

# Ethical considerations regarding the publication of identifiable patient photographs in academic journals

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**ETHICAL CONSIDERATIONS REGARDING THE PUBLICATION  
OF IDENTIFIABLE PATIENT PHOTOGRAPHS IN  
ACADEMIC JOURNALS**

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## LIST OF ABBERVATIONS

|             |  |
|-------------|--|
| AIC         | Akaike information criterion                                 |
| AUC         | area under curve   |
| BIC         | Bayesian information criterion                               |
| BMJ         | British Medical Journal                                      |
| CBCT        | cone beam computed tomography                                |
| CC          | Creative Commons   |
| CC BY       | creative commons attribution                                 |
| CC BY-NC    | creative commons attribution non derivatives                 |
| CC BY-NC-ND | creative commons attribution non commercial- non derivatives |
| CC BY-NC-SA | creative commons attribution non commercial-share alike      |
| CC BY-SA    | creative commons attribution share alike                     |
| CC BY- ND   | creative commons attribution non derivatives                 |
| CI          | confidence interval  |
| COPE        | Committee on Publication Ethics                              |
| CONSORT     | Consolidated Standards of Reporting Trials                   |
| Dentistry   | Dentistry, Oral Surgery and Medicine                         |
| DF          | degrees of freedom   |
| DOAJ        | Directory of Open Access Journals                            |
| DoH         | Department of Health   |
| GDPR        | General Data Protection Regulation                           |
| GMC         | General Medical Council                                      |
| HIPPA       | Health Insurance Portability and Accountability Act          |
| ICMJE       | International Committee of Medical Journal Editors           |
| IMI         | Institute of Medical Illustrators                            |
| IQR         | interquartile range  |
| JAMA        | Journal of the American Medical Association                  |
| JCR         | Journal Citation Reports                                     |
| MRI         | magnetic resonance imaging                                   |
| NHS         | National Health Service                                      |
| OA          | open access  |
| OR          | odds ratio   |
| ORL         | Otorhinolaryngology  |

PIPEDA      The *Personal Information Protection and Electronic Documents Act*  
WAME      The World Association of Medical Editors



# 1. INTRODUCTION

## 1.1. Scholarly communication

The purpose of scholarly communication in healthcare is to translate new evidence into practice and to increase the knowledge of scientists, practitioners, policy makers and the industry. Scholarly communication encompasses numerous activities – from conference presentations, seminar discussions, face to face conversations, email listservs and social media, preprints, grey (non-indexed) literature, and published articles in academic journals (1). Traditionally, the communication process involves different stakeholders: journal editors, peer reviewers, authors, readers, their funders and host institutions (publishers and librarians) aiming to transfer scientific information (1). Recently patients are becoming important stakeholders and patient involvement has been recognized as a valuable contribution in improving many activities within healthcare systems. Authors and funders of research have recognized the patients' views and experiences as a valuable contribution in conducting the research: in the planning of study design, conducting and reporting of the results and dissemination of the studies themselves (2). In 2014 BMJ journal adopted the Patient and Public Partnership strategy aiming to involve patients and the public in a number activities in order to develop the partnership among all relevant stakeholders to improve health, promote wellbeing and make health services more person-centric (3). The BMJ journal established the Patient Advisory Panel aiming to include patients to develop further co-production. Patients have become co-authors, reviewers, members of editorial boards, co producers in changing clinical practices, education, research and policies as well as members of organization conference committees and panel members of the BMJ Awards (3, 4).

Journal articles and books are considered the most important formal elements of scholarly communication, whereas conference presentations and pre-print articles are considered informal. The boundary between informal and formal scholarly communication is not always clear in all areas. Many unrefereed author's manuscripts have been cited in formal publications; on the other hand, some journal articles are becoming more informal with the addition of blog-like formats that also include the readers' comments. Despite many developments in scholarly communication, journal articles are still the most influential sources of information (1). From the early 2000s journal articles have made a shift from printed publications to web-based publications. One of the most important consequences of the new models of publishing driven by new technologies is that academic articles are now much more widely available. The

globalization of scientific publishing is also visible in the new web-based technologies in publishing (e.g. open access), the way research is conducted (e.g. use of networks, globalisation of research) and public policy (data sharing and changes to copyright). All of this generates many legal, privacy and ethical issues in terms of guidelines and policies.

## **1.2. Academic journals**

Academic journals represent the most important format for authors who seek to publish their scholarly work. By definition academic journals are “*periodicals carrying accounts of research written by investigators themselves and published after due peer review, rather than journalistically based magazines.*” (1).

The first scientific journal was founded in the 17<sup>th</sup> century in Paris, entitled *Le Journal des Scavans*. It was a digest publication of reviews, news and scholarly activities edited by Denis de Sallo de la Coudraye (5). Approximately at the same time, Henry Oldenburg, German theologian and natural philosopher, seeking the best way to report scientific findings, started a journal entitled *Philosophical Transactions of the Royal Society of London* (6). Oldenburg is considered the first editor and publisher of the first true scientific journal. He defined four main functions that academic journals have to embody: registration, dissemination, certification and archival record which, are still valid today (7). He is also considered the creator of scientific peer review (6). The peer review process, although it has some disadvantages, still assures the quality of journals’ publications requiring authors to follow legal, ethical and reporting guidelines (8, 9).

## **1.3. Open access**

Open access (OA) is an international movement that allows readers access to digital, online publications and data, free of charge and subscription in contrast to the traditional model of publishing where almost all publications were available only if the readers or their institutions were subscribed to the academic journals (10).

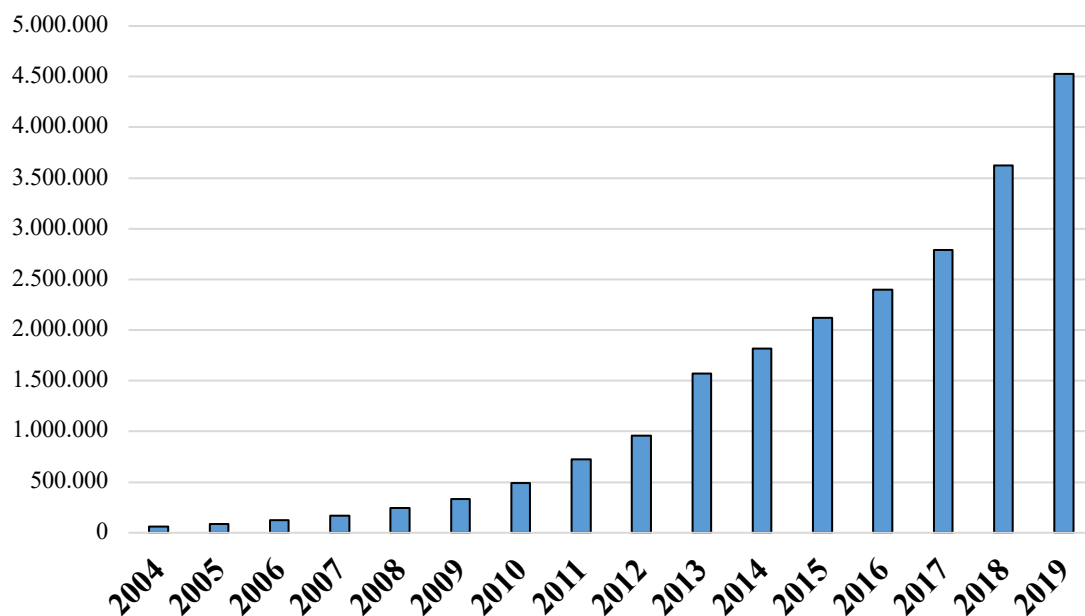
The traditional model of publishing implies printed journal copies will mostly be disseminated among the academic and research community. Readers, individuals and institutions subscribe to the journal for an annual fee or single issues and specific papers could also be purchased and a very small number of publications were available with. Authors are not often charged for publishing their accepted manuscript, but they can be. Also, many print journals provide subscriptions to their online issues, that are available prior to printed

publication (11). Furthermore, the traditional model usually involves transfer of copyright from the author to the publisher and reuse is strictly controlled by the publisher.

The most common OA model is when authors, their funders or institutions pay a publication charge. Most of the stakeholders in scientific publishing, including researchers, patients, funders, policy makers, support and promote open access because it allows sharing scientific information more widely (12). It has been reported that the main advantage of OA publications is free accessibility which provides for better dissemination of knowledge and echoes the public's interest (13). Also, OA represents an additional benefit for the authors since these publications have a higher citation rate (14).

However, OA has some disadvantages, such as increased cost for authors (15). It also has instigated the appearance of predatory journals and provides a threat to many small scholarly journals who operate on a non-commercial basis (16). According to the Directory of Open Access Journals (DOAJ), which indexes and provides access to high quality peer reviewed publications there are more than 15,000 OA journals, containing around 5 million articles in over 133 countries (17).

In 2019, the number of articles published in open access grew over 900,000, which represents annual growth of 25% (**Figure 1**).



**Figure 1.** Increase in the number of published articles in open access journals in the Directory of Open Access Journals (DOAJ) database (18).

Academic journals offer different forms of open access: full open access (Gold, delayed open access, self-archived (Green) open access and open access without any charge for the publication (Diamond) (**Table 1**) (10).

**Table 1.** Different types of open access journals (definitions from (10)).

| <b>Types of Open Access Journals</b> | <b>Description</b>  |
|--------------------------------------|---|
| <b>GOLD: Full</b>                    | Publication via publisher platforms, in full open access journals. This route may involve charge. The publication costs, known as ‘article processing charges’ (APCs), are covered by authors or by their institutions. |
| <b>GOLD: Hybrid</b>                  | Publication of individual articles on payment of an Article Processing Charge (APC) in subscription journals that allow open access.  |
| <b>GREEN</b>                         | The full text of academic publications is deposited in a trusted repository, a publicly accessible database managed by a research organisation.   |
| <b>DIAMOND</b>                       | Publication via diamond journals/platforms that do not charge author-facing publication fees (APCs). Diamond open access journals are usually funded via library subsidy models, institutions or societies.             |

Full OA journals have two main variants: immediate full OA and hybrid OA which means that only parts of the published articles are available in OA. Since digital technologies have been widely incorporated in all aspects of life, OA forms of publishing may enhance the dissemination of published articles. This means that every person that has access to the internet may freely read, download and disseminate all content from published material.

#### 1.4. Creative Commons licences

Traditionally, all intellectual and creative work has been protected by copyright. By definition a copyright is “*a set of exclusive rights given to authors to control most reuses of their work without their permission, subject to certain limitations and exceptions to these rights*” which is regulated by law (19).

In order that all intellectual and creative work might be disseminated freely, the copyright has been adjusted with Creative Commons Attribution Licences (CC BY Licences). Licences have been established by a non-profit organization aiming to promote sharing creative and academic work to contribute public commons knowledge and culture (20). Millions of people worldwide upload their writing, photographs, videos, music and other contents under CC BY licences to be used publicly. These licences do not repeal the copyright but are rather an extension within the copyright and are valid as long as the copyright is valid (21). They

allow others to copy, distribute, edit, remix, and build upon the published material (21). It is important to emphasise that by using material published under CC BY licences users must declare the name of the creator and provide the source of the material (21).

There are six types of CC licences based on six conditions (**Table 2**): attribution (by), share alike (sa) non derivatives (nd), non commercial (nc), non commercial-share alike (nc-na) non commercial non derivatives, (nc-nd).

**Table 2.** The type and description of Creative Commons Licences (definitions from (20)).

| <b>CC Licence Type</b>                                      | <b>Description</b>   |
|---|--|
| <b>Attribution<br/>CC BY</b>                                | This license lets others distribute, remix, adapt, and build upon your work, even commercially, as long as they credit you for the original creation. This is the most accommodating of licenses offered. Recommended for maximum dissemination and use of licensed materials.   |
| <b>Attribution-ShareAlike<br/>CC BY-SA</b>                  | This license lets others remix, adapt, and build upon your work even for commercial purposes, as long as they credit you and license their new creations under the identical terms. This license is often compared to “copyleft” free and open source software licenses. All new works based on yours will carry the same license, so any derivatives will also allow commercial use. This is the license used by Wikipedia and is recommended for materials that would benefit from incorporating content from Wikipedia and similarly licensed projects. |
| <b>Attribution-NoDerivs<br/>CC BY-ND</b>                    | This license lets others reuse the work for any purpose, including commercially; however, it cannot be shared with others in adapted form, and credit must be provided to you.   |
| <b>Attribution-NonCommercial<br/>CC BY-NC</b>               | This license lets others remix, adapt, and build upon your work non-commercially, and although their new works must also acknowledge you and be non-commercial, they don’t have to license their derivative works on the same terms.   |
| <b>Attribution-NonCommercial-ShareAlike<br/>CC BY-NC-SA</b> | This license lets others remix, adapt, and build upon your work non-commercially, as long as they credit you and license their new creations under the identical terms.  |
| <b>Attribution-NonCommercial-NoDerivs<br/>CC BY-NC-ND</b>   | This license is the most restrictive of our six main licenses, only allowing others to download your works and share them with others as long as they credit you, but they can’t change them in any way or use them commercially.  |

Among the CC licences, CC BY-4.0 achieves maximum dissemination and use of licenced materials (22). However, it can have unintended consequences and raises ethical questions around patient privacy.

According to recently updated DOAJ, there are 805 medical journals publishing over 707,000 articles in OA under CC Licences which is listed in **Table 3** (17).

**Table 3.** The number of medical journals and articles published in OA under different types of licences (17).

| License type            | Number of journals<br>(N=805) | Number of articles<br>(N=707269) |
|-------------------------|-------------------------------|----------------------------------|
| CC BY                   | 301                           | 505717                           |
| CC BY-NC                | 192                           | 72187                            |
| CC BY-NC-ND             | 159                           | 66239                            |
| CC BY-NC-SA             | 101                           | 47456                            |
| CC BY-SA                | 27                            | 6942                             |
| CC BY-ND                | 5                             | 2008                             |
| Publisher's own licence | 20                            | 6711                             |

### 1.5. Publishing individual patient data

Publishing patient data is common in medical research articles. We can differentiate non-identifiable and identifiable patient data. Most published articles contain non-identifiable data – numerical data, where the main outcomes are derived from the statistical analysis of aggregated data like summarised results of randomized controlled trials. Furthermore, images taken from pathology slides, ultrasound images, laparoscopic images, endoscopic views of internal organs as well as radiographic images are considered nonidentifiable data in published materials (23). On the other hand, identifiable patient data represents individual patient photographs, videos, initials, birthmarks, hospital numbers, prominent moles, scars, tattoos or other identifying marks, and their use in publications may violate patient privacy (23-25). Patient photographs, more commonly called clinical photographs, are widely used in medicine, not only in publishing but for educational or research purposes as well (26). Some medical disciplines use patient photographs more frequently, such as dermatology, facial, plastic and reconstructive surgery, dental medicine, and otorhinolaryngology.

Clinical photographs are a vital part of confidential patient medical records used to document the diagnosis of disease, treatment outcomes and follow up (27, 28). Publishing individual patient data such as patient facial photographs in academic journals represents a challenge for authors. The best current practices recommend avoiding publishing any type of identifying patient data unless it is important to deliver new and useful information (ICMJE) (24). Some medical disciplines, particularly those that deal with the head and neck region, more often publish individual patient photographs that may reveal their identity. It is quite challenging to show some specific features of pathology in the head and neck region without revealing the patient's identity.

True de-identification means that it would not be possible for a person to be recognised by friends, family or acquaintances or by himself/herself, but this is very difficult to achieve (25). Several techniques of facial de-identification have been proposed in the last decades, but none have proven to be successful. The most widely used technique for facial de-identification is covering the eye area with a black bar or, more recently, to blur or pixelate the eye area. De-identification with covering the eye area has been recognised as insufficient already in 1989. “distracting practice of placing a bar across the eyes in a photograph does not prevent the patient from being identified any more than dark glasses do” (29). Nowadays, some journals (e.g. *The Lancet*) ask authors not to use any de-identification technique on facial photographs as long as an informed consent for publishing the photograph has been obtained. However, this technique is still commonly used in academic literature (30). In the digital environment these traditional de-identification techniques have proven to be even more insufficient because there is software available which is designed to identify a person from a photograph with minimal censorship. For example, several websites such as Google Images, Social Mapper, Visual search, Amazon Rekognition, DeepFace, etc. can revert search an image but the technology is still in development and is not 100% accurate (31). However, that said DeepFace has achieved an accuracy of 97% (31).

#### **1.6. Patients’ perspectives in process of publishing in academic journals**

The patient-doctor relationship has been changing over the decades, but it has always been based on the Hippocratic Oath (32). The Hippocratic Oath represents the fundamental ethical principles in medicine that have been incorporated in all ethical guidelines until today. Confidentiality, beneficence, non-maleficence and avoiding harm are essential principles that are to be followed by all doctors.

A patient-doctor relationship should be fiduciary, which means that patients trust that their doctors would apply their professional expertise for their patients’ best interests and benefits or at least do no harm. However, nowadays patients are taking more responsibility in decision-making. In the past, a paternalistic type of relationship was more common, where doctors took an enormously larger part in decision-making. Today, there is more room for a patients’ autonomy (3, 33). A principle “Nothing about Me without Me” has clearly showed that nowadays a paternalistic model has shifted to a decision-sharing model in patient-doctor relationships (33). Patients are becoming informed and educated partners of doctors and maintain control over their conditions and decisions affecting their medical care (34). All

healthcare professionals are obliged to respect and preserve their patients' dignity, privacy, confidentiality in all aspects their medical care (34).

Patient medical documentation is confidential, as it contains a patients' personal data and may include clinical images (26). Clinical images appearing in medical documentation are radiographic, molecular, ultrasound, endoscopic, but in some disciplines, photographs of patients, parts of the body as well as facial photographs are present as well. All patients' images that may reveal their identity should not be taken without the patients' written consent (23, 24). Furthermore, any type of clinical photographing in healthcare institutions requires the obtaining of consent, regardless the purpose of the clinical photograph (35). Recent literature regarding patients' perspectives on medical photography shows that patients generally have a high level of acceptance regarding the use of their photographs for different healthcare purposes, regardless of geographical areas, gender, ethnicity and income (35-40). However, studies also show that patients' have confidence in health professionals regarding taking patients' photographs (35, 36, 38). Patients preferred to be photographed by their doctors, and they preferred using institutional cameras instead of personal devices such as smartphones, at the institutional location. De-identified clinical photographs were more acceptable for all types of purposes than identifying photographs (36, 38, 39).

### **1.7. Ethical and legal guidelines regarding publishing patient photographs**

The use of identifiable individual patient data such as patient photographs is regulated at different levels, including professional and governmental organizations (**Table 4**). They provide official guidelines for publishing clinical images in academic literature, social and mass media. These guidelines emphasize three important things: i) written informed consent must be obtained regardless of intended purpose when using an individual's personal data; ii) the person must be aware that he or she may not be able to control the future use of the material once it has been published online, iii) written informed consent must be obtained for a certain purpose; it is not applicable for other uses.

According to recent legislation (May 25, 2018) in the European Union (General Data Protection Regulation – GDPR), all identifying personal data that has been used in scientific research purposes should be de-identified as soon as possible, which means that data cannot be attributed to a person without the use of separate additional information (41). GDPR emphasises the principles of lawfulness, fairness and particularly transparency in data processing for scientific purposes (GDPR, Article 5) (42). These principles imply that participants are informed about the purpose for the use of their data and that they are in a



position to participate freely and according to their expectations. GDPR guidelines should be incorporated within informed consent forms in the EU and it should be assured that they are explained properly during the consenting process (43, 44). Ignoring or not respecting governmental guidelines in different countries may have legal consequences.

The International Committee of Medical Journal Editors (ICMJE), as the most influential and most respected organization in medical scholarly activities propose the highest ethical standards in terms of preserving patient privacy in academic publications and follows all mentioned legislation that both authors and journals should follow these guidelines (24). ICMJE recommendations regarding planning, conduct and reporting in human research are in accordance with the Helsinki Declaration, which was revised in 2013 (45), and COPE guidelines (46).

In Croatia, there are several professional organizations that set standards of professional work, which should cover clinical images. However, ethical codes of the Croatian Dental Chamber and the Croatian Medical Chamber do not include statements or policies on use of identifiable patient photographs for publishing or for any other purpose (47, 48). In the study of Broga et al., that investigated ethics policies present in the publication of biomedical journals from countries in Central and Eastern Europe (including Croatia), it showed that only 19-45% of journals had guidance regarding this issue (49).

**Table 4.** Professional and governmental organizations providing guidelines regarding the publishing of identifiable patient photographs

| Organization  | Guideline document   | Mention of consent for photo publication  | Geographical area |
|---|--|---|-------------------|
| <b>Professional organizations:</b>                              |  |   |                   |
| International Committee of Medical Journal Editors (ICMJE) (24) | Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals | <i>Patients have a right to privacy that should not be violated without informed consent. Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication.</i> | International     |

| <b>Organization</b>                            | <b>Guideline document</b>   | <b>Mention of consent for photo publication</b>   | <b>Geographical area</b> |
|--|---|---|--------------------------|
| Committee on Publication Ethics (COPE) (46)    | Journals' Best Practices for Ensuring Consent for Publishing Medical Case Reports | <i>Forms should indicate that signing the consent form does not remove the patient's rights to privacy. However, wording should make it clear that, even with the best efforts of medical staff at confidentiality, and even with the journal's best practices in place, the journal cannot guarantee anonymity. There is a risk that the patient may be identified by someone, somewhere, once the case report is published. This is especially true if the case is published freely online. Forms should make it clear what current and further uses might be made of the published case report, including as applicable publication in print or online and whether freely available or by subscription, in audio or video recordings and presentations, webinars, etc.</i> | International            |
| Institute of Medical Illustrators (IMI) (50)   | IMI National Guidelines-Consent in Clinical Photography                           | <i>Good practice dictates that consent for publication should only be obtained for a specific single use, not an overarching general release. If publication is to be in a journal, book, electronic media or on the Internet the patient should be warned that once published the consent cannot be withdrawn as the images are in the public domain. This is especially important for Internet publication.</i>   | United Kingdom           |
| General Medical Council (GMC) (51)             | Making and using visual and audio recordings of patients                          | <i>When making or using recordings you must respect patients' privacy and dignity, and their right to make or participate in decisions that affect them. This means that you must:<br/>give patients the information they want, or need, about the purpose of the recording<br/>make recordings only where you have appropriate consent<br/>be familiar with, and follow, the law<sup>4</sup> and local guidance and procedures that apply where you work</i>   | United Kingdom           |
| Department of Health (DoH) (52)                | Good practice in consent implementation guide: consent o examination or treatment | <i>If you wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it.<br/>.... patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.</i>   | United Kingdom           |
| <b>Governmental organizations:</b>             |   |   |                          |
| General Data Protection Regulation (GDPR) (41) | The impact of the EU general data protection on scientific research               | <i>Consent of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her</i>  | European Union           |

| Organization  | Guideline document  | Mention of consent for photo publication  | Geographical area        |
|---|---|---|--------------------------|
| Health Insurance Portability and Accountability Act (HIPAA) (53)  | Summary of the HIPAA Privacy Rule   | <i>he HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization.</i> | United States of America |
| National Health Service (NHS) (54)                                | Policy for Photography and Video Recordings of Patients. King's College Hospital NHS Foundation Trust | <i>Any patients wishing to film, auto-record or photograph any element of their care or treatment must ask for permission from the members of staff caring for them first.</i><br><br><i>The person carrying out the filming, photography or recording must make it clear to every member of staff involved what it is intended to be used for.</i>   | United Kingdom           |
| Office of the Privacy Commissioner of Canada (55)                 | The Personal Information Protection and Electronic Documents Act (PIPEDA)                             | <i>The purposes for which the personal information is being collected must be identified by the organization before or at the time of collection.</i><br><br><i>The knowledge and consent of the individual are required for the collection, use, or disclosure of personal information</i>   | Canada                   |
| India's Information Technology Act and Related Privacy Rules (56) | Privacy and the Information Technology Act - Do we have the Safeguards for Electronic Privacy?        | <i>Information Technology Act imposes a penalty on "any person" who, having secured access to any electronic record, correspondence, information, document or other material using powers conferred by the Act or rules, discloses such information without the consent of the person concerned</i>   | India                    |

### 1.8. Informed consent for publishing clinical images

Informed consent is a vital part in any healthcare activity that involves patients, the use their individual data or proposed treatment, and as such entails more than obtaining a signature on a form (57). Current ethical guidelines propose that patient informed consent should be obtained not only for treatment and research but also for taking patient clinical photographs as well as for publication (23, 24). Informed consent must be taken freely, without coercion, and must be based on a clear understanding of what approval means (58). The consenting process has been changing since patients have taken a bigger part in decision making and since new technologies have been established (59). Authors, their institutions, physicians and all other

relevant stakeholders that are involved in activities involving patient healthcare should provide all important information using plain language to explain the process, treatment procedures or purpose of publication. Furthermore, patients or their proxies should not feel rushed into giving their written consent (23, 60). Consent forms should be structured to explain to patients or their legal representatives all the possible purposes of use of the patient's data. It is recommended to explain to patients all the possible uses of their data from their medical records as well as other possibilities such as participation in research and/or publications (61). Regarding the publication of a patient's individual data such as clinical photographs, the patient should be informed of all potential issues in terms of preserving privacy and anonymity (61). Specifically, for the purpose of publication, it has been recommended that the person, whose individual data is going to be used, has an opportunity to read the final version of manuscript to be published and then decide whether or not to give consent (25). Recent recommendations also suggest that patients must be informed that almost all academic journals are available online and that most of them have some form of open access provided by creative commons licences that allow sharing and using in different purposes including even commercial ones. It is particularly important for patients to be aware that once published there is no guarantee an article containing their photographs could be removed from a publishing outlet (59, 61, 62).

