



Science Meeting – Scientific Report

Scientific report (one single document in WORD or PDF file) should be submitted online within two months of the event. It should not exceed seven A4 pages.

Proposal Title:

Methods for Conducting Process Analyses and Managing Economic Data in Clinical Trials of Complex Interventions, CReDECI Complex Interventions Reporting Criteria Consensus Meeting

Application Reference N°: 5044

1) Summary (up to one page)

This masterclass on 'Process Evaluations, Economic Evaluations, Reporting Complex Interventions' was the third one organised within the REFLECTION Network, after a successful masterclasses on 'Implementation of Complex Interventions' in October 2011 and 'Synthesising and Reporting Complex Interventions' in October 2012. The challenge of developing and evaluating complex interventions in healthcare has been increasingly acknowledged for example by the Medical Research Council's (MRC) framework. As nursing care frequently comprises complex interventions, the European Science Foundation has funded the REFLECTION RNP to build capacity in nursing researchers across Europe. This masterclass aimed to attract mostly post-doctoral researchers interested in the field of the Process Evaluations, Economic Evaluations and Reporting Complex Interventions. The three-day masterclass aimed to provide an overview of the fields of methods for conducting process analyses as part of clinical trials, measuring and analysing economic data in clinical trials, followed by a 'CReDECI' consensus workshop on reporting criteria for complex interventions.

Introducing the masterclass topics

A) Methods for Conducting Process Analyses in Clinical Trials of Complex Interventions
As noted by the MRC (2008) "Including a process evaluation [in a clinical trial] is a good investment, to explain discrepancies between expected and observed outcomes, to understand how context influences outcomes, and to provide insights to aid implementation." (p4). "A process evaluation is often highly valuable – providing insight into why an intervention fails unexpectedly or has unanticipated consequences or why a successful intervention works and how it can be optimised. Process evaluation nested within a trial can also be used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in

outcomes. Process evaluations should be conducted to the same high methodological standards and reported just as thoroughly as evaluation of outcomes.” (p12). However, there are many options available for process evaluation including both qualitative and bio-statistical approaches. This masterclass aimed to help participants develop knowledge of the range of methods which can be used to understand processes within a research study; critically appraise how best to assess fidelity and quality when implementing nursing activities or interventions; demonstrate understanding of how process evaluations can clarify causal mechanisms and identify contextual factors associated with variation in outcomes.

B) Managing Economic Data in Clinical Trials of Complex Interventions

Similarly, complex interventions present many challenges for health economics. “An economic evaluation should be included if at all possible, as this will make the results far more useful for decision-makers. Ideally, economic considerations should be taken fully into account in the design of the evaluation, to ensure that the cost of the study is justified by the potential benefit of the evidence it will generate, appropriate outcomes are measured, and the study has enough power to detect economically important differences. The main purpose of an economic evaluation is estimation rather than hypothesis testing so it may still be worth including one, even if the study cannot provide clear cost or effect differences, so long as the uncertainty is handled appropriately.” (MRC, 2008, p.12). This masterclass aimed to help participants critically evaluate core health economic concepts in the evaluation of complex interventions and activities in healthcare and nursing; understand the role of economic evaluation in estimating the scale of economic benefits from complex nursing and health care activities or interventions; demonstrate understanding of how such analyses can be incorporated in the design of evaluations of complex interventions and activities.

C) CReDECI: reporting criteria for complex interventions

High quality reporting is an integral part of the MRC framework at each stage of the research process (2008). Still, it has repeatedly been shown that reporting of complex interventions is not sufficient (Lenz et al., 2007; Möhler et al., 2011; Mayo-Wilson, 2011). 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 interventions seem warranted (Lenz et al., 2007; Glasziou et al., 2010). Comprehensive and transparent reporting of complex interventions 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 such as the CONSORT statement and its extensions do not sufficiently target complex interventions, guidelines for reporting complex interventions seem warranted. The first approaches have been published, but have not yet been evaluated (Glasziou et al., 2010; Möhler et al., 2012).

