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COHORT PROFILE: THE PRECIPITATING EVENTS PROJECT (PEP STUDY)

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Abstract: The Precipitating Events Project (PEP Study) is an ongoing longitudinal study of 754 nondisabled community-living persons age 70 years or older who were members of a large health plan in greater New Haven, Connecticut, USA. The study was established to rigorously evaluate the epidemiology of disability in older persons and to elucidate the role of intervening illnesses and injuries on the disabling process. Of the eligible members, 75.2% agreed to participate and were enrolled between March 1998 and October 1999. Participants have completed comprehensive home-based assessments at 18-month intervals and have been interviewed monthly over the phone with a completion rate of 99%. Detailed participant-level data on health care utilization are obtained annually through linkages with Medicare claims. Through June 2019, 702 (93.1%) participants have died after a median of 109 months, while 43 (5.7%) have dropped out of the study after a median of 27 months. Death certificates are available for all decedents. To date, 117 original reports have been published using data from the PEP Study, including many focusing on other high priority areas such as end of life, frailty, depressive symptoms, aging stereotypes, pain, sleep, and methodologic research. The PEP Study welcomes proposals to access data for meritorious analyses from qualified investigators.

Key words: Longitudinal study, disability, frailty, functional assessment, older persons.

Why was the cohort set up?

The Precipitating Events Project (PEP Study) was established in 1998 to rigorously evaluate the epidemiology of disability in older persons and to elucidate the role of intervening illnesses and injuries, i.e. events, on the disabling process. Previous epidemiological studies had relatively long assessment intervals, ranging from 6 to 24 months, and had focused almost exclusively on identifying vulnerable older persons at risk for disability (1). Relatively little was known, in contrast, about the role of intervening events that precipitate disability. A unique feature of the PEP Study is the completion of monthly interviews for more than 21 years to ascertain exposure to potential precipitating events and to assess a comprehensive set of basic, instrumental and mobility activities. The frequency of assessments has allowed the course of disability to be defined more accurately and strengthens temporal precedence between intervening events and disability outcomes, thereby supporting potential causal associations. In addition, as the number of decedents has accrued, the PEP Study has become a valuable resource for investigating disability and distressing symptoms at the end of life. Assembly of the cohort was supported by two private USA awards, while follow-up has been supported by the National Institute on Aging of the National Institutes of Health.

Who is in the cohort?

The PEP Study is an ongoing longitudinal study of 754 community-living persons age 70 years or older. Cohort assembly is summarized in Figure 1. Potential participants were identified from a computerized list of 3157 age-eligible members of a large health plan in greater New Haven, Connecticut, USA. Eligibility was determined during a screening telephone interview and was confirmed during an in-home assessment. Members were potentially eligible if they were nondisabled (i.e., required no personal assistance) in four basic activities of daily living (ADL)—bathing, dressing, walking inside the house, and transferring from a chair. Exclusion criteria included significant cognitive impairment with no available proxy, inability to speak English, diagnosis of a terminal illness, and plan to move out of the area during the next year. As previously described (2), persons were oversampled if they were physically frail, as denoted by a timed score greater than 10 seconds on the rapid gait test (i.e., walk back and forth over a 3-meter course as quickly as possible) (3). Only 4.6% of the 2735 health plan members who were alive and could be contacted refused to complete the screening telephone interview, and 75.2% of the eligible members agreed to participate and were enrolled between March 1998 and October 1999. Table 1 provides the baseline characteristics of the study participants. Persons who refused to participate did not differ significantly from those who were enrolled in terms of age or sex.

How often have they been followed up?

Comprehensive home-based assessments have been completed at 18-month intervals except at 126 months (due to lack of funds), and telephone interviews have been completed monthly. For participants who have significant cognitive impairment or are otherwise unavailable, a proxy is interviewed using a rigorous protocol, with demonstrated reliability and validity (4). Through June 2019, 702 (93.1%) participants have died after a median of 109 months, while 43 (5.7%) have dropped out of the study after a median of 27 months.

