ORIGINAL ARTICLE

Implementing an Advance Care Planning Program in German Nursing Homes

Results of an Inter-Regionally Controlled Intervention Trial

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SUMMARY

Background: Advance Care Planning (ACP) is a systematic approach to ensure that effective advance directives (ADs) are developed and respected. We studied the effects of implementing a regional ACP program in Germany.

Methods: In a prospective, inter-regionally controlled trial focusing on nursing homes (n/hs), we compared the number, relevance and validity of new ADs completed in the intervention region versus the control region. Intervention n/h residents and their families were offered professional facilitation including standardized documentation.

Results: Data from 136 residents of three intervention n/hs were compared with data from 439 residents of 10 control n/hs over a study period of 16.5 months. In the intervention region, 49 (36.0%) participating residents completed a new AD over the period of the study, compared to 18 (4.1%) in the control region; these ADs included 30 ADs by proxy in the intervention region versus 10 in the control region. Proxies were designated in 94.7% versus 50.0% of cases, the AD was signed by a physician in 93.9% versus 16.7%, and an emergency order was included in 98.0% versus 44.4%. Resuscitation status was addressed in 95.9% versus 38.9% of cases ($p<0.01$ for all of the differences mentioned above). In the intervention region, new ADs were preceded by an average of 2.5 facilitated conversations (range, 2–5) with a mean total duration of 100 minutes (range, 60–240 minutes).

Conclusion: The implementation of an ACP program in German nursing homes led, much more frequently than previously reported, to the creation of advance directives with potential relevance to medical decision-making. Future research should assess the effect of such programs on clinical and structural outcomes.

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An advance directive (AD) or "living will" is the written record of a person's wishes with regard to the limits of medical treatment in the hypothetical future event of the person's decisional incapacity in a medical crisis (1). More than four decades after its first description (2), the traditional approach to creating ADs has to be considered a failure conceptually and empirically (3). Advance directives are

- not widely used (4, 5)
- not available when needed (6)
- often not relevant (5)
- of dubious validity (5, 7), and
- frequently not honored by medical staff (4, 5).

There are many reasons to believe that the legal regulation of ADs in Germany in 2009 (8, 9) will prove no more effective than did the US Patient Self-Determination Act of 1991 (10).

Since the 1990s, however, a conceptual alternative to traditional ADs has emerged: advance care planning (ACP). Regional implementation of an ACP program requires a paradigm shift (11–13) *(eTable 1)*:

- ACP is regarded as a lifelong communication process with updates at regular intervals or when necessary
- Professional facilitation is actively offered to all members of a target group to help them develop and articulate their wishes regarding future treatment in the sense of an informed consent process—involving relatives whereever possible. Their wishes are documented on standardized regional forms, including a plan for emergency situations such as the POLST form (Physician Orders for Life-Sustaining Treatment) (14).
- The relevant regional health care institutions and professionals are involved and receive regular training and updates; they assume responsibility for ensuring that the completed, relevant and valid ADs are available when needed and honored reliably.

So far, no controlled prospective studies have been conducted to investigate the effects of a regional ACP program. Our study was designed to evaluate the feasibility of implementing an ACP program specifically developed for use in German nursing homes (n/hs) and associated health care structures of a given

town, and whether it leads to an increase in the number of clearly formulated, valid advance care plans.

Methods

The methodology is described in detail in the *eSupplement*; see also (15).

Study design

This prospective, inter-regionally controlled, non-randomized study compared an intervention region (four n/hs in one town of the German state of North Rhine–Westphalia) with a control region (five n/hs in each of two other towns in North Rhine–Westphalia) *(eTable 2)*.

The intervention took place at an institutional level. The primary object of analysis was the resulting ADs.

All residents of the participating n/hs were included. The recruitment phase ran from 1 February 2009 to 30 June 2009, the observation phase (data acquisition) from 15 February 2009 to 30 June 2010.

Intervention

Based on the US ACP program "Respecting Choices®" (11), we developed the ACP program "beizeiten begleiten®" (16), adapted to the specific circumstances in Germany. Implementation of the program involved:

- A 20-hour training course (9–13 February 2009) for the two to four non-physician facilitators from each participating n/h
- Four hours of training for the 20 primary care physicians who cooperated in the program
- Educative sessions (introductory presentations followed by discussions) for each of the following: nursing staff at the n/hs; nursing staff at the regional hospital; medical and paramedic emergency staff; professional guardians.

Furthermore, standardized forms had to be designed: personal ADs for residents capable of decision making; ADs by proxy for the legal proxies of those who were permanently unable to give consent; and a form for documentation of physician orders for life-sustaining treatment (i.e., an adaptation of the US POLST form: the "Hausärztliche Anordnung für den Notfall", HAnNo®: *eFigure*, cf. [17]).

The core of the intervention was the offer of professional ACP facilitation, communicated by flyers, posters and personal contact with the n/h residents. The certified "beizeiten begleiten" facilitators offered to the residents—involving relatives, whereever possible—conversations to support individual advance care planning, with the option to assist in the completion of a written AD after at least two sessions.

Moreover, the facilitation concept included involvement of the certified primary care physicians, who were asked to sign and thereby "validate" the resulting directives (in analogy to the informed consent standard).

End points and definitions

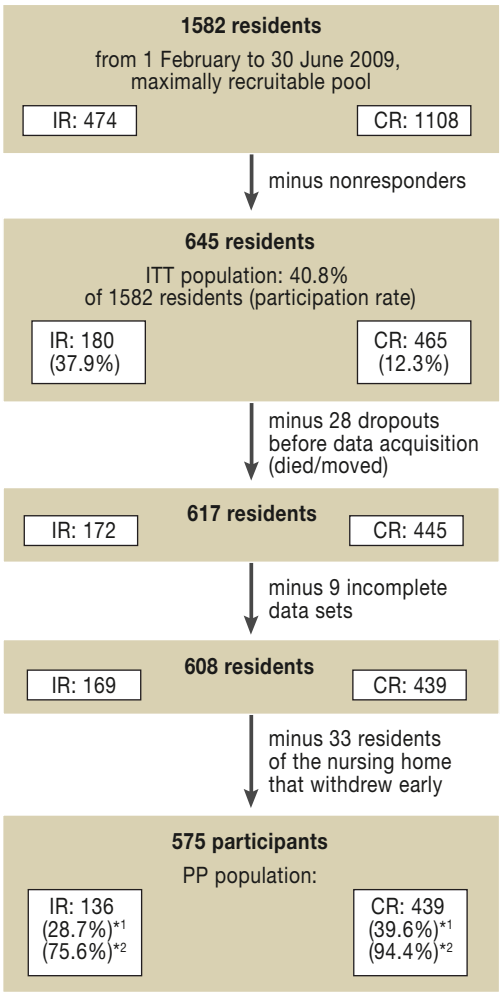
The primary end point was the number of new advance directives completed in the study cohort during the 16.5-month observation period, i.e., from the beginning of the intervention (t0 = the day before the intervention started, 15 February 2009) to the end of the intervention (t1 = 30 June 2010) (incidence). As a secondary end point we looked at the number of existing advance directives at the end of the observation period (t1), regardless of whether they had been written before or after t0 (prevalence).

