Terveystalo

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10:35 Author: Sarin, Sanna



SELF-MONITORING PLAN 2024

Suomen Terveystalo Oy



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Introduction

According to Section 27 of the Act on the Supervision of Social Welfare and Health Care (741/2023), the service provider must monitor the quality and appropriateness of its own operations and those of its subcontractors, as well as client and patient safety. The service provider must draw up a self-monitoring plan for each service unit to ensure the quality, appropriateness and safety of daily operations and to monitor the adequacy of the personnel involved in client and patient care, covering all services provided by the service provider and on its behalf in the service unit.

services. The self-monitoring plan must include a description of the procedure for reporting and learning from incidents.

Implementing self-monitoring at Terveystalo

This self-monitoring plan is implemented in all of Terveystalo Oy's sites/businesses and this self-monitoring plan also covers the operations of the Staffing service (HEPA). HEPA also follows the subscribers' self-monitoring plans, as the appointments take place on the subscribers' premises.

This self-monitoring plan does not describe the activities of Rela, Terveytalo Public Services Ltd, Terveystalo Kuntaturva Oy and TT Ålands Tandläkarna, which have their own self-monitoring plans.

In addition to this self-monitoring plan, a site-specific microbiology self-monitoring plan has been drawn up for those sites where clinical microbiology is performed in the local laboratory.

Health care service providers (traders and limited liability companies) operating in Terveystalo are committed to following Terveystalo's self-monitoring plan.

This self-monitoring plan refers to Terveystalo's processes, work instructions and other material available on the Terveystalo intranet.



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Information on the service provider and the establishments

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Jukka Pitkänen (LT, Occupational Health Specialist), Senior Physician, Occupational Health, Jaakonkatu 3 A, 6th floor, 00100 Helsinki, Finland, is the Director of Occupational Health Services at Suomen Terveystalo Oy.

In Terveystalo's Staffing services, the Director responsible for healthcare services is Jussi Sihvonen (Licentiate of Medicine), Senior Physician, Jaakonkatu 3 A, 6 krs, 00100 Helsinki, who is responsible for Staffing Services (excluding Specialist Physician Services, where Paula Reponen LL, Specialist in General Medicine, is the Chief Medical Officer).

The addresses and contact details of the offices can be found on the Terveystalo

website. E-mails can be sent to etunimi.sukunimi@terveystalo.com.



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Mission, values and principles

Mission statement and policies

Terveystalo offers a wide range of primary health care, specialised health care and well-being services to corporate and private customers and the public sector.

Terveystalo's digital reception is available 24/7, regardless of time and place. Health and wellbeing services are also available in around 370 locations across Finland.

In 2023, Terveystalo had approximately 7.6 million customer visits, of which 1.2 million were individual customers.

Strategy, Values and Mission:

Our strategy is to deliver data-driven integrated healthcare. We ensure the most effective prevention and treatment, and the best customer and professional experience. To achieve our mission, Terveystalo has two strategic objectives:

- industry-leading profitability
- positive impact on society as a whole

Terveystalo values:

- at the heart of it all, the human being
- medicine is piloting
- · health care reformer

The Terveystalo Mission:

• We are fighting for a healthier life. This is the mission of the Terveystalo. It means not only curing diseases, but helping people to live healthier lives. A healthier life also includes the social level, because healthier people also mean healthier work communities and a healthier society.

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Organisation and management of self-monitoring

The medical management of the health centre is responsible for the legality of the operations, the medical content of the services, the monitoring of the effectiveness of care and patient safety. The company also has an organisational structure for the management of commercial and operational activities, which is kept up to date on the intranet. The Chief Medical Officer chairs the Medical Forum (Läfo), which deals with the most important medical issues requiring policy. The Läfo is made up of the Chief Medical Officer's direct reports, as well as the Chief Medical Officers of the Business Areas.

The directors of health services (chief medical officers) are supported by a line organisation responsible for the guidance and supervision of services.

At the site level, the Chief Medical Officer and the other senior doctors are represented by the doctors and dentists in charge. The medical and dental directors are supported in their patient safety work by the health service managers, patient safety officers, quality officers and all front-line staff.

In case of absence/absence of the doctor in charge, a replacement will be agreed on a case-by-case basis by the Director of Health Services.

This self-monitoring plan describes the measures and procedures by which the managers of health care services and the doctors/dentists in charge fulfil their responsibilities under the law.

A review of the self-audit plan is part of the staff induction plan. Updates are reviewed at site level whenever substantial changes are made. The self-monitoring plan serves as a as a development tool and its implementation is monitored, for example, as part of annual internal audits. The

medical organisational structure of the Terveystalo is illustrated in the figure below (Figure 1).

Lääketieteellinen johtaminen Terveystalossa



Figure 1. Medical management in Terveystalo



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Description of activities and quality management, risk identification and corrective actions

Description of the activity

Terveystalo is one of the largest health service companies in Finland. The company offers a wide range of health, occupational health, medical, wellness and research services. Terveystalo's customers include private individuals, companies, communities, insurance companies and the public sector. Terveystalo's centralised monitoring and reporting practices, based largely on electronic systems, provide visibility of the activities of the whole network and thus support the implementation of self-monitoring.

Terveystalo verifies the qualifications of its health care personnel with the National Supervisory Authority before the start of employment or professional relationship and responds appropriately to feedback from supervisory authorities and customers regarding its personnel's activities and services.

Quality management

Operational system

Terveystalo is committed to high quality and continuous improvement. Terveystalo's quality is based on medical, functional, customer experience and professional experience. quality. Terveystalo has been awarded the SFS-EN ISO 9001:2015 quality system certificate by Labquality Oy. The certificate covers the group's management system, business lines, centralised group services, reception services, hospital services, occupational health services, imaging services, screening services, laboratory services, oral health services, customer services, health personnel leasing services, biobanking, telehealth services, wellness services, focus specialist units and child protection services. Terveystalo's ISO 14001:2015 Environmental Management System certification covers the network of medical centres providing healthcare services.

The Health Centre's quality system is based on patient safety and national legislation in the sector.

Terveystalo provides up-to-date guidance and electronic tools for both its salaried health professionals and self-employed (self-employed) workers. Occupational health care services are based on the Government Decree on the Principles of Good Occupational Health Care Practice 708/2013 and the amendment to the Decree 1038/2021. Each Terveystalo site providing occupational health care services has described its occupational health care activities in accordance with the Occupational Health Care Decree in the Occupational Health Quality Manual.

Terveystalo systematically monitors and measures medical quality and effectiveness, the efficiency of its operations and the availability of services, customer and employee satisfaction, and, as a pioneer in the industry, publishes these indicators on its website.

The performance of Terveystalo's operating system at the Group and site level is assessed through annual internal audits and quality visits, which include an interactive analysis of process development needs. Synergies in service development activities and patient safety performance are ensured by the Group Quality Steering Group.



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Terveystalo's common practices to ensure service quality, safety, customer focus and efficiency have been defined and published in the Terveystalo Operations Manual. The Manual describes Terveystalo's way of organising its core activities in a coherent and high-quality manner. The aim of the common operating methods and quality work is to support the realisation of the organisation's mission, vision and strategy, the development of operations and the continuous improvement of the quality of operations and results. The manual includes a process map, a code of conduct, work instructions, patient instructions and forms. The process map describes the flow, customers and results of the core processes of Terveystalo. A network of Group Quality Managers, Site Quality Managers and Patient Safety Managers in Terveystalo's sites guide the staff in the sites on how to comply with the Manual. In addition, the Group's service managers, hygienists, pharmacists, patient safety manager and safety manager audit the activities of their respective areas of responsibility and create national guidelines. Several training courses are organised annually in Terveystalo on quality, patient safety, facility security and data protection.

Contents of the operations manual:

- 1. Process map (operating system)
 - Customers
 - Process descriptions
 - Value added
- 2. Operational and quality policy
- 3. Operating environment and stakeholders.
- 4. Document management
- 5. Management of records
- Key legislation in the sector
- 7. Risk management
- 8. Deviations and corrective measures
- 9. Audits
- 10. Environmental management system

Labquality Oy's ISO 9001:2015 and ISO 14001:2015 documentation is reviewed annually by the company's main auditor.



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Audits

The ISO 9001 quality management system and ISO 14001 environmental management system include internal audits, management reviews and external audits.

Terveystalo has a strong focus on internal audits, and a comprehensive sample of the Group's operations and sites are audited annually. The Quality Steering Group defines quality priorities annually. Internal auditors are trained auditors from the Group services.

The results of the internal audits and the areas for improvement identified are reported at site, regional and Group level. Measures to address improvement areas are identified and assigned as part of the management/quality management team (management review) and follow-up procedures are agreed. Audit reports and development measures are available to all health system employees via an electronic tool for continuous improvement. Transparency promotes peer learning.

The evaluation criteria against which the audit compares the activities:

- Applicable laws, regulations, administrative provisions, permit conditions
- Applicable standards, e.g. ISO 9001:2015, ISO 14001:2015, ISO 13485:2016
- Organisational values, strategic priorities, code of conduct, principles
- Common organisational processes and guidelines Customer promises and agreements
- · Written objectives, indicators, measures, resources and monitoring

An external accredited auditor (Labquality Oy) annually assesses the compliance of Terveystalo's operations with the criteria of the ISO 9001:2015 quality standard and the ISO 14001:2015 environmental standard. In addition, all imaging units undergo a clinical audit in accordance with the Radiation Act.

Quality requirements for suppliers and subcontractors

Terveystalo expects suppliers to commit to the quality criteria defined in the contract and in force in each industry.

