Managing caries

Schwendicke, F.; Doméjean, S.; Ricketts, D; Peters, M.

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~~**Managing caries: from evidence to practice – or not?**~~

Managing Caries: the need for closing the gap between the evidence base and current practice.

Falk Schwendicke[1], Sophie Doméjean[2], David Ricketts[3], Mathilde Peters[4]

[1] Associate Professor, Department of Operative and Preventive Dentistry, Charité – Universitätsmedizin Berlin, Aßmannshauser Str. 4-6, 14199 Berlin, Germany
falk.schwendicke@charite.de

[2] Professor, Université Clermont1, UFR d'Odontologie; Centre de Recherche en Odontologie Clinique EA 4847, 2 rue de Braga, 63100 Clermont-Ferrand, France
sophie.domejean@udamail.fr

[3] Professor, Dundee Dental Hospital, Park Place, Dundee, DD1 4HR
d.n.j.ricketts@dundee.ac.uk

[4] Professor Emerita, University of Michigan, School of Dentistry, 1011 N. University D-2391, Ann Arbor, MI 48109-1078, USA
mcpete@umich.edu

Address correspondence to: Dr. Falk Schwendicke, Charité – Universitätsmedizin Berlin, Department for Operative and Preventive Dentistry, Aßmannshauser Str. 4-6, 14197 Berlin, Germany,
Phone: 0049 30 450 62556,
Fax: 0049 30 450 7562 556,
Email: falk.schwendicke@charite.de

Short title: Managing caries lesions – from evidence to practice

Abstract (1925 words)

Underpinned by a changing knowledge of the etiology of caries and its sequelae, and assisted by established and advancing dental materials, there is growing evidence supporting minimum intervention based on prevention and less invasive management of dental caries based on the principles of minimal intervention dentistry. This narrative review assesses both the evidence and the adoption of less invasive caries management strategies and describes ways how the gap between evidence and practice might be overcome.

Whilst there is increasing data supporting less invasive management of carioues lesions, these are not standard in most dental practices worldwide. Usually, clinical studies focused on efficacy as outcome, and did not take into consideration the views and priorities of other stakeholders, such as primary care dentists, educators, patients and those financing services. Involving these stakeholders into study design and demonstrating the broader advantages of new management strategies for caries might improve translation of research into practice.

In theory, clinical dentists can rely on a growing evidence in cariology regarding less invasive caries management optionsstrategies. In practice, further factors seem to impede adoption of these strategies. Future research should address these factors by involving major stakeholders and investigating their prioritized outcomes to narrow or close the evidence gap.

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Different and deeper understanding of the ubiquitous caries disease has revolutionized its traditional management in operative dentistry.[1] Rapid scientific progress in cariology, biomaterials science and tissue response have increased our knowledge about the disease process. Novel management strategies have been developed, and have led to a greater variety in treatment options and new guidelines for provision of optimal oral health care for groups and individuals.[2]

Black's principle of 'Extension for Prevention' has long guided conventional operative treatment of carioues lesions, however, the scientific advances of the last few decades has expanded our understanding of the etiology, onset and progression of caries the disease, and has led to a different view on lesion management.[3] The 21st century is marked by a radical change in philosophy towards prevention of the caries disease and less destructive, minimally invasive management of the carious lesions~~caries and~~, its sequels. Encouraged by this growing scientific insight about the process of disease, contemporary approaches, gathered together under the term 'minimum intervention or MI', take as a motto 'Prevention of Extension'.[4] This includes strategies that halt the disease process and preserve as much natural tooth structure as possible. Concurrent rapid development of adhesive materials and techniques has also contributed to advances in this area, while emerging bioactive materials may facilitate tissue repair and re-strengthening of partially disintegrated affected areas in the future. In addition, such strategies keep options open for individualized management – an important asset in view of the rapid advance of personalized medicine.~~.~~

~~Treatment~~ Management strategies for both non-cavitated and cavitated lesions therefore increasingly focus on less invasive options~~strategies~~ available, which are biologically rather than technically driven and increasingly supported by evidence. Key to this process is the professional judgment of the clinician, guided by scientific evidence. Management of non-cavitated surfaces by non- or micro-invasive means like fluoride varnishes or sealing is supported by sound evidence, while the impact on daily patient care through modified practice protocols and management is falling behind.[5-8] This raises ethical questions about clinical decision-making within our profession. Similarly, the conventional treatment of deep carious lesions is increasingly challenged, with a growing body of increasingly strong evidence supporting less invasive removal strategies for such deep lesions.[9] Yet, practical application of this evidence by our profession is lagging. Despite expanding evidence and educational efforts, the transfer of knowledge and adoption of less invasive approaches into daily practice seems to be slow.

