# The Dental, Oral, Medical Epidemiological (DOME) Study: Protocol and Study Methods

Galit Almoznino<sup>1,2,3</sup> Ron Kedem<sup>4</sup> Ronit Turgeman<sup>5</sup> Tarif Bader<sup>6</sup> Nirit Yavnai<sup>7</sup> Dorit Zur<sup>4</sup> Boaz Shav<sup>3</sup>

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Address for correspondence Galit Almoznino, DMD, MSc, MHA, MPH, Department of Oral Medicine, Sedation and Maxillofacial Imaging, Hebrew University, Hadassah School of Dental Medicine, Israeli Society of Oral Medicine (ISOM), P.O. Box 12000, Jerusalem 91120, Israel (e-mail: galit@almoznino.com).

### **Abstract**

**Objectives** To develop and present the methods utilized for the Dental, Oral, Medical Epidemiological (DOME) study.

**Methods** The DOME is an electronic record-based cross-sectional study, that was conducted to measure the dental, periodontal, and oral morbidities and their associations with systemic morbidities, among a nationally representative sample of young to middle-aged adults military personnel from the IDF (Israel Defense Forces). To that end, we developed a strict protocol including standardized terminology, data collection, and handling.

**Results** Data for the DOME study was derived simultaneously from three electronic records of the IDF: (1) a central demographic database, (2) the dental patient record (DPR), and (3) the medical computerized patient record (CPR). The established DOME repository includes socio-demographic, dental and medical records of 132,354 young to middle-age military personnel from the IDF, who attended the dental clinics during the year 2015. Records of general military personnel (N > 50,000), with no recorded dental visits during the study period, served as a control group regarding all other parameters except dental. The DOME study continues and is currently collecting longitudinal data from the year 2010 until 2020. The IDF employs a standardized uniform administrative and clinical work-up and treatment protocols as well as uniform computerized codes. We describe the standardized definitions for all the parameters that were included: socio-demographics, health-related habits, medical and dental attendance patterns, and general and dental health status. Multicollinearity analysis results of the sociodemographic and medical study parameters are presented.

**Conclusion** Standardized work-up and definitions are essential to establish the centralized DOME data repository to study the extent of dental and systemic morbidities and their associations.

### **Keywords**

- epidemiological studies
- dental health
- informatics
- oral health
- electronic medical records

<sup>&</sup>lt;sup>1</sup> Big Biomedical Data Research Laboratory, Hebrew University, Hadassah School of Dental Medicine, Jerusalem, Israel

<sup>&</sup>lt;sup>2</sup> Department of Oral Medicine, Sedation and Maxillofacial Imaging, Hebrew University, Hadassah School of Dental Medicine, Jerusalem, Israel

<sup>&</sup>lt;sup>3</sup>Department of Endodontics, Hebrew University, Hadassah School of Dental Medicine, Jerusalem, Israel

<sup>&</sup>lt;sup>4</sup>Medical Information Department, Medical Corps, Israel Defense Forces, Tel-Hashomer, Israel

<sup>&</sup>lt;sup>5</sup>Chief Dental Surgeon Headquarters, Medical Corps, Israel Defense Forces, Tel-Hashomer, Israel

<sup>&</sup>lt;sup>6</sup> Surgeon General's Headquarters, Israel Defense Forces, Ramat Gan and Department of Military Medicine, Hebrew University, Jerusalem, Israel

<sup>&</sup>lt;sup>7</sup> Medical Research and Academy Section, Medical Corps, Israel Defense Forces, Israel

### Introduction

Quantifying dental and oral morbidities in a meaningful and reproducible manner has been an ongoing challenge for oral epidemiologists and clinicians.<sup>1–3</sup> To develop policy and allocate resources for medical and dental care in an informed manner, health authorities need to be familiar with the data on the extent of dental and systemic morbidity. In Israel, there is no formal authority responsible for collecting dental and oral morbidity data, although the ministry of health has suggested that an epidemiologic survey should be performed every 5 years.<sup>4</sup> Consequently, there is a lack of information regarding the status of dental, periodontal, and oral morbidity among the Israeli population, and regarding its trends throughout the years.<sup>4</sup>

To address this gap in the literature, the current project, termed as "Dental, Oral, Medical Epidemiological (DOME)" study, aims to study the dental, periodontal and oral morbidities and analyze their associations with systemic morbidities, among a unique nationally representative sample of young to middle-aged adults, i.e., the military personnel in the Israel Defense Forces (IDF). The military population in Israel is large, and serves as a reliable source of data for epidemiologic studies among young and middle-aged adults, partially because conscription exists in Israel for all Jewish, Druze, or Circassian citizens over the age of 18.<sup>5</sup> Israeli Arabs, Druze women, and ultraorthodox religious Jewish citizens are exempt from military service<sup>6,7</sup> and therefore not included in this study.

