

REMOTE MONITORING OF PATIENTS WITH CARDIOVASCULAR IMPLANTABLE ELECTRONIC DEVICES: A HEALTH TECHNOLOGY ASSESSMENT SUPPLEMENT



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Reported interests

‘All experts and stakeholders consulted within this report were selected because of their involvement in remote monitoring activities or in the RIZIV-INAMI working group on telemedicine. Therefore, by definition, each of them might have a certain degree of conflict of interest to the main topic of this report’

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- **The external experts were consulted about a (preliminary) version of the scientific report. Their comments were discussed during meetings. They did not co-author the scientific report and did not necessarily agree with its content.**
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- **Finally, this report has been approved by common assent by the Executive Board.**
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APPENDIX 1. HEALTH PROBLEM AND TECHNOLOGY

Appendix 1.1. System characteristics from previous health technology assessments

The overview of system characteristic in this report is partly based on previous health technology assessments (HTA) but supplemented with information obtained from industry and information publicly available on the manufacturers' websites.

Appendix 1.1.1. Health Quality Ontario (2018)

The Health Quality Ontario review considered ICD, CRTs and Pacemakers. A replication of their schematic overview can be found in Table 1. Cardiac Resynchronization Therapy, and Permanent Pacemakers.¹

Table 1 – System characteristics from Health Quality Ontario

Table A1: Remote Monitoring of ICDs, CRTs, and Pacemakers—Systems' Characteristics

Features	CardioMessenger	CareLink	Latitude	Merlin.net	SmartView
Wireless communication (implanted device—monitor)	• Radiofrequency	• Radiofrequency	• Radiofrequency	• Radiofrequency	• Radiofrequency
Data transmission	• Cellular, landline	• Cellular (automatic monitor) • Cellular or WIFI (non-automatic monitor)	• Cellular, internet, landline	• Cellular, internet, landline	• Landline, wireless
Transmitter	• Mobile or Stationary	• Stationary (can be brought when travelling)	• Stationary	• Stationary (can be brought when travelling)	• Stationary (can be brought when travelling)
Effective communication range (distance from device to transmitter)	• 2 meters	• 3 meters	• Unknown	• 3 meters	• 3 meters



Data transmission (Patient needs to be near the transmitter for data to be sent)	- Data automatically sent from implanted device to monitor (daily) - Remote data transmission cannot be initiated by the patient - Data sent from the monitor to central database and made available to physician on secure site	- Data automatically sent from implanted device to monitor - Automatically reads implanted device information at times scheduled by the clinic (automatic model) - Non-automatic model requires patient initiation of transmission - Remote data transmission can be initiated by the patient (both automatic and non-automatic model) - Data sent from the monitor to central database and made available to physician on secure website	- Data automatically sent from implanted device information at times scheduled by the clinic - Remote data transmission may also be initiated by the patient - Data sent from the monitor to central database and made available to physician on secure site	- Data automatically sent from implanted device information at times scheduled by the clinic - Remote data transmission can also be initiated by the patient - Data sent from the monitor to central database and made available to physician on secure site	- Data automatically sent from implanted device information at times scheduled by the physician/clinic - Remote data transmission can be initiated by the patient - Data sent from the monitor to central database and made available to physician on secure website
Frequency of alerts transmission (Patient needs to be near the transmitter for alerts to be sent)	- Red alerts as events are detected - Daily for other alerts	- Automatic model: alerts sent by device to the monitor. If the device is not within range of the monitor, the device will attempt to send the data every 3 hours for 3 days - Non-automatic model: no alerts are sent	Alerts sent as detected	Daily alert check at 2 a.m.	Daily checks for alerts

Features	CardioMessenger	CareLink	Latitude	Merlin.net	SmartView
Remote alert setting by physician	• Yes	• No	• Yes	• Yes	• Yes
Physician/Clinic notification of alerts	- Fax, phone, email - Information made available on secure website	- Fax, phone, email - Information made available on secure website	- Phone, fax - Information made available on secure website	- Fax, phone, email, text - Information made available on secure website	- Fax, phone, email, text - Information made available on secure website
Can the physician re-program the device remotely (is the feature currently in use?)	• No	• No	• No	• No	• No

Source: Device manuals and personal communication with manufacturers.

Appendix 1.1.2. System characteristic from HAS (2017)

The overview of the Haute Autorité de Santé (HAS) was limited to ICD's.² A replication of their schematic overview can be found in Table 2.

Table 2 – System characteristics from HAS

Tableau 2 : caractéristiques techniques des systèmes de TLS

Nom du système	CARELINK	HOME MONITORING	LATITUDE NXT	MERLIN. NET	SMARTVIEW
Fabricant	MEDTRONIC	BIOTRONIK	BOSTON SCIENTIFIC	SAINT JUDE MEDICAL	LIVANOVA
Transmetteur	MYCARELINK (modèle 24950)  © MEDTRONIC	CARDIOMESSENGER SMART (modèle 401826)  © BIOTRONIK	LATITUDE (modèle 6290 & 6288)  © BOSTON SCIENTIFIC	MERLIN HOME (modèle EX1150)  © SAINT JUDE MEDICAL	SMARTVIEW (modèle KB911)  © LIVANOVA
Alimentation électrique	Secteur	Secteur + batterie	Secteur	Secteur	Secteur
Dispositifs compatibles avec le transmetteur	DAI, PM, moniteur cardiaque implantable	DAI, PM	- DAI, PM, balance, tensiomètre	DAI, stimulateur cardiaque	DAI
Mode de transmission DAI-transmetteur	- Automatique (radiofréquence) - Manuel (lecteur portable)	- Automatique (radiofréquence)	- Automatique (radiofréquence) - Manuel (radiofréquence)	- Automatique (radiofréquence) - Manuel (radiofréquence)	- Automatique (radiofréquence) - Manuel (radiofréquence)
Réseau(x) de télécommunications entre le transmetteur et le serveur	- Téléphonie mobile, avec itinérance entre opérateurs	- Téléphonie mobile, avec itinérance entre opérateurs	- Téléphonie filaire (non dégroupée, dégroupage total ou partiel), - Téléphonie mobile (adaptateur 3G), avec itinérance entre opérateurs - Internet patient (filaire)	- Téléphonie filaire (ligne non dégroupée) - Téléphonie mobile (adaptateur 2G-3G), avec itinérance entre opérateurs - Internet patient (WIFI)	- Téléphonie mobile, avec itinérance entre opérateurs
Transmission automatique calendaire	Fréquence programmable, initiée par le transmetteur	Quotidienne systématique, initiée par le DAI	Fréquence programmable, initiée par le transmetteur	Fréquence programmable, initiée par le DAI	Fréquence programmable, initiée par le transmetteur
Transmission automatique événementielle	- Interrogation quotidienne, initiée par le transmetteur	- Immédiate, en cas d'alertes générées par le DAI (ERI, arythmie ventriculaire ou choc inefficaces à énergie max) - Recherche quotidienne d'alertes par l'hébergeur dans les données transmises par le transmetteur	- Interrogation quotidienne, initiée par le transmetteur	- Interrogation quotidienne, initiée par le DAI,	- Interrogation quotidienne, initiée par le transmetteur,
Transmission manuelle	Initiée par le patient, avec lecteur portable	Non	Initiée par le patient, sans fil (radiofréquence)	Initiée par le patient, sans fil (radiofréquence)	Initiée par le patient, sans fil (radiofréquence)
Modalités de notification au médecin des alertes	Email, SMS	- Email, SMS, fax - Confirmation de réception de l'alerte nécessaire	- Email, SMS	- Email, SMS, fax, message téléphonique	- Email, SMS, fax



APPENDIX 2. CURRENT USE OF REMOTE MONITORING

Appendix 2.1. NIDHI (RIZV – INAMI) nomenclature codes for the follow-up of CIED implants

Table 3 – NIDHI (RIZV – INAMI) nomenclature codes for the follow-up of CIED

SSI control or reprogramming (475856, 475860)	Controle van de deugdelijkheid en/of herprogrammatie van een eenkamerpacemaker (SSI), met ondervraging van het geheugen en meting van de stimulatie- en gevoeligheidsdrempel, met protocol en tracés	Contrôle de la qualité et/ou reprogrammation d'un stimulateur cardiaque, chambre simple (SSI), avec interrogation de la mémoire et mesure du seuil de stimulation et de sensibilité, avec protocole et tracés
Heart defibrillator control or reprogramming (475893, 475904)	Controle van de deugdelijkheid en/of herprogrammatie van een hartdefibrillator, met meting van de stimulatie- en gevoeligheidsdrempel en met evaluatie van de performantie van de defibrillator, met protocol en tracés	Contrôle de la qualité et/ou reprogrammation d'un défibrillateur cardiaque, avec mesure du seuil de stimulation et de sensibilité, avec évaluation de la performance du défibrillateur, avec protocole et tracés
DDD or CRT-P control or reprogramming (475871, 475882)	Controle van de deugdelijkheid en/of herprogrammatie van een tweekamerpacemaker (DDD) of een driekamerpacemaker (CRT-P), met ondervraging van het geheugen en meting van de stimulatie- en gevoeligheidsdrempel, met protocol en tracés	Contrôle de la qualité et/ou reprogrammation d'un stimulateur cardiaque, chambre double (D.D.D.) ou chambre triple (CRT-P), avec interrogation de la mémoire et mesure du seuil de stimulation et de sensibilité, avec protocole et tracés

Appendix 2.2. Results of the data analysis from NIDHI data, EPS and BeMedTech data

Appendix 2.2.1. Yearly number of CIED implants

Table 4 – Number of implanted CIED per year, including replacement (BeMedTech and NIHDI)

BeMedTech	2018	2019	2020	Prop. 2018	Prop. 2019	Prop. 2020
ICD	2535	2428	2741	16.3%	15.3%	17.6%
PM	11755	11634	11013	75.5%	73.4%	70.8%
ILR	1270	1788	1810	8.2%	11.3%	11.6%
Total	15560	15850	15564	100%	100%	100%
NIHDI	2018	2019	2020	Prop. 2018	Prop. 2019	Prop. 2020
ICD	2164	2428	NA	14.6%	15.9%	NA
PM	11425	11259	NA	76.9%	73.9%	NA
ILR	1270	1548	NA	8.5%	10.2%	NA
Total	14859	15235	NA	100%	100%	NA

NA: not available

**Table 5 – Number of implanted loop recorders per year (NIHDI)**

NIHDI	2016	2017	2018	2019	2020
ILR	342	936	1270	1548	1695

*Appendix 2.2.2. Yearly follow-up of patients with CIED implants***Table 6 – Full nomenclature data on the number of unique patients for the follow-up for CIEDs (NIHDI)**

Medical acts					Description
Nomenclature codes/Year	2017	2018	2019	2020*	
475856	13 241	13 289	13 175	12 389	Control and/or reprogramming of a single chamber PM in an ambulatory setting
475860	2 938	2 879	2 718	2 766	Control and/or reprogramming of a single chamber PM in a hospital setting
475856-475860	14 587	14 660	14 634	13 186	Control and/or reprogramming of a single chamber PM
475871	57 045	57 825	59 363	57 559	Control and/or reprogramming of a double chamber PM or CRT-P in an ambulatory setting
475882	11 746	11 776	11 824	11 763	Control and/or reprogramming of a double chamber PM or CRT-P in a hospital setting
475871-475882	60 567	61 917	63 291	59 676	Control and/or reprogramming of a double chamber PM or CRT-P
475893	13 881	14 694	15 346	15 589	Control and/or reprogramming of a ICD or CRT-D in an ambulatory setting
475904	3845	3970	3825	3854	Control and/or reprogramming of a ICD or CRT-D in a hospital setting
475893-475904	14 751	15 592	16 347	16 031	Control and/or reprogramming of a ICD or CRT-D
Total number of patients	85 369	87 100	89 048	87 541	

*Data for 2020 are yet incomplete, so the decline in the numbers in 2020 is an artefact.



Table 7 – Estimated number of patients and mean number of in-clinic visits from EPS data (allowing to identify patients with controls for multiple CIEDs)

	Number of patients		Mean number of in-clinic visits	
	2018	2019	2018	2019
ICDs - CRT-D only	14 140	14 880	2.1	2.2
Single chamber PM only	11 160	11 560	1.6	1.6
Double chamber PM or CRT-P only	57 600	60 220	1.8	1.8
ICD - CRT-D + double chamber PM or CRT-P	1 460	1 100	3.0	3.0
ICD - CRT-D + Single chamber PM	180	320	3.7	3.1
ICD - CRT-D + double chamber PM or CRT-P + single chamber PM	40	0	6.0	1.0
Double chamber PM or CRT-P + single chamber PM	2 460	2 520	2.5	2.5
Total for patients with multiple implants	4 140	3 940	2.8	2.7
Total	87 040	90 600	1.8	1.8



Table 8 – Remote monitoring estimates from different data sources

Type of device (nomenclature code)	Nb patients 2018	Nb patients 2019	Nb patients with RM 2021	% patients with RM* 2021	Nb new patients 2019	Nb new patients with RM 2020	% new patients with RM 2020	% patients with RM in KCE survey 2021
ICDs-CRT-Ds (475893, 475904)	15 592	16 347	9 549	58.41%	2 808	900	32%	73%
Single chamber PMs (475856, 475860)	14 660	14 634	2 735	3.51%	11 634	900	8%	7%
Double chamber PM or CRT-P (475871, 475882)	61 917	63 291						
Total	87 100	89 048	12 284	13.8%	14 442	1 800	12%	28%
	INAMI		BeMedTech					Survey

*: denominator is extrapolated from the number of patients in 2019 (NIHDI data)

Appendix 2.3. Survey questionnaires

Appendix 2.3.1. Dutch language questionnaire

KCE-onderzoek over telemonitoring van patiënten met implanteerbare cardiale apparaten

Beste collega's,

hieronder vindt u een reeks vragen om het gebruik van telemonitoring in België beter te begrijpen. **Als u een vraag niet kan beantwoorden, ga dan gerust verder met de volgende vraag.**

Gelieve deze ingevulde vragenlijst uiterlijk tegen **woensdag 19 mei** terug te sturen naar:: kce_projects@kce.fgov.be; (met sophie.gerkens@kce.fgov.be in kopie)

Wij danken u bij voorbaat voor de tijd die u hieraan wil besteden,

Het KCE-team

**Vragenlijst voor de ziekenhuizen**

- 1) In welk ziekenhuis bent u aan het werk?

...

- 2) **Hoeveel patiënten** (ongeveer) met implanteerbare cardiale apparaten worden in uw ziekenhuis gevolgd? Onder deze patiënten: hoeveel patiënten (of welk percentage) worden **ook gevolgd via telemonitoring**?

Als er in uw ziekenhuis geen patiënten wordt gevolgd via telemonitoring, kan u in de onderstaande tabel het cijfer 0 invullen en direct doorgaan naar de laatste vraag (vraag 12).

Type cardiaal implantaat	Aantal patiënten die in uw ziekenhuis gevolgd worden (schatting)	Aantal patiënten ook gevolgd via telemonitoring	(Ofwel) aandeel (%) van de patiënten ook gevolgd via telemonitoring
Cardiale defibrillatoren (met of zonder cardiale resynchronisatie)	...	...	...
Klassieke pacemakers (single of double chamber)	...	...	...
Cardiale resynchronisatie therapie CRT-P (triple chamber)P	...	...	...
Implanteerbare cardiale monitors (implantable loop recorders)	...	...	...



3) Hoeveel **implantaatgerelateerde raadplegingen** worden er gemiddeld per patiënt per jaar uitgevoerd in uw centrum bij een stabiele patiënt?

Type cardiaal implantaat	Patiënten <u>niet</u> gevolgd via <u>telemonitoring</u>		Patiënten gevolgd via <u>telemonitoring</u>	
	Raadplegingen ter plaatse		Raadplegingen ter plaatse (met inbegrip van raadplegingen <u>wegens een waarschuwing</u> (alert))	<u>Geplande ondervragingen op afstand</u> / geplande opvolging
Cardiale defibrillatoren (met of zonder cardiale resynchronisatie)	...		...	...
Klassieke pacemakers (single of double chamber)	...		...	...
Cardiale resynchronisatie therapie CRT-P (triple chamber)P	...		...	...
Implanteerbare cardiale monitors (implantable loop recorders)	...		...	...



- 4) Voor alle patiënten die via telemonitoring worden opgevolgd, hoeveel raadplegingen ter plaatse worden er per jaar (ongeveer) veroorzaakt door een waarschuwing (alert)?

Type cardiaal implantaat	Gemiddeld aantal (jaarlijks) <u>niet-geplande</u> raadplegingen ter plaatse (gegenereerd door een waarschuwing) in uw ziekenhuis (schatting voor alle patiënten gecontroleerd door telemonitoring)
Cardiale defibrillatoren (met of zonder cardiale resynchronisatie)	...
Klassieke pacemakers (single of double chamber)	...
Cardiale resynchronisatie therapie CRT-P (triple chamber)P	...
Implanteerbare cardiale monitors (implantable loop recorders)	...

- 5) Vindt u telemonitoring ongeschikt voor sommige van uw patiënten? Zo ja, in welke omstandigheden en / of bij welke soorten patiënten? Zo niet, gelieve 0 in te vullen.

...

- 6) Wat zijn de moeilijkheden die u ondervindt bij het gebruik van telemonitoring? Als u geen problemen ondervindt, gelieve 0 in te vullen.

- 7) Wat zijn de belangrijkste voordelen van telemonitoring in uw praktijk?

- 8) Is er voor telemonitoring extra personeel nodig in vergelijking met de klassieke opvolging?



- 9) Wat is het beroepsprofiel en de precieze rol van de personen die betrokken zijn bij telemonitoring in uw ziekenhuis?

Type personeel	Rol	Aantal (in fulltime equivalenten / of tijd per week)
Artsen		
Verpleegkundigen		
Informatici		

- 10) Hebt u een idee van de jaarlijkse kosten per patiënt van de opvolging via telemonitoring? Aangezien dit niet wordt terugbetaald, hoe dekt het ziekenhuis dit bedrag nu?

- 11) Moet u een bijkomend betalen voor de technologie en / of het databeheer door de producenten? Is dit bedrag inbegrepen in de prijs van het implantaat?

...

- 12) Als er geen patiënten worden opgevolgd via telemonitoring in uw ziekenhuis, wat zijn dan de redenen waarom u geen telemonitoring gebruikt?

...

**Étude du KCE sur le télémonitoring des patients porteurs de dispositifs cardiaques implantables**

Chers Docteurs,

Voici ci-dessous une série de questions afin de mieux comprendre l'usage du télémonitoring en Belgique. **Si vous ne pouvez pas répondre à une question, n'hésitez pas à passer à la question suivante.**

Merci de renvoyer ce questionnaire complété à l'adresse suivante pour le mercredi 19 mai : kce_projects@kce.fgov.be; (sophie.gerkens@kce.fgov.be en copie)

Nous vous remercions d'avance pour le temps que vous nous consacrerez.

L'équipe du KCE

Questionnaire pour les hôpitaux

1) Dans quel hôpital travaillez-vous ?

...

2) (Environ) combien de patients porteurs de dispositifs cardiaques implantables sont suivis dans votre hôpital ? Parmi ceux-ci, quelle proportion (ou quel nombre de patients) est suivi(e) par télémonitoring ?

Si aucun patient n'est suivi par télémonitoring dans votre hôpital, vous pouvez indiquer le chiffre 0 dans le tableau ci-dessous et passer directement à la dernière question (question 12).

Type de dispositif cardiaque	Nombre de patients suivis dans votre hôpital (estimation)	Nombre de patients suivis par télémonitoring	(Ou) Proportion de patients suivis par télémonitoring
Défibrillateurs cardiaques (avec ou sans resynchronisation cardiaque)	...	...	...
Stimulateurs cardiaques simple chambre ou double chambre	...	...	...
Stimulateurs cardiaques triple chambre – CRT-P	...	...	...
Moniteurs cardiaques Implantables (Implantable Loop recorders)	...	...	...



3) Combien de consultations (liées à l'implant) sont en moyenne effectuées par patient et par an dans votre centre pour un patient stable?

Type de dispositif cardiaque	Pour les patients non suivis par télémonitoring	Pour les patients suivis par télémonitoring		
		Consultations physiques / sur place	Consultations physiques / sur place (incluant les consultations dues à une alerte)	Interrogation à distance planifiées / suivi à distance programmé
Défibrillateurs cardiaques (avec ou sans synchronisation)	...		...	...
Stimulateurs cardiaques simple chambre ou double chambre	...		...	...
Stimulateurs cardiaques triple chambre – CRT-P				
Moniteurs cardiaques Implantables (Implantable Loop recorders)	...		...	...

4) Pour l'ensemble de vos patients suivis par télémonitoring, (environ) combien de consultations physiques / sur place par an sont générées par une alerte ?

Type de dispositif cardiaque	Nombre moyen annuel de consultations sur place non programmées / générées par une alerte (estimation pour l'ensemble des patients suivis par télémonitoring dans votre hôpital)			
Défibrillateurs cardiaques (avec ou sans synchronisation)				
Stimulateurs cardiaques simple chambre ou double chambre				
Stimulateurs cardiaques triple chambre – CRT-P				
Moniteurs cardiaques				
Implantables (Loop recorders)				



- 5) Considérez-vous le télémonitoring inapproprié chez certains de vos patients ? Si oui, dans quelles circonstances et/ou chez quels types de patients ? Si non, vous pouvez indiquer 0 dans les cases correspondantes.

...

- 6) Quelles sont les difficultés que vous rencontrez dans votre utilisation du télémonitoring ? Si vous ne rencontrez pas de difficultés, notez 0.

...

- 7) Quels sont les avantages principaux du télémonitoring dans votre pratique ?

...

- 8) Le télémonitoring nécessite-t-il des ressources humaines supplémentaires par rapport au suivi classique ?

...

- 9) Quel est le profil professionnel et le rôle des personnes impliquées dans le télémonitoring dans votre hôpital?

Type de personnel	Rôle	Nombre (en équivalent temps plein) / ou estimation du temps par semaine
Cardiologue		
Infirmier/e		
Informaticien/ne		
...		



10) Avez-vous une idée du coût annuel par patient du suivi par télémonitoring ? Comme ce n'est pas remboursé, comment l'hôpital couvre-t-il ce montant actuellement ?

...

11) Devez-vous payer un montant pour la technologie fournie par les firmes et/ou la gestion des données par les firmes ? Ce montant est-il inclus dans le prix de l'implant ?

...

12) Si aucun patient n'est suivi par télémonitoring dans votre hôpital, quelles sont les raisons pour lesquelles vous ne réalisez pas de télémonitoring ?

...



APPENDIX 3. QUALITY APPRAISAL OF SYSTEMATIC REVIEWS ON CLINICAL OUTCOMES

The quality of the Ontario-HTA¹ (Table 9) and the HAS-HTA³ (Table 10) was appraised following the criteria of the AMSTAR 2 grid⁴. Although the selection of studies was done by only one reviewer and reasons for exclusion were not provided by individual studies, no critical failure was detected and both reviews were considered good-quality.

Table 9 – Quality appraisal of the Ontario-HTA based on AMSTAR-2 grid

1. Did the research questions and inclusion criteria for the review include the components of PICO?

For Yes:

- ☒ Population
- ☒ Intervention
- ☐ Comparator group
- ☐ Outcome

Optional (recommended)

- ☒ Timeframe for follow-up

- ☒ Yes
- ☐ No

2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?

