Defining quality indicators for heart failure in general practice with the RAND Delphi method

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Master of Family Medicine

Masterproef Huisartsgeneeskunde

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ABSTRACT

Achtergrond Hartfalen is een belangrijk chronisch gezondheidsprobleem met een toenemende prevalentie. Een hoog kwalitatief zorgplan voor hartfalen dringt zich op. Kwaliteitsindicatoren worden gebruikt om kwaliteit van zorg te meten en te evalueren. Bijgevolg werd deze studie opgezet om te bepalen welke kwaliteitsindicatoren in de huisartsenpraktijk, ingebed in het elektronisch medisch dossier, nuttig zijn om de kwaliteit van zorg voor hartfalen te monitoren.

Methode The RAND/UCLA geschiktheidsmethode, een gemodificeerde Delphi methode, werd toegepast om deze vooropgezette kwaliteitsindicatoren te bepalen. Allereerst werd een literatuurstudie uitgevoerd om een lijst met mogelijke kwaliteitsindicatoren voor hartfalen op te stellen. Ten tweede werden 25 van deze kwaliteitsindicatoren weerhouden op basis van het SMART-principe (specifiek, meetbaar, acceptabel, realistisch en indien relevant tijdsgebonden). Ten derde werd een expertpanel samengesteld met gezondheidsmedewerkers met ervaring in hartfalen (cardiologen, huisartsen en hartfalenverpleegkundigen). Tot slot werden deze 25 kwaliteitsindicatoren door het expertpanel beoordeeld op geschiktheid in 3 rondes.

Resultaten De weerhouden kwaliteitsindicatoren belichtten diverse aspecten van de zorg voor hartfalen. In ronde 1 werden 20 van de 25 kwaliteitsindicatoren geschikt bevonden en 5 onzeker. Na ronde 2 werden 19 kwaliteitsindicatoren geschikt bevonden, 4 ongeschikt en 2 onzeker. Tot slot werden deze finale 19 kwaliteitsindicatoren in ronde 3 gerangschikt in een top 10. De top 3 bestond uit de identificatie van de etiologie van het hartfalen (1), de differentiatie tussen hartfalen met en zonder gedaalde ejectiefractie (2) en de behandeling van hartfalen met een ACE-I en een β-blokker (3).

Conclusie In deze studie werden 19 kwaliteitsindicatoren voor hartfalen in de huisartspraktijk, extraheerbaar uit het elektronisch medisch dossier, geïdentificeerd. Deze kwaliteitsindicatoren faciliteren een kwalitatieve monitoring van de zorg voor hartfalen.

Background Heart failure (HF) is an important chronic health problem with increasing prevalence. A high-standard care plan for HF is forcing itself. Quality indicators (QIs) are used to measure and evaluate the quality of care. Therefore, this study aimed to determine which QIs in general practice, rooted in the electronic health record (EHR), are useful to monitor quality of care for patients with HF.

Methods The RAND/UCLA appropriateness method (modified Delphi method) was used to define these assigned QIs. First, a literature review was done to set up a list of possible QIs for HF. Second, by applying the SMART principle 25 QIs were withheld. Third, an expert panel was composed with health care providers experienced in HF (cardiologists, general practitioners and HF nurses). Fourth, the panelists rated the QIs for appropriateness in 3 rounds.

Results The withheld QIs highlighted divers aspects of HF care. In round 1, 20 of the 25 QIs were considered appropriate and 5 of them uncertain. After round 2, 19 QIs were rated appropriate, 4 inappropriate and 2 uncertain. In round 3 the final 19 appropriate QIs were ranked in a top 10. The top 3 comprised the identification of the etiology of HF (1), the differentiation between HF with preserved and reduced ejection fraction (2) and the treatment of HF with an ACE-I and a β-blocker (3).

Conclusion In this study 19 QIs for HF in general practice, extractable out of the EHR, were identified. These QIs enable a qualitative monitoring of HF care.

INTRODUCTION

Heart failure (HF) is an important chronic health problem since it is a prevalent disease associated with a strong impact on morbidity, mortality and quality of life (1), (2), (3). The prevalence and incidence of HF rise strikingly with increasing age (1), (2). With the forthcoming ageing of the population more people will suffer from HF and the burdening of health care systems will accrue (4). In Belgium, the care for HF currently consumes 1 to 2 % of the national health care budget, whereof more than 60% is spend on hospital admissions (5). Improving aspects of quality of care can be helpful to cut costs (6). Quality indicators (QIs) are used internationally to evaluate the quality of care, as they are explicitly defined and measurable items that refer to processes, structures and outcomes of health care (7).

Numerous medical actions described in guidelines are important for treatment and follow-up of patients with HF in general practice. But only those that are of important health benefit for the patient or efficiency gains for the community are suitable as QIs (8). The QIs must have a predetermined SMART-format that is specific, measurable, acceptable, realistic and if relevant time specific. Another benchmark is the operability of the QIs in the electronic health record (EHR), as this gains importance in these technological times (9). Analyzing coded data in the EHR, through a computerized extraction, can serve as a method to evaluate quality of care on a larger scale.

Multiple foreign initiatives have been undertaken to develop QIs for HF, like in the UK, the USA, the Netherlands, Canada and Germany (3), (10), (11), (12), (13), (14). In Belgium the experience with QIs is not very extensive, although it is growing (15). Initiatives are undertaken to measure and improve quality of care in hospital setting and nursing homes through projects as 'Vlaams Indicatorenproject' and 'Vlaams indicatorenproject voor woonzorgcentra' (16), (17). However, systematic projects for primary care are not available yet, although an important part of health care is provided in primary care. HF guidelines adopted to the Belgian context have been developed for general practice, but QIs are still missing (18).

Therefore this study aimed to determine which QIs in general practice, rooted in the EHR, are useful for monitoring quality of care for patients with chronic HF.

