PAM Pokrajinski arhiv Maribor

Moderna arhivistika

Časopis arhivske teorije in prakse
Journal of Archival Theory and Practice

Letnik 1 (2018), št. 1 / Year 1 (2018), No. 1

Maribor, 2018

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ISSN 2591-0884 (online)
ISSN 2591-0876 (CD_ROM)

Izdaja / Published by:
Pokrajinski arhiv Maribor / Regional Archives Maribor

Glavni in odgovorni urednik / Chief and Responsible editor:
Ivan Fras, prof., Pokrajinski arhiv Maribor, Glavni trg 7, SI-2000 Maribor,
telefon/ Phone: +386 2228 5017; e-pošta/e-mail: ivan.fras@pokarh-mb.si

Glavna urednica / Editor in chief:
mag. Nina Gostenčnik

Recenziranje / Peer review process:
Prispevki so recenzirani. Za objavo je potrebna pozitivna recenzija. Proces recenziranja je anonimen. / All articles for publication in the conference proceedings are peer-reviewed. A positive review is needed for publication. The review process is anonymous.

Lektoriranje / Proof-reading:
mag. Boštjan Zajšek, mag. Nina Gostenčnik

Prevajanje:
mag. Boštjan Zajšek (slovenščina), mag. Nina Gostenčnik (slovenščina, angleščina), Lučka Mlinarič (bosanščina, hrvaščina, srbščina)

Oblikovanje in prelom / Design and typesetting:
mag. Nina Gostenčnik

http://www.pokarh-mb.si/si/p/3/49/moderna-arhivistika.html

Prejeto / Received: 13. 03. 2018

1.01 Izvirni znanstveni članek *1.01 Original Scientific Article*

LESSONS LEARNED FROM IMPLEMENTED INTERNAL AND EXTERNAL DIGITISATION PROCESSES AT THE CROATIAN AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

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Abstract:

The goal of this work is to present and explain the differences between internal and external digitisation process instances in the Croatian Agency for Medicinal Products and Medical Devices. The study is to share lessons learned from Agency's digitisation practice, discuss the applicability of these process instances, and demonstrate ways of evaluating digitisation and accompanying capabilities. The Agency started with digitisation in 2013, and the program ran for four annual cycles. The Agency also established its internal process in 2016. For establishing it, the authors have used business process management methods – interviews, analysis and modelling. For constant process improvement, the authors use capability/maturity modelling methods, focused on the quality component, particular issues and preservation of results.

Key words:

assessment checklist, business processes model, capability/maturity model, digitisation process

Izvleček:

Izkušnje z izvedbo digitalizacije v Agenciji za zdravila in medicinske proizvode Republike Hrvaške

Namen prispevka je predstaviti in razložiti razlike med procesi digitalizacije dokumentacije, ki jo je izvedla Agencija za zdravila in medicinske proizvode Republike Hrvaške v svoji režiji in s pomočjo zunanjega izvajalca. Študija podaja izkušnje, pridobljene v praksi digitalizacije, obravnava možnost uporabe procesov in prikazuje načine evalvacije digitalizacije in spremljajočih storitev. Agencija je z digitalizacijo pričela leta 2013, program pa je tekel štiri leta. Svoj, notranji proces digitalizacije, je Agencija uvedla leta 2016. Za njegovo vpeljavo so avtorji uporabili metode upravljanja s poslovnimi procesi – razgovore, analize in modeliranje. Za stalno izboljšavo procesov so uporabili zmožnostne modelne metode, s katerimi so se osredotočili na kvaliteto komponent, posamezne težave in ohranitev rezultatov.

Ključne besede:

kontrolni seznam, model poslovnih procesov, model zrelosti/zmožnosti, postopek digitalizacije

1. Introduction

The Agency for Medicinal Products and Medical Devices (HALMED) is the regulatory authority in charge of medicines and medical devices on the Croatian market. In 2013, HALMED decided to digitise medicinal products', and medical devices' records. The reason is that - due to existing paper materials storage costs, reachable level of protection, and access possibilities for internal users - the institution should keep these dossiers for a period of 20 to 50 years, and some of their records even permanently. The series selected for digitisation are dossiers and files related to the registration of medicinal products, renewal and variation of medicinal products authorisations (3 series), post-authorisation or pharmacovigilance files (5 series), as well as medical devices dossiers and files (3 series).

At the time of the first digitisation project preparation, the total amount of HALMED material in the external third party archive was about 5.7 linear kilometres. At this time, even with significant accumulation of current records, the Agency has 3.5 linear kilometres of materials in the external storage facility. In 2013, HALMED contracted digitalisation and microfilm service with the Financial Agency (FINA) as the service provider. In 2016, HALMED supplemented its digitisation programme with internal digitisation process, and now HALMED is reducing its backlogs related to a vast amount of materials that needed to be digitised. Currently, after four digitisation cycles or projects, HALMED has digitised approx. 128.500 technical units in a series related to medicinal products and medical devices. The archival team members are conducting archival arrangement of remaining dossiers and other forms of technical units before starting the next digitisation cycle in 2019.

