

Chapter 8

Preparing a Procedures Manual for a Total Diet Study

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What Is a Total Diet Study Procedures Manual?

A total diet study (TDS) procedures manual is a document which specifies the roles of all relevant personnel participating in the study in relation to management, purchasing, preparing and storing of food samples for analysis. It is an important part of quality assurance and quality control (QA/QC) in a TDS and is an adjunct to good laboratory practices (GLP), which is the responsibility of the analytical laboratory. The manual provides detailed direction to sampling officers in collecting, handling and shipping of food samples, the types of foods, the total amounts of each food required and to sample preparers in preparing, storing and transporting of samples prior to analysis. It can help clarify critical aspects of a TDS, and reduce ambiguities and uncertainties in food sampling and preparation, leading to a more uniform and robust approach in the TDS. For example, sample variation among sampling officers within a country can, to a certain extent, be managed by careful adherence to the procedures manual. This is particularly important if food samples are collected from more than one region in a country or over more than one season. Therefore, this manual is designed as a reference tool for sampling officers, sample preparers and laboratory analysts as well as for TDS liaison officers who are responsible for coordinating the TDS sampling at the state/provincial/municipal levels. It is useful for planning and training prior to the TDS and for guidance during the TDS. It can also be used to identify any areas for improvement for the current TDS, as well as for future studies. It is a dynamic document that should be updated

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with any changes in personnel or procedures by an authorized person, usually the TDS project manager. It also ensures that valuable experience with TDSs is not lost and the associated intellectual capital in TDS procedures is secured over time.

When Is a TDS Procedures Manual Prepared?

It is important that the procedures manual and its associated Standard Operating Procedures (SOPs) contained therein are prepared before the TDS commences. Given the complexity of a TDS, preparing the manual in advance of the study will ensure that all aspects in regard to sampling, food preparation and handling have been addressed. In addition, a single consistent document outlining these procedures will enhance consistent performance by the different participants ensuring a robust and quality study.

How to Develop a TDS Procedures Manual and What Does It Include?

For a country undertaking their first TDS, the procedures manual should be drafted based on a TDS procedures manual that had already been developed in another country, preferably a country with experience in conducting TDSs. That manual should then be adapted using the collective knowledge of key members in the TDS management team (see below). It should then be distributed for comment to key end users (liaison officers, sampling officers, sample preparers and analysts) and designated stakeholders to ensure that all key components are correct and clear.

In developing a procedures manual, it is important to have already determined:

- Who will need to participate in the study and what are their roles?
- What are the types and nature of foods that will be sampled (see Chap. 6 – Preparing a Food List for a Total Diet Study)?
- What is the full list of analytes (see Chap. 7 – Selecting Chemicals for a Total Diet Study)?

These are essential elements of the study to be clarified prior to the development of the procedures manual, as it affects the type of information included in the manual, including sampling, preparation and handling requirements for the different food samples.

Total Diet Study Management Team

At the beginning of organizing a TDS project, it is important to form a TDS management team including all key personnel. Led by the TDS project manager,

