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Improving Clinical Procedures/Protocols with Structured Prose

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Unreadable Writing

Much clinical and laboratory documentation is unnecessarily hard to read. This failing is most evident in clinical protocols, clinical summaries, and other documents associated with drug regulation. Some of the problem is attributable to plain old bad writing: for example, chronic confusion of *shall* and *will*, religious overuse of the passive voice, long-winded expressions learned in Freshman Composition as a way of inflating a 300-word essay into 500 words. . . Much of it is due to faulty typographic conventions: 6-7" columns, old-fashioned use of underscoring and quotation marks for emphasis, justified monospaced typefaces with their attendant rivulets of white space coursing through the pages. . .

Paragraphs Impose

The most serious problem, though, is the tradition of using dense paragraphs to communicate definitions, facts, and procedures. Such paragraphs are so imposing and fatiguing that even a federal regulator, who is obliged to read them, must struggle to concentrate.

Presuming Against Paragraphs

Communicating *Ideas*

The paragraph is the unit of the idea. People who cannot write a paragraph with several smoothly connected sentences cannot express ideas. People who cannot read paragraphs—for example, executives who insist that all information be in "bullet" form—cannot comprehend ideas. (Most scientists report far more trouble writing the Introduction and Discussion sections of their papers—the parts containing ideas in paragraphs—than the factual Materials and Results sections.)

Communicating Facts

In contrast, the sentence is the unit of the fact or step. Individual sentences (or sometimes sentence fragments) communicate data, definitions, observations, steps in a process, directions. . . **The least usable, least readable way to communicate facts and processes is in dense paragraphs.** For straightforward data, the best modes are "bullets," lists, and tables. For processes, especially those involving decisionmaking or branching, the best mode is a diagram.

To illustrate, consider this characteristic specimen:

Exhibit 1 Definition of Informed Consent

In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.

Overlooking the evasive passive (Who does the informing?) and the oppressive overuse of *his or her* (which skillful editing can reduce without sexism), the central problem is the paragraph form itself. Consider this alternative:

Exhibit 2 Definition in Itemized Form

In any research on human beings, each potential subject must be adequately informed of

- the aims, methods, anticipated benefits, and potential hazards of the study
- the discomfort it may entail
- the right to abstain from participation in the study
- the freedom to withdraw participation at any time.

The physician should then obtain the subject's freely-given informed consent, preferably in writing.

At other times, a paragraph needs to be two lists. Consider this example:

Exhibit 3 Eligibility Criteria

Eligible Patients

Male patients ranging in age from 18 to 55 years, with either endoscopic evidence of active duodenal and/or gastric ulcer disease or a documented history of peptic ulcer disease were considered eligible for study participation. In addition, all patients had to have a basal acid output of at least 2.5 mEq/hr. Patients were excluded if they had any upper gastrointestinal tract surgery or had a recent history of complications of peptic ulcer disease (e.g. pyloric stenosis, perforation, gastrointestinal bleeding, etc.). Patients with either a history of alcohol or drug abuse in the past 12 months were also excluded.

With minor adjustments, this imposing paragraph becomes:

Exhibit 4 Eligibility Criteria in Itemized Form

Eligible Patients Must Be:

- Male
- 18 to 55 years old
- With either endoscopic evidence of active duodenal and/or gastric ulcer disease, OR a documented history of peptic ulcer disease
- A basal acid output of at least 2.5 mEq/hr

Excluded Patients Were Those With:

- Any upper gastrointestinal tract surgery
 - Recent history of complications of peptic ulcer disease (e.g. pyloric stenosis, perforation, gastrointestinal bleeding, etc.).
 - A history of alcohol or drug abuse in the past 12 months
-
-

Tables

Even simple statements of purpose can be so dense that they are nearly unreadable. Consider this example:

Exhibit 5 Purpose of an Assay

In this assay, the effects of agents believed to block or augment ion channels in cardiac muscle are evaluated using standard intracellular microelectrode recording techniques. Intracellular recordings are made from isolated guinea pig papillary muscles and the effects of drugs on duration and maximum upstroke velocity of action potentials, as well as resting membrane potential and effective refractory period are measured.