The quality indicators and targets set for Terveystalo's contracted suppliers are monitored in accordance with Terveystalo's SRM model. In addition, supplier audits are carried out for strategic and critical suppliers on an agreed annual basis. Suppliers are required to comply with Terveystalo's Supplier Code of Conduct.



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Customer satisfaction

The SFS-EN ISO 9001:2015 quality management system requires systematic monitoring of customer satisfaction and continuous development of customer-oriented operations. Terveystalo monitors the customer experience using the following methods:

- NPS (Net promoted score) a real-time referral index collected through text message feedback
- Expert customer satisfaction
- Effectiveness of care PEI (Patient Enablement Instrument), which measures the patient's sense of wellbeing.
- · Collecting and using direct customer feedback
- WheelQ -Customer satisfaction surveys

The Net Promoted Score (NPS) measurement, which is collected in real-time as text message feedback, is done by sending a question to the customer via SMS the day after the visit. The customer is asked to rate how likely (on a scale of 0-10) they would recommend Terveystalo to their friends or colleagues.

Requests to contact us via SMS are processed in the electronic feedback system in the same way as spontaneous feedback. It is also possible for the customer to opt-out of receiving the enquiries.

The specialist customer satisfaction measurement provides more accurate and targeted information on customer satisfaction along the service pathway, alongside the general NPS. The feedback is intended primarily to support the professional's own development, and as a coaching management tool for frontline staff. For health professionals, customer satisfaction is measured by the question "how satisfied were you with the service of our specialist?" (on a scale of 1-5).

Customers can spontaneously give feedback on our activities by filling in a customer feedback form, by letter, email, verbally, in person, at customer meetings and via the website. The Health Centre's website contains digital feedback forms for individual customers as well as for corporate, community and public sector customers. Customers will always receive a reply if they have requested to be contacted and have provided their contact details. Feedback can also be given anonymously.

The way in which customer feedback is handled is described in the Health Centre's operating system. Feedback is handled in a feedback system, which controls and records the workflow of feedback handling, as well as statistics and reports on the implementation and actions triggered by feedback. The agreed indicators and reports are monitored at all levels of the organisation. Quality audits always assess the handling of customer feedback, the analysis of the results and the resulting actions and the impact of those actions.



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Patient safety

Ensuring patient safety is a cornerstone of quality management. Patient safety is monitored and developed by the Quality Steering Group, which reports to the Chief Medical Officer, and the Patient Safety Working Group, which is chaired by the Chief Quality Officer. The role of the Quality Steering Group is to provide knowledge management and monitoring of key quality indicators related to the quality cycle (medical, functional, customer experience and professional experience quality), as well as policy and line development guidance related to quality and patient safety. The Patient Safety Working Group focuses on patient safety issues and defines priorities that change from year to year. Terveystalo also has a group-wide incident monitoring group, chaired by the Patient Safety Manager. The purpose of this working group is to monitor incidents in the different functions (e.g. laboratory, imaging, hospital), to make guidelines for the work instructions of the functions, and to develop the incident system and patient safety culture. The members of the working group will also address national-level incidents, identifying measures to be implemented at the corporate level and rolled out to the regions/offices. The Incident Monitoring Group prepares quarterly examples of incidents and corrective actions by function for use by the regions.

The Patient Safety Manager monitors the patient safety situation, e.g. incident reports, and reports regularly to the Quality Chief Medical Officer, the Patient Safety Team, the Medical Forum, and the Patient Safety Officers and responsible doctors.

There is a network of patient safety officers in the regions and/or sites, whose task is to handle site/area incident reports and, together with the site chairs, to ensure that with the root cause analysis and that the agreed corrective measures are implemented. The persons responsible for patient safety report regularly to the quality management team and the site/function on patient safety issues and incidents and their measures in accordance with the patient safety reporting template.

Every employee has both the right and the responsibility to report an incident when they become aware of a situation. Near-miss reporting is particularly encouraged because it is an effective way to improve operations without any patient harm having yet occurred. All employees at Terveystalo have easy access to record incident reports via the intranet and patient information systems. Patient safety incidents (both near misses and adverse events) are processed, reported and prevented through a common incident reporting system.

Root cause analysis is at the heart of incident management. It aims to identify and eliminate the root cause(s) of an incident at both site and corporate level. Through incident statistics and reporting, potentially recurring problems and guidance needs are identified. Corrective actions are communicated to staff through various networks, site meetings and training sessions. In addition to the site managers, the Group's Patient Safety Manager and the Service Manager of the function concerned by the incident are involved in the handling of serious incidents.

Every three years, employees who work in the health centre's nursing department complete an online course on patient and client safety as part of their patient safety assurance. The site's patient safety officers are regularly trained through online courses, Teams training, and an annual Quality and Patient Safety Day. Every two years, a patient safety culture survey is carried out for all staff, the results of which are reviewed at Group and regional level. The results are used to identify areas for development from national to regional level/activities. Measures to address these areas for improvement are regularly monitored.



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In the case of Human Resources Services, the Contracting Entity shall notify Terveystalo of any incident involving an employee of the Human Resources Service that has occurred on the premises of the Contracting Entity. These notifications are recorded in Terveystalo's incident system, and are processed by its own Human Resources Services.

according to the process described.

Terveystalo has selected the following as long-term trend indicators for patient safety:

- Near misses as a proportion of incidents
- Percentage of medical visits for compensated patient claims

In addition to the trend indicators, annually changing priorities are selected, the priorities for 2024

are:

- Aseptic behaviour; near misses as a percentage of recorded incidents
- Ensuring the competence of frontline staff in dealing with incidents
- Ensuring the safety of medicines in premises through a self-inspection of the premises

A surgical team checklist is in use in all of Terveystalo's surgical units. One member of the surgical team is always responsible for ensuring that all items on the checklist are reviewed and completed. The use of the checklist is documented on the anaesthesia form.

Data protection and security is monitored and steered by the Data Protection Group.



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Risk analysis and incident preparedness

Risk analysis and incident preparedness are carried out at every level of the Group. The Group's management defines the significant risks to the organisation and the procedures for dealing with them. Regional management ensures the management of organisational risks in the region, and the identification and response to local risks. The Group Preparedness Team provides guidance and direction on the management of sudden and potentially escalating crisis situations and crisis communications.

The Terveystalo's sites ensure that their day-to-day operations comply with the guidelines, achieve the objectives and results of their processes, and identify and prevent risks to patient and occupational safety. Implementation is monitored at local management and quality management team, regional organisation and Group level.

Each site has described its operating procedures and responsibilities in case of emergency. Emergency management guidelines, including treatment charts, have been compiled on a dedicated website on the intranet. An emergency is defined as both a first aid situation involving a person and an emergency situation on the premises (e.g. fire). The First Aid Operations Manual has been refined to describe exactly what to do and how to act in each case.

in the establishment, taking into account the size of the establishment, the number of staff and other relevant matters. For example, each site's patient first aid manual will describe who is responsible for checking and ensuring the proper functioning of first aid drugs and equipment, and first aid alarm systems. The first-aid manual will include

by the director of health services and the service manager annually at the site/activity, and practised in the site's first aid and CPR training.

In emergencies that are considered to be a crisis, the Group's crisis communication and emergency response guidelines are followed.

In the event of an emergency on the premises, each site has drawn up a safety manual, which is discussed in more detail in the chapter on premises. Occupational safety risk assessments are carried out in line with occupational health processes in the context of workplace surveys.

The following have been identified as high-risk activities for patient safety:

- 1. Surgical operations and measures
 - Eligibility for surgery and the consequences of misjudging it
 - assessing physical performance, identifying factors that increase the risk of surgery, improving surgical fitness and providing appropriate information to the patient. High risk patients include at least ASA 4 or in some cases ASA 3 patients.
 - Surgery-related infections
 - Surveillance of overnight patients
 - Patient follow-up after an operation or procedure and assessment of discharge eligibility



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2. Unsigned laboratory tests

In addition to the surgical team's checklist and instructions for the management of resuscitation, a perioperative anaesthesia manual has been developed to help manage the risks associated with surgery. The utilisation rate of the surgical team checklist is monitored as part of the Quality Index both in the Group and in the hospital units.

Local guidelines are in place to ensure the timely transmission to the patient of laboratory test results above or below the alert thresholds, according to which both alarming laboratory test results and abnormal ECG findings in symptomatic patients are handled at the sites. For samples examined in the central laboratory, the laboratory of the Terveystalo Kamp site is first notified centrally of alarming laboratory test results, from where the alarming laboratory test results are always forwarded to the requesting site, the requesting site or to a tele-physician for evaluation and processing.



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Continuous improvement and incident management

The following inputs, their analysis and corrective actions will ensure quality realisation and improvement:•

customer feedback (personal and subscriber customers)

- solution times
- time and cost of handling customer complaints• complaints

to the director of the health service

- complaints to the Regional State Administrative Agencies
 complaints to Valvira
- notifications to the Patient Insurance Centre
- annual risk assessment in line with risk management policy
 internal incident reporting
 - incident reporting, monitoring and reporting• near

misses

- events of interest
- incident costs• healthcare associated infections
- ISO 9001:2015 quality management system and ISO 14001:2015 environmental management system internal audits, management reviews and quality visits
- imaging self-assessment process and clinical internal audits• laboratory quality monitoring rounds
- Medicines safety audits in pharmaceutical care
- hygiene surveys (self-inspection for infection control)
- External audits of Labquality Oy under ISO 9001:2015 quality management system and ISO 14001:2015 environmental management system
- inspections and audits by official bodies:
 - Fimea (for hospital pharmaceutical centres)
 - Stuk (for imaging units using ionising radiation)
 - External clinical audits of imaging, Labquality Oy (for imaging units)• Tukes (pressure equipment inspections for instrumentation, electrical equipment inspections)
 - Kela direct compensation audits
- development channel: staff suggestions for improving operations and systems• supplier audits and surveys of customers who have used services
- annual internal audits
- improving the operational processes of the establishments themselves• The Heimo approach to digital development

Terveystalo is developing the monitoring of the efficiency and effectiveness of the patient care pathway from several different perspectives. For example, the Medical Quality Metrics and Dashboard, monitoring the efficiency and effectiveness of the care pathway in orthopaedic surgery with the Forte system, ensuring the traceability of prosthetic joints with the THL register and monitoring the effectiveness of long-term care with the Etydi tool.



