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From clinical practice guidelines, to clinical guidance in practice – Impacts for computerization

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ABSTRACT

This paper presents a case study of clinical guidance within oncology clinics. Close to all patients treated within the observed clinics were treated according to clinical practice guidelines in the form of either a research or a standard treatment protocol. The clinical practice guideline artifacts were however rarely applied in clinical practice. It was first when the guidelines were translated and transformed into second order guiding artifacts (SOGAs) they were applied. The SOGAs applied in clinical practice were activity specific holding space for relevant documentation. The transformation from clinical practice guideline to SOGA was executed according to a standard operating procedure. A wide number of physical features were applied to support quick overview and application in clinical practice. The clinicians were actively participating in the translation and transformation process obtaining ownership to the resulting artifacts. The implications for computerization of clinical practice guidelines are discussed.

1. Introduction

During the last decades electronic health records (EHRs) have been introduced with the aim of improving all aspects of quality of care, i.e., effectiveness, efficiency, patient orientation, timeliness safety, and equity of care [1,2]. Concurrently numerous clinical practice guidelines (CPGs), defined as: "*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances*" [3] have been published, for the same reasons [4].

The guidance provided by CPGs can be divided into different types: decision support [5,6], process support [7,8], documentation support [9–11] and task support [12]. Decision support provides guidance on appropriate actions for the specific clinical circumstances as reflected by the clinical data and the aim for post-conditions. Process support provides guidance on sequence of recommended activities for specific circumstances. Documentation support provides a framework of recommended documentation and may include documentation templates. Task support provides detailed recommendations on how to perform a specific action. The various types of guidance are, however, frequently intermixed in any individual CPG, and the various types of actions are closely intermingled in clinical work practice. The approach to guidance in some CPGs is a disease or condition, while it in others it is a task or process. Some CPGs are addressing a single profession, while others are addressing multiple professions that may have different practice models [13].

Although comprehensively recommended CPGs are however not vividly applied in clinical practice [14,15]. Therefore attempts have been made on promoting computerized CPGs as part of the general computerization within healthcare. CPGs have been computerized either as computer interpretable guidelines (CIG) [16], computer executable guidelines (CEG) [17] or integrated to the EHR [18]. This approach has however

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not induced a comprehensive application in clinical practice. A challenge may be that most computerizations of CPGs have been technology driven [17], while only a few attempts have been made on a user-centered approach in the design process [19,20].

Within oncology most patients are treated according to a thoroughly developed CPG [21]. Therefore it would be of interest to study how CPG based guidance is impacting clinical practice within oncology. How is the process from narrative CPG to execution in clinical practice being formed and to analyze the implications it may have for computerization of CPGs.

2. Methods

Protocols are a special type of CPGs, providing recommendations for a specific cure for a specific disease. Protocols have their origin within clinical research, where research protocols provide a detailed description of aims and activities in a research project. When the research project is over and the examined cure has proven superior to the existing treatment, it has become a tradition within oncology to remove all research specific parts from the protocol and turn it into a standard treatment protocol. Standard treatment protocols are thus less comprehensive than research protocols both regarding format and content but still providing detailed guidance on what to do. Oncology protocols include a standard patient pathway for the disease in case. 20–25% of the patients within oncology are treated according to a research protocol, while the others are treated according a standard treatment protocol.

2.1. *Methodology*

This study was part of a larger study of CPG application [22]. An observation study of CPG application was made in three Danish oncology clinics in spring 2008. Two observers (a physician (the author) and an anthropologist) each made two full days of observations in three oncology clinics, all in all 12 days of observations. Two of the observed clinics are situated in large university hospitals, and the last in a big regional hospital. The observers used structured observation templates for monitoring the application of guiding artifacts in clinical practice. Further ad-hoc interviews were made with end-users and with those responsible for transforming protocols into the guiding artifacts applied in practice. In the analysis of the data material the following steps were taken: familiarization with material, identification of key issues, indexing of data, charting and mapping and finally interpretation [23]. In all the clinics computerized patient administration systems (PAS) as well as CPOE for laboratory orders have been in use for decades. A medication – administration and order-entry application was under implementation and a module for physician's notes were being introduced during the observation period. Computers were accessible in all offices, including the examination rooms in the outpatient clinic but not in the treatment rooms where chemotherapy were administered. All clinical staff had access to the clinical IT systems.

3. Findings

In the observed clinics 50–110 protocols were currently in use. Each protocol encompassed 20–100 pages of narrative text in a binder, with the research protocols being the most comprehensive. Although close to all patients in the oncology departments were cared for according to a protocol, we found that the protocol binders were scarcely deployed [22]. We however found a comprehensive application of what we have named second order guiding artifacts (SOGAs); that is forms and standard order sets that have been transformed from CPGs and protocols according to a standard operating procedure.

3.1. *Transformation of protocols to second order guiding artifacts*

All the clinics have a research or project unit, staffed with experienced oncology nurses, where research and standard treatment protocols are managed. There exist articulated standard operating procedures for introduction of a new protocol into the clinics. When a senior staff member brings a new protocol into a clinic, the first step in the local translation process is the development of a preliminary 'treatment and examination' form by the research or project unit. This form presents an overview of all the activities prescribed in the protocol, i.e., the resource consumption required by the new protocol. The preliminary 'treatment and examination' form together with a short presentation of the professional aims of the protocol constitutes the basis for a managerial decision on initiation or rejection of the protocol in case. If it is decided to go on with the protocol, the adaptation process is then started. The adaptation entails that a local version of the protocol, that fits the local work practice and resources is made. This may entail changes of the types of activities and/or the sequence of activities. Based on the adapted protocol the transformation according to the standard operating procedure into a series of SOGAs (paper forms, documentation templates or standard order sets in the CPOE system) is made. During the transformation process the nurse responsible for the transformation consult relevant actors for discussions of details in the configuration of the SOGA. Further general CPGs like the one on administration of chemotherapy are taken into account in the transformation process. An overview of the adaptation and transformation process is provided in Fig. 1.

In the transformation process the protocols were chopped into tiny bits of information, each providing guidance for a specific clinical activity. As a protocol in one chapter may state guidance on how chemotherapy should be administered, in another chapter there may be guidance on monitoring of the patient while administering chemotherapy and in a third place (protocol or a general or local CPG) there may be guidance on what kinds of adjuvant therapy there should be administered in relation to the chemotherapeutic treatment. All these small bits of guiding information were in the transformation process brought together in a SOGA to support a specific clinical activity.

Within each of the observed clinics we found between twenty and thirty standard types of SOGAs, most of them