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Conceptual Study

MONITORING THE PANCHAKARMA PROCEDURES.

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ABSTRACT:

In view of increased incidences of refractory diseases attributable to change in the life style and environmental conditions, it is imperative to adopt safe and effective regimen that could effectively manage such conditions. Panchakarma is a specialty of Ayurveda having diversified preventive, curative and promotive actions indicated in the wide range of diseases / health problems.

Panchakarma is basically a bio-cleansing regimen which facilitates the body for better bio-availability of pharmacological therapies, besides achieving homeostasis of doshas. It also increases the acceptability of the body to various dietary regimens and use of rejuvenation therapy (Rasayan) for promotive health as well as therapeutic regimens. With the tremendous expansion of the use of Ayurveda worldwide, safety and efficacy of the medicines and procedures based therapies viz., Panchakarma have become important concern for both health authorities and public. The scientific presentation of the facts in universal manner is desired for the safe practice of Panchakarma. When employed skillfully and appropriately Panchakarma procedures are safe and effective for the prevention and management of number of health problems.

The purpose or object of the Monitory System should be- To ensure quality and safe practices of Panchakarma, To provide essential requirements of basic training to the providers of Panchakarma, To serve as a reference to other Panchakarma practicing persons. So there is need of such safety and efficacy guidelines and monitory system which will help the Panchakarma providing person to adopt and practicise.

There should be a generalized monitory system to prepare guidelines in the basis of number of facts which will observe and monitor procedures along with performance, safety, efficacy.

So there should be monitory system /guidelines providing practical technical guidance for monitoring the safety of Panchakarma procedure.

KEY WORDS: Panchakarma, Monitory system, Guidelines.

INTRODUCTION:

The use of Ayurveda esp. Panchakarma [procedures] is gaining worldwide importance and expanding rapidly across the world. Many people now take herbal medicines / products or Panchakarma procedures for their health care. But people sometimes reporting of adverse events without identifying proper causes (related with variety of

causes) making and giving negative impression regarding the Panchakarma procedures, so it has now become essential to monitor Panchakarma procedures in order to get rid of negative impressions of mass/people. Now days we observe a variety of techniques for performing Panchakarma procedures in different parts of India and world.

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Also currently, the negative feedback among mass/people is due to adverse events related to the improper use of Panchakarma procedures that are attributable either to poor /improper techniques, product quality or to improper use.

So there should be a generalized monitory system to observe and monitor procedures .In order to monitor Panchakarma procedures, i.e. to monitor performance, safety, efficacy and in particular, to analyze the causes of adverse events there should be institutional monitoring committee (or equivalent on state or national level) which will acquire specific technical expertise. This will include trained personnel in relevant technical areas and facilities to analyze the procedures done, so that there will be access to sufficient information and reliable information support. Also there should be ideal guidelines which will articulate technical issues relating to panchakarma data management and communication further.

So there should be monitory system /guidelines providing practical technical guidance for monitoring the safety of Panchakarma procedure.

Need for the system

Safety is a basic and important principle in treating the patient with Panchakarma procedures and a critical component of quality of Panchakarma. The Monitory system/guidelines will provide practical technical guidance for monitoring the Panchakarma procedures within the Ayurveda healthcare system. No doubt there are personal and cultural differences in the techniques, skills and use of different types of medicines in the Panchakarma procedures, they are all equally important.

But the system /guidelines should be formed with the view that, within current healthcare system monitoring of the Panchakarma procedures, so that enhanced and broadened ways will allow the successful monitoring of Panchakarma procedures. There is no intention to suggest that new different systems or disturb the age old traditional methods but to enhance and to get away from negative feedback already spread among mass/people about Panchakarma procedures

Obectives

The objectives are to:

• support Panchakarma Vaidyas or Doctors, to strengthen healthcare system in Ayurveda in order to carry out effective and safety monitoring of Panchakarma procedures

• provide technical guidance on the principles of good clinical practices in Ayurveda and the inclusion of Panchakarma procedures in national healthcare systems; and where these systems are not in place, to facilitate the establishment of an inclusive National Panchakarma procedures monitoring system

• provide standard definitions of terms relating to Panchakarma procedures and safety monitoring of Panchakarma procedures

• promote and strengthen Ayurveda esp.Panchakarma across India and World through better monitoring

• promote the safe, proper and skillful use of procedures by Vaidyas and therapists.

