Good clinical sense in diabetology
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Abstract
This article defines and explains the concept of good clinical sense. It defines good clinical sense as "the presence of sensory faculties, their usage and interpretation, by which one is able to practice good clinical medicine". Good clinical sense differs from good clinical practice (GCP) and good clinical acumen. It encompasses all steps of the clinical, diagnostic and therapeutic process, and encourages diligent practice of clinical medicine. Good clinical sense is integral to the practice of diabetology.

Keywords: Diabetes, SGLT2 inhibitors, insulin, GCP.

Introduction
Clinical medicine has existed since the beginning of mankind. Whether learnt by experience, from ‘eminence’ (teachers) or based on evidence,1 best possible care is provided by the medical fraternity. A robust system has developed to facilitate diagnosis, treatment, and follow up. This framework, which includes history taking, physical examination, ordering and interpretation of relevant investigations, arrival at a diagnosis, and management based upon this diagnosis, relies upon clinical acumen. This approach includes, within its ambit, and is not exclusive from, supposedly "modern" concepts such as person-centred care, patient-physician bonding and informed/shared decision making.

Such a framework applies equally well to acute as well as chronic disease. In fact, the need for such a systemic approach is greater in chronic care. Chronic disease management involves continuous and monitoring reappraisal of therapy to ensure that pre-agreed therapeutic goals are being met, without major safety and tolerability issues. It also requires greater commitment and proactive behaviour on part of the patient, and demands team work from all stakeholders.2

Clinical Challenges
In an ideal clinical scenario, the physician should be able to utilize his medical knowledge and communication skills, to search for leading clues, and reach an accurate diagnosis, with the help of minimal investigations. Once this is done, he should be able to, based upon his knowledge of pharmacology, and the patient’s characteristics, choose the appropriate treatment target and strategy for the individual patient. It is this process which is given the name ‘patient centered care’ or ‘individualized care’ in diabetes.3 However, this is easier said than done. The average physician finds it difficult to manage the wide variety of conditions that he is called upon to manage, and faces difficulty in shifting between the differing (and sometimes conflicting) needs of acute and chronic care delivery. At the same time, the steep increase in the number of diagnostic and treatment modalities available today makes it even tougher for him to keep up with modern technology.

Clinical Automation
To manage these demands, modern doctors increasingly rely on algorithms, guidelines and recommendations. The popularity of such document is proven by the fact that a Pubmed search using the three MeSH terms ‘algorithms’, ‘guidelines’, ‘recommendations’, throws up as many as 1249 hits.4 Doctors also utilize modern technology such as computerized check lists and e-records to ensure adherence to guidelines or protocols. Such dependence on automation does have its benefits. In acute care settings, especially, such systems minimize provider and delivery errors, and ensure that minimum operating standards are met by all health care providers. In chronic disease management, however, the same systems may reduce flexibility, reduce the ability to effect midcourse correction, and stifle the patient's contribution to his own care. All in all, excessive automation of chronic medical care may work against the patient centered, patient empowered spirit that is required in this field of medicine.

Good Clinical Practice
Another, simpler, but even more disturbing trend is being noted in recent years. Over dependence on evidence and guidelines has led to an erosion of what we would like to term as ‘good clinical sense’.

The term "good clinical practice" (GCP) has been defined in relation to clinical trial conduct.5,6 GCP is defined by European Medical Authority as "an international ethical
and scientific quality standard for designing, conducting recording and reporting trials that involve the participation of human subjects, compliance with this standard provides public assurance that the rights, safety and well-being of trial subject are protected, consistent with principal that their origin in the Declaration of Helsinki, and the clinical trial data are credible.5

As per World Health Organization, GCP is “a standard for clinical studies which encompasses the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of the studies and which ensures that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical product (diagnostic, therapeutic or prophylactic) under investigation are properly documented.6

However, these definitions are drug-focused, and not directly applicable to clinical medicine. They also do not convey the entire spectrum of responsibilities that a physician’s work entails. Therefore, the term GCP is not used frequently in the context of daily clinical practice.

