

Burnout among Dutch intensivists – a nationwide survey

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Abstract

Background

Burnout in healthcare workers is deleterious for patients as well as for the healthcare workers themselves, with consequences ranging from less job satisfaction to increased mortality rates. Burnout in intensivists is reportedly high with 50% of intensivists having a burnout in some series. The present study was done to estimate incidence and prevalence of burnout in intensivists in the Netherlands and to identify risk factors for burnout.

Methods

Two online questionnaires were sent: one to all intensivists in the Netherlands and one to the medical directors of Dutch ICUs.

Results

A reply was received from 308 out of 664 intensivists (46.4%). Results of 272 intensivists (41%) were evaluable, 12 of whom (4.4%) were diagnosed with burnout at the time of the questionnaire. No association was found between working conditions or personal characteristics and burnout. Intensivists who reported conflict with the hospital management and having complaints filed against them had a significantly higher burnout rate. From the medical directors questionnaire it was found that 7.4% of intensivists suffered from burnout in 2013. The lower incidence and prevalence of burnout in Dutch intensivists compared with foreign series might be explained by a lower workload for intensivists as compared with the literature or by different weighing of the burnout test results by different authors.

Conclusion

Incidence and prevalence of burnout among Dutch intensivists were found to be unexpectedly low as compared with the

literature. The burnout rate was significantly higher in intensivists involved in conflicts or complaints.

Introduction

Burnout was described by Maslach et al. as a response to chronic emotional and interpersonal stressors on the job.^[1] It is characterised by emotional exhaustion, cynicism or depersonalisation, and inefficacy or diminished personal accomplishment.^[1] Situational characteristics such as the demands of the job or the organisation as well as personal characteristics and coping styles may predispose to burnout.^[2] The current understanding is that burnout is a result of imbalance between job demands and job resources.^[3] In the Job Demands-Resources model demands have negative consequences such as strain or stress while resources or rewards have positive consequences resulting in motivation and resilience. An imbalance between positive and negative consequences or between resources and demands may result in burnout.

Burnout in healthcare workers has negative consequences for the workers themselves as well as for the patients they care for. The Dutch Bureau for Statistics found the burnout rate in the Dutch working population to be 14% (<http://www.cbs.nl/nl-NL/menu/themas/arbeid-sociale-zekerheid/publicaties/artikelen/archief/2015/cbs-en-tno-een-op-de-zeven-werknemers-heeft-burn-outklachten>). Healthcare workers with burnout have been found to suffer from post-traumatic stress syndrome, depression, worse sleep quality, worse teamwork quality, less job satisfaction and higher mortality rates.^[4] Their patients are at risk of medical errors and higher mortality; there is also a risk that a healthcare worker suffering from a burnout may be less mindful of the needs of families.^[4-7] Burnout is also found in

medical students.^[8] Burnout in intensivists may be a significant threat to the health of both the intensivists and their patients.^[9] The incidence of burnout in intensivists is reportedly high with burnout rates up to 51%, but the incidence and prevalence of burnout in Dutch intensivists is unknown.^[10-14] The objective of this study was to estimate prevalence and incidence of burnout in Dutch intensivists and to identify risk factors for burnout.

Methods

Intensivists questionnaire

On 9 September 2013, an email with a direct link to a questionnaire was sent by the Dutch Society for Intensive Care (NVIC) and on behalf of the investigators to all 664 intensivist-members of the NVIC asking them to participate in the study and fill out the 45-item questionnaire. A reminder was sent on 17 October 2013. The questionnaire was anonymous and contained questions on personal circumstances, working conditions and arrangements for shifts, compensation time and the Utrechtse Burnout Schaal Contactuele beroepen (UBOS-C) questionnaire to diagnose burnout. Because longer questionnaires were expected to illicit less responses, the decision was made not to add extra questionnaires testing respondents for other diagnoses besides burnout (such as engagement or safety climate). The percentage of burnout among the intensivists from this questionnaire was regarded as an estimate of burnout prevalence.

