Chapter

Risk Management in Biobanks

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Abstract

The administration of risks is usually an important corner stone of professional operations. Nevertheless, specifically for biobanking organizations, risk recognition, control, management, and easing are inevitably extremely critical elements of everyday operations. The costly kind of unique samples/cell lines, data and also other high-pitched value biobanking products and services such as cell-based drugs, and biologically active pharmaceutical materials call for tremendously precise planning—including the full spectrum of risks. In this chapter, we have included the common risks in biobanking and the management way and methods of risks in a biobanking institution.

Keywords: risk management, special risks, strategic risks, physical and chemical risks, biobanks

1. Introduction

What can biobankers do to ensure that their biobank does not have to struggle in case of an emergency? The best activity plan could be as follows:

> Implement risk assessment and risk determination processes specifically designed to address the needs of your biobank, come up with risk management and action strategies, and teach and train your staff in all these matters!

The management of risks is part of all business operations. However, for biobanking organizations, risk mitigation is unavoidably an overly critical element of day-to-day operations. The expensive nature of irreplaceable samples/cell lines, data, and other high-value products such as cell-based drugs and biologically active pharmaceutical ingredients calls for extremely accurate planning including the full spectrum of risks. These risks can be subdivided into the following categories:

- Reputation-related risks
- Ethical and data protection risks
- Financial risks
- Operative risks
- Standard lab risks

- Human resources risks
- Infrastructural risks
- IT risks
- Strategic risks
- Natural disasters

Risk assessments and determination are essentially rather subjective; they are very individual and are based on personal perception of an employee. Hence, it is recommended to assess the risks in a workshop involving employees from each level and field of biobanking activities such as:

- Management
- Public relation
- Human resources
- Financial officers
- Lab technicians
- Researchers
- IT specialists
- Ethics specialists
- Infrastructure specialists
- Medical doctors
- Strategy developer and network coordinator

Most risks that will be recognized in a workshop are of low probability. Years of mild weather are normal, while natural disasters are of low likelihood. Terrorism attacking biobanks is most probably also a minor aspect, except for sites that are near potential targets, such as governmental buildings and major airports. In the case of the abovementioned risks, occurrence of the damage will be irreparable. Thus, a biobank also needs an action plan for such unlikely events.

Further to evaluating the probability of a risk, the potential aftermath should also be considered in order to be able to calculate a real risk score. For example, a hurricane may be unlikely but could leave serious damage behind, including extended power outages.

If a biobank has not performed a realistic, well-researched risk assessment, then the risk mitigation strategy is based on guesswork, is not professional, and is just not acceptable compared to the efforts of collecting and storing samples and data. It is very important to have a comprehensive risk management plan in place that is up to date. It is easy to start with a well-researched and/or well-known risk assessment.

It is crucial to define the exact steps each biobank team member needs to follow in serious cases of emergency. A periodic review, update, and "walk-through" of the risk potential assessment are pivotal, and also the action plan should be renewed periodically. One of the most known and often implemented biobanking risk actions is the duplication of critical samples and their storage in multiple locations. This can be done on-site (same biobank, different storage locations) or off-site (an extramural provider of storage in a different location).

Many biobanks are starting enthusiastically without thinking about risks and possible dangers that may occur during implementation and running of a biobank. The professional approach is not only to think about it and determine the risks but also to include risk management in the biobank budget. There is an old English saying on flyers of storage constructing companies: "Don't be penny-wise and pound-foolish." This saying applies exactly here, when speaking about risks. Too many biobanks neglect risk management because they "do not have the funds for it." This is unacceptable and above all irresponsible, especially in public biobanks, where using the taxpayers' money too much is invested without protective mechanisms, like risk management. Admittance and maintenance of risk management not only into biobanks' daily routine but also into budget is pivotal for longevity of the given biobank initiative, as every task in the biobank requires assets and capabilities for performing the work accurate.

Cooperate, for collaborative exertion with supportive biobanks can be performed almost with every other biobank or biorepository in the world. Besides, a biobank can work with interventional research supportive organizations in their own country or area. Construct trusty collaborations with associates and encourage and promote relations, which can build up the risk vindication plan of your biobank/lab. In the event of a crisis or a disaster, it is improbable that a team of a biobank can manage and recover alone—without associates.

A respectable business managing and controlling plan comprises development and description of protection mechanisms to avoid dangers (which must be known). These risks must be predicted and managed to untroublesome issues. However, as is the case with natural disasters, not only a biobank but also any other institution is unable to always predict the future. If a biobank adopts a wide-ranging risk qualification and management plan, it can help to safeguard the protection of biobank bio specimens.

Staying with the example of off-site storage: Choosing an offsite storage facility includes asking the right questions to determine if the storage provider has the appropriate risk mitigation infrastructure in place, beginning with a realistic threat assessment of the location. The potential off-site storage provider should also provide an "emergency action plan (EAP)" in force as well as a plan for ensuring the safety of employees, for securing the facility, for addressing the media, and for notifying the relevant authorities following a disaster. Again, these plans should be written, reviewed at regular intervals independent of on-site or off-site storage solution in case changes are defensible, and tested via walk-through or table-top workouts to the extent possible and the employees trained on the procedures. Ideally, these trainings are also well documented, reviewed, reported, and repeated at least annually as well as every time if changes are made [1].

There is a list of information that should be available for emergency cases in a biobank (**Figure 1**).

