

REFLECTION Masterclass October 4th-6th, 2012

Synthesising and Reporting Complex Interventions

Institute for Social Medicine, University Hospital Lübeck, Lübeck, Germany

Scientific Meeting Report
1. Details

Activity	Masterclass 'Synthesising and Reporting Complex Interventions'
ESF record	REFLECTION network - Science Meeting No. 4260
Date of the event	Oct 4-6, 2012
Organisers	<p>Prof. Dr. Sascha Köpke Nursing Research Group, Institute for Social Medicine, University of Lübeck, Ratzeburger Allee 160, 23538 Lübeck, Germany</p> <p>Prof. Dr. Gabriele Meyer School of Nursing, Faculty of Health Science, University of Witten/Herdecke, Stockumer Straße 12, 58453 Witten, Germany</p>
Teachers / presenters	<p>14 presenters from 11 Universities:</p> <ul style="list-style-type: none"> • University of Hamburg (1) • University of Lübeck (3) • Witten/Herdecke University (2) • University of Düsseldorf • University of Exeter • University of Southampton • University of Cardiff • University of Leuven • University of York • University of Ulster • University of Dundee <p>Introduction by</p> <ul style="list-style-type: none"> • Prof. Alexander Katalinic, head of the Institute for Social Medicine, University of Lübeck • Prof. David Richards, chair of the REFLECTION network
Participants	<p>54 participants from 16 countries: Austria, Belgium, Cyprus, Denmark, Germany, United Kingdom, Greece, Ireland, The Netherlands, Norway, Portugal, Sweden, Slovakia, Spain, Switzerland, South Africa</p>
Location	University Hospital Schleswig-Holstein, Lübeck & University of Lübeck, Germany

2. Introduction

This masterclass on 'Synthesising and Reporting Complex Interventions' was the second one organised within the REFLECTION network, after a successful first masterclass on 'Implementation of Complex Interventions' organised by Radboud University Nijmegen (Prof. Theo van Achterberg and team) in October 2011.

As the first one, this masterclass aimed to attract mostly post-doctoral researchers interested in the important field of the synthesis and reporting of complex interventions with a sufficient knowledge on complex intervention research, who were not experts on this specific topic.

Recently, there has been increased interest and awareness in these topics among the scientific community as can be seen from a growing number of publications on these issues. In Germany, for example, the annually congress on evidence-based medicine in 2012 was explicitly concerned with complex intervention with a strong focus on syntheses of complex interventions.

Both topics importantly supplement the Medical Research Council's Framework for the development and evaluation of Complex Interventions (Craig et al. 2008) which is the basis of the activities of the REFLECTION network.

Introducing the masterclass topics (based on the application text)

A) Synthesis

Methodological problems in synthesising evidence from heterogeneous studies have been acknowledged (Lenz et al. 2007, Shepperd et al. 2009). Different bio-statistical approaches as e.g. meta-regression (Bower et al. 2006) or random effects models were proposed (Higgins et al. 2011, Riley et al. 2011). However, discussion remains if the body of knowledge can be extended by such proof-of-concept meta-analytic approaches (Mühlhauser et al. 2011). The problem of summarising and synthesising complex interventions goes beyond these issues. As in any post-hoc analysis, the results of the synthesis can only be as good as the underlying data. Here, it has been shown that recent strategies are not capable of sufficiently summarizing evidence from complex interventions due to non-availability of important data (Lenz et al. 2007). Considering the complexity of many interventions, this problem is of highest relevance in nursing. Prototypically this has been shown for fall prevention with more than 150 randomised controlled trials summarized in two Cochrane reviews with mainly inconclusive results (Mühlhauser et al. 2011). Apart from statistical approaches, different strategies have been proposed to target these challenges as e.g.

- systematic reviews acknowledging all available information about the complex intervention outlined in the MRC framework resulting in a summary focussing on all "active components" of the intervention and refraining from meta-analysis (Lenz et al. 2007),
- new rigorous methods for narrative reviews (Rodgers et al. 2009) or

- “realist reviews” asking “what works, for whom, under what circumstances?” i.e. by a very broad view on the available evidence aiming to reveal factors that enable or constrain the probability for an intervention to be effective (Pawson et al. 2005).

