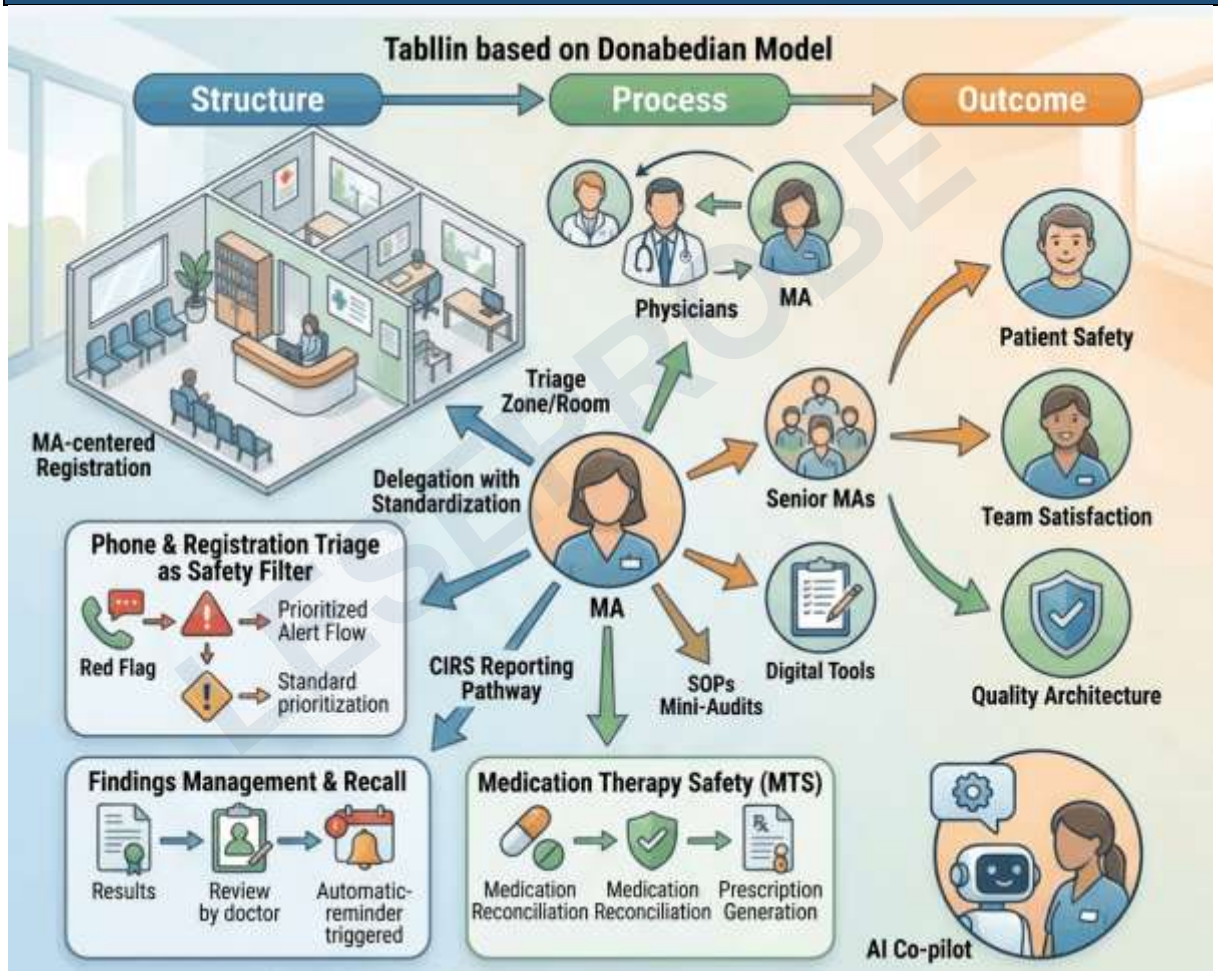
ClinicalOS – The clinical operating system for general practice

Volume 7

Practice Architecture & Team Processes



- Process Architecture & Patient Safety
- Medication Safety & AMTS
- Role & Responsibility Architecture
- Quality Culture & CIRS
- Triage & Safety Filters
- Digitization & AI-Copilot

Healthcare assistant (HCA) centred practice organisation, patient safety and quality management

About this sample

Volume 7 · Practice Architecture and Team Processes

This curated sample has 12 pages from a 73-page volume (approximately 15%, including the notice and end page). The chapters listed below are included in full. Original page numbers are retained; gaps are intentional. This overview and the PDF bookmarks cover the included sections. Cross-references may refer to the full volume.