METHODS

To define QIs for chronic HF the RAND/UCLA appropriateness method, which is a modified Delphi method, was used (8). The study was set up in 4 phases: a literature review, setting up a list of QIs, composing an expert panel and a rating procedure of the QIs in 3 rounds (19).

Phase 1: Literature review

First, different national and international guidelines on chronic HF were read (11),(18),(20),(21),(22). The recommendations in these guidelines were summarized and listed into different categories regarding their content (definition, diagnosis, therapy, comorbidities, follow-up, revalidation, multidisciplinarity and palliative care) (appendix 1). Subsequently, a literature review in MEDLINE was performed without time limit till the 23th of September 2016. The search strategy included different search terms on 'heart failure' and 'quality indicators'. The full electronic search strategy used can be found in appendix 2.

Phase 2: Setting up a list of QIs

The evidence from the guidelines as well as the information from the literature review was further summarized and formalized into possible QIs. Two researchers (MSmeets and BV) independently judged the list of possible QIs based on the SMART principle (specific, measurable, acceptable, realistic and if possible time specific). Furthermore, eligible QIs needed to be extractable out of the EHR.

Phase 3: Composing an expert panel

Multiple health care workers experienced in HF, with various medical backgrounds (purposive sampling), were contacted by email.

Phase 4: Rating procedure of the QIs

Round 1

In the first round the panelists were asked to individually rate the appropriateness of the possible QIs for HF in general practice taking into account the health benefit for the patient, the efficiency gains for the community and the extractability out of the EHR. They received a list with the possible QIs, the definition and the level of evidence. The rating was based on the following scoring principle: each QI was rated on a scale from 1 to 9, with 1 being a very low score and 9 an excellent score. The rating of each QI was evaluated as: appropriate (a median score from 7 to 9 without disagreement), inappropriate (a median score from 1 to 3 without disagreement) or uncertain (a median score from 4 to 6 or disagreement). Disagreement was defined as ratings that were spread over the entire spectrum from 1 to 9 or as polarization in the group defined in the IPRAS (inter-percentile range adjusted for symmetry) (8).

Round 2

The panelists were invited to a consensus meeting. During the meeting panelists were informed about the conclusions for each QI from the first round (appropriate – inappropriate – uncertain), their own ratings for each QI, the location of their responses relative to the overall distribution of the group, the median and the dispersion of the median. There was time for discussion about the QIs led by a moderator (MSmets). QIs that were classified as uncertain were first discussed, followed by QIs that were appropriate but showed wide dispersion (≥2) and at last those appropriate with small dispersion (<2). The definition of QIs could be adjusted in response to the discussion. After discussion on each QI the panelists were asked to individually score the QIs again. The rating results of this round were used to make the final decision on the appropriateness of the QIs for HF.

Round 3

All the panelists received information about the conclusions for each QI from round 2 (appropriate – inappropriate – uncertain), the overall distribution of the panel, the median, the dispersion of the median and information about the ability to extract elements of the QI out of the EHR. In a final step the panelists had to select the 10 most important QIs and rank them in a top 10.

RESULTS

Phase 1: Literature review

The literature review in MEDLINE yielded 2454 articles. As a first screening, titles and if necessary abstracts of these articles were checked on their relevance to the subject. This resulted in 514 articles in the first screening. Out of these 514 articles, 382 could be matched with the predefined categories from the guidelines. New information was possibly available in 132 articles. These 132 articles were more thoroughly checked in a second screening by reading the abstract (again) and if relevant the full text was read. After this procedure 16 of them were classified as relevant (figure 1).

