Reuse of single-use surgical equipment – Survey on current practice and attitudes in Croatia

Ponovno korištenje kirurških instrumenata namijenjenih jednokratnoj upotrebi – Upitnik o trenutnoj praksi i stavovima u Republici Hrvatskoj

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Aims: To gain an insight into current practice and attitudes regarding the reuse of single-use surgical equipment among surgeons and surgical residents in Croatia.

Methods: During May 2020, an online survey was shared among Croatian surgeons and surgical residents via email link. The survey included 10 questions seeking information on respondents' current positions at their departments, real-life practice about reusing single-use instruments, personal attitudes and knowledge about the current law frame.

Results: The majority of 53 participants reused single-use surgical equipment in their practice (92.5%). More than half of them reused many single-use devices such as harmonic scalpels, bipolar dissectors, staplers, single-use trocars, graspers, and scissors. The participants had divided opinions on safety issues, personal support of such practice and the necessity of disclosing to patients. However, the majority was inclined towards the use of new instruments if they found themselves with patients on the operating table (75.5%). Very few participants were aware of the current legal regulations and the law changes that would take effect in the near future (5.6%).

Conclusion: Current practice shows widespread reuse of single-use surgical equipment in Croatia despite the concerns of the involved surgeons. It seems that they recognize the potential safety and ethical issues, but at the same time, they are not well informed about the legal regulations of the practice which is alarming and calls for further education and preparation for the upcoming legal changes.

Key words: laparoscopy, patient safety, equipment reuse, single-use devices

Sažetak

Cilj: Istražiti trenutnu praksu i stavove kirurga i specijalizanata kirurgije o ponovnom korištenju kirurških instrumenata namijenjenih jednokratnoj uporabi u Hrvatskoj.

Metode: Tijekom svibnja 2020. godine provedeno je istraživanje putem upitnika koji je elektroničkom poštom podijeljen kirurzima i specijalizantima kirurgije. Upitnik se sastojao od 10 pitanja o njihovom trenutnom položaju na odjelu, svakodnevnoj praksi uporabe jednokratnih instrumenata u radu, osobnim stavovima i poznavanju važećeg zakonskog okvira.

Rezultati: Većina sudionika (92,5%) je ponovno koristila jednokratne kirurške instrumente u svojoj praksi. Više od polovine ispitanika je ponovno koristilo jednokratne instrumente, kao što su harmonični rezači, bipolarni disektori, stapleri, jednokratni troakari, hvatalice, škarice itd. Ispitanici su bili podijeljeni po pitanju

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sigurnosti ponovne uporabe jednokratnih instrumenata, osobnoga stava prema navedenoj praksi i potrebe upozoravanja bolesnika s takvom praksom. Većina ispitanika odabrala je biti operirana novim instrumentima, kada bi se našli na operacijskom stolu (75,5%). Samo nekolicina ispitanika bila je svjesna trenutne legislative i predstojećih zakonskih promjena (5,6%).

Zaključak: Trenutno je u Republici Hrvatskoj raširena praksa ponovnog korištenja kirurških instrumenata za jednokratnu uporabu. Unatoč zabrinutosti liječnika-ispitanika koji prepoznaju sigurnosne i etičke dileme o tome, oni istovremeno nisu dovoljno informirani o zakonskom okviru navedene prakse. Dobiveni podaci ispitivanja predstavljaju svojevrsno upozorenje i poziv na potrebu edukacije, te pripremu za predstojeće promjene i primjenu zakonske regulative ponovnog korištenja jednokratnih instrumenata.

Ključne riječi: laparoskopija; sigurnost bolesnika; ponovno korištenje; jednokratni instrumenti.

