Checklists on Corruption Risks in the Healthcare Sector

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Content

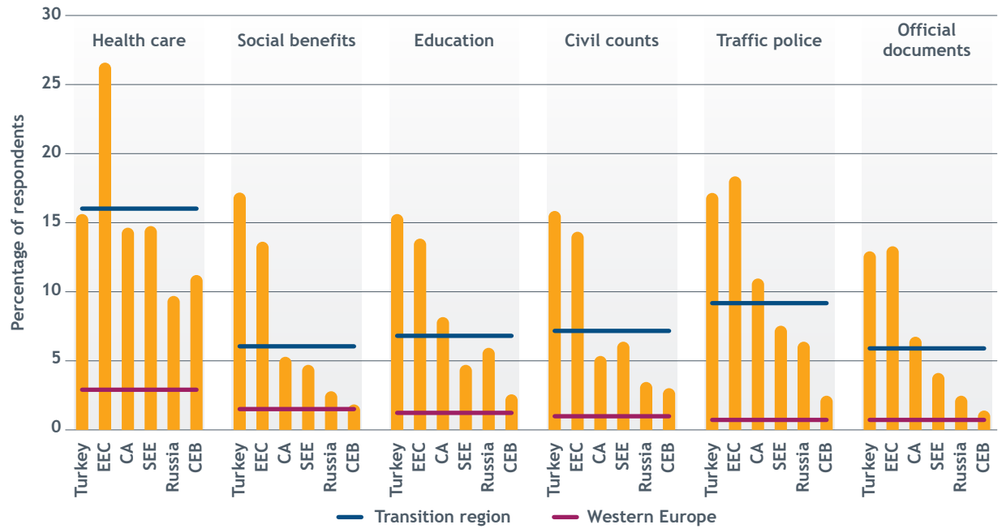
1. Health sector corruption

1.1. Overview

The health sector is a very complex and **challenging sector** for preventing corruption. It contains many stakeholders: hospitals, outpatient care providers, pharmacies, laboratories, drug producers, researchers, medical schools, licensing and oversight institutions, etc. It also consists of a myriad of processes, from hospital treatments, to clinical trials, to the approval of drugs, to organ transplants. At the same time, there is a significant **imbalance of information** – most people neither understand the biomedical complexities nor are able to judge what a "right" decision is medically or what risks a drug may carry.

52% mentions)".[1] This compares to a share of 24% in the 15 already existing Member States.[2] A 2016 survey among 30 countries in transition finds the health sector to rank first in terms of perceived corruption, both for European Union as well as for transition countries:[3]

By comparison, a recent survey by the European Union (2017)[4] shows a rather low average of informal payments in **EU Member States**. On average, 4% answered "yes" to the question "Apart from official fees did you have to give an extra payment or a valuable gift to a nurse or a doctor, or make a donation to the hospital?"



Source: LiTS III (2016).

Note: "Perceived corruption" refers to the proportion of respondents in each country who say people like themselves usually or always have to make unofficial payments or gifts while interacting with a given public service.

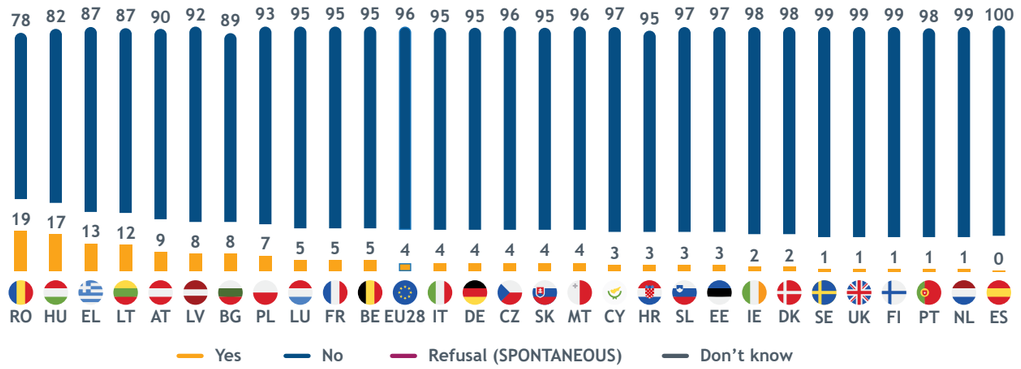
So it comes as no surprise that the health sector is among the **most corrupt** in probably all countries, in particular in countries in transition. For example, citizens of the 12 Member States that joined the European Union in 2004 and 2007 "rate people working in the public health sector as poorly as national politicians (ranked equally worst with

[1] Eurobarometer 2012, page 42, http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_374_en.pdf.

[2] Ibid, page 10.

[3] EBRD, Life in Transition Survey III, 2016, page 29, www.ebrd.com/what-we-do/economic-research-and-data/data/lits.html.

4 European Commission (2017), Special Eurobarometer 470, p. 84, http://open-data.europa.eu/en/data/dataset/S2176_88_2_470_ENG.



Variations and schemes of health sector corruption are endless. The following are selected stories that illustrate how various stakeholders can be involved in health sector corruption:

Hospitals

A patient first visits the physician in his/her private clinic and pays him/her through private insurance as well as via under-the-table payment (i.e. double payment). Once the physician is paid, the patient is admitted directly to the public hospital and he/she is placed higher on the waiting list. Hence, by visiting the physician in a private clinic, waiting lists in public hospitals are bypassed (Greece, Romania and Poland).[5]

One prominent U.S. hospital chain had paid physicians for patient referrals to the hospitals, funnelling of patients to affiliated home-health services even when the patients preferred another provider, setting performance targets in terms of 'complication rates' (which justify higher levels of reimbursement from public insurances), hiding paperwork and accounts from government auditors, and false billing. The hospital chain settled in the 1990s for a sanction of US$ 1 billion.[6]

Outpatient providers and laboratories

A U.S. physician admitted getting monthly cash bribes of roughly US$ 3,300 from employees of a biodiagnostic laboratory. He also periodically solicited and received several meals and tickets to entertainment and sporting events that cost thousands of dollars. In exchange, the physician referred patient blood samples to the lab, which generated about US$ 909,000 in business for the lab.[7]

Pharmacies

Pharmacies in the U.S. have been found paying illegal kickbacks to physicians for writing prescriptions. In one case, the FBI and other police agencies raided nine pharmacies and seized more than US$ 15 million in assets. Several pharmacies agreed to pay millions to settle civil allegations that they had improper financial relationships with doctors.[8]

Organ transplants

In one case from Brazil, a liver was about to be made available for the highest-ranking patient on the national waiting list for organ transplants. However, the entitled patient was never informed and the liver never reached him. Instead, by circumventing the rather lax monitoring system, the liver was flown in a private jet 1,000 km to another city, hauled to a private clinic involved into the corruption scheme, and implanted into the brother of a local famous movie director.[9] The actual recipient suffered from advanced liver cancer and was thus by law not eligible for a liver transplant (due to the high risk of reoccurrence).

[5] European Commission, Updated Study on Corruption in the Healthcare Sector, Final Report, September 2017, p. 147, https://ec.europa.eu/home-affairs/sites/homeaffairs/files/20170928_study_on_healthcare_corruption_en.pdf.

[6] Transparency International, Global Corruption Report 2006: Corruption and health, page 20, www.transparency.org/whatwedo/publication/global_corruption_report_2006_corruption_and_health.

[7] Pharmacy Choice (22 December 2015), Bribery probe nets $12M and more than 2 dozen doctors, www.pharmacychoice.com/News/article.cfm?Article_ID=1489485.

[8] Dallas News (February 2016), North Texas pharmacy in federal probe is accused of paying kickbacks to doctors, www.dallasnews.com/investigations/20160205-north-texas-pharmacy-in-federal-probe-is-accused-of-paying-kickbacks-to-doctors.ece.

[9] OECD/ACN, Expert Seminar "Effective Means of Investigation and Prosecution of Corruption" (2010), Proceedings of the Seminar, page 76, www.oecd.org/corruption/acn/47588859.pdf.

Research

More than half of the scientists involved in the U.S. testing of a type-II diabetes drug had received funding or other compensation from its manufacturer. The drug was fast-tracked through Food and Drug Administration approval in 1997 on the basis of their research. Three years later it was withdrawn from the market when it was shown to have caused liver failure in at least 90 patients. Newspaper reports and academic commentaries expressed concern that the financially conflicted scientists may have concluded that the drug was safer and more effective than the evidence warranted.[10]

Licenses and permits

In Croatia, one of the world's biggest pharmaceutical companies admitted to bribing Croatian doctors working for state bodies in charge of drug registration, paying the physician in cash and travel expenses.[11]

Medical guidelines

The head of the advisory diabetes expert group in Slovakia makes recommendations and takes part in the final vote on whether to approve a drug for coverage. He received almost 28,000 euros for consulting services from four pharma companies, among which were companies whose drugs the head reviewed positively.[12]

In a survey of two hundred U.S. expert panels that issued practice guidelines for doctors, one third of the panel members acknowledged that they had some financial interest in the drugs they considered.[13] One example: In 2004, after the U.S. National Cholesterol Education Program called for sharply lowering the desired levels of "bad" cholesterol, it was revealed that eight of nine members of the panel writing the recommendations had financial ties to the makers of cholesterol-lowering drugs.[14]

Marketing

Serbian pharmaceutical companies were bribing doctors to prescribe their cancer treatment drugs over those of competitors, even when they were not needed for patient treatment.[15] One major U.S. pharmaceutical company was charged with giving kickbacks to doctors and hospital workers in China who prescribed its medicines. In 2014, the company paid a nearly US$ 500 million fine, at the time the largest ever in China for a multinational. Five senior executives in China pleaded guilty, including the head of Chinese operations.[16]

Education

In a first-year pharmacology class at a top medical school in the U.S., one student grew wary as the professor promoted the benefits of cholesterol drugs and seemed to belittle a student who asked about side effects. The student later discovered something by searching online that he began sharing with his classmates. The professor was not only a full-time member of the medical faculty, but a paid consultant to 10 drug companies, including five makers of cholesterol treatments. The incident grew into a full-blown movement by more than 200 students and sympathetic faculty, intent on exposing and curtailing the industry influence in their classrooms and laboratories, as well as in the medical school's 17 affiliated teaching hospitals and institutes.[17]

Political and parliamentary oversight

In one of the Cantons of Bosnia and Herzegovina, the three main pillars of the Canton's health care

[10] The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns (2008), Chapter 7, Conflict of Interest in Biomedical Research, page 33, www.thehastingscenter.org/wp-content/uploads/Conflict-of-Interest-BB7.pdf.

