



UMEÅ UNIVERSITY

# Recognition of Temporomandibular Disorders

Validity and outcome of three  
screening questions (3Q/TMD)

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**Nationella kliniska forskarskolan i odontologi**

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*To my family – Happily ever after!*



# Table of Contents

|  |             |
|--|-------------|
| <b>Abbreviations and definitions</b>                             | <b>iii</b>  |
| <b>Abstract</b>  | <b>iv</b>   |
| <b>Sammanfattning på svenska</b>                                 | <b>vi</b>   |
| <b>Thesis at a glance</b>  | <b>viii</b> |
| <b>Original papers</b>   | <b>x</b>    |
| <b>Introduction</b>  | <b>1</b>    |
| Epidemiology   | 1           |
| Temporomandibular disorders (TMD)                                | 2           |
| Pain, chronic pain and related psychosocial factors              | 2           |
| TMD in the population  | 3           |
| Treatment need and decision making                               | 5           |
| Diagnostic accuracy  | 5           |
| Diagnostic methods for TMD                                       | 7           |
| Diagnostic Criteria for TMD (DC/TMD)                             | 7           |
| Screening methods  | 8           |
| 3Q/TMD – three screening questions for the recognition of TMD    | 9           |
| Rationale for this thesis  | 10          |
| <b>Objective</b>   | <b>11</b>   |
| Specific aims  | 11          |
| <b>Study-populations and methods</b>                             | <b>12</b>   |
| Index test, 3Q/TMD   | 12          |
| Prevalence of affirmative answers to the 3Q/TMD (Paper I)        | 14          |
| Validity studies of the 3Q/TMD (Paper II and IV)                 | 14          |
| Validity of the 3Q/TMD in the general population (Paper II)      | 14          |
| Validity of the 3Q/TMD in a specialist patient sample (Paper IV) | 15          |
| The outcome of 3Q/TMD on clinical decision-making (Paper III)    | 18          |
| <b>Results</b>   | <b>20</b>   |
| Prevalence of self-reported symptoms indicative of TMD (Paper I) | 20          |
| Criterion validity of the 3Q/TMD (Papers II and IV)              | 23          |
| Outcome of 3Q/TMD on clinical decision making (Paper III)        | 30          |
| <b>Discussion</b>  | <b>32</b>   |
| Prevalence of affirmative answers to the 3Q/TMD                  | 33          |
| Criterion validity of the 3Q/TMD                                 | 34          |
| Clinical decision making   | 38          |
| 3Q/TMD, prescribed treatment and treatment need                  | 39          |
| Methodological considerations                                    | 42          |
| Future directions  | 45          |
| <b>Main findings</b>   | <b>46</b>   |
| <b>Conclusions</b>   | <b>47</b>   |

|                         |           |
|-------------------------|-----------|
| <b>Acknowledgements</b> | <b>48</b> |
| <b>Amendments</b>       | <b>50</b> |
| <b>References</b>       | <b>51</b> |

# Abbreviations and definitions

|             |  |
|-------------|--|
| CPI         | Characteristic pain intensity  |
| DC/TMD      | Diagnostic Criteria for Temporomandibular Disorders.   |
| EBM         | Evidence-based medicine  |
| GCPS        | Graded Chronic Pain scale  |
| Index test  | Test or method evaluated in relation to a reference standard   |
| JFLS-20     | Jaw functional limitation scale  |
| NPV         | Negative predictive value  |
| NRS         | Numerical rating scale   |
| PDHS        | Public Dental Health Services  |
| PPV         | Positive predictive value  |
| Prevalence  | The proportion of individuals in a defined population, with a condition, at a set time-point   |
| Sensitivity | The ability of a test to correctly identify people with the target condition, 'the true positive'  |
| Specificity | The ability of a test to correctly identify people without the target condition, 'the true negative'                                     |
| TMD         | Temporomandibular Disorders. Umbrella term covering pain or dysfunction involving the masticatory muscles or the temporomandibular joint |
| TMJ         | Temporomandibular joint  |
| 3Q/TMD      | Three screening questions on jaw-face-temple pain and/or dysfunction with a frequency of once a week or more                             |
| 3Q-positive | Study participant with at least one affirmative answer to any of the 3Q/TMD  |
| 3Q-negative | Study participant with all three negative answers to the 3Q/TMD  |

# Abstract

## Background

Pain and dysfunction in the temporomandibular region (Temporomandibular Disorders, TMD) are common conditions in the general population with an estimated treatment need of 5-15% in the general population. However, in Sweden, traceable performed treatments are significantly lower. The reasons for this indicated under-treatment are not known. To easily detect patients with a potential TMD related condition, three screening questions, 3Q/TMD, have been introduced. The aim with this project was to evaluate the validity and outcome of the 3Q/TMD with the objective to recognize individuals with TMD and potential treatment need in the Public Dental Health service (PDHS).

## Methods

The thesis is based on four study samples; three from the PDHS in the county of Västerbotten, Sweden and one sample from the specialized orofacial pain clinic at the Academic Centre for Dentistry, ACTA, Amsterdam, the Netherlands. The bases for all studies are individuals' answers to the 3Q/TMD and quantitative approaches were used in the analyses. The prevalence of affirmative answers was evaluated in a large cross-sectional study over the lifespan. The validity of the 3Q/TMD in relation to the Diagnostic Criteria for TMD (DC/TMD) as reference standard was established in two case-control studies. The outcome of the 3Q/TMD on TMD treatment within general practice was evaluated in a cohort study.

## Results

Affirmative answers to the 3Q/TMD increased during adolescence. Women answered affirmatively to the 3Q/TMD significantly more often compared to men for all age groups except for the first and last parts of a one hundred-year lifespan. The highest prevalence was reported by women during their fertile period in life. In a general population sample, 74% of individuals with an affirmative answer qualified for a DC/TMD pain or dysfunctional diagnosis, as compared to 64% in a specialist patient sample. In the general population sample, for the individual 3Q/TMD questions, as well as combinations of questions, the negative predictive values were high (0.92-0.99). For the specialist sample, when at least one question was answered affirmatively the negative predictive value was high (0.90). The positive predictive value was high (0.89) when all three questions were positive. There was significantly more treatment performed or recommended for 3Q-positives (21.5%)

compared to 3Q-negatives (2.2%) ( $P < 0.001$ ). The odds ratio for TMD-related treatment for 3Q-positives versus 3Q-negatives was 12.1 (95% CI: 6.3-23.4).

## **Conclusion**

The 3Q/TMD is a convenient and valid tool to recognize individuals who would benefit from a further TMD examination within an adult, general population. Within specialized orofacial pain clinics, the questions are useful as guidance for further diagnostics. Although the 3Q/TMD was a factor related to TMD treatment, the majority of individuals with self-reported symptoms of TMD still did not receive traceable assessment or treatment. Factors associated with dentists' clinical decision-making in relation to TMD warrants further research. The utilization of the 3Q/TMD as a part of a decision tree for the clinician can improve the health care for patients with TMD and is therefore recommended within dentistry.

**Keywords:** Temporomandibular disorders, orofacial pain, screening methods, diagnostic accuracy, public health

# Sammanfattning på svenska

## Bakgrund

Smärta och funktionsstörningar i käksystemet (TMD) är vanligt förekommande och de flesta av dessa patienter kan behandlas framgångsrikt i tandvården. Tidigare studier har visat att det kan finnas en skillnad mellan det skattade vårdbehovet och utförd behandling för patienter med TMD i tandvården. Anledningen till detta är inte känt och har identifierats som en kunskapslucka av Socialstyrelsen. Den vanligaste orsaken till akut smärta i ansiktsregion är tandvärk medan kronisk smärta oftast är relaterat till smärttillstånd i muskulatur och käkled (TMD). Att leva med smärta har en negativ påverkan på livskvaliteten oavsett om smärtan är orsakad av tandvärk eller TMD. Kvinnor uppger symtom på TMD ungefär två gånger så ofta som män och förekomsten är som högst bland kvinnor i arbetsför ålder. Smärtan är ofta relaterad till stress och långvarig smärta ökar risken för såväl spridning till andra lokaliseringar som till sömnbesvär och nedstämdhet. Tidig intervention har visat sig betydelsefull för att minska risken för negativa konsekvenser relaterat till kroniska besvär. Sammantaget visar detta på vikten av ett system inom tandvården för att tidigt identifiera patienter som är i möjligt behov av fördjupad utredning och eventuellt behandling. Därför har tre screeningfrågor för TMD, 3Q/TMD införts inom tandvården. I Folk tandvården i Västerbotten infördes frågorna i maj 2010 som en obligatorisk del av den digitala hälsodeklarationen för samtliga patienter.

## Syfte

Syftet med avhandlingen har varit att synliggöra patienter med smärta och käkfunktionsstörning i befolkningen och att därmed förbättra omhändertagandet av patienter med TMD inom Folk tandvården. De specifika målen var att:

- i) beskriva förekomst av frekvent smärta och dysfunktion i ansikte, käke och käkled för män och kvinnor för olika åldersgrupper baserat på tre screeningfrågor
- ii) bedöma de tre screeningfrågornas validitet i förhållande till en diagnos enligt Diagnostic Criteria for TMD, DC/TMD i två olika populationer
- iii) utvärdera utfallet av 3Q/TMD på klinisk beslutsprocess inom Folk tandvården i Västerbotten, Sverige.

## Studiepopulation och metod

Avhandlingen baserades på fyra olika urval av patientpopulationer, tre från Folk tandvården i Västerbotten, Sverige och en från Specialistkliniken från

Academish Centrum Tandheelkunde Amsterdam, ACTA, Amsterdam, Nederländerna. Underlaget för samtliga studier var baserade på individuella svar på de tre screeningfrågorna. Förekomsten av de som svarat ja på någon av frågorna utvärderades i en tvärsnittsstudie bland nästan 140 000 individer och över ett helt livsspann. Validiteten för 3Q/TMD i relation till en diagnos enligt DC/TMD utvärderades i två fall-kontroll studier. Först undersöktes en studiepopulation från Folk tandvården i Västerbotten, Sverige för att representera allmän befolkningen. Därefter utvärderades screeningfrågorna bland de patienter som remitterats till en specialistklinik i Amsterdam, Nederländerna på grund av TMD relaterade besvär. Dessa representerar remitterade patienter. Utfallet av 3Q/TMD på TMD behandling i Folk tandvården utvärderades i en prospektiv kohort studie.

## Resultat

Förekomsten av de som svarat ja på någon av frågorna ökar under tonåren. Kvinnor svarar ja på någon av frågorna signifikant oftare än män i alla åldrar, utom i början och slutet av livsspannet. Den högsta prevalensen noterades för kvinnor i fertil ålder. I allmänbefolkningen kvalificerar 74% av de som svarat ja på någon av frågorna även för en DC/TMD diagnos. Motsvarande siffra för urvalet från specialistkliniken var 64%. I urvalet från allmänbefolkningen var det negativa prediktiva värdet högt för såväl alla enskilda frågor som för kombinationer av frågor (0.92-0.99). Bland de remitterade patienterna, var negativt prediktivt värde högt när individen svarade ja på minst en fråga (0.90). Positivt prediktivt värde var högt när individen svarat ja på alla tre frågorna (0.89). Behandling hade utförts eller rekommenderats signifikant oftare till de som svarat ja på någon av frågorna (21.5%) jämfört med de som svarat nej på alla tre frågor (2.2%) ( $P < 0.001$ ). Odds ratio för TMD behandling för 3Q-positiva jämfört med 3Q-negativa var 12.1 (95% CI:6.3-23.4).

## Slutsats

Sammanfattningsvis visar resultaten att en betydande andel av befolkningen, framför allt kvinnor i arbetsför ålder, har smärta och/eller funktionsstörningar i käksystemet. Frågorna är lämpliga för att screena patienter i behov av en fördjupad utredning. De som svarat nej kommer med stor sannolikhet inte att kvalificera för en diagnos enligt DC/TMD. Bland remitterade patienter kommer majoriteten att svara ja på någon av frågorna. I allmäntandvården får två tredjedelar av det som svarat ja på minst en fråga, inte ett synliggjort omhändertagande baserat på vad som är angivet i deras tandvårdsjournal. Detta kan tyda på brister bland allmäntandläkare och tandhygienister i kliniskt beslutsfattande för patienter med TMD.

# THESIS AT A GLANCE

140 3Q-positives  
160 3Q-negatives

## ANSWER

**3/4** any DC/TMD diagnosis  
3Q-negative probably no TMD

Validity?

## QUESTION II

DC/TMD EXAMINATION?

**5%** 3Q-positive women/men 2:1

## ANSWER

WHO HAS TMD?

3Q/TMD for screening frequent orofacial pain/dysfunction

PDHS Almost **140,000** individuals

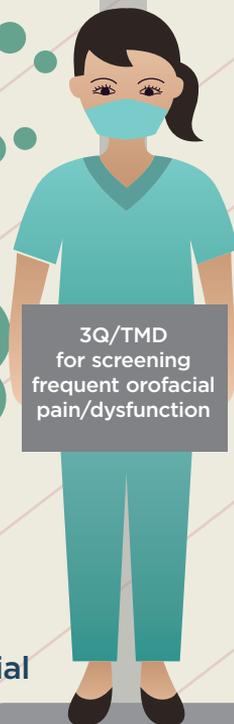
3Q/TMD for screening frequent orofacial pain/dysfunction

## QUESTION I

Prevalence?

TMD IS THE MOST COMMON CHRONIC ORO-FACIAL PAIN CONDITION IN GENERAL POPULATION

Västerbotten, Sweden





Outcome?

QUESTION III

300 3Q-positives  
500 3Q-negatives



ANSWER

**2/3**

of 3Q-positives  
no documented  
management

treatment in 3Q-positives  
ten times 3Q-negatives

TMD TREATMENT IN  
PUBLIC DENTAL  
HEALTH SERVICES  
(PDHS)?

THIS PATIENT  
NEEDS SPECIALIST  
CARE- I'LL REFER!

