

Ameliorating the Impact of Complications and Errors on Surgeons: Resilience Training for Surgeons.

(Resilience Training for Surgeons)

Research Protocol Version 1.1

11/06/18

Research Team Members (Role)

Dr. Helen Bolderston (Chief Investigator)

Mr Kevin Turner, MA DM FRS(Urol) (Principle Investigator)

Prof. Sine McDougall (co-investigator)

Dr Kevin Thomas (co-investigator)

Stephen Richer (Ph.D. Student)

Funders: Bournemouth University and Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust.

Sponsor: Bournemouth University.

Contents

1: Background	3
2: Aims and Objectives.....	3
3: Design.....	4
4: Participants	4
5: Sampling.....	4
Strategy	4
Sample Size	4
6: Recruitment	4
7: Randomisation	5
8: Data Collection.....	5
Data Collection Points.....	5
Primary Outcome Measures	6
Secondary Outcome and Process Measures.....	6
9: Data Analysis.....	6
10: Ethical Considerations.....	7
11: Data Protection and Storage.....	8
Recordings.....	8
Data.....	8
Confidentiality.....	8
12: Training Protocol with example timings.	9
Training Session 1	9
Training Session 2	15
Training Session 3	20
13: Timelines	24
14: References	25

1: Background

There is a high likelihood that surgeons will experience adverse outcomes due to patient complications following surgery sometime during their careers (Patel et al., 2010). Such adverse events can have undesirable effects on the surgeon in terms of quality of life and mental well-being (e.g. anxiety, feelings of regret) and lowered professional confidence and impaired perceptions of professional competence. Furthermore, numerous studies have indicated that these kinds of negative impacts can also lead to burnout and depression, (Pinto 2011, Shanafelt 2012). As well as the detrimental effects on surgeons and those around them, this in turn may lead to more errors and poorer outcomes for patients.

Research in a range of occupational settings has indicated that resilience plays an important role in ameliorating the impact of adverse events in high pressure environments. This project will use a randomised controlled trial research design to assess the efficacy of brief one-to-one Acceptance and Commitment Training (ACTr), designed to enhance surgeons' psychological resilience. According to acceptance and commitment therapy (Hayes, 2004), psychological flexibility is implicated in psychopathology. Psychopathology is primarily the consequence of psychological inflexibility i.e. inability to persist or change behaviour according to long-term values due to language and cognition skills (Hayes, 2006), which has particular significance when an individual is confronted with stress or adversity.

2: Aims and Objectives

The main aim of our research is to assess the efficacy of a brief Acceptance and Commitment Training course. We wish to ascertain whether such a course can increase surgeons' resilience by increasing psychological flexibility, valuing and self-compassion (all of which are expected to be positively impacted by this training). This research will fill a gap in the relevant research literature; namely that no research project as far as we are aware has evaluated ACTr as a means to enhance resilience in surgeons. In fact any research conducted on resilience training with a surgical population is rare.

3: Design

The proposed study will initially take the shape of a small pilot study (n=10) and following this a randomised controlled trial. (n=100)

The intervention will consist of Acceptance and Commitment Training (ACTr), on a 1:1 basis. Flaxman (2013) devised a workplace training program which will form the basis of this training protocol. ACT as a workplace training has been supported by numerous studies including Lappalainen et al (2007), Finnes and Ghaderi (2017). A recent manual, Flaxman, Bond and Livheim (2013), will be utilised for this study, with a bespoke tailoring to the surgeons' population. See section 12 for full details.

4: Participants

Trainee surgeons and consultant surgeons from local hospitals, initially Royal Bournemouth Hospital, Bournemouth, Dorset; and Poole Hospital, Poole, Dorset. Then the John Radcliffe Hospital, Oxford; Southampton General Hospital, Southampton and Portsmouth General Hospital.

5: Sampling

Strategy

Block randomisation (blocks of 4) will be used to help ensure equal-sized groups. An external statistician will generate random blocks of 4.

Sample Size

For the RCT, we intend to recruit 100 to allow for some attrition and still have approximately 45 participants per condition. This number is based on previous studies(e.g Flaxman and Bond, 2010) conducted using ACTr based training; this will give enough statistical power, particularly with regards to mediation analysis.

