Benefits and limitations of guidelines & ECT guidelines in Norway?

Svein Martin Luth

Nyköping, Sweden,

May 27 2016

Benefits and limitations of guidelines.

Clinical guidelines

- Clinical practice guidelines have a fairly long history, more than a century, but after World War II, the production rate of guidelines has increased, the last 25 years it has increased even more[1].
- ... are statements with recommendations intended to optimise patient care [2].
- The present understanding of the concept state that they are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative options [2].

- Guidelines developing methods have improved over the years.
- Moved fromexpert's opinions towards a more stringent and transparent methodology.
- Today many guidelines are based upon the <u>evidence-based method</u>, that includes scientific evidence, clinical experience and patients values and preferences [3].

Professional organisations and healthcare authorities develop clinical practice guidelines for many of reasons, but it may be grouped in two [4]:

- Guidelines as professional aid; assist clinicians in their daily work; they should provide assistance to patients in their decision making; they should provide assistance for healthcare planners to develop services for particular patient groups.
- Guidelines as means to external control; key recommendations can be translated to performance indicators; they could be used in policy making and coverage decisions [4].

Benefits

- intended to optimise patient care [2].
- assist clinicians in their daily work [4].
- assistance to patients decision making [4].
- assistance for healthcare planners to develop services for particular patient groups. [4].
- be used in policy making and coverage decisions [4].

Limitations

- Less individualized treatment
- Very often, recommendations are based on low quality evidence or clinical practice [2].
- be used in policy making and coverage decisions [4].
- Norwegian general practitioners used clinical practice guidelines to a limited degree only [5].

References

- Weisz G, Cambrosio A, Keating P, Knaapen L, Schlich T, Tournay VJ. The Emergence of Clinical Practice Guidelines. The Milbank quarterly. 2007;85:691-727.
- 2. Institute of Medicine (U.S.) . Board on Health Care Services Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Graham R. Clinical practice guidelines we can trust. Washington, D.C.: National Academies Press; 2011.
- 3. Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312(7023):71-2.
- 4. Burgers J, Smolders M, van der Weijden T, Davis D. Clinical practice guidelines as a tool for improving patient care. Improving Patient Care: the implementation of change in health care. 2nd ed. Oxford, UK: Oxford, UK: John Wiley & Sons, Ltd; 2013. p. 91-114.
- 5. Treweek S, Flottorp S, Fretheim A, Havelsrud K, Kristoffersen DT, Oxman A et al. [Guidelines in general practice--are they read and are they used?]. Tidsskrift for den Norske laegeforening: tidsskrift for praktisk medicin, ny raekke. 2005;125(3): 300-3.

ECT guidelines in Norway?

National ECT Guidelines

The Norwegian Directorate of Health

National ECT Guidelines

- The ECT guideline group started their work in January 2013, and completed its work in January 2016
- The draft is still in The Norwegian Directorate of Health, going trough an internal process, and shortly after the summer of 2016 it will go trough an external hearing in Norway.
- The working group consisted of 10 members: 5
 psychiatrist, 2 psychologists, 1 anesthesiologist,
 2 patients representatives.

What the group should look into?

- There was a need for national standardization with regard to:
- Indications for ECT
- What somatic and psychological examination / screening / monitoring should be done before, during and after treatment
- How ECT is practically conducted
- Type of expertise / requirements for skills and equipment
- Information and consent procedures

What can hopefully be achieved with guidelines in Norway?

- Optimizing the use of ECT
- Reduced regional variations
- Better legal protection
- The guideline also highlights ethical and legal issues, effects, side effects, long-term efficacy and patient safety

- NICE guidelines & other guidelines
- Used the evidence-based method
- Systematic literature search
- Patient experiences and values
- Clinical experiences
- Survey by The Norwegian
 Directorate of Health, the state in 2012 (Norway)

How was the process ending up at different recommendations?

- Systematic questions using the PICO on important outcomes
 - Population (P), Intervention (I), control (C), Outcome (O)
 - Method , indication , populations
- Literature search
 Guidelines , Knowledge Summaries / Meta-analysis
- We graded the quality of the documentation using the GradePro
- Formulated recommendation (for or against) and the strength of the recommendation by using structured methods

Ex. ECT 2 days vs 3 days per week?

- Clinical question: Should patients receiving ECT treatment be offered 2 or 3 times per week?
- Background: The standard procedure in Norway is that patients is treated with ECT two or three times per week. Three times per week may involve more practical (transportation, resource) challenges for patients and staff when psychiatric ward are not close to the somatic hospital where treatment is given . Three times may involve a greater cognitive burden for the patient. An elderly MA suggests that there is no difference in treatment effect when treatment is given twice versus three times per week

Recommendation We suggest that ECT is offered twice a week instead of three times per week.

