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Process Reliability and Psychological Stress in Urine Sample Collection for Drug Testing: A Pilot Study

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Authors' contributions

This work was carried out in collaboration between all authors. Authors KB and BH designed the study, developed the questionnaires, and performed the statistical analysis. Author KB wrote the first draft of the manuscript. Author MSS performed the empirical part of the study. All authors read and approved the final manuscript.

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ABSTRACT

Purpose: Drug testing by means of urine samples is part of the standard operating procedures in a wide range of related settings. In order to avoid sample manipulation by the client, samples are almost collected under direct observation. However, the supervision procedure is handled differently in different countries and settings leading to varying degrees of precision. Moreover, supervision seriously evokes psychological stress to the sample donor and, probably but still not evaluated, to the supervising staff. An alternative control method is the polyethylene glycol (PEG) urine marker system, which excludes the need of supervision during urination.

Aims: In the present study we evaluated by means of questionnaires a) the concrete procedure of supervised urine sample collection in a Forensic Psychiatry and b) the beliefs of supervising staffs regarding supervision and marker control with respect to safety, economy, and psychological stress. **Study Design:** Descriptive cross-sectional study.

Place of Study and Methodology: 116 employees of a public German Therapy Center for Forensic Psychiatry were asked to complete two different anonymous, closed ended questionnaires before and after a three month introduction phase of the PEG marker system. The initial questionnaire focused on real handling and safety aspects of supervision, the second on the comparison between supervision and marker system

Results: Even within a given institution, supervision is performed individually different with respect to distance to the genital, direct or indirect view, and accuracy. Supervision evokes serious psychological stress to both patient and staff. The marker system requires less working hours.

Conclusion: The PEG marker system is superior to supervision with respect to safety, time consumption, and psychological stress to patient and staff.

Keywords: Urine; manipulation; stress; supervision; marker; drugs.

1. INTRODUCTION

Drug testing by means of urine samples is part of the standard operating procedures in a wide range of related settings, ranging from medication-assisted treatment [1], addiction treatment [2], probation services [3] forensic psvchiatry [4], road safety (medicalpsychological assessment (MPA) in Germany under forensic conditions) [5] and workplace testing [6] to doping analysis in elite sports [7]. In order to preclude both false positive and false negative results, high quality standards need to be applied to the collection/handling of the specimens and the subsequent analysis in all cases.

Manipulation attempts by the patient are almost exclusively possible prior to and during sample collection by means of a) dilution via excessive intake of fluids, b) substitution of the urine sample or c) chemical manipulation by adding manipulation agents [8]. Accordingly, urine sample collection is always supposed to be executed in standardised-controlled conditions. However, the standards created to this effect are not uniform both between the target groups and in international comparison. Moreover, the respective procedures are defined with varying degrees of precision.

The most common method is supervision. In this instance, US-American guidelines [5,6,9] include mandatory requirements regarding observers of the same gender while prohibiting the use of mirrors or video cameras. British guidelines on drug testing in prisons, on the other hand, do not allow direct observation due to human rights considerations [10]. They do work with mirrors. The German criteria for chemical-toxicological analysis (chemisch- toxikologische Untersuchung, CTU) indicate directly observed sample collection [11], the World Anti Doping

Agency demands an unobstructed view of the sample when the urine leaves the genital of the patient [7]. The supervising person should be of the same gender in this instance.

No guideline provides a defined distance between the patient and supervisory body or between patient and mirror or between mirror and supervisor, respectively. The same applies to the position (to the side/frontal) towards the patient or the position of the patient (sitting down/standing up) during urination.

Aside from different interpretations of direct observation, the procedure suffers from additional problems in terms of human rights and the psychological strain it poses on the patient. The guidelines of the European Workplace Drug Testing Society illustrate the balancing act between human dignity and prevention of sample manipulation: "All specimens must be collected under circumstances that respect the dignity of the individual whilst ensuring that the sample is freshly voided and has not been tampered in any way" [12, p.9]. The psychological strain may be so strong that patients cannot urinate under direct observation [13,14], a phenomenon called paruresis according to Hammelstein [14].