2) Description of the scientific content of and discussions at the event (up to four pages)

The masterclass aimed to provide in-depth information on process evaluations, economic evaluations and reporting complex interventions. The masterclass was

intended to provide the opportunity to gain and exchange knowledge, to further discuss existing approaches and to set an agenda for further research concerning the process analyses and health economics in clinical trials of complex interventions. In platform presentations and workshops, experts from different fields provided an insight into the underlying problems of process and economic evaluations of complex interventions using examples from different health care areas with an emphasis on nursing research. Reporting as an important requirement for complex interventions research was also addressed.

Outline of the programme

The programme (see Appendix) included three days: Thursday Oct 3rd, Friday Oct 4th and Saturday Oct 5th. All presentations and workshops were held at the Faculty Hospital in Nitra. On Thursday evening there was a dinner for all participants at a restaurant and on Friday evening there was a guided tour through the historic centre of Nitra.

The topic for the first day was Process Analysis as a Part of Clinical Trials (Process Evaluations). After the introductions by prof. Eva Sollárová, dean of the Faculty of Social Sciences and Health Care, Dr. Tomáš Sollár, Masterclass organiser, the deputy director of the Institute of Applied Psychology and prof. David Richards, the chair of the REFLECTION Project, the programme started with the lecture on Normalisation Process Theory by prof. Carl May (University of Southampton).

After the Coffee & Tea break, the programme continued with lectures by Dr. Nienke Bleijenberg (University of Utrecht, topic: Process Evaluation of an Intervention for Frail Elderly People) and Dr. Henna Hasson (Karolinska Institutet, topic: Measuring Fidelity in Complex Interventions). After the lunch, the workshop by Dr. Richard Emsley (University of Manchester) focused on Mediation, Moderation and Process Evaluations in Clinical Trials. Last workshop on Thursday was on Combining Methods for Process Evaluations in Clinical Trials by prof. David Richards (University of Exeter) followed by discussion and feedback. In the evening all participants met for an informal dinner.

The topic for Friday was Measuring and Analysing Economic Data in Clinical Trials (Economic Evaluations). The Friday morning started with the lecture by prof. Unto Häkkinen (National Institute for Health and Welfare, Finland) on International Health Care Performance Comparison Using a Microeconomic Disease-based Strategy. The programme continued with two lectures addressing Economic Evaluation of Complex Interventions by prof. Sarah Byford (King's College London) and prof. Walter Sermeus (Katholieke Universiteit Leuven). The presentation by prof. Sarah Byford was presented via videoconference call and the participants could follow the slides on a printout provided by the organisers. After the lunch, prof. Katherine Payne (University of Manchester) addressed Challenges of Economic Evaluations in Complex Interventions in her workshop, followed by the lectures of prof. Julie Taylor (University of Edinburgh), prof. Ruth Harris (Kingston University) and Dr. Carlos Chiatti (Italian National Research Center on Aging). After discussion and feedback participants met for a guided city tour.

The last day focused on CReDECI Complex Interventions Reporting Criteria Consensus Meeting. After the introduction by Dr. Ralph Möhler (Witten/Herdecke University, Germany), prof. Sascha Köpke (University of Lübeck, Germany) and prof. Gabriele Meyer (Martin-Luther-University Halle-Wittenberg, Germany), the participants were asked to form three groups that worked on Development of a Draft Revised Criteria List. After the lunch, the programme continued with Formal Consensus Roundabout. The masterclass ended with summary by Dr. Tomáš Sollár and prof. David Richards.

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

3) Assessment of the results and impact of the event on the future directions of the field (up to two pages)

The procedure for participants' evaluation suggested at the 2012 Masterclass was used. 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. Participants were asked to evaluate the quality of presentations and workshops and were asked to suggest topics that should have been raised or should be included in future masterclasses. Finally, they rated the masterclass' level of difficulty and if they had gained important competencies. The results of the evaluation are outlined below.