Implementing different strategies for managing caries could lead to reduction of its biological and economic burden to society. Change, however, is difficult. Convincing traditionally-trained professionals to change their attitude, and ~~channeling~~channelling this into effective change in patient management on a daily basis, is even more difficult. Where does this leave our oral healthcare profession, so proud of becoming more and more evidence-based or, at least, evidence-informed? The jump needed to initiate actual scientific-evidenced change into clinical practice seems a route marred with invisible hurdles.

The present article narratively reviews recent evidence in support of the described less-invasive approaches toward carious lesions. In addition, it raises awareness of the incongruences between what is taught~~we teach~~, based on the constantly increasing strength of evidence, and how is done~~we act~~ in ~~our~~ daily practice. This calls for exploration of potential translational, professional and societal hurdles that impede wider adoption of less invasive strategies to manage carioues lesions~~disease~~. While striving to make oral health care economically sustainable, dealing with these issues may accelerate and impact improvement for generations to come.

The evidence: What is known

There is growing evidence supporting alternatives to the conventionally established ~~treatment~~ management ~~strategies~~ for non-cavitated or cavitated, deep carioues lesions: micro-invasive strategies~~treatment~~, i.e. sealing or infiltration of non-cavitated lesions has been investigated in numerous randomized controlled trials, which found these therapies~~reatments~~ efficacious to manage both occlusal and proximal lesions. S~~:~~ Sealing occlusal surfaces can prevent lesion progression. [10-16] F~~, and f~~or proximal surfaces, a recent meta-analysis found caries infiltration highly efficacious for arresting non-cavitated lesions compared with ~~the non invasive standard (fluoride varnish application, flossing advice) or~~ placebo ~~treatments~~ (OR [95%CI]=0.22 [0.09-0.57]; ~~total~~ events~~:~~ in infiltration group: 20/93, placebo group~~:~~ 48/93), with very limited heterogeneity ~~; heterogeneity: Thau^2=0.28, Chi^2=4.2, df=3 (Pp=0.24,~~) and inconsistency (~~-~~I^2 =29%,) between studies ~~OR [95%CI]=0.22 [0.09-0.57]).~~ [~~17~~ 10-17] Given that most studies in this field (and many other areas of dentistry) have high risk of bias and potentially suffer from bias introduced by industry sponsorship, caution is necessary when interpreting the strength of this evidence.[18,19] It can also be argued that many of the studies are carried out in secondary care, and data for effectiveness rather than efficacy remain sparse. Nevertheless, the existing studies demonstrate that alternative options for treating non-cavitated lesions are available and that these options seem to have the potential

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of managing carioues lesion without inducing the cycle of re-interventions, the sequelae of which will be discussed below in more detail.[20] It should be mentioned that the most relevant comparison – between the (invasive) standard of care and the (non- or micro-invasive) alternative interventions – was not evaluated at all for proximal lesions, and only few studies compared minimally -invasive restorations with sealing or non-invasive means for managing occlusal lesions.[12,21,22] These studies showed that sealing does arrest most lesions, and even intermittent presence of a sealant dramatically slowed down or halted the disease process.. Although sealants require re-treatments more often due to partial or total loss (i.e. repair or re-seal), caries experience is low under partially retained or missing sealants regardless of sealant retention.[23,24] Partially or formerly sealed teeth are not at a higher risk of developing caries than teeth that were never sealed.[25] Again, these findings should be evaluated in context of the lifecycle of a tooth.