In a recent study, performed within an opioid replacement therapy setting, clients perceived the regular external urine control as mainly positive. They stated that the testing "feels like a safety net" [15, p.8] and that it may increase efforts in treatment [15,p. 7]. In contrast, the supervised testing procedure itself was regarded as humiliating, horrible, demeaning, and in some patients memories of earlier misuse became present.

Besides the psychological stress put on the clients during supervised urine collection, the potential psychological harm for the supervising staff is largely unexplored.

Ingesting a marker substance shortly before providing the urine sample presents an alternative to direct supervision [8,16]. With this procedure, the patient swallows a defined mixture of short-chain polyethylene under supervision. glycols (PEG) PEG can then be traced in the urine. According to close examination by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA), these short-chain polyethylene glycols are neither subject to legislation covering medicines nor are they to be classified as drugs. After 40 minutes the PEG is detectable in the urine [16] so that it is impossible to substitute another person's urine sample. The agents detailed in scientific literature as effective for chemical manipulations of the original urine are also detectable, further excluding false- negative results [8]. Thus, using PEG markers allows urinating without direct observation.

The present investigation compares direct observation and marker testing from the subjective supervisors point of view. The focus was on reliability and practicability of the methods and the psychological stress imposed by these procedures.

2. METHODS

2.1 General Information

In the present cross-sectional study self-developed, closed-ended questionnaires were used. Initially, subjects received verbal and written information about the procedure and goals of the study and that they were totally free to participate or not. All procedures followed were in accordance with the tenets of the Declaration of Helsinki.

2.2 Subjects

All 116 employees (44% women) of a public Therapy Center for Forensic Psychiatry (TCFP) were asked to participate in the study. Their patients exclusively consist of male offenders.

2.3 Urine Sampling Procedure in the TCFP

In TCDP, urine sample collection with supervision is performed by two employees at a time. According to the facility's standard for drug

and alcohol screening procedures, the patients need to undress completely. Palms and soles, armpits as well as buttocks are checked and the testicles must be lifted. The urine is provided under direct observation. This procedure was executed exclusively until March 8th 2018. Thereafter, the polyethylene glycol (PEG) marker system was tested for three months, employing one staff member per instance to perform sample collection.

2.4 Questionnaires

Prior to and at the end of the PEG test phase, two different, anonymous questionnaires were used. All employees of the clinic were asked to complete the questionnaires and to then send them anonymously to the evaluation centre in Cologne, Germany. In order to ensure complete anonymity, the only personal data collected in both cases were gender, age within a range and the department or decade departments within the clinic where the respondents work. The questionnaire prior to the introduction of the marker consisted of 15 additional items regarding work routine, risk regarding manipulation. assessment psychological stress on the side of the individual staff member and the patient and time requirements during sample collection. Integer numbered Likert scales were used (Appendix A).

The questionnaire after the marker test phase included 7 additional items on the frequency of the individual marker use as well as questions comparing supervision and marker application to exclude manipulation. personally perceived psychological stress, the psychological stress of the patient and the time requirements during sample collection. The comparative questions were organized on a Likert scale ranging from integer numbers 0 to 10 with 0 to 4 representing decreasing preference of direct observation, 5 being a neutral position, and 6 to 10 representing increasing preference of marker testing (Appendix B).

2.5 Data Analysis and Presentation

If not otherwise stated, Likert-scale data are presented as median and their distribution of responses as bar charts. To compare the results between women and men, the percentage data are given, too.

3. RESULTS

3.1 Results of the Survey on Direct Observation Prior to the Introduction of Marker Testing

A total of 72 staff members (18 women and 54 men) participated in part 1 of the survey (prior to the introduction of marker testing). Considering the total staff of 116 employees this accounts for a participation of 62%. Since no women indicated to perform direct observation, only the 54 participating male staff members were taken into account in part 1, representing 83% of all male employees. 48 (90%) participants work in a therapy department. Table 1 shows the age distribution with a median of 41 to 50 years.

