Clinical Protocols: Introduction to a Useful Strategy in Clinical Practice

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Introduction

Oxford dictionary defines protocol as "rules, formalities of a procedure". In medical profession, protocols refer to a set of guidelines to manage a certain clinical or administrative problem. These can be developed to deal with any aspect of patient management, from waiting lists to infection control and role assignment to medical/paramedical staff to the structured training of staff. The protocols are like workflow guidelines in business management plans; they are meant to streamline day to day activities from chaos into a well-defined chain of activities.

Protocols are practiced in medical profession under various names like clinical guidelines[1] practice guidelines[2] and evidence based medicine[3]. These have been in practice in UK for decades and now many professional bodies encouraged by NHS arc producing guidelines for use by providers and at the same time a process of critical appraisal is developed to analyse these guidelines[4]. However, this idea has never been new; Plato in the 4th century BC had suggested that clinicians should obey guidelines prepared by council of professional doctors for use into their medical practice[5].

The aim of this article is to briefly review the use of protocols in clinical practice and how these can be constructed in our selling. Our own experience of using locally constructed protocols in our clinical routine is also described. The purpose is to generate discussion on a topic which is believed to be of vital importance.

Advantages of protocols

The Protocols bring harmony in clinical management, hence reduce bias at individual level. With set protocols, work flow becomes smooth and more purposeful. Common human omissions are easily eradicated and there is no confusion among the staff members. The burden of frequent queries from the trainees and junior staff is decreased as the management is streamlined. When the clinical conditions arc dealt according to predetermined guidelines, clinical practice can be easily audited mortared and further improved. In clinical Set up treatment becomes standardised which is unbiased by financial condition of the patient, the community he/she belongs to or role of the carer etc[6]. As the guidelines are usually based on latest scientific evidence, the trainee becomes well versed with recent literature[2]. These guidelines improve record keeping. hence epidemiological survey and eventually health policy making can be streamlined[7].

Protocols in clinical practice

These practical guidelines can be implemented in each and every' discipline[8]. However, their use is more so in critical and acute medical and surgical care. En fact, any clinical setup in the most appropriate field where protocols need to be in force and now increasing number of clinicians are adapting these guidelines based on recent literature[8]. They have been used in a variety of diverse conditions like hypertension, head injury[9], upper GE bleeding[10], chest pain[11] and in psychiatric practice[12]. There is a strong feeling that clinical protocols should be adapted according to the local set up and with a view to save costs without jeopardising the quality of healthcare. This is the best way of optimal use of limited resources[13]. In this brief article it is not possible to review the use of protocols in all the clinical settings. However, a brief introduction to the steps involved in construction of protocols and their application in our setting will be given. For details, readers are referred to a series of articles

on clinical guidelines in British Medical Journal throughout the year 19991,[4,5,14].

How to construct protocols

The first step in construction of protocol is the prioritization of the areas which can be done on the basis of different criterias incidence of a condition, resources available, manpower involved and mortality or morbidity associated with a disorder etc. This criteria for priority setting can be developed locally. Commonly the protocols are constructed for conditions where most uncertainty lies in the management, or when the condition is associated with high morbidity and/or mortality or where cost is the main constraint. These areas are thus identified for protocol development on priority basis. Once a few common conditions are defined, the subject has to be refined so that one specific aspect could be translated into protocols, otherwise the topic remains too broad a task to be covered in a comprehensive protocol. Therefore, this can be divided into various aspects like diagnosis of diabetes, identification of its complication like retinopathy, management of diabetic foot problem, treatment of diabetes in the community etc. Separate protocols can be developed for each of these sub-topics.

Once a topic is identified, a discussion group is formed. The members and expertise of the group, of course will vary in different settings. The group will define the objectives of protocols and hold discussions on various aspects of the subject. Finally a draft is prepared in the light of recent literature on the subject. Thus the most recent evidence in scientific practice is formulated into a local set of protocols according to the environment and facilities available. Workflow sheets are then prepared and put into practice. A supervisory role has to be assigned to someone who can overlook strict adherence to the guidelines and can evaluate the audit report[14]. The last part of the process is an external review of the implementation as well as frequent audit of the practice[13]. This process will help to eliminate the inconsistencies, identify the problems in implementation and update the knowledge base of a protocol. Thus over a period of time an elaborate protocol book can be established in an institution for a variety of clinical conditions and management problems.

Table 2. Steps in construction of clinical protocols.

1.	Prioritisation of area of interest
2.	Identification of subject area
3.	Refining of topic
4.	Group formation for discussion
5.	Defining objectives of the protocol
6.	Literature search
7.	Identification and analysis of evidence
8.	Initial draft and review
9.	Evolution of protocols according to local set up
10.	Preparation of workflow sheets and putting into practice
11.	Nomination of supervisor to monitor implementation
12.	Audit of practice
13.	Review by external peer
14.	Frequent audit and modification of protocol accordingly

These steps are summerised in Table 2 while the advantages have been depicted in Table 1.

Table 1. Advantages of clinical protcols.

