Czech national project of clinical practice guidelines development and its implementation in special education

(Scientific paper)

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Abstract: This statement paper provides a brief and clear background to the evidencebased medicine concept, systematic reviews and the development of clinical practice guidelines using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system and focuses on their application in the field of special education.

Its main objective is to suggest ways of applying clinical practice guidelines in the field of special education. The paper presents the first Czech national project for developing clinical practice guidelines mainly in the field of medicine and clinical practice with the main investigator being the Czech Health Research Council (AZV ČR). Some of the guidelines prepared within the project are relevant to special educators and the paper suggests that special teachers use the recommendations in their practice and in higher education. Moreover, it proposes that it is possible and useful to develop guidelines using the rigor of the GRADE methodology as described above, for issues directly pertaining to the field of special education, or education in general. In that process, it may be necessary to identify the challenges typical for the field of education and to suggest possible solutions. Finally, recommendations for special educators, for future research and for policy-makers are formulated. Specifically, the paper suggests that policy-makers, such as the Ministry of Education, Youth and Sports, develop national strategies for special-educational diagnostics and intervention based on rigorous methodology as described on the example of the Czech national project of guideline development in medicine and place special focus on the ethical aspects, social impacts and values and preferences of target populations.

Keywords: clinical practice guidelines, GRADE, special education, special educational needs, national educational policies

1 Introduction

In medicine, traditionally, physicians had been forming their clinical decisions on the available knowledge and clinical expertise. Logically then, the highest ranking experts with the presumably most accumulated knowledge and practice had been the ones to make the final decisions on the course of action and to guide the less experienced clinicians under their care.

As the medical field became more and more complex in the 20th century, some limitations to the above described approach have been observed; below are only a few of many examples:

- In case of rare diseases and conditions, the clinical expertise of one or few clinicians is insufficient to draw reliable conclusions.
- The view of one or few clinicians may be influenced by various biases, be it cultural and political norms, any form of prejudice, a form of specialisation that may draw a certain group of patients more than others and create the illusion that the condition is more common.
- Decisions may be based on the available knowledge, skills or equipment, rather than the best recognised standard of practice.
- Decisions in medicine are seldom a direct result of knowledge, information or evidence. Usually, there is a great number of factors to be taken into consideration (patient values, feasibility, cost effectiveness and many others) – this is a formidable task for any clinician to attempt to undertake alone.

Moreover, as we are dealing with an increasing number of information and research evidence, it is creating an added strain on the medical doctors, young and old alike. Much of the evidence, it must be noted, is invalid or irrelevant or too biased to be considered trustworthy. The issues of differentiating between the reliable evidence and of drawing conclusions from the growing body of information pose a pressing challenge. Evidence-based medicine is currently considered to be the best method of dealing with the described issues and the field is rapidly evolving.

Evidence-based medicine

"Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research." [1]

It should be noted here, that the common misconception that evidence-based medicine only draws on randomised controlled trials (RCTs) and considers any other evidence as invalid is outdated. There are many clinical questions that cannot be supported by evidence from RCTs and in EBM it is possible and necessary to incorporate non-randomized studies (NRS) into the decision-making process. [2] To describe this issue in more detail is outside of the scope of this article, however.

An integral part of evidence-based approach is the development of secondary research in the form of a systematic review. Organisations such as Cochrane Collaboration [3] or JBI Collaboration [4] have dedicated to improving health outcomes globally by producing research evidence related to evidence-based healthcare. Some organisations (eg. The Campbell Collaboration, [5]) include special subsections dealing with other than healthcare fields (eg. disabilities or education). Evidence-based approach may be applied to any field of human endeavour.

Systematic reviews

Systematic reviews, a form of secondary research, "aim to provide a comprehensive, unbiased synthesis of many relevant studies in a single document using rigorous and transparent methods. A systematic review aims to synthesize and summarize existing knowledge." [6] [7] One form of data analysis used in systematic reviews is called a meta-analysis. A general overview of the most commonly used steps in the process of the systematic review development is shown in Table 1.