For Partial Yes:

The authors state that they had a written protocol or guide that included ALL the following:

- ☒ review question(s)
- ☒ a search strategy
- ☒ inclusion/exclusion criteria
- ☒ a risk of bias assessment

For Yes:

As for partial yes, plus the protocol should be registered and should also have specified:

- ☒ a meta-analysis/synthesis plan, if appropriate, and
- ☐ a plan for investigating causes of heterogeneity
- ☐ justification for any deviations from the protocol

- ☐ Yes
- ☒ Partial Yes
- ☐ No

3. Did the review authors explain their selection of the study designs for inclusion in the review?

For Yes, the review should satisfy ONE of the following:

- ☐ Explanation for including only RCTs
- ☐ OR Explanation for including only NRSI
- ☐ OR Explanation for including both RCTs and NRSI

- ☐ Yes
- ☒ No

4. Did the review authors use a comprehensive literature search strategy?

For Partial Yes (all the following):

- ☒ searched at least 2 databases (relevant to research question)

For Yes, should also have (all the following):

- ☐ searched the reference lists / bibliographies of included studies

- ☒ Yes
- ☐ Partial Yes



- | | | |
|--|---|-----------------------------|
| ☒ provided key word and/or search strategy | ☒ searched trial/study registries | ☐ No |
| ☐ justified publication restrictions (e.g. language) | ☒ included/consulted content experts in the field | |
| | ☒ where relevant, searched for grey literature | |
| | ☒ conducted search within 24 months of completion of the review | |

5. Did the review authors perform study selection in duplicate?

For Yes, either ONE of the following:

- | | |
|---|--|
| ☐ at least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include | ☐ Yes |
| ☐ OR two reviewers selected a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder selected by one reviewer. | ☒ No |

6. Did the review authors perform data extraction in duplicate?

For Yes, either ONE of the following:

- | | |
|---|--|
| ☐ at least two reviewers achieved consensus on which data to extract from included studies | ☐ Yes |
| ☐ OR two reviewers extracted data from a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder extracted by one reviewer. | ☒ No |

7. Did the review authors provide a list of excluded studies and justify the exclusions?

For Partial Yes

- ☐
- provided a list of all potentially relevant studies that were read in full-text form but excluded from the review

For Yes, must also have:

- ☐
- Justified the exclusion from the review of each potentially relevant study

- ☐
- Yes
-
- ☒
- Partial Yes
-
- ☐
- No

8. Did the review authors describe the included studies in adequate detail?

For Partial Yes (ALL the following):

- ☒
- described populations
-
- ☒
- described interventions
-
- ☒
- described comparators
-
- ☒
- described outcomes
-
- ☒
- described research design

For Yes, should also have ALL the following:

- ☒
- described population in detail
-
- ☒
- described intervention in detail (including doses where relevant)
-
- ☒
- described comparator in detail (including doses where relevant)
-
- ☐
- described study's setting
-
- ☒
- timeframe for follow-up

- ☒
- Yes
-
- ☐
- Partial Yes
-
- ☐
- No

9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?

**RCTs**

For Partial Yes, must have assessed RoB from

- ☐ unconcealed allocation, and
- ☐ lack of blinding of patients and assessors when assessing outcomes (unnecessary for objective outcomes such as all- cause mortality)

For Yes, must also have assessed RoB from:

- ☐ allocation sequence that was not truly random, and
- ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome

- ☒ Yes
- ☐ Partial Yes
- ☐ No
- ☐ Includes only NRSI

NRSI

For Partial Yes, must have assessed RoB:

- ☐ from confounding, and
- ☐ from selection bias

For Yes, must also have assessed RoB:

- ☐ methods used to ascertain exposures and outcomes, and
- ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome

- ☐ Yes
- ☐ Partial Yes
- ☐ No
- ☐ Includes only RCTs

10. Did the review authors report on the sources of funding for the studies included in the review?

For Yes

- ☒ Must have reported on the sources of funding for individual studies included in the review. Note: Reporting that the reviewers looked for this information. No but it was not reported by study authors also qualifies

- ☒ Yes
- ☐ No

11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?**RCTs**

For Yes:

- ☒ The authors justified combining the data in a meta-analysis
- ☒ AND they used an appropriate weighted technique to combine study results and adjusted for heterogeneity if present.
- ☒ AND investigated the causes of any heterogeneity

- ☒ Yes
- ☐ No
- ☐ No meta-analysis conducted

For NRSI

For Yes:

- ☐ The authors justified combining the data in a meta-analysis
- ☐ AND they used an appropriate weighted technique to combine study results, adjusting for heterogeneity if present
- ☐ AND they statistically combined effect estimates from NRSI that were adjusted for confounding, rather than combining raw data, or justified combining raw data when adjusted effect estimates were not available

- ☐ Yes
- ☐ No
- ☐ No meta-analysis conducted



- ☐ AND they reported separate summary estimates for RCTs and NRSI separately when both were included in the review

12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?

For Yes:

- ☐ included only low risk of bias RCTs
☐ OR, if the pooled estimate was based on RCTs and/or NRSI at variable RoB, the authors performed analyses to investigate possible impact of RoB on summary estimates of effect.

- ☐ Yes
☒ No
☐ No meta-analysis conducted

13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?

For Yes:

- ☐ included only low risk of bias RCTs
☐ OR, if RCTs with moderate or high RoB, or NRSI were included the review provided a discussion of the likely impact of RoB on the results

- ☐ Yes
☒ No

14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?

For Yes:

- ☐ There was no significant heterogeneity in the results
☒ OR if heterogeneity was present the authors performed an investigation of sources of any heterogeneity in the results and discussed the impact of this on the results of the review

- ☒ Yes
☐ No

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?

For Yes:

- ☐ performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias

- ☐ Yes
☒ No
☐ No meta-analysis conducted

16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

For Yes:

- ☐ The authors reported no competing interests OR
☐ The authors described their funding sources and how they managed potential conflicts of interest

- ☒ Yes
☐ No

**Table 10 – Quality appraisal of HAS-HTA****Did the research questions and inclusion criteria for the review include the components of PICO?**

For Yes:

- ☒ Population
- ☒ Intervention
- ☒ Comparator group
- ☒ Outcome

Optional (recommended)

- ☒ Timeframe for follow-up

- ☒ Yes
- ☐ No

Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?

For Partial Yes:

The authors state that they had a written protocol or guide that included ALL the following:

- ☒ review question(s)
- ☒ a search strategy
- ☒ inclusion/exclusion criteria
- ☐ a risk of bias assessment

For Yes:

As for partial yes, plus the protocol should be registered and should also have specified:

- ☐ a meta-analysis/synthesis plan, if appropriate, and
- ☐ a plan for investigating causes of heterogeneity
- ☐ justification for any deviations from the protocol

- ☐ Yes
- ☒ Partial Yes
- ☐ No

Did the review authors explain their selection of the study designs for inclusion in the review?

For Yes, the review should satisfy ONE of the following:

- ☐ Explanation for including only RCTs
- ☐ OR Explanation for including only NRSI
- ☒ OR Explanation for including both RCTs and NRSI

- ☒ Yes
- ☐ No

Did the review authors use a comprehensive literature search strategy?

For Partial Yes (all the following):

- ☒ searched at least 2 databases (relevant to research question)
- ☒ provided key word and/or search strategy
- ☐ justified publication restrictions (e.g. language)

For Yes, should also have (all the following):

- ☐ searched the reference lists / bibliographies of included studies
- ☐ searched trial/study registries
- ☒ included/consulted content experts in the field
- ☒ where relevant, searched for grey literature
- ☒ conducted search within 24 months of completion of the review

- ☒ Yes
- ☐ Partial Yes
- ☐ No

**Did the review authors perform study selection in duplicate?**

For Yes, either ONE of the following:

- ☐ at least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include
- ☐ OR two reviewers selected a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder selected by one reviewer.

- ☐ Yes
- ☒ No

Did the review authors perform data extraction in duplicate?

For Yes, either ONE of the following:

- ☐ at least two reviewers achieved consensus on which data to extract from included studies
- ☐ OR two reviewers extracted data from a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder extracted by one reviewer.

- ☐ Yes
- ☒ No

Did the review authors provide a list of excluded studies and justify the exclusions?

For Partial Yes

- ☐ provided a list of all potentially relevant studies that were read in full-text form but excluded from the review

For Yes, must also have:

- ☐ Justified the exclusion from the review of each potentially relevant study

- ☐ Yes
- ☐ Partial Yes
- ☒ No

Did the review authors describe the included studies in adequate detail?

For Partial Yes (ALL the following):

- ☒ described populations
- ☒ described interventions
- ☒ described comparators
- ☒ described outcomes
- ☒ described research design

For Yes, should also have ALL the following:

- ☒ described population in detail
- ☐ described intervention in detail (including doses where relevant)
- ☐ described comparator in detail (including doses where relevant)
- ☐ described study's setting
- ☒ timeframe for follow-up

- ☒ Yes
- ☐ Partial Yes
- ☐ No

Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?

RCTs

For Partial Yes, must have assessed RoB from

- ☐ unconcealed allocation, and

For Yes, must also have assessed RoB from:

- ☐ allocation sequence that was not truly random, and
- ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome

- ☐ Yes
- ☐ Partial Yes
- ☐ No
- ☒ Includes only NRSI



- ☐ lack of blinding of patients and assessors when assessing outcomes (unnecessary for objective outcomes such as all- cause mortality)

For Yes, must also have assessed RoB:

NRSI

For Partial Yes, must have assessed RoB:

- ☒ from confounding, and
☒ from selection bias

- ☒ methods used to ascertain exposures and outcomes, and
☐ selection of the reported result from among multiple measurements or analyses of a specified outcome

- ☒ Yes
☐ Partial Yes
☐ No
☐ Includes only RCTs

Did the review authors report on the sources of funding for the studies included in the review?

For Yes

- ☐ Must have reported on the sources of funding for individual studies included in the review. Note: Reporting that the reviewers looked for this information. No but it was not reported by study authors also qualifies

- ☐ Yes
☒ No

If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?

RCTs

For Yes:

- ☐ The authors justified combining the data in a meta-analysis
☐ AND they used an appropriate weighted technique to combine study results and adjusted for heterogeneity if present.
☐ AND investigated the causes of any heterogeneity

- ☐ Yes
☐ No
☒ No meta-analysis conducted

For NRSI

For Yes:

- ☐ The authors justified combining the data in a meta-analysis
☐ AND they used an appropriate weighted technique to combine study results, adjusting for heterogeneity if present
☐ AND they statistically combined effect estimates from NRSI that were adjusted for confounding, rather than combining raw data, or justified combining raw data when adjusted effect estimates were not available
☐ AND they reported separate summary estimates for RCTs and NRSI separately when both were included in the review

- ☐ Yes
☐ No
☒ No meta-analysis conducted

If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?

For Yes:

- ☐ included only low risk of bias RCTs

- ☐ Yes



- ☐ OR, if the pooled estimate was based on RCTs and/or NRSI at variable RoB, the authors performed analyses to investigate possible impact of RoB on summary estimates of effect.

- ☐ No
☒ No meta-analysis conducted

Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?

For Yes:

- ☐ included only low risk of bias RCTs
☐ OR, if RCTs with moderate or high RoB, or NRSI were included the review provided a discussion of the likely impact of RoB on the results

- ☒ Yes
☐ No

Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?

For Yes:

- ☐ There was no significant heterogeneity in the results
☒ OR if heterogeneity was present the authors performed an investigation of sources of any heterogeneity in the results and discussed the impact of this on the results of the review

- ☒ Yes
☐ No

If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?

For Yes:

- ☐ performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias

- ☐ Yes
☐ No
☐ No meta-analysis conducted

Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

For Yes:

- ☐ The authors reported no competing interests OR
☐ The authors described their funding sources and how they managed potential conflicts of interest

- ☒ Yes
☐ No



APPENDIX 4. SEARCH STRINGS FOR RETRIEVAL OF CLINICAL STUDIES AND SYSTEMATIC REVIEWS

Appendix 4.1. MEDLINE

Date	September 02, 2020	
Database	Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to September 02, 2020>	
1	Defibrillators, Implantable/	16486
2	exp Cardiac Pacing, Artificial/	24794
3	exp Pacemaker, Artificial/	27262
4	1 or 2 or 3	58303
5	((cardiac or cardiovascular or cardio vascular) adj2 implant* adj2 electronic).ti,ab,kf.	1592
6	(cardiac resynchroni#ation adj2 (therap* or defibrillator* or device*)).ti,ab,kf.	7747
7	(Implant* adj1 (cardiac or cardioverter) adj1 (defibrillator* or device*)).ti,ab,kf.	13858
8	((implant* or dual chamber or biventricular or ventricular) adj1 defibrillator*).ti,ab,kf.	3895
9	pacemaker?.ti,ab,kf.	38232
10	biventricular pacing.ab,ti,kf.	1672
11	(ventricular resynchroni#ation adj2 (therap* or defibrillator* or device*)).ti,ab,kf.	28
12	(biventricular resynchroni#ation adj2 (therap* or defibrillator* or device*)).ti,ab,kf.	13
13	(atrial resynchroni#ation adj2 (therap* or defibrillator* or device*)).ti,ab,kf.	7
14	(CRT-D or CRT-Ds).ti,ab,kf.	954
15	(CRT-P or CRT-Ps).ti,ab,kf.	466
16	(ICD or ICDs).ti,ab,kf.	36973
17	(CIED or CIEDs).ti,ab,kf.	1008
18	5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17	86833
19	4 or 18	110729
20	Monitoring, Physiologic/	54801



21	Monitoring, Ambulatory/	8144
22	exp Telemetry/	13341
23	exp Telecommunications/	93122
24	Internet/	73201
25	20 or 21 or 22 or 23 or 24	217610
26	((remote or remotely) adj1 monitor*).ti,ab,kf.	2614
27	home monitor*.ti,ab,kf.	1912
28	((remote or remotely) adj2 (followup* or follow up*)).ti,ab,kf.	216
29	((remote or remotely) adj1 (interrogat* or manag* or notification* or patient monitor* or rhythm monitor* or data transmi*)).ti,ab,kf.	571
30	telemonitor*.ti,ab,kf,jw.	1631
31	tele-monitor*.ti,ab,kf,jw.	155
32	telemedicine.ti,ab,kf.	13661
33	tele-medicine.ti,ab,kf.	134
34	telecardio*.ti,ab,kf.	277
35	tele-cardio*.ti,ab,kf.	24
36	teleconsult*.ti,ab,kf.	1299
37	tele-consult*.ti,ab,kf.	103
38	telemetry.ti,ab,kf.	7309
39	26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38	27200
40	25 or 39	229165
41	19 and 40	2994
42	Cardiomessenger*.ti,ab,kf.	2
43	CareLink*.ti,ab,kf.	109
44	(Latitude* adj2 (patient management system* or remote monitor*)).ti,ab,kf.	13
45	Smartview*.ti,ab,kf.	1
46	Merlin?home*.ti,ab,kf.	1
47	Merlin?net*.ti,ab,kf.	9



48	(home monitor* system* adj3 biotronic).ti,ab,kf.	3
49	remote cardiac monitor*.ti,ab,kf.	10
50	42 or 43 or 44 or 45 or 46 or 47 or 48 or 49	145
51	41 or 50	3070
52	limit 51 to yr="2017-2020"	545
53	((systematic review or systematic literature review or systematic scoping review or systematic narrative review or systematic qualitative review or systematic evidence review or systematic quantitative review or systematic meta-review or systematic critical review or systematic mixed studies review or systematic mapping review or systematic cochrane review or "systematic search and review" or systematic integrative review).ti. not comment.pt. not (protocol or protocols).ti. not medline.st.) or (Cochrane Database Syst Rev.ja. and review.pt.) or systematic review.pt.	165172
54	meta-analys*.ti.	112653
55	meta-analysis.pt.	119074
56	exp Technology Assessment, Biomedical/	11151
57	health technology assessment.ti,kf.	1975
58	HtA.ti,kf.	603
59	53 or 54 or 55 or 56 or 57 or 58	260349
60	52 and 59	13
61	randomized controlled trial.pt.	512309
62	controlled clinical trial.pt.	93824
63	randomized.ti,ab.	531171
64	placebo.ti,ab.	216410
65	clinical trials as topic/	192774
66	randomly.ti,ab.	341007
67	trial?.ti.	298534
68	61 or 62 or 63 or 64 or 65 or 66 or 67	1345276
69	exp animal/ not humans/	4730642
70	68 not 69	1239612
71	52 and 70	74



Comments

Appendix 4.2. EMBASE

Date	4 Sep 2020	
Database	Embase.com	
#1	'cardiac implantable electronic device'/exp	54593
#2	'heart pacing'/exp	43241
#3	'artificial heart pacemaker'/exp	40584
#4	#1 OR #2 OR #3	122198
#5	((cardiac OR cardiovascular OR 'cardio vascular') NEAR/2 implant* NEAR/2 electronic):ab,ti,tn,kw,dn	2675
#6	('cardiac resynchroni\$ation' NEAR/2 (therap* OR defibrillator* OR device*)):ab,ti,tn,kw,dn	14826
#7	(implant* NEAR/1 (cardiac OR cardioverter) NEAR/1 (defibrillator* OR device*)):ab,ti,tn,kw,dn	21665
#8	((implant* OR 'dual chamber' OR biventricular OR ventricular) NEAR/1 defibrillator*):ab,ti,tn,kw,dn	5707
#9	pacemaker?:ab,ti,tn,kw,dn	13929
#10	'biventricular pacing':ab,ti,tn,kw,dn	2977
#11	('ventricular resynchroni\$ation' NEAR/2 (therap* OR defibrillator* OR device*)):ab,ti,tn,kw,dn	51
#12	('biventricular resynchroni\$ation' NEAR/2 (therap* OR defibrillator* OR device*)):ab,ti,tn,kw,dn	39
#13	('atrial resynchroni\$ation' NEAR/2 (therap* OR defibrillator* OR device*)):ab,ti,tn,kw,dn	14
#14	'crt d':ab,ti,tn,kw,dn OR 'crt ds':ab,ti,tn,kw,dn	3406
#15	'crt p':ab,ti,tn,kw,dn OR 'crt ps':ab,ti,tn,kw,dn	1515
#16	icd:ab,ti,tn,kw,dn OR icds:ab,ti,tn,kw,dn	81666
#17	cied:ab,ti,tn,kw,dn OR cieds:ab,ti,tn,kw,dn	2027
#18	#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17	118220
#19	#4 OR #18	203934
#20	'physiologic monitoring'/de	4945
#21	'ambulatory monitoring'/de	11455



#22	'home monitoring'/de	4625
#23	'self monitoring'/de	7789
#24	'patient monitoring'/de	89094
#25	'telemedicine'/exp	41763
#26	'telemetry'/exp	30029
#27	'internet'/de	108789
#28	#20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27	286979
#29	((remote OR remotely) NEAR/1 monitor*):ab,ti,tn,kw,dn	4526
#30	'home monitor*':ab,ti,tn,kw,dn	3092
#31	((remote OR remotely) NEAR/2 (followup* OR 'follow up*')):ab,ti,tn,kw,dn	473
#32	((remote OR remotely) NEAR/1 ('notification*' OR interrogat* OR manag* OR 'patient monitor*' OR 'rhythm monitor*' OR 'data transmi*')):ab,ti,tn,kw,dn	892
#33	telemonitor*':ab,ti,tn,kw,dn	2735
#34	'tele monitor*':ab,ti,tn,kw,dn	303
#35	telemedicine:ab,ti,tn,kw,dn	18424
#36	'tele medicine':ab,ti,tn,kw,dn	276
#37	telecardio*':ab,ti,tn,kw,dn	424
#38	'tele cardio*':ab,ti,tn,kw,dn	35
#39	teleconsult*':ab,ti,tn,kw,dn	1784
#40	'tele consult*':ab,ti,tn,kw,dn	192
#41	telemetry:ab,ti,tn,kw,dn	11816
#42	#29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41	39981
#43	#28 OR #42	295461
#44	#19 AND #43	5369
#45	cardiomessenger*':ab,ti,tn,kw,dn	20
#46	carelink*':ab,ti,tn,kw,dn	542
#47	(latitude* NEAR/2 ('patient management system*' OR 'remote monitor*')):ab,ti,tn,kw,dn	73



#48	smartview*:ab,ti,tn,kw,dn	18
#49	merlin?home*:ab,ti,tn,kw,dn	0
#50	merlin?net*:ab,ti,tn,kw,dn	0
#51	('home monitor* system*' NEAR/3 biotronic):ab,ti,tn,kw,dn	19
#52	'remote cardiac monitor*':ab,ti,tn,kw,dn	27
#53	#45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52	681
#54	#41 OR #53	12485
#55	#54 AND [2017-2020]/py	2646
#56	#55 NOT [medline]/lim	1529
#57	#56 NOT ('conference abstract'/it OR 'conference paper'/it OR 'conference review'/it)	251
#58	#57 AND ('meta-analysis'/exp OR 'meta-analysis' OR 'systematic review'/exp OR 'systematic review')	4
#59	#57 AND (random*:ab,ti OR placebo*:de,ab,ti OR ((double NEXT/1 blind*):ab,ti))	17
Comments		

Appendix 4.3. CINAHL

Date	Thursday, September 10, 2020 6:22:10 AM	
Database	Cinahl	
S1	(MH "Defibrillators, Implantable")	10,078
S2	(MH "Cardiac Pacing, Artificial+")	9,035
S3	(MH "Pacemaker, Artificial+")	7,567
S4	S1 or S2 or S3	21,727
S5	TI ((cardiac or cardiovascular or cardio vascular) N2 implant* N2 electronic N2 device*) OR AB ((cardiac or cardiovascular or cardio vascular) N2 implant* N2 electronic N2 device*)	800
S6	TI ((cardiac resynchroni#ation N2 (therap* or defibrillator* or device*))) OR AB ((cardiac resynchroni#ation N2 (therap* or defibrillator* or device*)))	3,954
S7	TI ((Implant* N1 (cardiac or cardioverter) N1 (defibrillator* or device*))) OR AB ((Implant* N1 (cardiac or cardioverter) N1 (defibrillator* or device*)))	7,265



S8	TI (((implant* or dual chamber or biventricular or ventricular) N1 defibrillator*)) OR AB (((implant* or dual chamber or biventricular or ventricular) N1 defibrillator*))	7,388
S9	TI pacemaker# OR AB pacemaker#	8,523
S10	TI ((CRT-D or CRT-Ds)) OR AB ((CRT-D or CRT-Ds))	481
S11	TI ((CRT-P or CRT-Ps)) OR AB ((CRT-P or CRT-Ps))	4,624
S12	TI ((ICD or ICDs)) OR AB ((ICD or ICDs))	6,716
S13	TI ((CIED or CIEDs)) OR AB ((CIED or CIEDs))	461
S14	S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13	24,210
S15	S4 or S14	32,467
S16	(MH "Monitoring, Physiologic")	21,245
S17	(MH "Electrocardiography, Ambulatory")	3,105
S18	(MH "Telemetry+")	2,008
S19	(MH "Telecommunications+")	135,717
S20	(MH "Internet")	49,423
S21	S16 OR S17 OR S18 OR S19 OR S20	159,456
S22	TI (((remote or remotely) N1 monitor*)) OR AB (((remote or remotely) N1 monitor*))	1,340
S23	TI home monitor* OR AB home monitor*	2,801
S24	TI (((remote or remotely) N2 (followup* or follow up*))) OR AB (((remote or remotely) N2 (followup* or follow up*)))	93
S25	TI (((remote or remotely) N1 (interrogat* or manag* or notification* or patient monitor* or rhythm monitor* or data transmi*))) OR AB (((remote or remotely) N1 (interrogat* or manag* or notification* or patient monitor* or rhythm monitor* or data transmi*)))	594
S26	TI telemonitor* OR AB telemonitor*	799
S27	TI tele-monitor* OR AB tele-monitor*	54
S28	TI telemedicine OR AB telemedicine	5,233
S29	TI tele-medicine OR AB tele-medicine	39
S30	TI telecardio* OR AB telecardio*	76
S31	TI tele-cardio* OR AB tele-cardio*	4
S32	TI teleconsult* OR AB teleconsult*	444