We counted both the directives signed by the individual him- or herself and those signed by a legal proxy (18), defined as documents according to § 1901 of the German Civil Code, in which a person or (in the case of permanent incapability to give consent) his or her representative (5, 19) had laid down limits for future medical treatment in the hypothetical event of incapability to give consent in future health crises.

Further secondary end points were:

- The relevance of the AD, operationalized by the clarification of the resuscitation status, which is particularly relevant in n/hs

FIGURE



Flow diagram of patient recruitment.
*1 Proportion of pool of residents
*2 Proportion of ITT population
IR, intervention region; CR, control region; ITT, intention-to-treat; PP, per protocol

TABLE 1

Baseline characteristics

Characteristic	IR (n = 136)		CR (n = 439)		p	ICC (proportion of variance between homes [%])
	Proportion	Number/n	Proportion	Number/n		
Personal ADs before t0	14.7%	20/136	17.2%	75/437	0.968	14.7
ADs by proxy before t0	2.2%	3/136	5.3%	23/437	0.147	–
Any ADs before t0	16.2%	22/136	20.8%	91/437	0.234	12.1
Legally appointed guardian	72.8%	99/136	60.7%	263/433	0.205	8.7
– Guardian = child/children	44.8%	43/96	34.9%	89/255	0.226	6.8
– Guardian = professional carer	36.5%	35/96	49.7%	126/255	0.244	11.9
Durable power of attorney	25.8%	34/132	25.2%	108/428	0.831	4.7
– Proxy = child/children	70.6%	24/34	72.6%	77/106	0.816	–
Age	82.1 ± 10.1 (n = 136) [min–max: 43–98]		81.9 ± 10.3 (n = 437) [min–max: 33–105]		0.865	4.4
Female	77.2%	105/136	73.1%	321/439	0.587	7.8
Widowed	64.2%	86/134	60.3%	261/433	0.447	–
Born in Germany	94.7%	125/132	95.1%	409/430	0.846	–
Catholic	70.2%	92/131	68.6%	297/433	0.382	–
Highest level of nursing care (level III)	29.6%	40/135	24.9%	108/434	0.416	–
Dementia	57.0%	65/114	43.8%	134/306	0.321	15.1
PEG tube in situ	14.7%	20/136	10.9%	47/433	0.430	13.8
– Fed via PEG tube	90.0%	18/20	95.6%	43/45	0.402	–

t0: 15 February 2009 (day before intervention began, beginning of observation period)
IR/CR, intervention/control region; ICC, intraclass correlation coefficient; AD, advance directive
n in single cells: number of patients with valid data
Proportion of variance between homes: proportion of pooled variance among patients accounted for by variance between homes (only stated when significant)

- The suitability of the AD for emergency situations, operationalized by the availability of an emergency plan containing unambiguous instructions to the responsible carers or emergency staff with regard to resuscitation.
- The validity of the AD, i.e., clear documentation of the author's ability to give consent at the time the directive was written, and of correspondence between the directive's text and the author's intention—operationalized by the signature of a physician.
- For patients able to give consent: the designation of a representative (proxy) for the event of acute or permanent inability to give consent.
- The cumulative amount of time required for the professional facilitation.

Evaluation and statistical analysis

The data from the resident samples are expressed as absolute and relative frequencies or means and standard deviations, respectively, after intervention and in the control group.

For every parameter, we report absolute numbers and relative proportions. Furthermore, we present the p-values of the corresponding factor in the model and the intraclass correlation coefficients (ICC) as a measure of sample heterogeneity.

The inferential analysis of the uniformly dichotomous study parameters was performed using logistic regression models.

Results

Participation rate and dropouts

Six hundred forty-five (40.8%) of the potentially recruitable residents of the 14 nursing homes agreed to participate in the study (intention-to-treat [ITT] population).

The proportion of persons with a high level of need for nursing care (care level III, i.e., the highest level) was significantly lower among the nonparticipants (14.9% versus 25.6%, $p<0.05$), while participants and nonparticipants were similar in terms of age, sex distribution and the proportion of persons with ADs (see [15] for details of the nonresponder analysis).

Despite agreement to participate, one of the four intervention n/hs was reluctant to implement the agreed measures from the outset (recruitment of only 21.8% of the residents, nonadherence to agreements, no formally completed facilitation) and withdrew from the study in April 2010 (early dropout).

TABLE 2

New advance directives written during the observation period t0 to t1 (incidence)

New advance directives (incidence)	IR (n = 136)	CR (n = 439)	p	ICC (proportion of variance between homes [%])
Personal ADs completed after t0	19 (14.0%)	8 (1.8%)	<0.001	---
ADs by proxy completed after t0	30 (22.1%)	10 (2.3%)	<0.001	---
Any ADs completed after t0	49 (36.0%)	18 (4.1%)	<0.001	---
Analysis of ADs completed after t0	**IR (n = 49)**	**CR (n = 18)**	**p**	**ICC (proportion of variance between homes [%])**
Validity criteria				
Signature of any third party	47 (95.9%)	14 (77.8%)	0.038	---
Signature of a physician	46 (93.9%)	3 (16.7%)	<0.001	---
Criteria for clarity / clinical applicability				
POLST-like emergency information sheet	48 (98.0%)	8 (44.4%)	0.015	50.2%
Resuscitation attempt in event of cardiac arrest in current state: yes or no	47 (95.9%)	7 (38.9%)	0.001	---
Archiving				
Advance directive to be found at their supposed repository	44 (89.9%)	17 (94.4%)	0.561	--
File: prominent note re advance directive	40 (81.6%)	9 (50.0%)	0.239	35.6%
File: prominent note re emergency information sheet	41 (83.7%)	0 (0%)	<0.001	--
File: prominent note re instruction NOT to resuscitate	40 (81.6%)	0 (0%)	<0.001	--
Transfer of AD with patient in event of hospital admission	**IR (n = 14)**	**CR (n = 4)**	**p**	**ICC (proportion of variance between homes [%])**
AD (copy) in medical record	3 (21.4%)	2 (50.0%)	0.261	---
Analysis of personal ADs completed after t0 (excluding ADs by proxy)	**IR (n = 19)**	**CR (n = 8)**	**p**	**ICC (proportion of variance between homes [%])**
Nomination of a proxy	18 (94.7%)	4 (50.0%)	0.181	---