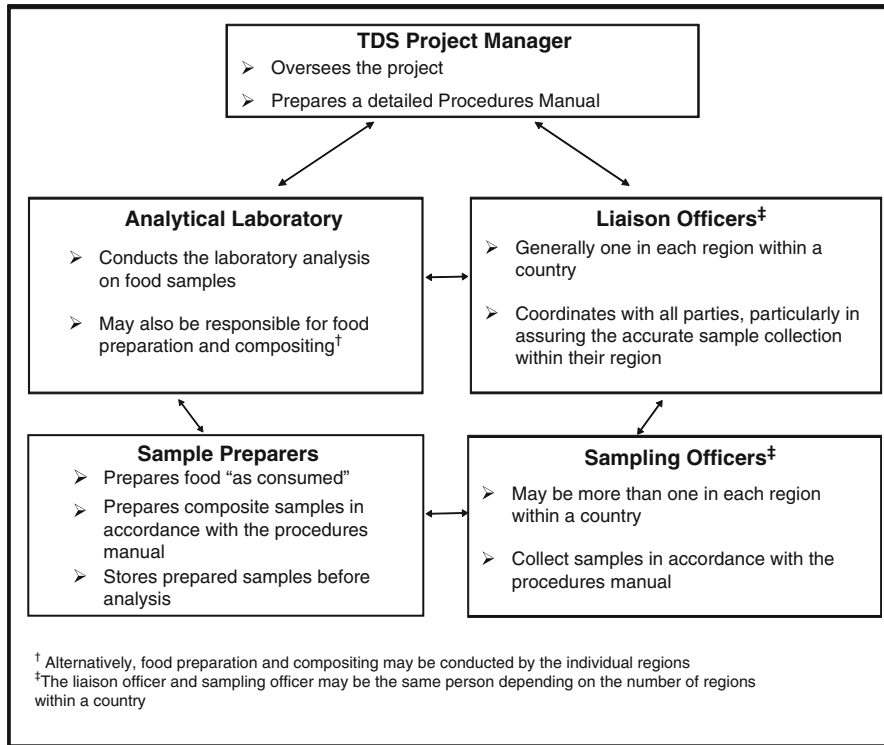


Fig. 8.1 The role of the participants in a TDS

members should include representatives of sampling and liaison officers, sample preparers and the analytical laboratory. Therefore, the first part of the procedures manual should include the identification of all TDS personnel and their contact information. A clear statement defining their roles and the responsibility of each participant should be included and is important to ensure all requirements are met. For example, in Australia, Food Standards Australia New Zealand (FSANZ) manages and coordinates the Australian TDS, however a total of eight distinct regions within Australia (states and territories) participate by purchasing food samples, which are forwarded directly to the analytical laboratory for sample preparation and analyses. Alternatively, food preparation and compositing may be conducted by the individual regions and forwarded to a central laboratory for analysis, or all activities (sampling, preparation and analysis) may be conducted in the regions and results forwarded to a central point for collation, assessment and report writing.

As there are a number of participants involved in the study, it is important that the roles and responsibilities of each participant are clearly communicated in the beginning. The complexity and flow of information between the various participants in a TDS is represented in Fig. 8.1. It is important that lines of communication are unambiguous and well understood.

Sampling

Purchasing Instructions for Food Samples

The procedures manual should contain specific instructions on the samples to be purchased for each region/country. This manual is designed so that all of the manual, or the relevant parts of it, can be taken with the sampling officer at the times of sample collection. Therefore it is imperative that the specific food types (where applicable) and total amounts for all analyses are stipulated. There are a number of factors which influence sample purchasing, such as the:

- Sampling period and purchase dates
- Sampling regions, districts or suburbs
- Retail outlets where samples are collected
- Foods to purchase
- Range of brands/use by dates/batch numbers

For additional information, please refer to Chap. 9 – Food Sampling and Preparation in a Total Diet Study.

Using Samples for Additional Analysis

As the TDS collects a wide variety of foods common to the typical diet, these representative foods can be used in additional exposure survey activities (see Chap. 51 – Polybrominated Diphenyl Ethers in Food in Australia—An Additional Use of the Australian Total Diet Study). This should preferably be decided prior to sampling and additional amounts of each food collected to account for the extra analyses. In this case, the buying instructions may need to specify particular retail outlets, the exact brands/varieties or types of the food that must be purchased, particularly if this additional data is to fill specific data gaps.

Sampling Instructions

Specific sampling instructions outlining the product to be sampled, the number of purchases for each region and the amount to be purchased in grams/milliliters or kilograms/liters should be included in the procedures manual. Additional comments can be included to guide the sampling officer in selecting specific brands or avoiding certain forms of the food. An example for almonds and apples is presented in Box 8.1.

Recording Purchase Information

Accurate documentation of all samples purchased for the study is important to ensure that comparable samples are collected in regions and for duplicate analysis

Box 8.1***Almonds***

Three purchases in total from each designated region in each designated sampling period.

Each Purchase: One Packet, 300 g minimum.

Comments: Any brands including House Brands. Do not purchase blanched, flaked or slivered almonds, or almonds in shell. The almonds should be shelled but still have their skin.

Sometimes these are described as 'raw'.

Apples

Three purchases in total from each designated region in each designated sampling period.

Each Purchase: Minimum weight 500 g.