S33	TI tele-consult* OR AB tele-consult*	37
S34	TI telemetry OR AB telemetry	1,410
S35	S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34	11,630
S36	S21 or S35	164,176
S37	S15 and S36	1,673
S38	TI Cardiomessenger* OR AB Cardiomessenger*	1
S39	TI CareLink* OR AB CareLink*	79
S40	TI ((Latitude* N2 (patient management system* or remote monitor*))) OR AB ((Latitude* N2 (patient management system* or remote monitor*)))	11
S41	TI Smartview* OR AB Smartview*	1
S42	TI Merlin#home* OR AB Merlin#home*	0
S43	TI Merlin#net* OR AB Merlin#net*	4
S44	TI (home monitor* system* N3 biotronic) OR AB (home monitor* system* N3 biotronic)	2
S45	TI remote cardiac monitor* OR AB remote cardiac monitor*	80
S46	S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45	171
S47	S37 or S46	1,752
S48	S47 - Published Date: 20170101-20201231	366
S49	S48 - Exclude MEDLINE records	176
S50	S49 - Peer Reviewed	167
S51	(TI (systematic* n3 review*)) or (AB (systematic* n3 review*)) or (TI (systematic* n3 bibliographic*)) or (AB (systematic* n3 bibliographic*)) or (TI (systematic* n3 literature)) or (AB (systematic* n3 literature)) or (TI (comprehensive* n3 literature)) or (AB (comprehensive* n3 literature)) or (TI (comprehensive* n3 bibliographic*)) or (AB (comprehensive* n3 bibliographic*)) or (TI (integrative n3 review)) or (AB (integrative n3 review)) or (JN "Cochrane Database of Systematic Reviews") or (TI (information n2 synthesis)) or (TI (data n2 synthesis)) or (AB (information n2 synthesis)) or (AB (data n2 synthesis)) or (TI (data n2 extract*)) or (AB (data n2 extract*)) or (TI (medline or pubmed or psyclit or cinahl or (psycinfo not "psycinfo database") or "web of science" or scopus or embase)) or (AB (medline or pubmed or psyclit or cinahl or (psycinfo not "psycinfo database") or "web of science" or scopus or embase)) or (MH "Systematic Review") or (MH "Meta Analysis") or (TI (meta-analy* or metaanaly*)) or (AB (meta-analy* or metaanaly*))	208,137



S52	(S50 AND S51)	2
S53	((MH randomized controlled trials) OR (MH double-blind studies) OR (MH single-blind studies) OR (MH random assignment) OR (MH pretest-posttest design) OR (MH cluster sample) OR (TI (randomised OR randomized)) OR (AB random*) OR (TI trial) OR ((MH sample size) AND (AB (assigned OR allocated OR control))) OR (MH placebos) OR (PT randomized controlled trial) OR (AB control W5 group) OR (MH crossover design) OR (MH comparative studies) OR (AB cluster W3 RCT)) NOT (((MH animals+) OR (MH animal studies) OR (TI animal model*)) NOT MH (human))	742,084
S54	((((MH randomized controlled trials) OR (MH double-blind studies) OR (MH single-blind studies) OR (MH random assignment) OR (MH pretest-posttest design) OR (MH cluster sample) OR (TI (randomised OR randomized)) OR (AB random*) OR (TI trial) OR ((MH sample size) AND (AB (assigned OR allocated OR control))) OR (MH placebos) OR (PT randomized controlled trial) OR (AB control W5 group) OR (MH crossover design) OR (MH comparative studies) OR (AB cluster W3 RCT)) NOT (((MH animals+) OR (MH animal studies) OR (TI animal model*)) NOT MH (human))) AND (S50 AND S53)	16
Comments		

Appendix 4.4. Cochrane Library

Date	04/09/2020 18:25:13	
Database	Cochrane@Wiley.com	
#1	[mh ^"Defibrillators, Implantable"]	963
#2	[mh "Cardiac Pacing, Artificial"]	1421
#3	[mh "Pacemaker, Artificial"]	717
#4	#1 or #2 or #3	2419
#5	((cardiac or cardiovascular or "cardio vascular") NEAR/2 implant* NEAR/2 electronic):ab,ti	135
#6	((("cardiac resynchronisation" or "cardiac resynchronization") NEAR/2 (therap* or defibrillator* or device*)):ab,ti	1344
#7	(Implant* NEAR/1 (cardiac or cardioverter) NEAR/1 (defibrillator* or device*)):ab,ti	1586
#8	((implant* or "dual chamber" or biventricular or ventricular) NEAR/1 defibrillator*):ab,ti	628
#9	pacemaker?:ab,ti	2466
#10	"biventricular pacing":ab,ti	332
#11	((("ventricular resynchronization" or "ventricular resynchronisation") NEAR/2 (therap* or defibrillator* or device*)):ab,ti	9
#12	((("biventricular resynchronization" or "biventricular resynchronisation") NEAR/2 (therap* or defibrillator* or device*)):ab,ti	1
#13	((("atrial resynchronization" or "atrial resynchronisation") NEAR/2 (therap* or defibrillator* or device*)):ab,ti	0



#14	(CRT-D or CRT-Ds):ab,ti	426
#15	(CRT-P or CRT-Ps):ab,ti	163
#16	(ICD or ICDs):ab,ti	4099
#17	(CIED or CIEDs):ab,ti	120
#18	#5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17	7981
#19	#4 or #18	8501
#20	[mh ^"Monitoring, Physiologic"]	2189
#21	[mh ^"Monitoring, Ambulatory"]	538
#22	[mh "Telemetry"]	278
#23	[mh "Telecommunications"]	6305
#24	[mh ^"Internet"]	3765
#25	#20 or #21 or #22 or #23 or #24	11738
#26	((remote or remotely) NEAR/1 monitor*):ab,ti	696
#27	home NEXT/1 monitor*:ab,ti	552
#28	((remote or remotely) NEAR/2 (followup* or "follow up" or "follow ups")):ab,ti	92
#29	((remote or remotely) NEAR/1 (interrogat* or manag* or notification* or (patient NEXT/1 monitor*) or (rhythm NEXT/1 monitor*) or (data NEXT/1 transmi*))):ab,ti	142
#30	telemonitor*:ab,ti	914
#31	tele-monitor*:ab,ti	84
#32	telemedicine:ab,ti	1520
#33	tele-medicine:ab,ti	29
#34	telecardio*:ab,ti	22
#35	tele-cardio*:ab,ti	6
#36	teleconsult*:ab,ti	125
#37	tele-consult*:ab,ti	26
#38	telemetry:ab,ti	394
#39	#26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38	3816



#40	#25 or #39	14693
#41	#19 and #40	361
#42	Cardiomessenger*:ab,ti	0
#43	CareLink*:ab,ti	68
#44	(Latitude* NEAR/2 ("patient management" NEXT/1 system*) or (remote NEXT/1 monitor*)):ab,ti	3
#45	Smartview*:ab,ti	1
#46	Merlin?home*:ab,ti	1
#47	Merlin?net*:ab,ti	2
#48	((((home NEXT/1 monitor*) NEXT/1 system*) NEAR/3 biotronic):ab,ti	4
#49	("remote cardiac" NEXT/1 monitor*):ab,ti	3
#50	#42 or #43 or #44 or #45 or #46 or #47 or #48 or #49	82
#51	#41 or #50	417
#52	#51 with Cochrane Library publication date Between Jun 2017 and Dec 2020, in Cochrane Reviews	1
#53	#51 with Publication Year from 2017 to 2020, in Trials	110
Comments		



APPENDIX 5. COMPARISON OF SYSTEMATIC LITERATURE REVIEWS ON ICD OR CRT-D

ICD, CRT-D	Jang 2020 ⁵	Alotaibi 2020 ⁶	Ontario HTA 2018 ¹	Sequeira 2020 ⁷	IQWiG 2019 ⁸
Patients	Adults with (1) ICD, CRT or PM or (2) wearable devices (e.g. remote-guided anticoagulation therapy)	Adults (age ≥ 18 years old) with diagnosis of HF with (1) ICD or CRT or (2) implanted hemodynamic monitoring systems	Adults implanted with ICD, CRT, or PM	Adults implanted with ICD or CRT	NR
Intervention	RM	RM	RM	RM	RM
Control	Standard monitoring	Standard monitoring	Standard monitoring	Standard monitoring	Standard monitoring
Outcomes	- atrial arrhythmia detection or - incidence of stroke; stroke, mortality, and bleeding for anticoagulation	all-cause mortality and heart failure (HF)-related hospitalization	- ICD shocks (total, appropriate, and inappropriate) - Arrhythmias (pacemaker recipients) - Time to detection of medical events - Time from detected medical events to clinical decisions - Worsening of heart failure NYHA functional class - Percentage of respondents to CRT - Stroke - Mortality (all-cause and cardiovascular) - Quality of life - Number of clinic visits (total, scheduled, and unscheduled) - Hospitalizations (all-cause, heart failure/cardiovascular)	- All-cause mortality, cardiovascular (CV) mortality - Major cardiovascular adverse events (MCVAE) (hospitalizations, stroke, surgery) - composite clinical endpoints - QoL outcomes, including EQ-5D, SF-36, quality-adjusted life year (QALY), and Minnesota Living with Heart Failure Questionnaire - costs, including annual costs per patient/year and labour costs for RM management	NR



			• Emergency department visits • Length of hospital stay • Remote monitoring system malfunction or issues with transmission of data or alerts • Patient adherence		
			Adverse events		
Search date	February 2020	June 2019	November 2018	February 2018	August 2017
Studies included					NR
Abraham 2016⁹	-	+ ^a	-	-	NR
Adamson 2011¹⁰	-	+ ^b	-	-	NR
Al-Khatib 2010¹¹	+	+	+	+	NR
Bohm 2016¹²	-	-	+	+	NR
Boriani 2013¹³	+	-	-	+ ^c	NR
Boriani 2017¹⁴	-	+	+	+	NR
Bourge 2008¹⁵	-	+ ^d	-	-	NR
Bulava 2016^e	-	-	-	+ ^f	NR
Calo 2013¹⁷	-	-	+	+	NR

^a Only 66% of patients had either a CRT-D or ICD in the remote monitoring group. Measured parameters by the device: pressure in pulmonary artery

^b "The trial was designed to enroll 1300 patients, but stopped at 400 patients because of IHM lead failures experienced from previous trials. A total of 202 treatment patients and 198 controls were randomized for 12-month follow-up. The primary safety end point was met, but the rate of HF equivalents was not different between groups. REDUCEhf was unable to test clinical efficacy end points adequately". Measured parameters by the device: right ventricle pressure

^c Presented preliminary results of MORE-CARE trial (Boriani 2017)

^d Patients were excluded if "they were presently implanted with an incompatible pacemaker or implantable cardioverter-defibrillator (ICD); were receiving cardiac resynchronization therapy (CRT) that had not achieved optimal programming for 3 months" Measured parameters by the device: right ventricle pressure

^e Bulava A, Osmera O, Snorek M, Novotny A, Dusek L. Cost analysis of telemedicine monitoring of patients with implantable cardioverter-defibrillators in the Czech Republic. *Cor Vasa* 2016;58:e293–10.

^f cost-analysis of study by Osmera et al. 2014, included also in Ontario-HTA¹⁶



Caravati 2013^g	-	-	-	+ ^h	
Crossley 2009 & 2011^{18, 19}	+	-	+	+	NR
Domenichini 2015²⁰	-	+ ⁱ	-	-	NR
Guedon-Moreau 2013 & 2014^{21, 22}	+	-	+	+	NR
Hansen 2018²³	-	+ ^j	-	-	NR
Heidbuchel 2015²⁴	-	-	+	+	NR
Hindrick 2014²⁵	-	+	+	+	
Landolina 2012²⁶	+	+	+	+	
Luthje 2015²⁷	-	+	+	+	
Morgan 2017²⁸	-	+	+	+	
Osmera 2014¹⁶	-	-	+	+	
Perl 2013²⁹	+	-	+	-	
Sardu 2016³⁰	+	-	+	-	
Van Veldhuisen 2011³¹	-	+	-	+ ^k	
Varma 2010³²	+	+	+	+	
Zabel 2017^{33, 34}	-	-	-	+ ^l	
Total	8	13	15	16	

^g Caravati FC, Zuffada F, Minoia C, Ponti R, Salerno-Uriarte JA. Cost saving and safety of ICD remote monitoring in the “real world”: a single centre experience. EHRA Europace; 2013;15(Suppl 2):ii206. Athens, Greece: Europace

^h only a conference proceedings is available (https://academic.oup.com/europace/article/15/suppl_2/ii171/519979)

ⁱ Only 61% (25/41) had a CRT-D and 63% had remote monitoring. Measured parameters by the device: lung impedance

^j This RCT was published in 2018 and not included in Ontario-HTA. It is included in our update of the literature review.

^k The trial does not compare RM vs. in-clinic visits. “Patients were randomized between access arm using a management strategy with access to all device-based diagnostic information, including an audible patient alert for increased pulmonary fluid retention, or to a control arm in which this information and an alert were not available. Whenever there was a device alert, the protocol always required a patient-physician contact. From stored device data, it was assessed when an alert had occurred in the access arm or would have occurred in the control arm if the alert had been programmed “on.”

^l Only an abstract was available, published twice^{33, 34}



APPENDIX 6. PRIMARY STUDIES EXCLUDED ON FULL TEXT

Studies	Reasons for exclusion
Sequeira et al. 2020 ⁷	Systematic review including RCTs comparing RM to standard monitoring in ICD and CRT-D patients (i.e. no PM), with publication date between 01 January 2005 and 15 February 2018 (see Appendix 3 for differences with Ontario-HTA)
Alotaibi et al. 2020 ⁶	Systematic review including RCTs published up to 14th of October 2019. Patients included were limited to adults with diagnosis of heart failure and the outcomes were limited to all-cause mortality and heart failure (HF)-related hospitalization (see Appendix 3 for differences with Ontario-HTA)
Jang 2020 ⁵	Systematic review mixing implantable cardiac devices and wearable devices, and limited to measuring atrial arrhythmia detection or incidence of stroke (see Appendix 3 for differences with Ontario-HTA)
IQWiG ⁸	Systematic review focused on advanced cardiac failure; included only 4 studies; only available in German (see Appendix 3 for differences with Ontario-HTA)
Geller et al. 2019 ³⁵	No comparison of RM vs. standard monitoring. The study is a sub-analysis of the IN-TIME trial and compare outcomes between ICD and CRT-D subgroups
Garcia-Fernandez et al. 2019 ³⁶	The RM-Alone group compared remote monitoring + remote interrogations with remote monitoring + in-clinic visits
Timmermans et al. 2018 ³⁷	Reports binary satisfaction level (yes/no) of participants in the RM arm of the REMOTE-CIED RCT. "Of 244 patients who reported their follow-up preferences, 44% preferred RM, 16% preferred in-clinic, and 40% expressed no preference". Abstract only is available
Kurek et al. 2017 ³⁸	Not a RCT. "Complete patient demographics, medical history, in-hospital results, hospitalizations, and mortality data were collected based on institutional registries and healthcare providers' records. Patients were divided into 2 groups based on RM presence and matched by means of propensity scores according to clinical characteristics"
Husser et al. 2019 ³⁹	This study analyses the information flow and workflow details from the IN-TIME trial
Varma et al. 2018 ⁴⁰	This study reports on the transmission reliability and effects on battery longevity in the TRUST trial
Cheung et al. 2018 ⁴¹	This study examines the association between the duration of atrial arrhythmias and risk of thromboembolic events in the IMPACT trial
Zakeri et al. 2020 ⁴²	Sub-group analysis of the REM-HF trial (comparing outcomes in patients with paroxysmal atrial fibrillation vs. persistent/permanent vs. none; all patients had RM)
Lopez-Villegas et al. 2019 ⁴³	This is a non-randomised, non-masked clinical trial
Zabel et al. 2017 ^{33, 34}	Only an abstract is available (published twice)

RM: Remote Monitoring



APPENDIX 7. RESULTS FROM PRIMARY STUDIES

This section presents the methods, the quality appraisal, and the outcomes from primary studies included for the update of Ontario-HTA

Appendix 7.1. RCTs on remote monitoring of ICDs or CRT-Ds

Appendix 7.1.1. RESULT trial

RESULT trial Tajstra et al. 2020 ⁴⁴	
Methods	Methods and outcomes
Methods	Prospective, single-centre, randomized, open label, parallel study
Participants	400 participants with mean age was 64 years; 81% were male. The majority of patients belonged to the NYHA Classification II or III. Patients were equipped with a ICD or CRT^m Inclusion criteria: symptomatic heart failure [New York Heart Association (NYHA) Class II–IV] documented at enrolment, with stable and optimal medical therapy for HF, a left ventricular ejection fraction of no more than 35%, the ability to independently comprehend and complete quality of life questionnaires and to give informed consent, with de novo implant of ICD or CRT-D implanted accordingly to European Society of Cardiology (ESC) current practice guidelines with wireless transmission capabilities within the last 4 weeks before enrolment. Exclusion criteria: Patients under 18 years of age, unable to use the technology due to mental or physical limitations, had a life expectancy of less than a year due to a non-cardiovascular disease or had current device complications (such as pocket infection, haematoma, lead fracture, etc.)
Interventions	Remote monitoring with 1 follow-up visit at 12 months after the patient's enrolment in the trial (but unscheduled visits could have been initiated either by the patient or by the supervising staff) (n=299) Of note, the monitoring staff included two physicians (a cardiology resident and a cardiology consultant) and two electrophysiology nurses, who daily analyse data derived from remote monitoring online systems and undertake adequate actions if necessary. A clinical response to remote alerts was triggered at the discretion of the monitoring staffⁿ.
Comparison	Standard monitoring with follow-up visits at 3, 6, 9, and 12 months after the patient's enrolment in the study (n=301)

^m Manufactured by four companies, equipped with remote monitoring systems: Carelink (Medtronic, USA), Merlin (Saint Jude Medical, USA), Latitude (Boston Scientific, USA), and Home Monitoring (Biotronik, Germany). The selection of the type of implanted device (regarding the manufacturer) remained at the discretion of the implanting physician.

ⁿ A clinical response to remote alerts was triggered at the discretion of the monitoring staff. When contacting patients on the basis of telemonitored data, telemonitoring staff held a standardized telephone interview to establish whether the patient's overall condition or dyspnoea had deteriorated, whether the patient's drugs compliance is effective, and whether the patient's weight had increased over the previous few days. The remote monitoring staff offered clinical and pharmacotherapy change and recommended contacting the family doctor, additional clinic visits, or urgent hospitalization. Unscheduled visits in both groups could have been initiated either by the patient or by the supervising staff.



Outcomes	Primary endpoint: composite of all-cause death and hospitalization due to cardiovascular reasons within 12 months after randomization. Hospitalization for cardiovascular reasons included: progression of HF; persistent arrhythmia; embolic episode; acute coronary syndrome. Secondary endpoints: all-cause death; hospitalization due to cardiovascular reasons; the average number of in-clinic visits (scheduled and unscheduled) per patient; the time to the first unscheduled visit in an outpatient clinic; the assessment of the quality of life of living study participants according to the Minnesota Quality of Life Questionnaire.
Analysis	The Student's t-test for continuous variables and the ch2 test with Yates' correction when appropriate for categorical variables were used. The difference in primary composite endpoint between groups was compared using the log-rank test and the Kaplan–Meier curves were drawn. Furthermore, the odds ratio (OR) with a 95% confidence interval (95% CI) was calculated. All analyses were performed on the basis of the intention-to-treat principle.
Results at month 12	• Primary endpoint: 39.5% vs. 48.5% (p=0.048) • All-cause mortality: 6% vs. 6% (p=0.9) • Hospitalisation due to cardiovascular reason: 37.1% vs. 45.5% (p=0.045) • Hospitalisation due to heart failure: 29.8% vs. 38.5%; OR=0.68 (95%CI: 0.48;0.95; p=0.029) • Myocardial infarction: 3.6% vs. 2.3% (p=0.46) • Ischaemic stroke: 1.3% vs. 0.7% (p=0.7) • In-clinic visits (scheduled/unscheduled), per patient-year: 2.5 vs 4.9 (p<0.001) • In-clinic visits (unscheduled), per patient-year: 2.1 vs. 1.5 (p=0.003) • Time to first out-patient visit, median (days): 48 vs. 54 (p=0.7) • Quality of life (Minnesota Quality of Life Questionnaire) at 12-month: 31.0 ±20.5 vs. 38.4±16.5 (p=0.33)
Notes	• At 12months after randomization, the transmission efficiency in the RM arm reached 86%. • Main benefits: less hospitalizations for heart failure and less in-clinic visits • Timeline was short to measure the primary endpoint • “investigators in the RESULT study have begun the evaluation of patients with HF and implanted ICD/CRT many years prior to the beginning of the trial. The authors deeply believe that the learning curve may be an important issue regarding the RC of CIEDs effectiveness” • No stratification by type of devices



RESULT trial Tajstra et al. 2020 ⁴⁴	Risk of bias	Support for judgement
Random sequence generation (selection bias)	Low	"All consecutive patients meeting inclusion criteria, after informed consent were prospectively randomized in a 1:1 fashion to either RM or clinic visits model via a centralized, concealed process designed by the manufacturer"
Allocation concealment (selection bias)	Low	See above
Blinding of participants and personnel (performance bias)	Unclear	No blinding was possible, open-labelled
Blinding of outcome assessment (detection bias)	Low	Hospitalisation and number of visits are hard outcomes
Incomplete outcome data (attrition bias)	Unclear	Up to 18% of participants either discontinued or were lost to follow-up; number are balanced across the 2 groups but individual characteristics are not provided
Selective reporting (reporting bias)	Low	Predefined outcomes. The trial was registered at www.clinicaltrials.gov under section NCT02409225.
Other bias		



Appendix 7.1.2. InContact trial

InContact trial Hansen et al. 2018 ⁴⁵	
Methods and outcomes	
Methods	Prospective, randomised, multicentre study conducted at 17 sites across Germany between 2010 and 2014. Patients were randomised 1:1 ratio into the 2 study arms. Participants in the control group were further randomized in 2 subgroups.
Participants	210 patients with new implantation of ICD or CRT-D^o with mean age 63.8 years, predominantly male (84.3%) (RM n=102; RM+phone n=53; CFU n=55), Inclusion criteria: age ≥ 18 and <80 years; ejection fraction $\leq 35\%$; New York Heart Association (NYHA) class I-III; sufficient home infrastructure to support the use of a Merlin@home™ transmitter. Exclusion criteria: second-degree Mobitz type II or third-degree atrioventricular block; severe renal insufficiency; a life expectancy < 12 months; pregnant; participating in a simultaneous study with an active therapy arm; experienced a myocardial infarction or undergone a coronary angiology in the 3 months prior to enrolment Overall, patients had a mean NYHA class of 2.3 ± 0.7 (42.9% NYHA III). The majority had ischemic cardiac disease (59.0%). The majority of patients received their ICD in a primary prevention setting (84.8%). The most frequently implanted device was a single chamber ICD (51.4%), followed by a CRT-D (32.4%) and dual-chamber ICD (16.2%).
Intervention	RM with quarterly automated follow-up via Merlin.net only (n=102)
Comparison ^p	1. RM with quarterly personal telephone calls with a physician/supporting nurse (remote+phone group; n=53) 2. Quarterly in-clinic visits only (visit group; n=55).
Outcomes	Primary endpoint: % of patients with a worse Packer score at month 13 compared to month 1. This composite outcome included HF-related death, hospitalisation, and deterioration of NYHA class or self-assessed health. Secondary endpoint: all-cause mortality; HF-hospitalisations; arrhythmias; unscheduled (in-clinic, telephone-based or remote) follow-ups, proportion of all follow-ups that had disease-relevant findings; number of delivered/appropriate ICD therapies; changes in QoL measured by the Minnesota Living with Heart Failure Questionnaire^q; adverse events
Analysis	For continuous variables, a t-test, Wilcoxon signed-rank test or Mann-Whitney U-test were used for two-way comparisons and a Kruskal-Wallis test for three-way comparisons. A chi-square test (or Fisher's exact test in the case of frequencies $< 5\%$) was used for comparing categorical variables. In cases where more than two subgroups were compared and the comparison was significant, Pairwise comparisons of the groups were carried out and p-values were adjusted using the Bonferroni method. To test for the non-inferiority of telemetry compared to personal contact, the 95% confidence interval (CI) for the difference in the proportions of patients

^o The most common ICD model was Fortify (36.2%) followed by Current + (18.1%) and Unify (12.4%). All other models were used at a frequency of $< 7\%$.