**64%**

any DC/TMD  
diagnosis

3Q-positives probably TMD

ANSWER

Referred patients have a variety  
of complex pain conditions

ACTA  
Amsterdam  
Netherlands



449 patients  
DC/TMD examination

370 3Q-positives  
79 3Q-negatives



ANSWER

Validity?

QUESTION IV



# Original papers

This thesis is based on the following original papers, which will be referred to in the text by their Roman numerals:

- I Lövgren A, Häggman-Henrikson B, Visscher CM, Lobbezoo F, Marklund S, Wänman A. Temporomandibular pain and jaw dysfunction at different ages covering the lifespan - A population based study. *European Journal of Pain*, 2016;20(4):532-40.
- II Lövgren A, Visscher CM, Häggman-Henrikson B, Lobbezoo F, Marklund S, Wänman A. Validity of three screening questions (3Q/TMD) in relation to the DC/TMD. *Journal of Oral Rehabilitation*, 2016;43(10):729-36.
- III Lövgren A, Marklund S, Visscher CM, Lobbezoo F, Häggman-Henrikson B, Wänman A. The outcome of three screening question (3Q/TMD) on clinical decision-making. *Journal of Oral Rehabilitation*, 2017 (In press).
- IV Lövgren A, Parvaneh H, Lobbezoo F, Häggman-Henrikson B, Wänman A, Visscher CM. Validity of three screening questions (3Q/TMD) in relation to the DC/TMD in a specialized orofacial pain setting. Submitted.

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# Introduction

From a patient's perspective it is easy to imagine that living with chronic orofacial pain and impairment of normal jaw function hampers daily living and impairs perceived health. From the clinician's point of view, it is just as easily imagined that an easy and robust routine could be helpful for the dentists in their clinical decision-making processes. The starting point for this thesis was to investigate if three screening questions related to frequent jaw pain and dysfunction could serve as a convenient tool to both detect individuals with a potential treatment need and as a reasonable guide in clinical decisions in dentistry. The intention of the thesis was to contribute with scientific support to a possible improvement of dental care guidelines for management of patients with such symptoms.

## Epidemiology

Epidemiology has been defined as 'the study of the distribution and determinants of health-related states or events' by the World Health Organization, (WHO) (1). Various methods can be used to address separate parts of epidemiological investigations, and these scientific methods form a basis for prevention and disease control. Incidence is the proportion of new onset of a condition within a defined time-frame, and is often reported on an annual basis. The incidence together with the duration will determine the prevalence of a condition. The prevalence is defined as the proportion of individuals with a condition in a defined population at a given time-point (2). The prevalence of a condition is directly related to the pre-defined criteria such as included signs and symptoms, their frequency and intensity. A longer duration will result in accumulation of occurrence, and thus a higher prevalence. The prevalence of a condition at a set time-point or period can be captured with a cross-sectional approach. However, there are many other benefits with epidemiological studies, and different areas have been defined by Morris (3). From a clinical perspective the prediction of individuals at risk, information on causes, and expectations on progress are all useful and important information that can be gained from population-based observational studies. Despite these benefits with observational studies, it is often not possible to conclude causal effects. In order to determine whether an association or causal relationship between exposure and outcome exists the Bradford Hills criteria can be used (4). These criteria define matters of importance when establishing causal effects such as strength, consistency, temporality and biological gradient. A more recent approach advocates the use of Hill's criteria as guide, but also to regard potential confounders and bias (5). Case-control study design is a suitable method to evaluate associations in

samples. In a case-control study the main goal is, with a representative study population, to reveal different outcomes due to exposure (2). This thesis focuses on associations of different factors in adult individuals with possible Temporomandibular disorders, TMD.

## **Temporomandibular disorders (TMD)**

The masticatory system includes the upper and lower jaw, jaw muscles, the temporomandibular joint (TMJ), the tongue, teeth, mimic muscles, and several cranial nerves. Even the cervical structures are involved in normal jaw function (6). The function of the masticatory system is closely related to both survival and social interaction. The importance of the masticatory system is also expressed in the definition of oral health as ‘oral health is multi-faceted and includes the ability to speak, smile, smell, taste, touch, chew, swallow and convey a range of emotions through facial expressions with confidence and without pain, discomfort and disease of the craniofacial complex’ (7).

TMD is the collective term used to describe musculoskeletal disorders in the jaw muscles, the TMJ or surrounding tissues (8). The term TMD was originally adopted by the American Dental Association in 1983 in an attempt to coordinate research efforts with a uniformed terminology (9). Symptoms indicative of TMD can be pain during jaw movements, impaired jaw movements, and joint sounds (8).

## **Pain, chronic pain and related psychosocial factors**

Pain is defined ‘an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage’ by the International Association for the Study of Pain, IASP (10). The emotional part of the pain sensation is described as a multifactorial experience including sensory, emotional, motivational, and cognitive dimensions (11). These aspects are all included in the biopsychosocial model of pain as advocated by Engel in the 1970s and are still relevant today (12, 13). A revision of the definition of pain has been proposed to underline the stressful component and to embrace the social aspects (14).

The acute or protective pain sensation can cause withdrawal reflexes, and thereby prevent potential tissue damage. When the pain continues for a longer period, and even after the damaged tissue has healed, it is referred to as non-protective pain. Persistent pain longer than three to six months, is regarded as chronic or long-standing pain (11, 15). Chronic pain can also be divided into local, regional and generalised/widespread, and may require different

treatment strategies (16). Chronic pain poses a negative impact on both the social life and the working life (17).

Chronic, moderate to severe pain is common and affects about 20% of the adult population in Europe (17). The transition from an acute into a chronic pain condition are not fully understood but may in part be related to several factors such as emotional stress, sleep disturbances, and depression, even though direct causal associations have not been revealed (8). A strong predictor for chronic back pain is previous chronic pain (18). Among individuals with musculoskeletal pain fear-avoidance beliefs, catastrophizing and distress were related to future sick-leave and impairment (19). It has also been suggested that chronic widespread pain is related to neurobiological origins with hypothalamic-pituitary-adrenal (HPA) axis dysfunction (20). Together with back pain, TMD is one of the most prevalent musculoskeletal disorders in the population (21).

### **TMD in the population**

Within dentistry, acute pain is often caused by toothache, whereas the majority of chronic pain conditions are related to TMD (8, 22, 23). The most common TMD pain conditions involve the masticatory muscles (myalgia), the TMJ (arthralgia), and headache associated with TMD (21). Dysfunction related to TMD is normally limitations and/or restrictions of the mandibular movement, impaired chewing and TMJ sounds during movements (8). Dysfunctions may be related to elicited pain during function, internal derangement of the TMJ, impaired neck function or combinations of these conditions. The most common intra-articular TMD condition is disc displacements, with or without reduction (24). The former is often associated with popping sounds, while the latter is associated with restricted jaw opening, especially in its acute stage. Degenerative intra-articular TMJ diseases can cause pain, joint crepitus and restricted jaw movements, but they may also be non-symptomatic. In rare cases, impaired jaw function can be related to late effects after radiation therapy (25), TMJ ankyloses (26), or neuro-muscular disorders (27). Dysfunction related to TMD with or without related pain can impair perceived oral health (28).

Over the years, different criteria have been used to define TMD, which is probably the reason for variations in the reported incidence and prevalence of TMD. The annual incidence of TMD pain is reported to be in the range of 2-4% (11), and of those approximately half reported continuing symptoms after six months (29, 30). The prevalence of TMD pain in the general population varies between studies and depends primarily on inclusion criteria and study populations. The most commonly reported prevalence ranges between 5-12%

(31-33). A systematic review reported that the prevalence of intra-articular TMDs were approximately 10% in a general population based sample (24).

Some features of the distribution of TMD are commonly described, i.e. an increase in prevalence during adolescents (34), a peak prevalence in the middle ages, and a women/men ratio of approximately 2:1 (35). Signs and symptoms related to TMD often fluctuate over time (36-38). In patients referred to specialized TMD/orofacial pain clinics, women are considerably more prevalent than men and pain related TMD is more prevalent than non-pain intra-articular TMD (24, 39, 40).

Even though the prevalence and distribution of signs and symptoms indicative of TMD are fairly well described based on cross-sectional studies, the aetiology is still not entirely unravelled and debated. At least two aspects are important to consider in relation to cause and effect. First, the study design needed to address this topic should be prospective and begin with a non-symptomatic study population. Second, as a consequence of the study methods used to evaluate risk, the results will be based and communicated on group levels. On the individual level the extrapolated estimates of risk may be low even though disease and related impairment are present. The aetiology of TMD is considered multi-factorial and has been described in terms of three types of possible contributing factors – predisposing, initiating, and maintaining factors (41).

The importance of dental occlusion as a causal factor to TMD has been debated over the years (42). Instead, several other risk factors have been proposed as predisposing factors in the development of TMD. Among these are, psychosocial factors (e.g. depression and catastrophizing), genetic risk factors (43-45) as well other pain conditions. Possible initiating factors has also been suggested, including somatic symptoms (46), bruxism (47) and sleep disturbances (48, 49). In terms of persistence of TMD, somatic awareness and depression are both examples of potential maintaining factors (50, 51). Furthermore, catastrophizing was both related to incidence of TMD pain and contributed to the progression of chronic TMD pain and disability (52). Taken together, the biopsychosocial model is widely adopted when discussing aetiology of TMD (53). With regard to consequences of TMD, the condition is also associated with severe distress in terms of a negative impact on the quality of life (54-56) with pain considered to be the main cause (57). It has been advocated that interventions in terms of early identification is important to prevent development of chronicity of pain in general and also specifically for TMD (44, 58-60). In addition to suffering on an individual basis, chronic TMD is also related to substantial costs for our society due to sick leave and increased costs for treatment (61). The degree of psychosocial

impairment and treatment-seeking behaviours was also suggested to be more important than physical findings when related to pain experience (62). Altogether, this implies the importance of appropriate identification, diagnosis and management of these patients.

### **Treatment need and decision making**

Health care seeking has been shown to be associated with worrying and with the character of pain, for example frequency, duration and intensity (63-65). Pain intensity is also associated with multiple appointments and the patient's utilization of different treatment modalities (66). Furthermore, treatment need was reported to vary with TMD diagnostic subgroups and concurrent pain from both muscles and joint were associated with a higher treatment need (67). According to the included studies in a meta-analysis, the estimated active treatment need for patients with TMD was in the range of 1-30% and a median of 16%, in the population (68).

In Sweden, the performed annual treatments possibly related to TMD has been about 0.5-1.5% over the years (69). The reasons for this discrepancy between estimated treatment need and performed treatment in Sweden is not known, and this constitutes a gap of knowledge within dentistry today.

Clinical decision-making plays a central role in every day practice in dentistry and medicine. This process is therefore of major interest since the outcome directly affects the patient. The human decision process has been extensively studied within the field of economy and psychology. These scientific fields are well beyond the scope of this thesis. However, it has been suggested that decision-making is closely related to recognition and often we make decisions based on intuitively incorrect assumptions (70). Within medicine, the patient and provider demographics both seem to relate to assessment and management of pain (71). Thus, characteristics such as gender, age and race are all factors related to risk of under-treatment (72). In addition, previous reports have identified uncertainties among general practitioners on the management of TMD patients (73). Taken together, these factors could all be related to the indicated under-treatment of TMD.

### **Diagnostic accuracy**

Diagnostic methods, as well as screening methods, are commonly evaluated based on the reliability and validity of the used test. The reliability is referred to as the reproducibility of a certain method, whilst validity is the accuracy of the method. In research settings a high reliability of the operator/examiner, is necessary in order to ascertain a correct inclusion of data (74).

There are different types of validity. A basic form of validity is the 'face validity' which refers to a subjective assessment of whether the test measures what it is supposed to measure or not. The criterion validity evaluates the ability of a test or method to predict the outcome of another test. Criterion validity is commonly used in order to determine the diagnostic accuracy of a test, such as a screening method, in comparison with a reference test.

There are several mathematical calculations with specific advantages, available for the assessment of the accuracy of a diagnostic test (75, 76). The diagnostic accuracy of a test can be reported as sensitivity – the ability of an index test to correctly define a positive test result when the disease is present, and specificity – the ability of a test to define a negative test result when disease is absent (77). The sensitivity and specificity of a test is calculated within a 'two by two table' and can be summarized as the ability of a test to identify 'true positives' and 'true negatives'. These estimates do not take the prevalence or pre-test probability into account.

In clinical practice, and on the individual basis, the clinical decision process will be based on the patient's actual complaints together with the findings on examination. Therefore, the predictive values of a test can be calculated to give an estimate of the accuracy for the individual patient. In calculations of predictive values, the prevalence of the condition is taken into account and will therefore affect the result. The positive predictive value is the probability that an individual will have a condition given a positive test result (77). The negative predictive value is the probability that an individual with a negative test result will not have the condition.

Previous reports have underlined the importance of the evaluation of a test in a representative setting and its relation to the actual clinical situation (78, 79). In clinical practice it is therefore important to evaluate the target population and how closely this matches the situation in the evaluated test. So, the need for a diagnostic test's characteristics will therefore differ, depending on, for example, the expected prevalence for the actual clinical situation. Within general practice, with a relatively low prevalence of TMD together with the fact that TMD is a non-mortal condition, a diagnostic test for TMD should preferably have a high specificity (80, 81). The suggested targets of diagnostic accuracy for a TMD diagnostic test have been a sensitivity >70% and a specificity >95% (79, 82). This will allow for correct identification of those without the condition and will result in few unnecessary initiated treatments. The risk taken with a related lower sensitivity is the increase of misclassification of an actual TMD complaint for healthy, which in turn may cause prolonged suffering. Within a specialized clinic the conditions are different due to an expected higher prevalence of both TMD pain and intra-

articular TMD with functional disturbances. In such settings, the benefits with a high sensitivity are warranted in order to precisely determine the probable diagnosis.