Several authors documented associations between health status and socioeconomic variables.<sup>8,9</sup> Associations between dental and periodontal morbidities and various systemic diseases had been also documented. In particular, periodontitis had been linked to various systemic diseases such as metabolic syndrome<sup>10-13</sup> and each of its components and consequences, including type 2 diabetes, 14 hypertension, <sup>15,16</sup> hyperlipidemia, <sup>17</sup> abdominal obesity, <sup>18</sup> cardiovascular disease, <sup>19</sup> and stroke. <sup>20</sup> The underlying mechanisms for these associations remain unclear, although inflammatory mechanisms seem to play an important role. 18,21-26 Moreover, there are well-known common risk factors, <sup>27</sup> such as increased age, smoking, and lifestyle, for many chronic diseases, including metabolic syndrome, hypertension, hyperlipidemia, diabetes type 2, and cardiovascular disease.<sup>28-30</sup> These risk factors had been also linked to oral health status, including periodontitis. 27,31,32

Based on an extensive literature review, the secondary goals of the DOME project were to evaluate the extent of dental and systemic morbidities and their complex associations. Specifically, the secondary aims were to analyze the associations and correlations between dental, periodontal, and oral morbidities and: socio-demographics, health-related habits, medical and dental attendance patterns, and general health status. It should be noted that medically complex patients serve in the IDF, in noncombat occupations, and even subjects deemed unfit for service for physical or mental health reasons can apply for volunteer positions.<sup>33</sup> Volunteers have the same access and rights to dental care

as soldiers in mandatory service. Criteria for volunteering in the IDF for military exemption recipients are publicly available.<sup>34</sup>

This paper aims to present and discuss in detail the development, and study methods of the DOME project, including the standardized terminology, data collection, handling, and analysis. In our series of papers that are due to follow, we will present the data on each specific dependent variable that we analyzed.

# **Methods**

The DOME project is a records-based study, which consists of the socio-demographic, dental and medical and records of young to middle-age military personnel, serving in mandatory and career service, who attended routine dental screenings and treatments at any of the military dental clinics of the IDF, between January 1st, 2015 and January 1st, 2016. Sociodemographic and medical parameters of these patients were compared with a control group data from the central IDF database, with records from over 50,000 general military personnel, with no recorded visits to military dental clinics during the study period. The control data were obtained on the mid-study period (June 30th, 2015). The DOME study continues and is currently collecting longitudinal data from the year 2010 until 2020. Data mining was performed by the Medical Information Department, General Surgeon Headquarter, Medical Corps, Tel-Hashomer, Israel. The database is completely anonymous.

All patients received free and unconditional treatment as IDF military personnel do not incur any medical and/or dental expenses. So, Commanders are obligated to allow their subordinates full access to all medical and/or dental services, independent of rank and position. Moreover, a baseline evaluation of dental status is performed during the mandatory dental examination which takes place during the first 4 months of recruitment.

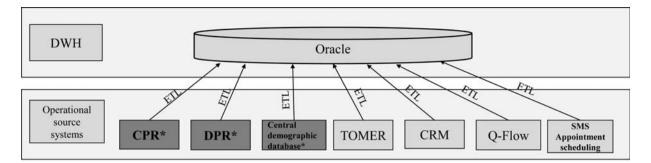
### **Ethical Considerations**

The study adhered to the STROBE guidelines and was approved by the Medical Corps, IDF, Institutional Review Board, approval number: IDF-1281–2013. Since this retrospective study only involved anonymous medical records analysis, the IRB gave an exemption from written informed consent.

### Results

### Informatics standards in the IDF Medical Corps

The data warehouse (DWH) of the IDF Medical Corps (Version 11 g of the Oracle Database) combines information from several operational source systems into one comprehensive database (Fig. 1). Data from the operational sources are extracted and then replicated to the DWH via ETL (Extract-Transform-Load) processes nightly. The ETL tool used is Informatica version 9.6.1. The collected data are classified in the DWH into Oracle database schema according to the data world of the original operational sources (e.g., computerized patient record [CPR] schema, dental patient record



\*Operational source systems used in the DOME study:

CPR: computerized patient record system

DPR: Dental Patient Record

TOMER: a table of treatment codes standardized across military clinics and services.

CRM- Customer relationship management system.

Q -Flow: a telephone appointment scheduling platform.

Fig. 1 The architecture of the data warehouse (DWH) of the IDF Medical Corps.

[DPR]schema, etc.). All pieces of information have two patient identifiers (civilian and military ID numbers), allowing all data from a specific individual to be combined into a single record.

Data collection: The records were extracted from the databases using the military ID number and validated using the civilian ID number. Data management from the DWH was performed using SAS version 7.1. To develop the DOME repository, data were drawn simultaneously from three electronic records:

- 1. Dental patient record: This electronic dental record system stores the data of all dental care in the IDF.5 The DPR includes the patient's dental, periodontal, and oral records as well as treatment plan and actual treatments, imaging results, and consultation requests. The DPR is stored on a structured query language server 2005.
- 2. Computerized patient record: is a comprehensive electronic medical record system found in all military primary care and specialty clinics.<sup>37</sup> It contains electronically maintained information about the patient's general health status and care. Data include clinical documentation, medical issues, medications prescribed, physicians' notes (e.g., medical history and follow-up), laboratory and imaging results, and consultation request.<sup>37</sup> The CPR is stored in version 11 g of the Oracle database.
- 3. *IDF's central demographic database*: keeps the records of the personal socio-demographic profiles of the military population.<sup>38</sup> The central demographic database is stored in version 11 g of the Oracle database.

