Search results for 2019 International Pressure Injury Guideline: Biophysical agents


Additional citations
Identified by working group members
n=36

QOL keywords
Patient education, self-care, self care, patient knowledge, wellbeing, happiness, quality of life, QOL, quality of life, self-esteem, consumer, engagement, involvement, lifestyle, preference, choice, literacy, EQ-5D, SF-36, patient reported outcome

Additional citations
Appraised for previous editions
n=6

Identified in pressure injury searches
n=11,177

Excluded after screening title/abstract
- Duplicate citations
- Included in previous guideline
- Not related to pressure injuries
n=8,128

Identified citations
n=3,085

Excluded based on key word searches
- Not related to the topic-specific questions
n=3,025

Identified in topic-specific key word searches for full text review and critical appraisal
n=60

Excluded after review of full text
- Not related to pressure injuries
- Not related to the clinical questions
- Citation type/research design not meeting inclusion criteria
- Non-English citation with abstract indicating not unique research for translation
n=46

Identified as providing direct or indirect evidence related to topic and critically appraised
n=14

Total references providing direct or indirect evidence related to topic
n=20

## Articles Reviewed for International Pressure Injury Guideline

The research has been reviewed across three editions of the guideline. The terms pressure ulcer and pressure injury are used interchangeably in this document and abbreviated to PU/PI. Tables have not been professionally edited. Tables include papers with relevant direct and indirect evidence that were considered for inclusion in the guideline. The tables are provided as a background resources and are not for reproduction.


### Measurement tools

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rutherford et al., 2018</td>
<td>Psychometric study evaluating a tool for measuring patient reported outcomes</td>
<td>Participants were a subgroup of another pressure injury study in UK (n=617) Recruited in secondray care hospitals</td>
<td>N/A</td>
<td>PU-QOL contains 10 scales for measuring: symptoms, physical functioning, psychological well-being and social participation specific to pressure ulcers. nine PU-specific outcomes: three symptom and six function scales</td>
<td>Internal consistency (Cronbach's alpha values ranging 0.795 - 0.97)</td>
<td></td>
</tr>
<tr>
<td>C. Gorecki et al., 2013</td>
<td>Psychometric study evaluating a tool for measuring patient reported outcomes</td>
<td>Participants recruited in England and Scotland NHS community trusts (n=229 for final psychometric analysis) Inclusion: Aged over 18 years</td>
<td>N/A</td>
<td>Patient-reported outcome tool, PU-QOL. PU-QOL contains 10 scales for measuring: symptoms, physical functioning, psychological well-being and social participation specific to pressure ulcers. patients rate the amount of “bother” attributed during the</td>
<td>• Reliability: (Cronbach’s alpha values ranging 0.89 - 0.97) • validity: correlation between PU-QOL and SF-12 scores (r &gt;0.30) and PU-QOL scales and sociodemographic variables (r &lt;0.30) were consistent with predictions). Author conclusion: PU-QOL instrument provides a standardized method for assessing PROs</td>
<td></td>
</tr>
</tbody>
</table>

(c) EPUAP/NPIAP/PPPIA. Not for reproduction.
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chaboyer et al., 2017</td>
<td>The aim of this study was to develop the Patient Participation in Pressure injury prevention (PPPIP) scale as well as undertake initial testing of some of its psychometric properties.</td>
<td>Participants recruited in 8 hospitals in Australia (1598 eligible, n=1332 responding to the PPPIP scale). Inclusion criteria: • 18 years or older, • expected hospital stay &gt; 48 hours • at risk of PI as measured by limited mobility • able to read English and consent. Exclusion criteria: • Admitted to the hospital for &gt; 36 hours prior to recruitment • maternity, pediatrics, mental health, dialysis, day surgery, ICU, emergency department, • previous trial participants • receiving end of life care.</td>
<td>Phase 1: PPPIP scale development Phase 2 Psychometric testing: The PPPIP scale was administered by a research assistant when patients developed a PI, was D/C’d from hospital, or reached 28 days in the study – whichever of these came first. Their responses were entered directly into the trial database.</td>
<td>Outcome measure: Patient Participation in Pressure Injury Prevention Scale items (PPPIP). Patient participation in pressure injury prevention scale items included 7 items on knowledge, decision making and family engagement</td>
<td>Outcome 1 Internal consistency reliability: Subsample A $ \times = 0.86 $ Subsample B $ \times = 0.86 $ Internal consistency reliability reported Summary of psychometric testing: The EFA and CFA suggest that the seven items in the PPPIP reflect a unidimensional measure that focuses on PIP, with high scores reflecting high-patient participation in PIP and low scores reflecting low-patient participation in PIP.</td>
<td>• 83.4% of participants completed PPPIP. of those 51.7% completed every item in the scale • Force-choice response • PPPIP was administered by research assistant, so not known if the scale could in a self-report form. • Sample reflected limits the generalizability of the current scale. • Measure of patient participation, distinctions between concepts such as participation, engagement and involvement are not clear.</td>
</tr>
<tr>
<td>de Laat, de Munter, van der</td>
<td>Cross sectional study</td>
<td>Recruited in 2 rehabilitation centers in Netherlands</td>
<td>N/A</td>
<td>• Questionnaire on demographics. Paraplegia</td>
<td>• mean PAM-score was 54 (±8.1) indicating a low level of health activation</td>
<td>Investigates patient engagement in care</td>
</tr>
</tbody>
</table>
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burg, Ulrich, &amp; Kloeters, 2017</td>
<td>exploring self management behavior of paraplegic individuals</td>
<td>(n=441 eligible, n=170 included, n=162 analyzed)</td>
<td></td>
<td>information, information about PU history, general health • Quality of life on EQ5D-3L and the VAS • Patient Activation Measure (PAM-score) used to measure extent of health activation. (0-100)</td>
<td>• Level of education (OR 2.2, p =0.017) and degree of paraplegia (OR 2.8, p = 0.036). were significantly associated with health activation • Pressure injury history and level of paraplegia not related to health activation</td>
<td>Peripherally related to pressure injuries Limited to paraplegic individuals</td>
</tr>
<tr>
<td>Kisala, Tulsky, Choi, &amp; Kirshblum, 2015</td>
<td>Validation of self-reported HRQOL tool for individuals with SCI and pressure ulcers</td>
<td>N=189 adults with traumatic SCI who experienced a pressure injury</td>
<td></td>
<td>30 items related to pressure injuries</td>
<td>12-item SCI-QOL Pressure Ulcers scale • Test re-test for 7-item version (n=245 participants) r=0.79, ICC (2,1) = 0.79 (95% CI 0.74 to 0.84) SCI-QOL PrU scale is a psychometrically sound measurement tool, which can reliably estimate HRQOL effects of PrUs in a traumatic SCI population.</td>
<td>Scale may be administered in its entirety or as a 7-item “short form”</td>
</tr>
<tr>
<td>Lourenco, Blanes, Salomé, &amp; Ferreira, 2014</td>
<td>Cohort study comparing HRQOL in individuals with SCI who do and do not have pressure injuries</td>
<td>Participants recruited in Brazilian outpatient clinic, rehab center, sports associate (n=120 total, n=60 with pressure injuries)</td>
<td></td>
<td>Brazilian/Portuguese version of the Self-Esteem Rosenberg Scale (RSE/UNIFESP-EPM)20 Includes eight subscales: physical functioning, role physical, bodily pain,</td>
<td>Pressure injury cohort had significantly lower scores (worse health status) on all SF-36 subscales (p&lt;0.0013) except for general health (p=0.109). The RSE/UNIFESP-EMP scale total score was significantly higher in the study group than in the control group (p=0.001), indicating that patients with • Self-esteem can be defined as the perception of self-worth and value, or in other words, the evaluation that the individual makes regarding himself.</td>
<td></td>
</tr>
</tbody>
</table>

Data Tables: 2019 Guideline Update: QOL
© EPUAP/NPIAP/PPPIA
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gélis et al., 2011</td>
<td>Psychometric study on a self-administered patient checklist on knowledge and prevention</td>
<td>Participants for the reliability study were recruited from 6 centers in France (n=138)</td>
<td>revised-Skin Management Needs Assessment Checklist (SMnac) self-administered, 12 question Likert score survey covering skin checks, preventing PU and preventing wounds.</td>
<td>general health, vitality, social functioning, role emotional, mental health Cronbach’s alpha values for the SF-36 and EPM/UNIFESP scale were 0.790 and 0.745, respectively</td>
<td>pressure ulcers had lower self-esteem than controls</td>
<td>The self-esteem and HRQoL of individuals with SCI are negatively affected because of loss of control over bodily functions and inability to perform self-care. Participants with pressure ulcers have negative experiences related to social and emotional. Therefore, routinely assess risk of developing PUs and HRQoL and self-esteem</td>
</tr>
</tbody>
</table>