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Introduction

Single-use medical instruments are designated by manufacturers for single-use only on a single patient. Nevertheless, single-use instruments are being used more than once in many countries around the world.¹ The practice of such reuse stems mainly over economic and environmental reasons, but also raises questions regarding safety. The topic has rendered polarized articles across the globe with proponents of bans versus reuse, fueled mainly by the scarcity of highquality clinical evidence. Besides ethical issues, the perspective is further blurred with the influence of the medical industry and financial incentives on relevant stakeholders.² Since there are no studies manuscripts about the reuse of single-use medical instruments in Croatia, we wanted to gain insight into the current practice and attitudes from the surgeons' point of view especially regarding the planned shift in legislation with Regulation (EU) 2017/745 coming into force on May 26, 2021.3 A short questionnaire was designed for this purpose and offered to Croatian surgeons and surgical residents directly involved in the issue of the reuse of single-use surgical equipment.

Methods

Design

We designed an electronic questionnaire administered via the free online survey site Survey Monkey which could be accessed only through the link embedded in the email invitation sent to 154 Croatian general surgeons and surgical residents. The participants were informed about the length of the survey, the investigator and affiliations, and that the survey's purpose was to obtain information regarding current practices and attitudes towards the reuse of single-use devices in surgery. The survey was designed to be simple, short and it has been tested by the author before starting to collect the responses. The survey was closed to the public, only accessible to visitors having

received email invitations with a link leading to a web page with the survey. The Ethical Board of Zadar General Hospital approved the study (Approval No. 02-2736/20-2/20). CHERRIES guidelines for the reporting results of internet surveys were followed.⁴

Survey administration

The survey was posted on a website that automatically captured responses. Web site address used for the survey was www.surveymonkey.com, which is a commercial service specialized in internetbased questionnaires with the option of designing and posting online surveys for free. Participation in the study was voluntary and anonymous. The interested party would click on the link within the email which allowed access to the survey. There were no incentives offered. The study window was open for one month (May 2020). The survey had a total of 10 items (one item per page). Items were ordered with reason starting with more general questions towards more personal choices. It was mandatory to complete the survey before submitting, which meant it was not possible to submit an incomplete survey. Items had a whole spectrum of possible answers covered, so we avoided a non-response option such as "not applicable" or "rather no say". If the participant could still not find the desired answer in the options provided, he/she could simply leave the page and the response would be unrecorded. Participants could review their answers through the Back button before, but not after the final submission.

Response rate

Unique site visitors were determined based on cookies. View rate was not tracked. The participation rate was estimated by dividing the number of invitations sent and the number of responses. There were 53 responses out of 154 invitations sent with a response rate of 34.4% which is the average response rate in similar surveys. The completion rate was

irrelevant because there was no option of submitting the partial response or only agreement to participate without completing the survey. The site had automated use of cookies which prevented users from taking the same survey multiple times.

Analysis

Only completed surveys were recorded and analyzed. After the expiration of one month, the survey was removed from the site and participants could not access the survey anymore. The survey was administered to a narrow, highly specialized group of participants; therefore, we consideed it to have a

Table 1 Survey with complete responses *Tablica 1. Upitnik s potpunim odgovorima*

representative sample without the need for weighting of items for propensity score calculation. The statistical tool used for the analysis was Statistica® 13.3.0 (TIBCO Software Inc.).

Results

A total of 53 participants completed the survey entitled "Reuse of single-use surgical devices in Croatia". Response rate was 34.4% (53 respondents/154 invitations). The survey was offered in the Croatian language only. Survey full text in English with responses is shown in Table 1.