Risk susceptible infrastructures such as biobanks should have backup capacities well in addition to the minimum requirements. Thus, this may imply to have 100% redundant storage and supply (e.g., electricity) capacity. Fully redundant working

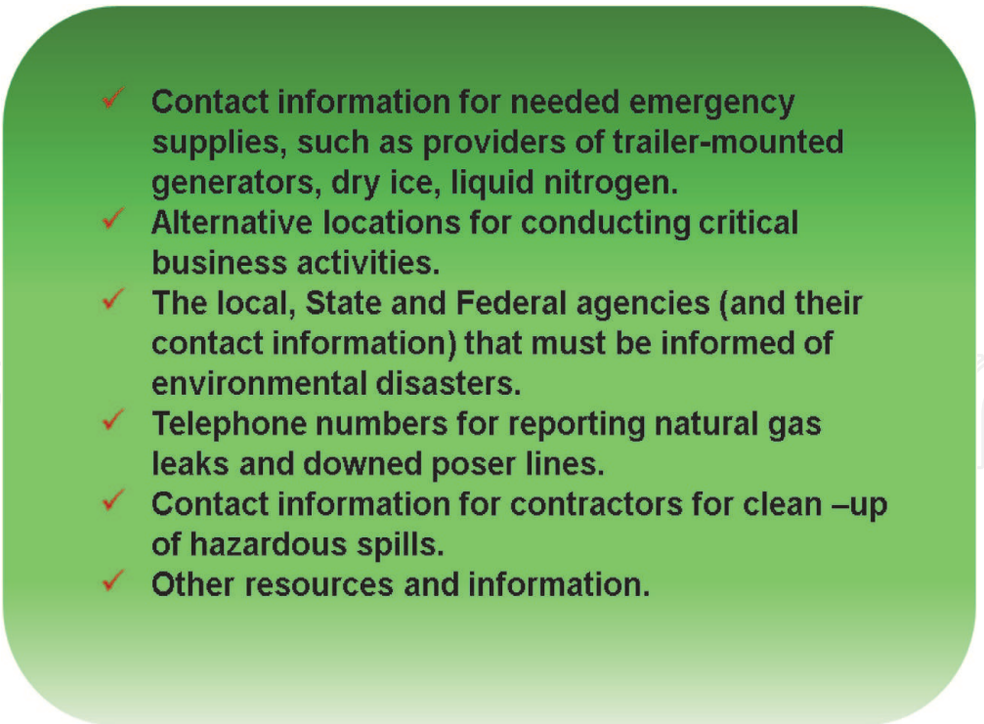

Figure 1.
Information emergency cases in a biobank. Adapted from: http://blog.fisherbioservices.com/bid/286295/Defense-in-Depth-Off-Site-Storage-for-Biological-Specimens-and-Biopharmaceuticals-Risk-Mitigation.

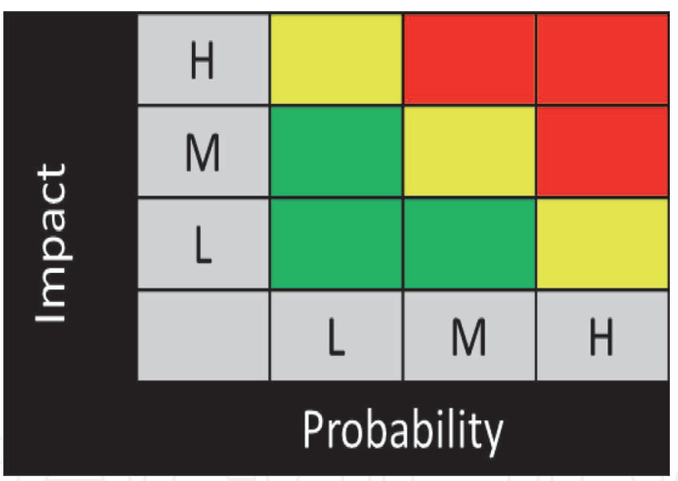

Figure 2.
Risk matrix adapted for use in qualitative risk analysis.

allows one unit to maintain accurate facility temperatures, while the other is serviced or repaired and at the same time may deliver extra cooling capacity for unexpected events [1].

Risk mitigation occurs at all levels of operations. Hence, in the following chapters, we will discuss and explore the possible risks and action strategies, if a risk occurs (**Figure 2**).

2. Risk management plan

In general a risk is an event or condition that, if it occurs, could have a negative effect on an organization.

The direct citation of the definition is as follows: "Risk Management is the process of identifying, assessing, responding to, monitoring, and reporting risks. Therefore, a risk management plan defines how risks associated with the organization will be identified, analyzed, and managed. It outlines how risk management activities will be performed, recorded, and monitored using templates and practices for recording and prioritizing risks."

The aim of risk management is to prevent that risks become a problem or to minimize the damage, which could occur because of risks. By consistently searching and analyzing possible risks, a possible operational blindness is eliminated as well.

One of the methods that can be used when identifying risks is a Strengths and Weaknesses, Opportunities, and Threats (SWOT) analysis. When using this tool, internal factors (Strengths and Weaknesses) and external factors (Opportunities and Threats) are analyzed. As the risks for a biobank are very comprehensive, an own risk management strategy should be implemented for each biobank.

2.1 Process

Risks will be actively identified, analyzed, and managed periodically. They will be identified as early as possible to minimize their impact. The steps for accomplishing this are outlined in the following sections. One defined responsible person should serve as the risk manager for the organization.

2.2 Risk identification

Risk identification involves the management team and includes evaluation of environmental factors, organizational culture, and the strategic plan of a biobank. Careful attention needs to be given to the business plan and the stakeholder analysis cost/effort estimates, resource plans, and other key project documents.

2.3 Risk analysis

All recognized existing and probable risks must be evaluated in a matter of classification of the potential variety of consequences in the real case. Criterion must be implemented and discussed for definition, categorization, and regulation of risks. The recognized top risks must be followed and reacted immediately, and there will be some risks which in the given period of development can be ignored.