1.	Produces workflow
2.	Reduces discrepancies
3.	Brings uniformity to patient management
4.	Eradicates omissions
5.	Reduces confusion of staff
6.	Makes record amenable to audit
7.	Makes record keeping easy
8.	Makes cost saving possible
9.	Optimal use of limited resources
10.	Improves compliance of physicians (and patients)

Application in Pakistan.

It is assumed that in Pakistan, protocols will be difficult to follow due to a number of reasons e.g., enormous workload and lack of proper paramedical and secretarial staff This is further complicated by a wide variation in clinical presentation and complications associated with common clinical conditions. These, however, are the very reasons that protocols need to be developed in our settings. As was mentioned previously, the development of the protocols will result in better work flow, uniformity in clinical practice, cost effectiveness in view of limited resources and improvement in patient management[15]. Ali et al[16] has described the use of protocols for the nianagement of hypertension in general practice in Pakistan a setting where any systematic workflow is considered very difficult. Another example is that of tuberculosis which is a major health problem in Pakistan. Due to tack of guidelines, this problem has been treated rather haphazardly in the past, resulting in a very serious problem of multiple drug resistant TB. According to WI10, Pakistan is one of the hot spots of MDRTB. Federal Ministry of Health constituted a Federal TB Board which keeping in view of the gravity of the problem and influence of lack of uniform guidelines, developed protocols for management of TB in the country[17] (Directorate of Tuberculosis National Guidelines). We describe the development and application of protocols in Plastic Surgery in hospital settings. This, we believe is a unique experience and would like to share this with our readers professional colleagues.

The Department of Plastic Surgery was established in 1997 in Hayatabad Medical Complex, Peshawar. In fact the unit was shifted from an attached specialty department with a General Surgery ward in Lady Reading Hospital, Peshawar where beds were shared with the main specialty. It was felt that ward policy in the General Surgical Ward adversely affected the independent working of Plastic Surgery Unit. Once it was in the new premises with independent staff and logistics, it was decided at the outset that appropriate, clinical protocols would be developed over the coming period of time. The common

areas of deli lip/palate, hypospadias, use of antibiotics, hand surgery and head and neck cancer were selected for the setting of protocols. A monthly total case audit was carried out from the beginning and recommendations from the meeting were added to the protocol book. At the end of three years, we have now a protocol book on the following aspects of clinical management:

1. Cleft lip and palate management
2. Use of antibiotics
3. Hypospadias management
4. Head and neck cancer

In addition, protocols have also been developed for streamlining the following areas of management in the department:

1. Adniission and waiting list criteria
2. Training of house officers
3. Training of residents on rotation froni other units like Orthopaedics, ENT etc.
4. Supervision of trainees in Theatres

To cite an example, following is a sumniary of the protocol Followed for the management of hypospad ias. Any patient with hypospadias has a history taken with particular regard to consanguinity of parents and family history and is then worked up fbr other congenital anomalies. If the child had anibiguous genitalia, karyotyping is carried out and the case is referred for genetic counseling. If there are undescended testes, lie is refered to paediatric surgeon for orchidopexy. In an othenvise normal child, if the phallus is small, topical testosterone is prescribed for six monthly intervals when the child is repeatedly examined. We have been using Aivar l3racka technique of two stage repair for this congenital anomaly of the male genital organ18. With a normal phallus size and no meatal stenosis, the child is scheduled for surgery for first stage of repair at the age of three and a half years. If there is meatal stenosis causing back pressure in the urinary tract, an early first stage is carried out with wide meatotomy to relieve his pressure at the same time. However, the second stage in both cases is carried out at the age of four, If as a complication, the child develops fistula, it is repaired again at an interval of six months. In both the stages a urinary catheter is used, latex in the first stage and silicone in the second stage and the patient remains on Amoxiclav fbr as long as there is an indwelling catheter. Generally catheter reniains in for five to seven days, Additionals in adults, cyproterone acetate is orally adniinistered For a fortnight to prevent nocturnal erection which might put tension on the suture lines. If' patient develops a urinary fistula, which is the only coniplication we have conie across. his follow up is at fixed at intervals of two weeks, three months and six months. If the fistula remains open by six months, it is then repaired. For all patients when healed, a fixed Follow up of two weeks, three months and six months is carried out. There is a plan for examining these patients when they are eighteen years old. This protocol is outlined in the form of workfiow diagram (Figure).

