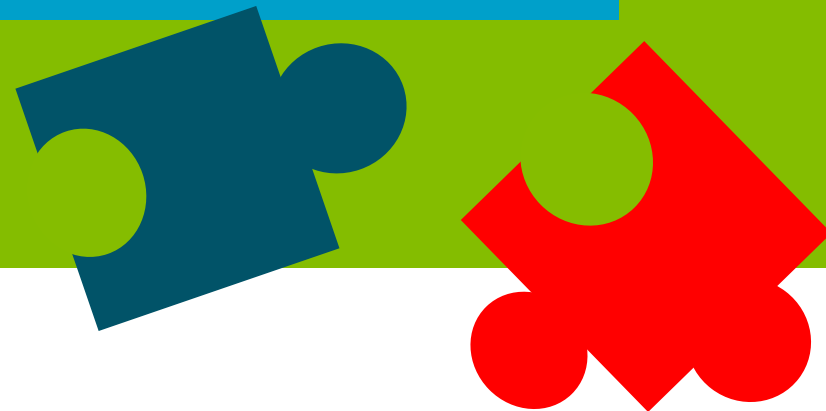


Statutory Health Insurance & Health Startups

DMEA, Berlin, April 10th 2019

Benjamin Westerhoff, Head of Product Strategy and Product Development, BARMER



BARMER, who?

- A large German **public payor**, subject to government regulation
- **> 9.2 million lives insured**, which equals a **~13%** market share in Germany
- **> 37bn € budget (2018)**, **15,500 employees** and 400 local offices

Expected outcomes of digitizing healthcare



Source: McKinsey, October 2018

Estimation: **34 Billion €** to be saved



Paperless data

€ 9 Bn.



Work flow/ automation

€ 6.1 Bn.



Patient self-care

€ 3.8 Bn.



Online interaction

€ 8.9 Bn.



Outcome transparency/ decision support

€ 5.6 Bn.



Patient self-service

€ 0.5 Bn.

The healthcare scheme and healthcare startups

Is it essentially two worlds colliding?

...Startups
being
Mr. Fantastic



In terms of flexibility it
probably feels like...

...while...

...The System
is being
The Thing

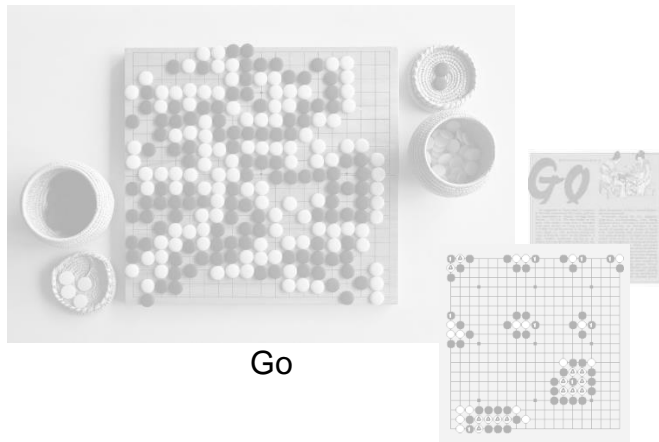


BARMER

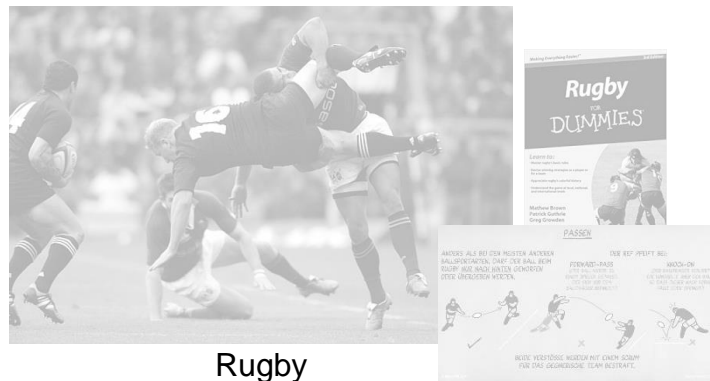
Every game entails certain rules

Rules are essential to every game. They basically define it.