2.3.1 Risk analysis

The likelihood and influence of manifestation for individually recognized risks should be evaluated by the team of the given biobank under the moderation of risk manager. The important criteria for this consideration are probability and impact.

Probability

- High—over <70%> likelihood of incidence
- Medium—over <30%> but under <70%> likelihood of incidence
- Low—under <30%> likelihood of incidence

Impact

- **High** are those risks which have the possible outcome of causing high expenses and big shifts of routine timetable or performance.
- **Medium** are those risks which have the possible outcome of causing slightly higher expenses and moderate shifts of routine timetable or performance.
- **Low** are those risks which have a possible outcome of causing some expenses and slight shifts of routine timetable or performance.

Breakdown of risk events, which are ranked by qualitative risk analysis and the consequence results, will be estimated (a numerical rating applied to each risk based on this analysis) and then documented in this section of the risk management plan.

2.4 Planning of risk response

For any major risk, an assignment together with responsible team/s or team member/s needs to be performed in order to monitor and to confirm the risk observation. For handling of the recognized major risks, individual tactics can be and should be carefully chosen:

- **Avoid**—Exclude the hazard by reducing or excluding the source
- **Mitigate**—Recognize ways to decrease the likelihood or the effect of the given risk
- **Accept**—No action needed
- **Transfer**—Nominate alternative party in charge for the given risk (e.g., outsourcing)

For any given risk, which will be moderated, the responsible "employee's group" needs to recognize ways to elude or as a minimum alert the risk or decrease its effect or chance of arising. This may comprise prototyping, calculations in the timetable, counting of additional resources, etc.

For any recognized major risk, which needs to be reduced or accepted, a development of action plan should be drawn for the incident of risk materialization and impact decrease.

2.5 Monitoring, controlling, and reporting

The level of risk needs to be followed, checked, and reported periodically. All change requests will be analyzed for their possible impact to the risk management. Management will be notified of important changes to risk status (**Figure 3**). To summarize, the following steps should be complied with the development of a risk management plan:

1. Identification of risks (brainstorming, cause and effect diagram, lessons-learned, analysis of documents)

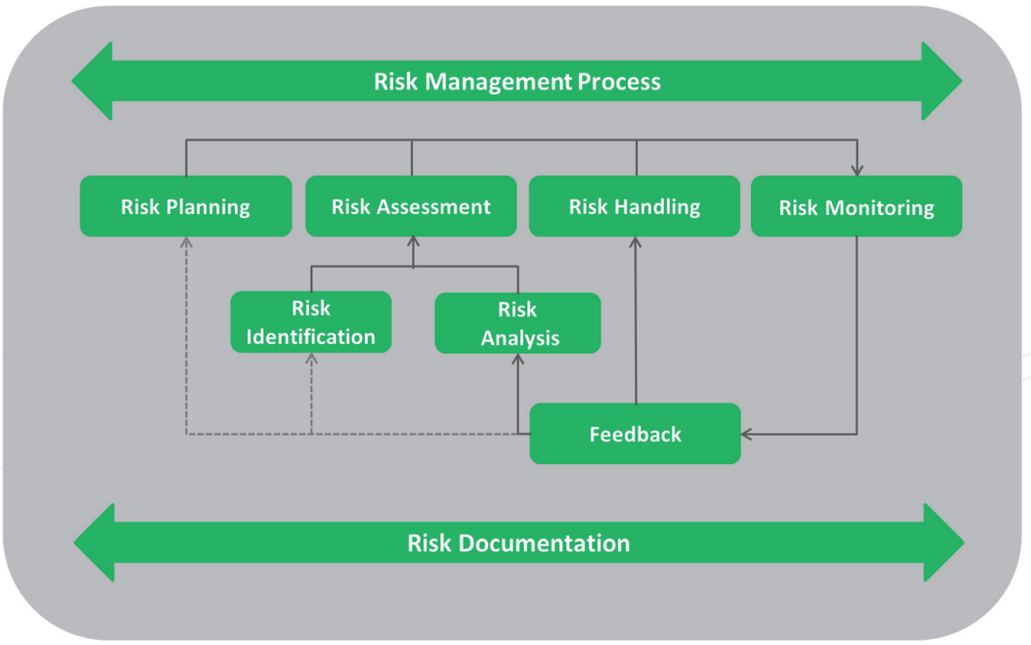

Figure 3.
Overview risk management process.

2. Analysis and evaluation of risks (development of a risk list, evaluation of probability and impact of occurrence for each identified risk)

3. Determine measures (in accordance to periodization—development of a catalogue of measures)

4. Monitoring risks (risk controlling—change of basic conditions, new risks, etc.)

5. Adapt planning

3. Important risk management tools

3.1 Risk assessment template

A risk assessment is a methodical technique of considering the routine and/or special work tasks, by means of thoughts on "what can go wrong." Then, it is the decision on appropriate control methods to avoid defeat, harm, or injury at the workplace. The calculation must comprise the controls, which are obligatory to exclude, decrease, or minimize the given risks.

This will depend on the organization and may vary depending on the nature of work. However, assessments must consider everyone who could be affected by that activity.

There are no unbreakable and/or reckless guidelines about how the risk assessments must be performed. Every organization, team, or department is different, so they may necessitate a somewhat diverse approach. It is nevertheless significant that risk assessments are conducted methodically and reflect all of the predictable risks.

ANALYSIS OF RISKS FOR _____ BIOBANK

Risk Manager: _____

Address of the organization	
Organizational unit	
Task of the organizational unit	
Risk owner	
Number of employees	
Description of risk assessment	
Risk monitoring	☐ Semi-annually ☐ Annually ☐ _____
Date and status	XX.XX.XXXX In progress Valid until Invalid since: XX.XX.XXXX
Signature risk owner and date of approval:	

3.2 SWOT analysis

The direct citation of the definition is as follows

> *A SWOT analysis is an acronym for strengths, weaknesses, opportunities, and threats and is a structured planning method that evaluates those four elements of a projector a company. A SWOT analysis can be carried out for a company, product, place, industry, or person. It involves specifying the objective of the company or project and identifying the internal and external factors that are favourable and unfavourable to achieve that objective* [2].