Preparation and cleaning of data for analysis: Following the integration of the extracted data from the IDF Medical Corps' DWH, the data was prepared, cleaned, harmonized, anonymized, and transformed into an Excel file suitable for analyses. The objective of this stage was to diminish noise by detecting and removing outliers (e.g., due to typographical errors) and by evaluating data quality. An outlier is a biologically irrelevant measurement (e.g., a height value of 4 m), or an impossible number of dental visits (e.g., hundreds per

year). Outliers are detected using nonparametric statistical analyses, due to lack of knowledge regarding the data distribution.

#### **Inclusion Criteria**

- 1. Military personnel in mandatory and career service.
- 2. The existence of subject data in the demographic database, CPR, and DPR. For controls: the existence of subject data in the CPR, and socio-demographic records.

### **Exclusion Criteria**

- 1. Excluded from military service.
- 2. Lack of socio-demographic, dental, or medical data in the demographic database, and/or CPR and DPR.

Data were taken simultaneously from the three sources according to the inclusion and exclusion criteria. This established the centralized data repository of the DOME study that includes socio-demographic, medical, and dental data of 132,354 records of subjects who attended the dental clinics and as well as records of controls (N > 50,000), with no recorded dental visits during the study period.

### Study Variables

Definitions of Dental, Periodontal, Oral, and Maxillofacial **Variables** 

Standardization Methods of the Dental Department of the IDF Medical Corps

Examinations and treatment plans were made according to the guidelines of the Dental Department of the IDF medical corps.5 According to these guidelines, the dental examinations were performed in military dental clinics, in an indoor setting, with optimal light, dental mirror, and UNC-15 (University of North Carolina, North Carolina, United States) periodontal probe, Hu-Friedy Manufacturing Co., Chicago, Illinois, United States.

The guidelines require a pair of vertical bilateral bitewings for the molar and premolar areas for all examinees and periapical radiographs for deep caries, endodontically treated teeth, and periodontal disease. 5 As part of the routine training, all military dentists complete a dental officers' course at the Military Medicine Academy, as the last chapter in their training as officers. During this course, the guidelines and protocols of the Dental Department of the IDF medical corps are reviewed. This ensures the standardization of evaluation, treatment, and administrative methods among all IDF military dentists. Quality assessment (QA) of treatment plans and adherence to these guidelines are checked regularly by the regional military chief dental surgeons. <sup>5</sup> This allows the medical-dental system to be homogenous, with standardized uniform administrative as well as clinical workup and treatment process.<sup>35</sup>

# Standardized Codes for Dental Procedures in the Dental Patient Record (DPR)

Standardized uniform codes are employed in the DPR for all dental procedures. **Table 1** presents the nomenclature of the standardized DPR codes for dental procedures and their equivalent nomenclature by the American Dental Association (ADA) Current Dental Terminology (CDT).<sup>39</sup>

Each dental code appears twice in the database per subject. The first time, in the treatment plan (as treatment needed) and then after the treatment was performed. Although orthodontic treatments are performed in the IDF, orthodontic treatment assessment was beyond the scope of this study.

# Mandatory Standardized Form to Record Health-Related Habits and Diagnoses in the DPR

The opening screen of the DPR includes a mandatory form filled by military dentists according to the guidelines of the Dental Department of the IDF medical corps which includes the following:

(a) Presence of periodontitis: Table 1 presents the nomenclature of the standardized DPR codes for periodontal examinations and procedures and their equivalent nomenclature by the ADA-CDT. The current periodontitis definitions were published in the special issue: Proceedings of the World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions. 40 This workshop was planned and conducted jointly by the American Academy of Periodontology (AAP) and the European Federation of Periodontology in November 2017. The special issue was published in June 2018,40 and it incorporates papers<sup>40–63</sup> that summarize the current /modern definitions used in the assessment of periodontal and periimplant diseases and conditions. In the present study, periodontitis is defined according to the guidelines of the AAP during 2010 to 2018,64 and thereafter (2018-2020) the definitions were according to the new guidelines presented above. Furthermore, even before 2018, routinely collected data (see below) included age, smoking habits, metabolic morbidity including diabetes, and for those with

diabetes the glycated hemoglobin (HbA1c) was also measured. Moreover, due to possible pseudo pockets, <sup>65</sup> radiographic bone loss was considered mandatory to establish a diagnosis of periodontitis according to the guidelines of the Dental Department of the IDF. Bitewing radiographs are routinely inspected by dentists for the loss of periodontal support. Radiographic bone loss is defined as a distance between the crestal margin and the cementoenamel junction, which is greater than 2 mm, in more than one tooth, with no visible cause, <sup>66</sup> such as faulty restoration, overhang, etc.