^p Participants in the control group were further randomized in 2 subgroups

^q The Minnesota Living with Heart Failure Questionnaire (MLHFQ) is a self-administered, disease-specific questionnaire composed of 21 items, each with a 6-point scale (0 = no impact of heart failure on QoL, 5 = a great deal of impact)



	with a worsened Packer outcome at 13-month follow-up was calculated. Where the lower bound of this 95% CI exceeded – 0.15, automated follow-up was considered non-inferior to personal contact.
Results at month 13 ^r	• Packer score improvement: 51.1% vs. 48.9%, p = 0.855 • Mortality: 4.9% vs. 5.6%, p = 0.832 • HF-hospitalisation: 9.8% vs. 12.0%, p=0.605 • ICD shocks: 8.8% vs. 8.3%, p=0.899 • Anti-tachycardia pacing: 15.7% vs. 13.0% (p=0.573) • Change in NYHA class: p=0.888 • Change in MLHFQ: p=0.472 • Unscheduled in-clinic visits per patient (mean±SD): 1.2 ± 2.6 vs. 0.9 ± 1.8 (p=0.550) • Stored tachycardia: 25% vs. 23% (p =0.579)
Notes	• Regardless of study group, daily automatic alarm checks were activated for all patients throughout the study period. • All patients attended an in-clinic visit at 1 month (±14 days) and 13 months (± 30 days) after ICD/CRT-D implantation, at which their Packer Heart Failure Clinical Composite Response score (Packer score) was determined, medication recorded, and QoL (MLHFQ) assessed. ICD/CRT-D function was then assessed for all patients at 4 and 7 months (± 14 days), either remotely or during the in-clinic appointment (visit group only). • The addition of a telephone call to quarterly automated follow-ups does not appear to be beneficial for improving outcomes

InContact trial Hansen et al. 2018 ⁴⁵	Risk of bias	Support for judgement
Random sequence generation (selection bias)	Unclear	No explanation given on the randomisation
Allocation concealment (selection bias)	Unclear	No explanation given on the randomisation
Blinding of participants and personnel (performance bias)	Unclear	Open-labelled
Blinding of outcome assessment (detection bias)	Low	No blinding + self-administered questionnaire, but unlikely for hard outcomes
Incomplete outcome data (attrition bias)	Unclear	10/102 lost to FU in RM group; 7/55 lost to FU in CFU. No explanation provided, nor characteristics presented.

^r We report here the results of the comparison between the RM with quarterly automated follow-up and both comparators together (RM with quarterly personal telephone calls and quarterly in-clinic visits only). Results are very similar if the comparator considered is only quarterly in-clinic visits. There was no difference neither when RM+quarterly personal phone call was compared to quarterly in-clinic visits only. No analysis was provided to compare RM+quarterly automated follow-up and RM+personal phone calls to the group of in-clinic visits only



Selective reporting (reporting bias)	Unclear	No study protocol is referenced
Other bias		

Appendix 7.1.3. INFRARED-ICD trial

INFRARED-ICD trial Leppert et al. 2020 ⁴⁶ Methods and outcomes	
Methods	Randomized controlled open-label trial (1 centre)
Participants	180 patients Inclusion criteria: patients ≥18 years with new implantation or replacement of a cardioverter–defibrillator (ICD) ^s Exclusion criteria: refusal to participate, insufficient language skills, inability to comply with the protocol, a history of severe psychiatric illness, or missing availability of a standard land phone line Characteristics: Study participants were mainly male (> 80% in both groups); 40.7% and 49.4% had a history of coronary artery disease in the RPM and CTL group, respectively, and the majority of participants (RPM 59.3% vs. CTL 63.0%) were provided with an ICD for primary prevention.
Interventions	RM in addition to the standard in-clinic visits every 3-6 months(n=92) ^t
Comparators	Standard in-clinic visits every 3-6 months (n=88)
Outcomes	Primary outcome: Quality of Life (QoL) measured by EQ-5D questionnaire at baseline and monthly during 1 year (postal survey) Secondary outcome: Hospital Anxiety and Depression Scale ^u ; Florida Patient Acceptance Survey ^v
Analysis	All analyses were conducted using univariate ANOVAs with repeated measurement and a Bonferroni post hoc test.

^s Medtronic n = 71; Biotronik n = 49; St. Jude Medical n = 34; and Boston Scientific n = 26

^t Except for the HomeMonitoring™ system (Biotronik™), that enabled daily automatic data transmission, the manual transmissions with the other RPM systems were scheduled in 3 month intervals.

^u Anxiety and Depression Scale (HADS). The HADS questionnaire consists of 14 items related to anxiety and depression in which patients respond using a 4-point Likert scale. Scores range from 0 to 21 points for both anxiety and depression. With respect to the subscales anxiety and depression, 0–7 indicates non-cases, 8–10 indicates doubtful cases, and 11–21 points indicates manifest depression/anxiety.⁴⁶

^v Device acceptance was measured using the 18-item Florida Patient Acceptance Survey (FPAS). A 5-point Likert scale was used, ranging from “strongly disagree” (1 point) to “strongly agree” (5 points). The 18 items contribute to four subscales: (1) return to function, (2) device-related distress, (3) positive appraisal, and (4) body image concerns. The three additional questions are filler items. A higher score indicates greater device acceptance. There are no absolute cut-off values for the FPAS, but based on a prior validation study, a score ≤ 65.5 is considered a correlate of poor device acceptance.⁴⁶



Results	- Mean change of QoL over 12 months: 3.9 points in RM vs. 1.2 points in SM (p=0.24) - No difference in Hospital Anxiety and Depression Scale ; No difference in Florida Patient Acceptance Survey
Notes	- Patients were blinded to their assigned study group for baseline assessment of patient-reported outcomes. - Patients with a missing response (defined as delay > 10 days in expected time of questionnaire return) were contacted by a study nurse (up to three reminder phone calls). After a maximum of three reminder calls without a response, this set of questionnaires was considered lost to follow-up. - There were 13 patients with no single questionnaire completed (RM group n=6; CFU group n=7). Moreover, in the RM group, only 62 of 86 patients (72%) were able to initialize the system by performing at least one successful transmission. So the group with true RM was 62 (vs 81 in the control group).

INFRARED-ICD trial Leppert et al. 2020 ⁴⁶	Risk of bias	Support for judgement
Random sequence generation (selection bias)	Low	“a block randomization provided by the Bielefeld University, the University of Munich was provided with the randomization result after successful enrollment of the patient.” Baseline values were similar between groups
Allocation concealment (selection bias)	Low	See above
Blinding of participants and personnel (performance bias)	Unclear	Not possible to blind patients and personnel
Blinding of outcome assessment (detection bias)	Low	Assessor-blinded analysis
Incomplete outcome data (attrition bias)	High	No data for 13 patients. No data on potential differences with remainders is provided. An intention-to-treat analysis was carried out (at least 1 questionnaire completed). However, the number of lost-to-follow up is balanced between the 2 trial groups. Moreover, only 62 of 86 patients (72%) were able to initialize the system by performing at least one successful transmission. No data on potential differences with remainders is provided. A per-protocol analysis was carried out.
Selective reporting (reporting bias)	Low	Pre-specified outcomes, research protocol registered in ClinicalTrials.gov (Identifier: NCT02888028)
Other bias		



Appendix 7.1.4. REMOTE-CIED trial

REMOTE-CIED trial Versteeg et al. Methods and outcomes 2019 ⁴⁷	
Methods	Multi-centered randomized trial (32 hospitals in 5 European countries)
Participants	595 European heart failure patients implanted with an ICD compatible with the Boston Scientific LATITUDEVR RPM system; mean age=65; 79% males; 33% NYHA Class III Inclusion criteria: (i) patients implanted with a first-time ICD (single chamber/dual chamber/biventricular) compatible with the LATITUDEVR Patient Management system from Boston Scientific and (ii) suffered from symptomatic heart failure (LVEF <_35% and New York Heart Association (NYHA) functional Class II or III) at the time of implantation. Exclusion criteria: (i) patients younger than 18 or older than 85 years of age, (ii) on the waiting list for heart transplantation, (iii) history of psychiatric illness other than affective/anxiety disorders, or (iv) were unable to complete the questionnaires due to cognitive impairments or (v) had insufficient knowledge of the language.
Interventions	RM with a yearly in-clinic ICD check-up (n=300). Intermediate check-ups were performed remotely at least every 6months (including a real-time electrocardiogram, tests of battery status, lead impedances, and sensing amplitude). During and in-between these scheduled check-ups, the clinics were notified when predefined RM alerts (e.g. low life battery, low/high shock lead impedance, device malfunction, arrhythmias, and weight change) or patient-initiated data transmissions were detected
Comparison	In-clinic visits every 3–6- month (n=295)
Outcomes	- Heart failure-specific health status measured by Kansas City Cardiomyopathy Questionnaire (KCCQ)^w (at 3, 6, 12 & 24 months) - ICD acceptance measured by Florida Patient Acceptance Survey (FPAS) (at 3, 6, 12 & 24 months).
Analysis	KCCQ and FPAS total and subscale follow-up scores between randomization groups were analysed using linear regression models with unstructured residual (i.e. generalized estimating equation type) covariance matrices
Results	No significant group differences in patients' health status (KCCQ; Beta coefficient=-2.9; p=0.29) and ICD acceptance (FPAS; Beta coefficient=1.2; p=0.68) were observed
Notes	The baseline FPAS score was significantly associated with ICD acceptance during follow-up (P<0.001)

^w The Kansas City Cardiomyopathy Questionnaire (KCCQ) is a 23-item, validated self-report questionnaire that quantifies physical limitations, symptoms, social functioning, and quality of life of patients with heart failure. These four health status subscales can be combined into a single overall summary score. The (sub)scale scores are transformed into a score from 0 to 100, with higher scores representing better health status. Poor health status is defined as a KCCQ overall summary score <50 points, and a 5-point difference represents a clinically meaningful difference between the groups and within individual patients



REMOTE-CIED trial Versteeg et al. 2019 ⁴⁷	Risk of bias	Support for judgement
Random sequence generation (selection bias)	Low	Patients were randomized in a 1:1 fashion to the RM group or In-Clinic group with the use of a blocked randomization procedure. To ensure that the relative percentage of ICD and cardiac resynchronization therapy defibrillator (CRT-D) patients was equal in both groups, a separate randomization procedure within these two subgroups of patients was used.
Allocation concealment (selection bias)	Low	
Blinding of participants and personnel (performance bias)	Unclear	No blinding, open-labelled
Blinding of outcome assessment (detection bias)	Unclear	No blinding, self-reported questionnaire
Incomplete outcome data (attrition bias)	Low	
Selective reporting (reporting bias)	Low	Study protocol registered at ClinicalTrials.gov (NCT01691586)
Other bias		



Appendix 7.2. RCTs on remote monitoring of pacemakers

Appendix 7.2.1. NORDLAND trial

NORDLAND trial ⁴⁸⁻⁵⁰	
Methods	Controlled, randomized, non-masked clinical trial in Nordland Hospital, Bodø, Norway
Participants	50 patients scheduled for implant with a pacemaker^x between August 2014 and October 2015 (follow-up until October 2016 ⁴⁹) The mean age was 75±12 years, and 52% of the patients were males. Inclusion criteria: patients ≥18 years; ability to give informed consent and to operate the home monitor; life expectancy > 1 year Exclusion criteria: patients scheduled for implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy (CRT); participation in other trials
Interventions	Remote Monitoring^y (n=25) (automatic routine transfers of data every three months)
Control	Standard monitoring (in-clinic visits)^z (n=25)
Outcomes	Primary outcome: Health-related quality of life (HRQoL) of the users with pacemakers was assessed through the Norwegian version EuroQol-5D and the self-rated HRQoL was analyzed through of the EQ-5D Visual Analogue Scale (EQ-5D-VAS) Secondary outcomes: Norwegian version of the Minnesota Living with Heart Failure Questionnaire ^{aa} (MLHFQ); Cardiovascular events (AE), including exitus, percutaneous coronary intervention, angina and lead dislodgement; monitoring visits and

^x Depending on their diagnosis, patients were implanted with either a single (VVIR) or a dual chamber (DDDR) pacemaker

^y Telemonitoring (Biotronik Estella SR-T/ DR-T or a Biotronik Evia SR-T/ DR-T home monitored by Biotronik Home Monitoring® system with data transmission from the implant to a wireless patient device, the CardioMessenger). "Every night, the CardioMessenger automatically collects and transmits important, encrypted health information to the Biotronik service center using the global network of T-Mobile and its partners (GPRS). The transmitted patient data is collected, automatically analysed and filtered at the Biotronik Home Monitoring Service Center, according to patients'needs as defined by their physician. Health and system-related issues are ranked and marked in order of importance. All event and trend reports can be accessed and reviewed on a protected online platform. Furthermore, according to pre-set definitions, the physician can receive automatic warnings (e.g. by e-mail or text message) concerning safety issues such as premature battery depletion, lead fracture etc."

^z Hospital monitoring (Biotronik Estella SR-T/ DR-T or a Biotronik Evia SR-T/ DR-T or St Jude Medical or Endurity SR/DR or a Sorin Reply 200 SR/DR)

^{aa} The Minnesota Living with Heart Failure Questionnaire consists of 21 important physical, emotional and socioeconomic ways heart failure can adversely affect a patient's life. the patient marks a 0 (zero) to 5 scale to indicate how much each itemized adverse of heart failure has prevented the patient from living as he or she wanted to live during the past 4 weeks. The questionnaire is simply scored by summation of all 21 responses <https://license.umn.edu/product/minnesota-living-with-heart-failure-questionnaire-mlhfg>



	transmissions from home vs. hospital; changes of medication and pacemakers reprogramming; Generic Short Patient Experiences Questionnaire (GS-PEQ ^{bb}) + questions from the telehealth patient satisfaction survey; costs ⁴⁸
Analysis	Continuous variables were assessed as mean $\pm$ standard deviation. Categorical data in both groups were compared using difference in proportions test (binomial method) or Chi-Square test or Fisher exact test. Wilcoxon signed ranks test was used for assessing differences in MLHFQ
Results	- EQ5D VAS at month 6: 72.7 (95%CI: 65.6; 80.0) vs. 59.8 (49.4; 70.1) (p=0.08) - EQ5D VAS at month 12: 71.5 (95%CI: 63.5;79.6) vs. 68.6 (59.9; 77.4) (p=0.65) - EQD utilities at month 6: 0.82 (95%CI: 0.69;0.93) vs. 0.76 (95%CI: 0.65;0.87) (p=0.54) - EQD utilities at month 12: 0.73 (95%CI : 0.68;0.91) vs. 0.78 (95%CI: 0.74;0.91) (p=0.53) - MLHFQ at month 6: 15.80 (95%CI: 7.2;4.4) vs. 13.21 (95%CI: 5.86; 20.56) (p=0.97) - MLHFQ at month 12: 9.2 (95%CI: 4.0;14.3) vs. 10.8 (5.5;16.0) (p=0.45) - Cardiovascular adverse events^{cc} at month 6: 8.0% vs. 4.2% had at least 1 event (p=0.40) - Cardiovascular adverse events at month 12: 8.0% vs. 4.0% had at least 1 event (p = 0.39) - Hospitalization after implant at month 6: 42.0% vs. 33.4% had at least 1 hospitalization (p=0.54) - Hospitalization after implant at month 12: 44.0% vs. 36.0% had at least 1 hospitalization (p=0.53) - Number of in-clinic visits at month 6: 1.24 vs. 1.17 (p = 0.26) - Number of in-clinic visits at month 12: 1.3 vs. 1.2 (p=0.30) - Patients' experience: no difference between groups except at month 6 (GS-PEQ), TM participants reporting receiving less information about their diagnosis/afflictions (median: 4 vs. 5 on a Licker scale of 5; p=0.046) and taking more time to attend a cardiology consultation at hospital than SM patients (median: more than 4 hours vs. 2-3 hours on a scale of 5; p=0.041)
Notes	- Participants in the control could have 4 different types of pacemakers against 2 in the intervention group - The improvement in MLFHQ at month 6 and month 12 was lower in the telemonitoring group. There was no difference at month 6 and month 12 because the MLHFQ was also lower at baseline: 20.20 (95% CI: 14.48; 25.92) vs. 28.96 (95% CI: 19.97;37.95) (p=0.07) - The very small sample size resulted in a low statistical power. Outcomes at 6 months were measured on 25 vs. 24 participants, and at month 12 on 23 vs. 23 participants - The differences in items 3 & 12 of GS-PEQ were marginally significant and could be due to multiple testing which was not accounted for in the analysis

^{bb} The Generic Short Patient Experiences Questionnaire (GS-PEQ) is a short set of questions on user experiences with specialist healthcare that covers certain relevant topics. It was created and has been validated in Norway. The questionnaire includes 10 questions about the following topics: outcome (2), clinician services (2), user involvement (2), incorrect treatment (1), information (1), organisation (1), and accessibility (1)

^{cc} Angina, lead dislodgement, percutaneous coronary intervention



NORDLAND trial ^{48, 49, 50}	Risk of bias	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"A person unrelated to the study prepared a total of 50 sealed envelopes, 25 which included a note reading "tele-monitoring" and 25 with a note reading "hospital monitoring". The envelopes were thoroughly mixed and numbered from 1 to 50"
Allocation concealment (selection bias)	High risk	"When a patient had accepted the invitation to participate in the study and signed the informed consent he was given a consecutive study number and allocated to follow-up in accordance with the specification included in the corresponding envelope. Thus, the investigators had no knowledge of or influence on the randomization result prior to inclusion." "The most positive or healthiest patients were in the telemonitoring group"⁴⁹ Indeed the MLHFQ was lower at baseline in the intervention group: 20.20 (95% CI: 14.48; 25.92) vs. 28.96 (95% CI: 19.97;37.95) (p=0.07)
Blinding of participants and personnel (performance bias)	Unclear	Patients and health staff knew the type of monitoring assigned, possibly this aspect may have influenced their enrolment. Risk of bias is high as main outcomes are based on auto-evaluation of quality of life
Blinding of outcome assessment (detection bias)	High risk	Risk of bias is high as main outcomes are based on auto-evaluation of quality of life
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	The trial protocol was registered in ClinicalTrials.gov (Identifier: NCT02237404)
Other bias		



Appendix 7.2.2. Watanabe trial

Watanabe et al. ⁵¹	
Methods	Non-inferiority, open-label, multi-centered (85 hospitals) randomized controlled trial
Participants	1274 patients in 85 hospitals, followed-up during 24 months. Inclusion criteria: patients ≥ 20 years with a pacemaker indication according to Japanese guidelines; had received (within 45 days) or were about to receive a single- or dual-chamber Biotronik pacemaker with RM capabilities; were willing and able to comply to study procedures including daily automatic RM surveillance; were geographically stable and likely to return for in-office evaluations over a follow-up period of 27 months. Exclusion criteria: patients with a life expectancy shorter than 27 months; likely to undergo heart transplant within 27 months, or participating in another cardiology study. Characteristics: The mean age was 77 ± 10 years. Both sexes were evenly distributed. Rhythm disturbances were sick sinus syndrome (45.2%), atrioventricular block (51.5%) including pacemaker dependent patients, and atrial fibrillation (33.9%). Major comorbidities were hypertension (61.1%), heart failure (25.0%), and diabetes mellitus (20.5%).
Interventions	Remote monitoring: 6-monthly remote follow-up (analysis of the accumulated RM data) + daily automatic Home Monitoring (n=636)
Comparison	Standard monitoring: 6-monthly in-clinic visits + daily automatic Home Monitoring (n=638)
Outcomes	Primary: a composite of death, stroke, or cardiovascular surgical procedure. Adverse events were assessed in both groups by screening hospital files. Secondary: safety events, i.e. fracture/fall, syncope Others: all patient's travel and waiting time and means of transport at the randomization and termination visits. Costs were calculated as the sum of insurance claims for in office or/and remote follow-up (both types of follow-ups are reimbursed in Japan) and for diagnostic procedures performed associated with follow-ups, for example, 12-lead ECG, chest X-ray, or biochemical test. In both study groups, the final in-office evaluation was performed at 24 months after randomization (27 months after enrolment). In either group, additional unscheduled in-office follow-ups could be initiated by patients or by physicians, based on symptoms, RM findings, or during hospital admissions. Device programming, RM alert settings, reactions to alerts and how to handle RM data if no alerts were received were at the discretion of the investigator.
Results	• Primary end point (composite of death, stroke, or cardiovascular surgical procedure): 10.9% (95%CI: 8.8; 13.1) vs. 11.8% (95%CI: 9.5; 14.1). Non-inferiority with 5% margin ($p=0.0012$). No significant difference for death or stroke separately (own calculation) • Median in-office visits per patient-year: 0.50 (IQR: 0.50; 0.63) vs. 2.01 (IQR: 1.93; 2.05) ($p<0.001$). 69.5% reduction of in-office follow-ups • Median follow-ups (in-office + remote) per patient-year: 1.85 vs. 1.76 ($p>0.05$)



	Median patient-individual follow-up costs per patient-year: 18 880 vs. 21 400 Yen ($p < 0.0001$). There was a 10% reduction in total costs. Follow-up reimbursement per year in RM was slightly higher because of the slightly higher rate of total (remote and in-office) follow-ups, but the costs associated with additional diagnostic procedures were lower (Table 4 in the paper).
Notes	- Good statistical power - Although the authors report that “All patients of the analysis cohort were analysed as randomized”, it seems that the true analysis was per-protocol. No replacement of missing values is mentioned. - Analysis underestimated total cost savings since it concentrated on payer costs and did not account for nursing and physician time, which is considerably reduced with remote management and patient costs (entailing time away from work, travel time, etc).

