JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 16, No. 3, March 2020

"Happy Trials to You"

Does the Clinical Research Enterprise Have a Burnout Problem? By Norman M. Goldfarb

According to 2018 Gallup survey, 23% of employees reported feeling burned out at work very often or always, while an additional 44% reported feeling burned out sometimes.³

The World Health Organization includes burnout in its International Classification of Diseases (ICD-11) as a "factor influencing health status or contact with health services."²

According to Melinda Smith, Jeanne Segal, and Lawrence Robinson:1

Burnout is a state of emotional, physical and mental exhaustion caused by excessive and prolonged stress. It occurs when you feel overwhelmed, emotionally drained, and unable to meet constant demands. As the stress continues, you begin to lose the interest and motivation that led you to take on a certain role in the first place.

Burnout may be the result of unrelenting stress, but it isn't the same as too much stress. Stress, by and large, involves *too much*, too many pressures that demand too much of you physically and mentally. However, stressed people can still imagine that if they can just get everything under control, they'll feel better.

Burnout, on the other hand, is about *not enough*. Being burned out means feeling empty and mentally exhausted, devoid of motivation, and beyond caring. People experiencing burnout often don't see any hope of positive change in their situations. If excessive stress feels like you're drowning in responsibilities, burnout is a sense of being all dried up. And while you're usually aware of being under a lot of stress, you don't always notice burnout when it happens.

Stress does not necessarily lead to burnout. In fact, stress comes in two flavors: "distress" and "eustress." The latter is a normal level of stress that is *beneficial*. Burnout occurs when stress moves from the beneficial to the overwhelming. When someone feels exhausted, dreads going to work, does not gain any satisfaction from what they doing, and loses confidence in their abilities, they have reached burnout and nothing good will result.⁴

Burnout can be caused by an unmanageable workload, unreasonable time pressure, monotony, lack of control, unclear job expectations, lack of supervisor support and communication, unfair treatment, dysfunctional workplace dynamics, an incompatible work environment, lack of social support, work-life imbalance, and other factors.^{5,6}

People in certain occupations are more prone to burnout than individuals working in other occupations. For example, 44% of physicians experience burnout.⁷ Patients, study participants, and caregivers can also experience burnout.⁸

The Survey

We conducted a survey in January, 2020 to find out whether clinical research professionals suffer from burnout. The 295 respondents rated 15 statements from a MindTools assessment instrument.⁹

- I feel that I have no one to talk to.
- I am harder and less sympathetic with people than perhaps they deserve.
- I feel that I am in the wrong organization or the wrong profession.
- I feel misunderstood or unappreciated by my co-workers.

- I am easily irritated by small problems or by my co-workers and team.
- I feel under an unpleasant level of pressure to succeed.
- I feel that I am achieving less than I should.
- I feel that I am not getting what I want out of my job.
- I have negative thoughts about my job.
- I find that I do not have time to plan as much as I would like to.
- I feel that I do not have time to do many of the things that are important to doing a good quality job.
- I feel that there is more work to do than I practically have the ability to do.
- I am frustrated with parts of my job.
- I feel run down and drained of physical or emotional energy.
- I feel that organizational politics or bureaucracy frustrate my ability to do a good job.

The sample size of 295 is large enough to support some conclusions but not large enough to be definitive, especially since the sample is likely to be biased by self-selection. People with high, medium or low levels of stress and burnout might have been more or less likely to participate in the survey. Additionally, the data are subjective and self-reported, and the MindTools instrument has not been scientifically validated. Nevertheless, comparisons across the measures and subgroups is illuminating.

Results and Discussion

We tabulated the respondents' answers on a scale of 0 (Not at All) to 4 (Very Often). According to MindTools, the following average scores indicate the following burnout levels:

0.0 to 0.2	None
0.3 to 1.1	Slight
1.2 to 2.3	Moderate
2.3 to 2.9	Serious
3.0 to 4.0	Severe

In our survey, the average respondent's average score was 2.15 (high-moderate according to MindTools). None of the respondents rated themselves as "Not at All" on all measures. Three sad souls rated themselves as "Very Often" on all measures. Chart 1 shows the distribution.

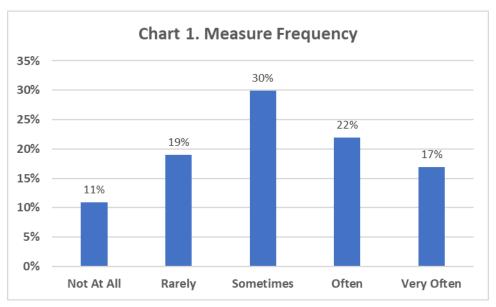


Chart 2 shows that 42% of respondents are experiencing a serious or severe level of burnout, which does not bode well for the future.

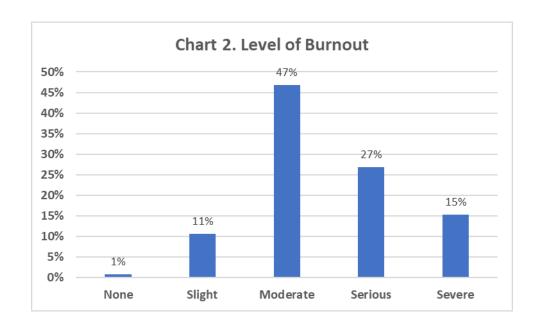
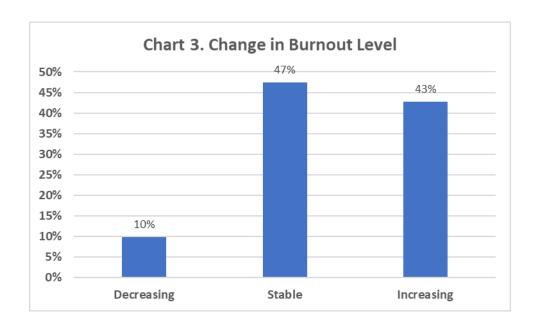


Chart 3 shows that most respondents reported that their burnout level was either stable or increasing, which also does not bode well for the future.