Whilst the evidence is growing for the non-invasive and micro- –invasive management of non-cavitated lesions, the evidence for when to 'treat' a lesion operatively, remove carioues tissues and place a restoration (i.e. the restorative threshold) is much less clear. This lack of evidence may explain the great variation in restorative treatment plans between dentists, which in turn could have significant financial impact.[7,26,27] Contemporary restorative thresholds for proximal lesions and occlusal lesions are likely to differ because of their unique anatomical differences. Non-cavitated proximal lesions should be treated preventively (non-operativelyi.e. non- or micro-invasively), as the caries process is mainly confined to the biofilm on the surface of the tooth, where lesion activity can be influenced positively by disrupting the biofilm in the presence of fluoride through oral hygiene procedures. Whilst bacteria have been reported in the enamel of non-cavitated smooth surface lesions, their numbers are low and unlikely to sustain lesion progression alone, and their presence does not appear to affect the ability to arrest the lesion.[28]

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Once cavitation has occurred on the proximal surface, significant bacterial invasion of tooth tissues occurs and operative intervention is indicated. However, establishing whether such a lesion is cavitated or not, is difficult from a clinical examination, as the marginal ridge remains intact until a late stage in the disease process, and the adjacent tooth makes direct visualization difficult. As such, the radiographic appearance is heavily relied upon in deciding a restorative threshold for proximal carious lesionses despite the fact that it is not a reliable predictor of cavitation: numerous studies have shown that only approximately 25% of lesions radiographically confined to enamel and up to the EDJ dentine-enamel junction (DEJ) are cavitated.[29] Such lesions should be radiographically monitored over time to assess if there is

lesion progression; alternatively, orthodontic tooth separation might be performed to allow visual inspection of the proximal surface.

Due to the anatomy of pits and fissures, and the fact that the initial carioues lesions occur bilaterally on the walls spreading into dentine on a wide advancing front, occlusal lesions are extensive (into the pulpal third of dentine) before frank cavitation occurs.[30] Unlike for proximal surfaces, heavy bacterial infection of the tooth tissues occurs prior to cavitation, and interventions are required before the lesion is cavitated. In two clinical studies it has been shown that detection of an obvious occlusal radiolucency on bitewing radiograph is the best predictor of heavily infected dentine; such lesions histologically would extend into the middle third of dentine or deeper.[31-33]

Historically, during cavity preparation complete caries removal was advocated. However, Fusayama and co-workers described two layers of carious dentine, the outer or infected zone and the inner, caries affected zone at the advancing front of the lesion. These two zones could be differentiated by various dyes and contemporary caries removal would only aim to remove carioues dentine from the outer zone. In deeper lesions there is a balance between the rate of caries progression and the ability of the pulp dentine complex reactions to protect itself.[34] More aggressive, "complete" carioues tissue removal in such cases where adequate pulp dentine complex reactions have not occurred runs the risk of pulpal exposure.[35,36] Teeth with exposed pulps are then usually treated with a direct pulp cap using calcium hydroxide.[37] Whilst the success rate of this form of treatment is good after three years for traumatically exposed teeth (92%) the outcome after a carious exposure is poor (33%), with success rates at 10 year only reaching 13%.[38,39] Avoidance of a carious exposure in an asymptomatic vital tooth is therefore of paramount importance. A recent systematic Cochrane review reported about the different approaches toward deep caries management strategies: ultra-conservative caries removal or , which is why a radical caries tissue removal has been questioned in five types of studies:

- three where no dentine has been removaled (, namely fissure sealant sstudies, ultra-conservative caries removal studies and studies on the Hall technique),, and
- two where carioues tissues removal has been removed in stages (stepwise excavation), andor where selective (partial) carioues tissue removal (definitive restoration placement has been selective (partial) and the tooth restored definitively with no re-entry); iIt included.

These techniques have been the subject of a systematic Cochrane review where they have been investigated in randomized controlled trials with complete caries removal as the control.[9] The most dramatic results from this systematic review pertained to the outcome of

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pulpal exposure. ~~If we look first at the~~Considering first the stepwise excavation studies, it appears that~~:~~ carioues tissue removal using this technique led to an overall 56% reduction in risk of pulpal exposure compared to complete ~~caries~~ removal (69% reduction in risk for primary teeth and 49% in permanent teeth). When selective carioues tissue removal was performed (i.e. a different excavation criterion used in the periphery than in pulpal areas), and the teeth restored definitively afterwards, there was a 77% reduction in risk of pulpal exposure compared to "complete" (non-selective) carioues tissue removal (pooled data for primary and permanent teeth). None of the included studies reported problems in relation to pulpal pathology or restoration retention when more conservative methods of excavation were adopted. Indeed in primary teeth, one study showed a significant reduction in risk of restoration failure in the Hall crown group compared to the conventional carioues tissue removal and restoration control group, this mainly being due to the inherent structural and retentive nature of a preformed crown. In summary and given the compiled clinical data as well as a wealth of non-randomized clinical trials, the strength of evidence for less invasive methods for caries management is rapidly gaining weight.[9,40]