Watanabe et al. ⁵¹	Risk of bias	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomized 1:1 to RM or SM by a centralized, concealed randomization process stratified by site.
Allocation concealment (selection bias)	Low risk	Patients were randomized 1:1 to RM or SM by a centralized, concealed randomization process stratified by site.
Blinding of participants and personnel (performance bias)	Unclear	Open-labelled trial
Blinding of outcome assessment (detection bias)	Low risk	An independent Clinical Event Committee consisting of 3 physicians, blinded to randomization assignment and investigational site, adjudicated primary end points by reviewing documented adverse events. Although neither investigators nor patients were masked to treatment allocation, hard outcomes were assessed.
Incomplete outcome data (attrition bias)	Unclear risk	The reasons for premature termination in RM and SM were loss to follow-up (8.2% versus 9.2%), withdrawal of consent (3.0% versus 3.8%), and exclusion per protocol (1.1% versus 0.8%; all $P > 0.2$). However, whether characteristics of participants with premature termination were similar between groups, and similar to the remainders is not described. Per-protocol analysis was realized, and no attempt to replace missing values was made.
Selective reporting (reporting bias)	Low risk	Study protocol registered at ClinicalTrials.gov (NCT01523704)
Other bias		



APPENDIX 8. SEARCH STRATEGIES ECONOMIC EVALUATIONS

Appendix 8.1. Search Strategies Defibrillators and Pacemakers

Appendix 8.1.1. Cochrane

Date	16/07/2020 20:02:43
Database	Cochrane@Wiley.com
Search strategy	
#1	[mh ^"Defibrillators, Implantable"] 961
#2	[mh "Cardiac Pacing, Artificial"] 1420
#3	[mh "Pacemaker, Artificial"] 717
#4	#1 or #2 or #3 2416
#5	((cardiac or cardiovascular or cardio vascular) NEAR/2 implant* NEAR/2 electronic NEAR/2 device*):ab,ti 129
#6	((("cardiac resynchronization" or "cardiac resynchronisation") NEAR/2 (therap* or defibrillator* or device*)):ab,ti 1331
#7	(Implant* NEAR/1 (cardiac or cardioverter) NEAR/1 (defibrillator* or device*)):ab,ti 1572
#8	((implant* or "dual chamber" or biventricular or ventricular) NEAR/1 defibrillator*):ab,ti 624
#9	pacemaker?:ab,ti 2446
#10	(CRT-D or CRT-Ds):ab,ti 423
#11	(CRT-P or CRT-Ps):ab,ti 160
#12	(ICD or ICDs):ab,ti 4050
#13	(CIED or CIEDs):ab,ti 116
#14	#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 7800
#15	#4 or #14 8371
#16	[mh ^"Monitoring, Physiologic"] 2181
#17	[mh ^"Monitoring, Ambulatory"] 535
#18	[mh "Telemetry"] 276
#19	[mh "Telecommunications"] 6212



#20	[mh ^"Internet"]	3729
#21	#16 OR #17 OR #18 OR #19 OR #20	11606
#22	((remote or remotely) NEAR/1 monitor*):ab,ti	681
#23	(home NEXT/1 monitor*):ab,ti	544
#24	((remote or remotely) NEAR/2 (followup* or "follow up" or "follow ups")):ab,ti	89
#25	((remote or remotely) NEAR/1 (interrogat* or manag* or notification* or (patient NEXT/1 monitor*) or (rhythm NEXT/1 monitor*) or (data NEXT/1 transmi*))):ab,ti	139
#26	telemonitor*:ab,ti	899
#27	tele-monitor*:ab,ti	84
#28	telemedicine:ab,ti	1487
#29	tele-medicine:ab,ti	28
#30	telecardio*:ab,ti	22
#31	tele-cardio*:ab,ti	6
#32	teleconsult*:ab,ti	123
#33	tele-consult*:ab,ti	26
#34	telemetry:ab,ti	389
#35	#22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34	3746
#36	#21 or #35	14502
#37	#15 and #36	357
#38	Cardiomessenger*:ab,ti	0
#39	CareLink*:ab,ti	68
#40	(Latitude* NEAR/2 ("patient management" NEXT/1 system*) or (remote NEXT/1 monitor*))):ab,ti	3
#41	Smartview*:ab,ti	1
#42	Merlin?home*:ab,ti	1
#43	Merlin?net*:ab,ti	2
#44	((home NEXT/1 monitor*) NEXT/1 system*) NEAR/3 biotronic):ab,ti	4
#45	("remote cardiac" NEXT/1 monitor*):ab,ti	3



#46	#38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45	82
#47	#37 or #46	413
#48	[mh ^"economics"]	40
#49	[mh ^"economics, medical"]	26
#50	[mh ^"economics, pharmaceutical"]	65
#51	[mh "economics, hospital"]	709
#52	[mh ^"economics, nursing"]	12
#53	[mh ^"economics, dental"]	2
#54	[mh /EC]	11295
#55	[mh "costs and cost analysis"]	10336
#56	[mh ^"models, economic"]	240
#57	[mh ^"markov chains"]	260
#58	[mh ^"monte carlo method"]	179
#59	[mh ^"quality-adjusted life years"]	1225
#60	#48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59	13492
#61	(econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*):ab,ti	27544
#62	(cost or costs or costing or costly):ti	12514
#63	(cost NEXT/1 effective*):ab,ti	23967
#64	(cost* NEAR/2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)):ab	14074
#65	(decision NEAR/1 (tree* or analy* or model*)):ab,ti	1209
#66	(markov or markow or "monte carlo"):ab,ti	1736
#67	(QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs):ab,ti	8438
#68	(adjusted NEAR/3 (quality or life)):ab,ti	4458
#69	(willing* NEAR/2 pay):ab,ti	1407
#70	sensitivity analys*s:ab,ti	24125



#71	#61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70	78419
#72	#60 OR #71	82554
#73	#47 AND #72	83
#74	#73 with Cochrane Library publication date Between Jan 2010 and Dec 2020	77

Comments*Appendix 8.1.2. Embase*

Date	15 Jul 2020	
Database	Embase.com	
Search strategy		
#1	'implantable cardioverter defibrillator'/de	39486
#2	'cardiac resynchronization therapy'/de	18911
#3	'artificial heart pacemaker'/exp	40314
#4	#1 OR #2 OR #3	92766
#5	((cardiac OR cardiovascular OR 'cardio vascular') NEAR/2 implant* NEAR/2 electronic NEAR/2 device*):ab,ti,tn,kw,dn	2616
#6	('cardiac resynchroni\$ation' NEAR/2 (therap* OR defibrillator* OR device*)):ab,ti,tn,kw,dn	14680
#7	(implant* NEAR/1 (cardiac OR cardioverter) NEAR/1 (defibrillator* OR device*)):ab,ti,tn,kw,dn	21438
#8	((implant* OR 'dual chamber' OR biventricular OR ventricular) NEAR/1 defibrillator*):ab,ti,tn,kw,dn	5672
#9	pacemaker:ab,ti,tn,kw,dn OR pacemakers:ab,ti,tn,kw,dn OR 'crt d':ab,ti,tn,kw,dn OR 'crt ds':ab,ti,tn,kw,dn OR 'crt p':ab,ti,tn,kw,dn OR 'crt ps':ab,ti,tn,kw,dn OR icd:ab,ti,tn,kw,dn OR icds:ab,ti,tn,kw,dn OR cied:ab,ti,tn,kw,dn OR cieds:ab,ti,tn,kw,dn	136181
#10	#5 OR #6 OR #7 OR #8 OR #9	153359
#11	#4 OR #10	199445
#12	'physiologic monitoring'/de	4890
#13	'ambulatory monitoring'/de	11422
#14	'home monitoring'/de	4576
#15	'self monitoring'/de	7658
#16	'patient monitoring'/de	88393



#17	'telemedicine'/exp	39994
#18	'telemetry'/exp	29607
#19	'internet'/de	107898
#20	#12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19	283140
#21	(remote OR remotely) NEAR/1 monitor*	4428
#22	'home monitor**'	5879
#23	(remote OR remotely) NEAR/2 (followup* OR 'follow up**')	467
#24	(remote OR remotely) NEAR/1 (interrogat* OR manag* OR notification* OR 'patient monitor*' OR 'rhythm monitor*' OR 'data transmi**')	866
#25	telemonitor*:ab,ti,tn,kw,dn	2478
#26	'tele monitor*':ab,ti,tn,kw,dn	302
#27	telemedicine:ab,ti,tn,kw,dn	17508
#28	'tele medicine':ab,ti,tn,kw,dn	268
#29	telecardio*:ab,ti,tn,kw,dn	404
#30	'tele cardio*':ab,ti,tn,kw,dn	34
#31	teleconsult*:ab,ti,tn,kw,dn	1596
#32	'tele consult*':ab,ti,tn,kw,dn	185
#33	telemetry:ab,ti,tn,kw,dn	11728
#34	#21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33	41546
#35	#20 OR #34	291440
#36	#11 AND #35	5335
#37	cardiomessenger*:ab,ti,tn,kw,dn	19
#38	carelink*:ab,ti,tn,kw,dn	525
#39	(latitude* NEAR/2 ('patient management system*' OR 'remote monitor*')):ab,ti,tn,kw,dn	71
#40	smartview*:ab,ti,tn,kw,dn	18
#41	merlin\$home*:ab,ti,tn,kw,dn	1
#42	merlin\$net*:ab,ti,tn,kw,dn	0



#43	('home monitor* system*' NEAR/3 biotronic):ab,ti,tn,kw,dn	18
#44	'remote cardiac monitor*':ab,ti,tn,kw,dn	27
#45	#37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44	661
#46	#36 OR #45	5701
#47	'economics'/de	239654
#48	'health economics'/de	39665
#49	'pharmacoeconomics'/de	7337
#50	'drug cost'/de	77178
#51	'drug formulary'/de	3351
#52	'economic aspect'/de	115931
#53	'economic evaluation'/exp	304992
#54	'cost'/exp	352569
#55	'quality-adjusted life years'/de	26472
#56	'monte carlo method'/de	40214
#57	#47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56	886370
#58	econom*:ab,ti,tn,kw OR price:ab,ti,tn,kw OR prices:ab,ti,tn,kw OR pricing:ab,ti,tn,kw OR priced:ab,ti,tn,kw OR discount*:ab,ti,tn,kw OR expenditure*:ab,ti,tn,kw OR budget*:ab,ti,tn,kw OR pharmacoeconomic*:ab,ti,tn,kw OR 'pharmaco economic*':ab,ti,tn,kw	533537
#59	cost:ti OR costs:ti OR costing:ti OR costly:ti	150797
#60	'cost effective*':ab,ti,tn,kw	187049
#61	(cost* NEAR/2 (util* OR efficac* OR benefit* OR minimi* OR analy* OR saving* OR estimate* OR allocation OR control OR sharing OR instrument* OR technolog*)):ab	129210
#62	(decision NEAR/1 (tree* OR analy* OR model*)):ab,ti,tn,kw	27123
#63	(markov:ab,ti,tn,kw OR markow:ab,ti,tn,kw OR monte:ab,ti,tn,kw) AND carlo:ab,ti,tn,kw	49959
#64	qoly:ab,ti,tn,kw OR qolys:ab,ti,tn,kw OR hrqol:ab,ti,tn,kw OR hrqols:ab,ti,tn,kw OR qaly:ab,ti,tn,kw OR qalys:ab,ti,tn,kw OR qale:ab,ti,tn,kw OR qales:ab,ti,tn,kw	46560
#65	((adjusted NEAR/2 (quality OR life)):ab,ti,tn,kw) OR ((willing* NEAR/2 pay):ab,ti,tn,kw) OR sensitivity:ab,ti,tn,kw) AND analys*s:ab,ti,tn,kw	346722



#66	#58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65	1182590
#67	#57 OR #66	1696618
#68	#46 AND #67	633
#69	#68 AND [2010-2020]/py	491
#70	#68 AND [2010-2016]/py	335
#71	#70 AND [english]/lim	321
#72	#69 NOT #71	170
#73	#72 NOT [medline]/lim	83
#74	#73 NOT ('conference abstract'/it OR 'conference paper'/it OR 'conference review'/it)	25

Comments

Appendix 8.1.3. Medline

Date	July 15, 2020	
Database	Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to July 15, 2020>	
Search strategy		
1	Defibrillators, Implantable/	16396
2	exp Cardiac Pacing, Artificial/	24694
3	exp Pacemaker, Artificial/	27172
4	1 or 2 or 3	58085
5	((cardiac or cardiovascular or cardio vascular) adj2 implant* adj2 electronic adj2 device*).ti,ab,kf.	1554
6	(cardiac resynchroni#ation adj2 (therap* or defibrillator* or device*)).ti,ab,kf.	7683
7	(Implant* adj1 (cardiac or cardioverter) adj1 (defibrillator* or device*)).ti,ab,kf.	13732
8	((implant* or dual chamber or biventricular or ventricular) adj1 defibrillator*).ti,ab,kf.	3872
9	pacemaker?.ti,ab,kf.	38010
10	(CRT-D or CRT-Ds).ti,ab,kf.	943
11	(CRT-P or CRT-Ps).ti,ab,kf.	459
12	(ICD or ICDs).ti,ab,kf.	36544



13	(CIED or CIEDs).ti,ab,kf.	980
14	5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13	85564
15	4 or 14	109838
16	Monitoring, Physiologic/	54625
17	Monitoring, Ambulatory/	8108
18	exp Telemetry/	13257
19	exp Telecommunications/	91918
20	Internet/	72777
21	16 or 17 or 18 or 19 or 20	215850
22	((remote or remotely) adj1 monitor*).ti,ab,kf.	2546
23	home monitor*.ti,ab,kf.	1890
24	((remote or remotely) adj2 (followup* or follow up*)).ti,ab,kf.	211
25	((remote or remotely) adj1 (interrogat* or manag* or notification* or patient monitor* or rhythm monitor* or data transmi*)).ti,ab,kf.	551
26	telemonitor*.ti,ab,kf.	1608
27	tele-monitor*.ti,ab,kf.	152
28	telemedicine.ti,ab,kf.	13126
29	tele-medicine.ti,ab,kf.	131
30	telecardio*.ti,ab,kf.	275
31	tele-cardio*.ti,ab,kf.	24
32	teleconsult*.ti,ab,kf.	1261
33	tele-consult*.ti,ab,kf.	98
34	telemetry.ti,ab,kf.	7239
35	22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34	26473
36	21 or 35	226990
37	15 and 36	2975
38	Cardiomessenger*.ti,ab,kf.	1



39	CareLink*.ti,ab,kf.	106
40	(Latitude* adj2 (patient management system* or remote monitor*)).ti,ab,kf.	13
41	Smartview*.ti,ab,kf.	1
42	Merlin?home*.ti,ab,kf.	1
43	Merlin?net*.ti,ab,kf.	9
44	(home monitor* system* adj3 biotronic).ti,ab,kf.	3
45	remote cardiac monitor*.ti,ab,kf.	10
46	38 or 39 or 40 or 41 or 42 or 43 or 44 or 45	141
47	37 or 46	3049
48	economics/	27203
49	economics, medical/	9082
50	economics, pharmaceutical/	2940
51	exp economics, hospital/	24543
52	economics, nursing/	3999
53	economics, dental/	1911
54	economics.fs.	423039
55	exp "costs and cost analysis"/	236829
56	models, economic/	10110
57	markov chains/	14315
58	monte carlo method/	28300
59	quality-adjusted life years/	12273
60	48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59	564070
61	(econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf.	425748
62	(cost or costs or costing or costly).ti.	110859
63	cost effective*.ti,ab,kf.	136016



64	(cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*).ab.	85204
65	(decision adj1 (tree* or analy* or model*).ti,ab,kf.	18581
66	(markov or markow or monte carlo).ti,ab,kf.	66891
67	(QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).ti,ab,kf.	27059
68	(adjusted adj1 (quality or life)).ti,ab,kf.	17420
69	(willing* adj2 pay).ti,ab,kf.	6570
70	sensitivity analys*s.ti,ab,kf.	34782
71	61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70	733105
72	60 or 71	1059147
73	47 and 72	210
74	limit 73 to yr="2010 -Current"	141
75	limit 73 to yr="2010-2016"	90
76	limit 75 to english	78
77	74 not 76	63
Comments		

Appendix 8.1.4. Cinahl

Date	Friday, July 17, 2020 7:33:15 AM	
Database	Cinahl	
Search strategy		
S1	(MH "Defibrillators, Implantable")	10,789
S2	(MH "Cardiac Pacing, Artificial+")	9,515
S3	(MH "Pacemaker, Artificial+")	7,937
S4	S1 or S2 or S3	23,042
S5	TI ((cardiac or cardiovascular or cardio vascular) N2 implant* N2 electronic N2 device*)) OR AB ((cardiac or cardiovascular or cardio vascular) N2 implant* N2 electronic N2 device*)	845



S6	TI ((cardiac resynchroni#ation N2 (therap* or defibrillator* or device*))) OR AB ((cardiac resynchroni#ation N2 (therap* or defibrillator* or device*)))	4,263
S7	TI ((Implant* N1 (cardiac or cardioverter) N1 (defibrillator* or device*))) OR AB ((Implant* N1 (cardiac or cardioverter) N1 (defibrillator* or device*)))	7,764
S8	TI (((implant* or dual chamber or biventricular or ventricular) N1 defibrillator*)) OR AB (((implant* or dual chamber or biventricular or ventricular) N1 defibrillator*))	7,908
S9	TI pacemaker# OR AB pacemaker#	8,975
S10	TI ((CRT-D or CRT-Ds)) OR AB ((CRT-D or CRT-Ds))	531
S11	TI ((CRT-P or CRT-Ps)) OR AB ((CRT-P or CRT-Ps))	4,970
S12	TI ((ICD or ICDs)) OR AB ((ICD or ICDs))	7,231
S13	TI ((CIED or CIEDs)) OR AB ((CIED or CIEDs))	494
S14	S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13	25,609
S15	S4 or S14	34,140
S16	(MH "Monitoring, Physiologic")	22,548
S17	(MH "Electrocardiography, Ambulatory")	3,252
S18	(MH "Telemetry+")	2,100
S19	(MH "Telecommunications+")	143,167
S20	(MH "Internet")	52,640
S21	S16 OR S17 OR S18 OR S19 OR S20	168,338
S22	TI (((remote or remotely) N1 monitor*)) OR AB (((remote or remotely) N1 monitor*))	1,393
S23	TI home monitor* OR AB home monitor*	2,921
S24	TI (((remote or remotely) N2 (followup* or follow up*))) OR AB (((remote or remotely) N2 (followup* or follow up*)))	96
S25	TI (((remote or remotely) N1 (interrogat* or manag* or notification* or patient monitor* or rhythm monitor* or data transmi*))) OR AB (((remote or remotely) N1 (interrogat* or manag* or notification* or patient monitor* or rhythm monitor* or data transmi*)))	618
S26	TI telemonitor* OR AB telemonitor*	835
S27	TI tele-monitor* OR AB tele-monitor*	53
S28	TI telemedicine OR AB telemedicine	5,284



S29	TI tele-medicine OR AB tele-medicine	43
S30	TI telecardio* OR AB telecardio*	79
S31	TI tele-cardio* OR AB tele-cardio*	4
S32	TI teleconsult* OR AB teleconsult*	453
S33	TI tele-consult* OR AB tele-consult*	37
S34	TI telemetry OR AB telemetry	1,490
S35	S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34	11,946
S36	S21 or S35	173,134
S37	S15 and S36	1,774
S38	TI Cardiomessenger* OR AB Cardiomessenger*	1
S39	TI CareLink* OR AB CareLink*	87
S40	TI ((Latitude* N2 (patient management system* or remote monitor*))) OR AB ((Latitude* N2 (patient management system* or remote monitor*)))	14
S41	TI Smartview* OR AB Smartview*	2
S42	TI Merlin#home* OR AB Merlin#home*	0
S43	TI Merlin#net* OR AB Merlin#net*	5
S44	TI (home monitor* system* N3 biotronic) OR AB (home monitor* system* N3 biotronic)	2
S45	TI remote cardiac monitor* OR AB remote cardiac monitor*	87
S46	S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45	188
S47	S37 or S46	1,859
S48	(MH "economics")	14,937
S49	(MH "Economic Aspects of Illness")	9,714
S50	(MH "economics, pharmaceutical")	2,335
S51	(MH "economics, dental")	147
S52	(MH "Economic Value of Life")	654
S53	MW "ec"	190,733
S54	(MH "costs and cost analysis+")	125,936



S55	(MH "quality-adjusted life years")	4,982
S56	S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55	268,789
S57	TI ((econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*)) OR AB ((econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*))	135,557
S58	TI cost or costs or costing or costly	54,590
S59	TI cost effective* OR AB cost effective*	46,656
S60	(AB cost* N2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*))	35,482
S61	TI ((decision N1 (tree* or analy* or model*))) OR AB ((decision N1 (tree* or analy* or model*)))	7,665
S62	TI ((markov or markow or monte carlo)) OR AB ((markov or markow or monte carlo))	6,252
S63	TI ((QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs)) OR AB ((QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs))	12,430
S64	TI (((adjusted N1 (quality or life))) OR AB (((adjusted N1 (quality or life)))	7,200
S65	TI (willing* N2 pay) OR AB (willing* N2 pay)	2,550
S66	TI sensitivity analys*s OR AB sensitivity analys*s	14,420
S67	S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66	241,839
S68	S56 or S67	419,577
S69	S47 and S68	124
S70	S69 - Published Date: 20100101-20201231	97
S71	S70 - Exclude MEDLINE records	35
S72	S71 - Peer Reviewed	34
S73	S72 - Published Date: 20100101-20170531; English Language	20
S74	S72 NOT S73	14
Comments		



Appendix 8.2. Search Strategies Implantable Loop Recorders

Appendix 8.2.1. Cochrane

Date	28/01/2021 19:18:42	
Database	Cochrane@Wiley.com	
Search strategy		
#1	(loop NEAR/1 recorder? NEAR/2 implant*):ab,ti	161
#2	(loop NEAR/1 recorder? NEAR/2 inject*):ab,ti	1
#3	(loop NEAR/1 recorder? NEAR/2 internal):ab,ti	5
#4	(loop NEAR/1 recorder? NEAR/2 insert*):ab,ti	13
#5	(loop NEAR/1 recorder? NEAR/2 subcutaneous):ab,ti	2
#6	(ILR or ILRs):ab,ti	119
#7	((implant* or internal or inject* or insert* or subcutaneous) NEAR/2 cardiac NEAR/2 monitor*):ab,ti	116
#8	((implant* or internal or inject* or insert* or subcutaneous) NEAR/2 "heart rate" NEAR/2 monitor*):ab,ti	1
#9	"Medtronic LINQ":ab,ti	1
#10	"Confirm Rx":ab,ti	6
#11	(LINQ NEAR/3 loop):ab,ti	4
#12	AngelMed Guardian System:ab,ti	0
#13	(Reveal NEAR/3 loop):ab,ti	14
#14	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13	308
#15	[mh ^"economics"]	40
#16	[mh ^"economics, medical"]	26
#17	[mh ^"economics, pharmaceutical"]	65
#18	[mh "economics, hospital"]	719
#19	[mh ^"economics, nursing"]	12
#20	[mh ^"economics, dental"]	2
#21	[mh /EC]	11543



#22	[mh "costs and cost analysis"]	10591
#23	[mh ^"models, economic"]	248
#24	[mh ^"markov chains"]	266
#25	[mh ^"monte carlo method"]	185
#26	[mh ^"quality-adjusted life years"]	1270
#27	#15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26	13824
#28	(econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*):ab,ti	29005
#29	(cost or costs or costing or costly):ti	12979
#30	(cost NEXT/1 effective*):ab,ti	25144
#31	(cost* NEAR/2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)):ab	14704
#32	(decision NEAR/1 (tree* or analy* or model*)):ab,ti	1300
#33	(markov or markow or "monte carlo"):ab,ti	1854
#34	(QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs):ab,ti	9083
#35	(adjusted NEAR/3 (quality or life)):ab,ti	4763
#36	(willing* NEAR/2 pay):ab,ti	1520
#37	sensitivity analys*s:ab,ti	25292
#38	#28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37	82438
#39	#27 OR #38	86650
#40	#14 and #39	47
Comments		



Appendix 8.2.2. Medline

Date	January 19, 2021	
Database	Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to January 19, 2021>	
Search strategy		
1	(loop recorder? adj2 implant*).ab,ti,kf.	672
2	(loop recorder? adj2 inject*).ab,ti,kf.	5
3	(loop recorder? adj2 internal).ab,ti,kf.	8
4	(loop recorder? adj2 insert*).ab,ti,kf.	57
5	(loop recorder? adj2 subcutaneous).ab,ti,kf.	9
6	(ILR or ILRs).ab,ti,kf.	522
7	((implant* or internal or inject* or insert* or subcutaneous) adj2 "cardiac monitor*").ab,ti,kf.	290
8	((implant* or internal or inject* or insert* or subcutaneous) adj2 "cardiac rythm monitor*").ab,ti,kf.	0
9	((implant* or internal or inject* or insert* or subcutaneous) adj2 "heart rate monitor*").ab,ti,kf.	17
10	"Confirm Rx TM loop recorder".ab,ti,kf.	1
11	"Medtronic LINQ ".ab,ti,kf.	3
12	"Confirm Rx".ab,ti,kf.	11
13	(LINQ adj3 loop).ab,ti,kf.	6
14	AngelMed Guardian System.ab,ti,kf.	3
15	(Reveal adj3 loop).ab,ti,kf.	161
16	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15	1346
17	economics/	27280
18	economics, medical/	9116
19	economics, pharmaceutical/	2969
20	exp economics, hospital/	24904
21	economics, nursing/	4002
22	economics, dental/	1915
23	economics.fs.	430093



