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Convergent and discriminant validity of quality of life measures used in burn populations

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1 **Convergent and discriminant validity of quality of life measures used in burn**  
2 **populations**

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24 Abstract

25 Introduction: The primary goal of this study was to investigate convergent validity, i.e. overlapping  
26 constructs, of the Burn Specific Health Scale-Brief (BSHS-B), the Short Form-36 items Health Survey  
27 (SF-36) and the European Quality Of Life Five Dimensions (EQ-5D) within the International  
28 Classification of Functioning Disability and Health (ICF) framework. A secondary goal was to examine  
29 the discriminant validity of the questionnaires according to burn severity (no surgery versus 1 or  
30 more surgeries).

31 Methods: A prospective multi-center study in adult patients with burns was conducted. At the 9  
32 months assessment, two generic questionnaires, i.e. the SF-36 and EQ-5D, and the BSHS-B were  
33 completed. Pearson correlations were used to evaluate convergent validity. Linear discriminant  
34 analysis was used to evaluate discriminant validity.

35 Results: At 9 months post-burn data from 184 persons were available of which 131 (71%) were male,  
36 mean TBSA burned was 11.8% (SD= 10.2). Sixty five (34%) patients did not need surgery, 128 (66%)  
37 patients required one or more surgeries. Higher convergence was shown between the generic SF-36  
38 and the condition specific BSHS-B whereas the EQ-5D showed lower convergence with the BSHS-B  
39 especially in the domain Activity. The generic scales discriminated across all scales whereas not all  
40 BSHS-B scales were able to differentiate problem levels across burn severity groups.

41 Conclusion: This study demonstrates that the ICF is useful to classify scales in order to identify  
42 overlapping areas as well as to uncover gaps in relation to patient reported outcomes. Both the SF-36  
43 and EQ-5D showed the ability to distinguish levels of functioning across burn severity groups. As the  
44 BSHS-B performed less well and relevant domains of functioning were not addressed, there is room  
45 for improvement and modification of this condition specific questionnaire to better capture burn  
46 patients' functioning.

47

## 48 INTRODUCTION

49                 During the last decade it has been acknowledged that functional outcome is an  
50 important parameter of treatment following burn injuries [1]. Functional outcome is often measured  
51 using patient reported outcome measures (PROMS). Expert consensus exists on using both generic  
52 and disease-specific Quality Of Life (QOL) questionnaires to capture the full impact of a health  
53 condition [2]. However, it is insufficiently understood if this combination indeed comprises the full  
54 spectrum of functioning as defined by the International Classification of Functioning, Disability and  
55 Health (ICF). The ICF is a worldwide used framework to describe the health condition of a patient in a  
56 bio-pycho-social context and it can also act as a framework to inventory and compare the content of  
57 PROMs [3].

58                 A previous theoretical classification showed the usefulness of the ICF to identify overlap  
59 and gaps in scales such as the Burn Specific Health Scale Brief (BSHS-B), the Short Form-36 items (SF-  
60 36) and the European Quality of Life 5 Dimensions (EQ-5D) [4]. In general the theoretical  
61 classification revealed that the subscales of the three questionnaires covered the Body function,  
62 Activity and Participation domains of the ICF. None of the subscales included items on Environmental  
63 factors and Body structures. The BSHS-B covered most ICF domains and was the only **one** to include  
64 Personal factors. The content comparison of the three questionnaires revealed considerable overlap  
65 across the questionnaires, particularly in the domain Body Function and Activity domains [4]. To our  
66 knowledge, there are no studies that empirically evaluate the overlap between generic and disease  
67 specific scales within the **ICF** framework.