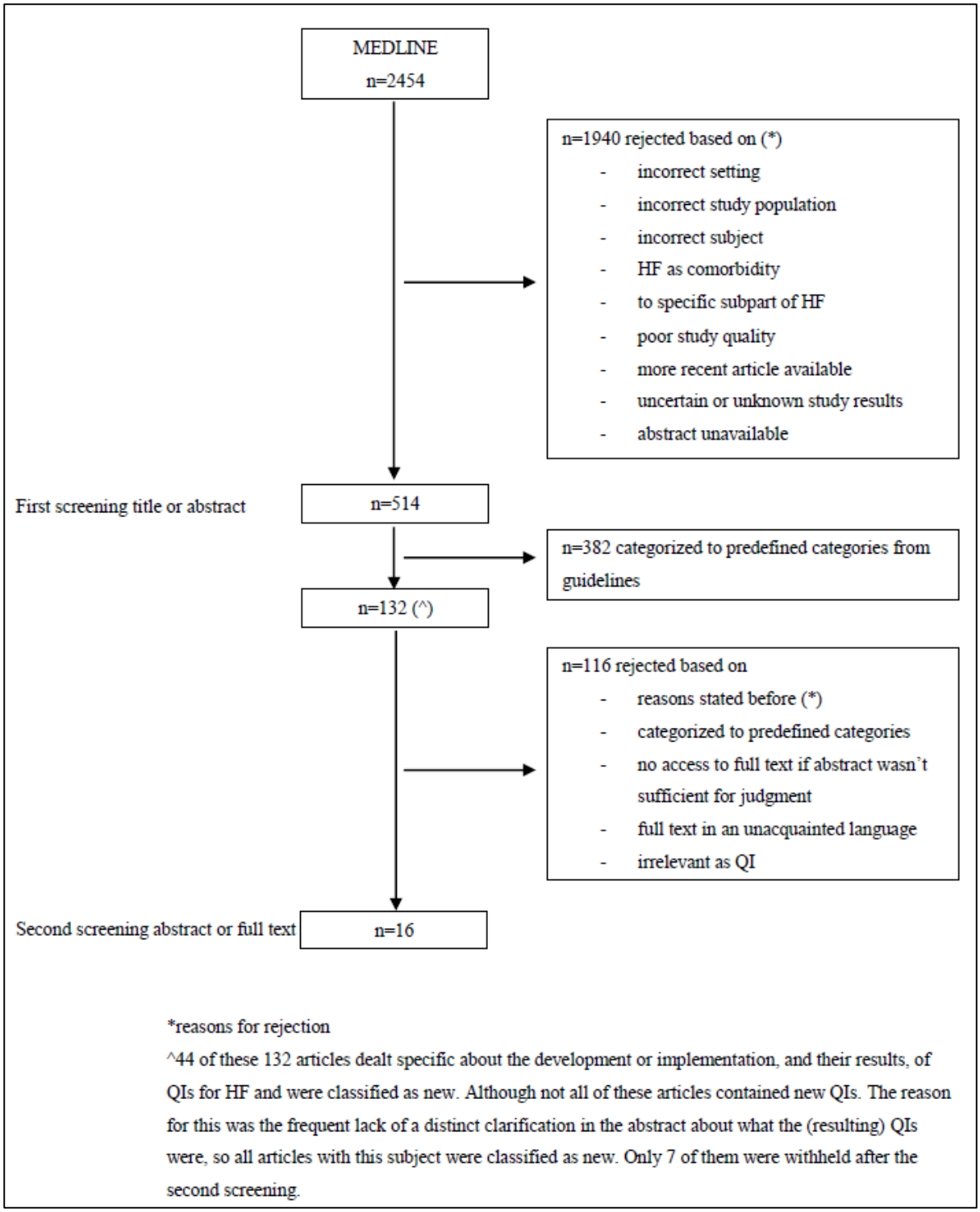


Figure 1: Literature review method.

Phase 2: Setting up a list of QIs

The evidence from the guidelines and the literature review yielded 164 possible QIs, of which 139 QIs from the guidelines and 25 from the literature review. After consensus between the 2 researchers on the SMART principle and the extractability out of the EHR, 37 QIs were

withheld, including none of the QIs retrieved by the literature review. QIs with similar subjects were combined and summarized into 25 final possible QIs (appendix 3).

Phase 3: Composing an expert panel

Initially a selection of 20 health care workers was invited by email. The group consisted of 5 general practitioners (GPs), 1 professor in general medicine, 4 cardiologists, 8 professors in cardiology and 2 heart failure nurses. From this group 3 didn't respond and 4 weren't interested to participate in the study. Finally the expert panel consisted of 13 members; 3 general practitioners, 1 professor in general medicine, 4 cardiologists, 4 professors in cardiology and 1 heart failure nurse (appendix 4).

Phase 4: Rating procedure of the QIs

Round 1

In total, 25 possible QIs of HF were introduced to the expert panel. After round one 20 were considered appropriate and 5 uncertain (table 1).

Round 2

The panelists were invited to the consensus meeting and 7 of them, namely 1 general practitioner, 4 cardiologists, 1 professor in cardiology and 1 heart failure nurse, were able to attend. They discussed the appropriateness of the QIs. It became clear that the purpose of the QIs and the consequences of their use were sometimes interpreted differently by the individual panelists, so the definition of a QI was further clarified. This resulted into clear statements from the panelists regarding the QIs namely; 'Is a GP an incompetent GP when his care does not meet the predefined QIs?', 'What is the relevance of this QI in general practice?' and 'Can a GP be held responsible for this aspect of HF care?'. With this in mind the panelists rated the QIs about devices and complex therapies lower. The importance of a correct diagnosis and basic pharmacological treatment was pointed out during the panel meeting. The cardiologists among the panelists weren't familiar with the extent of extracting medical information out of the EHR of the GP. Additional information about the extractability of data out of the EHR was therefore provided in round 3. However, some QIs that were considered very important but currently not extractable out of the EHR, like ejection fraction, were still withheld, because the panelists wanted to enhance further development of the EHR by software producers in the future. The discussion led to the adjustment of the definition of 2 QIs in order to make them more specific (italic appendix 3). After round 2, 19 QIs were judged to be appropriate of which 18 were also rated appropriate in the first round and 1 was previously rated uncertain. Four QIs were classified as inappropriate, of which one was rated appropriate and 3 uncertain in round one. Two QIs were categorized as uncertain, of which one was rated appropriate and one

uncertain in the first round. There was no evident coherence with the level of evidence of a QI and the degree of appropriateness, as the 19 appropriate QIs had a broad range of evidence (table 1).

Round 3

In the final round the 13 panelists ranked the 19 appropriate QIs in a top 10 in order of importance. This ranking of the QIs highlighted different aspects of HF care, among which defining the specific type of HF (HF with reduced or preserved ejection fraction) and the severity on functional status (NYHA classification). Furthermore technical investigations were considered indispensable to set the diagnosis of HF and to detect the underlying cause. Pharmacological treatment, consisting of an ACE-I (angiotensin-converting enzyme inhibitor) and a β-blocker supplemented with a MRA (mineralocorticoid receptor) if necessary and diuretics for congestion, was another essential keystone. Caution should always be considered when prescribing medication for other conditions to patients with HF. On the other hand motivating the patient to improve life style was considered essential. Evidently a regular follow-up with the GP was considered important as well (table 1).