24	exp "costs and cost analysis"/	241739
25	models, economic/	10396
26	markov chains/	14704
27	monte carlo method/	28970
28	quality-adjusted life years/	12788
29	17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28	573829
30	(econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf.	450468
31	(cost or costs or costing or costly).ti.	114810
32	cost effective*.ti,ab,kf.	143146
33	(cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*).ab.	89020
34	(decision adj1 (tree* or analy* or model*)).ti,ab,kf.	19883
35	(markov or markow or monte carlo).ti,ab,kf.	70003
36	(QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).ti,ab,kf.	28799
37	(adjusted adj1 (quality or life)).ti,ab,kf.	18567
38	(willing* adj2 pay).ti,ab,kf.	7081
39	sensitivity analys*s.ti,ab,kf.	37808
40	30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39	773331
41	29 or 40	1103492
42	16 and 41	69

Appendix 8.3. NHSHTA and NHSEED (CRD)

Search terms: (telemonitoring):TI OR (remote):TI OR (distance):TI IN NHSEED, HTA



APPENDIX 9. TEMPLATE DATA EXTRACTION – ECONOMIC EVALUATIONS

Template table based on original checklist by Drummond et al. on which critical appraisal for economic evaluations was based

1	Title
2	Reference (including all authors)
3	Conflict of interest and/or study funding
4	Country
5	Study question – clear and complete including statement of problem
6	Need for modelling – justified
7	Type of analysis (analytic technique)
8	Specific model design –complete description
9	Population – full description
10	Intervention
11	Comparator
12	Time horizon – appropriate and justified
13	Discount rate – inclusion and justification of rates used
14	Perspective
15	Costs
	• Cost items included
	• Measurement of resource use
	• Valuation of resource use
	• Data sources and references
	• Currency and cost year
16	Outcomes
	• Endpoints taken into account and/or health states
	• Valuation of health states
	• Treatment effect and Extrapolation



	• Utility assessment (Quality of Life)
	• Data sources for outcomes and references –values used in base case scenario and justification
17	Uncertainty
	• Scenario analysis
	• Sensitivity analysis – univariate and or multidimensional – ranges of values used and justification
18	Assumptions and discussion regarding their impact on the results
19	Results
	• Cost-effectiveness and/or cost-utility (base case)
	• Scenario analysis
	• Sensitivity analysis
20	Conclusions and applicability
21	Remarks – ongoing research which could affect results



APPENDIX 10. LEGAL CHAPTER: REVIEW OF CONSENT FORMS (GDPR) FOR CIEDS BY THE ESC REGULATORY AFFAIRS COMMITTEE / EHRA

Table 3 Review of consent forms for remote monitoring of CIEDs

	Abbot	Biotronik	Boston Scientific	Medtronic	Microport
Clear definition of remote monitoring	A few aspects are not clear	Most aspects are clearly defined	Most aspects are clearly defined	Some aspects are not well defined	Many aspects are not defined
Clear explanation of how the data will be treated	No	No	Yes	No	No
Numbers of partners	Doctor, hospital, the company, and partners	Doctor, service partners	Doctor, hospital, the company, and partners	Patient, doctor, hospital, and third party	Not defined
Duration of the contract	Not defined	Not defined	6 years after the disconnection	Not defined	Not defined
Who is the responsible for the data?	Physician, hospital	Physician	The hospital/clinic	Not defined	Hospital
Who is responsible for the personal data?	Physician, hospital	Physician	The hospital/clinic	Medical centre	Hospital
Who will have access to the data?	The company, a third party, doctor, and hospital	Not defined	The company, subcontractors, doctor, or other physician who will grant access, your hospital, health authorities	The company, third party. The roles of the doctor and hospital are not defined	Doctor, hospital, the company, and the patient
Will the data be stored outside the hospital?	Yes, USA	Not defined	Yes	Yes	Not defined
Who will store the data?	The company	Not defined	The company and subcontractors	The company and a third party	Not defined
Are the rights of the patient clearly explained?	No	No	Yes	No	No
Does the patient have access to the data and/or to withdraw consent? Is that process well defined?	No. Even if patient withdraws consent, his/her data will be used for 10 years.	Yes, but the process is not defined	Yes	Yes, by writing a letter to the physician	Yes
Will data be used for statistics or research purposes?	Yes	Medical technical research	Yes previous anonymization	Yes	Not defined
Is the responsibility of each party established (manage the data, database, maintenance of the data obtained, software)?	No	No	No	No	No
Is there clear identification of data that will be obtained, from the clinic, device, personal contact of the patient?	No	No	Yes	Yes	No

Continued

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J.C. Nielsen et al.


Table 3 Continued

	Abbot	Biotronik	Boston Scientific	Medtronic	Microport
Data access is clearly defined and justified	The company, a third party, doctor, and hospital	Medical technical research	The company, subcontractors, doctor, or other physician that will grant access, your hospital, health authorities	Yes	No
How long will the company keep the data	Not defined	Not defined	At least 6 years or more after the end of the service	Not defined	Not defined
Where will the data be stored (EU)?	USA	Not defined	Ireland and USA	The local country, Netherlands, and USA	Not defined
The patient has the choice of different options regarding the informed consent	No	No	Yes, (i) the data of the patient, (ii) the medical data and (iii) statistical purposes and research	No	No
In case of research purposes, the data will be anonymized	Yes	Yes	Yes	Yes	Not defined
Right to withdraw informed consent	Yes	Not defined	Contact the company, email or postal letter to the company or your hospital	Yes	Only the data of identification, not defined the medical data
Definition of the time of analysis of data	No, only in case of withdraw of the consent	Yes, during the working period of your doctor	No	No	Not defined
The utility is defined	Yes	Yes, only optimization of your treatment	Yes	Yes	Not clearly defined
Identification of the technical limitations of remote monitoring	No	Only those limitations linked to telephone networks	No	No	No
If more information is needed, is any web address or file offered?	No	No, contact the physician	No	No	No
Description of the limitations of the systems	No	Telecommunication systems of mobile phone	No	No	No
Are the informed consent forms consistent across countries?	No	No	No	No	No

Consent forms from five CIED manufacturers provided by cardiologists and manufacturers in January and February 2019 were reviewed.
CIED, cardiac implantable electronic device.



Source : Jens Cosedis Nielsen, Josef Kautzner, Ruben Casado-Arroyo, Haran Burri, Stefaan Callens, Martin R Cowie, Kenneth Dickstein, Inga Drossart, Ginger Geneste, Zekeriya Erkin, Fabien Hyafil, Alexander Kraus, Valentina Kutyifa, Eduard Marin, Christian Schulze, David Slotwiner, Kenneth Stein, Stefano Zanero, Hein Heidbuchel, Alan G Fraser, Remote monitoring of cardiac implanted electronic devices: legal requirements and ethical principles - ESC Regulatory Affairs Committee/EHRA joint task force report, EP Europace, Volume 22, Issue 11, November 2020, Pages 1742–1758, <https://doi.org/10.1093/europace/euaa168>



APPENDIX 11. INTERNATIONAL COMPARISON

Appendix 11.1. France

Appendix 11.1.1. Contacted expert

- Dr Laurence Guédon-Moreau - CHU de Lille – Medical specialist in cardiology, First author of the french good clinical practice guidelines on the remote monitoring of patients with CIEDs.

Appendix 11.1.2. Summary and sources

Source		
Main legal sources	• 2010 Decree on telemedicine, defining the mandatory minimum legal framework for telemedicine • ETAPES 2020: Order of 23 December 2020 setting out the specifications for experiments relating to remote monitoring (i.e. the ETAPES programme on Telemedicine Experiments - “<i>Expérimentations de Télémédecine pour l’Amélioration du Parcours En Santé</i>”) implemented on the basis of Article 54 of Law No. 2017-1836 on the financing of social security for 2018.⁵² • LPP 2021: Ameli, La liste des produits et prestations - LPP (Access May 2021); http://www.codage.ext.cnamts.fr/codif/tips/index_presentation.php?p_site=AMELI⁵³ • CCAM 2021: Aide au codage - Recherche d'actes médicaux CCAM (Access May 2021) https://www.aideaucodage.fr/ccam-4.2;⁵⁴ • CNEDIMTS 2020 : MERLIN.NET – Application mobile MYMERLINPULSE, système de télésurveillance pour défibrillateur cardiaque automatique implantable double chambre compatible⁵⁵ • HAS 2017 ² • HAS 2021 ³	
Definition: Telemonitoring vs teleconsultation	• Telemonitoring: Programmed reading of remote monitored data • Teleconsultation: involves simultaneous contact between the physician and his/her patient.	ETAPES - 2020 ⁵²
Which reimbursement?	• For the “treating/responsible physician”: ○ For ICDs and Pacemakers: €130 per patient per year (i.e. €65 per semester): A lump sum for the follow-up of data according to a time schedule recommended by professional associations (every three to six months, at least every six months) and the management of alerts (patient contact or visit, reorientation of the patient, treatment adaptation, etc., see also below in section “follow-up”). This payment is for the remote consultation. For face to face consultations (also if necessitated by an alert), the traditional amount is paid (see below). The monitoring centre must provide a telephone access for patients on working days and hours by the monitoring centres to answer patients/family/carers' clinical questions and must ensure patient educations and proper functioning of the system. Additional requirements for the company are described in HAS 2017.	ETAPES – 2020 ⁵² ; LPP 2021 ⁵³ ; CCAM 2021 ⁵⁴ ; HAS 2021 ³



- No reimbursement is currently available for loop recorders (a demand is in process of evaluation). Standard monitoring: consultations every 3-6 months (DEQP001-*Électrocardiographie, avec enregistrement événementiel déclenché et télétransmission* : €14.26)
- **For the RM system provider:**
 - For ICDs (separate from the implant): €864 for the remote monitoring of single or double chambers ICDs and €972 for the remote monitoring of triple chambers ICDs for both the transmitter and the data transmission, whatever the trademark (home monitoring - Biotronik, latitude - Boston, carelink - Medtronic, merlin.net - Abbott, smartview - Microport) (one-time payment).
 - For PM (Include in the price of the implant): PM are € 500 higher if combined with a telemonitoring system for single or double chambers system and € 700 higher for triple chambers and resynchronisation system.
 - Regardless of the mode of telecommunications set up between the transmitter and the data host, the communication costs must be covered by the company.
 - The company must provide a hotline for patients, their families and carers, as well as a technical assistance for health professionals, accessible via a free phone number on working days (9am-6pm). Additional requirements for the company are described in HAS 2017.
- **Face-to-face in-clinic follow-up is reimbursed as followed:** € 70.48 for secondary transcutaneous monitoring and adjustment of an ICD (per visit, DEMP001) and €60.41 for secondary transcutaneous monitoring and adjustment of a pacemaker (per visit, DEMP002).

Reimbursement conditions

For RM of ICDs:

LPP 2021⁵³

- Both the remote monitoring device and the compatible ICDs must be registered in the list of reimbursed services and products (L 165-1) or in the list of intra homogenous stay group (Groupe homogène de séjour – GHS – L 165-11);
- Same indications than for the compatible ICDs (L. 165-11 of the Social Security Code (intra-GHS);
- Data and alerts are transmitted to the practitioner in a programmed and automatic way (by fax, sms, or e-mail).
- The programming must include the following alerts: device malfunction (panne du boîtier), sensor malfunction, end-of-battery life indicator, and the prolonged interruption of transmission without prior patient-doctor agreement). The HAS also recommend the following alerts: the occurrence of ventricular and supra-ventricular rhythm disturbances, the delivered electric shocks, and the programming resets/anomalies;
- Face to face consultations are initiated in case of alerts and if the patient's condition so requires
- In the absence of an alert: An annual face to face consultation with the patient is required in order to maintain the link with the rhythmology centre and to check the validity of the patient's contact details so as to maintain the possibility of intervention. An annual contact with the treating physician and/or cardiologist is also required in order to maintain a care network around the patient;
- A protocol between the company and the treating physician must be draw up, including:
 - (i) The identification of the treating/responsible physician;
 - (ii) A description of:
 - the remote monitoring is organized, in accordance with good clinical practice and device's requirements;
 - how alerts are defined and how data are collected;
 - how to obtain the patient consent (example of informed consent:
<https://www.sfcadio.fr/sites/default/files/GROUPES/Rythmologie/consentement/telecardiologie.pdf>);



- the role of the both (a) the treating physician and other health professionals implied in the process and (b) the company at each stage of the procedure;
 - how to respond to alerts (both for the treating physician and the company), i.e. the description of the procedures and response times to be respected;
 - the practical procedures for maintaining regular contacts between the treating physician and the company in the absence of alert and
 - the procedures for regularly checking the validity of the patient's contact details and the action to be taken in the event of failure to transmit the information
 - the skills, training, and specialisations required for both the patient and the health professionals involved (routinely and in the event of an alert)
 - the rules for authorising and securing access rights to the information system supporting the system,
 - the rules for the security, traceability and confidentiality of the data transmitted and stored.
- (iii) A technical appendix specifying the maintenance of the system.

For RM of PM:

- The programming must include the following alerts: device malfunction (panne du boîtier), sensor malfunction, end-of-battery life indicator, and the prolonged interruption of transmission without prior patient-doctor agreement).
- Face to face consultations are initiated in case of alerts and if the patient's condition so requires
- In the absence of an alert: An annual face to face consultation with the patient is required in order to maintain the link with the rhythmology centre and to check the validity of the patient's contact details so as to maintain the possibility of intervention. An annual contact with the treating physician and/or cardiologist is also required in order to maintain a care network around the patient;

Exclusion criteria of the ETAPE Programme	• A co-morbidity that imply a life expectancy inferior to 12 months (based on the opinion of the physician) • Usual therapeutic compliance or adherence estimated to be low • No fixed place of residence	ETAPES - 2020 ⁵²
A required prescription	• A prescription must be renewed every year, except if the prescribing physician is the physician performing the remote monitoring. In this case, no prescription is required	ETAPES - 2020 ⁵²
Quality criteria and other organizational aspects	• One "face-to-face" consultation per year (instead of every 3-6 months), programmed remote monitoring every 3/6 months (at least every 6 months) and management of alerts. When the ICD is close to the indications for elective replacement, or when a particular problem with the ICD threatens patient safety, the programmed remote monitoring must be increased. If the patient's cardiovascular status is unstable, face-to-face follow-up is recommended to ensure appropriate medical management of the patient.	ETAPES – 2020 ⁵² ; CNEDIMTS 2020 ⁵⁵

The implementation of remote monitoring of ICDs should include the following medical management procedures:

- Informing the patient;
- Assessing the suitability of the patient and/or their caregivers for remote monitoring;
- Obtaining the patient's informed consent;
- Performing the initial set-up of the remote monitoring system;
- Analysing the data transmitted at calendar intervals;



	• Verifying and analysing new alerts and associated data transmissions; • Updating the medical profile and system settings; • Intervening (by calling the patient) if the data transmitted by the system so require; • Carrying out additional procedures justified by the teletransmitted data; • Drawing up a medical report following the analysis of the transmitted event data justifying an intervention and/or additional procedure; • Informing other medical professionals involved in the patient's cardiological care. Requirements specific for the centre: • Implementation of a remote ICD monitoring programme; • Prior assessment of the technical feasibility of the application; • Training of patients in the operating conditions of the remote monitoring system and in the procedures for starting up and using the mobile application; • Verification of the activation of the system by the patient, of its correct operation and of the quality of the transmissions, at the time of initiation of the remote monitoring • Implementation of a telephone access for patients.	
Legal aspects	• These systems cannot be considered as providing continuous remote monitoring with a real-time alert system and are not intended to manage medical emergencies nor to replace the emergency service such as SAMU. • The rhythmologist cardiologist (and/or the implantation centre) is responsible for monitoring the technical and medical data (essentially rhythmological) of the implanted prosthesis, transmitted by remote monitoring. He can manage them exclusively or in collaboration with the treating cardiologist and/or the treating physician, in particular for non-rhythmic data. This co-management must then be clearly defined, logically by contract. The medical responsibility cannot be engaged by a failure due to a technological third party. "The physician must, in accordance with Article R. 4127-71 of the Public Health Code (Article 71 of the Medical Code of Ethics), organise the technical and human resources intended to ensure remote monitoring. "	HAS 2017 ²
People implied in the process	• Responsible physician: medical specialist in cardiovascular pathology with expertise in rhythmology and cardiac stimulation • Other potential people implied: other medical specialists in cardiovascular pathology, nurses and the patient GP. The role of each person implied must be described in a protocole (see the reimbursement conditions). • The system must allow for the identification of physicians providing care to patients.	ETAPES - 2020 ⁵²
The role of nurses	• No specific requirements if the nurse works within the framework of his/her competences as defined in the public health codes, i.e. patient information; contact with patients to collect their symptoms and to ensure compliance with treatment (particularly when receiving alerts) or performing some specific acts either according to a written medical prescription or a protocol previously established, written, dated and signed by a physician, including checking that the remote monitoring system is working properly and monitoring the parameters transmitted, including alerts. The responsibility lies with the medical team. • A specific framework of cooperation can also be defined, involving a transfer of tasks from the physician to the nurse. This cooperation protocol between doctors and nurses is described in the order of 7 September 2020 and requires an authorisation from the regional health agency (agence régionale de santé - ARS, after validation by the High Authority of	ETAPES - 2020 ⁵²



Health (*Haute Autorité de Santé - HAS*). The cooperation protocol must detail the transferred activities or acts (usually carried out by the rhythmologist) and the organisation of the methods of intervention with the patient. The nurse involved in such a protocol has a duty to train, must register his or her application for membership with the ARS and performs his or her acts under his or her own responsibility, which requires an insurance guarantee. The implementation of the cooperation protocol must be monitored for 12 months.

- In the future, the potential implication of an advanced practice nurse (*Infirmier de pratique avancée*) will also be defined.
-

Appendix 11.1.3. HAS requirements for ICDs

In 2017, HAS published requirements concerning RM of ICDs. They can be obtained via the following link: https://www.has-sante.fr/upload/docs/application/pdf/2017-08/rapport_systemes_de_telesurveillance_pour_defibrillateurs_cardiaques_automatiques_implantables_07_20_2017-08-28_10-11-32_428.pdf

The following requirements can be found:²

- Requirements on technical aspects: p32-35
- Requirements on the medical activities: p35-37
- Requirements on other organizational aspects: p37-39

Appendix 11.1.4. HAS Requirements for ILRs

In 2021, HAS published requirements concerning RM of ILRs. They can be obtained via the following link: https://www.has-sante.fr/upload/docs/application/pdf/2021-03/rapport_ts_mci_vd.pdf

Requirements on organizational aspects are summarized p8-9.³



Appendix 11.2. The Netherlands

Appendix 11.2.1. Contacted expert

Dr Marcel van der Linde, Lid BBC NVVC (Cardioloog Nederlandse Vereniging voor Cardiologie)

Appendix 11.2.2. Summary and sources

Introduction

Source:

- KCE report 328 ⁵⁶;
- NZA: Wegwijzer bekostiging digitale zorg (March 2020)⁵⁷, available at https://puc.overheid.nl/nza/doc/PUC_316224_22/1/

Health insurance in the Netherlands is characterized by a (regulated) private market. Every citizen must choose a (private) health insurer and every health insurer is obliged to offer the coverage of health care provisions included in the basic health insurance package defined by the authorities, to accept every applicants and to not apply premium differentiation. Beside the basic health insurance package, health care insurers have also the possibility to extend their coverage to additional services. In order to be able to compete on the price of policies and the quality of care offered, health insurers negotiate the price, the volume, and the quality of health care provisions with health care providers (for more details see the KCE report 328 ⁵⁶).

For specialized medical care, including cardiology, this means that health insurers negotiate with the hospital / outpatient clinic or other certified health care institution forms which care services / care activities ("*Zorgactiviteit*") can be registered and declared for a specific diagnosis and a specific care episode. All these agreed care activities are covered by a Diagnosis-Treatment Combination ("*Diagnose Behandelings Combinatie*" - DBC) care product, covering the entire care episode (in- and outpatient care activities). For each care product, either a maximum price has been fixed by the NZa (regulated segment, 30% of DBCs) or the price is freely negotiated between the hospital and the health insurer (free segment, 70% of DBC). In the case of the monitoring of patients with implantable cardiac devices, the prices of the related DBC- care products are freely negotiated but an estimation of the national average price is provided on the website of the NZa (<https://www.opendisdata.nl/msz/zorgproduct>).

Which financing is available for remote monitoring activities provided by health care professionals?

Source:

- NZa: Wegwijzer bekostiging digitale zorg (March 2020)⁵⁷, available at https://puc.overheid.nl/nza/doc/PUC_316224_22/1/),
- NZa - Dbc-zorgproducten⁵⁸ (consulted in May 2021: <https://www.opendisdata.nl/msz/zorgproduct>),



- personal communication of Marcel van der Linde, Lid BBC NVVC

Telemonitoring is a declarable health care activity that can be used for all medical specialties if the remote monitoring of patients within a treatment plan / a care episode was agreed by the health insurer (“Zorgactiviteit code 039133 – Telemonitoring exclusief i.h.k.v. CardioMEMS studie, zie 032716” or “zorgactiviteit 032716 - Telemonitoring intra-arteriële pulmonalis druk i.h.k.v. CardioMEMS studie”).

For declaration and reimbursement, this care activity must currently always be combined with at least one timely consultation by the medical specialist or similar qualified healthcare professional, either physically done in the hospital / outpatient clinic or done remotely. The remote consultations can either be done:

- by phone (“Zorgactiviteit code 190164: Belconsult ter vervanging van een eerste polikliniekbezoek” or “Zorgactiviteit code 190162 - belconsult ter vervanging van een herhaalpolikliniekbezoek”);
- or online / screen-to-screen (“Zorgactiviteit code 190165: Screen-to-screen consult ter vervanging van een eerste polikliniekbezoek” or “Zorgactiviteit code 190166: screen-to-screen consult ter vervanging van een herhaalpolikliniekbezoek”).

Hereafter, the term (e)consult will be used to mention both face to face consultations and remote consultation (without distinction).

It should nevertheless be noted that a request to not automatically imply a (e-)consult when telemonitoring is declared has been introduced to the Dutch Health Care Authority (“Nederlandse Zorgautoriteit”-NZa). The evaluation is in process. The purpose and impact of this would be a reimbursement of the costs of the telemonitoring itself if (e)consultation has no medical added value. It would be a ‘forced’ activity and probably more costly (personal communication of Marcel van der Linde, Lid BBC NVVC).