For research purposes burnout can be diagnosed with the Maslach Burnout Inventory (MBI).^[15] The MBI is used by most authors on the subject. There are different versions of the MBI for different professional groups. The MBI for Human Services Survey (MBI-HSS) is appropriate for use in healthcare.^[16] The MBI-HSS contains 22 questions on the three dimensions of burnout, namely emotional exhaustion (nine questions), depersonalisation (five questions) and personal accomplishment (eight questions). The word 'burnout' does not appear in any of the questions. Typical questions are formulated like 'Do you experience.....?' with possible answers ranging from 'never' to 'every day' on a seven-point Likert scale. Questions are to be scored from 0 (never) to 6 (every day), resulting in separate scores for each of the three dimensions. High scores in emotional exhaustion and depersonalisation and low scores in personal accomplishment are indicative for burnout. Although most authors use the same MBI questionnaire, weighing of the results is not uniform.^[17] The MBI manual defines the upper third part of the scoring range as abnormal, but some authors use different cut-off values.^[15,18] The MBI manual does not give instructions on how to combine the three scores to diagnose burnout. Some authors combine scores to a single numerical value by adding all scores for emotional exhaustion and depersonalisation and subtracting all scores for personal accomplishment, using a cut-off value of -8, above which burnout is diagnosed. Others define burnout as having abnormal scores in all three dimensions

together. The MBI has been validated extensively by comparing results of the test in subjects with or without burnout as established by psychiatrists or psychologists.

The UBOS-C is the validated Dutch translation of the MBI-HSS and was used in the present study to define burnout.^[16] The UBOS-C contains eight questions on emotional exhaustion, five on depersonalisation and seven on personal accomplishment, totalling 20 questions instead of the original 22 in the MBI-HSS. This is the result of extensive testing and validation, eliminating two redundant questions. Contrary to the original MBI-HSS, cut-off values to determine abnormal scores are not defined as the upper third (as in the MBI-HSS) but as the upper fourth or 75th percentile.^[16] Instead of calculating the sum, mean scores for emotional exhaustion, depersonalisation and personal accomplishment are to be calculated. According to the UBOS-C a high score for emotional exhaustion is >2.38, a high score for depersonalisation is >1.80 for men and >1.60 for women and a low score for personal accomplishment is <3.70. Contrary to the MBI-HSS, the way burnout is diagnosed in the UBOS-C is unambiguously defined by a high score in emotional exhaustion (EE) in combination with either a high score in depersonalisation (DP) or a low score in personal accomplishment (PA) or both. To be able to compare our results with the literature we also reported on the three dimensions separately and we calculated the sum of all scores (EE+DP-PA) correcting for the fact that the UBOS-C has eight instead of nine questions on emotional exhaustion and seven instead of eight questions on personal accomplishment. This means that the sum was calculated as follows: $(9/8 * \text{SumEE}) + (\text{SumDP}) - (8/7 * \text{SumPA})$.

Medical directors questionnaire

On 24 March 2014, an email with a link to a questionnaire was sent to all medical directors of Dutch intensive care units asking them to participate in the study by answering questions about their unit and burnout in their staff. The questionnaire contained questions on the characteristics and size of the ICU and the final question was 'How many of your intensivists were suffering from burnout in 2013 in your opinion?' No diagnostic criteria or definition of burnout was given. A reminder email was sent on 7 April 2014. The percentage of burnout in the intensivists from this questionnaire was regarded as an estimate of burnout incidence in 2013.

Ethics, consent and permission

The need for ethical approval was waived by the local ethics committee (Medisch Ethische Toetsings Commissie Zuidwest Holland). Response to the questionnaires was regarded as consent and permission from the respondent to be included in the study.

Analyses

Questionnaires were analysed when no more responses were submitted (about six weeks after the reminders had been sent), by using Microsoft Excel and SPSS (SPSS, Chicago, Ill, USA). Continuous variables were compared using t-tests when normally distributed. We used the median values of the results to dichotomise results whenever possible and necessary to obtain two categories of results which could hence be analysed by the Fisher’s exact test to obtain p-values for comparison.

Results

Intensivists questionnaire

A response to the survey was received from 308 intensivists (46.4% of the 664 registered intensivists in the Netherlands). Twenty-one respondents were no longer practising intensive care and 15 responses were incomplete in such a way that it was impossible to conclude if the respondent was suffering from burnout, leaving responses of 272 individual intensivists (41.0%) to be studied. As judged by the UBOS-C, which requires a high score in emotional exhaustion and either a high score in depersonalisation or a low score in personal accomplishment or both to diagnose burnout, 12 intensivists out of 272 (4.4%) were suffering from burnout at the time of the questionnaire. UBOS-C scores are shown in table 1. When the corrected sum