So if you want to be a player in a certain game...



Go



Rugby

1

... you either accept the rules



2








or you don't get to play along.



Every market has its rules as well

Healthcare-schemes set certain frameworks.

German system

	Physicians	
	Pharmaceuticals	
	Adjuvants	
...	etc.	

	Digital Health	
---	----------------	--

Broader regulation for

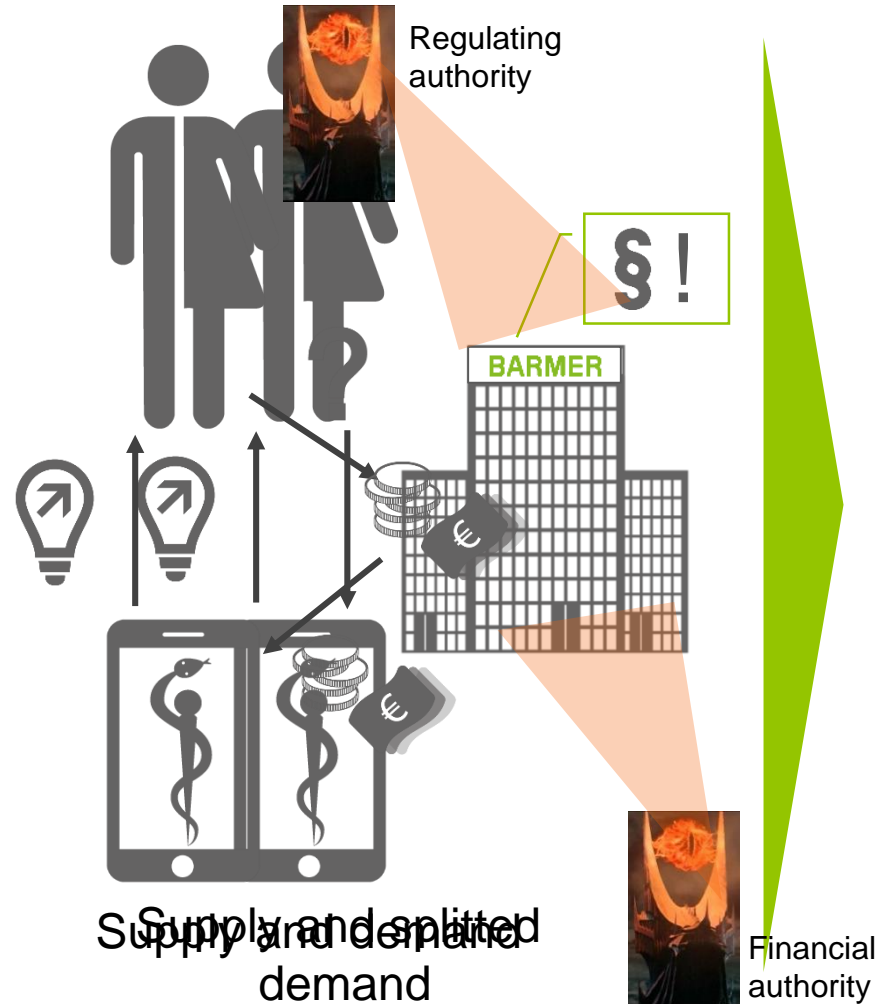
- Video-consultations (to be expanded shortly)
- Telemonitoring of cardiac devices

Other digital solutions and apps have no general approval procedure so far

- They can only be reimbursed by statutory health insurances if they fulfill all necessary criteria of the service type they apply for (e. g. prevention)
- No obligation to contract

B2C vs. B2B2C

Second health-market vs. first health-market



Legal authorization by social law?

1. What is the deficit?
2. Exact description of planned intervention, content and processes
3. Assumption / quantification of possible or aimed power
4. Description of measurements / concept for evaluation
5. Scenario for broad adoption into the healthcare system?
6. ...