### **Diagnostic methods for TMD**

Historically, TMD has been evaluated by the presence of signs and symptoms, for example, Helkimo's dysfunctional indices (83). The American Academy of Orofacial Pain (AAOP) has provided an international, diagnostic system that covers a broad spectrum of conditions but is without strictly defined criteria (84). In 1992, the Research Diagnostic Criteria for TMD, RDC/TMD, was established and intended for research purposes (82). The RDC/TMD is a strictly defined diagnostic method for the most common TMD conditions. The dual-axes system, incorporating psychosocial aspects into the TMD assessment has been regarded a paradigm shift within the field of orofacial pain. Even though the primary aim with the system was comparable outcomes for research, no other system was better available for clinical settings. Consequently, the RDC/TMD has been widely used also in clinics during the past decades. When first published, the RDC/TMD was not intended to be an end product and continued evaluations were anticipated and suggested. During the last decade, a thorough investigation of the reliability and validity of the RDC/TMD was undertaken. The reliability was good for myofascial pain, arthralgia, disc displacement with reduction and disc displacement without reduction with limited opening (85). However, the reliability was poor to marginally fair for disc displacement without reduction without limited opening and osteoarthritis. The validity of the axis I diagnoses did not meet the suggested target and a revision of these algorithms were considered necessary (86). The validity project resulted in an updated version for diagnostic assessment, the Diagnostic Criteria/TMD (DC/TMD).

### **Diagnostic Criteria for TMD (DC/TMD)**

The new DC/TMD criteria were published in 2014 and was recommended for both clinic and research due to improved reliability and validity. These new criteria have high sensitivity and specificity for the most common pain-related TMD diagnoses as well as for some of the intra-articular disorders (21). Just like its precursor, the DC/TMD consists of the dual axis system – axis I for assessment of a diagnosis, and axis II for an assessment of psychosocial factors of importance for prognosis and treatment planning. In addition to the DC/TMD, the expanded DC/TMD is in progress. The expanded version aims for providing criteria for the less common but clinically significant TMD such as adhesions, ankyloses, and contractures as well as other functional and pain conditions (87).

Axis I diagnoses are partly based on self-reported symptoms within the last 30 days. These are self-reported pain in the orofacial and temple area that is also provoked or modified by jaw movements. The intra-articular TMD is assessed by questions on joint sounds and functional limitations also referred to the last 30 days. These symptoms should then be reproduced and identified during the clinical examination. In addition, any provoked pain during examination should be familiar to the pain experienced by the patient in terms of 'a replication of the chief complaint', in order to yield a DC/TMD pain diagnosis (21).

Axis II consists of the short version suitable for screening in general practice, and the comprehensive version recommended for specialist settings. The focus has been on the validity of methods and the clinical applicability in terms of time consumption. Thus, we now have a reliable and valid system for TMD diagnostics. However, in daily dental care we need to identify who would benefit from a thorough TMD examination to confirm or exclude a diagnosis. In order to achieve this, effective screening methods for TMD are important.

### **Screening methods**

Screening is defined as 'the procedure undertaking testing people for early signs of disease' (88). Already in 1968 WHO published a ten-item criteria to be met before a screening procedure should be considered within public health (89). Among these are the importance of the health problem and an established policy on responsibilities for treatment. An acceptable screening method should be simple to apply and balanced in costs, but also be valid and possibly lead to an effective treatment (90). With regard to the benefits of TMD screening, it has been shown that for individuals suffering from TMD, the lack of an explanatory diagnosis cause uncertainties and has a negative impact on their daily lives (91). The majority of patients with diagnosed TMD, will benefit from conservative and single treatments (92). In addition, early intervention has been suggested to be important to prevent chronicity which may lead to a less time-consuming management (58). Taken together, and since patients with TMD already seem to go undetected within dentistry today, methods for identification of potential TMD related symptom may improve the health care system.

There is an array of suggested and available screening methods for TMD. The TMD pain screener is a three or six item questionnaire that has been validated in relation to the RDC/TMD (93). The questionnaire is suggested suitable to detect individuals with potential TMD pain due to its high sensitivity. However, this questionnaire does not include non-painful functional aspects of TMD. An important aspect of orofacial pain is the differentiation of TMD

pain from dental pain, primarily due to the diverging treatment approach. Another screening questionnaire for this purpose has been evaluated but was found not suitable for diagnostics due to low specificity (94). Since patients with TMD seem to go undetected and under-treated within general practice dentistry today, a screening method with a high specificity is warranted in order to identify individuals who may benefit from a further examination and decision-making with regard to possible treatment need.

### **3Q/TMD – three screening questions for the recognition of TMD**

Three screening questions, 3Q/TMD are suggested to detect patients with potential TMD. The 3Q/TMD consists of two questions on frequent jaw pain and one question to capture frequent functional aspects of intra-articular TMD.

Each question should be answered with a 'yes' or 'no' and are formulated as follows:

Q1: Do you have pain in your temple, face, jaw or jaw joint once a week or more?

Q2: Do you have pain once a week or more when you open your mouth or chew?

Q3: Does your jaw lock or become stuck once a week or more?

The two questions on pain (Q1 and Q2) were originally introduced in the county of Östergötland, Sweden in 2000. The frequency 'once a week or more' was found to correspond with the perceived treatment need (95). The reliability and validity of the questions have been determined in relation to the RDC/TMD in adolescents (96). The questions showed excellent reliability and validity when screening for a TMD pain diagnosis. The third question was introduced to detect also the intra-articular TMDs that may lead to functional disturbances of the TMJ. So from a consensus discussion among experienced specialist dentists, the Q3 was developed with so called 'face validity'. Thus, the 3Q/TMD has not been evaluated in an adult population and in relation to DC/TMD.

Even though the 3Q/TMD was introduced within the Public Dental Health Services (PDHS), in order to recognize patients with a potential TMD, the screening questions may also be valuable as guidance in further diagnostics when patients are already recognized. Such an example could be when a patient is seen by a specialist after referral. Patients referred to secondary specialized TMD/orofacial pain clinics have chronic complaints more prevalent compared to a patient population in primary dental health care. The

prevalence of non-TMD symptoms and complaints such as neuropathic pain, atypical odontalgia or dental pain and tooth wear, will also be higher in a specialist clinic setting as compared to the general population. Therefore, the outcomes from the general population cannot be extrapolated to a secondary or tertiary clinical setting.

### **Rationale for this thesis**

Given the multi-fold of potentially negative consequences of chronic TMD, it is reasonable to expect an awareness and even alertness for TMD related symptoms within primary dental care. The majority of individuals within both PDHS and private dental care in Sweden are examined on a regular basis in an annual or biannual recall system, and this is also why dentistry is an ideal platform for screening purposes. The screening questions, 3Q/TMD were introduced in order to recognize patients with a potential TMD. The two questions on frequent pain have been found to be valid for screening purposes within adolescents and in relation to the RDC/TMD, but at the time for that study, the third question on functional limitations had not been introduced. Furthermore, the criterion validity of the 3Q/TMD in adults has not been established. The questions have been in use within every day practice in PDHS in the county of Västerbotten, Northern Sweden since May 2010. It is not yet known however, whether the implementation of the 3Q/TMD have affected the clinical decision-making. Health care should be evidence-based and it is therefore reasonable to have scientific support for implementation of health care routines and guidelines.

# Objective

Since patients with TMD seem to go undetected and under-treated within dentistry, the objective of this project, was to recognize individuals with pain and dysfunction in the orofacial and temple region. The overall aim was to analyse the validity and outcome of the 3Q/TMD screening tool for symptoms indicative of TMD.

## Specific aims

The specific aims and related hypotheses addressed in this thesis are:

**Paper I** - to evaluate the prevalence, age and gender distribution of frequent pain and dysfunction in the jaw, face and temple region in the population  
- to identify the age-span when these symptoms increase

**Paper II** - to establish the validity of 3Q/TMD in relation to a DC/TMD diagnosis, pain intensity and functional limitations  
*Hypothesis* - the 3Q/TMD is an applicable method to identify patients at their regular dental check-ups with a more significant TMD diagnosis and functional impairment

**Paper III** - to evaluate the outcome of 3Q/TMD on clinical decision-making and if gender, age and the fee system the individual was assigned to are related to performed treatment  
*Hypothesis* - 3Q-positives will receive treatment related to TMD more often than those who respond negatively to all three questions  
- performed treatment is more frequent in women, younger ages and in patients signed up for dental plans

**Paper IV** - to establish the validity of the 3Q/TMD in a specialized TMD/orofacial pain setting  
*Hypothesis* - the majority of referred patients will answer affirmatively to the 3Q/TMD

## **Study-populations and methods**

This section provides an overview of the study-populations, methods and statistical approaches used in this thesis. The studies were based on data from three different patient samples from the PDHS in the county of Västerbotten, Sweden and one patient sample from a specialized orofacial pain clinic at the Academic Centre for Dentistry, ACTA, Amsterdam, the Netherlands.

The bases for all studies are individuals' answers to the 3Q/TMD and quantitative approaches were used in the analyses. A methodological overview of the study designs, study-populations and statistical analyses for the studies is provided in Table 1. The studies carried out in Västerbotten were approved by the Regional Ethical Board at Umeå University, prior to all data collections. The patient sample from ACTA was a retrospective medical file study. This study was judged by the Ethical Committee of ACTA to not fall under the provisions of the Medical Research Involving Human Subjects Act. Nevertheless, an ethical application for the study was submitted and approved by the Regional Ethical Board at Umeå University, Sweden. The STROBE statement was followed for the case-control- and cohort studies (97, 98).

### **Index test, 3Q/TMD**

Since May 2010, the 3Q/TMD has been a mandatory part of the digital health declaration in the dental record system of the Swedish version of the Dental Practice Management System, T4 (Eastman Kodak Company, New York, NY, USA) in the PDHS in Västerbotten, Sweden. Prior to the inclusion of the 3Q/TMD, dentists, dental hygienists and dental nurses at the PDHS in Västerbotten were informed about the inclusion of the three questions and how to use them in their daily practice. For the ACTA sample, the screening questions are answered by the patients in a web based questionnaire prior to their scheduled appointment.

In this thesis, 3Q-positives are defined as an individual with at least one affirmative answer to any of the 3Q/TMD, whilst 3Q-negatives are defined as individuals with negative responses to all three questions.

## Study-populations and methods

Table 1. Overview of the four studies

|                             | <b>Paper I</b>   | <b>Paper II</b>   | <b>Paper III</b>  | <b>Paper IV</b>  |
|-----------------------------|--|---|---|--|
| <b>Purpose</b>              | To analyse the prevalence of affirmative answers to the 3Q/TMD across the lifespan | To establish the validity of 3Q/TMD in relation to a DC/TMD diagnosis in an adult, general population | To evaluate the outcome of the 3Q/TMD on clinical decision-making           | To establish the validity of 3Q/TMD in relation to the DC/TMD in adults in a specialized orofacial pain setting    |
| <b>Design</b>               | Cross sectional  | Case-control  | Cohort  | Case-control   |
| <b>Participants</b>         | Consecutive patients from the PDHS in Västerbotten, Sweden<br><br>N= 137,718       | Randomly selected adults from the PDHS in Västerbotten, Sweden<br><br>N=300                           | Randomly selected adults from the PDHS in Västerbotten, Sweden<br><br>N=800 | Consecutive patients referred to ACTA, Amsterdam, Netherlands<br><br>N= 449  |
| <b>Variables</b>            | Individual answers to the 3Q/TMD   | Individual answers to the 3Q/TMD, Diagnosis according to the DC/TMD, CPI, JFLS-20                     | Individual answers to the 3Q/TMD, Prescribed treatment                      | Individual answers to the 3Q/TMD, Diagnosis according to the DC/TMD  |
| <b>Statistical analysis</b> | -Chi <sup>2</sup> test<br>-Kruskal-Wallis test<br>-Spearman's correlation test     | -Sens/Spec<br>-Predictive values<br>-Chi <sup>2</sup> test<br>-Mann-Whitney-U test                    | -Odds Ratio (OR)<br>-Chi <sup>2</sup> test                                  | -Sens/Spec<br>-Predictive values<br>-Likelihood ratios<br>-Post-test probabilities<br>-Spearman's correlation test |

## **Prevalence of affirmative answers to the 3Q/TMD (Paper I)**

### **Study-population**

In this cross-sectional study, all consecutive patients examined at the PDHS in Västerbotten, Sweden from May 2010 to October 2012 were included. Inclusion criteria were completed health declaration and at the same appointment a regular dental check-up. In all, 137,718 individuals (68,554 women and 69,164 men) were included. Ages ranged 103 years (1-104) and the mean age was 35.2 years (SD 22.7). The distribution of women and men was fairly even in all age groups.

### **Statistical methods**

The total database was analysed for the ten-year age groups. For 7 to 18 year-olds, each single year was analysed separately. Comparisons between men and women for the distribution of affirmative answers to 3Q/TMD were analysed with Chi<sup>2</sup> tests. Differences in prevalence of self-reported symptoms between the age groups were analysed with Kruskal Wallis tests for independent samples Mann-Whitney-U-test (M-W-U). For a sub-sample, i.e. 20-69 year-olds, an analysis regarding covariance between affirmative answers to the individual questions was evaluated with Spearman's correlation test.

Due to the large sample size a P-value <0.01 was considered statistically significant.

The statistical calculations were carried out with SPSS version 20 and 24.

## **Validity studies of the 3Q/TMD (Paper II and IV)**

Two case-control studies were conducted to determine the criterion validity for the 3Q/TMD in two different settings – in adults from a general population based sample (Paper II), and in adult patients referred to a specialized orofacial pain clinic (Paper IV). Due to their similarities in study design, Paper II and Paper IV are described in parallel in the following sections. Informed consent was obtained from all participants prior to the examinations.

### **Validity of the 3Q/TMD in the general population (Paper II)**

#### **Study-population (Paper II)**

The study population consisted of 7,831 individuals (n=524 3Q-positives, n=7,279 3Q-negatives) who attended the PDHS in Västerbotten in 2014 for their routine dental check-ups. The 3Q-positives were invited for examination in a randomized order (SPSS, random numbers) and together with age- and gender matched 3Q-negatives. The matching was done for gender and for age-

group in 10-year clusters. All participants were first invited by letter and then contacted by phone approximately one week later. In total, 335 3Q-positive and 342 3Q-negative patients were invited, and of these 152 3Q-positives and 148 3Q-negatives participated.