3.2.1 History

Albert Humphrey, a research manager and project leader at Stanford University between the 1960s and 1970s, invents the background of SWOT analysis method. He consumed a high amount of data from different top companies for the proof of the method. The aim was the recognition and identification of the causes of corporate planning errors. The subsequent research acknowledged a specific quantity of main areas to be addressed. The method, which is to be used to explore each life-threatening area, was named SOFT. *The direct citation of the categories is as follows:*

> *What is good in the present is Satisfactory, good in the future is an Opportunity; bad in the present is a Fault and bad in the future is a Threat.*

- *Strengths: characteristics of the company or project that give it an advantage over others*
- *Weaknesses: characteristics of the company that place the business or project at a disadvantage relative to others*
- *Opportunities: elements in the environment that the company or project could exploit to its advantage*

- *Threats: elements in the environment that could cause trouble for the business or project*

Identification of SWOTs is important because they can inform later steps in planning to achieve the objective. First, decision-makers should consider whether the objective is attainable, given the SWOTs. If the objective is not attainable, they must select a different objective and repeat the process (**Figure 4**) [3].

3.2.2 A practical example for biobanking

Within the HigherKos project "CONEKT—**Co**operation, **Ne**tworking and **K**nowhow **T**ransfer between Austria, Kosovo, Albania in the field of Biobanking" for two biobanks of CEE countries, a SWOT analysis was performed to determine the strengths, weaknesses, opportunities, and threats of each partner (**Table 1**).

If specific values related to your business offerings are established within the four quadrants of SWOT analysis, a strategic plan based on the learned information could be developed.

Therefore based on the SWOT analysis, a strategy paper was developed for each country. More efficient strategies for biobanking processes and use of existing infrastructure and knowledge in research were defined (**Figure 5**).

Figure 4.
Overview SWOT analysis. Adapted from source: https://conceptdraw.com/a462c3/preview–SWOT%20analysis%20matrix.

Strengths	Weaknesses
• **Access to focused patient collective** • **Already existing sample collections (blood, liquid body fluids, tissue, microbial cultures, DNA): disease and population based** • Access to public • Access to students • Support by opinion leaders/key players: minister of health, chairman of the local ethical committee board, dean of medical faculty • **Unique epidemiology profile (e.g., TBC, Crimean-Congo hemorrhagic fever, brucellosis)** • Already some experience with grants and interdisciplinary collaboration • Provided services: diagnostic, research, consulting	• **Limitation of health care system (motivation, low salaries of all personnel)** • HIS status: limited access to local clinical data • LIS status: new computer program since 05/2013, but no general access—only NIPH • No standardized biobank databank for sample management • No separate budget for pathology • **Lack of experience in biobanking** • Idea of academic career • No dedicated personnel • Lack of technical staff • Undertrained technical staff • Uncoordinated ethic landscape • **No QM system & SOPs for sample collection and handling (e.g., unsteady formalin concentration of tissue samples** • For tissue samples: no standardized formalin concentration • Restricted research possibilities due to sample treatment (formalin vs. fresh frozen tissue) • Infrastructure service: Maintenance of equipment is difficult • Lack of space • Sample circulation to private labs & loss of samples • Separate sample collections at departments UCCK, Forensic medicine & NIPHK • No informed consent data • Pencil-marked blocks & slides; storage in cardboard boxes & wooden racks) • Suboptimal safety conditions at pathology
Opportunities	**Threats**
• Collection opportunity potential • **International collaboration** • Interdisciplinary collaboration potential • Academic research potential (young generation) • **European (international and private funding** • **Collection of private institution**	• **Economic risks** • Low health care budget • **Sustainability** • Brain drain • **Legal & ethical changes** • Weak coordination of responsible authorities • No motivation of research and development (culture) • No health insurance system

Table 1.
SWOT analysis—example of one of the partners (HigherKos Project—CONEKT).

4. Implementation of a risk management plan

As mentioned before in the planning of biobank infrastructure and processes, a specific focus should be on risk management in the case of disasters and unexpected occurrences. In the future, risk management has to be a core competency of every biobank. In order to provide structure for a risk management plan, risks need to be categorized. On the one hand, managers/directors have to ensure that there is an effective management of both, few risks that are fundamental to the organizations and many risks that impact on day-to-day activities and have a shorter time frame

BIOBANK Pristina and Tirana - SWOT-Strategies

			environmental factors			
			Opportunities		Threats	
			European(international) and private funding	International collaboration	Sustainability	Economic risks
organisational factors	Strenghts	Unique epidemiology profile	Grant proposals, attract Pharma, USP research market, new research collaborators	complementary cooperation with Biobank Graz, networking, advertising of the unique profile, learn how to make a higher quality	contacts to research community, networking in fild of biobanking (BBMRI), funding, quality, personnel training	low socio-economic status gives rise to certain diseases -- catch money for documentation and collection of samples, sell infrastructure to keep collection
		Focused patient collective	starting with a register and retrospective studies, finding out own research strenghts, define own research fields or interests, standardisation of sample processing, enhance code identification of samples and documentation system, formulate an ethical frame	training at Biobank Graz to ensure quality of focused collective, combination of sample collections with national and international partners, implementation of Good Scientific Practice regulations	finding partners that are interested in focused patient collective (follow up), development of collection strategies, combination of different type of samples of same person, having reimbursement strategy, continuous education	open collectin to pharmacology, rethink profile and find another field of interest with the same infrastructure
	Weaknesses	Limitation of health care system (motivation)	project implementation (infrastructure and personnel), research results to clinic, Standard IT infrastructure to be used for public health	know how transfer in clinical and research disciplines, personell exchange programme, statistical comparison with other countries, development of national regulatoritives	dedicated biobank staff, gainig infrastructure, gaining oppinion leaders (different specialities), public presentation , implementation of regulator body	search for private third-party money and shut down collection, keep the storage
		Lack of experience	apply for mobility programmes (Erasmus, TAEX, COST, ministry of education, TEMPUS, HORIZON 2020), invitation of experts (focused workshops with experienced speakers)	information transfer, participation of network programmes with technical staff, dissemination of new biobanking ideas in CEE-network, participating/becoming part of BBMRI	working against brain drain, formulation of special contracts for staff	search for private third-party money and shut down collection, keep the storage