The evidence: What is done

As describe previously, the evidence underlying the evolution of caries management strategies from invasive restorative dentistry to the concept of ~~minimal interventional dentistry MI~~minimum intervention based on prevention and treatment using the least invasive of approaches (minimally invasive dentistry or MID) are now well embedded in the literature. Questionnaire surveys are a useful and practical tool to find out if the emerging changes in caries management and its underlying evidence have been implemented in everyday clinical practice. There is some criticism however that there might be little correlation between dentists' stated treatment intentions, as reported in questionnaire surveys, and the actual treatment provided in routine practice. Nevertheless, even if questionnaire surveys are not able to perfectly evaluate dentists' actual clinical decisions, they still provide a good reflection of their treatment philosophies and knowledge.

Restorative threshold is the most common topic of investigation in cariology using questionnaire administration. When dentists were surveyed in 1990, 20-44% of respondents reported that they would restore a proximal lesion radiographically confined to enamel depending on the patients' age.[41] This rose to 39% and 70% for scenarios for 30- and 12-year old patients, respectively, when the lesion reached the DEJ~~enamel dentine junction~~. Disappointingly, this has not changed in the last 20 years, with 39-66% of dentists surveyed

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in 2009 reporting that they would restore proximal lesions radiographically confined to enamel depending on the patients' caries risk status despite the fact that few would be cavitated.[8]

Questionnaire studies have been undertaken worldwide: Brazil, Colombia, Croatia, France, Iran, Israel, Japan, Kuwait, Norway, Scandinavia, USA, Scandinavia; the results of all these surveys highlight both the large variability among dental practitioners within and between countries, and the gap between the theory of MIDminimal invasive dentistry and everyday clinical practice.[7,8,42-54] For example, a French survey undertaken in 2002 showed that almost 50% of respondents would restored an occlusal lesion confined to enamel in patients with low caries risk.[45] Espelid et al. showed in 1995 and 1996 that 30% of Scandinavian dentists would undertake chose restorative treatment options for lesions radiographically confined to enamel.[53]

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Whilst support for micro-invasive treatment, i.e. sealing, instead of restorative management of non-cavitated occlusal lesions is growing, dental practitioners remain reluctant to adopt such practices.÷ Spanish data found 48% of the respondents to avoid sealants because they fear to seal carious enamel.[55,56] Only 22% agreed that "sealants, besides being a preventive method, can also have a restorative effect and can be used on incipient carioues lesions". This result clearly showed that, despite two decades of accumulated evidence, the concept of therapeutic sealants have not been adopted in clinical routine.[5,57]

The domain of deep caries management has also been investigated in various parts of the globe; four articles describe the attitude of samples of American (n=85), German (n=821), Brazilian (n=54) and Norwegian practitioners (n=222).[58-61] Although the surveyed samples were not fully representative, they gave useful insights into daily management of deep lesions in teeth with asymptomatic pulps. Complete dentine excavation was still considered the standard of care by 70%, 50% and 49% of the Brazilian, German and Norwegian respondents, and only 25%, 23% and 12% of the respective practitioners elected selective (partial) excavation. The German survey further inquired why dentists chose to perform a certain therapy: oOver 70% of the respondents agreed that "cariogenic microorganisms need to be removed completely, since caries might progress otherwise", and that "carioues tissue should always be removed completely, since residual caries is a risk for the vitality of the pulp". Vice versa, only 26% thought that leaving carious dentin in proximity of the pulp might be useful to avoid pulp exposure.[59]

In conclusion, available evidence has only incompletely translated into clinical practice. Since much dental treatment is irreversible, patients risk needless or inappropriate

interventions, with potentially adverse health and economic consequences.[62] The results of most surveys clearly demonstrate that it takes time for changes in fundamental philosophies to filter through to everyday clinical practice.[63] Underlying reasons why this path is steep and progress slow are not fully understood, but the discussed data indicate that both lack of knowledge and reluctance to adopt new strategies combined with doubts towards data gained in "artificial" research settings might be part of the problem. Further reasons for the described gaps in evidence implementation are likely, and are explored below before comprehensively discussing how to narrow or close these gaps.