Ethical standards propose obtaining written consent whenever it is possible. In certain situations when this is not possible, but the patient has the mental capacity for consent, a non-written consent must be witnessed and formally documented following institutional policies and local legislation (60). Patients who are under the legal age of maturity, lacking of mental capacity, the deceased or patients with deteriorating or fluctuating conditions must have a legal representative to sign a written consent document. In some exceptional circumstances, if there is no patients' legal representative and publication of individual data is in the public's interest, the institutional authorities such as the hospital board and an ethics committee in accordance with local legislation can provide approval.

Taking clinical images of children is particularly sensitive and requires not only consent from parents but also assent from children of certain age (63, 64).

### **1.9. The need for guidelines and policies on the publication of patient identifiable photographs**

There is little evidence in the literature about the relevant stakeholders' opinions on publishing patient identifiable photographs. Also, there is little evidence with regards to the implementation of ethical policies in academic journals on this issue. In recent study, Bennet

et al. (65) performed a review of the literature to examine current guidelines for the publication of facial photographs, using the PubMed database as well as societies' websites, legal requirements for clinical photography in the United States, Canada, the United Kingdom and Australia. The findings of this review showed the lack of consensus across all relevant clinical specialities and societies and the need to universalize publishing practices (65). Also, the study emphasised the importance and value of using patients' photographs in different medical disciplines and the importance of obtaining informed consent and approval for publication. Some medical journals provide clear instructions regarding the publishing of individual patient data, including facial photographs in their guidelines for authors. For example, the *BMJ* group provides their own consent form that is required to submit a manuscript containing patient identifiable photographs (23). *JAMA* requires that patients, whose identifiable photographs are going to be published in the article, read the article before they give an approval for publication (25). The *Lancet* does not recommend any type of facial photograph de-identification such as black bars over the eyes since it has been recognized as an insufficient method of anonymization as long as the informed consent for publication has been obtained (29, 66). However, despite clearly stated guidelines, there is little evidence from the literature regarding journal actual practices in publishing clinical images. It is still unclear how ethical standards regarding publishing identifiable patient clinical photographs have been implemented in the majority of medical journals. Few studies that have investigated journal guidelines regarding the publication of patient facial clinical photographs in terms of de-identification and the consenting process were performed on a small sample of journals. They demonstrated inconsistencies in policies and practices among medical journals and emphasized the need to establish a clear and uniformed consensus among healthcare professionals (67, 68).

Studies that investigated stakeholders' opinions are mostly patients' surveys and only a few studies surveyed clinicians regarding the importance of obtaining informed consent for different purposes within healthcare systems. The studies indicated the importance of patients' approval in that process (36-39, 69). Furthermore, qualitative research studies are lacking on these issues, although they might be very useful to generate a new hypothesis to be tested. I found only a single qualitative study, conducted using focus group interviews involving medical doctors and researchers working in low-resource settings with children (70). This study showed that all participants considered taking clinical photographs of children as a valuable resource in clinical and research practice but also an issue to be managed with particular care to avoid potential harm since such images appear in the digital environment. Authors emphasised the importance of obtaining informed consent and the need for better education

and training for application of ethical guidelines. They also recommended that informed consent forms should be customized in accordance with its purpose (70).

It is still unclear whether relevant stakeholders are educated sufficiently regarding the publication of individual patient data such as facial photographs and whether they are aware of potential issues in terms of protection of privacy and confidentiality. Furthermore, it is not clear whether ethical standards are adequately implemented in journal guidelines and whether published articles follow these guidelines when they contain identifiable patient photographs.

### **1.10. Literature review**

A comprehensive literature review for this dissertation was performed on September 26<sup>th</sup> 2018, and updated on September 15<sup>th</sup> 2020 with the aim of identifying all relevant studies regardless of publication date or language. The first search was performed in the Ovid (Medline) database with the following search strategy, developed with the help of a specialist from the Central Medical Library:

Search strategy\*

- 1 exp Photography/
- 2 "diagnostic techniques and procedures"/ or diagnostic imaging/ or exp cardiac imaging techniques/ or exp neuroimaging/ or exp radiography/ or exp tomography/ or exp ultrasonography/ or whole body imaging/
- 3 photograph\$.tw.
- 4 imag\$.tw.
- 5 ((medical or clinical or patient or dental) adj3 (record\$ or data)).tw.
- 6 ((eye\$ or face or facial) adj3 mask\$).tw.
- 7 ((eye\$ or face or facial) adj3 blurr\$).tw.
- 8 black stripe.tw.
- 9 (black stripe adj3 eye\$).tw.
- 10 or/1-9
- 11 confidentiality/ or exp informed consent/
- 12 exp Privacy/
- 13 ((patient or written or verbal or informed) adj3 consent).tw.
- 14 (patient adj3 (privacy or confidentiality or agreement or anonymity)).tw.

15 exp bioethics/ or exp ethics, clinical/ or ethics, research/ or exp professional misconduct/

16 ((bioethic\$ or ethic\$) adj3 (standard\$ or implicat\$ or responsib\$ or dilemma\$ or problem\$)).tw.

17 or/11-16

18 exp Publishing/

19 exp journal article/ or periodicals/

20 exp publications/ or exp teaching materials/

21 publish\$.tw.

22 (publication\$ or journal\$ or textbook\$ or handbook\$ or presentation\$ or poster\$).tw.

23 (article\$ or paper\$ or presentation\$ or poster\$).tw.

24 or/18-23

**25 10 and 17 and 24**

26 18 or 20 or 21 or 22

**27 10 and 17 and 26**

\*Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>.

The search was adapted to search the following databases: Scopus (71), CENTRAL (72), CDSR (73), DARE (74), CINAHL (75).

Synchronization and de-duplication were performed after the references were exported firstly into Notepad and then into EndNote.

A total of 15,935 references were analysed at the level of Abstracts. All relevant studies were extracted in full text format, as many as were available. This literature search was performed for a separate scoping review study that is not part of this dissertation. All full text articles that were eligible regarding the scope of research and methodology (n=33) were included as the references in the dissertation.

## 2. RESEARCH AIMS AND HYPOTHESES

The overall aim of this dissertation was to investigate the opinions and practices of different stakeholders about ethical policies/guidelines regarding publication of identifiable/facial patients' photographs in academic journals.

The specific aims were the following:

1. To investigate academic journals for their policies and actual practices with regards to publishing identifiable clinical photographs,
2. To investigate the stakeholders (health professionals, patients' and students') opinions on publishing identifiable clinical photographs in academic journals using a survey,
3. To gain deeper insights into the personal issues surrounding the publishing of a patient's facial photographs.

The hypotheses of the quantitative studies (aims 1 and 2 from above) were:

1. The study of academic journals' policies and actual practices on publishing identifiable clinical photographs
  - i. Most journals have publicly available policies on the publication of identifiable patient photographs.
  - ii. Journals require specific informed consent for the publication of patient photographs (independent of consent to take part in clinical trials).
  - iii. Articles that contain patient photographs describe de-identification and the consent process in the Methods section.
2. The study of stakeholders' opinions on publishing identifiable clinical photographs in academic journals
  1. Participants' views on the necessity and stringency of informed consent for publication will vary depending on the level of identity exposure in the images.
  2. Clinicians and students will have stricter requirements for consent to publish clinical images than patients.
3. The third study was qualitative in nature and thus no hypothesis was possible.



### **3. PARTICIPANTS AND METHODS**

#### **3.1. The study of academic journals' policies and actual practices on publishing identifiable clinical photographs**

##### *3.1.1. Study design, data sources and journal selection*

This cross-sectional study analysed two groups of journals from the Journal Citation Report (JCR) database in the period from January to April 2019, to assess journal policies and actual practices regarding the protection of privacy of identifiable patient photographs in the publishing process. JCR was chosen as the database that contains a collection of the most influential journals in the field (76) and could thus be considered as the source of journals with high quality publishing standards.

##### *3.1.2. Data sources and journal selection*

A total of 132 journals were analysed from two JCR categories: “Dentistry, Oral Surgery and Medicine” (Dentistry, n=91) and “Otorhinolaryngology” (ORL, n=41), indexed in the JCR in January 2019. These categories were selected for the analysis because the indexed journals publish articles related to the head and neck region, thus assuming that they would contain clinical facial images. For each category, the inclusion criterion was that a journal published clinical research studies, case studies or case reports. Furthermore, we analysed only the first issue of the journal containing clinical images. If clinical images were not found in the first issue, then the search was extended to second and third issue.

The final sample for analysis had 103 journals. All articles from the first issue in 2018 of each journal from the sample were analysed regardless of their categorization (editorial, review, original article, or other.). The exclusion criteria were no journal issue or volume (n=1) no impact factor (n=1), no online access (n=1), journals without journal policies or guidelines available in English (n=4), journals exclusively publishing research that does not involve clinical images (e.g. basic or epidemiological research) (n=14), and journals that did not publish any clinical image in the first, second and third issue of 2018 (n=9). For the group of journals that did not have any clinical image in the first issue, the search was extended to the maximum of the first three issues in 2018.

In a pilot exercise involving the first 20 journals, three researchers (including the PhD candidate) extracted the data together in order to establish a clear protocol regarding the inclusion and exclusion criteria. When a high level of agreement was established, the authors

continued separately to extract the data and tabulate it in specially designed Microsoft Excel tables.

### *3.1.3. Study outcomes*

In this study, primary and secondary outcome measures were assessed at two levels: at the level of the journals and at the level of the articles.

#### ***Primary outcomes***

At the level of the journals, the primary outcome was the prevalence of editorial policies on publishing clinical images and the requiring of the patient's consent for the publication of these images.

At the level of the article, the primary outcome was the prevalence of articles with clinical images that included a statement of patient's informed consent for the publication of the photograph.

#### ***Secondary outcomes***

At the level of a journal, the secondary outcome measures were:

- The prevalence of other editorial policies related to ethics and/or reporting completeness or transparency: The Declaration of Helsinki (45), CONSORT (Consolidated Standards of Reporting Trials) (77) reporting guidelines for clinical trials, COPE (Committee on Publication Ethics) policies (78) and ICMJE recommendations (24);
- General characteristics of a journal: JCR category, impact factor (as stated in 2018), volume, issue, total number of articles in the journal issue;
- Source of the editorial policy on the consent for clinical images (journal's own policy, publisher's policy, or a link to a specific external policy);
- The number of articles that contained at least one clinical photograph or image, and the total number of photographs or images published in the journal issue.

At the level of an article the secondary outcomes were:

- The type of published clinical images;
- Mention of an informed consent statement for participation in research;
- The method of photograph de-identification (e.g. covering or blurring the eye region).

#### *3.1.4. Statistics*

The categorical data was presented as frequencies, percentages and medians (with interquartile range, IQR) were used for continuous variables. The differences between the groups were tested using the chi squared test, with  $P < 0.05$  significance level. The differences between continuous variables were compared using the Mann-Whitney test. The logistic regression with the bidirectional stepwise method was performed to test which variables predicted that a journal had a policy on publishing clinical images and the patient's consent for them, and which variables predicted that an article had a statement of patient consent for the publication of a clinical image. Before the logistic regression analysis, the assumptions were checked to determine that there is no collinearity between variables. The logistic regression model changes were observed through the Akaike information criterion (AIC), the Bayesian information criterion (BIC) and the chi-squared test (79, 80). In the presentation of the models, due to the software characteristics and analysis type, only significant predictors were presented. The predictors for journals included the following variables: JCR category, journal impact factor; source of journal policy on publishing clinical images; and reference to the Declaration of Helsinki, ICMJE recommendations, CONSORT reporting guidelines, and/or COPE guidelines. Variables used as the potential predictors of requiring written consent for clinical images were the type of clinical images published in the articles and reported written consent for the research reported in the articles. The size of the significant predictors was presented as raw coefficients with standardized errors, standardized coefficients, z values, Vovk-Sellke Maximum P ratio and odds ratios with 95% confidence intervals (CI). The size of the prediction was presented as the r pseudo coefficients (Nagelkerke r squared) and an area under curve (AUC). All statistical analyses were performed using JASP statistical software (Jasp Team, Amsterdam, Netherlands, 2017).

### **3.2. The study of stakeholders' opinions on publishing identifiable clinical photographs in academic journals**

#### *3.2.1. Study design*

This cross-sectional study was conducted in the two largest Croatian cities – Split and Zagreb in the period from October 2017 to February 2018.

### 3.2.2. *Study outcomes*

The primary results were the percentages of all three groups of participants requiring written informed consent for publishing of clinical photographs with different levels of de-identification: X-ray of the upper and lower jaw, photograph of the oral cavity, photograph of the hands, photograph of a patient's face with a blurred eye area, a photograph of a patient's face with a black stripe covering the eyes, and a full face photograph without any de-identification. The secondary outcomes were the differences between all three groups of participants requiring written informed consent for the publishing of clinical photographs with different levels of de-identification.

### 3.2.3. *Participants*

All relevant stakeholders were invited and were grouped as three convenience samples: 1) patients, 2) students of medicine and dentistry and 3) healthcare professionals.

#### ***Patients***

The patients were recruited at the Department of Periodontology, Dental Outpatient Clinic Split, and at the Department of Internal Medicine of the University of Split Hospital Centre. In the period from October to December 2017, all patients coming to a previously arranged appointment and routine procedures were invited to fill in the questionnaire. We included patients over 18 years of age and who were able to give consent and were able to read and provide written responses. They were provided general information about the study, emphasizing the voluntary nature of the study and assurance that their decision to participate or not will not have any influence on their treatment. In order to determine that patients understood the questions of the survey sufficiently, a face validity pilot test of the questionnaire was performed on 10 patients for each group. This pilot study was performed by two practitioners, the doctor of dental medicine/periodontist (the PhD candidate) and the doctor of medicine/cardiologist at their departments before scheduled routine procedures. Based on the pilot study, the questionnaire was revised for enhanced clarity of language.

#### ***Students***

Students from the final two years of study of medicine and dental medicine programmes at the Universities of Split School of Medicine and the Zagreb School of Dental Medicine were recruited. In the period from October 2017 to February 2018, three researchers (including the PhD candidate) invited the students to participate in this study before regular lectures.

A separate survey was performed to include students attending the medical study programme in English, in order to increase the generalizability of this study. This survey was performed in April 2020 and was provided as an online survey on the SurveyMonkey platform (SurveyMonkey, Portland, OR, USA). A paper-based questionnaire could not be implemented due to the COVID-19 pandemic lockdown, as teaching was moved to a fully online format. The questionnaire was translated into English by a professional language expert.

### ***Healthcare professionals***

We invited the doctors of dental medicine and clinicians from the University of Split Hospital Centre (n=137), working at the Departments of Dermatology, Maxillofacial surgery, Otorhinolaryngology, Neurology and Neurosurgery; Dental Outpatient Clinic of the Split-Dalmatia County (n=25); and 37 private dental practices in Split (n=99). In the period from October 2017 to February 2018, two examiners (including the PhD candidate) went personally to participants' offices and offered them to fill in the questionnaire.

#### *3.2.4. Questionnaire*

The questionnaire consisted of two parts: an introductory part with demographic questions and the part with 8 questions regarding opinions of the conditions for the publication of patient data. The first draft of the questionnaire was tested for face-validity by 3 experts in the field of ethics, including a practising clinician, and 10 patients. In order to determine that patients sufficiently understood the questions of the survey, a face validity pilot test of the questionnaire was performed on 10 patients for each group. This pilot study was performed by two practitioners, the dental medicine doctor/periodontist (the PhD candidate) and the medicine doctor/cardiologist at their departments prior to scheduled routine procedures. Based on the pilot study, the questionnaire was revised for clarity of language and all received suggestions were incorporated in the final version of the questionnaire.

Clinical images and photographs used in the questionnaire were taken from patients treated at the Department of Periodontology, Dental Outpatient Clinic Split, after obtaining informed consent for use in the survey. Although all stakeholders received the questionnaires consisting of the same clinical images there were some differences within the introductory segment between three groups as well as in the second part regarding their opinion on provided clinical images. The demographic questions in the patients' questionnaire included the age, gender, level of education, whereas in students' and doctors' questionnaires their year of the

study and specialization type, publishing experience and journal editing experience were added.

Eight questions addressed the necessity of obtaining written patient consent for publication of patient data in academic journals.

This part of questionnaire differed in question formulation for patients and health professionals in terms of the respondents' perspective.

The first question was about the need of obtaining patient consent if the clinicians/authors plan to publish clinical studies containing general patient data in academic journals. The choice of answers in the patients' group was between:

- The doctors must always ask my permission
- I don't know
- Doctors can publish data without obtaining my consent
- It depends (please write your answer)

The choice of answers in the health professionals' questionnaire was between:

- The patients must always give their permission
- I don't know
- I can publish data without obtaining patient consent
- It depends (please write your answer)

The set of 6 questions addressed the respondents' opinions on publishing images with different levels of de-identification: 2) a panoramic X-ray image of the upper and lower jaw, 3) a photograph of the oral cavity, 4) a photograph of the hands, 5) a photograph of a patient's face with a blurred eye area, 6) a photograph of a patient's face with a black stripe covering the eyes, and 7) a full face photograph without de-identification. The choice of answers in the patients' questionnaire to these questions was between:

- My oral permission is sufficient,
- The doctor should obtain my written permission,
- It depends (open-ended answer),
- I don't know, and
- The doctor can publish without asking my permission.

The choice of answers in the health professionals' questionnaire to these questions was between:

- It is sufficient to obtain oral permission from the patients
- The patients should give written permission

- I don't know
- I can publish patients' images without obtaining their permission
- It depends (please write your answer)

The last question in the questionnaire was about the respondents' opinions about conditions for submitting a manuscript with associated patient images to a journal. The answer choices in the patients' group were between:

- It must be allowed to see the article as it will be submitted to the journal, even if I do not understand the language in which it is published.
- It must be provided me to see the article as it will appear in the journal and a translation if I do not understand the language.
- It must be allowed me to see my clinical photograph that will be published in the article, without the text of the article.
- Doctors do not need to provide me to see either the photograph or the text of the manuscript

The choice of answers in the health professionals' questionnaire to these questions was between:

- Allow patients to see the article as it will be submitted to the journal, even if they do not understand the language in which it is published.
- Provide patients with the article as it will appear in the journal and a translation if they do not understand the language.
- Allow patients to see the clinical photograph that will be published in the article, without the text of the article.
- I do not need to allow the patient to see either the photograph or the text of the manuscript.

The questionnaire forms for patients in English and in Croatian are attached in **Appendix 1** and **2**, while the questionnaire forms for healthcare professionals are attached in **Appendix 3** and **4**.

### 3.2.5. *Statistics*

Demographic characteristics of participants were presented as percentages, except age which was presented as median with an interquartile range (IQR). The Chi-square test was used to assess the differences between groups regarding the answers. Multiple logistic regressions

were performed to identify possible predictors (participants' characteristics) for the respondents' answers regarding the need of obtaining patient consent for clinical images with different levels of de identification. The results of the multiple logistic regression were shown as odds ratios (OR) and 95% confidence intervals (CI). The statistical analysis was performed using JASP 0.8.5.1 (Jasp Team, Amsterdam, Netherlands, 2017).

### *3.2.6. Ethics*

This study was approved by the Ethics Committees of the University of Split School of Medicine (Class: 003-08/11-03/0005, Reg. No. 2181,198-03-04/10-11-0038; Class: 003-08/13-03/0003, Reg. No. 2181-03-04-13-0038), University of Zagreb School of Dental Medicine, and the University of Split Hospital Centre.

## **3.3. Focus group study of stakeholders' opinions on publishing identifiable clinical photographs**

### *3.3.1. Study design and setting*

We chose focus group interviews as the methodological approach to research the question in order to encourage participants to develop further discussion about the topic, which is not possible in conducting individual interviews. The focus group interviews were semi-structured. The predefined questions were complemented with additional ones, in cases if there was need for more detailed explanation of the participants' experiences and opinions (81).

Four focus group interviews were conducted in the period from April 21<sup>st</sup> to April 24<sup>th</sup> 2020. The interviews were recorded via the ZOOM platform (ZOOM, San Jose USA) due to COVID-19 lockdown conditions. The duration of the interviews was about 1 hour. At the beginning of interview in each focus group, the PhD candidate informed the participants about the purpose and the aim of the study. The results of the previous study that investigated the stakeholders' opinions on the publication of identifiable patient photographs in academic journals were also presented in order to begin the discussion on the specific issue. PhD candidate conducted interviews along with an independent observer (IB).

The questions for the focus groups were prepared in advance, so that all four focus groups were asked the same six initial questions, as follows:

1. How do you explain the findings of this study – that patients often consider that the doctors do not have to ask them for permission to use their photograph in a publication or that it is sufficient to provide oral consent?



2. Where would you look for information about guidance and standards for obtaining consent for publishing a patient's clinical images?
3. Patient's clinical image could be used for different purposes – medical record, diagnostic aids and treatment planning, communication with colleagues, teaching and lecturing, research, publication (print and/or electronic media). Are they equally important in regard to consent?
4. Current publishing standards state that masking the patient's eyes in a full-face photograph is not anonymization and it not necessary. It is important to obtain patient's consent for the publication of the image and then publish it without alteration. Do you agree with this practice? What would you prefer to be done with your own identifiable clinical image? Which type of anonymization would you consider as the most effective?
5. What happens with clinical images of patients that have been published in academic journals?
6. When a clinical image is published in open access licence CC BY4, anyone can use it for any purpose. CC licences are a form of copyright licence, where a part of researcher's copyright is given up for the public's use. It is stated that this giving up of publishing rights does not override other rights. Does this include patient's right to privacy?

The interview guide and interview questions, including probe questions, are presented in **Appendix 5**. The focus groups with doctors, stakeholders and Croatian students were conducted in Croatian, while focus groups with students in English program were conducted in English. The materials and questions for both groups were prepared in the corresponding language at the beginning of the research phase and were back translated to ensure that there were no discrepancies in the questions. The quotations in the Results section are translations of quotes from participant from the focus groups conducted in Croatian and direct quotes from the focus groups conducted in English.

Participants were encouraged to develop a discussion regarding these themes and support their statements with examples from their experiences.

### *3.3.2. Data management and protection*

According to the guidance of the European Commission regarding ethics and data protection (82), personal data of all study participants and the information they provided were anonymised. Focus group interviews were voice-recorded. The transcripts were anonymised in

the course of the transcription process and were not linked to a specific participant. The interviews were transcribed using the software for qualitative text analysis (Google Docs Voice Typing, Google Mountain View, USA). The analysis was performed using the thematic analysis method (83). The initial step of the analysis process included identification of the initial codes according to the themes/questions which served as questions in the focus groups. Second level codes were defined by the grouping of the initial categories. Two independent coders (MR, DŠ) conducted the analysis and all disagreements were resolved by contacting the third researcher (IB). The transcript was examined for validity by the re-listening of the interviews and re-reading of the transcripts. This was done by the person not involved in the initial transcription (DŠ) and no differences were found between the recording and the transcript. The voice recordings were used only for the purposes of this dissertation and the ProDeM project. The saturation was achieved after analysis of first three groups because no new thematic categories emerged.