t0: 15 February 2009 (day before intervention began, beginning of observation period)
t1: 30 June 2010 (end of observation period)
IR/CR, intervention/control region; ICC, intraclass correlation coefficient; AD, advance directive
Proportion of variance between homes: proportion of pooled variance among patients accounted for by variance between homes (only stated when significant)
POLST: Physician Orders for Life-Sustaining Treatment (an emergency information sheet widely used in the USA; see www.polst.org) (14)

After excluding the 33 residents of this nursing home, 28 residents who died or moved away before data acquisition, and 9 residents with incomplete data, 575 residents of 13 nursing homes remained eligible for analysis (per-protocol [PP] population) *(Figure)*.

Sociodemographic data and advance directives before t0

The demographic data showed a predominantly female and Catholic collective, almost all of them born in Germany, with an average age of about 82 years *(Table 1)*. Approximately half of the residents showed signs of dementia, one quarter were classified as nursing care level III, and one eighth were being fed via a PEG tube. Over one fifth of pre-existing advance directives (26 of 121) were proxy directives. The proportion of residents with advance directives predating t0 did not differ significantly between the intervention region (16.2%) and the control region (20.8%). Significant differences between n/hs were found for the proportion of residents with one or more of the following characteristics: existence of an AD, signs of dementia, placement of a PEG feeding tube, male sex, and average age. However, there were no significant differences between the two regions.

Intervention effect: new advance directives during the observation period from t0 to t1 (incidence)

Over the observation period of 16.5 months, 36.0% of the participants (or their proxies) in the intervention region (IR) completed new ADs, compared to 4.1% in the control region (CR) (primary end point, $p<0.001$), based on the PP population (corresponding to 27.2% and 3.9% of the ITT population). Both personal ADs and ADs by proxy were much more frequent in the intervention region, while ADs by proxy made up the majority of the newly completed directives in both regions *(Table 2)*.

Analysis of the new ADs *(Table 2)* showed that all of the following parameters were far more frequent in the IR ($p<0.01$ in all cases):

TABLE 3

Analysis of all advance directives in existence at timepoint t1, completed before or after t0 (prevalence)

All directives at t1 (prevalence)	IR (n = 136)	CR (n = 439)	p	ICC (proportion of variance between homes [%])
All personal ADs at t1	40 (29.4%)	83 (18.9%)	0.092	8.1
All ADs by proxy at t1	33 (24.3%)	33 (7.5%)	<0.001	---
All ADs at t1	71 (52.2%)	109 (24.8%)	<0.001	4.9
Analysis of all ADs at t1	**IR (n = 71)**	**CR (n = 109)**	**p**	**ICC (proportion of variance between homes [%])**
Validity criteria				
Signature of any third party	66/71 (93.0%)	47/98 (48.0%)	<0.001	---
Signature of a physician	48/70 (68.6%)	14/98 (14.3%)	<0.001	---
Criteria for clarity / clinical applicability				
POLST-like emergency information sheet	53/71 (74.6%)	17/109 (15.6%)	<0.001	19.5
Resuscitation attempt in event of cardiac arrest in current state: yes or no	51/71 (71.8%)	11/98 (11.2%)	<0.001	21.0
Analysis of all personal ADs (excluding ADs by proxy)	**IR (n = 40)**	**CR (n = 83)**	**p**	**ICC (proportion of variance between homes [%])**
Nomination of a proxy	36/40 (90.0%)	27/78 (34.6%)	<0.001	---

t0: 15 February 2009 (day before intervention began, beginning of observation period)
t1: 30 June 2010 (end of observation period)
IR/CR, intervention/control region; ICC, intraclass correlation coefficient; AD, advance directive
Proportion of variance between homes: proportion of pooled variance among patients accounted for by variance between homes (only stated when significant)
POLST: Physician Orders for Life-Sustaining Treatment (an emergency information sheet widely used in the USA; see www.polst.org) (14)

- Designation of a proxy (in 94.7% vs. 50.0% of personal ADs)
- Signing of the AD by a third party (95.9% vs. 77.8%), particularly by a physician (93.9% vs. 16.7%)
- Completion of an emergency plan (98% vs. 44.4%)
- Resuscitation status clearly defined (95.9% vs. 38.9%), and presence of a corresponding eye-catcher on the resident's file (81.6% vs 38.9%).

Within each region, the n/hs did not differ significantly in terms of the proportion of residents with a new AD. Differences were found only in the rate of POLST-like emergency plans and in archiving (see the figures for "Proportion of variance between homes" in *Tables 2 and 3*).

Existing ADs could be actually found at their supposed repository with similar frequency in both regions *(Table 2)*. Prominent references (eye-catchers) in the file or on its back to the existence of an AD, an emergency plan, or a do-not-resuscitate order were significantly more frequent in the intervention region.

In only one third of the residents (of both regions) who had been transferred to hospital, a copy of the AD could be found in the hospital medical records *(Table 2)*.

Intervention effect: all advance directives at t1 (prevalence)

Table 3 provides an overview of all ADs (i.e., signed before or after t0) at the end of the observation period (t1 = 30 June 2010).

Although the intervention period was short, the intervention effect is clearly discernible (52.2% vs. 24.8%), despite the interference by ADs that were drawn up before the beginning of the intervention (t0 = 15 February 2009).

Time and effort required for the facilitation process in the intervention region

Sixty of the 74 persons who had an initial conversation with a facilitator went on to complete an AD. The median number of conversations was 2.5 (range 2 to 5), and the median total facilitation time amounted to 100 (60 to 240) minutes *(Table 4)*.

Discussion

This study is the first to show the feasibility and procedural efficacy of the introduction of a regional ACP program in Germany. At the same time, it is the first publication internationally of a prospective, inter-regionally controlled study of the implementation of an ACP program.