Figure 5.
SWOT strategies – practical example of two biobanks of CEE countries (HigherKos Project – CONEKT).

than longer-term strategic risks. These two types could be categorized as strategic and operational risks (**Figure 6**).

4.1 Strategic risks

Strategic risks are those that arise from fundamental decisions that managers/directors take concerning organization's objectives.

Strategic risks are often risks that organizations may have to take in order to expand and to continue in the long term. The following section describes some strategic risks of a biobank.

4.1.1 Unpredictable change of the strategic focus of the funding organization

Possible reasons

- No financial support because of a small budget
- Providers of samples do not feel recognized through scientific leadership in their collection strategy—they are worried about the scientific usage.

Possible consequences

- The biobank is no longer the strategic flagship of the funding organization
- A scientific character in leading the biobank would complicate sample procuring
- Certificate extension would be in danger

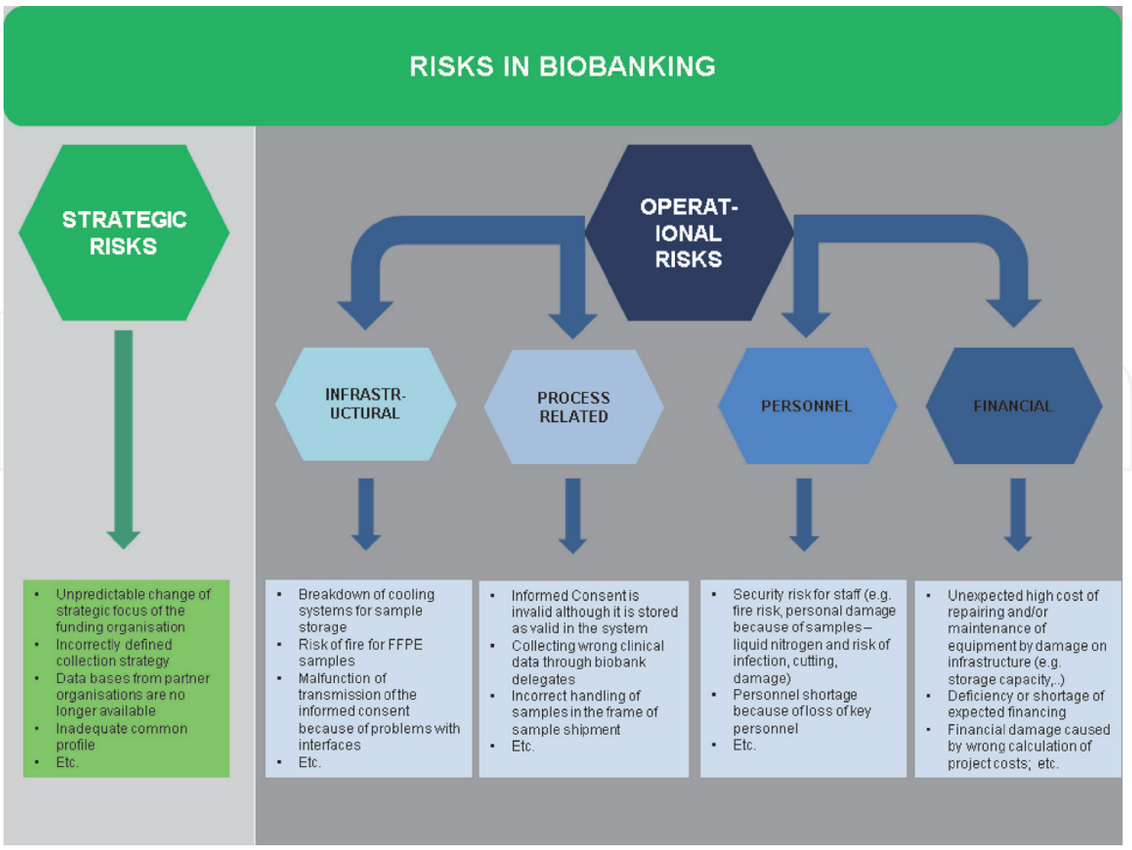

Figure 6.
Overview: risks in biobanking.