A far better mode of presentation is the table below:

Exhibit 6 Purpose in Table Form

Objective:	To study the agents believed to block or augment ion channels in cardiac muscle
Method:	Standard intracellular microelectrode recording
Subject:	Isolated guinea pig papillary muscles
Effects Measured:	<ul style="list-style-type: none">▪ Duration of action potentials▪ Maximum upstroke velocity of action potentials▪ Resting membrane potential▪ Effective refractory period

Surely, no one would prefer the first version to the second. Nor could anyone, no matter how intrepid, be expected to absorb the facts in the paragraph below:

Exhibit 7 Endoscopic Findings

One patient had both a gastric and duodenal ulcer (#S02) and nine other patients had a duodenal ulcer (#S03, #S05, #S06, #S07, #S16, #S19, #S21, #S23, #S24). Six additional patients who did not have discrete ulcers had either gastric and/or duodenal erosions. Three of these patients had both gastric and duodenal erosions (#S04, #S08, #S11) while three others had only duodenal erosions (#S12, #S15, #S17). Eight patients (#S04, #S08, #S10, #S11, #S14, #S17, #S21, #S23) had either a deformed pyloric channel and/or duodenum. Only one patient (#S20) had no gross mucosal breaks and neither gastritis nor duodenitis at the baseline endoscopic evaluation.

Consider this simpler alternative:

Exhibit 8 Endoscopic Findings in Tabular Form

Findings	N	Subjects (S#)
Gastric AND dudodenal ulcer	1	02
Duodenal ulcer alone	9	03, 05, 06, 07, 16, 19, 21, 23, 24
Gastric AND duodenal erosions (Without discrete ulcers)	3	04, 08, 11
Duodenal erosions alone (Without discrete ulcers)	3	12, 15, 17
Deformed pyloric channel and/or duodenum	8	04, 08, 10, 11, 14, 17, 21, 23
No gross mucosal breaks, gastritis, duodenitis	1	20

Playscript

For procedures, the table becomes a "playscript¹," a systematic assignment of responsibilities and steps. Playscripts are especially helpful when the responsibilities shift from person to person or agency to agency. The process below is typical:

Exhibit 9 Approval, Review Requirements

Institutional Review

Institutional Review Board approval will be obtained by the principal investigator prior to initiating the study. PharmcoLaboratories will provide the investigator with all necessary data for submission to the review committee and will retain in its files the signed Form FDA 1573 and written verification of Institutional Review Board approval. This study will comply with the Declarations of Helsinki and Tokyo.

Patient Information and Informed Consent

It is the investigator's responsibility to obtain written, informed consent for this study from all patients. The investigator or his staff will also inform each patient that he or she is free to withdraw from the study at any time without prejudice.

In contrast, consider this playscript version:

Exhibit 10 Approval, Review in Playscript Format

ACTOR	ACTION
Pharmco	1. Provides all data needed for review committee (This study will comply with the Declarations of Helsinki and Tokyo.)
Investigator	2. Gets Institutional Review Board approval
Pharmco	3. Files form FDA 1573
	4. Files verification of IRB approval
Investigator	5. Gets written, informed consent from patients
	6. Informs patients of right to withdraw at any time without prejudice

Checklists vs Decisions

Playscripts—like checklists in general—work best when there is a **presumption of success**. That is, when we expect nothing to go wrong, when there are no error paths or branching decisions. In many clinical and experimental procedures, though, the operators and investigators must make choices. And it is here that lists must yield to tables and other decision graphics.