Only a few controlled studies of the implementation of ACP programs have been published to date. A Canadian study can be regarded a milestone; however, its randomized assignment to intervention or control was at nursing home level rather than regional level. It showed improvement not only in process quality but also in outcome quality, evidenced by, for example, decreasing hospital admissions and lengths of stay with

unchanged satisfaction and mortality, as well as lower total costs in the intervention nursing homes (20).

In a retrospective longitudinal study in the La Crosse region (Wisconsin, USA), where the ACP program Respecting Choices® has been established since the 1990s (11), consecutive analysis of all nonsudden deaths showed that nearly all of the persons in this group had ADs and emergency plans (POLSTs) and that in almost all cases the wishes expressed therein were respected by the institution where the patient was last treated (21). The cost effectiveness of Respecting Choices® has not been systematically investigated, but in a nationwide survey La Crosse was the region with the lowest Medicare hospital costs in the last 2 years of life (12).

An Australian group implemented the ACP program Respecting Patient Choices® in a hospital and showed, in a randomized study, that deceased patients in the intervention group were much more frequently treated according to their wishes and that their relatives suffered far less from posttraumatic stress, anxieties, and depression (22).

In contrast to the Canadian and Australian studies described above, but in agreement with the study from La Crosse, our study chose the regional rather than the institutional level as the focus of the intervention because the systematic changes necessary for improved respect for patients' preferences stated in an AD cannot be achieved at institutional level alone. The intervention n/hs were therefore recruited from one region and compared with homes from another region to avoid spillover effects. In contrast to the La Crosse study, our study is prospective and included a control group. The observation did not focus on the deaths, but rather on all residents of the participating h/hs.

The most prominent finding of our study, alongside the nine times higher incidence of ADs in the intervention group over the 16.5-month observation period, is the predominantly high standard of the newly completed directives in the intervention region with regard to relevance and validity *(Table 2)*. Almost all of these advance care plans included designation of a proxy, were signed by a physician, and included—documented on our emergency plan adapted from the POLST form—clear instructions regarding resuscitation in the event of cardiac arrest; a glance at the back of the resident's file usually sufficed to ascertain the resuscitation status. The difference from the control region was considerable, even though the latter—with a smaller number of cases—performed better in this respect than did another collective that we had studied previously (5).

The overall prevalence of ADs at the end of the observation period (including directives predating the intervention) was higher in the intervention group (52%) than in the control group (25%) *(Table 3)*, but lower in both groups than in a study—of similar duration—by Molloy et al. (20) (70% versus 57%); in both studies there were more ADs by proxy than personal ADs (signed by the resident). While we found considerable differences between the intervention and control regions with regard to the relevance and validity of the ADs, Molloy et al. (20) report specific (treatment-relevant) stipulations in the ADs of both intervention and control n/hs; the validity of the ADs was not investigated.

TABLE 4

Time and effort needed for the "beizeiten begleiten" facilitation*

Residents/proxies who had at least one conversation with a facilitator (n = 74)	
Residents' age: median (range)	85 (79–99) years
Number of conversations per resident: median (range)	2 (1–5)
Duration of a conversation: median (range)	39 (10–70) minutes
Duration of facilitation (all conversations): median (range)	92.5 (10–240) minutes
Residents/proxies for whom facilitation led to an advance directive (n = 60)	
Number of conversations per resident: median (range)	2.5 (2–5) minutes
Duration of a conversation: median (range)	40 (23.3–70) minutes
Duration of facilitation (all conversations): median (range)	100 (60–240) minutes
Residents/proxies for whom facilitation did not lead to an advance directive (n = 12)	
Number of conversations per resident: median (range)	2 (1–3) minutes
Duration of a conversation: median (range)	33.3 (10–60) minutes
Duration of facilitation (all conversations): median (range)	60 (10–100) minutes

*Two of the three intervention nursing homes (with a total of 184 residents) documented the facilitation; the durations given include preparation and follow-up time.

Observation period: 15 February 2009 – 30 June 2010;
first conversation 18 February 2009, last conversation 21 June 2010

Limitations

The strengths of our study include minimal selection, because all three of the districts and 13 of the 14 n/hs that we initially approached participated. The study is not randomized, however, so an effect due to the pragmatically determined selection of regions (and thus of n/hs) cannot be excluded, so a future cluster-randomized study with inter-regional comparison seems desirable. The early withdrawal of one institution from the study may be an expression of possible barriers in accepting the intervention at n/h level and thus an indicator of limited generalizability of the results. The power of the study is also limited by the participation rate of 40.8% of residents (or their proxies), although our nonresponder analysis found no signs of systematic selection apart from a higher level of demand for nursing care. On the other hand, the incidence of new ADs, in relation to all potential participants of the intervention region, of 36.0% × 40.8% = 14.7% in 16.5 months of observation is probably underestimated, because our initial recruitment letter to the n/h residents contained no detailed description of the intervention, but requested that the nursing home's files be made available to the study team for 1.5 years. This barrier would not have been present if the intervention

had been implemented as part of standard care. In our experience the offer of a facilitated conversation is rather likely to receive widespread interest; a much higher participation rate could therefore be expected if implementation was not linked with a study.

Further evidence for the feasibility of our ACP program is provided by its integration into the institutional policies of the intervention n/hs and of the local hospital. The median time of 100 minutes required for the facilitation process is higher than the 60 minutes reported in the only comparable study to date (22). One reason for this difference could be that we documented the total time, including preparation and follow-up. We cannot judge whether the outcome "justifies" this effort (23), because we were unable to investigate, in a comparative way, relevant end points such as reduction of unwanted days in hospital, transfers between institutions, or parameters such as avoidance of time-consuming conflicts with relatives about contentious therapeutic interventions, or the overall level of satisfaction on the side of all parties involved. We see an urgent need for studies evaluating the outcome quality of a German ACP program. The results of the groups cited above (20–22) indicate that the costs in time and money of initial implementation of an ACP program, and continuous facilitation, are matched by savings due to such a program. Above all, however, it has to be questioned whether, in ethical terms, society can afford to continue in its failure to systematically elicit in advance the treatment preferences of the elderly and the chronically ill and make sure that these wishes are respected in the event of a future medical crisis.