During the preparation for the first digitisation cycle (2014-2015), HALMED's core team, which consisted of the authors of this article in the roles of project manager and representative of business users, was focused on particularities of digitisation of business process modelling, and on the quality of the expected results. For the process modelling, HALMED's team made use of business process management (BPM) methodology and Object Management Group's standard Business Process Model and Notation (BPMN). The modelled process and therefore also the contracted digitisation and microfilming service included all the tasks of the digitisation business process that could be conducted by the external service provider in its facilities and some additional tasks related to microfilming. Presently, after four cycles of external digitisation with the result of 24,8 million scans,[1] and in the third year of internal digitisation process, the authors can focus on the evaluation of the work previously done and on using that knowledge to further improve HALMED's digitisation programme.

In the part of the article dedicated to methodology, the authors explain BMP methods used for administering digitisation of HALMED's materials in the two variations of this process and in its generic form. In the section dealing with results, the authors discuss the benefits of using capability assessment tools in HALMED's digitisation process and its results which are being ingested into the institution's repository. In the article's conclusion,, based on the lessons learned from HALMED's case, the authors offer their findings related to institutional and external large-scale digitisation projects and processes and their recommendations on the management of these specific processes. In this article, the authors aim to answer three research questions that derived from managing HALMED's digitisation operations.

[1] *8 million scans in 2013/2014; 4.65 million scans in 2014/2015; 6.5 million scans in 2015/2016; 5,65 million scans in 2016/2017. Internal digitisation output is cca. 1.2 million scans (February 2016 - January 2018).*

RQ1: What kind of business process adjustments does each HALMED's digitisation process instance require?

RQ2: In particular, what issues should be addressed during the quality control of each digitisation process instances?

RQ3: Are HALMED's lessons learned applicable to other institutions with archival holdings and to what type of institutions?

2. Methods

About the methods

There are examples from archival science literature that emphasise the importance of applying BPM methods to archival practice. The archival practice could be enhanced mostly by designing new one and by streamlining and improving existing business processes, especially if this is done in attempts to introduce new technologies, automate workflows and implement archival information systems (archives management systems and digital archives). The goal of dealing with processes in archival management should be to achieve archival efficiency (Daines, 2011:130). Also, the practitioners in archives should deal with their business processes "to pinpoint the true bottlenecks that lead to the creation of backlogs." (Daines, 2011:139). The authors have approached digitisation in HALMED from the angle of business process (BP) practitioners and with business process management (BPM) apparatus. For the analysis of business process, the authors have used the interview method, comparison of external and internal business processes, and design of generic digitisation process model based on shared characteristics of both instances. In general, practitioners can evaluate business processes by capability or maturity models, various checklists or intellectual tools connected with the idea of the predicted or chosen progress in a selected practice. Capability or maturity models related to processes domain can serve for evaluating a specific process or the overall ability to manage processes (Pöppelbuß, Röglinger, and Becker, 2012).

Capability and maturity models are also used in archives management, although not as often as in records management practice. Although capability models approach bends the reality which is being assessed to suit evaluator's criteria, the matureness related apparatus provides opportunities to evaluate the as-is state of the inspected process or to benchmark it against the practice at hand or desired standards. The most prominent maturity models in archival management literature refer to repositories' preservation capabilities. The authors use capability models from the literature as well as the practical example, the Digitisation Quality Maturity Model (DQMM), previously designed by Rajh. [2] This practical example will be used for the evaluation of HALMED's external digitisation process. The authors have already used a similar tool on HALMED's digitisation process. While designing the internal digitisation process, the authors paid attention to preventing the occurrence of its anticipated weak spots and designed a checklist for evaluating metadata handling. It was used to avoid the anticipated weak spot of metadata handling and thus improve efficiency of the internal process during the

[2] *In a consultative project for the Croatian Civil Aviation Agency (CCAA) Rajh designed a capability or maturity model for digitisation process which was used to evaluate external digitisation service and which is predominantly suitable for examining external digitisation processes. The model was named Digitisation Quality Maturity Model (DQMM). The goal of this consultative service was to prepare CCAA for their external digitisation project. This capability tool deals with particular archival process, the process of digitisation. The authors apply this model to HALMED's external digitisation process.*

establishment of internal digitisation process in HALMED in 2016. The details about its implementation can be found in the section on literature (Rajh and Šimundža-Perojević, 2016).

About the process

HALMED carries out its digitisation as an external and an internal business process. External digitisation involves the provision of central digitisation tasks by an external service provider. Some tasks are carried out by HALMED before the main workflow takes place in the facilities of the external service provider (see Table 1).[3]

Table 1: Preparation for the external digitisation related tasks

Archival processing – arrangement and description in HALMED's archival management system (AMS)[4]
Creating lists for transfer of selected dossiers to the digitisation site
Packaging
Control of sent files

The summary of the digitalisation and microfilming main tasks as a part of the business process that occurs in external service provider's premises is available in Table 2.

Table 2: Main tasks in the external digitisation process instance

Transfer of materials from HALMED's archive and secondary site (the third party's facility) to the digitisation site
Preparation of dossier for scanning
Scanning
Image processing
Visual quality control of scanned pages
Indexing
Quality control of indexing
Creation of microfilms
Quality control of microfilms
Image conversion into PDF/A-1b files and OCR
Creation of XML files with metadata, packaging into ISO OAIS compatible submission information packages (SIPs) with preservation description information (PDI) metadata files (with various additional indices)
Quality control of XML files
Transfer of SIPs

[3] *In addition to these preparatory tasks, HALMED had to complete project management activities to keep the external digitisation project on the tracks. For these HALMED has used customised (and simplified) project management methodology and Microsoft Project tool.*

[4] *Centrix Pismohrana, an archival management system made by Omega Software d.o.o. company.*

In the part of the process conducted by the service provider, preparation task, indexing task and multilevel quality control were the most challenging and time-consuming activities. According to the information given by the service provider, about 40% of the total predicted digitisation costs are due to the preparation task workload. The task of indexing the digitised materials was done on the level of records set or between the technical units and actual records. In the external digitalisation projects, the service provider has invested considerable time in preparing different records for indexing because the majority of records in dossiers and technical units lacked content tags that would ease this task. HALMED decided to prepare an indexing guidance document and educate the third's party's personnel to mitigate the risk related to indexing. Šimundza-Perojević, as the representative of HALMED's business users, prepared the indexing guidance document. After the delivery of SIPs to HALMED, further tasks of the digitisation process are related to ingestion and preservation (see Table 3).