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Staff

This section describes in more detail the recruitment process, induction, appraisal interviews and skills development. It also describes the processes related to health and safety at work and patient safety.

Number and structure of staff

Terveystalo employs approximately 13 800 people, of whom 66% are employed and the rest are self-employed.

Recruitment

Our recruitment process involves verifying the qualifications of the person you are recruiting from the register of health professionals maintained by Valvira. Those working with children within the meaning of the law are required to submit a criminal record check before being hired. In addition, we verify the person's competence within the framework of a mandatory probationary period. Our recruitment process also includes a thorough review of the candidate's competences, licences and practical language skills in relation to the skills and qualifications required for the role.

Induction

The practical arrangements for the start of the employment relationship and the induction of new staff shall be the responsibility of the member of staff in charge, or a person designated by him. The induction of doctors at Terveystalo is assisted by the Medical Account Managers (LAVs), Liaison Managers and Resource Managers. The induction of dentists is assisted by Terveystalo's oral health service managers (PAVs), regional managers and the dentists in charge. The induction process ensures that the new employee receives the necessary information about the company, his/her unit and his/her role in order to be successful in his/her job. The Terveystalo's induction guidelines, as well as induction material for new practitioners, can be found on the intranet and in the e-learning environment. There are induction support materials and induction forms both for Terveystalo's activities and for the needs of different professional groups. Particular attention is paid to the medical care plan and to the use of equipment and supplies.

The induction of contract staff is documented in the personal data system. A performance survey is used to collect information on the success of the induction and the new employee's integration into the workplace. The questionnaire is sent to all new employees 60 days after the start of employment. It is possible to collect information from doctors on the success of their induction at an earlier stage by sending an induction questionnaire to the doctor who has started working with them, by the Medical Officer, the Liaison Officer or the Resource Manager.

The temporary employment agency is responsible for the professional competence and training of any temporary workers used in Terveystalo, for checking their professional qualifications with the National Inspectorate of Public Health and, if necessary, for checking their criminal record. Terveystalo shall be responsible for familiarising the temporary agency worker with the job and working conditions, occupational health and safety measures and, if necessary, arrangements for cooperation and information on occupational health and safety and occupational health care.



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Development Debates

A development interview with the frontline person will plan the objectives for the coming year, and your personal skills development needs. To identify competence needs, Terveystalo provides both job description and role-based guidance, and competence needs are supported by training. The purpose of Terveystalo's development discussions is to support the strategy and the setting of objectives, and to enable the development of staff competencies in line with the objectives. The aim is to hold a practitioner dialogue with practitioners once a year, with a responsible person appointed for each practitioner.

The chaperone is responsible for conducting the development interview. The performance appraisal interviews are recorded in the personnel system for staff members, from which the outcome of the interview can be verified. The supporting material for the development and apprenticeship interviews is checked annually by HR and the relevant experts to ensure that it is up to date.

Training and skills development

Terveystalo organises comprehensive training for its staff: supplementary professional training for different professional groups (e.g. For example, for doctors and dentists, Terveystalo's own Doctors' Days, for dentists and specialist dentists the Academy of Oral Medicine, for nurses the Nurses' Days, training in drug treatment and care, and first aid training for all staff at the sites), qualification training, administrative training (e.g. IT and pre-service training) and training in Terveystalo's own services (e.g. training days for imaging). It is important for Terveystalo to ensure that its staff receive adequate in-service training. In addition, Terveystalo offers career paths for its staff in medical and administrative specialist positions, as well as in chauffeur positions.

Health care professionals working as self-employed persons (self-employed persons) in Terveystalo are responsible for the level of their medical competence, its maintenance, and the implementation of adequate continuing education. In the case of a health professional working under contract for Terveystalo on behalf of another undertaking, the undertaking is responsible for the professional competence and training of the health professional. Terveystalo requires that health professionals working in its establishments have an adequate level of competence in accordance with their professional title.

Training is tracked using both a personal data system and an electronic training platform. The frontline staff will verify the completion of the training in the context of the appraisal interview. In particular, we monitor the implementation of the statutory radiation protection training, and the continuing training in occupational health care in accordance with the recommendations of the Ministry of Health and Social Affairs as part of quality audits. Terveystalo also acts as a trainer for doctors specialising in occupational health care. Theoretical training (periodic training) for doctors specialising in occupational health care is organised to support on-site training. Specialists in occupational health who are trainers of medical specialists will be given their own training and will be encouraged to participate in the pedagogical training of trainers provided by the University. Terveystalo has launched an on-site training package for doctors called "Knowledge to Skills".

The staff of the health centre are also trained through regular equality training.

Medicines licensing practices, ensuring competence

Nursing staff are required to have a valid medication licence issued by Terveystalo in accordance with Terveystalo's licensing policy. Practices for ensuring competence are defined in the Group-wide Pharmacotherapy Plan, and licences must be updated every 5 years. The procedures for ensuring competence are described in more detail in the Medication Care and Maintenance section.

The front office records the authorisations in the HR system, which forms the basis of the actual authorisation register for the HR management report. The role of the frontline worker is to monitor the validity of the medical authorisations through the report and to plan the renewal schedule together with the employee within the authorisation period.



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Monitoring well-being at work

In addition to day-to-day management, factors limiting well-being at work are also monitored in the annual talent survey. The survey measures the satisfaction of staff and professionals with the conditions for success at work, such as workload and the adequacy of work equipment. We also use the surveys to monitor staff's assessment of their own well-being at work. In accordance with Terveystalo's success management approach, the supervisor has a duty to monitor the employee's performance and, if he or she detects signs of changes in work performance, to discuss the matter openly with the employee as early as possible. The annual appraisal interviews also include instructions to discuss the individual's own well-being at work. Terveystalo also has practical guidelines for dealing with substance abuse problems.

An essential part of the training of first responders is training on how to deal with difficult situations, as well as early intervention in Terveystalo. A model for success management can be found on the intranet.

The risk factors at work are mainly blood injuries, the threat of violence, night work, ergonomics, and psychological well-being. All occupational health services for staff are provided by the company's own in-house occupational health service.

In acute cases of illness, staff can use all of Suomen Terveystalo Oy's locations within the framework of the occupational health care agreement. Preventive and non-urgent medical care is provided by designated occupational health physicians and occupational health nurses. The working capacity of staff is measured in various ways through health checks. At Terveystalo, well-being is systematically supported in four areas: healthy work, a healthy employee, a well-functioning work community and active management.

In addition to our occupational health services, development in the area of well-being is supported by our occupational pension insurance partners.

The first line manager is responsible for the employee's fitness for work, so if the first line manager has reasonable doubt about the employee's fitness for work, the first line manager will refer the employee for a medical assessment with a separate referral, as instructed.

Patient safety

At Terveystalo, every employee is responsible for patient safety, and therefore has both the right and the obligation to report to his or her supervisor any issues affecting patient safety that he or she observes, and to report any incidents to the electronic system.



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Safety and health at work

The safety at work of everyone working in the Group is the joint responsibility of the employer, front-line workers and staff, in accordance with their own defined safety responsibilities. The health and safety managers and the health and safety representatives elected by the staff assist the managers and staff in matters relating to health and safety and develop health and safety issues in the context of joint health and safety cooperation.

Job hazard assessment is one of the most important occupational safety development measures in the Group and is carried out in accordance with the existing annual plan by occupational group and site. The implementation of the Group's occupational safety measures based on the risk assessments, among other things, is carried out in the regions and sites, taking into account local conditions. Occupational safety plays a major role, for example in staff induction.

Terveystalo has guidelines for the management of various work safety and work cycle risks: threat and violence situations, dealing with an aggressive person, the Unlawful Threat Policy, working alone, cold work and cold injury management, measures in blood exposure situations, mental workload, harassment and other inappropriate treatment, etc.

Guidelines on occupational safety are followed throughout the Group. The guidelines are available on the intranet. As such, the work safety guidelines also apply to self-employed persons working at Terveystalo.



Inspected by Antti-Jussi Ämmälä 28.2.2024

Author: Sarin, Sanna

Premises

The site inspection reports of the establishments are stored with the permit documentation. The licensing coordinator guides and advises the directors of health services on the registration of service units. The Licensing Administration is under the authority of the Quality Surgeon.

Terveystalo mainly operates as a tenant in commercial and office buildings. The leases are generally long-term due to the nature of the operations.

Facilities and their maintenance

Terveystalo's premises services are responsible for the appropriateness and structural safety of the premises. The property management system (Fatman Frame) provides information on all the premises under lease. Normal property maintenance responsibilities in leased premises are mainly the responsibility of the property owner. The building services for the medical equipment of Terveystalo are the responsibility of Terveystalo. This building technology is managed/maintained by contracted partners.