[11] BalkanInsight (8 August 2012), Pharmaceutical Giant Settles Bribe Cases, www.balkaninsight.com/en/article/pharmaceutical-giant-settles-bribe-cases.

[12] Transparency International, Pharma companies in Slovakia: Uncovering conflicts of interest (9 December 2016), http://blog.transparency.org/2016/12/09/more-transparency-of-pharma-companies-helps-uncover-conflicts-of-interests/.

[13] Rosie Taylor and Jim Giles, Cash Interests Taint Drug Advice, Nature 437, 1070 (20 October 2005), www.nature.com/nature/journal/v437/n7062/full/4371070a.html (limited access).

[14] New York Times (20 July 2004), Seeking a Fuller Picture of Statins, www.nytimes.com/2004/07/20/health/seeking-a-fuller-picture-of-statins.html; quoted after The New York Review of Books/Marcia Angell (15 January 2009), Drug Companies & Doctors: A Story of Corruption, www.nybooks.com/articles/2009/01/15/drug-companies-doctorsa-story-of-corruption/#fn-11.

[15] Transparency International, Lives on the line as Serbia battles healthcare corruption, 22 December 2014, http://blog.transparency.org/2014/12/22/lives-on-the-line-as-serbia-battles-healthcare-corruption/).

[16] New York Times (1 November 2016), Drug Giant Faced a Reckoning as China Took Aim at Bribery, www.nytimes.com/2016/11/02/business/international/china-rules-glaxo-bribes-sex-tape-whistleblower-cautionary-tale.html?_r=0.

[17] New York Times (2 March 2009), Harvard Medical School in Ethics Quandary, www.nytimes.com/2009/03/03/business/03medschool.html?hp&_r=0.

system – the University Clinical Centre, the Faculty of Medicine of the State University, and the Chamber of Doctors, came under the close control of a prominent member of a political party. Civil society has criticised that a "powerful network of the political party" has captured "the three main pillars of the health care sector".[18]

California law allowed hospitals to pass on to insurance companies the full cost it had paid for medical hardware it used during spinal surgeries. The owner of one hospital admitted that his hospital exploited this law, which was often called the "spinal pass-through". He used hardware that he purchased at highly inflated prices from companies that he controlled. He passed this cost along to insurance providers. The hospital owner bribed a Senator so that the Senator would use his public office to preserve this "lucrative" law.[19]

1.2. The financial damage

Financially, health care is one of the largest industries in the world. The total global **expenditure** for health amounted to US$ 6.5 trillion in 2012.[20] This equals to about 10 percent of the global GDP.[21] Governments fund much of its operations.[22]

As the Financial Action Task Force (FATF) noted "the **size** and **specialised** nature of the health sector makes it an attractive target for corruption. Corruption in the pharmaceutical and medical device sector can occur throughout all stages of the business chain, from research and development to dispensing and promotion. The large number of steps involved in producing and dispensing medical products allows for numerous opportunities for corruption."[23]

Transparency International and others estimate health-related corruption **losses** in the billions of dollars.[24] The losses occur on the level of public budget, private insurers, or individual patients. For example, an estimated 5-10% of U.S. public sector health expenditures are lost to fraudulent overbilling.[25] By contrast, in the Russian Federation an estimated 56% of total health expenditures are "informal" payments by patients.[26]

One can also conclude the financial dimension of health sector corruption from the size of **sanctions** handed to medical companies. For example, one pharmaceutical company had to pay US$ 2.3 billion for off-label promotion of five of its drugs.[27]

Beyond the financial loss, corruption impacts the **access** to and **quality** of health service: resources are wasted that could be used for research; prices for services or products may inflate; essential drugs and medical devices are not available; citizens who are not able to pay bribes are shunned off the system; patients are exposed to medical risks from wrong treatments or unsafe drugs; etc.

1.3. International standards and guidance

There is no international standard embracing all or most of the corruption risks in the health sector. None of the international anti-corruption standards specifically refers to the health sector, but they "only" contain general provisions against corruption (prevention, criminalisation, etc.). In the area of health-related standards, standards and guidance exist on some isolated aspects of the health sector.

[18] Transparency International (March 2018), The Case Study of the Capture of Sarajevo Canton's Health Care Sector, 20 pages, https://ti-bih.org/wp-content/uploads/2018/05/State-capture_-BH-Case_health-sector_Canton-Sarajevo.pdf.

[19] FBI (21February, 2014), California State Senator Ronald Calderon Charged with Taking Bribes in Exchange for Official Acts on Behalf of Hospital Owner and Independent Film Studio That was Actually an FBI Front, https://archives.fbi.gov/archives/losangeles/press-releases/2014/california-state-senator-ronald-calderon-charged-with-taking-bribes-in-exchange-for-official-acts-on-behalf-of-hospital-owner-and-independent-film-studio-that-was-actually-an-fbi-front; Reuters (13 June 2016), Ex-California lawmaker to plead guilty in corruption case: prosecutors, www.reuters.com/article/us-california-lawmaker-corruption-idUSKCN0YZ2F1.

[20] WHO, Spending on health: A global overview, Fact sheet No. 319, April 2012, www.who.int/mediacentre/factsheets/fs319/en/.

[21] Deloitte, 2016 Global health care outlook, page 7, https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2016-health-care-outlook.pdf.

[22] Ibid.

[23] FATF (2013), Best practices paper, The Use of the FATF Recommendations to Combat Corruption, at no. 60, www.fatf-gafi.org/media/fatf/documents/recommendations/BPP-Use-of-FATF-Recs-Corruption.pdf.

[24] Transparency International, Global Corruption Report 2006: Corruption and health (note 4), page 25.

[25] Mackey and Liang, Combating healthcare corruption and fraud with improved global health governance, BMC International Health and Human Rights 2012, 12:23, page 2, www.ncbi.nlm.nih.gov/pmc/articles/PMC3519514/pdf/1472-698X-12-23.pdf.

[26] Ibid.

[27] Department of Justice (2 September 2009), Justice Department Announces Largest Health Care Fraud Settlement in Its History, www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history.

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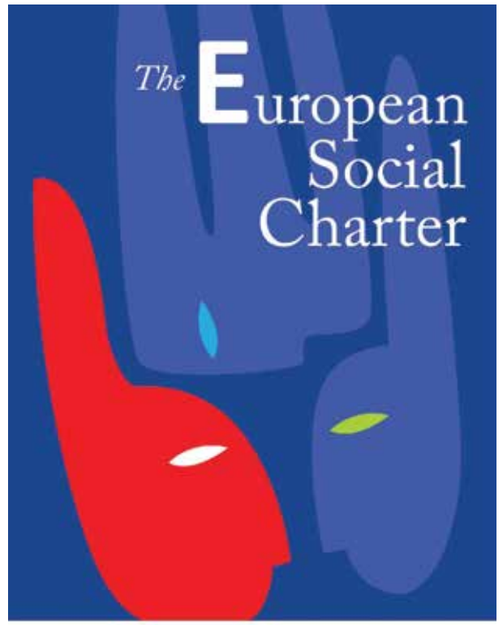
International Conventions and Recommendations

The Council of Europe's "European **Social Charter**" generally states that "everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable."[28] The Charter echoes the wording of Article 12 of the United Nation's "International Covenant on Economic, Social and Cultural Rights" of 1966.[29] Without the Charter, its Explanatory Report, or the International Covenant explicitly stating this, corruption is one factor that can infringe the stated right.

On a more specific level, the Council of Europe "Convention on Human Rights and **Biomedicine**"[30] of 1997 contains provisions in Chapters V and VI that protect persons undergoing research or organ transplantation from abuse of power or conflict of interest violations without specifically referring to these terms. One should also mention in this context the World Medical Association (WMA) "Declaration of Helsinki – Ethical Principles for **Medical Research** Involving Human Subjects" (1964).[31]

The Council of Europe "Recommendation Rec(2001)13 of the Committee of Ministers to member states on developing a methodology for drawing up guidelines on **best medical practices**"[32] contains provisions on the independence and transparency of the process. Even though the Recommendation does not explicitly refer to corruption, independence and transparency are important in preventing it.

Academic authors have called for developing "an international **binding treaty** protocol on global health corruption and establishing the necessary global health governance framework".[33] However, so far no respective effort appears to be underway.



Resolutions

The Council of Europe Parliamentary Assembly Resolution 1946 (2013) on "Equal access to health care" calls on member States to "introduce measures to combat corruption in the health sector, in close co-operation with the Group of States against Corruption (GRECO)".[34] So far GRECO has not made health sector corruption a topic of its evaluation rounds.

Guidance

International organisations and NGOs have issued handbooks on selected health related issues, which also expressly or impliedly provide guidance on aspects of integrity and corruption:

- Council of Europe (2014), Prison health care and medical ethics, 87 pages;[35]
- Council of Europe (2012), Guide for Research Ethics Committee Members, Steering Committee on Bioethics, 55 pages;[36]

[28] Part 1 no. 11. ETS 163, European Social Charter (Revised) Strasbourg, 3 May 1996, first and revised versions of 1961 and 1996, www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf93.

[29] Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966.

[30] Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (ETS 164), www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf98.

[31] As last amended in 2013, www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (emphasis by author).

[32] Recommendation Rec(2001)13 adopted by the Committee of Ministers of the Council of Europe on 10 October 2001.

[33] Mackey and Liang (note 20), page 3 (emphasis by author).

[34] At no. 6.6, http://assembly.coe.int/nw/xml/XRef/Xref-XML-2HTML-en.asp?fileid=19991&lang=en.

[35] www.coe.int/t/dgi/criminallawcoop/Presentation/Documents/Publications_HealthCare_manual_Web_A5_E.pdf.

[36] www.coe.int/t/dg3/healthbioethic/Activities/02_Biomedical_research_en/Guide/Guide_EN.pdf.