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Data are otherwise available for 99.2% of the 86,130 monthly interviews. Information on completion of the comprehensive assessments is provided in Table 2. The completion rate during follow-up has ranged from 89.5% at 216 months to 96.2% at 18 months. The percentage of assessments completed with assistance of a proxy has increased over time, as the prevalence of significant cognitive impairment has increased. To enhance retention, a telephone version of the comprehensive assessment is completed when participants have moved out of the area or when they do not permit a home-based assessment. Deaths are ascertained from local obituaries and/or an informant. A copy of the death certificate is obtained, and a certified nosologist provides ICD-10 codes for the immediate and underlying causes of death (5).

Figure 1

Assembly of study cohort. Persons who were physically frail were oversampled. After the prespecified number of nonfrail participants were enrolled, potential participants were excluded if they had a low likelihood of physical frailty based on the telephone screen and, subsequently, if they were found not to be physically frail during the in-home assessment

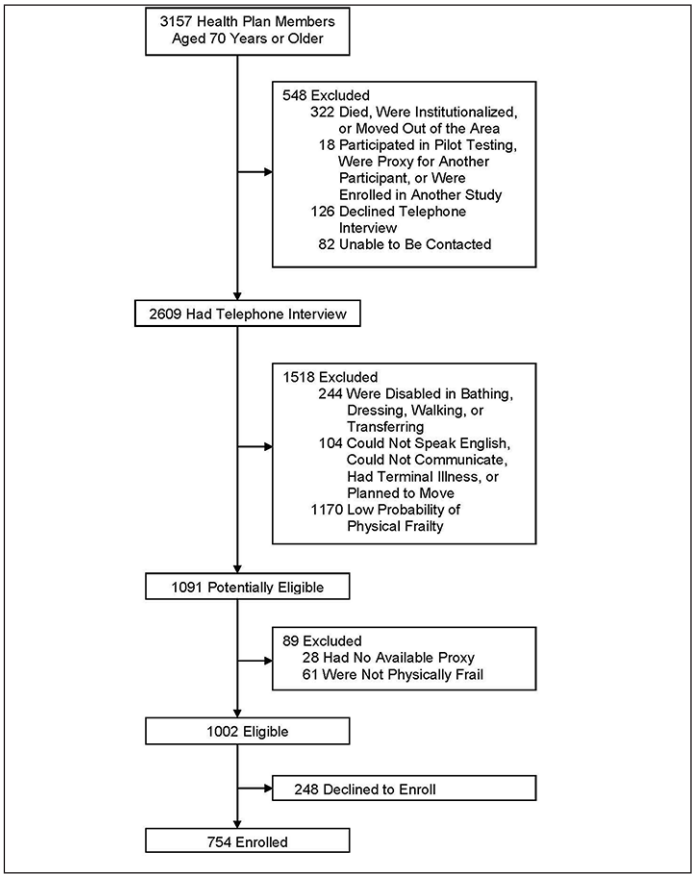

Table 1

Core Elements of the Comprehensive Assessments and Baseline Characteristics of Participants in the PEP Study (N=754)