Before the clinical examination all participants completed the 3Q/TMD a second time. These responses were used in the analysis since they most closely matched the current complaints of the participants. In addition, all individuals also completed the DC/TMD Symptom Questionnaire (DC/TMD-SQ) and parts of the DC/TMD axis II.

### **Clinical examination (Paper II)**

All individuals underwent a standardized clinical examination according to the DC/TMD protocol (21). The clinical examinations were carried out by a single blinded examiner (AL, author of the thesis) who had been formally trained for two days and calibrated in accordance with the DC/TMD Training and Calibration Guidelines (99). The reliability test showed that the examiner had substantial to almost perfect reliability (Cohens Kappa values) for the tested diagnoses, i.e. myalgia (0.82), myofascial pain with referral (0.88), headache attributed to TMD (1.0), arthralgia (right 0.87, left 0.88), and disc displacement with reduction (right 0.64, left 0.85).

### **Validity of the 3Q/TMD in a specialist patient sample (Paper IV)**

#### **Study-population (Paper IV)**

Consecutive patients referred to the Orofacial Pain Clinic at ACTA between September 2014 and May 2016 were assessed. Inclusion criteria were at least 18 years old, referred for a possible TMD complaint, and complete intake examination. The study sample consisted of 449 adults (72% women) with a mean age of 44.5 years (SD 14.2 years, 18-76 years).

Preceding the intake visit, as part of the usual care, all patients filled-out a questionnaire regarding their general and oral health, physical complaints, and psychosocial factors. This questionnaire included questions advocated for the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) (21) as well as the 3Q/TMD.

#### **Clinical examination (Paper IV)**

At the intake visit, all patients underwent the standardized clinical examination according to the DC/TMD protocol (21). The intake examination was performed by a well-trained dentist as part of the usual care. Dentists involved in the collection of clinical data were calibrated annually to perform

a standardized DC/TMD examination. The calibration was supervised by a dentist previously trained and calibrated in the DC/TMD clinical examination by an official DC/TMD Training and Calibration Centre according to the DC/TMD Training and Calibration Guidelines (99).

**Reference standard for the validity studies (Paper II and IV)**

As a reference standard to compare the outcomes of the 3Q/TMD, the following DC/TMD diagnoses were used:

Pain-related TMD:

- Myalgia
- Arthralgia

Subgroup of intra-articular TMD:

- Disc displacement with reduction with intermittent locking
- Disc displacement without reduction with limited opening
- Disc displacement without reduction without limited opening
- Subluxation

For the evaluation of the two questions on pain, Q1 and Q2, individually and combined, a DC/TMD pain related diagnosis (arthralgia or myalgia) was used as reference standard. For the question on functional disturbances, Q3, a subgroup of intra-articular TMD diagnosis was used (i.e. disc displacement with reduction and intermittent locking, disc displacement without reduction with and without limited opening or subluxation). Diagnoses disc displacement with reduction and degenerative joint disorder were regarded primarily related to joint sounds, and may not include functional limitations such as jaw locking or restricted movements. Therefore, these DC/TMD diagnoses were not included as a reference standard. For combinations of at least one affirmative, two or more affirmatives and all three affirmatives, any of the reference standard diagnoses were used.

**Statistical methods (Paper II and IV)**

Descriptive statistics are presented for the proportions of DC/TMD diagnoses and affirmative answers to the 3Q/TMD.

The sensitivities and specificities were calculated by standard formulas (2). For calculations of positive and negative predictive values, which are dependent on prevalence of the condition, the following approximations of prevalence (24, 32, 100) were used (Table 2).

Table 2. Approximations of prevalence used in calculations of predictive values for the different samples.

|                            | <i>General population sample</i> | <i>Specialist sample</i> |
|----------------------------|----------------------------------|--------------------------|
| <i>TMD pain</i>            | 10%                              | 50%                      |
| <i>Intra-articular TMD</i> | 5%                               | 50%                      |

Based on these estimates, the positive and negative predictive values (PPV and NPV, respectively) were calculated (77). Confidence intervals for sensitivity, specificity and predictive values were calculated according to the Wilson 'score' method (101).

From axis II, the results in this thesis are based on information from the Graded Chronic Pain Scale (GCPS) and Jaw Functional Limitation Scale-20 (JFLS-20) (102, 103). GCPS is a valid and reliable seven item questionnaire to assess characteristic pain intensity (CPI) as well as the disabling consequences of chronic pain. GCPS is a valid method to detect changes over time and has been extensively used in research areas on chronic pain (104). The individuals' responses to the GCPS are compiled into grade 0-4 where 0 is 'no pain' and 'no dysfunction' and 4 is 'high disability and severe limitation'. It has been recommended that individuals within grade 1-2 should primarily be considered for single conservative treatments, whereas multimodal treatments or referral should be considered for individuals that score 3 and 4 (105). The twenty item JFLS-20 covers three main constructs regarding jaw function – mastication, vertical jaw mobility, and emotional and verbal expression. No cut-offs have yet been provided even though the JFLS-20 is recommended to measure changes over time, for example, before and after performed treatment. Additional calculations for 'severe TMD' in the general population were based on the CPI from the Graded Chronic Pain Scale (102) and Jaw functional limitation scale, JFLS-20 (103). The CPI was determined by a numerical rating scale (0-10) for current pain, worst pain in the past month and average pain the past month. The mean value was calculated. For the JFLS-20, since no definite cut-offs for the JFLS-20 are provided yet, the data were dichotomized into any item 5 or more as '1' and the remaining as '0'. 'More severe TMD' were defined; CPI was 3 or more or JFLS-20 was 1. For comparison of severity levels between 3Q-positives and 3Q-negatives, the M-W-U test was used. A non-parametric method was used since both the JFLS-20 and CPI are ordinal data and not normally distributed.

To analyse the relationship between affirmative answers to the individual questions the Spearman's correlation test was used.

The statistical calculations were carried out with SPSS version 22 (paper II),

and version 24 (paper IV); a P-value  $<0.05$  was considered statistically significant.

### **The outcome of 3Q/TMD on clinical decision-making (Paper III)**

Dental health care in Sweden is provided by private dental clinics and by the PDHS. About half of the adult population in Västerbotten receives their regular dental care within the PDHS. The fees for dental care is either paid for in a fee-for-service system or by subscription dental care (106). In the latter, the dentist and patient agree on a fixed pre-defined charge that is valid for three years and is dependent on the patient's estimated individual risk for the need of dental care. In 2010, about 20% of the adult population in Västerbotten, Sweden had signed up for a subscription dental care.

#### **Study-population**

This cohort study was conducted within the PDHS in Västerbotten Sweden. The study population consisted of 23,423 adults (20-71 years old, men/women ratio 1:1) who had their dental check-ups within the PDHS in the county of Västerbotten, Sweden between June 2010 and May 2011. In total, 6.6% (n=1,546) reported an affirmative answer to at least one of the 3Q/TMD.

A sample of 300 3Q-positives and 500 3Q-negatives were randomly selected from the total study population (SPSS random numbers). The final analysis was carried out on 293 3Q-positives and 497 3Q-negatives since ten dental records had to be excluded due to missing data. The distribution of gender and age among 3Q-positives and 3Q negatives are presented in Table 3.

Table 3. Distribution of gender and age among 3Q-positives and 3Q-negatives.

|                     | <i>Gender distribution (N)</i> | <i>Age distribution</i>  |
|---------------------|--------------------------------|--|
| <i>3Q-positives</i> | 71% (207) ♀<br>29% (86) ♂      | 20-71 yrs., mean age 41.9, SD 13.5<br>21-70 yrs., mean age 39.6, SD 13.7 |
| <i>3Q-negatives</i> | 52% (259) ♀<br>48% (238) ♂     | 20-71 yrs., mean age 42.7, SD 15.0<br>20-71 yrs., mean age 41.3; SD 13.7 |

The 3Q-positives consisted of a significantly higher proportion of women compared to the 3Q-negatives ( $\text{Chi}^2=26.18$ ;  $P<0.001$ ). There was no significant difference in age between men and women (M-W-U= 71,247.0;  $P=0.18$ ) or between 3Q-positives and 3Q-negatives, (M-W-U=70,814.5;  $P=0.52$ ).

### **Variables extracted from the dental records**

The twelve-month period after the completion of the health declaration and dental examination was studied. This time period was chosen since it was assumed that TMD related treatment performed and possibly related to the individuals' answer to the 3Q/TMD, reasonably would have been completed within this time. Data were extracted from the dental records independently by two examiners, who were blinded to whether the patients were 3Q-positive or 3Q-negative.

The following data were extracted from the dental records within a twelve-month period from the dental examination:

- profession of the examiner (dentist or dental hygienist)
- fee item(s) charged related to TMD
- TMD related treatment carried out but not charged for
- an entrance in the record that the patient declined recommended treatment
- any other dental problems noted at the appointment that might be related to an affirmative answer to any of the 3Q/TMD (i.e. endodontic treatment or extraction due to toothache)
- whether the patient was signed up for a subscription dental plan

After independent data extraction by the two examiners, the inter-rater reliability of the extracted data was established. For all situations where inconsistencies in variables extracted by the examiners were found, the two examiners had a discussion to reach a consensus. The consensus agreement for each variable was used in the analyses.

### **Statistical methods**

Descriptive statistics were used for frequencies of the extracted variables. Treatment was considered as the positive outcome 'any treatment' in the case of one or more of the following treatments noted in the patient's record: occlusal appliances, information and/or jaw exercise, referrals to TMD specialist clinic, treatment not charged for, or patient declines proposed treatment. Univariate logistic regression analysis was used to determine the association between the 3Q/TMD (independent variable) individually and in combination, in relation to 'any treatment' (dependent variable). Independent variables with a P-value <0.1 were entered in a multivariate analysis. Results were considered statistically significant if the confidence interval did not include 1 (one) and the P-values were <0.05. The database was analysed with SPSS v 24.

## Results

### Prevalence of self-reported symptoms indicative of TMD (Paper I)

The highest prevalence of affirmative answers was related to Q1, frequent pain, among both women and men. The prevalence was significantly higher among women than men for all questions and combinations of questions (Table 4). The largest women to men ratio was found when all three questions were answered affirmatively.

Table 4. Prevalence of average, crude distribution of affirmative answers to the 3Q/TMD over the lifespan 1-104 year-olds to the individual questions (n= 137,718). Chi<sup>2</sup> and P-values represent differences between women and men in relation to affirmative answers.

|                     | <i>Total population (%)</i> | <i>Women (%)</i> | <i>Men (%)</i> | <i>Chi<sup>2</sup></i> | <i>P- value</i> |
|---------------------|-----------------------------|------------------|----------------|------------------------|-----------------|
| <i>Q1</i>           | 3.4                         | 5.1              | 1.7            | 1183.6                 | P < 0.0001      |
| <i>Q2</i>           | 1.6                         | 2.4              | 0.9            | 514.8                  | P < 0.0001      |
| <i>Q3</i>           | 2.0                         | 2.7              | 1.2            | 383.7                  | P < 0.0001      |
| <i>At least one</i> | 5.0                         | 7.1              | 3.0            | 1,243.3                | P < 0.0001      |
| <i>Two or more</i>  | 1.5                         | 2.3              | 0.7            | 662.1                  | P < 0.0001      |
| <i>All three</i>    | 0.5                         | 0.8              | 0.2            | 254.3                  | P < 0.0001      |

No significant differences in prevalence of 3Q-positives between boys and girls were found up to the beginning of the teen-age period (Fig. 1). From the age of 13 and onwards girls reported affirmatively to any of the questions significantly more frequently as compared to boys (Chi<sup>2</sup>=4.529, P=0.033). The first significant increase in symptoms was related to Q3, thereafter Q1 followed by Q2.

## Results

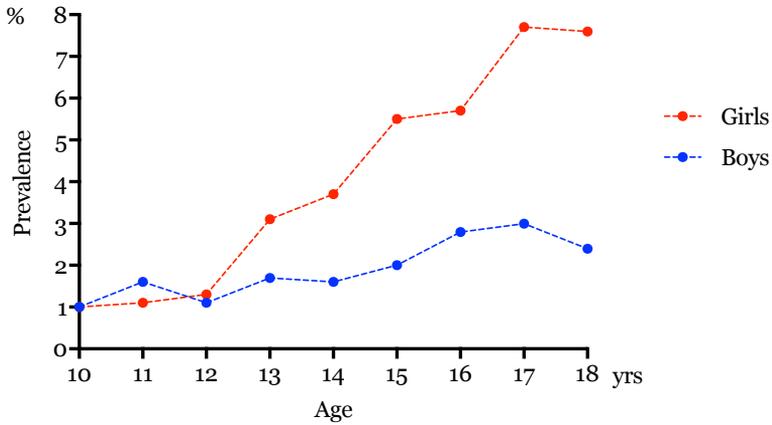


Figure 1. Prevalence (%) of affirmative answers to any of the 3Q/TMD in boys and girls (n=21,267). The first significant increase in prevalence of affirmative answers between boys and girls were found from the age of 13 and onwards ( $\text{Chi}^2=4.529$ ,  $P=0.033$ ).

The overall, highest prevalence of the included separate symptoms was reported between the ages of 20 to 59 years (n=70,048) (Fig. 2). For this age range, women reported frequent jaw pain and dysfunction 2.5 times as often as men ( $\text{Chi}^2$  test value 959.86,  $P<0.0001$ ).

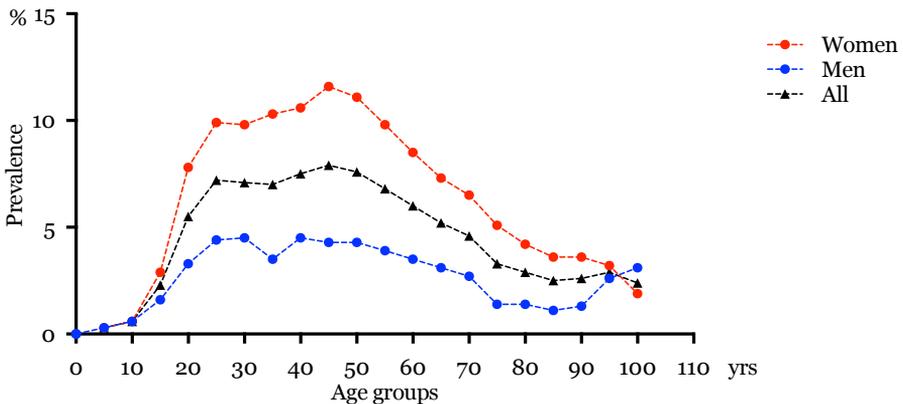


Figure 2. Prevalence (%) of affirmative answers to any of the 3Q/TMD in the different age groups (n= 137,718).