### *3.3.3. Participants*

We included stakeholders across different positions in the publishing process, both established healthcare professionals and future healthcare professionals on the one side, and patients whose data had been used in publications on the other side. Four focus group interviews were conducted with the following participants: 1) patients from the Department of Dental Medicine University of Split Hospital Centre (n=8); 2) clinicians who deal with the head and neck area and have experience in publishing from the departments of Dental Medicine, Dermatology, Neurology, Maxillofacial Surgery and Otorhinolaryngology, University of Split Hospital Centre (n=8); 3) final year students of medical studies in Croatian (n=7) and 4) final year students of medical studies in English at the School of Medicine (n=5). Focus groups were matched by gender, age and educational level.

#### *3.3.3.1. Inclusion criteria and exclusion criteria*

Eligibility criteria for focus group members were the following:

- Patients: Patients were recruited from the Department of Dental Medicine, University Hospital Split: they were of both genders and aged 20-60 years, with a high school or university degree (4 male and 4 female participants).
- Students: Final year students of both genders attending medical studies in Croatian or English at the University of Split School of Medicine.

- Doctors: Doctors of both genders employed at University of Split Hospital Centre and School of Medicine, aged 30-65.

#### 3.3.3.2. Recruitment strategy

The eligibility for participation in the focus group interviews was assessed by two researchers (MR and IB) and in cases of disagreement, the third researcher (AM) mediated the final consensus. The purposive sampling was used in order to enhance diversity and the inclusion of different stakeholders.

Researchers were recruited by three researchers (the PhD candidate and two others). In the recruitment process, we invited potential participants via an invitation letter that provided information about the overall aim of the focus group. The participants received the invitation letter via email in which we presented the aims and objectives of the ProDeM project, together with the details of the participation in the focus group interview (**Appendix 6**). After detailed reading and answering their questions, all participants electronically signed providing written informed consent.

#### 3.3.3.3. Informed consent

Before the focus group interview, the participants received the information letter (**Appendix 6**) and an informed consent form (**Appendix 7**). The information on the project included its purpose, funding, recruiting processes, methodologies, expected risks/adverse effects, beneficiaries of research results, communication of research results, all matters concerning data collection, analysis and protection of the participants personal information, the participants' opportunities for leaving the study and for viewing, and if relevant, commenting on transcriptions of interviews and quotations.

By signing the informed consent form, the participants agreed to maintain the confidentiality of the information discussed by all participants and researchers during the focus group session.

The informed consent form was structured according to the guidelines set forth by the USSM Ethics Committee.

#### 3.3.4. Ethics

The ethics approval for conducting the focus group was obtained from the Ethics Committee of the USSM (Class: 003-08/20-03/0005 Reg. No.: 2181-198-04-20-0048), under

the project funded by the Croatian Research Foundation “Professionalism in Health: Decision Making in Practice and Research” (principal investigator: Prof. Ana Marušić, MD, PhD). All information obtained from this research will be used solely for the purposes of this dissertation and the ProDeM project and will be erased after 10 years.

#### 3.3.4.1. Participants’ burden and risk

All information gathered during focus group interviews will be used only for the purposes of this PhD dissertation and the ProDeM project. All participants gave consent for the recording of the interview. The focus group study posed a small risk of discovering sensitive information, for instance certain participants’ experiences in publication of identifiable patient data. Therefore, the focus group facilitators emphasised that participants were not to repeat what was said in the focus group interviews to others in the focus group introduction and debriefing.

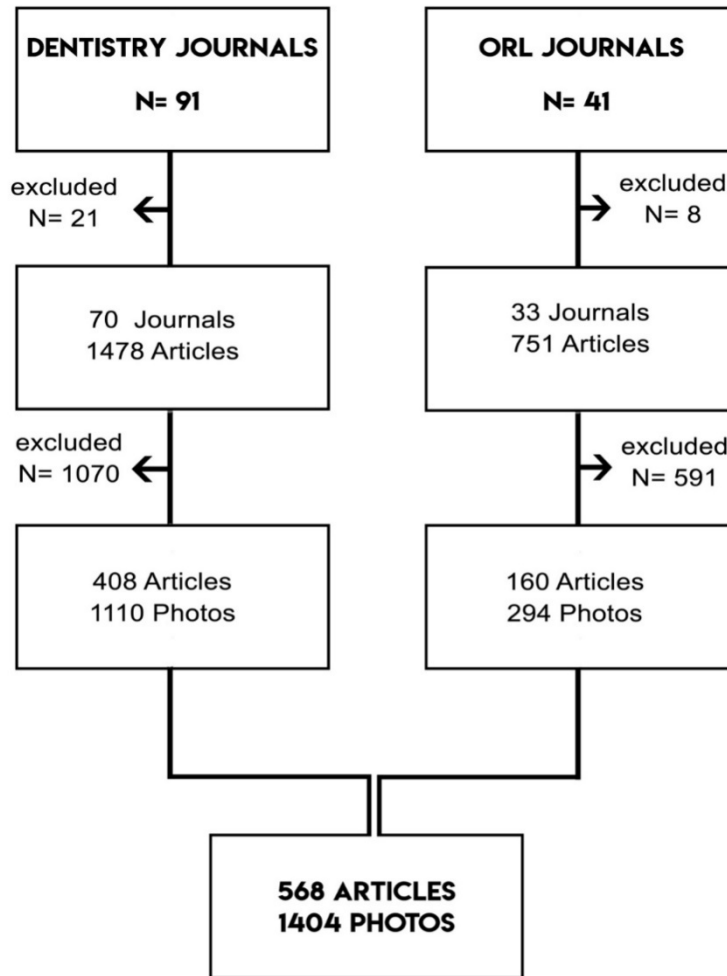
## 4. RESULTS

### 4.1. The study of academic journals' policies and actual practices on publishing identifiable clinical photographs

All journals (n=103) from two JCR categories, “Dentistry, Oral surgery and Medicine” (n=70) and “Otorhinolaryngology” (n=33) that were included in the analysis are listed in **Appendix 8**. The journals which published at least one clinical image in the first issue (or in second and third if in the first were no images) in 2018 (**Figure 2**). Their median impact factor was 1.67 (interquartile range (IQR)=1.26 to 2.38). The majority of the journals were from the Dentistry JCR category (n=70, 68%) and most of the journals (n=92, 89%) published articles in some form of open access.

In total, we analysed the data from 103 journals, which contained 568 articles, which again contained 1404 photographs (**Figure 2**). (**Figure 2**). The median number of articles published in an issue was 15 (IQR=13-16). Journals from the Dentistry JCR category published significantly more articles (n=408, 72%) and images (n=1110, 79%) than journals in the ORL JCR category (n=160, 28% and n=294, 21%, respectively) (P<0.001).

Only about half of the journals (n=52%) had a specific policy regarding clinical images. For comparison, 74% journals (n=76) mentioned the Declaration of Helsinki, 68% (n=70) mentioned the ICMJE Recommendations, 54% (n=56) mentioned the CONSORT reporting guidelines and 29% (n=30) mentioned the COPE guidelines (**Table 5**). However, the single predictor that a journal will have a publicly available policy on clinical images in their guidance for authors was having a reference in the guideline to the ICMJE Recommendations (OR=3.00, 95% 1.26 to 7.14), which explained only 8% of the variance of the criterion. Of the journals with a policy, 26 (49.1%) journals referred to the publisher's policy on clinical images, while 13 (24.5%) journals had their own policies and 14 (26.4%) journals provided a link to other policies (e.g. ICMJE Recommendations, COPE guidelines and/or Declaration of Helsinki) (**Table 5**).



**Figure 2.** The flow diagram of the selection of journals, articles and clinical images for the analysis.

**Table 5.** Characteristics of journals publishing clinical images in Dental Medicine and ORL JCR categories

| Characteristic   | Total               | Dental Medicine JCR category | ORL JCR category    | P*               |
|--|---------------------|------------------------------|---------------------|------------------|
| <b>Number of journals (%)</b>  | 103 (100.0)         | 70 (68.0)                    | 33 (32.0)           | <b>&lt;0.001</b> |
| <b>Journals with editorial policies:</b>   |                     |                              |                     |                  |
| Policy on clinical images (%)  | 53 (51.5)           | 39 (55.7)                    | 14 (42.4)           | 0.208            |
| Declaration of Helsinki (%)  | 76 (73.8)           | 54 (77.1)                    | 22 (28.9)           | 0.259            |
| ICMJE Recommendations (%)  | 70 (68.0)           | 46 (70.0)                    | 24 (72.7)           | 0.477            |
| CONSORT reporting guideline (%)  | 56 (54.4)           | 43 (61.4)                    | 13 (39.4)           | <b>0.036</b>     |
| COPE guidelines (%)  | 30 (29.1)           | 16 (53.3)                    | 14 (42.4)           | <b>0.041</b>     |
| <b>Source of journal policy on clinical images:</b>                                      |                     |                              |                     |                  |
| Total  | 53 (100.0)          | 39 (73.6)                    | 14 (26.4)           |                  |
| Journal's own  | 13 (24.5)           | 6 (15.4)                     | 7(50.0)             | 0.071            |
| Publisher's policy   | 26 (49.1)           | 22 (56.4)                    | 4(28.6)             | 0.062            |
| Link to ICMJE, COPE, and/or Declaration of Helsinki                                      | 14 (26.4)           | 11 (28.2)                    | 3(21.4)             | 0.837            |
| <b>Articles published in 2018 first issue</b>  | 568 (100)           | 408 (72)                     | 160 (28)            | <b>&lt;0.001</b> |
| <b>Median number of articles per issue (IQR)</b>   | 20 (13 to 31)       | 20 (20 to 27)                | 21 (15 to 32)       | <b>&lt;0.001</b> |
| <b>Total number of clinical images in articles</b>                                       | 1404 (100)          | 1110 (79)                    | 294 (21)            | <b>&lt;0.001</b> |
| <b>Median number of images in an article (IQR)</b>                                       | 2 (2 to 2)          | 2 (2 to 2)                   | 1 (1to 2)           | <b>&lt;0.001</b> |
| <b>Statement in article on obtaining informed consent for research</b>                   | 261 (46)            | 209 (51)                     | 52 (32)             | <b>&lt;0.001</b> |
| <b>Statement in article on obtaining informed consent for clinical image publication</b> | 45 (8)              | 42 (10)                      | 3 (2)               | <b>&lt;0.001</b> |
| <b>Median Journal impact factor (IQR)</b>  | 1.67 (1.26 to 2.39) | 1.68 (1.32 to 2.26)          | 1.51 (1.05 to 2.45) | 0.431            |

JCR – Web of Science Journal Citation Reports, ORL – Otorhinolaryngology, ICMJE – International Committee of Medical Journal Editors, COPE – Committee on Publication Ethics, IQR – interquartile range

\*Chi squared test.

Of the total of 568 published articles, 260 (46%) contained a statement on obtaining the participant's informed consent for research. These articles were published more often in Dentistry journals (n=209, 80%) than in ORL journals (n=51, 20%) ( $P<0.001$ ).

The median number of clinical images per article was 2 (IQR=1 to 3), with Dentistry journals publishing significantly more images per article (median=2, IQR=1 to 4) than ORL journals (median=1, IQR=1 to 2,  $P<0.001$ ). Articles in journals from the two JCR categories differed in the type of images they published (**Table 6**). ORL journals had fewer articles with clinical images (OR=0.93, 95% CI 0.89 to 0.98), fewer x-ray images (OR=0.02, 95% CI 0.01 to 0.09), photographs showing a part of the face (OR= 0.46, 95%CI 0.29 to 0.73), and statement on the consent for a clinical photo (OR= 0.55, 95%CI 0.35 to 0.86). They had more articles with endoscopic images (OR=10.70, 95%CI 3.68 TO 31.12) or MRI images (OR=3.97, 95%CI 1.83 to 8.63). The total amount of the variance explained by the predictors was 45%.

Photographs with a recognizable face were found in 13% (79/568) of the articles, constituting 9% (128/1404) of the total sample of images. Only 13 (16%) of these 79 articles publishing recognizable patient facial images included a statement that patients had given consent for the publication of the clinical image.

Among articles containing photographs with a recognizable face, 27 (34%) had a total of 41 photographs where some method of de-identification was used. Covering of the eye region was the most common method of de-identification, followed by the blurring of the eye region (**Table 6**). Only 6 (22%) out of 27 articles with de-identified face photographs had a statement on patient consent for the publication of the photographs. This compares to 21 articles reporting patient consent for image publication out of 489 (4%) articles containing all other types of photographs ( $P<0.001$ ).



**Table 6.** Type of clinical photographs published and de-identification method in articles from dental and ORL journals

| Type of clinical image (n=1404)                             | Total      | Dental medicine JCR category (n=1110) | ORL JCR category (n=294) | P*     |
|---|------------|---------------------------------------|--------------------------|--------|
| X-ray   | 286 (20.4) | 275 (24.8)                            | 11 (3.7)                 | <0.001 |
| Histology slide   | 82 (5.8)   | 59 (5.3)                              | 23 (7.8)                 | 0.103  |
| Ultrasound  | 20 (1.4)   | 11 (1.0)                              | 9 (3.1)                  | 0.008  |
| CBCT  | 209 (14.9) | 141 (12.7)                            | 68 (23.1)                | <0.001 |
| MRI   | 48 (3.4)   | 14 (1.3)                              | 34 (11.6)                | <0.001 |
| Endoscopic view   | 59 (4.2)   | 5 (0.5)                               | 54 (18.4)                | <0.001 |
| Part of the face  | 572 (40.7) | 499 (45.0)                            | 73 (24.8)                | <0.001 |
| Recognizable face   | 128 (9.1)  | 106 (9.5)                             | 22 (7.5)                 | 0.273  |
| <b>Recognizable face included in clinical image (n=128)</b> |            |                                       |                          |        |
| No de-identification  | 87 (67.9)  | 78 (72.9)                             | 9 (40.9)                 | <0.003 |
| De-identification method:                                   | 41 (32.1)  | 29 (27.1)                             | 12 (59.1)                |        |
| covered eye region  | 38 (92.7)  | 26 (89.7)                             | 12 (100)                 | <0.001 |
| blurred eye region  | 3 (7.3)    | 3 (10.3)                              | 0 (0.0)                  |        |

ORL – otorhinolaryngology, JCR – Web of Science Journal Citation Reports, CBCT – cone beam computed tomography, MRI – magnetic resonance imaging

\*Chi squared test

In order to determine there was no collinearity between variables, the variance inflation factors were calculated for both regression models (**Table 7**). The models had acceptable characteristics (**Table 8**) and two variables predicted whether the instructions for the authors were present or whether the consent for clinical images was obtained: the presence of ICMJE Recommendations and the presence of a photograph of a recognizable face in the article (**Table 9**). The only predictor of the presence of the statement on the patient’s consent for the clinical photograph in an article was the presence of a clinical photo of the recognizable face (OR=2.81, 95% CI 1.41 to 5.63), but the amount of explained variance was very small (only 3%) (**Table 9**).

**Table 7.** Variance inflation factors (VIF) for both regression models

|   | VIF   |
|---|-------|
| <b>Model A: Instruction for anonymization</b>     |       |
| JCR   | 1.11  |
| ICMJE instructions                                | 1.23  |
| Consort   | 1.74  |
| Helsinki  | 2.02  |
| COPE  | 1.550 |
| No of articles                                    | 1.650 |
| Articles with clinical photos                     | 1.730 |
| Impact factor                                     | 1.159 |
| Photo policy                                      | 1.217 |
| <b>Model B: Consent for clinical photo</b>        |       |
| Number of photos in the article                   | 1.884 |
| Part of the face                                  | 1.614 |
| X ray   | 1.538 |
| Histology   | 1.047 |
| CBCT  | 1.193 |
| MRI   | 1.106 |
| Endoscopy   | 1.189 |
| Recognizable face                                 | 1.220 |
| JCR category (1-dentistry, 2-Otorhinolaryngology) | 1.323 |

Predictors with VIFs greater than 5 would be considered as problematic.

CBCT – cone beam computed tomography, MRI – magnetic resonance imaging

**Table 8.** Comparison of regression models before and after bidirectional\_stepwise analysis of the prediction of whether journal policy contains Instructions for photo anonymization and whether the consent for publication of clinical photography has been obtained

| Criterion   | Model development  | Model | Deviance | AIC    | BIC    | DF  | $\chi^2$ | P*           | Nagelkerke R <sup>2</sup> |
|---|--|-------|----------|--------|--------|-----|----------|--------------|---------------------------|
| <b>Instructions for photo anonymization (0-no, 1-yes)</b> | No predictors  | 0     | 142.7    | 144.70 | 147.34 | 102 |          |              |                           |
|   | ICMJE Guidelines   | 1     | 136.2    | 140.23 | 145    | 101 | 6.47     | <b>0.011</b> | 0.08                      |
| <b>Consent for clinical photo obtained (0-no, 1-yes)</b>  | No predictors  | 0     | 314.5    | 316.53 | 320.87 | 567 |          |              |                           |
|   | Type of clinical photo in the article: recognizable face | 1     | 307.0    | 311.0  | 319.69 | 566 | 7.52     | <b>0.006</b> | 0.03                      |

AIC – Akaike information criterion, BIC – Bayesian information criterion. The better model of prediction results in lower size of AIC and BIC. DF – degrees of freedom.  $\chi^2$  – chi squared test

\*Comparison of models with or without specific predictor, Chi-squared model significance from the previous model.

**Table 9.** The characteristics of significant predictors in the prediction of whether journal policy contains instructions for photo anonymization and whether the consent for publication of clinical photography has been obtained

| Model criterion                                    | Predictors   | Coefficients Estimate | Robust standard error | Standardized coefficients | Odds ratio (95% CI) | Z    | P*           | Vovk-Sellke Maximum P ratio | AUC   |
|--|--|-----------------------|-----------------------|---------------------------|---------------------|------|--------------|-----------------------------|-------|
| Instructions for photo anonymization (0-no, 1-yes) | ICMJE guidelines (0-no, 1-yes)                           | 1.09                  | 0.443                 | 0.515                     | 3.00 (1.26 to 7.14) | 2.48 | <b>0.013</b> | 6.49                        | 0.616 |
| Consent for clinical photo obtained (0-no, 1-yes)  | Type of clinical photo in the article: recognizable face | 1.03                  | 0.354                 | 0.358                     | 2.81 (1.40 to 5.63) | 2.91 | <b>0.004</b> | 18.55                       | 0.581 |

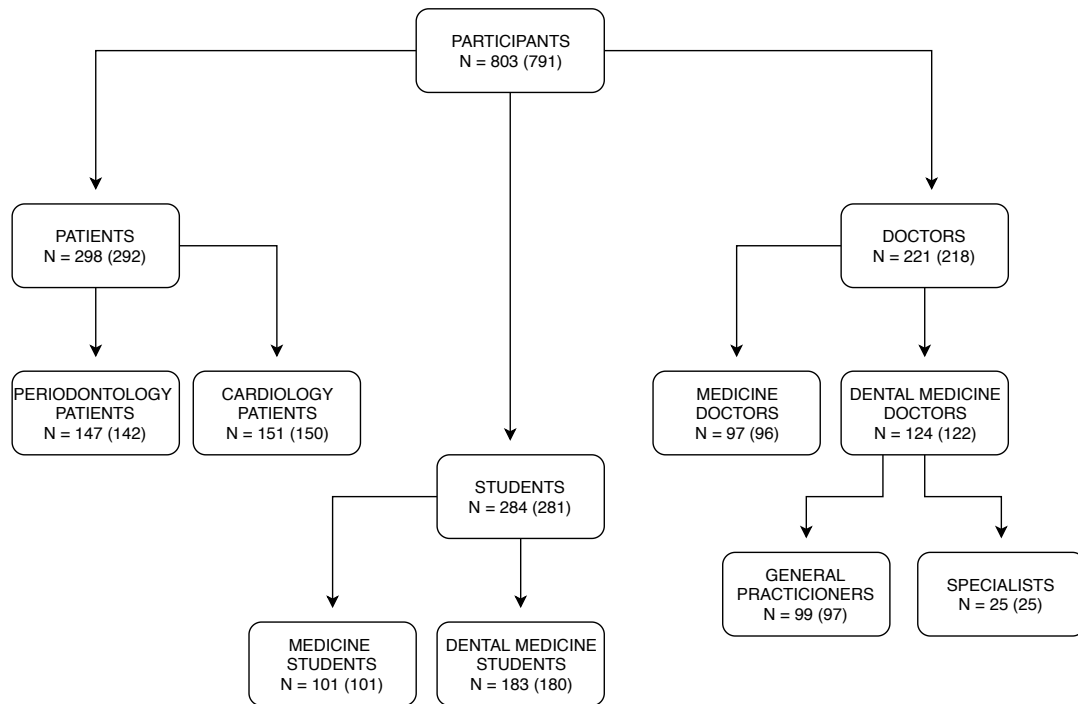
Z – ratio of coefficients estimate and standard error, the significant predictors should be at least 2 to be considered significant, AUC – area under the curve.

\*Variable significance. Vovk-Sellke Maximum P ratio. Vovk-Sellke Maximum p -Ratio: Based on the p-value, the maximum possible odds in favour of  $H_1$  over  $H_0$  equals  $1/(-e p \log(p))$  for  $p \leq 0.37$

#### 4.2. The study of stakeholders' opinions on publishing identifiable clinical photographs in academic journals

We surveyed a total of 803 participants. The final analysis included 791 properly completed surveys whereas the rest of 12 questionnaires with missing data were excluded. A final sample for analysis was consisted of three groups of participants: 292 patients, 281 students and 218 doctors (**Figure 3**). In a separate study 33 medical students of the study programme in English filled the questionnaire.

The response rate for patients could not be calculated. Among the students' group, all students of dental medicine from the University of Split filled the survey correctly, 72% of medical students from the University of Split, 63% of students of medical students in English and 58% of dental medicine students from the University of Zagreb. The response rate in doctors' group was 85%.



**Figure 3.** The flow diagram of participants in the study (numbers show total number of respondents who completed the survey; total number of participants for analysis after excluding those with missing survey data are shown in brackets).

In all three groups there was a higher number of women than men. In the patients' group the median age was 55 (IQR=22), 23 (IQR=1) in students' group and 40 (IQR=18) in doctors' group. The level of education of patient participants was high school degree or university degree. Among the healthcare professionals, 44% of them had experience in publishing and only 6% of them had experience in journal editing (**Table 10**).

**Table 10.** Demographic characteristics of participants (N=791)

| No. (%)                                      | Patients<br>(n=292) | Students                      |                     |                  | Doctors                       |                    |                  |
|--|---------------------|-------------------------------|---------------------|------------------|-------------------------------|--------------------|------------------|
|  |                     | Dental<br>medicine<br>(n=180) | Medicine<br>(n=101) | Total<br>(n=281) | Dental<br>medicine<br>(n=122) | Medicine<br>(n=96) | Total<br>(n=218) |
| <b>Gender</b>                                |                     |                               |                     |                  |                               |                    |                  |
| Female                                       | 167<br>(57.19%)     | 154<br>(85.56%)               | 63<br>(62.38%)      | 217<br>(77.22%)  | 76<br>(62.30%)                | 50<br>(52.08%)     | 126<br>(57.80%)  |
| Male   | 125<br>(42.81%)     | 26<br>(14.44%)                | 38<br>(37.62%)      | 64<br>(22.78%)   | 46<br>(37.70%)                | 46<br>(47.92%)     | 92<br>(42.20%)   |
| <b>Age<br/>(years),<br/>median<br/>(IQR)</b> |                     |                               |                     |                  |                               |                    |                  |
|  | 55 (22)             | 23 (1)                        | 23 (1)              | 23 (1)           | 40 (17)                       | 40 (18.25)         | 40 (18)          |
| <b>Education</b>                             |                     |                               |                     |                  |                               |                    |                  |
| No<br>elementary<br>school                   | 3<br>(1.03%)        | -                             | -                   | -                | -                             | -                  | -                |
| Elementary<br>school                         | 10<br>(3.42%)       | -                             | -                   | -                | -                             | -                  | -                |
| High school                                  | 165<br>(56.51%)     | -                             | -                   | -                | -                             | -                  | -                |
| University<br>degree                         | 113<br>(38.7%)      | -                             | -                   | -                | -                             | -                  | -                |
| <b>Published<br/>paper<br/>before</b>        |                     |                               |                     |                  |                               |                    |                  |
| No   | -                   | 159<br>(88.33%)               | 97<br>(96.04%)      | 256<br>(91.10%)  | 84<br>(68.85%)                | 39<br>(40.62%)     | 123<br>(56.42%)  |
| Yes  | -                   | 16<br>(8.89%)                 | 4<br>(3.96%)        | 20<br>(7.12%)    | 38<br>(31.15%)                | 57<br>(59.38%)     | 95<br>(43.58%)   |
| <b>Experience<br/>of journal<br/>editing</b> |                     |                               |                     |                  |                               |                    |                  |
| No   | -                   | 172<br>(95.56%)               | 101<br>(100%)       | 273<br>(97.15%)  | 118<br>(96.72%)               | 87<br>(90.62%)     | 205<br>(94.04%)  |
| Yes  | -                   | 3 (1.67%)                     | -                   | 3<br>(1.07%)     | 4 (3.28%)                     | 9 (9.38%)          | 13<br>(5.96%)    |

Comparing the respondents' answers to the first survey question about the need of informed consent for publishing general patient data from a clinical study in an academic journal, opinions differed among the stakeholders. Out of 49% patients considered doctors are allowed to publish their data without informed consent as well as 36% of the students and 33% of the doctors (**Table 11**).