Personal expectations

65.9% of the participants felt that all their expectations were met by the masterclass, 31.7% of participants stated that more than half of their expectations were met and 2.4% of participants stated that about half of their expectations were met.

Lectures

79% of the participants rated the general quality of lectures as good or very good. On a 5-point Likert scale (1 being very low quality and 5 being very good), 4 of the 7 lectures received mean ratings better than four. These were the lectures by Carl May on Normalisation Process Theory (4.6 ± 0.5), Henna Hasson on Measuring Fidelity in Complex Interventions (4.1 ± 0.8), Walter Sermeus on Economic Evaluation of Complex Interventions (4.4 ± 0.6) and group of lectures by Julie Taylor, Ruth Harris and Carlos Chiatti (4.3 ± 0.7). Individual comments indicated possible further topics for lectures – mixed methods.

Workshops

The rating of the workshops was similar to the lectures with 88% rating the quality of the workshops as good or very good. All the 6 workshops received marks over 4, in range from 4.3 (± 0.8) for Richard Emsley on Mediation, Moderation and Process Evaluations in Clinical Trials to 4.6 (± 0.8) for Katherine Payne on Challenges of Economic Evaluations in Complex Interventions. Participants suggested following topics for future masterclass workshops: challenges, pros and cons of using the MRC to guide complex interventions, more in-depth look at the topics already covered, e.g. patient-reported outcomes, statistical methods in RCTs / complex interventions, clinical significant differences, using the EQ-5D, etc.

General evaluation

The difficulty of the sessions in general was rated as adequate (6.9 ± 1.9 SD on a 10 cm visual analogue scale with 0=easy and 10=hard). 80% of participants strongly or mostly felt that they have gained "important competencies" by attending the masterclass. When asked about suggestions for future masterclasses, the participants called for more time for plenary and group discussions and exchange of ideas and experience, and suggested more careful planning of videoconference presentations to avoid technical complications that occurred during one of the lectures. Suggested topics included using new technology (IT, web-based) methods for collecting data, complex interventions in Horizon 2020, experience developing European collaborative studies, etc., translational research in nursing, mixed methods research, measuring nursing outcomes, including instruments/tools.

In summary, the content and the organisation of the masterclass were well perceived by the participants.

4) Annexes 4a) and 4b): Programme of the meeting and full list of speakers and participants

Annex 4a: Programme of the meeting

Thursday (October 3rd)

Topic: **Process Analysis as a Part of Clinical Trials (Process Evaluations)**

Type	Time	Topic	Person/s
L all	9.00-9.30	Arrival at the Venue	
L all	9.30-10.00	Opening & Welcome	Dean (Faculty of Social Sciences and Health Care, Slovakia) Tomas Sollar (Constantine the Philosopher University in Nitra, Slovakia) David Richards (University of Exeter, UK)
L all	10.00-11.00	Normalisation Process Theory	Carl May (University of Southampton, UK)
	11.00-11.10	Coffee & Tea	
L all	11.10-11.50	Process Evaluation of an Intervention for Frail Elderly People	Nienke Bleijenberg (University of Utrecht, Netherlands)
	11.50-12.30	Measuring Fidelity in Complex Interventions	Henna Hasson (Karolinska Institutet, Sweden)
	12.30-13.30	Lunch	
W all	13.30-15.30	Mediation, Moderation and Process Evaluations in Clinical Trials	Richard Emsley (University of Manchester, UK)
	15.30-15.45	Coffee & Tea	
W all	15.45-16.15	Combining Methods for Process Evaluations in Clinical Trials: What are we Looking for?	David Richards (University of Exeter, UK)
L all	16.15-17.00	Discussion and Feedback	
Social	19.00	Conference Dinner	

L: Plenary lecture/session; W: Workshop

Friday (October 4th)