Complex Rules

Nowhere is the paragraph more unwieldy than in presenting procedures with branches, paths, skips, and loops. (Everyone who has ever tried to follow I.R.S. instructions knows this painfully.) In paragraph form, even simple allocation rules are a muddle. Consider this example:

Exhibit 11 Allocation Rule

Patients were clinically and bacteriologically evaluable if they presented with signs and symptoms of meningitis and a susceptible organism was recovered from the CSF. Patients were clinically evaluable if they presented with signs and symptoms of meningitis and demonstrated the presence of an organism in the CSF by either antigen detection tests or gram stain.

Contrast this murky passage with the simple Decision Table below:

Exhibit 12 Allocation Rule as Decision Table

<i>IF :</i>			
Signs & Symptoms of Meningitis	Y	Y	Y
Susceptible Organism from CSF		Y	N
Antigen Detection or Gram Stain			Y

<i>THEN :</i>			
Clinical Evaluation		■	
Bacteriological Evaluation		■	■

Branches and paths

The materials served least well by paragraphs are complicated procedures that include branches and loops. When readers are asked to trace a unique path through a logical circuitry of sentences, even the most intrepid will get tired and inattentive. Consider Exhibit 13, a typical procedure for controlling unreviewed changes in clinical protocols.

Exhibit 13 Protocol Change Control

If an investigator makes changes before starting the study, these changes should be noted on the signed copy of the protocol. For Domestic studies and for International studies conducted under a US IND, the Protocol Approval Form will be attached to the protocol and the revised pages listed on the area provided on that form. Approval of these changes must be initialed by the original protocol approvers in the space provided on the form.

For International studies which are not conducted under a US IND, the Field Protocol Approval Form will be attached to the protocol and circulated for review and approval. It is the responsibility of the project chairman to evaluate changes to a protocol and either accept and approve them or disprove them.

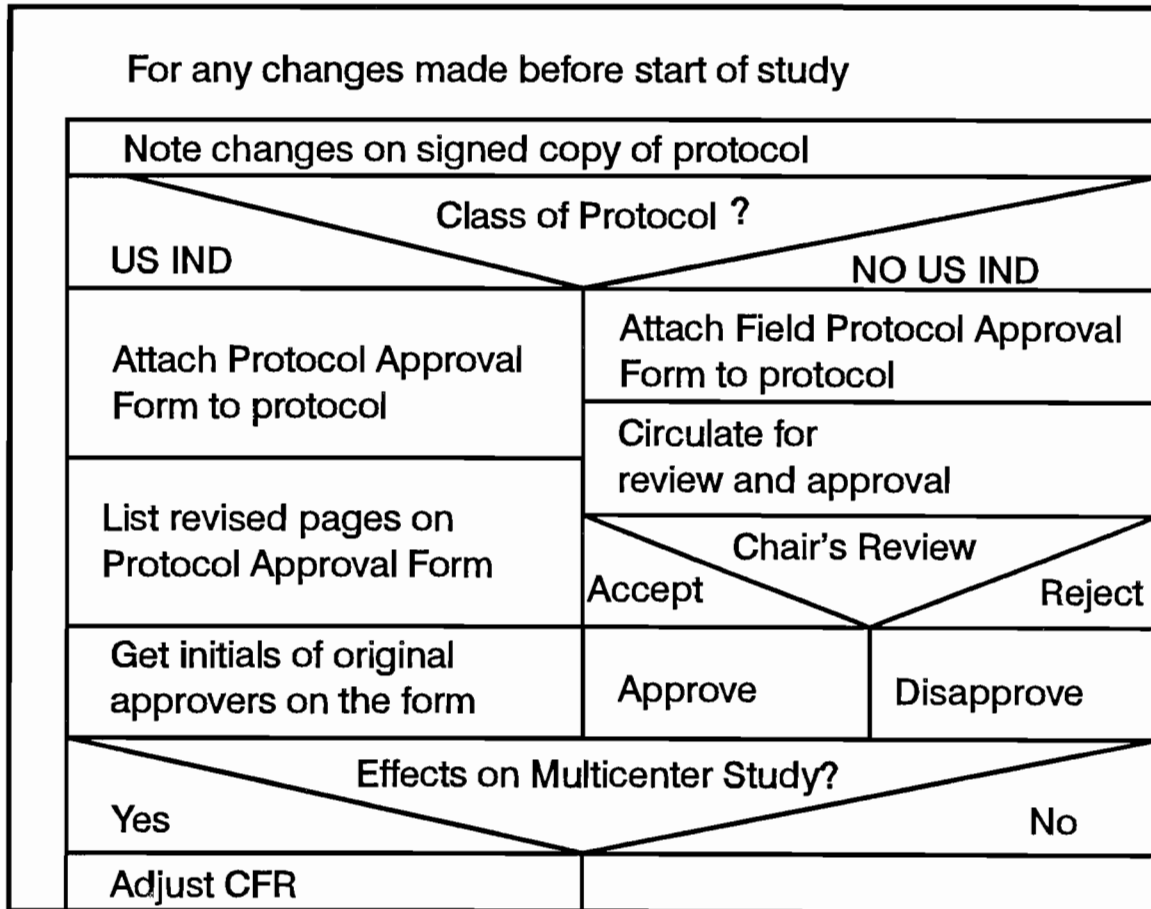
For all protocols, the impact of any changes on a multicenter study must be identified. CRF adjustments may then be necessary.