- (b) The number of missing teeth: Is the count of missing teeth for any reason, including extractions due to decay, periodontal, or orthodontic reasons. Wisdom teeth were not included in the count.
- (c) The presence of oral soft tissue disease or suspected pathological lesions in the soft tissues of the oral cavity and lips during a dental examination is recorded routinely as are all suspected pathological X-ray findings in bitewings and/or periapical and/or panoramic X-rays during a dental examination.
- (d) Assessment of oral health-related habits: These include three questions aimed to assess the oral health-related habits of the patients:
  - Teeth brushing: Do you brush your teeth at least once a day? yes/no.
  - 2. *Cariogenic diet consumption*: Do you consume snacks and/or sweets between meals or instead of meals? yes/no.
  - 3. Sweetened beverages consumption: Do you consume at least one cup per day of sweetened (artificial and/or sugar-based) beverages? yes/no.

Assessment of the current smoking status and alcohol consumption (yes/no) was found in the CPR as recorded by the general physician.

### **Definitions of the Sociodemographic Variables**

The following socio-demographic variables drawn from the IDF's central demographic database were included:

- 1. Age: in years; Sex: men/women.
- 2. Service type and duration: measured in months.<sup>7</sup>
- 3. *Type of army unit*: combat or support.<sup>7</sup>
- 4. *Education*: (a) high school graduate with 12 years of school education, (b) technical college graduate, and (c) academic education.
- 5. *Intellectual capability and quality group:* All draftees are thoroughly screened for physical and mental pathology 1 year before mandatory military service, to determine their eligibility for service and their potential for various military roles. 6,67 Screening includes the intellectual capability score (ICS) and quality group score (QGS):
  - (a) *Intellectual capability score*: Intelligence is based on an evaluation of verbal, nonverbal, and mathematical cognitive abilities, taken at this first draft.<sup>5,6,67</sup> The sum of the test results forms a validated measure of

Table 1 Nomenclature of the standardized Dental Patient Record (DPR) codes for dental procedures and their equivalent nomenclature in the American Dental Association (ADA) Current Dental Terminology (CDT)-2018<sup>44</sup>

DPR code—abbreviations of the procedure in Hebrew	ocedure in Hebrew				
Emergency dental/medical referrals	Urgent referral of a patient to a specialist evaluation because of a pathological finding suspicious to be a significant medical condition (e.g. suspected cancer, systemic illness)	None			
Dental examination	Comprehensive oral evaluation for a new or established patient	D0150			
Oral medicine examination	Comprehensive oral evaluation—new or established patient	D0150 D0160			
Periodontal examination	Comprehensive periodontal evaluation—new or established patient—done by a periodontist	D0180			
Periodontal scaling and root planning	Periodontal scaling and root planning—four or more teeth per quadrant	D4341			
Periodontal maintenance	Periodontal maintenance	D4910			
Temporomandibular disorders examination	Comprehensive evaluation of temporomandibular disorders—new or established patient	None			
Oral hygiene instructions	Oral hygiene instructions	D1330			
Caries arresting medicament application	Interim caries arresting medicament application—per tooth	D1354			
Scaling	Scaling in presence of generalized moderate or severe gingival inflammation—full mouth, after oral evaluation	D4346			
Scaling done by a dental hygienist	·				
Scaling and root planning	Periodontal scaling and root planning	D4341 D4342			
Amalgam surface-1	Amalgam—one surface, permanent	D2140			
Amalgam surface-2	Amalgam—two surfaces, permanent	D2150			
Amalgam surface-3	Amalgam—three and more surfaces, permanent	D2160			
Amalgam crown	Amalgam—four or more surfaces, permanent	D2161			
Resin-based composite	Resin-based composite—one to four surfaces, anterior	D2330, D2331 D2332, D2335			
Composite crown	Resin-based composite crown, anterior	D2390			
Root canal treatment-1 (RCT-1)	Endodontic therapy, one root canal (excluding final restoration) <sup>a</sup>	D3310			
Root canal treatment-2 (RCT-2)	Endodontic therapy, two root canals (excluding final restoration) <sup>a</sup>	D3320			
Root canal treatment-3 (RCT-3)	Endodontic therapy, three root canals (excluding final restoration) <sup>a</sup>	D3330			
Root canal treatment-4 (RCT-4)	Endodontic therapy, four root canals (excluding final restoration) <sup>a</sup>	D3330			
Root canal treatment-5 (RCT-5)	Endodontic therapy, five root canals (excluding final restoration) <sup>a</sup>	D3330			
Total number of teeth with endode	ontic treatment = RCT-1 + RCT-2 + RCT-3 + RCT-4 + RCT-5				
Atypical root canal treatment-1 (ARCT-1)	Endodontic therapy, atypical root canal anatomy, one root canal (excluding final restoration) <sup>a</sup>	D3310			
Atypical root canal treatment-2 (ARCT-2)	Endodontic therapy, atypical root canal anatomy, two root canals (excluding final restoration) <sup>a</sup>	D3320			
Atypical root canal treatment-3 (ARCT-3)	Endodontic therapy, atypical root canal anatomy, three root canals (excluding final restoration) <sup>a</sup>	D3330			
Atypical root canal treatment-4 (ARCT-4)	Endodontic therapy, atypical root canal anatomy, four root canals (excluding final restoration) <sup>a</sup>	D3330			
Total number of teeth with atypica	Il root canal anatomy with endodontic therapy= ARCT-1 + ARCT-2 + AR	CT-3 + ARCT-4			
Retreatment root canal-1 (RRC-1)	Retreatment of previous root canal therapy, one root canal (excluding final restoration) <sup>a</sup>	D3346			