68                 Furthermore, it is important to investigate if the scales are able to discriminate between  
69 burn severity groups. Discriminant validity is a characteristic of a measure that evaluates the ability  
70 to discriminate between groups with known differences. Prior **studies [5,6]** used total body surface  
71 area (TBSA) affected, number of surgeries, or length of stay (LOS) in hospital as burn severity  
72 measures. The reliability and validity of the BSHS-B was recently examined in minor burn injuries **[7]**  
73 but it remains unclear how well the different subscales can discriminate between burn severity  
74 groups. **However, the EQ-5D was sensitive** for different levels of burn severity [8]. In a prospective  
75 **longitudinal study LOS was associated with more problems in all EQ-5Ds dimensions excluding Usual**  
76 **Activities at 3 and 6 months. At 12 months post burn longer LOS was still associated with more**  
77 **problems in Mobility and Pain [8]**. The number of surgeries [9] has been shown to negatively affect  
78 health related quality of life (HRQOL) [10] and was suggested to outperform somewhat better  
79 compared to TBSA as a predictor of long-term HRQOL and speed of recovery [10]. As subscales of  
80 PROMs are more often used to identify problem areas in specific health domains [11], it is interesting

81 to evaluate whether the scales are able to detect differences in problem levels in groups that are  
82 known to differ from each other.

83 The aim of this study was twofold: 1) to empirically investigate the overlapping  
84 constructs of the BSHS-B, the EQ-5D and the SF-36 within the ICF framework. It was hypothesised  
85 that overlapping subscales should show correlations exceeding .50 [12,13] and 2) to examine  
86 discriminant validity, i.e., how well the scales are able to discriminate between burn severity groups.

87

## 88 METHODS

### 89 Patients

90 This study was reviewed and approved by the ethics committees of the Martini Hospital,  
91 Groningen, The Netherlands, and Ghent University Hospital, Belgium. A prospective multicenter  
92 cohort study using the BSHS-B, the SF-36 and EQ-5D to assess QOL 9 months after burn injury was  
93 conducted. The results of this study are part of a larger prospective cohort study on psychological  
94 problems and quality of life [10, 14]. Adult patients with acute burns admitted to one of six burn  
95 centers in the Netherlands and Belgium between March 2003 and April 2005 requiring  
96 hospitalization for at least 72 hours were included in this study. Patients were excluded when they  
97 were unable to complete the self-report questionnaires because of poor Dutch proficiency or  
98 cognitive disorders. In this study 311 adult burn patients met the inclusion criteria. Fifty-one patients  
99 (16%) refused to participate. Informed consent was obtained from 260 patients. We obtained 9  
100 months follow-up data from 184 patients (71%).

### 101 Procedure

102 Eligible patients were invited to participate in the study during hospitalization. After  
103 signing the consent form the first questionnaires were administered during hospitalization. Once  
104 patients left the burn center follow-up questionnaires were sent by regular mail, including a letter  
105 and a prepaid return envelope. Non-responders were reminded within 1 month after the  
106 questionnaires were sent. No further efforts were undertaken to collect the measures.

### 107 Measures

108 The BSHS-B, EQ-5D and SF-36 were completed 9 months after the burn injury. The EQ-  
109 5D is a widely used generic assessment tool which distinguishes five dimensions: Mobility, Self-Care,  
110 Usual Activities, Pain/Discomfort and Anxiety/Depression [8, 10, 15]. The EQ-5D covers three  
111 domains of the ICF; the domain (impairments in) Body function with subscales Pain/Discomfort and  
112 Anxiety/Depression, the Mobility and Self-Care subscales assess Activity (limitations) and Usual

113 Activities inventories Participation (restrictions) [4]. Each dimension or subscale has three response  
114 levels: 1= no problems, 2= moderate problems or 3= extreme problems. A Visual Analogue Scale for  
115 General Health can also be part of the EQ-5D but was not included in the analyses of this study. The  
116 EQ-5D was translated into more than 60 languages and is used worldwide [8]. The EQ-5D is short and  
117 easy to use.