6: Recruitment

Recruitment will initially be through Royal Bournemouth Hospital and will be initiated by Mr Kevin Turner, MA DM FRCS(Urol) (Principal Investigator). An invitation email will be sent to potential participants (again identified by Mr Turner) and further information regarding the study will be forwarded to the potential participant on their request only.

7: Randomisation

Participants will be allocated one of two groups, the experimental group (who will receive ACTr) or the wait-list control group. Participants allocated to the wait-list control will be offered the same ACTr sessions once the current study has ended.

8: Data Collection

Data Collection Points

T1 – 2 Weeks before training session one. Via email/on-line questionnaires.

S1- First training session

Interval (4 weeks RCT, 2 weeks Pilot)

T2 – Immediately before the beginning of training session two.

S2 – Second Training session

Interval (4 weeks RCT, 2 weeks Pilot)

T3 - Immediately before the beginning of training session three.

S3 – Third Training session

T4 –Within two week of completion of training session three.

T5- Follow-up, 12 weeks after training session three. Via email.

Primary Outcome Measures

Resilience - Brief Resilience Scale (BRS)

General Health - General Health Questionnaire (GHQ-12)

Secondary Outcome and Process Measures

CBI (Copenhagen Burnout Inventory)

DASS21 (Depression Anxiety and Stress Scale)

VLQ (Value Living Questionnaire)

WAAQ (Work related Acceptance and Action Questionnaire)

AAQII (Acceptance and Action Questionnaire)

SCS (Self Compassion Scale)

SPS (Sense of Preparedness Scale)

9: Data Analysis

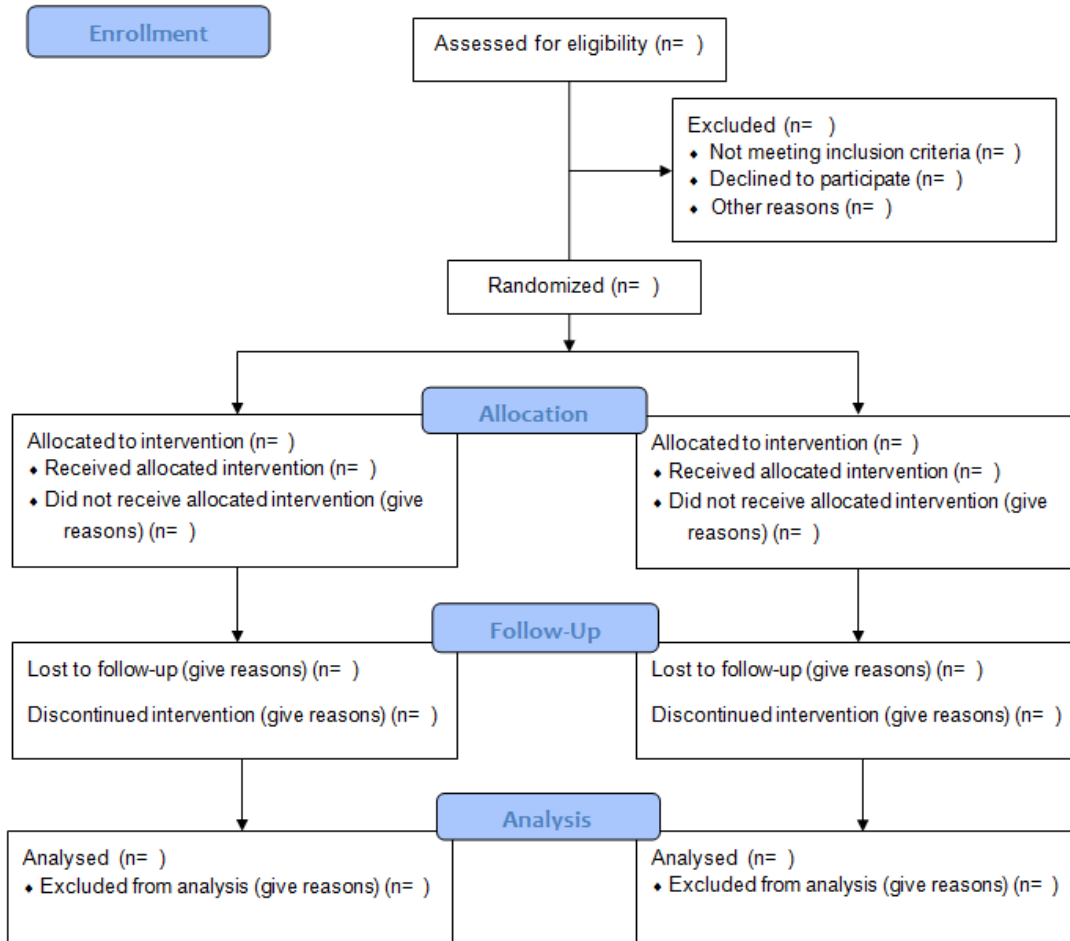
Data will be analysed on an intention-to-treat basis. For the pilot study a series of analyses of variance with time (1-5) as a within-subjects factor will be employed to examine changes in outcome and process measures. For the RCT, a series of analyses of variance will be conducted with time(1-5) as a within-subjects factor and condition (treatment vs control) as a between-subjects factor.