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KEY MESSAGES

- Advance care planning (ACP) is a new, regional concept to bring about qualified advance directives and to make sure that they are reliably honored.
- The ACP program "beizeiten begleiten" links the training of facilitators and primary care physicians with regional measures to implement advance directives.
- The rate of newly written qualified advance directives, signed by physicians and with clear guidance regarding relevant treatment issues in emergency situations, was far higher in the intervention region.
- The costs of ACP in time and money have to be weighed against the benefits for all parties involved and the putative savings.
- In Germany as elsewhere, the potential of ACP should be more widely recognized, further investigated, and broadly utilized.

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Conflict of interest statement

"beizeiten begleiten®" is a registered wordmark and logo of the University of Düsseldorf and the University of Augsburg, "HAnNo®" a registered wordmark and logo of the University of Düsseldorf. The authors developed these wordmarks and logos, but possess no commercial rights thereto.

Beyond that, the authors declare that no other conflicts of interest exist.

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ORIGINAL ARTICLE/e-SUPPLEMENT

Implementing an Advance Care Planning Program in German Nursing Homes

Results of an Inter-Regionally Controlled Intervention Trial

Jürgen in der Schmitten, Katharina Lex, Christine Mellert, Sonja Rothärmel, Karl Wegscheider, Georg Marckmann

Study design, setting, inclusion criteria, and time frame

This prospective, inter-regionally controlled, nonrandomized study compared an intervention region (four nursing homes in one town of the German federal state of North Rhine–Westphalia) with a control region (five nursing homes (n/hs) in each of two towns in North Rhine–Westphalia). Criteria for the choice of intervention and control towns were distance from the study center (<50 km), medium size (40 000 to 80 000 inhabitants), the presence of a local hospital (convenience sample), and a minimum distance of 20 km from one another to avoid spillover effects. The three primarily approached district administrations agreed to participate, as did 13 of 14 primarily approached n/hs; the remaining n/h was recruited with one additional approach (i.e., minimal selection in recruitment). The distribution of organizations running the n/hs was similar: two Catholic, one Protestant, and one municipal in the intervention region, compared with five Catholic, two Protestant, and three private in the control region. For details of the structure of the nursing homes see *eTable 1*.

The intervention took place at institutional level. The primary object of analysis was the resulting advance care plans (resident level).

To demonstrate an increase in the rate of advance directives (ADs) in the intervention group versus the control group from 10% to 20% at a level of significance of 5% (two-sided) and with power of 90%, we calculated that at least 266 participants would be needed in each group. As planned, there were four participating nursing homes in the intervention town and five in each of the two control towns. Included were all residents of the participating n/hs living there at the beginning of the recruitment period and residents who moved in during the recruitment period (no exclusion criteria). The recruitment phase ran from 1 February 2009 to 30 June 2009, with a letter being sent to all residents via the administration of each n/h. The observation phase (data acquisition) ran from 15 February 2009 to 30 June 2010. All residents, or in the case of incapability to give consent their legally appointed representatives, were asked to give their agreement in writing to our inspection of their case notes (in the n/h and, if applicable, the hospital) and to the analysis of their pseudonymized data and any advance directives found in their chart (15).

Ethics committee approval

The study was approved by the ethics committee of Düsseldorf University Hospital (# 3116 of 16 November 2008).

Data acquisition

Data acquisition began with a survey that involved the following:

- Inspection of the case notes
- A structured interview with each resident or, in the case of incapability to give consent, the legally appointed representative
- A structured interview with the responsible nurse.

In a second survey, ADs contained in the residents' files were identified and analyzed. In the case of inpatient treatment in the local hospital, the medical records were inspected for the presence of a copy of the AD.

In the intervention region the trained facilitators (see *Intervention* below) documented the number and duration of their conversations with the residents and all instances of completing an AD.

Intervention

All authors except for KW attended a one-week training course in La Crosse (Wisconsin, USA), where the regional ACP program Respecting Choices® is well established. Having completed this course they were certified facilitators and instructors for Respecting Choices. Based on Respecting Choices, the authors then developed an ACP program tailored to the circumstances prevailing in Germany (beizeiten begleiten®) (16).

Besides repeated discussions with the administrators of all participating institutions, implementation of this program involved the following:

- A 20-hour training course (9–13 February 2009) for the two to four non-physician facilitators recruited from each participating n/h and from the outpatient hospice service. This course was led by

the authors (except KW), involved the directors of the US ACP program Respecting Choices, Bud Hammes und Linda Briggs, and was followed by supervision and support of the facilitators.

- Four hours of training for the 20 cooperating primary care physicians who were the principal providers of medical care for the residents of the homes, followed by four optional 1.5-hour meetings over the next 2 years.
- Separate information events (introductory presentations followed by discussion) for nursing staff at the n/hs and at the regional hospital, for hospital and emergency physicians, for emergency medical service paramedical staff, and for professional guardians.

In addition, standard documents had to be designed: personal ADs and ADs by proxy for the legally appointed representatives of those who were permanently unable to give consent, as well as a document for emergency orders for use by primary care physicians (the *Hausärztliche Anordnung für den Notfall*, HAnNo®: *eFigure 1*, cf. [17]).

The core of the intervention was the offer of ACP facilitation, communicated by flyers, posters and personal contact with n/h residents. The certified "beizeiten begleiten" facilitators offered to the residents—involving relatives, whereever possible—conversations to support individual advance care planning, with the option to assist in the completion of a written AD after at least two sessions. In the case of agreement, the facilitators arranged appointments for meetings with residents and their relatives.

Moreover, the concept foresaw a second step in which certified primary care physicians verified

a) the patients' (or proxies') ability to give consent, and
b) their understanding of the implications of the intended stipulations.

The documents were then signed by the primary care physician and thus "validated" (in analogy to the informed consent standard).

Furthermore, agreements were made with the h/hs regarding structural procedures, e.g., for regular updating and standardized archiving of these directives and their transfer with the resident in the case of admission to hospital.

The n/hs were not charged a fee for the training courses, but the staff were not compensated for their time. The primary care physicians were paid € 40 for each "validation" of an AD.

No interventions were carried out in the control region. Care homes and residents were approached with the request to participate in a study with the aim of improving compliance with resident's wishes.

End points and definitions

The primary end point was the number of newly written advance directives in the study cohort during the 16.5-month observation period, i.e., from the beginning of the intervention (t0 = the day before the intervention started, 15 February 2009) to its end (t1 = 30 June 2010) (incidence).

As a secondary end point we looked at the number of advance directives at the end of the observation period (t1), regardless of whether they had been written before or after t0 (prevalence).