- Transparency International (2016), Corruption in the pharmaceutical sector, Diagnosing the challenges, 58 pages;[37]
- Transparency International (2016), Diagnosing corruption in healthcare, 32 pages;[38]
- UNDP (2011), Fighting Corruption in the Health Sector – Methods, Tools and Good Practices, 76 pages;[39]
- UNODC/WHO (2013), Good governance for prison health in the 21st century, 42 pages;[40]
- WHO (2002), Regulating entrepreneurial behaviour in European health care systems (English and Russian), 240 pages;[41]
- WHO (2011), Good Governance for Medicines programme: an innovative approach to prevent corruption in the pharmaceutical sector, 27 pages.[42]

1.4. State of research

Above mentioned handbooks aside, there is in particular the following international literature on corruption in the health sector:

- DfID (2010), Addressing Corruption in the Health Sector, 38 pages;[43]
- European Commission (2013), Study on Corruption in the Healthcare Sector, 331 pages;[44]
- European Commission (2017), Updated Study on Corruption in the Healthcare Sector, Final Report, 187 pages;[45]
- Institute of Medicine (2009), Conflict of interest in medical research, education, and practice, 436 pages;[46]
- Mackey and Liang (2012), Combating healthcare corruption and fraud with improved global health governance, 7 pages;[47]
- Transparency International (2006), Global Corruption Report 2006: Corruption and health, 378 pages;[48]
- USAID (2006), Procurement Strategies for Health Commodities, An Examination of Options and Mechanisms within the Commodity Security Context, 66 pages;[49]

The following reports are examples of specific assessments of parts of the health sector:

- CEMI (2013), Corruption Risk Assessment in the Healthcare System of **Montenegro**, 128 pages;[50]
- Council of Europe (2011), Risk Assessment: Corruption in the Health Sector in **Albania**, 42 pages;[51]
- Council of Europe (2009), Ethical Conduct in Health Services, in: Academic Researches on Public Ethics, Volume 2, Ethics for the Prevention of Corruption in **Turkey**, 160 pages (pages 402-562);[52]
- Transparency International **Italy** (2013), Corruption and Waste in the Health System, 96 pages;[53]
- U4 (2013), Addressing corruption through sector approaches: Exploring lessons from the **Moroccan** anti-corruption strategy for the health sector, Practice insight 2013:2, 15 pages;[54]

[37] www.transparency.org.uk/publications/corruption-in-the-pharmaceutical-sector/.

[38] http://www.transparency.org.uk/publications/diagnosing-corruption-in-healthcare/.

[39] www.undp.org/content/undp/en/home/librarypage/democratic-governance/anti-corruption/fighting_corruptioninthehealthsector.html.

[40] www.who.int/hiv/pub/prisons/prison_health/en/.

[41] www.euro.who.int/en/about-us/partners/observatory/publications/studies/regulating-entrepreneurial-behaviour-in-european-health-care-systems-2002.

[42] www.who.int/healthsystems/topics/financing/healthreport/25GGM.pdf.

[43] www.dfid.gov.uk/Documents/publications1/How-to-Note-corruption-health.pdf.

[44] https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-is-new/news/news/docs/20131219_study_on_corruption_in_the_healthcare_sector_en.pdf.

[45] https://ec.europa.eu/home-affairs/sites/homeaffairs/files/20170928_study_on_healthcare_corruption_en.pdf.

[46] www.nap.edu/catalog/12598/conflict-of-interest-in-medical-research-education-and-practice.

[47] https://bmcinthealthhumrights.biomedcentral.com/articles/10.1186/1472-698X-12-23.

[48] www.transparency.org/whatwedo/publication/global_corruption_report_2006_corruption_and_health.

[49] http://pdf.usaid.gov/pdf_docs/Pnadh233.pdf.

[50] http://cemi.org.me/en/product/english-corruption-risk-assessment-in-the-healthcare-system-of-montenegro/.

[51] www.bu.edu/actforhealth/Risk%20Assessment/Vian_2011_Risk_Assessment2_Albania.pdf.

[52] https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016806ee055.

[53] www.transparency.it/corruption-and-waste-in-the-health-system/.

[54] www.u4.no/publications/addressing-corruption-through-sector-approaches-exploring-lessons-from-the-moroccan-anti-corruption-strategy-for-the-health-sector/.

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- UNDP (2014), Corruption Risk Assessment in the Health Sector in **Kosovo***, 36 pages;[55]
- USAID (2005), **Armenian** Reproductive Health System Review: Structure and System Inefficiencies that Hinder Access to Care for Rural Populations, 50 pages;[56]
- USAID (2005), Governance in **Bulgaria's** Pharmaceutical System, A Synthesis of Research Findings, 83 pages;[57]
- USAID (2005), Analytical Paper on Corruption in the Health Sector (**Azerbaijan**), 43 pages.[58]

[55] www.ks.undp.org/content/kosovo/en/home/library/democratic_governance/saek-corruption-risk-assessment-in-health.html.

[56] http://pdf.usaid.gov/pdf_docs/Pnadp127.pdf.

[57] http://pdf.usaid.gov/pdf_docs/Pnadf523.pdf.

[58] http://pdf.usaid.gov/pdf_docs/Pnadp872.pdf.

* *This designation is without prejudice to positions on status, and is in line with UNSC 1244 and the ICJ Opinion on the Kosovo Declaration of Independence.*

2. INSTRUCTIONS ON THE CHECKLISTS

2.1. Objective

As shown above, there are several handbooks on various aspects of preventing and controlling corruption in the health sector. Similarly, risk assessments have been conducted covering one or several parts of the health sector. However, the handbooks or risk assessment reports do not immediately translate into a checklist which practitioners can use to **reciprocate** the assessment in another jurisdiction. In other words, there is yet no **overall checklist** for risk assessments in the health sector combining all major stakeholders and processes. Such a checklist would need to provide questions for each process and would need to universally apply to the health system in any given society.

With these Checklists it is intended to close this gap. **"Risk assessment"** in the sense of this document means: Reviewing whether there is a full set of controls in place, to minimise the risks for corruption. In other words: Where are possible gaps in the integrity framework? Thus, risk assessment does not mean quantifying or prioritising which risk or which part of the health sector is most prone to corruption.

The comprehensive approach does not mean that one has to conduct the risk assessment in the entire health sector. However, having the **entire** health sector in perspective allows the reader to make an informed decision: What questions would the risk assessment look at if conducted in this part?

Obviously, the Checklists can only provide a basic set of questions providing the **direction** into which one should look. One needs to **tailor** the questions to the specific circumstances and needs to exercise close scrutiny of all **details** in legislation and practice linked to each question.

2.2. Defining "Health Sector"

2.2.1. What is included?

"Health sector" is a broader term than "health care" or "health services". The term "consists of organized public and private health services (including health promotion, disease prevention, diagnostic, treatment and care services), the policies and activities of health departments and ministries, health related nongovernment organizations and community groups, and professional associations."[59] Thus, the following are the main stakeholders of the health sector:

- Hospitals;
- Outpatient health care providers;
- Laboratories;
- Pharmacies;
- Health insurers;
- Producers of pharmaceuticals and medical devices;
- Medical schools and training institutions;
- Oversight and licensing bodies;
- Interest groups.

All above stakeholders are **financed** by various sources depending on the given system (general taxation; social health insurance; voluntary or private health insurance; out-of-pocket payments; donations to charities). These Checklists apply to any health sector, no matter what the specific financing pattern is in any given jurisdiction.

Equally, most of above stakeholders or processes can be **private** or **public**, such as private or public hospitals. Again, these Checklists apply in principle, no matter whether the stakeholder or process is private or public, and how they are financed. Obviously, certain corruption risks are less prevalent for private stakeholders. For example, informal payments for admission to a public hospital are more likely to occur than in a private hospital. In public hospitals, often more patients compete for admission than a public hospital can handle at one time; private hospitals are profit-oriented, will want patients to seek treatment, and less patients can afford their care anyhow. However, in particular **conflict of interest** is an issue affecting public and private health care providers equally (e.g. financial incentives by pharmaceutical companies paid to doctors for giving preference to certain drugs).

2.2.2. What is not included?

One stakeholder that is generally important for the health sector is not important in the context of corruption: **insurers**. They lose billions of Euros each year to irregularities, however not to corruption, but to fraud.[60] Fraud is not corruption, and it is not included in this methodology (see below "Defining Corruption"). This also concerns systems in which the State is by and large the insurer if only by providing a national health service. However, any corruption risk assessment needs to keep the insurance scheme in mind, as it might set **perverse incentives** for diagnosing patients as more sick than they actually are. For example, in Germany insurance companies providing health insurance as is mandatory under German law were entitled to extra lump sums from a public health fund for every patient with certain grave diseases. The purpose of the fund is to compensate insurers who happen to take on more "high risk" patients than other insurers. Some insurance companies sent consultants who would advise doctors on how to aggravate their diagnosis. Doctors as well would get more money if their patients formally suffer from more serious diseases. The case caused a scandal followed by criminal investigations.[61]

The health sector turns over large amounts of money. There are many entry points along the financing chain (from ministries to local governments to the eventual health care units) where stakeholders could divert (embezzle) money from the public budget into private pockets. Sound **public financial management** is the main mechanism addressing this risk (including the planning, budgeting, and disbursal stage of financing). A public financial management system should apply and is usually in place across all sectors. It is thus not an issue specifically related to the medical sector. Thus, it is not part of this checklist. However, the internal financial management of hospitals is included, not least because of the risk stemming from cash transactions with patients.

There are particular corruption risks in **prisons**, since people are deprived of many liberties which citizens outside prisons enjoy.[62] However, corruption risks related to health care in prisons are rather related to the prison situation than to specifics of the health care. Furthermore, there is already guidance on "Prison health care and medical ethics" by the Council of Europe available.[63]

Doping in **sports** is related to medical care as well as to corruption. It is a special field of medical care and is mainly related to corruption in sports. It is therefore also excluded from these Checklists.

The **Global Fund** is an international funding mechanism created in 2001 to support public-private collaborations to fight HIV/AIDS, tuberculosis, and malaria. Until September 2015, the Global

[59] WHO (1998), Health Promotion Glossary, www.who.int/healthpromotion/about/HPG/en/.