	Responses (N)	Percentage
1. Where do you work? / Gdje radite?		
Clinical Hospital in Zagreb	15	28.30%
Klinička bolnica u Zagrebu		
Clinical Hospital outside Zagreb	7	13.21%
Klinička bolnica izvan Zagreba		
General or County Hospital	31	58.49%
Opća ili županijska bolnica		
Specialized Hospital	0	0.00%
Specijalizirana bolnica		
Private Surgical Practice	0	0.00%
Privatna kirurška ambulanta		
2 What is a second into a side of W. "		
2. What is your current job position?/Koji posao trenutno radite?	7	12 210/
Academic Surgeon and/or Head/Chief of Department	/	13.21%
Akademski kirurg i /ili šef odjela	3	5.66%
Academic Surgeon	3	3.00%
Akademski kirurg Specialist/Board Certificated Surgeon	28	52.83%
•	28	32.83%
Specijalist/Certificiarni kirurg Resident/Registrar	15	28.30%
	13	28.30%
Specijalizant		
3. Do you use resterilized or reprocessed surgical single-use instruments in y	our hospital (e. g. tro	ocars, grasper
Ultracision, Ligasure, etc.)? / Koristite li resterilizirani ili prerađeni kirur:	ški instrumenti za je	dnu uporabu
vašoj bolnici (trokari, hvatači, Ultracision, Ligasure, itd.)	-	_
No, we have never used them.	2	3.77%
Ne, nismo ih nikada koristili		
Not lately, but we used them in the past.	2	3.77%
Nedavno ne, ali smo ih koristili u prošlosti.		
Yes, we use "in-house" resterilized single-use devices.	49	92.45%
Da, koristimo "interne" resterilizirane uređaje za jednokratnu upotrebu.		
Yes, we use instruments reprocessed by a third-party company.	0	0.00%
Da, koristimo instrumente koje prerađuje neovisna tvrtka.		

4. What type of resterilized surgical single-use instruments do you use? / K	oju vrstu resterili	iziranih kirurškii
instrumenata za jednu uporabu koristite?	10	02.450/
Harmonic scalpels (Ultracision etc.)	49	92.45%
Harmonski skalpeli (Ultracision)	44	83.02%
Bipolar vessel sealing devices (Ligasure etc.) Uređaji za bipolarno zatvaranje krvnih žila (Ligasure itd.)	44	83.02%
· ·	34	64.15%
Staplers	34	64.15%
Klamerice	27	60.010/
Single-use trocars	37	69.81%
Jednokratni trokari	20	56,600/
Single-use graspers, dissectors, scissors, etc.	30	56.60%
Hrvatači za jednu uporabu, rastavljači, škare, itd.	10	25.050/
Tackers (ProTack etc.)	19	35.85%
Takseri (Pro Tack, itd.)		
We don't use nor have ever used resterilized single-use instruments.	3	5.66%
Ne koristimo i nikad nismo koristili resterilizirane kirurške instrumente za		
jednokratnu uporabu.		
5. Do you personally believe that the reuse of single-use instruments is safe		ierujete li osobn
da je ponovna upotreba instrumenata za jednokratnu uporabu sigurna za p	acijente?	
Yes, I believe it is safe.	23	43.40%
Da, vjerujem da je sigurna		
No, I'm afraid it is not safe.	30	56.60%
Ne, vjerujem da nije sigurno		
6. If you could decide on the reuse of single-use instruments in your hospital,	you would?/D)a možete odluči
		a mozeic oaiaci
o ponovnoj upotrebi instrumenata za jednokratnu upotrebu u vašoj bolnici,		a mozere oaraer
		45.28%
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I'd prefer to be operated with a new device because of bleeding risk.	8	15.09%
Radije bih se operirao novim uređajem zbog rizika krvarenja.	4	7.550/
I'd prefer to be operated with a new device because of thermal injury risk.	4	7.55%
Radije bih se operirao novim uređajem zbog rizika termalne povrede		
I'd prefer to be operated with a new device because of all the above-	21	39.62%
mentioned risks.		
Radije bih se operirao novim uređajem zbog svih gore navedenih razloga.		
9. Is it legal to reuse single-use instruments in Croatia? / Je li legalno	ponovno koristi	ti instrumente za
jednokratnu upotrebu u Hrvatskoj?		
Yes, I know it is legal.	3	5.66%
Da, znam da je legalno.		
I think it is legal, but I'm not sure.	8	15.09%
Mislim da je legalno ali nisam siguran.		
No, it is not legal.	10	18.87%
Ne, nije legalno.		
I think it is not legal, but I'm not sure.	14	26.42%
Mislim da nije legalno, ali nisam siguran.		
I don't know.	18	33.96%
Ne znam.		
10. Are you familiar with the information that the Legal Act (EU) 2017/7-	45 regulating th	e reprocessing of
single-use medical devices comes into force in Croatia on May 26, 2020?		
Jeste li upoznati s informacijom da pravni akt (EU) 2017/745 koji regulir	a ponovnu upot	trebu medicinskil
uređaja za jednokratnu uporabu stupa na snagu u Hrvatskoj 26. svibnja 202		
Yes, I know about it and my hospital is already prepared for the shift.	0	0.00%
Da, znam. Moja se bolnica već pripremila za promjenu.		
Yes, I know about it and my hospital is preparing for the shift.	3	5.66%
Da, znam. Moja se bolnica priprema za promjenu.		
Yes, I have heard about the new legislation, but my hospital is not making	11	20.75%
any prearrangements.		
Da, čuo sam za novi zakon, ali moja bolnica ne donosi nikakve ranije		
pripreme.		
No, I have never heard about it.	39	73.58%
Ne, nisam nikada čuo o tome.		