118 The *SF-36* is a generic measure made up of 36 items that are combined to form eight  
119 subscales [16, 17] and covers (impairments in) Body Function with its subscales Mental Health,  
120 Vitality and Bodily Pain. Within the ICF domain Activity (limitations) the subscale Physical Functioning  
121 was found and the Participation (restriction) domain is covered by multiple subscales: Role-Physical,  
122 part of the subscale Bodily Pain, Social Functioning and Role-Emotional [4]. Scoring is a two-step  
123 process. Most (29) items responses comprise Likert-type scales (three or six point scales), seven  
124 items have a binary response set (1= 0 or 2=100). Each of the question responses relate to a different  
125 pre-coded numeric value. For each of the eight subscales an aggregate percentage score is produced.  
126 The percentage scores range from 0% (lowest or worst possible health) to 100% (highest or best  
127 health). In the second step scores are averaged across items constituting a scale [18, 19].

128 The *BSHS-Brief* (*BSHS-B*) is the most recent version of this burn specific instrument. It  
129 includes 40 items comprising 9 domains [20, 21], covering each domain of the ICF framework. Heat  
130 sensitivity, Sexuality and Affect comprised Body Function, Hand Function and Simple Abilities  
131 measure Activity limitations, Work and Interpersonal Relationship cover the domain Participation  
132 and Treatment Regimens and Body Image assess Contextual Factors [4]. Item responses are scored  
133 on a 5-point scale ranging from 0 (= all the time/great difficulty) to 4 (= never/no difficulty). Mean  
134 scores are calculated for each subscale and high scores indicate a good perceived health status [4].

### 135 Statistical analysis

136 Construct validity was examined using a priori hypotheses for discriminant and  
137 convergent properties of the instrument. Convergent validity refers to how well subscales correlate  
138 with other measures that are assumed to be related. Convergent validity, assessing the overlap  
139 between measures, was investigated using Pearson correlation coefficients among different  
140 subscales [12, 22]. The degree of correlations are outlined as follows: small 0.10 to 0.29, moderate  
141  $\geq 0.30$  to 0.49 and strong  $\geq 0.50$  [23]. We hypothesized that subscales of the EQ-5D, the SF-36 and the  
142 BSHS-B theoretically classified as overlapping, were highly correlated (Table 1). Strong correlations  
143 indicate that the subscales assess similar constructs [12].

144 Discriminant validity evaluates the ability to discriminate between groups with known  
145 differences [24]. In this study discriminant validity was assessed by comparing two groups: those

146 requiring no surgery versus those requiring  $\geq 1$  surgery. To describe discriminant validity a linear  
147 discriminant analysis was used to determine classification capacity of the different subscales of the  
148 SF-36, EQ-5D and BSHS-B in the two predefined groups (no surgery versus  $\geq 1$  surgery). In the analysis  
149 Box's M analysis for evaluation of equality of co-variances and calculation of correctly predicted  
150 classification or hit ratio were included. Statistical significance was considered if  $p < .05$ . Analysis  
151 were performed using SPSS 20.0.

152

## 153 RESULTS

### 154 Demographic and clinical characteristics of patients

155 A total of 184 participants completed the 9 month assessment of which 131 (71%) were  
156 male and 53 (29%) were female. Participants were on average 39.0 years old (SD= 12.8). The mean  
157 TBSA burned was 11.8% (SD= 10.2). The mean LOS in hospital was 23.0 days (SD= 21.0). The median  
158 number of surgeries was 1 (ranging between 0 and 16, SD= 1.8). Sixty five (34%) patients did not  
159 need surgery, 128 (66%) patients required one or more surgeries.

160

### 161 Convergent validity between BSHS-B, EQ-5D and SF-36 subscales.

162 Correlations between the subscales of the BSHS-B and the EQ-5D are shown in the  
163 upper part of Table 2. The negative correlations reflect a high score on an EQ-5D subscale as  
164 indicative of poor health state while a high score on the BSHS-B subscale is indicative of better  
165 health. Only two correlations exceeded .50. Within the Body Function domain, Affect ( $r = -0.69$ ) was  
166 most strongly related with Anxiety/ Depression. Within the Participation domain, Work (BSHS-B) and  
167 Usual Abilities (EQ-5D) revealed a strong ( $r=-0.63$ ) correlation. Correlations within the Activity  
168 domain across the questionnaires were low.