A separate analysis was carried out among adults 20-69 years of age (N=82,262). The covariance of affirmative answers to the 3Q/TMD are presented in a Venn diagram (Fig. 3). There was a statistically significant correlation between distribution of affirmative answers of all questions (Correlation coefficient Q1:Q2 = 0.482; Q2:Q3 = 0.329; Q1:Q3 = 0.260,  $P < 0.0001$ ). The strongest association, and also illustrated by the large overlap between the circles, was found between Q1 – frequent pain, and Q2 – pain on function. The majority of individuals with an affirmative answer to Q3 did not report concurrent and frequent pain.

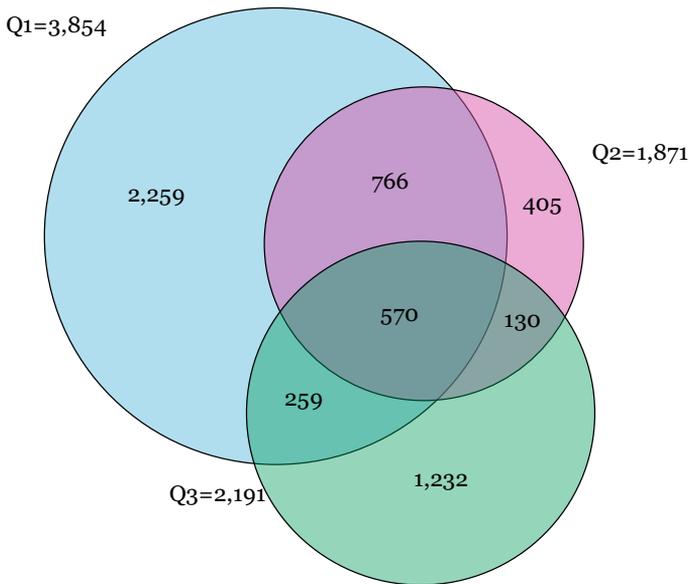


Figure 3. Relationship between affirmative answers to the individual questions 3Q/TMD in a subsample of 20-69 year-olds (N=82,262).

Of these 20-69 year-olds, overall 6.7 % (women 9.6%; men 3.9%;  $\text{Chi}^2=1069.192$ ,  $P < 0.0001$ ) reported affirmatively to at least one of the questions, and 0.7 % (women 1.1%; men 0.2%;  $\text{Chi}^2= 215.14$ ,  $P < 0.0001$ ) to all three questions. The women to men ratio was significantly higher when all three questions were affirmative, as compared to any of the questions (2.4:1 (95% CI: 2.3-2.6) vs 3.7:1 (95% CI: 3.4-5.1)).

### Criterion validity of the 3Q/TMD (Papers II and IV)

The distribution of diagnoses used in the analysis in relation to the 3Q/TMD is presented in Figure 4. From the general population (Paper II), 74% qualified for a DC/TMD diagnosis used as a reference standard, as compared to 64% from the patient sample (Paper IV). Among the 3Q-negatives in the different samples, the distribution of reference diagnosis was nearly equal. Pain related TMD was common in both samples and myalgia was the most frequent diagnosis used as a reference standard. There was a large overlap between the diagnosis myalgia and arthralgia in both samples. An arthralgia diagnosis without concurrent myalgia was present in three individuals (one 3Q-positive and two 3Q-negatives) in the general population and 28 individuals (28 3Q-positives/ 0 3Q-negatives) among the patient sample. The most frequent intra-articular TMD diagnosis in both samples was disc displacement without reduction without limited opening.

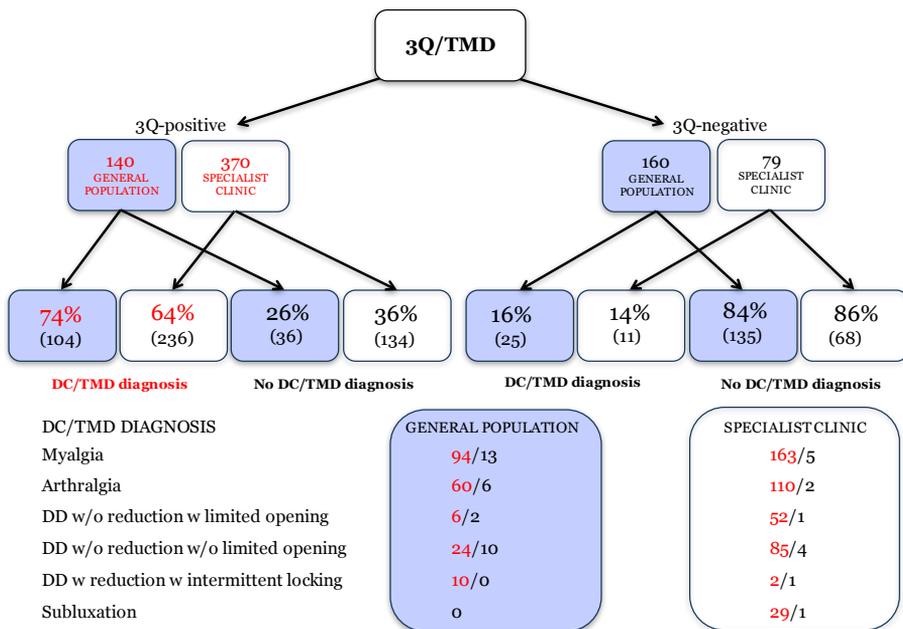


Figure 4. Distribution of the diagnoses used in the analysis for the general population sample (blue boxes) and specialist sample (white boxes). Red text indicates number and percentage of individuals with a DC/TMD diagnosis. DD = disc displacement.

For the excluded diagnoses, disc displacement with reduction and degenerative joint disease, distributions in the general population were even between 3Q-positives and 3Q-negatives. In the specialist sample, the majority of these diagnoses were found among the 3Q-positives (Table 5).

Table 5. Frequency distribution of disc displacements with reduction and degenerative joint disease among the general population sample (PDHS) and the specialist clinic sample (ACTA).

|   | <i>General population 3Q-positives</i><br>n (%) | <i>General population 3Q-negatives</i><br>n (%) | <i>Specialist sample 3Q-positives</i><br>n (%) | <i>Specialist sample 3Q-negatives</i><br>n (%) |
|---|---|---|--|--|
| <i>Disc displacement with reduction</i> | 32 (48.5)                                       | 34 (51.5)                                       | 71 (72.4)                                      | 27 (27.6)                                      |
| <i>Degenerative joint disease</i>       | 27 (56.3)                                       | 21 (43.8)                                       | 37 (88.1)                                      | 5 (11.9)                                       |

In the extracted sample from the PDHS population, 3Q-positives reported significantly higher CPI and JFLS-20 scores as compared to the 3Q-negatives (M-W-U 3,194.50; 3,996.0, P<0.001).

The distributions of affirmative answers to the individual questions for the general population (Paper II) and the specialist sample (Paper IV) are presented in Venn diagrams (Fig. 5).

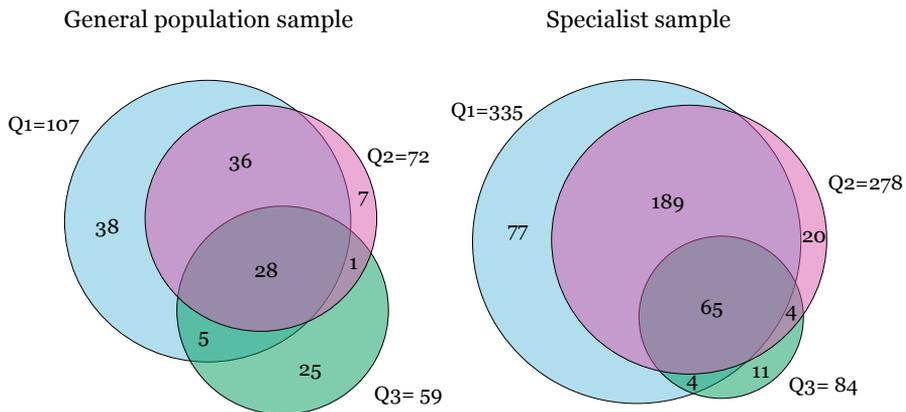


Figure 5. Venn-diagrams on the distribution of affirmative answers to the individual questions 3Q/TMD; extracted sample from the general population sample (N=300) to the left, and the specialist sample (n=449) to the right.

## Results

In the general population sample, the significantly highest sensitivities were observed when Q1, and Q1 or Q2 were answered affirmatively. There was no significant difference in the related specificity. For the two questions on pain, Q1 and Q2, the negative predictive values were high (0.95-0.99) (Table 6). The highest positive predictive value was related to when both Q1 and Q2 were positive (0.59). The negative predictive values were in general high. The same patterns were found for 'more severe TMD'. The only significant change in the general population and 'more severe' was related to a decrease of the positive predictive value among the 'more severe TMD' when at least two questions were affirmative.

Table 6. Sensitivities, specificities, PPVs and NPVs for the two questions on pain (Q1 and Q2) in relation to a TMD pain diagnosis (myalgia or arthralgia) with estimated prevalence for the different samples. A 95% confidence interval (CI) is given within parenthesis.

| <i>Sample</i>                                 | <i>3Q/TMD</i> | <i>Sensitivity</i> | <i>Specificity</i> | <i>PPV</i>       | <i>NPV</i>       |
|---|---------------|--------------------|--------------------|------------------|------------------|
| <i>General population (10%)</i>               | Q1            | 0.78 (0.70-0.84)   | 0.89 (0.83-0.93)   | 0.44 (0.39-0.50) | 0.97 (0.94-0.98) |
|   | Q2            | 0.56 (0.49-0.63)   | 0.94 (0.88-0.98)   | 0.51 (0.45-0.57) | 0.95 (0.92-0.96) |
|   | Q1 or Q2      | 0.82 (0.74-0.88)   | 0.87 (0.81-0.91)   | 0.41 (0.36-0.47) | 0.98 (0.95-0.99) |
|   | Q1 & Q2       | 0.52 (0.45-0.59)   | 0.96 (0.90-1.0)    | 0.59 (0.53-0.65) | 0.95 (0.92-0.96) |
| <i>General population 'more severe' (10%)</i> | Q1            | 0.87 (0.79-0.93)   | 0.82 (0.76-0.86)   | 0.35 (0.30-0.41) | 0.98 (0.95-0.99) |
|   | Q2            | 0.70 (0.63-0.76)   | 0.92 (0.86-0.96)   | 0.49 (0.43-0.55) | 0.97 (0.94-0.98) |
|   | Q1 or Q2      | 0.90 (0.82-0.96)   | 0.79 (0.73-0.83)   | 0.32 (0.27-0.38) | 0.99 (0.96-1.0)  |
|   | Q1 & Q2       | 0.67 (0.60-0.73)   | 0.94 (0.88-0.98)   | 0.55 (0.49-0.61) | 0.96 (0.93-0.97) |
| <i>Specialist sample (50%)</i>                | Q1            | 0.94 (0.90-0.97)   | 0.41 (0.35-0.47)   | 0.61 (0.57-0.65) | 0.87 (0.85-0.88) |
|   | Q2            | 0.83 (0.77-0.88)   | 0.55 (0.48-0.61)   | 0.65 (0.61-0.69) | 0.76 (0.74-0.77) |
|   | Q1 or Q2      | 0.96 (0.93-0.98)   | 0.33 (0.27-0.39)   | 0.59 (0.55-0.63) | 0.89 (0.87-0.90) |
|   | Q1 & Q2       | 0.81 (0.75-0.86)   | 0.63 (0.56-0.68)   | 0.69 (0.65-0.73) | 0.77 (0.75-0.78) |

In the specialist sample, the significantly highest sensitivity was related to an affirmative answer to Q1, and Q1 or Q2. The specificity, in general, was low. The highest positive predictive value was related to when Q1 and Q2 were

positive. The negative predictive values were significantly lower for the patient sample as compared to the general population sample.

For the question on functional disturbances, Q3, the sensitivity was low in both samples (Table 7). There were no significant changes in sensitivity or specificity between general population and the ‘more severe TMD’. The specificity was significantly higher in the specialist sample when compared to the general population. Negative predictive value was high in the general population (0.97), and no significant changes were observed when compared to the ‘more severe TMD’. The positive predictive value was highest within the patient sample.

Table 7. Sensitivities, specificities, PPVs and NPVs for Q3 in relation to a subgroup of intra-articular TMD diagnosis (disc displacement with reduction and degenerative joint disease excluded) with estimated prevalence for the different samples. A 95% confidence interval (CI) is given within parenthesis.

| <i>Sample</i>                                | <i>3Q/TMD</i> | <i>Sensitivity</i> | <i>Specificity</i> | <i>PPV</i>       | <i>NPV</i>       |
|--|---------------|--------------------|--------------------|------------------|------------------|
| <i>General Population (5%)</i>               | Q3            | 0.45 (0.38-0.52)   | 0.86 (0.80-0.90)   | 0.15 (0.10-0.21) | 0.97 (0.94-0.98) |
| <i>General population 'more severe' (5%)</i> | Q3            | 0.55 (0.48-0.62)   | 0.85 (0.79-0.89)   | 0.16 (0.11-0.22) | 0.97 (0.94-0.98) |
| <i>Specialist sample (50%)</i>               | Q3            | 0.48 (0.40-0.56)   | 0.96 (0.93-0.98)   | 0.92 (0.88-0.95) | 0.65 (0.64-0.66) |

## Results

In all three samples, for combinations of positive answers in relation to any of the diagnoses used in the analysis, the significantly highest sensitivity was related to when at least one question was answered affirmatively (Table 8). For every increase in affirmative answer, the sensitivity was significantly lower, in general. For specificity, as the balancing number, the highest values were related to when two or more questions were answered affirmatively. The highest positive predictive value was related to when at least two questions were positive. At least two positives and all three positives were related to significantly higher positive predictive values when compared to at least one positive. In addition, when two or more were positive, the inclusion of ‘more severe TMD’ significantly lowered the positive predictive value. The negative predictive value in the general population was generally high and no significant differences were observed. The inclusion of ‘more severe TMD’ did not significantly increase the negative predictive values. In the patient sample, the highest negative predictive value was related to when at least one question was answered affirmatively.