Table 1. Age distribution of participating male staff

Age group (years)	Number	Percent
< 30	8	15
31 - 40	13	24
41 - 50	14	26
> 50	19	35

For control purposes, 43 (80%) individuals exclusively use direct visual contact, 3 (6%) individuals exclusively use a mirror, and 8 (13%) individuals use both options. 43 (80%) investigators keep a distance of 1 m to 1.5 m with a median of 1 m between themselves and the patient's genitalia. The exact distribution is shown in Fig. 1. For those using a mirror, the distribution pattern regarding the distance between the mirror and the genitals is comparable.

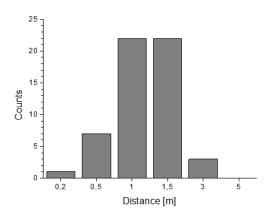


Fig. 1. Frequency distribution regarding the distance between patients genital and examiner

42 (78%) of the respondents allowed their patients to urinate either sitting down or standing up. For 12 respondents (22%), only standing was permitted. When urinating while sitting down, 37 (69%) respondents thought direct observation was impossible, 13 (24%) believed they could perform a successful direct observation, and 4 individuals did not specify.

Fig. 2 shows the distribution pattern on the frequency of patients not being able to urinate under direct observation (median frequent). The average delay was between 5 minutes and 15 minutes for 47 (87%) of the respondents. Regarding the individually experienced maximum delay, 17 (31%) of the employees stated a time span greater than 30 minutes, 8 (15%) greater than one hour, and 25 (46%) greater than two hours.

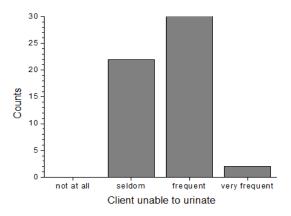


Fig. 2. Frequency distribution on how often patients cannot urinate under supervision

Four questions focused on subjective assessments regarding the direct observation that was each answered on a scale of 1 to 10 and are illustrated in Figs. 3 to 6.

Pooling the scaling points 1 to 5 in Fig. 3 as predominantly not useful and the points 6 to 10 as predominantly useful yielded a ratio of 15% to 85% between the two groups with a median of 9. The same approach yielded a ratio of 30% to 70% in favour of certainty regarding the recognition of manipulation attempts with direct observation (median 7). Also, 38 (70%) of the respondents indicated that they were personally uncomfortable with direct observation (median 8), and 53 (98%) believed that the patient was uncomfortable with direct observation (median 10).

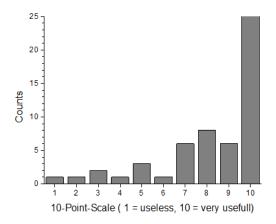


Fig. 3. Distribution pattern on the usefulness of direct observation

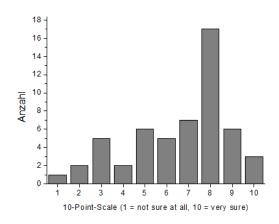


Fig. 4. Distribution pattern on how surely manipulation attempts are recognized during direct observation

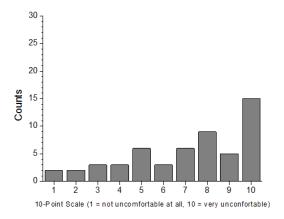


Fig. 5. Distribution pattern on how uncomfortable the staff member is with direct observation

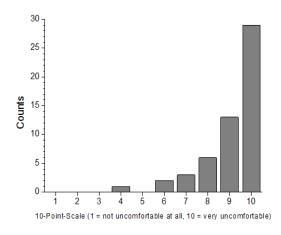


Fig. 6. Distribution pattern on how uncomfortable the staff member believes direct observation to be for the patient

Fig. 7 shows the self-assessment of the respondents on how closely they look at the patient's genital during direct observation (median 8).