The level of protection of the site in terms of access control, burglary and fire protection is determined by the activities taking place on the premises. If the property owner has these systems in place, they will be used. Each premises will be protected by a burglar alarm system. Fire protection will be in accordance with the Finnish Building Code, with particular emphasis on fire protection in cutting rooms.

Implementation and supervision of spatial planning

Facilities services lead the structural engineering design and implementation of facilities. The facilities are designed in collaboration with the facility managers and users, following a design and implementation process.

Room cards have been drawn up for the different activities to ensure uniform, functional, high-quality and efficient premises. The room cards are always indicative and are applied according to the building and the environment. The necessary room cards will be provided to designers on a case-by-case basis.

The indicative work specifications are drawn up for each site for building services, plumbing systems and gas systems. The specifications will cover, for example, telecommunications network requirements, ventilation, cooling, camera and sound systems, etc.



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Author: Sarin, Sanna

Safety guide

The Group has drawn up safety instruction models (medical centre, surgical unit, oral health unit, inpatient ward, service housing, family and pupil care and child protection), which describe the risks to safety on the premises, the measures to prevent them and the procedures to be followed in the event of a risk materialising. A safety manual must be drawn up for each establishment, which is responsible for its own safety manual.

The Director of Health Services appoints a safety officer for each site, who is responsible for drawing up, updating and disseminating the safety manual in the form of safety walks in the site.

The establishment reviews its own security policy at least every two years, and always when changing premises. The essential information is transferred from the general emergency plan of the building to the safety manual, which is a more detailed document than the general emergency plan.

In addition to the safety instructions, the cutting site shall also draw up an exit safety report, which shall be submitted to the local emergency services and, for information, to the building control authority.

The pharmaceutical contact person and the safety officer complete the list of chemicals in use in the site's safety manual and ensure that up-to-date safety data sheets are available for these substances. Establishments also have an electronic chemical register where it is possible to create an establishment's list of chemicals and find an up-to-date safety data sheet for each chemical in use.

Organisation of medical premises, access control, burglary and fire protection

The 13 hospital sites of the Terveystalo have their own medical centre.

Medicines shall be stored in lockable premises of sufficient size and purpose, accessible only to persons authorised to handle medicines. Medicinal products shall be stored in a locked area intended for that purpose, such as a separate lockable medicine cabinet or a medicine room with access control.

Keys to the medicine cabinet or room and access control are arranged to prevent unauthorised persons from handling medicines. Particular attention will be paid to medicines that are at risk of misuse. The drugs themselves shall be kept in a separate locker, locked and access control shall be arranged to prevent unauthorised persons from gaining access to them.

Alcohol refers to denatured ethanol, spirits and industrial/kitchen alcohol. Alcohol storage must be lockable to prevent unauthorised access. Alcohols are highly flammable chemicals. No more than 25 litres of flammable liquids may be stored in office rooms and similar spaces.

In accordance with the establishment's safety manual, the establishment will take into account the more detailed descriptions given for gases and flammable liquids, for example.



Author: Petri Bono, 6.3.2024 09:39 Inspected by Antti-Jussi Ämmälä 28.2.2024

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Author: Sarin, Sanna

Medical devices: health care equipment, supplies and software

This section describes in more detail the life cycle management of Terveystalo's medical equipment, and equipment safety. It describes the procedures for the acquisition, commissioning, maintenance and removal of medical equipment. The section also discusses who is responsible for what, and what to do in the event of an emergency.

Responsible persons and medical device monitoring system

Terveystalo has a monitoring system in place to ensure the safety of medical devices and their use, in accordance with the obligations of professional users (719/2021, § 34).

The tracking system records the information required for traceability of the devices used, transferred or otherwise controlled by the units, as well as the devices installed on the patient. In Group Services, the Technology Manager is responsible for the core processes and guidelines for device management and liaising with the authorities. The Technology Manager reports to the Group's Quality Surgeon, who acts as the responsible person for professional users as defined in Section 32 of the Medical Devices Act 719/2021. Healthcare devices are registered in the device register, which contains the monitoring data required by law and regulations. In the sites, the counterparts of the Group Technology Manager are the Equipment Managers, who are responsible for equipment safety in their sites in cooperation with the designated responsible users of the equipment. Staff report incidents involving healthcare equipment through the Terveystalo's internal electronic system. The Technology Manager and the Patient Safety Manager monitor the reports through the system, and assist in root cause analysis where necessary. Incidents are reported to Fimea as required by law, and to the Radiation Safety Centre for equipment using ionising radiation. A safety licence is obtained from the Radiation Safety Centre for each imaging unit and for the use of radiation in the oral cavity and operating theatres.

For ionising radiation and magnetic safety, the radiation safety experts and medical physics experts are the designated hospital physicists. The physicists also act as liaison officers between the radiation safety facilities and the radiation safety authority, managing the safety authorisations for equipment using radiation, the radiation safety assessment and the management plan and any changes thereto. The activities concerning the use of radiation in the Health Centre are described in the Radiation Safety Assessment and Management System.

The safety assessment summarises the overall radiation safety structures, practices and responsibilities related to radiation use at Terveystalo. The document describes the radiation exposure arising from Terveystalo's operations in both normal and abnormal exposure situations, the classification of radiation activities, measures to optimise radiation protection and prevent abnormal events, and the radiation safety management system.

Purchase of medical equipment

The procurement of medical devices follows a designated process description. The procurement of medical equipment is carried out in accordance with the investment plan, taking into account sustainability issues. Investment plans take into account the life cycle model of the equipment, equipment safety and criticality, and compliance of medical devices and in vitro diagnostic medical devices.

The procurement of medical devices is centralised in the Group Services' experts, who ensure that the medical devices comply with the requirements of EU regulations (e.g. MDR 2017/45, IVDR 2017/746) and national legislation, taking into account possible transition periods. The devices to be procured are required to meet the performance, patient and user safety requirements for their specified intended use, as well as the documentation required for the use and traceability of the device in accordance with EU compliance requirements

in line with. In addition, the equipment to be purchased is subject to specific security and data protection requirements defined by Terveystalo. The decentralised procurement of small equipment is carried out in accordance with the product catalogues approved by the above-mentioned experts via an electronic purchasing system. The content of the catalogue is evaluated and updated annually.



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Introduction, familiarisation and prior authorisation procedures for medical devices

The introduction of a medical device follows a designated process description. Prior to commissioning, the authorisation procedures for ionising radiation equipment, pressure equipment and clinical trial equipment are ensured.

The introduction of a health care device using ionising radiation requires a safety licence as defined in the Radiation Act 859/2018, or an amendment to an existing safety licence. A radiation safety officer is appointed and his or her competence is verified for each site-specific part of the management system. In addition, the site manager(s) and the radiation safety expert and medical physics expert are appointed. The safety authorisations for radiation-using equipment, their modification and termination, as well as the organisation of expert services in accordance with the Radiation Act, are centrally managed by the physicists in the group services. The Radiation and Nuclear Safety Authority approves the use of radiation facilities and structural radiation protection in safety licences.

Pressure equipment used in healthcare is registered in the Pressure Equipment Register of the Finnish Safety and Chemicals Agency (Tukes) when it is put into service, in accordance with the Pressure Equipment Act 1144/2016 and Government Decree 1549/2016 on the safety of pressure equipment. For autoclaves with a chamber volume of more than 200 barL, a use supervisor has been appointed who is responsible for commissioning pressure equipment inspections on the registered pressure equipment and for the safety of the pressure equipment in accordance with Chapter 10 of the Pressure Equipment Act. The controller is also responsible for the registration and notification of the owner, the holder, the location and the operating light source of the pressure equipment and any changes thereto... The controller shall ensure that an installation plan for autoclaves with a chamber capacity of more than 1000 bar L is drawn up before the autoclaves are put into service and checked by an approved inspection body.

In the event of a malfunction or hazard, the supervisor shall prevent the use of the pressure receptacle until the deficiency which endangers the safe operation of the pressure receptacle has been corrected.

Terveystalo follows Good Clinical Practice (GCP) in clinical trials, taking into account the Helsinki Declaration of Principles on Ethics. Clinical trials are notified, authorised, conducted and reported in accordance with EU Regulations MDR 2017/745 or IVDR 2017/746 and national legislation and guidelines. If the clinical trial includes a medical device and a drug component or if the medical device is part of the drug delivery, the requirements of EU Regulation CTR 2014

/536 obligations. For clinical device testing, the person in charge of the device testing, together with the sponsor, is responsible for fulfilling the notification obligation to Fimea.

Before the device is put into service, the users of the device are familiarised with its operation. This training will be provided through online training and physical training. A responsible user will be appointed for the healthcare device and will instruct other staff on the safe use of the device. The responsible user also ensures that the user manual and technical manual are available and up-to-date, organises the acceptance inspection, warranty period monitoring and warranty review, informs other users of the impact of any updates or modifications to the device, ensures the maintenance and safety of the device and records monitoring data on the device, such as maintenance, faults and incidents, in the device register.

Before a medical device is put into service, the acceptance inspection ensures that the device has been received as ordered, installed properly and is fully functional and safe to use (e.g. electrical safety measurements have been carried out). It is also checked that the vendor has trained the users so that they have sufficient technical and functional knowledge to use the equipment safely. The condition of the equipment is monitored particularly carefully throughout the guarantee period.