Table 3: Ingestion and preservation in HALMED after the main digitisation tasks

Validation of SIPs – automated task carried out by HALMED's Digital Archival Information System (DAIS – an ISO OAIS compliant digital archive in HALMED)
Ingestion of SIPs and their transformation to archival information packages (AIPs)
Archival description in HALMED's AMS – automated task of AMS based on description of original dossier in paper form
Final quality control in AMS viewer by HALMED's archival team

At the end of each of the external digitisation cycles, HALMED archival team starts the process of destructing the materials (according to decisions of Croatian National Archives). The final task in HALMED is always to update AMS (see Table 4).

Table 4: Tasks in HALMED after the main digitisation tasks and ingestion

Destruction of materials
Updating AMS and generating additional description

The internal digitisation process instance differs from the external one and it consists of the tasks presented in Table 5. Some parts of the process, like transfer are relatively straightforward because they pertain to the same workflow of documentation in HALMED. Some other parts were facilitated in advance, during the process design phase, by carefully selecting specific technologies and boosting their communication capabilities.

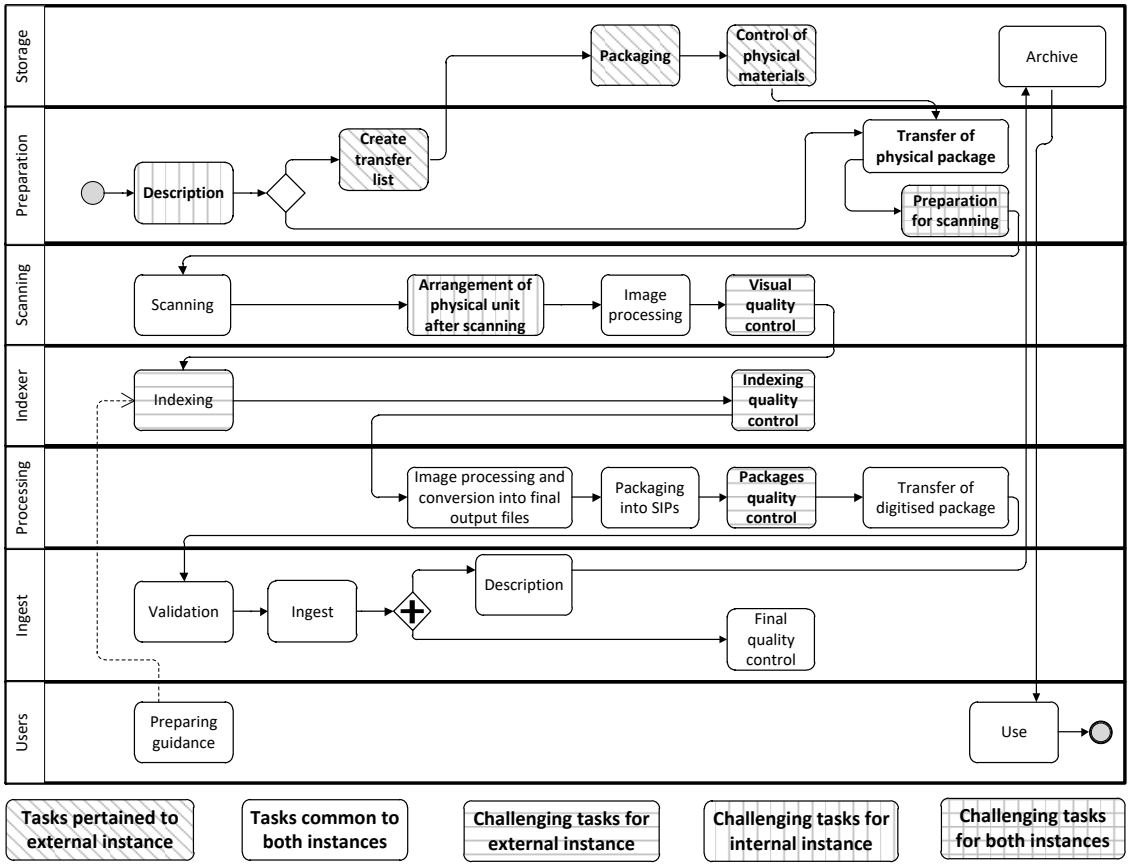
Table 5: Internal digitisation process in HALMED