	QI	Round 1		Round 2		Round 3	Conclusion
		Median	Dispersion	Median	Dispersion	Ranking	
1	For all patients with HF a differentiation between HF with preserved ejection fraction or reduced ejection fraction should be made.	7	1,30	9	0,47	**2**	Appropriate
2	For all patients with HF the NYHA classification should be made to evaluate the severity of symptoms.	7	1,96	8	0,74	**8**	Appropriate
3	For all patients with elevated (NT-pro)BNP and symptoms suggestive of HF further investigation is indicated. Echocardiography, blood analysis and if necessary chest X-ray should be performed.	9	1,49	9	0,53	**5**	Appropriate
4	For all patients with HF the etiology should be identified. Blood analysis, ECG and echocardiography are necessary.	9	1,18	9	0,37	**1**	Appropriate
5	For all patients with asymptomatic LV systolic dysfunction with or without a history of myocardial infarction an ACE-I is recommended in order to prevent or delay the onset of HF.	9	1,21	9	0,17	(11)	Appropriate
6	For all patients with stable coronary artery disease with or without LV systolic dysfunction an ACE-I is recommended in order to prevent or delay the onset of HF.	6,5	1,89	4	0,71		Uncertain
7	For all patients with asymptomatic LV systolic dysfunction and a history of myocardial infarction a β-blocker is recommended in order to prevent or delay the onset of HF.	8	1,80	8,5	0,31	(16)	Appropriate
8	All patients with HF should be motivated and counseled for smoking cessation.	8	2,45	8	0,76	(17)	Appropriate
9	For all patients with HF an assessment of relevant lifestyle risk factors should be made and if relevant awareness of possible improvements should be raised.	8	1,86	9	0,53	**9**	Appropriate
10	All patients with HF should be vaccinated for influenza and pneumococcal vaccination should be evaluated.	8	1,59	8,5	0,20	(14)	Appropriate
11	All patients with HF should be provided with clear information about HF and the treatment plan to support self-management.	8	1,88	8	1,32	(12)	Appropriate
12	For all patients with HF and symptoms of congestion loop diuretics should be initiated.	8	1,11	9	0,37	**6**	Appropriate
13	For all patients with HF with reduced ejection fraction an ACE-I and β-blocker is recommended.	9	1,33	9	0	**3**	Appropriate
14	For patients with intolerable side effects on an ACE-I, an ARB is recommended to replace the ACE-I.	9	2,37	9	0,17	(15)	Appropriate
15	For all patients with HF with reduced ejection fraction remaining symptomatic despite treatment with an ACE-I or ARB and a β-blocker, a MRA is added.	9	1,75	9	0,33	**4**	Appropriate
16	For all patients with HF with reduced ejection fraction remaining symptomatic despite treatment with an ACE-I or ARB, β-blocker and MRA, digoxin is added.	4	2,53	2	0,25		Inappropriate
17	For all patients with HF with reduced ejection fraction NSAID, antiarrhythmic drugs (class 1 and 3, expect amiodarone), diltiazem, verapamil and glitazones should be avoided.	8	2,17	9	0,17	**10**	Appropriate
18	For patients with HF under optimal pharmacological therapy and a prolongation of the QRS complex (>120 ms) and a LV ejection fraction < 35% cardiac resynchronization therapy should be evaluated.	7	2,24	3	0,49		Inappropriate
19	For patients with HF and a history of ventricular arrhythmia causing haemodynamic instability an implantable cardioverter-defibrillator should be evaluated. For patients with HF under optimal pharmacological therapy remaining symptomatic and a LV ejection fraction < 35% and ischemic heart disease or dilated cardiomyopathy an implantable cardioverter-defibrillator should also be evaluated.	7	2,20	5	1,08		Uncertain
20	For all patients with HF and atrial fibrillation and a CHA2DS2-VASc ≥2 medication to prevent thromboembolism is recommended.	9	2,22	9	0	(13)	Appropriate
21	For patients with HF and; bradycardia with pauses >3 seconds, or symptomatic bradycardia and a resting ventricular rate <50/min in sinus rhythm, or symptomatic bradycardia and a resting ventricular rate <60/min in atrial fibrillation, the need for any rate limiting medications prescribed should be evaluated and adjusted. If after adjustment of therapy symptoms are persisting β-blockers should be reduced in dose or withdrawn or pacing should be evaluated.	6	1,71	2,5	0,39		Inappropriate
22	All patients with HF should be evaluated regularly in the general practice.	8	2,02	9	0,24	**7**	Appropriate
23	For all patients with HF an ECG and an echocardiography should be repeated regularly.	7,5	2,14	7,5	0,70	(19)	Appropriate
24	For patients with HF with difficulties with up titration of medication or hospital admission it can be useful to monitor (NT-pro)BNP.	5	2,51	3	0,52		Inappropriate
25	For all patients with HF advanced care planning should be discussed as soon as possible in the process of HF.	6	2,47	7	0,98	(18)	Appropriate

Table 1: Results of rating the 25 possible QIs. Limited versions of the QIs are displayed, more extensive version can be found in appendix 3. NYHA (New York Heart Association), ACE-I (angiotensin-converting enzyme inhibitor), ARB (angiotensin receptor blocker), MRA (mineralocorticoid receptor).

DISCUSSION

This study defined 19 QIs for HF, extractable out of the EHR, in general practice. These QIs, defined in a predetermined evidence-based method, will facilitate the evaluation of the genuinely achieved quality of care for HF. A computerized extraction from the EHR will enhance their usability.

The identified QIs from the current study covered topics that were in line with the topics of previously reported QIs. However, in our study the extractability out of the EHR was an important prerequisite for a QI which was not stated in other studies (3), (10), (11). NICE (national institute for health and care excellence) defined 7 QIs, of which 5 were similar to the QIs of the current study and 2 handle about cardiac revalidation to improve exercise tolerance (3). This subject did not reveal in our selected QIs, because cardiac revalidation is not the responsibility of GPs in Belgium as the prescription is limited to cardiologists. ACC/AHA (American college of cardiology/American heart association) identified 11 QIs for outpatients with HF that all match our QIs (10). However the ACC/AHA categorized follow-up of weight, blood pressure, volemic status and functional capacity all as separate QIs, while we defined them under one heading, namely regular follow-up by a GP. In the Netherlands 2 structural QIs were defined (11). Patient education, with discharge instructions if applicable, to promote self-management was equal to QI 11 in our study. The other QI supports the use of an up-to-date medication schedule that is shared among different health care providers. This QI was not withheld in our study and was already rejected in the SMART pre-selection, because of difficulties with extraction out of the EHR. In general we could conclude that the content of the QIs was quite similar, since the QIs in the current study were developed with evidence from similar guidelines (11), (23), (21), (18), (22). Though the number of our QIs exceeded the amount in other studies. A reason for this difference could be the lack of experience with the RAND/UCLA appropriateness method for the majority of the panelists, what probably made them rate the QIs rather high. Therefore, the definition and the method of developing QIs were clarified again during the second round. An additional interpretation of this larger number is the extensive literature review done, consisting of multiple guidelines and a MEDLINE search. This was more extensive in comparison with the method NICE used, although none of the QIs of the MEDLINE search in our study were withheld (3), (24). Restrictions of inclusion for the QIs that were set by ACC/AHA were striking different and could also account for the higher number of QIs (9). For example, the dimensions of HF care for the QIs were predetermined, the class of recommendation of the evidence was restricted and exclusively patients with an