Demographic	
Age (years), mean ± SD	78.4 ± 5.3
Female sex, n (%)	487 (64.6)
Non-Hispanic white ethnicity, n (%)	682 (90.5)
Education (years), mean ± SD	12.0 ± 2.9
Currently married, n (%)	361 (47.9)
Living alone, n (%)	298 (39.5)
Health-related	
Number of self-reported, physician-diagnosed chronic conditions (of 9), mean ± SD	1.8 ± 1.2
Number of prescription medications, mean ± SD	4.0 ± 2.4
Hearing impairment[a], n (%)	163 (21.6)
Visual impairment[b], n (%)	133 (17.6)
Weight loss ≥ 4.5 kg in past year, n (%)	175 (23.2)
Frailty[c], n (%)	194 (25.7)
Self-rated health (0 – 5), mean ± SD	3.0 ± 0.9
Functional Status[d]	
Basic activities (0 – 14), mean ± SD	0.4 ± 1.0
Instrumental activities (0 – 10), mean ± SD	1.6 ± 2.4
Mobility activities (0 – 8), mean ± SD	2.2 ± 1.7
Cognitive or Psychosocial	
Score < 24 on Mini-Mental State Examination (53), n (%)	86 (11.4)
Score ≥ 20 on Center for Epidemiological Studies-Depression Scale (54), n (%)	100 (13.3)
Low functional self-efficacy[e], n (%)	241 (32.0)
Low social support[f], n (%)	167 (22.2)
Social activities (0 – 20) (55), mean ± SD	8.5 (3.3)
Behavioral	
Current smoker, n (%)	63 (8.4)
Low physical activity[g], n (%)	232 (30.8)
Body mass index ≥30 kg/m2, n (%)	165 (21.9)
Physical capacity	
Slow gait speed[h], n (%)	322 (42.7)
Score on Short Physical Performance Battery (56), mean ± SD	6.8 ± 2.9
Muscle weakness	
Grip strength[i], n (%)	407 (54.0)
Upper extremity[j], n (%)	223 (29.6)
Lower extremity[j], n (%)	270 (35.8)
Slow manual dexterity based on 9-hole pegboard test[k], n (%)	288 (38.2)
Slow gross motor coordination based on 10 finger taps[k], n (%)	303 (40.2)
Low peak expiratory flow[l], n (%)	175 (23.2)

a. Missed 4 of 4 tones based on 1000 and 2000 HZ measurements for the left and right ears; b. Value greater than 26% as assessed with a Jaeger card; c. Met 3 or more of the 5 criteria from the Fried phenotype (57); d. Activities were scored as "0" for no personal help and no difficulty, "1" for difficulty but no help, and "2" for help. A fourth mobility item, also scored as 0, 1, or 2, was based on the average amount of time (in hours) walked per day (>0.75, 0.25–0.75, or <0.25) (58); e. Score ≤ 27, denoting worst quartile based on the first 356 enrolled participants who had been selected randomly from the source population (59); f. Score ≤ 18 on Medical Outcomes Study (MOS) Social Support Scale (28); g. Score < 64 for men and <52 for women on Physical Activity Scale for the Elderly (PASE) (60); h. Time > 10 seconds to walk back and forth over a 3-meter course as quickly as possible (2); i. Value ≤ gender- and body mass index-specific cut-points provided by Fried et al (61); j. Assessed with hand-held Chatillon MSE 100 dynamometer; weakness was denoted as worst sex-specific quartile for nondominant limb, based on the first 356 enrolled participants who had been selected randomly from the source population (56); k. Slowness was denoted as worst quartile, based on the first 356 enrolled participants who had been selected randomly from the source population (56); l. Value less than 10% of the standardized residual percentile (62)

Table 2
Completion of the Comprehensive Assessments over Time

	Alive	Deceased	Completed	Refused[b]	Proxy	Telephone
Assessment[a]	N	n	n (%)[c]		n (%)[d]	
Baseline	754		754 (100)		9 (1.2)	
18 months	708	46	681 (96.2)	27 (3.8)	32 (4.7)	21 (3.1)
36 months	656	52	626 (95.4)	30 (4.6)	54 (8.6)	25 (3.9)
54 months	588	68	558 (94.9)	30 (5.1)	68 (12.2)	34 (6.1)
72 months	523	65	493 (94.3)	30 (5.7)	91 (18.5)	39 (7.9)
90 months	467	56	440 (94.2)	27 (5.8)	97 (22.0)	29 (6.6)
108 months	401	66	378 (94.3)	23 (5.7)	100 (26.5)	30 (7.9)
144 months	265	136	245 (92.5)	20 (7.5)	77 (31.4)	20 (8.2)
162 months	212	53	195 (92.0)	17 (8.0)	70 (35.9)	24 (12.3)
180 months	159	53	143 (89.9)	16 (10.1)	46 (32.2)	21 (14.7)
198 months	125	34	112 (89.6)	13 (10.4)	40 (35.7)	17 (15.2)
216 months	86	39	77 (89.5)	9 (10.5)	24 (31.2)	7 (9.1)
234 months	69	17	63 (91.3)	6 (8.7)	31 (49.2)	7 (11.1)

a. A comprehensive assessment was not completed at 126 months due to lack of funds; b. Values include participants who had dropped out of the study.; c. The denominator includes the number of participants alive at the relevant time point; d. The denominator includes the number of participants who completed the relevant assessment.