During the commissioning phase, the responsible user of the equipment shall record the equipment data in the equipment register as comprehensively as possible (719)

/2021 34§). The register of equipment also includes equipment owned by self-employed persons for the treatment or examination of patients. If the self-employed person uses his own equipment, he undertakes to comply with the same requirements for ensuring the safety and performance of the equipment as mentioned above, as are imposed on the equipment owned by the Health Centre. The practitioner is responsible for the monitoring, licensing and notification procedures for his/her own equipment, but Terveystalo can provide support in these.



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Maintenance of healthcare equipment

Scheduled and emergency maintenance of healthcare equipment follows designated process descriptions. Periodic maintenance and in-service inspections of healthcare equipment are carried out in accordance with regulatory requirements and manufacturer's instructions to ensure that the equipment is in good working order, safe, functional and capable of providing accurate diagnostic information during use (719/2021 § 32(2)). Guidelines have been drawn up on the frequency and pass criteria for maintenance, and their implementation is regularly monitored. Measurements are performed with traceable calibrated or otherwise appropriate equipment. Detailed reports of the measurements are produced, showing the results of the measurements and the pass criteria for the results.

Documents are kept throughout the lifetime of the device.

The appropriateness of the premises where healthcare equipment is used is assessed through periodic inspections in accordance with internal guidelines. In addition to the assessment, the Terveystalo's internal technology maintenance team participates in the implementation of designated equipment maintenance activities, and makes observations on the safety of medical facilities during their annual visits to each site, reporting any deficiencies. When designing new medical facilities, equipment placement takes into account government regulations and recommendations, as well as occupational and patient safety considerations. Adequate structural protection shall be planned for areas where ionising radiation equipment is to be used. When the equipment is commissioned, maintenance experts and physicists take measurements to verify the structural protection, if necessary. The Radiation Protection Authority carries out inspections of new and, where appropriate, existing strong rooms for the use of equipment using ionising radiation.

The medical equipment maintenance team at Terveystalo receives regular training by attending manufacturers' maintenance training courses and general training sessions on hospital technology. A radiation safety officer and an electrical safety officer have been appointed for maintenance activities. The following are involved in the maintenance of radiation equipment

persons maintain further training in radiation protection in accordance with the Radiation Act 2018/859 and the STM Decree on ionising radiation 1044/2018. A quality assurance programme has been drawn up for the X-ray operations of the Health Centre, the contents of which are described in the Safety Assessment.

The pressure equipment supervisor is responsible for monitoring the use and condition of pressure equipment (autoclaves), for making the statutory declarations relating to the pressure tank and for arranging for the periodic inspections of all registered autoclaves to be carried out in good time (2016/1144 § 70). In the event of a malfunction or hazard, the supervisor shall prevent the use of the pressure tank until the deficiency that endangers the safety of the use of the pressure tank has been remedied.



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Medical device emergencies

Exceptional circumstances for a healthcare device or supply include:

- incidents involving a healthcare device or equipment (self-reported and manufacturer-reported suspected incidents)
- fires, water damage and other accidents
- failure of healthcare equipment

The actions and responsibilities in different types of emergency situations are described in work instructions (e.g. information, removal of equipment or supplies, notification of the authority, recording in medical records).

Any incident or accident involving a patient or staff member is reported in the incident system. In the event of an incident, the person who observed the incident reports the incident to the electronic system. Through the notification system, the handling of the incident, the investigation of the cause, the corrective and preventive measures and the notifications to the authorities can be monitored and promoted by the person in charge of the professional user within the meaning of Law 719/2021. The members of the Group's Incident Team participate in the handling of incidents and, if necessary, request the opinion of the responsible person or medical management on the safety of the treatment procedures or equipment. Incident reports are always recorded in the Health Centre's reporting system.

A notification is made to Fimea in accordance with the Medical Devices Act 719/2021 §33. Incidents involving software classified as medical devices are handled in accordance with uniform procedures, taking into account the parallel reporting obligations under the Customer Information Act. The procedures describing the obligations for software covered by the Customer Information Act 703/2023 are described separately. In the case of an abnormal event in the use of radiation, notification is also made to the Radiation and Nuclear Safety Authority. Deviations in the use of radiation that do not require immediate notification to the authority are reported to the Radiation and Nuclear Safety Authority in a specified format on an annual basis.

If the threat of an incident affects the wider organisation, the Group's technology and procurement teams will ensure that.

- the Terveystalo offices are informed without delay of an incident or serious suspicion of an incident the incident or suspicion is also widely distributed when the seriousness or
- it is not possible to reliably estimate the extent of the damage. In the event of a crisis, the guidelines on crisis communication and emergency management will be followed.
- the supplier of the equipment or accessories is contacted and the necessary measures are agreed.
- Instructions on how to follow up are communicated to the sites in cooperation with the service line of the function (e.g. returns/credits of supplies).

In the event of an accident, the internal safety manual of the establishment is followed.



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Withdrawal of a healthcare device

The decommissioning of healthcare equipment follows a designated process description. Where possible, efforts are made to recycle healthcare equipment - either by selling it, returning it to the manufacturer for recycling or disposing of it in an environmentally friendly and safe way, in accordance with the Terveystalo's waste management guidelines. Any notifications to the Radiation and Nuclear Safety Authority and the Finnish Safety and Chemicals Agency related to the disposal of the equipment will be coordinated centrally. Information on the radioactive equipment is kept in the equipment register for at least five years after decommissioning.

Own products

Terveystalo manufactures in-house medical device software as in-house devices in accordance with MDR 2017/45, Article 5, while operating in accordance with the requirements of the certified ISO 13485:2016 quality management system. The declarations of conformity of Terveystalo's in-house device software can be found on the Terveystalo website. Terveystalo does not manufacture or distribute proprietary products for physical medical devices or supplies.

Distribution, dispensing and devices to be implanted in the patient

Terveystalo acts as a non-reportable distributor for devices classified as medical devices that are provided to patients. The medical devices to be supplied to patients are limited and their recall procedures are described in separate guidelines. For Class III implantable devices, an implant card is issued to the patient/customer (719/2021, §§36). Terveystalo enables and secures the patient's access to the data of the device implanted in him/her. The implant card requirements do not apply to sutures, hooks, dental fillings, braces, crowns, screws, wedges, plates, wires, pins, clamps and connectors.



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Medicines and medical care

Medical care network

Medication safety is an important part of safe and appropriate care for the client/patient, i.e. client and patient safety. At Terveystalo, the promotion and monitoring of medication safety, as well as the coordination of national medication management and the harmonisation of practices, are part of the Group's medication management tasks. The Group's pharmaceutical care team includes a chief pharmacist and two pharmacists. Group Pharmacy is aligned with the medical management and is responsible for planning, implementing and managing measures to improve medication safety and risk management. Specialty Managers act as medical experts to support the Group's Pharmaceutical Care function.

The role of the Chief Pharmacist is to organise national policies for the legal, safe, effective and appropriate management and care of medicines, and to oversee the safety of medicines as part of patient safety.

The pharmacists in the Group Pharmacy Service are responsible for the development and implementation of work instructions for pharmaceutical care, as well as the development and coordination of pharmaceutical care processes. The tasks also include coordinating and supporting the activities of Terveystalo's pharmaceutical care network, conducting staff training and induction, developing and maintaining the basic pharmaceutical range, pharmaceutical care quality work such as internal audits and developing self-monitoring.

In the 13 hospital units of the Terveystalo, where there is a pharmaceutical centre, the pharmacist or pharmacist in charge of the pharmaceutical care and ensuring the availability of medicines is the nurse in charge of the pharmaceutical centre. The pharmacy nurse ensures that the procurement, storage, preservation, delivery and provision of information on medicines are carried out properly and in a way that promotes the safety of medicines. The medical centre nurse shall also ensure that drugs are handled, stored and accounted for properly. Pharmacists and pharmacists are responsible for developing the drug treatment processes in their units, and for ensuring medication safety through ward visits and inspections. Pharmacy nurses also support other sites in the region with their pharmaceutical expertise, for example in the development and updating of medication management plans and in matters related to medication safety in the units.

In the hospital units with medical centres, there are designated and trained medical officers for each function. Their tasks include monitoring deviations, cleaning the medicine cabinet and monitoring the shelf life of medicines, as well as ensuring the correct storage temperature and the safety of medicines in the unit.

In each Terveystalo location without a pharmaceutical centre, a pharmaceutical care contact person, e.g. an experienced nurse, and a deputy designated and trained by the pharmaceutical care department, are appointed and trained by the pharmaceutical care department.

In all Terveystalo sites that provide medication management, the management bears overall responsibility for the implementation and conditions of safe medication management. In each Terveystalo site, a responsible doctor/dentist is appointed who is responsible for the overall management of medication. The frontline staff supervise and monitor the implementation, planning and quality of medication management in accordance with the site's medication management plan. Each person providing or participating in the provision of medical care is responsible for his/her own actions and for compliance with the site's pharmacovigilance plan.



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Drug treatment plan

A medication management plan can be used to improve the process of medication management in the workplace, and to increase understanding of medication safety. Consistent policies will increase medication safety. Preventable harm can be avoided by committing to uniform policies that support safe medication management, as described in the medication management plan.

The primary objective of the Terveystalo Group-wide medication management plan is to support all sites that provide medication management in ensuring the safety of the medication management process. In the development of the Terveystalo Medication Treatment Plan, the guidance of the STM, Safe Medication Treatment Guide (publication 2021:6) has been taken into account. The Group-wide Medication Care Plan is prepared and annually updated by the Group's Medication Management together with the medical centre nurses, specialty managers, responsible physicians and service managers and approved by the Terveystalo Chief Medical Officer. The Group Medication Care Plan provides a framework for the implementation of medication care at Terveystalo's sites and serves as a guiding document that defines the tasks and responsibilities related to medication care, medication safety and the site-specific medication care plan.