[60] FBI, What We Investigate – Health Care Fraud: "Health care fraud costs the country tens of billions of dollars a year", www.fbi.gov/about-us/investigate/white_collar/health-care-fraud.

[61] German Economy Online (11 October 2016), Health insurance: allegations of fraud of TK-in-chief for Zoff, http://germaneconomyonline.blogspot.com.tr/2016/10/health-insurance-allegations-of-fraud.html; Die Zeit (11 October 2016), Wettbewerb mit falschen Kranken (in German), http://www.zeit.de/wirtschaft/2016-10/krankenkassen-krankenhaeuser-aerzte-patienten-betrug-abrechnungsbetrug.

[62] See the example from Serbia: „A dentist and his assistant working at the Nis prison were arrested and suspended for accepting bribes from a convict needing treatment" (Transparency International, Lives on the line as Serbia battles healthcare corruption, 22 December 2014, http://blog.transparency.org/2014/12/22/lives-on-the-line-as-serbia-battles-healthcare-corruption/).

[63] See above note 30.

Fund awarded more than US$27 billion that support more than 1,000 programmes in 151 jurisdictions.[64] On the national level, "Country Coordinating Mechanisms" including "Local Fund Agents" oversee disbursement. Corruption risks involving the diversion of money from the Global Fund are not an inherent feature of a certain health system, but rather of large-scale, multilateral financing programmes. They are thus not part of these Checklists.

Construction of medical buildings entails the general corruption risks related to the construction sector. Similarly, **privatisation** (e.g. selling public hospitals to private firms) is a corruption risk not specific to the medical sector. Both aspects are thus not covered by these Checklists.

2.3. Defining "Corruption"

The term "corruption" for the purpose of these Checklists derives from the following international standards:

- Council of Europe Criminal Law Convention on Corruption (ETS 173);[65]
- Council of Europe Recommendation (2000)10E 11 May 2000 on Codes of Conduct for Public Officials;[66]
- United Nations Convention against Corruption (UNCAC).[67]

2.3.1. What is included?

From the above standards, the following forms of corruption are relevant in the health sector:

- **Bribery** (for example informal payments for receiving treatments);
- **Embezzlement** (for example diverting hospital funds to private accounts);
- **Abuse of functions** (for example subjecting patients illegally to clinical trials);
- Abuse of **conflict of interest** situations (for example referring patients to other health care providers in which the referring doctor has a personal or financial interest);
- **Trading in influence** (a politicians receives a favour to use his/her influence over health sector officials).

All above forms of corruption are more or less equally important in the health sector. However, **trading in influence** is probably rather rare to prove. This offence requires that someone received an undue advantage in order to influence a public official. As the European Commission's "Study on Corruption in the Healthcare Sector" noted: "Decision-making processes are complex as many different actors [...] play a role. They all depend on each other's inputs. Parties influencing each other is a crucial and valued part of the decision making process. A conflict of interest might arise, but at the same time influencing a decision is of course not an illegal or undesired act in itself. In such a process it is difficult to determine if someone's really 'misused' his or her position to the benefit of others. In addition, it is not always clear if there is an actual link between the 'undue advantage' and someone's decision or influence."[68] However, trading in influence can be highly relevant in particular when it comes to licencing or to parliamentary oversight.

2.3.2. What is not included?

Fraud is prevalent phenomenon in the health sector and accounts for a substantial part of financial losses. In the U.S., health care fraud has been estimated to cost $60 billion per year, or 3% of total health care expenditures.[69] Fraud occurs for example where care providers invoice insurances for patients who do not actually exist or for services which were not actually rendered;[70] where patients deceive the care provider or the insurance about their identity or health status in order to obtain services; where pharmaceutical distributors deliver counterfeit drugs;[71] or where medical researchers present results based on fake evidence. However, these Checklists will not address fraud for the following reasons: None of the international anti-corruption conventions lists fraud as a form of corruption. Furthermore, health insurers have already been dedicating vast resources to the prevention and detection of fraud in the health sector in order to avoid financial losses. Finally, fraud would open a wide new field of risk patterns and countermeasures to be considered; it would thus simply overload an already complex task. Nonetheless, insofar fraud is directly linked to embezzlement by public officials, it is included into these Checklists (for example where a financial officer overbills the insurer and diverts the proceeds into his/her private pockets).

Medical care and research is full of **ethical** dilemmas. Under what circumstances are researchers allowed to remove organs from a living person for transplantation purposes? Should researchers be allowed to use cells from dead embryos? Should parents be allowed to choose a future child's sex? Answering above questions in a certain direction might colloquially be labelled as "corruption". However, for these Checklists, ethical violations beyond above mentioned technical forms of corruption are not considered corruption.

2.4. Larger context of health governance

As in any other sector, fighting corruption depends on the larger governance context. For the health sector, some of these issues are:

- To what extent do all citizens have health **insurance**?
- Is there a significant **shortage** of health services?
- Can patients choose between different health care providers (**competition**)?
- Are there **incentives** for health care providers to provide good service in return for public financing?
- Do low **wages** of medical staff create a motive for soliciting bribes?
- Are citizens in general "health literate" (**awareness** and education)?
- Do patients have enforceable **rights** towards insurances and health care providers and are these enforced in practice?

All these governance issues[72] are highly relevant for achieving any sustainable results in preventing corruption. However, including all these issues would go beyond the scope of these Checklists. This is even more so for the many factors outside the direct control of the health sector (level of democratic governance and rule of law, income, etc.) that can affect health sector corruption. The Checklists thus concentrate on core anti-corruption measures, which directly address in particular conflict of interest and bribery.

2.5. Structure

2.5.1. Clustering risks

For the purpose of these Checklists, corruption risk is defined as any factor facilitating the occurrence of corruption.[73] In other words, a risk is the absence of "legal and institutional arrangements [that] help to prevent or control corruption".[74]

One way of clustering risks could be around **forms** of corruption. The USAID has chosen this way in one of its handbooks on corruption risk assess-

[64] The Global Fund, www.theglobalfund.org/en/financials/.

[65] http://conventions.coe.int/Treaty/en/Treaties/Html/173.htm.

[66] https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016806cc1ec.

[67] www.unodc.org/unodc/en/treaties/CAC/.

[68] See above at note 39, page 95.

[69] Steve Musau, Taryn Vian, Fraud in hospitals, U4 Brief 2008:8, www.cmi.no/publications/3028-fraud-in-hospitals.

[70] U4 Brief, ibid; Association of Certified Fraud Examiners (2013), 10 popular health care provider fraud schemes, www.acfe.com/article.aspx?id=4294976280.

[71] DfID (2010), Addressing Corruption in the Health Sector, www.dfid.gov.uk/Documents/publications1/How-to-Note-corruption-health.pdf.

[72] For a general overview see: WHO, Good governance, Definition and mandate, www.who.int/healthpromotion/conferences/9gchp/good-governance/en/; Council of Europe, Health Policy, www.coe.int/t/dg3/health/default_en.asp.

[73] RCC (2015) "Corruption Risk Assessment in Public Institutions in South East Europe – Comparative Research and Methodology", page 18, www.rcc.int/pubs/30/.

[74] Council of Europe/Tilman Hoppe (2013), Designing and Implementing Anti-corruption Policies, Handbook, page 19, http://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016806db0d7.

ment.[75] It lists corruption risks and counter measures around the various forms of corruption, such as bribery, nepotism, etc.

This approach has one major disadvantage: People who are not corruption experts do not think in corruption offences; they think in terms of **everyday processes**, such as the admission to a hospital, the treatment, and the discharge. Even for corruption experts it is more natural to think this way. Furthermore, each process in the health sector has its own particularities that may induce corruption, and each stakeholder has its particular interests that point towards certain corruption risks. One needs to breakdown these processes for each stakeholder in order to obtain a sufficient degree of detail.

Therefore, these Checklists cluster corruption risks around the major **stakeholders** of the health sector (hospitals, drug producers, oversight bodies, etc.). For each stakeholder, there may be several main processes, such as there is in a hospital "patient care" and "procurement". For each main process, the checklist divides into a separate part.

In addition, there are two important **processes** within the health sector, which are not linked to a specific stakeholder, but which involve a varying set of contributors: research and medical guidelines (standard setting). Therefore, these Checklists also dedicate one checklist to each of these two processes.

By this approach of breaking down a complex case into stakeholders and processes, the Checklists follow the logic of the **RCC's "Corruption Risk Assessment** in Public Institutions in South East Europe - Comparative Research and Methodology" (2015).[76] The Checklists are thus a further concrete illustration of what a risk assessment could look like in a concrete sector.

2.5.2. Patterns of questions

Some of the above mentioned processes contain repeating patterns of risks. For example, committees take decisions on pharmaceutical licensing as well as on clinical trials - the risks in both cases are similar (conflict of interest, bribery, independence of the committee, etc.). Whenever the same or a similar pattern occurs, the same or similar set of questions applies. Some of these patterns are:

- Bribery risks;
- Conflicts of interest;
- Managing assets (inventory, medical supplies, etc.); Collegial decisions (advisory boards, licensing committees, etc.).

The risk and the related set of questions thus appear in more than one checklist. Most set of questions could apply to similar situations in other sectors as well (e.g. a committee rendering decisions in the telecommunications sector). The exercise of applying these Checklists in the health sector should thus facilitate any future risk assessment in another sector.

2.5.3. Organisational versus regulatory risks

Some corruption risks can solely be detected and addressed by a desk review of laws (**regulatory** risks), while some corruption risks are purely organisational and require an in-field examination of processes (**organisational** risks). Many corruption risks need both, a review of laws and regulations as well as of processes. The RCC's Study on "Anti-Corruption Assessment of Laws in South East Europe ('**Corruption Proofing**')" (2015)[77] focuses on risks contained in laws and regulations. It is the twinning study to above mentioned study on risk assessment. For those users of these Checklists, who focus on corruption proofing, the number of questions in the Checklists that have a clear regulatory side are marked in bold. Corruption proofing experts can focus on answering these questions, while all other questions provide them with the overall picture and with the option of deepening their review by reviewing processes.

[75] USAID (2005), Tools for Assessing Corruption & Integrity in Institutions - A Handbook, http://pdf.usaid.gov/pdf_docs/Pnadf529.pdf.

