Legal and Ethical Impacts of COVID-19 on the Practice of Occupational Medical Practitioners

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Medicines and Related Substances Act (Act No 101 of 1965)
Hazardous Substances Act (Act No 15 of 1973)

• SAHPRA (SA Health Products Regulatory Authority), with role of both Medicines Control Council and of Directorate of Radiation Control = independent entity reporting to National MoH

• SAHPRA regulates in vitro diagnostics as Class D: COVID-19 test kits may only be manufactured, imported, exported or distributed/sold at wholesale level by SAHPRA-licensed medical device establishments

• Abbott IgG SARS -CoV -2 assay was approved by SAHPRA on Friday 14-8, pending guidance of testing by a DOH algorithm....unfortunately SAHPRA retracted approval on Monday 17-8

• Labs also need SAHPRA clearance, before they can offer testing
Legal Impacts of COVID-19 on the Practice of OMPs

• Does the health establishment you are in charge of conform to the Regulations relating to Notifiable Diseases?

• Does/Can the health establishment you are in charge of conform to DM Regulations for employers: e.g. 24 h dedicated services, EAP

• Are responsible persons designated, including the extension of the scope of nurses in occupational health establishments?

• Does the health establishment you are in charge of conform to the DOH COVID-19 IPC standards?

• How does the OMP deal with colleagues/employees who do not follow DOH COVID-19 standards?

• How does the OMP deal with ‘legal’ requirements which may not stand up to (legal and/or ethical) scrutiny: vulnerable employees, obligatory testing, reporting social COVID cases etc.
Ethical Impacts of COVID-19 on the Practice of Occupational Medical Practitioners

Dr. JNR Lapere
1. Bioethics paradigms in ‘Codes’, ‘Rules’ or ‘Guidelines’ (HPA S 61A)
2. Ethical framework applied to novel circumstances in ethical decision making
3. But is framework adequate?
   • Frontline workers working with inadequate PPE. Do employees shift limits of professional and ethical obligations? What are the ethical obligations of their employers?
   • Triage policies for admission, ICU, ventilator use?
   • Research and fast tracking of therapies?
   • Use of artificial intelligence?
   • Vaccine hesitancy?

Sources Guest Editorial COVID-19: Advancing Empirical Bioethics Research Connie M. Ulrich, Emily E. Anderson & Jennifer K. Walter Published online: 13 Jul 2020
1. “Dominant bioethics paradigms neglect OH
   1. Focus on individual dr-patient relationship
   2. Tendency to ignore contextual resource issues and institutionalised discrimination
   3. OH more oriented to groups; to prevention
2. Ethical codes alone may be insufficient to protect human rights
3. Rights seen as one of many competing ethical concepts”

Source: ‘Dual Loyalties: Ethical and human rights obligations of occupational health professionals. By Prof Leslie London, Centre for Occupational & Environmental Health Research, School of Public Health & Family Medicine, University of Cape Town
SARS-CoV-2 ethics HPCSA guidance to health practitioners

1. “HPCSA professional standards framework should be adhered to as far as it is practical in these circumstances”

2. “..practitioners may be required to depart from their established procedures, although this should be done responsibly, reasonably and in the best interest of patients”
SARS-CoV-2 and bioethics

- Doctor-patient relationship
- Consent, vulnerability, and/or coercion
- Psycho-social care for patients
- Comorbidity issues
- Law versus ethics
- Dual loyalty
- Colleagues
- Occupational disease
- Testing and screening
- Clinical research ethics
- ‘Telehealth’
Core ethical values and standards

1. Respect for persons
2. Non-maleficence
3. Beneficence
4. Human rights
5. Autonomy
6. Integrity
7. Truthfulness
8. Confidentiality
9. Compassion
10. Tolerance
11. Justice
12. Professional competence and self-improvement
13. Community
Ethical reasoning

1. Define issue at hand
2. Gather information and consult authoritative sources
3. Consider options
4. Make a moral assessment
   1. What are the likely consequences of each option?
   2. What are the most important values, duties, and rights?
   3. Which weighs the heaviest?
   4. What are the weaknesses of the health care practitioner’s individual view concerning the correct option?
   5. How would the health care practitioner himself or herself want to be treated under similar circumstances?
   6. How does the health care practitioner think that the patient would want to be treated in the particular circumstances?
5. Discuss proposed solution with those whom it will affect
6. Act on decision with sensitivity to others affected
7. Evaluate decision and be prepared to act differently in the future
1. “HPCSA professional standards framework should be adhered to as far as it is practical in these circumstances”
2. “..practitioners may be required to depart from their established procedures, although this should be done responsibly, reasonably and in the best interest of patients”
Suspected infection