(Continued)

Table 1 (Continued)

DPR code—abbreviations of the procedure in Hebrew	Nomenclature	Equivalent ADA CDT-2018 code	
Root canal retreatment-2 (RRC-2)	Retreatment of previous root canal therapy, two root canals (excluding final restoration) <sup>a</sup>	D3347	
Root canal retreatment-3 (RRC-3)	Retreatment of previous root canal therapy, three root canals (excluding final restoration) <sup>a</sup>	D3348	
Root canal retreatment-4 (RRC-4)	Retreatment of previous root canal therapy, four root canals (excluding final restoration) <sup>a</sup>	D3348	
Root canal retreatment-5 (RRC-5)	Retreatment of previous root canal therapy, five root canals (excluding final restoration) <sup>a</sup>	D3348	
Total number of teeth with retreati	ment of previous root canal therapy = $RRC-1 + RRC-2 + RRC-3 + RRC-4 + RRC-1$	RRC-5	
Extraction	Extraction erupted tooth or exposed root (elevation and/or forceps removal)	D7140	
Surgical extraction	<ul> <li>Extraction erupted tooth requiring removal of bone and/or sectioning of a tooth and including elevation of the mucoperiosteal flap if indicated.</li> <li>Removal of an impacted tooth (soft tissue/partially bony/completely bony).</li> </ul>	D7210, D7220 D7230, D7240	
Implant placement	Surgical placement of implant body: endosteal implant	D6010	
Second stage implant surgery	Second stage implant surgery	D6011	
Implant removal	Implant removal, by a report	D6100	
Crown	Crown-porcelain/ceramic Crown-porcelain fused to high noble metal Crown-porcelain fused to a predominantly base metal crown-full cast predominantly base metal Crown-full cast noble metal	D2740 D2750 D2751 D2791 D2790 D2792	
Implant-supported crown	Implant-supported porcelain/ceramic crown Implant-supported porcelain fused to metal crown (titanium, tita- nium alloy, high noble metal) Implant-supported a metal crown (titanium, titanium alloy, high noble metal)	D6065 D6066 D6067	
Interim abutment	Interim abutment	D6051	
Direct post and core	Prefabricated post and core in addition to a crown	D2954	
Indirect post and core	Post and core in addition to the crown, indirectly fabricated	D2952	
Occlusal guard	Occlusal guard	D9940	
Missed appointment	Missed appointment	D9986	

<sup>&</sup>lt;sup>a</sup>Equivalent endodontic CDT codes, address endodontic treatment according to the tooth (anterior, premolar, and molars), while the DPR classifies according to the number of root canals.

- general intelligence (IQ) scored on a 9-point scale that is adjusted from time to time. <sup>68,69</sup> The ICS score ranges from 10 to 90, with 90 being roughly equivalent to an IQ of 135 and above. <sup>67</sup>
- (b) *Quality group score*: This score integrates several personality characteristics designed to assess combat suitability and future military performance.<sup>69</sup> It is comprised of educational background, test scores, and a personal interview, which are combined with an actuarial procedure into a single 16-point scale score between 41 and 56.<sup>67,69</sup>
- 6. *Socio-economic status (SES)*: SES was based on the locality of residence taken from Israeli Ministry of the interior
- records, which stratifies all local councils and municipalities data into 10 socio-economic docile groups determined by the Israeli Central Bureau of Statistics.<sup>70</sup> The SES considers age distribution, available workforce, level of unemployment, level of education (proportion of undergraduate students and those entitled to a high school diploma), average per capita income, and proportion of income support recipients. SES was classified into three categories: low (1st–4th deciles), medium (5th–7th), and high (8th–10th), as reported previously.<sup>71–73</sup>
- 7. Countries of origin and countries of birth: The country of origin for Israeli-born individuals was defined by paternal or paternal grandfather's country of birth if the father was

- born in Israel, as described previously. <sup>38,74,75</sup> Countries of origin and countries of birth were categorized into the following geographic areas: Western Europe, Former Soviet Union (FSU), Asia, Ethiopia, Africa, North America, South America, and Israel.
- 8. The locality of residence: was determined according to both stratification of urban versus rural as well as Jewish versus non-Jewish population in the area. The locality was classified into three categories: urban Jewish, urban non-Jewish, and rural.
- 9. *Living in central versus peripheral rings of a city/town*: the central ring is the economic, employment, and social center of a city/town compared with its peripheral areas.

