RESEARCH

Knowledge Fields and Inner Patterns in Clinical Laboratory Science

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OBJECTIVE: The purpose of the study was to clarify the knowledge base of clinical laboratory science (CLS). This research was motivated by questions concerning the knowledge base itself and its abilities to meet the demands of reality. The following questions were therefore asked to achieve the purposes of the study:

- What are the knowledge fields and inner patterns in CLS?
- Which research objects could CLS focus on in order to promote development in practice, education, and research?

DESIGN: The findings of the study were arrived at by means of hypothetical-deductive approach and inductive, content analytical strategy. The journal *Clinical Laboratory Science* of the American Society for Clinical Laboratory Science (ASCLS) provides the source material for the analysis.

SETTING: Åbo Akademi University. Faculty of Social and Caring Sciences.

RESULTS: The findings of the study are discussed in the light of starting points of the theory of science and lead to nine hypotheses concerning CLS.

CONCLUSION: The purpose of the present study was to create clarity in CLS as a science of its own. This has been achieved by capturing and describing facts and qualities, and thereafter presenting fundamental hypotheses in CLS. The results of this study give a thought structure for continued development and deepening within the theory and practice of CLS.

ABBREVIATIONS: ASCLS = American Society for Clinical Laboratory Science; CLS = clinical laboratory science; MT = medical technologist.

INDEX TERMS: Clinical laboratory science; epistemology; ontology; origins.

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Marcel Proust's "*The real voyage of discovery consists not in seeking new lands, but in seeing with new eyes*" was the polestar in this research process. Representatives of the clinical laboratory have worked hand in hand with other fields of healthcare and nursing, to seek the knowledge base of their work. My interest in this inquiry has always been in providing the best for the patient, in developing a knowledge base from a holistic perspective and, thus, developing the content of education and training.

The central aim of clinical laboratory practice is—with good care as a guiding principle—to protect and safeguard the patient's integrity and health. This goal leads to different types of activities within a clinical perspective, thus examining both a body of knowledge and an activity. In Finland, medical technologists (MTs) are trained at Polytechnics and the length of the education is three and a half years. Discussions concerning the body of knowledge (knowledge base) have been carried out among educators who represent today's education of MTs in Finland. Discussions, however, have not been undertaken regarding an intrinsic description of the knowledge and skills at a fundamental ontological level; rather descriptions have often remained at scientific technological knowledge levels. To move forward toward a university degree, a separate body of knowledge and professional description that could reflect the unique knowledge for MTs in Finland, has been discussed, principally among technically engaged MTs and educators involved in the training of MTs. The aim of this study, thus, is to create clarity in CLS as it is seen as a science.

THE KNOWLEDGE BASE WITHIN CLINICAL LABORATORY PRACTICE

During the last several years, evaluation of the various areas of health services has come more and more to the fore in discussions concerning the content of science and possibilities for application. This is also the case in clinical laboratory work. The intent is to evaluate and develop the knowledge and sphere of activity. This involves asking whether laboratory work consists of its own unique knowledge and if it is founded on its own science. In international literature, and above all, in American literature, the concept of CLS is encountered.[1] The stand taken for CLS in the United States appears primarily in the journal *Clinical Laboratory Science*, partly in the journal's name, as well as in many articles. In a lead article from 1988 in *Clinical Laboratory Science*, Doig and others, pur-

port that it is CLS and not sciences; since CLS is something more than a collection of various disciplines such as clinical chemistry and hematology, etc. It is also pointed out that those carrying out their profession within CLS are in possession of knowledge that has been developed from a broad, general basis.[2,3] The philosophic application of CLS is seen primarily in the Code of Ethics that was accepted by the ASCLS in June 1995.[4] The International Association of Medical Laboratory Technologists (IAMLT) has stated in its Code of Ethics, point 1, that "medical laboratory technologists shall be dedicated to the use of clinical laboratory science to benefit mankind".[5]