Archival processing – arrangement and description in HALMED's AMS
Transfer of materials to digitisation room
Preparation of dossier for scanning
Scanning
Image processing
Indexing
Image conversion into PDF/A-1b files
Packaging into ISO OAIS compatible submission information packages (SIPs) with preservation description information (PDI) metadata files (with various additional indices)
Quality control before ingestion task
Validation of SIPs – automated task carried out by HALMED's Digital Archival Information System (DAIS – an ISO OAIS compliant digital archive in HALMED)
Ingestion of SIPs and their transformation to archival information packages (AIPs)
Archival description in HALMED's AMS – automated task of AMS based on description of original dossier in paper form
Final quality control in AMS
Destruction of materials
Updating AMS and generating additional description

The internal process instance in HALMED's case does not include the transfer of materials from the third party's facility. The purpose of this process is to capture active, current medicinal products' dossiers. Therefore, there are no lists for transfer from the secondary archival storage and the workflow is continuous. In this process, HALMED's digitisation team decided to use less metadata due to the fact that the process and all intermediate results of the process are completely run and controlled by HALMED's internal team. The process involves neither the creation of microfilm nor the updating of XML with the microfilm related metadata. Indexing is done at the record set level, as in the external digitisation process. According to the business process analysis, most of the operator's time is spent on preparing the dossiers for the next step (scanning), and on returning the units into their original conditions (after the scanning task). Quality control is a group of tasks that teams should address with adequate rigor.

After analysis of both process instances, it is possible to propose a generic business process model for the digitisation in HALMED. The generic digitisation model applicable to both of HALMED's cases includes mutual executable tasks and outlines the differences between external and internal process instances (see Picture 1). This process model represents an anticipated flow of tasks and shows certain symmetry of tasks related to the quality component of the process (control of physical materials, visual quality control, indexing quality control, packages control, final quality control). It also emphasises the symmetry of tasks related to packaging and transfer of physical materials or digitised files. In HALMED's case, the starting point of digitisation is the description of materials that need to be digitised in the archives management application.

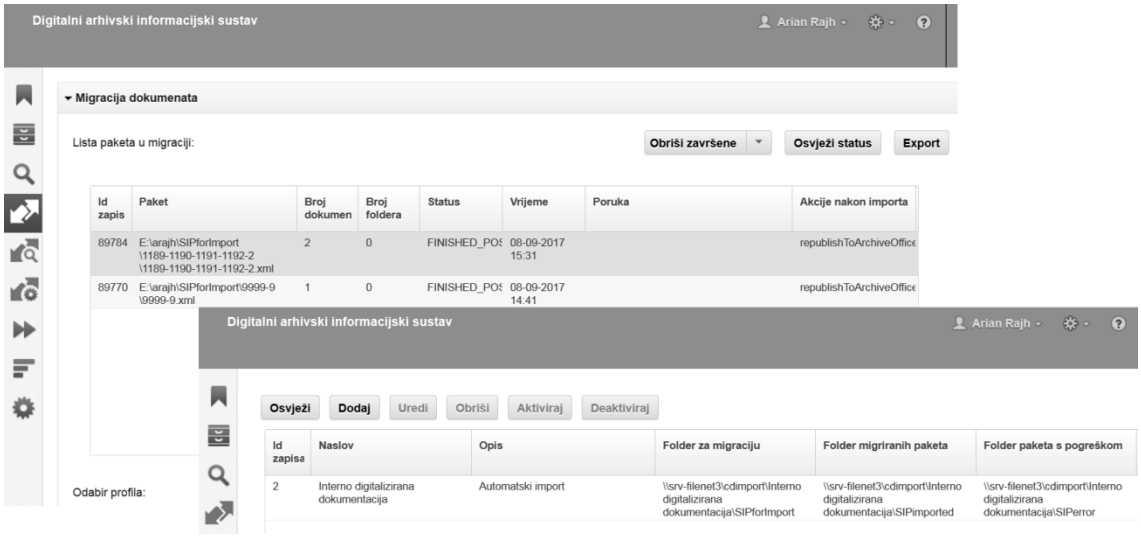
HALMED had some dossiers that were not registered in AMS before the digitisation, but this option and its workflow were set up as exceptions. Microfilming and destruction of materials tasks were omitted from the generic process as they are not relevant for understanding the process itself.



Picture 1: Generic digitisation process derived from external and internal instances of HALMED's digitisation process

It is now possible to answer RQ1 – the external process instance requires considerable attention for preparation, indexing and quality control, and that concerns both the service provider and the client. HALMED's internal digitisation team is more focused on the description, preparation and returning of physical records into technical units after scanning. Indexing and quality control do not present an issue for HALMED's internal team. The most challenging tasks, according to opinions of the third party digitisation team members, were the ones related to preparation, indexing and quality control performed at their premises. The most time-consuming parts of HALMED's internal digitisation process are the registration or description of physical originals, preparation of dossiers or files for scanning and doing recurring physical arrangement of records after scanning. In both instances, scanning, image processing, and creation of SIPs do not present an issue because both systems are designed to carry on these jobs without involving much human effort. Validation and ingestion are also automatized[5] so there are no reported difficulties concerning these tasks (see Picture 2).