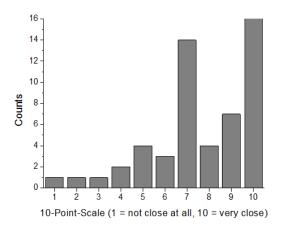


Fig. 7. Distribution pattern on how closely urination is observed

3.2 Results of the survey after the threemonth trial using marker testing

With 73 employees (31 women and 42 men), participation in the survey after the three- month trial phase with marker testing was comparable to the initial survey. Since all women also acted as investigators during marker testing and all questionnaires were evaluable, the following results included the answers of 73 individuals and thus 63% of the staff members. Their age distribution is shown in Table 2.

Table 2. Age distribution of the participating staff members	;
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Age group (years)	Number of women	Percent of women	Number of men	Percent of men
< 30	3	10	5	12
31 - 40	7	23	14	33
41 - 50	7	23	9	21
> 50	13	42	14	33

22 (71%) of the women and 19 (45%) of the men had personally used the marker system up to 20 times, 9 (29%) of the women and 23 (55%) of the men indicated to have used the system more than 20 times. The median of all staffs was in the range between 11 and 20 times.

Regarding the question of which method has a stronger effect on excluding sample manipulation, 4 (5%) of the employees indicated direct observation, 8 (11%) thought both methods were equivalent, and 61 (84%) preferred marker testing. The distribution pattern was comparable for women and men with a median of 8 (Fig. 8).

The majority of staff members preferred the marker system with regard to the reduction of time spent on sample collection (median 7). In comparison to the female staff members this result was more pronounced with the male staff members who, with the exception of two employees, all had experience with direct observation as well. 6 (14%) of male employees preferred direct observation, 4 (10%) regarded both procedures as equivalent, and 32 (76%) favored the marker system (Fig. 9). 11 (26%) rated the time saving effect as a little, 8 (19%) as noticeable, 12 (29%) as strong, and 6 (14%) as very strong.

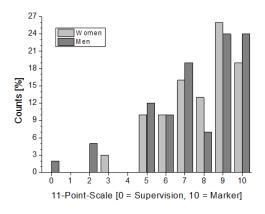


Fig. 8. Distribution pattern on which method is more effective to exclude sample manipulation

With regard to personal psychological stress 38 (91%) of men and 25 (81%) of women preferred the marker method, 1 (2%) of men and 5 (16%) of women saw no advantage of one system, and 3 (6%) of men or 1 (3%) woman, respectively, preferred direct observation (Fig. 10). The median of all staffs was 9.

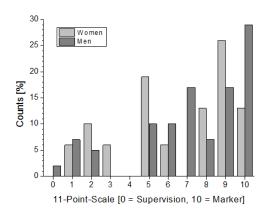


Fig. 9. Distribution pattern on which control procedure is superior in terms of time requirements

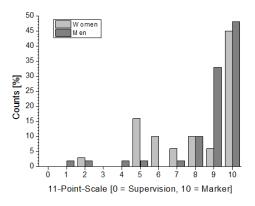


Fig. 10. Distribution pattern on which method is preferred in terms of personal psychological stress

The result was even more unambiguously in favour of marker testing with regard to the patients psychological stress resulting in an overall median of 10. All women preferred the

marker system. Among men, it was 96%. Another 2% indicated a neutral rating or rated direct observation as superior, respectively (Fig. 11).

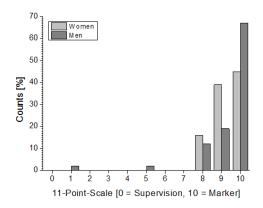


Fig. 11. Distribution pattern on which method is preferred with regard to the patients psychological stress

4. DISCUSSION

The main finding of the present study is that staffs perceived supervision as a heavy burden on one's own psyche and as a very heavy burden on the psyche of the patients. These clear results are surprising to some extent since Likert scales are known to be sensitive to distortion caused by the central tendency and the social desirability bias [17,18]. Since the participating staffs used supervision for years, it could have been expected that sight control was put in a more favourable light. In contrast, the results speak against supervision and agree with the findings of Monwell et al. [15], which investigated the effects of supervised urine control from the patient's points of view.