Table 8. Sensitivities, specificities, PPVs and NPVs for combinations of questions in relation to any DC/TMD diagnosis (disc displacement with reduction and degenerative joint disease excluded) with estimated prevalence for the different samples. A 95% confidence interval is given within parenthesis.

| <i>Sample</i>                                 | <i>3Q/TMD</i> | <i>Sensitivity</i> | <i>Specificity</i> | <i>PPV</i>       | <i>NPV</i>       |
|---|---------------|--------------------|--------------------|------------------|------------------|
| <i>General Population (10%)</i>               | At least one  | 0.81 (0.73-0.87)   | 0.79 (0.73-0.83)   | 0.30 (0.25-0.36) | 0.97 (0.94-0.98) |
|   | Two or more   | 0.50 (0.43-0.57)   | 0.97 (0.91-1.0)    | 0.65 (0.59-0.70) | 0.95 (0.92-0.96) |
|   | All three     | 0.21 (0.15-0.29)   | 0.99 (0.93-1.0)    | 0.70 (0.64-0.75) | 0.92 (0.90-0.94) |
| <i>General population 'More severe' (10%)</i> | At least one  | 0.93 (0.85-0.99)   | 0.71 (0.66-0.75)   | 0.26 (0.21-0.32) | 0.99 (0.96-1.0)  |
|   | Two or more   | 0.66 (0.59-0.72)   | 0.93 (0.87-0.97)   | 0.51 (0.45-0.57) | 0.96 (0.93-0.97) |
|   | All three     | 0.29 (0.23-0.36)   | 0.98 (0.92-1.0)    | 0.62 (0.56-0.67) | 0.93 (0.90-0.95) |
| <i>Specialist Sample (50%)</i>                | At least one  | 0.96 (0.92-0.98)   | 0.34 (0.28-0.40)   | 0.59 (0.55-0.63) | 0.90 (0.88-0.91) |
|   | Two or more   | 0.77 (0.72-0.82)   | 0.64 (0.58-0.71)   | 0.68 (0.64-0.72) | 0.74 (0.73-0.75) |
|   | All three     | 0.24 (0.19-0.29)   | 0.97 (0.93-0.98)   | 0.89 (0.85-0.93) | 0.56 (0.55-0.57) |

## Results

The relationship between the predictive values and different prevalence for the two samples when at least two questions were positive are presented in Figure 6. The figures illustrate the increase of positive predictive value and decrease of negative predictive value, following the differences in prevalence when at least two questions were answered affirmatively.

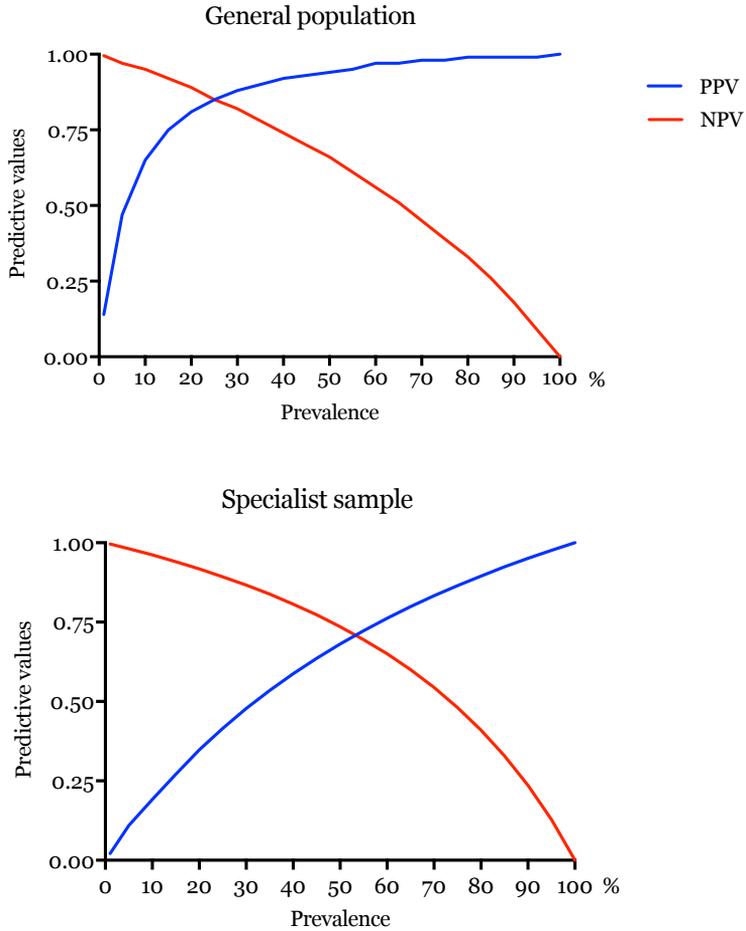


Figure 6. The positive and predictive values based on the diagnostic accuracy of at least two affirmative answers in relation to any DC/TMD diagnosis for the general population and specialist patient sample. Blue lines illustrate the PPV and red lines the NPV as functions of prevalence, respectively.

## Results

The differences between extrapolated data from the general population to a specialist sample, and the actual specialist sample are presented in Table 9. When all three questions were positive, the extrapolated measures on sensitivities and specificities from the general population on the predictive values matched the patient sample. For all other questions and combination of questions, significant changes were observed between the expected and extrapolated measures of sensitivities and specificities on the predictive values, when compared to the patient sample.

Table 9. Positive and negative predictive values (PPV and NPV) for the 3Q/TMD when calculated based on the extrapolated results from the general population sample and from the specialist clinic sample. Both estimates are based on an approximated prevalence of 50%. A 95% confidence interval is given within parenthesis.

| <i>Sample</i>             | <i>3Q/TMD</i> | <i>PPV</i>       | <i>NPV</i>       |
|---------------------------|---------------|------------------|------------------|
| <i>General population</i> | Q1            | 0.88 (0.82-0.93) | 0.80 (0.78-0.82) |
|                           | Q2            | 0.90 (0.84-0.95) | 0.68 (0.66-0.70) |
|                           | Q1 or Q2      | 0.86 (0.80-0.91) | 0.83 (0.81-0.85) |
|                           | Q1 & Q2       | 0.93 (0.87-0.98) | 0.67 (0.65-0.69) |
|                           | Q3            | 0.76 (0.72-0.79) | 0.61 (0.58-0.64) |
|                           | At least one  | 0.79 (0.73-0.84) | 0.81 (0.79-0.83) |
|                           | Two or more   | 0.94 (0.88-0.99) | 0.66 (0.64-0.68) |
|                           | All three     | 0.96 (0.90-1.0)  | 0.56 (0.54-0.58) |
| <i>Specialist sample</i>  | Q1            | 0.61 (0.57-0.65) | 0.87 (0.85-0.88) |
|                           | Q2            | 0.65 (0.61-0.69) | 0.76 (0.74-0.77) |
|                           | Q1 or Q2      | 0.59 (0.55-0.63) | 0.89 (0.87-0.90) |
|                           | Q1 & Q2       | 0.69 (0.65-0.73) | 0.77 (0.75-0.78) |
|                           | Q3            | 0.92 (0.88-0.95) | 0.65 (0.64-0.66) |
|                           | At least one  | 0.59 (0.55-0.63) | 0.90 (0.88-0.91) |
|                           | Two or more   | 0.68 (0.64-0.72) | 0.74 (0.73-0.75) |
|                           | All three     | 0.89 (0.85-0.93) | 0.56 (0.55-0.57) |

## Outcome of 3Q/TMD on clinical decision making (Paper III)

### Dental treatments extracted from the patient records

The distribution of different types of treatments related to TMD, either carried out or recommended, among cases and controls is presented in Figure 7. A patient could receive multiple types of treatment and be represented in more than one of the subgroups. Occlusal appliance therapy was the most frequently performed treatment (6.1% of the 3Q-positives). In addition, 17.1% of the cases had received treatment related to TMD that was not charged for (information, instruction, and jaw exercises). In 10.6% of the 3Q-positives and 1.4% of the 3Q-negatives, symptoms indicative of TMD were registered in the dental records, but no treatment was deemed necessary by the dentist. The exclusion of these individuals did not significantly influence the OR, i.e. 13.8 (95% CI 7.1-26.7).

| Variable   | 3Q-positives<br>n (%) | 3Q-negatives<br>n (%) | OR<br>(95% CI)             |
|--|-----------------------|-----------------------|----------------------------|
| <b>All TMD treatments (carried out or recommended)</b> | <b>63<br/>(21.5)</b>  | <b>11<br/>(2.2)</b>   | <b>12.1<br/>(6.3-23.4)</b> |
| Occlusal appliance                                     | 18<br>(6.1)           | 3<br>(0.6)            | 10.8<br>(3.2-36.9)         |
| Referral to specialist                                 | 8<br>(2.7)            | 0                     | 1.03<br>(1.01-1.05)        |
| Jaw exercises and/or advice and instructions           | 6<br>(2.0)            | 2<br>(0.4)            | 5.2<br>(1.0-25.8)          |
| Treatment carried out but not charged for              | 50<br>(17.1)          | 6<br>(1.2)            | 16.8<br>(7.1-39.8)         |
| Treatment recommended but patient declined             | 20<br>(6.8)           | 2<br>(0.4)            | 18.1<br>(4.2-78.2)         |
| <b>No TMD treatment deemed necessary</b>               | <b>31<br/>(10.6)</b>  | <b>7<br/>(1.4)</b>    | <b>8.3<br/>(3.6-19.1)</b>  |
| No TMD treatment or comments in the records            | 199<br>(67.9)         | 479<br>(96.4)         |                            |

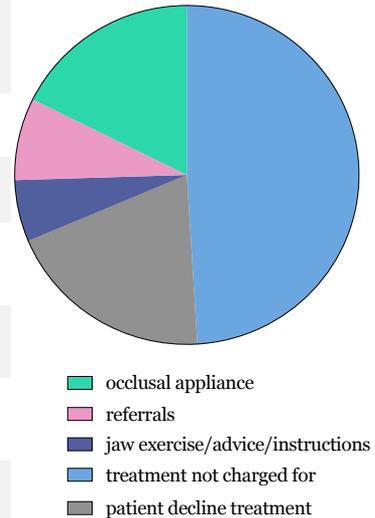


Figure 7. Number of treatments provided or recommended to 3Q-positives and 3Q-negatives (percentage distribution within parentheses). Odds-ratio for treatment provided to 3Q-positives versus 3Q-negatives including 95% confidence intervals within parenthesis. The pie chart represents percentage distribution of 'any TMD treatment'.

Treatment related to TMD had been carried out or recommended for 21.5% of the 3Q-positives and for 2.2% of the 3Q-negatives ( $\text{Chi}^2=80.78$ ;  $P<0.001$ ). The odds ratio for treatment as related to the outcome of the 3Q/TMD was 12.1 (95% CI 6.3-23.4).

When extrapolating the treatment from the study to the total population, the weighted performed treatment for the general population within the PHDS in the county of Västerbotten was 3.5%.

The 3Q/TMD was analysed in relation to any TMD treatment for the individual questions, and for combinations of the questions. Affirmative answers to all three individual questions showed a significant association with TMD treatment. For the individual questions, the strongest association was found between Q1, frequent pain, and TMD treatment (OR=7.7, 95% CI 4.6-12.8). In a multivariate analysis the strongest associations were related to Q1 and if Q1 or Q2 were positive. Twenty-two percent (6/27) of individuals with all three affirmative questions had received any TMD treatment.

Aside from the 3Q/TMD, no other significant associations with TMD treatment were found.

## Discussion

The basis for this thesis is the evaluation of three screening questions 3Q/TMD in adults. The questions were designed with the intention to recognize individuals with frequent; orofacial and temple pain, pain on jaw function and catching/locking of the jaw. The different settings approached specific aspects of the relation between answers to the 3Q/TMD and gender, age, selected DC/TMD diagnosis and carried out or recommended TMD treatment. The pattern of prevalence of frequent symptoms indicative of TMD over the lifespan, in terms of affirmative answers to the questions, resembles other musculoskeletal pain conditions. The majority of individuals in the general population sample with an affirmative answer to any of the questions qualified for a DC/TMD diagnosis. At the same time a negative answer to the 3Q/TMD related to absence of the conditions that were used as reference diagnoses. The clinical decision-making, in terms of traceable performed or recommended TMD treatment was significantly and positively related to affirmative answers to the 3Q/TMD. However, for the majority of individuals with an affirmative answer, a decision-making could not be traced in the dental records. This may indicate an oversight of patients with TMD by dental caregivers.

Establishment of a diagnosis can be a challenging task. The process normally involves a case history to collate information about the patient's symptoms together with a clinical examination of signs that can provoke and confirm the symptoms. In addition to history taking and clinical examination, additional tests may also be included in diagnostic process. The diagnosis is essential in medical care since it defines the condition and thus confirms the patient's complaints. The diagnostic process is influenced by the professional's current knowledge and interpretation of gathered data. The diagnosis is important for the clinicians' decision of appropriate management of the identified condition. A diagnosis is also influenced by predefined criteria and classification algorithms. Our belief system will influence how a patient's complaint or symptom is labelled. It should be emphasized that the 3Q/TMD was not included with the aim to arrive at a TMD diagnosis. The intention with the screening questions is to identify patients with a probable TMD or other conditions that may need a further examination and management.