already established diagnosis of HF were included. In the Netherlands they opted only for QIs about processes of HF care with the highest profit margin (11).

The current study represented a first step in the development of QIs for HF in general practice in Belgium, facilitating the evaluation of quality of care for patients with HF. These QIs could be used by individual GPs to reflect and improve their quality of HF care by doing a clinical audit in their EHR. Additionally, policy makers could use these QIs to identify gaps in the quality of care on a larger scale, stimulate research and set up quality improving projects. Furthermore, it could be applied as a control mechanism. However, further research is needed to assess the implementation of the QIs into practice and to evaluate the feasibility of extracting the QIs out of the EHR.

Strengths of this study were the profound literature review, which allowed us to evaluate all the available evidence on QIs of HF. Using the RAND/UCLA appropriateness method to define the appropriateness of QIs was an asset, as it has great tradition in this matter (8). Furthermore, the composition of a diverse expert panel allowed us to take into account different aspects of HF care. The pre-selection based on the SMART principle and the extractability out of the EHR were innovating as a computerized method enhances feasibility. A shortcoming of the study was the limited turnout on the consensus meeting, which implied an under-representation of GPs. But the approval of all panelists was obtained by agreeing with the chosen QIs by ranking them in a top 10 in round 3. Another limitation was the inexperience of the panelists with the development of QIs and the extractability out of the EHR.

CONCLUSION

With the RAND/UCLA appropriateness method 19 QIs were identified for HF care in general practice. A notable feature of these QIs was the extractability out of the EHR, which made them suitable for computerized data processing. The QIs highlighted multiple aspects of HF care. Setting the diagnosis of HF by means of technical investigations and a basic pharmacological treatment, with an ACE-I, β-blocker and a MRA if necessary, were pointed out to be of major importance in HF care. Next, these QIs should be implemented in Belgian health care to prove their relevance.

APPENDIX

Definition
Diagnosis and work-up
Medical history interview
Physical examination
Technical investigations
(NT-pro)BNP
ECG
Blood analysis
Chest X-ray
Spirometry
Urine analysis
Echocardiography
Other imaging
Treatment
Prevention
Non-pharmacological
Pharmacological
HF with preserved and reduced ejection fraction
Diuretics
HF with reduced ejection fraction
ACE-I
β-blocker
ARB
MRA
Diuretics
Digoxin
Tripeltherapy
Hydralazine + isosorbide dinitrate
ARB + neprilysin-inhibitor
If - channel inhibitor
n-3 polyunsaturated fatty acids
IV inotropics
Medication to avoid
HF with preserved ejection fraction
Devices
Co-morbidities
Angina and coronary artery disease
Cachexia
Cancer
Central nervous system (including depression, stroke and autonomic dysfunction)
Diabetes
Erectile dysfunction
Gout and arthritis
Hypokalaemia and hyperkalaemia
Hyperlipidaemia
Hypertension
Iron deficiency and anaemia
Kidney dysfunction (including chronic kidney disease, acute kidney injury, cardio-renal syndrome, and prostatic obstruction)
Lung disease (including asthma and chronic obstructive pulmonary disease)
Obesity
Sleep disturbance and sleep-disordered breathing
Valvular heart disease
Atrial fibrillation
Ventricular arrhythmias
Symptomatic bradycardia, pauses and atrio-ventricular block
Referral
Follow-up
Revalidation
Multidisciplinary team management
Palliative and end-of-life care

Appendix 1 : Categories to classify the evidence from guidelines and literature review. ACE-I (angiotensin-converting enzyme inhibitor), ARB (angiotensin receptor blocker), MRA (mineralocorticoid receptor).

((quality indicator*[Title/Abstract]) OR quality criterion*[Title/Abstract]) OR quality measure*[Title/Abstract]) OR performance indicator*[Title/Abstract]) OR performance measure*[Title/Abstract]) OR outcome measure*[Title/Abstract]) OR outcome indicator*[Title/Abstract]) OR audit[Title/Abstract]) OR outcome assessment[Title/Abstract]) OR process assessment[Title/Abstract])) OR "Quality Indicators, Health Care"[Majr:NoExp])) AND ((heart fail*[Title/Abstract]) OR cardiac fail*[Title/Abstract]) OR myocardial fail*[Title/Abstract]) OR heart decompensation[Title/Abstract]) OR cardiac decompensation[Title/Abstract]) OR myocardial decompensation[Title/Abstract]) OR heart insufficiency[Title/Abstract]) OR cardiac insufficiency[Title/Abstract]) OR myocardial insufficiency[Title/Abstract]) OR diastolic dysfunction[Title/Abstract]) OR heart ventricle fail*[Title/Abstract]) OR systolic dysfunction[Title/Abstract])) OR ((("Heart Failure"[Majr:NoExp]) OR "Heart Failure, Diastolic"[Majr:NoExp]) OR "Heart Failure, Systolic"[Majr:NoExp])).

Appendix 2: Search terms in MEDLINE.

