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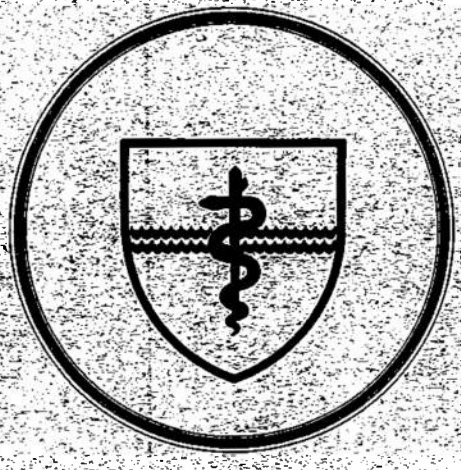

REPORT NUMBER 1012

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INTERIM REPORT - JULY 1982 - SEPT 1983

by

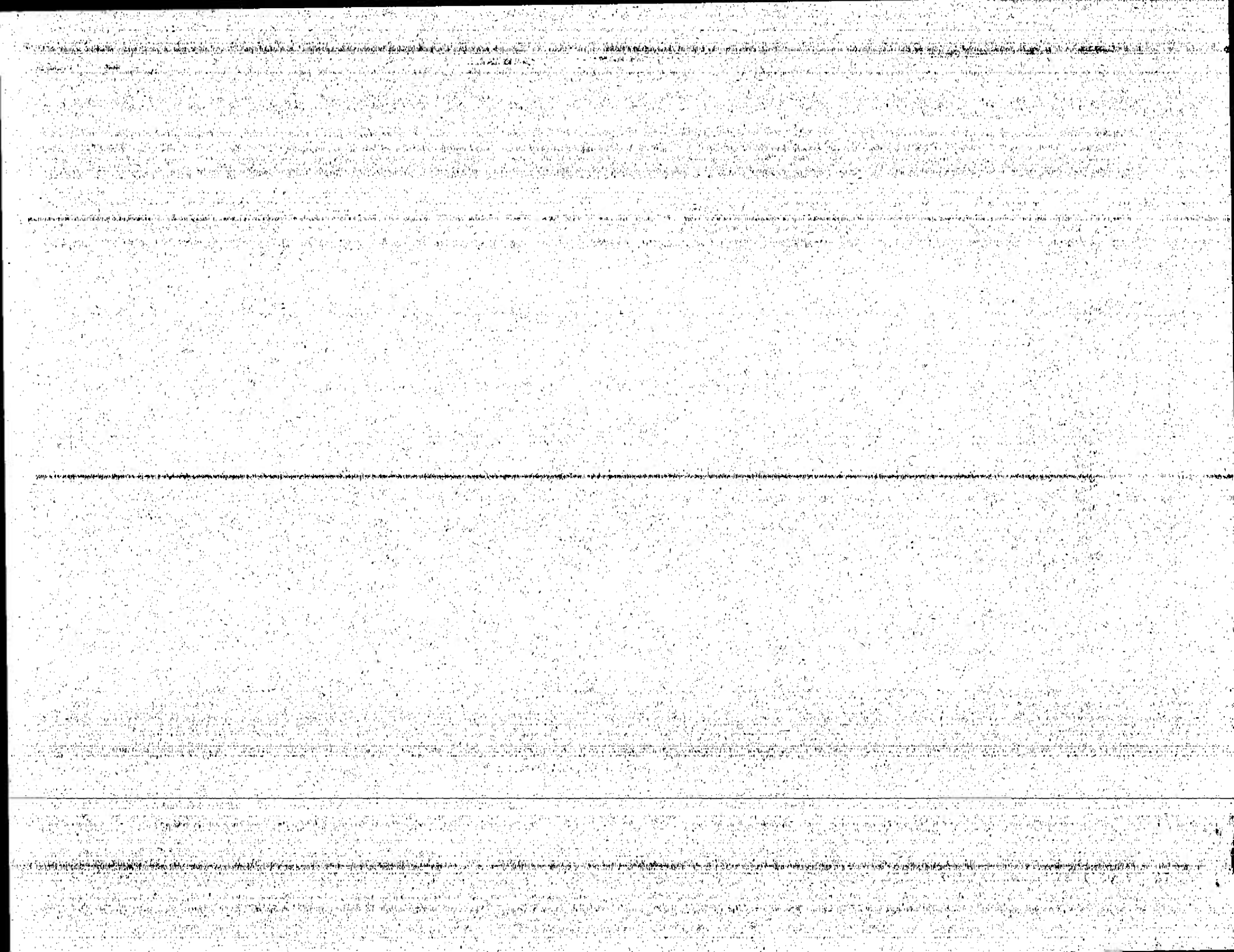
Steven F. OSBORNE
LT, MC, USNR

Naval Medical Research and Development Command
Research Work Unit M0095.001-1045

Released by:

W. C. MILROY, CAPT, MC, USN
Commanding Officer
Naval Submarine Medical Research Laboratory

19 December 1983



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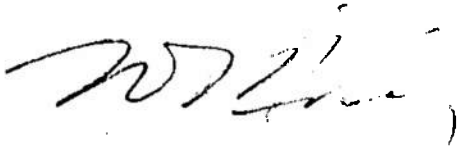

W. C. MILROY, CAPT, MC, USN
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NavSubMedRschLab

SUMMARY PAGE

THE PROBLEM

To provide an interim report summarizing the first fifteen months of Sea trials experience with the Computer-Assisted Medical Diagnosis of Abdominal Pain Project; Work Unit #63706N-M0095.001-1045.

THE FINDINGS

Results of the first fifteen months of sea trials experience show good correlations between the computer diagnosis and both the submarine Hospital Corpsman's initial diagnosis and the final diagnosis in the limited number of cases reported. The datasheet has been particularly useful. However, unless the percentage of presenting abdominal pain cases that are reported increases substantially, it is unlikely that the computer model will be validated at the end of the five-year trial.

APPLICATIONS

The information will be useful to those following the progress of this research in computer-assisted medical diagnosis in isolated environments.

ADMINISTRATIVE INFORMATION

This report was submitted for review in November 1983, and was approved for publication in December 1983. It is designated as NAVSUBMEDRSCHLAB Report Number 1012.

Published by the Naval Submarine Medical Research Laboratory

ABSTRACT

This report summarizes the experience with the Computer-Assisted Medical Diagnosis of Abdominal Pain project from 1 July 1982 - 30 September 1983. During this period, 30 cases of abdominal pain presenting at sea were reported to the Naval Submarine Medical Research Laboratory. Seventy-three percent of these came from the Experimental Group, twenty-seven percent from the Control Group. Review of sick call logs and personal discussions with submarine Hospital Corpsmen disclosed that 80-90% of cases went unreported, largely because of the paperwork involved and concern for uses to be made of the data. Personal visits to submarine Hospital Corpsmen were made to allay these concerns.

The datasheet was found helpful by all who used it. The computer program supported the Medical Department Representative's initial diagnosis 75% of the time or better, and was appreciated when used.

The potential value of this project as a sophisticated decision aid to the submarine medical department representative is underscored by the results to date. A rigorous scientific trial to validate the computer program is necessary for medical safety. At present, the outlook for eventual validation is gray because of insufficient case reporting.

COMPUTER-ASSISTED DIAGNOSIS PROGRAM FOR ACUTE ABDOMINAL PAIN

I. BACKGROUND

The Naval Submarine Medical Research Laboratory (NSMRL) is tasked with developing new methods and procedures for assisting the medical department representative (MDR) aboard deployed United States Navy submarines. Paramount among the duties of the MDR is the evaluation and treatment of crewmembers who are ill. The history and physical exam are the cornerstone of the evaluation, with laboratory facilities being modest. Consultation with other medical personnel is attempted only in emergencies and if the mission permits it. With the knowledge that computer-assisted diagnosis was under study elsewhere, NSMRL saw an opportunity to develop a computerized diagnostic aid for use by the MDR. Since abdominal pain was the most frequent chief complaint in medical evacuations from submarines, a computer program to assist in developing a differential diagnosis of this condition was initiated several years ago. The intent was (and is) to provide a "sophisticated decision aid" to supplement the modest laboratory facilities and to compensate for the lack of a consultant.

A prototype program was formulated in conjunction with Dr. F. T. de Dombal from the University of Leeds Hospital in the United Kingdom. It was modified for the submarine population and made ready for sea trials. Proper scientific and medical protocol required that the project be conducted as an experiment and that a control (C) and experimental (E) group be formed. A protocol was approved by the Committee for the Protection of Human Subjects which involved informed consent for participation from MDR's and their randomization into a control and experimental group. The Control group has the datasheet, reference manual, and (recently) the training program. A five-year study period was projected from the anticipated case load so that statistical requirements could be met. The case load was estimated from incidence data for abdominal pain supplied by MDR's. General descriptions of the program have been previously reported.[1-4]

In January 1982 approval was granted for Fleet T&E support. In May 1982 training of Squadron Medical Officers and Squadron Corpsmen was accomplished with concomitant distribution of computer tapes and instructional materials. Individual submarine corpsmen were then trained by Squadron Medical Personnel. In July 1982 sea trials were initiated. This report summarizes results from July 1982 through September 1983.