Table 1: General steps in the formation of a systematic review (JBI, [6])

General steps in creating a systematic review according to the JBI manual [6]	Notes
Formulating a review question	Should be sufficiently detailed and use a PICO format (or modifications as applicable)
Defining inclusion and exclusion criteria	Detailed and defined ahead of the search
Locating studies through searching	Specified databases, date of search, search terms, the whole search strategy in appendix
Selecting studies for inclusion	A list of excluded studies and reasons for exclusions in appendix, detailed and transparent
Assessing the quality of studies	Using standardised assessment tools
Extracting data	Using a standardised and pre-specified data extraction tool
Analysing and synthesizing the relevant studies	Meta-analysis or other forms of analyses as applicable
Presenting and interpreting the results, potentially including a process to establish certainty in the body of evidence (through systems such as GRADE)	Transparent, describing the rationale in detail, including conflict of interest, funding and other important information

Clinical practice guidelines

Systematic reviews, then, as a body of evidence accumulated and systematically analysed to answer a specific review question, are the stepping stone for the development

of clinical practice guidelines. The process of guideline development aims to formulate specific recommendations for action and practice to end-users. [8]

"Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." [9]

Although, the paper has, so far, been focusing on the field of medicine, it must be emphasised at this point, that guidelines may concern professionals from all kinds of fields and each guideline should, ideally, clearly and in a visible space specify the end-users and state all the concerned professions and stakeholders. There are medical guidelines that, although primarily dealing with medical issues in the clinical setting, also concern, in part, special educators. Examples are presented in the paper.

It should also be mentioned here that, in the process of implementing evidence (ie. going from evidence through guideline development to practice), both individual clinical expertise and the best available external evidence needs to be considered and neither alone is enough. "Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients." [1]

Currently, the most respected organisation dealing with the methodology of guideline development is the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group. [10] The GRADE Working Group is a collaboration of various experts, mainly methodologists and clinicians. In 2000, the group proposed a system for developing recommendations, which is described in the GRADE Handbook. [11] The GRADE system has been used by an increasing number of organisations across the globe. Although the development of guidelines or sets of recommendations is not new, what is new is the systematic methodology that is being continually revised and refined and the aim to adopt a unified approach by professional organisations developing guidelines. Table 2 lists simplified general steps in the guideline development.

Table 2: *General steps in the guideline development (GRADE,* [11])

Specifying health care/clinical questions

Choosing outcomes of interest and rating their importance (e.g. mortality as an outcome may be more important in the decision-making process than minor adverse events)

Evaluating the available evidence (not based on the study design only – a more rigorous methodology needs to be used)

Considering evidence in light of values and preferences of patients and society, feasibility, cost effectiveness, equity, and other important factors

Formulating recommendations based on evidence and expert consensus, if needed

Suggesting ways of implementation into practice

2 Guideline development in the Czech Republic

Many professional medical organisations in the Czech Republic develop guidelines in one form or another. At present, however, there are no Czech organisations that use the GRADE system for developing guidelines. The methodology of developing guidelines by Czech medical organisations is not transparent. They usually only contain a general statement that the guideline was developed based on the current evidence, often without a direct link to the supporting evidence. [12–14]

There is a pressing need, therefore, to develop and implement a national strategy for developing guidelines that would reflect the latest scientific and methodological standards. The first Czech national project for developing clinical practice guidelines that was formed based on the identification of that need is currently underway and has over 40 guidelines in different stages of development (see Figure 1 for example). [15] The project's main investigator is the Czech Health Research Council (AZV ČR) and is partnered by the Ministry of Health of the Czech Republic and the Institute of Health Information and Statistics of the Czech Republic. The project guarantees a consistent level and quality of the developed guidelines, and hopes to improve the provided health services.

The project involves experts in epidemiology, biostatistics, public health, health services agencies and in the respective medical fields. It already prepared a uniform methodological approach [16] for the preparation of guidelines, education [17] and training in the guideline development and established cooperation with many professional medical organisations in the Czech Republic as well as abroad. The list of guidelines underway is available online. [18] The topics range across all medical fields, such as cardiology, neurology, oncology, many of which concern more health care professionals and in some cases also other professionals within or outside of the health care system. Some guidelines touch on public health issues such as vaccination or deal with diagnostic methods that are being used in all medical fields.