Does the product fulfill all criteria (quality, certification, ux, data-protection, benefits for customers and health-care providers...)

Regulation for direct contracting

What are the requirements? Does the project fit?

§ 20 SGB V
Individualprävention

§ 20a SGB V
Nichtbetriebliche Prävention

§ 20b SGB V
Betriebl. Gesundheitsmanagement

§ 5 SGB XI
Prävention in stationärer Pflege

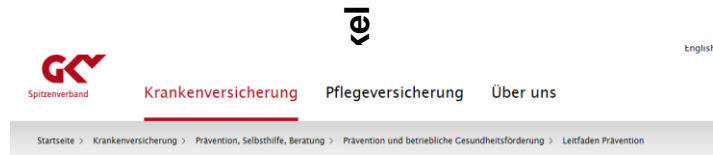
§ 20h SGB V
Selbsthilfe

§ 43 SGB V
Erg. Leistungen zur Rehabilitation

§ 140 SGB V
Besondere Versorgung

Primary prevention only!

Verhaltens- und Verhältnisprävention
Handlungsfelder
Lebenswelt
Effektstärke
Gesundheits
Medizin
Evidenz
Partizipation
Optimierung
Schnittstelle
Evaluation
Prozess-, Struktur
Ergebnisqualität



Leitfaden Prävention

Mit dem GKV-Leitfaden Prävention legt der GKV-Spitzenverband in Zusammenarbeit mit den Verbänden der Krankenkassen auf Bundesebene die inhaltlichen Handlungsfelder und qualitativen Kriterien für die Leistungen der Krankenkassen in der Primärprävention und betrieblichen Gesundheitsförderung fest, die für die Leistungserbringung vor Ort verbindlich gelten. Der Leitfaden bildet die Grundlage, um die Versicherten zu unterstützen, Krankheitsrisiken möglichst frühzeitig vorzubeugen und ihre gesundheitlichen Potenziale und Ressourcen zu stärken. Maßnahmen, die nicht den in diesem Leitfaden dargestellten Handlungsfeldern entsprechen, dürfen von den Krankenkassen nicht durchgeführt oder gefördert werden.



Hinweis: Der Leitfaden Prävention wird zurzeit modulweise weiterentwickelt und existiert derzeit nicht als zusammenhängende Printversion. Kapitel 1-2 sowie Kapitel 4-7 wurden unter Einbeziehung unabhängigen wissenschaftlichen Sachverständigen der

Guideline on prevention

Wirtschaftlichkeit
Effektstärke
Übertragbarkeit
Prävalenz
Intervention, Inhalte & Prozesse
Versorgungsdefizit
Schnittstellen
Prozess-, Struktur- und Ergebnisqualität
Evaluation
Number needed to treat
Systemintegration
Medizinische Evidenz

Selective contracts especially require

proven cost efficiency

§ 140a SGB V Besondere Versorgung

(1) Die **Krankenkassen können Verträge mit den in Absatz 3 genannten Leistungserbringern über eine besondere Versorgung der Versicherten abschließen**. Sie ermöglichen eine **verschiedene Leistungsspektren übergreifende oder eine interdisziplinär fachübergreifende Versorgung (integrierte Versorgung)** durch **Leistungsanbieter oder deren Gemeinschaften besondere ambulante Versorgung**. **73a, 73c und 140a in der am 22. Juli 2015 geltenden Fassung geschlossen wurden**, gelten fort. Soweit die Versorgung der Versicherten nach diesen Verträgen durchgeführt wird, ist der Sicherstellungsauftrag nach § 75 Absatz 1 eingeschränkt. Satz 4 gilt nicht für die Organisation der vertragsärztlichen Versorgung zu dem Zweck, die Versorgung der Versicherten zu verbessern.