In Terveystalo, the sites draw up a site- or department-level medication plan on a separate medication plan template. The site/department-specific Medicines Treatment Plan is based on the Group-level Medicines Treatment Plan. The site/departmental pharmacovigilance plan shall consider the pharmacovigilance, policies and associated risks at that site in more detail than the corporate pharmacovigilance plan. The size, scope and complexity of the site will determine the level at which the pharmacovigilance plan is drawn up. In the larger Terveystalo hospital sites, individual functions draw up a departmental medication management plan. Responsibility for organising the development, implementation and monitoring of the medication management plan lies with the site management. The medication management plan is drawn up in a multidisciplinary way in the site, in cooperation between the different professional groups. The site/departmental medical treatment plan is approved by the doctor in charge of the site/department.

The aim is for the plan to serve as a practical tool for quality development and the promotion of medication safety. The site manager is responsible for keeping the pharmacovigilance plan up to date, updating it and putting it into practice. All staff involved in the management of medicines should be familiar with the site and departmental medication management plan. Each employee is responsible for ensuring that the policies described in the medication management plan are followed.

The Group-wide medication management plan and the site/departmental medication management plans are updated at least annually and when there is a substantial change in activity.



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Ensuring medication safety

In all Terveystalo sites that provide medication management, the management bears overall responsibility for the implementation and conditions of safe medication management in their sites. In each Terveystalo site, a responsible doctor/dentist is appointed who is in charge of the overall pharmaceutical care. The responsible doctor acts as the medical chaperone for the doctors in the unit in situations where local expertise is required. policies. The role of the frontline staff is to ensure that the staff involved in the provision of medication management in the establishment have the necessary skills and that the conditions are right for safe medication management. The frontline staff shall supervise and monitor the implementation and quality of drug treatment in accordance with the drug treatment plan and decide on the division of labour and cooperation between different staff groups in the implementation of drug treatment, making the best possible use of the skills of each professional group. Each person providing or participating in the provision of medical care is responsible for his or her own actions and for ensuring that the practices of the establishment are in accordance with the pharmacovigilance plan.

At the Terveystalo sites, medication management is carried out by healthcare professionals trained in medication management, as defined in the site's medication management plan. The provision of medication requires a valid, written authorisation to administer medication issued by the responsible doctor at Terveystalo. Ensuring competence in medication management is defined in Terveystalo's medication management plan for each professional group and function, based on the recommendations of the STM, Safe Medication Management Guide.

Medication authorisations consist of three parts:

- 1. on theoretical studies
- 2. about the tests
- 3. practical demonstrations, which are given at the Terveystalo premises.

Medication safety is ensured and its implementation in the units is regularly assessed through internal self-monitoring, medication safety audits, which are used to develop operating models that promote and support medication safety. Medicines safety is also ensured by the Group's pharmaceutical care department through internal audits and quality visits carried out in collaboration with the quality function. Pharmacovigilance liaison officers carry out a self-audit of medication safety once a year. Pharmaceutical staff (pharmacist or pharmacist) in the hospital units with medical centres carry out medication safety audits once a year for the various activities of the hospital units. Pharmaceutical safety audits may also be carried out at other sites in the region, if necessary. The medication safety of the medical centre is verified by a peer review carried out by the medical centre nurse of another Terveystalo site. The peer review of the medical centre also involves the Group's pharmaceutical service.

Findings from inspections are addressed and corrective action is taken on the spot.

Monitoring the consumption of medicines

The basic range of medicines available at the Health Centre includes those regularly used in the establishment. The purpose of the basic medicines list is to harmonise and guide the procurement and use of medicines and to ensure effective and safe drug therapy in accordance with the functional nature of the unit. The establishment of the pharmaceutical stock of a site takes into account the size of the site, the need for drug treatments and the basic range of medicines available at the Health Centre.

Medicines are ordered at the place of business by the pharmacy liaison officer or the pharmacy nurse. Only medicines ordered by the medical centre nurse or the pharmaceutical contact person at the place of business are used for the treatment of the client. The on-site pharmacy nurse or pharmacy liaison officer shall regularly check the medicines to ensure that there are no out-of-date or otherwise unsuitable medicines in stock. The procurement, consumption and waste of medicines are regularly monitored by the medical centre managers, the Group's pharmaceutical management and procurement.

Consumption of drugs and OTC medicines is monitored through order and delivery volumes, as well as through consumption tracking forms per pack.



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Deviations in the implementation of medication

Medication safety can be compromised at any stage of the drug treatment process. Individual employees must play their part in ensuring that agreed procedures are followed. In the culture of the Health Centre, we ensure an open and confidential atmosphere where people dare to speak openly and are treated without fear of blame.

It is the right and duty of every health professional to report an incident. The procedure to be followed in the event of a medical emergency is set out in a separate work instruction. Identifying, recording, analysing and learning from incidents is a key element in the development of customer and patient safety. The purpose of the incident reporting system used at Terveystalo is to facilitate the identification of incidents detected at the

reporting and learning from patient care incidents. An incident includes both near misses and adverse events.

The Group's Pharmaceutical Care and Medical Centre Managers monitor and, if necessary, support the site in dealing with incidents. Group Pharmacy also identifies the need for new guidelines and initiates action where necessary.

The Health Centre's offices report adverse reactions related to the use of medicines and blood products to Fimea or the Blood Service. The official notification is entered in the internal incident report of Terveystalo.



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Hygiene practices

Infection control planning, guidance and training are based on researched, good practice and current legislation. Administratively, infection control is the responsibility of the Chief Medical Officer.

The most important infection control practices are regularly updated guidelines, which have been compiled into an easy-to-find set of guidelines on the intranet.

The day-to-day infection control work is managed by the Group Hygienist, supported by the Infectious Diseases Doctor and a designated hygiene liaison officer at each site and dental clinic. The hygiene officers carry out an annual hygiene survey of their sites, which provides information that can be used to target prevention measures directly to areas for improvement. They monitor the infection situation in their premises and the results of surface cleaning tests, and inform and instruct workers on hygiene practices. Hygiene officers act as a link to the hygienist in their establishment and participate in infection control training.

The policy and planning of infection control measures, the implementation and effectiveness of control measures, and the monitoring of operations and premises are regularly discussed with those involved in patient and client safety and occupational safety. Infection control activities are also regularly monitored in terms of hygiene and equipment management through quality audits, in accordance with ISO 9001 and ISO 14001, and quality visits.

In Terveystalo's patient safety structures, the hygienist is part of the Patient Safety Team, the Group's Incident Team and the Patient Safety Team, which monitor and develop patient safety indicators, quality and their implementation.

Hand hygiene

The most important infection control measure is proper hand hygiene. There are written and pictorial guidelines on hand hygiene. Good hand hygiene aims to break the transmission of microbes from patient to patient or from patient to staff and from staff to patient. The guideline focuses on the correct use of hand sanitiser, the correct use of protective gloves and skin care. It also provides guidance on the use of jewellery and other watches and devices worn on the hands and wrists.

Hand lotions are readily available in appropriate racks and dispensers for clients, patients and staff. Hand hygiene is regularly emphasised in staff training and induction.

The range of hand sanitisers to be provided to the establishments and any necessary changes are regularly evaluated by experts. The consumption of hand sanitisers is monitored and targets and indicators for consumption are developed for the different activities.

Aseptic action

Aseptic practice, important for the control of healthcare associated infections and patient safety, is included in the standard precautions guideline. Standard precautions are the aseptic basis for all healthcare work. In addition to hand hygiene, it includes the correct use of protective equipment and correct working practices, such as aseptic work sequences, exudate disinfection, prevention of puncture and cut injuries, cough hygiene and waste management.

In oral health services, special attention is given to eliminating the risk of aerosol-borne infections through aseptic practices, equipment solutions and aseptic guidelines, such as wiping and related disinfectants, protection and proper equipment care.



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Maintenance and sterilisation of equipment

The supply of clean, disinfected, sterile and functional equipment for patient examination and treatment needs. Instrument maintenance includes washing, drying, checking, servicing, assembling, packing, sterilising, storing and sorting instruments and medical supplies for users.

Properly performed equipment care ensures patient and worker safety by maintaining the equipment used in treatment in such a way that it does not pose a risk of infection. This is done in accordance with guidelines and by trained instrument caretakers and trained professionals. The guidelines apply to all instrument care points in hospital services, surgeries and oral health facilities.

Washing machines and autoclaves for equipment maintenance are regularly tested in accordance with guidelines drawn up in cooperation with technology experts to ensure they are in good working order. The equipment is serviced regularly in accordance with the equipment register, and faults are repaired as soon as necessary. Experts are consulted in the selection, purchase and commissioning of new equipment and materials, and the Group's procurement criteria require the tenderer/product manufacturer to provide detailed instructions on cleaning, disinfection and other maintenance of equipment and materials.

The Group Hygienist coordinates the activities and uniform practices in the field of instrument care.

Cleaning and laundry

Cleaning and laundry services are outsourced, with the service provider being responsible for guidelines and quality control. The instructions of the service providers are checked and required to be in line with the hygiene instructions of the Health Centre, and the work is carried out in accordance with the agreed service descriptions for the activities.

Regular quality rounds are carried out with cleaning service providers and regular surface hygiene samples are taken from pre-agreed sites to ensure the quality of the service and its maintenance.