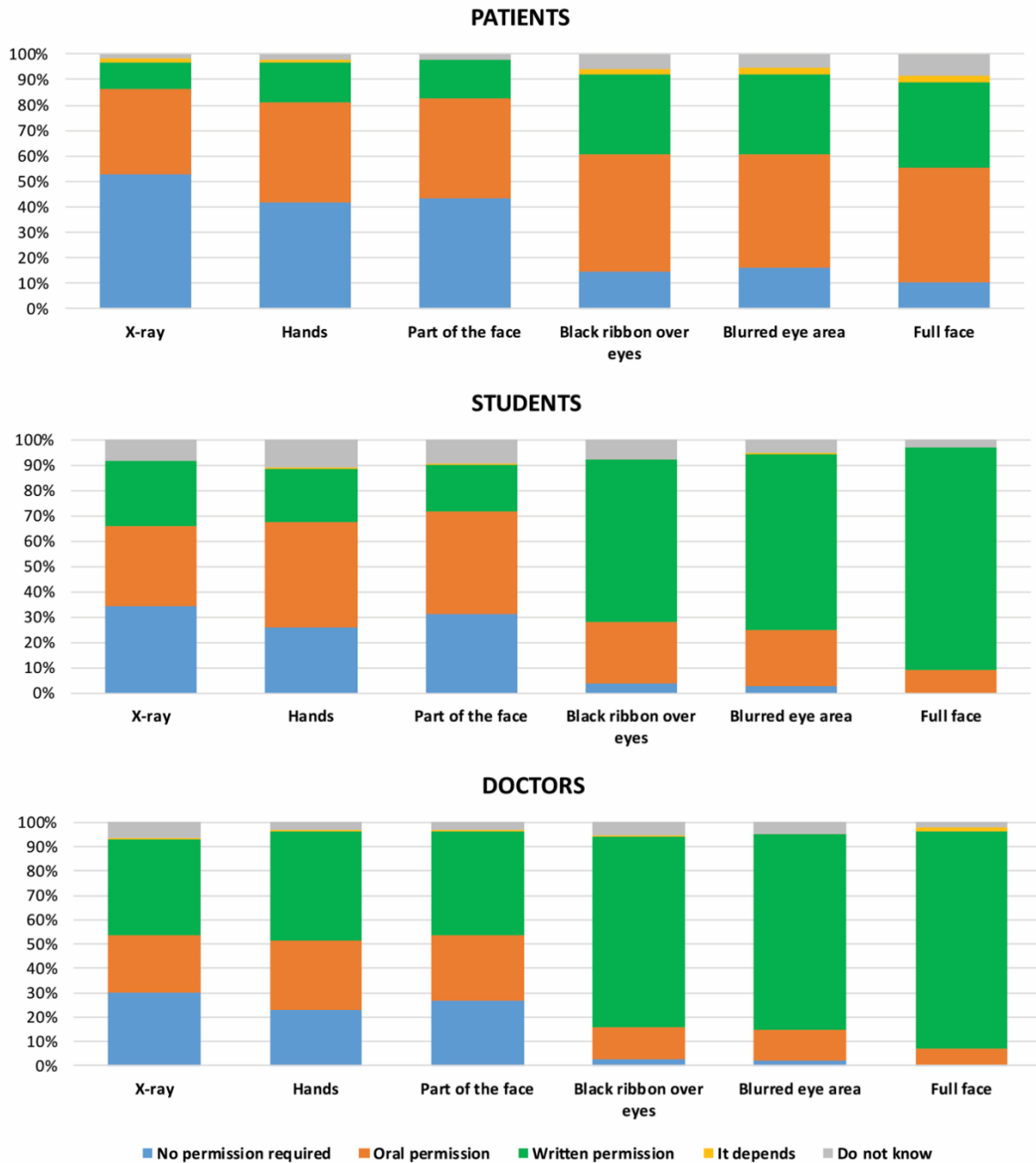
The answers on the last survey question regarding the importance of providing the manuscript with the associated patients' photographs to patients before submitting in order to obtain informed consent, also differed among the groups. While most of the patients and doctors considered there was no need to show patients either the image or the paper to be published, most students thought that they should be provided to patients to see and read, with a translation to simple native language if necessary (**Table 11**).

**Table 11.** Opinions by survey respondents (patients, students, doctors) about consent for not publishing patients' clinical photographs and about the necessity and conditions for patients to see the article prior to publishing (N=791).

|  | <b>Patients<br/>(n=292)</b> | <b>Students<br/>(n=281)</b> | <b>Doctors<br/>(n=218)</b> | <b>P*</b>        |
|--|-----------------------------|-----------------------------|----------------------------|------------------|
| <b>Collecting clinical data but not clinical images (question 1 in the survey):</b>                                    |                             |                             |                            |                  |
| No informed consent needed   | 144 (49.32)                 | 100 (35.59)                 | 71 (32.57)                 | <b>&lt;0.001</b> |
| Patients' approval always required   | 121 (41.44)                 | 142 (50.53)                 | 125 (57.34)                |                  |
| It depends   | 7 (2.40)                    | 5 (1.78)                    | 3 (1.38)                   |                  |
| Do not know  | 20 (6.85)                   | 34 (12.10)                  | 19 (8.72)                  |                  |
| <b>For publishing, patient must see (question 8 in the survey):</b>  |                             |                             |                            |                  |
| Manuscript that will be published, regardless of the language (which patient might not understand)                     | 36 (12.33)                  | 22 (7.83)                   | 17 (7.80)                  | <b>&lt;0.001</b> |
| Manuscript that will be published, but translated into Croatian (if patient does not understand the original language) | 86 (29.45)                  | 108 (38.43)                 | 59 (27.06)                 |                  |
| Clinical image that will be published, but without a the text of the manuscript  | 26 (8.90)                   | 71 (25.27)                  | 48 (22.02)                 |                  |
| Neither the manuscript not the clinical image before they are published  | 139 (47.60)                 | 80 (28.47)                  | 92 (42.20)                 |                  |

\*Chi-squared test.

Answers to six survey questions regarding the patient images with different levels of de-identification, showed there was a general trend in the opinion of all stakeholders which was that more stringent forms of permission were needed as the level of identifiability increased (**Figure 4, Table 12**). In case of presented facial photographs without any de-identification, 33% of the patients answered that written permission for publication was required, as well as 88% of the students and 89% of the doctors surveyed.



**Figure 4.** Opinions of survey respondents (patients, students, doctors) regarding consent for publishing clinical photographs of patients with different levels of identifiability (N=791). Answers to each individual question differed between the three groups ( $P < 0.001$ , Chi-square test)

**Table 12.** Frequencies of the respondents' questionnaire answers among all three groups of stakeholders.

|                               | <b>Patients<br/>(n=292)</b> | <b>Students<br/>(n=281)</b> | <b>Doctors<br/>(n=218)</b> | <b>P*</b>        |
|-------------------------------|-----------------------------|-----------------------------|----------------------------|------------------|
| <b>X-ray</b>                  |                             |                             |                            |                  |
| No permission required        | 154 (52.74)                 | 97 (34.52)                  | 97 (30.28)                 | <b>&lt;0.001</b> |
| Oral permission               | 98 (33.56)                  | 88 (31.32)                  | 88 (23.39)                 |                  |
| Written permission            | 31 (10.62)                  | 72 (25.62)                  | 72 (39.45)                 |                  |
| It depends                    | 4 (1.37)                    | 1 (0.36)                    | 1 (0.46)                   |                  |
| Do not know                   | 5 (1.71)                    | 23 (8.19)                   | 23 (6.42)                  |                  |
| <b>Hands</b>                  |                             |                             |                            |                  |
| No permission required        | 122 (41.78)                 | 73 (25.98)                  | 73 (22.94)                 | <b>&lt;0.001</b> |
| Oral permission               | 114 (39.04)                 | 116 (41.28)                 | 116 (28.44)                |                  |
| Written permission            | 47 (16.1)                   | 59 (21)                     | 59 (44.95)                 |                  |
| It depends                    | 2 (0.68)                    | 2 (0.71)                    | 2 (0.46)                   |                  |
| Do not know                   | 7 (2.4)                     | 31 (11.03)                  | 31 (3.21)                  |                  |
| <b>Part of the face</b>       |                             |                             |                            |                  |
| No permission required        | 127 (43.49)                 | 87 (30.96)                  | 87 (26.61)                 | <b>&lt;0.001</b> |
| Oral permission               | 114 (39.04)                 | 115 (40.93)                 | 115 (27.06)                |                  |
| Written permission            | 45 (15.41)                  | 51 (18.15)                  | 51 (42.66)                 |                  |
| It depends                    | 0 (0)                       | 2 (0.71)                    | 2 (0.46)                   |                  |
| Do not know                   | 6 (2.05)                    | 26 (9.25)                   | 26 (3.21)                  |                  |
| <b>Black ribbon over eyes</b> |                             |                             |                            |                  |
| No permission required        | 42 (14.38)                  | 11 (3.91)                   | 11 (2.75)                  | <b>&lt;0.001</b> |
| Oral permission               | 135 (46.23)                 | 68 (24.2)                   | 68 (12.84)                 |                  |
| Written permission            | 92 (31.51)                  | 180 (64.06)                 | 180 (78.44)                |                  |
| It depends                    | 6 (2.05)                    | 0 (0)                       | 0 (0.46)                   |                  |
| Do not know                   | 17 (5.82)                   | 22 (7.83)                   | 22 (5.5)                   |                  |
| <b>Blurred eye area</b>       |                             |                             |                            |                  |
| No permission required        | 48 (16.44)                  | 8 (2.85)                    | 8 (2.29)                   | <b>&lt;0.001</b> |
| Oral permission               | 129 (44.18)                 | 61 (21.71)                  | 61 (12.39)                 |                  |
| Written permission            | 92 (31.51)                  | 196 (69.75)                 | 196 (80.28)                |                  |
| It depends                    | 7 (2.4)                     | 1 (0.36)                    | 1 (0.46)                   |                  |
| Do not know                   | 16 (5.48)                   | 15 (5.34)                   | 15 (4.59)                  |                  |
| <b>Full face</b>              |                             |                             |                            |                  |
| No permission required        | 30 (10.27)                  | 0 (0)                       | 0 (0.46)                   | <b>&lt;0.001</b> |
| Oral permission               | 132 (45.21)                 | 25 (8.9)                    | 25 (6.42)                  |                  |
| Written permission            | 97 (33.22)                  | 247 (87.9)                  | 247 (89.45)                |                  |
| It depends                    | 8 (2.74)                    | 1 (0.36)                    | 1 (1.38)                   |                  |
| Do not know                   | 25 (8.56)                   | 8 (2.85)                    | 8 (2.29)                   |                  |

\*Chi-squared test.



Multiple logistic regression analyses were performed to test whether clinical photographs with different levels of de-identification were predictors to require written informed consent. The results showed that doctors were more likely than patients to require written informed consent for any type of image regardless of the level of identification. Furthermore, doctors and students were more likely than patients to require written informed consent for the clinical images as the level of de-identification decreased (**Table 13**).

**Table 13.** Odds for choosing "need for written or oral approval" over "no need for informed consent" for publishing of patients' clinical photographs with different levels of de-identification, based on the respondents' status as patients, students and doctors

|                  | <b>None</b>             |           | <b>X-ray of the skull</b>               |           | <b>Hand</b>                    |           |
|------------------|-------------------------|-----------|---|-----------|--------------------------------|-----------|
| <b>Predictor</b> | <b>OR (95% CI)</b>      | <b>P*</b> | <b>OR (95% CI)</b>                      | <b>P*</b> | <b>OR (95% CI)</b>             | <b>P*</b> |
| <b>Age</b>       | 1.000 (0.986-1.014)     | 0.989     | 1.005 (0.991-1.019)                     | 0.467     | 1.008 (0.993-1.022)            | 0.288     |
| <b>Gender</b>    |                         |           |   |           |                                |           |
| Males            | Reference               | -         | Reference                               | -         | Reference                      | -         |
| Females          | 1.164 (0.843-1.608)     | 0.355     | 1.279 (0.933-1.753)                     | 0.127     | 1.527 (1.098-2.122)            | 0.012     |
| <b>Group</b>     |                         |           |   |           |                                |           |
| Patients         | Reference               | -         | Reference                               | -         | Reference                      | -         |
| Students         | 1.646 (0.946-2.866)     | 0.078     | 2.213 (1.282-3.819)                     | 0.004     | 2.126 (1.208-3.741)            | 0.009     |
| Doctors          | 2.100 (1.375-3.206)     | <0.001    | 2.663 (1.747-4.060)                     | <0.001    | 2.724 (1.747-4.249)            | <0.001    |
|                  | <b>Part of the face</b> |           | <b>Face, black ribbon over the eyes</b> |           | <b>Face, eye areas blurred</b> |           |
| <b>Predictor</b> | <b>OR (95% CI)</b>      | <b>P*</b> | <b>OR (95% CI)</b>                      | <b>P*</b> | <b>OR (95% CI)</b>             | <b>P*</b> |
| <b>Age</b>       | 1.013 (0.998-1.027)     | 0.08      | 0.989 (0.967-1.011)                     | 0.335     | 0.995 (0.974-1.016)            | 0.638     |
| <b>Gender</b>    |                         |           |   |           |                                |           |
| Males            | Reference               | -         | Reference                               | -         | Reference                      | -         |
| Females          | 1.502 (1.09-2.071)      | 0.013     | 1.241 (0.705-2.183)                     | 0.454     | 1.533 (0.879-2.672)            | 0.132     |
| <b>Group</b>     |                         |           |   |           |                                |           |
| Patients         | Reference               | -         | Reference                               | -         | Reference                      | -         |
| Students         | 2.081 (1.196-3.622)     | 0.01      | 2.834 (1.055-7.613)                     | 0.039     | 5.492 (1.997-15.108)           | <0.001    |
| Doctors          | 2.510 (1.626-3.874)     | <0.001    | 5.269 (2.081-13.336)                    | <0.001    | 8.214 (3.070-21.973)           | <0.001    |

\* Multiple logistic regressions.

Question about "Entire face" was not analysed due to an insufficient variance in answers.

Abbreviations: OR – odds ratio, CI – confidence interval

Additional analysis within the groups showed some differences in the participants' answers. Comparing the answers between patients surveyed at Department of Periodontology and Department of Internal Medicine several differences were found. Patients from the Department of Periodontology, more often considered that consent was required for general patient data (20% vs 22%,  $P=0.004$ ), x-ray image (20% vs 25%,  $P=0.010$ ), part of the face (22% vs 33%,  $P=0.005$ ) and full-face photographs without de-identification (38% vs 40%,  $P=0.040$ ). We did not perform a multiple logistic regression analysis with these findings because the patient subgroups were too small, as were the differences between them which themselves could have been random. However, students' and doctors' groups were analysed to investigate the differences in answers regarding their specific branch of the health profession.

Dental medicine students and doctors were more likely than medical students and doctors to answer that informed consent for publication of a patient's photograph must be obtained (**Table 14**). As the level of de-identification decreased, it was more likely that they would consider that approval was required. On the other hand, it was more likely for medical students compared to patients to consider that approval was required only in cases of an x-ray of the skull or a photograph of a face with the eye areas blurred. Finally, medical doctors did not differ from patients in consideration of written approval when they were presented with no picture or with an x-ray of the skull. As the level of identifiability increased, the probability of considering written approval as mandatory also increased.

#### *4.2.1. Survey of students of medical studies in English*

In order to increase the generalizability of our survey results, we conducted another study among students of medical studies in English using the same questionnaire translated in English. While Croatian students and medical students of the study programme in English were not different regarding obtaining written patient consent for identifiable patient photographs, students of medical studies in English were more stringent when they were asked whether it was needed that there be written informed consent for non-identifiable patient images than the Croatian ones (**Table 15**). Furthermore, Croatian dental students were more stringent than Croatian medical students regarding the publishing non-identifiable patient images and were similar in their answers to the students of medical studies in English (**Table 15**). Also, most students of medical studies in English considered that patients should be able to read the manuscript (and for it to be translated if needed) that contained their photographs in order to consent to such publication (**Table 15**).

**Table 14.** Odds for choosing "need for written or oral approval" over "no need for informed consent" for the publishing a patient's clinical photographs with different levels of de-identification, based on the respondents' status as patients, dental medicine and medicine students and doctors of dental medicine and doctors of medicine.

| Predictor                | None                |        | X-ray of the skull               |        | Hand                    |        |
|--------------------------|---------------------|--------|----------------------------------|--------|-------------------------|--------|
|                          | OR (95% CI)         | P*     | OR (95% CI)                      | P*     | OR (95% CI)             | P*     |
| Age                      | 1.001 (0.986-1.015) | 0.934  | 1.006 (0.992-1.021)              | 0.375  | 1.008 (0.994-1.023)     | 0.257  |
| <b>Gender</b>            |                     |        |                                  |        |                         |        |
| Males                    | Reference           | -      | Reference                        | -      | Reference               | -      |
| Females                  | 1.1 (0.792-1.527)   | 0.57   | 1.256 (0.91-1.734)               | 0.165  | 1.435 (1.027-2.003)     | 0.034  |
| <b>Group</b>             |                     |        |                                  |        |                         |        |
| Patients                 | Reference           | -      | Reference                        | -      | Reference               | -      |
| Dental medicine students | 1.949 (1.08-3.516)  | 0.027  | 2.294 (1.281-4.107)              | 0.005  | 2.778 (1.505-5.125)     | 0.001  |
| Medicine students        | 1.297 (0.674-2.498) | 0.436  | 2.318 (1.214-4.426)              | 0.011  | 1.455 (0.749-2.826)     | 0.268  |
| Dental medicine doctors  | 2.912 (1.735-4.886) | <0.001 | 4.438 (2.609-7.550)              | <0.001 | 4.397 (2.447-7.901)     | <0.001 |
| Medicine doctors         | 1.455 (0.865-2.447) | 0.158  | 1.507 (0.896-2.535)              | 0.122  | 1.721 (1.015-2.917)     | 0.044  |
| Predictor                | Part of the face    |        | Face, black ribbon over the eyes |        | Face, eye areas blurred |        |
|                          | OR (95% CI)         | P*     | OR (95% CI)                      | P*     | OR (95% CI)             | P*     |
| Age                      | 1.013 (0.999-1.028) | 0.07   | 0.989 (0.967-1.011)              | 0.336  | 0.995 (0.974-1.016)     | 0.644  |
| <b>Gender</b>            |                     |        |                                  |        |                         |        |
| Males                    | Reference           | -      | Reference                        | -      | Reference               | -      |
| Females                  | 1.459 (1.054-2.02)  | 0.023  | 1.156 (0.657-2.033)              | 0.615  | 1.495 (0.856-2.611)     | 0.158  |
| <b>Group</b>             |                     |        |                                  |        |                         |        |
| Patients                 | Reference           | -      | Reference                        | -      | Reference               | -      |
| Dental medicine students | 2.299 (1.276-4.144) | 0.006  | 5.131 (1.448-18.186)             | 0.011  | 6.825 (1.989-23.418)    | 0.002  |
| Medicine students        | 1.827 (0.945-3.534) | 0.073  | 1.587 (0.529-4.758)              | 0.41   | 4.233 (1.227-14.605)    | 0.022  |
| Dental medicine doctors  | 3.248 (1.899-5.556) | <0.001 | 8.846 (2.029-38.566)             | 0.004  | 11.799 (2.73-50.990)    | 0.001  |
| Medicine doctors         | 1.896 (1.119-3.215) | 0.018  | 3.487 (1.168-10.412)             | 0.025  | 5.828 (1.714-19.824)    | 0.005  |

\* Multiple logistic regression.

Question about the "Entire face" was not analysed due to insufficient differences in answers.