[5] *Migration and ingestion module of HALMED's digital archive was developed by Ericsson Nikola Tesla d.d. in the project Preparations for eCTD and the implementation of Digital Archival Information System.*



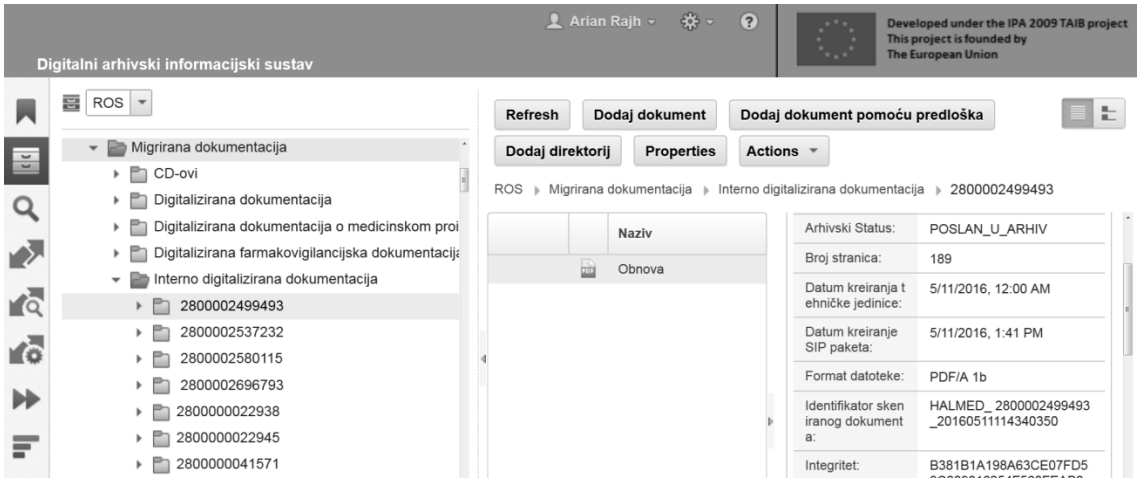
Picture 2: Automation of validation and ingesting through HALMED's Digital Archival Information System

3. Digitisation results and assessments of digitisation process instances

The result of both of HALMED's process instances is a submission of an information package that consists of a PDF/A file or files (record sets) and an XML file per package with indices (see Picture 3). Internal digitisation process includes in XML file additional checksum per PDF/A file as a mechanism for confirming the integrity of package content. XML from the external process includes more metadata then the one derived from the internal process. Although operators should check the final result before and after it is ingested into the repository, the quality control should also take account of intermediate results like scanning results and image processing results. The authors find it disappointing that some digitisation projects avoid quality assurance component during their implementation.

To answer RQ2, the authors would say it is important to inspect each intermediate result for evaluation of a digitisation process as a failure to prepare quality outputs in each process step will lead to failures in the final result. This is easier to achieve in internal then in external digitisation process; it is clear that an entirely internally operated digitisation is easier to control. However, in external digitisation where clients do not have control of processes' tasks carried out in provider's premises, the quality control measures should be set up and implemented prior to the process itself, in the form of evaluation of provider's environment and process. The evaluation of process matureness provides a useful methodology for clients and their digitisation project managers. Capability or maturity models are tools "designed to assess the maturity (i.e. competency, capability, level of sophistication) of a selected domain based on a more or less comprehensive set of criteria"(de Bruin et al., 2005).

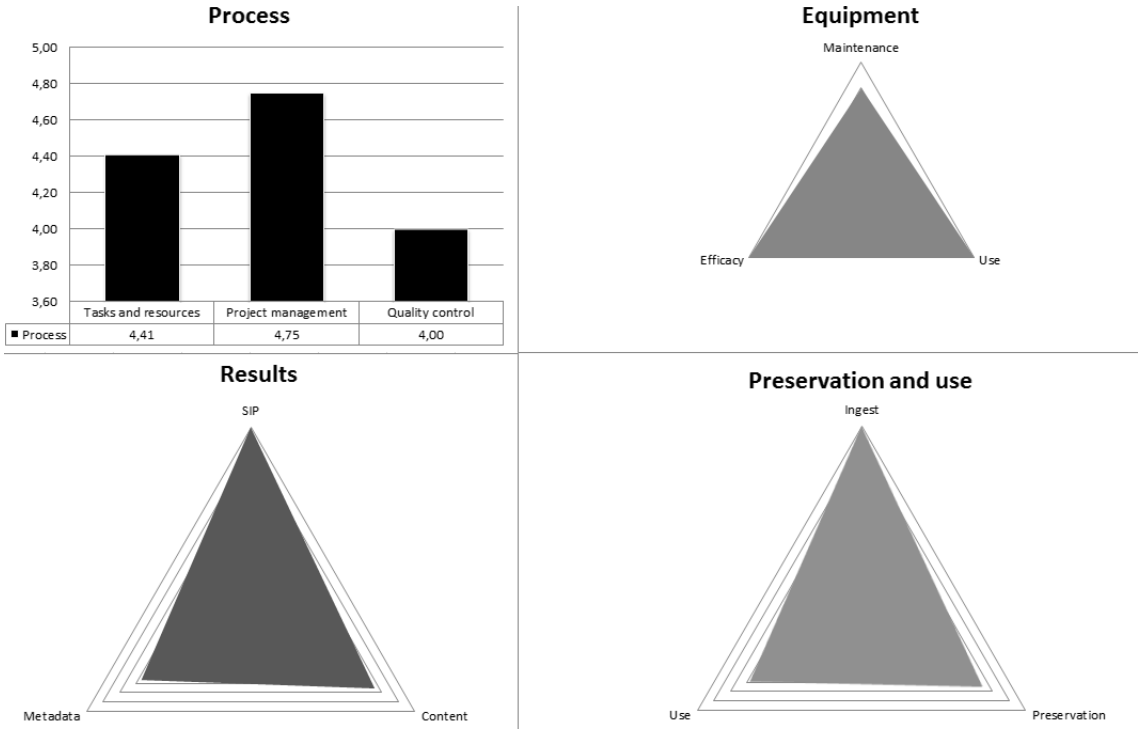
The project was initiated by A. Rajh as a part of his Ph.D. research (2008-2010); it was financed by EU Commission (2011) and implemented in 2013-2014.