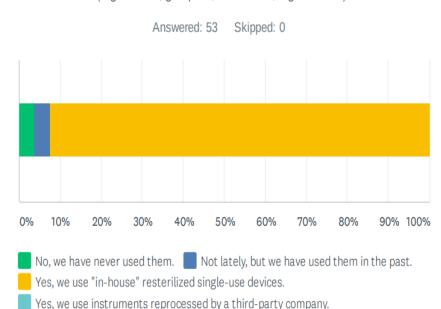
The first item is aimed at discerning the hospital rank where participants practice. The distribution of participants correlated to the number of University Hospitals with surgery departments located in the Croatian capital of Zagreb (six hospitals), University Hospitals outside Zagreb (three hospitals) and the General/County Hospitals across Croatia (22 hospitals).⁵ None of the respondents was affiliated with a specialized hospital or private surgical practice.

The second item aimed at stratifying the level of education/experience and the authority for making decisions on the reuse of single-use devices in surgical departments. More than half of the participants (52.8%) were board-certificated surgeons (attendings/consultants) without academic titles or managing positions. Residents were represented with more than

a quarter (28.3%) while academic surgeons and surgeons in leading positions had an appropriate contribution with 18.8%. The results obtained showed a satisfactory representation of participants both from smaller hospitals as well as larger university hospitals. Also, the structure of education and experience was fairly distributed among the groups.

In the third item, the vast majority of participants (92.4%) confirmed the reuse of instruments being resterilized "in-house" (Picture 1). None of the participants used instruments reprocessed by a third-party company. Only 2 participants (3.7%) declared they had never used resterilized instruments.

In the fourth item, participants could tick the boxes on a list of commonly reused instruments. The poll ranked highly sophisticated and the most expensive



Do you use resterilized or reprocessed surgical single-use instruments in your hospital (e.g. trocars, graspers, Ultracision, Ligasure etc)?

Figure 1 Participants' answers about the reuse of disposable instruments in their hospitals Slika 1. Odgovori ispitanika o ponovnoj uporabi jednokratnih instrumentata u njihovim bolnicama

devices as the most common pick. Harmonic scalpels were most popular, being reused by 92.4%, bipolar dissecting devices were being reused by 83%, followed by single-use trocars reused by 69.8%, staplers reused by 64.1%, single-use graspers/endoscissors reused by 56.6% and tackers reused by 35.8% of participants.

The fifth item revealed that more than half of the participants (56.6%) had safety concerns about the reuse of single-use instruments versus 43.4% who considered the practice safe (Picture 2). The word "believe" was purposely used in the question to evoke the sentiment of surgeons instead of their professional opinion.

In the sixth item, 45.2% would ban the practice, 37.7% would allow reuse of certain instruments and 16.9% would encourage reuse as much as possible for economic and environmental reasons.