[76] 107 pages, see above note 73.

[77] www.rcc.int/pubs/28/.

3. CHECKLISTS

Checklist 1: Hospitals

Part 1: Patients care

Procedure	Risk	Question
Appointment Reception Visitors Emergency room	Informal payments: extorting or accepting bribes in exchange for facilitating or providing service. Favouritism: giving preference to particular patients.	1. What system of public (online) waiting lists (with the option of numbers representing patients' names) do hospitals maintain?[78] 2. Who – internally and externally – supervises and audits the management of the waiting lists? How often, what have been the results, and have the results been made available to the public? 3. Is a "Patients Rights Bill" or similar document visibly displayed in public areas and does it qualify as comprehensive?[79] 4. Is an exhaustive list of out-of-pocket fees (including their size) visibly displayed in public areas? 5. Are internal control mechanisms in place to check if patients referred by physicians in private clinics are admitted to the hospital (where the same physicians work in double practice) with preference on the waiting list?
Medical exams Medical treatment Hospitalization	Informal payments: Extorting or accepting bribes in exchange for facilitating or providing service.	**Conflict of interest**[80] 6. What particular restrictions are professional and financial ties of hospitals with other health sector stakeholders subject to (e.g. business ties, referral incentives, financing of equipment, sponsoring,[81] etc.)?

[78] Transparency International, Global Corruption Report 2006: Corruption and health (note 4), page 25; For guidance on some good practices see: NHS (2004), A Guide to Good Practice, Chapter 2: Managing waiting lists, http://www.wales.nhs.uk/technologymls/cymraeg/resources/pdf/tools/service_dev/Guide%20to%20Good%20Practice%20Outpatients.pdf; Auditor General Scotland (February 2013), Management of patients on NHS waiting lists, http://www.audit-scotland.gov.uk/docs/health/2013/nr_130221_nhs_waiting_lists.pdf and www.audit-scotland.gov.uk/docs/health/2013/nr_131212_nhs_waiting_lists.pdf.

[79] For examples see: Prince of Wales Hospital, Hongkong, Patients' Rights and Responsibilities, http://www3.ha.org.hk/pwh/content/comm/charterpamphlet_e.html, http://www3.ha.org.hk/pwh/content/comm/patientcharter_e.html; American Hospital Association (2003), The Patient Care Partnership, http://www.aha.org/advocacy-issues/communicatingpts/pt-care-partnership.shtml; WHO Resource Center, Patients' rights, www.who.int/genomics/public/patientrights/en/.

[80] See for a model law on conflict of interest: Council of Europe/Tilman Hoppe (2015), Legislative Toolkit on Conflict of Interest, http://tilman-hoppe.de/ECCU-PCF-Toolkit_REG_-2_2015.pdf; Western Balkan Recommendation on Disclosure of Finances and Interests by Public Officials (2014), http://www.respaweb.eu/download/doc/Asset+Standard+FIN+14+12+10.pdf/45571feb5cde81505de6e2e67b566b3b.pdf.

[81] See for a model provision on sponsoring: model law on conflict of interest: Council of Europe/Tilman Hoppe (2015), Legislative Toolkit on Conflict of Interest, Article 8 and comments, http://tilman-hoppe.de/ECCU-PCF-Toolkit_REG_-2_2015.pdf.

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Procedure	Risk	Question
Prescriptions	Abuse of power: deciding on unnecessary medical interventions in order to maximise fee revenue (fee-for service systems), or omitting necessary interventions (fee-per patient systems). Favouritism: giving preference to particular patients. Violation of conflict of interest standards: preferring medical interventions in which the medical staff or the hospital have a particular interest (kick-back schemes, secondary income, business of close persons, etc.). Violation of conflict of interest standards: preferring third party support (e.g. laboratories) in which the medical staff or the hospital have a particular interest (kick-back schemes, secondary income, business of close persons, etc.). Violation of conflict of interest standards: favouring the prescription of medication in which the doctor has a particular interest (kick-back schemes, secondary income, business of close persons, intellectual property, etc.). Informal payments: soliciting or accepting bribes in exchange for providing prescriptions or other certificates. Violation of conflict of interest standards: provision of free drug samples.	7. To what extent do hospitals have to disclose (online) their funding sources, in particular from health businesses (producers of drugs or devices, etc.), or free samples they have received for distribution? 8. What particular restrictions are professional and financial ties of staff with other health sector stakeholders subject to? 9. To what extent administrative and medical staff has to disclose institutional and personal interests related to their work? 10. How do oversight bodies (e.g. health ministry, integrity body, court of auditors) proactively look for compliance with conflict of interest provisions (cross-checking of databases, reviewing of files, etc.)? 11. What sanctions are violations of conflict of interest provisions subject to? 12. Does the criminal offence of abuse of function cover medical decisions taken in favour of private interest? 13. What restrictions are there in place on the access by drug and medical device sales representatives, except by invitation, in accordance with institutional policies, in certain specified situations for training, patient safety, or the evaluation of medical devices? 14. What clear limits are in place for the distribution of industrial samples of drugs and devices to patients (e.g. limiting distribution to patients who lack financial access to medications)? 15. Do hospitals disclose to what extent they have received free samples for distribution? 16. Do hospitals publicly disclose participations in clinical trials?
Discharge Follow-up appointment	Informal payments: extorting or accepting bribes in exchange for facilitating or providing discharge, or for follow-up appointments.	**Abuse of function** 17. Do regulations provide clear limits on unnecessary medical interventions, and provide clear obligations on providing all necessary interventions?

Procedure	Risk	Question
	Violation of conflict of interest standards: referrals to medical entities in which the medical staff or the hospital have a personal interest (kick-back schemes, secondary income, business of close persons, etc.).	18. Does the offence of abuse of function cover performing unnecessary medical interventions or omitting necessary interventions? 19. Do insurance and remuneration (bonus) schemes set perverse incentives for unnecessary medical interventions or for omitting necessary interventions by financially rewarding the hospital and/or doctor? 20. How is it possible for a patient to review or challenge a medical diagnose? **Bribery** 21. Does the offence of bribery cover all staff with decision-making power and all those who are potential targets of petty or large bribery? 22. Are there clear limits on what is “due” and “undue advantage” received from patients or medical producers (meals, travel, gifts, sponsoring of conference costs, kick-back fees, etc.), thus clearly delineating the boundaries of bribery? 23. Is gift acceptance prohibited? 24. Is the prohibition on gift acceptance publicly displayed throughout the hospital?
Paying fees, bills	Embezzlement: diverting user-fees for personal advantage. Informal payments: accepting bribes in exchange for reduced bills or for deferring payments. Favouritism: reducing bills or deferring payments for particular patients.	25. To what extent are cash-payments for out-of-pocket fees avoided as much as possible? 26. To what extent are unavoidable cash-payments collected under central instructions, by separate collection points (ideally external, such as banks or post offices), recorded electronically, and documented in computer print receipts? 27. To what extent do monetary transactions take place only in publicly visible places and has the installation of surveillance cameras been considered for these areas? 28. To what extent are cash-payments subject to intense regular audits? 29. How is access to cash and its transport regulated and limited? 30. How is intentional or reckless overcharging of patients sanctioned (e.g. criminal or administrative fines)?

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General Accountability
31. Are all payments and medical decisions kept on file and do patients have the right to access their medical records?
32. Is there a code of conduct for administrative and medical staff in place covering all essential situations staff faces?
33. Does administrative and medical staff receive training on integrity and ethics?
34. Is there a complaints hotline?
35. Are statistics on the turnover and results of the hotline publicly (online) available?
36. Is there a designated internal or external person with the function of a patient's ombudsman, having sufficient independence to carry out his/her work?
37. Is administrative and medical staff subject to spot checks or integrity tests in order to identify patterns of irregularities and need for action?[82]
38. Are all processes in the hospital subject to regular audits?
39. Are reports of hospital audits available to the public?
40. Are disciplinary statistics available (online) to the public?
Particularity for psychiatric hospitals and other hospitals with secure units
41. Is the decision on the forced institutionalisation of a patient subject to external control, ideally by a practitioner from outside the institution, in order to avoid the possible conflict of interest of the institution in reimbursements of health care services?

Part 2: Human Resources

Procedure	Risk	Question[83]
Hiring and promotions	Sale of positions: extorting or accepting bribes to influence hiring and promoting decisions, including extortion of a share of salaries.	1. How are open positions advertised in advance? 2. How are statistics on number of staff and fluctuations made publicly available? 3. Is it possible to hire or promote without a competitive process and how are these options limited, well documented, and supervised? 4. Are all applicants asked the same questions relating to the selection criteria and are responses documented? 5. Are interview notes made by each member of the selection committee kept on the recruitment file?

[82] Council of Europe/Tilman Hoppe (2016), Legislative toolkit on integrity testing (model provisions with commentaries), 69 pages, http://tilman-hoppe.de/TP_ECCU_-_PCF-REG_52016_IntegrTesting_Toolkit).pdf.

[83] The questions are modelled after the web-resource of the Independent Commission Against Corruption (ICAC), New South Wales, Knowing your risks, Recruitment and selection, www.icac.nsw.gov.au/preventing-corruption/knowing-your-risks/recruitment-and-selection/4303.

Procedure	Risk	Question[83]
		6. How are selection committees composed in a way that allows an objective decision, in particular by including members independent from those immediately affected by the selection decision? 7. Are potential internal applicants kept off any part of the recruitment process, such as acting as the contact person for potential candidates, preparing position descriptions or framing advertisements? 8. Is all information kept confidential prior to the interview? 9. Are vacancies filled promptly so that periods during which employees undertake more senior duties are not unduly extended, to the disadvantage of other potential applicants? 10. Are personal details verified with original documentation or certified copies? 11. Are reasons documented if applicants were not short-listed or not interviewed? 12. Are selection decisions documented and kept on file? 13. Are selection decisions available to the public? 14. Do unsuccessful applicants have a possibility for appeal? 15. Are human resource decisions subject to regular audits?
Discipline[84]	Sale of accountability: offering and accepting bribes to interfere with disciplinary procedures. Favouritism: interfering with disciplinary procedures for particular staff members. Abuse of power: not enforcing disciplinary liability for irrelevant reasons (beautifying statistics, maintaining a culture of impunity, etc.)	16. Are disciplinary sanctions available for any substantial breach of policy and procedures? 17. Are sanctions applied in practice? 18. To what extent are disciplinary statistics publicly available? 19. Are anonymous staff surveys conducted from time to time to assess workplace culture and corruption risks? 20. Are the organisational structure and reporting lines clear so employees know whom to report to, and whom they are supervised by, and so no employee is left unsupervised?