Picture 3: An internally digitized dossier ingested into HALMED's Digital Archival Information System

The maturity of digitisation can be evaluated as the maturity of any business process, by selecting and using one of many maturity models from BPM domain (Röglinger, Pöppelbuß and Becker, 2012). Another solution would be to develop specific maturity models for digitisation process. An example of the second option was an assessment of HALMED's process done according to Digitisation Quality Maturity Model (DQMM), a model previously developed by A. Rajh in the project with the Croatian Civil Aviation Agency. In the text below, the authors show the data gathered in the assessment of HALMED. The model grades the quality of digitisation into five levels,[6] and comprises four broad criteria and twelve distinguished dimensions. Criteria are related to the digitisation process, equipment used, results delivered, ingestion, and archiving and use of the digitised material.

[6] *Levels: 1 Initial, 2 Weakly controlled, 3 Defined, 4 Managed, 5 Good practice. Dimensions comprise specific questions with answers awarded with points ("Yes"/ "No"/"I don't know" option and "I do not know"/"I strongly disagree"/"I disagree"/"I don't agree nor disagree"/"I agree" /"I strongly agree" option.*



Picture 4: DQMM Graphical representation of calculated results of assessment of HALMED's external digitisation process – improvement opportunities

Table 6: DQMM evaluation of HALMED's external digitisation process

Process			
Tasks and resources		4,41	
Project management		4,75	**4,4**
Quality control		4,00	
Average	4,39		
Equipment			
Maintenance		4,00	
Use		5,00	**4,7**
Efficacy		5,00	
Average	4,67		
Results			
SIP		5,00	
Content		3,78	**4,0**
Metadata		3,33	
Average	4,04		
Preservation and use			
Ingest		5,00	
Preservation		3,67	**4,0**
Use		3,40	
Average	4,02		
Total	**4,28**		

Three digitisation process dimensions are process tasks, process management, and quality control itself. Three equipment related dimensions are the maintenance, utilisation, and the efficacy of the system. Three dimensions related to the results are the submitted package dimension, the content dimension, and the metadata dimension. The last three dimensions are related to ingesting, archiving and use of materials. Each dimension of the digitisation quality assessment tool comprises a set of questions relevant for assessing it. MS Excel table supports the model with built-it macro functions, automated calculus and graphical representation of calculated results. For an illustration of the effectiveness of the model, CCAA opted for Submission Information Packages

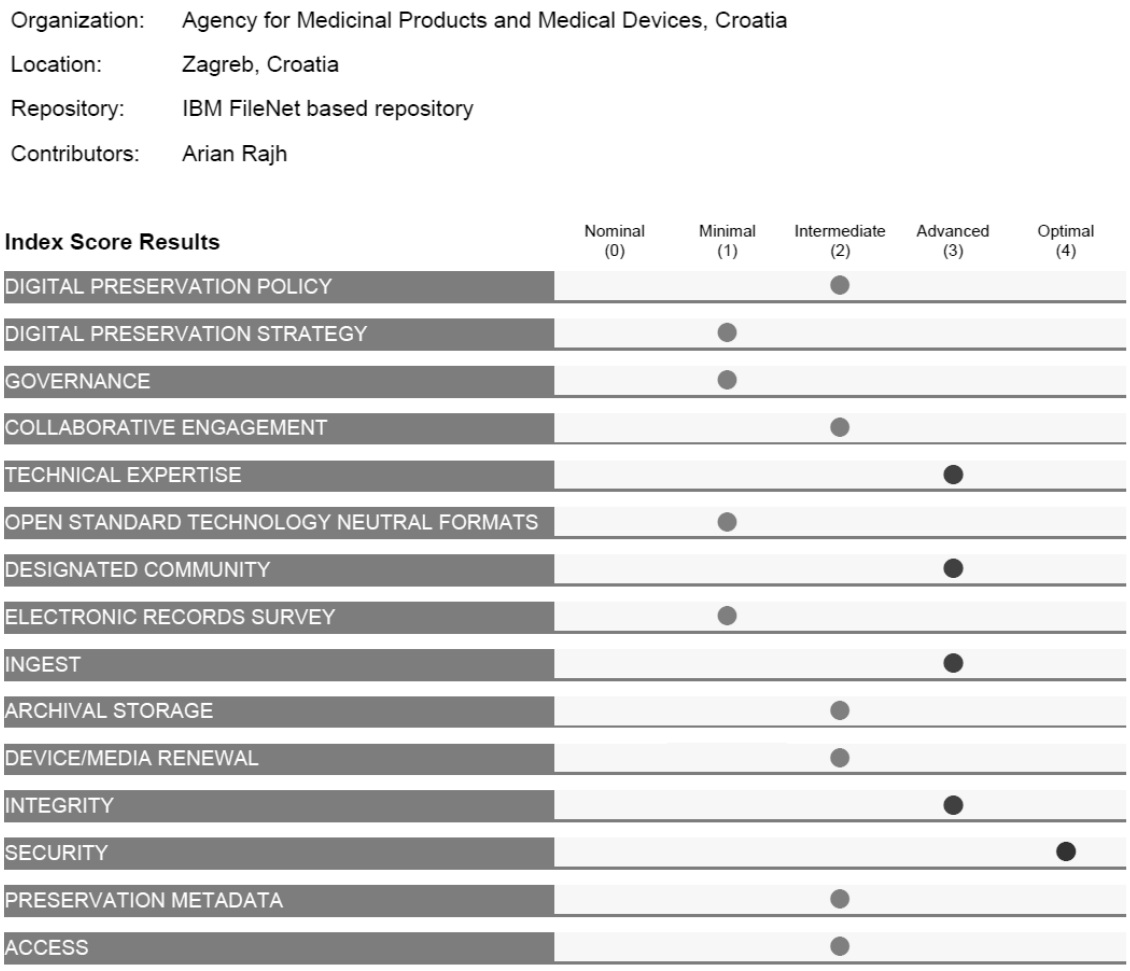
(SIPs) with PREMIS in METS descriptions in XML files, and the evaluation done using this model showed specific issues with generating of XML.[7] Issues were then confirmed in routine quality control process and corrected. The authors of this article apply the same model to HALMED's external digitisation process. Assessment of HALMED's external digitisation process showed that there is room for improvement in areas of maintenance of equipment, enhancement of the content, metadata handling, preservation and use of materials (see Picture 4). HALMED's grades per each dimension of the model (on a scale from 1 to 5) were 4.39 (process), 4.67 (equipment), 4.04 (results), and 4.02 for preservation and use dimension (see Table 6). Digitisation practitioners can also inspect distinctly problematic or critical parts of the digitisation processes for which they are responsible. For example, because HALMED has learned through its external digitisation program that metadata handling could cause delays in the process, it decided to apply metadata management concepts prescribed in ISO 23081 and ISAD(G) standards. The goal was to increase archival efficiency. HALMED evaluated the application of metadata concepts from the standards by developing and implementing customised metadata checklist (Rajh and Šimundža-Perojević 2016). Compared to HALMED's external process and its metadata related issues, the result of the evaluation showed greater maturity of this part of HALMED's internal digitisation process.