The distinctive criterion for a science, especially in northern Europe and Scandinavia, is autonomy. Autonomy can be examined as a synthesis of three levels, that is to say, theoretical, sociological, and psychological. The theoretical level defines the scientific knowledge, the ideology of the science, and the nature and function of research. The sociological level is represented by the social norms within that science: possession of a professor's position, the right to present doctoral dissertations and to publish scientific journals. The psychological level sheds light on the identity, the researcher's paradigm, and the occupational paradigm within the science. The three levels have a certain autonomy in relation to each other. At the same time they are dependent upon each other. The levels are related to the stage of development of the science.[6] To be able to clearly define a science, a clear and explicit choice of approach is implied. If the aim is to reach the heart of the science and describe what is unique about it, the researcher should be open-minded and have a holistic approach. However if a researcher chooses to concern himself or herself with the traditional 'doing level' it can be difficult to find the ontology of the science.[7]

The development of knowledge within science can occur on various levels. The metatheoretical level is concerned with issues that touch upon the formation of knowledge and in paradigm development. This takes place through fundamental research. The issues concerning science are clarified and established. This is where, among other things, the demand that method-theory-ontology form a coherent form for current science is established. The ontological starting-points become the foundation upon which science rests. At the theoretical level, the factual knowledge concerning current activities is developed. Science at this level is not identical with technology or practical activities. The data that are developed here constitute the starting point for the clinical laboratory theories.[8,9] The activities at the technological level differ from the scientific level by having a different goal. The goal of technology is practical benefit.

Clinical laboratory theories are also developed at this level. These consist of a theoretical and a practical part. Although the utilitarian aspect here is very important, it is of the greatest importance to preserve the unique element in one's own area. If science is directed too much by society's demand for it to be useful, it runs the risk of losing its own profile. CLS's technology, as a scientific sub-area, comprises knowledge about aims, methods, and conditions for clinical laboratory work. Technological knowledge is, by its very nature, interdisciplinary and consists of empirical and ethical knowledge. The interdisciplinary nature of technology leads to a body of concepts consisting of concepts from many different sciences. Technology's field of knowledge spans theoretical, practical, social, communicative, innovative, and informative qualifications.[9-12]

METHODS

CLS is still trying to find its form and position. Hence the goal of the study becomes to get a clear picture of CLS as a science using the journal *Clinical Laboratory Science* as its starting-point. By capturing and interpreting data and qualities in order to arrive at what is 'really real' in CLS, this researcher endeavors to offer a thought structure for a 'deepening' of understanding within the field. In order to achieve the aim of the study the following questions are posed:

- What are the knowledge fields and inner patterns in CLS?
- Which research objects could CLS focus on in order to promote development in practice, education, and research?

Design of the study

The routes to seeking knowledge can be described as "the way of discovery or the way of proof".[13] In qualitative research the way of discovery exists as a means for obtaining and developing knowledge. The way of discovery results in theories or hypotheses. According to Eneroth, the first foundation stone in a qualitative method is a holistic approach to the world and its various phenomena.[14] With the help of a qualitative method, a researcher wishes to obtain information about what kinds of qualities a certain phenomenon contains.

Qualitative research methods take as their starting point 'patterns', meaning the phenomena that are being studied.[14] An explorative approach can be applied when a new area of science is to be described. CLS is 'still in the making' and therefore the central phenomena and concepts within the science must be discovered and explained. With the help of an explorative descriptive design, fundamental information about the 'what-why-when-how-where-and-in-which context' may be arrived at and can be described.[15]

The present research approach is hypothetical-deductive. Research according to the hypothetical-deductive method starts with a problem, which is clearly delineated. A hypothesis is put forward as an explanation to the problem. The hypothesis is then tested through observations or experiments until proven false, or assumed to be true if it cannot be proved to be false. The purpose of the hypothetical-deductive method is to obtain true hypotheses. However, the main aim of some research is the hypotheses themselves.[17] Thus this study ends in the putting forward of hypotheses. The core content of the theory of science forms a foundation for reflection. Data processing is based upon an inductive strategy. With the help of various

dialogues within the text, structures emerge. The structures in the categories are examined, where quality and meaning in the category are considered an aspect of reality. This appears in direct quotations from the data. In the same way, data in the text form aspects of each quality. The shape that emerges is then discussed in view of the theory of science and background of the study.

DATA ACQUISITION AND SELECTION

The journal, *Clinical Laboratory Science*, forms the source for the analysis for this study. The journal is American in origin and specific to the science from a conceptual point of view. Articles from the 1988 to 1997 volumes covering ten years, were chosen. Each volume contained six issues. The researcher had access to 55 issues out of a total of 60.