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Note on Translation, Content, Use and Liability

This English edition is a translation of the original work written in German. The concept, structure, and core medical content of ClinicalOS were originally developed for German general practice and the German healthcare system, to provide practising GPs, trainee GPs, healthcare assistants (HCAs) and medical students with a structured, practice-oriented learning and reference resource. The content is based on current medical literature, guideline-based sources and practical experience in general practice.

During the linguistic adaptation, references to guidelines, clinical practices and regulatory frameworks in other English-speaking settings were taken into account and highlighted where relevant and feasible; in some areas, differences from German recommendations are also presented explicitly. However, the translation does not constitute a systematic adaptation of every medical, therapeutic or regulatory aspect to all English-speaking countries. Professional guidelines, marketing authorisations, approved dosages, prescribing procedures, reimbursement rules and regulatory requirements may vary between countries;

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Chapter 1. Introduction — Why practice architecture is patient safety

1.1 Introduction — The hidden quality problem in general practice

General practice is a highly complex field of medicine operating under resource constraints. A practice with three doctors and six medical assistants handles 80–120 patient contacts daily, coordinating laboratory tests, imaging, referrals, prescriptions, DMP documentation, eAU, e-prescriptions, CIRS and billing — all of which are carried out in parallel, are interdependent and time-critical.

The PRACtICe study (2012) showed that 1 in 8 patients in GP practices is affected by prescribing errors, and 1 in 20 prescriptions contains an error. [1] These are not isolated cases — they represent systemic failure in practices lacking an explicit process architecture.

Manual 7 bridges the gap between clinical knowledge (Manual Volumes 1–6) and the reality of day-to-day practice. Not as a bureaucratic handbook, but as an operating system: functional, healthcare assistant (HCA)-centred, implementable.

> **CLINICAL PEARL — Processes protect patients — not intentions**
> *A good doctor working within a poor process will make more errors than an average doctor working within a good system. This has been demonstrated by patient safety research over the past 25 years. [3] Manual 7 responds with system design rather than appeals.*

1.2 Theoretical framework — The Donabedian model as the guiding principle

All chapters of Manual 7 follow the Donabedian model: structural quality (resources, roles, equipment) → process quality (workflows, SOPs, handover procedures) → outcome quality (patient safety, quality of care, team satisfaction). [3]

Quality dimension	Definition	Typical questions in Manual 7
Structural quality	Resources, roles, equipment, process architecture	Who is responsible? What tools are available?
Process quality	How are processes carried out, documented and monitored?	Which SOP? Which handover procedure? Which recall procedure?
Outcome quality	Clinical outcomes, safety, efficiency, satisfaction	Have findings been fed back? Have errors been prevented?

1.3 Why medical practice assistants are the key operational personnel

In German GP practice, the healthcare assistant (HCA) is the operational hub for most patient contacts: initial contact, triage, appointment management, follow-up, preparation of documentation, processing of findings, preparation of claims, emergency response, and interface management. [16]

Manual 7 therefore structures each chapter around an explicit healthcare assistant (HCA) module: what the healthcare assistant prepares, decides, escalates — and what they do not. This is not an unfounded elevation of their role, but a reflection of reality.