Besides evaluating the maturity of the process, it is advisable to evaluate the repository and the organization's readiness to preserve its digitised content over an extended period. There are several maturity models from the literature which are applicable for this purpose – (1) Digital Preservation Capability Maturity Model (DPCMM) and DigitalOK self-assessment tool, (2) E-ARK Maturity Model for Information Governance A2MIGO, (3) Preservica Digital Preservation Maturity Model, (4) Adrian Brown's model, and (5) Becker's, Antunes', Barateiro's, and Vieira's Capability Model for Digital Preservation. Repositories could be evaluated in ISO OAIS/ISO 16363 certification process too (Giaretta, 2018). DPCMM and A2MIGO become the most used models recently. Dollar's and Ashley's DPCMM divides matureness of preservation into five levels (from nominal to optimal). It consists of fifteen components out of which seven components refer to activities that organisation does to secure its repository, and eight digital preservation services with the focus on assurance, preservation and monitoring of environment-related activities. "DigitalOK" self-assessment tool is linked to DPCMM. A2MIGO model, developed in E-ARK project, also divides maturity into five levels, from initial to optimising. It has three broad categories (management, processes, infrastructure) and various assessment criteria. HALMED assessed the maturity of its preservation environment by using DPCMM and DigitalOK with results shown in Table 7 (also see Picture 5).

[7] *SIP is the form of content organization transferred from producer to archive, according to ISO 14721 standard for Open Archival Information Systems; METS (Metadata Encoding and Transmission Standard) is a standard for transfer of metadata and PREMIS (PREservation Metadata: Implementation Strategies) is a standard for preservation of digital objects. They are all commonly used in archives.*

Table 7: Evaluation of HALMED's preservation capability according to the Digital Preservation Capability Maturity Model (Dollar and Ashley) (carried out by A. Rajh, January 2018)

1 Policy	2 Strategy	3 Governance	4 Collaboration	5 Expertize	6 Standards and formats	7 Community	8 eRecords analysis
3	4	1	2	2	1	2	1
9 Ingest	10 Storage	11 Device and media renewal	12 Integrity	13 Security	14 Metadata preservation	15 Access	35 pts (60 max.) Lower advanced level
4	3	2	3	4	1	2	



Picture 5: Evaluation of HALMED's preservation capability according to DigitalOK (Digital OK self-assessment report, http://www.digitalok.org, carried out by A. Rajh, January 2018)

According to DPCMM, HALMED's most solid dimensions are Strategy, Ingest and Security. This is due to the management of risk related to technology and format obsolescence and required transformations to preservation formats, to implemented ingestion or migration module, and well-addressed security issues on a system level. According to DQMM, ingestion of SIPs and SIPs themselves were also HALMED's strong points (see Table 6).