Comments: Include a number of varieties: Pink Lady, Fuji, Jonathans, Gala, Bonza, Red Delicious, Golden Delicious, Granny Smith and any other commonly available variety.

if necessary. While the primary purpose of the TDS is to estimate dietary exposure to contaminants, nutrients, additives, pesticide and veterinary drug residues and assess the risk to public health and safety, results can also inform about potential areas for further investigation in relation to compliance with the relevant regulatory limits. Therefore, detailed information for each food purchase should be recorded. This is facilitated by using an appropriate spreadsheet program. The multiple purchases of each food should be clearly identified in the spreadsheet and labeled (e.g. A, B, C etc.). For each purchase of the same type of food (e.g. A, B and C), the following information must be recorded:

- Variety/brand (e.g. Pink Lady apples, cherry tomatoes)
- Batch/lot number/expiry date (where applicable)
- Country of origin
- Purchase date
- Store/location of purchase

An example of the type of information to be recorded is shown in Table 8.1.

As there may be more than one region involved in the collection of food samples, the procedures manual should provide an appropriate template which can be completed as samples are purchased. This assists in the consistency of sample recording between sampling officers in different regions. Such a template also simplifies the merging of information from different sampling periods. Accurate recording at the time of sample purchase is particularly relevant for foods that are purchased unlabeled such as fruit and vegetables, or meats from a delicatessen.

Table 8.1 An example of the level of detail of total diet study sample information that could be recorded

Food	Purchase ID	Variety/brand	Batch/Lot no./ expiry date (if applicable)	Country of origin	Buying date (d/m/y)	Store name/ suburb
Apples	A	Pink Lady	N/A	Australia	22/8/07	Griffins Foods, Auckland
Apples	B	Royal Gala	N/A	Australia	22/8/07	Green Grocer, Christchurch
Apples	C	Delicious	N/A	Australia	24/8/07	Speight's, Wellington
Peanut butter	A	Mark and Spencers	23 JUL 08	Australia	22/8/07	Marks and Spencers, Auckland
Peanut butter	B	Skippy	178955553	USA	22/8/07	Richard's Market, Christchurch
Peanut butter	C	All Black	KW00009	New Zealand	24/8/07	Kiwi Minimart, Wellington

If resources permit, sampling officers could be provided with laptop computers to record the sampling information, which can then be forwarded electronically to the sample preparation facility. If not, a standard copy of the sampling spreadsheet template should be provided to sampling officers in hard copy and/or in electronic form. Some information will need to be recorded at the time of purchase, such as variety and country of origin of unpackaged foods (e.g. fruit and vegetables). It is important that the sampling spreadsheet is completed fully and accurately by the sampling officer. A hard copy of the completed sampling spreadsheet should be sent with the corresponding food samples.

Another option for recording sample information is to photograph the products. This could be done by either the sampling officer or the sample preparation facility/laboratory. Photographs would be taken in addition to recording information on the sampling spreadsheet and could serve as a more detailed record of the products. For example, in addition to brand name and country of origin which are recorded on the sampling spreadsheet, other information such as manufacturing details, ingredients and nutrition panel information could be captured. If photographs are to be taken, it is suggested that a color digital camera be used for this purpose. Also, more than one photograph may be needed per product to capture all the required information. For fresh products, photographs could be taken by the sampling officer with sample information recorded on a sign which is photographed with the product.

Transportation of Food Samples

Prior to sample collection, suitable sample containers, transportation containers and ice bricks, if required, should be obtained. Consultation with the analytical laboratory as to the most appropriate containers and types of transportation is advised.

For sensitive samples, laboratories may even coordinate the delivery of sample and provide transportation containers and ice bricks to the liaison officers in each region.

Only foods that are purchased in an unpackaged state (e.g. cold meats from a delicatessen) need to be placed in sample containers. All other foods should be sent in unopened original packaging to the sample preparation facility/laboratory to ensure the integrity of the product and avoid any cross-contamination. The liaison officer should organize secure storage for the sample and transportation containers and ensure they remain free of contamination and are not used for any purpose other than the TDS.

Transportation containers should be packed in a manner that ensures the perishable samples are maintained in a chilled or frozen state. Samples are to be placed in the transportation containers with sufficient packing material so that the samples are not damaged. Packing material such as newspaper or polystyrene chips around the samples would assist with this. A list of the purchasing information should accompany the samples upon dispatch to the analytical laboratory.

Sample Preparation

There are a number of aspects to consider regarding sample preparation, some of which are discussed below while others are discussed in Chap. 9 – Food Sampling and Preparation in a Total Diet Study.