Characteristics:
- Mean age 45.9±14.9 years
- 75% sample male
- 60% had complete injury (ASIA-A)
- 66% had no Pus, 25% had one PU of Pus present, 65% were grade III=IV

- Previously, English language psychometric properties have been tested:
  - Internal consistency (Cronbach’s alpha: 0.85); test-retest reliability (ICC=0.90)

  In this study, French version was tested: Feasibility and acceptability (n=12)
  - Patients found the survey and its easy to use

  Reliability (n=138)
  - Intraclass coefficient (ICC) = 0.899 (95% CI 0.862 to 0.927)

- Participants were all recent SCI patients, or had been recently hospitalized so may have had recent education Self-administered tool, unclear on conditions for administration

Level of Evidence: 4
Quality of evidence: low
Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lane, Selleck, Chen, &amp; Tang, 2016</td>
<td>Retrospective cohort study investigating efficacy of smoking cessation in individuals with SCI</td>
<td>Groups recruited through electronic record review at an outpatient wound clinic in the US</td>
<td>• Smoking cessation program initiated at the wound clinic and based on US national guidelines using the 5As program&lt;br&gt;• Controls- seen in the 6-months prior to the smoking cessation program (n=83)&lt;br&gt;• Cases- seen in the 6-months after the smoking cessation program was introduced (n=75)</td>
<td>• Chart review</td>
<td>Impact of smoking cessation on smoking status&lt;br&gt;There was a statistically significant increase in the number of participants who stopped smoking during the period of observation (44% vs 21%) (χ²= 4.45, p=0.03)&lt;br&gt;&lt;br&gt;Impact of smoking cessation on choice to have PU surgery&lt;br&gt;There was no statistically significant difference in percent of participants who desired and underwent surgery (45% control versus 35% case, p=0.35)&lt;br&gt;&lt;br&gt;Impact of smoking cessation on PU healing&lt;br&gt;• More smokers than non-smokers had a PU (smokers 24.1% versus non-smokers 10.8%, p=0.03)&lt;br&gt;• Smokers had higher decrease in number of wounds (65.2% versus 33.3%, p=0.03)&lt;br&gt;• Smokers experienced significant increase in total wound size compared to non-smokers and smokers who stopped smoking (17.8cm³ versus -14.2cm³ versus -170.3cm³, F=5.6, p=0.004)</td>
<td>• Factors that could influence success of smoking cessation program (e.g. baseline number, social factors such as other smokers in family) were not collected&lt;br&gt;• Relied on report of patient re smoking status&lt;br&gt;• Small sample size&lt;br&gt;• Relied on data base entries&lt;br&gt;• Full extent of intervention was not reported (e.g. how many sessions per patient)&lt;br&gt;• Sustainability not demonstrated&lt;br&gt;• Unclear who assessed wounds and what strategies used for same</td>
</tr>
</tbody>
</table>
| Schoeps, Tallberg, & Gunningberg, 2017 | Pretest-post test to improve knowledge of | Convenience sample of individuals undergoing surgery (n=31) | Patient information sheet left on bed | • Non-validated questionnaire<br>• Data collected 2 days after pamphlet left | • There was a significant increase in patients receiving information about PU risks (13% vs 28%, p=0.013) | Non-validated data collection<br>Self reported (including pressure injuries) |}

Clinical Question 2: What are effective strategies for engaging individuals in pressure injury prevention and treatment?
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Quality of evidence</th>
</tr>
</thead>
</table>
| Houlihan et al., 2013; Mercier, Ni, Houlihan, & Jette, 2015 | RCT comparing a self-efficacy telephone intervention | Participants recruited in the community US (n=142)  
Inclusion: MS or SCI  
Using wheelchair > 6 hours/day  
Private residents with phone access  
Health insurance  
Exclusion: Category/Stage II or greater pressure injury  
Severe depression  
Bipolar disorder  
Characteristics: 38% female  
Mean age 48 years  
46.5% history of pressure injuries | Randomized to receive: “CareCall” which is an automated telephone-based voice response system. Intervention provides education, cognitive behavioral interventions, screening, referrals and alerts a nurse for follow-up. (n=71)  
Usual care consisting of a resource book (n=71) |  
- PUSH scale  
- Patient Health Questionnaire—9 depression scale  
- Cornell Services Index  
- Craig Hospital Inventory of Environmental Factors-Short Form Question 5 |  
- There was a significant increase in patients receiving information about PU causes (13% vs 48%, p=0.001)  
- There was a significant increase in patients receiving information about PU prevention (14% vs 47%, p=0.001)  
- Participation in care  
- 46% of post-pamphlet group reported engaging in PU prevention including moving in the bed, moving feet and changing position  
Pressure injuries  
- Intervention did not have an overall positive impact on reducing the number of pressure ulcers at 6 months, controlling for baseline number of pressure ulcers, age and gender.  
  - In women receiving intervention  
  - there were no pressure ulcers at the 6-month visit (p = 0.04)  
Feasibility and acceptability  
- 22% of intervention group were non-adherent (missing 3 or more calls in a row, 3 separate times over 6 months  
- Average call length 12.6 minutes(see Mercier et al 2015)  
- Described as most useful by 70% of participants (see Mercier et al 2015)  
- Written support was described as useful by 10% of individuals with SCI and 6.3% of MS. (see Mercier et al 2015) | No evidence the pamphlet decreased PU Quality: low | Level of evidence: 1  
Quality: moderate |
<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carlson et al., 2017</td>
<td>To test the efficacy of a lifestyle-based intervention designed to reduce incidence of Medically serious pressure injuries (MSPrIs) in adults with SCI.</td>
<td>Participants recruited in rehabilitation facility in US (n=170 plus 62 non-randomized controlled)</td>
<td>Randomized to either: • The Pressure Ulcer Prevention Program (PUPP) consisted of six modules. Lifestyle-based intervention, knowledge on prevention, and application to a person’s circumstances, information, activities, and exercises. Ongoing and intensive exposure to PUPP content (n=83) • Control group: no intervention (n=87) Standard care included clinic visits to undergo skin checks and receive necessary medical treatment and advice when a PI was present.</td>
<td>• Blinded assessments of annualized MSPrI incidence rates at 12 and 24 months, based on: skin checks, quarterly phone interviews with participants, and review of medical charts and billing records. • Secondary outcomes included number of surgeries and various quality-of-life measures</td>
<td>Annualized MSPrI rates • No significant difference • 12 months: 0.56 intervention versus 0.48 controls • 24 months: 0.44 intervention versus 0.39 control • Rate ratio for serious MSPrIs at 12 months in intervention group was 1.15 (95% CI 0.76 to 1.76, p=NS) • Rate ratio for serious MSPrIs at 24 months in intervention group was 1.14 (95% CI 0.72 to 1.82, p =NS) Both groups improved significantly on: • physical functioning (effect size (ES) =0.40 for intervention, 0.50 for control) • physical role limitations (ES=0.72 for intervention and 0.32 for control) • emotional role limitations (ES=0.31 for intervention and 0.38 for control) • social functioning (ES=0.28 for intervention and 0.38 for control) • pain (ES=0.41 for intervention and 0.33 for control) • depression (ES=-0.36 for intervention and -0.33 for control).</td>
<td>• Limited generalizability • Participants had higher MSPrI rate, require a more intensive intervention, and sustain greater PI risk even with intervention services. Results of this study may not be directly applicable to more typical SCI populations</td>
<td>1</td>
<td>high</td>
</tr>
<tr>
<td>Hossain et al., 2017</td>
<td>And home visit care program compared to standard treatment</td>
<td>Community-based individuals with SCI in Bangladesh (n=30)</td>
<td>Intervention: telephone support (fortnightly for one year, monthly for second year) and home visit (3 times over 24 months ) providing education and support; small financial</td>
<td>• SF-12 • Pressure injury incidence • Beck Depression scale</td>
<td>Pressure injury incidence a telephone support and home visit education program was associated with no significant difference in pressure injury incidence compared to standard care (20% vs 13.3%, p = not reported)</td>
<td>• Small sample size, failed to reach statistical power but was designed to test sample sizes for a future study</td>
<td>1</td>
<td>moderate</td>
</tr>
</tbody>
</table>
### Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arora et al., 2017</td>
<td>To determine the effectiveness of telephone-based management of pressure ulcers in people with spinal cord injury in low- and middle-income countries</td>
<td>Participants were recruited in community settings in Bangladesh and India (n=120)</td>
<td>• Mean age 35 years</td>
<td>support for equipment (n=15 randomized, n = 14 completed) Control group (n=15 randomized, n = 14 completed) Intervention delivered by a trained physiotherapist</td>
<td>Feasibility 87% of phone calls and 100% home visits were delivered</td>
<td>• No inter-group analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participants were randomized to:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention group: (n=60)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pamphlet with information about PU management</td>
<td></td>
<td></td>
<td>Size of pressure injury</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• free to seek any help or medical assistant</td>
<td></td>
<td></td>
<td>The mean between-group difference for the size of the PU at 12 weeks, adjusted by baseline size , was 2.3cm² favoring the intervention group (95% CI -0.3 to 4.9; P=0.008).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Weekly phone calls from a trained health-care professional (nurse or physiotherapist) for 12 weeks.</td>
<td></td>
<td></td>
<td>Confident in managing pressure injury (10-point NRS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• reinforcing self-help strategies, minimizing psychological stress and enhancing engagement with life.</td>
<td></td>
<td></td>
<td>Between group difference of 1.7 (1.0 to 2.3; P&lt;0.001) favoring intervention group</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Participants and families received education and advice about appropriate seating, bed overlays, cushions, equipment, diet, nutrition and wound dressings. Advise about techniques to relieve pressure and when to seek further medical or nursing attention. Some were advised to remain on strict bed rest. Advise to minimize dampness associated with incontinence,</td>
<td></td>
<td></td>
<td>QoL rating (EQ-SD 100-point VAS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Three trained, blinded assessors.</td>
<td></td>
<td></td>
<td>Improvements in quality of life were superior in intervention group (mean between-group difference on EQ-SD VAS, 10.5, 95% CI 4.5 to 16.6; p=0.001)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Time of healing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Primary outcome: size of PU at 12 weeks (length and width expressed as cm²)</td>
<td></td>
<td></td>
<td>The results of our primary outcome (size of PU) do not provide conclusive evidence that people with SCI can be supported at home to manage their Pus through regular telephone-based advice.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Secondary outcomes:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o PUSH</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o depth of PU</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Undermining</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Braden scale</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o HADS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Participation items (WHODAS), Utility score (EQ-SD-5L), Self-rated health (EQ-SD-VAS), Participants’ impression of PU status,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Participants’ confidence to manage PU,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Clinician’s impression of PU status,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Participants’ satisfaction,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Participants’ PU at baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