The seventh item contained an ethical dilemma. A significant number of participants (41.5%) thought that patients should know of the reuse of single-use devices used on them before surgery. Almost the same percentage (39.6%) felt that patients should not know such technical details along with an additional 18.8% who were concerned that disclosure might trigger a lawsuit in case of postoperative complications.

The eighth item represented a personal dilemma, sometimes referred among a surgeons as the "if it

were me" test, aiming to unveil the real attitude towards reused instruments. Somewhat expectedly most of the participants (75.4%) preferred to be operated with a new device. Only a quarter (24.5%) were consistent in declaring they would not mind the choice of a surgical device. Those who were against were discordant in giving reasons for their anxiety ranging from bleeding risk (15%), cross-infection risk (13.2%), thermal injury risk (7.5%) to combined risk (39.6%).

The ninth item tested the knowledge on the lawfulness of the practice in Croatia. Once again, a diversity of answers reflected the confusion and unfamiliarity among a surgeons where one-third (33.9%) did not know whether the practice was legal or not (Picture 3). More than a quarter (26.4%) thought it was illegal, but they were not sure. A significant number of participants (18.8%) claimed the practice was illegaland 15% thought it was legal, but they were not sure. Only a fraction (5.6%) claimed it was legal for sure.

Lastly, the tenth item was about the future legal constraints. Note: due to the international health emergency COVID-19, the European Commission decided to postpone the deadline by one year. The distribution of replies showed that individuals, as well as the relevant institutions, were not prepared for the changes. The majority (73.5%) had never heard about

the forthcoming change (Picture 4). Some had heard about the new legislation, but their hospitals were not making prearrangements (20.7%). A minority claimed

they knew about it and their hospitals were starting to prepare for the change (5.6%). None of the participants declared that their hospital was prepared for the shift.



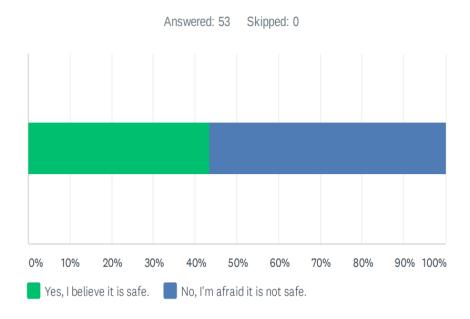


Figure 2 Participants' attitudes about safety of reusing single-use instruments Slika 2. Stavovi ispitanika o sigurnosti ponovne uporabe jednokratnih instrumenata

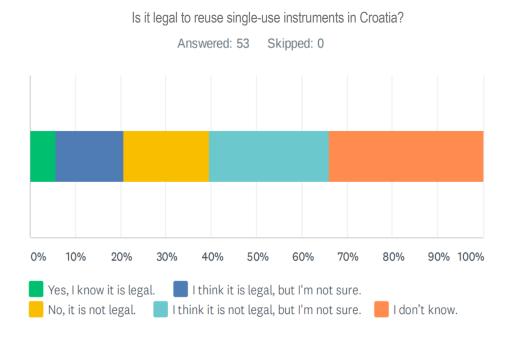


Figure 3 Participants' opinions about legality of reuse of single—use instruments in Croatia Slika 3. Mišljenja ispitanika o zakonitosti ponovne uporabe jednokratnih instrumenata u Republici Hrvatskoj

Are you familiar with the information that legal act (EU) 2017/745 regulating the reprocessing of the single-use medical devices comes into force in Croatia on 2020/05/26?