Handling Purchases for Food Preparation

Each purchase provided by the sampling officer should arrive at the sample preparation facility in separate packaging. Purchases from each region will be in certain number lots specified by the project manager. Each purchase will represent a primary sample. Unprocessed, raw foods, such as steak and chicken fillets, will be in separate packages clearly labeled with the name of the food and primary sample identification code which will correspond with the detailed information on the spreadsheet completed by the sampling officer. The sample spreadsheet should be checked by the preparation facility for completeness and to ensure that recorded information corresponds to sample labels.

General Food Preparation Instructions

As storage and preparation of food are known to affect the concentration of some chemicals in food, an analysis of foods prepared ‘as consumed’ will result in more accurate estimations of dietary exposure. As a variety of foods are collected for the TDS, some samples will require preparation to an ‘as consumed’ state such as peeling (e.g. oranges or bananas) or cooking prior to analysis (e.g. beef and chicken).

In the USA, sample preparation is conducted in a dedicated TDS kitchen using the same utensils and equipment. Simple food preparation may be conducted by sampling or liaison officers in the regions and prepared samples forwarded directly to the laboratory for analysis, or alternatively, can be completed by the laboratory conducting the analyses. Preparation by a single sample preparation facility/laboratory offers the advantage that it can control for variations in preparation among different regions and between sampling periods. However, for some countries, cooking styles or recipes may be quite different in the regions and regional preparation may be preferred. In either case, specific instructions should be detailed in the procedures manual as to general handling of food samples prior to and following preparation, as well as detailed instructions on how each individual food type should be prepared. These instructions should be clear, defining all terms such as frying, boiling and washing. While these preparation procedures seem straight forward, there are small differences in how individuals would carry this task out. For example, in frying a food, should oil be used? Questions such as this should be pre-empted and specific guidance provided in the procedures manual glossary.

Procedures Manual Glossary

A brief glossary defining generic terms used in the procedures manual is important to ensure consistency in sample preparation. Cooking practices involving boiling water, frying, grilling, washing, microwaving and mixing can be widely interpreted by individuals. Therefore specifying what these terms mean will assist in controlling variation in the preparation methods. The glossary of terms should be developed under the supervision of the TDS project manager and should be specific to the country's food preparation practices.

Preparing Food Samples for Analysis

Primary samples (individual purchases) should first be prepared in their 'as consumed' state. For some samples this may require cooking. In preparing foods for TDS analysis, it is imperative that preparation instructions are followed exactly and that any deviation be carefully documented. For example, any juices from fruit are regarded as an integral part of the food being prepared for analysis. However, the proportional amount of juice and seeds (for fruits where seeds are typically eaten) must therefore be included in the sample containers. An example of preparation requirements for some typical foods consumed in Australia is demonstrated in Table 8.2.

Once food is prepared to an 'as consumed' state, it is important that the sample remains homogeneous and does not separate out. This is particularly important for liquid samples. Therefore, all samples should be mixed well to ensure the sample is homogenous prior to transfer to sample containers for storage. For each sample, a sufficient amount of the prepared primary sample should be retained in an amount which would allow for additional analyses if required.

Table 8.2 The preparations required for some foods which are not purchased in an “as consumed” state

Food	Preparation instructions
Apples	Remove core and stem (do not peel)
Bacon	Remove rind and dry fry
Bananas	Remove peel
Beans, green	Top and tail, remove string if necessary and microwave until just cooked
Broccoli	Remove stalk and microwave
Chicken breast	Grill and discard fat in grill tray
Eggs	Hard boil for 5 min in unsalted tap water and remove shell
Lamb chops, loin	Grill. When cooked, cut all the meat away from the bone and trim off excess fat. Discard the bone and fat in the grill tray
Pasta	Boil in tap water according to the instructions on the packaging (do not add salt)
Potatoes	Wash, peel and boil in unsalted tap water

Preparing Composite Samples for Analysis

As multiple samples of the same food types may be collected in one region, it may be necessary to combine a portion of each purchase to produce ‘composite samples’ (see Chap. 9 – Food Sampling and Preparation in a Total Diet Study). Compositing of individual samples should be done only after preparatory work (e.g. peeling or cooking) on individual purchases is complete and they are in an ‘as consumed’ state. If composite samples are to be prepared and analyzed, this should be repeated for each primary sample (individual purchase) in the composite sample. The composite sample should be labeled with a unique identifier that will definitively link to the primary sample information recorded by the sampling officer. The contrast of individual versus composite sample preparation and analysis is depicted in Fig. 8.2.