Topic: **Measuring and Analysing Economic Data in Clinical Trials (Economic Evaluations)**

Type	Time	Topic	Person/s
L all	9.00-10.30	International Health Care Performance Comparison Using a Microeconomic Disease-based Strategy	Unto Häkkinen (National Institute for Health and Welfare, Finland)
	10.30-11.00	Coffee & Tea	
L all	11.00-11.45	Challenges of Economic Evaluations in Complex Interventions I – VIDEO conference	Sarah Byford (King's College London, UK)
L all	11.45-12.15	Economic Evaluation of Complex Interventions: Our Experience	Walter Sermeus (Katholieke Universiteit Leuven, Belgium)
	12.15-13.15	Lunch	
W all	13.15-15.15	Challenges of Economic Evaluations in Complex Interventions II	Katherine Payne (University of Manchester, UK)
	15.15-15.45	Coffee & Tea	
L all	15.45-16.45	Further Experiences Evaluating the Economics of Complex Interventions	Julie Taylor (University of Edinburgh, UK) Ruth Harris (Kingston University, UK) Carlos Chiatti (Italian National Research Center on Aging, Italy)
L all	16.45-17.00	Discussion and Feedback	All
Social	18.00-19.30	Guided City Tour	

L: Plenary lecture/session; W: Workshop

Saturday (October 5th)

Topic: **CRedeCI Consensus Workshop**

Type	Time	Topic	Person/s
W all	9.00-10.00	CRedeCI Consensus Meeting Part 1 – Introduction	Ralph Möhler (Witten/Herdecke University, Germany) Sascha Köpke (University of Lübeck, Germany) Gabriele Meyer (Martin-Luther-University Halle-Wittenberg, Germany)
	10.00-10.15	Coffee & Tea	
SG 2 groups	10.15-12.15	CRedeCI Consensus Meeting Part 2 – Development of a Draft Revised Criteria List	Ralph Möhler (Witten/Herdecke University, Germany) Sascha Köpke (University of Lübeck, Germany) Gabriele Meyer (Martin-Luther-University Halle-Wittenberg, Germany)
	12.15-13.15	Lunch	
W all	13.15-14.15	CRedeCI Consensus Meeting Part 3 – Formal Consensus Roundabout	Ralph Möhler (Witten/Herdecke University, Germany) Sascha Köpke (University of Lübeck, Germany) Gabriele Meyer (Martin-Luther-University Halle-Wittenberg, Germany)
	14.15-14.30	Coffee & Tea	
L all	14.30-15.30	Summary Farewell	Local team David Richards (University of Exeter, UK)

L: Plenary lecture/session, W: Workshop, SG: Small groups

Annex 4b: Full list of speakers and participants

Participants

Alexandra	Archalousová	Silesian University in Opava, Faculty of Public Policies, The Institute of Nursing
Katrin	Balzer	Institute for Social Medicine and Epidemiology, University of Lübeck, Germany
Sivera Caroline	Berben Bradbury Jones	Radboud University Nijmegen Medical Centre University of Manchester
Gunilla Anna	Carlsson Castaldo	Department of Health Sciences, Lund University Provincia Religiosa S. Marziano di don Orione – Piccolo Cottolengo Milan Italy
Sophie Martin Margita Lisa Andrea	Cès Dichter Drienovská Ekstam Giordano	Université catholique de Louvain German Center for Neurodegenerative Diseases Institute of clinical psychology, Faculty Hospital Nitra Lund University, Department of Health Sciences Foundation IRCCS Neurological Institute C. Besta Milan Italy
Tove Aminda	Hanssen	University Hospital North Norway, University of Tromsøe, Norway
Maria Adriana Oliver Rudolf	Henriques Herber	Nursing School of Lisbon University of Dundee (UK) and Heinrich-Heine-University Dusseldorf (Germany)
Daniela Breeda Natalja Marlène Susanne	Holle Howley Istomina Karam Kean	German Center for Neurodegenerative Diseases University College Dublin Klaipeda University Université catholique de Louvain The University of Edinburgh, School of Health in Social Science
Erika	Křištofová	Department of Nursing, Faculty of Social Sciences and Health Care, Constantine The Philosopher University in Nitra
Helena Miroslava	Leino-Kilpi Líšková	University of Turku, Department of Nursing Science Department of Nursing, Faculty of Social Sciences and Health Care, Constantine The Philosopher University in Nitra
Dagmar	Mastiliaková	Silesian University in Opava, Faculty of Public Policies, The Institute of Nursing
Tone Elin	Mekki	Centre for Care Research West Norway, University College of Bergen
Riitta	Meretoja	University of Turku: Hospital District of Helsinki and Uusimaa
Jozefína	Mesárošová	Department of Nursing, Faculty of Social Sciences and