The background to the journal *Clinical Laboratory Science* is found in the striving for professionalization that has existed for many decades and especially during the latter part of the 1900s. Beginning in 1935 the journal was published under the name *The American Journal of Medical Technology*. In 1984 the name was changed to *The Journal of Medical Technology*. Since 1988 the journal has been published under the name *Clinical Laboratory Science*. ASCLS has published the journal on a bimonthly basis, six issues per year. Over the years this publication has given practitioners, researchers, administrators, educators, students, and representatives of industry the opportunity to influence the development of clinical laboratory work, both on a theoretical and a practical level.[16] Space has been given for specialist articles, review focus articles, research findings from a theoretical and practical perspective, and discussions as well as room for students' work and related articles.

With a view to giving a clear presentation of the journal together with doing justice to this publication, the researcher first read carefully all the articles and then chose to examine the contents more closely.[1] The study excluded commercial texts and discussions on American healthcare policy as well as training issues related to clinical laboratory practice. The contents were pre-grouped into subject areas such as the clinical laboratory entity, education, management, and organization together with quality issues. Subject areas were specified with subheadings related to content, partly to facilitate a summary and also to be able to evaluate a primary emphasis concerning the journal's contents.

To capture and describe qualities in CLS a selection of major articles for closer analysis was undertaken using articles concerning all the phases of the clinical laboratory process including: patient´s problem and need–clinical question; clinical question–test selected and ordered; guidance of the patient–preparation for the examination; examination; collection of the specimen (sample) for clinical testing; preparing the sample; analyzing the sample; recording the result; assessment of the result; and notification of the result to the caring department or directly to the patient. The selection of articles was made easier by the researcher familiarizing herself with the journal during the first reading and during a review of contents. Articles that concerned administration, health policy, and teaching methods were excluded.

ANALYSIS AND SUMMARY OF DATA

Content analysis can be applied to a study in which the purpose is to analyze documents: written, spoken, or symbolic materials. Methods can be quantitative, manifest, or qualitative latent. A quantitative content analysis means, among other things, that the researcher presents, numerically, the degree in which the analyzed material is represented in various categories. In a qualitative contents analysis the study is directed at certain properties in the content materials. To answer the question concerning the knowledge field and inner pattern of CLS, a 'latent contents analysis' was chosen. By means of this method, the researcher seeks to reach the underlying meaning and qualities in the material. The meaning emerges inductively in the material and cannot be forced onto the material in advance.[6,14,18-22]

In the examination of this material, analysis and synthesis are united. The material is differentiated into conceptual elements and brought together to a scientific conclusion.[6] The data analysis process can occur on various abstract levels and levels of understanding that can be noticed in a concept formation. On a surface level, the linguistic structure and construction of the texts are examined; on the context level, the texts are examined in relation to their context; and on the existential level, the texts' deeper meanings are studied. The researcher aims at studying the texts at the contextual and existential levels. Data are summed up finally in one or more essential forms. From the static perspective, the permanence of the material is sought.[14]

The process for data analysis and data processing can be described step-by-step as follows:

1. The researcher reads the materials and obtains an overall view of the contents of the journal.
2. The researcher reads the materials again and notes what could construe various categories in the material (semi-structured precoding).
3. Detailed data analysis is taken. The researcher separates the text in order to obtain similar categories. At this stage the researcher asks the following questions: What is the text about? What is its starting point? What are the contents? What is happening? What is the aim? Why does the activity described in the text exist?
4. The researcher codes the content of the text entity 1, for example, as A.
5. The researcher analyzes text entity 2 and if the contents are the same as in the text entity 1, designates it as A, otherwise it is designated as B and so on. The researcher continuously compares new coded data in one category with previous texts coded in the same category in order to be able to develop its characteristics.

6. The analysis proceeds in this manner such that the contents in each text entity are compared and coded with previously analyzed material, and thus new contents are discovered and new categories emerge on the basis of the coded text entities. The work with coding continues until a theoretical saturation is reached, which happens when the analysis no longer contributes to discovering something new about the category.