The methodology of guideline development

The purpose of the Czech clinical practice guidelines is to:

- provide recommendations and procedures for the diagnostic and therapeutic process in clinical practice when deciding on the course of action;
- ascertain priorities by Ministry of Health;
- provide basis for determining the need of equipment, medications etc.;
- enable the development of quality assessment criteria in healthcare;
- provide materials for undergraduate and postgraduate education;
- foster communication between patients and healthcare personnel and provide information for patients.









2 Léčba HCV

2.1 Detekce viremické HCV infekce a rozhodnutí o léčbě

Klinická otázka 4: Detekce viremické HCV infekce a rozhodnutí o léčbě

P (Pacient)	Osoba s prokázanou HCV infekcí
l (Intervence)	Detekce sérové HCV RNA
C (Komparace)	HCV negativní populace
O (Výstupy)	3. Prevalence HCV RNA pozitivity infekce
	v testované skupině
	4. Procentuální část infikovaných osob, u kterých
	byla zahájena protivirová léčba přímo působícími
	virostatiky (DAA).

Doporučení 4

Section (Section)	5	GRADE	
Doporacem/ Promasem	Úroveň	elis	
Při reaktivním sérologickém vyšetření anti-HCV protilátek, je doporučenou a	.0000		
preferovanou strategii ke stanovení diagnózy viremické HCV infekce vyšetření HCV	/ DAMA	£	
RNA kvantitativní nebo kvalitativní metodou detekce nukleových kyselin (NAT).	0000		
Eseje detekující HCV core (p22) antigen, které mají s NAT srovnatelnou klinickou	0000	C+	
senzitivitu, jsou alternativou NAT v indikaci diagnózy viremické HCV infekce ¹ .		-	
Legenda: 1 Metody detekce HCVcAg nejsou v ČR dostupné, metodě nebude dále věnována poz	na pozomost.		

2.1.1 Východiska pro použití detekce nukleových kyselin pro průkaz viremické HCV infekce

expozice HCV) a k rozlišení, kdo potřebuje další vyšetření (konfirmaci aktivní virové replikace) a kdo nikoliv. Přibližně 15 – 45 % osob, které jsou infikovány HCV je schopno spontánně HCV Detekce anti-HCV protilátek slouží k průkazu aktivní nebo prodělané HCV infekce (ti. Diagnóza viremické HCV infekce u osob anti-HCV pozitivních odliší osoby, které jsou aktivně infîkovány a které jsou indikovány k léčbě od osob se spontámí eliminací infekce. Tato infekci eliminovat (225). Tyto osoby jsou anti-HCV pozitivni, avšak nejsou infikovany HCV diagnostika se provádí použitím NAT technologií, které detekují HCV RNA.

2.1.1.1 Testování nukleových kyselin (NAT)

Kvantitatívní NAT se ve velké míře používaly pro hodnocení virové nálože a identifikaci osob K detekci viremické HCV infekce jsou dostupné kvantitativní a kvalitativní metody



Nairodni portal
 Projekt: Klinické doporučené postupy
 Registrační číslo: CZ 03.2.63/0.0/0.0/15_039/0008221

Figure 1: An example of a title page and a chapter containing recommendations in clinical practice guideline on the testing and treatment of hepatitis C virus infection

Časná diagnostika a léčba chronické virové Adaptované doporučené postupy: hepatitidy C

 Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection. WHO; Vydáno Ženevě v červenci 2018, dostupné na

https://www.who.int/hepatitis/publications/hepatitis-c-guidelines-2018/en/ 2. Guidelines on hepatitis B and C testing. WHO; Vydáno v Ženevě v únoru

2017, dostupné na

https://www.who.int/hepatitis/publications/guidelines-hepatitis-c-b-

testing/en/

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Verze:

Guidelines may be developed using the process of adaptation, in which the available guidelines are assessed using the AGREE II instrument [19] and the methodologically best guideline is translated and applied in the Czech Republic. Another option is the process of adolopment, which is used when an existing foreign guideline needs some changes to be applicable to the Czech healthcare. The most time-consuming and resource demanding process is developing guidelines *de novo*. It is used when there are no existing guidelines available for the given clinical question or the existing guidelines are not suitable for adaptation/adolopment.

