

Federal Ministry of Education and Research. Interdisciplinary Workshop. Berlin 11-12- September 2017
«Networking and methods in research on palliative care»

Focus on Health Services Research. Quantitative methods

Massimo Costantini
Scientific Director

Arcispedale Santa Maria Nuova - IRCCS, Reggio Emilia

About this presentation:

- Health Services Research. A definition
- Methodology for HSR
 - ✓ some reflections on study designs
- Two examples of Health Services Research
 - ✓ Needs assessment in palliative care
 - The ISDOC study
 - ✓ Assessment of the effectiveness of an intervention
 - the MRC framework and the LCP trial

About the speaker:

In relation to this presentation, I declare that there are no conflicts of interest.

Health Services Research: An Evolving Definition of the Field

... is the **multidisciplinary field of scientific investigation** that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours **affect** access to health care, the quality and cost of health care, and ultimately our health and well-being.

Its research domains are individuals, families, organizations, institutions, communities, and populations

Definition adopted on June 2000 by the Board of Directors of the Association for Health Services Research (AHSR), now the Academy for Health Services Research and Health Policy

Lohr KN & Steinwaxhs DM.

Health Serv Res. 2002 Feb; 37(1): 15–17.

Health Services Research: relationships between

some independent variables ...

- social factors
- financing systems
- organizational structures
- organizational processes
- health technologies
- personal behaviours



- **... and some dependent variables (in PC)**
- access to palliative care
- the quality of palliative care
- the cost of palliative care
- quality of life, satisfaction with care

- **Health Services Research** uses quantitative and qualitative methods, alone or combined together (mixed methods studies)
- **Quantitative research** uses the epidemiological approach to define and shape all the aspects of a study, including its design.

... **the question being asked** determines the appropriate research architecture, strategy, and tactics to be used – not tradition, authority, experts, paradigms, or schools of thought.

Sackett DL, Wenneberg JE 1997

The general aims of quantitative Health Service Research in palliative medicine

- **To describe needs and problems** of people at the end of their lives and their families (frequency, risk factors, trends).
- **To explain the causal relationships** between some dependent variables and one or more independent variables (see definition)
- **To assess the effectiveness of interventions** (a new service, a new organisation of care, a quality improvement programme, a training programme, etc.)

Any attempt to rank study designs according to their inherent value makes little sense, since it is the main objective that defines the most appropriate design for a specific study

Study design	Methodology	General aim
Cross-sectional	Observational	Descriptive–analytic
Retrospective cohort study	Observational	Analytic–descriptive
Prospective cohort study	Observational	Analytic–descriptive
Case–control	Observational	Analytic
Quasi-experimental	Experimental without randomization	Analytic
Experimental	Experimental with randomization	Analytic

An example of Health Services Research

Assessing the palliative care needs

The Italian Survey of the Dying Of Cancer-ISDOC

(estimating needs and problems of cancer patients during their last 3 months of life and of their family members)

The Italian Survey of the Dying Of Cancer-ISDOC

Study design: mortality follow-back survey

Target population: last three months of life of deceased for cancer in Italy aged ≥ 18 yrs. (about 160.000 per year)