To prepare composite samples, the number of primary samples (individual purchases) to be combined in the composite must be known and is specified in the procedures manual. In determining the number of primary samples used to make a composite sample, it is worth noting that compositing samples eliminates the possibility of determining variations in analyte concentration among the individual samples. The larger the number of primary samples included in one composite, the less likely a sample with a high level will be detected. Therefore the number of individual samples to be combined into one composite must be carefully considered. For example, if nine individual purchases are combined into one composite, each primary sample contributes 1/9th of the final volume and therefore each sample is diluted one in nine (Fig. 8.3a). In contrast, if nine individual purchases are split into three groups of three individual samples and one composite is only made up of three individual purchases, then each primary sample contributes 1/3rd of the final volume and therefore each sample is diluted one in three (Fig. 8.3b).

Composite samples should be prepared by accurately measuring the minimum amount required of each primary sample and combining in a vessel for further mixing or blending. Solids and semi-solids should be weighed (grams/kilograms) and

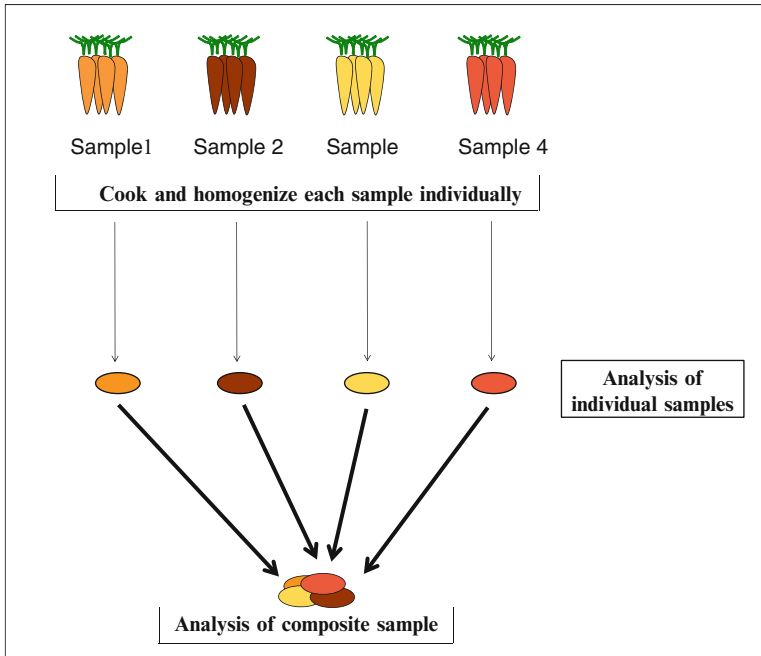


Fig. 8.2 A comparison of the preparation and analysis of individual and composite samples

liquids measured by volume (milliliters/liters). For example, if a composite was made up of three individual samples (primary purchases), the minimum amount of each sample would be one third of the total amount required for the composite sample allowing for some wastage. An example for fruit juice is depicted in Fig. 8.4, where 300 ml of fruit juice is required for triplicate analysis for each analysis. This would require at least 100 ml of each primary sample ('purchase') of fruit juice to prepare the composite sample.

Once all of the primary samples are added together, the composite sample should be homogenized or mixed thoroughly to ensure the sample is homogeneous. Sometimes homogenization may be needed prior to compositing if the primary sample is not uniform (e.g. a hamburger). If the sample is a liquid, it should not be allowed to separate before compositing. The composite sample should be transferred to a suitable sized labeled storage container, with enough sample to allow for all the analytical tests specified as well as one repeat analysis of each specified test. This may also include a sufficient amount for one inter-lab check test if required. The container should be labeled in a way that the composite sample can be definitively linked to its three constituent primary samples and the analytical results.

Unused composite samples should be stored for a period of time that is agreed upon between the project manager and the analytical laboratory, after completion of the study. This period of time should be documented in the procedures manual, as well as in the contract with the laboratory (see Chap. 14 – Commercial Analytical Laboratories—Tendering, Selecting, Contracting and Managing Performance).