We counted both the directives signed by patients and those signed by legal representatives (18), defined as documents according to § 1901 of the German Civil Code, in which a person or (in the case of permanent incapability to give consent) their representative (5, 19) had laid down limits for medical treatment in the hypothetical event of incapability to give consent in future health crises.

Further secondary end points, largely based on a prestudy (5), were:

- The relevance of the AD, operationalized by the clarification of the resuscitation status, which is particularly relevant in n/hs
- The suitability of the AD for emergency situations, operationalized by the availability of an emergency plan (analogous to the US POLST form [Physician Orders for Life-Sustaining Treatment]) containing unambiguous, unconditional (yes/no) instructions to the responsible carers or emergency staff with regard to resuscitation.
- The validity of the AD, i.e., clear documentation of the author's ability to give consent at the time the directive was written, and of correspondence between the directive's text and the author's intention—operationalized by the signature of a physician.
- For patients able to give consent: the designation of a representative (proxy) for the event of acute or permanent inability to give consent.
- The cumulative amount of time required for the professional facilitation.

Evaluation and statistical analysis

The intention-to-treat (ITT) population consisted of the residents who had given legally valid consent to participate in the study. Since the primary aim of the study was to establish the feasibility and efficacy of the intervention, the inferential analysis was performed in the per-protocol (PP) population, comprising all evaluable patients in whom the protocol was followed.

The data from the resident samples were described by absolute and relative frequencies or means and standard deviations, respectively, by intervention and control. Since the parameters of the study were all dichotomous (i.e., comprised yes/no variables), logistic regression models were used for inferential analysis. To assess the treatment effect, the group (intervention versus control) was incorporated as a factor in the model.

In designing the model we proceeded from the basic assumption that there might be greater differences between the nursing homes with respect to individual parameters than could be expected from the heterogeneity of the residents within the homes (cluster effect).

Such an effect can lead to falsely low p-values. We therefore incorporated the respective n/h as a further contingent effect alongside the individual error term in each of the inferential evaluation models.

For each parameter we report the absolute numbers and proportions by group, together with the p-values of the associated factor in the model and the intraclass correlation coefficient (ICC). The ICC estimates the proportion of total variance represented by home variance within the samples and thus conveys an impression to what extent the occurrence of the event under investigation depends on the individual characteristics of the n/hs (ICC) or of the residents (100% – ICC). The proportions of variance are included in the tables only when the presence of a cluster effect can be confirmed with the aid of the associated likelihood ratio test ($p<0.05$).

The time taken up by facilitation was expressed in terms of simple frequencies together with the medians and ranges of the durations of the conversations.

eTABLE 1

Comparison of the participating nursing homes

Region	Nursing home	Places	Agency
IR	IR-1	80–109	Public, non-profit making (Catholic)
IR	IR-2	80–109	Public, non-profit making (Catholic)
IR	IR-3	110–139	Public, non-profit making (Protestant)
IR	IR-4	80–109	Municipal
Total: 421/median: 101			
CR, town A	CR-A1	110–139	Public, non-profit making (Catholic)
CR, town A	CR-A2	80–109	Public, non-profit making (Catholic)
CR, town A	CR-A3	50–79	Public, non-profit making (Catholic)
CR, town A	CR-A4	140–169	Public, non-profit making (Protestant)
CR, town A	CR-A5	50–79	Public, non-profit making (Catholic)
Total: 503/median: 100			
CR, town B	CR-B1	80–109	Public, non-profit making (Catholic foundation)
CR, town B	CR-B2	110–139	Public, non-profit making (Protestant)
CR, town B	CR-B3	140–169	Private
CR, town B	CR-B4	80–109	Private
CR, town B	CR-B5	20–49	Private
Total: 482/median: 100			

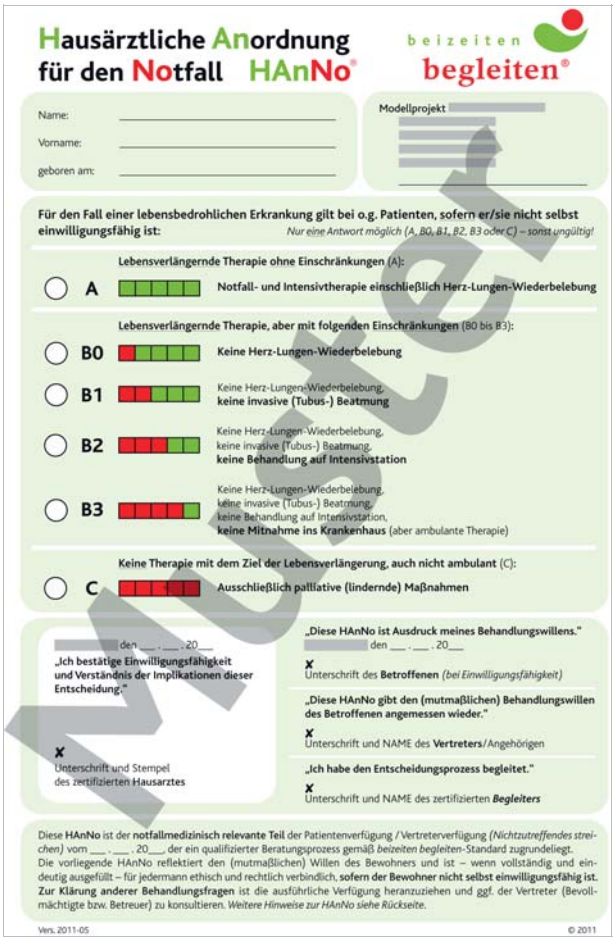
IR/CR: intervention/control region
Number of places given in ranges of 30, beginning at 20

eTABLE 2

Comparison of advance care planning (ACP) and the traditional approach to advance directives (ADs)