As was to be expected, the procedure of direct supervision was executed differently on a more detailed level. The majority of employees preferred direct visual contact, 11 (15%) used both direct observation and observation through a mirror, and 4 (5%) indicated that they only observed through a mirror. Although the majority considered direct observation of the urination process to be impossible with a patient sitting down, 58 (80%) of the staff members permitted the sitting position. This could suggest an internal compromise between the awareness that controls are useful and the psychological stress both for themselves and the patient. The majority obviously accepted that manipulation attempts

cannot be ruled out to a very high degree. Correspondingly, the answer distribution on how closely urination is observed showed two peaks and was widespread as a whole. The basic rejection of direct observation was even more pronounced with workplace testing under private-law conditions. According to Egbert et al. [19] it must be assumed that most businesses do not collect urine samples under direct observation.

A large majority of the employees at the TCFP rated the marker system as more reliably precluding a manipulation attempt. The other comparisons also proved the marker system to be vastly superior. It is less time consuming while at the same time demonstrating significantly less psychological stress for both the supervisor and the patient.

There are two main limitations of the present study: First, our results are based on a limited number of subjects and, secondly, we exclusively investigated the situation within the setting of a public therapy centre for forensic psychiatry. Therefore, the present outcome cannot be simply transferred to the wide field of urine drug testing. However, the response rate of the questionnaires with over 80% of the male staff members in phase 1 and more than 60% of women and men in phase 2 can be rated as good to very good. Thus, the result is to be considered to be representative at least of the situation of the participating clinic. Moreover, the age distribution in both phases allows the conclusion that the majority of participants had long-term working experience and accordingly sufficient experience with urine sample collection. Since supervised urine sample collection causes comparable pressure and harm to the clients in different settings [13.15.19] we feel that the PEG-marker system is superior regardless of the setting. To substantiate this statement, further studies are encouraged including the financial implications of avoiding analysis of substituted and thus invalid urine samples

5. CONCLUSION

From the point of view of the acting supervisors, the marker system improves drug screenings at all levels. Employees have more time to carry out their actual duties, safety with respect to manipulations increases, and the psychological stress is significantly reduced on both sides.

CONSENT AND ETHICAL APPROVAL

As per university standard guideline participant consent and ethical approval has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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APPENDIX A

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APPENDIX B

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4.	How often of	did you	persona	lly use th	ie marke	r syste	em in the	last 3 mor	nths?		
	t all □	1-10	•		-20 □		21-30		> 30 []	
	Did you also marker?	o perfo	rm direct	observa	tion prior	to the	test pha	se with the	-	es	no
6.	Direct obserperformed by time require	by only	one pers								rd to
not at	all 🗆	a little	e 🗆	not	iceably [strongly	<i>,</i> \Box	very st	rongl	y 🗆
prefer dire correspon	ase assess of the control of the con	ion the uivalend	strongest ce of both	t and 10 h procedi	if you proures:	efer ma	arker tes	ting the str	rongest.	5	
direct	observation	1							mark	er sy	stem
0 🗆	1 🗆 🗎	2 🗆	3 🗆	4 🗆	5 🗆	6 □	7 □	8 🗆	9 🗆	10	0 🗆
8. direct	Which meth		ould you p	orefer per	rsonally	with re		,		er sy	
	1		1 -	1	1 -					<u> </u>	
9.	In your opin	cal stre		nod woul	d the pa	tient pr	refer with	regard to			
	observation					T				er sy	
0 🗆	1 🗆 🗎	2 🗆	3 □	4 🗆	5 🗆	6 🗆	7 🗆	8 🗆	9 🗆	10	0 🗆
10.	Which meth collection?		you prefe	er in term	ns of the	time re	equired to	o perform	urine sa	mple	
direct	observation								mark	er sy	stem
0 🗆	1 🗆 🗎	2 🗆	3 □	4 🗆	5 🗆	6 □	7 □	8 🗆	9 🗆	10	0 🗆
(http://creativ	m et al.; This is vecommons.org original work is	g/license:	es/by/4.0), v								
	Т		er review i o://www.se	history fo		aper ca	n be acc	essed here 1/27160	e:		

12