RESULTS

The articles reviewed in *Clinical Laboratory Science* related to the clinical laboratory process were analyzed by means of the latent content analysis. After having read the articles in question, the researcher made an outline description of the field of knowledge and patterns of facts (semi-structured pre-coding) that appear in the text. Next, a more detailed analysis of the data was made; the researcher separated the original text into main categories and subcategories, and stated the contents of the categories. With the aim of illustrating the foundation for the categorization, typical examples from all the articles are presented in the form of direct quotations.

During the course of the analysis process, essential forms in CLS were developed. After presentation of results in each essential form, including main and subcategories, a summary of the figuration of facts in each main category as well as what is important in it is provided.

The person/the patient - the origin of CLS

The person, the patient is the origin in CLS and is therefore the first essential form. The main category — person/patient includes the subcategories of a person/patient as a unique, indivisible entity as well as a person/patient as an individual with various levels of existence, e.g., at the level of cells and molecules, the levels of tissue and substance, and the level of organs.

Subcategory A
Unique person/patient

Content of the subcategory
Indivisible entity, dignity, existence

The subcategory is manifested by:
"I want to let you know exactly who I am. I am a human being with all the emotions and needs of other human beings… I am still a person, a person with feelings who has a certain amount of pride. Please do not take this from me. Many times, pride is all I have left...I have lost my job and may lose my home and savings.... Is that any legacy to leave a loving spouse and two young children? I need food, water, friendship, warmth, love, sex, and security, both physical and financial. I also need to be touched by another human being. This is called skin hunger."[23]

"...viewing patients as a member of their family and the community, not as a tube of blood on an automatic sampler..."[24]

Subcategory B
Biological person/patient

Content of the subcategory
Biological structure, function and development. Specific qualities are related to the level of cells and molecules, tissue and substance, and organs.

The subcategory is manifested by:
"Tetraiodothyronine (T4; thyroxine) is a low molecular weight (777 daltons), iodine containing hormone secreted by the thyroid gland. Derived peripherally from conversion of T4 to T3 at sites of tissue action, triodothyronine (T3) is the more biologically potent hormone. Important physiologic functions, including carbohydrate, protein, and lipid metabolism,.... T4 overproduction (hyperthyroidism) or underproduction (hypothyroidism) result in clinically important consequences."[25]

In summary, it can be noted that the *person/patient as an origin* in CLS is perceived both from a holistic perspective and from a biological perspective. The person/patient is seen, on the one hand, as a unique individual with his/her own thoughts, feelings, experiences, suffering, and vulnerability that must be understood in relation to his/her total life situation, and as a biological individual with specific biological qualities. These specific qualities relate to levels of cells and molecules, levels of tissues and substance, and levels for which organs are manifested, e.g., in the form of molecular weight, cell morphology; color, shape, size, degree of maturity, number of cells, cell division; concentrations; or as normal physiological-pathophysiological properties. Equally important, humans are unique individuals, as described above. The core of meaning in this category is *respect for a person's/patient's integrity from a holistic and a biological perspective.*

Encounter and relationship—a unifying force in CLS

A unifying force—encounter with the patient as well as the relationship to what the patient submits to the professional, e.g., a specimen constitutes essential form number two in CLS. The patient's wish to relate to the professional, the encounter between the patient and the professional, including technology, as well as the relationship between the patient's specimen and the professional appear as subcategories in the main category of encounter/relationship.

Subcategory A
Patient's wish to relate to the professional

Content of the subcategory
To relate to the whole individual. Reciprocity

The subcategory is manifested by:
" I also need to be touched by another human being. Will you stay near as I leave this life and enter another? ...see me as a human being and not a number or a disease. Please help me to under-

stand.... Give me a little of your precious time. Not a lot of time but quality time. Time enough to remind me that I am a worthy human being.... Please forgive me if I am less than courteous to you.... If you can dry but one tear, do it."[23]

"Patients who wish to take control of their healthcare want to skip the *middle man*, and deal directly with the laboratories."[26]

Subcategory B

Encounter between the patient and the professional, including an encounter with technology.

Content of the subcategory

Unique human/patient, unique patient specimen, unique human patient test/examination. Specific problem solving—harmony between the unique patient and valid quality requirements

The subcategory is manifested by:

"..as we participate in office and home testing, where our contact and expertise with patients is maximized... to assist seniors in dealing with medical terminology..."[27]

"At the time of original venipuncture, the technologist had noted that the patient´s blood had a bright red, arterial-like color, even though it was a venous sample"[28]

"*Patient identification:* The blood collection process can be monitored and tracked by using a closed system once the patient and specimen have been positively identified"[29]

Subcategory C

Relationship between the patient's specimen and the professional.