Cleaning pays particular attention to the specificities of healthcare, such as the disinfection of excreta stains, the cleanliness of cleaning equipment and its cleaning after use, and the correct organisation of work.

The cleaning instructions also take into account the use of the necessary detergents and disinfectants and their recommended use.

The laundry guidelines are based on the service providers' instructions on laundry and its sorting. The facilities follow the instructions for laundry handling given in the standard precautions or for the care of patients in solitary confinement.



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Author: Sarin, Sanna

Prevention of healthcare associated infections

Care-associated infections are systematically controlled through guidelines and expert advice from a hygienist and an infectious disease doctor.

The aim of the Communicable Diseases Act is to prevent the spread of communicable diseases in Finland. The purpose of the Act is to protect the population through, for example, vaccination, health checks and monitoring the spread of communicable diseases.

Terveystalo ensures and monitors that its personnel meet the eligibility requirements of the Communicable Diseases Act. This means that all vaccinations are taken unless there is a clear reason for not doing so, such as illness or a medical condition that prevents the vaccine from being taken. All our services treat patients of all ages, and therefore these conditions apply in principle to all those who work with clients, including customer service staff and staff of service providers.

The presence of infectious diseases and highly drug-resistant microbes is monitored and guided by positive laboratory findings from the central laboratory Synlab. Patients, appropriate protection for clients and staff, and instructions for the positioning of patients. The proper use of antimicrobials is also monitored centrally.

The guidelines on contact precautions in surgeries, examinations, procedures, inpatient wards and operating theatres aim to prevent the transmission of harmful microbes to other patients, staff or visitors by cutting off microbial pathways and to ensure patient and occupational safety.

Particular attention is paid to preventing the spread of highly drug-resistant microbes by determining whether the patient under treatment is a carrier and, if necessary, testing the patient for MRSA, VRE and MDRs before entering the surgery or procedure.

Patients with vomiting-flu symptoms are treated in the ward with contact precautions and, if symptoms are present, a stool sample is taken, which is usually tested for at least Clostridium Difficile and norovirus.

Standard precautions always serve as a basic level of infection control, supplemented as necessary by space isolation and protective treatment methods when contact, droplet or airborne precautions are required according to the microbe in question. All these procedures are subject to guidelines.



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10:35

Author: Sarin, Sanna

Infection surveillance

Continuous insight monitoring is in place in the sites that perform surgery and procedures. Infection surveillance is used to assess the effectiveness of control measures, to target control measures correctly and to evaluate the effectiveness of interventions.

Patients are given an infection surveillance form to take home with them after the procedure. They are instructed to contact the site where the procedure was performed if they develop symptoms of infection, seek treatment and return the follow-up form to the site where the patient will receive the necessary treatment, and the information on the form is recorded in an electronic monitoring system that is regularly monitored in the sites by quality management teams.

The national situation is monitored by a hygienist who, together with the infectious disease doctor, analyses the situation. The follow-up period for surgical site infections is 30 days, for prosthetic joint surgery at least 1 year.

The electronic surveillance programme provides real-time information on the infection situation in the operating theatres and on the occurrence of minor procedure-related infections in the surgeries. Deviations in the incidence of infections require further investigation and intervention. The hygienist coordinates the necessary investigations.

In addition, groups of procedures can be examined more closely and their infection status monitored more closely, e.g. prosthetic joint, shoulder, anterior cruciate ligament, uterine, breast and hernia surgery can be examined.

The Group Hygienist and the Hygiene Liaison Officers at the sites provide monitoring information to the sites for the evaluation of control measures. If the situation so requires, the immediate detection of an outbreak or significant finding enables a rapid response to prevent the development of an outbreak and to target control measures correctly.

Food service

Food service in inpatient wards and recovery rooms complies with the requirements of the Food Act regarding the transport, serving and storage of food. There are guidelines for monitoring the expiry dates and correct serving and storage temperatures of stored food served to patients, and good hand hygiene is observed when handling food.

A hygiene pass is not required in wake-up rooms or for handling food served in inpatient wards, as the food is ready-to-eat and the job does not involve handling perishable non-prepackaged food.

A hygiene pass is required for handling and preparing non-prepackaged food in e.g. service housing, home care and inpatient wards. A self-monitoring plan is required for food service subcontractors.

The temperature of hot patient food served in the wards is monitored and recorded daily. Patient food refrigerator and freezer temperatures are monitored and documented on a weekly basis.



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Author: Sarin, Sanna

Waste management

The waste management guidelines comply with the waste legislation in force. The handling of waste on the premises, appropriate waste storage facilities and containers, transport and storage are instructed and organised in such a way that waste does not pose a hazard or nuisance at any stage of waste management. Particular attention has been paid to special healthcare waste to ensure that infectious, accidental, biological and hazardous waste is handled safely at every stage until disposal.

The establishments have valid contracts for the use of waste facilities and for the transport, treatment and disposal of waste with real estate and waste transporters.

In the procurement of materials, the aim is to reduce waste, to apply the principles of sustainable development and to minimise the environmental impact of operations.



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10:35 Author: Sarin, Sanna

Medical records and processing of personal data

This section describes the recording, processing and confidentiality of patient data, as well as the related staff training and skills assurance.

Respecting the privacy of customers and the protection of personal data is at the core of Terveystalo's values. This is achieved by processing personal data in accordance with applicable legislation and Terveystalo's privacy policy. The Data Protection Policy defines how Terveystalo ensures that personal data is processed lawfully and otherwise appropriately. The Privacy Policy is available on Terveystalo's intranet.

Recording and processing of patient data

Terveystalo processes patient data and other personal data of customers in accordance with data protection and patient legislation, for the purposes stated in the Terveystalo Privacy Policy. The key provisions are the EU General Data Protection Regulation (EU 2016/679, the Data Protection Regulation), the Data Protection Act (1050/2018), the Act on the Processing of Customer Data in Social and Health Care (703/2023) and the Act on the Status and Rights of Patients (785/1992, the Patient Act). Terveystalo's Privacy Policy is available on Terveystalo's website and at every Terveystalo office.

According to the Customer Information Act, health care must create and maintain patient records. The law specifies who can draw up the documents and what information must be included in them. Health professionals and other persons involved in the provision of services must record in the patient's medical records the information necessary and sufficient to ensure the organisation, planning, implementation, monitoring and supervision of the patient's care. These entries must be accurate, clear and comprehensible.

The storage of patient records is regulated in more detail in the Customer Information Act. Patient records and other material generated in the course of research and treatment are kept for at least the period specified in the Client Information Act. At Terveystalo, the IT department is responsible for backing up electronic medical records and for deletion routines after the retention period.

Separate guidelines have been drawn up for the handling and disposal of paper medical records. Records managers have been appointed and trained at the Terveystalo sites.

Patient records and other personal data of customers constitute a personal data file within the meaning of the GDPR. At Terveystalo Finland, the data in patient records are stored in Terveystalo's patient register, which is shared between Terveystalo and the various service providers operating there, either as self-employed persons or through separate companies. The healthcare professionals using the patient register have concluded a separate contract with Terveystalo Finland for the provision of reception services.

The Chief Medical Officer is responsible for the medical centre network's patient register. The patient register for oral health services is the responsibility of the Chief Oral Health Officer.



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10:35 Author: Sarin, Sanna

Confidentiality

Terveystalo complies with the obligation of confidentiality of patient data. Persons working at Terveystalo or performing tasks for Terveystalo may not, without the patient's consent or a legal provision, disclose to a third party information contained in patient records. Persons personally involved in the treatment of a patient or in related tasks are only entitled to access patient data to the extent required for their work. The obligation of confidentiality shall survive the termination of the employment relationship or the termination of the assignment. Everyone working at Terveystalo has signed a personal confidentiality undertaking.

Access rights and access control

Individual access rights to patient information systems are granted. User access rights shall be granted in accordance with the user roles required by the job functions. User ID orders are authorised by the Director of Health Services or a front-line manager or other designated person (e.g. a medical account manager). Changes to role-specific access are approved by the Chief Medical Officer. Access to patient information systems is only allowed with personal user IDs. Access rights are removed on termination of employment or professional contract or in the event of long-term absence.

Terveystalo strives to ensure the implementation of access control, the lawful processing of patient data and the protection of patients' privacy through appropriate access control. The use of patient information systems is monitored on the basis of access logs, either through Terveystalo's own monitoring or on the basis of requests for clarification from patients. Investigations may also be initiated by the management of the establishment or on the basis of self-reporting by staff, which can also be done anonymously.

In the event of suspected misuse, these will be investigated in accordance with predefined procedures. If Terveystalo believes that the processing of patient data has been unlawful, it will take the necessary follow-up action. Intentional non-compliance with instructions in the processing of patient data will also lead to action. Employees of Terveystalo are ultimately responsible for their own actions under threat of sanctions under labour, criminal and tort law.



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10:35

Author: Sarin, Sanna

Staff induction and skills assurance

Taking data protection into account has been defined as the responsibility of everyone working at Terveystalo. Each person involved in the processing of patient data is obliged, in accordance with his or her duties, to ensure compliance with data protection requirements, taking into account the applicable legislation and the instructions issued by Terveystalo.

Terveystalo has given written instructions to the persons handling patient data on the proper handling of patient data and the procedures to be followed in this regard. Persons working at Terveystalo have undertaken to comply with the instructions by signing a confidentiality and user commitment. It is the responsibility of front-line staff to instruct their subordinates on the guidelines, as necessary. Internal and external audits are carried out to assess the compliance of the Terveystalo site with the data protection guidelines.

