

Chapter 5

Data Collection in the Real Environment

5.1 Consent and Confidentiality

It required a considerable effort to gain approval to institute the current study and to obtain the renewal after 3 years of data collection. Initially all trauma care providers were notified, and arrangements made by the principal investigator (PI: Colin Mackenzie) to discuss concerns and answer questions. Approximately 15 meetings were scheduled over a 6 week period in which the outline of videotaping the anesthesia care providers was presented to nurses, surgeons, trauma technicians, operating room technicians, and other personnel who work in the resuscitation and operating room areas of the Shock Trauma Center. The protocol was submitted to the Shock Trauma Research Committee, to the Trauma Resuscitation Committee, and to the Operating Room Committee. The consent form and Institutional Review Board submission included the following provisions: 1) people who did not want to participate and unintentionally were videotaped in the course of patient care would have the option to have their image covered by a video-overlay mask; 2) the patients were *not* the subjects of the study, the anesthesia care providers were, so we requested that videotaping should occur without patient consent; 3) we angled the camera, and restricted the field of view so that it was extremely difficult to recognize the patient's face. If this was recognizable and for public display of video vignettes (at scientific meetings, etc.), a video-overlay mask would be used to maintain patient confidentiality. 4) The videotapes would be maintained under lock and key in the PI's laboratory, remote from patient care areas; 5) Quality Assurance Guidelines would be followed to maintain the maximum possible protection available under the law for these videotapes to be considered non-discoverable.

The IRB sent the protocol to the University and Hospital Legal Counsels for their opinions. The legal opinion was that although it was probably impossible to maintain these tapes as non-discoverable, they believed that they would create a favorable impression on any jury. The efforts of the 6-10 person trauma team around the injured patient gives a strong signal that everything possible is being done to resuscitate a particular patient. Risk management was also involved in the review of the protocol. Some 3 months after submission approval was given to proceed.

Despite the approval and discussions, there were still about a third of anesthesiology attendings and the majority of nurse anesthetists who refused to participate. However, once underway, we were able to gather ample data with a core of 10 or so participants.

The renewal request for continued IRB approval was submitted 2 months before the renewal date to ensure continuation of this funded project. The protocol was again submitted to legal counsel. The consideration of the protocol was delayed for 2 months until the protocol expired. The protocol was not renewed until 6 months later. All videotaping had to cease and after numerous meetings, letters to the Dean (of the School of Medicine of the University where the study was conducted), etc., we obtained agreement to proceed. The major hold-up was that the IRB believed that we were coercing the anesthesia care providers to participate. We were able to show that, in essence, the participants (described in all of the papers published as the Level One Trauma Anesthesia Simulation Group - or LOTAS group) were all co-investigators whose names appeared on the papers. In other words, implied approval was given by the participants.

5.2 Recording of Activities during Resuscitation

For each admitting area, a fixed miniature video camera was suspended from the ceiling, with microphones mounted immediately above the patient's head and feet. The video images were overlaid with patient physiological data, which were directly obtained from patient monitoring equipment. (Equipment list and configurations are described in detail in Mackenzie *et al.*, 1994.) The attending anesthesiologist and/or the nurse anesthetist started the recording voluntarily, just prior to the arrival of the patient. Along with video tapes, the participants in a case were requested to submit patient records for later review and to complete a questionnaire about the case (see the post trauma questionnaire attached). The patient records contained basic information about the patient status prior to admission and treatment received (such as drug names and doses). The questionnaire was used to obtain the anesthesia care providers' own performance assessment as well as any unusual circumstances (*e.g.*, fatigue). All patient identifiers were removed to preserve confidentiality.

5.3 Companion Data Collection

The participants and non-participant subject matter experts (SMEs) were requested to review video tapes and to provide commentaries, usually within a week. Interviews were conducted for a small number of cases where what had occurred appeared to be unclear. Over 100 cases were so video taped over the three year period, and they covered a wide variety of cases and team compositions. No efforts were made to screen out any particular types of cases, and in fact it was difficult if not impossible to predict the cases to be recorded.

Data collection was organized by treatment sessions (*i.e.* cases). A treatment session, of course, pertains to a particular patient, but there may be more than one session analyzed for a given patient, for example, when separate recordings are made in the admitting area

and in the operating room for a given patient. For each session, the overall strategy is to extract information from the following sources:

- Videotapes from the treatment session with that patient
- physiological data that was logged from that patient during the treatment session
- The hard-copy anesthesia record or admitting area consultation form that was completed by the anesthesiologist for that session
- The post-trauma questionnaires that were completed by the anesthesiologists and/or CRNA for that session
- An anesthesiologist subject matter expert, preferably one of those who participated in the video taping, viewed the tapes along with the data analyst
- Surgical summary or procedures carried out and Laboratory blood analyses, obtained through Shock Trauma Computer Network.