Content of the subcategory

A unique fragile, vulnerable patient and his/her specimen. Qualitative adjustment of methods and equipment to the unique patient specimen

The subcategory is manifested by:

"...observed lower reticulocyte counts on patient smears prepared outside the routine laboratory hours....the problem of EDTA specimen stability for reticulocyte counting."[30]

"A complete patient history including exercise habits is an essential part of patient information in all circumstances and should be available when interpreting laboratory data."[31]

In summary, it can be noted that the figuration of facts in the essential form *encounter and relationship* confirm *a unifying force* in CLS. Closeness, commitment, respect, security, relief, reciprocity, trust, and trustworthiness are qualities that originate from the encounter between the patient and professional as well as from a relationship to the patient's specimen—something that the patient submits to the professional, to take care of in the best possible way. Awareness of the vulnerability of the unique patient motivates an ethical point of view, including respect for a unique patient by means of listening, discussing, attempting to understand each patient and his/her situation, and by helping him/her in accordance with his/her needs. The figuration of facts concerning the unique, fragile, and vulnerable patient's specimen/test is permeated by precision, a use of systems, scientifically verified knowledge, and a qualitative adjustment of methods and equipment when the professional is entrusted with the unique patient specimen or when the test is conducted in the patient's presence. The core of meaning in this category is *reverence for and care of the patient.*

The patient's health—the goal-orienting force in CLS

The patient's health as the committing and goal-orienting force appears as essential form number three in CLS. The main category of a patient's health includes the subcategories of: patient's health pattern from a holistic perspective, patient's biological health pattern from a general perspective, and a patient's specific biological health pattern form the basis of the data gathered.

Subcategory A

Patient's health pattern from a holistic perspective

Content of the subcategory

Health as a part of life
Health, suffering, reconciliation
Health resources, obstacles to health

The subcategory is manifested by:

"I want to let you know exactly who I am. I am a human being with all the emotions and needs of other human beings. Because of my medical condition my emotions and needs may be somewhat exaggerated... Because of my medical condition I have lost my job and may lose my home and my savings. I may even lose my life. I have many fears. A fear of death... Do you know what it feels like to have your body fail you when you need it so badly? I do not know what to expect on the other side of life. I fear financial ruin... I fear loss of control... I fear loss of family and friends... I fear dying alone... I fear the unknown... I am afraid... I fear pain... I want to tell you how much you mean to me. You are often my only link to life. I need you. I also need you to respect me as a person.[23]

"... complaining of exhaustion, headaches, dizziness, blurring of vision, nausea and lack of appetite."[28]

"Patients who wish to take control of their healthcare..."[26]

Subcategory B
Patient's biological health pattern from a general perspective

Content of the subcategory
Comparability, generalizability

The subcategory is manifested by:
"It should be noted that the literature divides reference ranges for newborns and infants into several categories, e.g., at birth, 12 hours, one day, and one week. The reference range for white blood cell (WBC) counts is actually quite large. Newborns can have leukocyte counts from 9.0 to 30.0 x 10^9/L, with a mean of 15.0 to 20.0 x 10^9/L."[32]

"All results from the 20 healthy individuals tested were between 5.9 and 11.2 μg/dL, confirming the validity of the suggested range of 4.5 to 12.0 μg/dL."[25]

Subcategory C
Patient's specific biological health pattern

Content of the subcategory
Relativity, individuality, exactness

The subcategory is manifested by:
"Initially, the patient's hemoglobin (HGB) and hematocrit (HCT) were evaluated... On the third hospital day, however, the HGB and HCT began to drop and continued to decline for the next six days... Laboratory results reflect a variety of influences: direct tissue damage, expected compensatory mechanisms, treatment effects, and postburn complications."[33]

"For most analytes, the patient condition is a relatively minor consideration, but blood gas data can vary from minute to minute."[34]