Definition			
1. For all patients with HF a differentiation between HF with preserved ejection fraction or reduced ejection fraction should be made.			
Definition	HF with reduced ejection fraction: LV ejection fraction ≤ 40% HF with preserved ejection fraction: LV ejection fraction > 40%	Grading	/
2. For all patients with HF the NYHA classification should be made to evaluate the severity of symptoms.			
Definition	NYHA I : No limitation of physical activity. NYHA II : Slight limitation of physical activity. NYHA III : Marked limitation of physical activity. NYHA IV : Symptoms of HF at rest. For patients with HF and a comorbidity with similar presenting symptoms the NYHA classification is less reliable.	Grading	1C
Technical investigation			
3. For all patients with elevated (NT-pro)BNP and symptoms suggestive of HF further investigation is indicated. Echocardiography, blood analysis and if necessary chest X-ray should be performed.			
Definition	Blood analysis is performed to detect the etiology of HF or comorbidities, to evaluate the patient's suitability for particular therapies (Na, K, creatinine and eGFR), to evaluate an acute coronary syndrome or sustained myocardial ischemia. Chest X-ray has little additional value in the diagnosis of new onset of HF, but is important to differentiate between HF and pulmonary problems.	Grading	1C
4. For all patients with HF the etiology should be identified. Blood analysis, ECG and echocardiography are necessary.			
Definition	Blood analysis should include: CRP, hemoglobin, hematocrit, leucocytes with differentiation, glucose, Na, K, creatinine, eGFR, uric acid, liver function tests, TSH, lipid profile and if necessary ferritin and transferrin saturation. An ECG to determine heart rhythm, heart rate, QRS morphology, QRS duration and to detect other abnormalities.	Grading	1C
Treatment			
Prevention			
5. For all patients with asymptomatic LV systolic dysfunction with or without a history of myocardial infarction an ACE-I is recommended in order to prevent or delay the onset of HF.			
Definition	ACE-I for asymptomatic LV systolic dysfunction and a history of myocardial infarction ACE-I for asymptomatic LV systolic dysfunction without a history of myocardial infarction	Grading	1A 1B
6. For all patients with stable coronary artery disease with or without LV systolic dysfunction an ACE-I is recommended in order to prevent or delay the onset of HF.			
Definition		Grading	2A
7. For all patients with asymptomatic LV systolic dysfunction and a history of myocardial infarction a β-blocker is recommended in order to prevent or delay the onset of HF.			
Definition		Grading	1B
Non-pharmacological			
8. All patients with HF should be motivated and counseled for smoking cessation.			
Definition		Grading	1C
9. For all patients with HF an assessment of relevant lifestyle risk factors should be made and if relevant awareness of possible improvements should be raised.			
Definition	Lifestyle risk factors should include - Smoking - Alcohol - Drugs - Physical exercise - Body weight	Grading	 1C 1C/2C 2C 1C 1C
10. All patients with HF should be vaccinated for influenza and pneumococcal vaccination should be evaluated.			
Definition	Influenza vaccination	Grading	1B

	Pneumococcal vaccination		2C
11. All patients with HF should be provided with clear information about HF and the treatment plan to support self-management.			
Definition	Self-management is an important feature of a successful treatment of HF. *The patient is better aware of his/her disease and will be more compliant.* It yields an improvement of quality of life and it can ameliorate the prognosis. Patient education should be sustained for a longer period of time and regularly repeated. *Oral as well as written information (brochure) can be helpful.* The information should be individualized and information about prognosis should be included.	Grading	
Pharmacological			
Heart failure with preserved and reduced ejection fraction			
12. For all patients with HF and symptoms of congestion loop diuretics should be initiated at low doses and if necessary augmented until clinical improvement. Electrolytes and renal function should be monitored.			
Definition	K, Na and renal function should be monitored on week 1, week 4 and after dose augmentation. Afterwards every 4 weeks for 3 months, every 3 months for 1 year and every 6 months after 1 year or when necessary. Precaution for significant hypokalemia (<3,5 mmol/l), significant kidney dysfunction (eGFR < 30 ml/min) and hypotension (< 90 mmHg).	Grading	1B
Heart failure with reduced ejection fraction			
13. For all patients with HF with reduced ejection fraction an ACE-I and β-blocker is recommended. An ACE-I should be initiated at low doses, followed by gradual dose increments. Electrolytes and renal function should be monitored. Adjust an effective β-blocker in a clinical stable patient treated with low dose ACE-I. A β-blocker should be initiated at low doses, follow by gradual dose increments. Heart rhythm, blood pressure and clinical status should be monitored at initiation and augmentation.			
Definition	**ACE-I** Enlapril: 2,5mg pd => 20mg pd Ramipril 1,25mg pd => 10mg pd Captopril: 6,25mg pd => 3x50mg pd Linisinopril: 1,25mg pd => 20mg pd Perindopril: 2mg pd => 4mg pd Augmentation every 2 to 4 weeks. Electrolytes (K) and renal function should be monitored at initiation, after 1 to 2 weeks and after every dose augmentation. **β-blocker** Metoprolol: 12,5 – 50mg pd => 200mg pd Bisoprolol: 1,25mg pd => 10mg pd Carvedilol: 3,125mg 2xpd => 50mg 2xpd Nebivolol: 1,25mg => 10mg pd Asthma, AV-block, sinus bradycardia and sick sinus syndrome are contraindications.	Grading	1A 1A
14. For patients with intolerable side effects on an ACE-I, an ARB is recommended to replace the ACE-I. An ARB should be initiated at low doses, followed by gradual dose increments. Electrolytes and renal function should be monitored.			
Definition	A cough may occur with an ACE-I, not with an ARB. Angioedema may occur with an ACE-I, but uncertainty if changing to an ARB is an option. Candesartan: 4-8mg pd => 32mg pd Valsartan: 2x40mg pd => 2x160mg pd Losartan: 12,5mg pd => 150mg pd Redouble dose after 2 to 4 weeks. Electrolytes and renal function should be monitored at initiation and after 1 to 4 weeks after dose augmentation. 1, 3 and 6 months after initiations and every 6 months afterwards.	Grading	1A
15. For all patients with HF with reduced ejection fraction remaining symptomatic despite treatment with an ACE-I or ARB and a β-blocker, a MRA is added. A MRA should be initiated at low doses, followed by gradual dose increments. Electrolytes and renal function should be monitored.			
Definition	Spironolactone: 12,5-25mg pd => 2x25mg (eGFR 30-49:12,5mg pd=>12,5-25mg pd) Eplerenone: 25mg pd => 50mg pd (eGFR 30-49: 25mg every other day =>25mg pd) Electrolytes and renal function should be monitored at initiation, 1 to 4 weeks after initiation and every 4 weeks after stabilization. 1, 2, 3 and 6 months after setting the correct dose and every 6 months afterwards.	Grading	1A
16. For all patients with HF with reduced ejection fraction remaining symptomatic despite treatment with an ACE-I or ARB, β-blocker and MRA, digoxin is added. Patients must have a sinus heart rhythm or atrial fibrillation (rest rate > 80/min or exercise > 110-120/min).			
Definition	Digoxin 0,25 mg pd. For elderly or patients with a reduced kidney function a lower dose of 0,125 mg pd or 0,0625 mg pd is recommended.	Grading	2B