Professional group	Primary role in Manual 7	Core processes
Doctor	Final clinical decision, taking over escalation	Diagnosis, treatment, prescribing, review of critical findings
Senior Healthcare Assistant / Practice Manager	Process management, team coordination, quality management	CIRS, audit, training, day-to-day management, recall monitoring
healthcare assistant (HCA)	Standardised implementation and preparation	Triage, follow-up, processing of findings, documentation, billing
VERAH / NäPA	Delegated care tasks	Monitoring of patients with chronic conditions, home visits, structured feedback
Trainee doctor	Clinical medical duties under supervision	Consultations, CIRS training, record-keeping training
Locum / part-time	Operational reliability within an external framework	SOPs and quick reference cards; no improvised decision-making

1.4 Ten fundamental principles of Manual 7

- 1. Every core process has a primary role — not ‘the team’.
- 2. Delegation is only safe with standardisation, training, clear boundaries and an escalation process.
- 3. Near misses are more valuable than actual errors — a CIRS reporting culture from day one.
- 4. No recall without designated responsibility and a timeframe.
- 5. Red flags halt operations — this is logged; there is no room for discretion.
- 6. Every assessment of findings is documented — even ‘unremarkable’ ones (Section 630h of the German Civil Code [14]).
- 7. SOPs in two formats: full versions for induction, and 90-second quick-reference cards for locums.
- 8. AMTS begins with medication reconciliation — not with the prescription.
- 9. An audit without consequences is worthless: every audit must result in one specific action.
- 10. G-BA QM Guidelines 2024: error management, CIRS and AMTS are mandatory — not an optional programme. [6]

1.5 Mini-audit — Where does your practice stand today?

Test question	Yes / No	Warning sign if 'No'
Is there a designated primary role for each core process?		Responsibilities are implicit and dependent on the individual.
Does the system still function during holidays, sick leave or when staff are covered by stand-ins?		Practice relies too heavily on individuals.
Is there a defined CIRS reporting procedure?		G-BA QM-RL 2024 makes this mandatory. [6]
Is a recall created for every request for findings?		Systematic gaps in the return of findings.
Is there a red-flag list for triage at reception and on the telephone?		A 20% misassessment rate has been documented. [8]
Is there a structured medication reconciliation process at check-in?		Risks of drug interactions remain undetected.
Is at least one mini-audit carried out per quarter?		Systematic blind spots remain undetected.

QUICK REFERENCE

• Manual 7 is not a quality management folder — it is the practice's operational system.
• Patient safety is achieved through process design, not through attention alone.
• Healthcare assistants (HCAs) are the key operational personnel — each chapter contains a specific HCA module.
• G-BA QM Guideline 2024: CIRS, AMTS and error management are no longer optional. [6]
• 10 fundamental principles: Role — Delegation — Near Miss — Recall — Red Flag — Documentation — SOP — AMTS — Audit — Obligation.

Chapter 3. Quality of Consultation and Documentation

3.1 Introduction

The consultation is at the heart of medical practice — and the place where most errors occur or are prevented. A structured consultation with comprehensive documentation is not a bureaucratic burden, but an active measure to ensure patient safety. For medical assistants, preparing for the consultation is a core operational task: reviewing the medical record, taking vital signs, flagging outstanding findings, and clarifying the follow-up status.

> **CLINICAL PEARL — Preparation is half the diagnosis**
> *A healthcare assistant who has checked the medical record, medication, outstanding findings and recall status within 5 minutes gives the doctor a crucial information advantage. This is not a service — it is clinical patient safety.*

3.2 SOAP format — The structured consultation format

The SOAP format (Subjective / Objective / Assessment / Plan) is the international standard for documenting consultations. It ensures completeness and traceability.

SOAP element	Content	HCA contribution
S — Subjective	Symptoms, duration, nature, course (from the patient's perspective)	Document the reason for the visit; flag any red flags
O — Objective	Vital signs, physical examination findings, laboratory results, ECG	Record vital signs and enter them into the patient record system
A — Assessment	Medical assessment: diagnosis, differential diagnoses, risk assessment	Doctor only; healthcare assistant (HCA) flags any abnormalities
P — Plan	Treatment, prescription, referral, follow-up appointment, safety netting	Set follow-up date; prepare prescription

3.3 Healthcare assistant (HCA) preparation — 5 steps before the consultation

Step	Task	Time
1	Open the file: check last contact, current medication and long-term diagnoses	60 sec.
2	Check outstanding test results: are the results available? Have they been communicated to the patient?	30 sec.
3	Recall status: was this planned or unplanned? Is a DMP due?	30 sec.