Gaps in evidence translation

Whilst one goal of evidence-informed~~based~~ dentistry certainly is the generation of evidence itself – first via (pre-) clinical research, then via evidence synthesis (systematic reviews, meta-analyses) – the real benefit of an evidence-inform~~bas~~ed approach only emanates after implementing this theoretical evidence into practice.[64-66] In medical science, this "evidence translation" is usually slowed or stopped by two problems, each causing an "evidence gap".[67] First, a basic scientific idea, which was shown to be efficacious, requires an applicable method, which practitioners can handle (i.e. a dental material or device). Second, the then available method needs to disseminate into general practice, i.e. it has to be used, which requires practitioners to alter their diagnostic or treatment scripts.[68] For both examples used within this paper, the first evidence gap was closed or not present at all: resin sealeants have been available for decades, and resin infiltration can be performed using a commercially available kit, which was found safe and applicable.[69] Less aggressive excavation does not require any new method or device at all, and can probably easily be adopted regardless of the setting. Thus, translation seems to be impeded by the second evidence gap only.

One main reason why there may be a particular hurdle to evidence translation at this stage is that it is beyond the reach of those with direct interest or motives (researchers, patent-holders, industry), as several other decision-makers are involved. It is important to address outcomes relevant to all of these stakeholders, and these outcomes are not necessarily congruent with those usually generated by clinical trials. Definition and validation of these outcomes as well as applicable methods to control these outcomes should be sought before further engaging into further (research) projects at this level of evidence translation: b~~B~~elow we discuss some examples of such outcomes.

Change

The process of change is obviously facilitated through the practicing dentist. Watt et al in 2004 and Banerjee, more recently in 2013, reported about the~~investigated~~ the barriers and facilitators to change in dental practices among UK dental practitioners.[70,71] C~~They showed that c~~hanges in behavior of dentists are influenced by a range of factors:

1. Practitioners need to be equipped with the appropriate knowledge and skills to enable them to implement desired change. Future interventions, however, should target not only knowledge and skills, but norms, attitudes and beliefs using a theory-grounded framework based on an understanding of the psychological barriers impeding change.[72~~1~~,73~~2~~]
2. Remuneration systems need to reduce the perceived financial risks associated with change.
3. Further facilitators include regular patient attendance, loyal staff, regular training and staff meetings, open communication and access to peer support. The latter, peer support, was confirmed as a positive factor, with lateral knowledge transfer in small networks of dental practitioners being more important than vertically transported knowledge, i.e. via guidelines or academic advice.[74~~3~~]

The dissemination of ~~evidence based~~appropriate diagnostic and treatment concepts needs improvement at both pre-and post-graduate educational levels.[70,75~~4~~,76~~5~~] Education of the teaching faculty (‘teaching the teachers’) should receive greater emphasis, as the variability shown among practitioners also exist among educators.[77~~6~~,78~~7~~] Harmonization of dental curricula, evidence-based teaching, and the use of standardized criteria for caries detection, diagnosis, treatment decisions and treatment performance should be established and implemented in student clinics. In this sense, teaching efforts in cariology and operative dentistry in North America, South America, Europe and Japan should aim at aligning and reducing existing variations in terms of quality of content or quantity of hours. Existing efforts towards a core curriculum for cariology or operative dentistry are thus helpful.[79~~8~~,~~9~~82]

As described, third-party payers and the political framework should not be neglected in the discussion, since they set the tone regarding remuneration and the regulatory environment of clinical dentistry, for example via definition of standard treatment pathways or reimbursement rules.[84~~3~~,85~~4~~] This external framework certainly shapes the decision making of both dentists and patients. In this sense, remuneration incentives potentially distort the relationship between clinical needs, individual demands, and the provided treatment. In France, for example, dentists are paid per item of treatment provided, with only certain treatments being approved by insurers. Restorative treatments are listed, whilst prevention

and non-invasive care are not eligible for reimbursement. The importance of incentives has also been demonstrated for the implementation of preventive fissure sealing programs into practice or the provision of regular dental check-ups.[865,876]