### **Definitions of General Health Status Parameters**

## Mandatory Standardized Form for Recording General Health Status Diagnoses in the Computerized Patient Record

Medical care is provided according to the guidelines of the IDF Medical Corps. <sup>69</sup> During the education and training military physicians are taught the appropriate military medical terminology and guidelines. <sup>69</sup> QA of health care was performed regularly by QA teams, as was previously detailed. <sup>76</sup>

General health status parameters are drawn from the CPR include:

1. *Medical profile*: During the draft process, all recruits undergo a through a medical and psychiatric evaluation, to determine eligibility for service.<sup>67</sup> Subsequently, each examinee is given a specific standardized numerical code, termed the medical profile. The medical profile is a scoring system the IDF uses to determine medical suitability. Although the scale is ordinal, it is nonsequential,<sup>67</sup>

- and includes the following values (from highest to lowest): 97 (most physically capable), 82, 77, 72, 65, 64, 45, 35, 30/25, 24, 21 (unfit for service for medical health reasons). Explanation regarding each score can be found in IDF websites (http://draftidf.co.il/profile/). The medical profile is updated during military service according to the soldier's physical or mental state, either by the authorities or by the soldier.<sup>67,77</sup> In the present study, the medical profile was categorized as follows: high: 73 to 97, intermediate: 65 to 72, and low profile: 21 to 64.
- 2. *Medical diagnoses*: include the current medical diagnoses of the patient in the CPR, documented by a primary care provider and/or specialists.
  - (a) Complex variable definitions: The Medical Corps developed complex variable definitions for three medical conditions: hypertension, hyperlipidemia, and diabetes (~Table 2). These definitions are generated and stored in the computerized database and are used to periodically assess these morbidities by IDF authorities.
  - (b) Other diagnoses recorded in the CPR and collected for the current study include obstructive sleep apnea, fatty liver, anemia, osteoporosis, status post (S/P) transient ischemic attack, and S/P stroke.
  - (c) *Family history* of the following: diabetes, heart problems, stroke, sudden death, and alcoholism.
  - (d) *Auxiliary examinations*: including blood pressure and body mass index (BMI). <sup>68,78</sup>
- 1. Systolic and diastolic blood pressure Blood pressure is routinely measured by a medic before any medical examination, after 5–10 minutes of rest in the sitting position, with an appropriately sized cuff on the right arm, at heart level using a manual sphygmomanometer, as detailed elsewhere.<sup>78</sup>

Table 2 Complex variable definitions for hypertension, diabetes, and hyperlipidemia

Diagnosis	Criteria for diagnosis establishment
Hypertension	<ol> <li>Valid military disability code for hypertension.</li> <li>Results of the blood pressure test at any stage prior to the examination period that meet the following criteria:         <ol> <li>One measurement higher or equal to 110 mm Hg diastolic or 180 mm Hg systolic.</li> <li>Two measurements higher or equal to 100 mm Hg diastolic or 160 mm Hg systolic.</li> <li>Three measurements higher or equal to 90 mm Hg diastolic or 140 mm Hg systolic.</li> </ol> </li> <li>Treatment—a patient who was treated with three prescribed antihypertensive medications from 1 y prior to the examination period until the present examination.</li> </ol>
Diabetes	<ol> <li>Having a valid military disability code for diabetes.</li> <li>Prescribed medications for diabetes, other than the Glucophage category within the preceding year, from 1 y before the examination period until the present examination.</li> <li>Prescribed medications for diabetes, from the Glucophage category, from 1 y before the examination period until the present examination.</li> <li>Receiving prescription (code ICD 250) following the diagnosis of diabetes mellitus.</li> <li>Results of HbA1c above 6.5% at any stage before the examination period.</li> <li>Results of blood-glucose levels above 200 mg/dL on the year before the examination period.</li> </ol>
Hyperlipidemia	<ol> <li>An LDL test was made in the last 5 y, and in the last examination checkup, they received an LDL test result of 160 and above.</li> <li>The lipid profile test was taken in the last 5 y, and in the last examination the triglyceride results were above 200, and the non-HDL cholesterol result was above 190.</li> <li>Valid military disability code for hypertension.</li> </ol>

Abbreviations: ICD, International Classification of Diseases; LDL, low-density lipoprotein.

Table 3 Multicollinearity tests:	Pearson	's correlation	on between	socio-dem	ograpnic p	arameters	
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		Sex	Education	SES	Age	Medical profile	QGS score	ICS score
Sex	Pearson Correlation	1.00	0.10	0.01	0.16	0.05	0.06	0.02
	Sig. (two-tailed)		< 0.001	< 0.001	< 0.001	<0.001	< 0.001	< 0.001
Education	Pearson correlation	0.10	1.00	0.12	0.68	-0.05	0.20	0.24
	Sig. (two-tailed)	< 0.001		< 0.001	< 0.001	<0.001	< 0.001	<0.001
SES	Pearson correlation	0.01	0.12	1.00	0.08	0.00	0.07	0.08
	Sig. (two-tailed)	< 0.001	< 0.001		< 0.001	0.0540	< 0.001	<0.001
Age	Pearson correlation	0.16	0.68	0.08	1.00	-0.10	0.08	0.09
	Sig. (two-tailed)	< 0.001	< 0.001	< 0.001		<0.001	< 0.001	< 0.001
Medical profile	Pearson correlation	0.05	-0.05	0.00	-0.10	1.00	0.06	0.02
	Sig. (two-tailed)	< 0.001	< 0.001	0.0540	< 0.001		< 0.001	< 0.001
QGS score	Pearson correlation	0.06	0.20	0.07	0.08	0.06	1.00	0.90
	Sig. (two-tailed)	< 0.001	< 0.001	< 0.001	< 0.001	<0.001		< 0.001
ICS score	Pearson correlation	0.02	0.24	0.08	0.09	0.02	0.90	1.00
	Sig. (two-tailed)	<0.001	<0.001	< 0.001	< 0.001	<0.001	<0.001	