The seven elements of an ACP program (16)		Comparison with traditional approach to ADs
1. Active promotion	Every person in the target group (e.g., every inhabitant of a given region over 60, as in Respecting Choices, or all residents of nursing homes, as in "beizeiten begleiten") is repeatedly offered professional assistance to draw up an AD. Institutions and individuals are free to decide whether to take part. Experience: At least among the severely ill, the existence of a AD is the rule, not the exception (21).	Not widespread—the writing of an AD is a personal mattter; the initiative to draw up a traditional AD or to accept any offer of assistance that may be available must come from the person concerned. Experience: The existence of an AD remains the exception even in nursing homes, e.g., 12% in a study published in 2007 (5).
2. Qualified processual support (facilitation) in development and clarification of individual treatment preferences	Specifically trained nonmedical and medical personnel facilitate a process of one or (usually) more discussions, not rarely taking up several hours altogether, culminating in the writing of an individual AD, in concordance with the standard of informed consent. The facilitators do not give “advice”! Whenever possible, the designated representative and/or family members should be involved in the conversations. The regional health care system includes a corresponding professional role (facilitators) and a uniform ACP concept with defined quality standards and provides sufficient resources for the facilitators to attain qualification and fulfill their role.	Qualified medical or nonmedical facilitation is possible, and various institutions offer services of variable quality to individuals interested in writing an AD. No regional concept exists, however, and the services offered are not formally part of the health care system. ADs in German nursing homes are usually forms that show no signs of the authors having received advice and are insufficiently clear (irrelevant) with regard to critical treatment questions (4, 5).
3. Professional documentation	A regional ACP program includes the development of meaningful standard forms, particularly a document for emergency orders that contains clear instructions for nurses and emergency paramedical staff (17). Documentation of the individual wishes regarding treatment (or supervision thereof) is the task of the professional facilitator, who, along with the primary care physician, takes formal responsibility for the validity of the directive, i.e., for agreement between the author's intention and the document's content.	Documentation is generally carried out by the person concerned, usually on one of the more than 200 forms available over the Internet or elsewhere, sometimes written out by hand. The validity of the directive can be confirmed by a qualified facilitator, but in practice this is very rarely done (5).
4. Archiving, access and transfer	Responsibility for proper archiving of an AD, for its transfer between institutions together with the patient, and for its constant accessibility lies with the institution or the responsible officers of the system, not with the patient.	Responsibility for an advance directive being available when needed lies with the person concerned or his/her relatives.
5. Regular updating	All persons concerned view the written AD just as an intermediate result in an ongoing conversation process. It is updated at least every 2 to 5 years, and particularly if there is any relevant change in health status; again, the system takes the initiative.	It is recommended to update an AD; however, the person concerned has to take the initiative. Many people imagine that the documentation of an AD (not uncommonly drawn up in a notary's office together with a power of attorney for health care) is a one-time act; ADs are frequently years or even decades old.
6. Observance and implementation by third parties	All those involved in patient care are trained to make sure that ADs are reliably honored. Empirical studies indicate that in regions with ACP programs patients' advance-documented wishes are respected practically without exception (21, 22).	Empirical studies show that even in the rare cases where an AD exists and is readily accessible, it is often not honored (4, 5).
7. Installation of a process of continuous quality assurance	ACP programs are viewed as a system whose process and outcome quality has to be continuously monitored and improved by mechanisms installed specifically for this purpose (11).	The traditional AD is not embedded in a system and whether it is honored or not is not systematically checked.

eFIGURE



Hausärztliche Anordnung für den Notfall HAnNo®

beizeiten begleiten®

Name: _____

Vorname: _____

geboren am: _____

Modellprojekt _____

Für den Fall einer lebensbedrohlichen Erkrankung gilt bei o.g. Patienten, sofern er/sie nicht selbst einwilligungsfähig ist: *Nur eine Antwort möglich (A, B0, B1, B2, B3 oder C) – sonst ungültig!*

Lebensverlängernde Therapie ohne Einschränkungen (A):

○ **A** **Notfall- und Intensivtherapie einschließlich Herz-Lungen-Wiederbelebung**

Lebensverlängernde Therapie, aber mit folgenden Einschränkungen (B0 bis B3):

○ **B0** **Keine Herz-Lungen-Wiederbelebung**

○ **B1** Keine Herz-Lungen-Wiederbelebung, **keine invasive (Tubus-) Beatmung**

○ **B2** Keine Herz-Lungen-Wiederbelebung, keine invasive (Tubus-) Beatmung, **keine Behandlung auf Intensivstation**

○ **B3** Keine Herz-Lungen-Wiederbelebung, keine invasive (Tubus-) Beatmung, keine Behandlung auf Intensivstation, **keine Mitnahme ins Krankenhaus** (aber ambulante Therapie)

Keine Therapie mit dem Ziel der Lebensverlängerung, auch nicht ambulant (C):

○ **C** **Ausschließlich palliative (lindernde) Maßnahmen**

_____ den __.__.20__

„Ich bestätige Einwilligungsfähigkeit und Verständnis der Implikationen dieser Entscheidung."

✘ Unterschrift und Stempel des zertifizierten **Hausarztes**

„Diese HAnNo ist Ausdruck meines Behandlungswillens."

_____ den __.__.20__

✘ Unterschrift des **Betroffenen** *(bei Einwilligungsfähigkeit)*

„Diese HAnNo gibt den (mutmaßlichen) Behandlungswillen des Betroffenen angemessen wieder."

✘ Unterschrift und NAME des **Vertreters**/Angehörigen

„Ich habe den Entscheidungsprozess begleitet."

✘ Unterschrift und NAME des zertifizierten ***Begleiters***

Diese **HAnNo** ist der **notfallmedizinisch relevante Teil** der Patientenverfügung / Vertreterverfügung *(Nichtzutreffendes streichen)* vom __.__.20__, der ein qualifizierter Beratungsprozess gemäß *beizeiten begleiten*-Standard zugrundeliegt. Die vorliegende HAnNo reflektiert den (mutmaßlichen) Willen des Bewohners und ist – wenn vollständig und eindeutig ausgefüllt – für jedermann ethisch und rechtlich verbindlich, **sofern der Bewohner nicht selbst einwilligungsfähig ist. Zur Klärung anderer Behandlungsfragen** ist die ausführliche Verfügung heranzuziehen und ggf. der Vertreter (Bevollmächtigte bzw. Betreuer) zu konsultieren. *Weitere Hinweise zur HAnNo siehe Rückseite.*