		Health Care, Constantine The Philosopher University in Nitra
Alvisa	Palese	Udine university/Hull university
Ľuboslava	Pavelová	Department of Nursing, Faculty of Social Sciences and Health Care, Constantine The Philosopher University in Nitra
Mona Kyndi	Pedersen	Clinic for Internal Medicine, Aalborg University Hospital
Ľubor	Pilárik	Department of Psychological Sciences, Faculty of Social Sciences and Health Care, Constantine The Philosopher University in Nitra
Ľubica	Poledníková	Department of Nursing, Faculty of Social Sciences and Health Care, Constantine The Philosopher University in Nitra
Martina	Romanová	Institute of Applied Psychology, Faculty of Social Sciences and Health Care, Constantine the Philosopher University in Nitra
Mária	Semanišinová	Department of Nursing, Faculty of Social Sciences and Health Care, Constantine The Philosopher University in Nitra
Alica	Slamková	Department of Nursing, Faculty of Social Sciences and Health Care, Constantine The Philosopher University in Nitra
Margaret	Smith	Division of Nursing, Occupational Therapy and Arts Therapies
		School of Health Sciences, Queen Margaret University
Andrea	Solgajová	Department of Nursing, Faculty of Social Sciences and Health Care, Constantine The Philosopher University in Nitra
Riitta	Suhonen	University of Turku, Department of Nursing Science
Jana	Turzáková	Institute of Applied Psychology, Faculty of Social Sciences and Health Care, Constantine the Philosopher University in Nitra
Tomáš	Sollár	Institute of Applied Psychology, Faculty of Social Sciences and Health Care, Constantine the Philosopher University in Nitra
Thérèse	Van Durme	Université catholique de Louvain
Gabriela	Vörösová	Department of Nursing, Faculty of Social Sciences and Health Care, Constantine The Philosopher University in Nitra
Dana	Zrubcová	Department of Nursing, Faculty of Social Sciences and Health Care, Constantine The Philosopher University in Nitra

Speakers

Nienke	Bleijenberg	University Medical Center Utrecht department Julius Center for Health Sciences and Primary Care, Netherlands
Sarah	Byford	King's College London, UK
Carlos	Chiatti	I.N.R.C.A. Direzione Scientifica, Italy
Richard	Emsley	University of Manchester, UK
Unto	Häkkinen	National Institute for Health and Welfare, Finland
Ruth	Harris	Faculty of Health, Social Care and Education, Kingston University, UK
Henna	Hasson	Karolinska Institutet, Sweden
Sascha	Köpke	University of Lübeck, Germany
Carl	May	University of Southampton, UK
Gabriele	Meyer	Martin-Luther-University Halle-Wittenberg, Germany
Ralph	Möhler	Witten/Herdecke University, Germany
Katherine	Payne	University of Manchester, UK
David	Richards	University of Exeter, UK
Walter	Sermeus	Katholieke Universiteit Leuven, Belgium
Julie	Taylor	University of Edinburgh, UK