Data Tables: 2019 Guideline Update: QOL © EPUAP/NPIAP/PPPIA Page 9
### Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Hilgart et al., 2015 | Observational study investigating utility of an online education package for people with SCI | Participants with SCI were recruited from a rehabilitation in the US (n=8, 7 completed study) | Internet-delivered interactive education program developed by a range of health professionals. Includes 3 Cores (overview and personal risk; PUs in real life; and healthy skin behaviors), modules, follow-ups and diaries. Participants were given access to the program for 6 weeks. | Program usage Measured through login numbers, completion of cores, use of diaries, follow-ups and modules. | Study completion 1/8 participants did not complete the evaluation | • 12.5% drop out  
• Very small sample size  
• Participants not representative of SCI population, which is primarily male  
• Potential sample bias  
• Participants paid to participate  
|  |  |  |  |  |  | Indirect evidence: PU not an outcome measure |

- Mean time since injury 7 years
- Mix of complete and incomplete SCI
- PU Category/Stage II (n=35); III (n=83) and IV (n=2)
- The groups were similar at baseline

- Each week goals were negotiated and were reviewed at the next phone call. Control group: (n=60)
- Pamphlet with information about PU management and were free to seek any help or medical assistant that they deemed appropriate

- Self-reported time for PU resolution
- Follow up period 12 weeks

- Internet-delivered evaluation questionnaire (15 Likert scales questions and 3 open ended response questions) covering experiences and perceptions
- Study completion 1/8 participants did not complete the evaluation

- Program accessed mean 14.86±10.75 unique times over 6 weeks (range 7 to 38)
- Mean diary entries 19.57±13.21 (range 5 to 42)
- Mean module completion 6.86±4.45

- Evaluation 86% found program helpful in behavioral support for skin care activities
- 71% rated program as mostly or very effective for themselves
- 71% rated diaries as mostly or very helpful in tracking daily skin care
- 86% stated they were able to follow program
- 86% rated program as somewhat, mostly or very helpful in promoting confidence in skin care
<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Guihan et al., 2014 | To compare a multicomponent motivational interviewing self-management intervention with a multicomponent education intervention to improve skin-protective behaviors and prevent skin worsening | Participants recruited in SCI centers in the US (n=143)  
Inclusion criteria:  
- Aged ≥18 years  
- Category/Stage III or IV pelvic pressure injury  
- SCI > 6 months prior  
Exclusion criteria:  
- terminal diagnosis  
- severe psychiatric comorbidities or cognitive impairments  
- severe hearing loss  
- wound not expected to heal  
- discharged to nursing home  
Participant characteristics:  
- mean age 59.3±11.5  
- 97.2% male  
- white 68.5%, black 26.6%, Hispanic American 4.2%, other 0.7% | Participants randomized to intervention or control  
Regimen for intervention group  
- 7 conference calls 45-60mins covering self-management, skin education, problem solving, self-monitoring skills, communty resource utilization, relaxation, stress management, improving provider relationships, development of action plans  
- Phone call reminders  
- study materials sent by mail  
- Participants received motivational interviewing 8 times over 24 weeks to elicit talk of change in behavior related to improving skin care  
Regimen for comparison group  
Same number of audiotaped calls and same schedule but providing education and advice only plus the written SCI education guide.  
Group leaders received training in chronic disease self-management and were | Recorded number of guideline recommended skin care behaviors using a self-administered skin care behavior check list over previous week  
- skin status by digital photography and planimetry  
- health care utilization  
- Skin related visits using international classification of diseases  
- self-reported days of bedrest resulting from skin problems  
- self-management assessment using self-efficacy scales  
- the pressure ulcer knowledge test  
- patient health questionnaire  
Skin care behaviors  
Possible self-reported skin care behaviors being conducted (%)  
Change over time was not significant for either group at 6 months (p=0.45)  
There was a non-significant greater improvement in intervention vs control from admission at 3 months (mean 83.5%±17.5 vs 79.5%±19.6 P=0.21) and at 6 months (mean 85.0%±15.2 vs 83.0%±14.6 P=0.41).  
Skin status:  
52.8% experienced worsening not significant between groups. SM+MI 35(49.3%) vs 39(54.2%) P=0.51. within 0-3 months SM+MI 26(36.6%) vs 28(38.9%) and 4-6months 9(12.7%) vs 11(15.3%) P=0.86.  
VA health utilization  
no difference between groups  
Skin related visits  
no difference between groups  
Feasibility  
Intervention group, 81% received minimum of 4 calls vs education control 86% received of 4 minimum calls | Underpowered  
- High attrition rate  
- Inadequate dose of SM+MI and control treatment (especially group calls)  
- Poor reliability between site coordinators  
- Behavior checklist not validated  
- Healing and worsening captured in only largest pressure injury  
- Several people involved in interventions without mention of reliability  
- Not enough information on other patient factors | Level of evidence: 1  
Quality: moderate quality |
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Kim & Cho, 2017 | To develop a self-efficacy enhancement program and evaluated its effects on the self-care behaviors, self-care knowledge, and self-efficacy regarding pressure ulcer prevention in patients with a spinal cord injury. | Participants recruited in 6 hospitals in Korea (n=47)  
Inclusion criteria: spinal cord injury undergoing rehabilitation after receiving acute treatment  
≥20 years old; Able to use a wheelchair independent self-care >6 months post-spinal cord injury diagnosis  
no cognitive impairment, psychiatric history, or pressure ulcer history; Internet access at home | The experimental group participated in the 8 week self-efficacy enhancement program that consisted of small group face-to-face intervention (education and skills training), education with computer animation, phone counseling, face-to-face counseling, and self-management records. (n=24)  
The control group participants did not receive training in, or demonstrations of, selfcare skills and were only given information with a booklet (n=23). | The pretest data were collected in both the experimental and the control groups including the demographic characteristics, clinical characteristics, self-care knowledge, self-efficacy, self-care behaviors, and skin condition.  
The post-test data on self-care knowledge, self-efficacy, self-care behaviors, and skin condition | Eight week outcomes  
The experimental group showed a significantly greater improvement in self-care knowledge, self-efficacy, and self-care behaviors for pressure ulcer prevention than did the control group.  
Pressure ulcer outcomes  
One participant in the control group developed a pressure ulcer, none of the participants in the experimental group developed a pressure ulcer (p>0.05) | Limitation Some measurement instruments needing testing for reliability and validity.  
follow-up period in this study might have been insufficient to accurately evaluate the effectiveness of a self-efficacy enhancement  
Small sample size |
| Rottkamp, 1976 | To determine the effectiveness of a body positioning | Participants were recruited in a SCI service (n=10)  
Inclusion: | Randomized to receive:  
Intervention | Nurses observed position changes  
Short term, 24 hour follow up | Frequency of position changes increased significantly in experimental groups vs control (p=0.016)  
Use of prone position unchanged | Very small study  
Subjective outcome measures  
Minimal methods reported |