[84] The questions are modelled after the web-resource of the Independent Commission Against Corruption (ICAC), New South Wales, Knowing your risks, Supervision of Staff, www.icac.nsw.gov.au/preventing-corruption/knowing-your-risks/supervision-of-staff/4304.

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Procedure	Risk	Question[83]
		21. To what processes for reporting misconduct do employees have access to that provide alternatives to reporting through their supervisor, who may be involved in corrupt activity? 22. Do position descriptions for supervisors set out the supervisory responsibilities of the role? 23. Is the performance of supervisory responsibilities assessed in regular/annual performance reviews? 24. Is staff rotated to ensure that supervisory relationships do not become too close or interdependent?
Second income	Absenteeism: not showing up for work or working fewer hours than required, while being paid as if full time. Abuse of resources: using hospital equipment, space, vehicles or budget for private business, friends or personal advantage; using paid time for the same purposes.	25. What clear limits and disclosure requirements are in place on secondary incomes? 26. What explicit restriction exists on the use of hospital resources for private purposes/secondary jobs? 27. Do audits include performance supervision of employees? 28. Are employees with secondary jobs subject to special scrutiny? How?

Note: For conflict of interest related to patients see Part 1; for salaries to "ghost staff" see below Part 4

Part 3: Procurement and inventory

Procedure	Risk	Question
Procurement	Informal payments: soliciting or accepting bribes in exchange for winning a tender (bribes, kick-backs, etc.). Violation of conflict of interest standards: favouring a bidder in which the procurement official has personal interest. Collusive bidding by contractors (bid-rigging) based on secret agreements.	1. Is the hospital's procurement framework in line with national procurement regulations concerning all procurements? 2. Are advanced tools available and does the hospital make use of them, such as online procurement, procure-to-pay software, and similar tools? 3. Are national procurement regulations and tools in line with international standards (e.g. as reviewed by external assessments of the procurement framework)?
Use of resources	Several other forms of corruption: change order abuse; co-mingling of contracts; excluding qualified bidders; leaking of bid information; failure to meet contract specifications; false, inflated or duplicate invoices; false statements and claims; imprest fund abuse; manipulation of bids; fictitious vendor; product substitution; purchases for personal use or resale; rigged specifications; split purchases; unbalanced bidding; unjustified sole source awards; unnecessary purchases.[85]	[Note: A detailed review of each aspect of the procurement framework would exceed the scope of this exercise. It would also double efforts that are usually done in most countries under mechanisms reviewing the existing procurement framework applying to the entire public sector. This Methodology thus refers to existing methodologies and assessments regarding the procurement framework.]
	Stealing medicines and medical supplies or equipment for personal use, use in private practice or re-sale. Diversion of controlled substances.	4. What procedures are in place for tracking inventory of items purchased and used?[86] 5. Is there an asset management system in place that includes asset registers and inventories of resources so that any losses can be easily identified? 6. Are records kept that show when resources are allocated to employees and returned? 7. Are all resources secured using methods commensurate with their value to reduce the likelihood of theft? 8. Are hard and soft copies of sensitive and confidential asset records secured with limited access to storage units/computer codes in which they are stored? 9. Are records kept for the purchase, disposal and valuation of resources regularly reviewed to identify irregularities? 10. Is the use of resources regularly audited, for example checking drug log books against medical records, to identify irregularities? 11. Are records reviewed that are kept of resources which are misused or stolen to help determine the risks to the agency and the risk management strategies required? 12. Is access to controlled substances (e.g. opiates) more limited and are supervision and audit mechanisms tighter?

[85] IACRC (2012), The Most Common Procurement Fraud Schemes and their Primary Red Flags, http://iacrc.org/procurement-fraud/the-most-common-procurement-fraud-schemes-and-their-primary-red-flags/.

[86] The questions are modelled after the USAID Handbook (see above note 66), page 110 (Asset Management).

Procedure	Risk	Question
		13. Are duties segregated in the management of resources so that individuals are not responsible for approving their own usage or purchasing of public resources? 14. Is there a procedure to make sure that employees return resources when they leave the agency or no longer require the resource for their duties? 15. In case the hospital sells assets: Are procedures in place to ensure that assets are appraised and sold competitively for fair market value?

Part 4: Finances

Procedure	Risk	Question
Budget spending	Diversion of public budget: procurement officials collude with suppliers in overcharging the hospital while both sides profit financially (kick-back schemes, see above under procurement). Ghost-staff: salaries are paid for fictitious health workers and diverted to accounts of public officials. [Note: salary fraud such as unjustified overtime payments is not covered by this Methodology.]	1. To what extent is the hospitals budget transparent to the public and does it show income and expenditure in sufficient detail to allow tracking of funds? 2. Is the hospital subject to regular internal and external financial audits? 3. Are access controls in place for the payroll system such as passwords, routine verification procedures and authorisation levels? 4. Are functions segregated to ensure that no one person has complete control over any aspect of the payroll process? 5. Can auditors or supervisors conduct unannounced spot checks to verify the existence of staff? 6. Are records kept on staff rosters? 7. Are payroll systems regularly audited?
Fee revenue	Diversion of fee revenue: financial officials alter receipts showing in internal records a smaller amount than actually received. Diversion of fee revenue: financial officials post fee revenue to refund accounts, and later on send it as fictitious refund to a non-existing client.	1. To what extent are cash-payments for fees foreseen by the hospital? 2. Are cash-payments collected under central instructions, by separate collection points, recorded electronically, and documented in computer print receipts? 3. Are cash-payments subject to intense regular internal and external audits? 4. Is access to cash and its transport regulated and limited?

Checklist 2: Outpatient providers

Outpatient providers can be doctors in single practice or health centres with several doctors and medical staff. The procedures are in essence the same for outpatient providers as they are for hospitals. Thus, Checklist 1 applies accordingly.

Checklist 3: Laboratories, imaging services

Procedure	Risk	Question
Provision of results	Informal payments: soliciting or accepting bribes in exchange for interfering with the lab procedure. Violation of conflict of interest standards: favouring certain lab results in which the laboratory has a particular interest (kick-back schemes, secondary income, close persons, etc.).	Informal payments: questions 21-24 of Checklist 1 Part 1 apply accordingly to laboratories and their staff. Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly to laboratories and their staff.
Cooperation with doctors and hospitals	Bribery: providing doctors with financial incentives in exchange for referrals of patients (kick-back schemes, secondary income, etc.).	

Checklist 4: Pharmacies

Procedure	Risk	Question
Provision of drugs	Extortion: extorting or accepting bribes in exchange for providing drugs from limited supply. Informal payments: soliciting or accepting bribes in exchange for providing prescription drugs without prescription.	Informal payments: questions 21-24 of Checklist 1 Part 1 apply accordingly to pharmacies and their staff. Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly to pharmacies and their staff.
Cooperation with pharmaceutical suppliers	Violation of conflict of interest standards: favouring the sale of medication in which the pharmacist has a particular interest (kick-back schemes, secondary income, business of close persons, intellectual property, etc.). Bribery: payments in exchange for promoting the use of drugs beyond their approval.	
Cooperation with doctors	Bribery: providing doctors with financial incentives in exchange for referrals of patients with prescriptions (kick-back schemes, secondary income, etc.).	

Checklist 5: Human organ transplantation

Procedure	Risk	Question
Donation	Informal payments: extorting or accepting bribes in exchange for circumventing rules concerning living or dead donors. Abuse of power: removing organs in contradiction to rules in order to gain financially.	1. What clear written statutory rules and limits on donations are in place? 2. To what extent are donations subject to oversight?
Placement on wait lists	Informal payments: extorting or accepting bribes in exchange for placement or prioritising on list. Favouritism: giving preference to particular patients.	3. Are there clear written statutory criteria on the placement and allocation of organs? 4. Are decisions documented on file? 5. Are waiting lists subject to scrutiny by interested parties (with the option of numbers representing patients' names)? 6. Are violations of provisions subject to sanctions? 7. Are placement and allocation subject to external oversight and audits? Informal payments: questions 21-24 of Checklist 1 Part 1 apply accordingly. Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly.
Allocation	Informal payments: extorting or accepting bribes in exchange for deciding on a matching donor. Favouritism: giving preference to particular patients.	

Checklist 6: Medical Research

Part 1: Non-clinical research

Procedure	Risk	Question[87]
Basic medical research Preclinical research	Personal or institutional violation of conflict of interest standards: financial ties, personal relationships, political or religious beliefs, institutional affiliations, academic commitments by anybody involved in the research.	Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly to independent researchers.
Publication	Personal or institutional violation of conflict of interest standards: financial ties, personal relationships, political or religious beliefs, institutional affiliations, academic commitments by anybody involved in the drafting process, editorial decisions, or peer-reviewing. Disguised violation of conflict of interest standards: publications are written by "ghost" authors – people who fill the criteria for authorship but who are not listed as authors or acknowledged in the paper.	Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly to all stakeholders in the publication process (authors, editors, peer reviewers). In addition: 1. Do academic and editorial regulations prohibit scientific publications that are controlled by industry or that contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged? 2. Is ghostwriting criminalised (e.g. as fraud)?

[87] Some of the questions are inspired by: World Association of Medical Editors – WAME (2009), Conflict of Interest in Peer-Reviewed Medical Journals, www.wame.org/about/conflict-of-interest-in-peer-reviewed-medical, and Institute of Medicine (2009), Conflict of interest in medical research, education, and practice (see above note 40).