169 Correlations between the subscales of BSHS-B and the SF-36 as categorized within the  
170 ICF domains are shown in the lower part of Table 2. High scores on the SF-36 and BSHS-B reflect a  
171 good health state. Again, within Body function, the Affect subscales were strongly related ( $r=-0.67$ ).  
172 Within the Participation domain several high correlations were observed, with Work and Role  
173 Physical showing the highest correlation. Within the Activity domain, Physical Functioning and Hand  
174 Function were related. When comparing the overlap between the two generic scales, the  
175 theoretically assumed overlap was confirmed by correlations exceeding 0.50. Only one correlation  
176 was lower, this being Role Emotional and Usual Activities. Correlations are shown in Table 3.

177                   The highest correlations were indeed observed between subscales that were classified  
178 within the same ICF domain. However, other significant correlations appeared, providing insight in  
179 how domains are inter-connected. A combination of the scales provides additional insight in problem  
180 areas.

181

#### 182 Discriminant validity of the HRQOL subscales between burn severity groups

183                   Table 4 presents the mean scores for the BSHS-B for the two severity groups. A higher  
184 problem level was found in the  $\geq 1$ -surgery group. However the differences between the severity  
185 groups in the subscales Affect, Heat Sensitivity, Simple Abilities, Hand Function and Interpersonal  
186 Relationship did not reach statistical significance. The largest differences between groups were found  
187 with respect to Work, Body Image and Treatment Regimens. When tested by Box's M the subscale  
188 Work showed a significant unequal co-variance between both groups and should be interpreted with  
189 caution. The cross validated classification showed that overall between 69.4 and 69.8% was correctly  
190 classified. This is shown in Table 4 as the discriminant analysis (DA) hit ratio.

191                   Regarding the mean EQ-5D subscale all domains showed a statistically significantly  
192 higher problem level in the  $\geq 1$ -surgery group. Both groups presented the most difficulties in the  
193 subscales Pain/Discomfort, Anxiety/Depression and Usual Activities, as shown in Table 5. Figure 1  
194 shows the problem levels of the five dimensions. When tested by Box's M the following subscales  
195 showed a significant unequal co-variance between both groups and should be interpreted with  
196 caution, i.e., Mobility, Self-Care and Usual Activities. The cross validated classification showed that  
197 overall between 69.7 and 70.1% was correctly classified.

198                   The SF-36 subscales were also able to discriminate across severity groups. In the no-  
199 surgery group lowest scores were found in the impairments in the subscales Vitality and Mental  
200 Health and for the  $\geq 1$ -surgery group lowest scores were found in subscales Vitality and Mental  
201 Health as well as Role Physical and Role Emotional at 9 months post injury. All subscales detected  
202 statistically significant differences between the severity groups. When tested by Box's M the  
203 subscales Physical functioning and Social functioning showed a significant unequal co-variance  
204 between the groups. The cross validated classification showed that overall between 68.2 and 71.7%  
205 was correctly classified.

206

## 207 DISCUSSION

208           The present study empirically demonstrates the convergence between the generic EQ-  
209 5D and SF-36 and the BSHS-B on subscale level in line with a prior theoretical classification within the  
210 ICF framework [4]. The convergence between the two generic scales was stronger than the overlap  
211 with the burn specific scale, as reflected by higher correlation coefficients across the subscales.  
212 Furthermore, the correlations between the SF-36 and BSHS-B were on average higher as compared  
213 to those found in the EQ-5D – BSHS-B comparison. This study also elucidated underlying relationships  
214 between domains that provide insight which burn specific domains affect the generic domains of  
215 functioning. Furthermore, the results of this study suggest that the generic questionnaires  
216 outperform the BSHS-B regarding the ability to differentiate problem levels between burn severity  
217 groups. Further study may be required to establish the nature of these differences, i.e., if these  
218 differences are a true reflection of the situation (hand function may be affected in only a subsample  
219 of the patients that needed surgery) or whether it is due to the lack of sensitivity of the scale.