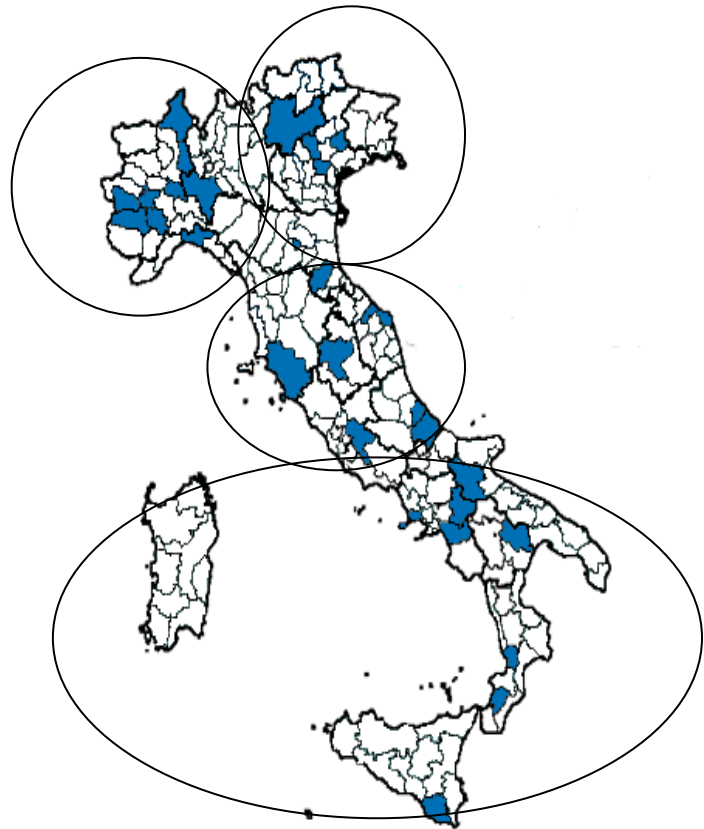
Study sample: 2.000 cancer deaths representative of the target population

Sampling procedures

- 30 Local Health Districts (from 197) stratified by 4 geographical areas
- We sampled 2,000 death certificates of deceased for cancer (ICD-IX 140-239): a fixed proportion (8.4%) of cancer deaths in each LHD

Methodology of assessment:

- For each deceased patient: identification of the non-professional caregiver
- interview with the non-professional caregiver 4 – 12 months after patient's death about the last 3 months before death



The Italian Survey of the Dying Of Cancer-ISDOC

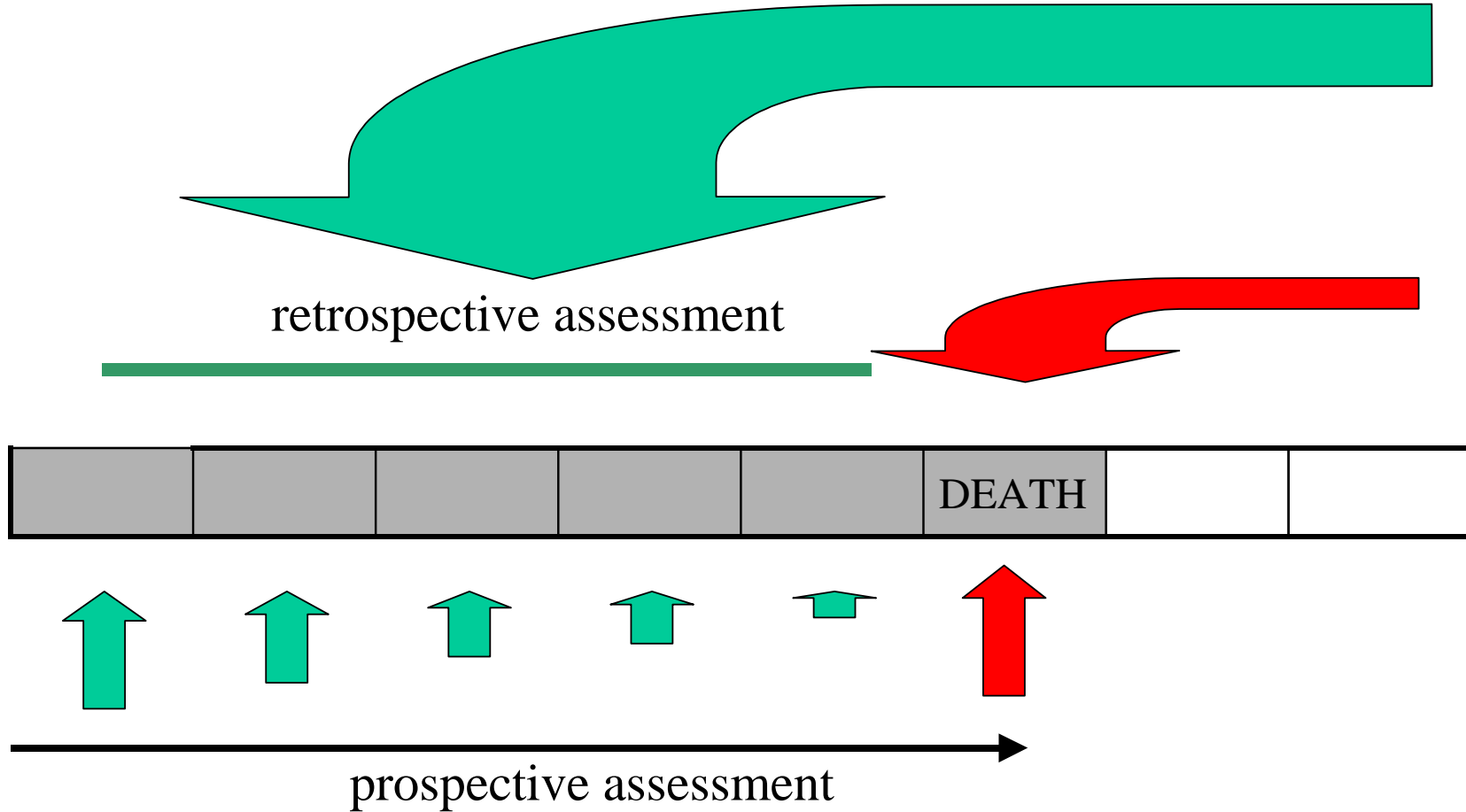
- **Tool for assessment:** semi-structured interview (adapted from VOICES) about:
 - multidimensional problems of the patient
 - non-professional resources and support
 - use, need and satisfaction with received care
 - health and social services
 - information from and communication with
 - evaluation of health professionals

