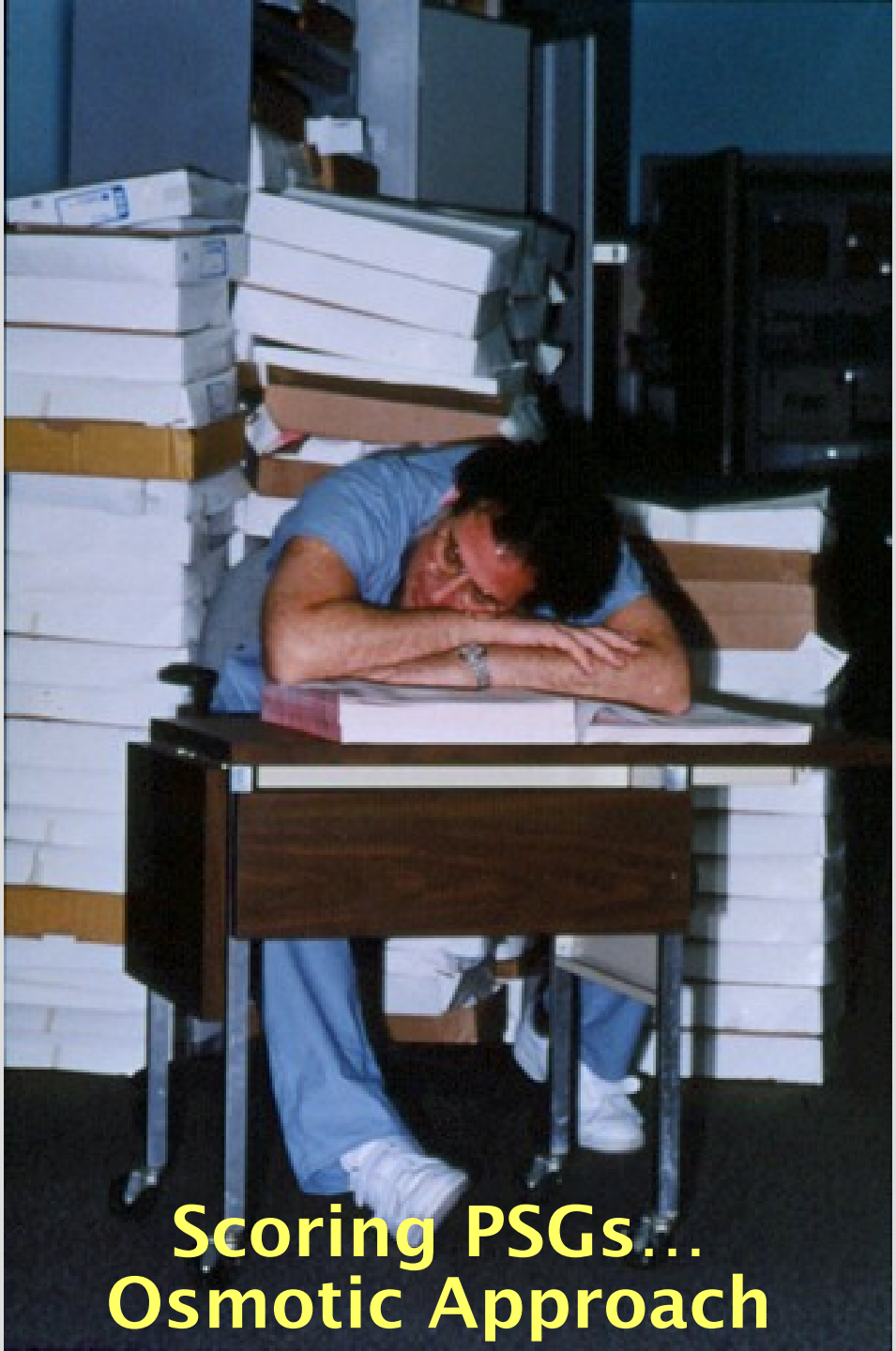


Electronic Interchange for Polysomnographic Data Workgroup Meeting

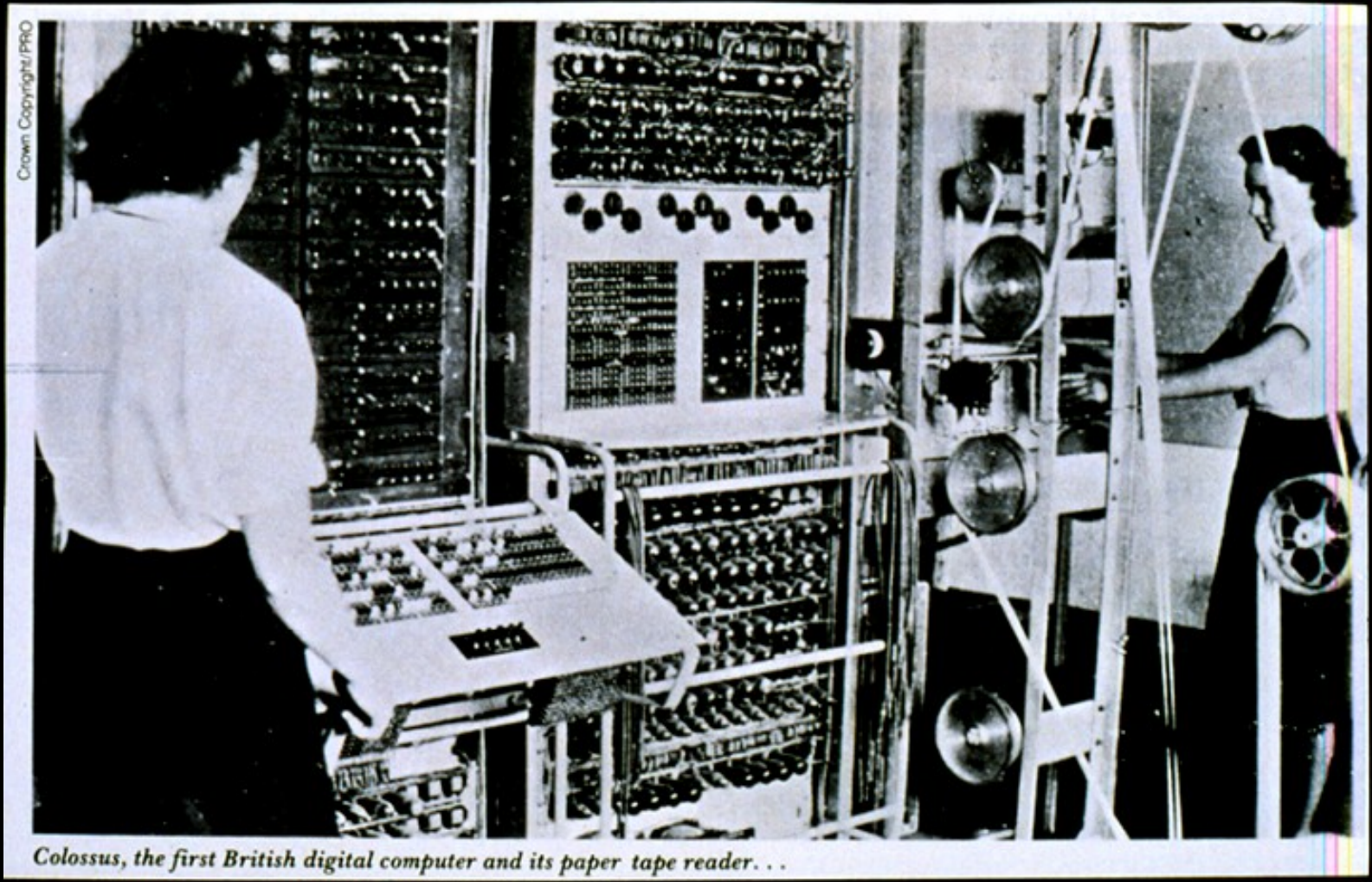
January 27, 2006

Philadelphia, PA

Needs of the Clinical Sleep Community

Max Hirshkowitz

Baylor College of Medicine &
Michael E. DeBakey VAMC



Colossus, the first British digital computer and its paper tape reader. . .

When computers looked like this . . . .
Data Interchange Format was not such a big deal

Physical media format standards come and go in the blink of an eye because storage technology has advanced so rapidly

By contrast, software standard formats appear to evolve slower

- They may begin as proprietary formats
- If very successful, they may become “defacto” standards
- Sometimes they are created by academic initiatives
- Sometimes they are created through industry cooperation,

So… I was asked to come up with a wish list.