So far, none of these approaches have been proven to sufficiently address the complex problems of summarising and synthesising complex interventions.

B) Reporting

Recently, it has been shown that reporting of complex interventions is not sufficient (Möhler et al. 20011, Mayo-Wilson 2007). In this context, it has been questioned if new approaches are necessary in order to disseminate all available information concerning a certain complex intervention. Here, conventional publication policies are still not sufficient to allow access to and linking of the full body of knowledge. Therefore, special databases covering all relevant publication and supplementary information on complex intervention seem warranted (Lenz et al. 2007, Glasziou et al. 2010). Comprehensive and transparent reporting of complex intervention has been proposed as important for long-term implementation, preparation of systematic reviews on complex interventions, judgement of interventions’ clinical benefit, reproduction of interventions’ evaluation, and adaption of interventions into different settings (Möhler et al. 2012). Since available reporting guidelines as e.g. the CONSORT statement and its extensions do not sufficiently target complex interventions, guidelines for reporting complex interventions seem warranted. First approaches have been published, but not yet been evaluated (Glasziou et al. 2010, Möhler et al. 2012).

3. Aim of the masterclass

The masterclass aimed to provide in-depth information on synthesising and reporting complex interventions. It was intended to allow participants to reflect on these issues and provide the basis for discussion. Platform presentation and workshops by experts from different fields were intended to provide a thorough insight into the underlying problems and possible solutions of synthesising and reporting complex interventions.

4. Outline of the programme

The programme (see Appendix) included half a day on Thursday the 4th of October and two full days on Friday the 5th and Saturday the 6th. All presentations and workshops were held at the campus of the University of Lübeck situated within the University Hospital Lübeck (UKSH). On Thursday evening there was a guided tour through the historic centre of Lübeck and on Friday evening a dinner for all participants was held at a restaurant within a historic building in the centre of Lübeck.

The first two days were concerned with the synthesis of complex interventions. After the introductions, the programme started with two introductory lectures by Prof. Ingrid Mühlhauser

(University of Hamburg) and Dr. Michael Simon (University of Southampton). In the afternoon, participants were asked to choose between three workshops. One was an introductory workshop for participants not very familiar with the masterclass' topics led by the organisers (G. Meyer & S. Köpke). The other two workshops focussed on specific topics of summarising complex intervention: HTA by Dr. Dagmar Lühmann (University of Lübeck) and Public Health interventions by Dr. Ruth Turley (University of Cardiff). All workshops were based on workshop leaders' own work to allow participants to learn from and discuss about real world examples.

Friday morning started with two video lectures from Dr. Karin Hannes (University of Leuven) and Dr. Kate Flemming (University of York) both addressing the important aspect of including qualitative data in the synthesis of complex intervention. This experiment of allowing presentations via video link worked extremely well especially with Dr. Hannes who was easily understood and the participants being able to see the presentation slides while Dr. Hannes was lecturing. Kate Flemming had provided her presentation slides in advance so that the participants could see her talking and in parallel could follow the slides on a printout provided by the organisers. This was reported to be slightly demanding, but overall participants and presenters were very happy with this form of presentation which surely is resource-saving.

The second part of the morning was also concerned with lectures on specific topics of synthesising complex interventions. First Ralph Möhler from Witten-Herdecke University discussed if the Cochrane methodology allows for guidance of authors on synthesising complex interventions. Afterwards Prof. David Richards (University of Exeter) and Dr. Markos Dintsiros (University of Düsseldorf) presented on meta-regression and economic analyses, two further topics of special interest in this context.

After lunch, participants split in three groups and attended three workshops held by Dr. Ruth Turley (University of Cardiff) on "narrative reviews, Katrin Balzer (University of Lübeck) on "evidence linkages, and Prof. Brendan McCormack (University of Ulster) on "realist reviews". In the late afternoon all participants again gathered in the lecture hall to discuss the most important aspects raised in the workshops.

