Systematic implementation of an advance directive program in nursing homes: a randomized controlled trial

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of the Let Me Decide advance directive (LMD) programme was examined. The LMD programme provides a range of health care choices for life-threatening illness, cardiac arrest and feeding for individuals in nursing homes. According to the programme, individuals (or their proxies) could choose different levels of care if they were in a reversible condition with an acceptable quality of life, or in an irreversible condition with an unacceptable quality of life. The level of care could be chosen for life-threatening illness (intensive to palliative), nutrition (intubation to basic), and cardiopulmonary resuscitation (CPR). Registered nurses attended a workshop to train as health care facilitators, so that they could educate hospital staff, nursing home staff, residents and families about the directives and measuring a person's capacity to complete the directives.

Type of intervention
Patient care management.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised individuals living in nursing homes.

Setting
The setting was a nursing home. The economic study was carried out in Ontario, Canada.

Dates to which data relate
No dates for the effectiveness and resource use data were reported. The costs were estimated from 1997 data.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out both retrospectively on a sample of patients different from that used in the effectiveness study, and prospectively on the same patients included in the effectiveness analysis.

Study sample
Power calculations to determine the sample size were not performed. Of the 215 nursing homes in Ontario initially surveyed, 171 responded, 150 were interested in the study, and 78 had health care choices documented for less than
25% of the residents. Finally, three pairs of nursing homes were chosen. These were matched according to the proportion of residents hospitalised annually, case-mix indices and the proportion of deaths occurring in a hospital. Head nurses classified the residents as competent or incompetent (using the Standardised Mini-Mental State Examination) and proxies were contacted for those classified as incompetent.

There were 636 residents in the three nursing homes allocated to the intervention group and 656 residents in the three nursing homes allocated to the control group. In the intervention group, there were 228 competent residents (36%) and 408 incompetent residents (64%). In the control group, there were 267 competent residents (41%) and 389 incompetent residents (59%). Of the 636 intervention residents, 527 agreed to participate. Seventy residents refused, 28 died or left, 2 were incompetent and had no proxy, 6 were undecided, and 3 proxies were not contacted. Of the 656 control residents, 606 agreed to participate. Twenty-five residents refused, 18 died or left, 4 were incompetent and had no proxy, and 3 were undecided.

**Study design**
This was a prospective, pair-matched randomised trial, which was carried out in six nursing homes that represented the unit of randomisation. The method used for randomisation was not described. The patients were followed for 18 months after enrolment. Complete directives were reviewed and signed by the attending physicians. After one year, the health care facilitators contacted competent residents and proxies of incompetent residents to update the directives. Satisfaction questionnaires were completed at baseline, 6, 12 and 18 months after the beginning of the study. Seventy per cent of the intervention residents (444 out of 636) and 57% of the control residents (374 out of 656) completed the advance directives.

**Analysis of effectiveness**
It appears that the analysis has been limited to patients who completed the final assessment (treatment completers only). The primary outcomes used were:

- the choice of the advance directives (LMD, Do Not Resuscitate, or other such as living wills, directives, power of attorney and no hospital),
- satisfaction with health care,
- deaths, and
- hospitalisations.

The questionnaire used to estimate satisfaction was not described and relied on a prior study. The satisfaction score ranged from 0 (lowest) to 7 (highest). Consenting and no-consenting patients were comparable. Differences in the consent rate between the intervention and control homes were not statistically significant. However, there was a higher percentage of male residents in the intervention than in the control nursing homes (odds ratio 0.51, 95% confidence interval, CI: 0.35 - 0.76). A weighted analysis of covariance was performed to determine whether there was a statistically significant difference in satisfaction between the groups.

**Effectiveness results**
In terms of the choice of the advance directive, 395 of the intervention group residents chose LMD, 27 chose Do Not Resuscitate, and 22 chose other directives. In the control group, 266 residents chose Do Not Resuscitate and 108 chose other directives.

More specifically, for irreversible conditions, 70% of competent residents chose palliative care, 47% basic feeding and 91% no CPR. For reversible conditions, 41% chose intensive care, 35% intravenous feeding and 67% no CPR. For irreversible conditions, 66% of proxies for incompetent residents chose palliative care, 56% supplemental feeding and 97% no CPR. For reversible conditions, 51% chose limited care, 48% supplemental feeding and 84% no CPR.

The mean satisfaction score for competent residents changed from 4.77 (standard deviation, SD=1.10) at baseline to
5.07 (SD=1.17) at the end of follow-up in the intervention group, and from 5.09 (SD=0.98) to 5.10 (SD=1.11) in the
control group.

The post-intervention adjusted difference of -0.16 (95% CI: -0.41 - 0.10) was not statistically significant, (p=0.24).

The mean satisfaction score (SD) for incompetent residents changed from 5.49 (1.04) at baseline to 5.71 (1.03) at the
end of follow-up in the intervention group and from 5.44 (1.11) to 5.61 (1.15) in the control group.

The post-intervention adjusted difference of 0.07 (95%CI: -0.08 to 0.23) was not statistically significant, (p=0.37).

The proportion of deaths was 24% in the intervention group and 28% in the control group, (p=0.20).