Diagrams for Decisions

Though we still have the same problems with tortuous syntax and subprofessional editing, the real difficulty is in the paragraph form itself—its unsuitability for branching instructions. Here, the straightforward solution is a process diagram or decision graphic. Most medical writers are familiar with the basics of flowcharts and "decision trees," but few use them in clinical documents—except, perhaps, in the attachments.

Nassi-Shneiderman Charts A particularly powerful drawing tool that combines flowcharts, decision tables, and decision trees is the **Nassi-Shneiderman Chart**², developed in the early 1970s as a tool for systems analysts. Exhibit 14 shows the procedure above as an N-S Chart.

Exhibit 14 Nassi-Shneiderman Version of Procedure



Structured Forms *Prove* the Procedure

Benefits

The principal beneficiary of these changes is the reader—regulator, investigator, or clinical operator. But I must also stress the benefit to the writers: namely, that casting the text in these austere and structured forms tests our understanding of the material itself.

Testing Procedures

Put bluntly, it is nearly impossible to "fake" information in this form. For example, in preparing this article I attempted to turn several passages into tables or diagrams, only to discover that their texts were impenetrably ambiguous. Try as hard as I might, I could not follow the process. And the unresolved questions were nearly always critically important: allocating tests to populations, assigning review responsibility, clarifying eligibility.

Better Reviews

Further, structured forms enhance the quality of technical reviews. Although prose paragraphs can contain a series of acceptable sentences, each of them coherent and correct, the substance of the paragraph can be incomplete. For example, if we are told that eligibility for a study is defined by sex, age cohort, and history of a certain disease, is it clear that we need **eight eligibility rules** to cover the eight combinations of three criteria? If the paragraph addresses only three or four of the logical categories, would the reviewers comment on the **missing** information?

Usability

A writer who cannot render factual or procedural information in tabular or diagrammatic form probably does not understand it fully. And the resultant document will be far less usable and readable than it should be.

References

1. Matthies, Leslie H. *The New Playscript Procedure* (Second Edition), Stamford, Ct.: Office Publications, Inc., 1977
2. Nassi, I. and Shneiderman, B "Flowcharting Techniques for Structured Programming," *ACM SIGPLAN Notices*, 8:8, pp.12-26, 1973. See also Weiss, E. H., "Visualizing a Procedure with Nassi-Shneiderman Charts," *J. Technical Writing and Communication*, Vol. 20(3), pp.237-254, 1990