Mediation analysis based on regression will be used to test the role of study processes to ascertain whether outcome measure changes are mediated by process measures.

Furthermore the Jacobson and Truax (1991) method of assessing change for each individual participant will be used in both the pilot and the RCT studies. This will be used to determine whether the magnitude of change for a given client is statistically reliable.



CONSORT 2010 Flow Diagram



Data collected will be presented and analysed descriptively. The consort flow diagram (2010, figure 1.) will be followed to document relevant recruitment data.

Figure 1 (Consort 2010 Flow Diagram)

10: Ethical Considerations

Ethical approval will be sought from the university ethics team and the Integrated Research Application System (IRAS). The researcher will undertake 'Good Clinical Practice' training. Informed consent will be gained at the time of recruitment and verbally prior to the start of each session. Participants will be made aware of their right to withdraw at any time. In the highly unlikely event that participants experience an unexpected uncomfortable response during the session, emotional 'grounding techniques' will be utilised by the trainer. Furthermore, Clinical Psychologist Helen Bolderston (Chief Investigator) contact details will be made available to participants, as will details of the BMA's Doctors for Doctors website and helpline (who can offer ongoing counselling).

11: Data Protection and Storage

Recordings

Training sessions will be recorded as a further safeguard and assessment tool. The only purpose of recording the sessions is to ensure the ACTr process is being delivered accurately and correctly. Randomly selected section of sessions will be assessed by an independent ACTr assessor (Dr Bolderston will source the assessor and this will be kept on file) to rate fidelity to the established ACTr protocol. If, a randomly selected recording identifies the participant or anyone else, it will NOT be forwarded to the independent assessor, and another recording will be randomly selected.

Data

All information will be kept on a secure university hard drive. All data will be password protected. All data will be identified only by participant number. An Excel file linking participant to participant number will be kept on a separate drive, on a separate computer, password protected. Paperwork will be kept in a locked filing cabinet in a locked office at Bournemouth University,. Computers are both password secure and encrypted. NO personal information will be kept on laptop computers.

Confidentiality

The NHS code of confidentiality will be adhered to. Both Dr Helen Bolderston and Mr Kevin Turner are both NHS employees and as such have been trained within the last 12 months in Information Governance and Confidentiality. Bournemouth University staff will adhere to the requirements of the Data Protection Act. Furthermore, Access to personal data will be limited to the research team. All data will be anonymised at the earliest possible stage. Personal information will not be kept once participants have completed their 3-month follow-up session. Participants may withdraw at any time and all personal data will be destroyed if this is the case.

12: Training Protocol with example timings.

Training Session 1

- *Develop a rapport with individuals and create a climate of safety and warmth.*
- *Describe the basic format, content and aim of the training.*
- *Install hope that training has the potential to be unusual, interesting and effective*
- *Range of empirically supported ACT exercises as per Flaxman, Bond and Livheim (2014) such as those outlined below*

Day 1	Phase	Intervention	Detail
9.00	Welcome and Introduction	Mindfulness or values warm-up exercise	Re-consent Recording sessions - rationale Designed to build rapport, engage and be 'ACT' consistent. To gather hopes and expectations for the training. Introductions

