Data
Management
and
Report
Generation
Data Management and Report Generation

Introduction

Bone densitometry investigations generally involve computer controlled acquisition, processing and analysis of data. The increasing prevalence of osteoporosis heightens the need to identify those at risk and can produce an unexpectedly high demand on a newly introduced densitometry service. This in turn will entail the accrual of copious amounts of data that require a comprehensive database structure together with careful storage and backup procedures in order to maintain data integrity. The rigorous quality assurance procedures that should be implemented to monitor and ensure accuracy and precision of the results, add to this burden of data management.
**Data Management**

Most commercially available bone densitometry systems provide software tools for the maintenance of both patient and quality assurance data. However, the user needs to be aware of the extent and limitations of these tools and how best to employ them to assist with the management of their routine referrals and clinical trials. In units with only one densitometer, the software provided may suffice. However, in larger centres a more comprehensive and automated system is highly desirable.

All computer based clinical systems must provide a file structure, or database, such that the record of one patient cannot be mistakenly associated with another. This is an essential criterion when considering the purchase of equipment. Data integrity is generally achieved with the aid of a unique identifier, a code that is unique to each patient, which is allocated by the system and is an integral part of the file containing the patient’s biographic information. If the scan or investigation results are subsequently stored in separate files, as in a relational database, this unique identifier is also incorporated in those files in order to provide a cross reference. Alternatively the biographic file may contain a separate field which indicates the name of the file in which relevant results are located.

Some computer based systems, such as those supplied by GE-Lunar (GE-Lunar, Madison, WI) provide facilities for grouping patient files into separate directories (computer filing systems) which is useful where several research studies and clinical referrals may be conducted on a single machine. Participation in clinical drug trials normally requires the setting up of a separate file system for each trial.

Properly organised and separated data files provide ease of access for each particular study but have the disadvantage of the need to search several directories to determine previous attendance when given only the patient’s name. Other systems, such as Hologic (Hologic Inc., Waltham MA) store all patient files in one directory but provide user defined search routines that enable patients attending for particular studies to be easily identified. This method relies on an initial entry of a unique code related to each study in one of the fields provided. It is well worth taking time when setting up a densitometry service to ensure, as far as possible, that the database is structured to address future requirements.

A densitometry centre fortunate to have more than one system for determining bone density also needs to take steps to ensure that a
patient’s previous visits can readily be identified so that follow up studies can be carried out on the same machine. This is crucial even where the machines are of the same type from the same manufacturer as inter machine differences may exceed the minor changes that occur in bone density, whether as a result of age or menopause related loss or treatment gain. The methods for achieving ease of patient identification where multiple databases exist include a card index system and a separate patient administration computer database.

The first is slow but useful where requests are received on cards although cards would need to be made out for those attending for research or clinical trials. Additional details regarding the relevant densitometry system and database would need to be manually entered and, if easy access to results is required, the densitometry results would also need to be included. Manual entry is tedious and a potential source of human error.

The second requires manual entry onto a computer of relevant machine, database and patient details and, if required, densitometry results. This is again prone to human error and entails a time consuming duplicate entry of patient details. A preferred method would provide for amalgamation of the densitometry databases into one patient administration database.

Transfer of Quality assurance data from the densitometer facilitates monitoring of equipment performance parameters using more sophisticated analysis tools such as Microsoft Excel or SPSS. In some densitometry centres, additional data is collected from the patient on clinical, social and lifestyle factors thought to influence bone density and osteoporosis risk. If these details are entered into an electronic database they may be merged with the bone densitometry results and used for automated generation of more individualised reports.

Thought should be given to database management at the outset, with due consideration for future potential development, as restructuring a poorly designed set up can prove difficult and expensive.

Careful attention should also be paid to the establishment of data backup and archive procedures to ensure space availability on the computer system and security of patient data. Computers are currently a prime target for opportunist thieves. Assuming the computer is physically secure, it is still prone to software or hardware failure that may incur loss of data. Software should be available on the system to enable novice users to
achieve copying of data to an appropriate backup media. Consideration should be given to the amount of computer memory required for the storage of image files when choosing the backup media. The manufacturers provide recommendations on backup and archive intervals but individual centres should determine their optimum routine based on workload and quantity of data at risk. It should also be noted that the backup media is not foolproof and it is recommended to keep more than one copy in separate locations. These copies may be in the form of daily archive disks of patient investigation results and weekly, more comprehensive, backup discs. It is recommended that the backup disc be stored in a secure location in a separate room.

Any person responsible for the management of databases containing personal details on individuals must be fully informed of the need to ensure confidentiality and safety of that data. This is especially important where sensitive medical details are concerned. The Data Protection Act of 1984 requires registration of databases and system managers. Larger healthcare providers should have a data protection officer who will be able to advise on such matters. Due consideration should also be given to confidentiality when disposing of computers on which patient details have been held.

**Report Generation**

In order that bone densitometry assessment may assist in the clinical management of the patient, a meaningful report must be supplied that is understandable to the referring physician\(^2\). Referrals for densitometry may be received from several sources dependent upon the specific contract agreements for each densitometry centre. The service may provide for a report of the measurement only or, preferably, for result interpretation and patient management guidance.

A technical assessment of the results, including osteoporosis status and possibly fracture risk assessment based on patient’s results and age, may be given. This would require a reasonable understanding by the referring practitioner of bone densitometry, osteoporosis risk assessment and management. Where individualised reports are produced by an experienced physician, providing a clinical summary and management advice, specialist knowledge is made available to the referring practitioner. Ideally, the process should be automated.

Where a technical report is to be provided, only limited clinical details are required in order to ensure the appropriateness of the request and aid in the interpretation of the results. The printing of appropriate criteria for referral on a densitometry request card, to be checked off
by the referring clinician, may aid in reducing inappropriate referrals. Factors influencing the densitometry procedure, such as hip replacements, laminectomy or radiologically diagnosed vertebral fracture, should be included on the request card as patient obtained history may prove unreliable. When a more comprehensive report and guidance is to be given, full details of the patient’s relevant history need to be obtained.

Generally, the referring physician, especially if a GP, requires to know “Do they have the disease?”, “Are they likely to develop the disease?”, “Do they require treatment and if so for how long?”. The scan printout generated by the densitometry system software may prove over elaborate and unhelpful. Often, especially with DXA, results are expressed in several forms: actual density (g/cm2), relative to young normal (T score), relative to age matched (Z score), as a percentage of either young or age matched (% young normal/age matched). The World Health Organisation\(^3\) define osteoporosis in postmenopausal women as a bone mineral density value of the spine, hip or forearm of more than 2.5 SD below young normal mean. The T score therefore tends to be used for the diagnosis of the disease whereas the Z score or age-matched comparison may be of use in decisions regarding treatment, especially in the elderly\(^4\). It is helpful for the GP to be provided with an interpretation of the results and recommendation on patient management. Investigations not resulting in a prompt, clear, concise, clinically useful report will soon fall into disrepute in this age of limited resources and rising demand on healthcare services.

**References**