- **Contracts have to mandatorily involve a physician / physicians**

- **Quality has to outperform broadly available healthcare**

(2) (...) ... sie insbesondere **darauf ausgerichtet ist, die Qualität, die Wirksamkeit und die Wirtschaftlichkeit der Versorgung zu verbessern**. Die **Wirtschaftlichkeit der besonderen Versorgung muss spätestens vier Jahre nach dem Wirksamwerden der zugrunde liegenden Verträge nachweisbar sein**. Für die Qualitätsanforderungen zur Durchführung der Verträge gelten die **Bedingungen der Bundesmantelverträge für die Leistungserbringung in der vertragsärztlichen Versorgung** Mindestvoraussetzungen entsprechend. Gegenstand der Verträge **darf die Versorgung betreffen**. Vereinbarungen über zusätzliche Vergütungen für Diagnosen können nicht Gegenstand der Verträge sein.

- **The cost-efficiency has to be indicated prospectively and proven retrospectively (after 4 years)**

(3) Die Krankenkassen können nach Maßgabe von Absatz 1 Satz 2 Verträge abschließen mit:

1. nach diesem Kapitel zur Versorgung der Versicherten berechtigten **Leistungserbringern** oder deren Gemeinschaften,
2. Trägern von Einrichtungen, die eine besondere Versorgung durch zur Versorgung der Versicherten nach dem Vierten Kapitel berechnete Leistungserbringer anbieten,
3. Pflegekassen und zugelassenen Pflegeeinrichtungen auf der Grundlage des § 92b des Elften Buches,
4. Praxiskliniken nach § 115 Absatz 2 Satz 1 Nummer 1,
5. pharmazeutischen Unternehmen,
6. **Herstellern von Medizinprodukten im Sinne des Gesetzes über Medizinprodukte**,
7. Kassenärztlichen Vereinigungen zur Unterstützung von Mitgliedern, die an der besonderen Versorgung teilnehmen.

Market opportunity

Which operational obstacles derive from the track in terms of scalability?



§ 20 SGB V Individualprävention

- Certification by „Zentrale Prüfstelle Prävention“ (ZPP)
- Mostly direct to consumer marketing
- 80-100% Adherence (customer needs to stick to the program)

Contract with insurer only needed if e. g. direct reimbursement is strived for

§ 20a SGB V Nichtbetriebliche Prävention

§ 20b SGB V Betriebl. Gesundheitsmanagement

§ 5 SGB XI Prävention in stationärer Pflege

- Finding partners within the setting (e. g. schools, kindergartens, municipalities etc.)
- Contract with insurer
- Mostly indirect to consumer marketing

§ 140 SGB V Besondere Versorgung

- Finding physicians who are willing to work with you
- Contract with insurer
- Direct to consumer marketing
- Informed consent by every single user
- Invoice-process

Which criteria are important to us when evaluating a Health App



Safety

- Medical product/CE-mark
- Other certificate from official sources
- Transparency on sources of finance
- Clarity on potential risks, and plan for preventative actions



Data security

- Data collected in the app are not shared
- Data protection rules are fully applied
- Clarity on reason for collecting any data
- Clarity on where data is kept (which country)



Patient centricity

- Clearly stated aim/therapy focus
- Clarity on end users targeted (patient, doctor, physiotherapist)
- Clear communication on target group – it should be easily visible for whom this app is useful for



Link to existing patient pathway

- App supports patient-physician interaction
- Integration of online and offline therapy
- Clear explanation of patient benefit/outcome, ideally initial read-outs from trials
- Clearly linked to medical knowledge



Usability

- UI/UX and usability are first class
- Ease of use (low number of clicks, intuitive to use)
- Limited need for patients to enter data
- Highly targeted to patient need