220           This study supports significant content overlap in the generic scales as hypothesized in a  
221 prior study using the ICF as the leading framework [4]. Our results are in line with those of Öster et  
222 al. [8] in which the EQ-5D index and Visual Analogue Scale (VAS) correlated well with all SF-36  
223 subscales ranging between 0.55 and 0.78. This suggests that similar constructs of HRQOL were  
224 measured. Moreover, the correlations between the scales provided insight into underlying problem  
225 areas for example, Vitality showed higher correlations with psychological domains such as  
226 Anxiety/Depression (EQ-5D) as compared to physical domains suggesting that psychological  
227 problems largely affected vitality. This provides valuable insight into underlying problem areas.

228           The overlap between the EQ-5D and BSHS-B was modest. Only two out of five  
229 hypothesized overlapping subscales showed correlations exceeding 0.50, i.e. Anxiety/Depression –  
230 Affect and Usual Activities – Work. These results support previous research that showed comparably  
231 low associations between BSHS-B subscales and EQ-5D index at 6 and 12 months post burn injury [8].  
232 Especially Hand Function and Sexuality respectively showed low correlations with the EQ-5D index  
233 and those subscales were relatively independent to other reported health related problems [25]. The  
234 findings in this study suggest that both questionnaires measure different components of HRQOL and  
235 seem complementary to a large extent. Despite its brevity, the EQ-5D was well able to discriminate  
236 between severity groups and further supports its usefulness in burn populations.

237                   Somewhat stronger associations were found between the subscales of the SF-36 and the  
238 BSHS-B. This supports the previously demonstrated validity of the SF-36 in burn populations [16]. The  
239 BSHS-B subscale Work was strongly associated with several SF-36 subscales in different domains of  
240 functioning and showed lower associations with psychological symptoms as was also reported in a  
241 prior study [17]. In contrast to earlier findings, however, no evidence of high associations between  
242 Heat Sensitivity, Treatment Regimens and Body Image (domain Skin involvement) and role concerns  
243 (Social Functioning, Vitality and Mental Health) was detected [17]. The lower associations between  
244 appearance related problems and social difficulties in our study may be explained by the lower mean  
245 TBSA burned in this group of patients. Contextual factors comprised by the subscales Treatment  
246 Regimens and Body Image of the BSHS-showed relatively high associations with other ICF domains.  
247 This is not that surprising as Contextual Factors are known to influence (facilitate or hinder) all  
248 components of functioning [1, 26, 27].

249                   This study suggests that the generic scales were better able to discriminate problem  
250 levels across burn severity as five out of nine BSHS-B subscales (Affect, Heat Sensitivity, Simple  
251 Abilities, Hand Function and Interpersonal Relations) did not strongly discriminate between these  
252 groups. The finding that affect was more severely disturbed according to the generic scales in the  
253 more severely burned group (with subscales Anxiety/Depression in EQ-5D and Mental Health in SF-  
254 36) underscores the lower sensitivity in the BSHS-B. These results also support previous findings  
255 which reported a superior sensitivity of the SF-36 subscales compared to the BSHS-B over time [16].  
256 However, one could argue that problem levels in some of the scales may have been too small to  
257 detect differences across the severity groups. For example Hand function will be affected only in  
258 persons with hand burns which will not necessarily be true in all respondents in the more severe  
259 burn group. On the other hand, the generic measures may be too broad, also including pre-existing  
260 health problems that may have little to do with the burn injury. Other study methods, e.g.,  
261 qualitative approaches may be needed to elucidate this issue. Furthermore the short version of the  
262 BSHS was used in this study. Longer versions such as the BSHS-Revised (BSHS-R) or the BSHS-  
263 Abbreviated (BSHS-A) may score differently on sensitivity.