5.4 Fatigue Measurement

Synwork was used to assess the ability of anesthesiologists to carry out four simultaneous tasks over a five-minute period. The tasks tested are similar to those performed in clinical anesthesia and include monitoring of visual and auditory signals, setting alarms, mental arithmetic and short-term memory storage and retrieval. We used Synwork to determine whether there was a decrement in performance of these tasks over a twelve-hour period and compared night with day shifts.

Each anesthesiologist achieved asymptotic performance on Synwork during ten practice sessions (Fig. 5.1). Synwork was then performed at the start, middle (7-8 hours after start) and end of a 12 hour shift, both during the day (7am-7pm) and at night (7pm-7am). Testing was performed randomly over a three-week on-call period for up to three day and night shifts per subject with a minimum of twelve hours rest between each shift. Results were compared by paired t-tests ($p < 0.05$ was significant).

Results There were no differences between total scores on Synwork at the start, middle or end of a 12 hour day or night shift (Fig. 5.2). Nor were there differences between daytime and nighttime scores. In addition, we examined the four individual components of Synwork (memory, math, visual, auditory) and found no differences between nighttime and daytime performance in the four components or in performance of these four tasks within the twelve-hour shift.

Synwork has previously been used to assess performance of combat pilots and the effects of sleep deprivation. The similarity of the multitasking software to the tasks of anesthesiologists make it a potentially useful assessment of fatigue in the clinical environment. During 12-hour shift work, we were unable to detect any decrement in performance of Synwork either in total score or in any of the individual components.

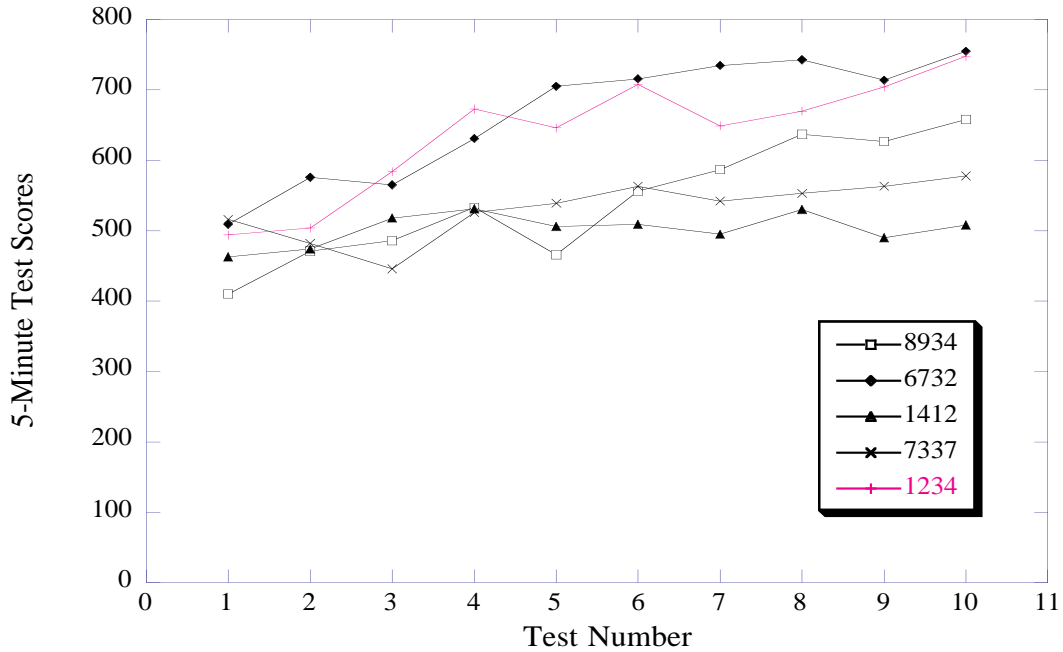


Figure 5.1: Practice Synwork scores of five subjects studied (labeled by four digit identification numbers) showing asymptotic performance after 6–8 attempts.