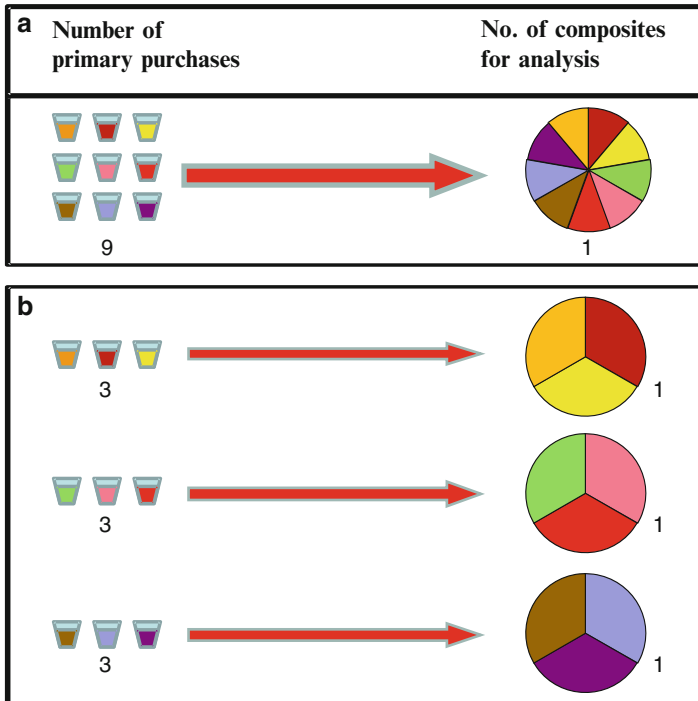


Fig. 8.3 A comparison of the proportion each primary sample contributes to a composite sample

General Instructions for Handling Individual and Composites Samples

General instructions including precautions to take when handling individual and composite samples and any specific washing instructions for reusable equipment should be included in the procedures manual. Issues to consider include:

- Avoiding cross contamination
- Carefully selecting the equipment and utensils used for food preparation
- Gloves
- Washing of equipment used in preparation

Additional information on these aspects are available in Chap. 9 – Food Sampling and Preparation in a Total Diet Study.

Storing Prepared Samples

Prepared samples should be stored in sealed sample containers that are clearly marked with identifying numbers that correlate with the sample recording on the sampling

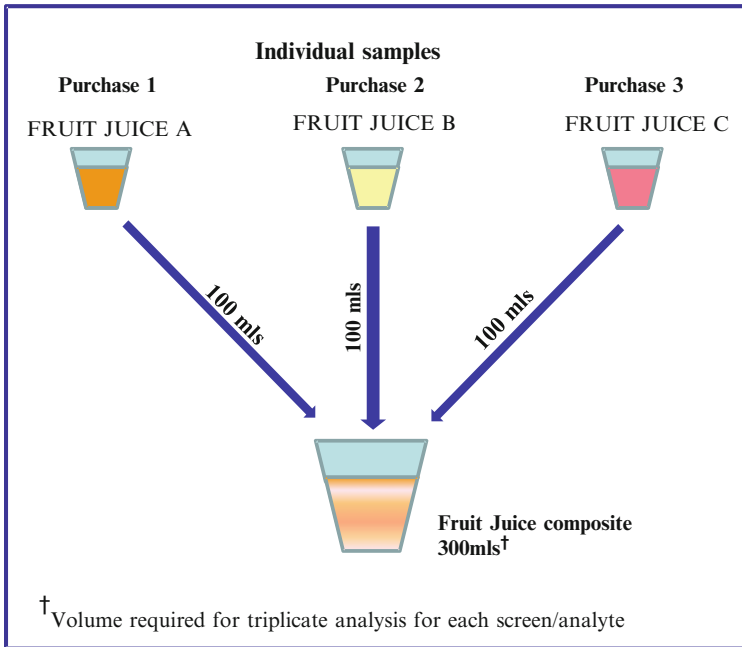


Fig. 8.4 An example of the preparation of a composite sample

spreadsheet. Samples should be stored in a manner that does not compromise the integrity of the sample as it may be required for further analysis. Advice from the analytical laboratory should be sought as to the best storage conditions for the food samples noting that some samples may have temperature or light sensitivities.

Conclusion

Total diet studies typically have a large number of people involved in the study and potentially from a number of regions within a country. Consistency in sampling and preparing foods is essential to reduce variability in the study, and also enable more effective comparisons between studies. Therefore the accuracy and comprehensiveness of the procedures manual is critical as it influences the manner in which food samples are purchased, handled, prepared, and stored before analysis. These decisions can influence the quality and representative nature of the entire total diet study.