Possible coping strategies

- Regular information exchange with the funding organization and cooperative partners
- Close cooperation in establishing and implementation of the collection strategy
- Establishing a long-term strategy for financing
- Developing general conditions for collection strategies and developing rights and obligations for scientific leadership

4.1.2 Incorrectly defined collection strategy according to bio specimens

Possible reasons

- An insufficient adaptation of the list of collection criteria
- An insufficient trained personnel
- An insufficient infrastructure and/or instrument-qualifications for labs and storage

Possible consequences

- Samples are not used or useable in scientific projects

Possible coping strategies

- For each cooperation an individual collection strategy will be developed, which will be defined together with the cooperation partners.
- Intensive cooperation with the areas of research of the organization.
- Specification of risks, including infrastructure, equipment and personnel (e.g. documentation of near-accident)

4.1.3 Databases from partner organizations are no longer available

Possible reasons

- Unclear contract situation with partner organizations
- Expiration of the cooperation contract

Possible consequences

- No access to data of the partner organization

Possible coping strategy

- Better contractual protection and control

4.1.4 Inadequate common profile

Possible reasons

- Lack of personnel—not enough time for PR activities

Possible consequences

- Less projects—less project requests → risk of interruption of third-party funding

Possible coping strategies

- Higher prioritization of PR activities and lobbying
- More budget for PR activities and presentations at congresses

4.1.5 A bad strategy for public relation activities for the donors

Possible reasons

- Inadequate information transfer to donors
- Inadequate trained medical personnel for the informed consent procedure
- A hardly comprehensible informed consent

- Low level of awareness and transparancy (e.g. by a lack of public events and publications)

Possible consequences

- Reduced number of donors
- Increased number of withdrawals

Possible coping strategies

- Easy understandable informed consent
- More time for personnel training and informed consent procedure with donors
- Creation of visual informed consent information if possible in various languages
- Cooperation with media representatives
- Implementation of a marketing concept for specific positioning on the biobanking market

4.1.6 Changes of legal and ethical aspects

Possible reasons

- New national/European/international regulation
- Further development of the field in the society
- New constitution of an ethical committee/IRB
- Test cases that force the legislative organs to sharpen the law

Possible consequences

- Loss of ethical approval and stop of operation (in best case until the new approval is in place)
- Completely new development and/or sharpening of own governance
- Termination of biobank (if it is not allowed at all by law)

Possible coping strategies

- Cooperation with legislative organs on new regulation (being informed and prepared, having an influence from the beginning)
- Preparation of own approvals, applications, and governance in accordance with new regulation/law in advance
- Dialog with other biobank sand interest groups to be informed and exchange of experience about implementation

4.1.7 Wrong assessment of the stakeholder analysis

Possible reasons

- Newly appointed (external) personnel without knowledge of internal/external dependencies
- Misestimating the importance of individual stakeholders
- Lack of farsightedness of operational management

Possible consequences

- Loss of possible funding by specific stakeholders
- Less favourable political standing and/or support
- Loss of sources of sample/data
- Bad image

Possible coping strategies

- Stakeholder analysis with all levels of management including carrier organization and environment
- Discussion of first results with key players internally/externally, researchers, and politics with an intention to complete the analysis
- Repeating first assessment, e.g., after 3 and 6 months, and implementing a strategy of renewal of assessment after each year
- Investigation of such analysis of comparable institutions and other local cooperation partners

4.1.8 New strategic trends in the market of biobanking

Possible reasons

- New research technology
- New hot topics in science
- New standards in biobanking and the pre-analytical field
- Population health-driven trends (novel infectious agents, healthy aging research and/or fertility research)

Possible consequences

- Being out of trend
- Less projects—less project requests
- Risk of interruption of third-party funding

Possible coping strategy

- Continuing research market analysis
- High priority of congress and conference participation
- Evaluation of the requests that are not processed and implementation of strategies to close the gap (if applicable)

4.2 Operational risks

Not only strategic risks need to have awareness, but it is important to have an insight to "the bottom" of the organizations, e.g., if infrastructure is disturbed or key staff is leaving because of dissatisfaction, then operating the biobank may run into trouble before all new plans can be implemented. These are operational risks—risks connected with internal resources, systems, processes, and employees of the organization. The following section describes some operational risks of a biobank.

4.2.1 Infrastructural risks

4.2.1.1 Breakdown of cooling systems for low-temperature sample storage

Possible reasons

- Infrastructural, technical reasons
- Missing backup devices and strategies

Possible consequences

- Tissue or blood samples can be damaged (depends on temperature and duration of breakdown)
- In a worst case (duration of breakdown and period until detection of the problem), the samples are not useable any more (loss of samples)

Possible coping strategy

- Staff training in accordance to validated Standard Operation Procedures
- Define responsible staff and representatives
- Installation of backup systems
- Development of an "emergency plan" for the weekend and public holidays
- Current maintenance of cooling systems through qualified technical personnel
- Installation of monitoring systems

- If possible—expand personnel resources
- Conclude service agreements

4.2.1.2 Risk of fire for FFPE samples

Possible reasons

- Electric spark, dust, no or defective smoke detector

Possible consequences

- Loss of samples through heat and fire
- Danger to staff

Possible coping strategy

- Regular fire protection inspections
- Installation and maintenance of fire protection systems

4.2.1.3 Malfunction of transmission of the informed consent because of problems with interfaces

Possible reasons

- Technical failure

Possible consequences

- Error is not detected → samples are not available for research
- Error is detected → additional time required for new data entry or new transmission of data

Possible coping strategy

- A second transmission of stored documents is possible
- A second scan of informed consent is possible

4.2.1.4 Breakdown of backup systems

Natural disasters such as super-storms, droughts and earthquakes must also be taken into consideration by developing the risk management plan of a biobank but also it is important to have a breakdown plan—if the case arises. Among others, the recovery after disasters can be one of the most challenging tasks of biobank management and staff. There are several examples in the literature that show the challenges of such situations. It is important to note that the staff of the given biobank have to monitor the whole infrastructure in a way that does not harm them directly, e.g., the freezers, tanks, and other storage capacities. If the breakdown

affects also the electricity supply, there must also be a plan "B" for this supply, as a variety of technicians, engineers and scientists, who are usually quite familiar with standard infrastructure must act together as a team and need the electricity supply for disaster management.