But be careful what you wish for…

For example:

"I want a home apnea monitor that is"

1. Well validated
2. Fairly reliable
3. Widely available
4. Portable

Home Apnea Monitors

* Well Validated
* Fairly Reliable
* Widely Available
* Portable
* Not Reimbursable
* Not FDA Approved

No, No, No…

I want a portable PSG system!

Fig. 3

(total sleep time/time in bed) can be computed, and abnormalities in the sleep pattern detected. Sleep periods which are most likely to contain dreams (stage 1 REM sleep) can be detected, and the sleeper awakened by the attendant for a report of the ongoing dream before the memory of it fades and disappears.

A mobile unit (shown in Figure 3) now in use by the University of Florida Sleep Laboratory allows EEG recording to take place in the home while the telemetry equipment in a van a block away unobtrusively records the brain waves being emitted in the patient's own bedroom.

The experimental manipulation of normal sleep patterns has proved to be an invaluable technique in evaluating the relationship between sleep and physiopathology, as well as that between sleep and psychopathology. The effects of various pharmacologic agents on normal sleep are of considerable interest.

II. Effect of Clorazepate Dipotassium* on the sleep patterns of healthy young adults

A. *Subjects:* Twelve healthy male medical students from 20 to 25 years of age participated in a sleep laboratory evaluation of the effects of an anxiolytic agent, clorazepate dipotassium, upon the EEG parameters of sleep. Health status was determined by responses to questions on the Cornell Medical Index, a physical examination and clinical interview, and responses to the 16PF Questionnaire. In addition, the SMA 12, a complete blood count, and urinalyses were done before and after the study.

*Transene®, (Abbott-35616) Abbott Laboratories

B. *Study Design:* The design of the study may be outlined as follows:

STUDY DESIGN

Time	Medication	Purpose
Night 1	none	adaption
Night 2 - 4	none	establish baseline
Night 5 - 7	1 placebo capsule t.i.d.*	establish placebo baseline
Night 8 - 15	7.5 mg. clorazepate dipotassium t.i.d.	assess drug effect
Night 16 - 18	1 placebo capsule t.i.d.	assess drug withdrawal effect

*Matching capsules of placebo and clorazepate dipotassium were administered, "single-blind", during the day.

Each subject completed a questionnaire concerning his day time activities, and a mood check-list (the Loor-Duston Mood Scale). He was then wired for a three-channel EEG and a two-channel EOG recording (Grass Model 78 EEG) as shown in Figure 4.

Fig. 4

The subject went to bed at his usual bedtime, and was allowed to sleep as many hours as he usually did. If still asleep at the end of his usual time, he was awakened. He then completed the mood check-list again, and a questionnaire providing a subjective evaluation of his sleep during the preceding night.

C. *Results:* EEG and EOG data were recorded for about eight hours nightly on each subject. The data were scored minute by minute for the entire night. The influence of clorazepate dipotassium on 20 sleep variables of the EEG record, as well as changes of the mood check-list scores, and data resulting from the subjective evaluation of sleep, were analyzed by means of multivariate statistical techniques.

But seriously, what are the needs?

- For Clinical Evaluations
- For Clinical Research
- For Clinical Training Programs