Data Tables: 2019 Guideline Update: QOL

© EPUAP/NPIAP/PPPIA  
Page 12
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>education program</td>
<td>Sensory impairment in positioning Upper body mobility No plans for discharge or surgery Can tell the time, differentiate direction and read</td>
<td>• body-positioning training sessions of 10 to 60 mins duration, 6 to 12 times/week • Verbal encouragement from nurses • Written steps and illustrations provided • Skills demonstration and practice • Written positioning schedule Control • Usual care</td>
<td>Frequency of intervals of prolonged skin pressure were significantly fewer in experimental group (p=0.004)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brace &amp; Schubart, 2010</td>
<td>Case series reporting effectiveness of an e-learning program for people with PU and SCI</td>
<td>Participants recruited from two sites, a trauma hospital and an outpatient rehabilitation Center in the USA. (n=27 met inclusion, n=16 completed study) Inclusion: • SCI at any level • aged ≥18 years and of any ethnic group • with or without current PU or PU history • medically stable • transferred to an acute rehabilitation facility Exclusion: • non-English speaking • medically unstable Characteristics: Mean age 41 years (range 34 to 72) Mean hospital duration: 18.6 weeks</td>
<td>• E-learning program on PU prevention and management in adults (see also Schubart, 2012) • Pre-and post-test assessment using 20 multiple choice questions addressing the primary focus of the E-learning program. The questionnaire was validated in a population of 12 nurses.</td>
<td>• Median pre-test score was 65% (range 25% to 100%). Median post test score was 92.5% (range 75% to 100%) • 15/16 participants achieved improved scores on post-test compared to pre-test. • PU staging questions were more frequently answered incorrectly. Study conclusions: an E-learning program is associated with increased knowledge regarding PU staging, prevention and support services in patients with SCI.</td>
<td>• Indirect evidence, PU occurrence is not an outcome measure • Sample size small • No statistical analysis so unclear if the findings are significant • Broad ethnic and age groups selected but no analysis to indicate if the program was equally effective for all demographics. • Sample had a high education level at commencement with almost 50% having attended tertiary or greater education.</td>
<td>Indirect evidence Quality of evidence: low</td>
</tr>
</tbody>
</table>
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>J. Schuhart, 2012</td>
<td>Case series reporting on a patient education e-learning package for individuals with SCI</td>
<td>Participants recruited from an outpatient rehabilitation Center in the USA. (n=15, n=14 completed)</td>
<td>E-learning program on PU prevention and management in adults (also pilot - tested in earlier study Brace 2010) Program allowed participants to complete the learning package in multiple sittings over a two week timeframe. Participants evaluated the program</td>
<td>Assessment of e-learning program using validated tools with Likert scales: Internet Evaluation and Utility (ease of use, convenience, engagement, enjoyment, layout, privacy, satisfaction and acceptability) Internet Impact and Effectiveness Questionnaire (usefulness, comprehension, credibility, likelihood of returning, mode of delivery and helpfulness)</td>
<td>Participant assessment of e-learning package: The program scored very favourably on all items related to potential access barriers and favourably for items related to utility, impact and effectiveness. Knowledge: The median score for pre-program knowledge and skin care management practice was 96 (possible score: 0 to 120; range 70–100). Post-program use median score was 107 (range 97–114). The greatest improvement was in the responses to knowledge and practice questions about skin checks and preventing skin problems (p&lt;0.005). Study conclusions: People with an SCI who have at least high school level education rated an e-learning package</td>
<td>Small sample size from limited ethnic background Questions assess perceived knowledge and their perceived ability to perform preventive actions. No real insight in the objective knowledge or practice of the participants PU not an outcome Non-validated assessment tools No statistical analysis Details of program not reported</td>
</tr>
</tbody>
</table>
# Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Garber, Rintala, Holmes, Rodriguez, &amp; Friedman, 2002</td>
<td>Quasi-experiment comparing a multi-faceted education program to no education</td>
<td>Veterans with SCI recruited in US Post-surgery for a Category/Stage III or IV PU</td>
<td>Four one-hour sessions that included: Didactic, written, training of family, knowledge test (n=20) No intervention (n=21)</td>
<td>Internet Adherence Questionnaire (barriers to use) Assessment of effectiveness of program was made using Needs Assessment Checklist, a non-validated structured tool to assess self-perceived knowledge and self-perceived care ability Skin Care Knowledge and Practice Questionnaire Assessments via phone interview 6 month followup</td>
<td>highly with respect to utility, impact and effectiveness and perceived that their knowledge had increased after using it; however, there was no objective assessment conducted</td>
<td></td>
</tr>
<tr>
<td>Rintala, Garber, Friedman, &amp; Holmes, 2008</td>
<td>Randomized controlled trial investigating an education</td>
<td>Participants were individuals with SCI recruited from a veterans affairs medical center in US (n=41)</td>
<td>● All participants received standard care pre and post surgery. Participants were randomized to receive:</td>
<td>Primary outcome was time to pressure ulcer recurrence Self assessed health status</td>
<td>There was a main effect of time (admission versus discharge, F = 37.23, p &lt; 0.0001), no main effect of group (intervention group versus control group, F = 1.22, p &lt; 0.28), and an interaction effect (time by group, F = 4.72, p &lt; 0.04). Both groups gained some knowledge during their hospitalization, but the enhanced education group gained more (20 versus 10 percentage points gained).</td>
<td></td>
</tr>
</tbody>
</table>

- **Ref**: Reference
- **Type of Study**: Study type
- **Sample**: Description of sample
- **Intervention(s)**: Details of intervention(s)
- **Outcome Measures & Length of Follow-up**: Details of outcome measures and length of follow-up
- **Results**: Study results
- **Limitations and comments**: Limitations and comments
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
|     | program post-surgery to reduce PU recurrence rates | Post-surgery for a Category/Stage III or IV PU | o enhanced education and monthly structured follow up intervention for 2 years after discharge (group 1, n=20, n=18 analyzed)  
- monthly contacts for up to 2 years after discharge to assess skin status, with no education during or after hospitalization (group 2, n=11, n=10 analyzed)  
- minimal contact via mail every 3 months for up to 2 years after discharge only to assess skin status, but received, with no education during or after hospitalization (group 3, n=10, n=10 analyzed) | • Pressure Ulcer Knowledge Test (non-validated)  
• Skin status was assessed through phone interview  
• Follow up was 2 years (or until recurrence) | • For group 1 odds ratio (OR) of a PU by 24 months was 0.228 (95% CI 0.080 to 0.647, p=0.003)  
• No significant differences between groups 2 and 3 in recurrence | allocation concealment  
- Study did not reach sample size required for statistical power  
- Groups 1 and 2 participated in another study concurrently  
- Non-equivalent groups at baseline  
- Self-assessed outcomes  
- Two participants had MS, both assigned to group 1  
- Knowledge outcomes not reported |

**Standard education**
1 to 2 hours of 1:1 education on prevention incl nutrition, smoking, skin inspection and care; a manual that included sections on PU prevention; training for families by phone/mail; therapist-supervised progressive sitting program and education on transfers and seating.

**Enhanced education**
1 to 4 additional hours 1:1 over four sessions on etiology, prevention and pressure relieving devices; one session for families; additional education monthly for 25 minutes via phone.