Be clear on who your target group is

Key lever	Example	Potential source of revenue
Time saving	<ul style="list-style-type: none">• Planning help for care personnel• Sleeping-pillow in nursery homes	<ul style="list-style-type: none">• Hospital or doctor that benefits from envisaged time savings
Improved patient/ consumer experience	<ul style="list-style-type: none">• Test your body fluids at home• Patient diaries/tracker• High-end toothbrush with app	<ul style="list-style-type: none">• Patients willing to pay for the extra benefit, care and information
Cost saving	<ul style="list-style-type: none">• Psychological coaching• Back-pain training	<ul style="list-style-type: none">• Insurances willing to engage in joint evaluation to push solutions
Better outcomes	<ul style="list-style-type: none">• Telemedicine for heart failure patients• hybrid closed-loop artificial pancreas	<ul style="list-style-type: none">• Insurances• Health systems
Great marketing device	<ul style="list-style-type: none">• 😊	

Focus on your lever and build your case around it!

Note: Fewer doctoral visits are no cost-savings in the German system

Digital solutions in healthcare and prevention

Einschlafhilfe Schlafenszeit

Audio-Einschlafhilfe



BARMER Kindernotfall-App

Infos und Anleitungen in Notsituationen



BARMER Teledoktor-App

Teledoktor für die Hosentasche



BARMER App (Services)

Alles Wichtige online erledigen + Gesundheitsmanager



BARMER Bonus-App

Digital Bonuspunkte sammeln + Plus-Challenge



BARMER Arzt- und Krankenhaussuche App

Digitaler Arztfinder



Kniekontrolle

38 Trainingsvideos zur Stärkung des Knies & individueller Trainingsplan



Mimi Hörtest & Music

Anzeige des individuellen Hörvermögens & Höralters



mySugr

Diabetes App inkl. Startpaket (Messgerät & Teststreifen)



M-Sense (BGM) + Headache Hurts (Uni)

Migräne & Kopfschmerz-App



Pelvina
Beckenbodenkurs

7Mind

Entspannungs-/Achtsamkeitscoach



Kaia
Rückentraining



fitbase

Rückengesundheit, Ernährungskurse, Achtsamkeits-, Resilienz-, Augen- und Sehtraining, Mausarm-Übungen



Online Training PRO MIND

psychische Gesundheit, Diabetes und Depression, Schlaf und Regeneration



MindDoc by Schön Klinik

Online-Verhaltenstherapie per Videochat inkl. Online-Trainings zur Unterstützung



Squin

Rauchentwöhnung



Everybody

Förderung der Körperzufriedenheit, Selbsthilfe bei Essstörungen



Memore

Förderung geistiger und körperlicher Fähigkeiten per Videospiel-Plattform



PädExpert

Online-Einbindung weiterer Fachärzte zur Diagnostik, Therapie u. Verlaufsbeurteilung



App auf Rezept

Therapie bei funktioneller Sehschwäche bei Kindern



AdAM

Anwendung für digitalunterstütztes Arzneimitteltherapie- und Versorgungsmanagement