The Italian Survey of the Dying Of Cancer-ISDOC

- All the 30 **LHDs** participated
- We could sample the planned 2.000 **death certificates**
- **Identification of the caregiver** was successful for 1.900 (95.0%)
- **An interview** with caregivers for 1.289 (64.5%) of the sample
 - Reasons of not-interview: refusals (19.2%), caregivers not located (8.1%), too ill or deceased (2.3%), staff error (1.1%)
 - days from the patient's death: median 234 (103 – 374)
 - discomfort caused by the interview: 9.3% much and 5.2% very much
- **Determinants of response rate:**
 - **higher response rate** for patients with a high education level or deceased at home
 - **lower response rate** when the caregiver is the spouse

Assessing the last period of life

Retrospective vs. prospective studies



The Italian Survey of the Dying Of Cancer-ISDOC

- Results published in 13 articles and in 1 book
- It allowed to get information about
 - Information received by Italian cancer patient (diagnosis and prognosis)
 - Actual and preferred place of death
 - Impact of EoL care on family and caregiver
 - Inequity in the provision of and access to PC
 - The experience of caregivers in EoL care
 - The cancer Trajectories at the End of Life
 - Psychological distress experienced by patients
 - The provision of unconventional cancer treatments
 - Prevalence, distress, management, and relief of pain
 - End-of-life care in Italian hospitals

Question # 1.1: if you want to study the quality of EoL care received by a specific group of patients in one or more settings of care, do you choose a retrospective or a prospective design?

- 1) I always choose a prospective design. It allows me to get valid information directly with the patient and not from a proxy such as the non-professional caregiver. The representativeness is not important in these kind of studies.
- 2) I always choose a retrospective design. It allows me to get results that are representative of the target population. The validity is not important in these kind of studies.
- 3) It depends by the aim of the study. There are pros and cons in both choices. Both are biased but both have elements of validity (correct)