4. Conclusions and recommendations

Dealing with business processes is not a problem for archival practitioners, and capability evaluations are being successfully conducted in archival environments. HALMED decided to model its digitisation process in order to keep track of all of its specificities, to satisfy its initial requirements, and to apply improvements that the process involves. DQMM applied to HALMED covers specificities of its external process of digitising textual materials in PDF/A output form. Therefore, this model cannot be simply replicated in each institution that digitises its archival materials but the principle of managing the digitisation process should be applicable to a variety of cases. This principle can be described as follows: to model the particular digitisation process; define objects and questions of assessment; group these questions in dimensions and categories; add points to the possible answers; define the range of points and map them to maturity levels; and, also, to create a technology-assisted tool to facilitate evaluations. In addition, it is advisable to use preservation capacity models found in the literature section for examining preservation environment in which digitised materials will be kept. To answer RQ3 about the applicability of HALMED's cases and its lessons learned to a variety of digitisation processes of different institutions, the authors would like to say that the lessons learned apply to some extent because some regularities across digitisation processes exists, and there are requirements and critical issues common to all processes. Combining HALMED's digitisation tasks in the generic model holds promise of a greater applicability of the process. Nevertheless, the authors would like to state that internal processes are appropriate for institutions with constant accruals and open archival holdings. External digitisation processes are usually easier to set-up and implement then internal processes that typically require significant initial investments in equipment and staff training. They are more suitable for time-bounded digitisation projects for institutions with closed archival holdings and backlogs. External digitisation is appropriate for digitising large quantities of backlog materials; for the sustenance of the state achieved it is advisable to continue with the internal digitisation. There is a difference in the level of control between these two instances and the quality control component should put additional effort into checking the external digitisation final result as it may not be possible to control all the intermediate results. The combination of business process modelling and assessment of its maturity is something that digitisation practitioners should consider. The authors recommend an approach that consists of setting up preservation environment and designing the digitisation process that suits the needs of the organisation. The digital environment is essential to preserve the results of digitisation processes. Once it is developed, the environment should be assessed with one of the preservation capability models or, if financially and operationally possible, according to ISO OAIS/ISO 16363 procedure. Assessment findings should be used for the digital archive or repository improvement and thus for organisation's further growth.

POVZETEK

IZKUŠNJE Z IZVEDBO DIGITALIZACIJE V AGENCIJI ZA ZDRAVILA IN MEDICINSKE PROIZVODE REPUBLIKE HRVAŠKE

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Digitalizacija administrativnega dokumentarnega in arhivskega gradiva se lahko izvaja kot notranji proces ustanove, ki ustvarja arhivsko gradivo (in-house), ali pa jo zanjo opravi zunanji ponudnik storitve (outsourcing). Čeprav gre za enaka procesa in bi morala biti njuna osnova enaka, prihaja med obema procesoma do nekaterih razlik. Agencija za zdravila in medicinske pripomočke na Hrvaškem (HALMED) je z zunanjim izvajanjem digitalizacije pričela leta 2013. V letu 2016 je HALMED izdelal svoj notranji proces digitalizacije in tako je bila leta 2017 digitalizacija medicinske dokumentacije vključena v triletni strateški plan ustanove. HALMED je oba načina digitalizacije izvedel na enakem korpusu dokumentov z istimi, visoko zastavljenimi cilji, kar daje ustrezno podlago za jasno primerjavo procesov notranje in zunanje digitalizacije. HALMED kot ustvarjalec proizvaja relativno obsežno zbirko dokumentov, le-ta se na letni ravni močno povečuje. Prispevek lahko služi kot praktičen primer za podobne institucije, ki ustvarjajo arhivsko gradivo s stalnim dopolnjevanjem.

Referenčni okvir za izvedbo primerjalne analize v primeru HALMED-a vključuje splošen proces digitalizacije administrativnega dokumentarnega in arhivskega gradiva, predlagane podprocese nadzora kvalitete in splošne standarde, vezane na digitalizacijo. Poleg primerjave stopenj procesa digitalizacije z njenim generičnim modelom vključuje osnova za primerjalno analizo še odzive na kontrolne sezname. Kontrolni seznami so bili predhodno pripravljeni. Prvi kontrolni seznam se nanaša na učinkovito rabo metapodatkov v procesu digitalizacije. Avtorji so ta seznam v HALMED-ovih procesih digitalizacije začeli uporabljati že leta 2015, proces notranje digitalizacije so izboljšali leta 2017. Drugi kontrolni seznam je zastavljen širše; pokriva procese digitalizacije, opremo, rezultate in njihovo obdelavo. Prispevek se nadaljuje s podobnimi študijami, povezanimi z glavnimi prednostmi in slabostmi notranje in zunanje digitalizacije. Avtorji obravnavajo prednosti in omejitve posameznih stopenj procesa digitalizacije za ustanove z arhivskim gradivom s stalnimi dopolnitvami. Zastavili so si naslednja raziskovalna vprašanja: (1) Katere prilagoditve poslovnih procesov zahteva vsaka stopnja procesa digitalizacije? (2) Na kaj je potrebno biti pozoren med nadzorom kakovosti pri vsaki stopnji procesa digitalizacije? (3) Ali lahko izkušnje HALMED-a uporabijo tudi drugi ustvarjalci arhivskega gradiva, in če da, kateri?

Avtorji so za proučevanje odgovorov na zastavljena vprašanja uporabili znanstvene metode ter raziskali uporabnost več modelov in kontrolnih seznamov pri procesu digitalizacije kakor tudi okolje za hrambo digitalizatov.

Ob koncu so avtorji podali priporočila za ustanove, ki hranijo arhivsko gradivo in se to venomer povečuje. Ponujajo tudi predloge glede digitalizacije v ustanovah, ki imajo precej zaprto arhivsko gradivo – s ciljem zagotoviti večjo učinkovitost digitalizacije in ukrepov na področju materialnega varstva.

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