL DISCUSSION AND CONCLUSIONS

This project was kind of special due to the outbreak of COVID-19 in the middle of it. The situation in general before the outbreak was that video consultations were only very limited used (and much less than expected) in the studied countries and from the literature it became clear that the implementation of video consultations in health care is confronted with many barriers and remained slow. Also it appeared that there is no firm evidence that video consultations are equal or better than face-to-face consultations but also no evidence that they lead to negative health effects.

But COVID-19 was disruptive in this: remote care in general and video consultations in particular became no longer an option but in many cases a first choice to intervene. The implementation of video consultation was set up and accomplished in a few days, many new providers appeared, conditions of use of video consultation applications were changed and made more attractive (e.g. free), (temporary) reimbursement rules were created and extended, several assessment lists of providers were published and the use of video consultations exploded. Reality suddenly forced things and reality is currently running ahead of policies.

Conclusions we could draw from the literature review were:

- Confusing terminology prohibiting to disentangle specific effects of video consultation or specific factors to implement video consultations
- Despite an enormous amount of primary and secondary studies, there
 is currently no firm evidence that video consultations are equal or better
 than face-to-face consultations and no firm evidence that video
 consultations has no negative health effects
- There are many factors that influence the implementation of video consultations in particular and telehealth in general. These factors are patient-related, provider related, technology related and health system related. It is not clear what the influence of each factor is and how they are interrelated.

However, it need to be mentioned that the chosen method of 'review of reviews' is not ideal. A consequence of this method is you lose clear sight on the primary studies and what exactly was the content of the intervention and control conditions that were compared and on how and when effects were measured. Also the studied reviews have often mixed patient populations and probably inhibit to see if interventions work better in one patient population compared to another one. Moreover, the studied reviews were often of suboptimal methodological quality.

Nevertheless, it is clear that the current state of evidence regarding the use of video consultations might be large but remains inconclusive. More robust research is needed to establish which patients and under what conditions can profit the most from video consultations. What works, where, how and for whom?

Conclusions we could draw from the international comparison:

- In Belgium there were before the COVID-19 crisis, only a very few pilotprojects with video consultation and no specific legislation
- This contrasts to the situation in our neighbouring countries France and the Netherlands, where there is already a long history with the use of video consultations, reimbursement rules and active governmental support to implement video consultations
- Video consultations are embedded in the legislation and reimbursement frameworks of France and the Netherlands, several documents were developed in these countries on how to organize video consultations in a proper way and on what conditions apply to guarantee remote care of good quality
- However, despite a long history and governmental support, the implementation of video consultations remained difficult and stayed behind expectations in France and the Netherlands

It is not clear if these findings are very specific to the use of video consultations only, or if they also apply to the use and implementation of more general telehealth interventions or even to innovations in general. When scanning reviews on the barriers and facilitators in implementing

telehealth interventions, it appears that the same factors also exist there and that it is important to tackle these factors simultaneously. But even then, there is no guarantee that the implementation will go smoothly and rapidly, as testimonied by the long history in the Netherlands.

One of the recurrent mentioned barriers is the reimbursement/remuneration issue: this is certainly an important factor but only one of the many; and when this issue is solved, there remain many other barriers that could impede further implementation.

Next to this, the impossibility to perform a physical examination limits the use of video consultations. Therefore video consultations must be applied with caution and after careful consideration; video consultations could never replace all face-to-face consultations. Professional (and patient) organizations need to develop guidelines on when a video consultation is an option and when is **NOT** an option and on what circumstances and conditions video consultations may be used.

It has to be discussed if patient agreement is necessary for all situations (e.g. emergency care), if video consultation with extended infrastructure for physical examination (e.g. smart stethoscopes) can be applied, if the condition as put forward by the task force¹⁶⁷ 'Video or audio communication is not stored by the participants in the communication' should be kept, etc...

The WHO ¹⁴⁶: states that 'despite the mixed available evidence on effectiveness spanning a wide range of health conditions, client-to-provider telemedicine has the potential to expand access to health services. It may also potentially reduce the burden of travel and decrease inequities for populations that have difficulties in accessing health services through conventional approaches' and recommends 'the use of client-to provider telemedicine to complement, rather than replace, the delivery of health services and in settings where patient safety, privacy, traceability, accountability and security can be monitored'.

For further implementation, an overarching clear governmental policy on the use of telehealth is needed, together with action plans and financial stimulating incentives. And both providers and patients must be persuaded of the advantages and feel safe when they use video consultations. And of

course the applications for video consultation need to perform well, must be cheap and easy to use.