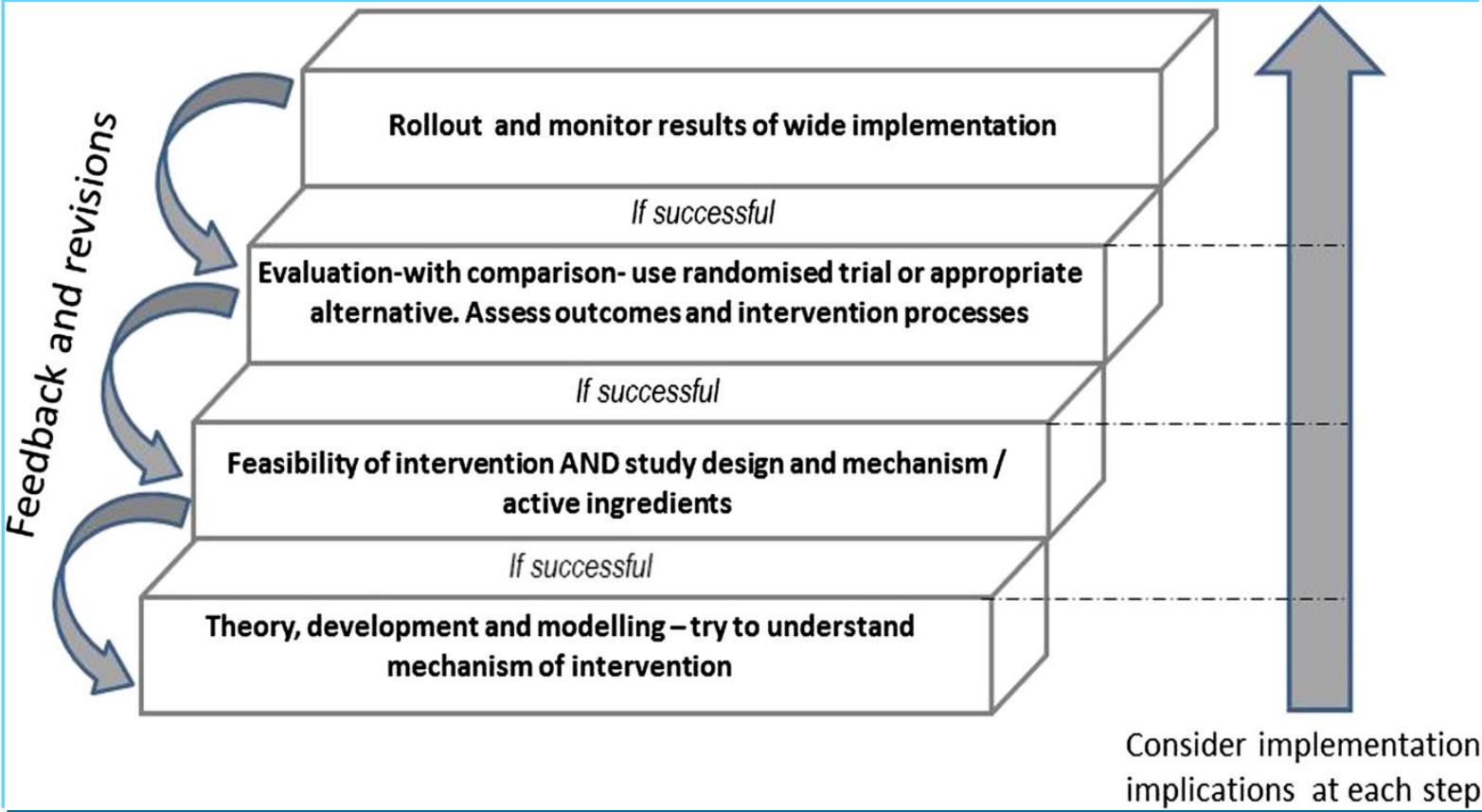
An example of Health Services Research

Assessing the effectiveness of interventions

The LCP-I cluster trial

(assessing the effectiveness of the LCP-I in improving the quality of end-of-life care for cancer patients in hospitals and for their family)

Key steps in developing and evaluating PC interventions (from the MORECare Statement on good practice)



the assessment of the effectiveness is just an advanced step in the process of assessment of a complex intervention