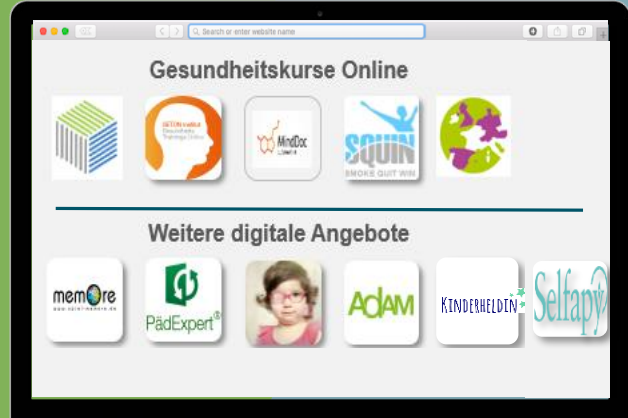
Kinderheldin

Hebammenberatung via Telefon und Chat



Selfapy

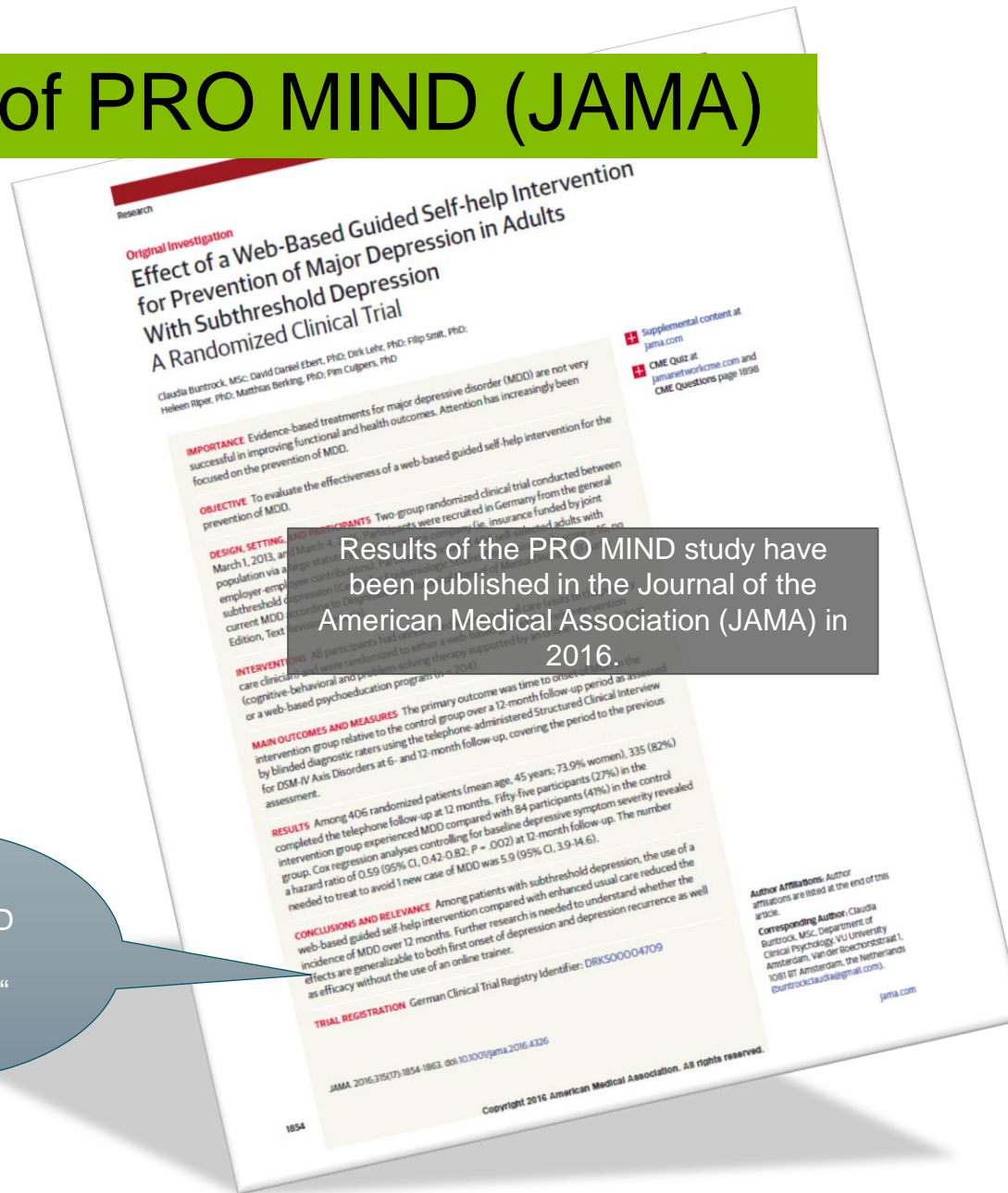
Gesund abnehmen, gesund ernähren



Evidence, anyone?



Effects of PRO MIND (JAMA)



Results of the PRO MIND study have been published in the Journal of the American Medical Association (JAMA) in 2016.

"...PRO MIND avoids depressions!"