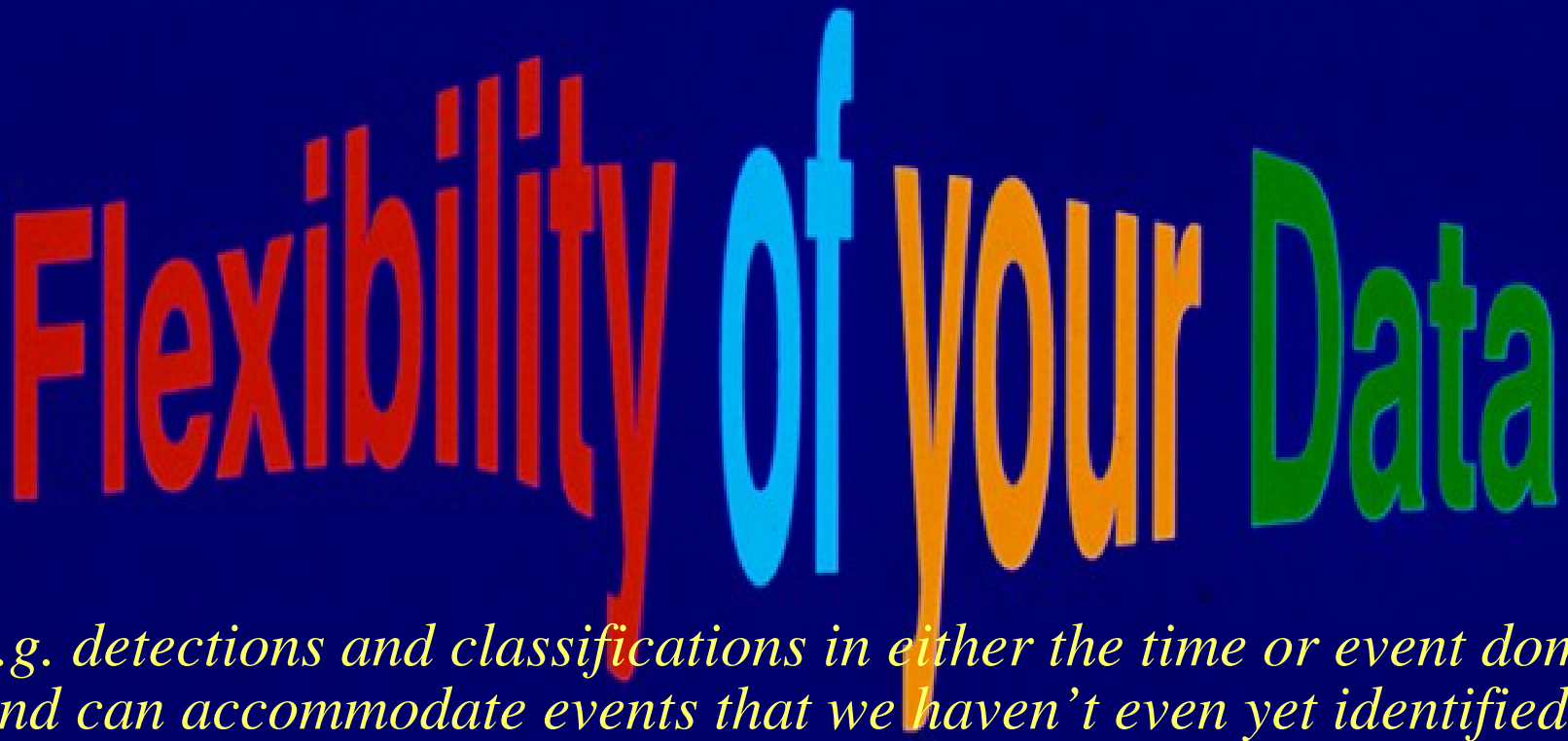
Some Scenarios

- Contract Scoring
- Outsourced Scoring
- Inter-laboratory Calibration
- Central Scoring for Clinical Research
- Retrieving Archived Data
- Record Review on any computer for case conferences or in-services
- New analytic approaches

Some Requirements

- Any pre- and post- sleep calibrations are stored with the recording
- All results of scoring are stored with recording (e.g. stage classifications, CNS arousals, apnea event identification, leg movements detection)
- What the technologist was seeing during the recording process, at any given time, can be displayed on demand
- What the scorer was seeing when they scored an event can be displayed on

The #3 Most Important Feature of the Electronic Interchange PSG Data File should be:



e.g. detections and classifications in either the time or event domain and can accommodate events that we haven't even yet identified

The #2 Most Important Feature of the Electronic Interchange PSG Data File should be:

FLEXIBILITY OF YOUR DATA

e.g. can be output to file formats readable by other programs for database archiving, analysis, or automatic report generation

The #1 Most Important Feature of the Electronic Interchange PSG Data File should be:

e.g. can be viewed on any computer having to install propriatary software or use dongles, cookie, unformatted sectors… etc.

The Road Ahead

- Automatic Scoring
- Standardize System (son of R&K)
- More Home Monitoring (if payers pay)
- Greater Use of Auto-titration (if payers pay)
- Unemployment Check