Table 1. Scores of 272 Dutch intensivist on the UBOS-C, the Dutch version of the Maslach burnout inventory.

| Emotional exhaustion (EE) | |
|---|-----------|
| Very Low (<= 0.37) | 24 (9%) |
| Low (0.38-0.99) | 68 (25%) |
| Average (1.00-2.37) | 151 (56%) |
| High (2.38-3.62) | 25 (9%) |
| Very high (>= 3.63) | 4 (1%) |
| Depersonalization (DP) | |
| Very Low (<= 0.19) | 30 (11%) |
| Low (0.20-0.59) | 101 (37%) |
| Average (0.60-1.59 for women, 0.60-1.79 for men) | 120 (44%) |
| High (1.60-2.59 for women, 1.80-2.79 for men) | 18 (7%) |
| Very high (>= 2.60 for women, >= 2.80 for men) | 3 (1%) |
| Personal accomplishment (PA) | |
| Very Low (<= 2.99) | 5 (2%) |
| Low (3.00-3.70) | 31 (11%) |
| Average (3.71—4.70) | 112 (41%) |
| High (4.71-5.56) | 107 (40%) |
| Very high (>= 5.57) | 17 (6%) |
| Combined diagnosis of burnout | |
| (Very) High EE and (very) high DP and (very) low PA | 5 (2%) |
| (Very) High EE and (very) high DP | 6 (2%) |
| (Very) High EE and (very) low PA | 1 (0.3%) |
| Total | 12 (4.4%) |

According to the UBOS-C a high score for EE is > 2.38, a high score for DP is > 1.80 for men and > 1.60 for women and a low score for PA is < 3.70 and burnout is diagnosed with a high score for EE and either a high score for DP or a low score for PA or both.

Table 2. Personal characteristics and working conditions of 272 intensivists with or without burnout according to the UBOS-C questionnaire.

| | Total (n=272) | No burnout (n=260) | Burnout (n=12) | p |
|---|---------------|--------------------|----------------|----------------------|
| Gender | | | | |
| Male | 187 (69%) | 182 (70%) | 5 (42%) | ns ⁽¹⁾ |
| Female | 85 (31%) | 78 (30%) | 7 (58%) | |
| Mean age in years (SD) | 46 (8) | 46 (8) | 46 (6) | ns ⁽²⁾ |
| Marital status | | | | |
| Married or living together | 242 (89%) | 231 (89%) | 11 (92%) | ns ⁽¹⁾ |
| Single | 22 (8%) | 21 (8%) | 1 (8%) | |
| Years of experience in intensive care | | | | |
| 0-10 | 159 (58%) | 153 (59%) | 6 (50%) | ns ⁽¹⁾ |
| >10 | 112 (41%) | 106 (41%) | 6 (50%) | |
| Primary specialty | | | | |
| Anaesthesiology | 106 (39%) | 98 (38%) | 8 (67%) | ns ⁽¹⁾ |
| Internal medicine | 137 (50%) | 133 (51%) | 4 (33%) | |
| Level of the ICU | | | | |
| 1 or 2 | 137 (50%) | 130 (50%) | 7 (58%) | ns ⁽¹⁾ |
| 3 | 126 (46%) | 121 (47%) | 5 (42%) | |
| Number of intensivists working in the ICU | | | | |
| 0-6 | 131 (48%) | 123 (47%) | 8 (67%) | ns ⁽¹⁾ |
| 7 or more | 137 (50%) | 133 (51%) | 4 (33%) | |
| Working part time or fulltime | | | | |
| Part time (<75%) | 16 (6%) | 15 (6%) | 1 (8%) | ns ⁽¹⁾ |
| Fulltime (>=75%) | 253 (93%) | 242 (93%) | 11 (92%) | |
| Weekly number of days for patient care | | | | |
| 0-2.5 | 125 (46%) | 121 (47%) | 4 (33%) | ns ⁽¹⁾ |
| 2.5-5 | 141 (52%) | 133 (51%) | 8 (67%) | |
| Duration of the longest shift | | | | |
| 24 hrs or less | 121 (44%) | 117 (45%) | 4 (33%) | ns ⁽¹⁾ |
| More than 24 hrs | 143 (53%) | 135 (52%) | 8 (67%) | |
| Compensation after nightshift | | | | |
| Less than a whole day | 87 (32%) | 83 (32%) | 4 (33%) | ns ⁽¹⁾ |
| A whole day or more | 160 (59%) | 154 (59%) | 6 (50%) | |
| Duration of weekend shift | | | | |
| One day or less | 106 (39%) | 102 (39%) | 4 (33%) | ns ⁽¹⁾ |
| More than one day | 147 (54%) | 139 (53%) | 8 (67%) | |
| Staying at the hospital during nightshifts | | | | |
| Only when necessary | 180 (66%) | 171 (66%) | 9 (75%) | ns ⁽¹⁾ |
| All the time | 81 (30%) | 78 (30%) | 3 (25%) | |
| Monthly nightshifts on weekdays | | | | |
| 0-4 | 88 (32%) | 84 (32%) | 4 (33%) | ns ⁽¹⁾ |
| 4 or more | 178 (65%) | 171 (66%) | 7 (58%) | |
| Monthly weekend shifts | | | | |
| 0 or 1 | 68 (25%) | 66 (25%) | 2 (17%) | ns ⁽¹⁾ |
| 2 or more | 195 (75%) | 185 (71%) | 10 (83%) | |
| Weeks of vacation annually | | | | |
| 0-6 | 158 (58%) | 150 (58%) | 8 (67%) | ns ⁽¹⁾ |
| 7 or more | 114 (42%) | 110 (42%) | 4 (33%) | |
| Time since last vacation | | | | |
| Less than a month ago | 86 (32%) | 81 (31%) | 5 (42%) | ns ⁽¹⁾ |
| More than a month ago | 186 (68%) | 179 (69%) | 7 (58%) | |
| Having complaints filed against you last year | | | | |
| None | 193 (71%) | 188 (72%) | 5 (42%) | 0.044 ⁽¹⁾ |
| One or more | 79 (29%) | 72 (28%) | 7 (58%) | |
| Cooperation with hospital management | | | | |
| Good or neutral | 238 (88%) | 231 (89%) | 7 (58%) | 0.009 ⁽¹⁾ |
| Bad | 34 (13%) | 29 (11%) | 5 (42%) | |