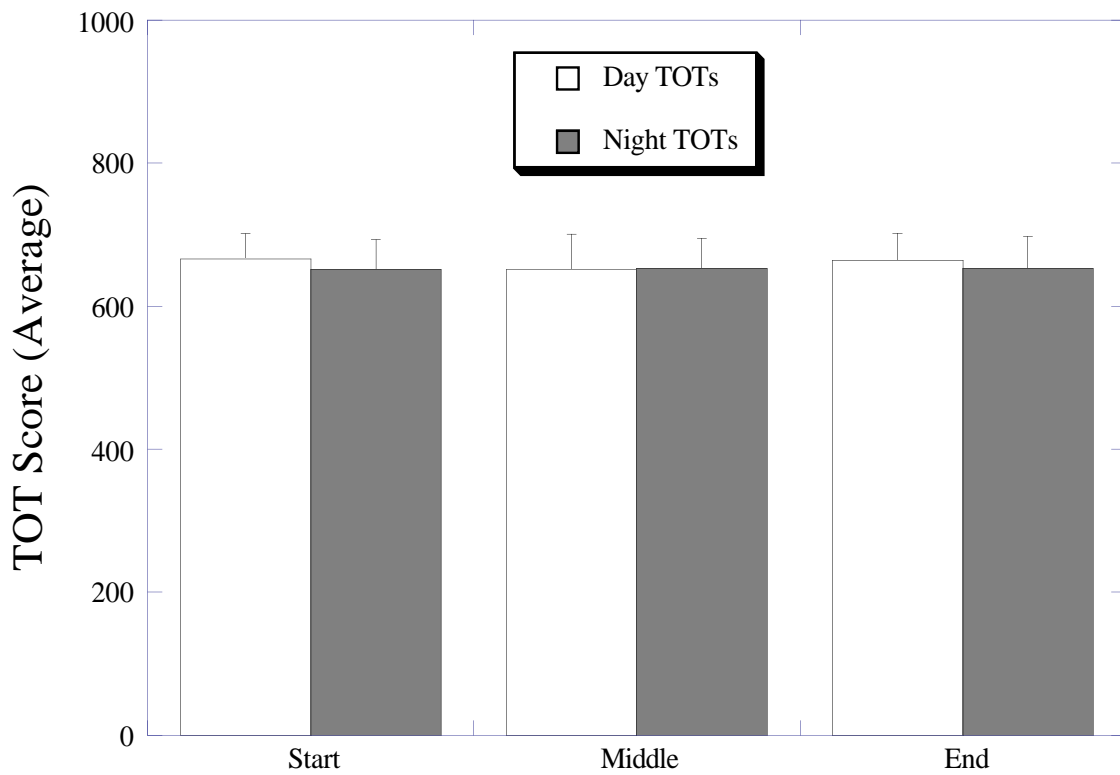


Figure 5.2: Mean and standard errors of total (TOT) Synwork scores for day and night at three point during a shift: start, middle, and end of a shift.

5.5 Post-Trauma Questionnaire

Immediately following a videotaped session of acute trauma patient resuscitation and treatment, a 30-item Post-Trauma Questionnaire (PTQ) was completed by the lead anesthesiologist, and occasionally by an assisting anesthesiologist or Certified Registered Nurse Anesthetist (CRNA). For our purposes, the lead anesthesiologist was considered to be the care provider who had overall professional responsibility for the patient and was responsible for hands-on care of the patient. Sometimes the care provider who completed the questionnaire was supervised by another person. In some cases both the lead anesthesiologist and the hands-on care provider completed questionnaire.

The PTQ was a pencil and paper questionnaire which solicited information on aspects of the case, the team, and the individual care provider. The PTQ was developed by trauma anesthesiologists in conjunction with experimental psychologists, and included requests for comments on identification of case difficulty (on a scale with extremes of best/worst, most/least), own performance, the occurrence of stressful events, misjudgments in management and whether the same management would be repeated. Additionally, the PTQ asked for subjective assessments of perceived stress, fatigue, case difficulty, ones own performance, team-work and effectiveness on interaction with specific team members (e.g., separate items for surgeons, CRNAs and nurses). We have 89 completed Post-Trauma Questionnaires.

Fatigue: There were five items on the PTQ that quantify fatigue:

- the number of hours last slept
- the number of hours awake (since last slept)
- what hour of the shift did the case occur
- how long ago was your last shift (in days)
- the number of hours during the present shift actively involved in patient care

Experience: There were four items on the PTQ that quantify experience. Additionally, there were two demographic items from a demographic form completed by participating anesthesiologists, that also quantified experience.

- the number of cases similar to the current case, (that the anesthesiologist has ever managed)
- how long it has been since the anesthesiologist has managed a similar case
- the number of times the anesthesiologist has worked with the 'duty' surgeon
- how long it has been since the anesthesiologist has worked with the 'on duty' surgeon

The demographic:

- years as an anesthesiologist
- years as a trauma anesthesiologist

Patient Injury Severity: There are four items on the PTQ that quantify patient injury severity. They are standardized trauma ratings, assessed at the time the patient arrives. The scales are:

- Abbreviated Injury Score (AIS)
- Glasgow Coma Scale (GCS)
- American Society of Anesthesiology, physical status (ASA)
- Trauma Anesthesiology Grade (TAG)

A linear scale was provided for each subjective assessment. SMEs were asked to rate their perceptions by marking the appropriate position on the linear scale. They were requested to assess how they perceived stress, fatigue, and case difficulty on a scale anchored at each extreme by 'most' and 'least'. Additionally, the participants were also asked to rate their perception of their own performance, team-work, and the effectiveness of interaction among team members on a scale anchored at each extreme by 'best' and 'worst'.