- There is evidence that ECT given two days per week have comparable treatment effect with three times per week, leading to overall fewer treatments in a treatment series.
- By choosing twice per week, it extended the duration of treatment significantly.
- There is uncertainty with regard to cognition, but a trend towards fewer cognitive side effects of 2 days per week
- Subgroup ratings Especially populations that are vulnerable to cognitive disorders of ECT (older pas with brain damage, mental retardation, patients with dementia) may have particularly good advantage of getting treatment twice per week

 Regarding consent: Directorate of Health recommends the use of written consent for ECT, to prove that a valid consent exists.

Indication Moderate to severe depression
 We propose to offer ECT for patients with
 moderate to severe depression who have not
 profited from other treatments

ECT as the first line treatment

- We suggest that ECT may be offered as firstline treatment for patients with <u>severe</u> <u>depression</u>, where the need for especially fast effect is present because of danger to life and health.
- We suggest that patients with <u>psychotic</u> depression can be offered ECT as first-line treatment

Maintenance treatment

- We recommend psychopharmacological maintenance therapy to prevent relapse of depression after discontinuation of ECT series.
- We suggest ECT as maintenance for patients who do not have sufficient effect of psychopharmacological treatment or whom prefer ECT above medications.
- Where maintenance ECT is administered as part of maintenance therapy, it should be documented in the records which specialist that is responsible for patient care.
- ECT maintenance treatment should be evaluated every 3-6 months.

Bipolar Disorders:

Severe depressive episode

We suggest to offer ECT for patients with moderate to severe depression in bipolar disorder who have not profited from other treatments

For treatment resistant mania :

We suggest that ECT may be tried when the sever manic episode is prolonged and where other treatments have not proven effective.

Mixed phases:

The working group believes that there is no basis for a general recommendation for the use of ECT for mixed phases of bipolar disorder.

Schizophrenia:

The working group believes that there is no basis for a general recommendation for the use of ECT in schizophrenia.

Catatonia

We suggest that ECT can be considered when there is a life threatening catatonic state, and where other treatments have failed

Electrode placement, current, pulse width and frequency of treatment

- As initial electrode position we suggest bifrontal or right-sided unilateral electrode placement chosen over bitemporal electrode placement.
- We recommend high dose unilateral ECT over low dose.
- Age -based dosing: Recommended initial dose equal to the patient's age x 5 (in mC) at right-sided unilateral electrode placement and 0.5 ms pulse width.
- Stimulustitrering: We recommend initially 5-6 X seizure threshold (mC) at right-sided unilateral electrode placement and 0.5 ms pulse width.
- We recommend that initial dosing in bitemporal and bifrontal electrode placement is about half the recommended doses for unilateral electrode placement.
- We recommend that ECT is given with narrow pulse width rather than ultra narrow pulse width
- We suggest that ECT is offered twice a week instead of three times per week

Standards of treatment 1

- Each ECT localization should designate a ECT responsible specialist with overall medical responsibility for ECT operations on site.
- It should be drawn up educational programs (both theoretical and practical) at each ECT localization.
- There should be established a system for approval / certification at each ECT localization.
- Approved / certified ECT operators should perform a minimum of 25 ECT treatments annually, and to participate in ECT courses / conferences every two years to maintain approval / certification.

Standards of treatment 2

- ECT devices that provide constant current of a "brief pulse square wave stimili" should be used and with continuous monitoring of convulsive seizure.
- Good routines for preparation and cleaning of ECT apparatus, ordering supplies and who is responsible for this, should be established on each ECT localization.
- It should be established separate rooms for different part of the ECT business that satisfy requirements for proper business, including the safeguarding of confidentiality
- It should appear in the records who is responsible for patient care before, during and after ECT treatment

Standards of treatment 3

- There should be procedures to evaluate the efficacy and possible side effects of the treatments consecutively in a series, including assessment of further indication for treatment.
- Each treatment should be evaluated and documented immediately, for instance in a so-called " ECT form " .
- The individual patient should be evaluated weekly during the ECT-index course.
- Each enterprise should facilitate that experience consultants or former patients can provide information to patients considering ECT.
- Each ECT clinic should have a planned follow-up of patients
- Patients should be summoned to control 6 months after stopping the ECT series to assess any symptoms of relapse or side effects after ECT.

National ECT Guidelines in Norway

- The practice of ECT will be more Evidencebased
- Will be normative and contribute to more equal / uniform /practice of ECT, and reduce regional variations)
- All in all: <u>improved ECT-quality</u>
- ...and hopefully it will be a good inspiration / startingpoint for a Norwegian national quality register for ECT

National quality register for ECT

 The Working Group recommends that it as soon as possible is taken an initiative to establish a process in terms of a national quality register for ECT