Integration of Computer-Assembled Digital Images and Text Data as Evidence for the Oncological Record

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Digitally created visual images of pertinent patient data have been integrated with text information to formulate a visual evaluation and summary sheet (VESS) using computer processing. The VESS incorporates images of a patient's physical appearance, radiological images, pharmacokinetic graphs, and text information into a 1-page document of the patient's condition. Thus, computer processing of digital images and other information helps to refine patient data presentation, analysis, interpretation, and communication. This form of data management is especially valuable in oncological research, where clinical trials demand rapid, ongoing assessment of results and analysis of large amounts of data. The VESS is an effective mechanism for monitoring both the progress of individual patients and the endpoints of the overall clinical trial.

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THIS ARTICLE presents a computer-generated evaluation and summary technique that has been employed to monitor the effectiveness of new oncological drugs and treatments on patients undergoing cancer therapy. This single-page summary form, termed a visual evaluation and summary sheet (VESS), includes text data and digital camera images of pertinent radiology studies, visual manifestations such as rashes, other skin lesions, enlarged lymph nodes, mucositis, and/or graphs of pertinent data obtained during treatment that are collected, sized, and collated by computer processing.

One mission in the Division of Cancer Research of the National Health Research Institutes is the evaluation of new drugs and treatment modalities for cancer therapy. Both appropriate patient management and proper monitoring of the research protocols require conscientious and explicit use of current clinical evidence.¹ Evidence should be meticulously and precisely collected in a timely and systematic manner so that any missing information can be recognized promptly and rectified.^{2,3}

Cancer patients who have completed or are undergoing a predetermined number of treatment courses under a research protocol require evaluation of the response to treatment and of toxicity incurred as a result of the treatment in order to

determine subsequent clinical management.⁴ Documentation of tumor size is vital as an index of objective treatment response. Monitoring patient progress requires review of cumbersome medical files, radiographic studies, computerized tomographic scans, magnetic resonance images, nuclear medicine scans, and a meticulous matching of the original data with information recorded on many different case report forms. It is an immense task to gather and analyze these data. Use of the computer-generated VESS has replaced much of that task.

MATERIALS AND METHODS

Digital images were obtained with a Nikon COOLPIX600 Digital camera using a maximum matrix of $1,024 \times 768$ pixels (1.08 M pixels). The Nikon imaging software (Nikonview 600) was used for image editing and optimization. After transmitting image files onto the computer hard disk, they were cropped to the area of interest; adjusted for brightness, contrast, saturation and sharpness; and stored as joint photographic experts group (JPEG) files. An unprocessed image file usually occupied about 220 KB of memory, whereas the final JPEG file took between 100 and 150 KB after editing.

The computer employed was an IBM Aptiva, with a 166 MHz Pentium II central processing unit and 32 MB of random access memory. The operating system was Chinese Windows 95. Chinese Microsoft Word 97 was used to create a Word document combining text and image files. Images were imported using the "Insert Picture from File" function, dragged to the desired position, and scaled to the desired size. Text boxes were used to include text descriptions employing the "drawing tools" on the Tools menu.

Handheld photography of radiology images on a view box such as radiographs, CT and/or MR images, sonograms, and nuclear medicine studies can be performed with a steady hand. The immediate display of the image on the liquid crystal display (LCD) permits an immediate decision to save the image or to delete it and repeat it. Selecting images that show the maximum diameter of lesion at the same level in studies taken at different time intervals requires the expertise of a radiologist or an

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experienced and trained physician and/or nurse. Digital photography of superficial skin lesions or rashes, lymph node nodules, oral mucositis, pharmacokinetic graphs, chromosome studies, comparative genomic hybridization figures, and other graphical data is easier to perform.

After assembly, a VESS page requires 1 to 8 MB of memory. It is adjusted to fit onto an A4-size paper (210 mm × 297 mm or about 8.25 × 11.75 inches). Printing in either color or black and white is done at 720 dots per inch, using an Epson Stylus Color Ink Jet printer on photo-quality ink jet paper. It takes 2 to 8 minutes to print each VESS page, either immediately upon completion or later on demand from the stored image. Prior versions of the VESS are used to generate updated versions to avoid redundant reentry of information that has not changed. Several annotated images from different days that show tumor size can be shown together, if desired. Alternatively, manually referring from a current VESS to one or more from earlier dates also is easy.

RESULTS

All cancer clinical patients in the Division of Cancer Research of the National Health Research Institutes have been monitored using the VESS technique since September 1998. Interval determination of change or lack of change in tumor size is documented by adding the new images and data to a revised VESS. The time savings in clinical terms and in monitoring the research protocols have been significant.