Abbreviations: OR – odds ratio, CI – confidence interval

**Table 15.** Comparison of students from the medical programme in English or Croatian.

|                                    | Students of medical studies in English (N = 33) | Croatian students (N = 281) | P <sup>a</sup>   | Croatian students of medicine (N = 101) | P <sup>b</sup>   | Croatian students of dental medicine (N = 180) | P <sup>c</sup>   |
|------------------------------------|---|-----------------------------|------------------|---|------------------|--|------------------|
| <b>Gender</b>                      |   |                             |                  |   |                  |  |                  |
| Male                               | 8 (24.2)  | 64 (22.8)                   | 0.850            | 38 (37.6)                               | 0.160            | 26 (14.4)                                      | 0.158            |
| Female                             | 25 (75.6)                                       | 217 (77.2)                  |                  | 63 (62.4)                               |                  | 154 (85.6)                                     |                  |
| <b>Age (median, IQR)</b>           | 25 (24 - 27.5)                                  | 23 (23 - 24)                | <b>&lt;0.001</b> | 23 (23 - 24)                            | <b>&lt;0.001</b> | 23 (23 - 24)                                   | <b>&lt;0.001</b> |
| <b>No photograph</b>               |   |                             |                  |   |                  |  |                  |
| No informed consent needed         | 8 (24.2)  | 100 (35.6)                  | 0.362            | 40 (39.6)                               | 0.199            | 60 (33.3)                                      | 0.621            |
| Patients' approval always required | 20 (60.1)                                       | 142 (50.5)                  |                  | 43 (42.6)                               |                  | 99 (55)  |                  |
| It depends                         | /   | 5 (1.8)                     |                  | 2 (2)                                   |                  | 3 (1.7)  |                  |
| Do not know                        | 2 (6.1)   | 34 (12.1)                   |                  | 16 (15.8)                               |                  | 18 (10)  |                  |
| <b>X-ray</b>                       |   |                             |                  |   |                  |  |                  |
| No permission required             | 5 (15.2)  | 97 (34.5)                   | <b>0.003</b>     | 35 (34.7)                               | <b>0.003</b>     | 62 (34.4)                                      | <b>0.006</b>     |
| Oral permission                    | 7 (21.1)  | 88 (31.3)                   |                  | 31 (30.7)                               |                  | 57 (31.7)                                      |                  |
| Written permission                 | 19 (57.6)                                       | 72 (25.6)                   |                  | 25 (24.8)                               |                  | 47 (26.1)                                      |                  |
| It depends                         | /   | 1 (0.4)                     |                  | /                                       |                  | 1 (0.6)  |                  |
| Do not know                        | 1 (3.0)   | 23 (8.2)                    |                  | 10 (9.9)                                |                  | 13 (7.2)                                       |                  |
| <b>Hands</b>                       |   |                             |                  |   |                  |  |                  |
| No permission required             | 4 (12.1)  | 73 (26)                     | <b>0.003</b>     | 33 (32.7)                               | <b>&lt;0.001</b> | 40 (22.2)                                      | <b>0.015</b>     |
| Oral permission                    | 12 (36.4)                                       | 116 (41.3)                  |                  | 35 (34.7)                               |                  | 81 (45)  |                  |
| Written permission                 | 16 (48.5)                                       | 59 (21)                     |                  | 15 (14.9)                               |                  | 44 (24.4)                                      |                  |
| It depends                         | /   | 2 (0.7)                     |                  | 2 (2)                                   |                  | /  |                  |
| Do not know                        | /   | 31 (11)                     |                  | 16 (15.8)                               |                  | 15 (8.3)                                       |                  |
| <b>Part of the face</b>            |   |                             |                  |   |                  |  |                  |
| No permission required             | 5 (15.1)  | 87 (31)                     | <b>&lt;0.001</b> | 33 (32.7)                               | <b>&lt;0.001</b> | 54 (30)  | <b>0.006</b>     |
| Oral permission                    | 10 (30.3)                                       | 115 (40.9)                  |                  | 40 (39.6)                               |                  | 75 (41.7)                                      |                  |
| Written permission                 | 17 (51.5)                                       | 51 (18.1)                   |                  | 11 (10.9)                               |                  | 40 (22.2)                                      |                  |
| It depends                         | /   | 2 (0.7)                     |                  | /                                       |                  | 2 (1.1)  |                  |
| Do not know                        | /   | 26 (9.3)                    |                  | 17 (16.8)                               |                  | 9 (5)  |                  |
| <b>Black ribbon over eyes</b>      |   |                             |                  |   |                  |  |                  |
| No permission required             | 1 (3.0)   | 11 (3.9)                    | 0.059            | 7 (6.9)                                 | <b>0.016</b>     | 4 (2.2)  | 0.128            |
| Oral permission                    | 2 (6.1)   | 68 (24.2)                   |                  | 28 (27.7)                               |                  | 40 (22.2)                                      |                  |

|   | Students of medical studies in English (N = 33) | Croatian students (N = 281) | P <sup>a</sup> | Croatian students of medicine (N = 101) | P <sup>b</sup> | Croatian students of dental medicine (N = 180) | P <sup>c</sup> |
|---|---|-----------------------------|----------------|---|----------------|--|----------------|
| Written permission  | 28 (84.8)                                       | 180 (64.1)                  |                | 57 (56.4)                               |                | 123 (68.3)                                     |                |
| It depends  | /   | /                           |                | /                                       |                | /  |                |
| Do not know   | 1 (3.0)   | 22 (7.8)                    |                | 9 (8.9)                                 |                | 13 (7.2)                                       |                |
| <b>Blurred eye area</b>   |   |                             |                |   |                |  |                |
| No permission required  | 1 (3.0)   | 8 (2.8)                     | 0.264          | 4 (4)                                   | 0.117          | 4 (2.2)  | 0.327          |
| Oral permission   | 3 (9.1)   | 61 (21.7)                   |                | 25 (24.8)                               |                | 36 (20)  |                |
| Written permission  | 28 (84.8)                                       | 196 (69.8)                  |                | 67 (66.3)                               |                | 129 (71.7)                                     |                |
| It depends  | /   | 1 (0.4)                     |                | /                                       |                | 1 (0.6)  |                |
| Do not know   | /   | 15 (5.3)                    |                | 5 (5)                                   |                | 10 (5.6)                                       |                |
| <b>Full face</b>  |   |                             |                |   |                |  |                |
| No permission required  | /   | /                           | 0.487          | /                                       | 0.231          | /  | 0.560          |
| Oral permission   | 1 (3.0)   | 25 (8.9)                    |                | 10 (9.9)                                |                | 15 (8.3)                                       |                |
| Written permission  | 31 (93.9)                                       | 247 (87.9)                  |                | 87 (86.1)                               |                | 160 (88.9)                                     |                |
| It depends  | /   | 1 (0.4)                     |                | /                                       |                | 1 (0.6)  |                |
| Do not know   | /   | 8 (2.8)                     |                | 4 (4)                                   |                | 4 (2.2)  |                |
| <b>For publishing, patient must see:</b>  |   |                             |                |   |                |  |                |
| Neither the article or the clinical photography before the article is published                       | /   | 80 (28.5)                   | 0.005          | 28 (27.7)                               | 0.005          | 52 (28.9)                                      | 0.005          |
| Clinical photography that will be published, but without a written part of the article                | 9 (27.3)  | 71 (25.3)                   |                | 28 (27.7)                               |                | 43 (23.9)                                      |                |
| Article that will be published, regardless of the language (which patient might not understand)       | 4 (12.1)  | 22 (7.8)                    |                | 6 (5.9)                                 |                | 16 (8.9)                                       |                |
| Article that will be published, but translated (if patient does not understand the original language) | 19 (57.6)                                       | 108 (38.4)                  |                | 39 (38.6)                               |                | 69 (38.3)                                      |                |

<sup>a</sup> students from the medical studies in English vs. Croatian students

<sup>b</sup> students from the medical studies in English vs. Croatian students of medicine

<sup>c</sup> students from the medical studies in English. Croatian students of dental medicine

#### **4.3. Focus group study of stakeholders' opinions on publishing identifiable clinical photographs**

Thirty individuals were contacted and agreed to participate but 2 subsequently cancelled due to the issues with Internet connection, leaving 28 focus group participants. We formed four focus groups with different stakeholders:

1. Patients from the Department of Dental Medicine, University Hospital Centre Split (n=8);
2. Doctors from Departments of Dentistry, Maxillofacial Surgery, Neurology, Dermatology and Otorhinolaryngology, University Hospital Centre Split (n=8; 4 dental medicine doctors, 1 specialist in maxillofacial surgery, 1 in dermatology, 1 in neurology, and 1 in otorhinolaryngology);
3. Final year students of medical studies in Croatian at USSM (n=7); and
4. Final year students of medical studies in English at USSM (n=5).

Participants were coded according to focus group and consecutive numbers as follows: F1- patients, F2- doctors, F3- students of the medical studies in Croatian and F4 students of the medical studies in English along with the number of each participant starting with P1 to P28. Six main topics could be derived from the focus group discussions: 1) reasons for the patients' high trust in their doctors, 2) finding of information regarding guidance and standards for the publishing of the patients' images, 3) the need for informed consent regarding data from medical records for different purposes, 4) the use of de-identification techniques for publishing facial photographs, 5) accessibility of patients' photographs published in academic journals, 6) protection of patient privacy rights in open access academic journals.

##### *4.3.1. Reasons for patients' high trust in their doctors*

The patients emphasised that medical photographs as part of confidential medical documentation require particularly careful maintenance.

*F1/P7...[patient photographs] are confidential and I think that doctor should ask patient consent in all these situations even if the photographs show hands of the patient suffering from arthritis and you cannot recognize whose hands are at first. I think that it is extremely important from the patient-doctor relationship trusting perspective, confidence in healthcare*

*system, confidence that your medical documentation will not be used in any purpose since you will not be informed about that.*

The patients stated that they should always be informed and asked about the use any the type of their photographs. It was important for them to build the trust in doctors and health care institutions and their opinion was that consenting process is the best model to achieve this trust.

The opinion of doctors was that the patients were lenient regarding obtaining informed consent for the publication of their identifiable photographs in academic journals because they believed in doctors' ethical behaviour.

*F2/P14: ... □ Doctors' □ politeness and decency implies explaining to the patients the purpose of the use of their photographs. That means that we consider us □ doctors □ as ethical persons, that know ethical principles and that we are not going to abuse it, of course.*

The students' opinion was that the doctors' authority was an important factor in decision making, confirming the predominant role of the doctors. However, they also thought that the type of clinical photograph might affect their decision whether the doctor should obtain patient consent or not.

*F4/P1: ... I think it has a lot what to do with authority and how much trust the patient puts in the doctor. But maybe also with these type of images. They are images of a part of body that people maybe wouldn't want to hide as much as if it were other regions of the body so maybe it also has to do with that.*

The students of medical studies in English emphasised the difference between Croatian and German patients in patient-doctor relationships.

*F4/P5: ... I experienced that Croatians are ... that they trust their doctors and maybe don't ask many details when it comes to treatments or different options of treatments. So that is even a case in Germany but I would think that German patients are a little bit more critical in general.*

*F4/P4: ... But I feel also in Germany the doctors are more to present more possible ways to treat a certain disease or some injury or whatever. And then the patient in the end chooses what to do and I feel like here it is ... maybe it is wanted or it is not, I don't really know, but there I have the feeling that the doctor is not the one that presents the possibilities but the doctor is the one who decides about what will be the treatment and I see that the system major difference.*



Students of medical studies in English also considered the Croatian healthcare system to be more traditional than that in Germany and the students that had experienced both healthcare systems considered that German patients had a more active role in decision making than Croatian patients.

#### 4.3.2. *Finding the information about guidance and standards for publishing patients' images*

When asked where they would look for the instructions for publishing patient facial photographs, doctors considered it would be the journals' instructions for authors. Also, they mentioned ethics committees of their institutions if they would not be able to find the relevant information in the journals' instructions.

*F2/P14...If I would like to publish in the journal, I would look at the instructions for authors first, their guidelines and requirements of some obliged documents. Furthermore, if they would ask some documents, I would ask my someone from university or hospital ethics committee.*

Doctors expressed their expectations that academic journals, as well as their institutions, should be up to date with current best ethical practices.

Patients did not provide a precise answer but they were familiar with GDPR and stated that it was a reliable document regarding to personal data protection..

*F1/P7...Dental records have been used as an identification method even in forensics. I think that GDPR protects all personal data requiring consent to be used.*

They emphasised the medico-legal aspect of dental documentation and considered GDPR as a legal protection of their data and its maintenance.

Students would first consult older colleagues that had publishing experience, their supervisors and the internet.

*F4/P26: ...I would also check in with more senior authors, there is someone else on the paper I am working with, maybe my supervisor or anyone who maybe has more experience. [inaudible] Of course they would probably point me to some guidelines but I would also contact someone that I can talk to.*

*F4/P27: ...I would definitely check with the journal, check with somebody who had more experience, maybe Google and see what are general guidelines*

#### 4.3.3. *The need for obtaining informed consent from patients regarding the use of data from medical records for different purposes*

The patients considered it was mandatory to give their consent if their photographs would be shown to many people. However, their opinion was if the doctors would send or show these photographs to colleagues in order to consult and help, informed consent would not be required.

*F1/P6...As long as the photograph is shown to numerous people it requires a stronger protection and consent should be more detailed. When my doctor would send my photograph to another colleague in order to help to some another person expecting that this use should be remained in those circle of health professionals, I think that I do not need to give consent for this purpose.*

They expected their doctors' behaviour would be in accordance with ethical norms regarding patient privacy and confidentiality.

Doctors considered that they were not obliged to ask patients to use their photographs. Their opinion was that they as healthcare professionals were most competent to make such decisions.

*F2/P14...As long as photographs are used in good and positive purposes, there is no need to obtain the consent for education, showing students, publication in journal. Of course, it implies that it will not be any type of abuse. It is mandatory to protect dignity and identity as far as possible.*

Students emphasised the importance of obtaining informed consent for any purpose taking into consideration different circumstances and respecting the fact that every clinical image nevertheless might be de-identified is an image of that patient.

*F3/P21...Honestly, I would obtain written informed consent to be documented, because as first you never know who are you dealing with and as second, if patient comes to you, maybe he/she comes to you because has not the confidence in another doctor that you planned to consult from some reason.*

Students stated that it is not possible to predict all potential issues in order to use patient data and suggested obtaining informed consent for any purpose to prevent violation of patient privacy and confidentiality.

*F4/P26...I would definitely ask consent for everything, realistically, but I believe the x-rays are very anonymous and I am sure most patients, especially in Croatia, would be like "why are you asking me now about*

*that.” Sure, if it is not fully visible but it's me but the picture of the tooth, that is kind a like...Still a little bit more identifiable, maybe the patient is more personally connected to that photo [inaudible] or whatever.*

#### 4.3.4. *The use of de-identification techniques for publishing facial photographs*

The opinion of the patients' was that masking the eye area is not a sufficiently adequate method of de-identification, but they thought that it provides partial comfort. They emphasised the importance of knowing what was the photograph going to show in order for them to make a decision and give consent for the publication.

*F1/P1...Again, it depends what it is all about. For instance, if it is something what [one of participants] does, it doesn't matter, it is about the teeth. But, again, if it is something else...*

Doctors stated that although such techniques of de-identification used in publications were insufficient, they were more likely to be published using the black stripes over the eyes regardless of if they would be pictured or their patients in such publication.

*F2/P9... If I were on the photograph that is going to be published, I would not like to be without eyes concealed....I would prefer to use a wide black stripe [to mask the eyes on patient facial photograph].*

However, some of them stated that the de-identification techniques were useless since they did not preserve identity.

*F2/P16...My attitude is little bit different here. When someone would ask consent to publish my photograph [if I were patient], I would have accepted or I would not. It depends. It does not mean that I would. If I would not feel comfortable I have not accepted my photograph to be published. But it does not make me any difference to apply black bar and masking the eyes as we can see it is insufficient.*

Doctors' opinion was that the most important issue in making a decision what type of photograph to publish is to allow the patients to decide what they felt comfortable with.

Students' opinion was that it was important to explain to the patients both possibilities, the publication of patient facial photographs with and without masking the eye area, and then allow them to decide.

*F4/P25...I would explain exactly that to the patient and I would say look it is all possible, it would make no difference to your identity but you might feel more comfortable with it and then the patient decides.*

#### 4.3.5. Accessibility to patients' photographs published in academic journals

Patients were not aware of the issues related to publishing identifying photographs in open access. After they were presented with basic information about what it means to publish a photograph in open access, they were concerned about the misuse of their photographs.

*F1/P2... [patient photographs] remain in journal database forever, as far as I know... They are available to anybody that buys that journal or finds other way to get it. Overall, I think that we all know what Sci-Hub is.*

Patients clearly stated that online publications, including the ones from academic journals are widely disseminated, which might be a potential risk to the preservation of patient privacy and confidentiality.

The students gave examples of different uses of clinical photographs published in journals, as well as potential risks of publishing in open access journals.

*F3/P21: ...People copy and put them in their presentations if they need them for the lectures and seminars.*

*F4/P26: ...I think the main difference is whether the journal is published online or not, is it open access or not. I think that is a huge issue...If this photo is something that someone can find on the internet easily or it is a physical copy of the journal. This really changes their issue.*

Students stated that facilitated accessibility to the articles published in academic journals online, increases the level of risk in terms of privacy protection which stakeholders should to be aware of.

#### 4.3.6. Protection of patients' privacy rights in open access publications

The patient group was aware of the importance of obtaining informed consent after conducting the consenting process properly.

*F1/P6...I think that [patient] must be introduced with that [all circumstances of patient photo publication] and in that case it is not abuse, it is just use. Because, if you consent to use it, and third part is allowed to be used by anyone and it becomes possible that your photo appears in the some commercial material or something else that you were not aware in the moment of consenting... You must consent...*

Croatian students stated that all open access licences were not appropriate to use in academic publications and were against the use of articles that include patients' photographs in commercial purposes as it is allowed under CC BY licences.

*F3/P21: ...It should be regulated by law. For instance, if some clinic downloads the photograph of some patient that was published in some article and uses in commercial purposes, it is not responsibility of the patient, doctor neither journal editor. It is responsibility of that clinic and its owner that used that photograph. It should be limited by the law.*

They expressed the concern that some licences allow for the commercial use of published material as long as the source and authors are recognized.

Medical students in the English programme considered that doctors/authors who publish their patients' individual data had the primary responsibility for protecting their patients' rights for privacy and confidentiality. Also, their opinion was that all stakeholders needed better education on this issue.

*F4/P26... I think it is something all of us need to get educated more on and it should be specified more clearly in consent form. Or the author should somehow keep track of where they are submitting and [inaudible]. I think the responsibility should be more up to the authors here.*

Doctors considered that patients were not interested in academic publications and were not sufficiently educated on this topic.

*F2/P9... [patients] are not aware. They don't bother with that. I think that they do not know what academic journal is at all, they know about the books and conferences. I think that they are not familiar with the concept [of academic journal].*

## 5. DISCUSSION

The findings from the studies described in this dissertation highlight important problems and challenges in the publishing of clinical images of patients. Academic journals that regularly publish articles with identifiable patients' photographs do not have clear policies and practices regarding consent for such photographs. Relevant stakeholders (patients, doctors and medical/dental students) have a rather lenient position on what type of consent is required for publication of identifiable photographs in research articles. The reasons behind such a lenient position may be insufficient information and education on important aspects of publishing identifying clinical images in research articles, especially those published in open access.

### 5.1. The study of academic journals' policies and actual practices on publishing identifiable clinical photographs

This study showed that the guidelines regarding the consenting process for publication of patient identifiable photographs in prestigious journals in the fields of otorhinolaryngology and dentistry, oral surgery and medicine are not always clear or transparent or are often missing. Journal articles containing identifiable patient photographs mostly do not state that informed consent for photographic publication was obtained. Only half of these journals included guidance about publishing clinical images of patients in their instructions to authors although they published a median of 2 such images per journal article in their first issues in 2018.

#### 5.1.1. *Strengths of the study*

Our study analysed all types of clinical images and all types of ethical consent in journal articles, as well as journal ethical policies from two JCR categories (Dentistry and ORL). Thus, the study provides a more general picture of the problem of facial photographs than previous smaller studies that were performed on smaller journal samples have done. Shintani and Williams analysed the presence of facial photographs and the use of masking of the eye area in 3 oral surgery journals published between 2009 and 2011. and showed there was no declaration of informed consent for de-identified facial photographs. They also showed that journals did not have uniform and clear policies regarding preserving patient privacy (67).

Similarly, another study that reviewed the anonymization guidelines of 13 respected medical journals such as British Medical Journal, New England Journal of Medicine, Annals of Internal Medicine, Lancet, JAMA and some other from the field of maxillofacial and oral surgery and otorhinolaryngology. The analysis included 2011 to 2012 issues and found that 8 journals lacked specific instructions (68). The study showed there was no consistency on this issue among the journals. According to their results, de-identification failed in 87% of the analysed photographs. The comprehensive analysis in our study showed that journals still do not have clear policies for publishing facial photographs even in journals that regularly publish research in the head and neck region. These journals also mostly do not require authors to indicate that written consent was obtained for the publication of facial photographs.

Considering the reasons for the unsatisfactory number of journals containing clear policies on publishing identifiable photographs in our study, we did not find significant predictors to explain these results. The exception was a journal's reference to the ICMJE Recommendations, but the explained variance was small. In the study of Carniero et al. that analysed the presence of reporting guidelines and ethics policies in dental journals, journals with a higher impact factor were stricter than those with lower impact factors (84). Further studies should be conducted to explore the underlying factors for the lack of public presence of policies for patient consent for image publication in academic journals.

Comparing journals from the ORL and Dental Medicine JCR categories, they differed in the frequency and type of clinical images presented in articles. ORL articles contained fewer declared statements of consent for clinical photographs. The reasons for these findings could be partially explained by the number of journals, as our sample contained two times more dental than ORL, journals as well as of the type of published clinical images. ORL journals published more nonidentifiable clinical images such as MRI and endoscopic view, which may be considered anonymous, so that patient consent was not needed. Also, there was no evidence from literature about differences in attitudes and opinions regarding publishing clinical images between dental and ORL professions and further studies should be conducted to explore them. Although it has been recognised as insufficient many years ago (29), the most common technique of de-identification for facial photographs is covering the eyes with a black stripe. This is a standard practice even today. Furthermore, studies that analysed the techniques of de-identification demonstrated that covering more than one identifying part of the face, such as the eyes, nose and mouth was not successful (85). Our study showed that journals still publish such photographs. A possible explanation is the preference of patients and/or authors with

regards to the covering of the eyes feeling in such facial photographs is more convenient for publication than full face photographs although they do not provide complete preservation of identity. In our study of opinions of different stakeholders (patients, students and doctors) on how comfortable they would be when a patient's photograph was published with different levels of de-identification (86) that all stakeholders recognized different levels of de-identification of recognizable photographs and were more likely to consent to publishing facial photographs with a covered or blurred eye area. These methods may provide more comfort to the patients and be more likely to get published than non-covered facial photographs. There is still an effort among authors to continue finding novel methods of facial de-identification (68, 85, 87). These methods include concealing not only eye area but also eyebrows as it was proposed in study of Roberts et al. or using the techniques where original patient's facial image is blended with other facial images to create a unique facial composite as it was described in study of Englestadt et al. (68, 87). Although the majority of journals in our study did not explicitly provide guidelines for de-identification, there are some notable exceptions among the journals. For example, the *Lancet* advises authors to not to apply any method of de-identification if an appropriate informed consent for publication was obtained (66). However, several software programs have been developed to facilitate identification of a person in a photograph and relate him/her with their name (31).

Professional guidelines such as ICMJE Recommendations (24) emphasize that authors should preserve their patients' privacy and confidentiality as long as possible and that publishing any type of identifying patient information should be avoided unless it is necessary to deliver new, valuable findings. In our study, we found that only 13% of the articles contained identifiable patient photographs, which indicates that ICMJE Recommendations are generally followed and that identifiable patient photographs are published only when necessary. However, although the same guidelines also clearly state that if authors plan to publish any type of patient identifiable data, including facial photographs, informed consent should be obtained, in our journal sample only 16% of the articles declared that written patient consent for photograph publication was obtained. These results clearly show that journal practices were below the desirable level of clarity and full transparency regarding the ethical aspects of publishing identifiable patient clinical images.

Since publishing practices of academic journals have shifted from printed copies available only in the libraries or by subscription to online publications, changes in the consenting process have become necessary. The digital environment provides many benefits



and nowadays it is easier than ever to find health information, including scientific articles. As our study showed, almost all academic journals included in our analysis were available online and the majority of them had different forms of open access (89% in our journal set).

One of the ways to provide open access to published material, including scientific articles are Creative Commons (CC) licenses, which give readers permission to “copy, distribute, display and perform the work and make derivative works and remixes based on it” so long as the author(s) and the source of the article are acknowledged (20). CC licences presume that the authors waive a part of their copyright for the published articles containing patient photographs in a way that protects their intellectual rights. In this way, the authors’ and the journal’s rights are protected. However, the photographs published in an article are actually co-owned by the patients themselves, but their rights are not protected under CC licences.

Unrestricted open access removes the boundaries between academic publications and search engines such as Google (e.g. Google Images), and provides the possibility to create image databases which are out of the control of authors, editors and journal publishers (59). It is not clear whether the patients are aware of the fact that they may not be able to control the future use of their own photographs even when they give consent for publication.

Furthermore, journal publishing practices are not consistent regarding the process of publication of patient identifiable photographs. Some journals, like those from the BMJ group, provide their own patient consent form for the publication of clinical images, whereas others refer to the respective publisher’s consent form for publishing clinical photographs (e.g. journals published by Wiley and Quintessence). These examples show the diversity of journal practices on the consenting process which may be confusing for the authors. The within the study of Marshall et al. they analysed the appearance of patient photographs of the face and genitalia from studies of transgender research published in OA publications with Google images searches. The results showed 35 (37%) of photographs from 94 publications were easily available (59). This study analysed photographs of the vulnerable population of transgender people published in articles and clearly showed the low level of protection of privacy and confidentiality in academic publications. Furthermore, authors emphasised the need to revise or develop a new consenting process as well as journal publishing policies on identifiable patient photographs in scientific articles regarding the digital environment, particularly in open access publishing (59).

### *5.1.2. Limitations of the study*

The findings from our study should be considered in light of several limitations. We analysed the citation database containing most influential journals in the field (JCR) and we did not include other databases. Since only high quality (76) journals were part of this study, our results may be considered as an underestimation of the problem of clarity and availability of the policies for patient confidentiality in clinical image publishing in the global community of scientific journals. We also analysed only two JCR journal categories: dentistry and ORL, and only the first issue of each journal in the study sample. All journals that were not available in English were excluded. Furthermore, we checked journal websites for the presence of guidelines, but it is possible that the journals did have policies but not available online.

In our study set, the statement for the consent obtained for publishing clinical images was not available in the articles (e.g., as an anonymised supplementary document), so we cannot make conclusions about whether patients were fully aware of what such publication means in terms of the availability and use of their photographs in the digital environment.