1. From the moment COVID-19 is suspected, PUI should be isolated, and infection control measures immediately instituted
2. Only PUI should be tested
SARS-CoV-2 ethics HPCSA guidance to health practitioners

Personal protective equipment: Should PPE not be available

1. Information on what to do may be sought from the NICD’s clinical guidance (*COVID-19 Disease: Infection Prevention and Control Guidelines Version 2 (21st May 2020)*)

2. Factors to consider:
   1. Whether treatment can be delayed
   2. Whether additional steps can be taken to minimise risk of transmission
   3. Prioritisation of practitioners at higher risk of infection
   4. Identification of action likely to result in least harm under circumstances

3. Practitioners should bring concerns regarding their conditions of work and risk to their health, to attention of employers, HPCSA or Office of Health Standards and Compliance as soon as possible
HPCSA *General* Ethical Guidelines for good practice in Telemedicine

1. Practitioner responsible for treatment, decisions, recommendations, keeping detailed records
2. Documented medical evaluation (clinical history, underlying conditions, contra-indications) must be obtained before providing treatment
3. Treatment based solely on online questionnaire is not acceptable standard of care
4. Informed consent same as in standard practice for face-to-face consult
5. Telemedicine restricted to instances with existing healthcare-patient relationship
6. Quality and safety of patient care must not be compromised and the best available resources are used in securing and transmitting patient information
HPCSA COVID-19 Ethical Guidelines for good practice in Telemedicine

1. HPCSA hereby permits the use of Telehealth
2. Practitioners may charge a fee
3. Telehealth is restricted to established practitioner-patient relationship
4. Telephone and/or virtual consultations for new patients is discouraged
5. Where practitioners are in doubt whether a telehealth consultation will be in best interest of patient, they are encouraged to advise patients to present themselves for face-to-face consultation to seek assistance at health care facility closest to them
6. Revised Telehealth provisions only applicable during COVID-19 pandemic
Conditions for a Practitioner to divulge information regarding a patient

1. In terms of a Statutory provision
2. At the instruction of a court
3. In the public interest (e.g. persons prone to harm as result of risk related contact)
4. With consent of the patient
Disclosures for notifiable disease or to endangered third parties

1. Practitioners to seek express consent before disclosing information

2. If all available means of obtaining consent have failed
   1. Personal information may be disclosed in public interest where benefits to individual or to society of the disclosure outweigh public and patient's interest in keeping the information confidential, (e.g. partner of HIV positive patient, who after counselling refuses to disclosure status to partner; e.g. notifiable disease reporting)
   2. Practitioner must weigh possible harm (to patient, and overall trust between practitioners and patients) against benefits that are likely to arise from the release of information (e.g. employee with health condition posing danger to co-workers or clients)
Disclosures for reporting to authorities

1. Practitioners must co-operate by providing relevant information wherever possible
2. Notification of some communicable diseases is required by law
3. In other cases, practitioners to provide anonymised form, when that would be sufficient
4. Where it is not practicable to seek consent, practitioners must consider whether disclosure would be justified in the public interest, against possible detriment to patient
5. Automatic transfer of personal information to registry before informing patient is unacceptable, save in exceptions (e.g. court decision)
SARS-CoV-2 and Doctor-patient relationship: confidentiality

Disclosures where health care practitioners have dual responsibilities

1. Disclosure to employer with whom the practitioner has contractual obligations

2. Patient to be told at the earliest opportunity about:
   1. Purpose of disclosure
   2. Extent of information to be disclosed
   3. The fact that relevant information cannot be concealed or withheld

3. Practitioners to show form and ensure patient understands scope of information requested

4. Obtain, or have seen, written consent to disclosure from patient

5. Disclose only information relevant to request for disclosure

6. Practitioners must check whether patients wish to see report

7. Disclosures without patients’ consent to employers can be justified only in exceptional circumstances (e.g. to protect others from risk of death or serious harm)
SARS-CoV-2 and Doctor-patient relationship: confidentiality