(1) Fisher Exact test (2) Student t Test.

of scores was used, which is not in accordance with the UBOS-C manual but enables comparing our results to some reports in the literature, 42 respondents (15.4%) were diagnosed with burnout with a combined score above -8. Respondents from the intensivists questionnaire reported a mean number of 7.7 (± 3.5) intensivists working in their unit, a mean number of 14 (± 6) beds, a mean number of residents per unit of 8.8 (± 7.5) and a patient-to-nurse ratio of 1.25.

We did not find a significant difference in sex, age, number of children, years of experience or primary speciality of intensivists with or without burnout (table 2). Neither did we find a significant difference in working hours, number of weekend or nightshifts, days of compensation after night shifts, amount of vacation or time since last vacation in intensivists with or without burnout. We did, however, find that burnout was more frequent in intensivists who had complaints filed against them and also in intensivists who experienced poor cooperation with the hospital management (table 2).

Medical directors questionnaire

The questionnaire among medical directors of Dutch ICUs was sent to 73 medical directors registered at the NVIC. Evaluable responses were received from 25 out of 73 medical directors (34%). These 25 medical directors reported on a total of 189 intensivists, 14 of whom were judged by the medical directors to have suffered a burnout episode in 2013 (7.4%). This figure was regarded as an estimate of the incidence of burnout in 2013. Table 3 shows characteristics of the ICUs of these 25 medical directors. Table 4 shows the relationship between the characteristics of the ICUs and the number of intensivists

Table 3. Results of the questionnaire among 73 medical directors of Dutch ICUs regarding burnout in intensivists in their units.

| | n=25 |
|---|----------|
| What is the number of beds in your ICU? | |
| <10 beds | 7 (28%) |
| 10-20 | 13 (62%) |
| >20 beds | 5 (20%) |
| What is the level of your ICU? | |
| Level 1 | 6 (24%) |
| Level 2 | 11 (44%) |
| Level 3 | 8 (32%) |
| How many intensivists work in your ICU? | |
| 1 | 0 |
| 2-5 | 9 (36%) |
| 6-10 | 11 (44%) |
| 11-15 | 4 (16%) |
| 16-20 | 1 (4%) |
| >20 | 0 |
| How many intensivists in your unit had a burnout in 2013? | |
| 0 | 13 (52%) |
| 1 | 8 (32%) |
| 2 | 3 (12%) |
| I don't know | 1 (4%) |

with burnout as judged by the medical director, and also that burnout is more frequent in middle-sized ICUs and in level 2 ICUs. Depending upon both the volume and services provided, ICUs in the Netherlands range from level 1, mostly in smaller hospitals with more basic services, to level 3 with more facilities, mostly in teaching and academic hospitals. Most middle-sized ICUs are level 2. In the survey of intensivists this finding could not be confirmed.