The COVID-19 crisis forced health care providers and patients to use video consultations; an explosive increase in the use of it is seen worldwide, and there are already some studies that show that the attitude of both professionals (and their associations) and patients became more positive. 349-355

The COVID-19 crisis will without doubt have led to a definitive breakthrough of video consultations in health care, but also to a hush and rush of actions that need to be revisited and well-thought off in the coming months. WHO also warned that digital health interventions are often widely rolled out in the absence of careful examination of the evidence base on benefits and harms.



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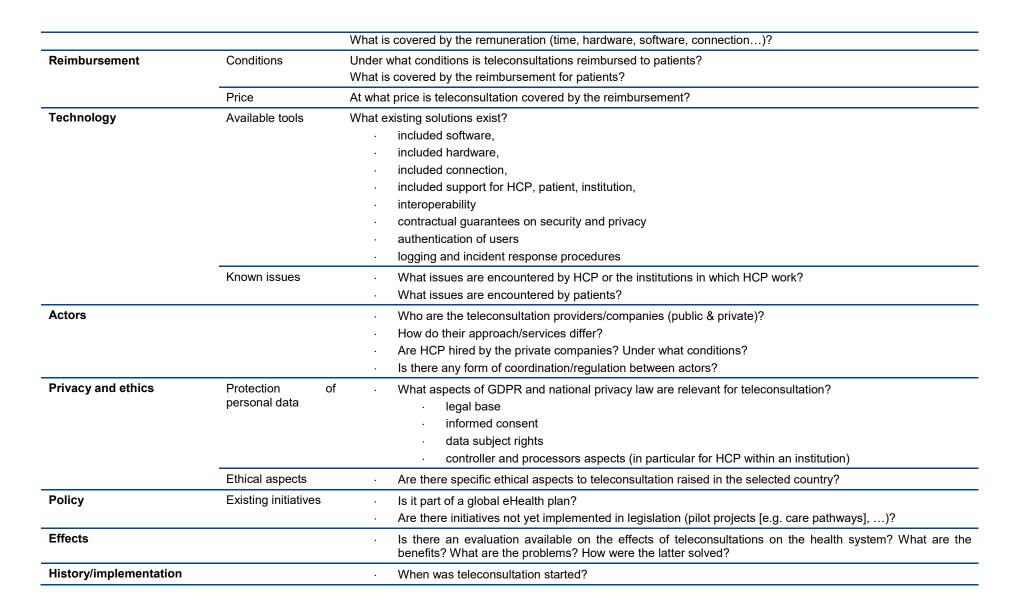
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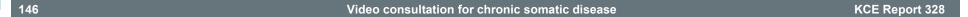
■ APPENDICES

APPENDIX 1. TOPIC LIST INTERNATIONAL COMPARISON

Topic	Subtopic	Questions to be answered
Legislation	Applicability	 What is the legislation that defines teleconsultation? What is the legislation that defines applicability; the place it has within the health care process [equivalence to a law]: which HCP can use teleconsultations, which patients are eligible, what type of type of consultations are allowed, in what setting is teleconsultation allowed (in hospital, private practice,) What is the legislation that defines the implementation conditions [equivalence to a royal decree]: technology requirements security requirements privacy requirements
	Liability	What is the specific legislation for teleconsultation (on top of more general or health care specific liability laws) for
	Certification	What is the legislation on certification of teleconsultation solutions? · are only certified solutions accepted, · what are the requirements for certification
Funding	Budget	What is the budget (total and per subitem if any)?
	Authority	What authorities or bodies fund (national, federated, patients,)? Is there public / private funding?
Remuneration	Recipients	Who receives remuneration (HCP, institution for which a HCP works)?







- · How was teleconsultation implemented
- · What barriers/facilitators were encountered during implementation?
- · How were barriers in implementation solved?
- · What is current scale of teleconsultation?
 - How many HCP are using teleconsultation?
 - How many patients are seen by teleconsultation?