II. DATA COLLECTED

One hundred and three submarines are actively enrolled in the study, with 52 in the control group and 51 in the experimental group. The enrollment numbers fluctuate with additions to the fleet and decommissionings (or transfers to the shipyard). To

date, there have been 30 cases of abdominal pain reported to NSMRL. Twenty-two (73%) of these were from the experimental group and 8 (27%) from the control group. Twenty-six of the 30 cases are fully documented with the remainder in various stages of follow-up. Eight of the thirty involved medical evacuation from the submarine (four each from the C and E groups).

Table I shows the six possible categories of diagnosis with the program. Abbreviations are arbitrary and are those used in the actual computer printout.

Table II summarizes the 26 documented cases in approximate chronological order. The "Initial Diagnosis" and "Computer Diagnosis" are made at the time of presentation of the crewmember. The "Final Diagnosis" is made one week after initial presentation, or upon resolution of the illness, whichever is later. Hospital data is used for final diagnosis when the crewmember was referred for evaluation. If the crewmember recovered without the need for hospital or physician follow-up, the final diagnosis is made from data supplied by the MDR.

III. PRELIMINARY ANALYSIS OF DATA

Table III summarizes cases as reported with the totals of final diagnoses shown.

From Table II, concordance between the MDR's initial diagnosis and the final diagnosis was as follows: Experimental Group (13/18), 72%; Control Group (7/8), 88%. Concordance between the computer diagnosis and the final diagnosis was: Experimental Group (13/18), 72%; Control Group (8/8), 100%. Concordance between the MDR's initial diagnosis and the computer diagnosis was: Experimental Group (17/18), 94%; Control Group (7/8), 88%.

Table IV lists the 18 cases from Table II where medical evacuation was not required. From Table IV, concordance between the MDR's initial diagnosis and the final diagnosis was as follows: Experimental Group (12/14), 86%; Control Group (4/4), 100%. Concordance between the computer diagnosis and the final diagnosis was: Experimental Group (11/14), 79%; Control Group (4/4), 100%. Concordance between the MDR's initial diagnosis and the computer diagnosis was: Experimental Group (13/14), 93%; Control Group (4/4), 100%.

Table V lists the 8 cases from Table II where medical evacuation was required. From Table V, concordance between the MDR's initial diagnosis and the final diagnosis was as follows: Experimental Group (1/4), 25%; Control Group (2/4), 50%. Concordance between the computer diagnosis and the final diagnosis was: Experimental Group (1/4), 25%; Control Group (3/4), 75%. Concordance between the MDR's initial diagnosis and the computer diagnosis was: Experimental Group (4/4), 100%; Control Group (3/4), 75%.

These tabulations are made for the reader's convenience. The limited number of cases makes any conclusions (positive or negative) about the impact of the

Table I

Categories of Diagnosis

Diagnostic Category	Abbreviation
Appendicitis	APPY
Nonspecific Abdominal Pain	NONSAP*
Renal Colic	RCOLIC
Perforated Duodenal Ulcer	PERFDU
Cholecystitis	CHOLE
Small Bowel Obstruction	SMBOBS

*Defined as abdominal pain that is non-surgical, not life-threatening, and not requiring medical evacuation.