### *5.1.3. Recommendations*

Our study showed that policies of highly respected dental and ORL journals are not in line with the current ‘gold standard’ recommendations (ICMJE) or even legal requirements regarding the consenting process for photo publication (GDPR) (24, 41). The publication of individual patient data, including patient facial photographs, should be allowed only if the consenting process has been conducted properly. Informed consent for participation in a study usually does not cover the consent for publishing patient individual data (62). This requires either a separate document to be provided to the patient or inclusion of this information in the informed consent form. It must be assured that patients are informed about the benefits and especially the potential risks of publishing their identifiable images. It is almost impossible to control further dissemination once articles containing their photographs are released, especially in the environment of online publishing. Moreover, it is also highly recommended that authors should provide to patients the manuscript before submitting it to a journal, so that they can see which identifiable photographs of themselves will be included in the published article. Patients should be informed about the context of the use of their identifiable data before giving approval. Ideally, the patient’s consent should be always obtained in written form. However, in exceptional situations when it is not possible, authors should assure that oral consent must be

witnessed and documented in accordance with legal requirements and institutional practices (60).

Protection of personal data has been improved with the legal framework of the European Union Data Protection Regulation (GDPR) in 2018 (41). Other countries have similar legislation for patient data management in scientific publications (53, 55, 56). Journals and publishers, as well as authors are obliged to follow legal requirements for patient data protection.

Patient privacy protection might be easily affected using new, developing software in order to find and identify a person whose photographs have been published in academic journals. Thus, authors should, during the informed consent process, inform the patients about OA publishing including under which license their photograph and/or other identifying data will be published, and what that means. Patients should be aware that OA provides not only free dissemination of the original publication but also re-use of material, including images. The consent form should contain this information.

The new policies regarding consenting process should be developed in collaboration with relevant stakeholders, particularly patients, whose autonomy, privacy and confidentiality should be of special concern in this case.

## **5.2. The study of stakeholders' opinions on publishing identifiable clinical photographs in academic journals**

After assessing the policies of journals on publishing patient photographs, our next study investigated the opinions on this issue by important stakeholders – patients, medical professionals, and students as future medical professionals. To the best of our knowledge, this is the first study that analysed the opinions of different stakeholders regarding the publishing process of identifiable patient photographs using the same questionnaire and methodological approach. In a separate study, in order to test the generalizability of the findings on the sample of Croatian participants, we surveyed medical students of the final two years of medicine study program in English.

We used the same survey for different stakeholders – patients, students and doctors were asked about approval for the publishing clinical images graduated with different levels of de-identification. The survey was designed to clearly differentiate different patient images that may be published in a scientific article. Our study showed that opinions about the need for a written consent for publishing clinical images were generally proposed under current ethical guidelines and differed among all three groups. Although the patients were the most lenient regarding the obtaining written informed consent for all types of clinical images, neither students nor doctors demonstrated a desirable level of knowledge on this issue.

In the separate study, where medical students of the medical studies in English were surveyed with the same questionnaire, we observed similar trends as were previously showed in Croatian students. Students did not differ regarding the identifiable photographs, most of them considered that obtaining written informed consent was needed. However, the majority of students of medical studies in English considered that a written informed consent was needed for the photographs of the part of the face or body (hands) as well as for x-ray images, significantly more often than students from the Croatian medical study program. Also, they were more likely to obtain written informed consent from patients for publication after reading the article contained patient clinical photographs comparing to Croatian students.

### *5.2.1. Strengths of the study*

To the best to our knowledge, this is the first study that tested three groups of relevant stakeholders about different levels of de-identification of patients' clinical images using the

same survey. Our results showed that patients were able to recognize differences among clinical images but had low awareness of the importance of providing written consent for publishing all types of clinical images, including facial photographs. As we used the same survey for different groups of participants, we could compare the opinions of different stakeholders. The patients were most lenient in their opinion of when a written informed consent was necessary. However, both current and future medical professionals did not show adequate knowledge on this issue.

The results of our study regarding patients can be considered reliable as the patients included in the study were adults who were fully capable of making decisions about their health, including the publication of photographs (88). Also, the questionnaire was piloted for face validity with a group of patients to ensure that that we used plain language in the survey. This ensured that the patients' answers were not influenced by the complexity of the topic. And finally, since it was very few answers on the open-end questions, we justified the survey intelligibility.

The low level of awareness of the importance of obtaining written informed consent among the study participants might be expectable, since professional guidelines or policies on the use of patient individual data including photographs in publications are not well developed in Croatia (47). Several previously conducted studies Croatia regarding the importance of obtaining informed consent properly indicated the low awareness and knowledge among health professionals and patients as well. In their study, Jukić et al. investigated the understanding of the consenting process among patients and their clinicians in hospital healthcare setting and reported large discrepancies in the perception of informing patients properly during the consenting process (89). Also, this study showed that clinicians did not considered that they should inform in details patients about planned clinical procedure and treatment (90). These findings indicate that a paternalistic model of patient-doctor relationship is still prevalent in Croatia, that patients still have high level of confidence in their physicians. This finding is supported by several other studies conducted in Croatian healthcare setting (89, 91, 92), as well as by the differences in opinions between medical students from Croatia and abroad. Furthermore, publishing practices of journals in countries of East and South East Europe (including Croatia) mostly lack professional and ethical guidelines. The study of Broga et al. showed that only 24% of medical journals had policies regarding observance of patients' privacy rights and confidentiality of medical information (49). The conclusions of this study indicated that in East and South East Europe is lower awareness about medical ethics, patient

privacy rights and confidentiality of medical information both in the public as well as for professional purposes.

However, several studies that investigated patients' opinions on publishing facial photographs showed even in the different social, economic and cultural setup that patients in general have a high level of confidence in health professionals and they consider medical photography valuable and acceptable (36-39, 69). In United Kingdom, Lau et al conducted the study that analysed patients' perception on medical photography at the outpatient clinic of plastic and reconstructive surgery. It was shown that although the patients had high acceptance of medical photography for all purposes including publications, they preferred the use of non-identifiable photographs (38). Another study of Adayemo et al. conducted using similar methodology as Lau et al. among Nigerian patients which represents the different cultural setting. They analysed the acceptance and perception towards clinical images among patients attending oral and maxillofacial and plastic surgery clinics and that also had the high acceptance of medical photography for all purposes as well as higher preference towards non-identifiable photography (36). It seems that it is prevailing patients' opinion that doctors have competence to make important decisions regarding the management of medical data and that they are a submissive partner in the patient-doctor relationship (38, 69).

In our study, we investigated how different levels of de-identification of clinical images would affect participants' opinion on the necessity of obtaining written consent for publication of their clinical images. In a situation of high level of de-identification, all stakeholders were most permissive in their decisions. Health care professionals and even students were expected to have adequate knowledge about the importance of informed consent, but our study showed that it is not achieved in Croatian healthcare and education system. Subsequently, Croatian patients did not show satisfactory level of knowledge regarding the protection of privacy in publications. We found that since clinical images had a higher level of identifiability (e.g. facial photographs vs part of the body or X rays) patients were more likely to require their written consent for publishing their images. Only a third of patients considered that written consent was required for the publication of the full-face photograph without any de-identification. In contrast, different cultural setting and different patient population also may have impact on patients' opinion on the necessity of informed consent. In study of Leger et al. they surveyed patients from dermatologic outpatient clinics in New York in order to investigate the acceptance on the use of identifiable vs non-identifiable clinical photographs for different purposes (39). Although this study also showed high acceptance of medical photography for

different purposes such as education, medical consulting and publishing, patients were more likely to think that written informed consent was need for the use of their photographs rather than oral consent. Also, it was emphasised that patient-cantered approach was more recommendable to inform policy and physician practice for the use of clinical photographs (39).

In our study, doctors had the most stringent criteria and were more likely than students to recognize ethical dilemmas probably because they had higher clinical experience and better ethical training (93). However, they did not recognise the importance of obtaining written informed consent for publication of clinical images with different level of de-identification. They thought that oral consent was still acceptable in many situations, which is not in line with the best current ethical practices. Jukic et al. investigated opinions on informed consent in six Croatian hospitals that included clinicians of different specialties (89). The study showed that less half of clinicians were fully informed about the importance and obtaining informed consent. These findings indicate that there is still paternalistic patient-doctor relationship established in Croatia and implicates a huge disproportion in decision making and diminishing patient' position. However, analysing the results of studies that conducted in the UK and the USA among the health professionals, they were comparable with our results. Hubbard et al. surveyed dermatologists in the UK on use of digital cameras and showed similar results regarding the practices of obtaining informed consent as we found in our study (94). Verbal consent was still highly implemented in clinical practice and the process of taking clinical images was not always compliant with current legislation (94). In contrast, Rimoin et al. in their study that surveyed dermatologic surgeons in United States on the same topic and with the similar methodology, showed that they pursued written informed consent although the study had a small response rate (17%) (95). It seems that in different cultural settings there is variable awareness of importance of obtaining written informed consent among the health professionals and these findings indicate the need for harmonized and standardized guidelines on appropriate use of medical photography.

In our study, students of medicine or dental medicine and doctors in these two professions were more stringent regarding the conditions of publication of clinical images than patients. This might be explained with differences in the level of education as well as professionalism. Subgroup analysis showed that students of dental medicine, as well as dental medicine doctors were more stringent in their opinion about consent for publishing clinical images than medical doctors and students. Considering their education at the University, they

receive similar ethics education during their curriculum – 30-60 direct class hours in a separate ethics course (96-98) and the differences in opinions we observed might be explained with the scope of professional interest. The dental professions are strictly focused on the orofacial region in comparison to medical professions. Medical students of study programme in English were generally more stringent regarding the written consent for non-identifiable clinical images. Furthermore, they were more stringent than Croatian dental students for the questions where dental students differed from Croatian medical students. These findings might be explained with different cultural and healthcare settings since the students received the same education. As our previous study indicated, the relationship between doctors and patients in Croatia is still paternalistic, whereas in Western European countries paternalistic model is acceptable only for an emergency room or surgery setting. In Western European countries, patient-centered model of communication is more acceptable in primary healthcare setting including all situations when patients are suffering from chronic diseases (99). The best investigated model of patient-doctor relationship is among oncological patients where the benefits of patient-centered and shared decision making approach are clearly shown (100, 101).

Previous studies did not stratify different types of clinical images whereas our study showed that patients recognized differences. This study did not investigate other factors that might have an impact on their decision such as diagnosis, patient condition or treatment which could be tested in future research. Even more, these studies were conducted only with patients or healthcare professionals, whereas we included different stakeholders, both patients as well as health professionals seeking for wider picture of this issue. Additionally, we included students of medical studies in English in order to analyse the influence of different social and cultural setting in our research.

The last question in the survey was about the necessity of providing the manuscript containing patient's photographs to them before submitting. Almost half of the patients and doctors considered that reading the manuscript containing patient clinical images before publication is not needed, whereas more than half of the Croatian students thought that it must be provided to read a translated manuscript with an image or only the image that is a part of the manuscript. Students of medical studies in English were even more stringent, most of them were aware of the importance of providing the manuscript to patients for reading. These findings could be explained with educational level and the age of our participants. The education level of patients' group was mostly high school level which may indicate that they had lower digital skills of accessing online publications and their dissemination. In the other



hand, in our study, the age of doctors' and students' group significantly differed which might affect the differences in answers among them. Younger generations are more familiar with digital environment in general which could explain our findings that all student subgroups were more stringent than doctors regarding the reading of the manuscript before publication. Since social media has been increasingly been using, particularly among younger population, it generated the development of many software programs for photo identification (31). Students might be more aware of the issues of online publications, where is not always clear threshold between identifying and de-identifying clinical photograph.

### 5.2.2. *Limitations of the study*

Our study had several limitations. It was not possible to calculate the response rate for the patient sample group since it is not strictly defined population like health professionals. However, we had high response rates from doctor and student sample groups, which makes our results generalizable for Croatian population as well as other European countries with similar economic, social, cultural and historical setting. The results may not be applicable to other EU countries with different health care systems and/or different doctor-patient relationship models.

The survey design has an inherent limitation of socially desirable answers. Furthermore, survey questions were about hypothetical situation involving photograph of unknown person, not the photograph of patients themselves. The characteristics of specific situation (e.g. emergency, oncological cases) are also important, as well as the context in which the clinical images are going to be used when patients make real decisions to give their approval for the publication. Schlidman et al. interviewed cancer patients about their perceptions and views on information and treatment decision making and showed that patients changed criteria regarding the stage of disease (102). At the beginning of their treatments, they felt more trustful and confident to their physicians with limited interest to deeper insight of their condition whereas in the latter stages of disease they wanted to participate more active in decision making of treatments, seeking for more information regarding their diagnosis and condition. This study clearly showed how severity of disease and complex treatment such as oncologic therapy in certain time period may affect and change one's health problem. Similarly, patient's decisions for publication of their images might depend of many factors that should be investigated in further studies.

The patients may have a different view of using images about their own photographs and students/doctors may make a different decision in a concrete clinical case. In this study,

individual patients presented at the doctors' offices were invited to fill in the questionnaire. It is possible that patients accepting to participate in the study might feel that it is expected from them to please their doctors due to strong traditional doctor-patient relationship in the framework of the Croatian health care system. Patients might have different aspirations or motivations for the participation in the research, some of them were more likely to fill the survey, which resulted that our patient sample was formed as a self-selective. Although we found the differences between two patient subgroups but those subgroups were too small. Since we used convenience sampling and due to small number of subgroup participants, found differences could be considered random.

Based on these findings, further studies should be conducted to investigate opinions of other stakeholders, policy makers, journal editors, law professionals. Also, it would be helpful to design a questionnaire to test real situations with patients' own photographs applying different levels of de-identification instead hypothetical ones as it were in our study.

The impact of different geographical, social and cultural settings should be also investigated on this issue aiming to target as more as possible contributing factors that influence on obtaining patient approval for the publication their sensitive data.

### *5.2.3. Recommendations*

In our study, all stakeholders lacked in knowledge on ethical and legal standards regarding the preserving the privacy and confidentiality in publishing patient individual data in academic journals. The ICMJE Recommendations state that the publication of identifiable patient data should be limited only to those situations when important information should be delivered to the scientific community (24). These ethical standards have been strengthened with law regulations in Western countries (41, 53, 55). In Europe, general principles such as the respect of lawfulness, fairness and transparency of GDPR are also relevant for research (GDPR, Article 5) (42). GDPR also requires the use of appropriate safeguards to put in place for the protection of all individual health related data in research process (Article 9) (42).

The best current ethical and legal practices emphasize the importance of conducting of consenting process properly. Obtaining patient consent is more than signing the form, patients must be introduced with the purpose of use their individual images and all potential risks. Written forms of informed consent may be long and complex which increases possibility that patients do not understand the content or even not read it at all (90, 103). Authors are obliged

to provide all relevant information regarding the research using plain language to assure that patients understood all circumstances of publication (60, 61).

Written informed consent for publication of patient clinical photograph should be obtained as a separate consent (e.g. treatment consent, participation in the studies...) either in the same informed consent form or as a separate form, specific for publications. Furthermore, the patients should read the manuscript containing their photographs before publishing.

Also, it would be important to implement these demands in journal guidelines in order to improve publishing practices since almost all medical journals are available online and most of them are some type of open access (30). Patients should be introduced that OA publications allow unrestricted dissemination and even more, the photographs from OA publications might be found even in a Google Images (59). Also, patients should not feel rushed in giving their approval with respect to their special circumstances in treatment process (e.g. emergency, surgery, trauma). Even more, study of Everett et al. showed that when patients gave their informed consent for the treatment, they recalled hardly about potential benefits, risks and alternative procedures which indicates the sensitivity and complexity of the consenting process (104). Finally, the education and training in medical ethics should be improved among all stakeholders regarding the consenting process for publishing patient individual data. It would be important that new practices in obtaining patient written consent establish the need to provide of all relevant information in order to assure patient understanding before giving their approval.

However, there are several practical difficulties to conduct informed consent ideally. Although consent forms should always be written, in some specific cases it is not possible. Patients that are not able to express their opinion in writing, but have a full mental capacity to participate in the consenting process, it should be provided to obtain a witnessed, non-written consent following all local legislation and institutional practices (60). If patients lack capacity to give their approval freely, informed consent could be obtained from their legal representative. Patients with fluctuating or deteriorating conditions may be able to give their approval in early stages of these conditions, whereas in more advanced stages legal representatives should do so. Minors are also not able not able to sign written consent, although older children give their assent, but their parents or legal representatives should sign instead of them (23, 105). Study of Hubbard et al. investigated patients' acceptance of medical photography among adult and paediatric patients at the dermatology department in France and showed that although medical photography was highly accepted, the paediatric respondents

were more stringent than adult ones (94). These findings confirmed that vulnerable populations such as children need even higher protection in publishing their individual data and the need to conduct consenting process properly. Finally, in some situations, when authors want to publish some individual clinical images that could be important to scientific and/or clinical audience and it is not possible to obtain the written consent from patients neither their proxies, the approval should be provided by institutional authorities and ethic committees with respect to local legislation. These rare cases should be documented properly, as well.

### **5.3. Focus group study of stakeholders' opinions on publishing identifiable clinical photographs**

The findings of the study on the opinion of stakeholders showed that patients had the high level of confidence in doctors regarding privacy protection and potential issues in publications and were lenient regarding the obtaining written informed consent for the publication of their clinical photographs. Also, health professionals did not show adequate knowledge regarding best current ethical practices on this issue. In order to investigate these findings in more detail and explore underlying reasons why stakeholders had such opinions, we conducted a qualitative study in four focus groups involving patients, doctors and medical students. We found that patients with higher education level had strict expectations regarding the publication patient photographs in academic journals. Both patients and health professionals (current and future) honestly stated that they were not familiar enough with consenting process and publishing issues in terms of patient privacy protection regarding publication of their images in journal articles.

#### *5.3.1. Strengths of the study*

The participants in all focus groups showed the awareness of potential issues regarding publishing patient individual data, such as facial photographs in terms of confidentiality and privacy protection. When they were asked about current ethical guidelines that are applicable to the practices of publishing clinical images in academic journals, most of them said that they were not aware of such guidance.

Focus group participants mostly recognized the importance of obtaining written informed consent for different purposes within healthcare system as the best ethical practices propose. Written informed consent could not be valid if consenting process was not conducted properly (106). Regarding the publication clinical photographs that may reveal patients' identity, consenting process should include all relevant information of online publishing. They should be aware of great possibilities of dissemination of such publication and impossibility to retract them. Recently published studies showed that since academic journals are available in digital environment there is a need to change consenting process and provide harmonized and uniformed guidelines for publication patient identifiable data (59, 65, 70).

In this study, patients expressed a high level of interest in decision making regarding the publishing their clinical photographs and they considered that the conducting consenting

process properly is essential to build a good patient-doctor relationship. Although patients' group was balanced regarding the gender and education level, they had higher education level than the participants in the survey study, as they all had university degree which could affect the differences in opinion regarding the importance of obtaining written consent on the publication of clinical photographs. Patients from the focus group were more stringent regarding obtaining written informed consent and emphasised the importance of receiving all relevant information.

However, their knowledge regarding the issues of online publications was poor. Generally, there are many potential issues to violate patients' privacy in online publications. In the terms of the copyright that protects someone's intellectual or creative work the journals and authors are protected in publishing articles containing patient photographs whereas it is unclear whether patient privacy is protected. It is particularly important for open access journals that publish under CC BY Licences where there are no guidelines in terms of protection patient privacy rights for such publications. Most of the journals in their instructions for authors cite or provide link on ICMJE Recommendations in order to follow ethical guidelines in research process including patient privacy protection where it is not mentioned anything regarding the patient data protection in articles published under CC BY licences. These publishing practices were not familiar to patients and they even strengthened patients' opinions regarding the importance of written informed consent. In this study patients confirmed that they had to be familiar with all circumstances in order to make decision and were not familiar with the conditions of CC BY licences that allow article dissemination and reuse freely.

On the other hand, doctors had different opinion on the importance of obtaining written informed consent. Doctors' considerations were dominantly from the position of power and authority, expressing their opinion that they had to take the responsibility for their patients in decision making. They considered that they were more competent in decision making than their patients, confirming the predominating paternalistic model of patient-doctor relationship in Croatia (89, 91). These findings are in line with our previous study indicating that Croatian physicians still implement traditional models of communication in clinical settings which is not acceptable to all patients. In focus groups, patients clearly stated that they wanted to be informed fully in order to decide whether consent particular procedure or activity or not.

As several studies conducted in Croatian healthcare setting showed the paternalistic model of patient-doctor relationship has been established in Croatia which is also indicated our previous study (86, 89, 92). Furthermore, in this focus group study, students clearly recognised

this model and their opinions on patient-doctor relationship in Croatian setting were in line with previous findings. For example, one student from Germany, compared Croatian and German patients and recognised the differences in decision making regarding the doctors as well as patients' position (90). Students emphasised that doctors' authority in Croatia is predominant in all situations in healthcare system while in Germany patients took over more independent position which could be defined as decision-shared patient-doctor relationship. In German healthcare system has been recognized that it is important to take into account patients' communicative needs, to share information, decision making and to provide emotional support (101). Using the patient-centered model of communication, health professionals might not only improve patients' satisfaction with communication and patients' well-being, but also might produce better treatment outcomes (101).

Similar to patients' group, all students participating in this study considered that written consent should be obtained for all purposes. Since Croatian students have more permissive attitudes towards the necessity of obtaining written informed consent in previous study, Croatian students from this focus group study were more stringent on this issue. In contrast, students of medical studies in English confirmed the findings from the survey, they did not differ in their opinions on the necessity of written informed consent considering it obliged for all purposes in both studies. It might be explained with different study setting. Focus group interviews provide more room for discussion and brainstorming than survey which might affect these differences in opinion (107).

Considering the use of techniques that conceal identifiable parts of the face such as the eye area, it would be needed to emphasize the differences between two terms that are used interchangeably: anonymization and de-identification. Recently published scoping review of Chevrier et al. investigated how the research community used, comprehends and defines the terms of de-identification and anonymization (108). Anonymization should be used in situations when it is not possible to relate the data with particular person in any situation, whereas de-identification means that explicit identifiers are concealed or removed (109). Since academic publications are established in digital environment, the interest is growing for privacy-enhancing techniques in the research community. This study emphasized the need to use properly these two terms following law definitions of GDPR and HIPPA (108).

In our study, all participants agreed that the technique of de-identification with black stripe over the eyes does not provide full patient anonymization. This technique was still more preferable for publishing patients' photographs than full-face photographs since de-identified

photographs provide are more acceptable for patients. These findings are in line with our previous study which showed that stakeholders preferred publishing the photographs with black stripe over eyes in contrast to full face photographs and that this type of de-identification is still present in published journal articles. However, some doctors claimed that it would not be appropriate to use de-identification techniques since these do not provide anonymity and concluded that this should be decided by patients themselves. As discussed previously, the full patient de-identification in publications is not always possible to achieve and should not be used without patients' consent (58, 110, 111).

De-identification of facial photographs is particularly complex or even impossible to achieve (25). Even if the clinical photograph could be de-identified sufficiently showing only the part of the body, it still remains the issue of the context in which is going to be published increasing the possibility that person could be recognized by close friends and family. Case studies in medical literature include various information about a patient, that can also make a patient identifiable, even without a clinical image and authors and journal editors should be aware of the importance of obtaining informed consent for the publication after patient had opportunity to read the manuscript (25, 112).

The recent case or article retraction because of patient identifiability in a figure from a published article illustrates this problem. In 2018 BMJ journal retracted case report showing clinical photographs of the patient's buttocks with the skin lesions caused by parasite worms (113). The patients were a couple from UK that had been infected on a Caribbean cruise. UK tabloids published those photos and the BMJ retracted the case report in order to avoid potential violation of confidentiality and protecting personal information. Although BMJ has high standards in publication ethics and even its form of informed consent for publication, this case report was withdrawn on patients' request. As already emphasised, dissemination of publications in digital environment is not possible to completely control, this case report still could be found on the Internet, in a daily newspaper. This example clearly shows the importance of explanation before obtaining informed consent from patients, especially in the era of online publications.

All participants in the focus group showed the lack of knowledge regarding the terms and conditions of online publications. It implies that consenting process would not be conducted properly since patients could not be fully informed, and subsequently patient consent could not be valid. Furthermore, these issues may generate legal consequences since patients' privacy rights are protected by law (e.g. GDPR, HIPPA). Interestingly, students also were not



educated about open access publishing which indicates a lack of up to date information in educational setting. Students recognized that OA publishing model generates many ethical issues in terms of protection of patients' privacy. They even considered that CC BY licences were not appropriate for publishing scientific articles, since the articles (especially those containing clinical images) published under such licences might be widely used, even in commercial purposes. This might be partially explained by the finding that students were more aware of potential issues since they probably have been using Internet frequently and are better introduced with potential risks in digital environment than older colleagues.