The rationale for assessing the Liverpool Care Pathway in cancer patients

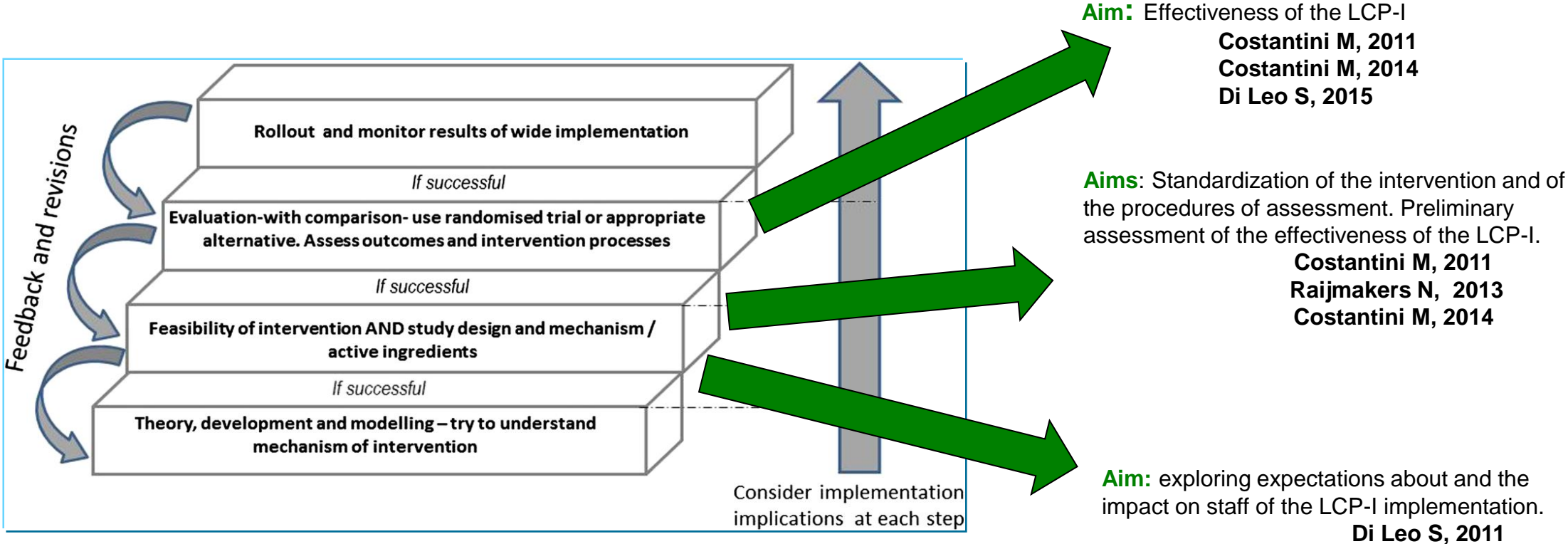
- ✓ A **high proportion** of cancer patients dying in hospital
- ✓ Global evidence about **poor quality** of end-of-life care
- ✓ An **increasing “demand”** of good care at the end of life
- ✓ Evidence show that it is **possible** in the hospices
- ✓ The **right** to receive good palliative care
- ✓ LCP as the more structured end-of-life care **pathway**
- ✓ **Aimed at** transferring the hospice model into hospitals
- ✓ A 2011 **Cochrane systematic review** did not find evidence about its effectiveness



The Liverpool Care Pathway for the dying patients (LCP)

- ❑ **developed by** Royal Liverpool University Hospital and Liverpool's Marie Curie Hospice in the late 1990s **to help doctors and nurses provide quality end-of-life care**
- ❑ **a care pathway organized** into sections ensuring that evaluation and care is continuous and consistent.
- ❑ **activated when** the multi-professional team caring for the patient agrees that all reversible causes for the patient's conditions have been considered and that the patient is in fact "dying"
- ❑ **not intended to replace** the skill and expertise of health professionals
- ❑ **targeted** at all settings of care (primarily hospitals)