Table 4. Number of intensivists with burnout related to the characteristics of the ICU as judged by the medical directors of the units (n=25).

| | Number of intensivists with burnout |
|-----------------------------------|-------------------------------------|
| Level of the ICU | |
| Level 1 | 0/29 |
| Level 2 | 9/68 (13%) |
| Level 3 | 5/92 (5%) |
| Number of beds in the ICU | |
| <10 beds | 0/34 |
| 10-20 | 12/87 (14%) |
| >20 beds | 2/68 (3%) |
| Number of intensivists in the ICU | |
| 2-5 | 2/37 (5%) |
| 6-10 | 10/84 (12%) |
| 11-15 | 2/51 (4%) |
| 16-20 | 0/17 |

Discussion

In this nationwide study on burnout among Dutch intensivists we found a low burnout rate with an incidence of 7.4% in 2013 and prevalence of 4.4%. Whereas sex, age, years of experience, workload or vacation were not associated with burnout, having a conflicting relationship with hospital management and complaints filed against the intensivist were associated with burnout. When the corrected sum of scores was used, which is not in accordance with the UBOS-C manual but enables comparison of our results with some literature reports, 15.4% of the respondents were diagnosed with burnout.

The burnout rate in intensivists in the present study differs considerably from what is reported in the literature. Shanafelt et al. in their nationwide study with over 7000 responders found 45.8% of US physicians to have burnout symptoms and they found burnout to be associated with workload.^[19] Burnout was found in 31% of Dutch medical residents,^[20] in 20% of Dutch general practitioners,^[21] in 50% of residents in a Michigan University Hospital^[22] and in 76% of residents in a Washington University Hospital.^[23] Guntupalli and Fromm found high emotional exhaustion scores in 29% of American intensivists, high depersonalisation scores in 20% and low personal accomplishment scores in 59%; we found 11, 8 and 13% respectively.^[10] The authors did not attempt to find an association between burnout and workload or any other explanatory factors. Similarly, abnormal scores were found for emotional

exhaustion in 54%, for depersonalisation in 40% and for personal accomplishment in 40% of American intensive care nurses and respiratory therapists without a combined score being reported.^[24] Burnout in colleagues was found to be an independent predictor of burnout in intensive care nurses, which led the investigators in this study to call burnout a contagious condition.^[25] Poncet et al. found one-third of 2392 French intensive care nurses to have burnout symptoms.^[26] Although most authors used the MBI-HSS to diagnose burnout, a comparison of the results is still difficult as different ways of weighing the results were used. Some authors diagnosed burnout only with a high score in emotional exhaustion, a high score in depersonalisation and a low score in personal accomplishment, so all three combined, resulting in a burnout prevalence between 3 and 9%.^[12,27] Several authors used the method of combining points by adding emotional exhaustion and depersonalisation and subtracting personal accomplishment points, where a score of -8 or higher indicates burnout and with a prevalence of burnout reported at between 31 and 51%.^[11,13,14,27]

What could explain the low burnout rate found in the present study? A cultural difference or Dutch doctors being less prone to suffer from burnout is not supported by existing literature as other categories of Dutch doctors have been found to have high burnout rates.^[20,21] Workload is commonly found to be associated with burnout.^[13,18,24] When comparing workload in Dutch ICUs in 2013 with workload as presented in a national study in France, Dutch ICUs had the same mean number of beds,^[14] twice as many intensivists (7.7 vs. 3.6), three times more residents (8.8 vs. 2.7) and 1.2 vs. 3.0 patients per nurse, *table 5*.^[14] Although a head-to-head comparison is lacking we speculate that the low rate of burnout in Dutch intensivists as compared with French intensivists in this study may be explained by the difference in workload. This can be regarded as a confirmation of the conclusions of Embriaco, Guntupalli, and Shanafelt, among others, that workload is an important determinant of burnout with a dose-response relationship even