Good Clinical Acumen
In practice, the term ‘clinical acumen’ is heard more often. Acumen means, according to the dictionary,7 keen insight, or shrewdness. A physician with good clinical acumen is one who is able to, in Sherlock Holmes style, ferret out cues and clues, which help achieve the correct diagnosis, and allow institution of appropriate therapy. The phrase “good clinical acumen” carries an elitist feeling, as it seems to belong to a select group of (senior), (more experienced) physicians who are held in esteem by other members of the fraternity.

Good Clinical Sense
Sense, in contrast, is a relatively simpler and humbler term, for which we can all aspire. The definition of ‘sense’ that the dictionary8 conveys is: any of the faculties, by which humans perceive stimuli. This suggests sense to be a quality that we all possess (or should possess). We propose the following definition: Good clinical sense is the presence of sensory faculties, their usage and interpretation, by which one is able to practice good clinical medicine. We therefore reinforce a call given by medical teachers of every generation: to please use good clinical sense while managing diabetes.

It may seem that this manuscript repeats, common knowledge, and adds nothing to what we already know. However, in the current era of evidence-based and information-based medicine, we must not lose sight of clinical sense. Good clinical sense should permeate every step of the therapeutic process, from team-building and history-taking, to management and follow-up (Table 1).

The recent spate of case reports linking sodium glucose co-transporter inhibitors (SGLT2i) therapy with ketoacidosis,9 however, prompted us to address the issue. In many cases where SGLT2i have been blamed for ketoacidosis it is actually lack of good clinical sense which has been the culprit.

Facets of Good Clinical Sense
Various facets of good clinical sense are listed in the Table. One must make the effort to build a strong ‘therapeutic alliance’ with the patient, to achieve optimal outcomes. A complete history taking is essential, and detailed questioning may elicit cues such as past history of pancreatitis or gestational diabetes mellitus. Physical examination, conducted carefully, can reveal signs suggestive of autoimmune disorders (vitiligo, goiter, arthritis) or insulin resistance (acanthosis nigricans, skin tags), which may help plan further action. Investigations should be ordered rationally, with regards to utility and economy. Treatment, too, must be crafted in a sensible manner. Incomplete dietary management, delaying insulin therapy when absolutely indicated, or starting drugs without understanding their mode of action or contraindications, are all against good clinical sense. In chronic disease such as diabetes, follow up is equally important. Good clinical sense includes assessing insulin technique and insulin injection sites, ensuring that medication is being taken properly, that lifestyle related advice is being followed, and making sure that the patient returns for regular reappraisal of therapy.

Vol. 65, No. 8, August 2015

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<tr>
<th>Table: Components of good clinical sense.</th>
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<tr>
<td>• Effective communication: building a therapeutic alliance</td>
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<td>• Empathic history taking</td>
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<td>• Comprehensive physical examination</td>
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<td>• Rational investigations</td>
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<td>• Evidence-based therapy</td>
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<td>• Understand the effects and limitation of treatment modalities being used</td>
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<td>• Know how to prescribe the treatment safety</td>
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<td>• Watch for relevant warning symptoms, signs and laboratory abnormalities</td>
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<td>• Institute dose change/drug change as appropriate</td>
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<td>• Regular follow-up</td>
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Vol. 65, No. 8, August 2015
Good Clinical Sense and Public Health

Good clinical sense is not limited just to the patient-physician interaction and prescription. The physician has a responsibility not only to the individual patient, but to the entire public. This is fulfilled by taking active part in pharmaco-vigilance. Any observation of warning symptoms or signs, which may prompt safety signals, should be reported. Any observation which is potentially life-threatening, health-threatening, or of public health importance, should be assessed immediately and carefully. Such reports will strengthen a collective pool of wisdom, which in turn will facilitate dissemination of good clinical sense across the healthcare fraternity.

Conclusion

While there will always be a need for guidelines and recommendations, these cannot be interpreted without good clinical sense. Medical educationists should focus not only on knowledge, but also on development of good clinical sense.

References