Quality of evidence: low
## Data Tables: 2019 Guideline Update: QOL

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Hartigan, Murphy, & Hickey, 2012 | A quasi-experimental case series with pre-test, post-test | Consecutive sample of community dwelling older adults attending an assessment/treatment clinic in Ireland (n=75 commenced study, n=59 completed study) | • Patient education leaflet on preventing PU based on 2009 EPUAP/NPUAP guideline that was reviewed by experts for content and readability. The leaflet scored 5.5 on the Flesch–Kincaid Grade Level indicating the text was appropriate to a reading age of an 8–10 year old.  
  • Participants were given one week to read the leaflet  
  • NB: copy of leaflet is included with this reference. | Knowledge levels  
  • Patients knowledge tested pre and post receiving the leaflet  
  • Knowledge test was administered by a nurse data collector  
  • Questionnaire was reviewed by experts and pretested for readability and ability to understand  
  • Questionnaire consisted of 10 open ended questions and 1 multiple choice question  
  PU risk  
  Assessed by nurse data collector | Knowledge  
  • In pre-test, 32% did not know what a PU was, this decreased to 9% at post-test (p=not reported)  
  • Prior to receiving the leaflet, 77% (n=43) of participants could identify what might cause a PU versus 89% (n=50) post-test (p=not reported)  
  • The post-test survey identified that the majority of patients could identify possible anatomical body areas where a pressure ulcer would be most likely to occur. (p=not reported)  
  • Participants exhibited improvements in knowledge for all questions.  
  Study conclusions: the PU prevention education leaflet was associated with improved knowledge of PU in older community dwelling adults at risk of PU. | • No statistical tests were applied to compare pre and post test results.  
  • Only 11 questions asked, recall bias may have been present  
  • Demographics of participants e.g. education levels were not reported  
  Level of evidence: 2  
  Quality of evidence: low |

### Quality of Life background

Not for Reproduction
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Jackson et al., 2017 | Qualitative research exploring patient experiences with PI in home setting | 12 participants with pressure injuries living in UK | None | Semi structured interviews | Themes:  
- Loss of mobility and independence associated with pressure injury (unable to perform home chores, feeling handicapped and dependent)  
- Loss of privacy and dignity (requiring physical help, odor and leakage)  
- Loss of social engagement and ability to perform preferred activities (Housebound, odor, sense of loss for preferred activities)  
- Loss of personal control and autonomy | 12 participants only in one area of UK |
| Latimer, Chaboyer, & Gillespie, 2014 | Qualitative research exploring patient experiences with PI prevention | Participants were recruited in Australian hospitals (n=20) | None | Semi structured interviews | Themes:  
- Experiencing PI (many emotions, enduring pain, relieving pressure, smelling odor)  
- Participating in PIP (Enabling, knowing about PI, involving in care decisions  
- Self determining  
- Resourcing PIP and treatment (costly, trying to access information, struggling to get help, prolonging healing) | Small sample, some participants were not PI patients |
| Degenholtz, Rosen, Castle, Mittal, & Liu, 2008 | Cross-sectional and Longitudinal study | Participants recruited two non-profit nursing homes in USA in a 4 year | None | Resident interviews  
Dependent Variable:  
- Resident self-reported QOL in 11 | Longitudinal multivariate analysis (n=140)  
- Having ≥one PU stage II or higher for two-consecutive 6-month periods was | Observed association does not imply causation |

---

(C) EPUAP/NPIAP/PPPIA Not for Reproduction
### Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Quality of evidence: moderate</th>
</tr>
</thead>
</table>
| Dunn, Carlson, Jackson, & | Qualitative cross-case secondary analysis | Case profiles from a previous qualitative study conducted in a US | None | dimensions (comfort, functional competence, relationships, privacy, dignity, autonomy, meaningful activity, security, individuality, spirituality, food enjoyment) measured on a previously validated scale. | associated with significant declines in three domains of QOL:  
- autonomy (p=0.047),  
- security (p=not reported), and  
- spiritual well-being (p=not reported).  
- Having depressive symptoms was the only other independent variable besides PUs that was associated with decline on 3 or more QOL domains (comfort, meaningful activities, and food enjoyment)  
- Residents who recovered from a PU stage II or higher maintained a statistically significant decline in functional competence (p=0.003) after their recovery. | • Study did not investigate potential ways to address decline in QOL associated with PU  
• The sample was drawn from only two nursing homes and only residents without significant cognitive impairment, limiting the generalizability of the results. | |
| | | | | Independent Variables:  
- PUs identified as ≥one PU stage II or higher as identified on the minimum data set (MDS)  
- depressive symptoms  
- physical disability  
- use of physical restraints  
- pain | | Longitudinal multivariate analysis conducted for residents who completed ≥ two interviews | Study conclusions: the study found evidence that for older nursing home residents, stage II or greater PUs lasting greater than 6 months are associated with decline in self-reported autonomy, security and spiritual wellbeing and recovery for a stage II or greater PU is associated with a decline in self-reported functional competence. | |

**Data Tables:** 2019 Guideline Update: QOL  
© EPUAP/NPIAP/PPPIA  
Page 19
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Quality of evidence:</th>
</tr>
</thead>
</table>
| Clark, 2009       | Qualitative   | Rehabilitation center were analyzed (n=19) | Inclusion:  
- Included in the parent study (n=20)  
- Community dwelling adults with SCI  
- Personal profiles selected with adequate information about one or more responses to a low-grade ulcer | Lacking adequate knowledge: overlooking a PU or underestimating danger  
Procrastinating: delaying action on the basis of emotion, negating consciously  
Experiencing cognitive dysfunction  
Diverting attention: attending to comorbidities, desiring activity, attending to external exigencies  
Avoiding social discomfort  
Being thwarted from receiving adequate medical help  
Relying on self or caregiver help  
Adhering to medical recommendations | (but demographics not reported)  
- Based on self-report and recall of events, memory lapses or misrepresentation of history may limit findings  
- Methodology could have allowed researchers to categorize differently  
- No opportunity to pursue follow-up for more complete responses | Moderate |
| C. Gorecki, Nixon, Madill, Firth, & Brown, 2012 | Qualitative study | Participants recruited from hospital and community settings in England and Northern Ireland (n=30)  
- A purposive sampling method considering | Face-to-face semi-structured interviews: Participants described how PU affected their lives by recounting specific relevant events.  
- Events (participant reported issues) were sorted into | Identification of 16 contributory factors presented thematically in two topics: experience of care and individual patient factors  
Experience of care factors included:  
- adherence versus non-adherence to treatment,  
- hospitalization,  
- inconsistencies, | Limited to a population with PU  
- Further areas of research were identified | 5 (qualitative)  
High |
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Galhardo, Magalhaes, Blanes, Juliano, & Ferreira, 2010 | Cross-sectional study to evaluate HRQOL and depression of older community dwelling individuals with PU | Participants were outpatients at health centers in Brazil from 2005 to 2006 (n=42) | None | Participants were visited in their home and interviewed.  
PU measurement:  
- PU presence confirmed by examination  
- PU classification according to NPUAP staging system  
HRQOL measurement: | Participants with PU had significantly lower HRQOL scores than those without PU in all SF-36 domains (p ranged from <0.0001 to 0.014)  
- Participants with PU had the lowest SF-36 scores for physical functioning physical role limitations and emotional role limitation (p<0.0001 versus those without PU for all).  
71.4% of participants with PU rated their current health status as slightly worse or much worse that 12 months before, versus 38% of those without PU. | Small sample size  
- People with cognitive impairments were excluded  
- Participants were described as having low educational and income levels | Level of evidence: 3  
Quality of evidence: moderate |
<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yarkin, Tamer, Gamze, Irem, &amp; Huseyin, 2009</td>
<td>Cohort study investigating the psychiatric and QOL of participants (and their caregivers) with PU</td>
<td>The study included successive participants (n=20, n=17 included) scheduled for PU surgery in Turkey between 2006 and 2008 and their caregivers (n=20, n=18 included) Excluded: • Progressive depression Characteristics: • 15/17 participants were paraplegic and</td>
<td>• None</td>
<td>• SF-36 includes 8 dimensions – physical functioning, social functioning, role limitations (physical), role limitations (emotional), mental health, vitality and pain. • Geriatric Depression Scale (GDS-15) cut off point of ≥ 6 to identify possible case of depression</td>
<td>• 80.9% of participants with PU had light or severe depression versus 19.1% of those without PU. • There was no direct relationship between degree of depression on GDS-15 and number or severity of PU • Study conclusions: Older adults with PUs living in the community have high rates of depression and lower scores on measurements of HRQOL than those who do not have PU, despite having similar co-morbidities.</td>
<td></td>
</tr>
<tr>
<td>Ref</td>
<td>Type of Study</td>
<td>Sample</td>
<td>Intervention(s)</td>
<td>Outcome Measures &amp; Length of Follow-up</td>
<td>Results</td>
<td>Limitations and comments</td>
</tr>
<tr>
<td>-----</td>
<td>---------------</td>
<td>--------</td>
<td>-----------------</td>
<td>----------------------------------------</td>
<td>---------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Thein, Gomes, Krahn, &amp; Wodchis, 2010</td>
<td>Retrospective population-based study exploring impact of HRQOL of PU</td>
<td>Participants recruited from 89 LTC homes in USA (n=16,531)</td>
<td>None</td>
<td>Records analysis of MDS scores over 5 years</td>
<td>Factors associated with having a low MDS-HIS were having a PU, older age, being female, recent hip fracture, multiple comorbidities, changes in health, end stage disease, clinical depression, psychotropic medication and use of restraints. Participants with a PU had significantly lower MDS-HIS than those without a PU (0.26±0.13 versus 0.36±0.17, p=0.001). Multivariate analysis found PU to be a significant factor in lower MDS-HIS</td>
<td>Limited assessment of changes in HRQOL over time. Scores may not be generalizable. Minimal knowledge about the LTC setting environments. Significant differences between participants with and without PU for factors known to impact on HRQOL.</td>
</tr>
</tbody>
</table>