			<p>– name, work details, 2 activities they do on automatic pilot and 2 activities they perform with more psychological awareness</p> <p>We teach ACT skills experientially as well as didactically so there'll be a mix of information sharing, skills practices, discussion, goal setting etc.</p> <p>Confidentiality: It's not therapy but it is personal.</p> <p>What do you hope to get out of it personally?</p> <p>Important to attend every session</p> <p>It's a psychological and behavioural skills training program – training - not therapy</p> <p>Research evidence</p> <p>Training is not limited to work-related resilience and wellbeing – the skills can be applied to all areas of life</p> <p>Practicing skills between sessions is an essential part of the training</p>
--	--	--	---

9.20	Overview of the training	Presentation of two skills organising diagram.	<p>To offer empirical evidence for both ACT in occupational settings and for particular processes or components - e.g. mindfulness</p> <p>Two broad related skills: mindfulness and values-based action</p> <p>The diagram is basically an overview of the entire training</p> <p>More about mindfulness and values-based action</p> <p>Mindfulness evidence base – can be used to enhance resilience in people who are already fairly resilient, and can also be used to reduce stress, burnout, depression and so on, when people are going through challenging times</p> <p>Values-based action – goal setting with a difference</p> <p>Together they can also help when we're experiencing loss of purpose in life, self-doubt, increase effectiveness and performance</p>

9.35	Introduction to mindfulness	<p>Raisin exercise</p> <p>Brief mindfulness of body and breath.</p>	<p>Rest of the session – an introduction to the two main skills</p> <p>Present-moment awareness training</p> <p>Widely recognized effective introduction to mindfulness (Kabat-Zinn 1990). Aid recognition of the experiential distinction between automatic-pilot and present moment awareness.</p>
9.50	Break		
10.00	Introduction to Values-Based Action	Values card sort.	<p>(I) Provide practical definition of values from ACT perspective. Show potential benefits of guiding daily behaviour through personally chosen values. (ii) Encourage participant to choose one value for one life domain and translate into a series of specific actions (for next session). (iii) Help participant anticipate the thoughts and feelings that may function as internal barriers to valued behavioural activation.</p>

10.20	Introduction to Values-Based Action (continued)	Compass metaphor.	Activate nature of valuing (Hayes et al. 1999). Using the metaphor to illustrate the distinctions between values, value-based goals and value based actions and to illustrate that values are not 'in the future' but available as a potential guide to action in each and every moment.
10.30	Presentation of rationale for the program	Two sheets of paper technique.	One sheet has word 'VALUE' written on it, the other "'UNHELPFUL" THOUGHT/FEELING/MOOD' Geared towards helping client make personal values a more prominent guide to daily actions and life goals.

10.40	Discussion of home practice assignments	Home practice handouts; Environmental reminders: Coaching around effective goals setting – worksheet 3 valued based actions 10-minute mindfulness of breath	<p>Define one value and translate into specific actions for the next session. To notice what it is like deliberately taking actions that are guided by personal values. To become aware of any internal barriers that actually (or almost) interfere with value-directed action.</p> <p>Reminder that participant can make contact between sessions if there are any concerns or queries</p>

Training Session 2

(4 weeks after session 1; 2 weeks for pilot)

- **Reduce excessive entanglement with unhelpful thought content.**
- **Undermine experiential avoidance.**
- **Cultivate acceptance skills.**
- **Range of empirically supported ACT exercises as per Flaxman, Bond and Livheim (2014) such as those outlined below**

Day 2	Phase	Intervention	Detail
8.45	Data Collection	Collect Data	
9.00	Opening mindfulness	Mindfulness of breath; noticing thoughts and	Involves participant sitting in upright position, eyes closed of unfocused and cast down towards floor, hands resting

	practice and brief review	feelings and allowing them to come and go.	comfortably on lap or arms of chair. Participant will be invited to become aware of physical sensations before setting attention on sensation of movement in the abdomen whilst breathing.
9.10	Home practice review	Discussion	Clarify understanding of the key feature of mindfulness and value-based action processes. Emphasise the importance of generalising mindfulness and value-based action from the session to daily life. Provide reinforcement to participants who have engaged in mindful and value-based action exercises outside the training. Getting clues about barriers – what got in the way if homework was difficult to complete,
9.20	Presentation of training rationale	Passengers on the bus metaphor.	ACT metaphor found in numerous ACT texts (Hayes et al. 1999). Used to portray the functional link between mindfulness and value-based action. Illustrates person driving bus to some extent distinct from own thought and feelings. Some passengers (thoughts/feelings) can be unhelpful and exert subtle/not so