RCT: patients with subclinical symptoms of depression

406 participants
202 intervention group
204 control group
335 took part in the follow-up interviews

After 12 month in time, 49% of the participants in the control-group developed a clinical depression whereas in the control-group only 34% developed a clinical depression

The „number needed to treat“ is 5.9. Meaning within every sixth participant a depression is avoided.

So this meant for us, that providing our customers with subclinical depressions with ProMind is a good decision.

Source: JAMA. 2016; 315(17):1854-1863

Effects of Fontane (TIM HF II) – Telemedical intervention

Articles

Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial

Friedrich Koehler, Kerstin Koehler, Oliver Deckwart, Sandra Prescher, Karl Wegscheider, Bridget-Anne Kirwan, Sebastian Winkler, Erik Vettorazzi, Leonhard Bruch, Michael Oeff, Christian Zugck, Gesine Daer, Herbert Naagele, Stefan Stark, Christian Buttler, Udo Sechter, Christiane Angermann, Gunturum Gola, Roland Prondzinsky, Frank Edelmann, Sebastian Spethmann, Sebastian M Schellong, P Christian Schuler, Johann Bauersachs, Brunhilde Wellge, Christoph Schoebel, Mios Tajacic, Henryk Dreger, Stefan D Anker*, Kai Stangl*

Summary

Background Remote patient management in patients with heart failure might help to detect early signs and symptoms of cardiac decompensation, thus enabling a prompt initiation of the appropriate treatment and care before a full manifestation of a heart failure decompensation. We aimed to investigate the efficacy of our remote patient management intervention on mortality and morbidity in a well defined heart failure population.

Methods The Telemedical Interventional Management in Heart Failure II (TIM-HF2) trial was a prospective, randomised, controlled, parallel-group, unmasked (with randomisation concealment), multicentre trial with pragmatic elements introduced for data collection. The trial was done in Germany, and patients were recruited from hospitals and cardiology practices. Eligible patients had heart failure, were in New York Heart Association class II or III, had been admitted to hospital for heart failure within 12 months before randomisation, and had a left ventricular ejection fraction (LVEF) of 45% or lower (or if higher than 45%, oral diuretics were being prescribed). Patients with major depression were excluded. Patients were randomly assigned (1:1) using a secure web-based system to either remote patient management plus usual care or to usual care only and were followed up for a maximum of 393 days. The primary outcome was percentage of days lost due to unplanned cardiovascular hospital admissions or all-cause death, analysed in the full analysis set. Key secondary outcomes were all-cause and cardiovascular mortality. This study is registered with ClinicalTrials.gov, number NCT01878630, and has now been completed.

Findings Between Aug 13, 2013, and May 12, 2017, 1571 patients were randomly assigned to remote patient management (n=796) or usual care (n=775). Of these 1571 patients, 765 in the remote patient management group and 773 in the usual care group started their assigned care, and were included in the full analysis set. The percentage of days lost due to unplanned cardiovascular hospital admissions and all-cause death was 4.88% (95% CI 4.55-5.23) in the remote patient management group and 6.64% (6.19-7.13) in the usual care group (ratio 0.80, 95% CI 0.65-1.00; p=0.0460). Patients assigned to remote patient management lost a mean of 17.8 days (95% CI 16.6-19.1) per year compared with 24.2 days (22.6-26.0) per year for patients assigned to usual care. The all-cause death rate was 7.86 (95% CI 6.14-10.10) per 100 person-years of follow-up in the remote patient management group compared with 11.34 (9.21-13.47) per 100 person-years of follow-up in the usual care group (hazard ratio [HR] 0.70, 95% CI 0.50-1.00; p=0.0460). Cardiovascular mortality was not significantly different between the two groups (HR 0.671, 95% CI 0.47-0.96; p=0.031).

Interpretation The TIM-HF2 trial suggests that a structured remote patient management intervention, restricted to a well defined heart failure population, could reduce the percentage of days lost due to unplanned cardiovascular hospital admissions and all-cause mortality.