Applying the MORECare framework to the LCP assessment



The LCP cluster trial



Liverpool Care Pathway for patients with cancer in hospital: a cluster randomised trial

Massimo Costantini, Vittoria Romoli, Silvia Di Leo, Monica Beccaro, Laura Bono, Paola Pilastrì, Guido Miccinesi, Danila Valenti, Carlo Peruselli, Francesco Bulli, Catia Franceschini, Sergio Grubich, Cinzia Brunelli, Cinzia Martini, Fabio Pellegrini, Irene J Higginson, and the Liverpool Care Pathway Italian Cluster Trial Study Group

Summary

Background The quality of care provided to patients with cancer who are dying in hospital and their families is suboptimum. The UK Liverpool Care Pathway (LCP) for patients who are dying was developed with the aim of transferring the best practice of hospices to hospitals. We therefore assessed the effectiveness of LCP in the Italian context (LCP-I) in improving the quality of end-of-life care for patients with cancer in hospitals and for their family.

Methods In this pragmatic cluster randomised trial, 16 Italian general medicine hospital wards were randomly assigned to implement the LCP-I programme or standard health-care practice. For each ward we identified all

Lancet 2014; 383: 226-37

Published Online

October 16, 2013

[http://dx.doi.org/10.1016/S0140-6736\(13\)61725-0](http://dx.doi.org/10.1016/S0140-6736(13)61725-0)

See Comment page 192

Palliative Care Unit, Istituto di

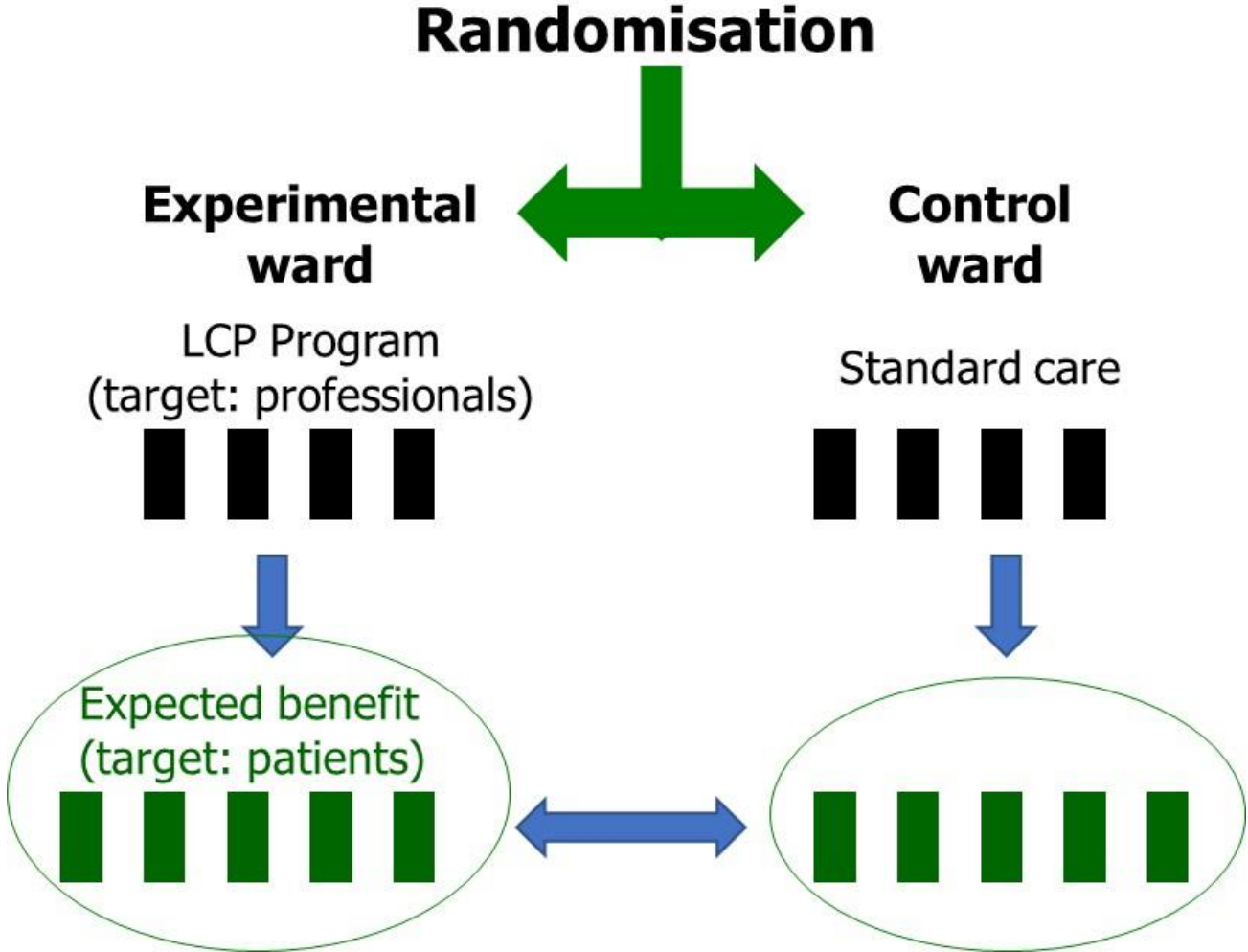
Primary aim: to evaluate the effectiveness of the LCP-I Program in improving the quality of end-of-life care provided to cancer patients who die on hospital medical wards as compared to standard healthcare practices