In summary, it must be noted that the *patient and his/her experienced, total, and objectively biological health is the goal-orienting force* in CLS. Health is to be seen as more than a part of life and not only as a result of biological analysis. A laboratory test that explores the biological health pattern is to be seen in relation to the patient's total health situation, to the agreed reference ranges and to the patient's own biological reference values. 'Health is relative', and the biological health pattern may vary from one individual to another, from day to day, depending on age, gender, and the like. CLS may be able to provide patient a choice, because of increased awareness of health hazards and biological health patterns. The core of meaning in this main category comprises *care of the patient's total and biological health.*

Clarification of the patient's biological health pattern—a motivating force in CLS

A motivating force in CLS is to clarify the patient's biological health pattern and this constitutes essential form number four. This essential form is characterized by the process, including technology, that a patient's specimen/test is submitted to in order to achieve a laboratory test result. The main category of bioanalysis as well as the subcategories of biological materials include the objects of analysis, reference materials of analysis, methods and instruments of analysis, procedures of analysis, and quality of analysis that are formed on the basis of articles in the journal *Clinical Laboratory Science.*

Subcategory A
Biological materials as the object of analysis

Content of the subcategory
Goal-oriented, specific

The subcategory is manifested by:
"The data on pathogenic versus non-pathogenic zymodemes (differences based on isoenzyme patterns) suggests that some of the strains of *E. histolytica* may not cause disease... antigen detection in stool..."[35]

"...and provides a testing menu appropriate for a family practice clinic: CBC, chemistry profile, thyroid testing, urinalysis, pre-natal screens, and serological tests..."[24]

Subcategory B
Reference material of analysis

Content of the subcategory
Comparability, exactness

The subcategory is manifested by:
"We evaluated RE by a precision study using single-lot multi-constituent (Lypho-check, Levels I, II, and III; Bio-Rad laboratories, ECS div., Anaheim Ca), and Abbott assay-specific T4 control materials. Each control material was assayed in duplicate for T4 concentration in a minimum of 16 runs on different days. A hemolysate of red blood cells (RBCs) was prepared by washing a sample of RBCs three times with physiological saline, followed by 1:4 dilution and lysis with distilled water."[25]

Subcategory C
Methods and instruments of analysis

Content of the subcategory
Analytical performance; physical and biochemical qualities; analytical capacity and purposefulness

The category is manifested by:
"We can look forward to more specific and sensitive diagnostic techniques, ...which use monoclonal antibodies coupled with various methodologies such as enzyme-linked immunosorbent assay (ELISA) and immunofluorescent assay (IFA)....Electron microscopy is presently the most sensitive method for examining intestinal tissue,..."[35]

"This method uses dry-reagent technology in the form of test cards (Keto-Site®) to determine exclusively B-OHB levels in blood, serum or plasma based on the enzymatic reaction....Optical density measurements were obtained using a Gilford Spectrophotometer Model 250 for both specimens and GDS B-OHB controls at a wavelength of 505 nm."[36]

"Differential information would be entered directly through a differential pad. The results would be generated by the instrument and transmitted directly from the instrument to the computer. The answers would be checked for accuracy on a word sheet that would become part of the chart copy when the patient report was printed."[37]

Subcategory D
Procedure of analysis

Content of the subcategory
Analytical flow including well-defined sequences

The subcategory is manifested by:
"Four drops of blood were added to a commercially available reticulocyte staining system utilizing dry brilliant cresyl blue stain...mixed and incubated between 10 to 20 minutes. Wedge smears were prepared and allowed to air dry. Reticulocytes was counted under a 100X oil objective over five fields of approximately 200 RBCs/field."[30]

Subcategory E
Quality of analysis

Content of the subcategory
Exactness, regularities related to the method of analysis; exactness, regularities related to biomedical diagnosis

The subcategory is manifested by:
"A stepwise multiple regression analysis was performed using sex, age, body mass index (BMI), previous cholesterol value, and smoking as independent variables and cholesterol as the dependent variable... to predict cholesterol levels."[38]

"Linearity-defined as the percent difference between observed versus expected T4 concentration calibrator solutions containing ....Precision of the T4 method in the AxSYM immunoassay analyzer was good (<10%) to excellent (<5%) at T4 concentrations ranging from low (3.4 μg/dL) to high (18.4 μg/dL)....Although the value we obtained for the analytical sensitivity...[25]

In summary, it can be noted that the *motivating force to clarify a patient's biological health pattern* by means of scientific methods comprises *a responsibility to protect the patient's biological integrity*, including exactness in relation to the method, equipment and procedure in achieving a laboratory test result. Each subcategory includes specific qualities. The biological material as an object of analysis is well defined. Methods, instruments, and reagents are essential to analyze the 'object'. They must be specific for the purpose, have certain biochemical and physical qualities, reference capacity, and an advanced control system. The procedure of analysis is described clearly step by step with specific quality requirements. The quality of analysis is examined from a method-of-analysis-related and biomedicine-related point of view, including such qualities as analytic and diagnostic specificity and sensitivity, precision, correlation, interference, etc.