In the evening all participants met for an informal dinner within a historic location in the city centre of Lübeck.

The third and last day was concerned with the reporting of complex interventions. This was introduced by Ralph Möhler who reported on guidelines for the reporting of complex interventions. Afterwards participants split into two groups and had the opportunity to discuss more specific topics held by Katrin Balzer on "quality appraisal" and Mary Wells (University of Dundee) on "reporting context" in complex interventions. Again both workshops were based on recent work from the workshop leaders.

After lunch the group met in 6 small groups lead by the local team to discuss further research needs and to prepare a joint commentary on the recent Cochrane review on fall prevention in community dwelling elderly (Gillespie et al. 2012). This strongly recognised systematic review and meta-analysis prototypically allows discussing the challenges of synthesising and reporting

complex intervention. The masterclass closed with a plenary discussion about the masterclass and its implications for future research.

All presentations and workshop contents were subsequently made available through the REFLECTION website.

5. Participants' evaluation

At the end of the masterclass, all participants were asked to fill in a structured evaluation sheet addressing personal expectations and if these were met by the programme. Also participants were asked to evaluate the quality of presentations and workshops in general as well as each single event. Here, they were also asked to suggest topics that should have been raised or should be part of future masterclasses. Finally, they were asked about the masterclass' level of difficulty, if they had gained "important competencies", and for further remarks. In addition participants discussed the masterclass within the final session on Saturday afternoon. Here, it emerged that participants were very satisfied with the organisation before and during the workshop and were very grateful for the opportunity to attend such a high profile meeting on very little costs due to the funding by the ESF and the two local funders (Possehl Foundation & Sparkassen Foundation). The results of the written evaluation are outlined below.

a) Personal expectations

70% of the participants felt that most of their expectations were met by the masterclass. Only 1 participant stated that less than half of his/her expectations were met.

b) Lectures

92% of the participants rated the general quality of lectures as good or very good. On a 5-point Likert scale (1 being very good and 5 being very low quality), 5 of the 8 lectures received mean ratings better than two. These were the lectures by David Richards on meta-regression (1.4 ± 0.6 SD), Karin Hannes (video lecture) on the synthesis of qualitative and quantitative data (1.5 ± 0.6 SD), Michael Simon (1.7 ± 0.7 SD) on literature search, and the 2 lectures by Ralph Möhler on Cochrane reviews and reporting guidelines (1.8 ± 0.7 SD). The three remaining lectures received mean ratings between 2.0 and 2.6. The last one being the presentation by Markos Dintsios on economic evaluations showed a marked variance between ratings. Personal remarks indicated that participants who had already dealt with economic evaluations found this lectures very helpful whereas others had problems to follow.

Individual remarks indicated possible further topics for lectures. Here participants stated process evaluation, individual patient data (IPD) meta-analysis, theory development and modelling (incl. reporting of these phases), and introduction on complexity science.

More time was called for to deal with mixed methods, economic analyses, and qualitative appraisal.

c) Workshops

The rating of the workshops was comparable to the lecture with 82% rating the quality of

the workshops as good or very good. Here, 4 of 8 workshops received marks below 2. These were the workshops by Mary Wells on reporting context (1.3±0.6 SD), Brendan McCormack on realist reviews (1.6±0.9 SD), and both workshops by Ruth Turley on public health reviews and narrative reviews (1.6±0.7 SD). The four remaining workshops received mean ratings between 2.0 and 2.6. Individual remarks indicated possible further topics for workshops. Here participants stated feasibility, process evaluation, and evidence-based health care. More time could have been spent on realist reviews, harvest plots and logic model. One participant would have wished more exercise to assess Cochrane reviews and qualitative studies in small groups.

d) General evaluation

The difficulty of the sessions in general was rated as adequate (4.6±1.5 SD on a 10cm visual analogue scale with 0=too hard and 10=too easy). More than half of the participants felt that they had mostly or strongly gained “important competencies” by attending the masterclass. When asked about possible lessons learned for future masterclasses, individual participants called for more interactive workshops and the use of different lecture-methods as e.g. including videos, pictures, and stories. Some felt that there should be more time for lectures or that these should contain less information. One participant would have preferred the provision of hand-outs before the masterclass.