Possible reasons

- Natural disasters
- Human factor
- Planning of insufficient backup capacities
- Incorrectly integrated backup systems (no jump-in in case of emergency)
- No alarm system and 24/7 monitoring
- Backup system is not functional and or outdated

Possible consequences

- Loss of samples and data
- Loss of money and time
- No new projects—no third-party money
- Obligation to pay out partners (storage services)
- No space for new samples, stop of collection of essential samples caused by storage space restrictions

Possible coping strategy

- Exact planning of backups (at least 3 times backup storages and databases)
- Regular tests and controlling of function of backups and integration systems
- Alarm systems
- 24/7 monitoring with stand-by duty
- Large local and extramural backups

4.2.1.5 Hardware or software errors of productive systems

Possible reasons

- Operational error
- Programming error
- Production error

- Installation error
- Lack of maintenance

Possible consequences

- Faulty documentation of samples → sample-related data are difficult to find; worst case is the loss of sample-related data
- Samples cannot be used for projects
- Image loss

Possible coping strategies

- Continuous improvement of the database system
- Structured evaluation and procurement (requirement specification)
- Implementing testing periods before launching
- Demand-oriented staff training
- Regular process monitoring

4.2.2 Process-related risks

4.2.2.1 Informed consent is invalid although it is stored as valid in the system

Possible reasons

- Invalidity of the IC cannot be detected during scanning and monitoring and therefore is stored as valid in the system

Possible consequences

- Samples cannot be used for projects
- Image loss

Possible coping strategy

- Staff training (staff who is scanning documents)
- Follow-up of stored documents is possible

4.2.2.2 Collecting wrong clinical data through biobank delegates

Possible reasons

- Biobank delegate gets the wrong patient identification from the biobank
- Wrong documentation in the clinical subsystem

Possible consequences

- Output of samples with wrong clinical data → cause error results
- Image loss

Possible coping strategy

- Continuous improvement of data administration
- Regular process monitoring

4.2.2.3 Incorrect handling of samples in the frame of sample shipment

Possible reasons

- Wrong or inadequate labeling for shipment
- Incorrect packaging

Possible consequences

- Samples are no longer usable
- No fulfillment of the contract
- Additional costs for the biobank
- Loss of image

Possible coping strategy

- Testing of all available shipment companies with exact documentation, for decision about a partner in shipment (including cost–service calculation)
- Continuous training of personnel involved in shipment
- Exact procedure description of labeling and packaging with easy availability for the personnel (with exact pictures and measurements)

4.2.2.4 Non-traceability of samples because of wrong allocation of samples during storage

Possible reasons

- Loss of attention while manual labeling samples
- Badly readable sample codes by poorly labeling
- Bad documentation
- No well-trained staff

- Lack of time
- High error rate of systems for storage of samples or for input of sample-related data

Possible consequences

- Valuable samples get lost and cannot be used for projects
- Longer period to find samples
- Waste of biobank resources

Possible coping strategies

- Staff training according to Standard Operation Procedures of the biobank
- Precise working while handling with samples
- "Four-eye principle"
- Regular process monitoring
- Automated identification and process of samples
- Further development of concepts
- Expanding of personnel resources

4.2.2.5 Improper handling of samples in processing

Possible reasons

- No well-trained staff
- Lack of time
- Cryosamples may defrost (long handling time, transport, long shipping time)
- Tissue could get damaged during the freezing process

Possible consequences

- Samples are not usable for projects
- Waste of biobank resources (storage capacity, liquid nitrogen, etc.)

Possible coping strategies

- Staff training according to Standard Operation Procedures of the biobank
- Precise working

- Careful handling of samples
- Detailed information about shipping conditions and requirements
- Expanding of personnel resources

4.2.2.6 Incomplete pseudonymization and anonymization of process-related data

Possible reasons

- Negligent breach of data protection regulations of biobank staff
- Design or implementation errors of the used pseudonymization software

Possible consequences

- Image loss
- Sanctions because of breach of data protection law
- Action of affected patients

Possible coping strategies

- Continuous scientific testing and validation of data protection measures and software components
- Regular staff training
- Externalization of parts of this risk through outsourcing of pseudonymization/anonymization by data custodians

4.2.2.7 Insufficient informed consent discussion of the medical doctor for collection of samples

Possible reasons

- Lack of time
- Lack of staff

Possible consequences

- Complaints because of inadequate informed consent discussions
- Image loss
- Scandalization

Possible coping strategies

- Training of medical doctors according to informed consent Standard Operation procedure

- Integration of biobank processes into clinical processes of cooperating departments
- PR that revocation of the IC is possible at any time

4.2.2.8 Data protection has been violated

Possible reasons

- Hackers
- Burglary
- Non-compliance of data protection directive
- Software error

Possible consequences

- Image loss
- Sensible data escape outside
- Extortion because of date theft
- Claims for damages

Possible coping strategies

- Appointment of a biobank data protection officer
- Data protection training for the staff
- Sensible data is not printed on paper
- Storage of data in access-protected databases
- Network security
- Externalization of parts of this risk through outsourcing of pseudonymization/anonymization by data custodians

4.2.2.9 Mix-up of samples or sample related data

Possible reasons

- Incorrect labeling of samples
- Damaged labeling
- Direct mix-up of samples

- Wrong documentation in the internal database system
- Lack of time
- Lack of staff

Possible consequences

- Image loss
- Worthlessness of samples
- Wrong samples used in projects → wrong results
- Project partners get lost
- Claim of the biobank

Possible coping strategies

- Staff training according to Standard Operation Procedures of the biobank
- "Four-eye principle"
- Follow-up diagnosis through pathologists
- Approval through the biobank management
- Automated identification and process of samples
- Systematic control cuts
- Expanding of personnel resources