CONFIGURATION OF FACTS IN CLS

The reason for defining CLS has been born from the need to develop the work, and the need to define the knowledge base for a specific professional body, that is to say MTs. An aim of this study thus became to create clarity in CLS as a science. In order to be able to capture that 'something', the 'really real' configuration of facts, that could lead to the adoption of the science and its origin, the study has been characterized by an open view on knowledge and reality.

The configuration of facts that has emerged by means of a latent content analysis of certain selected articles from the journal *Clinical Laboratory Science* expresses the essence and inner patterns of CLS. The person/the patient is the origin within CLS and he/she is seen from a holistic point of view and from a biological point of view. The unifying force is the encounter and the contact with the patient, as well as the relationship to which the patient submits to the professional, often the specimen. The goal-orientating force is the patient and his experienced, total and objective biological health. Elucidating the patient's biological health pattern is what constitutes a primary motivating force. Other forces that emerge set in motion activities and processes in order to help the patient in the best way. What is essential in CLS is one's regard for a human's integrity from a holistic and a biological point of view, reverence for and care of the patient, and his/her health including a responsibility for safeguarding the biological integrity of a patient.

The statement that the idea of a human within CLS is synonymous with that to be found in caring science is not in total agreement with the configuration of facts that have appeared in the journal *Clinical Laboratory Science*.[39] Knowledge about the biological human is predominant. It can be noted that knowledge about a human from a holistic perspective and about the encounter with the human/the patient in a clinical laboratory context is imperfect. This appears clearly in the subcategory 'the patient's desire to meet the professional'. Does this indicate that researchers, educators, and all persons involved in a clinical laboratory context have not opened their eyes to the whole task?

Health should be seen as a part of life and not merely as the result of biological analysis. The laboratory examination and information that ensues and that charts the biological health pattern, is to be seen in relation to the patient's health viewed as a whole. Knowledge from CLS can serve patients and facilitate freedom of choice for the patient, starting from an increased awareness about the relation of health hazards to his/her biological health pattern. The need for laboratory professionals to safeguard each patient's biological health and biological integrity, by reliable laboratory examination performance is seen in the demands for quality, which characterize the entire bioanalytical processes.

Whether CLS is based on an interdisciplinary or a multidisciplinary foundation, has not been thoroughly discussed. Doig states in the *Clinical Laboratory Science* lead article in 1988 that the science is CLS and not sciences since CLS is more than a collection of various sciences.[2] She does not take a position concerning multi-disciplinary or interdisciplinary science but, instead, gives a viewpoint for a science of its own. Hentinen points out that training in the option CLS should be multidisciplinary. My interpretation in the study of the paradigm of Medical Laboratory Technologists (MT) 1988 is that professionals put into practice interdisciplinary knowledge in the exercise of their profession.

Representatives of CLS endeavor to find an autonomous science of their own as a basis for the practical work. This is seen in the possibility to study this science, in the scientific journal, and in the effort to carry out basic research and development models. The scientific paradigm is weak in that disagreement exists concerning the knowledge base. An autonomous science contains a unique theoretical core, based upon its own basic motive and can never constitute a series of reduced scientific theories or realities, but it is a unique reality where a unique pattern emerges.[40] Basic research, which is not directly connected to economic activity and vocational training, is needed in order to discover the unique knowledge pattern in a science without being influenced by the complexity and the multi-disciplinary application of knowledge in practice. By developing knowledge within the fundamental research and establishing it through applied research and development work, the new knowledge reaches an acceptance among the people involved in the practical work. The issue of whether CLS is an autonomous science or whether it is founded on an inter-disciplinary or a multi-disciplinary basis is not answered in this study. However, it can be stated that the technological level is represented by multidisciplinary and interdisciplinary application of knowledge. The figuration of facts shows that systematic and applied research is needed in CLS, among other things, to promote development in clinical laboratory practice (Table 1).