In the GRADE system, evidence compiled by systematic reviews is assessed based on criteria for downgrading and upgrading and a final quality of evidence level is determined (see Table 3). Observational studies start with low quality of evidence and can be upgraded, if we are certain in the results. RCTs start with high quality of evidence and can be downgraded for risk of bias and other factors.

Table 3: Quality of evidence using the GRADE system

GRADE			
Quality of evidence	Symbol	Explanation	
high	ӨӨӨӨ	We are very confident that the true effect lies close to that of the estimate of the effect.	
moderate	ӨӨӨ	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.	
low	ӨӨӨӨ	Our confidence in the effect estimate is limited : The true effect may b substantially different from the estimate of the effect.	
very low	0000	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.	

Recommendations that are formulated by a wide expert panel can either be strong, if we are confident in them, or weak, if new evidence is very likely to change the recommendation (Table 4). Strong recommendations can sometimes be made based on low or even very low quality of evidence. Similarly, even high quality of evidence can lead to formulating a weak recommendation. It is *not true*, therefore, that RCTs are always of high evidence and always lead to strong recommendations.

Table 4: Strength of recommendations using the GRADE system

GRADE				
Strength of recommendation	Symbol			
Strong for an intervention 11				
Weak for an intervention	1?			
Weak against an intervention \$\frac{1}{2}\$?				
Strong against an intervention	11			

Within the Czech guideline development project, guidelines using various methodologies are adapted, and consequently transformed into the GRADE methodology. An example of a transformation table from one methodology to GRADE is provided below. (Table 5)

Table 5: Transformation of the quality of evidence according to SIGN methodology to the GRADE system

SIGN	GRADE		
Level of Evidence	Quality of evidence	Symbol	Explanation
1++	high	ӨӨӨӨ	We are very confident that the true effect lies close to that of the estimate of the effect.
2++	moderate	ӨӨӨ Ө	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substan- tially different.
2+	low	ӨӨӨӨ	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
2-			We have very little confidence in the effect estimate:
3	very low	0000	The true effect is likely to be substantially different from the estimate of effect.
4	EC	EC	Expert consensus

Using guidelines in special education

As mentioned above, some guidelines being developed by the Czech national project may concern non-healthcare professionals, i.e. special teachers, among others. Some of the guidelines that are being prepared and may be of use to special educators are guideline on Diabetes mellitus type I, on the treatment of autoimmune neuromuscular diseases and on the treatment of convulsive status epilepticus in children and adults. [18] As the project progresses, more guideline topics will be added. For quick orientations and use in practice, executive summaries (see Figure 2) will be prepared for each guideline that will serve as overviews of the most important messages and recommendations.

Moreover, it is also possible to develop guidelines using the rigor of the GRADE methodology as described above, for issues directly pertaining to the field of special education, or education in general. In the world, the practice of guideline development is slowly spreading from the fields such as medicine, clinical practice or nursing to all other fields of human endeavour. Even in fields such as education, in which there are few RCTs and many issues may only be dealt with based on qualitative evidence, it is possible and useful to create systematic reviews and develop guidelines using the GRADE system. In that process, it may be necessary to identify the

Použití inzulínové pumpy a glukózových senzorů u pacientů s diabetem léčených inzulínem

Adaptovaný doporučený postup

Diabetes Technology — Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline (2016)

Continous Glucose Monitoring: An Endocrine Society Clinical Practice Guideline

a update výše uvedených

Advances in Glucose Monitoring and Automated Insulin Delivery: Supplement to Endocrine Society Clinical Practice Guidelines (2018)

2.1.2. Doporučujeme použití otevřené kontinuální monitorace glukózy u dospělých pacientů s diabetem 1. typu s výbornou kompenzací, kteří jsou ochotní a schopní používat tyto přístroje téměř denně. (1 (⊕⊕⊕⊕)