In summary, the content and the organisation of the masterclass were well received by the participants and the mixture of lectures, workshops, and small group work seems to have met most participants’ needs. The difficulty of the content seems to have been just right for most participants, although surely there could have been more time for further and in-depth discussion. For the organisers, the video lectures were an exciting experiment that turned out very well and maybe this could be picked up by future masterclasses in order to save resources. The same applies to not providing hand-out to all participants, but making pdf-files of the presentations available directly after the masterclass.

6. Outlook

The masterclass in Lübeck has been a further proof for the successful concept of masterclasses on specific aspects of complex interventions within the REFLECTION network. It has attracted even more participants from all over Europe than the first masterclass in Nijmegen. Also, we were able to recruit experts in the field from outside our working groups, some of them members of the European Academy of Nursing Science (EANS) and the REFLECTION network, but also some from other contexts as e.g. evidence-based medicine (I. Mühlhauser), health technology assessment (D. Lühmann), or the Cochrane collaboration (K. Hannes & R. Turley).

Most participants were from the area of nursing science, but there were also psychologists, physicians, physiotherapists, biostatisticians and health economists, a fact that surely contributed to successful inter-disciplinary discussions and networking throughout the

masterclass. The concept of bringing together persons from different contexts and countries could definitely be realized during the three intensive days in Lübeck.

There were few participants from East Europe, but participants from all REFLECTION-funding countries.

To be able to have a lasting result from the masterclass, we had offered two options for the final session on Saturday afternoon, either to jointly create an agenda for future research or to discuss the recent Cochrane review on fall prevention in community dwelling elderly (referred to above) and work out aspects for a comment to be submitted to the Cochrane group. The participants opted for the second choice and based on the discussion, the organisers have drafted a comment that will be circulated with the participants soon and then be submitted in the name of the masterclass participants. We find this a suitable way to have a lasting result from participation in the masterclass besides the many new aspects that came up during the lectures, workshops, and discussions. Also during the final discussion, the group decided to create a new REFLECTION group that should prepare a consensus conference on the reporting guidelines recently developed by the organizers group (Möhler et al. 2012) and presented by Ralph Möhler. This consensus conference is planned for the EANS scientific meeting in Aarhus, Denmark in January 2013.

7. References

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8. Appendix: Masterclass programme

Thursday (October 4th)

12.30-14.00, Entrance of the lecture hall, Building No. 53

Registration • Coffee & Snacks

14.00-16.00, Lectures, Lecture hall, Building No. 53

14.00-14.30 • Opening & Welcome • Alexander Katalinic, University of Lübeck • David Richards, University of Exeter

14.30-15.15 • Challenges of evaluating, synthesising and reporting complex interventions • Ingrid Mühlhauser, University of Hamburg

15.15-16.00 • Successful literature search strategies: optimizing precision and the “number needed to read” • Michael Simon, University of Southampton

16.00-16.45, Coffee break, Entrance of the lecture hall, Building No. 53

16.45-17.45

Workshops: Meta-analysis of complex interventions: current methodological limitations and challenges – different views, different challenges (please choose one)

Room A, Institute for Social Medicine, Building No. 50

Experiences from Health Technology Assessments • Dagmar Lühmann, University of Lübeck

Room B, Institute for Social Medicine, Building No. 50

Experiences from Public Health • Ruth Turley, University of Cardiff

Room C, School of Nursing, Building No. 37

(Synthesis of) Complex interventions for beginners • Gabriele Meyer & Sascha Köpke

18.30-20.00 Guided city tour

Meeting point: **Holstentor**, historic centre of Lübeck

Friday (October 5th)**9.30-11.00, Lectures, Lecture hall, Building No. 53**

9.30-10.15 • Integration of qualitative and quantitative data in systematic reviews – how far could we go? • Karin Hannes, University of Leuven (via video conference)