Each clinical trial protocol requires completion of 6 different case report forms: consent, registration, on-study form, checklist, flow sheets, and measurement forms. The data contained in the single-page VESS covers most of the items on these 6 forms, as shown in Table 1. Figures 1 and 2 provide are VESS examples for 2 different patients.

DISCUSSION

“Information design” is about managing the relationship between people and information so that the information is accessible to and usable by people.⁵ However, medical charting often has focused on data entry, accuracy, and completeness to measure up to stringent auditing, but in a suboptimal format for clinical decision making. The aim in medical record design should be to enable optimal retrieval and use of patient data,^{6,7} and the best format for data presentation is that tailored to the decision to be made.⁸

The visual summary/evaluation sheet (VESS) has been designed in a problem-orientated format.⁹ All data have been organized in vertical columns for faster reading.^{5,10} With visual enhancement and documentation of pertinent and critical informa-

Table 1. Case Report Medical Information Available in VESS Form

Clinical Trial Case Report Forms	VESS
Consent form	No
Registration form	
Protocol and case no.	Yes
Name	Yes
Age	Yes
Sex	Yes
Hospital number	Yes
On-study date	Yes
Patient address and telephone no.	No
Onstudy form	
Past history	Yes, pertinent, limited
Diagnosis	Yes, pertinent, limited
Eligibility and ineligibility criteria	No
Tumor extent	Yes, pertinent
Checklist	
Present history	Yes
Pathology	Yes, limited
Flow sheet	
Performance status	Yes, serial
Weight	Yes, serial
Analgesic consumption	Yes, serial
Other drug information	No, may select recording
Laboratory data	Yes, serial
Toxicity grade	Yes, worst toxicity documented
Measurement form	
Tumor measurement: image studies (X rays, CT scans, MR images, PET scans, radionuclear scans)	Yes, pertinent, concise
Superficial skin lesions/nodules: measure/describe	Yes, measurement and visual image
Date of initial response	Yes
Date of response confirmation	Yes
Response rate	Yes, highlighted
Date of progression	Yes
Summary and evaluation sheet	
Total drug dose	No
Response	Yes
Toxicity	Yes, visual image if possible or necessary
Progression free survival	Yes, stated
Survival	Yes, stated, follow-up date recorded if still alive
Miscellaneous	
Pharmacokinetic graph	Can be inserted
Subsequent management	Optional

tion,^{11,12} data becomes less ambiguous and easier to find and interpret.¹³ It becomes easier for a clinician to rapidly grasp relevant clinical data for decision making; it is also less error-prone because all data

Protocol: Phase II of PFL in ADVANCED/METASTATIC BREAST CANCER. **Patient no.** x
Patient Yxx **Hosp no** xx **Age** 34 **Sex** F **Onstudy** 1998/10/8 menarche-12;G₂P₁A₁ **Offstudy** N/A
 1996/6 L't breast (2x2cm infiltrating ductal) Ca, refused surgery, took Chinese herbal medication.
 1998/1 extensive left chest tumor, ER30%+, PR10%+, multiple bone, left neck skin & fascial plane of muscle group, submental & submandibular space involvement. CEA=175, CA153>250.
 1998/2/26 & 1998/4/6&30 CAF (500;50;500), 1998/5/5-6/10 Left chest wall RT 5000cGy.
 1998/8/3 right breast cancer, modified radical mastectomy, axilla 12/12+ nodes, .
 1998/9/29 Disseminated breast CA, bone, liver, lung, chest wall & skin metastases, septic gastrostomy (for feeding), port A. Post radiotherapy hypothyroidism, free T4=0.99, TSH=40.
 1998/10/8 PFL **Courses** 19 **Dose intensity** 100%
RR PR **Toxicity** grade 2 leucopenia.

98/10/8 Left back skin: infiltration.	98/10/22 CXR: Left pleural effusion.	1998/10/8 C ₁ D ₁ PS=3, wt=50kg, alb.=3.7, CEA=166, CA153>240, ALP/GGT/LDH=181/73/317. CT abdo 98/10/7 ☐:R't breast base swollen, & pleural effusion. ☐: L't side chest wall swollen, liver mets. Skin: tumor. Liver: 2x1.6cm:baseline 100%
	98/10/7 Bone scan: spine, ribs, pelvis metastases.
98/11/19 skin improved.	98/12/21 CXR: effusion gone.	1998/11/19 C ₆ D ₁ PS=1, wt=50kg, alb.=3.7, CEA=159, CA153=152, ALP/GGT/LDH=118/38/256 CT abdo 98/11/19 ☐:R't breast base improved. ☐: L't chest wall improved. Skin: tumor improved. Liver: 1.4x1.1cm:PR* 48%
1999/2/24 skin better with 1 nodule.	99/2/25 CXR: still normal.	1999/1/15 C ₆ D ₁ PS=1, wt=50kg, alb.=4, CEA=67, CA153=77, ALP/GGT/LDH=83/19/226 CT abdo 99/1/15 ☐:R't chest wall minimal tumor, effusion cleared. ☐: L't chest wall normal. Skin: tumor improved. Liver: 0.6x0.8cm:PR 15%
	99/2/25 bone scan: spine, pelvis, ribs much improved.	
Progression free survival: 153* days (response continuing, updated on 1999/3/10). Overall survival: 153* days. Subsequent therapy: not applicable .		