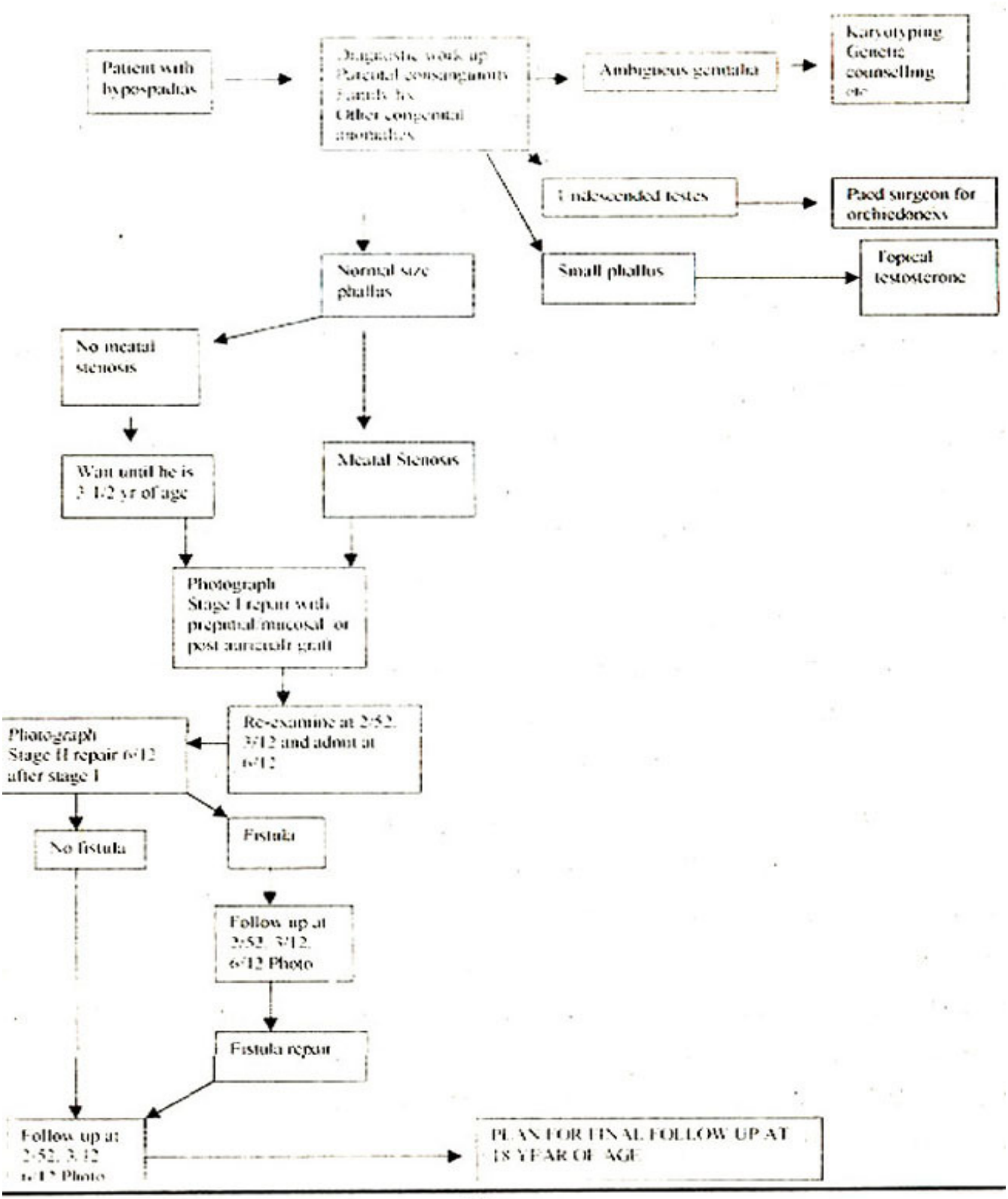

Figure.

Way forward

The experience we gained froni implementation of guidelines in Plastic Surgery and Psychiatry as'well as from discussion with other colleagues who had the experience of these guidelines gave us a Few

thought-provoking assertions. First of all, the initiative and implementation should conic from the top of the! clitlical hierarchy in the set up. If there is resistance froni the superiors, protocols can easily be bypassed. Secondly, these tools should be dynamic and not static instruments of clinical management. At least a monthly clinical audit should be carried out, taking one protocol at a time so that a detailed scrutiny can be carried out of the outcome. Thirdly!, the lessons learned from these audit meetings should be translated into practical reforms. Last but not least, evolution of protocols should be a continuing process so that newer and the latest newer areas can be identified for streamlining the management of patients.

These clinical guidelines can be evolved in an individual unit on pilot basis and then extended to other units in an institute. From the above example, it is clear that this protocol can be easily followed anywhere in Pakistan. This trend can grow from an individual hospital to provincial health authority and then perhaps at national level where institutions like College of Physicians and Surgeons Pakistan, College of Family Medicine, Pakistan Medical and Dental Council can establish their own guidelines. Now that there are many professional bodies in the country, it is these bodies which should take it upon themselves for making these protocols in their own specialty. They would have the interest groups available for each set of protocols and these groups could be motivated to work on these lines. This can ultimately bring treatment strategies in the whole country to a certain standard[19].

These units in return can audit and compare outcome with each other, this will improve and further refine the protocols. At the same time training of the specialists-intrainnig can be standardised and evaluation would be easy at a uniform level. With tuning of the whole unit, institute or health system in one particular routine drill, the process would be cost effective in terms of resources and manpower and time. Thus output can be tremendously increased especially in our resource-starved set up.

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