For the monitoring of patients with a **pacemaker** (diagnosis 803: follow-up after implantation of a pacemakers – “Follow-up na PM implantatie”), two DBC - care products are possible, depending of the number of (e)consults performed and always with the activity “Controle op de werking van cardiale implanteerbare elektronische devices (CIED's) of uitwendige cardioversie-defibrillator (LifeVest), inclusief het eventueel gebruik van de cardioverter, 033311” performed:

- More than two (e)consults, with an average price of €300 in 2019 (“Zorgproduct 219699014: Diagnostiek/ ingreep en/of meer dan 2 polikliniekbezoeken/ consultaties op afstand bij de nazorg na hartafwijking en/of ingreep”)
- 1 – 2 (e)consults, with an average price of €170 in 2019 (“Zorgproduct 219699023: 1 of 2 polikliniekbezoeken/ consultaties op afstand bij de nazorg na hartafwijking of ingreep”)

For the monitoring of patients with an **ICD** (diagnosis 804: follow-up after implantation of an implantable ICD or follow-up of wearer of external cardioversion defibrillator (LifeVest) – “Follow-up na ICD-implantatie of bij drager van uitwendige cardioversie-defibrillator (LifeVest)”), two DBC-care products are possible, also depending of the number of (e)consults performed and always with the activity “Controle op de werking van cardiale implanteerbare elektronische devices (CIED's) of uitwendige cardioversie-defibrillator (LifeVest), inclusief het eventueel gebruik van de cardioverter, 033311” performed:

- More than two (e)consults, with an average price of €365 in 2019 (“Zorgproduct 219699016: Diagnostiek/ ingreep en/of meer dan 2 polikliniekbezoeken/ consultaties op afstand bij de nazorg na inbrengen van inwendige defibrillator (ICD) of het dragen van uitwendige defibrillator (LifeVest)”)



- 1 – 2 (e)consults, with an average price of €175 in 2019 (“Zorgproduct 219699027: 1 of 2 polikliniekbezoeken/ consultaties op afstand bij de nazorg na inbrengen van een inwendige defibrillator (ICD) of het dragen van een uitwendige defibrillator (LifeVest)”)

For the monitoring of patients with an **implantable loop recorder**, the same applies for e.g. conduction disturbances (DBC 404) or syncope (DBC 909) with the activity “Controle op de werking van cardiale implanteerbare elektronische devices (CIED's) of uitwendige cardioversie-defibrillator (LifeVest), inclusief het eventueel gebruik van de cardioverter, 033311” performed

For conduction disturbance (Diagnose 404 ‘Impuls- en geleidingsstoornissen):

- More than two (e)consults, with an average price of €390 in 2019 (“Zorgproduct 099899075: Diagnostiek/ ingreep en/of meer dan 2 polikliniekbezoeken/ consultaties op afstand bij een impuls en/of geleidingsstoornis van het hart”)
- 1 – 2 (e)consults, with an average price of €190 in 2019 (“Zorgproduct 099899085: 1 of 2 polikliniekbezoeken/ consultaties op afstand bij een impuls of geleidingsstoornis van het hart”)

For syncope (Diagnose 909 (other)) :

- More than two (e)consults, with an average price of €445 in 2019 (“Zorgproduct 099599002: Diagnostiek/ ingreep en/of meer dan 2 polikliniekbezoeken/ consultaties op afstand bij een ziekte van het hart en/of vaatstelsel”)
- 1 – 2 (e)consults, with an average price of €210 in 2019 (“Zorgproduct 099599007: 1 of 2 polikliniekbezoeken/ consultaties op afstand bij een ziekte van het hart of vaatstelsel”)

As shown above, the same care product is used for a remote monitoring or an in-clinic monitoring. This is usual in the Netherlands. Health care products are described as functionally as possible and it is especially the care activity that is described, but not who provides the care or where it is performed. This gives healthcare providers and healthcare insurers a lot of room to make their own choices about the use of digital healthcare. This also allows healthcare providers to change the process of care within the existing product by partially replacing face-to-face care with digital care, without change of the negotiated price.

Which financing is available for the equipment and services provided by the fabricant / distributor?

Source:

- NZa: Wegwijzer bekostiging digitale zorg (March 2020)⁵⁷, available at https://puc.overheid.nl/nza/doc/PUC_316224_22/1/

Medical devices used in the context of telemonitoring fall within the scope of specialist medical care and are paid as part of the DBC.

**Which quality criteria and other organizational aspects are included in the reimbursement conditions?**

Source:

- NZa - Dbc-zorgproducten⁵⁸ (consulted in May 2021: <https://www.opendisdata.nl/msz/zorgproduct>),
- Personal communication of Marcel van der Linde, Lid BBC NVVC,
- Personal communication with Dutch health insurers
- Expert consensus published by the Netherlands Society of Cardiology, available at : https://www.nvvc.nl/Richtlijnen/Definitief%20product_CIED%20Remote%20monitoring%20versie%20final%2014-10-2011%20nvh.pdf ⁵⁹

As stated in the previous section, for declaration and reimbursement, each remote monitoring activity must currently always be combined with at least one timely consultation by the medical specialist or similar qualified healthcare professional, either physically done in the hospital / outpatient clinic or done remotely.

Moreover, if a remote monitoring is performed, the same requirements have to be fulfilled than with an in-clinic follow-up, with the same reporting and time investment of the healthcare professionals. This is the same rule for all forms of digital health care (personal communication of Marcel van der Linde, Lid BBC NVVC).

To obtain additional information on requirements imposed by the health insurers, all health insurers mentioned on the website of the association representative of Dutch health insurers (Zorgverzekeraars Nederland) were contacted without success.⁶⁰ Only two insurers that do not consider RM of CIEDs patients responded. Nevertheless, in the Netherlands, compliance with guidelines and consensus are required. In 2011, the Netherlands Society of Cardiology published an expert consensus on the standard care for the RM of patients with CIEDs including quality, technical and legal aspects.⁵⁹ Such consensus can be found here (https://www.nvvc.nl/Richtlijnen/Definitief%20product_CIED%20Remote%20monitoring%20versie%20final%2014-10-2011%20nvh.pdf) and contain a.o. the following specifications:⁵⁹

- RM cannot be an obligatory patient care;
- It is not a continuous 24 h/d, 7d/w monitoring;
- Device companies are not responsible for delays or lack of alerts and follow-up due to failing landline or global system for mobile Communications technology;
- Attention should be given to the patient's informed consent, including information on the expectations and restrictions of RM (not an emergency service, use of the standard way if serious acute events), the contribution and responsibilities of the patient (proper handling of the transmitter, ensuring proper communication with the centre), the timing of unscheduled transmission, analysis of data and feedback to the patient, and if done, an agreement on the use of data for assessing long-term CIED performance;
- A protocol should formalize the manufacture's interaction with the cardiologist, allied professional and hospital as well as their responsibilities;



- Security and confidentiality of data must be ensured (encrypted messages, secure websites)
- Increasing the uniformity of methods of remote CIED monitoring as well as standardized presentation of data would be needed;
- They also recommended required alerts and thresholds for scheduled and unscheduled monitoring as well as optional alerts.

It should also be noted that the Netherlands funds a program (called 'MedMij') that develops specific standards and a label confirming that health data can be exchanged in a safe and reliable way (see the KCE report on teleconsultations for details).⁵⁶

Who is implied in the RM process?

Source:

- personal communication of Marcel van der Linde, Lid BBC NVVC

Concerning general (e)consultation as well as the monitoring of patients with implantable cardiac devices, they can be registered and declared by a medical specialist, a nurse specialist, a physician assistant or a clinical technologist, provided that they are certified and skilled for these activities. In general these kind of healthcare professionals work together and have complimentary functions around the patients (personal communication of Marcel van der Linde, Lid BBC NVVC).

Appendix 11.3. Germany

Appendix 11.3.1. Contacted expert

Uncertain aspects were checked by a German expert via Lydie Van Cauwenberghe (Medtronic). Such expert has nevertheless not read the whole description.

Appendix 11.3.2. Summary and sources

Introduction

A distinctive characteristic of the German healthcare system is the separation of inpatient and outpatient care. This separation is reflected in the reimbursement mechanism overall, and in the reimbursement for CIED telemonitoring specifically. Typically, hospitals are responsible for operations, with inpatient services, including cardiac implants, reimbursed via diagnosis related groups (DRGs). However, certain procedures may also be performed in an outpatient setting, and then reimbursed as part of the catalogue for outpatient services (Einheitlicher Bewertungsmaßstab, or EBM). Regular follow-up device checks are performed in the outpatient sector through outpatient cardiologists or outpatient care centres within hospitals. The SHI generally reimburses physicians for outpatient services, which are part of the EBM, via lump sum payments to the Associations of Statutory Health Insurance Physicians (Kassenärztliche Vereinigungen).⁶¹



Which financing is available for remote monitoring activities provided by health care professionals?

In December 2015 (Bewertungsausschusses vom 15 Dezember 2015), the telemedical functional analysis of implanted cardioverters or defibrillators and implanted systems for cardiac resynchronization therapy was included in the EBM as the first telemedical service. This service has been part of the standard care in the statutory health insurance system since then.

Source: <https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/guv-19-lp/dvpmg.html> (published 06/05/2021).

ICDs and CRTs:

Physician outpatient services relating to the remote functional analysis of ICDs and CRTs (i.e. regular scheduled device checks) are reimbursed at the same level as that for face-to-face follow-ups, i.e. €44.5 for ICDs checks and €54.73 for CRTs (See Table 11). The functional analysis of the device consists in remotely:

- Checking the battery condition,
- Checking and documentation of the collected parameters and measured values,
- Control of the functionality of the electrode(s)

RM activities other than this “functional analysis” (such as the management of unscheduled alerts), are not covered yet but should be reimbursed this year for ICD and CRT devices after a positive decision from the authorities (GBA) (see below the box “The new DVPMG law”). This should lead to additional reimbursement for healthcare professionals and manufacturers. Source: personal communications with Lydie Vancauwenberghe (Medtronic, June 2021)

PMs and ILRs:

So far, there is no reimbursement for the remote monitoring (nor the functional analysis) of PMs and ILRs.

Source: https://www.kbv.de/media/sp/EBM_Gesamt_-_Stand_2._Quartal_2021.pdf

Table 11 – Coverage of RM activities provided by health care professionals

	Remote functional analysis	In-office functional analysis
CRT		
EBM code	13576	13575
Description	Telemedical functional analysis of an implanted system for cardiac resynchronization therapy (CRT-P, CRT-D)	Functional analysis of an implanted system for cardiac resynchronization therapy (CRT-P, CRT-D)



Mandatory performance content	• Telemedical functional analysis of an implanted system for cardiac resynchronization therapy (CRT-P, CRT-D), • Checking the battery condition, • Checking and documentation of the collected parameters and measured values, • Control of the functionality of the electrode(s)	• Personal doctor-patient contact, • Functional analysis of an implanted system for cardiac resynchronization therapy (CRT-P, CRT-D), • checking the battery condition, • Checking and documenting the programmable parameters and measured values by printing out the programmer, • Control of the functionality of the electrode(s)
Points	492	492
Fee	€54.73	€54.73
Conditions	• The calculation of the fee schedule item 13576 presupposes in the event of illness at least a functional analysis according to the fee schedule item 13575 - if possible in the doctor's office of the telemedicine monitoring contract doctor. • The calculation of the fee schedule item 13576 requires proof of compliance with the requirements according to Annex 31 to the Federal Umbrella Contract Physicians (BMV-Ä). • The fee schedule items 13575 and 13576 can be calculated in total no more than five times per case of illness.	• The fee schedule items 13575 and 13576 can be calculated in total no more than five times per case of illness.

ICD

EBM code	13574	13573
Description	Telemedical functional analysis of an implanted cardioverter or defibrillator	Functional analysis of an implanted cardioverter or defibrillator
Mandatory performance content	• Telemedical functional analysis of an implanted cardioverter or defibrillator, • checking the battery condition, • Checking and documentation of the collected parameters and measured values,	• Personal doctor-patient contact, • Functional analysis of an implanted cardioverter or defibrillator, • checking the battery condition, • Checking and documenting the programmable parameters and measured values by printing out the programmer,



Points	Control of the functionality of the electrode(s) 400	Control of the functionality of the electrode(s) 400
Fee	€44.50	€44.50
Condition	- The calculation of the fee schedule item 13574 requires at least one functional analysis per case of illness in accordance with the fee schedule item 13573 - if possible in the doctor's office of the telemedicine monitoring contract doctor. - The calculation of the fee schedule item 13574 requires proof of compliance with the requirements according to Annex 31 to the Federal Umbrella Contract Physicians (BMV-Ä). - The fee schedule items 13573 and 13574 are billable a total of a maximum of five times per case of illness.	The fee schedule items 13573 and 13574 may be billed a total of a maximum of five times per case of illness.

PM

EBM code	Not telemedical equivalent was found.	13571
Description	-	Functional analysis of a pacemaker for antibradycardial therapy
Mandatory performance content	-	Personal doctor-patient contact, Functional analysis of a pacemaker for antibradycardial therapy, checking the battery condition, Checking and documenting the programmable parameters and measured values by printing out the programmer, Control of the functionality of the electrode(s)
Points	-	216
Fee	-	€24.3

**Conditions**

-

The fee schedule item 13571 can be calculated a maximum of five times in the event of illness.

Source: Kassenärztliche Bundesvereinigung Berlin, Stand 2021/2, erstellt am 01.04.2021 - https://www.kbv.de/media/sp/EBM_Gesamt_-_Stand_2._Quartal_2021.pdf

The new DVPMG law (not enforced yet)

Services relating to remote monitoring of cardiac devices are not reimbursed yet. However, the draft law on the Digital Modernization of Care and Nursing Care (Digitale Versorgung und Pflege Modernisierungs Gesetz - DVPMG) was adopted by the Bundesministerium für Gesundheit on 20/01/2021 and the new law will likely be enforced in mid-2021.

This law has several objectives, one of them being the expansion and the attractiveness of telemedicine, such as cardiac telemonitoring:

- (1) Insured persons are entitled to the supply of medical products that are required as transmission devices for performing telemedical treatments that are subject to payment, provided that these devices are not to be regarded as general objects of daily use.
- (2) In addition to providing the devices, the claim includes the telemedical infrastructure required for their use, which guarantees the telemedical functionality, in particular IT-related services for wireless data transmission or data backup. Sentence 1 applies accordingly if the transfer takes place with everyday objects.
- (3) The manufacturers provide the insured persons with the transmission devices according to Paragraph 1 and the telemedical infrastructure required for their use according to Paragraph 2 on the basis of a statutory health insurance prescription or a prescription issued by an outpatient clinic and calculate the costs incurred for this directly with the health insurance companies from.

Sources: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/D/DVPMG_BT_bf.pdf
<https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/guv-19-lp/dvpmg.html> published 06/05/2021

Which financing is available for the equipment and services provided by the fabricant / distributor?

The providers typically responsible for the implant – the hospitals – are reimbursed using DRGs.

In the Operation and Procedure Code (OPS), which is used to code operations and medical procedures, section 5-377 lists the codes referring to all pacemakers, defibrillators and event recorders that can be implanted. There is a separate code (5-377.e) to be used additionally for the devices equipped with an automatic remote monitoring system (Source: OPS version 2021, Chapter 5, Heart surgery (5-35...5-37) <https://www.dimdi.de/static/de/klassifikationen/ops/kode-suche/opshtml2021/block-5-35...5-37.htm>). However, this separate OPS code for RM doesn't impact the reimbursement (personal communications with Lydie Vancauwenberghe - Medtronic, June 2021).

Moreover, there is no regular funding of telemonitoring infrastructure and support services, although some compulsory health insurers like DAK, have agreed on individual contracts with physicians and an industry partner on the reimbursement of telemonitoring infrastructure.⁶¹ Costs for external transmission devices



(transmitters) in connection with the provision of telemedical services are not billable. Source: https://www.kbv.de/media/sp/EBM_InnereMedizin_20210401_V1.pdf (accessed 10/06/2021).

The forthcoming “New DVPMG law” should allow a better reimbursement of the RM system infrastructure (see the box above).

Which quality criteria and other organizational aspects are included in the reimbursement conditions?

The prerequisite to the reimbursement of a remote functional analysis for an ICD or a CRT is a prior in-office functional analysis (if possible in the doctor's office of the telemedicine monitoring contract doctor) and the approval of the responsible Association of Statutory Health Insurance Physicians. Both control modalities (in-office and remote) may be billed in total a maximum of 5 times per year.

Source: <https://www.kbv.de/html/online-ebm.php>

Who is implied in the RM process?

Federal Ministry of Health – Notice of a decision of the Federal Joint Committee on an amendment to the Directive Methods of contract medical care: Telemonitoring in heart failure. 17 December 2020

For the purposes of this Directive, telemonitoring in the event of heart failure means a data-based and timely management, which is generally carried out in cooperation between a primary attending physician (PBA) and a medical telemedicine centre (TMZ).

- (1) The PBA is responsible for the guideline-compliant care of the patient with heart failure and for the treatment measures resulting from telemonitoring.
- (2) The TMZ is responsible for the processes related to the implementation of telemonitoring: data collection, analysis, sighting and notification, as well as coordination with the PBA. Decisions that are important for the successful implementation of telemonitoring are coordinated between PBA and TMZ. The TMZ may, after appropriate prior consultation with the PBA, temporarily assume their function in cases of non-accessibility. If the patient was already a patient with a PBA that meets the structural and procedural requirements for a TMZ before the telemonitoring, the two functions can be taken over together.

TMZ must be doctors licensed to participate in contract medical care in accordance with § 95 SGB V, licensed medical care centers, authorized physicians or authorized institutions.

The implementation and billing of telemonitoring for heart failure in the TMZ requires a corresponding approval by the responsible association of statutory health insurance physicians. Telemonitoring in the TMZ may only be provided by specialists in internal medicine and cardiology (cardiologist) at the expense of statutory health insurance.

Source:

<https://www.bundesanzeiger.de/pub/de/amtliche-veroeffentlichung?1>

https://www.g-ba.de/downloads/39-261-4648/2020-12-17_MVV-RL_Telemonitoring-Herzinsuffizienz_BAnz.pdf



Appendix 11.4. Discussion – Stakeholder meeting

Appendix 11.4.1. *Proposal of BeHRA*

Télémonitoring des défibrillateurs
cardiaques implantés :
Une proposition de modèle de
financement en Belgique

Dr Georges H. MAIRESSE, MD, FESC
Cardiologie, Electrophysiologie
Cliniques du Sud-Luxembourg, Arlon
Chairman of BeHRA



BeHRA
Belgian Heart Rhythm Association

**“e.Health is not an option,
it is a fact”**

Loukianos Gatzoulis
DG Information Society And Media
European Commission





Les bénéfices du télémonitoring

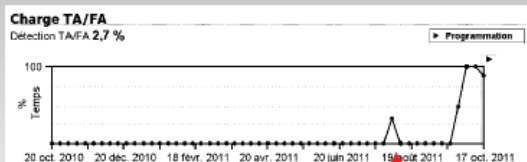
Un diagnostic plus précoce
pour une meilleure prise
en charge et une
reprogrammation plus
précoce

Automatic Remote Monitoring of Implantable Cardioverter-Defibrillator Lead and Generator Performance : The Lumos-T Safely RedUces RouTine Office Device Follow-Up (TRUST) Trial

	Télécardiologie	Contrôle programmé
Fibrillation ventriculaire	10,5	45
Tachycardie ventriculaire	12,9	46,6
Tachycardie supra-ventriculaire	16,6	42,1
Fibrillation atriale	25,2	46,8

délai entre le début du trouble du rythme et l'intervention (en jours)

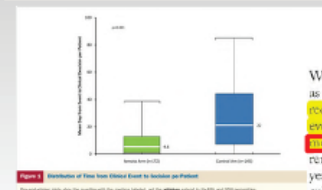
Un traitement plus
précoce aux
anticoagulants :
éviter des AVC



Le patient est appelé et anticoagulé

Une prise en charge de
la décompensation
cardiaque plus précoce :
des hospitalisations plus
courtes

The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) Trial



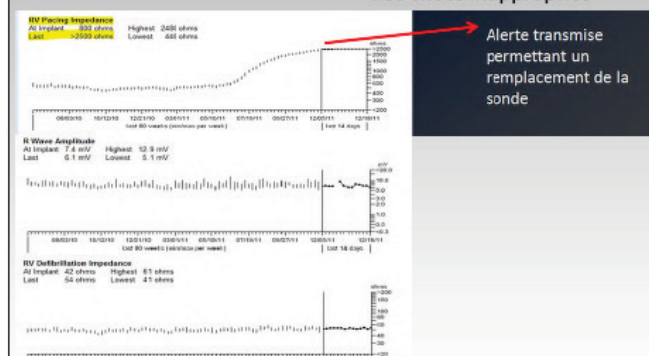
Wireless remote monitoring with automatic clinician alerts as compared with standard in-office follow-up significantly reduced the time to a clinical decision in response to clinical events and was associated with a significant reduction in mean length of hospital stay. Clinics employing wireless remote monitoring may expect fewer total clinic visits per year while not increasing the rate of ED visits or cardiovascular hospitalizations for their patients.

G. Crossley et al
JACC : 2011 : 57; 181-1189

-1800 dollars par
hospitalisation



Un diagnostic plus
précoce des
complications : éviter
des chocs inappropriés



Des déplacements
pour contrôles
moins chers



La charge de travail et
le coût hospitalier du
télémonitoring en
Belgique

Questions posées à tous les centres E belges, via tous les membres effectifs du BeHRA

1. Are you performing télémonitoring of ICDs? YES / NO
2. Which telemonitoring systems/brands are followed at your hospital?
 - a. Biotronik : Corallo Messenger YES / NO
 - b. Boston scientific : Latitude YES / NO
 - c. Medtronic : CareLink YES / NO
 - d. St Jude Medical : Merlin.net YES / NO
- Alternative, (if you think that the question about company's is to personal):
How many different telemonitoring systems/brands are used in your hospital? Circle one: 1 - 2 - 3 - 4?
3. How many ICD patients in total are you following using telemonitoring?
4. What is the average time PER WEEK that your PARAMEDICAL staff uses for the telemonitoring of ALL your ICD patients (including training of the patient, daily checks of the websites, programmed trans telephonic follow-ups, solving technical problems, response to incidents, filing and administration of your telemonitoring tracings...)
5. What is the average time PER WEEK that YOU or OTHER DOCTORS from your site uses for the telemonitoring of ALL your ICD patients (including training of your staff, training of the patient, regular checks of the websites, programmed trans-telephonic follow-ups, response to incidents, action to the patient when needed, filing and administration of your telemonitoring tracings...)

Enquête
BeHRA



- 15 centres ont répondu
 - Centres établis (>100 pat)
 - Centres en développement (20-100 pat)
 - Expériences ponctuelles (<20 pat)
- Données sur 1,576 patients (estimation 5,000 à 6,000 porteurs d'ICD vivants en Belgique)
(estimation 2,000 porteurs d'ICD actuellement suivis en télémonitoring)

Réponses enquête BeHRA

- Le temps moyen par semaine consacré par un paramédical sous supervision est de :
 - 4.5 ± 4.3 minute par patient et par semaine (avec une variabilité de 0 pour le médecin qui travaille seul, à 10 min/patient/jour dans un centre en développement)
 - moyenne de 0.9 minute/patient/jour ouvrable
 - Il faut $\frac{1}{2}$ ETP pour le suivi de 200-250 patients
- Le temps moyen par semaine consacré par un cardiologue est de :
 - 1.4 ± 1.1 minute par patient et par semaine
 - moyenne de 0.3 minute/patient/jour ouvrable.

Réponses enquête BeHRA

- En considérant
- -à 60.000 EUR le coût moyen annuel d'un paramédical
 - -à 120.000 EUR le coût annuel d'un cardiologue
 - -à 220 le nombre de jours travaillés annuels
 - -donc à 220 jours x 7,5 heure/j x 60 min/h = 99.000 minutes = un horaire annuel on pourrait estimer
 - -le coût de la minute paramédicale à 0.6 EUR/min
 - -le coût de la minute cardiologique à 1.2 EUR/min
 - et le coût du suivi télécadiologique (tel que pratiqué actuellement), et sur base de 250 jours ouvrables/an à $(0.9 \times 0.6 \times 250) + (0.3 \times 1.2 \times 250)$
= 225 EUR/an /patient

Il est évident que ceci ne concerne que un suivi en PERIODES OUVRABLES. Un suivi quotidien y compris WE et fériés serait d'un coût au moins doublé

Calcul de coût pour l'hôpital

Une proposition :



Certains pays (Allemagne, USA) ont autorisé un remboursement par contrôle transtéléphonique réalisé, mais en limitant leur nombre à x/an.
Le BEHRA estime plus intéressant pour le patient et le système de sécurité sociale un remboursement forfaitaire, couvrant les contrôles transtéléphoniques programmés, mais aussi le suivi permanent des alertes.