Abbreviations: ICS, intellectual capability score; QGS, quality group score; SES, socio-economic status.

2. Body Mass Index (BMI) and the diagnosis of obesity – BMI is defined as the weight (in kilograms) in light clothing divided by height (in meters, without shoes) squared, as reported previously. Bobesity was defined according to the modification of the World Health Organization subgroups as BMI  $\geq$  30 kg/m², as reported elsewhere. BMI values were also analyzed as a continuous variable.

#### **Medical and Dental Attendance Patterns**

These variables evaluate health care utilization during the study period:

1. *The total number of dental appointments*: the number of dental appointments the subject attended.

- 2. *Non-attendance to scheduled dental appointments*: failure to attend a scheduled dental appointment is recorded in the DPR, the total of missed appointments was calculated.
- 3. The total number of appointments with a general physician: the number of medical appointments the subject attended.

### **Multicollinearity Analysis**

Data were tabulated, and statistical analyses were performed using SPSS software version 22.0 (IBM, Chicago, Illinois, United States). In our series of papers that are due to follow, we will present the data of each dental, periodontal, and oral-dependent variable.

Multicollinearity analysis using Pearson's correlation was performed to assess correlations between independent variables. The statistical significance was set on 0.01 (two-

 Table 4
 Pearson's correlation between categorical medical parameters

		Hypertension	Diabetes	Hyperlipidemia	Sleep apnea	Impaired glucose tolerance	Heart disease
Hypertension	Pearson correlation	1.00	0.10	0.06	0.04	0.03	0.10
	Sig. (two-tailed)		< 0.001	<0.001	< 0.001	<0.001	< 0.001
Diabetes	Pearson correlation	0.10	1.00	0.02	0.04	0.08	0.07
	Sig. (two-tailed)	< 0.001		<0.001	< 0.001	<0.001	< 0.001
Hyperlipidemia	Pearson correlation	0.06	0.02	1.00	0.03	0.01	0.03
	Sig. (two-tailed)	< 0.001	< 0.001		< 0.001	0.0008	< 0.001
Sleep apnea	Pearson correlation	0.04	0.04	0.03	1.00	0.02	0.04
	Sig. (two-tailed)	< 0.001	< 0.001	<0.001		<0.001	< 0.001
Impaired glucose tolerance	Pearson correlation	0.03	0.08	0.01	0.02	1.00	0.03
	Sig. (two-tailed)	< 0.001	< 0.001	0.0008	< 0.001		< 0.001
Heart disease	Pearson correlation	0.10	0.07	0.03	0.04	0.03	1.00
	Sig. (two-tailed)	<0.001	<0.001	<0.001	< 0.001	<0.001	

Note: Correlation is significant at the 0.01 level (two-tailed).

tailed). A correlation result  $r \ge 0.8$  was considered as an exclusion criterion to include both variables in the multivariate model. Multicollinearity analysis results of the study parameters are presented in **Tables 3** and **4**.

### **Discussion**

This paper describes the methods and protocol of the DOME study for assessing socio-demographics, health-related habits, medical and dental attendance patterns, general and dental health status. Due to the amount of the data assessed and appropriate for presentation, we decided to publish the methods as a separate paper and then analyze the results and present them in other papers.

Measurements of dental caries level and missing teeth: The oldest and most commonly cited measurement in global literature for caries evaluation is the decay missing filled index (DMF), developed by Klein et al<sup>79</sup> and modified by the World Health Organization.<sup>80</sup> This measurement is used in epidemiological studies where a representative sample of the population is clinically examined using an explorer, mirror, and gauze (without X-ray imaging), checking the number of teeth with caries (decay), the number of teeth missing due to caries (missing), and the number of restored teeth due to caries (filled). This measurement sums the number of affected teeth and can be used at the resolution of morbidity of single teeth or at the level of which tooth surfaces are affected by caries. However, the DMF index has its limitations, especially due to the lack of integration of Xray imaging which may lead to undiagnosed and untreated hidden occlusal, or interproximal, caries.<sup>81</sup> Since the DOME study is records based, it includes the routine evaluation of dental caries performed in IDF dental clinics, based on both clinical and radiological examinations.