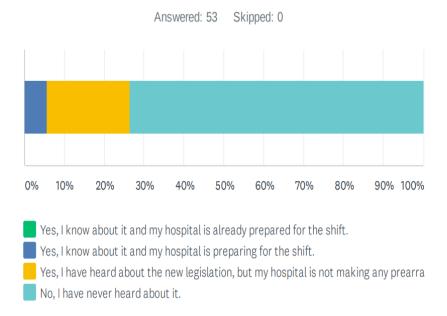


Figure 4 Respondents' awareness about the existence of the Regulation (EU) 2017/745 on reprocessing of the single-use instruments and the date of entry into force in Croatia

Slika 4. Informiranost ispitanika o postojanju zakonskog akta EU 2017/745 o regulaciji uporabe jednokratnih instrumenata te o datumu stupanja na snagu u Republici Hrvatskoj

Discussion

Survey results obtained on an equally distributed sample of surgeons regarding the hospital rank and career position confirmed widespread reuse of a range of single-use surgical instruments in Croatia. However, surgeons expressed concerns regarding the safety of such practice, especially when it comes to a personal level. They were hesitant to disclose the reuse of single-use instruments to their patients. Noteworthy is their reluctance to undergo a relatively simple surgical procedure such as laparoscopic appendectomy with instruments that are not brand new, although they were unsure about the specific reason. Especially worrying is the ignorance about the current law regulation and the forthcoming legal changes.

The practice of reusing disposable instruments is as old as the beginning of single-use instruments production in the late 1970s. To further elucidate terminology, we should distinguish reprocessing from a simple resterilization. Reprocessing refers to recovery, refurbishing, sterilization and labeling of instruments usually by some third-party company holding equal liability as the original equipment manufacturer. The reprocessor guarantees functionality and sterility of reprocessed instruments with traceability in case of attributable malfunction of the product.

Typically, instruments are resold to the hospital at 50% of the original price. Onsite resterilization, or "inhouse" reprocessing is a far more widely and less stringently regulated practice occurring in most developed and underdeveloped countries. It usually implies meticulous washing, packing and sterilization which in turn costs only a fraction of the original price.¹ The main reason for the simple resterilization of disposables is the country's destitution or if patients pay for high-tech devices out of their own pockets.^{2,6} Reprocessing is a well established, generally safe practice, completely rationalized and legislated in developed countries. The initiative stems from economic and environmental reasons with the United States globally and Germany in Europe being the leaders in the field. Very relevant to our country is the regulation on medical devices for human use issued in 2017 by the European Union.³ The date by which the regulation was to be fully implemented by replacing the previous directives was originally defined as May 26, 2020. Following the international health emergency COVID-19, the European Commission decided to postpone the deadline by one year to May 26, 2021.³ Croatia as a member state has an obligation to implement the above-mentioned regulation. Until then the matter was not precisely regulated as informed through correspondence with the Agency for Medicinal Products and Medical Devices of Croatia