Funding German Federal Ministry of Education and Research.

Copyright © 2018 Elsevier Ltd. All rights reserved.

Introduction

Heart failure is a chronic disorder, the management of which should potentially benefit from a remote patient management approach.^{1,2} One of the most challenging issues in the management of heart failure is to reduce hospital admission and readmission rates for worsening heart failure.³ Remote patient management includes a broad range of interventions, including uptitration of drugs in the outpatient setting, patient education, and management of



Published Online August 25, 2018
[http://dx.doi.org/10.1016/S0140-6736\(18\)31880-4](http://dx.doi.org/10.1016/S0140-6736(18)31880-4)
See Online/Comment [http://dx.doi.org/10.1016/S0140-6736\(18\)32995-0](http://dx.doi.org/10.1016/S0140-6736(18)32995-0)
*joint last authors
Centre for Cardiovascular Telemedicine, (Prof F Koehler MD, K Koehler MD, O Deckwart MSc, S Prescher MSc, B Wellge MSc), Department of Cardiology and Angiology (C Schoebel MD, M Tajacic MD, H Dreger MD, Prof K Stangl MD), Campus Mitte, Charité—Universitätsmedizin Berlin, Berlin, Germany, Department of Cardiology (Prof F Edelmann MD), and Division of Cardiology and Metabolism (Prof S D Anker), Campus Virchow, Charité—Universitätsmedizin Berlin, Berlin, Germany, (M Walter MD, H Naagele MD), Department of Cardiology (Prof K Zugck MD), Municipal Hospital Brandenburg/Havel and Brandenburg Medical School, Brandenburg/Havel, Germany (M Oeff MD), Cardiology Practice “Im Staber Thor”, Straubing, Germany (C Zugck MD), Clinic for Internal Medicine, St Josef, Krankenhaus Potsdam, Potsdam, Germany

Lancet. Published online August 25, 2018 [http://dx.doi.org/10.1016/S0140-6736\(18\)31880-4](http://dx.doi.org/10.1016/S0140-6736(18)31880-4)

12 month

Randomization of patients suffering from heart failure (NYHA II and III); LVEF <= 45; no depression; ...

838 participants within the study
765 intervention
773 control

Reduction of unplanned cardiovascular hospital admissions (intervention 3.8 days vs. control 5.6 days) = - 32%

Less days lost to overall hospital admission or death (intervention 17.8 days vs. control 24.2 days) = - 26%

Decrease in mortality
Intervention ~ 8 / 100 vs. control ~ 11 / 100 = - 31%

Quelle: Koehler et al. (2018); The Lancet Volume 392, ISSUE 10152, P1047-1057



We need clear market access pathways

What do we expect to change

▶ **More flexibility for health insurances** to contract with start-ups

▶ New pathways for **market access**, e.g.

▶ New **pricing models** are needed as digital products have different economics (e.g., no logistics, quicker development, no material costs, better scalability)

▶ New **protections** are needed as most digital solutions could have „generic“ versions

- **Short-term access** until further evidence is gathered through real-world-evidence
- **Renewed access**, as decisions may need revisions after major release changes
- **Pay-per-use-models**: Digital solutions are paid for active users
- **Pay-for-performance-models**: Digital solutions are paid for evidence created
- **Bundled payments**: Existing standard of care are matched with digital add-ons (e.g., inhaler and tracker)

Conclusion

- We support medical-progress and appreciate the opportunities digital health offers
- Key driver has to be a concrete deficit in healthcare / a medical need
- Innovations and digital health need to integrate into functioning healthcare-processes and create benefits on behalf of patients and healthcare-providers
- We require evidence-based solutions and informational self-determination
- It is important to us that the medical-progress is measured by outcomes (i. e. functionality and quality of life), as well as cost-effectiveness
- There are good examples of innovative health-care-services verifiably proving to increase the quality of health-care

If one doesn't understand the underlying problem...



...technique will not solve the problem, but rather only make it more expensive!