Step	Task	Time
4	Take vital signs and record them in the patient record system (BP, pulse, weight, SpO_2 if applicable)	2–3 mins
5	Briefly pre-record the reason for today's visit in the PMS (MFA field)	30 sec.

3.4 Safety-netting — What the patient should do if their condition worsens

Safety-netting refers to the doctor's advice on warning signs following the consultation. It is a mandatory part of the documentation and the most common omission in liability cases (see Chapter 10).

Situation	Content of safety-netting	Role of the healthcare assistant (HCA)
Acute infection	"If fever >39°C, shortness of breath or no sign of improvement after 48 hours → report immediately"	Check documentation in the PMS free-text field
New medication	"If skin changes, swelling or dizziness occur, stop the medication immediately and call"	Note the telephone number on the prescription envelope
Lab results pending	"Results will be available in 2 days — we will call you if anything is abnormal"	Create a follow-up task in the patient management system
Follow-up	"Please book an appointment in 4 weeks' time — I'll enter this into the system"	Set recall date

3.5 AI Scribe — Process rules for automated documentation

AI Scribes (Navida, Abridge, Nuance DAX) automatically generate consultation records. They take the pressure off — but require clear process rules.

Step	Responsibility	Standard
1. Patient consent	healthcare assistant (HCA)	"Our system records the conversation for the medical records. Everything is checked by the doctor. Do you agree?"
2. Admission	AI system	The consultation is transcribed and structured
3. Medical review	Doctor (mandatory)	Read through and approve each AI transcript before finalisation
4. Finalisation	Doctor	Save to PMS only after medical approval
5. Fallback	Healthcare assistant (HCA) + doctor	In the event of a failure: manual documentation; backup template at the workstation

3.6 HCA module — Example wording

Situation	Wording
Recording vital signs	“Mrs M., I’m just going to take your blood pressure and pulse — this is part of your examination today.”
Addressing the AI Scribe	“Our documentation system is recording this conversation for your medical records. The doctor will review everything. Do you agree?”
Follow-up after consultation	“The doctor recommends a follow-up in 4 weeks. Shall I book an appointment straight away?”
Lab results pending	“Your blood test results aren’t in yet. I’ll set up a callback — we’ll get in touch as soon as the results are available.”

3.7 Error library — Consultation and documentation

Error type	Typical example	Cause	Corrective action
Safety net not documented	Patient returns in a worse condition — no evidence of informed consent	Not a mandatory field	Safety-Net as a mandatory field in the PMS template
Vital signs missing	BP not recorded, despite patient having hypertension	No standard preparation procedure for healthcare assistants	5-step preparation as a standard HCA routine
AI output not checked	Incorrect findings finalised in the report	No approval protocol	Mandatory medical review prior to finalisation
Follow-up not created	Laboratory result remains pending	No standard recall procedure	Recall required for every outstanding result as a mandatory task for healthcare assistants (HCA)
Retrospective documentation	Entry made 2 days later without a timestamp	Time pressure	Documentation on the day of the consultation; PMS timestamp

3.8 Mini-audit — Quality of consultation

Assessment question	Yes / No	Warning sign if 'No'
Does the healthcare assistant systematically take vital signs before every consultation?		Objective data is missing for the doctor's assessment.
Is safety netting established as a mandatory field in the documentation?		The most common liability gap in German medical malpractice cases.
Are AI scribe reports reviewed by a doctor before finalisation?		AI output is a draft, not a final document.
Is there a defined preparation process for healthcare assistants (HCA) (5 steps)?		Information is missing from the doctor's records at the wrong time.
Are outstanding findings flagged before the consultation?		Gaps in follow-up within findings management.

QUICK REFERENCE

• SOAP: Subjective → Objective → Assessment → Plan — document each element.
• 5-step preparation for the healthcare assistant (HCA): file, findings, recall, vital signs, reason for the appointment — in 5 minutes.
• Safety-netting: always document — what should the patient do if their condition worsens?
• AI Scribe: Obtain patient consent; medical review is mandatory before finalisation.
• Section 630h of the German Civil Code (BGB): Not documented = not carried out — the burden of proof lies with the practice. [14]

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