Skulde 1898 telasta, & tv porovalia is standardini efferioritoritoria cobbini gliotariori dolariori di celerie Skulde 1898 telasta, & tv porovalia is standardini efferioria il speciali di celerie di standardi montorare gliudo, un circulta di celerie si speciali montorare gliudo, un comprenda di celerie di speciali di celerie di celeri di celerie di celerie di celerie di celerie di celerie di celerie di

Použití inzulínové pumpy a glukózových senzorů u pacientů s diabetem léčených inzulínem

Stránka 24 z 105







33.6 případu na 100 pacient/roků a 0 případů na 100 pacient/roků během 6měsíčního sledování užívatelů kontinuálního montoru po skončení studie [91]. Tyto důkazy dlouhodobého zlepšení kompenzace glykémie ukazují na výrnam schopnosti a znalosú plúvatele technologie kontinuálního minorace glukčey, na pohlou částecho, vyvetělovat stalní ji mých rodnomovaných studií teter a zladly pacienty s horší kompenza glykémie je s snaze prodasta sulkení výskytu tělké rypoglykémie [92, 93]. V evropský znadské muliteretrické radomnízované kontrolované studií zahmující dospělé pacienty s diabetem 1. typu z glykovaným hemoglobínem cást, 585 mmol/Ji nod 100 kl. jed.

2.1.2.1. Pediatrie

Pledchozi doporučené postupy ES doporučují CGM pro pediatrické pacienty s hodnotami Hab_{AL} 53 mmol/mol pro snížení rizíla hypoglydenie a pro pacienty Pabb_{AL} and Sž memol/mol, kelí pou strópnoj hodnáre plátroj téměř na demí bázi. Tyto doporučené postupy odem nebrly utčené pro děti pod 8 let. Doporučené postupy ES z roku 2011 doporučovaly občasné použití CGM pro porozumění výkyvům glykémie a/nebo změnám v inzulinovém režimu (95).

Nedávno publikovaná doporučení od Laffel et al. [96] poskytují přehled, kdy použít CGM (např. u pacientů <2 roby, internzilkovaný rezulinový režin. "Está hypopkánej syndnom enzopoznání hypopkénien, vypoda vzavánálita glykémie, populini internzilkovaný intulinivy režin. "Está hypopkánej syndnom enzopusu od souživatelní di internýní naktorivolu gykkémie, ochota opozívat číron ponzace gykámie, porozumění vlevým na kontrolu gykkémie, ochota Audoli interné programy používat číron se odenávatelní po stevitely povlátel se na systému odene od odení a dodenecení s elabetem Přístup navčený ja odětel se hodenecení s elabetem Přístup navčený ja odětel se dopetem jedenecení s elabetem Přístup navčený ja odené se ja (99). Pro dopskéh postemy je pořeba individuální přístup při volbě přístroje vhodněho pro daného pocienta, se znalostí předností a slabní alždého ze systémů.

Existují další témata ke zvákení při použití CGM u pediatrických pacientů. Situace ve škole může učiní CGM a vzdálené monitorování náročným, protoče rozliče mohou mit očekávala a přání náročnější, než zo je schopen školní systém poskynouc Erie et al. [100] zkoumal odpovědí 33 rodičů a 17 pečovatelů dětských pacientů noskich kontinuální monitor se vzdáveným monitor gene vžděveníce a pečující osoby uvedy snížené obavy a stres při použití CGM a cektové pozitivní dojem a pocit komfortu z použití přístroje.

Registrační číslo: CZ.03.2.63/0.0/0.0/15_039/0008221

Projekt: Klinické doporučené postupy

Národní portál klinických doporučených postupů Figure 2. An example of an executive summary of a Czech clinical practice guideline on the use of continuous insulin infusion therapy diabetes mellitus type I (title page and one of the pages with recommendations) challenges typical for the field of education and to suggest possible solutions and it is suggested that researchers and methodologists deal with this issue in future research, starting by performing a search of literature on the methodology of guideline development in education and special education, analysing existing guidelines and consulting with respected organisations dealing with guideline development in the fields, and concluding by forming a list of possible challenges and solutions. (See *Recommendations for future research* below.)