17. For all patients with HF with reduced ejection fraction NSAID, antiarrhythmic drugs (class 1 and 3, expect amiodarone), diltiazem, verapamil and glitazones should be avoided.			
Definition		Grading	1A
Devices : implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy (CRT)			
18. For patients with HF under optimal pharmacological therapy and a prolongation of the QRS complex (>120 ms) and a LV ejection fraction < 35% CRT should be evaluated.			
Definition		Grading	2A
19. For patients with HF and a history of ventricular arrhythmia causing haemodynamic instability an ICD should be evaluated. For patients with HF under optimal pharmacological therapy remaining symptomatic and a LV ejection fraction < 35% and ischemic heart disease or dilated cardiomyopathy an ICD should be evaluated.			
Definition	Ventricular arrhythmia Ischemic heart disease Dilated cardiomyopathy	Grading	1A 1A 1B
Comorbidities			
20. For all patients with HF and atrial fibrillation and a CHA2DS2-VASc ≥2 medication to prevent thromboembolism is recommended.			
Definition	CHA2DS2-VASc : Congestive heart failure (1), Hypertension (1), Age ≥ 75 (2), Diabetes (1), Stroke (2), Vascular disease (1), Age 65–74 (1), Sex female (1)	Grading	1A
21. For patients with HF and; bradycardia with pauses >3 seconds, or symptomatic bradycardia and a resting ventricular rate <50/min in sinus rhythm, or symptomatic bradycardia and a resting ventricular rate <60/min in atrial fibrillation, the need for any rate limiting medications prescribed should be evaluated and adjusted. If after adjustment of therapy symptoms are persisting β-blockers should be reduced in dose or withdrawn or pacing should be evaluated.			
Definition		Grading	2C
Follow-up			
22. All patients with HF should be evaluated regularly in the general practice. A consult should be planned in days to 2 weeks with changes in clinical situation or adjustments of the medication plan. A consult every 3 to 6 months is sufficient for stable patients.			
Definition	Follow-up of a patient with HF should include : blood pressure, weight, functional capacity, volemic status, heart rhythm, cognitive and nutritional status, pharmacological treatment (adjustments, side effects and compliance) and blood analysis (electrolytes, eGFR and creatinine).	Grading	
23. For all patients with HF an ECG and an echocardiography should be repeated regularly (every year).			
Definition		Grading	
24. For patients with HF with difficulties with up titration of medication or hospital admission it can be useful to monitor (NT-pro)BNP.			
Definition		Grading	2B
Palliative care			
25. For all patients with HF advanced care planning should be discussed as soon as possible in the process of HF.			
Definition	*Advanced care planning is a process of reflection and dialogue between patient, his or her loved ones and one or more health care providers (including a doctor). In this process future treatment goals are discussed and planned. These treatment goals are based on what the patient defines as qualitative health care and are adjustable to the changing situation. They guide decisions about care at the end of life at the moment it is impossible for patient to express his/her thoughts* (25).	Grading	

Appendix 3: The 25 final possible QIs. Italic marks the modified definition of the QIs after round 2. LV (left ventricle), NYHA (New York Heart Association), ACE-I (angiotensin-converting enzyme inhibitor), ARB (angiotensin receptor blocker), MRA (mineralocorticoid receptor).

Panellist	Sex	Geography	Function	Hospital / General practice
1	Male	Vlaams-Brabant	Professor in cardiology	Universitair ziekenhuis Leuven
2	Male	Vlaams-Brabant	Professor in cardiology	Universitair ziekenhuis Leuven
3	Male	Vlaams-Brabant	Cardiologist	Universitair ziekenhuis Leuven
4	Male	Vlaams-Brabant	Cardiologist	Universitair ziekenhuis Leuven
5	Male	Vlaams-Brabant	Cardiologist	Universitair ziekenhuis Leuven
6	Male	Limburg	Cardiologist	Jessa Ziekenhuis
7	Female	Antwerpen	Professor in cardiology	Universitair ziekenhuis Antwerpen
8	Male	Antwerpen	Professor in cardiology	Universitair ziekenhuis Antwerpen
9	Male	Leuven	Professor in general practice	ACHG Leuven
10	Female	Antwerpen	General practitioner	Huisartsenpraktijk Dokters&Co
11	Female	Antwerpen	General practitioner	Huisartsenpraktijk Haverveld
12	Male	Antwerpen	General practitioner	Artsenpraktijk Mol
13	Female	Leuven	Heart failure nurse	Universitair ziekenhuis Leuven

Appendix 4 : Expertpanel.