Disclosure without consent to protect the patient or others

1. Disclosure where failure to do so may expose patient or others to risk or death or serious harm
2. Where third parties are exposed to risk so serious that it outweighs patient's right to confidentiality
3. Practitioners should seek consent to disclosure where practicable
4. Practitioners should generally inform the patient before disclosing the information

E.g. A colleague who is placing patients at risk – first should consult experienced colleague, or seek advice from a professional organisation
OMP & Vulnerable employees: HBA- vs Psychosocial risks

1. Medical ethics define:
   1. Permissibility of the release of information to the employer
   2. Duties and obligations of the OMP
2. Workers’ informed consent
3. Protection of confidential information
4. Acceptable method of providing information to employer
5. OMP may be required to disclose information for specific statutory requirement
6. The OMP must not disclose personal information without express and written consent
OMP & Vulnerable employees: communication duty

1. Process and purpose of the examination, screening or test
2. Uncertainties and risks attached to the process
3. Any significant medical, social or financial implications
4. Follow up plans, including the availability of counselling and support services
5. Extent of the information which will be disclosed
6. Likely consequences of the disclosure
7. To whom will the information be given
8. OMP’s duty to ensure that the worker understands the scope of the information requested
9. OMP must check whether workers wish to see report and then share report with workers
OMP & Vulnerable employees: worker autonomy

1. OMP to respect worker’s autonomy and right to voluntary decision-making: worker to determine what is in the workers’ best interests
2. OMP to give a balanced view of the options
3. Substance of the information given to the employer
   1. Only information relevant to COVID-19 vulnerability
   2. OMP must, always, be able to substantiate factuality
4. Know that pressure may be put on workers by employers
OMP & Vulnerable employees: worker constraints

1. If worker withholds consent: OMP to attempt to persuade the worker to consent
2. If consent refused: consequences should be explained to worker
3. Exceptional circumstances in which disclosure without consent could be permissible would include an instance where the disclosure protects the worker or others or can be justified in the public interest
1. How to deal with ‘health’ reporting duties of employers?
2. How to deal with blatant contradictions: permissible taxi occupation, ‘gathering’, testing..?
3. How to deal with ‘policing-function’ of the OMP?
4. Public queries: HPCSA Guidance to health practitioners, COVID-19 outbreak in South Africa: ‘Practitioners are advised to refer to NICD FAQ when attending to queries from the public’
5. **Query:** Opinions of non-OMP’s address the above and then public/community priorities override occupational health practices as defined by DMR/DoEL because of non-historical governmental guidelines – Disaster versus Occupational Health ethics. and
SARS-CoV-2 and Bioethics: dual loyalty in OH

1. Dual loyalty is an ethical and Human Rights dilemma if there:
   1. Is simultaneous obligation to third party
   2. Obligations are incompatible
   3. There is pressure on the OMP
   4. The OMP’s skill is made to serve a social role

2. Dual loyalty exacerbated by employment contract, role conflict, bias, institutional discrimination, etc.
SARS-CoV-2 and Bioethics in OH
Social COVID-19 versus Work-acquired COVID-19

1. Occupational disease ethics: no presumption?
2. Benefits: social self-quarantine versus work-acquired self-quarantine
3. Testing and screening queries
   1. Should the OMP oblige where employers demand asymptomatic employees to be tested?
   2. Or COVID-healed employees to be tested prior to RTW?
   3. Or contractor-employees to be tested prior to being allowed access on site?
Query: How to deal with sick certificates ‘influenza, but not COVID’, where the employee was not PCR tested?

Query: How to deal with ‘special COVID-19 medicine mixtures’ prescribed/dispensed by GP?

Query: How to deal with consulting expert OMP (vs. clinical OMP)
1. OMP work capacities: therapeutic relationship, impartial examiner, researcher, advisor
2. All parties must be aware of, and understand the practitioner’s role
3. Even in such a role, ethical practice required

Source: ‘Dual Loyalties: Ethical and human rights obligations of occupational health professionals’. By Prof Leslie London, Centre for Occupational & Environmental Health Research, School of Public Health & Family Medicine, University of Cape Town
SARS-CoV-2 and Bioethics in OH

The end