Table II

Case Data in Approximate Order of Submission

Crewmember	E/C	Initial Diagnosis	Computer* Diagnosis	Final** Diagnosis	MEDEVAC Occurred
1	E	RCOLIC	RCOLIC	OTHER (UTI)	NO
2	E	RCOLIC	RCOLIC	RCOLIC	NO
3	E	NONSAP	NONSAP	NONSAP	NO
4	E	NONSAP	NONSAP	NONSAP	NO
5	E	NONSAP	NONSAP	NONSAP	NO
6	E	NONSAP	NONSAP	NONSAP	NO
7	E	APPY	APPY	NONSAP	YES
8	C	NONSAP	{NONSAP 71%} {APPY 29% }	NONSAP	NO
9	C	RCOLIC	RCOLIC	OTHER (pyelo-nephritis)	YES
10	E	APPY	APPY	APPY	YES
11	E	NONSAP	NONSAP	OTHER (bleeding ulcer)	YES
12	E	NONSAP	NONSAP	NONSAP	NO
13	C	NONSAP	NONSAP	NONSAP	YES
14	C	APPY	NONSAP	NONSAP	YES
15	C	APPY	APPY	APPY	YES
16	E	NONSAP	NONSAP (93%)	NONSAP	NO
17	E	NONSAP	NONSAP	NONSAP	NO
18	E	NONSAP	NONSAP	NONSAP	NO
19	E	APPY	APPY	APPY	NO
20	E	NONSAP	NONSAP	OTHER (ulcerative colitis)	NO
21	C	NONSAP	NONSAP	NONSAP	NO
22	E	NONSAP	{APPY 86% } {NONSAP 13%}	NONSAP	NO
23	C	NONSAP	NONSAP	NONSAP	NO
24	C	RCOLIC	RCOLIC	RCOLIC	NO
25	E	APPY	APPY	APPY	NO
26	E	CHOLE	CHOLE	NONSAP	YES

* The computer program calculated a probability > 95% for the category specified unless noted otherwise. The computer diagnosis is not available to the MDR aboard control group units; it is calculated by NSMRL from the submitted datasheet.

** If a specific final diagnosis is known, but it is not among the five specific categories, it has been labelled "OTHER." This applies to cases 1, 9, 11, 20.

Table III

Final Diagnosis in the Experimental and Control Groups

	Experimental Group	Control Group
APPY	3	1
NONSAP	11	5
RCOLIC	1	1
PERFDU	0	0
CHOLE	0	0
SMBOBS	0	0
OTHER	3	1
MEDEVAC OCCURRED	4 (of above)	4 (of above)

Table IV

Data From 18 Cases Not Requiring Medical Evacuation

CREWMEMBER	E/C	Initial Diagnosis	Computer Diagnosis	Final Diagnosis
1	E	RCOLIC	RCOLIC	OTHER (UTI)
2	E	RCOLIC	RCOLIC	RCOLIC
3	E	NONSAP	NONSAP	NONSAP
4	E	NONSAP	NONSAP	NONSAP
5	E	NONSAP	NONSAP	NONSAP
6	E	NONSAP	NONSAP	NONSAP
12	E	NONSAP	NONSAP	NONSAP
16	E	NONSAP	NONSAP (93%)	NONSAP
17	E	NONSAP	NONSAP	NONSAP
18	E	NONSAP	NONSAP	NONSAP
19	E	APPY	APPY	APPY
20	E	NONSAP	NONSAP	OTHER (Ulcerative Colitis)
22	E	NONSAP	{APPY 86% } {NONSAP 13%}	NONSAP
25	E	APPY	APPY	APPY
8	C	NONSAP	{NONSAP 71%} {APPY 29% }	NONSAP
21	C	NONSAP	NONSAP	NONSAP
23	C	NONSAP	NONSAP	NONSAP
24	C	RCOLIC	RCOLIC	RCOLIC

Table V

Data from 8 Cases Requiring Medical Evacuation

CREWMEMBER	E/C	Initial Diagnosis	Computer Diagnosis	Final Diagnosis
7	E	APPY	APPY	NONSAP
10	E	APPY	APPY	APPY
11	E	NONSAP	NONSAP	OTHER (Bleeding Ulcer)
26	E	CHOLE	CHOLE	NONSAP
9	C	RCOLIC	RCOLIC	OTHER (Pyelonephritis)
13	C	NONSAP	NONSAP	NONSAP
14	C	APPY	NONSAP	NONSAP
15	C	APPY	APPY	APPY

computer program quite speculative. Several times this number of cases would be required to make such an assessment.

In case #11, the computer program's NONSAP diagnosis was incorrect. The MDR agreed with the program's assessment of a benign abdomen, but he correctly evaluated hematemesis as serious and recommended medical evacuation. The crewmember recovered ashore without surgery although the administration of several units of blood was required. In the remainder of the cases, the computer diagnosis was correct or reasonable. The crewmember in case #7 had an appendectomy ashore with findings of a normal appendix. The program weighs urinary tract problems (cases #1 and #9) towards RCOLIC. The computation of RCOLIC by this program is an area of continuing evaluation.