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ATTACHMENTS

	Reg. nr.	Titel van de studie	Status	Beheer
	mp11422	Bepalen van kwaliteitsindicatoren voor hartfalen in de huisartsenpraktijk met de RAND Delphi methode **Student(en):** Marie Smets **Promotor:** Bert Vaes	Gunstig advies van OBC	

Gunstig advies van OBC

2016-03-23 18:11:17

Bekijk status geschiedenis

Ingestuurd in verkeerde rubriek: is praktijkverbeterend.

Student(en): Marie Smets
Promotor: Bert Vaes (bert.vaes@med.kuleuven.be - u0087897 - Acad. Centr. voor Huisartsgeneeskunde)
Faculteit: Geneeskunde
Opleiding: Master in de huisartsgeneeskunde (Leuven e.a.)
Het onderzoek is: monocentrisch
De opdrachtgever is: academisch (universiteit,...)
Het onderzoek is: Overige.

BIJKOMENDE GEGEVENS:

Achtergrond: Een patiënt met hartfalen definiëren blijft een moeilijke opgave, maar desalniettemin is het van fundamenteel belang deze patiënten op te sporen om hen zo een adequate opvolging en behandeling te kunnen garanderen. Met behulp van kwaliteitsindicatoren voor hartfalen, ingebed in het elektronisch medisch dossier (EMD), kan de kwaliteit van zorg gemonitord worden. Het gebruik van deze kwaliteitsindicatoren geeft de mogelijkheid om systematisch AUDITs in het EMD te verrichten.

Vraagstelling: Welke kwaliteitsindicatoren voor hartfalen moeten in het EMD aanwezig zijn om de kwaliteit van zorg voor hartfalen met behulp van clinical AUDITs te monitoren?

Methodologie: Voor mij onderzoeksopzet zal ik gebruik maken van de RAND Delphi methode.
Daarbij zal ik vooreerst een grondig literatuuronderzoek rond hartfalen via de waterval-methode verrichten, hierbij wordt relevante informatie opgelijst en samengevat. Ook wordt een gerichte zoekstrategie uitgewerkt en toegepast om reeds bestaande kwaliteitsindicatoren rond hartfalen uit de literatuur te extraheren. Vervolgens wordt een lijst van mogelijks geschikte indicatoren en hun definities opgesteld.
Verschillende artsen met ervaring in hartfalen worden gecontacteerd om deel te nemen aan deze studie. Uiteindelijk wordt een multidisciplinair expertenpanel bestaande uit 7 tot 15 artsen samengesteld.
In een eerste ronde zal hen gevraagd worden om individueel een lijst van indicatoren met betrekking tot hartfalen te beoordelen naar geschiktheid met een score van 1 (ongeschikt) tot 9 (geschikt) om de kwaliteit van zorg rond hartfalen te monitoren. Vervolgens zal in een tweede ronde dezelfde lijst nogmaals op dezelfde wijze gescoord worden met ditmaal informatie omtrent de frequentie van gekozen scores in de groep en de verhouding van hun eigen score hiertegenover. In deze ronde is er plaats voor debat over de geschiktheid van de verschillende indicatoren alvorens opnieuw te scoren.
Deze gegevens zullen statistisch verwerkt worden en indicatoren zullen verdeeld worden in geschikt – ongeschikt – onzeker.
Het eindresultaat zal een lijst zijn met geschikte kwaliteitsindicatoren voor hartfalen in de huisartsenpraktijk, degene die geregistreerd kunnen worden in het EMD zullen weerhouden worden.

Approved protocol



Betreft uw aanvraag Ethische begeleiding masterproeven met titel "Bepalen van kwaliteitsindicatoren voor hartfalen in de huisartsenpraktijk met de RAND Delphi methode" (mp11422)

VERWIJDEREN BEANTWOORDEN ALLEN BEANTWOORDEN DOORSTUREN

Martine Goossens <martine.goossens@med.kuleuven.be>

wo 23/03/2016 18:11

Markeren als ongelezen

Aan: Bert Vaes;

CC: Marie Smets;

English version below

Geachte Heer/Mevrouw

De Opleidingspecifieke Ethische Begeleidingscommissie van de opleiding "Master in de huisartsgeneeskunde (Leuven e.a.)" heeft uw voorstel tot Masterproef "Bepalen van kwaliteitsindicatoren voor hartfalen in de huisartsenpraktijk met de RAND Delphi methode" onderzocht en gunstig geadviseerd. Dit betekent dat de commissie van oordeel is dat de studie, zoals beschreven in het protocol, wetenschappelijk relevant en ethisch verantwoord is. Dit gunstig advies van de commissie houdt niet in dat zij de verantwoordelijkheid voor de geplande studie op zich neemt. U blijft hiervoor zelf verantwoordelijk. Indien u van plan bent uw masterproef te publiceren kan deze e-mail dienen als bewijs van goedkeuring.

Dear Mr/Ms

The Supervisory Committee on Medical ethics of the "Master in de huisartsgeneeskunde (Leuven e.a.)" programme has reviewed your master's thesis project proposal "Bepalen van kwaliteitsindicatoren voor hartfalen in de huisartsenpraktijk met de RAND Delphi methode" and advises in its favour. This means that the committee has acknowledged that your project, as described in the protocol, is scientifically relevant and in line with prevailing ethical standards. This favourable advice does not entail the committee's responsibility for the planned project, however. You remain solely responsible. If you intend to publish your master's thesis, this e-mail may be used as proof of the committee's consent.

Ingestuurd in verkeerde rubriek: is praktijkverbeterend.

Met vriendelijke groeten

Opleidingsspecifieke begeleidingscommissie van de opleiding Master in de huisartsgeneeskunde (Leuven e.a.)

Approval OBC