Plan of action

To monitor Panchakarma procedures, following actions may be useful -

- Clear identification of the techniques of Panchakarma procedures
- The usefulness of the Panchakarma procedures in diseased/Swastha
- Skillful managed technical staff
- Medicines passed through QC
- Identification and Management of the risks /Adverse events
- Reporting of Adverse events to Monitoring Committee
- Good communication between Vaidyas
- Panchakarma Data Management of all the events
- Risk identification, communication and solution for the same

Sr.No.	Action	Techniques useful
1.	Clear identification of the techniques of Panchakarma procedures	 Through proper and critical study of Samhita texts Through proper observation and performance of procedures
2.	The usefulness of the Panchakarma procedures in diseased/Swastha	 By critical study of procedures already performed by Vaidyas across India By performing clinical trials
3.	Skillful managed technical staff	 Training the persons as Panchakarma Sahayak (Panchakarma Assistant /Therapist) Managing the skillful staff

4.	Medicines passed through QC	Raw material QCIn process QC
		 End product QC Preparation (SOP) of various Kalpas used in Panchakarma
5.	Identification and Management of the risks/adverse events	 Identification of risks during procedures (e.g burns) Skillful management of such risks Methods of avoiding such risks Recommendations should be on how to record and report adverse events occurring during clinical trials should be covered by national guidelines on good clinical practice
6.	Reporting of Adverse events to Monitoring Committee	 Collection and reporting of Adverse events through proper channel to Monitoring Committee (Reports from Vaidyas/Ayurvedic Physicians, Reports from consumers/Rugna/Patients, Manufacturers of medicines, Reports from other sources like Clinical trials or Experimental trials etc)
7.	Good communication between Vaidyas And Monitory System	 Proper and good communication among Vaidyas will help to carry out better, safe and efficient Procedures strengthening communication and awareness at all levels (global, regional, national, local and community) Communication should be established at many different levels, for example, between: the Monitory System and Vaidyas the Monitory System and providers of herbal medicines Vaidyas and providers of herbal medicines, and consumers and patients the Monitory System and consumers the national Monitory System and such centres in other countries, within the region or in other regions the Monitory System and the mass media.
8.	Panchakarma Data Management of all the events	 <i>Quality of Data.</i> Serious efforts should be made to ensure that there are quality controls on data processing and that the data elements of reports are as complete and accurate as possible. Mechanisms to check for duplications should be instituted. <i>Data storage.</i> Computer databases should be managed to as high a standard as possible to facilitate access to and use of the data. Software should be selected with expert advice so that analytical needs can be met. <i>Data analysis.</i> Programmes / Soft wares should be developed to provide for regular analyses and data output appropriate for local needs.
9.	Risk identification, communication and solution for the same	 Communication of safety information is a shared responsibility between monitory system national regulatory agencies, manufacturers and health

 professionals (Vaidyas). Different risk communication agents can be used, including:
 adverse reaction bulletins or articles distributed in reputable journals public advisories or warnings Giving information to Vaidyas through seminars
 /CME/workshops regularly Various methods are available using Internet /emails/Social networking sites
 direct mailing to health professionals and providers of herbal medicines briefings to the mass media briefings to patient/consumer associations
 education sessions at health professional society meetings/CME/Workshops.
 In order to reach consumers and the wide range of providers of herbal medicines successfully, messages should be tailored to suit the recipients, including translation into local languages where appropriate.

These require:

- 1) Ability to monitor Panchakarma procedures through better reporting systems, skilful technical investigation of incidents and responsible sharing of data
- Greater capacity to anticipate adverse events and to probe systemic weaknesses that might lead to problems
- 3) Identification of existing knowledge resources, within and outside the Ayurveda and other life sciences helping Ayurveda
- 4) Improvements in the health-care delivery system, so that structures are reconfigured, incentives are realigned, and safety and quality are placed at the core of the system
- 5) Expanding the source of case reports, for example by: – involving all persons providing of Panchakarma procedures, including performing and using of traditional proceduresstrengthening the role of providers, such as pharmacists and health-care professionals, working in the community
- Involving manufacturers of herbal medicines
- Facilitating consumer reporting
- Developing systems of information exchange involving Monitory System, consumer organizations and manufacturers' association

- 6) Strengthening capacity to carry out monitoring of Panchakarma Procedures at Institute level /District level /national level by:
- Training staff in relevant technical areas
- ensuring access to facilities for analyzing procedures suspected of causing adverse reactions
- providing access to reliable information touching every aspect of procedural part
- Developing a standard classification and/or coding system with standardized terms and definitions

In response to above needs, Monitory system (at Institute /District/State/National level) should be constituted with the help of AYUSH, CCIM and relative State Councils. Also plans should be made to organize a series of training workshops to strengthen Panchakarma in terms of safety monitoring of in India. Also this will help to increase our share (share of Ayurveda) in National Health care System and National Health Programmes.

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