Table 1. Clinical laboratory science divided into systematic and applied science

Clinical Laboratory Science	
Systematic	Applied, contextual
Motives and basic values	The patient and his/her health
Concepts, terminology, definitions, clauses	Encounter with the patient
Model construction	Care for the patient
Theory formation	Care for the specimen submitted by the patient
	Goals, methods, and conditions of the caring process
	Goals, methods, and conditions of the caring technology
	Goals, methods, and conditions of bioanalysis

According to Fawcett and Downs certain issues have to be borne in mind in the development of the science.[41] Is the phenomenon of interest? Does it have a relevance in a practical task? Is it possible to implement the innovations that may possibly be developed? Are the innovations equal in all respects with the 'clients' expectations? Do the innovations result in favorable results, etc.? In the studies of clinical laboratory work it can be noted that there are phenomena and problem situations, which no one deals with because they do not 'belong to their area of competence'. An example is the phenomenon related to collecting of specimens/examination from the patient's point of view.

As for the development of methods in the bioanalytical process, research regarding the specificity and sensitivity of laboratory diagnostics in relation to various states of ill-health falls within the scope of clinical laboratory medicine. Proposals for research objects within CLS and clinical laboratory work are shown in Table 1. Knowledge is given its significance by means of the context. Research and knowledge development are absolutely necessary within the metatheoretical, theoretical, and technological levels of CLS in order to arrive at a body of knowledge, which will be able to serve the whole of clinical laboratory work.

Without genuine interest and care for the patient the researcher, educator, or practitioner cannot develop qualitatively good clinical laboratory activities. In order to be able to keep the wording of one's promise; "I promise to put into practice my knowledge of CLS for the welfare of mankind and also to work for the development of clinical laboratory work", research and development work for the whole field of activities should be encouraged. The findings of the study are discussed in the light of the starting points of the theory of science and lead into the following nine hypotheses about CLS:

- The person/the patient is the origin in CLS.
- The encounter and the relationship is a unifying force in CLS.
- The patient's health is the goal-orienting force in CLS.

- Clarification of a patient's biological health pattern is the motivating force in CLS.
- The core of meaning in CLS comprises respect for a person's/patient's integrity from the holistic and biological perspective, reverence for and care of the patient and his/her total, experienced, and biological health including responsibility to protect the patient's biological integrity.
- CLS studies intradisciplinary motives, develops concepts, models and theories.
- CLS studies specific qualities in a person's/patient's biological health pattern in his/her prenatal development stage, during his/her whole lifetime and even post mortem.
- CLS studies qualities concerning the encounter between the patient and the professional and qualities concerning the relationship to a patient's specimen.
- CLS studies goals, methods, and conditions in the context of a specific caring process, caring technology, and bioanalysis.

The formal requirements that are placed on research and its findings are that they shall be able to be considered valid and agree with generally accepted requirements for scientific objectivity. In natural science and quantitative studies the results are judged among other things, on the basis of criteria such as probability, reliability, and validity.[6] The appropriateness of qualitative research methods should be examined from other aspects than the ones just cited.[14,42,43] Eneroth says further that while qualitative research methods strive to find a concept (a connected whole of qualities) on the basis of observations, quantitative research methods try to find certain observations in relation to a given concept to measure the degree/extent of its appropriateness for the phenomenon. [14] Burns points out that a qualitative study should be examined in relation to its descriptive clarity and vividness, its methodological congruity, its analytical precision, its theoretical connection, and heuristic relevance.[42] Larsson has proposed the criteria awareness of perspective, internal logic, and ethical value, wealth of meaning, structure and theoretical growth, discourse, and heuristic value, as well as empirical foundation for the evaluation of qualitative research.[43] The critical discussion of this study is not included in this article. It was principally carried out in accordance with Larsson's criteria on the grounds that these criteria are the latest ones to have emerged in research methodology.

The purpose of the present study was to create clarity in CLS as a science of its own. This has been achieved by means of capturing and describing facts and qualities, and thereafter presenting fundamental hypotheses in CLS. The results of this study give a thought structure for continued development and deepening within the theory and practice of CLS.

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