			<p>subtle) influence over driver's actions. Removing passengers may not be helpful.</p> <p>A lot of unpacking – it's a key learning from the training – your thoughts/memories/emotions/bodily sensations/urges can all be saying do one thing and you can choose to do another, because it's in the service of your value</p>
9.40	Untangling from thought barriers to valued action	<p>Hand in the face metaphor</p> <p>Old film metaphor</p> <p>Self-reflection on unhelpful thought content</p> <p>Thoughts on screen exercise.</p> <p>2 of 4 options?</p>	<p>Cognitive Defusion. Defusion exercises train people to take unhelpful thoughts a bit less seriously; notice the ongoing process of thinking; and learn experientially that thoughts do not have to control action (Harris, 2009). ACT's defusion strategies focus primarily on helping participants relate differently to thoughts that interfere with valued action.</p>
9.55	Break		
10.05	Mindfulness of mood/emotion	<p>Brief mindfulness of stressful event or</p>	<p>Enhancing the participant experiential <i>acceptance</i> skills. Defusion and acceptance are related processes within the ACT model.</p>

		<p>thought – locating in the body</p> <p>Physicalizing exercise</p>	<p>And it is useful to organise them under the same theme of noticing and untangling from internal barriers to valued action.</p> <p>This in turn feeds into the broader purpose of gradually increasing the prominence of people's personally chosen values as a guide to goals and daily action (Flaxman et al., 2013)</p>
10.25	Defining values and value-based goal and action planning	<p>Construction of four-week values-based goal plan and action plan.</p>	<p>Define values in at least two areas of life (preferably different areas as defined on Day 1. Set suitable specific short-term, medium term and long term goals that would help to bring one or two values to life. Participants will be encouraged to set 4 short-term value based goals they are motivated to achieve in next 4 weeks.</p>
	Discussion of home practice assignments	<p>Home practice handout; environmental reminders; public commitment to one value -based goal</p>	<p>Participants are invited to engage mindfully in three value-based actions over the next weeks. These values should be selected by the participant from those identified in the previous /Defining values' exercise.</p> <p>Think about continuing mindfulness practice homework – doing every day activities mindfully – brushing teeth, walking from car to hospital etc.</p>

			Reminder that participant can make contact between sessions if there are any concerns or queries
--	--	--	--

Training Session 3

(4 weeks after session 2 for RCT, 2 weeks for pilot)

- **Booster Session.**
- **Further rehearsal of exercises; basic mindfulness training, physicalizing exercise, diffusion, mindfulness of thought, value-based goal and action planning.**
- **Range of empirically supported ACT exercises as per Flaxman, Bond and Livheim (2014) such as those outlined below.**

Day 3	Phase	Intervention	Process/Reason/function
8.45	Data Collection	Collection of Data	
9.00	Welcome Back	Two-skills diagram.	Welcome back to part three and to reaffirm the empirical evidence for both ACT in occupational settings and for particular processes or components - e.g. mindfulness Also, any evidence to do with medical professional in particular
9.10	Opening	Mindfulness of body	Preparation involves participant sitting in upright position, eyes

	mindfulness practice	and breath.	<p>closed or unfocused and cast down towards floor, hands resting comfortably on lap or arms of chair. Participant will be invited to become aware of physical sensations before setting attention on sensation of movement in the abdomen whilst breathing.</p> <p>Function of starting with a mindfulness practice:</p> <p>Bring attention into the room and the present moment</p> <p>More likely to be fully engaged in later exercises if do mindfulness practice now</p> <p>Brief inquiry after the practice</p>
9.20	Home practice review	Discussion	<p>Clarify understanding of the key feature of mindfulness and value-based action processes. Emphasise the importance of generalising mindfulness and value-based action from the session to daily life. Provide reinforcement to participants who have engaged in mindful and value-based action exercises outside the training.</p>
9.35	Assessing value consistency	Self-reflection on value-consistent and inconsistent actions	<p>An important part of values work involves asking participants to reflect on the value consistency or inconsistency of their recent patterns of behaviour. Participants asked to rate both the</p>