Proposition de Création d'un code : aaaaaa/----- : Honoraire annuel de surveillance par télémonitoring d'un défibrillateur cardiaque implanté ou d'un pacemaker de resynchronisation CRT-P, permettant une intervention de l'équipe cardiologique vers le patient dans les 3 jours ouvrables de la transmission d'un incident ou d'une information clinique.

Valeur : K 198 (valeur actuelle du K : 1,133594)

Règles interprétatives :

- Ce code ne peut être porté en compte qu'une seule fois par année civile par le cardiologue qui effectivement assure le télémonitoring du patient durant cette année. Le patient ne peut donc changer de centre pour son télémonitoring qu'une fois par année.
- Il ne peut être porté en compte que par un cardiologue travaillant dans un hôpital disposant d'un agrément pour un programme cardiaque E.
- Il est cumulaire avec les codes d'honoraires 475856 – 475860, 475871 – 475882, et 475893 - 475904 du suivi normal des défibrillateurs et pacemakers tels que décrits à l'AR du 17 octobre 2008.

Le forfait all-in ?

Suivi selon nomenclature 2010 :

$102594 + 475075 + 475893 = 164,51 \text{ EUR}$

3 contrôles/an = 493,53 EUR

Suivi selon nomenclature 2012 :

$102594 + 475893 = 115,77 \text{ EUR}$

3 contrôles/an = 347,31 EUR

Suivi forfait all-in :

$347,31 \text{ EUR} + 225 \text{ EUR} = 572,31 \text{ EUR}$

Le problème du all-in : Répartition entre centre implantateur, centre E assurant le télémonitoring, centre référent et cardiologue référent...

Quid des contrôles intercurrents ?

Nous savons qu'il y a eu en 2009 13.544 codes 475893 (suivi ICD, patient externe) et 3.567 codes 475904 (suivi ICD, patient hospitalisé)

Il y a en Belgique environ 6.000 porteurs vivants porteurs d'ICDs

Certains patients ne seront JAMAIS suivis en télémonitoring

- -ICD non compatibles
- -réseau téléphonique non compatible
- -télémonitoring vécu comme anxiogène
- -patient non compliant
- -refus par le patient
- -refus par le cardiologue

Estimation 2011 : 2.000 patients actuellement en télémonitoring

Impact
budgétaire

Impact
budgétaire

Estimation 2011 : 2.000 patients actuellement en télémonitoring

Budget année 1 : $2.000 \times 225 = 450.000 \text{ EUR}$

Estimation des années futures dépend de 3 phénomènes :

- a/La création d'un code de nomenclature pourrait attirer une majorité de tous les patients implantés avec un boîtier compatible avec un système de télémonitoring, pour atteindre en 2 ans 3.000 des patients actuellement implantés (+500 patients en année 2 et encore +500 en année 3)
- b/ 2/3 des patients nouvellement implantés seront suivis par télémonitoring (1.000 sur les 1.500 annuels)
- c/L'impact des CRT-P est minime : <5% du nombre des ICDs.

▪ Budget année 2 : $(2.000 + 500 + 1.000 = 3500) \times 225 = 787.500 \text{ EUR}$

▪ Budget année 3 : $(3500 + 500 + 1.000 = 5000) \times 225 = 1.125.000 \text{ EUR}$

▪ Budget année 4 : $(5000 + 1.000 = 6.000) \times 225 = 1.350.000 \text{ EUR}$

▪ Budget année 5 : $(6000 + 1.000 = 7.000) \times 225 = 1.575.000 \text{ EUR}$



- Centres E avec intérêt dans le télémonitoring
- Au moins 2 cardiologues rythmologues
- Equipe cardiologique assurant une disponibilité permanente 52 semaines/an
- Possibilité de contacter 7/7 24/24 un cardiologue compétent pour le suivi des défibrillateurs.
- Gestion des alertes et transmissions du télémonitoring dans les 72 heures

Projet pilote ?

Le coût du device et du service

- Fourniture du moniteur au patient + transmission des données (GSM) + site internet + support technique + SAV
- Estimation : 1 EUR/jour
- Estimation Carelink : 1,300 EUR/device

Coût

Création d'une liste distincte (comité technique des implants) pour les ICD et CRTP avec capacité de télémonitoring

Proposition minimaliste

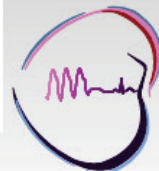


En résumé :

- Valeur ajoutée du télémonitoring des ICD et CRTP
- Cout médical/paramédical hospitalier : 225 EUR/an
- Budget année 1 : <500.000 EUR/an
- Budget en année pleine: 1.500.000 EUR/an

En résumé :

Merci de votre attention...



BeHRA
Belgian Heart Rhythm Association



Appendix 11.4.2. Proposal of RM systems providers

Voorstel van de CRM-leden van be.MedTech voor de vergoeding van remote monitoring (RM) bij patiënten met implanteerbare hartapparaten

- I. Naar analogie met terugbetalingsmodellen in bestaande RIZIV-overeenkomsten (conventies) [Ref], stellen de bedrijven een forfaitaire vergoeding per patiënt voor. Deze vergoeding dekt het materiaal, software, diensten en alle technische ondersteuning die nodig is voor het initiëren en opvolgen van een patiënt met een remote systeem.

Het honorarium van de artsen maakt geen deel uit van dit voorstel. Voor de prestaties van de artsen zou een aparte vergoeding moeten voorzien worden. Dit kan eventueel door het gelijkschakelen van een face-to-face consult met een remote consult of via een aparte al dan niet forfaitaire vergoeding.

Zich baserend op de kostenanalyse van de verschillende bedrijven, lijkt een forfait van € 0.8 per dag en per patiënt een billijke vergoeding. Deze forfait zou jaarlijks kunnen uitbetaald worden.

- II. He lijkt ons ook wenselijk de minimale technische vereisten waaraan een RM-systeem moet voldoen in de overeenkomst te integreren. In haar “*Rapport d’évaluation technologique: Rapport d’évaluation de télésurveillance pour défibrillateurs cardiaques automatiques implantables – CNEDIMTS – Juillet 2017*”, geeft de « Haute Autorité de Santé – HAS » van Frankrijk een omschrijving van deze minimale technische vereisten. Deze zouden als referentie kunnen dienen voor het opstellen van de criteria in België:

Minimale technische vereisten

De Commissie is van mening dat de technische ondersteuning die nodig is voor de implementatie van telemonitoring alle garanties moet bieden die nodig zijn voor de bescherming van patiëntgegevens, in overeenstemming met de geldende wetgeving en moet voldoen aan specificaties en vereisten met betrekking tot:

1. *Het opstarten van automatische kalenderverzendingen. De kalendertransmissies moeten kunnen gerealiseerd worden op gedefinieerde data of intervallen.*
2. *Het initiëren van automatische verzending van gebeurtenissen (alerten)*
3. *Automatische overdracht van de DAI (ICD) naar de zender, draadloos, op afstand van opgeslagen gegevens*
4. *Automatische verzending van de zender naar de datahostserver*
5. *Ondersteuning voor communicatiekosten*
6. *Overdracht van gegevens die identiek zijn aan die welke persoonlijk met een programmeur kunnen worden bekeken*
7. *Het activeren van waarschuwingen bij technische en klinische gebeurtenissen*
8. *De veilige hosting van individuele gezondheidsgegevens, in overeenstemming met de geldende regelgeving*
9. *Persoonlijke, veilige en permanente toegang tot de verzonden gegevens*



10. *Terbeschikkingstelling en onderhoud van de interface voor gegevensconsultatie, software en bijbehorende applicaties*
11. *Gegevens exporteren in een interoperabel formaat*
12. *Kennisgeving in de vorm van waarschuwingen van technische en klinische gebeurtenissen*
13. *Het verstrekken van het materiaal dat nodig is voor de overdracht van gegevens aan de patiënt*
14. *Technische bijstand voor patiënten, hun families en verzorgers*
15. *Herstel van de zender (en zijn verbindingen)*
16. *De praktische en theoretische opleiding, initiële en voortgezette opleiding van professionele gebruikers*
17. *Technische bijstand voor gezondheidswerkers*
18. *Opstellen van een technische bijlage.*

- III. De forfaitaire vergoeding zou enkel van toepassing zijn op patiënten die actief via RM gevolgd worden. In het geval van remote monitoring kan nagegaan worden of de patiënt effectief gebruikt maakt van de aangeboden remote diensten. De verdelers zouden kunnen controleren op jaarlijkse of halfjaarlijkse basis of de toestellen door de patiënt nog geconnecteerd zijn voor remote monitoring. Het jaarlijks rapporteren van het aantal geregistreerde actieve systemen zou als referentie kunnen dienen voor het berekenen van de jaarlijkse forfaitaire vergoeding.
- IV. De bedrijven zijn geen voorstander van een gedifferentieerde terugbetaling voor de verschillende types van toestellen (ICD, PM, Single/Dual/CRT, hartmonitoren). De kosten voor het initiëren en opvolgen van de verschillende toestellen zijn vanuit het standpunt van de bedrijven vergelijkbaar. De industrie is ervan overtuigd dat voor elk van deze types patiënten remote monitoring een meerwaarde kan betekenen. Het is de taak van de wetenschappelijke verenigingen en van de vergoedingsautoriteiten om te bepalen welke patiënt het meest baat heeft bij RM en voor een vergoeding in aanmerking kan komen.
- V. In de bestaande conventies verloopt het toekennen van het forfait via de ziekenhuizen. Zij ontvangen het forfait en betalen, in principe, hetzelfde bedrag terug aan de bedrijven. Indien mogelijk en in het belang van administratieve vereenvoudiging zouden deze bedragen rechtstreeks aan de industrie kunnen gestort worden.

¹Twee concrete voorbeelden van bestaande RIZIV-overeenkomsten:

- Overeenkomst inzake cardiorespiratoire monitoring thuis bij pasgeborenen en zuigelingen. <https://www.riziv.fgov.be/nl/themas/kost-terugbetaling/door-ziekenfonds/gespecialiseerde-centra/Paginas/cardiorespiratoir-toezicht-op-zuigelingen.aspx>
- Slaapapneusyndroom: tegemoetkoming in de kosten van een thuisbehandeling met een nCPAP-toestel, met een auto-CPAP-toestel of met een mandibulair repositieapparaat. <https://www.riziv.fgov.be/nl/themas/kost-terugbetaling/ziekten/ademhalingsziekten/Paginas/slaapapneusyndroom-tegemoetkoming-thuisbehandeling.aspx>



APPENDIX 12. PEOPLE INVITED AT THE STAKEHOLDER MEETING

Only experts and stakeholders that sent us a declaration of their conflicts of interests were mentioned in the colophon. The list of all people invited at the stakeholder meeting can be found below.

Institution/Organisation	First Name	Name
Patients' associations		
LUSS	Bernadette	Pirsoul
VPP	Marit	Mellaerts
PRT	Stephanie	Wermeester
Federal institutions		
RIZIV - INAMI	Marleen	Louagie
RIZIV - INAMI	Pieter	Geentjens
RIZIV - INAMI	Frédéric	Lecomte
RIZIV - INAMI	Marta	Moreira Carrico
RIZIV - INAMI	Eva	D'haese
FOD Volksgezondheid – SPF Santé Publique	Erik	Vertommen
RM systems' providers + BeMedTech		
BeMedTech	Koen	Bruylant
Medtronic	Lydie	Vancauwenberghe
Medtronic	Paul	Van De Voorde
Abbott	Yves	De Wilde
Abbott	Rita	Saeys
Boston Scientific	Hugo	Geeraert
Boston Scientific	Rémi	Delépine
Biotronik	Manuel	Sabbe
Biotronik	Alexander	van den Oever
Microport	Jos	Backers
Microport	James	Burm



Microport	Sven	van Dun
Experts in innovation		
Agoria	Absil	Carole
Agoria	Alexander	Olbrechts
Representatives of medical specialists		
ABSyM-BVAS	Bart	Dehaes
Representatives of hospitals		
Association belge des Directeurs d'Hôpitaux (ABDH)	Paul	d'Otreppe
Zorgnet-Icuro	Marc	Geboers
Zorgnet-Icuro	Peter	Raeymaekers
Santhea	Michel	Praet
GIBBIS	Dieter	Goemaere
Sickness funds		
MC	Fabien	Delcourt
CM	Frigg	Eulaers
MC	Adélie	Jonckheere
Socmut	Bart	Demyttenaere
MLOZ	Murielle	Lona
Solidaris	Marie-Pascale	Versailles
Medical specialists listed in the RIZIV-INAMI convention for ICDs		
Universitair Ziekenhuis Gent (UZGent)	Dr. B. Drieghe, Dr. F. Van Heuverswyn, Dr. L. Timmers, Dr. J. Depooter	
Universitair Ziekenhuis Antwerpen (UZA)	Dr. H. Miljoen Dr. J. Saenen Dr. A. Sarkozy Dr. H. Heidbüchel	



Universitaire Ziekenhuizen Leuven (UZ Leuven - Gasthuisberg)	Dr. R. Willems Dr. J. Ector Dr. C. Garweg Dr. P. Haemers Dr. B. Klop Dr. T. Robyns
C.H.U. de Liège - Sart Tilman	Dr. L. Vancasteren Dr. A. Delcour
ULB - Hôpital Erasme	Dr. R. Casado Arroyo Dr. J. Abagattas De Torres
CHU Brugmann	Dr. Th. Verbeet Dr. J. Castro Dr. T. Nguyen
Cliniques Universitaires de Mont Godinne	Dr. D. Blommaert Dr. O. Xhaet
Onze-Lieve-Vrouwziekenhuis	Dr. P. Geelen Dr. P. Peytchev Dr. T. De Potter
A.Z. Sint-Jan Brugge	Dr. R. Tavernier Dr. M. Duytschaever Dr. M. Tahmaseb Dr. S. Knecht J.-B. Le Polain de Waroux
Ziekenhuisnetwerk Antwerpen –AZ Middelheim	Dr. Y. De Greef Dr. B. Schwagten Dr. M. Wolf
C.H.R. de la Citadelle Liège	Dr. J.M. Herzet DR. C. Barbraud



Virga Jesse Ziekenhuis	Dr. J. Vijgen Dr. D. Dilling-Boer Dr. P. Koopman J. Schurmans T. Philips
AZ Delta	Dr. P. Pollet Dr. W. Anné Dr. W.- J. Acou
AZ Maria Middelaes Gent	Dr. F. Provenier Dr. B. François
ZOL - Autonome Verzorgingsinstelling	Dr. M. Rivero-Ayerza Dr. W. Mullens Dr. H. Van Herendael Dr. M. Dupont Dr. D. Nuyens Dr. L. Pison Dr. P. Nijst
Centre Hospitalier Regional Namur	Dr. X. Carryn Dr. N. Feller Dr. O. Deceuninck
Cliniques Universitaires St. Luc	Dr. Chr. Scavee Dr. S. Marchandise Dr. Q. Garnir Dr. V. Varnavas Dr. A-C Pouleur (added)
Universitair ziekenhuis Brussel	Dr. J-B Chierchia Dr. C. De Asmundis Dr. J.A. Sieira-Rodriguez-Moret Dr. E. Ströker

Some people were not in the list of invited but participated to the stakeholders meeting and reported their declaration of conflict of interest. They were therefore listed in the colophon. Finally, some people are neither mentioned in the colophon nor in the list of invited people but have participated to the stakeholder meeting, such as Dr Koen van Bockstal (OLV Hospital Aalst) and Dr. Ward Heggermont (OLV Hospital Aalst).



APPENDIX 13. VALIDATION PROCESS

In each KCE report, three validators are invited to read and assess the final scientific report. The objective of this external scientific validation of KCE reports is to obtain a high-quality, objective opinion on the research carried out. The validation relates to the content of the scientific report and not to the recommendations.

The three validators involved in the final phase of this report were:

- Mr Julien Mousques (Health economist, IRDES, France)
- Dr Haran Burri (Medical specialist in cardiology, University Hospital of Geneva, Switzerland);
- Dr Ivan Blankoff (Medical specialist in cardiology, CHU Charleroi, president of the Belgian Heart Rhythm Association – BeHRA);

Mr. Julien Mousques and Dr Haran Burri confirmed that this is a valid report that represents the scientific state of the art and had only minor comments.

Dr Ivan Blankoff also confirmed that this is a valid report that represents the scientific state of the art but had major comments. His major comments are reported hereafter:

1. **Dr Ivan Blankoff:** With extensive experience in clinical practice and use of telemonitoring, there is no doubt that telemonitoring allows extremely quick detection of 2 types of problems, hardware (potential) problems such as lead failure or battery depletion and clinical problems (mainly arrhythmias with the current technology). No one can deny that early detection of some hardware problems prevents inappropriate ICD shocks which can be extremely damaging for patients, knowing some patients can receive up to 50 truly inappropriate ICD shocks just over a few minutes so before they can reach qualified help. Not to mention the consequences for a patient... In most cases, with the use of telecardiology, the lead problem would have been detected and measures taken before any inappropriate shock would be delivered to the patient. No doubt other hardware problems (leads, battery) can be remotely followed allowing intervention if/when necessary, so not needing the patient to do frequent face-to-face follow-ups, sometimes on a very regular time scale. No doubt that early detection of some arrhythmias allows quick intervention and prevents potential complications, such as, for example, detection of asymptomatic long pauses in patients with a history of unexplained syncope and carrying a loop recorder. The fact that this report suggests that there could be insufficient hard data proving improvement in mortality, hospitalization or maybe some other so-called “important endpoints” does not prove that telemonitoring does not bring major added value to patients which I find not clearly stated in the conclusions of this report.

KCE response: The aim of KCE HTA reports is to analyse the impact of ‘new’ technologies based on solid scientific evidence (retrieved from RCT). Based on such evidence, and following the discussion during the validation meeting on the lack of focus on patients aspects, it is now more clearly stated in the conclusion that: *“Chapter 4 (on efficacy and safety of remote monitoring) highlighted the following advantages for the patients, i.e. a ‘protocol-based’ reduction of in-clinic visits, an earlier detection of events, a reduced risk of inappropriate shocks and a lower burden of atrial arrhythmias, but,” that “overall, there was no significant effect of remote monitoring on their health-related quality of life (see sections 4.3.2 and 4.3.3).”*

2. **Dr Ivan Blankoff:** Although not reimbursed, telemonitoring has been in place in Belgium in several hospitals for up to 10 years, costing time, money and various human and technical resources. One can also ask why this would be maintained and developed if no added value was to be found for the patients.



KCE response: This point was also highlighted in the survey performed in chapter 3 of the report. The fact that a technology is used for many years is nevertheless not necessarily a proof of its cost-effectiveness and is therefore not an argument to conclude for a reimbursement. It should nevertheless be noted that, based on the available evidence, we conclude a non-inferiority of these systems.

3. **Dr Ivan Blankoff:** If appropriately implemented (which deserves further debate), there is no doubt (even if out-of-scope for this KCE report) that remote device management reduces the number of in-office follow-up for patients with CIED (for example simply when getting close to criteria for battery change - Elective replacement indicator). These “unnecessary” visits can carry a heavy burden for many patients. The possibility of telemonitoring to reduce face-to-face visits is clearly added value as not only demonstrated during the Covid pandemic but also in a time of limited medical resources and of need to suppress all unnecessary travelling. Any measure that can avoid a face-to-face consultation without harm should be made possible and encouraged by all means.

KCE response: Small reductions in the mean number of face-to-face visits by patients was self-reported by the Belgian centres participating in the survey but should be further demonstrated by data registration. Moreover, as shown in the survey, the workload and the need for human resources could be superior because of the additional work related to alert management and remote data interrogations.

4. **Dr Ivan Blankoff:** Although an important issue, the opinion of patients’ associations is not well established in this report. The aim of these associations is mainly to guarantee or improve quality of care so clearly relevant to the field of telecardiology. I feel it would have been important to include patients (for example via associations) in the analysis. In the vast majority of patients, one cannot deny that telemonitoring offers (a feeling of) security to patients, even more when a (potential) problem (usually hardware, lead or battery) requires to be followed on a very regular (sometimes daily) basis. These aspects of patients/physicians’ satisfaction and convenience were not enough considered in the report (considered out-of-scope) nor in the conclusions.

KCE response: Patients’ associations were invited during the stakeholder meeting and made useful comments (comments received from the LUSS to better highlight the patients’ aspects in the international comparisons, which was done in the discussion). Moreover, to analyze patients’ aspects, we focus on the impact on the health-related quality of life of the patients (for example measured using the generic EQ-5D instruments, as recommended in the Belgian guidelines for economic evaluations) rather than on other elements such as patients satisfaction. After the discussions during the validation meeting, it should nevertheless be noted that a specific section on patients’ aspects was added in the conclusion:

“Ethical issues and social aspects were also not addressed and should be explored in more detail at a later stage. Concerning the impact of remote monitoring on patients, no specific chapter was written, but some aspects were analyzed in the following chapters:

- *Chapter 4 (on efficacy and safety of remote monitoring) highlighted the following advantages for the patients, i.e. a ‘protocol-based’ reduction of in-clinic visits, an earlier detection of events, a reduced risk of inappropriate shocks and a lower burden of atrial arrhythmias, but, overall, there was no significant effect of remote monitoring on their health-related quality of life (see sections 4.3.2 and 4.3.3). It should, nevertheless, be noted that in this report, aspects such as patients/physicians’ satisfaction and convenience of use were not considered. A summary of these aspects can be found in the HRS experts consensus of 2015⁶² but the analysis of the content of this consensus following KCE methods for good clinical practice guidelines was out-of-scope for this report.*
- *Chapter 6 (on legal aspects) and chapter 7 (on organizational aspects in other countries) highlighted the importance of patients’ privacy protection (with respect to the GDPR), of cybersecurity, of the patients’ informed consents and of other patients’ rights such as the right to refuse RM and to access their*



data, as well as the need for more transparency a.o. on safety aspects to better inform them. In analyzed countries, an attention was also paid to the fact that no financial contribution could be asked to the patients for RM systems and data transmission.”

5. **Dr Ivan Blankoff:** It appears important that readers are informed that the Heart Rhythm Society (HRS) consensus document and the European Society of Cardiology (ESC) very recent guidelines (published 1 month ago) both give strong recommendations for the use of telemonitoring. Guidelines are not used in this KCE reports but it is important to stress this reality when you know that doctors currently have the legal obligation to follow international guidelines, to be able to prove it by keeping track of this and that hospital accreditation also requires demonstration of good practices including adherence to national and international guidelines. How would it be understood that doctors and hospitals have the obligation to follow these guidelines if stated that this technology is not proven useful and therefore not reimbursed ? This would lead to a somehow contradictory situation where hospitals and cardiologists would have the legal obligation to use telemonitoring when authorities, possibly based on a report with its known limitations, could decide not to support the technique because possibly not enough evidence for gain.

KCE response: These guidelines are now cited in chapter 7 and in the conclusions. Nevertheless, we mentioned that the content and the validity of these guidelines were not analyzed following KCE methods for good clinical practice guidelines (out-of-scope of this HTA study). The aim of HTA reports is to make recommendations based on strong evidence related to among others the clinical efficacy of a technology via systematic reviews of the literature (RCTs) rather than using expert consensus.



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