APPENDIX 2. SEARCH RESULTS PER DATABASE

Database	N hits on 04/12/19
Pubmed	426
Embase	366
CINAHL	250
Cochrane	19
Evidence NHS	373
Total	1434



APPENDIX 3. METHODOLOGICAL ASSESMENT WITH AMSTAR-2 OF INCLUDED REVIEWS

Review first author																	
	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14	Item 15	Item 16	Overall rating
Armfield, N. R. ³³	no	no	no	partial yes	no	no	no	no	no	no	no meta- analysis included	no meta- analysis included	no	no	no meta- analysis included	yes	Critically Low quality
Aronow WS 34	yes	partial yes	yes	partial yes	no	no	yes	partial yes	yes	no	yes	no	no	no	yes	no	Low quality
Batsis JA ³⁵	no	yes	yes	partial yes	no	no	no	partial yes	partial yes	no	no meta- analysis included	no meta- analysis included	yes	yes	no meta- analysis included	yes	Moderate quality
Bauce K ³⁶	no	no	no	partial yes	no	no	no	partial yes	no	no	no meta- analysis included	no	no	no	no meta- analysis included	no	Low quality
Cottrell MA ³⁷	yes	partial yes	yes	partial yes	yes	yes	no	partial yes	partial yes	no	yes	yes	yes	yes	no	yes	Moderate quality
Flodgren G ¹⁵	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	High quality
Grona SL ³⁸	yes	partial yes	yes	partial yes	yes	yes	no	partial yes	partial yes	no	no meta- analysis included	no meta- analysis included	yes	no	no	yes	Moderate quality
Health Policy Advisory Committee on Technology ³⁹	no	no	no	no	no	no	no	no	no	yes	no meta- analysis included	no meta- analysis included	no	no	no meta- analysis included	yes	Critically Low quality
Inglis SC ⁴⁰	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	High quality
Lee SWH ⁴¹	Yes	Partial Yes	No	Partial Yes	no	Yes	No	Partial Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Moderate quality

Nordheim LV ⁴²	Yes	Partial Yes	Yes	Yes	Yes	no	Yes	Yes	Yes	No	No meta- analysis conducted	No meta- analysis conducted	Yes	NA (only 1 study included)	No meta- analysis conducted	Yes	Moderate quality
Orlando JF ⁴³	Yes	Partial Yes	Yes	Partial Yes	Yes	Don't know	No	Partial Yes	Yes	No	No meta- analysis conducted	No meta- analysis conducted	No	No	No meta- analysis conducted	Yes	Low quality
Ostherr K ⁴⁴	Yes	Partial Yes	No	Partial Yes	Yes	Yes	No	Partial Yes	Yes	No	No meta- analysis conducted	No meta- analysis conducted	No	No	No meta- analysis conducted	Yes	Low quality
Ovtcharenko N ⁴⁵	Not clear	No	No	Partial Yes	Yes	Don't know	No	No	No	No	No meta- analysis conducted	No meta- analysis conducted	No	No	No meta- analysis conducted	Yes	Critically Low quality
Pedrozo Campos Antunes T ⁴⁶	Not clear	No	No	Partial Yes	Yes	Don't know	No	Partial Yes	No	No	No meta- analysis conducted	No meta- analysis conducted	No	No	No meta- analysis conducted	Yes	Critically Low quality
Rush KL ⁴⁹	Not clear	Partial Yes	No	Partial Yes	Yes	Don't know	No	Yes	Yes	No	No meta- analysis conducted	No meta- analysis conducted	Yes? (papers were rejected for low quality ratings)	No	No meta- analysis conducted	Yes	Moderate quality
Rush KL ⁴⁸	Not clear	Partial Yes	No	Partial Yes	Yes	Yes	No	Yes	Yes	No	No meta- analysis conducted	No meta- analysis conducted	No	No	No meta- analysis conducted	Yes	Low quality
Wagg AJ ⁵⁰	Not clear	Partial Yes	No	Partial Yes	Don't know	Don't know	No	Partial Yes	Yes	No	No meta- analysis conducted	No meta- analysis conducted	No	No	No meta- analysis conducted	No	Low quality
Zandbelt LC ⁵¹	Yes	Yes	Yes	Partial Yes	Yes	Yes	No	Partial Yes	Partial Yes	No	No meta- analysis conducted	No meta- analysis conducted	No	No	No meta- analysis conducted	Yes	Low quality

Item 1: inclusion of PICO components; item 2: a priori design; item 3: explanation of study selection; item 4: comprehensive search strategy; item 5: study selection in duplicate; item 6: data extraction in duplicate; item 7: list of excluded studies with reasons; item 8: describe studies in adequate detail; item 9: risk of bias (RoB) assessment; item 10: report of individual study funding sources; item 11: appropriate methods for statistical combination if appropriate; item 12: assess impact of RoB on synthesis; item 13: account for RoB in interpretation of review; item 14: explanation of heterogeneity in results; item 15: likelihood of publication bias; item 16: any potential sources of conflict.