2/17 were quadriplegic
• 18 (15 sacral, 3 trochanteric) deep PUs with exposed bone and muscle
• All participants had flap surgery, during follow-up 5 participants had recurrent PU

Indicates increasing anxiety
• SF-36 includes 8 dimensions – physical functioning, social functioning, role limitations (physical), role limitations (emotional), mental health, vitality and pain.

SF-36 scores were compared to the national average.

Participant group had SF-36 scores significantly worse than the national average postoperatively for all domains (p<0.05) except physical role limitations. Values on all domains increased over 6 months (unclear if this was significant) suggesting that surgery for PU is related to improvements in QOL.

Caregivers had preoperative values for social function (p<0.05), mental health (p<0.05) and emotional role limitations (p<0.05) that were significantly worse than the national average.

Caregivers had postoperative values for social function (p<0.05) and mental health (p<0.05) that were significantly worse than the national average.

Study conclusions: people with PU requiring surgical intervention and their caregivers have QOL ratings significantly worse than the national average. Whilst these values improve within 6 months of surgery but are still below the national average.

Discussion is not related to the research findings (e.g. discusses influence of age on adaptation but age of participants is not reported).

No statistical comparison of pre and post values. Both are compared to national average only.
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essex, Clark, Sims, Warriner, &amp; Cullum, 2009</td>
<td>Multicenter cohort study exploring impact of health related quality of life</td>
<td>Multicenter study in 4 hospitals in UK between 1996 to 1998 with recruitment stratified by specialty (n=218 participants with PU and n=2,289 without PU)</td>
<td>• None</td>
<td>• Minimum Data Set- Health Status Index (MDS-HIS) derived from mapping MDS scores for cognition, self-care, mobility, sensation, emotion, pain onto Canadian Health Utilities Index 2 (HUI2).</td>
<td>scores for participants with PU (coefficient −0.022±0.004, p&lt;0.001) Study conclusions: Having a PU of stage II or greater was associated with lower HRQOL for adults in long term care, although this effect was contributed to by a range of comorbidities also associated with decreased HRQOL.</td>
<td>including cognition, physical dependence and restraint use. Predictors of study could only account for 38% of variability in LTC residents and were unable to adjust for facility or socioeconomic factors</td>
</tr>
</tbody>
</table>

• No significant difference in age, length of stay, marital status between participants with and without a PU
• Significantly more with PU than those without PU were males (34% versus 30%, p=0.001)
• Participants with PU had a significantly lower BMI
• Participants with PU were more likely to have severe cognitive impairment (38% versus 26%, p<0.001)
• Participants with PU were more likely to need total assistance with ADLs (67% versus 34%, p<0.001)
• Participants with PU significantly more likely to have incontinence, reduced mobility requiring turning, polypharmacy and regular use of restraint (all p<0.001).

• A multi center study investigated HRQOL using the Short Form -36 (SF-36)
• Follow-up pilot study included a survey with structured

Multi center cohort study
• PCS score adjusted for age, gender and comorbidities was significantly lower for having a PU (coefficient −3.12, 95% CI −4.79 to −1.44, p=0.001)
• PCS score adjusted only for age and gender was significantly lower for

• Small sample size impeded control for comorbidities
• Accuracy of information on comorbidities in both studies relied on the Level of evidence: 3 Quality of evidence: moderate
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>(HRQOL) of PU</td>
<td></td>
<td></td>
<td></td>
<td>interview using SF-36, EQ-5 D and pain VAS to investigate HRQOL</td>
<td>having a PU (coefficient −4.05, 95% CI −5.75 to −2.35, p&lt;0.001)</td>
<td>completeness of the medical records available</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>HRQOL tools:</td>
<td>• MCS score adjusted for age, gender and comorbidities was significantly lower for having a PU (coefficient −1.50, 95% CI −2.94 to −0.05, p=0.04)</td>
<td>• Potential participants with severe co-morbidities were less likely to consent, and many of these people had PU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• SF-36 includes 8 dimensions – physical functioning, social functioning, role limitations (physical), role limitations (emotional), mental health, vitality and pain. Physical component summary (PCS) score summarizes physical dimensions of SF-36</td>
<td>• MCS score adjusted only for age and gender was significantly lower for having a PU (coefficient −1.88, 95% CI −3.31 to −0.44, p&lt;0.001)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mental component summary (MCS) summarizes mental dimensions of SF-36</td>
<td>• SF-36 scores indicated that patients with PU had significant poorer physical functioning (mean score difference 22.3, 95% CI 10.6 to 34.0, p&lt;0.001), and role limitations due to physical problems (mean score difference 12.9, 95% CI 2.83 to 23.0, p=0.02)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• EQ-D pain VAS</td>
<td>• No significant differences in PCS or MCS</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• EQ-5D showed a trend for participants with PU to have a lower score (mean difference 0.29, 95% CI −0.04 to 0.62, p=0.08).</td>
<td>• Pain scores on the EQ-5D VAS were significantly worse for participants with PU (p=0.02), but this was not supported by the validated pain VAS (p=0.06)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Study conclusions: PU has a significant negative impact on both physical and mental dimensions of HRQOL above and beyond that related to comorbid conditions for older hospitalized adults</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pilot study

• SF-36 scores indicated that patients with PU had significant poorer physical functioning (mean score difference 22.3, 95% CI 10.6 to 34.0, p<0.001), and role limitations due to physical problems (mean score difference 12.9, 95% CI 2.83 to 23.0, p=0.02)
• No significant differences in PCS or MCS
• EQ-5D showed a trend for participants with PU to have a lower score (mean difference 0.29, 95% CI −0.04 to 0.62, p=0.08).
• Pain scores on the EQ-5D VAS were significantly worse for participants with PU (p=0.02), but this was not supported by the validated pain VAS (p=0.06)
• Study conclusions: PU has a significant negative impact on both physical and mental dimensions of HRQOL above and beyond that related to comorbid conditions for older hospitalized adults

Inclusion:
- age ≥16 years
- able to give consent

Characteristics:
- Participants with PU were significantly older than those without (mean age 75.8±13 versus 64.3±17.9, p<0.001)
- PU participants more likely to have diabetes, PVD, cancer and orthopaedic or neurological diagnoses and people with PU more likely to have CVD or no comorbidity