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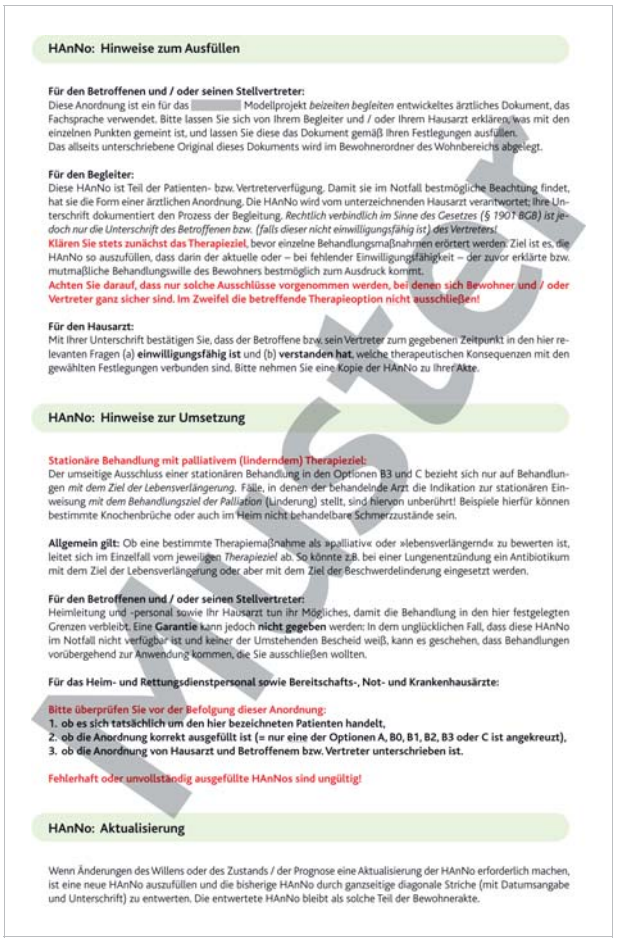

HAnNo: Hinweise zum Ausfüllen

Für den Betroffenen und / oder seinen Stellvertreter:
Diese Anordnung ist ein für das _____ Modellprojekt *beizeiten begleiten* entwickeltes ärztliches Dokument, das Fachsprache verwendet. Bitte lassen Sie sich von Ihrem Begleiter und / oder Ihrem Hausarzt erklären, was mit den einzelnen Punkten gemeint ist, und lassen Sie diese das Dokument gemäß Ihren Festlegungen ausfüllen.
Das allseits unterschriebene Original dieses Dokuments wird im Bewohnerordner des Wohnbereichs abgelegt.

Für den Begleiter:
Diese HAnNo ist Teil der Patienten- bzw. Vertreterverfügung. Damit sie im Notfall bestmögliche Beachtung findet, hat sie die Form einer ärztlichen Anordnung. Die HAnNo wird vom unterzeichnenden Hausarzt verantwortet; ihre Unterschrift dokumentiert den Prozess der Begleitung. *Rechtlich verbindlich im Sinne des Gesetzes (§ 1901 BGB) ist jedoch nur die Unterschrift des Betroffenen bzw. (falls dieser nicht einwilligungsfähig ist) des Vertreters!*
Klären Sie stets zunächst das Therapieziel, bevor einzelne Behandlungsmaßnahmen erörtert werden. Ziel ist es, die HAnNo so auszufüllen, dass darin der aktuelle oder – bei fehlender Einwilligungsfähigkeit – der zuvor erklärte bzw. mutmaßliche Behandlungswille des Bewohners bestmöglich zum Ausdruck kommt.
Achten Sie darauf, dass nur solche Ausschlüsse vorgenommen werden, bei denen sich Bewohner und / oder Vertreter ganz sicher sind. Im Zweifel die betreffende Therapieoption nicht ausschließen!

Für den Hausarzt:
Mit Ihrer Unterschrift bestätigen Sie, dass der Betroffene bzw. sein Vertreter zum gegebenen Zeitpunkt in den hier relevanten Fragen (a) **einwilligungsfähig ist** und (b) **verstanden hat**, welche therapeutischen Konsequenzen mit den gewählten Festlegungen verbunden sind. Bitte nehmen Sie eine Kopie der HAnNo zu Ihrer Akte.

HAnNo: Hinweise zur Umsetzung

Stationäre Behandlung mit palliativem (linderndem) Therapieziel:
Der umseitige Ausschluss einer stationären Behandlung in den Optionen B3 und C bezieht sich nur auf Behandlungen *mit dem Ziel der Lebensverlängerung*. Fälle, in denen der behandelnde Arzt die Indikation zur stationären Einweisung *mit dem Behandlungsziel der Palliation* (Linderung) stellt, sind hiervon unberührt! Beispiele hierfür können bestimmte Knochenbrüche oder auch im Heim nicht behandelbare Schmerzzustände sein.

Allgemein gilt: Ob eine bestimmte Therapiemaßnahme als »palliativ« oder »lebensverlängernd« zu bewerten ist, leitet sich im Einzelfall vom jeweiligen *Therapieziel* ab. So könnte z.B. bei einer Lungenentzündung ein Antibiotikum mit dem Ziel der Lebensverlängerung oder aber mit dem Ziel der Beschwerdelinderung eingesetzt werden.

Für den Betroffenen und / oder seinen Stellvertreter:
Heimleitung und -personal sowie Ihr Hausarzt tun ihr Mögliches, damit die Behandlung in den hier festgelegten Grenzen verbleibt. Eine **Garantie** kann jedoch **nicht gegeben** werden: In dem unglücklichen Fall, dass diese HAnNo im Notfall nicht verfügbar ist und keiner der Umstehenden Bescheid weiß, kann es geschehen, dass Behandlungen vorübergehend zur Anwendung kommen, die Sie ausschließen wollten.

Für das Heim- und Rettungsdienstpersonal sowie Bereitschafts-, Not- und Krankenhausärzte:

Bitte überprüfen Sie vor der Befolgung dieser Anordnung:
1. ob es sich tatsächlich um den hier bezeichneten Patienten handelt,
2. ob die Anordnung korrekt ausgefüllt ist (= nur eine der Optionen A, B0, B1, B2, B3 oder C ist angekreuzt),
3. ob die Anordnung von Hausarzt und Betroffenem bzw. Vertreter unterschrieben ist.

Fehlerhaft oder unvollständig ausgefüllte HAnNos sind ungültig!

HAnNo: Aktualisierung

Wenn Änderungen des Willens oder des Zustands / der Prognose eine Aktualisierung der HAnNo erforderlich machen, ist eine neue HAnNo auszufüllen und die bisherige HAnNo durch ganzseitige diagonale Striche (mit Datumsangabe und Unterschrift) zu entwerten. Die entwertete HAnNo bleibt als solche Teil der Bewohnerakte.

Emergency form for the advance care planning (ACP) program *beizeiten begleiten* (adapted from the US POLST form):
"Family physician's orders for life-sustaining treatment in case of emergency"