Pain is a subjective and emotional experience and therefore diagnosis and assessment should be based on the patient's reported symptoms and related consequences. From an ontological perspective, it is also relevant to consider aetiology and an understanding of why a condition develops, remains or diminishes. This thesis used three methods in order to gain knowledge of

possible benefits of a screening tool, 3Q/TMD, for the individual as well as for the dental health care. One apparent reflection is that this research also raises new questions and topics with the overall aim to understand both the nature of TMD and how it can be managed within the dental health care systems.

### **Prevalence of affirmative answers to the 3Q/TMD**

The distribution of answers to both the individual and combinations of the individual questions in 3Q/TMD was analysed in a large, cross-sectional, population based, observational study that covered the lifespan. Rather than testing a specific hypothesis, this deductive method produces information of distribution and point-estimates on prevalence. This in turn can generate thoughts of possible aetiological factors and thus hypotheses for further research questions.

The general pattern of the prevalence of affirmative answers was an increase during adolescence, a peak in the middle ages and then a decrease thereafter (Paper I). This pattern was similar for all individual questions, as well as for the combinations of any affirmative answer to the questions. During the fertile periods of women's lifespan, the prevalence was approximately twice of that in men. This distribution of prevalence over the lifespan resembles and is comparable with many other pain conditions, such as headaches, abdominal pain and back pain (107, 108). In addition, the results are also in line with previous reports on orofacial pain and TMD in relation to gender and age in the general population (108-111). Among patients referred due to a TMD complaint, a similar pattern was observed (42). So, affirmative answers to the 3Q/TMD at different ages seem comparable with many other musculoskeletal conditions in terms of the distribution over the lifespan. This implies that affirmative answers to the 3Q/TMD are likely to identify a TMD condition.

In relation to the second aim, to identify the age-span when these symptoms increase (Paper I) a significant increase of affirmative answers to 3Q/TMD were observed during adolescence. This increase was significantly higher in girls, as compared to boys from early adolescence. These results are comparable to a previous study based in adolescents on only the two questions on pain (34). A prospective study in young adolescents observed that female gender together with other pain complaints predicted first onset of facial pain (112), with girls reporting significantly more symptoms compared to boys from the beginning of adolescence. In a qualitative study on adolescents, the informants described that living with TMD pain had substantial impact on their daily life (113). These findings indicate that the clinicians in primary dental care should pay attention to presence of signs and symptoms of TMD in teenagers, and especially in girls.

In line with the biopsychosocial model, the observed differences in prevalence of TMD between men and women and at different ages may be related to biological, psychological and social factors (53). Among the proposed biological factors are hormonal factors (114), genetic variations (43) and general health status (49). Furthermore, psychological factors such as stress and the social context may further contribute to both TMD and related comorbidities. In addition to other social factors, cross-cultural aspects in patients with TMD have been identified (115). Therefore, the prevalence of affirmative answers in different cultures are likely to be affected by cultural differences as well. An evolutionary perspective may also be considered since the higher prevalence of TMD among women coincides with the fertile period of life. What can the benefit of TMD pain be among women? Pain may be an adjacent component of a higher state of alertness and consciousness of the central nervous system in females during the fertile period, aimed at protecting the offspring. However, these protective aspects may also cause an increased vulnerability among women to develop and maintain pain conditions during their fertile periods of life.

From a health-care perspective TMD may need management from different health-care professionals, which puts demand on an organized system for multimodal team examination and management. On the level of the individual clinician, TMD management requires both competence and enough time to capture important aspects of the patient's case history, expectations and needs.

### **Criterion validity of the 3Q/TMD**

The validity of the 3Q/TMD was established in relation to the DC/TMD in two different patient samples, general population (Paper II) and patients referred to a specialized orofacial pain clinic (Paper IV). The reference standard DC/TMD used for these criterion validity studies comprise a strict criteria-based diagnostic system. Both the case history and the clinical examination is structured in detail; the data are then further processed in predefined algorithms and results in a probable diagnosis. The DC/TMD was chosen due to its reliability and validity for the most common TMD diagnoses (21). However, there are a variety of additional pain conditions that can disturb normal jaw function such as neuropathic pain, atypical odontalgia, fibromyalgia and cervical pain. In addition, there are also several non-painful conditions related to TMD, apart from the most common intra-articular TMD used as a reference standard in this investigation. The prevalence of both painful and non-painful conditions is expected to be much higher in a specialized TMD clinic compared to a general population based clinic like the PDHS. The prevalence of more rare conditions is also expected to be much

higher in a specialist setting (24). Therefore, affirmative answers to the 3Q/TMD in a specialized clinic can be related to a TMD diagnosis, but also to several differential diagnoses. Despite these differences between primary and secondary dental care, the distribution of the most common TMD related pain and intra-articular TMD conditions used as a reference standard in the two samples was surprisingly similar. In particular, the distribution of diagnoses among the 3Q-negatives was similar between the patient samples. Among the 3Q-positives in the PDHS population, three out of four individuals qualified for a DC/TMD diagnosis used as reference standard, as compared to 64% of the 3Q-positives in the specialist clinic. In both samples, the major reason that 3Q/TMD positives did not qualify for a TMD diagnosis was due to their answers in the DC/TMD symptom questionnaire. One part of the outcome with regard to the 3Q/TMD of the sample drawn from the PDHS was probably related to the research setting itself. In a clinical setting, the clinician can further explore an obvious discrepancy between answers in the questionnaire, oral case-history and findings from the clinical examination. Due to the blinded conduction of the study, such deflection from the examination protocol was not considered acceptable.

The diagnoses disc displacement with reduction and degenerative joint disorder were excluded from the reference standard. The reason was that the main symptoms of these conditions are joint sounds, whereas the third question was constructed with the aim was to capture more severe dysfunctional symptoms requiring treatment. In a report based on patients at a TMD specialist clinic, patients with disc displacement with reduction generally rated their complaints as minor, whereas those with disc displacements without reduction more often rated their complaints as fairly or very severe (100). Disc displacement with reduction and degenerative joint disease was found fairly stable over an 8-year observational time period, and the authors concluded that it was not possible to identify individuals at risk of a progression (116). In clinical practice and on an individual basis, joint sounds can however be severely disturbing and cause limitations of social activities. Also, the popping, clicking itself can be related to pain as in symptomatic disc displacements. Patients with these conditions may demand treatment and this may be a reason to why these diagnoses were more frequent in 3Q-positives in the specialist clinic sample.

Both 3Q/TMD and the DC/TMD diagnosis used as reference standard are based on self-reported pain and dysfunction but with two important differences. Firstly, the 3Q/TMD focuses on pain or dysfunction with a frequency of once a week or more, whereas the DC/TMD is based on reported symptoms within the last 30 days. Secondly, in the 3Q/TMD the first question, Q1, focuses on reported pain and Q2 on pain on function. However, in order

to qualify for a DC/TMD pain diagnosis the criteria are based on pain as well as that the pain should be provoked or modified by function. The observed variation of outcomes in terms of sensitivity and specificity for the 3Q/TMD in the two patient samples may reflect these differences.

In the PDHS population sample, the questions on pain, Q1 and Q2, and combinations of these questions showed substantial validity. This outcome is probably related to the DC/TMD reference standard, requiring both self-reported pain and pain provoked by function. In general, the negative predictive values were high, indicating that the questions are excellent for ruling out a TMD diagnosis on the individual level. In the specialist clinic sample at least one affirmative answer was enough to yield an equally positive predictive value and a slight decrease in negative predictive value as compared to the general population sample. When all three questions were answered affirmatively there was no significant difference in sensitivity or specificity between the two patient samples. Due to the estimated higher prevalence in the specialist clinic sample, the positive predictive value was high, and significantly higher when compared to the general population. So, in the specialist clinic sample, when all three questions were answered affirmatively, the clinician can primarily focus on a TMD related approach for further diagnostics.

The question on functional disturbances, Q3, showed fair-to-moderate validity in the general population. Even though the positive predictive value was low, the specificity was high and thus encouraging for screening purposes to rule out a probable dysfunctional diagnosis. In the specialist clinic sample, the sensitivity was similar, but specificity significantly higher compared to the general population sample. Once again the 3Q/TMD seems valid for absence of intra-articular TMD. On the individual level and due to the estimated higher prevalence within the specialist clinic sample the positive predictive value was high (0.92). An affirmative answer to Q3 in a specialist clinic setting could therefore primarily be related to a TMD.

The diagnostic value of joint sounds is not clear (117). The possibilities of a clinical assessment only of an intra-articular TMD have been previously questioned (118). The DC/TMD has only shown acceptable validity for an intra-articular TMD, and therefore the reference standard itself has been better suggested for screening purposes rather than for diagnostics (21, 119). In a recent meta-analysis on the validity of clinical protocols to assess disc displacement disorders it was concluded that the validities of both RDC/TMD and the DC/TMD were poor (120). Instead, for assessment of an intra-articular TMD diagnosis magnetic resonance imaging (MRI), computed tomography (CT)/ cone beam computerized tomography (CBCT) or

arthrography is advocated. However, these methods should only be used when such a result could change the treatment protocol. Furthermore, a previous report showed that even in asymptomatic individuals, disc displacements were present on MRI in approximately 30% (121, 122). Thus, an evaluation of the Q3 in relation to MRI examination could provide additional information. In this research we chose to rely on a clinical protocol for the evaluation of symptomatic intra-articular TMD. Altogether, the results show that the Q3 has different benefits in different settings. In the general population, the Q3 is useful to screen for the absence of a subgroup of intra-articular TMD whereas in the specialist clinic, the high positive predictive value predicts a probable subgroup of intra-articular DC/TMD diagnosis.

Although 3Q-positives reported significantly higher pain intensity and more limitations of jaw function, the inclusion of 'more severe TMD' did not significantly affect the diagnostic accuracy. This can be interpreted as if the screening questions already include those with a more severe TMD. The inclusion of 'once a week or more' was previously shown to be more clinically relevant for headache and in relation to TMD related to perceived treatment need in adolescents (95, 123).

Due to the fact that the DC/TMD was recently launched, previous validity studies on screening questionnaires have mostly been conducted in relation to the RDC/TMD. The use of the question 'Do you have pain in the face, jaw, temple, in front of ear or in the ear in the past month?' has been previously shown to be a good predictor for TMD (124). This question is quite similar to the Q1, apart from the difference in frequency. When compared to a previous study on the two screening questions on pain (Q1 and Q2) in adolescents (96), the general adult population showed lower sensitivities. Aside from the different reference standards used for adults, the prevalence of other orofacial pain complaints is probably higher compared to adolescents. The broad nature of the questions may cause an affirmative answer among adults related to toothache, which will decrease the sensitivity. As previously mentioned, and in relation to the RDC/TMD, the TMD pain screener has been recommended for the screening of a probable TMD pain condition. Based on the aforementioned arguments on characteristics of methods suitable for screening purposes for TMD, such as preferably high specificity, the TMD pain screener might be more suitable for specialist clinics than general population due to the high sensitivity.

The population at hand, the setting and the expected prevalence in relation to the diagnostic accuracy, are all important to acknowledge in relation to predictive values. From the validation study in a PDHS population an extrapolation was done by applying the results and calculating predictive

values with an estimated higher prevalence in order to correspond to the expected higher prevalence in a TMD specialist setting. This however, did not resemble the outcome in the TMD specialist clinic (Paper IV). The effect of different prevalence on predictive values for the two patient samples further illustrates the effect of samples and prevalence. As it seems, and due to the impact on negative predictive values, the 3Q/TMD is better suited for in low prevalence situations such as in the general population. Overall, our two studies confirm the notion that results from one sample cannot automatically be extrapolated to other circumstances. No matter what test or method is applied in a clinical situation, the outcome of the test will be interpreted by the individual clinician in the decision-making process. However, our results reinforce the importance of evaluating a diagnostic or screening method in the setting it should later be applied in.

### **Clinical decision making**

The human decision process is a complex phenomenon and there is a broad base of literature on theories of clinical judgement and decision-making available (125). A variety of sources of information are processed and considered when decisions are taken. However, it has been suggested that we are susceptible to over-estimate what we know, and also to not fully recognize what we do not know (70). In decision-making we tend to replace probabilities by similarities, and decisions are based on frequencies rather than likelihood (126). Also memories and previous experiences seem to be involved in decision-making where more recent events are related to the decision made (127). Moreover, on the individual basis there are large inter-individual differences in decision-making, as well as intra-personal differences between occasions on the same objective basis (128). With regard to this, decisions on TMD treatment are no exception (129). In general, we are uncertain of how to describe our decision process (128). Furthermore, it has been argued that the more complex the decision, the less likely it is that an intuitively based decision will yield a positive outcome (127). Therefore, usage of decision-support tools is recommended to minimize the effect of human intuition and decisions based on gut feeling (127).

In daily clinical practice, the care conducted and produced is a continuous sequence of decision making. Health care should be effective and minimize harm, but also be equal and involve patients as part of the decision-making. In clinical practice, the lack of reliable guidelines can be troublesome and lead to decisions based on subjective evaluations. This has also been stressed in community based debates, and it has been shown that demographics, education and gender was related to inequalities and discrimination in health care (130). A review on teaching clinical judgement concluded that ‘training

in clinical judgement is essential for the transition of students into competent practitioners' (131). In an evaluation of ethical decision-making in dental students, it was suggested that a systematic approach could make the decision process simple and to quickly yield to an ethical decision (132). Also the importance of including decision-making in dental education was stressed. In the clinical situations, there is often a limited amount of time for each decision to be made (129). Even though the neurobiological relationship between stress and decision-making is not fully understood, stress has been suggested to potentiate decision biases (133). For the clinician, a stressful work-schedule may therefore be one reason for the indicated oversight of patients with TMD found in the present thesis.

Evidence-based medicine (EBM) refers to the incorporation of best available scientific evidence, clinical experience and patients' values into clinical practice (134). A systematic review showed that guidelines can improve the process and structure of care (135). The effects of guidelines on the quality of care are less convincing due to a high variability in outcomes. Moreover, difficulties related to attitudes, routines and organisation have been identified in with regard to implementation of EBM and clinical guidelines (136). Thus, how guidelines are applied and what factors are important for the utilization of guidelines are not fully understood. As a part of EBM, decision trees have been suggested in order to reduce biased clinical decisions (137). As an example of a brief decision-tree in dentistry, 3Q/TMD is already implemented in daily routine care. Therefore, it is reasonable to assume that the questions are also associated with detectable clinical decision making in the patients' dental records. The issue of how the 3Q/TMD is used and relate to clinical decision-making in PHDS is discussed in the next section.