Inclusion:
- age ≥16 years
- able to take part interview

Characteristics:
- People with PU had a significantly higher consent rate (80% versus 35%)
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. Gorecki et al., 2010</td>
<td>Prospective mixed methods study with emphasis on qualitative research Investigating HRQOL</td>
<td>Purposive sampling to include adults of varying age, settings, PU severity, location, clinical specialty, and experience with different treatments in Northern England and Ireland (n=30) Exclusion: • patients with no PU • PU healed in last 3 months • unconscious, confused, cognitively impaired • unable to speak English Characteristics: • Mean age 62yrs, range 22 to 94 yrs • 56% of sample was male. • 19 participants had other chronic health problems including SCI and MS. • 15 had severe PU, 12 had superficial PU. 13 had &gt; one PU • PU duration ranged from 1 month to 9 years</td>
<td>None</td>
<td>• Data analysis using both inductive and deductive processes. • Single interviews conducted at the patient’s home or clinical setting lasting a mean of 42 minutes.</td>
<td>• Four domains identified: symptoms, physical functioning, psychological well-being, and social functioning. <strong>Symptoms</strong> pain and discomfort commonly reported as interrupting sleep and daily activity. Exudate and odour identified as interfering with daily life, intimacy and closeness and contributing to self-imposed isolation, emotional distress, self-consciousness. <strong>Physical functioning</strong> 4 sub-domains of daily activity, mobility, general malaise and sleep identified. PUs reported to have negative impact on physical functioning. <strong>Psychological well-being</strong> Negative psychological well-being that categorised as mood, anxiety and worry, self-efficacy and dependence, appearance and self-consciousness. <strong>Social functioning</strong> disrupted or limited, participants felt isolated, lonely and left out. No major differences could be attributed by age, gender, PU severity or location.</td>
<td>• Limited to English-speaking British nationals • Researcher identified power of study, attrition rates, design flaws, reliability &amp; validity • 10% of interviews and transcripts reviewed by a second researcher for quality assurance.</td>
</tr>
</tbody>
</table>
## Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ghaisas, Pyatak, Blanche, Blanchard, &amp; Clark, 2015</td>
<td>Retrospective analysis of outcomes of one cohort in trial to identify associations between PU status and lifestyle change</td>
<td>• 17 in hospital or community, 13 in community settings</td>
<td>None</td>
<td>• Participants were classified as having achieved lifestyle changes vs no changes</td>
<td>Study conclusions: for patients of all age and PU severity, impact of PU on HRQOL influences 4 domains: symptoms, physical functioning, psychological wellbeing, and social functioning</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria:</td>
<td>• SCI</td>
<td>• Treatment note review to categorize participants based on making lifestyle changes</td>
<td>• Participants were classified as having improved or worsening PU status</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria:</td>
<td>• Completed 12 months of the intervention with sufficient participation</td>
<td>• Participants were classified as having improved or worsening PU status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Experienced PU during intervention period</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Poor adherence to lifestyle changes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hug et al., 2017</td>
<td>To investigate whether persons with greater levels of general self-efficacy</td>
<td>• Participants were recruited from community settings in Switzerland between 2011 and 2013 (n=511 included, n=52)</td>
<td>No intervention</td>
<td>• Main Outcome Measurements. Self-efficacy was assessed by the GSE scale comprising 10 items</td>
<td>General self-efficacy was not related to PU prevention activities without other interacting factors</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>When adding interacting factors of sociodemographic, lesion related, and lifestyle-related confounders to the</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Self-reported data could have been biased by social desirability and the real values might be</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Background – Self Care Skills**

- Retrospective analysis of outcomes for the treatment group in a previously conducted trial. All participants who completed 12 months of the intervention were eligible for inclusion (n=47 eligible, n=17 included)
- Inclusion criteria:
  - SCI
  - Completed 12 months of the intervention with sufficient participation
  - Experienced PU during intervention period
- Exclusion criteria:
  - Experience no PU
  - Poor adherence to lifestyle changes
- No intervention
- Main Outcome Measurements. Self-efficacy was assessed by the GSE scale comprising 10 items
- General self-efficacy was not related to PU prevention activities without other interacting factors
  - When adding interacting factors of sociodemographic, lesion related, and lifestyle-related confounders to the
  - Self-reported data could have been biased by social desirability and the real values might be

---

*Level of evidence: 3
Quality: low*
### Background: Knowledge Levels and Education Needs

**McInnes, Chaboyer, Murray, Allen, & Jones, 2014**

- **To survey hospitalized patients' views on a) their perceived roles in PIP and, b) factors that enable or**
- **Participants recruited in orthopaedic and neurology wards in Australia (n=51)**
  - Inclusion criteria
  - 18 years and older, admitted to hospital > 24 hours
  - **Data collection through interviews using a study specific questionnaire. Took 10-15 minutes to administer.**
  - 5 demographic questions
- **Strategies participants identified for patient participation in PIP**
  - Themes: Keep the skin healthy, Listen to your body, Looking after the inside
  - **Participant nominated strategies to facilitate patient participation in PIP**
  - Manage pain and discomfort, Work together, Ongoing PI education

**Limitations and comments**
- Small convenience sample

**Indirect evidence: 5**
**High quality**
### Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
| Thietje et al., 2011 | Prospective cohort study investigating acquisition of knowledge of SCI patients about SCI-complications | Consecutive admissions to a German hospital between 2005 and 2008 of patients with a traumatic or non-traumatic SCI (n=214 completed knowledge tests) | Development of knowledge about PUs and bladder management in SCI patients throughout a first hospital admission of 3 to 6 months duration for SCI | 18 fixed or multiple-choice questions. 5 open ended questions. Content analyses. | Author conclusions: To ensure successful participation in PIP, patients require education throughout admission, management of pain and discomfort and a supportive and collaborative relationship with health care staff. Health professionals should identify patient ability and motivation to prevent PI, work in partnership with patients to adhere to PIP, and ensure that PIP actions are facilitated with appropriate pain relief. | Inhibit patient participation in PIP strategies.  
Exclusion criteria:  
- Not verbal in English  
Participant characteristics:  
- Mean age 65 years (range 19-93)  
- 55% female  
- 74% surgical admissions  
Inclusion:  
- aged ≥18 years  
- patient’s first admission to hospital  
- minimum duration of admission of 3 months  
Exclusion:  
- incomplete database record  
- severe cognitive impairment  
- cranio-cerebral injury or malignancies with short life expectancy  
Development of knowledge about PUs and bladder management in SCI patients throughout a first hospital admission of 3 to 6 months duration for SCI |  
Functional ability  
- Ability to perform everyday tasks and overall impact of disability measured using SCIM-II (validated tool) consisting of scales for self-care, respiration and sphincter management and mobility.  
Knowledge of SCI-related topics  
- Knowledge tested using Knowledge Boberg Score (un-validated tool) including PUs and bladder management.  
- Knowledge was classified as poor, average or good  
- Participants had initial poor level of knowledge (KBS) and functional ability (SCIM-II score) in every day care that significantly (p<0.001) improved by discharge.  
Knowledge  
- At discharge 22.4% participants had poor knowledge, 30.4% had average knowledge and 47.2% had good knowledge of SCI-related topics.  
- Mean total KBS increased from 5.44 to 11.24 at discharge (p<0.001), after 30 months mean score decreased to 10.8.  
- Patients aged ≥65 years achieved lower knowledge scores by discharge compared with younger patients (p<0.001)  
Functional ability  
- Mean total SCIM-II score increased from 26.84 on admission to 58.32 at discharge (p<0.001) and continued to improve, peaking at 66.65 after 18 months.  
Information sources | Knowledge score has not validated  
- Education levels were not reported  
- Content of information courses is not reported therefore replicability is limited  
- Personal factors may be involved in the relative importance of different health professionals as an information source | Indirect evidence (PU not an outcome)  
Quality of evidence: low |
<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>J. R. Schubart, Hilgart, &amp; Lyder, 2008</td>
<td>Qualitative study using needs assessment methodology to explore education needs on PU for SCI patients</td>
<td>Purposive sampling to recruit participants from a US rehabilitation (n=16 SCI individuals)</td>
<td>• An initial review of an evidence-based guideline was used to determine recommended PU prevention education needs. Participants completed an interview and a survey regarding what they considered their education needs were and their feelings about PU prevention.</td>
<td>Thematic analysis using NVivo software.</td>
<td>Perception of risk People who considered themselves at risk had usually experienced a PU in the past. Those who had not experienced a PU considered themselves at low risk and practiced less preventative actions. PU education • previous education limited to initial post-injury care period. • Education had been fear-oriented for older patients.</td>
<td>Unclear how the guideline were used or how interviews were synthesised into themes and recommendations. Recommendations seemed contrary to some information in the interviews (e.g. fear)</td>
</tr>
</tbody>
</table>