What has been measured?

Comprehensive assessments

The core elements of the comprehensive assessments are provided in Table 1, by domain. In addition, expanded modules on bathing (6, 7), sleep (8) and fatigue (9) were added to the comprehensive assessments starting at 36, 90 and 108 months, respectively; and age stereotypes (10, 11) were assessed at baseline and 108 months. With few exceptions, data on the core elements were 100% complete at baseline and greater than 95% complete during follow-up. To account for these missing data, sequential Markov Chain Monte Carlo imputation for multivariate normal data has been used.

Monthly interviews

Participants are interviewed monthly to ascertain their exposure to intervening events, monitor their health care utilization, and reassess their functional status. The intervening events include illnesses and injuries leading to hospitalization, emergency department visit, or restricted activity (12, 13). For the self-reported hospitalizations, discharge summaries are obtained and information is extracted on dates of admission and discharge, diagnosis on admission, primary and other diagnoses at discharge, major procedures, and discharge location. If participants have restricted activity, they are asked sequentially whether they have had any of 24 prespecified problems (Box 1) in the past month and whether the problem(s) caused their restricted activity. An additional set of questions asks about doctor visits and admissions to a nursing home or hospice in the past month. Finally, the presence of disability is assessed in four basic activities (bathing, dressing, walking inside the house, and transferring from a chair), five instrumental activities (shopping, housework, meal preparation, taking medications, and managing finances), and four mobility activities (walk ¼ mile, climb flight of stairs, lift/carry 10 pounds, and driving) (14, 15). Multiple imputation is used to address the small amount of missing monthly data on functional status (16).

Box 1
Potential Problems Leading to Restricted Activity[a]

1) pain or stiffness in your joints	14) difficulty with sleeping
2) pain or stiffness in your back	15) nausea, vomiting, diarrhea, or other stomach (abdominal) problem
3) leg pain on walking	16) a problem with your memory or difficulty thinking
4) weakness of your arms or legs	17) been depressed
5) swelling in your feet or ankles	18) been anxious or worried
6) been fatigued (no energy/very tired)	19) frequent or painful urination
7) difficulty breathing or shortness of breath	20) lost control of your urine and wet yourself
8) chest pain or tightness	21) has a family member or friend become seriously ill or had an accident
9) poor or decreased vision	22) experienced the death or loss of a family member or friend
10) been dizzy or unsteady on your feet	23) a change in your medications
11) a fall or injury	24) a problem with alcohol
12) been afraid of falling	25) other reason(s) for restricted activity
13) cold or flu symptoms	

a. Restricted activity is defined as a "Yes" response to one or both of the following questions: "Since we last talked on (date of last interview), have you cut down on your usual activities due to an illness, injury or other problem?" and "Since we last talked on (date of last interview), have you stayed in bed for at least half a day due to an illness, injury or other problem?"

Medicare data

Detailed participant-level data on health care utilization (from 1997 forward) are obtained annually through linkages

with Medicare claims, using procedures adapted from prior studies (17). Claims are divided into files based on billing form and location of care (inpatient hospital, outpatient, skilled nursing facility, hospice, and home health) (18). Assessment data are available from the Long Term Care Minimum Data Set (MDS) and Home Health Outcome and Assessment Information Set (OASIS).

What has it found? Key findings and publications

To date, 117 original reports have been published using data from the PEP Study, including several led by investigators outside of Yale. (9-24) A complete listing is provided in the Supplementary Material and is available at https://medicine.yale.edu/intmed/geriatrics/research/disability.aspx. Three major areas of investigation include the epidemiology of disability, the role of intervening events on the disabling process, and disability and distressing symptoms at the end of life.