### **3Q/TMD, prescribed treatment and treatment need**

The evaluation of the outcome of 3Q/TMD on clinical decision-making showed that an affirmative answer to any of the 3Q/TMD was associated with prescribed TMD treatment. Still, according to the dental records, approximately two-thirds of the individuals with an affirmative answer to at least one of the 3Q/TMD did not receive a clinical decision. This could imply that the 3Q/TMD is not utilized as intended within the PDHS in Västerbotten. In the multivariate analysis, an affirmative answer to Q1 solely and Q1 or Q2 was associated with TMD treatment. This result is reasonable since pain, and pain intensity explicit has been found to be associated with treatment seeking (65, 138). On the other hand, Q3 was not associated with carried out or recommended TMD treatment. There are a number of possible reasons for this finding. It may reflect that in the clinical decision process, clinicians still do not consider an affirmative answer to Q3 important. As previously

mentioned, uncertainties are related to a poorer outcome of decision-making. The clinical diagnostic procedures for intra-articular TMD have a low sensitivity, which can prevent reliable diagnostics. In turn, this can lead to a refrain of diagnostics among clinicians due to the uncertain method itself. Individuals with non-painful, intra-articular TMD often reported their complaints as minor (100), which could lead to a general opinion that these conditions are less commonly in need of treatment or that effective treatment methods are lacking. Altogether, this may have led to an oversight of an affirmative answer to the Q3. It cannot be ruled out that an affirmative answer might have been discussed in the clinical situation even if the outcome of the discussion was not noted in the dental records.

Over the past decades, along with an increased scientific knowledge regarding possible risk factors for the onset and perpetuation of TMD, management of TMD and treatment need has also been evaluated. The term ‘treatment need’ reflects two different aspects in the clinical situation (139). The normative treatment need is based on the assessment of the clinician (sometimes referred to as ‘objective’), whereas the perceived treatment need refers to the individual’s experienced need for treatment (sometimes referred to as ‘subjective’ or demand for treatment). The ‘true’ treatment need has been suggested to be somewhere in-between the objective and subjective estimates (140). As for any other reported frequency, the outcome will differ depending on criteria, definition and population. A commonly reported treatment need for TMD in the population is around 10%, even though there is a wide range of estimated treatment need reported (141). A previous meta-analysis on treatment need for TMD showed a median of 16% in adult non-patient samples (68). The same study found that estimates based on clinical signs, e. g. normative treatment need, were higher compared to self-reported symptoms. On the other hand, it was also shown that the demand for TMD treatment is lower than the estimated and normative treatment need, which could perhaps help explain parts of the above-mentioned discrepancy (92). In relation to perceived treatment need, a few factors were previously identified to be associated with treatment seeking and treatment demand. Among these were pain intensity, diagnostic subgroup, and physical signs and symptoms (65, 67, 129).

In the cohort sample (Paper III), the percentage distribution of TMD treatment carried out or recommended out was nearly equal in men and women. The matter of how treatment need is related to gender is somewhat debated. In some reports female gender has been identified as a factor related to treatment need and in another gender was not a factor (67, 68, 129). Also, previous reports have suggested that women have a higher active treatment seeking behaviour than men (142), and as consequence of decision-making

women are referred more often than men (100). However, the higher proportion of treatment need in women might be a consequence of the higher proportion of women in patient samples rather than a higher treatment need. Therefore, the idea that women would be more susceptible to express a treatment demand should be questioned (142). However, women report their complaints as more severe and long-lasting than men do (100, 143, 144). In line with the biopsychosocial approach in pain management (145), it is reasonable to expect that gender differences should be properly considered in TMD management.

With regard to the aim, to identify factors related to the clinical decision-making process for patients with TMD, we found no other specific, independent variables to explain the outcome of this process. It is possible that a study with a qualitative approach among care givers could provide more detailed answers regarding factors of importance to better understand and to describe the difference between estimated treatment need and the treatment carried out. With regard to the risk of discrimination due to age, this has been investigated but no obvious result indicated an age related difference in treatment need (67, 129). In this study, no data on the sex of the examiner was available, which could have been of interest when evaluating eventual gender differences in clinical decision making. This is especially so since the inter-individual variability is large regarding decision-making for TMD (129), and female dentists seem to rate pain intensity higher than male dentist do (146). Taken together, results on treatment need and gender is inconclusive and may warrant further studies. Still, since gender itself seems related to the risk of under-treatment, the clinician ought to be aware of possible systematic, discriminatory behaviours.

Among the treatment provided, the most frequently used was occlusal appliances. These results are in line with previous studies (100, 147, 148) and with reports that general practice dentists felt confident in providing a patient with an occlusal appliance (147). However, there are other important aspects of TMD treatment such as information and jaw exercises. These types of treatment were less commonly identified in the dental records, even though they are recommended in Sweden in the national guidelines on the management of TMD. This may partly be related to the fee-system in use in Sweden at the time of the data collection, which is supported by the fact that a large part of the provided treatment was not charged for. Furthermore, it may be that patients with a need of multimodal treatment are already referred to specialist clinics, and as illustrated by the fact that the vast majority of individuals referred also answered affirmatively to the 3Q/TMD.

An extrapolation of the prevalence of treatments identified in the selected cohort to the total population, yield a total calculated TMD treatment in the population of 3.5%. When compared to the reported TMD treatment carried out in Västerbotten, Sweden during the same period the figure was less than 1% (69). This difference observed between the reported treatments as compared to actual treatment extracted from the dental records, may indicate difficulties in clinical practice to charge for TMD treatment.

The results of our study suggest that a majority of patients with at least one affirmative answer do not receive advice or treatment despite the strong association found between an affirmative answer to 3Q/TMD and a TMD diagnosis. In the light of the indicated under-treatment of TMD, evaluations of dentists' knowledge and attitudes have been studied. Within dentistry uncertainties in diagnostics and management of TMD were previously identified (73). In a previous mixed-model survey among German dentists, several uncertainties related to clinical decision-making related to TMD were found (149). For example, the estimated treatment need was higher among dentists with a more recent graduation. In contrast, TMD treatment was less provided during the first decades after graduation. In relation to management, while providing an occlusal appliance was a well-established method, other treatment modalities were less often mentioned. Due to the fact that the most common TMD can be managed successfully by general dental practitioners, the importance of diagnostics and management of TMD in dental education in Europe has been stressed (150). Since the now launched and recommended DC/TMD is available, this can lead to an improvement in diagnostic procedures. The DC/TMD itself also provides a decision-tree with an algorithm-based diagnostic system. In 2011, National Guidelines in adult dental care in Sweden was launched. These guidelines provide an evidence-based support and hierarchy of recommended treatment modalities for the most common TMD diagnoses (16). Taken together, the possibilities for EBM within dental care for patients with TMD are reasonably good. As a part of the clinical decision process and decision trees available we also have the 3Q/TMD. Even so, these results imply that evidence-based TMD management is often not provided to the patients. Altogether, this signifies that decision-making, risk of under-treatment, and TMD management need to be incorporated in the undergraduate training together with continuous education among general practitioners.

### **Methodological considerations**

There seems to be some features related to the presence of TMD that resembles the universal nature of musculoskeletal disorders, such as the distribution over a lifespan and the gender distribution. Other are rather

related to the setting and study population, such as the prevalence and distribution of diagnoses.

In paper I, the data were collected as part of the daily clinical routine, thus it is not possible to confirm the assessment of individuals' answers to the 3Q/TMD. It is reasonable to assume that responses from individuals with a quite low or high age are less reliable. This is partly related to why the study-populations in the other studies were based on samples 20-70 year-olds. If the assessment of answers to the screening questions is in some way biased in the clinical setting, it is assumed that the questions are likely filled out as all negative if not properly asked, rather than positive. This would in turn result in an actual higher prevalence than that now reported.

For the case-control and cohort studies, the reliable assessment of included data was accomplished by reliability tests of examiners. Even though the validity of the 3Q/TMD has been established, the reliability of the questions has not been assessed. This may be regarded as a limitation of the study design. Even though the criterion validity was established in relation to a valid reference standard, there are other aspects of a possible affirmative answer that were not taken into account. Another study design would be needed to fully capture this.

The structure of the question may also capture individuals with frequent headaches. Even though headache attributed to TMD is already in this sample due to the concurrent myalgia diagnosis, other headache diagnoses are also possible. This is especially so, since a large overlap between tension-type headache and headache associated with TMD probably exists (151).

## **Clinical implications**

We now know that approximately three out of four individuals with at least one affirmative answer to the 3Q/TMD in the general population, also will qualify for a TMD diagnosis. A negative answer is also related to the absence of the most commonly reported TMD conditions. Within every day practice clinicians continuously will meet these patients. There are many reasons why patients' complaints should be addressed properly within health care organizations. Among those are ethical considerations on an equality basis and prevention in terms of reduction of suffering, but also reduction of societal costs related to prolonged periods of illness and multiple health care seeking. The benefits with early identification in order to prevent acute pain to transgress into a chronic condition were stressed previously. Moreover, individuals with chronic pain related to TMD may benefit from multimodal and multidisciplinary treatment (53, 152). Providing this more complex treatment is a more challenging and time-consuming task for the practitioner as well as involving a more complex patient journey which again reinforces the importance of early intervention (58). Furthermore, based on the fact that individuals with TMD often report care-seeking at multiple health-care institutions, this in itself is related to increased costs for the society. Even though the cost-effectiveness explicitly has not been studied in relation to the 3Q/TMD, it can be assumed that three short questions with yes/no answers is a convenient and rapid method; therefore, the 3Q/TMD is a suitable method for screening purposes in clinical practice.

It should be kept in mind however, that these questions only address the physical part of TMD. As advocated previously, the psychosocial aspects of TMD management are also important. In order to adequately address these parts of the screening process, additional questions are needed for patients diagnosed with a TMD. In axis II, in the DC/TMD, such screening for depression and anxiety are available. Together with the GCPS in order to establish the consequences of chronic pain, these instruments could further improve the overall screening process within general dental practice.

## **Future directions**

In line with the recommendation that decision trees in medicine should embrace both available evidence and patient values, some further evaluations of the 3Q/TMD may be implied. First a qualitative approach could reveal important information on both patients' and clinicians' perspectives on TMD assessment and management. Also, as previously discussed, a qualitative approach could yield additional information on other aspects of affirmative answers besides the relation to the most common TMD. Part of these aspects could also be assessed by a more thorough evaluation of the psychosocial aspects related to TMD, which are available in the axis II questionnaires but in parts not included in this thesis. An additional quantitative approach of the relationship between affirmative answers to the 3Q/TMD and axis II findings are likely warranted.

To provide clinicians with robust evidence on the benefits with the use of the 3Q/TMD in clinical practice, an evaluation on the relation between an affirmative answer and treatment need could be relevant. Furthermore, research is needed to evaluate the actual use of the 3Q/TMD in clinical practice and if information and education on how to use the questions increase the recognition of these patients. Due to the potential benefits with early identification in primary care and subsequently multimodal treatment, further efforts are needed in order to synchronize primary medical care and dental care for some patients with TMD.

The results from this thesis suggest that the 3Q/TMD should be included in health declarations in dentistry as well as medicine. Furthermore, the health care system should provide an equal, holistic and effective approach. In my opinion, for patients with TMD, health care providers should work in a broad perspective, in order to recognize and guide the patient through the health care system; again, with the main objective to improve health care for the individual patient.

## Main findings

- affirmative answers to the 3Q/TMD increase during adolescence
- women respond affirmatively to the 3Q/TMD significantly more often than men for all age groups except the first and last decade of a one hundred years lifespan
- the highest prevalence was reported by women during their fertile period in life
- in the general population sample, three out of four 3Q-positives qualified for a DC/TMD pain or subgroup of intra-articular diagnosis
- for the individual 3Q/TMD questions, as well as combinations of the questions, the negative predictive values in relation to TMD were high in the general population
- 3Q-positives reported significantly higher characteristic pain intensity levels and higher functional impairment
- in the specialist clinic sample, two out of three of 3Q-positives qualified for a DC/TMD pain or subgroup of intra-articular diagnosis
- the highest positive predictive values were found when Q1 and Q2 or when Q3 were answered affirmatively
- there was significantly more treatment performed or recommended for 3Q-positives as compared to 3Q-negatives
- the odds ratio for TMD-related treatment for 3Q-positives versus 3Q-negatives was 12.1 (95% CI:6.3-23.4)
- the majority of the 3Q-positives still did not receive a traceable prescribed treatment or clinical decision

## Conclusions

Taken together, the results in this thesis suggest that:

- the 3Q/TMD is a suitable, convenient and valid screening method to detect individuals who would benefit from a further TMD examination
- the 3Q/TMD are useful as guidance for further diagnostics within specialized orofacial pain clinics
- the importance of evaluation of a test in a representative setting and milieu is reinforced with regard to diagnostic accuracy
- there is not an established relationship between affirmative answers to 3Q/TMD and treatment need
- the reasons for under-treatment of TMD are still unrevealed and this question remains unanswered
- factors associated with dentists' clinical decision-making in relation to TMD warrants further research and efforts within dental health care

Finally, the utilization of the 3Q/TMD as a part of a decision tree for the clinician can improve the health care for patients with TMD and is therefore recommended within dentistry. The 3Q/TMD may also be introduced as a screening method in primary medical health care, to recognize individuals with a possible need of multidisciplinary assessment.

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## **Amendments**

In paper I the used translation of Q2 was 'Does it hurt...?'. For the following papers the translation was changed to 'Do you have pain...?' in analogy with the original two questions on TMD pain. The used wording in Swedish in both the clinical setting as well as in the research projects was the same all along. Therefore, we assume this did not affect the outcomes.

In paper I, the Spearman's correlations are as follows:  
(Correlation coefficient Q1:Q2 = 0.482; Q2:Q3 = 0.326; Q1:Q3 = 0.257,  
P < 0.0001).

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