Part 2: Clinical research

[Note: For the permission of the clinical research see Checklist 7, Part 1]

Procedure	Risk	Question[88]
Selecting a medical facility and engaging investigators	Violation of conflict of interest standards: medical staff interferes with the trial because they are committed to a particular outcome (because of financial or other personal or institutional interests). Violation of conflict of interest standards: investigators feel professionally pressured into participating in the research. Hidden bribery: fees or in-kind donations to institutions or medical staff for conducting the trial exceed market values and thus have the potential to influence the decision-making. Informal payments: Extorting or accepting bribes in exchange for facilitating the engagement of investigators.	Informal payments: questions 21-24 of Checklist 1 Part 1 apply accordingly to (research) investigators. Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly to (research) investigators. In addition: 1.To what extent does the employer reward investigators professionally for participation in clinical trials? 2. To what extent does a research ethics committee review risks from professional pressure on investigators to participate in the research? 3. Is the engagement in writing and has it to be kept on file with his/her main employer? 4. Are engagements subject to external oversight and audits, in particular in order to ensure that fees do not exceed market value? 5. Do publicly owned facilities ensure that the research adheres to minimum ethical standards, including public access to the results notwithstanding the outcome?

[88] Several questions are based on the following sources: Harvard University, Edmond J. Safra Center for Ethics, The Pharmaceutical Industry, Institutional Corruption, and Public Health http://ethics.harvard.edu/pharmaceutical-industry-institutional-corruption-and-public-health; Pharmaceutical Compliance Monitor (2012), Addressing the Risk of Corruption in International Clinical Trials, www.pharmacompliancemonitor.com/addressing-risk-corruption-international-clinical-trials/1563/; Council of Europe (2012), Guide for Research Ethics Committee Members, Steering Committee on Bioethics, at 6.C.22.1 (above note 31); for a case study: MotherJones (2010), The Deadly Corruption of Clinical Trials, www.motherjones.com/environment/2010/09/dan-markingson-drug-trial-astrazeneca.

Procedure	Risk	Question[88]
Informed participant consent	Abuse of power: participating patients are not duly informed on the scope and risks of the trial in light of per participant fees paid by the testing company, or do not consent at all. Undue financial influence: payments and rewards to participants are disproportionately high to encourage them to accept a risk they would otherwise not accept. Violation of conflict of interest standards: investigators feel professionally pressured into recruiting participants.	6. Are there clear regulations on the information of participants and on their consent? 7. Is upfront information and consent required to be in writing? 8. Are payments appropriate to the burden and inconvenience of the research but not at a level that might encourage participants to accept a risk that they would otherwise not accept (e.g. representing a substantial proportion of income or the only source of income)? 9. Is research on individuals not able to consent permitted by law (children, mentally impaired)? 10. If so, are there clear regulations on the medical justification and proportionality of the trial, assessment of the lack of capacity to consent, legal representation, objections by the participant not able to consent, and documentation? 11. Are there additional precautions for participants able to consent but vulnerable to coercion (prisoners, military personnel, etc.)? 12. Does the employer reward investigators professionally for recruiting participants? 13. Does a research ethics committee review risks from professional pressure on investigators to recruit participants?
Results	Violation of conflict of interest standards: pressure is exerted to stop a trial, suppress adverse data, or to extend the trial for the benefit of the facility or the investigator.	14. Are decisions on ending or extending trials documented in writing and kept on file? 15. Does the research ethics committee review all trials including their results when being ended or extended? 16. Are all results of the trial continuously documented and kept on file? 17. Do interested parties or oversight bodies have access to the results and files?

For oversight on research see below at Checklist 11.

Checklist 7: Licenses and permits

Part 1: Permission for clinical trials

This checklist concerns the process where drugs or medical devices are approved for trial, in particular on patients. Hospitals and research institutions usually have research ethics committees. In addition, there are public oversight bodies which need to approve trials. There may be additional stakeholders involved, such as national insurers.

Step	Risk	Question[89]
Ethical review	Violation of conflict of interest standards: financial or personal ties of members of the research ethics committee influence objective decision-making. Hidden bribery: fees or in-kind donations to members of the committee exceed market values and thus have the potential to influence the decision-making. Informal payments: extorting or accepting bribes in exchange for facilitating a particular decision of the committee.	Informal payments: questions 21-24 of Checklist 1 Part 1 apply accordingly to (research) committee members. Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly to (research) committee members. Furthermore, the following set of questions applies regarding the independence and accountability of the committee: Appointment 1. Is the process by which members are appointed and their membership is renewed transparent? 2. Are names, qualifications, method of appointment, responsibilities publicly available (online)? 3. Who appoints the members and are there written rules on the appointment? 4. Is the term of office of members clearly prescribed, and do memberships rotate to some extent? 5. Is membership in the committee incompatible with functions closely related to clinical trials? Do cooling off-periods apply for members with former positions with stakeholders who have a business interest in the outcome of the trial? 6. Does the composition of the committee represent a balance of stakeholder interests (scientific expertise, philosophical, legal or ethical backgrounds, and lay views) and do all members have an equal standing? Decision-making 7. Are meetings announced in advance, open to the public, the media, or all staff members?

[89] The questions are modelled after: USAID "Governance in Bulgaria's Pharmaceutical System, A Synthesis of Research Findings" (see above note 50), page 20-24; Council of Europe (2012), Guide for Research Ethics Committee Members, Steering Committee on Bioethics, at 5.A.2 "Composition of RECs" (see above note 31).

Step	Risk	Question[89]
		8. Are decisions and explanations published (online)? 9. Are there clear, written, and published rules and criteria for the decision-making by the committee? Are the medical criteria evidence-based? 10. Are records of meetings kept on file? 11. Are stakeholders with an interest in the decision prohibited from influencing committee members outside formal procedures (lobbying rules)?[90] 12. Do committee members have to disclose attempts of being influenced outside committee procedures? 13. Are decisions explained in writing and kept on file? Powers 14. Is the committee informed of all payments and rewards to the institution, to investigators and to participants in relation to the trial? 15. Does the committee review proper consent of participants? 16. Does the committee have access to files of the clinical trial at any stage? 17. Does the committee review the ending or extension of a trial? Oversight 18. Are there institutionalised consultations with the public to ensure that all stakeholder views are taken into account and that no one group has undue influence? 19. What forms of official oversight of this process exist (the public, the health professions, the courts/administrative law review, supreme audit agency, parliament)?

[90] See Council of Europe/Tilman Hoppe (2016), Legislative Toolkit on Lobbying (English and Russian), Annex 1 "Advisory Groups".

Step	Risk	Question[89]
Regulatory oversight (permission of trials)	Violation of conflict of interest standards: financial or personal ties of the decision makers influence objective decision-making. Informal payments: extorting or accepting bribes in exchange for facilitating a particular decision by the oversight body.	Informal payments: questions 21-24 of Checklist 1 Part 1 apply accordingly to regulatory oversight decision-makers. Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly to regulatory oversight decision-makers. Committee: In case the regulatory oversight body is lead or advised by a committee, the above additional questions apply. In addition, the following questions apply: 20. Is registration of clinical trials mandatory before conducting the trial and are sanctions foreseen for non-compliance (EU Directive 536/2014)? 21. Are registers open to the public? 22. Is there an obligation for conductors of clinical trials to make the raw data of trials publicly available (as done for example by the European Medicines Agency) in order for anybody to verify whether the reported results are accurate, no matter whether they are positive or negative?

Part 2: Approval of drugs and medical devices

This checklist concerns the process where drugs are approved for market use. To this end, drugs need to comply with manufacturing guidelines on quality management, appropriate packaging and labelling, assuring the appropriate concentration of active pharmaceutical ingredients, batch testing, laboratory controls and certificates of analysis (Good Manufacturing Practices). The checklist largely resembles questions in Part 1.

Step	Risk	Question
Approval	Violation of conflict of interest standards: financial or personal ties of the approval body influence objective decision-making. Hidden bribery: fees or in-kind donations to members of the committee exceed market values and thus have the potential to influence the decision-making. Informal payments: soliciting or accepting bribes in exchange for facilitating a particular decision of the committee.	Informal payments: questions 21-24 of Checklist 1 Part 1 apply accordingly to regulatory oversight decision-makers. Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly to regulatory oversight decision-makers. In case the approval body is lead or advised by a committee, the above additional questions apply regarding the independence and accountability of the committee. The composition of any approval committee should include a clinical pharmacist or pharmacologist, a physician, economist and medical specialists who can prepare and/or review drugs.

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Part 3: Listing of drugs and medical devices

This part concerns lists which privilege drugs and medical devices for purposes such as: qualifying for reimbursement by public insurance; qualifying as essential for being stocked in pharmacies or hospitals; being prioritised in financing, such as drugs related to HIV, cancer, plagues, etc. Essentially the same corruption risks apply to this process as to the approval of drugs. Questions of Part 2 thus apply mutatis mutandis.

Part 4: Accrediting health care providers

Procedure	Risk	Question
Accrediting hospitals	Sale of licence: extorting or accepting bribes to influence licensing decisions. Violation of conflict of interest standards: interfering with licensing procedures in order to favour particular applicants.	Informal payments: questions 21-24 of Checklist 1 Part 1 apply accordingly to regulatory oversight decision-makers. Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly to regulatory oversight decision-makers. In case the licensing body is lead or advised by a committee, the above additional questions (Part 1) apply regarding the independence and accountability of the committee. In case licensing decisions are not taken by a collegial body, the following questions apply: 1. Are there clear, written, and published rules and criteria for the decision-making by the licensing body? 2. Are stakeholders with an interest in the decision prohibited from influencing decision-makers outside formal procedures? 3. Do decision-makers have to disclose attempts of being influenced outside formal procedures? 4. Are decisions explained in writing and kept on file? 5. Are decisions available to the public? Are statistics on decisions published regularly? 6. Is there a public online database for medicines under review and those that are already registered? 7. Do decision-makers receive training on ethics and integrity? 8. Can applicants appeal decisions to the courts? 9. Is the licensing body subject to regular external audits (e.g. court of auditors, inspection boards, parliament).
Licensing medical staff	Sale of licence: extorting or accepting bribes to influence licensing decisions. Violation of conflict of interest standards: interfering with licensing procedures in order to favour particular applicants.	
Licensing pharmacies	Sale of licence: extorting or accepting bribes to influence licensing decisions. Violation of conflict of interest standards: interfering with licensing procedures in order to favour particular applicants.	
Licensing pharmaceuticals providers	Sale of licence: extorting or accepting bribes to influence licensing decisions. Violation of conflict of interest standards: interfering with licensing procedures in order to favour particular applicants.	