Data Tables: 2019 Guideline Update: QOL © EPUAP/NPIAP/PPPIA Page 30
### Quality of Life, Education and Wellbeing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
</table>
|     |              | • Aged 20 to 59 years with wide spread  
• Primarily Caucasian, 2 African Americans  
• Most had been injured more than 10 years  
• 50% had experienced several PU, 37.5% had never experienced a PU | • | | • Opportunity for education limited to time when had a PU requiring care.  
• Preferred face-to-face education from other SCI patient or health professional, (less frequently, Internet)  
• Some participants believed education is delivered too early, when in shock or denial, and this was ineffective.  
• Family members also need education. | Environmental considerations  
• home environment and available equipment influenced ability to implement PU prevention. Access to appropriate care  
• limited access to service after acute care and had frustration dealing with health systems and insurance. Education needs were prioritised as:  
• SCI learners and caregivers need to be aware that SCI poses lifelong risk for PU that may be serious and/or life threatening.  
• SCI learners need to take charge of own skin care and to feel empowered to partner with health care providers.  
• SCI learners need PU prevention strategies that fit with their level of functioning and activity and can be updated as risk changes.  
• SCI learners need strategies for coordinating social supports for both family and paid caregiving situations. |
|     |              |        |                 |                                       |         | • Small sample, although saturation was reached.  
• May not be generalizable to other countries. |
Quality of Life, Education and Wellbeing: data extraction and appraisals

**Table 1: Level of Evidence for Intervention Studies**

<table>
<thead>
<tr>
<th>Level</th>
<th>Experimental Designs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>• Randomized trial</td>
</tr>
<tr>
<td>Level 2</td>
<td>Quasi-experimental design</td>
</tr>
<tr>
<td></td>
<td>• Prospectively controlled study design</td>
</tr>
<tr>
<td></td>
<td>• Pre-test post-test or historic/retrospective control group study</td>
</tr>
<tr>
<td>Level 3</td>
<td>Observational-analytical designs</td>
</tr>
<tr>
<td></td>
<td>• Cohort study with or without control group</td>
</tr>
<tr>
<td></td>
<td>• Case-controlled study</td>
</tr>
<tr>
<td>Level 4</td>
<td>Observational-descriptive studies (no control)</td>
</tr>
<tr>
<td></td>
<td>• Observational study with no control group</td>
</tr>
<tr>
<td></td>
<td>• Cross-sectional study</td>
</tr>
<tr>
<td></td>
<td>• Case series (n=10+)</td>
</tr>
<tr>
<td>Level 5</td>
<td>Indirect evidence: studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models</td>
</tr>
</tbody>
</table>

**Table 2: Levels of evidence for diagnostic studies in the EPUAP-NPUAP-PPPIA guideline update**

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Individual high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 2</td>
<td>Non-consecutive studies or studies without consistently applied reference standards.</td>
</tr>
<tr>
<td>Level 3</td>
<td>Case-control studies or poor or non-independent reference standard.</td>
</tr>
<tr>
<td>Level 4</td>
<td>Mechanism-based reasoning, study of diagnostic yield (no reference standard).</td>
</tr>
</tbody>
</table>

**Table 3: Levels of evidence for prognostic studies in the EPUAP-NPUAP-PPPIA guideline update**

<table>
<thead>
<tr>
<th>Level 1</th>
<th>A prospective cohort study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 2</td>
<td>Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.</td>
</tr>
<tr>
<td>Level 3</td>
<td>Case-series or case-control studies, or low quality prognostic cohort study, or retrospective cohort study.</td>
</tr>
</tbody>
</table>

**APPRAISAL FOR STUDIES PROVIDING DIRECT EVIDENCE (i.e. ELIGIBLE FOR SUPPORTING AN EVIDENCE-BASED RECOMMENDATIONS)**

Each criteria on the critical appraisal forms was assessed as being fully met (Y), partially met or uncertain (U), not met/not reported/unclear (N), or not applicable (NA). Studies were generally described as high, moderate, or low quality using the following criteria:

- High quality studies: fully met at least 80% of applicable criteria
- Moderate quality studies: fully met at least 70% of applicable criteria
- Low quality studies: did not fully meet at least 70% of applicable criteria
## Quality of Life, Education and Wellbeing: data extraction and appraisals

### RCTS

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Focussed question</th>
<th>Assignment randomised</th>
<th>Adequate concealment method</th>
<th>Subjects and investigators blinded at commencement</th>
<th>Only difference between groups was treatment</th>
<th>Valid, reliable outcome measure</th>
<th>% drop out in study arms is reported and acceptable</th>
<th>Intention to treat analysis</th>
<th>Comparable results for multiple sites</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>14241</td>
<td>Arora et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>1</td>
<td>High</td>
</tr>
<tr>
<td>3045</td>
<td>Guhan et al., 2014</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
<td>Moderate</td>
</tr>
<tr>
<td>14584</td>
<td>Kim &amp; Cho, 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
<td>High</td>
</tr>
<tr>
<td>18261</td>
<td>Hossain et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

### CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL/PSYCHOMETRIC

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Focussed question</th>
<th>Sampling method</th>
<th>Representative sample</th>
<th>States number invited</th>
<th>Clear outcome measures</th>
<th>Valid reliable outcome measure</th>
<th>Comparable results for multiple sites</th>
<th>Confounders identified and accounted for</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality/</th>
</tr>
</thead>
<tbody>
<tr>
<td>14534</td>
<td>Chaboyer et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y NA</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>NA (psychometric)</td>
</tr>
<tr>
<td>18265</td>
<td>Rutherford et al., 2018</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y NA</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>NA (psychometric)</td>
</tr>
<tr>
<td>71</td>
<td>C. Gorecki et al., 2013</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y NA</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>NA (psychometric)</td>
</tr>
<tr>
<td>14620</td>
<td>de Laat et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y NA</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>High</td>
</tr>
<tr>
<td>9200</td>
<td>Kisala et al., 2015</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>4</td>
<td>NA (psychometric)</td>
</tr>
</tbody>
</table>

### QUALITATIVE STUDIES

Data Tables: 2019 Guideline Update: QOL
**Quality of Life, Education and Wellbeing: data extraction and appraisals**

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Clear statement of aims</th>
<th>Qualitative method is appropriate</th>
<th>Recruitment is appropriate and sample justified</th>
<th>Clear, explicit and appropriate methods for data collection</th>
<th>Researcher’s role in data collection and analysis and potential bias addressed</th>
<th>Ethics clearance</th>
<th>In-depth description of analysis technique indicates rigorous process</th>
<th>Clear findings stated</th>
<th>Research contributes to the existing knowledge</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>15738</td>
<td>Jackson et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>5</td>
<td>High</td>
</tr>
<tr>
<td>1404</td>
<td>Latimer et al., 2014</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>5</td>
<td>High</td>
</tr>
<tr>
<td>6271</td>
<td>McInnes et al., 2014</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>5</td>
<td>High</td>
</tr>
</tbody>
</table>

**COHORT STUDIES**

| Author/year         | Focussed question | Comparable source populations | States number invited | Likelihood of outcome at enrolment considered | Per cent drop out in study arm & reported | Comparison bw drop out and participants | Clear outcome measures | Assessment blinded, or discuss potential bias | Valid, reliable assessment with supporting reference | More than one measure of exposure | Confounders identified and accounted for | Provides confidence intervals | Minimal bias | Relable conclusions | Level of evidence | Quality |
|---------------------|-------------------|-------------------------------|------------------------|-----------------------------------------------|-------------------------------------------|-------------------------------|------------------------|-----------------------------------------------|--------------------------------------------------------------------------------|---------------------------------|---------------------------------------------|---------------------|---------|
| 2942                | Lourenco et al., 2014 | Y                             | N                      | Y                                             | N                                         | Y                             | U                      | Y                                                             | N                                                                | N                                             | N                                             | Y                   | U       |
| 13701               | Lane et al., 2016   | Y                             | N                      | N                                             | N                                         | U                             | U                      | Y                                                             | Y                                                                | N                                             | Y                                             | N                   | U       |
| 6709                | Ghaisas et al., 2015 | Y                             | N                      | U                                             | NA                                        | N                             | U                      | Y                                                             | N                                                                | N                                             | Y                                             | N                   | U       |
Quality of Life, Education and Wellbeing: data extraction and appraisals

References


Quality of Life, Education and Wellbeing: data extraction and appraisals


Data Tables: 2019 Guideline Update: QOL

© EPUAP/NPIAP/PPPIA