Epidemiology of disability

Findings from the PEP Study have demonstrated that disability among older persons is a complex and highly dynamic process with considerable heterogeneity and multiple potential pathways (16, 25). Newly disabled elders have high rates of recovery, but those who recover are at high risk for recurrent disability (26). Lending support to efforts designed to promote physical activity among vulnerable older persons (27), PEP investigators have shown that habitual physical activity is associated with shorter time to recovery and longer duration of recovery (28). Subsequent work has demonstrated frequent transitions between states of independence and disability over time, with frail participants having higher rates of transitions to states of greater disability and lower rates of transitions to states of lesser or no disability (29). These findings support the supposition that a key consequence of frailty is unstable disability, in which persons experience substantial fluctuation in function in the setting of minor external events (30). Multistate models have also been used to evaluate gender differences in disability (31), investigate the role of depressive symptoms on the disabling process (32) and determine the effect of prior disability history on subsequent functional transitions (33).

More recently, the monthly PEP data have been used to evaluate functional trajectories before and after a serious fall injury (34), critical illness (35), and major surgery (36). For each of these acute events, the pre- and post-trajectories were quite varied but highly interconnected, suggesting that the likelihood of functional recovery is greatly constrained by the pre-event trajectory. Subsequent studies have highlighted the adverse consequences of frailty, cognitive impairment, and sensory impairments on functional recovery after these acute events (37-41).

Role of intervening events on the disabling process

Factors such as frailty and cognitive impairment may make older persons susceptible to developing disability, but they do not directly lead to disability in most cases. Findings from the PEP Study have shown that disability is commonly precipitated by an intervening illness or injury leading to hospitalization or restricted activity (12). The population-attributable fractions associated with hospitalization and restricted activity were 0.48 and 0.19 for any disability and 0.82 and 0.05 for disability with nursing home admission. While cardiac (coronary heart disease, congestive heart failure, arrhythmia, etc) was the most common diagnostic category for hospitalization, fall-related injury conferred the highest risk, with 79.4% of hospital admissions for a fall-related injury leading to any disability and 58.8% to disability with nursing home admission. A subsequent study found that fall-related injuries are associated with worse disability outcomes and a higher likelihood of long-term nursing home admissions than all other conditions leading to hospitalization (considered collectively) (14). These findings are important because fall-related injuries are costly and preventable (42-44). Pronounced deleterious effects of intervening illnesses and injuries have also been found for long-term disability in community mobility (15) and transitions between states of independence and disability (45).

Disability and distressing symptoms at the end of life

As the number of decedents has accrued over time, the PEP Study has become a valuable resource for end-of-life research. In a study of 383 decedents (5), five distinct trajectories of disability were identified in the last year of life, from least disabled to most disabled (Figure 2). When the distribution of the disability trajectories was evaluated according to the condition leading to death, a predominant trajectory was observed only for advanced dementia and sudden death (Figure 3). These results suggested that the need for services at the end of life to assist with basic actitivies of daily living is at least as great for older persons dying from organ failure and frailty as for those dying from a more traditional terminal condition such as cancer and is much greater for older persons dying from advanced dementia. In a subsequent study (46), strong associations were found between the occurrence of acute hospital admissions and the course of disability in the last year of life for each of the trajectories.

Additional end-of-life research has shown that symptoms leading to restrictions in daily activities are common during the last year of life and increase substantially about five months before death (47), that the burden of these restricting symptoms decreases substantially after the start of hospice (48), and that hospice is suitably targeted to older persons with the greatest needs based on the burden of restricting symptoms and disability (49). Most recently, days spent at home, an important patient-centered outcome, has been evaluated at the end of life. Only 3 of 10 community-living older persons spent the entire period in the last 6 months of life at home, as opposed

to a health care facility, and more than a third were at home for fewer than 150 days (50).

Figure 2

Disability trajectories in last year of life among 383 decedents. The severity of disability is indicated by the mean number of basic activities of daily living (ADLs) in which the participants had disability (possible range: 0 to 4). The solid lines indicate the observed trajectories, and the dashed lines indicate the predicted trajectories. The I bars indicate 95% confidence intervals for the observed severity of disability