IV. PROBLEM AREAS

After six months of sea trials, only 2 cases of abdominal pain had been reported to NSMRL. Periodic interviews of Squadron Corpsmen disclosed that MDR's in the Control Group were unhappy with their role of "data collection" without the benefit of computer output. MDR's in the Experimental Group, while not having the same concern, were unhappy with the extra paperwork requirements. Some MDR's hadn't received training and tapes for several months after the study was initiated. There was a general misunderstanding about just which presentations of abdominal pain were to have a datasheet completed (i.e., all presentations or just the "serious" cases?).

Beginning in February 1983, better contact with Squadron Medical personnel was established. A letter was sent to all Squadron/Group Commanders and to individual submarine commanders requesting completion of a new medical evacuation form (when indicated) and noting the highlights of the computer-assisted diagnosis program. It was requested that MDRs complete a datasheet and forward it, along with supporting SF-600 entries and follow-up (when possible) to NSMRL for all cases of acute abdominal pain, severity unspecified. Validation of the category NONSAP is as necessary as validation of other categories. The training program was modified to allow its inclusion in the Control Group tapes. Previously, the training program could have been (hypothetically) misused to allow a diagnosis of a real patient's illness.

In May 1983, onboard visits to New London-area submarines were initiated. The program objectives were reinforced with the actual user with distribution of updated tapes occurring at these visits. In June and July 1983, similar visits to all submarine ports in CONUS plus Pearl Harbor were accomplished. Approximately 55 MDRs were interviewed, onboard the submarine when possible. Medical log books or sick call log books were reviewed with the MDR. Instances where a datasheet may have been completed were noted, with encouragement given to complete one for similar cases in the future. Most of those interviewed expressed a better understanding of, and greater interest in, the project afterwards.

While there has been an increase in data submitted over the past 9 months, the review of medical logs or sick call logs showed that about 10-20% of presenting cases were sent to NSMRL. Collection of data at this rate would yield only 10-20% of the data required by the fifth year of the study. If all cases presenting were completed, the amount of data would be more than adequate. In one instance, NSMRL learned of a medical evacuation for appendicitis from the submarine's Squadron Corpsman. No data were submitted. When NSMRL researchers visited that submarine, there was a new MDR aboard. The crewmember was present and now well after his appendectomy. The datasheet, which is essential, was never found, having been apparently discarded.

On the other hand, there have been several reports of MDRs utilizing the datasheet to assure a complete history and physical exam of the abdomen (both in the experimental and control groups). One MDR in a radio message to a shore-based facility used terminology directly from the datasheet to describe his ill crewmember's condition. He was praised for having sent a clear, concise, complete message that left out no essential data. A medical evacuation was then recommended by the Squadron Medical Officer. Several MDRs in the experimental group have expressed reassurance in having the computer program reaffirm their initial diagnostic impression. The value of this latter point in both complicated and less difficult

cases should not be underestimated.

V. PLANS

A vigorous effort to personally interact with the user of the system will continue. There is no impediment to this in the local (New London, CT) area. Distant locations require scarce travel funds to visit. Such a visit is planned for FY84, funds permitting, to interact with units not yet seen. A periodic note with highlights of the system's usage will be sent to all submarines. The crossover between the experimental and control groups (one for one switch of roles between groups), scheduled for December 1984, may be advanced six months. The introduction of a related chest pain system will be pointed out.

VI. OUTLOOK

After 15 months of sea trials, only 10-20% of the number of cases expected by this time were received. The fact that more cases were available means that MDR acceptance of the entire system, including reporting requirements, is sub-optimal. It is obvious that the control group is unhappy with their role, but there is no scientifically acceptable alternative to a control group. Encouragement and personal contact are the only inducements to compliance that can be offered outside of the recent addition of the training program. The requirement from the Committee for the Protection of Human Subjects to designate the MDR as the "subject" and request completely voluntary cooperation, with the right to omit any aspect of the project, hampers our efforts. It is recognized, however, that this is the nature of medical research.

The anecdotal experience to date, based on 26 completely documented cases, suggests that the datasheet serves its purpose well and that the diagnostic program is probably valuable as an extended decision aid to the MDR.

VII. ACKNOWLEDGEMENTS

I am indebted to: George Moeller, Ph.D. for advice and editorial comment; HMC(SS) D. G. Johansen, and HM3 M. M. Speckhahn for technical assistance; LTjg D. A. Kobus for review; and E. M. Perkins for manuscript preparation.

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