The number of hospitalisations per patient was 0.27 in the intervention group versus 0.48 in the control group,
(p=0.001). The number of hospitalised days per patient was 2.61 in the intervention group versus 5.86 in the control
group, (p=0.01).

Clinical conclusions
The effectiveness analysis showed that the LMD programme was the most preferred alternative in the group of
residents who received it. It reduced the length and number of hospitalisations in comparison with patients who did not
receive this option, without increasing the death rate. There was no difference in the satisfaction of competent residents
and the proxies of incompetent residents.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation.
Therefore, the study was classified as a cost-consequences analysis.

Direct costs
Discounting was not relevant since the costs per patient were incurred during 18 months. The unit costs and the
quantities of resources used were not presented separately. The health services included in the economic analysis were
LMD programme, hospitalisations (tests, procedures, emergency department visits and inpatient days) and nursing
home drugs. The cost/resource boundary adopted in the study appears to have been that of the third-party payer.

Resource use was estimated using the sample of patients who were included in the effectiveness study for the 18-month
period, and the data were collected prospectively. A retrospective review of resource consumption in the 12 months
prior to the implementation of the LMD programme was also carried out. This was based on patients different from
those included in the prospective analysis of effectiveness. The costs were derived from the Ontario Case Costing
Project, the Ontario provincial fee schedule, the Ontario Ministry of Health price list and the Ontario Drug Benefit
formulary. A 10% pharmacy mark-up and a standard dispensing fee were added to each prescription. The price year
was not explicitly stated, but most of the costs were estimated in 1997.

Statistical analysis of costs
The costs were presented as mean and median values. The unpaired t-test was used to test the statistical significance of
differences between the costs estimated in the two groups.

Indirect Costs
The indirect costs were not considered.

Currency
Canadian dollars (Can$).
Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The LMD programme cost Can$113.

The mean hospitalisation costs per patient were Can$1,772 in the intervention group and Can$3,869 in the control group, (p=0.003).

The mean nursing home drug costs per patient were Can$1,606 (median: Can$1,069) in the intervention group and Can$1,370 (median: Can$901) in the control group, (p=0.149).

The total mean costs per patient were Can$3,490 (median: Can$1,499) in the intervention group and Can$5,239 (median: Can$1,812) in the control group, (p=0.013).

Synthesis of costs and benefits
The costs and benefits were not combined as a cost-consequences analysis was performed.

Authors' conclusions
Nursing home residents and the proxies for incompetent residents were willing to use advance directives when offered by trained nurses. The implementation of the advance directive programme was effective in reducing the hospital costs, as significantly more intervention patients expressed their willingness to remain in the nursing home rather than to receive care in an inpatient setting. This was achieved without affecting mortality or the residents' satisfaction.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was clear. Policies for advance directives existing in nursing homes were selected to reflect the standard approach used for residents. However, the content of these policies was not described. You should decide whether this represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used a randomised controlled trial, which was appropriate for the study question. The unit of randomisation was the nursing home and the sample selection method was described accurately. The study groups were matched on the basis of selected factors. However, despite the random allocation, the study groups were unbalanced since more men were included in the intervention group. Statistical tests and adjusted analyses were carried out to account for baseline differences. The length of and loss to follow-up were reported. The basis of the effectiveness analysis was treatment completers only.

The authors noted that the main limitation to the internal validity of the study was the lack of power calculations, which were needed to ensure that an appropriate sample size was recruited. In fact, the observed differences in the satisfaction scores failed to reach statistical significance and this may have been due to an underpowered design. The tool used to estimate satisfaction was not reported but the authors stated that it represented a validated instrument. The evidence came from several centres that were geographically distant from each other. This should enhance the transferability of the results to other samples of nursing home residents.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.

**Validity of estimate of costs**
The perspective adopted in the study was not explicitly stated, but appears to have been that of the third-party payer in Ontario. If this is the case, all the relevant categories of costs were included in the analysis. The source of the cost data was reported for each item, but few details of the cost analysis were provided. Specifically, the quantities of resources used and the unit costs were not reported and the price year was unclear. A breakdown of the costs was provided for gross categories only. This makes it difficult to replicate the economic analysis. The costs were treated stochastically and median values were presented. This reflected a typical skewed distribution of the costs. The estimates were specific to the study setting and sensitivity analyses were not performed, which limits the transferability of the results to other settings. Wide variations in costs may occur in other contexts.

**Other issues**
The authors stated that two earlier trials assessed the implementation of advance directives, but the conclusions of these studies were uncertain due to the limitations in the sample of individuals or the design of the analysis. Comparisons with the results of other studies were not carried out. The authors addressed the issue of the generalisability of the study results to other settings by stating that, regardless of the reimbursement system used (or not), every health care system has the incentives to reduce hospitalisations and the overall health care costs. Therefore, the savings observed in the current study (which were realised in every comparison carried out in the analysis) could be transferable to other settings and countries. The study referred to nursing home residents and this was reflected in the conclusions of the study. The authors discussed some strengths and limitations of their analysis.

**Implications of the study**
Nursing homes should educate nursing staff about advance directives, and equipment for the provision of symptom relief and palliative care should be installed. The authors highlighted the need for their study to be replicated in other settings in order to strengthen the case for a widespread programme of systematic implementation of certain types of advance directives in nursing homes.

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