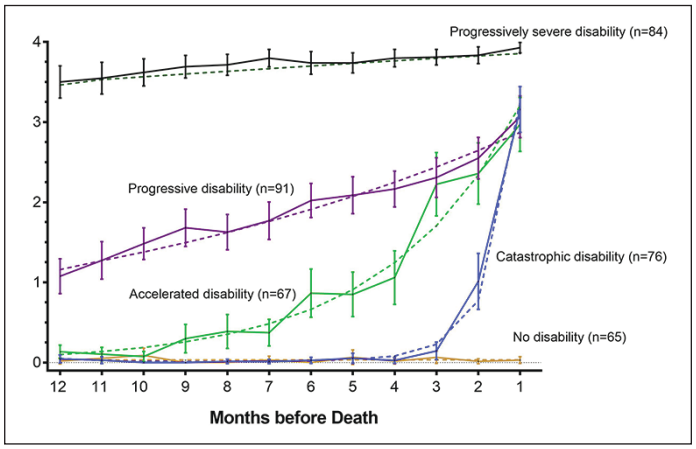

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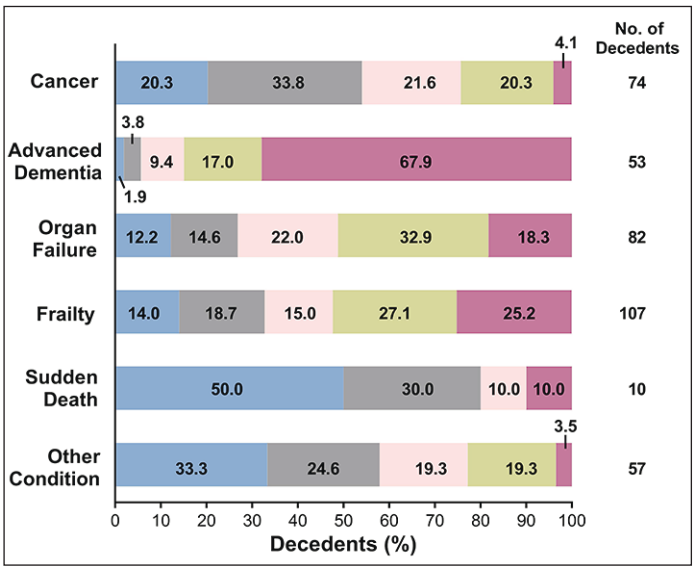
Figure 3

Distribution of disability trajectories in last year of life, according to condition leading to death among 383 decedents. The values within the bars are the percentages of decedents with the disability trajectories



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What are the main strengths and weaknesses?

The PEP Study has several important strengths, including the frequency of assessments, long duration of follow-up, high retention, completeness of data collection, and linkage to Medicare data. While many other longitudinal studies have completed assessments at regularly-spaced intervals, usually ranging from 6 months to 5 years, no other study to our knowledge has interviewed participants as frequently as PEP. The availability of data from monthly interviews over the course of more than 21 years makes PEP a unique resource for prospectively investigating function, symptoms, and health care utilization in older persons, including at the end of life. The comprehensive assessments at 18-month intervals provide high quality data on a core set of aging-relevant factors from multiple domains, including demographic, health-related, functional, cognitive, psychosocial, behavioral, and physical capacity. The linkage to Medicare data provides opportunities to evaluate high priority problems such as serious fall injuries, critical illness, and major surgery.

Potential weaknesses include generalizability and absence of biological markers. Because PEP participants were members of a single health plan in a small urban area, findings may not be generalizable to older persons in other settings. Generalizability, however, depends not only on the choice of the study sample but also on the stability of the sample over time (51). One of the great strengths of PEP is the low attrition rate. The generalizability of PEP findings is also enhanced by the high participation rate, which was greater than 75%. To reduce respondent burden and minimize attrition, serum and other biological specimens were not collected during the home visits at the outset of the study (in 1998). Although less invasive alternatives to venipuncture, such as dried blood spots (52), became available during the next decade, "value added" was felt to be limited given the attrition of the cohort due to deaths. The PEP Study was designed to elucidate the epidemiology of disability rather than the biological underpinnings of disability.

Can I get hold of the data? Where can I find out more?

The PEP Study welcomes proposals to access data for meritorious analyses from qualified investigators. Requests for an application and all other enquiries should be directed to Thomas Gill [thomas.gill@yale.edu].

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