The confidentiality of the patient relationship requires particular care in handling patient data. The main guidelines and regulations relating to the processing of patient data have been compiled in Terveystalo's Patient Privacy Handbook. The Patient Privacy Manual is available on Terveystalo's intranet. The guidelines relating to patient records are approved by the Chief Medical Officer of Terveystalo.

Data protection is part of the induction of people working at Terveystalo. It is the responsibility of the front-line employee to ensure that the induction is carried out and properly documented for their own employees. Everyone working at Terveystalo must complete training on data protection and data security and regularly update their data protection knowledge. It is the responsibility of the line manager to ensure that this is followed up. Regular training on data protection is provided to all Terveystalo employees. Appropriate records are kept of the training.

Everyone working at Terveystalo is obliged to report all data protection-related shortcomings and malfunctions. In the event of a personal data breach as defined by law, it will be reported to the appropriate authorities in accordance with a separate process.

Data Protection Officer

Suomen Terveystalo Oy has appointed a data protection officer. The role of the Data Protection Officer is based on the EU General Data Protection Regulation. The Data Protection Officer is an internal expert who assists the organisation in complying with data protection regulations. The Data Protection Officer is also responsible for, among other things, receiving communications from data subjects and cooperating with the supervisory authority. Contact details of the Data Protection Officer: tietosuoja@terveystalo.com.



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10:35 Author: Sarin, Sanna

Information security

Data protection is closely linked to information security, and information security measures are necessary to ensure data protection. Data security means, inter alia, contractual, organisational and technical measures to ensure the confidentiality and integrity of data, the availability of systems and the exercise of data subjects' rights.

The purpose of information security is to protect data and information systems. Terveystalo's information security objectives, responsibilities and means of implementation are defined in the information security policy. The key objectives of the information security policy are to protect personal data (e.g. customer and patient data) and intellectual property rights and to ensure their proper handling; to comply with the obligations laid down in laws, regulations, standards, government regulations and contracts; to identify threats to Terveystalo's operations and to manage information risks appropriately; and to ensure the reliability and cost-effectiveness of data processing.

Information security is an integral part of ensuring and developing Terveystalo's overall operations.

Data security is the responsibility of every Terveystalo employee and every person working on behalf of Terveystalo within the scope of their duties. Each employee is not only obliged to follow the instructions he/she has been made aware of, but also to help others to follow information security working practices.

- It is the responsibility of the Director of Health Services to ensure that every professional working in or on the premises has the effective capacity to address information security in their work and that any deficiencies identified are remedied.
- The Director of Finance is responsible for the management and development of information security. The Group Chief Information Security Officer, appointed by the CFO, is responsible for the day-to-day management of information security.
- The responsibilities of the Chief Information Security Officer include promoting information security-related development projects, developing guidelines, providing advice and training, defining technical information security requirements, monitoring and reporting on the information security situation and handling information security incidents in cooperation with the Chief Information Security Officer, the Group's General Administration and the business areas. The Chief Information Security Officer reports to a member of the Group Management Team. The Chief Information Security Officer has the authority and responsibility to conduct information security mapping and audits. He/she is responsible for taking action to remedy any identified security threats and breaches and for reporting them to the authorities as appropriate.
- Every person working at Terveystalo is obliged to report any information security deficiencies and problems to the information security organisation. The information security policy is developed in accordance with the findings. The development is the responsibility of the Chief Information Security Officer.



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10:35 Author: Sarin, Sanna

Terveystalo has prepared a separate information security plan for information systems (THL Order 3/2021). The information security plan contains explanations on how to ensure the requirements related to the processing of social care client and patient data and information systems, including the following areas:

- · General security practices,
- Procedures in case of errors and problems and continuity management, Staff training and skills maintenance and development,
- Instructions for the use of information systems and their use in accordance with the instructions,
- Basic information, descriptions and compliance with essential requirements of information systems, Installation, maintenance and updating of information systems
- Access rights management and authentication policies,
- Access management and access monitoring practices for client and patient information systems, Physical security
 as part of the security of the information systems environment,
- Management of workstations, mobile devices and support services for the operating environment,
- Secure use of platform and network services for data protection and preparedness and Security policies for connecting to and using Kanta services.



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Patient ombudsperson

Welfare regions must organise the activities of patient ombudsperson and social ombuds also in social and health care services organised and provided by private providers (Act on Patient Ombudsperson and Social Ombuds 739/2023, §2).

In order to provide information to patients, the Health Centre's website, as well as the customer areas in the branches, provide instructions on the activities of patient advocates. Instructions for staff have been posted on the intranet



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Author: Sarin, Sanna

Strengthening patient involvement and handling reminders

Terveystalo has a Terveystalo app, where patients can access their own data using either their online banking credentials or a mobile certificate. The app displays information such as visits to doctors or nurses, diagnosis codes, vaccination and allergy information and some laboratory test results.

Reference values for laboratory test results are shown for quantitative tests. The app is not intended to reduce the physician's responsibility for care, but to empower patients to participate in their own care.

The app has been developed, and will continue to be developed. Currently, in addition to the above, the application can be used to make appointments, manage consents and denials in the patient information system, and allow reminders to be sent, e.g. for a check-up appointment.

Patients and their relatives can give feedback to Terveystalo on the Terveystalo website. Quality managers at the sites ensure that feedback is handled in accordance with the process and patients are directed to contact the patient advocate in the wellbeing area if necessary.

Patients and/or their relatives are instructed to contact the Patient Ombudsman if there is any suspicion of malpractice or any other matter relating to the patient's rights that has not been resolved to the patient's satisfaction in the establishment.

Patients can submit a reminder under the Patient Act using the secure form on Terveystalo's website. The reminder will be forwarded directly to the doctor in charge of the office that the patient has selected on the form. You can also mail or otherwise deliver the reminder directly to the Terveystalo office.

The objections are discussed at the office with the doctor/dentist in charge and the person(s) concerned. The aim is to ensure that nothing similar happens again and that the client receives a written explanation of what happened, with reasons.

The level of response to reminders is reinforced through regular training sessions, especially for the doctors in charge of the sites and the quality managers. The training sessions will focus on guidance from the authority on the content of the reminder and the timeframes for handling it.

An electronic and secure "Patient Incident Report" form is also available on the Terveystalo website. This is intended to catch those incidents that are not detected or reported by staff. Patients have a different perspective on things, and they notice different things than health professionals.

The reports are processed at the sites under the leadership of the Patient Safety Officer and, if necessary, by the Group's Incident Team.



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10:35

Author: Sarin, Sanna

Complaints and other supervisory matters

Requests for clarification from the Authority in relation to complaints and control matters are stored in the feedback management system (restricted access).

Complaints

The requested answers to the request for clarification of the complaint (full investigation) will be provided:

- For the establishment, the answers are given by the person(s) concerned and the doctor/dentist in charge or other manager responsible for the services.
- The replies are sent to the Chief Medical Officer or the Chief Oral Health Officer, as appropriate, who gives his or her own reply.
- The answers are then forwarded to the National Supervisory Authority or the Regional State Administrative Board.

The matter of the complaint is discussed at the site level under the direction of the doctor in charge. The aim is to ensure that this does not happen again if the complaint has revealed a shortcoming. If necessary, the Group Chief Medical Officer will take action.

Surveillance issues

Supervision issues concerning the professional are discussed at the site level between the doctor/dentist in charge and the director of health services.

Controls on an establishment may take the form of control visits (announced or unannounced) or controls based on written procedures. These are also dealt with at establishment level by these persons and, where appropriate, by other front-line staff.

Where necessary, the Chief Medical Officer and/or the Chief Physicians are also informed of supervisory matters.

Allegations of patient harm

If there is a suspicion of patient harm in the facility, the staff will direct the patient/person to contact the patient advocate in the wellness area. Staff should record

an incident report is also entered into the electronic system. Measures, defined on a case-by-case basis, aim to eliminate the root cause of the problem. The incident is reviewed by the doctor/dentist in charge at the site. Similarly, the need for more specific guidelines or processes at Group level will be assessed. The patient advocate in the well-being area will guide, advise and, if necessary, assist the patient and/or relatives in filing a patient complaint, reminder and/or complaint.

The Patient Insurance Centre sends a summary of all patient requests for clarification and the related solutions to the service manager of the Patient Safety Team at Terveystalo. In this way, Terveystalo's medical management is fully informed of all suspected and actual claims throughout the group. On receipt of a request for clarification or a solution, the service manager enters it into the feedback management system, through which it is forwarded to the office concerned for processing. Requests for clarification and solutions are processed at the site by the responsible doctor

/ the dentist in charge, and assess how to prevent a similar incident in the future. The measures are recorded in the feedback management system and their implementation is monitored by the site management.



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Author: Sarin, Sanna

Monitoring of self-monitoring, responsible persons and documentation

This document forms the basis of Terveystalo's self-monitoring plan. The self-monitoring plan is supplemented by, among other things, the operations manual, process map, work instructions and task descriptions referred to in this document.

The self-monitoring plan is reviewed every 4 months and updated if necessary. The updated version is reviewed by the Quality Manager and approved by the Chief Medical Officer. The first version of the Health Centre's self-monitoring plan was published in May 2013 and this update reflects the situation in February 2024.

The self-monitoring plan is discussed at group, regional and site level. Management is responsible for ensuring that all staff are aware of the contents of the self-monitoring plan and can act accordingly. Quality audits ensure that each establishment knows how to operate in accordance with the self-monitoring plan. Any anomalies identified through audits and other means outlined in the self-monitoring plan are investigated as quickly as possible and corrective action is taken as planned.