Study design: randomised cluster trial

Population: 308 cancer patients deceased from 16 hospitals

Intervention: Italian version of the LCP programme (LCP-I)

The LCP cluster trial



... The objective of the LCP-I programme was to improve the quality of care for patients dying with cancer, but the targets of the intervention were the ward professionals. The effect of the LCP-I programme was measured on clusters of patients and their families in hospital wards...

Costantini M, et al. Lancet 2014

Procedures of assessment

(for all eligible patients who died from cancer)

- ❖ **Interview with family members** on the last week in ward
 - ✓ the Toolkit after-death bereaved family member interview (*Teno J 2001*)
 - ✓ 33 questions → seven 0-100 scales (0 the worst care)

 - ✓ the VOICES (Addington-Hall 1995; Costantini 2005)
 - ✓ three symptoms (pain, breathlessness, vomiting)
- ❖ From clinical documentation information about **drugs and procedures** of the last two days of life (Raijmakers N 2012)
- ❖ Telephonic **interviews with GPs** about communication with the ward

The study was underpowered

	the planned trial	the trial
Recruitment	20 wards	16 wards
Pts per cluster	15-20	14-15
ICC	0.01 – 0.05	0.12

Unbalanced compliance

	LCP-I (No.=147)	CTR (No.=161)
Compliance at the interviews		
Family members interviewed	81%	70%
Refused	16%	25%
Type of interview		
face to face (%)	78%	69%
telephone (%)	22%	31%

High variability in LCP-I implementation

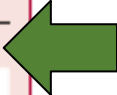
- ❖ One ward received only partially the LCP-I intervention
- ❖ High variability in participation to the training programme
- ❖ High variability in the use of the LCP-I clinical documentation during the experimental implementation (14% - 75% of cancer deaths on LCP-I)
- ❖ After the implementation 3 hospitals stopped using the LCP-I
- ❖ High variability in the use of the LCP-I clinical documentation at the end of the experimental implementation (4% - 58% of cancer death on LCP-I)