		over past 2 weeks.	importance they attach to a particular value in their life at this moment in time and effective, successful or consistent they had been at pursuing this value over the last few weeks (Wilson et al., 2010). Any high discrepancy between value importance and value consistency may indicate a particular value of life is that is being neglected. VLQ? Bull's-eye?
9.50	Mindfulness of thought and feeling	Thoughts on clouds exercise, contacting the resilient 'observer' perspective.	Reaffirm and enhance the participant experiential <i>acceptance</i> skills. Defusion and acceptance are related processes within the ACT model. And it is useful to organise them under the same theme of noticing and untangling from internal barriers to valued action. This in turn feeds into the broader purpose of gradually increasing the prominence of people's personally chosen values as a guide to goals and daily action (Flaxman et al., 2013) Observer self: and who is it who's doing the noticing? Dream metaphor Hierarchical relationship between observer self and content of experience rather than just a separate relationship Reflection on these practices – their uses and implications

10.10	Break		
10.20	Values-based goal and action planning	Short-term, medium term and long term values-based goal-setting exercise; values-based action map	Define values in at least two areas of life (preferably different areas as defined on Day 1. Set suitable specific short-term, medium term and long term goals that would help to bring one or two values to life. Again, participants will be encouraged to set 4 short-term value based goals they are motivated to achieve in next 4 weeks.
10.30	Recommendation for continued practice	Home practice handout; top tips for building a valued life.	Handout for home practice. Tips for future practice after this final session.
10.40	Final personal reflections on the training	Discussion	Discuss with participant the three training days, assessment of course delivery, potential for improvements. Reminder that participant can make contact post training if there are any concerns or queries

13: Timelines

2017-2018	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug
Training and Data Collection												

2018-2019	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug
Training and Data Collection												
Write Up												

14: References

Clarke, S., Kingston, J., Wilson, K.G., Bolderston, H., Remington, B. (2012). *Acceptance and commitment therapy for a heterogeneous group of treatment-resistant clients: A treatment development study*. *Cognitive Behavioural Practice*, Vol 19, Issue 4, 560-572

Finnes, A., Ghaderi, A., Dahl, J., Nager, E., Enebrink, P. (2017) Randomized Controlled Trial of Acceptance and Commitment Therapy and a Workplace Intervention for Sickness Absence Due to Mental Disorders. *J Occup Health Psychology*.

Flaxman P., Bond, F., Livheim, F. (2013): *The Mindful and Effective Employee: An Acceptance and Commitment Therapy Training Manual for Improving Well-Being and Performance*. New Harbinger Publications; 2013

Flaxman P., Bond, F. (2010) A randomised worksite comparison of acceptance and commitment therapy and stress inoculation training. *Behavioural Research and Therapy*. 2010 Aug;48(8):816-20.

Hayes, S. C., Luoma, J. B., Bond, F. W., Masuda, A., & Lillis, J. (2006). Acceptance and Commitment Therapy: Model, processes, and outcomes. *Behaviour Research and Therapy*, 44(1), 1-25.

Hayes, S. C., Bissett, R., Roget, N., Padilla, M., Kohlenberg, B. S., Fisher, G., Masuda, A., Pistorello, J., Rye, A. K., Berry, K., & Niccolls, R. (2004). The impact of acceptance and commitment training and multicultural training on the stigmatizing attitudes and professional burnout of substance abuse counsellors. *Behaviour Therapy*, 35, 821-835

Jacobson, N., Truax, P. (1991) Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. *J Consult Clinical Psychol*. 1991 Feb;59(1):12-9.

Lappalainen, R., Lehtonen, T., Skarp, E., & Taubert, E. (2005). Training students a few hours in CBT and in ACT: A randomized controlled trial. Paper presented at the meeting of the European Association of Behavioural and Cognitive Therapies, Tessaaloniki, Greece, September.

Pinto, A., Faiz, O., Davis, R., Almouadaris, A., & Vincetnt, C. 'Surgical complications and their impact on patients' psychosocial well-being: a systematic review and meta-analysis'. *BMJ Open* 2016 Feb 16; Vol. 6 (2), pp. e007224. *Date of Electronic Publication*: 2016 Feb

Shanafelt TD, Balch CM, Bechamps G, Russell T, Dyrbye L, Satele D, Collicott P, Novotny PJ, Sloan J, Freischlag J. Burnout and medical errors among American surgeons. *Ann Surg*. 2010 Jun; 251(6):995-1000.