In the Czech Republic, moreover, a system of supportive educational measures is being preferred for education of pupils with special educational needs and it is declared that the system aims for the preference of the inclusive form of education of that group of pupils. The practical implementation of the system of inclusive education has, so far, been drawing primarily on expert opinions and experience and is lacking research evidence. It is in the interest of the Ministry of Education, Youth and Sports of the Czech Republic as well as of the university research institutions to develop guidelines for special-educational diagnostics and intervention based on rigorous methodology as described on the example of the Czech national project of guideline development in medicine. Some of the most pressing issues to be addressed by developing guidelines are:

- the identification of populations of pupils with special educational needs (according to age, type of needs and functional abilities and other characteristics) for whom other forms of education besides the full or partial inclusion should be preferred. The outcomes to be considered here are the effect of inclusive education on peer-relationships and social competencies, academic outcomes, cognitive skills, self-concept, etc.
- the identification of the most effective teaching methods that may be transferred to the socio-cultural specifics of the Czech educational environment.
- the integration of research evidence dealing with the experiences of pupils with special educational needs (and their parents, teachers and classmates) with inclusive education within the process of the national educational policies development, with emphasis on the ethical aspects of inclusion.
- the identification of the most effective strategies for fostering the transformation
 of the educational environment in light of the philosophy of inclusive education
 and their implementation in the national setting; meaning strategies related to
 policy making, transformation of the school climate, attitudes of the teaching staff
 and all learners, teaching strategies, etc.
- the identification of the risks of inclusive education (e.g. bullying, ridicule or social exclusion of pupils with special educational needs) and the formation of strategies to overcome them.

A noteworthy development in this regard is the formation of Palacky University Evidence-Based Education working team: Mentee Centre, at the Faculty of Education in Olomouc, Czech Republic, that is affiliated with the Czech National Centre for Evidence-Based Healthcare and Knowledge Translation at the Medical faculty of the Masaryk University in Brno, and is the pride owner of the status of a mentee group under the JBI Collaboration in Adelaide, Australia. The aim of the working team is to establish, in due time, the Palacký University Center for Evidence Based Education and Arts Therapies and to dedicate to the creation and implementation of a secondary research in the field of education and arts therapies. One of the partial objectives of the working team could, in time, also be the use of guideline development methodology in the field of inclusive and special education.

3 Conclusions

The article provides a brief and clear background to the evidence-based medicine concept, systematic reviews and the development of clinical practice guidelines using the GRADE system. Its main aim, however, is to suggest ways of applying clinical practice guidelines in the field of special education. It does so by introducing the first Czech national project of clinical practice guideline development with a rigorous and unified methodology based on the GRADE system and how the project is relevant to the field of special education. Special educators may find recommendations related to their field on the website of the project, although not all will be relevant. [18] Furthermore, the paper provides examples of Czech clinical practice guidelines and the methodology of their development. It also suggests to implement the GRADE system [11] into the guideline development processes in the field of education/special education and proposes ideas for future research below.

Recommendations for special educators

- to identify Czech clinical practice guidelines that are relevant to the field of special education and to use them in practice and in higher education [18].
- to become familiar with the rigor of methodology of developing guidelines using the GRADE system [11].
- to apply the GRADE system in developing guidelines in the field of special education.

Recommendations for future research

 to identify the challenges in developing guidelines in the field of special education and propose possible solutions in light of the current scientific knowledge in collaboration with the GRADE Working group – performing a search of literature, analysing existing guidelines, consulting with respected organisations and providing recommendations for guideline development in the field of education/special education.

Recommendations for policy-makers

- to develop guidelines for special-educational diagnostics and intervention based on rigorous methodology as described on the example of the Czech national project of guideline development in medicine.
- to integrate research evidence into national educational policies development process with rigorous methodology.
- to place special focus on the ethical aspects, social outcomes and all target groups' experiences, values and opinions (eg. that of pupils, their parents, teachers, assistants, classmates and others) in formulating recommendations for educational interventions and strategies.

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