Additionally, in the DMF, the evaluation of missing teeth is based only on teeth missing due to caries, and not due to other reasons The possibility of a patient recall bias regarding the cause of dental extraction was considered in the IDF, and therefore the missing teeth count includes missing teeth for any reason.

Evaluation of periodontitis: The clinical entity of "established periodontitis" is described in the literature following assessment of probing depth (at six sites around each tooth) and clinical attachment loss (the difference between probing depth and recession).<sup>66</sup> In this study, the diagnostic criteria to assess periodontitis were strict and included both clinical and radiographic evaluation. Without a radiograph, the diagnosis of periodontal disease may be inaccurate. 66 Moreover, the errors inherent to the use of a periodontal probe including variation in probing force, visual errors in identifying the cement-enamel junction (CEJ), relative attachment level landmarks, fluctuations in gingival inflammation (pseudo-pockets), and misrecording of measurements are well known. 65 Therefore, the current study included alveolar bone loss as a requirement for diagnosing periodontal disease, based on the assumption that a "true" loss of periodontal support has occurred since the damage can only be seen in radiographs after 3 months.<sup>66</sup> In support, the new 2018

periodontitis classification supports our strict protocol which utilizes radiographic attachment loss and includes an assessment of age, smoking, and medical co-morbidities as risk factors for future progression of alveolar bone loss.<sup>82,83</sup>

Evaluation of socio-demographic parameters: Education, race, and socio-demographic parameters are associated with higher oral health literacy, and therefore, affect the likelihood of seeking professional dental advice. <sup>84</sup> Identifying atrisk populations for oral diseases, based on socioeconomic characteristics, enhances the effectiveness of preventive campaigns by focusing interventions, adopting specific strategies, and obtaining active participation of target populations. <sup>85</sup> Israel is known as an immigrant's state. Specifically, the FSU and Ethiopia were considered as separate ethnic groups in the military database, as these populations immigrated to Israel in the 1990s and have unique cultural characteristics.

Evaluation of oral health-related habits: In 2016, the Israeli Central Bureau of Statistics reported a high carbohydrate consumption level among Israeli soldiers. Moreover, according to the Health knowledge, attitudes, and practice survey conducted by the Israeli ministry of health in 2011, 22.8% of the Israeli population consume sweet beverages daily. Therefore, the evaluation of oral health-related habits and their associations with dental and systemic morbidities in the DOME study is essential.

Evaluation of systemic morbidity: Data regarding systemic morbidity in the DOME study was based on doctor diagnoses, complex variable definitions (for diabetes, hypertension, and hyperlipidemia), auxiliary tests including blood examinations, medical attendance patterns, and medications taken by the patient. The complex variable definition bases a diagnosis on the results of several methods, such as clinical evaluation, auxiliary tests, and medications used. Complex variable definitions reduce the false positive rate that may arise from basing a diagnosis on a single measurement.

The complex variable definition is also in line with the new 2018 classification of periodontitis.  $^{83}$  One of the criteria for the diagnosis of diabetes in the complex variable definition is HbA1c >6.5%, which is a grade modifier in the new 2018 classification of periodontitis.  $^{83}$  HbA1c <7% is classified as grade B and HbA1C >7% is classified as grade C in the new classification.  $^{83}$ 

The diagnosis of obesity is of importance in light of the report by the Knesset Labor, Social Affairs, and Health Committee, in 2016. They reported that 70% of military personnel gain weight during their service and 22% suffer from being overweight. Tonsidering the world epidemic of "Diabesity," it is important to assess the metabolic profile of a nationally representative sample of young to middle-aged individuals, and its association with dental, periodontal, and oral morbidities.

### **Strengths and Limitations**

The main strengths of the present study are the large sample size (132,354 dental attendees and >50,000 general military personnel of nonattendees) and the strict protocol for

utilizing socio-demographic, medical, and dental databases. Record driven data did not rely on the reports of patients, which eliminates recall bias. The IDF socio-demographic, medical and dental systems are homogenous, with standardized, uniform administrative and clinical work-ups and treatment protocols and computerized codes. Clinical examination and radiographic assessment were included in the data for dental parameters, whereas clinical and laboratory data were included for the medical parameters. The large proportion of immigrants in Israel means that our data covers multiple ethnicities, which may enhance the generalizability of the results.

Limitations of this study include the possibility of recall bias in some self-reported health-related behaviors. Undesirable habits (e.g., smoking, cariogenic diet, etc.), may be underreported. Due to the cross-sectional study design, we cannot assume causality, and therefore the DOME study can only address associations and correlations between the variables. Although multiple ethnicities were included, the results can only be generalized to Jewish, Druze, and Circassian young and middle-aged adults who are current Israeli residents, and further studies are needed to explore residents of other countries.

### **Conclusion**

The goal of the current manuscript was to present the study methods including the standardized terminology, data collection, and handling of the DOME study. Standardized work-up and definitions are essential to establish a centralized socio-demographics, dental, and medical data repository to study the extent of dental and systemic morbidities and their associations. In the next papers, we will present the data on each specific dependent variable analyzed.

### Conflict of Interest

None declared.

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