Subgroup Analysis

Chart 4 shows that burnout was lowest at research sites (n=163), substantially higher at study sponsors (n=58), and higher still at clinical research organizations (CROs) (n=61). Research site personnel might not appreciate the pressure on study sponsor personnel. The data support the reputation for high pressure at many CROs.

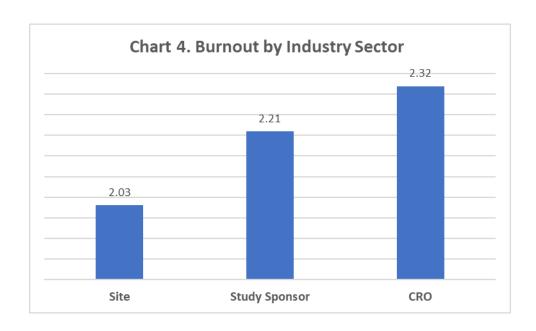
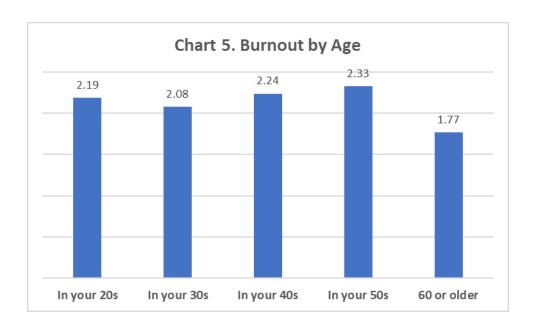


Chart 5 shows that burnout starts a bit above average for respondents in their 20s (n=20), dips in their 30s (n=79), rises through their 40s (n=90) and 50s (n=66), and then declines substantially for those 60 or older (n=40). This pattern is not surprising. It would probably show more variation if stress did not cause departures from high-pressure positions or the industry as a whole.



Additional Results

Clinical research associates (n=26) reported a burnout level of 2.24, somewhat higher than the 2.12 score of clinical research coordinators (n=88). Note that many CRAs are not field monitors, a particularly grueling and high-turnover position.

The burnout level of respondents from the U.S. and Canada (n=227) was 2.14, lower than the 2.16 score of respondents from other countries (n=68).

The 2.16 burnout for male respondents (n=45) was essentially the same as the 2.15 level for female respondents (n=246).

Respondent Perceptions

Chart 6 shows that the 15 respondent measures vary substantially in their contribution to burnout for clinical research professionals:

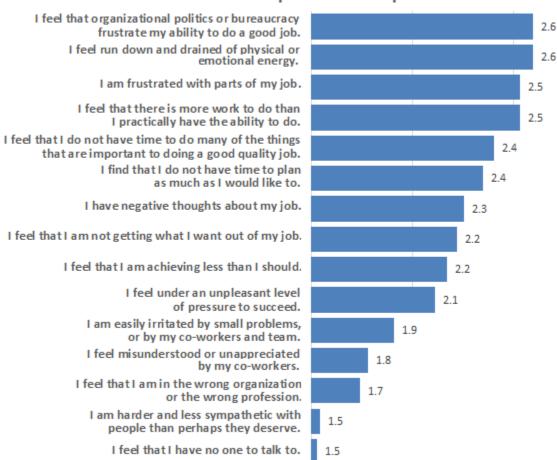


Chart 6. Respondent Perceptions

One interpretation of this chart is that many people in the clinical research industry are frustrated that bureaucracy, inefficiency and overwork interfere with their ability to make important and high-quality contributions to a vital cause: saving people's health and lives.

Measures to Take Against Burnout

The first step for dealing with burnout in yourself or others is to determine whether there a problem. The MindTools instrument is a good place to start. The second step is to identify the causes. The third step is to address the causes.

Engage with colleagues, family and friends to share your concerns, discuss potential causes, and identify possible solutions in yourself or the work environment. Just talking to people can reduce stress, unless their negative attitude only makes things worse. It helps to know that you are not alone in your feelings or in your search for solutions.

Find a healthier perspective on your and your colleagues' situation. Consider your and their priorities and expectations. Are they consistent with your and their mental health? Can you and they set boundaries and find a sustainable and fulfilling life balance?

Other popular ways to reduce stress include setting and sticking to goals and priorities, using to-do lists, obtaining clarification, giving yourself rewards, taking a break, exercising, reducing caffeine intake, spending time with friends and family, laughing, learning to say no, taking a yoga class, practicing mindfulness, listening to soothing music, taking deep breaths, spending time with your pet, and talking with a mental health professional.^{10,11} Self-care assessment worksheets are readily available online.¹²

Even if you do not feel burned out, consider benchmarking your current level, taking steps to reduce the level, and checking your level periodically to monitor changes up or down.

Conclusion

People have different tolerances for these measures of burnout and can thrive at different levels. It is not a population that burns out but an individual. We can, however, say that a population with a high average burnout score is more likely to include individuals that will soon burnout. People do not usually start jobs in a burnt-out condition; it develops over time as a function of their self-care and their environment, both of which are under somebody's power to control or at least influence.

Acknowledgement

The author gratefully acknowledges the contributions of Miriam Duston, LCSW, Therapist, Sacramento Children's Home Counseling Center.

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