

# **Scientific review of the Renewing Health project**

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# Technical review, May 2011

## Recommendation

*"Take steps to clarify the underlying scientific questions driving each of the trials, to improve the rigour of the study protocols ... and ensure they contribute useful evidence in their respective areas"*

# Scientific review

- requested by EU
- Richard Wootton, Reinhard Prior, Kristian Kidholm
- October/November 2011

# Aims of the RH project

- wide-ranging (and sometimes not entirely clear)
- scientific Qs represent a (small) part of the overall aims

# Rationale for the RH trials

- at present, the evidence of the value of e-health/telemedicine in chronic diseases is *equivocal*
- in some diseases the position has become more confused since the RH project was planned

# TM in chronic diseases

- COPD. Two systematic reviews in 2010 reached opposite conclusions
- diabetes. Unclear
- heart failure. Cochrane review contradicted by two recent (large, well-powered) trials

# Conduct of the RH trials

- considerable efforts have been made to carry out the trials in accordance with best practice
- standardised methodology
- standardised data collection

# Aggregation of data

- collecting the data centrally will be useful if an analysis of the entire dataset is possible/useful
- the potential value of a meta-analysis is unclear at this stage

# RCTs

Literature

	RCTs	Subjects
COPD	11	994
Diabetes	54	4,670
Heart failure	44	13,053

# RCTs

## Literature

	RCTs	Subjects
COPD	11	994
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## RH Project

	RCTs	Subjects
COPD	9	1,220
Diabetes	7	1,200
Heart failure	5	?600

# Suggestions

- investigate the possibility of meta-regression as a potential means of analysing the value of the different interventions
- explore the possibility of individual patient data (IPD) meta-analysis. This is an established technique in cancer trials work, but has not previously been used in telemedicine
- explore the data on the control patients

## ... suggestions

- analyse the combined dataset to allow the performance of the interventions to be compared, e.g. in terms of cost per occasion of service
- analyse the combined dataset to allow the performance of the interventions to be compared in a cost-utility analysis, e.g. in terms of the cost of QALYs gained

## **... suggestions**

- analyse the data from trials within disease categories to allow the performance of the interventions to be compared in a cost-effectiveness analysis, e.g. in terms of the cost of the effect achieved within a disease group.

# Main points

- clarify/re-state the Research Question for each trial, e.g. "to determine the clinical- and cost-effectiveness of the e-health/telehealth intervention in patients with disease X"
- state clearly the perspective from which the economics are being examined, e.g. societal, health system or patient costs

## ... main points

- define the effect of interest in each disease group. This is likely to be HbA<sub>1c</sub> (diabetes), travel cost (leg ulcers), readmission/mortality (both COPD and heart disease)
- focus on measuring cost-effectiveness in each trial, i.e. calculating the cost of the effect achieved, and the ICER
- ensure that all the trials are registered

## ... main points

- ensure that the individual trial results will be analysed using an appropriate statistical method. For example, testing differences between groups using t-tests is probably inappropriate. Analysis of covariance is recommended
- recalculate the required sample sizes in each trial using conventional levels of significance/power to ensure that accusations of unethical practice can be refuted.

# Conclusion

- well-conducted e-health/telemedicine trials will contribute to the evidence base
- they may not provide answers to the fundamental scientific questions
- the wider aims of the RH project may be important