4.2.2.10 Less or no samples because of uncooperative medical personnel of the clinical partner

Possible reasons

- Bad communication
- Lack of staff
- Image loss
- Lack of information

Possible consequences

- Lack of samples with rare entities
- Loss of samples

Possible coping strategies

- Training of medical personnel of the clinical partners
- Integration of biobank processes into clinical processes of cooperating departments
- Problem discussions
- Information and motivation of clinical personnel
- Current presentations and reporting about the biobank
- Expanding of personnel resources

4.2.2.11 No informed consent when including samples (serum, cryo)

Possible reasons

- IC is incorrect
- IC gets lost
- IC has been withdrawn
- IC is unscannable
- IC has not been obtained

Possible consequences

- Samples are not usable for research projects

Possible coping strategies

- Training of medical personnel of clinical partners
- Integration of biobank processes into clinical processes of cooperating departments
- Process control through a traffic light system
- Comprehensive IC in all clinical departments of the hospital

4.2.2.12 The informed consent is invalid although it is marked as valid in the system

Possible reasons

- Invalidity of the informed consent cannot be detected when scanning

Possible consequences

- Samples are not usable for research projects
- Image loss

Possible coping strategies

- Staff training (personnel who is scanning ICs)

4.2.2.13 Samples are not usable or inadequate

Possible reasons

- Long ischemia time because of long waiting period in the surgery department
- Poor communication by biobank staff
- Wrong allocation in handhelds
- Thawing of samples

Possible consequences

- Samples are not usable for projects
- Storage capacities are wasted

Possible coping strategies

- Precise working
- "Four-eye principle"
- Staff training
- Current communication with cooperating partners

4.2.2.14 Project requests or project-related data get lost

Possible reasons

- Hardware/software problems
- Accidental deletion of project data

Possible consequences

- Difficulties in re-identification of samples and related clinical data

Possible coping strategies

- Staff training
- Data backup

4.2.2.15 External transport of samples to the biobank is too long and incorrect

Possible reasons

- Too long ischemia time because of long waiting periods in the operating room
- Poor communication between biobanking staff and clinical partners
- Wrong allocation in the handheld devices (e.g., wrong location, wrong diagnosis, etc.)
- Thawing of samples
- Staff for the transport was informed too late

Possible consequences

- Samples are not usable for projects
- Storage capacities are wasted
- Loss of value of samples

Possible coping strategies

- Rapid information transfer

4.2.3 Personnel risks

4.2.3.1 Security risks for staff (e.g., fire risks, personal damage because of samples (liquid nitrogen), risk of infection, cutting damage, etc.)

Possible reasons

- Careless handling
- Ignoring of safety regulations (usage of devices, chemicals, etc.)

Possible consequences

- Sick leave
- Lifelong handicap or invalidity

Possible coping strategy

- Staff training
- Security training
- Safety notes

- Supply safety clothing and safety devices
- Documentation of near-accidents, including related adaption of processes

4.2.3.2 Personnel shortages because of loss of key personnel

Possible reasons

- Too little money and less professional prospects
- Too less education of professional personnel

Possible consequences

- Problems in execution of all processes
- Failure of IT support
- Failure of biobank management

Possible coping strategies

- Implementing representation rules
- Implementing attractive conditions and development opportunities for staff
- Expanding personnel resources

4.2.4 Financial risks

4.2.4.1 Unexpected high costs of repairing and/or maintenance of equipment after damage of infrastructure (e.g., storage capacity)

Possible reasons

- Incorrect or unplanned usage
- No regular maintenance
- Unexpected error
- Natural disasters
- Deterioration of old equipment

Possible consequences

- Unbudgeted repair costs—no money for other essentials (consumable, personnel, etc.)
- Unbudgeted repair costs—no budget—loss of equipment (storage capacity, other robotics)

Possible coping strategies

- Regular training of new and skilled personnel on correct usage of equipment
- Lab books with errors and error handling
- Regular maintenance of infrastructure with professional staff
- Replacement of old equipment in time
- Budgeting of backup funds for contingency

4.2.4.2 Financial damage caused by loss of samples (natural disasters)

Possible reasons

- Natural disasters
- Supply chain damage

Possible consequences

- Loss of samples and data, e.g., loss of money and time
- No new projects—no third-party money
- Possible: obligation to pay out partners (storage services)
- Functioning stop!

Possible coping strategy

- Extramural backup for samples and data
- Budgeted backup funds
- Insurance with reliable coverage

4.2.4.3 Deficiency or shortage of expected financing

Possible reasons

- New political orientation
- Country budget struggling
- No successful applications
- No written agreements

Possible consequences

- No budget for new investments
- No money for running costs and essentials (consumable, personnel, etc.)

Possible coping strategies

- Budgeted backup funds
- Planned low cost run of biobank
- Collection slow down and sharpening
- Active advertisement for projects
- Acquiring of third-party funds

4.2.4.4 Financial damage caused by wrong calculation of project costs

Possible reasons

- Incomplete calculation guidelines
- Lack of training of personnel and controlling
- Underestimation of efforts and expenses
- Communication errors (internal and external)

Possible consequences

- Budget deficits
- No money for running costs and essentials (consumable, personnel, etc.)
- No recognition of real costs—customer loss

Possible coping strategies

- Regular and documented training of personnel
- Calculation guidelines proven by external professional body
- Detailed communication with project partners and customers with usage of check lists
- Timely communication about possible change of costs

4.2.4.5 Financial damage caused by loss of samples in the course of a project

Possible reasons

- Wrong or insufficient documentation
- Incomplete identification concept
- Untrained personnel
- Communication errors (internal and external)

Possible consequences

- No money for running costs and essentials (consumable, personnel, etc.)
- Obligation to pay the expenses of project partner

Possible coping strategies

- Detailed and consequent training of personnel
- Extramural backup for samples and data
- Budgeted backup funds
- Insurance with reliable coverage

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