(HALMED). We were instructed to elicit further guidance and clarifications from the Ministry of Health but our repetitive emails during the one-year period remained unanswered. It seems that poor legislation is rather a rule not an exception globally. A 2019 report on a survey conducted in China where reuse of singleuse medical devices is prohibited, reveals that extensive reprocessing is taking part in almost every Chinese hospital. Similar to our group of respondents, Chinese participants had a generally positive attitude towards reprocessing and reuse of single-use devices, however many of them had concerns about hygienic and functional safety. Almost identical portions of respondents had an ambivalent attitude towards using reprocessed single-use devices for themselves, with the cost reduction being a significant factor in willingness to accept the reuse of single-use devices.⁶ Another country without a "clear policy" towards the reuse of single-use devices was Argentina, whose reallife situation has been analyzed in a review published in 2017. Authors had panel discussions with 10 surgeons who confirmed the active practice of reusing single-use devices, despite the fact that at that time Argentina did not have registered reprocessing companies.⁸ A 2018 survey from Stanford University conducted on a mixed group of patients, physicians and medical practitioners surprisingly reported that 77% of participants were unaware that the Food and Drug Administration allowed single-use devices reprocessing and reuse. Worth mentioning is that 92% of patients and 68% of physicians participating in the survey felt that hospitals should inform patients of the practice as a part of their care. Authors conclude that further education could overcome patients' concerns.9 The very same assertion is valid for our society, including dialogue with patient's associations and media representatives. In general, the public is poorly informed about the benefits and risks of reuse of disposable surgical instruments, and sporadic newspaper articles mention the practice under heated headlines rendering angry and negative comments.¹⁰ The paucity of firm evidence in this field of healthcare introduces ambiguity and results in emotional discussions. Studies sponsored by original manufacturers or reprocessing companies with contradictory results and inherited biases are contributing to scientific indecision. 11-13 The properly designed and conducted clinical trials on reuse and refurbishing of the surgical equipment are scarce with only a few relevant references. 14-16 Most of the reviews in the field invoke further clinical research.^{8,17,18} In 2018 Portuguese authors reported excellent clinical and financial results of reusing linear staplers and harmonic scalpels retrieved from the certified reprocessing company after Portugal had allowed reprocessing in 2012 which could serve as an exemplar. 19 A prominent aspect of the reprocessing issue being frequently neglected is the sustainability of healthcare. It is estimated that 10% of total greenhouse gas emission originates from the healthcare sector.²⁰ A single operating room generates daily the same volume of waste as an average family of four during one week with disposables contributing the most.²¹ Initiatives like greening the operating room and rising awareness of sustainability are gaining popularity and becoming increasingly important.²² Interventions such as the choice of anesthetic gas, reuse of disposable surgical instruments, using reusable gowns and drapes, efforts in reduction of waste and increased recycling can reduce the carbon footprint of an average laparoscopic hysterectomy by up to 80%.²³ A survey on the members of the American Society of Anesthesiologists published in 2015 reported that 48.4% of participants had an affirmative attitude towards equipment reprocessing, but with alarming cognition of inadequate organization of sustainability programs at the hospital level and lack of information about reuse and recycling.²⁴ The latter result strikingly resembled responses elicited on the current reprocessing status in Croatia.

The 2020 global health crisis related to the COVID-19 pandemic pushed all Croatian hospitals into an unprecedented endeavor with overcrowded wards with positive patients, insufficient staffing but also a dearth of drugs and personal protective equipment.²⁵ In our hospital, the Department of Trauma and Orthopedic Surgery was turned into a dedicated COVID unit. Intensive Care Unit (ICU) capacity was halved at the expense of COVID-ICU. All elective surgery was postponed and only emergency cases were carried out.²⁶ Almost overnight surgical masks were removed from the shelves and kept under lock. It became apparent that our practice towards disposables had been wasteful so we had to awaken our inherited sensible "reduce and reuse" behavior. Search for relevant literature on reprocessing and reusing disposable medical equipment on the Portal of Croatian Scientific and Professional Journals (HRČAK) in March 2021, found only one paper discussing the problem of COVID-related waste generated by single-use masks in Croatia.²⁷ Further Google searches retrieved the undergraduate thesis on challenges in the use of disposable and reusable surgical gowns and drapes published in 2018, and the 2019 congress abstract on challenges in reprocessing of sophisticated instruments in Central Hospital Sterilization Departments which emphasized the importance of the introduction of new technologies and continuous education. 28,29 This is where available research in the Croatian language on the practice of reuse of disposable medical equipment in Croatia exhausts.

A potential limitation of our study is the relatively low response rate. Part of responders might incline towards reprocessing but at the opposite end of the spectrum proponents of disposables might be also interested in participating in the survey making the sample balanced, which makes response bias less likely. The individuals who considered this topic mundane and unattractive might have abstained from taking the survey.

Conclusion

The practice of reuse of single-use surgical equipment in western countries is rationalized and legislated providing leadership for countries in transition. Legal inconsistency and non-transparency result in the loss of public trust and may facilitate or trigger lawsuits even in cases when adverse events or complications are inevitable. Further clinical studies and education of relevant stakeholders, as well as raising public awareness, could have an appeasing effect and the ability to subdue apprehension of single-use devices reuse.

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