Consequently, payers or political stakeholders should be involved when change is attempted. For them, clinical efficacy – as demonstrated by short- or medium-term RCTs – might be of limited value: They focus on the political opportunity of decisions, which is often greatly affected by (financial) costs.[843,854] These are then balanced against the long-term benefits of changing the *status quo*. Costs and health distributional effects (health equity) are often also used to justify decisions.[843,854] The demonstration of cost-effectiveness and long-term sequels emanating from changing current approaches regarding caries treatment is needed to address these stakeholders. Moreover, new caries detection and treatment aids need to be evaluated not only regarding their absolute cost-effectiveness but also their distributional effects of costs and health between populations.[887,898] Changing the current approach of treating proximal caries lesions was shown to have great potential for both long-term cost-savings and increased health effectiveness (longer tooth retention) compared with the invasive standard of care.[890] For treating deep caries lesions, a cost-effectiveness analysis demonstrated that the initial treatment of the lesion (which is assumed to be daily routine in many practices!) has great impact on both the long-term costs (which are mainly driven by re-treatments like root-canal treatment) and the retention of the tooth (which is compromised by early follow-up treatments, for example after pulpal exposure).[910] Selective excavation was found to retain teeth for a mean of 4 years (8%) longer than complete excavation at significantly (mean 33%) lower lifetime costs. Given that deep lesions are also frequently concentrated in only few individuals, it is likely that changing the approach towards treatment of deep lesions will be beneficial especially in those with highest needs.[921] In this sense, change might also have beneficial effects with regards to health equity.[932]

Lastly, those stakeholders often called the “experts”, i.e. researchers, have to acknowledge that clinical trials should not only focus on what they themselves deem important (tooth retention, restoration survival): Instead, trial outcomes should include what is important to all stakeholders, and the conduct of trials and their reporting need to adhere to specific standards in order to generate evidence that is substantial and comparable.[943] In this sense, clinical research needs to be more aware of why it is performed, and needs to be more accountable to those who pay for it and expect a certain (mediate) benefit from it.

Research addressing the many different aspects of caries management has come a long way and gets stronger each day. Evolving understanding of biological aspects of the disease

process with concurrent increased availability of applicable materials and techniques have given our profession the knowledge and tools for leading the change towards improved contemporary caries management. To promote this change, however, we should not solely rely on substantial evidence provided by clinical trials, even when increasingly supported by practice-based research. To close the evidence gap and achieve wider adoption by the profession and increased implementation in everyday dental practice the other stakeholders in daily dental care should also be involved and related issues addressed to accelerate the pace of adoption. Other than having a single focus on producing clinical scientific evidence alone, future clinical trials should be designed to include other stakeholder-related questions as well, and by doing so increase the usability of their outcomes: societal limitations such as remuneration, or liability may hamper implementation more than the lack of scientific evidence. The same applies to dissemination of new knowledge and evidence via alternative professional circuits instead of more conventional education pathways.

Moreover it may be hypothesized that, from a patient point of view, less aggressive interventions and ultimately preservation of teeth may fulfil patient expectation and may be associated with patients satisfaction and improvement of their quality of life. Unfortunately very little is known in terms of patient demand toward caries management. Indeed, most of the studies aim to assess patient satisfaction related to various specific clinical procedures or clinical devices e.g. Hall technique, atraumatic restorative treatment, rubber dam, laser, chem~~i~~omechanical excavation. [95,99] Cariology research should not only focus on techniques but also address patient expectations and patient-cent~~i~~ered quality metrics including patient-reported outcome measures like patients' satisfaction with dental health status. [100]

In conclusion, convincing long-term evidences related to clinical procedures and patient expectation are~~is~~ needed that encompasse~~s~~ all aspects that influence the daily clinical decision-making at the chairside. In addition, the data gained needs to be provided in such a way that the outcomes are relevant to lay people and society in general. Such clinical trials, putting the practical boundaries of applied procedures in wider perspective, could produce outcomes more relevant for advancing adoption and in the end have a greater impact on achieving change in the actual daily patient care. To accomplish the adoption of this change in MI clinical practice, the process may profit from combined trials that also take other stakeholder's issues into account, facilitating a faster, more coherent and sustained change.

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