Table 5. Workload in the ICU in the present study as compared to workload in the Embriaco study.

| | France 2003 ^[14] | Netherlands 2013 |
|--|-----------------------------|-------------------------|
| Mean annual admissions per unit | 600±310 | 900[30] |
| Mean ICU length-of-stay (days) | 7.9±2.6 | 3.1 ⁽¹⁾ |
| Mean ICU mortality | 19.3% | 8.9 % [30] |
| Mean number of patients per nurse | 3.0 | 1.2[30] |
| Mean number of intensivists per unit | 3.6±2.2 | 7.7 ±3.5 ⁽²⁾ |
| Mean number of interns/residents per ICU | 2.7±2.0 | 8.8 ±7.5 ⁽²⁾ |
| Mean number of ICU beds per unit | 14±7 | 14±6 ⁽²⁾ |

⁽¹⁾ www.stichting-nice.nl, ⁽²⁾ present study

though, as a result of the low burnout rate, we did not find this association within our own results.^[10,14,19]

We recognise several limitations of the current study. With a response rate of 41% selection bias may have occurred, as burnout subjects might feel less tempted to answer questionnaires or intensivists who were more interested in the subject or less busy might be more likely to answer the questionnaire. However, the response rate of the intensivists questionnaire is similar to what was expected from the literature. A meta-analysis on response rates of internet surveys revealed a mean response rate of 39.6% and a recent survey on burnout in academic professors in the Netherlands had a response rate of 36% when counting evaluable results.^[28,29] Likewise, medical directors and intensivists may have been too busy or not interested in the subject. Although we investigated known risk factors for burnout, we did not investigate factors that may increase resilience against burnout or protect subjects from having a burnout. Given the small number of intensivists diagnosed with burnout by the questionnaire it was difficult to confirm associations between risk factors and burnout. In the intensivists' questionnaire, burnout was diagnosed using the validated UBOS-C questionnaire; however, burnout diagnosis based on UBOS-C may differ from a psychiatrist's diagnosis. Burnout was assessed differently in the two questionnaires: by means of the UBOS-C in the intensivists questionnaire, but in the medical directors questionnaire it was left entirely to the medical directors to define burnout, without uniform diagnostic criteria.

Conclusion

In conclusion, we found an unexpectedly low incidence and prevalence of burnout among Dutch intensivists as compared with most of the literature. This could not be explained solely by different weighing of test results. The burnout rate was significantly higher in intensivists involved in conflicts or complaints. It is hypothesised that the difference might be partially explained by lower workload in Dutch ICUs. Given the low burnout rate future research should focus on aspects that protect Dutch intensivists from burnout rather than what causes burnout.

Key messages

Previous studies have shown that burnout is associated with workload and that the burnout rates in intensivists are very high, approaching 50% in some studies. In this study in Dutch intensivists burnout rates were much lower, with an incidence of 7.4% and a prevalence of 4.4% and this might be explained by a lower workload for intensivists in the Netherlands.