The LCP cluster trial

	LCP-I wards (n=119)		Control wards (n=113)		Difference (preintervention adjusted)				Difference (not preintervention adjusted)			
	Number*	Mean score	Number*	Mean score	Mean (95% CI)	pvalue	ICC	Effect size	Mean (95% CI)	pvalue	ICC	Effect size
Overall quality of care	118	70.5	111	63.0	7.6 (-3.6 to 18.7)	0.186	0.12	0.33	8.0 (-1.8 to 17.8)	0.110	0.10	0.34
Informing and making decisions	117	73.5	110	64.3	9.2 (-0.9 to 19.3)	0.076	<0.01	0.31	6.6 (-1.3 to 14.6)	0.102	<0.01	0.22
Advance care planning	22	NE	24	NE	NE	NE	NE	NE	10.1 (-14.4 to 34.7)	0.424	<0.01	0.24
Respect, dignity, and kindness	115	78.8	109	70.4	8.4 (0.3 to 16.6)	0.043	<0.01	0.28	8.5 (0.3 to 16.6)	0.042	<0.01	0.28
Family emotional support	117	46.6	109	38.6	8.1 (-4.3 to 20.4)	0.203	0.09	0.29	7.3 (-3.7 to 18.4)	0.195	0.08	0.26
Coordination of care	115	81.4	110	76.8	4.5 (-3.9 to 13.0)	0.296	0.04	0.19	4.8 (-2.9 to 12.5)	0.221	0.03	0.20
Family self-efficacy	116	48.9	110	44.4	4.5 (-5.1 to 14.2)	0.360	0.01	0.16	0.7 (-7.5 to 9.0)	0.863	0.01	0.02

Higher mean scores indicate better quality of care for the variables. All estimates (means [95% CI] and effect sizes) are cluster adjusted. LCP-I=Italian version of Liverpool Care Pathway. ICC=intraclass correlation coefficient. NE= not estimable. *Samples for which the means were estimated.

Primary endpoint



- No significant difference in primary end-point: **Overall quality of care P-value = 0.186**
- All the 10 outcomes show a positive effect. The Effect Size from 0.16 to 0.33; ORs from 1.3 to 2.0
- Significant differences for two secondary endpoints: Respect, dignity and kindness (P-value=0.043) and breathlessness (P-value = 0.026)

The LCP cluster trial

- ❑ better control of **breathlessness**
OR=2.0; p=0.026
- ❑ no differences for **pain**
OR=1.3; p=0.461
- ❑ no differences for **nausea-vomiting**
OR=1.5; p=0.252

Question # 2.1: According to these results (see primary and secondary endpoints), do you think the LCP-I is an effective intervention ?

- 1) According to the results, (primarily the primary endpoint) I cannot recommend the LCP-I programme that should be considered non effective in improving the quality of care for patients dying with cancer.
- 2) Yes, because all the outcomes show an improvement in experimental arm as compared to the standard arm. The difference in the primary endpoint was not significant, but a consistent improvement was observed. Moreover a significant improvement was observed for two secondary outcomes.

Question # 2.2: A Mixed method approach (integrating qualitative and quantitative) is possible and appropriate also in the phase 3, aimed at assessing the effectiveness of a complex intervention (for example the effectiveness of the LCP-I)?

- 1) Yes it is possible and also recommended. For the LCP-I trial see Di Leo S, et al. 'Less ticking the boxes, more providing support': A qualitative study on health professionals' concerns towards the Liverpool Care of the Dying Pathway. *Palliat Med* 2015;29(6):529-537.
- 2) In theory yes, but in practical it is very difficult designing and performing a qualitative analysis in a phase that, for its nature, is merely quantitative.

Some thoughts at the end of my presentation

- It is possible (and it exists) good Health Service Research in PC
 - we need more (good) research in palliative care. Policy makers should ask for and fund more HSR in PC
 - we need more evidence-based decisions in health care. We should demand from policy makers that results from HSR are taken into consideration in the decision-making process
- HSR should provide policy makers with more evidence-based estimates of the PC needs of cancer and non-cancer patients and their families
- We also need HSR for expanding the evidence available on the effectiveness of services and, more in general on care solutions
- Programs aimed at improving the quality of care and educational interventions often are implemented on the basis of expert beliefs, paradigms, or schools of thought. We need more HSR on that.



HENRY ALLESPI

Care should be focused on maintaining the patient's dignity and supplying effective palliation

Thanks !