Using identifying photographs from vulnerable patient populations requires a special attention (59, 70, 105). In the qualitative study of Devakumar et al., focus group interviews were conducted among health professionals, both clinicians and researchers, who had working experience in low-resource settings (70). The aim of their study was to explore the importance of ethical approach of taking photos of children for medical and research purposes. The study showed that although relevant stakeholders agreed that clinical photographs were valuable resource, they emphasised the potential harms/danger regarding online publications. They suggested to customize consenting process to specific situation in order to protect child's privacy following established ethical guidelines. They also recommended the guidelines of General Medical Council, a UK professional organization, although the study investigated different geographical and social settings (51). Furthermore, this study did not include children or their parents or guardians which are important stakeholders and could help to have a whole picture on this issue.

In contrast, in our study we included patients as important stakeholders to find out why they thought the informed consent was important for publication of clinical photographs. Patients' opinion should be in focus to create recommendations and guidelines for publications since potential harms of publishing might the most affect themselves. Furthermore, study of Marshall showed the possibilities of the sharing clinical photographs published in open access journals outside the research community implicating the importance of the revision of consenting process and addressing potential missuses (59). Our study clearly indicated the health professionals, including medical students of the final year were lack in knowledge regarding all possibilities of open access publishing and possible allowed uses of clinical photographs published under Creative Commons Licences.

### *5.3.2. Limitations of the study*

An important limitation of our study was that we had only four groups of participants divided in four focus groups: patients, students of medical studies in Croatian and English and doctors. We chose these participants in order to better investigate the findings from the previously survey. After conducting the interview in the third focus group, no new themes emerged and the saturation was achieved. Further studies should include more different stakeholders such as different patient populations, journal editors, policy makers and law representatives. Different social and cultural setting might have an impact on stakeholders' considerations regarding the issues of protection patients' privacy in academic publications. The inclusion of students from outside of Croatia allowed greater generalizability of our findings, as we identified possible differences related to health care systems in different countries.

### *5.3.3. Recommendations*

The focus group study addressed several ethical issues regarding publication of patient photographs in academic journals. Since patients showed an increased interest in decision making regarding publication their individual data in academic journals, it would be important to provide relevant information based on established ethical guidelines in order to protect their privacy and confidentiality in digital environment. Patients recognized the importance to be informed properly, not only for the publication purposes but in general, to create a trustful patient-doctor relationship. Also, a huge issue has been emerged since many journals are available online in the form of the open access regarding the dissemination of published material. Overall, clinical images represent a vital part of confidential patients' medical records (40) and it is questionable is it appropriate that could be found on Internet browser such as Google Images.

There is a need to revise consenting process according to new challenges of publishing in digital environment based on opinions and experiences of all relevant stakeholders, especially authors, journal editors and policy makers. For instance, World Association of Medical Editors (WAME) on their official website does not contain any recommendation regarding open access publishing and CC BY Licences (114). Furthermore ICMJE, as a most respectful organization for the recommendations in scholarly work also does not declared ethical guidelines regarding open access publications. Since journals' and authors' rights are protected by copyright, it still remains unclear whether patients' rights are protected in such

publications. Fletcher in her opinion paper, with significant title “Whose wound is it anyway? Issues relating to wound photography”, discussed the problems of medical photography that is usually considered as an ownership of the photographers, clinicians and institutions (115). It seems that patients signing informed consent for publication waive their right on the ownership of their clinical photographs. In this context, authors that are going to publish patients’ photographs have the major responsibility to protect patient’s privacy rights. It means that health professionals, clinicians and researchers along with policy makers, professional societies as well as different patients’ groups should harmonize and upgrade existing ethical guidelines according to new publishing possibilities. For example, in most recently published editorial of Ahmed et al. on behalf of British Society of Dermatology it was proposed how to publish patient photographs ethically. They emphasised the necessity of obtaining separate patient written consent for the publication of patient’s photographs regardless of the level of de-identification in dermatologic journals (116).

Furthermore, clear guidelines should be easily available for both patients and health professionals in order to follow them for different purposes. Finally, the education of health professionals starting from university level of education to different workshops and training should be provided as a part of life-long learning in medical profession.

## 6. CONCLUSIONS

This dissertation aimed to address some of the issues in the publishing of identifiable patient photographs in academic journals. We used different methodological approaches to explore current publishing practices in publishing patient photographs, as well as the opinions of relevant stakeholders, both patients and healthcare professionals on this topic.

We analysed academic medical journals in order to investigate current publishing practices and showed that the policies and practices regarding ethical recommendations for the publication of identifiable patient photographs are not harmonized with current best practices.

The awareness of all relevant stakeholders about patient's privacy rights in the scientific publication process was under desirable levels and current best practices. In the survey study we demonstrated that both patients and healthcare professionals were not well aware of the protection of patient privacy rights in academic publications as a part of written consent. Furthermore, the results of the focus group study showed that patients' and healthcare professionals' leniency towards written informed consent for publishing photographs of patients could be related to the paternalistic nature of the patient-doctor relationship as a predominant communication model in the setting of the Croatian healthcare system.

New skills are needed to ensure that a patient's data, including clinical images, are published in an ethical way in the current digital environment. All relevant stakeholders should participate in creating of a new consenting process with more attention on preserving a patient's rights regarding their privacy and confidentiality as well as legal aspects regarding publication in academic journals in the digital era. Journal publishers and editors should provide clear and publicly available policies regarding the publication of identifiable patient photographs and ensure that these policies are implemented properly with respect to both legal and ethical requirements.

## 7. SUMMARY

**Aims:** The overall goal of this thesis was to explore the problem of consent for publication of clinical images, particularly identifying photographs of the face. The specific aims were 1) to assess journal policies on actual practices of publishing patient photographs and reporting on the obtaining of consent for publication; and 2) to explore the opinions of different stakeholders (patients, students, doctors) about the types of consent needed for publishing patient photographs, particularly in the digital form.

**Methods:** The analysis of policies and practices was performed in a cross-sectional study. The opinions of doctors, patients and students were explored using two methodological approaches: 1) a cross-sectional questionnaire study including doctors and students of medicine and dental medicine at the Universities of Split and Zagreb, and patients attending dental and medical hospital and outpatient services in Split, and 2) a qualitative focus group study involving patients and doctors and students of medicine and dental medicine at the University of Split.

**Results:** Current publishing practices in high-quality academic journals were not consistent and lacked a statement of obtained written informed consent for the publication of patient identifiable photographs. Only 52% of Dentistry and ORL journals included guidance about publishing clinical images of patients in their instructions to authors. From the total articles sample containing identifiable patient photographs, only 16% of articles (13/79) declared a statement regarding the obtained written consent for the publication. Relevant stakeholders' opinions, about the need for written consent in regards to the publishing of patient identifiable photographs, were not in line with current ethical guidelines. In the survey study, patients were most lenient regarding the need for obtaining written informed consent, followed by students and doctors. Only 33% of patients considered that written informed consent is required for the publication of the photograph of the face without any de-identification, mostly considering oral permission sufficient. Furthermore, doctors and students were more stringent requiring written informed consent for such publication (88-89%) but also more than half of the doctors (58%) considered that they are not obliged to provide the manuscript containing patient's identifiable photographs that is going to be published. The focus group study explained these findings were due to the paternalistic patient-doctor relationship as a predominant model in the Croatian healthcare setting. Doctors considered that they were not obliged to ask patients to use their

photographs. Patients and students considered health professionals in the Croatian healthcare system have a dominant role in the patient-doctor relationship and that patients were not informed properly in most situations.

**Conclusion:** Current policies and practices of journals publishing research related to the face and neck region, in regard to obtaining and reporting of patients' consent for publishing identifiable patient photographs are not harmonized with best practices. The opinions of stakeholders in the publication of patient photographs in academic journals (patients, students, doctors) do not have a sufficient level awareness of the processes and requirements for obtaining informed consent for publishing patient's photographs, especially in the environment of open access publishing. There is a need for measures at different levels (information, education, professional policy-making) to implement adequate protocols for the protection of patient's rights regarding publication of their photographs in academic journals.

## 8. SAŽETAK

**Ciljevi:** Cilj ove doktorske disertacije bio je istražiti problem objavljivanja kliničkih slika u znanstvenim časopisima, osobito fotografija lica koje otkrivaju identitet pacijenata. Posebno smo istražili: 1) upute časopisa za objavljivanje kliničkih fotografija pacijenata s naglaskom na upute o uzimanju pacijentovog informiranog pristanka za objavu fotografija i aktualne prakse da se u objavljenim člancima koji sadrže takve fotografije deklarira pacijentov pristanak, 2) mišljenja različitih dionika (pacijenata, studenata i doktora) o vrsti informiranog pristanka koji bi bio potreban za objavljivanje fotografija pacijenata, osobito u digitalnom formatu.

**Metode:** Upute časopisa i prakse publiciranja kliničkih fotografija analizirane su u presječnom istraživanju. Koristeći dva metodološka pristupa, istražena su mišljenja pacijenata, studenata i doktora: 1) presječno istraživanje temeljeno na upitniku uključilo je pacijente koji su se liječili u Stomatološkoj poliklinici Split i Kliničkom bolničkom centru Split, liječnike, studente medicine i dentalne medicine Sveučilišta u Splitu i Zagrebu te 2) kvalitativno istraživanje u fokus grupama koje je uključilo pacijente, doktore i studente medicine i dentalne medicine Sveučilišta u Splitu.

**Rezultati:** Trenutna praksa publiciranja u visoko kvalitetnim časopisima nije usklađena i objavljeni članci ne sadrže uvijek izjavu o dobivenom pacijentovom pristanku za objavu identificirajućih kliničkih fotografija. Samo 52% dentalnih i ORL časopisa imalo je jasna pravila za objavljivanje kliničkih fotografija u uputama za autore časopisa. Od ukupnog uzorka članaka koji su sadržavali identificirajuće pacijentove fotografije samo 16% članaka (13/79) imalo je deklariranu izjavu o dobivenom pacijentovom pristanku za objavu. Mišljenje relevantnih dionika o važnosti pisanog informiranog pristanka za objavljivanje identificirajućih fotografija nije bilo u skladu s trenutnim etičkim uputama. U presječnom istraživanju u kojem smo koristili upitnik, pacijenti su se pokazali najpopustljivijima obzirom na uzimanje pisanog informiranog pristanka. Samo je 33% pacijenata smatralo da je pisani informirani pristanak potreban za objavljivanje fotografija lica bez korištenja tehnika de-identifikacije. Nadalje, doktori i studenti su bili stroži u traženju pisanog informiranog pristanka za objavljivanje fotografija lica (88-89%), ali više od polovice doktora (58%) smatralo je da nisu obavezni pokazati članak pacijentima koji sadrži njihove identificirajuće fotografije prije objavljivanja. Kvalitativno istraživanje u fokus grupama objasnilo je ove nalaze paternalističkim modelom

odnosa između pacijenata i doktora u hrvatskom zdravstvenom sustavu. Doktori su smatrali da nisu obvezni pitati pacijente ako žele koristiti njihove fotografije. Pacijenti i studenti su iznijeli mišljenje da u hrvatskom zdravstvenom sustavu doktori još uvijek imaju dominantnu ulogu u odnosu na pacijente i da pacijenti nisu dobro informirani u svim situacijama.

**Zaključak:** Trenutna pravila i praksa objavljivanja kliničkih fotografija područja glave i vrata vezano za uzimanje pisanog pacijentovog pristanka nisu usklađena s najboljim etičkim standardima. Mišljenje dionika (pacijenata, studenata i doktora) o objavljivanju fotografija pacijenata u znanstvenim časopisima pokazuje nedovoljan nivo svjesnosti o važnosti pisanog informiranog pristanka, posebno ako se članak objavljuje u časopisima s otvorenim pristupom. Potrebne su mjere na više različitih razina (informiranje, edukacija, donošenje novih pravila) za implementirati adekvatne protokole koji bi štitili pravo pacijenata na privatnost kod objave njihovih fotografija u znanstvenim časopisima.



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## 10. CURRICULUM VITAE

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### **Education:**

2005 Doctor of Dental Medicine (University of Zagreb, School of Dental Medicine)

2012 Specialist in Periodontology (University of Zagreb, School of Dental Medicine)

2014 Master of Sciences (University of Zagreb, School of Dental Medicine)

### **Work experience:**

2018 to present – the assistant at Department of Oral Medicine and Periodontology, University of Split, School of Medicine, Study Program of Dental Medicine

2017 to present – delegate of Croatian Society of Periodontology in European Federation of Periodontology

2012-2018 – Dental Outpatient Clinic (Split)

2006-2012 – Outpatient Clinic for Internal Medicine and Periodontology “Aurer” (Zagreb)

2005-2006 – Dom zdravlja Zagreb-Zapad (Zagreb)

### **Published studies relevant for doctoral dissertation:**

**Roguljić M**, Peričić TP, Gelemanović A, Jukić A, Šimunović D, Buljan I, Marušić M, Marušić A, Wager E. What Patients, Students and Doctor Think About Permission to Publish Patient Photographs in Academic Journals: A Cross Sectional Survey in Croatia. *Sci Eng Ethics*. 2020 Jun;26(3):1229-1247. doi: 10.1007/s11948-019-00134-y.

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### **Original scientific paper under revision:**

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## **11. APPENDICES**

**Appendix 1.** Patient questionnaire in Croatian.



*Poštovani/poštovana,*

*Pozivamo vas na sudjelovanje u istraživanju o Vašim stavovima vezanim za prava pacijenata prilikom objavljivanja **kliničkih podataka o pacijentima i kliničkih fotografija pacijenata** od strane njihovih liječnika u **stručnim medicinskim časopisima**.*

*Sudjelovanje je dragovoljno.*

***Ispunjavanjem ovog upitnika Vi ste pristali na istraživanje.***

*Upitnik je u potpunosti **anoniman**, a rezultati će biti korišteni i analizirani u doktorskoj disertaciji naziva: „**Evaluacija etičnosti publiciranja ljudskih fotografija u kirurškim i njima srodnim časopisima**“, te će biti objavljeni u medicinskim časopisima. Istraživanje se izvodi u okviru projekta „**Profesionalizam u zdravstvu**“ Hrvatske zaklade za znanosti, a odobrilo ga je **Etičko povjerenstvo Medicinskog fakulteta sveučilišta u Splitu**.*

|  |   |   |
|--|---|---|
| <b>Spol</b><br>(zaokružiti)                      | 1) MUŠKO                                | 2) ŽENSKO   |
| <b>Dob</b> (godine)                              |   |   |
| <b>Titula</b><br>(zaokružiti jedno od ponuđenog) | 1) Dr. med. dent.<br><br>2) Dr. med.    | 3) Student dentalne medicine<br><br>4) Student medicine |
| <b>Specijalizacija</b>                           | DA      NE<br><br>Ako DA, navesti koja: | Za studente – godina studija (upisati)                  |
| <b>Iskustvo objave rada u časopisu</b>           | DA      NE                              |   |
| <b>Iskustvo rada u uredništvu časopisa</b>       | DA      NE                              |   |

*Zahvaljujemo Vam na utrošenom vremenu i poklonjenoj pažnji!*

**Mentorica: dr. sc. Elizabeth Wager**

**Pristupnica: dr. Marija Roguljić**

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**1. Ako liječnik želi objaviti studiju slučaja o Vama bez objavljivanja slike (npr. opis Vaše bolesti, liječenja i slično) u znanstvenom medicinskom časopisu dostupnom na internetu, treba li liječnik od Vas prvo zatražiti dopuštenje (s tim da Vaše ime ne će nigdje biti otkriveno)?**

- a) Liječnik treba uvijek tražiti moje dopuštenje.
- b) Ne znam.
- c) U redu je da liječnik objavi takve podatke a da ne traži moje dopuštenje.
- d) Ovisi (objasnite svojim riječima):

---

**2. Što u slučaju ako liječnik želi objaviti kliničku fotografiju (kao što je rendgenska snimka slična prikazanoj) iz Vaše povijesti bolesti (s tim da Vaše ime ne će nigdje biti otkriveno)?**

- a) Dovoljno je da od mene liječnik traži usmeno dopuštenje.
- b) Potrebno je da mi liječnik ponudi obrazac za moje pismeno dopuštenje.
- c) Ne znam
- d) U redu je da liječnik objavi takve podatke a da ne traži moje dopuštenje.
- e) Ovisi (objasnite svojim riječima):



---

**3. Što ako liječnik želi objaviti fotografiju koja uključuje Vaše lice kao na prikazanoj slici (s tim da Vaše ime ne će nigdje biti otkriveno)?**

- a) Dovoljno je da od mene liječnik traži usmeno dopuštenje.
- b) Potrebno je da mi liječnik ponudi obrazac za moje pismeno dopuštenje.
- c) Ne znam.
- d) U redu je da liječnik objavi takve podatke a da ne traži moje dopuštenje.
- e) Ovisi (objasnite svojim riječima):



---

**4. Što ako liječnik želi objaviti fotografiju s Vašim licem, ali na kojoj su Vaše oči zamućene kao na slici (s tim da Vaše ime neće nigdje biti otkriveno)?**

- a) Dovoljno je da od mene liječnik traži usmeno dopuštenje.
- b) Potrebno je da mi liječnik ponudi obrazac za moje pismeno dopuštenje.
- c) Ne znam.
- d) U redu je da liječnik objavi takve podatke a da ne traži moje dopuštenje.
- e) Ovisi (objasnite svojim riječima):



---

**5. Što ako liječnik želi objaviti fotografiju s Vašim licem, ali na kojoj su Vaše oči zatamnjene kao na ovim slikama (s tim da Vaše ime ne će nigdje biti otkriveno)?**

- a) Dovoljno je da od mene liječnik traži usmeno dopuštenje.
- b) Potrebno je da mi liječnik ponudi obrazac za moje pismeno dopuštenje.
- c) Ne znam.
- d) U redu je da liječnik objavi takve podatke a da ne traži moje dopuštenje.
- e) Ovisi (objasnite svojim riječima):



---

**6. Što ako liječnik želi objaviti fotografiju na kojoj se vidi dio Vašega lica, ali ne i cijelo lice kao na prikazanoj slici (s tim da Vaše ime ne će nigdje biti otkriveno)?**

- a) Dovoljno je da od mene liječnik traži usmeno dopuštenje.
- b) Potrebno je da mi liječnik ponudi obrazac za moje pismeno dopuštenje.
- c) Ne znam.
- d) U redu je da liječnik objavi takve podatke a da ne traži moje dopuštenje.
- e) Ovisi (objasnite svojim riječima):



---

**7. Što ako liječnik želi objaviti fotografiju na kojoj je vidljiv neki od Vaših udova, kao na priloženoj slici (s tim da Vaše ime ne će nigdje biti otkriveno)?**

- a) Dovoljno je da od mene liječnik traži usmeno dopuštenje.
- b) Potrebno je da mi liječnik ponudi obrazac za moje pismeno dopuštenje.
- c) Ne znam.
- d) U redu je da liječnik objavi takve podatke a da ne traži moje dopuštenje.
- e) Ovisi (objasnite svojim riječima):



---

**8. Da bih dao/dala dopuštenje za objavljivanje moje slike želim vidjeti:**

- a) Članak kakav će biti objavljen na internetu, bez obzira na to što će biti na jeziku koji ne razumijem.
  - b) Članak kakav će biti objavljen na internetu, ali preveden na hrvatski, ukoliko ne razumijem jezik na kojemu je napisan.
  - c) Kliničku fotografiju iz moje povijesti bolesti kakva će biti objavljena u članku, ali bez pisanog dijela članka.
  - d) Ne trebam vidjeti članak ni fotografiju jer imam povjerenja u svojega liječnika.
- 

***Hvala Vam na sudjelovanju u anketi!***

## Appendix 2. Students' and Doctors questionnaire in Croatian

### SVEUČILIŠTE U SPLITU MEDICINSKI FAKULTET

*Poštovani/poštovana,*

*Pozivamo vas na sudjelovanje u istraživanju o Vašim stavovima vezanim za prava pacijenata prilikom objavljivanja **kliničkih podataka o pacijentima i kliničkih fotografija pacijenata** od strane njihovih liječnika u **stručnim medicinskim časopisima**.*

*Sudjelovanje je dobrovoljno.*

*Ispunjavanjem ovog upitnika Vi ste pristali na ovo istraživanje.*

*Upitnik je potpuno **anoniman**, a rezultati će biti korišteni i analizirani u doktorskoj tezi naziva: „**Evaluacija etičnosti publiciranja ljudskih fotografija u kirurškim i njima srodnim časopisima**“, te će biti objavljeni u stručnim medicinskim časopisima.*

|  |  |   |                  |  |
|--|--|---|------------------|--|
| <b>Spol</b><br><br>(upisati broj u zatamnjeno polje) | <b>1) MUŠKO</b>                                    |   | <b>2) ŽENSKO</b> |  |
| <b>Dob</b>   |  |   |                  |  |
| <b>Titula</b><br><br>(zaokružiti jedno od ponuđenog) | <b>1) Dr. med. dent.</b><br><br><b>2) Dr. med.</b> | <b>3) Student dentalne medicine</b><br><br><b>4) Student medicine</b> |                  |  |
| <b>Specijalizacija</b>                               | <b>DA NE</b><br>-----<br>Ako DA, navesti koja:     | <b>Za studente - godina (zaokružiti)</b><br><br><b>1 2 3 4 5 6</b>    |                  |  |
| <b>Uredništvo u časopisima</b>                       | <b>DA NE</b>                                       |   |                  |  |

*Zahvaljujemo Vam na utrošenom vremenu i poklonjenoj pažnji!*

**Mentorica: dr. sc. Elizabeth Wager**

**Pristupnica: dr. Marija Roguljić**

---

1. **Ako biste željeli objaviti studiju slučaja o Vašem pacijentu bez objavljivanja slike (npr. opis bolesti, liječenja i slično) u znanstvenom medicinskom časopisu dostupnom na internetu, trebate li od Vašeg pacijenta prvo zatražiti dopuštenje (s tim da pacijentovo ime ne će nigdje biti otkriveno)?**

- e) pacijent treba uvijek dati svoje dopuštenje
- f) ovisi
- g) ne znam
- h) u redu je objaviti takve podatke bez pacijentovog dopuštenja

---

2. **Što u slučaju ako želite objaviti kliničku fotografiju (npr. rendgensku snimku sličnu prikazanoj) iz povijesti bolesti Vašeg pacijenta (s tim da pacijentovo ime ne će nigdje biti otkriveno)?**

- f) Dovoljno je pacijentovo usmeno dopuštenje
- g) Potrebno je pacijentu ponuditi obrazac za njegovo pismeno dopuštenje
- h) Ne znam
- i) U redu je objaviti takve podatke bez traženja pacijentova dopuštenja
- j) Ovisi (objasnite svojim riječima)



---

3. **Što ako želite objaviti fotografiju koja uključuje lice Vašeg pacijenta, sliku sličnu prikazanoj (s tim da pacijentovo ime ne će nigdje biti otkriveno)?**

- f) Dovoljno je pacijentovo usmeno dopuštenje
- g) Potrebno je pacijentu ponuditi obrazac za njegovo pismeno dopuštenje
- h) Ne znam
- i) U redu je objaviti takve podatke bez traženja pacijentova dopuštenja
- j) Ovisi (objasnite svojim riječima)



4. Što ako želite objaviti fotografiju s licem Vašeg pacijenta, ali na kojoj su pacijentove oči zamućene kao na slici (s tim da pacijentovo ime ne će nigdje biti otkriveno)?

- a) Dovoljno je pacijentovo usmeno dopuštenje
- b) Potrebno je pacijentu ponuditi obrazac za njegovo pismeno dopuštenje
- c) Ne znam
- d) U redu je objaviti takve podatke bez traženja pacijentova dopuštenja
- e) Ovisi (objasnite svojim riječima)



5. Što ako želite objaviti fotografiju s licem Vašeg pacijenta, ali na kojoj su pacijentove oči zatamnjene kao na ovim slikama (s tim da pacijentovo ime ne će nigdje biti otkriveno)?

- a) Dovoljno je pacijentovo usmeno dopuštenje
- b) Potrebno je pacijentu ponuditi obrazac za njegovo pismeno dopuštenje
- c) Ne znam
- d) U redu je objaviti takve podatke bez traženja pacijentova dopuštenja
- e) Ovisi (objasnite svojim riječima)



6. Što ako želite objaviti fotografiju na kojoj se vidi dio pacijentovog lica, ali ne i cijelo lice (kao na prikazanoj slici, s tim da pacijentovo ime neće nigdje biti otkriveno)?