Fig 1. Visual evaluation/summary sheet of a breast cancer patient who underwent treatment "PFL." There are 6 CT scan images, 3 chest radiographs, 2 bone scans, and 3 images of the patient's skin. The document was 8.7 MB in size and took 5 minutes to print out in color. N/A, not applicable; L't, left; ER, estrogen receptor; PR10%+, progesterone receptor; G₂P₁A₁, 2 pregnancies, 1 live birth, 1 abortion; CA, carcinoma; R/T, radiotherapy; RR, response rate; PR, partial response; C₁D₁, day 1 of course 1; PS, performance status; Wt, weight; Alb, albumin; ALP/GGT/LDH, alkaline phosphatase/gamma glutaryl transferase/lactate dehydrogenase; CT abdo, computerized tomography of the abdomen.

Protocol: Phase II of MEFLEP in ADVANCED/METASTATIC PANCREATIC CANCER. **Patient no.** x
Patient Yxx **Hosp no** xx **Age** 37 **Sex** F **Onstudy** 1998/2/5 non-smoker, no DM **Offstudy** 1998/10/19
 1997/2 unexplained backache and pancreatitis, spontaneously resolved
 1998/2 pancreatic cancer (adenocarcinoma) with multiple liver metastases.
 1998/2/5 MEFLEP **Courses** 17 **Dose intensity** 100%
RR Partial Response **Toxicity** grade II neutropenia

1998/1/18 pre-treatment PS=2, weight=41kg, albumin=3.9g%, morphine=90mg per os daily, LDH=498IU/L, CA125=666 Pan: 5x3.5cm:baseline 100%
1998/2/27 C2D9 PS=1, weight=40kg, albumin=4.5g%, morphine=none LDH=246IU/L, CA125=1138 Pan: 4x2cm:PR* 46%
1998/6/20 C10D11 PS=0, weight=44kg, Morphine=none, albumin=4.4g% LDH=137IU/L, CA125=34 Pan: 3x1.5cm:PR 26%
1998/8/25 C14D13 PS=0, weight=45kg, Morphine=none, albumin=4.2g% LDH=163IU/L, CA125=32 Pan: 0x0cm:near CR 0%
Progression free survival 256days Survival 398+days (1999/3/10) Subsequent therapy: gemcitabine based chemotherapy.	Progression 1998/10/19 PS=1, weight=45kg, morphine=40mgqd, CA125=227

Fig 2. Visual evaluation/summary sheet of a patient with pancreatic cancer who underwent treatment "MEFLEP." There are 8 CT scan images, the document was 4.8 MB in size, and it took 4 minutes to print out in black and white.

needed to support a decision can be viewed as a 1-page structured abstract rather than as digest information spread over several pages.^{7,13,14} *Adequate letter differentiation and rate of comprehension in reading can still be attained with appropriate font selection and spacing.*¹⁵ Interpretation of visual images is faster when they are labeled with their message rather than their content,¹⁴ a principle employed in the VESS.

Clinical errors in interpretation of data can be induced by lapse in attention¹⁴; information also blurs with time,¹⁴ and unavoidably memory becomes fallible with increasing age.¹⁶ Thus, data should be recorded as soon as it is elicited to avoid distortions as well as omissions.¹⁷

Digital imaging lightens the cumbersome task of recording the details of each picture frame as it is taken by a regular camera and takes the uncertainty out of having recorded an inferior quality image, discovered only after film development and that cannot be corrected. Digital images are immediately available for transmission and communica-

tion to a wide audience through e-mail, slide projection, television, and transmission on the Worldwide Web, and with present day technology and prices, it is highly amenable and affordable to the physician population at large.¹⁸⁻²⁰

The VESS certainly does have shortcomings. Image resolution is inferior to that of regular film, and in order to accommodate all relevant images on 1 page, image size must be compromised. The image selection process can be biased because not all the images are viewed, although signed approval by the principal investigator after completion of the VESS can be made compulsory. To the unskilled, it takes longer to enter pertinent information by computer than by writing; thus, formulation of the VESS can be time consuming and much slower than hand recording,^{21,22} but with practice, the production process becomes accelerated. In short, the goal of the VESS is to provide the right data on the right patient, at the right time and place, as well as in the right format and language.

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