10.30-11.15 • Synthesis of qualitative research on complex interventions • Kate Flemming, University of York (via video conference)

11.15-11.30, Coffee break, Entrance of the lecture hall, Building No. 53**11.30.-13.15, Lectures, Lecture hall, Building No. 53**

11.30-12.05 • Cochrane reviews – Are they prepared for synthesis of complex interventions? • Ralph Möhler, Witten/Herdecke University

12.05-12.40 • Meta-regression for determination of active components of complex interventions • David Richards, University of Exeter

12.40-13.15 • Economic analyses in the context of evaluation of complex interventions • Ch. Markos Dintisios, vfa Berlin & Department of Public Health University of Düsseldorf

13.15-14.15, Lunch, Entrance of the lecture hall, Building No. 53**14.15-17.00, Workshops with three rotating topics (see extra page)****Room A, Institute for Social Medicine, Building No. 50**

Topic I (45 min) • Break (15 min) • Topic III (45 min) • Break (15 min) • Topic II (45 min)

Room B, Institute for Social Medicine, Building No. 50

Topic II (45 min) • Break (15 min) • Topic I (45 min) • Break (15 min) • Topic III (45 min)

Room C, School of Nursing, Building No. 37

Topic III (45 min) • Break (15 min) • Topic II (45 min) • Break (15 min) • Topic I (45 min)

17.00-17.30, Coffee break, Entrance of the lecture hall, Building No. 53**17.30-18.15, Plenary discussion, Lecture hall, Building No. 53**

Moderation: Gabriele Meyer, Witten/Herdecke University • Sascha Köpke, University of Lübeck

19.30 Masterclass Dinner

“Die Zimberei”, historic centre of Lübeck, Königstraße 57

Saturday (October 6th)**9.30-10.15, Lecture, Lecture hall, Building No. 53**

General guidelines for reporting complex interventions • Ralph Möhler, Witten/Herdecke University

10.15-10.45, Coffee break, Entrance of the lecture hall, Building No. 53**10.45-12.30, Workshops with two rotating topics (see extra page)****Lecture hall, Building No. 53**

Topic I (45 min) • Break (15 min) • Topic II (45 min)

Room A, Institute for Social Medicine, Building No. 50

Topic II (45 min) • Break (15 min) • Topic I (45 min)

12.30-13.30, Lunch, Entrance of the lecture hall, Building No. 53**13.30-14.30, Small group work, Institute for Social Medicine, Building No. 50**

Preparing a joint commentary on the recent Cochrane review on fall prevention in community dwellers (Gillespie et al. 2012)
and/or

Drafting ideas for a conjoint research agenda on synthesising and reporting complex interventions (6 working groups)

14.30-15.00, Coffee break, Entrance of the lecture hall, Building No. 53**15.00-16.00, Plenary discussion & Farwell, Lecture hall, Building No. 53**

Research agenda presentation, summary & farewell • Moderation: Gabriele Meyer, Witten/Herdecke University • Sascha Köpke, University of Lübeck

Rotating workshop topics – Friday (October 5th), 14.00-16.45**Topic I (Rotation sequence: Room A – Room B – Room C)**

What narrative reviews contribute to synthesis of complex interventions • Ruth Turley, University of Cardiff

Topic II (Rotation sequence: Room B – Room C – Room A)

Evidence linkage in test-treatment trials – Creating complexity • Katrin Balzer, University of Lübeck

Topic III (Rotation sequence: Room C – Room A – Room B)

The contribution of realist reviews to judgments on complex interventions • Brendan McCormack, University of Ulster

Rotating workshop topics – Saturday (October 6th), 10.45-12.30**Topic I (Rotation sequence: Lecture hall – Room A)**

Reporting complex interventions – quality appraisal • Katrin Balzer, University of Lübeck

Topic II (Rotation sequence: Room A – Lecture hall)

Reporting context in complex interventions • Mary Wells, University of Dundee