Disclosures

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Verkorte productinformatie ECALTA (opgesteld: september 2014). **De volledige productinformatie (SPC) is op aanvraag verkrijgbaar.** **Samenstelling:** ECALTA bevat 100 mg anidulafungine per injectieflacon. De gereconstitueerde oplossing bevat 3,33 mg/ml anidulafungine en de verdunde oplossing bevat 0,77 mg/ml anidulafungine. **Indicaties:** Behandeling van invasieve candidiasis bij volwassen patiënten. **Farmacotherapeutische groep:** Antimycotica voor systemisch gebruik, andere antimycotica voor systemisch gebruik, ATC-code: J02 AX 06. **Dosering:** De behandeling met ECALTA moet worden uitgevoerd door een arts die ervaring heeft met de behandeling van invasieve schimmelinfecties. De eenmalige aanvangsdosis van 200 mg dient op dag 1 te worden toegediend, daarna gevolgd door dagelijks 100 mg. Er zijn onvoldoende gegevens beschikbaar om een behandeling van langer dan 35 dagen met de 100 mg dosis te onderhouden. De veiligheid en werkzaamheid van ECALTA bij kinderen jonger dan 18 jaar zijn niet vastgesteld. Op basis van de momenteel beschikbare gegevens kan geen doseringsadvies worden gedaan. Het wordt aanbevolen om ECALTA toe te dienen met een infusiesnelheid die niet hoger is dan 1,1 mg/minuut (overeenkomend met 1,4 ml/minuut wanneer gereconstitueerd en verdund conform instructies). ECALTA mag niet worden toegediend als een bolusinjectie. **Contra-indicaties:** Overgevoeligheid voor de werkzame stof of voor één van de hulpstoffen; overgevoeligheid voor andere geneesmiddelen uit de groep van echinocandinen. **Waarschuwingen en voorzorgen:** ECALTA is niet onderzocht bij patiënten met *Candida-endocarditis*, osteomyelitis of meningitis. De werkzaamheid van ECALTA is alleen geëvalueerd in een beperkt aantal neutropene patiënten. Verhoogde waarden van leverenzymen zijn waargenomen bij gezonde personen en patiënten die met anidulafungine werden behandeld. Bij een aantal patiënten met een ernstige onderliggende medische aandoening die gelijktijdig meerdere geneesmiddelen kregen naast anidulafungine, zijn klinisch significante leverafwijkingen opgetreden. Gevallen van significante leverstoornis, hepatitis en leverfalen kwamen soms voor tijdens klinische onderzoeken. Bij patiënten met verhoogde leverenzymen tijdens behandeling met anidulafungine dient te worden gecontroleerd op tekenen van verslechterende leverfunctie en dient het risico/voordeel van voortzetting van behandeling met anidulafungine geëvalueerd te worden. Anafylactische reacties, waaronder shock, zijn gemeld bij het gebruik van anidulafungine. Indien deze reacties voorkomen, dient de behandeling met anidulafungine te worden stopgezet en dient passende behandeling te worden gegeven. Infusiegerelateerde bijwerkingen zijn gemeld bij het gebruik van anidulafungine, waaronder uitslag, urticaria, blozen, pruritus, dyspneu, bronchospasmen en hypotensie. Infusiegerelateerde bijwerkingen komen weinig voor wanneer de snelheid waarmee anidulafungine wordt geïnfundeed niet hoger is dan 1,1 mg/minuut. In een onderzoek bij ratten is verergering van infusie-gerelateerde reacties door gelijktijdige behandeling met anestheticum waargenomen waarvan de klinische relevantie onbekend is. Men dient voorzichtig te zijn bij het gelijktijdig toedienen van anidulafungine en anestheticum. Patiënten met een zeldzame erfelijke fructose-intolerantie dienen dit geneesmiddel niet te gebruiken. **Bijwerkingen:** Bijwerkingen waren meestal licht tot matig en leidden zelden tot stopzetting van de behandeling. De meest gerapporteerde, zeer vaak voorkomende bijwerkingen ($\geq 1/10$) zijn: hypokaliëmie, diarree, misselijkheid. Vaak ($\geq 1/100$, $< 1/10$) zijn waargenomen: hyperglykemie, convulsie, hoofdpijn, hypertensie, hypotensie, bronchospasme, dyspneu, braken, verhoogde alanine-aminotransferase, verhoogde alkalische fosfatase in het bloed, verhoogde aspartaat-aminotransferase, verhoogde bilirubine in het bloed, cholestase, uitslag, pruritus, verhoogd creatininegehalte in het bloed. Soms ($\geq 1/1000$, $< 1/100$) zijn waargenomen: coagulopathie, blozen, opvliegers, pijn in de bovenbuik, verhoogde gamma-glutamyl-transferase, urticaria, pijn op de infusieplaats. Bijwerkingen van spontane meldingen met frequentie niet bekend (kan met de beschikbare gegevens niet worden bepaald) zijn: anafylactische shock, anafylactische reactie (zie "Waarschuwingen en voorzorgen"). **Afleveringsstatus:** UR. **Verpakking en Registratienummer:** ECALTA, 100 mg poeder voor concentraat voor oplossing voor intraveneuze infusie: EU/1/07/416/002 (1 injectieflacon met 100 mg poeder). **Vergoeding en prijzen:** ECALTA wordt vergoed volgens de beleidsregel dure geneesmiddelen in ziekenhuizen. Voor prijzen wordt verwezen naar de Z-Index tax. **Voor medische informatie over dit product belt u met 0800-MEDINFO (6334636).** **Registratiehouder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, Verenigd Koninkrijk. **Neem voor correspondentie en inlichtingen contact op met de lokale vertegenwoordiger: Pfizer bv, Postbus 37, 2900 AA Capelle a/d IJssel.**