- a) Dovoljno je pacijentovo usmeno dopuštenje
- b) Potrebno je pacijentu ponuditi obrazac za njegovo pismeno dopuštenje
- c) Ne znam
- d) U redu je objaviti takve podatke bez traženja pacijentova dopuštenja
- e) Ovisi (objasnite svojim riječima)



7. Što ako želite objaviti fotografiju na kojoj je vidljiv neki od pacijentovih udova, kao na priloženoj slici (s tim da pacijentovo ime neće nigdje biti otkriveno)?

- a) Dovoljno je pacijentovo usmeno dopuštenje
- b) Potrebno je pacijentu ponuditi obrazac za njegovo pismeno dopuštenje
- c) Ne znam
- d) U redu je objaviti takve podatke bez traženja pacijentova dopuštenja
- e) Ovisi (objasnite svojim riječima)



---

8. Da bih objavio/la članak smatram potrebnim da:

- e) Pacijent vidi članak kakav će biti objavljen na internetu, bez obzira što će biti na jeziku koji ne razumije
- f) Pacijent vidi članak kakav će biti objavljen na internetu, ali preveden na hrvatski, ukoliko ne razumije jezik na kojem je napisan
- g) Pacijent vidi kliničku fotografiju iz njegove povijesti bolesti kakva će biti objavljena u članku, ali bez pisanog dijela članka.
- h) Smatram da ne trebam tražiti pacijentovo dopuštenje za objavljivanje članka

---

***Hvala Vam na sudjelovanju u anketi!***



### Appendix 3. Patients' questionnaire in English

#### University of Split School of Medicine

*Dear Sir, Dear Madam*

*We are asking you to participate in the research about your attitudes regarding to patient rights when clinical data and clinical photos of patients are prepared for publishing in medical journals.*

*Participation is voluntary and there is no impact on your treatment in the Clinic.*

***Filling out this questionnaire you give consent for the research.***

*The questionnaire is anonymous and data will be used and analyzed in the doctoral thesis named: "Evaluation of ethical aspects of publishing human photographs in medical journals" and it will be published in medical journals.*

|  |  |                       |   |                            |
|--|--|-----------------------|---|----------------------------|
| <b>Sex</b><br>(write number in burred field)             | <b>1) MALE</b>                                       |                       | <b>2) FEMALE</b>  |                            |
| <b>Age</b>   |  |                       |   |                            |
| <b>Education level</b><br>(please choose one of options) | <b>low skilled</b>                                   | <b>medium skilled</b> | <b>high skilled</b>   | <b>master's degree PhD</b> |
| <b>Department</b><br>(mark „X“ in blurred field)         | Department of periodontology,<br>Dental Clinic Split |                       | Department of internal medicine,<br>Cardiology<br>University Hospital Split |                            |

*Thank you for your participation!*

**Menhtor: dr. sc. Elizabeth Wager**

**Student: dr.Marija Roguljić**

---

**1. If your doctor wants to publish the study about your medical case without publishing the photograph (e.g. description of your disease, treatment etc..) in the medical journal available on web, should (s)he ask your permission ( your name will be unpublished)?**

- i) Doctor always must ask my permission
  - j) It depends
  - k) I don't know
  - l) Doctor can publish the data without asking my permission
- 

**2. If doctor wants to publish clinical photograph (e.g. X Ray showed) from your medical history ( your name will be unpublished)**

- k) Doctor should ask my oral permission
- l) Doctor should give me written form for my written permission
- m) It depends
- n) I don't know
- o) Doctor can publish my data without asking my permission



---

**• If doctor wants to publish clinical photograph of your face, similar this one from your medical history (your name will be unpublished)**

- a) Doctor should ask my oral permission
- b) Doctor should give me written form for my written permission
- c) It depends
- d) I don't know
- e) Doctor can publish my data without asking my permission



- If doctor wants to publish clinical photograph of your face with blurred eye area, similar this one from your medical history (your name will be unpublished)



- f) Doctor should ask my oral permission
- g) Doctor should give me written form for my written permission
- h) It depends
- i) I don't know
- j) Doctor can publish my data without asking my permission

- If doctor wants to publish clinical photograph of your face with black stripe in the eye area, similar this one from your medical history (your name will be unpublished)



- a) Doctor should ask my oral permission
- b) Doctor should give me written form for my written permission
- c) It depends
- d) I don't know
- e) Doctor can publish my data without asking my permission

- 6) If doctor wants to publish the photograph of the part of the face similar on the showed photograph (your name will be unpublished)



- a) Doctor should ask my oral permission
- b) Doctor should give me written form for my written permission
- c) It depends
- d) I don't know
- e) Doctor can publish my data without asking my permission

- 7) If doctor wants to publish the photograph of your limbs similar on the showed photograph (your name will be unpublished)



- a) Doctor should ask my oral permission
- b) Doctor should give me written form for my written permission
- c) It depends
- d) I don't know
- e) Doctor can publish my data without asking my permission

- 8) If I give permission for publishing I want to see:

- i) Paper in the form prepared for publishing on web regardless I don't understand the language
- j) Paper in the form prepared for publishing on web and the translated paper if I don't understand language
- k) Clinical photograph from my medical history that will be published in the paper without written part of the paper.
- l) I don't want to see anything because I trust my doctor

---

***Thank you for participating in the survey!***

**Appendix 4.** Students' and doctors' questionnaire in English

**University of Split  
School of Medicine**

*Dear colleagues,*

*You are invited to participate in a study about your attitudes regarding patient rights when individual clinical data and clinical images of patients are to be published in medical journals.*

*Participation in the study is voluntary.*

***By filling out this questionnaire you give consent to participate in the study.***

*The questionnaire is anonymous and data will be used and analyzed in the doctoral thesis entitled: "Ethical considerations regarding publication of identifiable patient photographs in academic journals". The results will be published in medical journals. This study is part of the project "Professionalism in Health Care" supported by the Croatian Science Foundation, and has been approved by the Ethical Committee of the University of Split School of Medicine.*

|  |   |  |   |  |
|--|---|--|---|--|
| <b>Gender</b><br>(circle the number)               | <b>3) MALE</b>  |  | <b>4) FEMALE</b>  |  |
| <b>Age</b> (in years)                              |   |  |   |  |
| <b>Education level</b><br>(please mark one answer) | <b>Doctor of medicine<br/>Doctor of dental medicine</b> |  | <b>Student of medicine<br/>Student of dental medicine</b> |  |
| <b>Specialty</b>                                   | <b>YES NO</b>   |  | <b>For students – year of study (please, fill in)</b>     |  |
|  | If YES, please fill in which one:                       |  |   |  |
| <b>Experience in publishing scientific papers</b>  | <b>YES</b>  |  | <b>NO</b>   |  |
| <b>Experience in journal editing</b>               | <b>YES</b>  |  | <b>NO</b>   |  |

*Thank you for your participation!*

**Mentor: Elizabeth Wager, PhD**

**PhD student: Marija Roguljić, DMD**

---

**1. If you want to publish an article about your patients' medical case without publishing a photograph of them (e.g. a description of their disease, treatment, etc. without the patients' name) in a medical journal that is freely available on the web, should you obtain their permission?**

- a) The patients must always give their permission
  - b) I don't know
  - c) I can publish the data without obtaining patients' permission
  - d) It depends (please write your answer)
- 

**2. If you want to publish a clinical image (similar to the x-ray below and without the patient's name) from your patients' medical history, should you obtain their permission (the patients' name would not be published)?**

- a) It is sufficient to obtain oral permission from the patients
- b) The patients should give written permission
- c) I don't know
- d) I can publish patients' images without obtaining their permission
- e) It depends (please write your answer)



---

**3. If you want to publish a clinical photograph of a patient's face (similar to the one here and without the patient's name), should you obtain their permission (the patients' name would not be published)?**

- a) It is sufficient to obtain oral permission from the patient
  - b) The patient should give written permission
  - c) I don't know
  - d) I can publish a patient's photograph without obtaining their permission
  - e) It depends (please write your answer)
- 



**4. If you want to publish a clinical photograph of your patient's face with a blurred eye area (similar the one here and without the patient's name), should you ask their permission (the patients' name would not be published)?**



- a) It is sufficient to obtain oral permission from the patient
- b) The patient should give written permission
- c) I don't know
- d) I can publish a patient's photograph without obtaining their permission
- e) It depends (please write your answer)

---

**5. If you want to publish a clinical photograph of patients' faces with a black stripe across the eyes (similar to the one here and without the patient's name), should you obtain their permission (the patients' name would not be published)?**



- a) It is sufficient to obtain the patients' oral permission
- b) The patients should give written permission
- c) I don't know
- d) I can publish patients' photographs without asking their permission
- e) It depends (please write your answer)

---

**6. If you want to publish a photograph of part of a patient's face (similar to this one and without the patient's name), should you obtain the patient's permission (the patients' name would not be published)?**



- a) It is sufficient to obtain the patient's oral permission

- b) The patient should give written permission
  - c) I don't know
  - d) I can publish a patient's clinical photograph without asking their permission
  - e) It depends (please write your answer)
- 

**7. If you want to publish a photograph of a patient's limbs (similar to the one here) should you obtain their permission (the patients' name would not be published)?**

- a) It is sufficient to obtain the patient's oral permission
- b) The patient should give written permission
- c) I don't know
- d) I can publish a patient's photograph without asking their permission
- e) It depends (please write your answer)



**8. If you want to publish a paper containing patients' facial photographs you should:**

- a) Allow patients to see the article as it will be submitted to the journal, even if they do not understand the language in which it is published.
- b) Provide patients with the article as it will appear in the journal and a translation if they do not understand the language.
- c) Allow patients to see the clinical photograph that will be published in the article, without the text of the article.
- d) I do not need to allow the patient to see either the photograph or the text of the manuscript.

---

***Thank you for participating in the survey!***



**Appendix 5.** The Interview guide and interview questions for qualitative, focus group study.

### **Interview guide**

*First, I would like to thank you for accepting our invitation to participate in this interview. As it was mentioned in the invitation letter, this interview will be conducted as a part of the ProDeM project (Professionalism in Decision Making in science and practice).*

*The aim of the project is to understand how decisions about health care and research are made in practice.*

*In this interview we would like to hear your opinions on the issues of publishing patient identifiable data in academic journals that are accessible online. Further, we would like to hear your opinion regarding the responsibilities and potential risks of launching publications associated with patient identifiable data.*

*I would like to point out that there are no right or wrong answers so please feel comfortable to express your opinion. Your opinion is very valuable to us and will contribute to the further development and the goal of the project.*

*This focus group is confidential; hence everything said will be used, as mentioned in the invitation letter, only for the purposes of the ProDeM project.*

*During the focus group, my colleague and I will take notes and the conversation will be recorded. The recording is only to ensure we have all your answers. The transcription will be anonymous, and tapes will be destroyed after a certain period (end of the project).*

### Background description

Previously we conducted the study about stakeholders' opinions about informed consent for publication of patient clinical photographs with different level of identifiability in academic journals. We included patients, students of the final two years of medicine and dental medicine and dental and medicine doctors. They all were surveyed with the same questionnaire that consisted of the most common clinical images such as X-rays, photograph of the hand, part of the face, photograph of the face with eye area blurred or covered and photograph of the face without any deidentification technique. They were asked about the type of consent a patient would need to provide for each type of image. We also asked them whether the patient should read the manuscript before giving consent for publication of a clinical photograph. The results of our study showed that Croatian patients considered that doctors were not required to ask them for permission about publication of their photographs in academic journals. Dental students and medical and dental doctors had similar opinions on this issue – although stricter than those of the patients, they were below current ethics standards for publishing research.

(present the figure from the article)

### Research questions

The focus group study will be guided by the following research questions:

1. How do you explain the findings of this study – that patients often consider that the doctors do not have to ask them for permission to use their photograph in a publication or that it is sufficient to provide oral consent?

Probes:

- What would you expect to answer on this question?

- Why?
2. Where would you look for information about guidance and standards for consent for publishing patients' clinical images?
- Which type of guidance would you considered as the standard in practice?
3. Patient's clinical image could be used for different purposes (medical record, diagnostic aids and treatment planning, communication with colleagues, teaching and lecturing, research, publication (print and/or electronic media)). Are they equally important in regard to consent?
- Probes:
- How would you rank the importance, or seriousness of informed consent for those uses? (here the participants will jointly rank the possible uses of clinical images)
  - Would your opinion change if clinical images were identifiable (e.g., full face) vs non-identifiable (e.g., panoramic y-ray of the teeth)
4. Current publishing standards state that masking the patient's eyes in a full face photograph is not anonymization and it not necessary. It is important to obtain patient's consent for the publication of the image and then publish it without alteration. Do you agree with this practice? What would you prefer to be done with your own identifiable clinical image? Which type of anonymization would you consider as the most effective?
- Probes:
- Would you feel more comfortable if your eyes were covered even if you can be easily identified?
5. What happens with patients' clinical images that have been published in academic journals?
- Probes:
- What patients' clinical images can be used once they are published? Do you know of any examples?
6. When a clinical image is published in open access licence CC BY4, anyone can use it for any purpose. CC licences are a form of copyright licence, where a part of researcher's copyright is given up for the public use. It is stated that this giving up of publishing rights does not override other rights. Does this include patient's right to privacy?
- Probes:
- When a patient gives consent for publishing an identifiable clinical image in a publication under CC BY4 licence, does he or she gives up his or her right for privacy?
  - Are patients aware of what can happen with their clinical image once it is published?
  - Whose responsibility it is to ensure that patients are fully informed about consent for publishing their photographs? What is the responsibility of the patient, the researcher, the journal/publisher, the reader?

**Appendix 6.** Invitation letter for the participants of focus groups.

Marija Roguljić, DMD, periodontist  
Department of Oral Medicine and Periodontology  
University of Split, School of Medicine, Study of Dental Medicine  
Split, Šoltanska 2

Split, April 15<sup>th</sup> 2020.

**INVITATION LETTER FOR THE PARTICIPATION IN THE RESEARCH**

Dear sir/madam/ colleague,

as a part of PhD project supervised by dr. Elizabeth Wager and ProDeM project led by professor Ana Marušić, we are recruiting participants for focus groups of patients, clinicians and medical students to discuss the issue of publication of identifiable patient data such as facial photographs in academic journals. Upon acceptance of this invitation, you will be notified about one-hour tele-conference session/interview in which you should participate. We will provide you with the informed consent form containing all information relevant to the research topic. We will also answer any additional questions you might have.

In short, during the interview you will be able to state your opinion about how the patient privacy should be protected if doctors/researchers wish to publish patients' photographs/identifying information (e.g. face photos or photos of an affected body part) in an academic journal. The interviews will be conducted in roughly 15 days' time.

If you are interested, you can email your answer and questions on this address:

[marijarog@gmail.com](mailto:marijarog@gmail.com).

Looking forward to your response!

Sincerely,

Marija Roguljić, Elizabeth Wager and Ana Marušić

**Appendix 7.** Informed consent for participation in the qualitative, focus group study.

**INFORMED CONSENT FOR PARTICIPATION IN THE RESEARCH SUPPORTED BY CROATIAN FOUNDATION FOR SCIENCE (HRZZ): “Professionalism in healthcare: decision making in practice and research, ProDeM” FOCUS GROUP INTERVIEW STUDY REGARDING PATIENT CONSENT ON PUBLICATION OF CLINICAL PHOTOGRAPHS IN ACADEMIC JOURNALS**

This research, titled ‘*Ethical considerations regarding publication of identifiable patient photographs in academic journals*’, has been conducted supported by the HRZZ grant: ‘*Professionalism in healthcare: decision making in practice and research, ProDeM*’ and it is a part of PhD research of **Marija Roguljić, DDS**, under the supervision of **dr. sc. Elizabeth Wager**.

The aim of this research is to investigate patients', students' and doctors' opinions on the need for, and type of, informed consent to publish patients' clinical photographs in academic journals. Our research is part of the *ProDeM* project lead by prof. dr. sc. Ana Marušić.

**Description of the Project**

Using focus groups we want to investigate what participants think about obtaining consent for the publication of identifiable patient photographs in academic journals. Information obtained in the focus groups will help identify the key elements that are significant in decision making regarding the consent process for publishing patient photographs. In this study we will include patients, final year medical students from USSM (from both the Croatian and English-language study programmes), and clinicians who deal with the head and neck area (dental medicine doctors, dermatologists, neurologists, otorhinolaryngologists and maxillofacial surgeons). In the introduction to the focus groups we will emphasize the confidentiality of information and discussion of all participants and researchers. All participants should commit to the confidentiality of all information and discussion during the focus group and give consent for anonymised findings to be published.

**Use of data and dissemination of research findings to participants**

The focus group interviews will be audio recorded and the subsequent interview transcriptions will be made fully anonymous. Informed consent forms will be stored separately from the audio files and interview transcripts. All data material will be stored encrypted and safely at SharePoint, a web-based collaborative and GDPR compliant platform, for 5 years after the last publication from the study. SharePoint will be administered by the scientists from the *ProDeM* project. The findings from the focus group interviews will be analysed, published and made publicly available. Each participant in the focus group interview may at any time demand removal of his/her interview data by a simple request to the coordinator of the study, prof. dr. sc. Ana Marušić (ana.marusic@mefst.hr). Data that have already been published, cannot be removed. No personal identifiable information will be mentioned or disclosed at any point. To promote open science and avoid research waste, anonymised data from the focus group interviews will also be made available on the project's OSF (Open Science Framework) site: <https://osf.io/49fbk/>. Here, all names and other identifiers (information on country, university etc.) will be removed to ensure full anonymity.

## Data breach

In case of a data breach, affected participants will be contacted and data will be temporarily removed from the compromised storage. All internal transfer of sensitive data will be done through secure pathways. Specifically, the secure Sharepoint work space established for the *ProDeM* project will be used for data transfer.

## Supervision

Prof. dr. sc. Ana Marušić ([ana.marusic@mefst.hr](mailto:ana.marusic@mefst.hr)) can be contacted for questions regarding Data Protection in the *ProDeM* project or the officer for personal data protection of USSM ([dpo@mefst.hr](mailto:dpo@mefst.hr)).

## Consent

Participation is voluntary and participants are free to withdraw from the study at any time and without giving any reason for withdrawing by contacting prof. dr. sc. Ana Marušić ([ana.marusic@mefst.hr](mailto:ana.marusic@mefst.hr)). By signing the consent form, you indicate that you are in agreement with all of the statements below:

- I have read the information provided about the study. I have had the opportunity to ask questions and my questions have been sufficiently answered. I have had enough time to decide whether I would like to participate.
- I am aware that participation in the study is voluntary. I also know that I can decide at any moment to not participate or to withdraw from the study. I do not have to provide any reasons for not participating or terminating enrolment in the study.
- I give consent to the audio recordings of the focus group interview.
- I give consent to the collection and use of my interview data in line with established data protection guidelines and regulations (GDPR).
- I give consent to having my interview data safely stored for five years on SharePoint after the last publication from the study.
- I give consent to having my anonymised transcribed interview data made publicly available on OSF. I understand that this means that the anonymised data can be used for research purposes other than the ones described above. I am also aware that this means that my anonymised information may be used in countries outside of Europe and that the regulations for data processing and storage in those countries may not comply with those of the European Union.
- I agree to maintain the confidentiality of the information discussed by all participants and researchers during the focus group interview.
- I want to participate in this study.

Participant's signature:

Name in Block letters:

Contact's signature:



Day/month/year

**Appendix 8.** List of the journals from JCR categories Dentistry, Oral Surgery and Medicine and Otorhinolaryngology included in the analysis (N=103)

| <b>Dentistry, Oral Surgery and Medicine Journals (N=70)</b>             |
|---|
| Journal of Clinical Periodontology                                      |
| Clinical Oral Implants Research   |
| Journal of Dentistry  |
| Journal of Prosthodontic Research                                       |
| Clinical implant dentistry  |
| International Endodontic Journal  |
| Journal of Endodontics  |
| Clinical Oral Investigations  |
| The Journal of Prosthetic dentistry                                     |
| Oral diseases   |
| Journal of Oral pathology and Medicine                                  |
| Caries Research   |
| Oral & Maxillofacial Surgery  |
| Operative dentistry   |
| Ortodontics & Craniofacial research                                     |
| Journal of oral rehabilitation  |
| European journal of orthodontics  |
| Journal of Cranio-Maxillo-Facial surgery                                |
| Dentomaxillofacial Radiology  |
| American Journal of Orthodontics & Dentofacial orthopedics              |
| Journal of Oral and Maxillofacial surgery                               |
| Journal of Prosthodontics-Implant Esthetic and Reconstructive Dentistry |
| International Journal of Computerized Dentistry                         |
| Oral surgery, Oral medicine, Oral pathology and Oral radiology          |
| Journal of Applied Oral science   |
| The International Journal of Oral & Maxillofacial implants              |
| The Journal of Adhesive dentistry                                       |
| Medicina Oral Patologia Oral Cirurgia Oral                              |
| European Journal of Oral sciences                                       |
| Korean Journal of Orthodontics  |
| Head & Face Magazine  |
| BMC Oral health   |

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| The Angle Orthodontics  |
| Journal of Oral & Facial Pain and Headache                      |
| Journal of Esthetic and Restorative Dentistry                   |
| Acta Odontologica Scandinavica                                  |
| Australian Dental Journal                                       |
| Odontology  |
| Dental Traumatology   |
| International Dental Journal                                    |
| International Journal of Pediatric Dentistry                    |
| International Journal of Dental Hygiene                         |
| Australian Endodontic Journal                                   |
| Oral and Maxillofacial Surgery Clinics of North America         |
| The International Journal of Prosthodontics                     |
| Implant Dentistry   |
| British Dental Journal  |
| Clef Palate Craniofacial Journal                                |
| British Journal of Oral and maxillofacial Surgery               |
| Progress in Orthodontics  |
| international journal of periodontics and restorative dentistry |
| Brazilian Oral Research   |
| Journal of Oral Implantology                                    |
| Cranio The Journal of Craniomandibular practice                 |
| Quintessence International                                      |
| Journal of Orofacial Orthopedics                                |
| European Journal of Pediatric Dentistry                         |
| Journal of Oral Science   |
| Journal of Dental Science                                       |
| Seminars in Orthodontics  |
| Oral Radiology  |
| Oral oncology   |
| Journal of Periodontology                                       |
| Journal of Periodontal Research                                 |
| European Journal of Oral Implantology                           |
| The Journal of American dental association                      |
| Journal of dental research                                      |
| Archives of oral biology  |
| Journal of Clinical Pediatric Dentistry                         |

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| Journal of Evidence based Dental practice                   |
| <b>Otorhinolaryngology journals (N=33)</b>                  |
| JAMA Otolaryngology -Head and Neck Surgery                  |
| Ear and Hearing   |
| Rhinology   |
| Hearing Research  |
| Clinical Otolaryngology                                     |
| Dysphagia   |
| Head & Neck   |
| International forum of allergy and rhinology                |
| Otolaryngology-Head & neck surgery                          |
| The Laryngoscope  |
| Otology & Neurotology                                       |
| Audiology and Neurotology                                   |
| Trends in Hearing   |
| The American Journal of Rhinology & Allergy                 |
| Journal of Otolaryngology - Head & Neck Surgery             |
| European archives of Oto-Rhino-Laryngology                  |
| Annals of Otology Rhinology and Laryngology                 |
| Current opinion in Otolaryngology & Head and Neck Surgery   |
| Clinical and Experimental Otorhinolaryngology               |
| Brazilian Journal of Otorhinolaryngology                    |
| Auris Nasus Larynx  |
| International Journal of Pediatric Otorhinolaryngology      |
| Acta Otorhinolaryngologica Italica                          |
| Acta Oto-Laryngologica                                      |
| American Journal of Otolaryngology                          |
| Logopedics Phoniatrics Vocology                             |
| European Annals of Otorhinolaryngology-Head & Neck Diseases |
| ORL- Journal for Oto-Rhino-Laryngology Head & Neck Surgery  |
| Ent-Ear Nose & Throat Journal                               |
| Journal of Laryngology and Otology                          |
| Journal of International Advanced Otology                   |
| Folia Phoniatica et Logopedica                              |
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