Checklist 8: Medical guidelines

The Council of Europe Recommendation Rec(2001)13[91] describes medical guidelines as "tools for making decisions in health care more rational, for improvement in quality of health care delivery and for strengthening the position of the patient. [...] Important points for attention when developing a policy on such guidelines from a managerial perspective include the possibilities of 'systematic bias' in drawing up guidelines." To this end, the Recommendation states that guidelines "be produced by multiprofessional groups in a systematic, independent and transparent fashion, using appropriate quality criteria" and that the "source of financial support must be transparent".[92]

In essence, the same questions apply to the "multiprofessional group" developing the medical guidelines that apply to permission for clinical trials (Checklist 7, Part 1). In addition, the following question applies: "Is the source of financial support for developing the guideline transparent to the public?"

Checklist 9: Marketing and distribution of pharmaceuticals and devices

Part 1: Marketing

Procedure	Risk	Question
Marketing with health care providers	Bribery and encouraging conflict of interest violations: providing doctors with financial incentives in exchange for promoting products to patients (kick-back schemes, secondary income, gifts, bribes, etc.). Bribery and abuse of power: encouraging the illegal promotion of unapproved uses of drugs or devices. Encouraging conflict of interest violations: provision of free samples for other uses than for patients who lack financial access to medications. [?]	1. What detailed restrictions on marketing medical products to health care providers are in place, in particular on granting advantages to health care providers for prescribing or promoting medical products? 2. To what extent are health care providers obliged to disclose financial or similar advantages they receive from providers of medical goods, including for observation studies for certain medical goods? 3. Are doctors obliged to prescribe generic medicines in preference to brand-name medicines or the most cost-effective option? 4. Are violations subject to dissuasive sanctions?

Procedure	Risk	Question
Marketing with patients	Influencing the patient information systems (see also above Checklist 8).	1. To what extent is mass marketing to users of pharmaceuticals banned[93] or at least subject to detailed restrictions (including the prohibition on misleading statements or on promoting unapproved drugs, restrictions on promoting prescription drugs, or restrictions on the use of certain promotion techniques such as pictures of medical authorities or the promise of particular results)?[94] 2. Are providers of medical goods prohibited from distributing free samples to patients?
Patient information	Violation of conflict of interest standards: the author of the information has a financial or personal interest in a particular medical position which influences the objectivity of the information.	3. What legal limits are in place on misinforming patients on health risks? 4. To what extent are authors of patient information required to disclose any direct or indirect funding of the development or dissemination of the information? 5. Are adequate sanctions available in case of non-compliance with the above obligations?
Marketing with policy-makers	Interest groups: non-transparent or unethical lobbying of decision makers through third parties (non-governmental organisations, patient self-help groups, etc.).	6. What mechanisms are in place for disclosing lobbying activities, e.g. through public lobbying registries? 7. Do legal guidelines define boundaries for ethical lobbying?[95]
Marketing with education providers	Influencing the objectivity of professional education (see below at Checklist 10).	
Post-market surveillance studies		8. Are health care providers obliged to survey the market after introducing the product? 9. Which state body is mandated with monitoring compliance with the post-market survey obligation? 10. Are adequate sanctions available in case of non-compliance? 11. Are post-market surveillance studies publicly available?

[93] As is the case in most countries for prescription drugs: Gary Humphreys, Direct-to-consumer advertising under fire, Bulletin of the World Health Organization, Volume 87: 2009, Number 8, August 2009, page 576, www.who.int/entity/bulletin/volumes/87/8/09-040809.pdf.

[94] For an overview on respective laws in the United States see: National Conference of State Legislatures (2015), Marketing and Direct-to-Consumer Advertising (DTCA) of Pharmaceuticals, www.ncsl.org/research/health/marketing-and-advertising-of-pharmaceuticals.aspx; a comparative overview is found here: C. Lee Ventola, Direct-to-Consumer Pharmaceutical Advertising Therapeutic or Toxic?, Pharmacy and Therapeutics 2011 Oct; 36(10):669-674, 681-684, www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/; www.who.int/bulletin/volumes/87/8/09-040809/en/.

[95] See Council of Europe/Tilman Hoppe (2016), Legislative Toolkit on Lobbying (English and Russian), Annex 1 “Advisory Groups”.

Part 2: Distribution

This Part 2 of the Checklist only applies in case the state itself manages the distribution. In this case, in particular the risk of embezzlement of public property exists. This Part of the Checklist concerns asset management and thus largely follows the questions of Checklist 1 Part 3 (inventory).

Procedure	Risk	Question
Storing Distributing	Stealing medicines and medical supplies or equipment for personal use, use in private practice or re-sale. Diversion of controlled substances. Informal payments: soliciting or accepting bribes in exchange for preferential distribution of supplies in shortage.	Questions -12 of Checklist 1 Part 4 “Inventory” apply accordingly. Questions 13-15 are not relevant in the context of distribution.

Checklist 10: Professional education

Part 1: Medical schools

Procedure	Risk	Question
Funding by medical industry (financial and in-kind)	Institutional and personal violation of conflict of interest standards: the interest in obtaining or maintaining the industrial funding source leads the medical school and its staff to favouring the products or services of the funder. Hidden bribery: fees or in-kind donations to faculty members exceed market values and thus have the potential to influence the objectivity of education.	Informal payments: questions 21-24 of Checklist 1 Part 1 apply accordingly to medical schools and their staff. Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly to medical schools and their staff. In addition: 1. Do medical schools disclose the number of industry sponsored scholarships and training positions? 2. Are there restrictions on the access by drug and medical device sales representatives, except by faculty invitation, in accordance with institutional policies, in certain specified situations for training, patient safety, or the evaluation of medical devices?

There are further corruption risks related to medical schools. Such risks include in particular informal payments (soliciting or accepting bribes in exchange for facilitating or providing entrance or graduation, favouring students related privately to the professor, etc.). These risks are not specific to the medical sector, but concern education in general. They are thus not included in this Checklist, but should be subject of a checklist on the education sector.

Part 2: Continuing medical education

In essence, the same questions apply as in Part 1 of this Checklist.

Checklist 11: Oversight institutions

Procedure	Risk	Question
Hospital oversight	Violation of conflict of interest standards: preferring hospitals in which the staff of the oversight institution has a personal interest (financial or personal affiliation with hospital, etc.). Violation of conflict of interest standards: one and the same state body manages and oversees hospitals. Informal payments: soliciting or accepting bribes in exchange for influencing the objectivity of oversight.	The questions of Checklist 7 Part 4 apply. In addition: 1. Are management of public hospitals and oversight of public hospitals separate tasks exercised by two separate bodies? 2. Do authorities conduct random, regular inspections? 3. Do authorities apply and enforce applicable sanctions?
Pharmaceutical oversight (registration of pharmaceutical companies, oversight of production, postmarketing safety monitoring)	Violation of conflict of interest standards: preferring producers in which the staff of the oversight institution has a personal interest (financial or personal affiliation with pharmaceutical company, etc.). Informal payments: soliciting or accepting bribes in exchange for influencing the objectivity of oversight.	The above set of questions for hospital oversight applies accordingly.
Research oversight, including research ethics	Violation of conflict of interest standards: preferring research applications in which the staff of the oversight institution has a personal interest (financial or personal affiliation with pharmaceutical company or academic institution, etc.). Informal payments: soliciting or accepting bribes in exchange for influencing the objectivity of oversight.	4. Are independent committees in charge of supervising and monitoring medical research and hospital ethics? 5. Do the committees fulfil the criteria of Checklist 7 Part 1?
Hospital ethics	Violation of conflict of interest standards: preferring results in which the staff of the hospital ethics committee has a personal interest (financial or personal affiliation with pharmaceutical company affected by the decision, etc.). Informal payments: soliciting or accepting bribes in exchange for influencing the decision.	
Parliamentary oversight	Violation of conflict of interest standards: favouring medical providers or producers in which the members the committee have a personal interest (financial or personal affiliation with medical provider affected by the decision, etc.). Informal payments: soliciting or accepting bribes in exchange for influencing parliamentary decisions. Political finance: party or campaign donations with an aim of influencing parliamentary decisions. Lobbying: non-transparent lobbying by the medical providers or producers through third parties (non-governmental organisations, patient self-help groups, etc.).	Informal payments: questions 21-24 of Checklist 1 Part 1 apply accordingly to parliamentarians. Violation of conflict of interest standards: questions 6-11 of Checklist 1 Part 1 apply accordingly to parliamentarians. 6. Do committee meetings take (also) place in public? 7. Are minutes and findings of meetings published? 8. Are stakeholders with an interest in the decision prohibited from influencing committee members outside formal procedures (lobbying rules)?[96]
Civil society	Violation of conflict of interest standards: favouring medical providers or producers in which the civil society organisation or its members have a particular interest (funding by or personal affiliation with a medical provider or producer, etc.).	9. Do medical businesses have to disclose all financial and in-kind donations to civil society organisations? 10. Do civil society organisations engaged in the medical sector disclose (voluntarily/mandatorily) all financial and in-kind donations received, at least above a de minims threshold?
Integrity oversight	Lack of enforcement: lack of supervision leads to lack of compliance with integrity rules.	11.Is an integrity body in charge of verifying a sample of financial and non-financial interest disclosures (asset declarations)? 12. Is an integrity body in charge with advising on or implementing risk assessments in the health sector? 13. Is an integrity body in charge with advising on or implementing risk assessments in the health sector? 14. Are at least drafts of legal regulations corruption proofed? 15. Do investigative bodies have to follow-up on (substantiated) anonymous criminal complaints? 16. Can the oversight body conduct spot checks or integrity tests in order to identify patterns of irregularities and need for action?[97]

[96] See Council of Europe/Tilman Hoppe (2016), Legislative Toolkit on Lobbying (English and Russian), Annex 1 "Advisory Groups", http://tilman-hoppe.de/TP_-_ECCD_PCF_REG_Lobbying_Toolkit.pdf.

[97] Council of Europe/Tilman Hoppe (2016), Legislative toolkit on integrity testing (model provisions with commentaries), 69 pages, http://tilman-hoppe.de/TP_ECCU_-_PCF-REG_52016_IntegrTesting_Toolkit).pdf.

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