264                   For use in clinical practice ideally there should be minimal overlap between generic and  
265 disease specific instruments to lower the cost of scoring of a number of different measures.  
266 However, it is also important to measure all relevant areas of functioning to capture the full impact  
267 of a condition. This may add another layer of decision-making and complexity when measuring  
268 HRQOL for clinical purposes. This study showed that according to the ICF framework, applying both  
269 generic and condition specific measures, did not address the full scope of problems following burn  
270 injury. None of the generic scales includes Body Structure and other relevant impairment in Body

271 Function (e.g., itch or stigma, coping). Whilst Personal factors can be found in the BSBS-B in the  
272 subscale Treatment Regimens and Body Image but this is still limited. Personal factors may include  
273 various aspects such as gender, race, age, coping styles, education, profession, past and current  
274 experience, individual psychological assets and other health conditions, all of which can affect health  
275 and functioning [27]. As illustrated in this study, problems in the participation area were associated  
276 with both physical and social problems but the BSBS-B did not make the underlying problems  
277 explicit. For example stigmatisation may be an underlying problem [26]. These findings indicate there  
278 is room for improvement regarding the burn specific instrument both in defining necessary problem  
279 areas of functioning currently not included as well as a critical reflection on domains that add little  
280 information from a clinical perspective (e.g., treatment regime). In summary, despite the burden to  
281 the patient and the clinician it seems necessary to combine a generic measure and a condition  
282 specific measure as they are complementary and still incomplete. New technologies such as  
283 computerized testing can help limit the burden of duplication in the future [11, 29].

284 Some limitations merit note. This study was part of a larger study design that required  
285 patients with adequate cognitive functioning. Older patients and those suffering from cognitive  
286 disorders were not included. Proxy assessment of HRQOL in those with mental and cognitive  
287 problems would be an alternative for self-reports and should be considered in future studies [2]. In  
288 addition persons who were lost to follow-up were statistically younger and may have had a better  
289 quality of life. The impact of these biases may limit generalization to the general burn population.  
290 The time frame chosen to compare the questionnaires may have influenced the results, as more  
291 problems may be experienced at earlier time points. Furthermore, there was a sample size difference  
292 between the no surgery and the  $\geq 1$  surgery group and the measures slightly differ in their  
293 timeframe; the EQ-5D examines current health status, the SF-36 uses a 4 week period and the BSBS-  
294 B does not specify the timeframe. The sample and timeframe differences may have affected the  
295 accuracy of the comparison. Finally, although the correlation boundaries used in this study are  
296 accepted in the literature to be classified as high, it can be argued it would be more appropriate to  
297 label them moderate. However, as the questionnaires used different time frames and they also differ  
298 in their approach (i.e., EQ-5D uses a decision theory approach including single items as indicators of  
299 health domains; both SF-36 and BSBS-B use a profile approach that includes multiple items) it was  
300 assumed that a generous application of correlation boundaries could be justified.

## 301 CONCLUSION

302 The results of this study illustrate that the ICF framework is useful to classify scales in  
303 order to identify overlapping areas. Scales that are largely overlapping unnecessarily increase the

304 burden and should be avoided. The psychometric assessment of the relationship between the EQ-5D,  
305 the SF-36 and the BSHS-B shows that convergence is higher between the generic measures (EQ-5D  
306 and SF-36) as compared to the BSHS-B. Both generic scales performed well regarding discriminant  
307 validity. Additionally, the ICF framework previously appeared useful to identify gaps regarding  
308 domains that are currently overlooked. Consequently, there is room for improvement, particularly  
309 regarding the burn-specific measure. This study also illustrated that a short generic scale such as the  
310 EQ-5D can provide interesting information but should be combined with a more comprehensive  
311 condition-specific scale in order to capture the full impact. Of notice, the use of a coherent  
312 timeframe across the scales should be considered to better attune the measurements. Overall, this  
313 study supports the view that currently the most frequently used scales to measure functioning fall  
314 short to measure the full impact of a burn injury.

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316

317

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